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Magnetic Resonance Imaging (MRI) Safety





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April 2025

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Goal and Objectives

Goal

This course will enable the learner to provide a safe environment for patients and staff who are in the presence of the MRI scanner.

Objectives

1. Describe basic knowledge of magnetic fields and their influence on objects near them.
2. Describe the importance of safety when working around the MRI scanner.
3. Identify precautions that should be taken to avoid accidents when working near the MRI scanner.
4. Identify precautions that should be taken when patients have implantable devices or metallic foreign bodies.

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The MRI Magnet

Magnetic resonance imaging (MRI) is a noninvasive, painless medical test that helps physicians diagnose and treat medical conditions by providing views of the inside of the human body.

The MRI uses a powerful magnetic field, radio waves, and a computer to produce detailed three-dimensional pictures of internal body structures.



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The MRI Magnet *(cont.)*

Most people have had some experience with natural magnets and their attractive forces, such as, attaching papers to a refrigerator door.

The MRI scanner is a large magnet (10,000 lbs.) with a tremendously strong magnetic pull. The magnet in the MRI scanner creates a force field which can affect objects that are close to it. As you approach the MRI scanner, the attractive force field increases rapidly.

The strong magnetic field can have adverse effects on patients and staff who are within the scanner's magnetic force field.



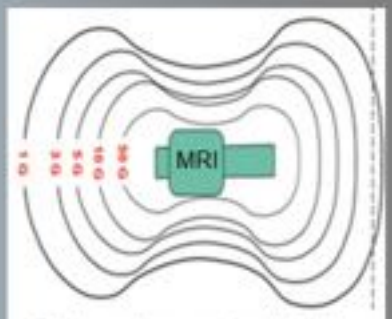
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Magnetic Field Hazards

All MRI magnets have a magnetic field that extends into the exam room.

The various distances from the magnet consist of ***GAUSS Lines***, *which measure the attractive force of the magnet at a certain distance.*

As Gauss Line distances decrease, the magnetic field strength increases, until the field is so strong, it can cause any ferromagnetic object* to have a missile effect.



Distance closer, strength higher

*An object attracted by a magnet and can become magnetized.

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Magnetic Field Hazards *(cont.)*

Ferromagnetic metal alloys usually contain iron, nickel, or cobalt. These elements are found in most metal objects.

Examples of ferromagnetic objects:











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Magnetic Field Hazards *(cont.)*

The Missile Effect

This refers to the capability of the MRI magnetic field to attract a ferromagnetic object into the scanner with considerable force.

It can cause:

- Delayed patient care
- Possible injury to patient or staff
- Possible damage to the MRI scanner
- Approximate cost due to each "missile effect" incident: **$250,000**







It takes **96 hours** to:

- Turn the magnet off
- Remove the object
- Power back up

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The MRI Magnet is Always On!

The MRI Magnet is Always On!

The MRI Magnet is Always On!

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Test Your Knowledge

Which of the following items should you remove from your pockets prior to entering the strong magnetic field of an MRI system?

- ○ Scissors
- ○ Safety pin
- ○ House key
- ◉ All of the above

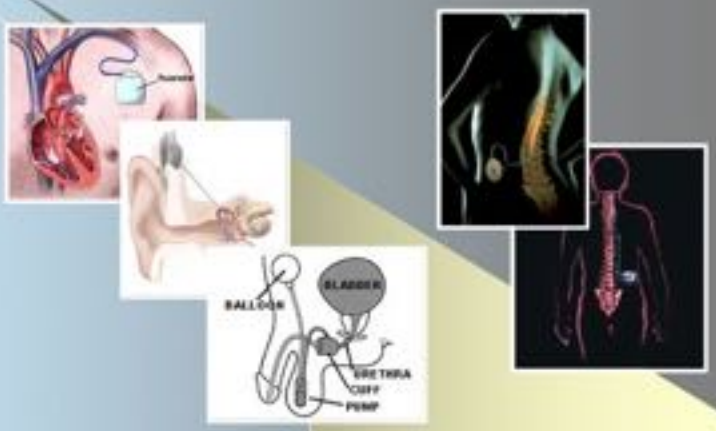
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Magnetic Field Hazards *(cont.)*

MRI staff should ensure that implants are **"MR Conditional"** and should instruct patients to immediately report any burning sensations experienced during the scan.

Displacement and Heating of Surgical Implants:

- Cardiac pacemakers
- Neurostimulators
- Pain control pumps
- Penile implants
- Cochlear implants

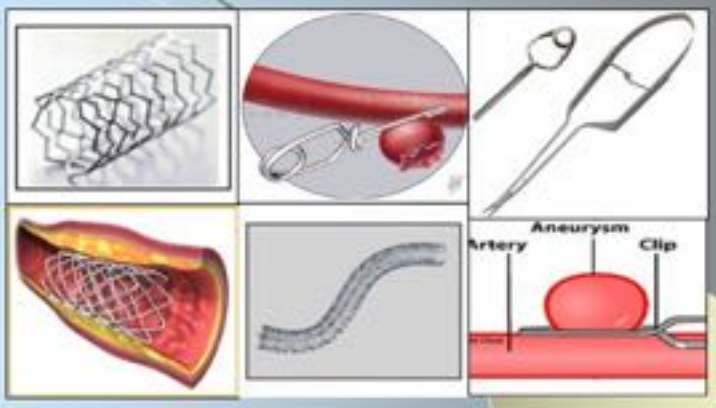


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Magnetic Field Hazards *(cont.)*

Displacement (movement) of these implants may cause a life-threatening situation!

Stents and Aneurysm Clips:



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Magnetic Field Hazards *(cont.)*

Electromagnetic Interference with Electronic Devices

Mechanically- or electrically-activated implants may stop or malfunction in the presence of the MRI magnetic field.

Patients with pacemakers have died during or shortly after MRI exams due to disruption of pacemaker function by the MRI system.

Hospital staff with pacemakers or other implanted electronic devices could also be affected, if they come within the strong magnetic field of the MRI.



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Magnetic Field Hazards *(cont.)*

All patients with body piercing jewelry must be screened for jewelry removal before they have an MRI scan!

Risks for these patients include:

- Discomfort or painful sensations due to possible displacement of the jewelry.
- Patient burns due to heat generated from the interaction between the jewelry and the electromagnetic fields.



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Magnetic Field Hazards *(cont.)*

All patients with transdermal patches must be screened for patch removal before they have an MRI scan.

Transdermal Patches:

Some patients are now wearing trans-dermal patches for medication delivery.

Many of these patches contain aluminum foil or other metallic components which can cause excessive heating, leading to burns in patients undergoing a MRI scan.





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Magnetic Field Hazards *(cont.)*

All patients with tattoos must be screened before they have an MRI scan.

Tattoos:

Many patients scheduled for an MRI scan will present with tattoos.

These tattoos will be either cosmetic or decorative and can be located anywhere on the body.

Some of these tattoos will contain ferromagnetic material, which can cause heating, swelling, or burning at the tattoo site.



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The MRI Magnet is Always On!

The MRI Magnet is Always On!

The MRI Magnet is Always On!

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Magnetic Field Hazards *(cont.)*

Pregnancy **All pregnant patients must be screened before they have an MRI scan.**

MR imaging is recognized as a beneficial diagnostic tool to assess a wide range of diseases and conditions that affect pregnant women and their fetuses.

MR imaging in pregnant women should only be performed in cases where the referring physician and radiologist agree that the findings of the MRI has the potential to change or alter the care of the mother or fetus and that the benefit outweighs the risk.

The Policies, Guidelines, and Recommendations for MRI Imaging, Safety, and Patient Management issued by the Safety Committee of the Society for MRI imaging states:



"MRI may be used for pregnant women if other non-ionizing diagnostic imaging is inadequate, or if the MRI provides important information that would otherwise require exposure to ionizing radiation (CT, fluoroscopy, etc.)."



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Summary of MRI Hazards

Hazard	Possible Danger
Body-piercing jewelry	Displacement; Heat
Transdermal skin patches	Burning
Tattoos	Burning
Aneurism clips	Displacement
Stents	Displacement
Cochlear implants	Displacement
Penile implants	Displacement
Pacemakers	Malfunction or Stop

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MRI Patient Safety Labels

Click each label to learn more:



MRI Safe Equipment Label
No Restrictions



MRI Conditional Equipment Label
Equipment needs to be tested prior to use



MRI Unsafe Equipment Label
Equipment is strongly ferromagnetic and must not be used in the scan room

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Thermal Injury Protection

Electrical currents can be induced while in the magnet bore and cause thermal injury.

More tips:

- Cold compresses can be used over heavy tattoos to reduce tissue heating.
- Surface coils should be checked before scanning.
- Unused electrically-conductive materials outside the patient should be removed.

Arms and legs should not cross or touch each other.


Proper Positioning of MRI Patient in Bore



Improper Positioning of MRI Patient

The patient's body should not touch the inner bore of the magnet.



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Emergency Shutdown (Quenching)

A loss in superconductivity can result in massive heat gain in the magnet, producing cryogen boil-off and release. This is called "quenching."

- The resulting damage caused by quenching is costly and time-consuming.
- Emergency quenching should be avoided.
- If extended power loss is expected, the magnetic field can be ramped down to prevent quenching. Backup or temporary power should be available at all times.



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Patient Hearing Protection

- MRI systems can produce a very noisy environment for the patient.
- All patients should be offered hearing protection, especially when using systems which have sound pressures above 99 dB.



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Patients with Claustrophobia - Anxiety - Emotional Distress

- Many patients experience anxiety prior to and during MRI exams. Some may not be able to complete the exam due to claustrophobia.
- It can be helpful to use audio and visual distractions.







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Patients Requiring Immediate Medical Attention

- When a patient needs immediate medical care in the scan room, all responders must have sufficient training in MRI safety.
- This applies to medical/technical staff, as well as police, fire, and security personnel.
- If resuscitation is needed, the patient should be moved from the scanner to a safe area.
- Emergency and disaster plans should be in place and conducted periodically.



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Screening

All **patients** and any **family members** entering the MRI Scanner must be screened by the MRI technologist.

All **ancillary staff** entering the MRI Scanner must verbally be screened by the MRI technologist.

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Screening Patients

All patients must complete the Magnetic Resonance Imaging Information Form* before they have an MRI scan.

* These forms are not currently used at Grayling Hospital or Otsego Memorial Hospital.

Outpatient

1 of 2

MUNSON HEALTHCARE

Form #4941 (06/21) Page 1 of 2

MAGNETIC RESONANCE IMAGING (MRI) PATIENT INFORMATION / ASSESSMENT

4941

Patient Legal Name: _____
(Last) (First) (Middle Initial)

Date of Birth: ____/____/____ Age: _____ Height: _____ Weight: _____ (lbs.)

Have you had surgery on the area being scanned today: ☐ Yes ☐ No If yes, when? _____

Previous radiology exams on the area being scanned today: ☐ Yes ☐ No

If yes, what type of exam: ____ X-RAY ____ Cat Scan ____ Ultra Sound ____ MRI ____ PET

Briefly describe why your doctor wants this MRI: _____

_____

_____

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Screening Patients *(cont.)*

All patients must complete the Magnetic Resonance Imaging Information Form* before they have an MRI scan.

* These forms are not currently used at Otsego Memorial Hospital.

Inpatient

1 of 3

MUNSON HEALTHCARE

Form #12254 (06/20)

RN RADIOLOGY MRI CHECKLIST

RN TO COMPLETE WITH PATIENT PRIOR TO MRI

☐ Is the MRI questionnaire filled out and signed by the patient?

☐ Does the patient have any implants?
- o If yes, is the make and model identified?
- o Do you need assistance identifying?

☐ If the patient is in the ER:

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Screening Patients *(cont.)*

Patients with Metallic Foreign Bodies

- All patients with a history of injury by a metallic foreign body must be screened and evaluated before being placed in the magnetic field of an MRI scanner.
- Examples of metallic foreign bodies:
  - ✓ BBs
  - ✓ Bullets
  - ✓ Pellets
  - ✓ Shrapnel
  - ✓ Buckshot
  - ✓ Eye or body metal fragments





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Screening Patients *(cont.)*

Patients with Implants

- Information that must be supplied by the patient, a family member, or by hospital staff for a patient with an implant includes:
  - ✓ Make and model of implant
  - ✓ Manufacturer of implant
  - ✓ Date of implant insertion
- Medical Alert Cards: Most people who get an implant receive a medical alert card stating whether or not the implant is MRI compatible. These cards should be checked by the MRI technologist.



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The MRI Magnet is Always On!

The MRI Magnet is Always On!

The MRI Magnet is Always On!

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Safety Considerations

Zones of Exclusion

Joint Commission standards require Radiology to have four zones of exclusion when performing MRI exams.

Click the buttons to discover the zones.

Reception Desk	Patient Dressing Room	MRI Control Room	MRI Magnet Room
Zone 1: General Public	**Zone 2:** Unscreened MRI patients	**Zone 3:** Screened MRI patients and MRI personnel	**Zone 4:** Screened MRI patients under constant direct supervision or trained MR personnel

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References

Gould, T., & Edmonds, M. (2010, October 25). How MRI works. In *howstuffworks*. Retrieved September 15, 2022, from https://science.howstuffworks.com/mri.htm

MR safety. (n.d.). In *American College of Radiology (ACR®)*. Retrieved September 22, 2022, from https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety

MR safety. (n.d.). In *The MR Core Research Facility*. Retrieved September 15, 2022, from https://www.mrc.wayne.edu/safety.htm

Munson Medical Center Policies and Procedures. (2022, January 3). *MRI safety*. PolicyStat.

Further Questions? Call Heather Davis, Radiology, ext. 57244

Preparing A Patient For Surgery



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Jeannette Reynolds, MSN, BBA, RN, CPAN

October 2025

MUNSON HEALTHCARE

Goal and Objectives

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Goal:

This course provides information on the Preprocedure checklist and provides rationale on inpatient preparation for surgery or a procedure.

Objectives:

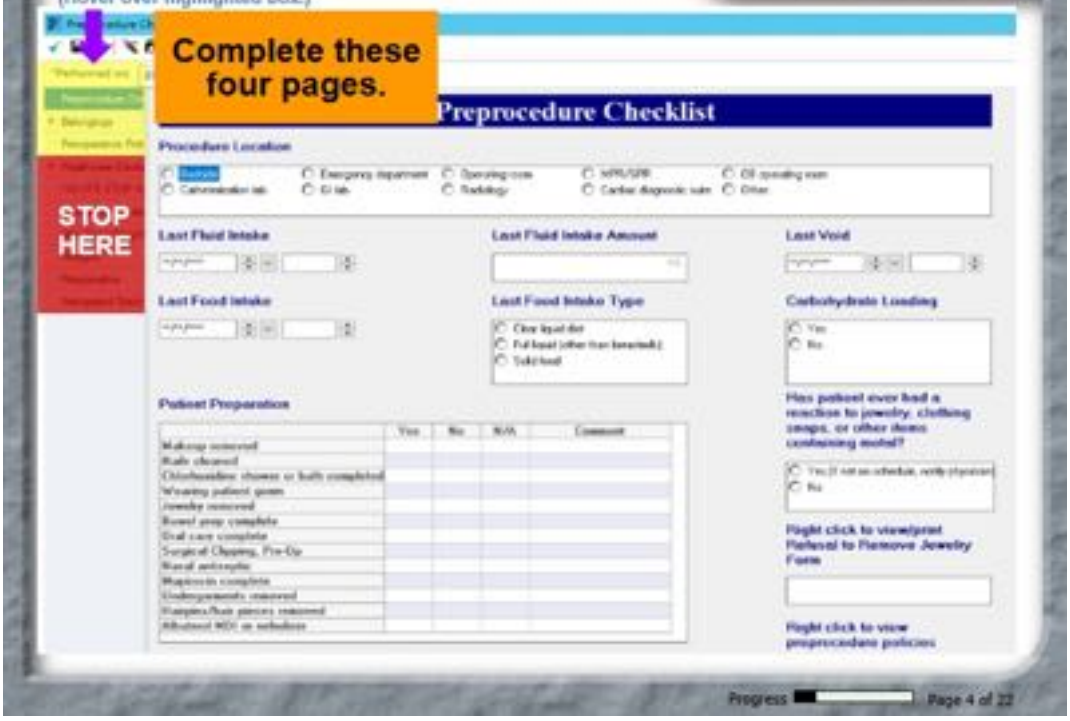
1. Accurately complete the Preprocedure checklist for a patient going to the Operating Room (OR), Medical Procedure Room (MPR), or Interventional Radiology (IR).
2. Correctly perform the pre-surgical hygiene elements when preparing a patient for surgery or a procedure.
3. Explain the importance of the Beta Blocker regimen during the peri-operative period.

Preprocedure Checklist

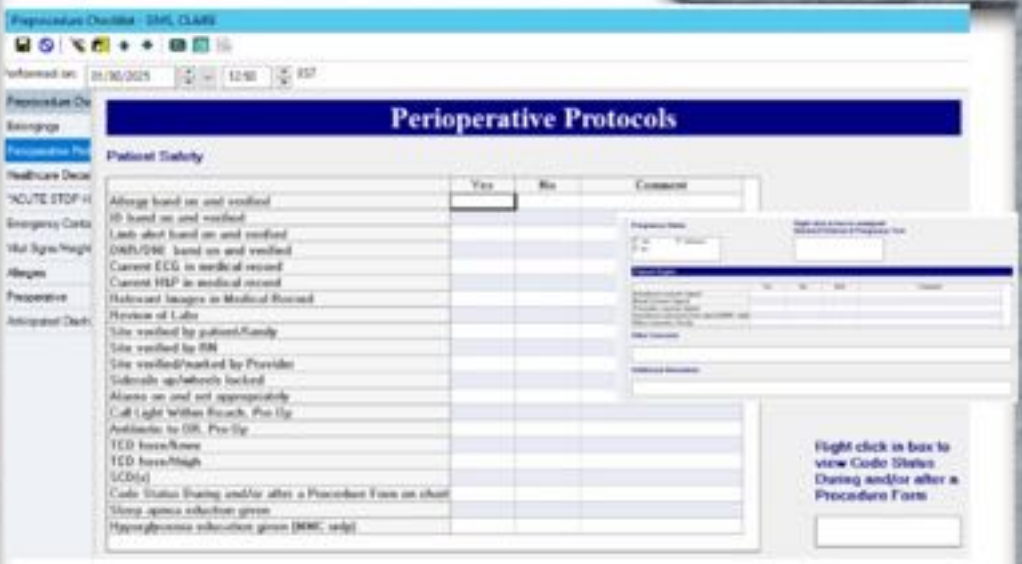
- Begin the Preprocedure checklist as soon as you know the patient is going to surgery - ideally the day before surgery.
- Must be completed for every patient going to the OR, MPR, or IR for surgery or procedure.
- With the patient's chart open, click AdHoc.
- Select preprocedure checklist.
- The acute care nurse will complete the first 4 pages of the powerform.

Preprocedure Checklist *(cont.)*

(Hover over highlighted box.)



Preprocedure Checklist *(cont.)*



Nursing - Careset Orders



- Order your careset for Nursing - Inpt Preprocedure/Pre-Op Prep Checklist. Enter the careset as a 'Nurse per Protocol' (exception for patients scheduled in Maternity OR).
- Adjust the dates of CHG baths and nasal decolonization to correlate with day of surgery.
- Everything you do to help prepare the patient prior to their arrival in pre-op benefits the patient and prevents delays in surgery start times.

Treatment Decision Form

- Check code status in PowerChart.
- If the patient is anything except a full code, print a Treatment Decision Form (form #4511) and page the surgeon to complete it.
- Patients going to the operating room **do not** automatically become full codes. A Treatment Decision Form must be completed prior to surgery and will include a date/time to resume patient's preprocedure code status.



History and Physical (H&P)

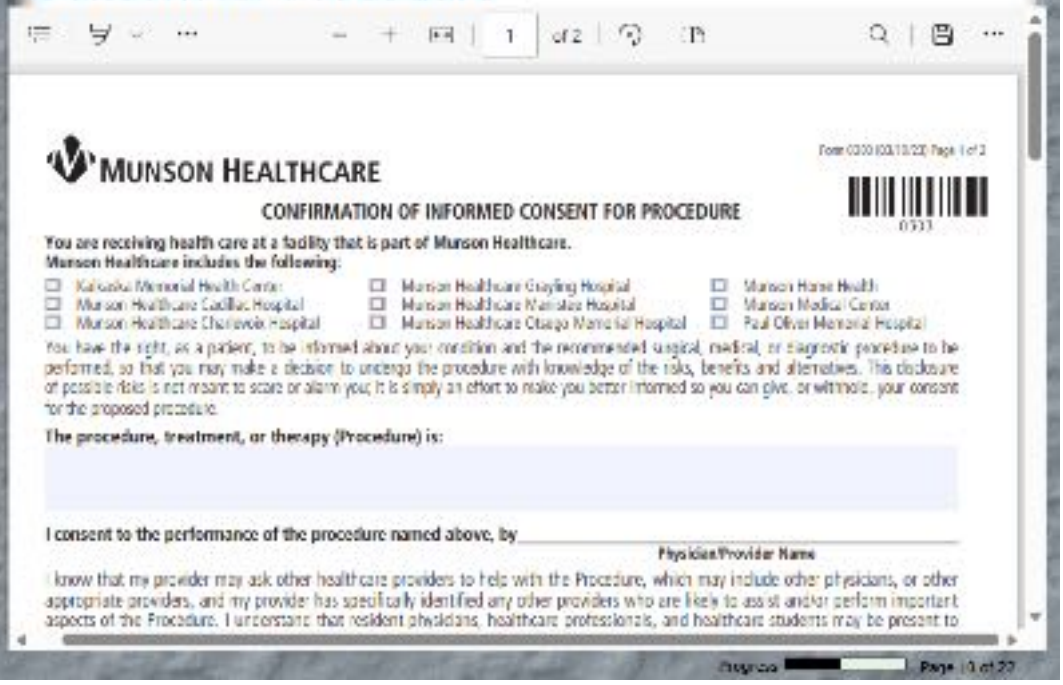
- For all surgical or invasive procedures involving anesthesia or sedation, a valid H&P must be on the patient chart prior to start of the procedure. A valid H&P must have been completed within 30 days (not 31 or more days prior to admission or procedure).
- The surgeon must document in the patient's electronic record (H&P, consult, or progress note) the planned course of action and applicable side of the procedure, if warranted.
  - Writing an order is NOT acceptable as the surgical plan.
- In emergency cases, where completion of an H&P is not feasible, the surgeon should make a notation of relevant history and physical findings in the patients progress notes, if time allows.

Informed Consent

- Informed consent is a process of communication between a provider and patient to reach an agreement or permission to perform a procedure. The patient (or designee) signature on the form confirms that a provider has:
  - Reviewed the procedure.
  - Discussed the risks, benefits, or alternatives.
  - Answered all the patient or designee questions.
- The informed consent process could occur on the inpatient floor or at the site of the procedure.
- The patient and the provider performing the procedure will both sign the form (#0303) "Confirmation of Informed Consent for Procedure" (often referred to as CIC) ideally at the time of the informed consent discussion. The form must be signed prior to performing an invasive procedure.
- The signature of the provider performing the procedure **is required** on the form confirming the informed consent process has been completed.
- Consents are valid for 90 days.

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Confirmation of Informed Consent for Procedure



MUNSON HEALTHCARE

CONFIRMATION OF INFORMED CONSENT FOR PROCEDURE

You are receiving health care at a facility that is part of Munson Healthcare.
Munson Healthcare includes the following:

- ☐ Kalkaska Memorial Health Center
- ☐ Munson Healthcare Cadillac Hospital
- ☐ Munson Healthcare Charlevoix Hospital
- ☐ Munson Healthcare Grayling Hospital
- ☐ Munson Healthcare Manistee Hospital
- ☐ Munson Healthcare Otsego Memorial Hospital
- ☐ Munson Home Health
- ☐ Munson Medical Center
- ☐ Paul Oliver Memorial Hospital

You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be performed, so that you may make a decision to undergo the procedure with knowledge of the risks, benefits and alternatives. This disclosure of possible risks is not meant to scare or alarm you; it is simply an effort to make you better informed so you can give, or withhold, your consent for the proposed procedure.

The procedure, treatment, or therapy (Procedure) is:

I consent to the performance of the procedure named above, by _____
Physician/Provider Name

I know that my provider may ask other healthcare providers to help with the Procedure, which may include other physicians, or other appropriate providers, and my provider has specifically identified any other providers who are likely to assist and/or perform important aspects of the Procedure. I understand that resident physicians, healthcare professionals, and healthcare students may be present to

Informed Consent Process - Nurse's Responsibility

The nurse serves an important role in the process to optimize patient care and workflow.

- Review the provider's order and electronic record for the planned operative procedure.
- The RN may enter the procedure on the consent form using no abbreviations, or if available, use the procedure-specific consent form.
  - If needed, clarify any abbreviations, illegible or unusual order, and any discrepancies with the provider performing the procedure.
- Confirm the performing provider and patient have both signed, dated, and timed the CIC.
  - If the informed consent discussion occurred with the provider, but the provider did not have the patient sign the form at the time of the discussion, **nursing personnel may facilitate signature of the patient or the designee ONLY in situations where the patient or designee has no questions.**
  - Confirm the form is placed in the patient's chart and travels with the patient to the procedural area. If there is no provider or patient signature, inform the pre-procedure staff during hand-off communication.
  - The form may be sent to preop holding with only the patient's signature.

Checklist Components






Lab Tests

- Check all current lab values and report any abnormal findings to the surgeon.
- Obtain a urine pregnancy test (per Pre and Post Surgical/Procedural Adult Protocols) on all females between menarche and menopause. Women who have had tubal ligation still need a pregnancy test. Women who have had hysterectomies do not.
- Notify the pre-op RN of abnormal lab findings during handoff report.

Checklist Components






ECG Prior to Surgery?

When:

- There needs to be a normal ECG on the chart from the last year, or the last 6 months if the last ECG was abnormal and patient is stable.
- If using a paper ECG from another facility, it needs to be verified and signed.

Who:

- Any patient with a history of a previous MI, angina, arrhythmia, renal failure, medication-dependent diabetes, or CVA.
- Any patient 45 years or older with a history of hypertension or history of ≥ one pack per day smoker.
- All patients 45 years or older having major vascular, intra-abdominal, thoracic, neurological, or orthopedic surgery.

Checklist Components






IV Access

- Ensure a patent large bore IV. Refer to Pre and Post Surgical/Procedural Adult Protocols for catheter size required based on the type of surgery.
- If the patient has Heparin infusing, follow the physician orders regarding continuation/discontinuation.
- Discuss with the pre-op RN during handoff report if the patient's IV infusions should be discontinued prior to sending the patient to the peri-operative area.

Checklist Components






NPO

- NPO except clear liquids and medications after midnight.
- Stop clear liquids 4 hours before scheduled surgery time.
- If the surgeon's NPO orders conflict with the Pre-Procedure Nothing By Mouth Policy, page the anesthesiologist for clarification.
- Sips of water with meds are ok.

Pre-Surgical Hygiene

Prior to the pre-surgical bathing:

- **Remove all body jewelry** (including wedding bands).
- Remove hair clips, pins, rubber bands, etc.
- Remove body piercings.
- Remove makeup and nail polish.



Patient who did not remove ring prior to going into OR.

Pre-Surgical Hygiene *(cont.)*

The patient should have a total of three (3) chlorhexidine gluconate (CHG) baths **if required:**

- Two nights before surgery
- The night before surgery
- The morning of surgery

Example: If the patient's surgery is on Tuesday, bathe with CHG on Sunday night, Monday night, and Tuesday morning.

What if the patient is admitted the night before surgery?

You must ensure two (2) CHG baths are completed:

- The night the patient was admitted
- The morning of surgery

How to Give a CHG Bath

- Wash the entire body (from neck down) with CHG.
  - Cleanse groin area (avoid CHG on mucous membranes).
- Avoid scrubbing the skin too hard with CHG.
- Do **not** use regular soap after the CHG.
- Do **not** rinse the CHG off of the skin.
- Place the patient in a clean gown after the CHG bath (all clothing, including underwear, should be removed).
- Place clean linens on the bed after the CHG bath.

Pre-Surgical Hygiene *(cont.)*

Two nights before surgery:

- Give a soap and water bath ***prior*** to the first CHG prep bath.
- Shampoo hair with regular shampoo.
- Wash face with regular soap/cleanser.
- After the soap and water bath, give the first CHG bath, using either the wipes or the liquid.

The night before surgery:

- Wash face with regular soap or cleanser.
- Give the second CHG bath in the same manner as the previous night.
- Brush teeth and use mouth rinse.

Day of Surgery Preparation

- Use the Preprocedure checklist.
- Complete the 3rd CHG (last) bath. Place a clean hospital gown on the patient.
  - Clean under finger nails.
  - Confirm oral care is completed.
  - Encourage the patient to void prior to sending to pre-op.
    - Bathroom availability is limited in pre-op.
  - Remove the patient's underwear.
  - Inform the pre-op RN when medication patches are left on the patient.
- Complete nasal decolonization, if required.
- Document vital signs prior to transfer.
  - Report abnormal findings to the pre-op RN.
- Send the patient with dentures, glasses, and hearing aids.
- Call hand-off report to the pre-op RN.

Obstructive Sleep Apnea

- Communicate with the pre-op RN if your patient uses a CPAP or BiPAP and discuss if the device should be sent with the patient to the perioperative area.
- Ensure settings are documented, so that the machine can be used accurately postoperatively.

Antibiotics

- The surgeon or a covering physician shall write specific orders for all patients requiring prophylactic pre-operative antibiotics.
- Confirm an order for preoperative antibiotics is placed in PowerChart by the surgeon or covering provider.
  - Pre-op antibiotics should be administered by the pre-op nurse or anesthesia provider to ensure they are administered within one hour prior to the incision window.
- If the patient is on oral antibiotics, give prior to the patient going to pre-op.
- Ensure **scheduled antibiotics** are given as ordered.
- If a scheduled antibiotic is due during the perioperative period, please send it to OR with the patient.

Beta Blockers

Patients on a beta blocker at home should receive their beta blocker during the perioperative period (24 hours prior to surgery through discharge from PACU).

- Stress associated with surgery increases heart rate, myocardial contractility, and myocardial oxygen demand, putting the patient at risk for an acute myocardial infarction (AMI).
- Beta blockers offer cardioprotection for patients with a history of MI and hypertension. They diminish the effects of epinephrine and other stress hormones.
- An MI during surgery results in a nine-fold increase in unstable angina, MI, and cardiac death in the post-op period.
- If the patient's heart rate is greater than 50 and the systolic blood pressure is greater than 100, administer and document beta blocker in PowerChart.
- If held or stopped for a specific reason, it must be documented. This also applies to the perioperative period. Communicate this to the pre-op RN during handoff.
- NPO does **not** mean the patient should not receive their beta blocker. If in doubt, clarify with the surgeon and document who ordered the hold and why it is being held.

Miscellaneous Medications

Aspirin (ASA)

If the patient has a cardiac stent and takes a daily 81mg dose of ASA at home, they must have their ASA dose within 24 hours of surgery start time. There are rare instances where the bleeding risk outweighs the benefits and a surgeon may order the ASA be held.

- If the patient is having a neurosurgery procedure, confirm with surgeon prior to administering aspirin.

Anticoagulants/Anti-platelet medications

- Most anticoagulants will need to be held for invasive procedures/surgery.
- Verify the surgeon's order if anticoagulants are to be held or continued. If no order is present addressing the patient's anticoagulation status, page the performing provider.

Other medications

Medications such as anti-seizure, Parkinsons, anti-rejection, and chronic pain, should be continued, if ordered.

Please call pre-op holding and ask to speak with the charge nurse if you are unsure about giving a medication.

References

Munson Medical Center Policies and Procedures

- Surgical Antibiotic Prophylaxis
- Pre-Procedure Nothing by Mouth Policy
- Ensuring H&Ps are Present Before Surgery/Invasive Procedure
- Skin Preparation of the Surgical Patient
- Jewelry Removal Prior to Surgery
- Pre and Post Surgical/Procedural Adult Protocols
- Plan of Care – Nursing Process in the OR
- Inpatient Pre-Procedure/Pre-Op Checklist and Patient Preparation

Munson Healthcare Policies and Procedures

- Informed Consent - Diagnostic or Therapeutic Procedures and Treatments

MUNSON HEALTHCARE

Overview of Procedural Sedation

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October 2023

Goal and Objective

Goal

This course will ensure standardized practice for delivering sedation/analgesia during diagnostic and therapeutic procedures performed outside of the operating room, according to MHC policy. The ultimate outcome is to provide for the safety of our patients during sedation.

Objective

After completing this course, the participant will be able to identify the four levels of sedation.

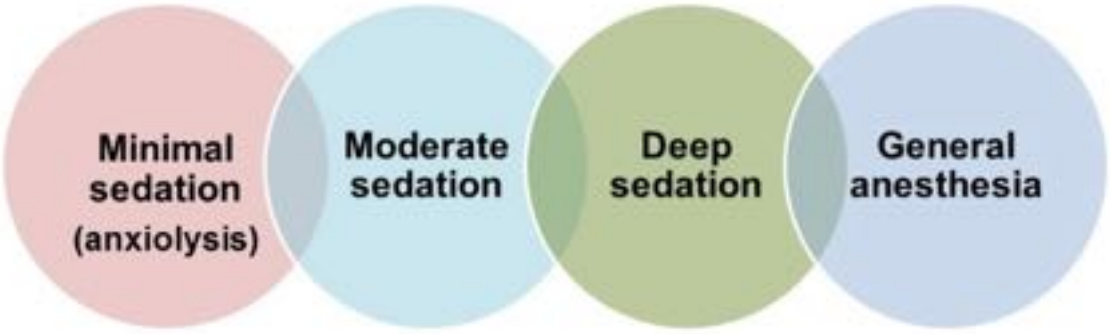
Exclusion List: Non-Procedural Sedation

The sedation policy and this education module **do not apply** when analgesics or sedative agents are given for the following:

- Pain management (analgesics given by **any** route).
- Minimal sedation (anxiolysis).
- Sedation during emergent medical care in an unstable patient.
- Sedation during ongoing ventilation therapy.
- Sedation for end of life/palliative care.
- Treatment of medical conditions such as delirium, alcohol withdrawal, traumatic brain injury, etc.

Four Levels of Sedation

In order to provide safe and effective care for patients receiving sedation, it is imperative that health care providers understand the four levels of sedation:



Minimal Sedation

This is a continuum. To understand, we will begin with minimal sedation, also known as anxiolysis.

Description	*Minimal Sedation*	*Moderate Sedation/Analgesia*	*Deep Sedation/Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	Maybe inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis)

Key Points – Minimal Sedation

- Anxiolysis is medication therapy given to reduce anxiety and to help patients relax, e.g., diazepam (Valium) PO or midazolam (Versed) IVP prior to a procedure.
- The patient continues to respond normally to verbal commands.
- This level of sedation has no effect on airway, breathing, or the cardiovascular system.
- Cognitive function and physical coordination may be impaired.



Moderate Sedation/Analgesia

Description	Minimal Sedation	Moderate Sedation/Analgesia	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	No response even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	Maybe inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Moderate Sedation

During moderate sedation, the patient experiences a depressed level of consciousness during which they retain their ability to maintain a continuously patent airway. The patient will respond appropriately to physical stimulation and verbal commands, yet maintain partial amnesia.

The patient receives relief from anxiety and pain, allowing them to tolerate unpleasant procedures.

Moderate sedation/analgesia also expedites the course of procedures that are uncomfortable and require the patient to not move:

- Central line placements
- Scope procedures (endoscopy, bronchoscopy)
- Chest tube placement
- Painful wound debridements

Moderate Sedation *(cont.)*

Key Points – Moderate Sedation

- The patient is able to respond to verbal commands.
- No interventions are needed to protect the airway or maintain heart rate and blood pressure, but close monitoring is essential.
- Cardiac monitoring is required for a patient with cardiovascular disease or dysrhythmia.
- Consents need to be signed before sedation is administered.



Clinical Characteristics of Moderate Sedation

Clinical characteristics of moderate sedation include:

- Maintenance of protective reflexes, i.e., gag reflex, ability to swallow, and ability to breathe without assistance.
- Independent and continuous maintenance of a patent airway.
- Purposeful response to physical stimulation and/or verbal commands.
- Easily aroused, with the provider talking in a normal tone of voice.
- Minimally depressed level of consciousness.
- Slightly slurred speech.

Example:

In a normal tone of voice, the nurse asks the patient to take a deep breath and open their eyes. The patient should be able to follow this type of command at this level of sedation.

Clinical Characteristics of Moderate Sedation *(cont.)*

Key Points – Moderate Sedation

- Important: A reflex withdrawal from a painful stimulus is not considered a purposeful response and is a sign the patient is progressing to general anesthesia.
- All practitioners involved with moderate sedation must be prepared to "rescue" the patient from a deeper level of sedation than was intended.



Knowledge Check

During a procedure requiring moderate sedation, who is required to know how to rescue a patient from a deeper level of sedation than intended?
(Choose all that apply.)

- ☑ The registered cardiovascular invasive specialists (RCIS) assisting with the procedure
- ☑ The registered nurse (RN) assisting with the procedure
- ☑ The provider performing the procedure

Deep Sedation/Analgesia

Description	Minimal Sedation	Moderate Sedation/Analgesia	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	Maybe inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Deep Sedation

Deep sedation is used for procedures such as cardioversions, closed reductions of joint dislocations, or fractures. Patients who are deeply sedated cannot be easily aroused, but they do respond purposefully to repeated or painful stimulation, such as a vigorous sternal rub.

Deep Sedation *(cont.)*

Key Point: A reflex withdrawal from a painful stimulus is **not** considered a purposeful response and is a sign the patient is progressing to general anesthesia.



The patient's respiratory status may be affected and spontaneous respirations may be inadequate.

- Assistance may be needed to maintain a patent airway.
- Ventilation assistance may be required.

Progression from Moderate to Deep Sedation

Clinical indications: Progression from moderate to deep sedation/anesthesia:

- Not easily aroused
- Partial or complete loss of protective reflexes
- Difficulty maintaining a patent airway independently
- Unable to respond to physical stimulation or verbal commands
- Severely slurred speech

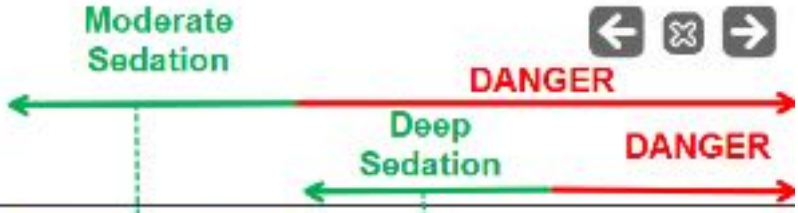


Key Point:
ALL practitioners involved with deep sedation MUST be prepared to "rescue" the patient from deep sedation or general anesthesia.

Progression from Moderate to Deep Sedation *(cont.)*

Clinical indications: Identifying a patient is in deep sedation:

- Similar to general anesthesia, the patient may be unable to maintain a patent airway.
- Loss of protective reflexes (unable to swallow, no cough, no gag reflex).
- The patient purposefully responds to repeated painful stimulation, such as a vigorous sternal rub.



	Minimal Sedation Anxiolysis	*Moderate Sedation/ Analgesia ("Conscious Sedation")*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Knowledge Check

Characteristics of anxiolysis include: (Choose all that apply.)

- ☐ Reflex withdrawal from a painful physical stimulus
- ☑ Ability to respond normally to verbal commands
- ☐ Diminished respiratory rate or blood pressure
- ☑ Ability to maintain a patent airway
- ☑ Administering midazolam (Versed) to a stressed patient prior to a procedure

Knowledge Check *(cont.)*

Drag the type of sedation to the light blue box beside its description.

Type of Sedation	Description
Deep Sedation	The patient is unresponsive to verbal commands, but does purposefully resond to a sternal rub. Assistance may be needed to maintain a patent airway and adequate ventilation.
Minimal Sedation (Anxiolysis)	The patient continues to respond normally to verbal commands. This level of sedation has no effect on airway, breathing, or the cardiovascular system.
Moderate Sedation	The patient is able to open their eyes and raise their hand when asked.

References

American Society of Anesthesiologists. *Position on monitored anesthesia care.* Last amended on October 23, 2019

Munson Healthcare Policies and Procedures. (2022, December 16). *Sedation.* PolicyStat.

MUNSON HEALTHCARE

Procedural Sedation: Roles and Responsibilities

Amy Krug, BSN, RN, CGRN
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October 2023

Goal and Objectives

Goal

This course will ensure standardized practice for delivering sedation/analgesia during diagnostic and therapeutic procedures performed outside of the operating room, according to MHC policy. The ultimate outcome is to provide for the safety of our patients during sedation.

Objectives

1. Identify who is qualified to order, administer, and monitor patients receiving moderate and deep sedation.
2. Describe the expected nursing care during procedural sedation.

Responsibilities

At MHC, Registered Nurses (RNs) and Registered Cardiovascular Invasive Specialists (RCIS) who will be monitoring sedated patients during procedures and administering moderate sedation are responsible for the following:

- Knowing the Sedation policy.
- Maintaining competence in sedation medication administration.
- Identifying when a patient has progressed to a deeper level of sedation than intended and intervening as needed.

NOTE: RNs and RCIS do not administer deep sedation for procedures.

Education Requirements

The education requirements for RNs and RCISs include:

Upon hire:

- Current BLS certification.
- Completion of the online HealthStream assignment.
- Completion of the airway station during RN orientation.
- Completion of the cardiac rhythm competency, the Basic ECG interpretation exam, or current ACLS certification.

Periodically thereafter:

Completion of periodic sedation education and demonstration of competence.

Provider Credential Check



At MHC, all physicians, physician assistants (PAs), nurse practitioners (NPs), and oral surgeons must be credentialed to provide sedation/analgesia.

Credential information is available via MHC Intranet.

Click Tools & Resources.

Provider Credential Check



At MHC, all physicians, physician assistants (PAs), nurse practitioners (NPs), and oral surgeons must be credentialed to provide sedation/analgesia.

Credential information is available via MHC Intranet.

Click Tools & Resources.

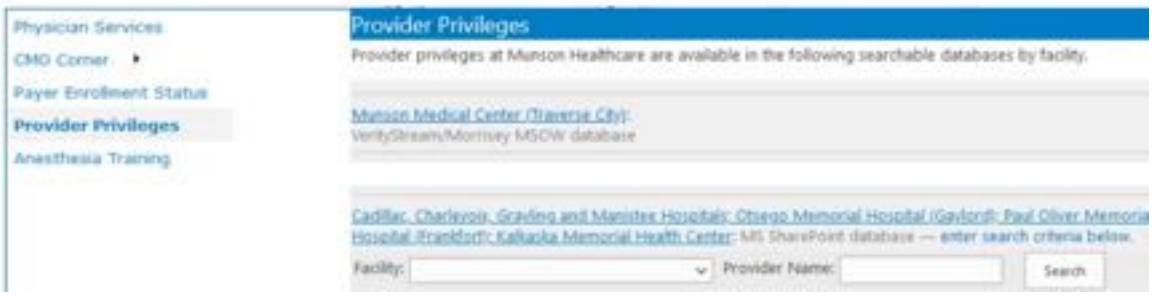
Click Physician Privileges.

Provider Credential Check



At MHC, all physicians, physician assistants (PAs), nurse practitioners (NPs), and oral surgeons must be credentialed to provide sedation/analgesia.

Credential information is available via MHC Intranet.



Knowledge Check

Who can administer moderate and deep sedation for procedural sedation (assuming they have the proper credentials and have completed the education)? (Choose all that apply.)

- [x] Oral Surgeon
- [ ] ICU RN who is ACLS-certified
- [x] Physician
- [x] Physician Assistant
- [x] Nurse Practitioner

Pre-procedure Responsibilities: Provider Assessment

The proceduralist/provider is required to complete a comprehensive assessment of the patient prior to performing the procedure. This includes:

- A determination of the patient's American Society of Anesthesiologists Classification (ASA Class).
  - This is used as a guideline for **NPO status**.
- An airway assessment.



Key Points:

- Anesthesiology can be consulted on any case, but consultation is **advisable** for patients with an ASA Class of IV or V.
  (See next page for description.)
- The pre-procedure assessment must be documented by the anesthesia provider.

Pre-procedure Responsibilities: ASA Classification

American Society of Anesthesiologists Classification ("ASA Class") [6]	
ASA I	A normal healthy patient
ASA II	A patient with mild systemic disease
ASA III	A patient with severe systemic disease that limits activity but is not incapacitating
▷ ASA IV	A patient with severe systemic disease that is a constant threat to life
▷ ASA V	A moribund patient who is not expected to survive without the operation or procedure
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes

▷ = Anesthesia consultation advised.

Pre-procedure Responsibilities: RN/RCIS Role

The RN or RCIS assisting with a procedure requiring sedation must ensure the following documentation is complete:

- Patient/family education
- Patient monitoring during procedure
- Time-based documentation during procedure

Prior to the procedure, the RN/RCIS must ensure all necessary supplies and equipment are available.



Pre-procedure Responsibilities: Patient Preparation

Procedural sedation preparation is the same as any other procedure or surgery.

- Ensure all orders and diagnostic tests are complete, e.g., lab tests, x-rays, skin preps, etc.
- Verify the patient's NPO status. Follow orders based on ASA class.
- Educate the patient and family regarding the procedure scheduled and expectations of sedation; CONSENT SIGNED prior to any administration of sedation.

Pre-procedure Responsibilities: Patient Preparation *(cont.)*

Validate all required components are complete:

1. Valid H&P is less than 30-days old with reassessment of the patient documented within 24-hours of admission prior to the procedure.
2. Validation of the correct surgical/invasive procedure
3. Evaluation immediately prior to the procedure
4. Medications
5. Allergies and previous drug reactions
6. Patient's age
7. Patient's weight
8. Pre-procedure laboratory and other diagnostic testing
9. Consent

Pre-procedure Responsibilities: Patient Preparation *(cont.)*

- Ensure a comprehensive assessment of the patient is completed.
- Perform a baseline pain assessment.
- Verify patent IV access.
- Pre-oxygenate the patient via nasal cannula at a flow rate of 2 L/m (unless medically contraindicated).
- Verify emergency equipment is available and in working condition.
- Identify the patient, using two identifiers. Validate the correct patient, procedure, and site.
- Perform a time-out prior to beginning the procedure.



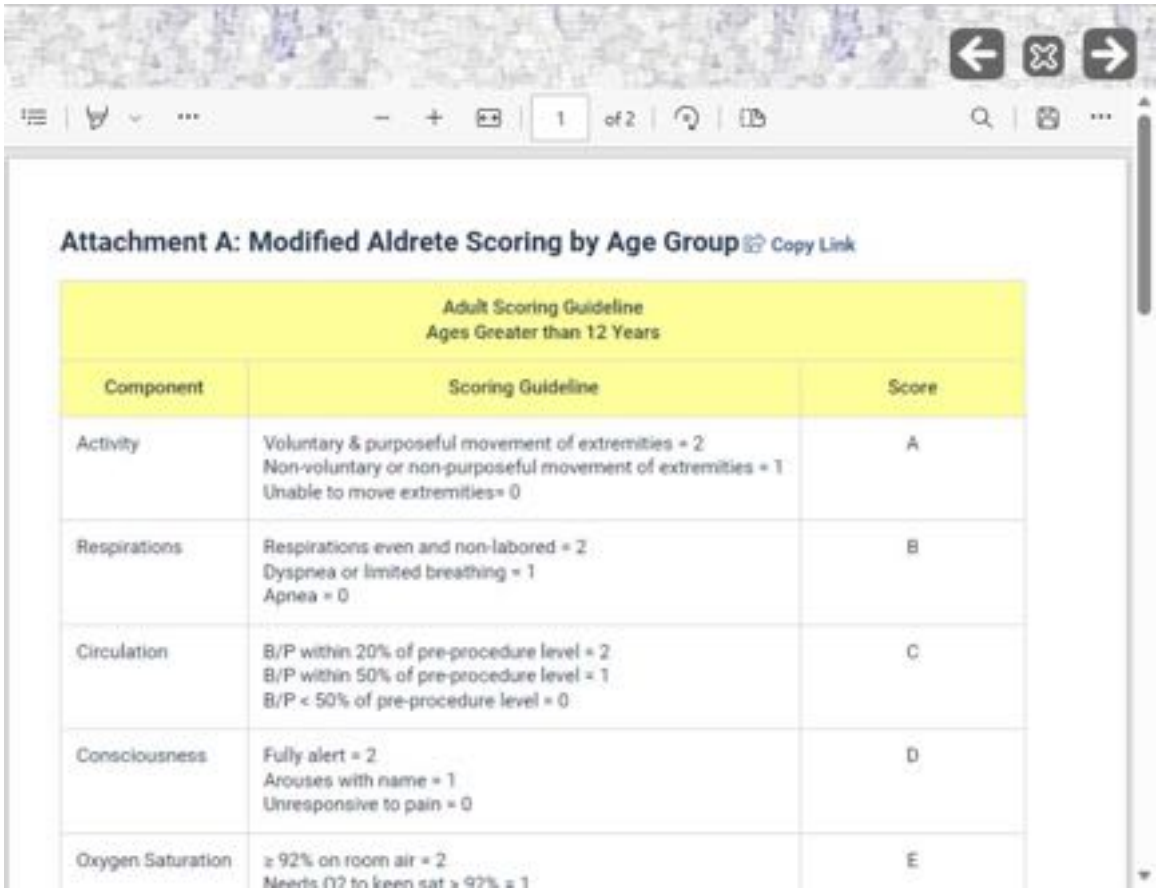
Pre-procedure Responsibilities: The Modified Aldrete Score (or validated tool)

Modified Aldrete Scoring is a measurement tool rating post-procedure recovery of consciousness, activity, respirations, and blood pressure.

- A pre-procedural Aldrete score is necessary to establish an accurate baseline of the patient's status.
- Pre-existing conditions should be considered when evaluating the patient's score.
- A post-procedural score should equal the pre-procedural baseline score prior to discharge from the recovery area.

PRINT the Modified Aldrete Scoring document for use with answers on the quiz.





1 of 2

Attachment A: Modified Aldrete Scoring by Age Group

Copy Link

Adult Scoring Guideline Ages Greater than 12 Years		
Component	**Scoring Guideline**	**Score**
Activity	Voluntary & purposeful movement of extremities = 2 Non-voluntary or non-purposeful movement of extremities = 1 Unable to move extremities= 0	A
Respirations	Respirations even and non-labored = 2 Dyspnea or limited breathing = 1 Apnea = 0	B
Circulation	B/P within 20% of pre-procedure level = 2 B/P within 50% of pre-procedure level = 1 B/P < 50% of pre-procedure level = 0	C
Consciousness	Fully alert = 2 Arouses with name = 1 Unresponsive to pain = 0	D
Oxygen Saturation	≥ 92% on room air = 2 Needs O2 to keep sat ≥ 92% = 1	E



Knowledge Check

The Modified Aldrete Scoring Guideline used to compare the patient's pre- and post-sedation status includes: (Choose all that apply.)

- [x] Activity
- [x] Respirations
- [ ] Pulse
- [ ] Cardiac rhythm
- [x] Blood pressure

Pre-procedure Responsibilities: Baseline Assessment

Immediately prior to medication administration, assess the following baseline parameters:

- Blood pressure
- Heart rate
- Respiratory rate
- Oxygen saturation
  - Maintain adult $SpO_2 \geq 92\%$ and pediatric $SpO_2 \geq 95\%$.
- End-tidal CO_2 level
  - Maintain CO_2 at 35 – 45 mmHg.
  - The CO_2 level will increase if the patient's ventilatory status is compromised.
- Level of consciousness
- Cardiac rhythm
  - Continuous ECG monitoring is required for **all** patients with a cardiac history or expected dysrhythmias, and for **all** deep sedation cases.
- Modified Aldrete score

Knowledge Check

Pre-oxygenation at 2 L/m via nasal cannula is required for all procedural sedation cases, unless medically contraindicated.

- (●) True
- ( ) False

Pre-procedure Responsibilities: Time-Out

Key Point: A "time-out" is **mandatory** prior to the start of the procedure.





During the time-out, the entire procedural team must pause, including the patient when possible, and verify the:

- Correct patient, using two patient identifiers
- Correct procedure
- Correct site (if applicable), including laterality

There must be **100% agreement** of the team **prior to starting** the procedure.

The time-out **must be documented** in the patient's medical record.

Intra-procedure Responsibilities: Monitoring

At a minimum, the following parameters should be monitored and documented **after every medication administration** and **every 5-10 minutes** during the procedure, following each additional dose of medication and more frequently as the patient's clinical needs dictate.

- Blood pressure
- Heart rate
- Respiratory rate
- Oxygen saturation
  - Maintain adult $SpO_2 \geq 92\%$
  - Maintain pediatric $SpO_2 \geq 95\%$.
- Identification and management of adverse events
- Level of consciousness
- Medication: dose, route, time
- Modified Aldrete score
- Pain level
- $EtCO_2$ level

Intra- & Post-procedure Assessment Considerations

Monitor the following to determine the patient's tolerance to the procedure:

- Significant variances in blood pressure, heart rate, respiratory rate and effort, SpO_2, and end-tidal CO_2.
- The patient's response **or** lack of response to verbal and physical stimuli.
- Facial grimacing and physical posturing, tensing, or flaccidity.

When observing the above, ask yourself:

- "Is the patient sedated enough?"
- "Is the patient experiencing pain?"
- "Is the patient over-sedated or at risk of being over-sedated?"

Post-procedure Monitoring

Post-procedure, the following page lists parameters which should be monitored continuously and documented **every 15 minutes**, depending on the patient's condition and the procedure performed.

Documentation will continue through the post-procedure period until the patient reaches 8 or greater on the Modified Aldrete score.

Post-procedure Responsibilities: Monitoring

At a minimum, the following parameters should be monitored and documented **after every medication administration** and **every 5-10 minutes** during the procedure, following each additional dose of medication and more frequently as the patient's clinical needs dictate.

- Blood pressure
- Heart rate
- Respiratory rate
- Oxygen saturation
  - Maintain adult $SpO_2 \geq 92\%$
  - Maintain pediatric $SpO_2 \geq 95\%$.
- Identification and management of adverse events
- Level of consciousness
- Medication: dose, route, time
- Modified Aldrete score
- Pain level
- $EtCO_2$ level

Post-procedure Responsibilities: Monitoring *(cont.)*

- Blood pressure
- Heart rate
- Respiratory rate
- Oxygen saturation
  - Maintain adult $SpO_2 \geq 92\%$
  - Maintain pediatric $SpO_2 \geq 95\%$.
- Identification and management of adverse events.
- Level of consciousness
- Medication: dose, route, time
- Modified Aldrete score
- Pain level
- Nausea
- End-tidal CO_2 level
  - Maintain CO_2 at 35 – 45 mmHg.
  - The CO_2 level will increase if the patient's ventilatory status is compromised.
- Cardiac rhythm
  - Continuous ECG monitoring is required for **all** patients with a cardiac history or expected dysrhythmias and for **all** deep sedation cases.

Post-procedure Assessment Considerations

- Patients may continue to be at significant risk for persistent/residual sedation effects or for developing complications after the procedure is completed.
- The reassessment and documentation of vital signs will revert to unit-specific standards of practice once the post-procedure monitoring criteria have been met.
- The patient's pain level may become more acute as the level of sedation decreases and will need to be treated accordingly.

Post-procedure and Over-Sedation

Over-sedated patients will require an extended recovery period.

Key Points:

- Monitor Patient - If the patient received a reversal agent due to over-sedation, they must be monitored for a minimum of two hours after the last dose of the reversal agent.
- Submit a VOICE File:
  - When a reversal agent is used to rescue a patient.
  - If there are any complications or adverse outcomes.



Discharge from Procedural Units

Patients are either discharged to their inpatient unit or discharged to home from the procedural unit.

Patients may be discharged when **at least** 30 minutes have elapsed since the last dose of sedation/analgesia was given.



Key Points:

If a reversal agent was administered, the patient must be monitored for at least 2 hours after the last dose of reversal agent was given.

Monitoring can continue on an inpatient unit.

Discharge Criteria

Prior to discharge, the following criteria must be met:

- Vital signs must be stable.
- Modified Aldrete score must be ≥ 8.
- None, or mild nausea with no active emesis.
- Patient is arousable with protective reflexes intact.
- Pain-free, mild discomfort, or controlled with analgesics.
- Mobility must be back to pre-procedure baseline.

Interpreting the Modified Aldrete Score

A patient requires either **a score ≥ 8** or **a proceduralist/provider's order** to be transferred or discharged from the procedural unit. Other department/ procedural-specific discharge criteria may also need to be applied.



Key Point:

A score < 8 indicates the patient should be closely monitored with interventions applied as indicated.

Discharging Inpatients vs. Outpatients

Inpatients:

- A full hand-off report must be given to the next provider of care.

Outpatients:

- Written discharge instructions must be reviewed with the patient and responsible party.
- Discharge instructions include the hospital- and department-specific instructions and the 24-hour minimum restrictions mandated for patients who have received pain or sedative agents, including an emergency phone number.



Key Point:

A responsible individual **must** be available to transport the patient home.

Knowledge Check

You are caring for a patient immediately post-bronchoscopy. She is very groggy, but arouses when you call her name. She can move her extremities when asked, but she keeps falling back to sleep. Her respirations are non-labored, but her respiratory rate is 9-10. Her blood pressure is 108/68 (baseline was 124/78). She needs O_2 at 2 L/m via nasal cannula to keep her oxygen saturation at 93%.

What is her Modified Aldrete Score?

- ○ 4
- ○ 5
- ○ 6
- ◉ 7
- ○ 8

Knowledge Check *(cont.)*

Continuing with the same patient in the previous question, what does her score need to be for her to be discharged from the procedural area?

- ○ Greater than or equal to 4
- ○ Greater than or equal to 6
- ◉ Greater than or equal to 8
- ○ Greater than or equal to 10

Reference

Munson Healthcare Policies and Procedures. (2022, December 16). *Sedation*. PolicyStat.

Symptom Management for Procedural Sedation

Amy Krug, BSN, RN, CGRN
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October 2023

Goal and Objectives

Goal

This course will increase the participant's knowledge of managing potential symptoms associated with patients receiving procedural sedation.

Objectives

1. Identify when a patient has progressed to a deeper level of sedation.
2. Identify nursing interventions appropriate to the patient's rescue needs.

Common Side Effects of Sedation

The most common side effects of sedation administration are:

- Respiratory depression
- Hypotension
- Nausea and vomiting
- Paradoxical response

The most common adverse effect of opioids, especially when combined with sedatives, is respiratory depression.

If left untreated, respiratory depression can progress to apnea, followed by cardiac arrest.

$EtCO_2$ and pulse oximetry may show early signs of respiratory distress.



Treatment of Respiratory Depression

- **Stop all administration of opioids and sedatives!**
  - The duration of these medications depends on the drug, dose, route of administration, and the patient's condition.
- Maintain an open airway:
  1. Reposition the head/neck using the chin-lift or jaw-thrust.
  2. Provide oxygen therapy. Be prepared to use an ambu bag if necessary.
  3. Insert a nasal or oropharyngeal airway as necessary.
- If airway management is not effective, administer the appropriate reversal agent:
  - Flumazenil (Romazicon) for benzodiazepines.
  - Naloxone (Narcan) for opioids.
- Call MRT as appropriate.

If the patient does not respond to airway management maneuvers and the reversal agent, call a Code Blue (5-5555)!

Knowledge Check

The most common side effect of sedation administration is:

- (●) Respiratory Depression
- ( ) Paradoxical Response
- ( ) Nausea and Vomiting
- ( ) Hypotension

Knowledge Check *(cont.)*

If respiratory depression occurs while I am assisting with a procedure that requires sedation, I should do all of the following: (Choose all that apply.)

- [ ] Reposition the head/neck by tucking the chin to the chest.
- [x] Provide oxygen therapy, assisting with ventilation, if necessary.
- [x] Insert an oropharyngeal airway, if needed.
- [x] Administer the appropriate reversal agent.

Hypotension

Hypotension is most likely caused by vasodilation, blood loss during the procedure, or a pre-existing condition, but could also be caused by sedation. The cause of the hypotension determines the treatment.

Possible treatments:

- IV fluid replacement
- Vasopressors
- Blood transfusion
- If you suspect the cause is over-sedation, administer reversal agents per protocol:
  - Flumazenil (Romazicon) for benzodiazepines.
  - Naloxone (Narcan) for opioids.

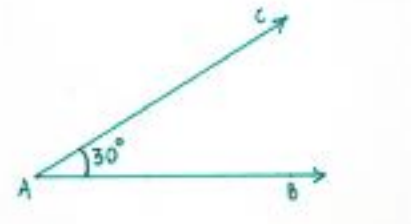


Nausea and Vomiting

Aspiration is a major concern with the patient receiving sedation.

Treatment for nausea and vomiting:

- Position the patient to prevent aspiration. The preferred position is Semi-Fowlers with the head of the bed at 30 degrees and the patient on his/her side.
- Suction as necessary to maintain a patent airway.
- Administer an antiemetic.
- Patient to remain NPO until awake and alert.



Paradoxical Responses

The desired effect of moderate sedation or analgesia is a relaxed and cooperative patient. The patient is sedated but can be aroused and is able to follow simple commands.

If a patient has a sensitivity to a specific drug, a paradoxical response can occur. Consider a paradoxical response if the patient becomes any of these:

- Agitated
- Uncooperative
- Combative
- Disoriented

Paradoxical Responses *(cont.)*

A thorough patient assessment is imperative to determine the actual cause of the patient's symptoms.

Paradoxical responses are seen more often in patients with a history of alcohol or IV drug abuse (most frequent).

Other causes to consider include:

- Hypoventilation due to hypoxia.
- Inadequate dosing of pain medication during a painful procedure.

Over-sedation

Symptoms:

- Decreased respiratory function (hypoventilation, decreased respiratory rate, or apnea)
- Decreased cardiovascular function (hypotension or dysrhythmias)
- Confusion
- Decreased level of consciousness that can progress to coma
- Depressed/absent cough and gag reflex
- Decreased response to physical/verbal stimuli

Treatment of Over Sedation

Treatment:

- Ensure an open airway.
- Encourage or stimulate the patient to breathe.
- Administer supplemental oxygen to increase or maintain oxygen saturation greater than or equal to 92%.
- Ventilate with ambu bag if spontaneous ventilation is inadequate.
- Administer reversal agents per protocol:
  - flumazenil (Romazicon) for benzodiazepines.
  - naloxone (Narcan) for opioids or narcotics.
- If hypotensive, infuse IV fluids or consider vasopressors.
- Reposition patient to semi-fowlers.
- Consider MRT or RT evaluation, if approriate.
- If patient uses home CPAP/BiPAP, also use it post-procedure.

If the patient does not respond to airway management maneuvers and the reversal agent, call a Code Blue (5-5555)!

Knowledge Check

Symptoms of over-sedation include: (Choose all that apply.)

- [x] Decreased response to stimuli
- [x] Decreased respiratory rate
- [ ] Agitation
- [x] Hypotension

Knowledge Check *(cont.)*

If a patient is in respiratory arrest and does not respond to airway management and reversal agents, I should:

- (•) Call a Code Blue.
- ( ) Call and MRT.
- ( ) Call the provider.

Reporting Requirements

Whenever it is necessary to administer a reversal agent, a VOICE file must be completed. Access the form from the MHC Intranet.

Other complications related to sedation to be reported include:

- Incidents in which the patient slips into a level of sedation that is greater than intended, e.g., moderate to deep sedation.
- Profound hypotension (50% decrease from pre-procedure mean blood pressure)
- Cardiac arrest
- Defibrillation
- Respiratory arrest
- Seizures
- Aspiration
- Medication errors
- Vomiting



Knowledge Check

I must fill out a VOICE file for the following situations: (Choose all that apply.)

- ☑ If a patient slips into a deeper level of sedation than intended.
- ☑ Profound hypotension
- ☑ Medication errors
- ☑ If a reversal agent is required to control an adverse reaction, such as respiratory depression.

References

Munson Healthcare Policies and Procedures. (2022, December 16). *Sedation*. PolicyStat.

Munson Healthcare Policies and Procedures. (2021, April 20). *Flumazenil Protocol*. PolicyStat.

Munson Healthcare Policies and Procedures. (2022, February 21). *Standing Order/Protocol for Adult Naloxone (Narcan)*. PolicyStat.

Procedural Sedation Medication Guidelines

Lauren Wolf, PharmD, BCPS, BCCCP

December 2025

Goal and Objectives

Goal

This course will increase the participant's knowledge of administering medications for procedural sedation.

Objectives

1. Identify staff who can administer sedation.
2. Select the appropriate medication and dose for reversing over sedation.

Introduction

Dosage guidelines for procedural sedation and reversal agents are approved by the Pharmacy and Therapeutics (P & T) Committee at Munson Medical Center.

These guidelines are intended for initial doses and may be exceeded or decreased according to the patient's history, previous response to sedatives or other clinical circumstances.

Prior to administration, the P & T Committee must review and approve the use of all medications not listed in the approved guidelines.



Guidelines Location

Nurses and Registered Cardiovascular Invasive Specialists (RCIS) should be familiar with medication guidelines before administering sedation. The medication guidelines are attached to the Sedation policy.

Moderate & Deep Sedation/Analgesia Drug Usage Guidelines are listed below. **Print** the document to use as a reference for upcoming questions.

Attachment C: Moderate Sedation/Analgesia Drug Usage Guidelines

A. IVP by RN or ED Trained Pharmacist in the presence of the provider credentialed for moderate sedation

B. Not intended for Neonates - Unless otherwise indicated

Drug	Pharmacokinetics	Drug Dosage & Administration	Precautions / Contraindications
Diazepam (Valium)	Onset: IV: 1-3 min	Adults IV: 5-10mg - no faster	• Titrate to effect. Do not dilute.

Facility-specific IV Push and Infusion Guidelines

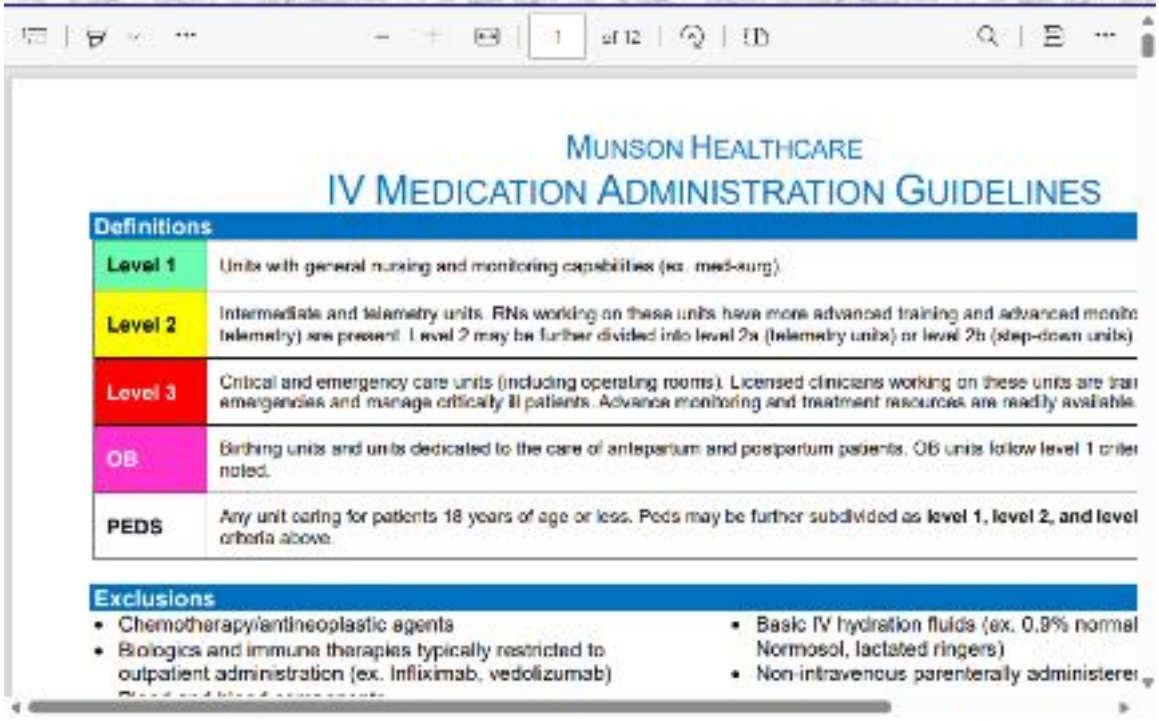
Munson Healthcare has an IV Push/Infusion Chart to assist staff with decisions regarding the administration of medications. This chart can be found on the Intranet on the Pharmacy Department site.

The chart contains various topics, including:

- Medications administered by IV push or by infusion.
- Approved medications per department.
- Medications a nurse can give during a Code Blue.
- Medications requiring a physician be present during administration.

NOTE: See the IV Push Chart on the next slide.

MMC IV Push Chart



MUNSON HEALTHCARE

IV MEDICATION ADMINISTRATION GUIDELINES

Definitions

Level 1	Units with general nursing and monitoring capabilities (ex. med-surg).
Level 2	Intermediate and telemetry units. RNs working on these units have more advanced training and advanced monito telemetry) are present. Level 2 may be further divided into level 2a (telemetry units) or level 2b (step-down units)
Level 3	Critical and emergency care units (including operating rooms). Licensed clinicians working on these units are trai emergencies and manage critically ill patients. Advance monitoring and treatment resources are readily available.
OB	Birthing units and units dedicated to the care of antepartum and postpartum patients. OB units follow level 1 crite noted.
PEDS	Any unit caring for patients 18 years of age or less. Peds may be further subdivided as **level 1, level 2, and level** criteria above.

Exclusions

- Chemotherapy/antineoplastic agents
- Biologics and immune therapies typically restricted to outpatient administration (ex. Infliximab, vedolizumab)
- Basic IV hydration fluids (ex. 0.9% normal Normosol, lactated ringers)
- Non-intravenous parenterally administere

Who Can Administer Sedation?



Medications for **moderate** sedation may be given by a registered nurse (RN) or registered cardiovascular invasive specialist (RCIS) in the presence of the physician, physician assistant (PA), nurse practitioner (NP), or oral surgeon credentialed in moderate sedation and in advanced airway management.

Who Can Administer Sedation? *(cont.)*

Medications for **deep** sedation, can **ONLY** be administered by a provider credentialed in deep sedation.



- **Exception: Propofol** - a critical care RN may give propofol (Diprivan) IVP for an emergent intubation while a physician is present and performing the intubation.
  - Critical care is defined by the IV Push/Infusion Chart to include these units:
    - ✓ ICU
    - ✓ ED
    - ✓ PACU
    - ✓ OR
    - ✓ A2 (critical)
    - ✓ A3 (critical)
    - ✓ IR

Knowledge Check

A patient is scheduled for a wound debridement at the bedside. The physician orders hydromorphone (Dilaudid) 0.1-0.5mg IV titrated over 1 minute for moderate sedation.

This is an approved dose according to the MMC Moderate Sedation Guidelines.

- (●) True
- ( ) False

Knowledge Check *(cont.)*

A patient is scheduled for a synchronized cardioversion. The physician orders propofol (Diprivan) at 1mg/kg per minute over 60 seconds.

How long do the effects of propofol (Diprivan) last?

- ( ) 1-2 minutes
- (■) 3-10 minutes
- ( ) 12-20 minutes
- ( ) 25-30 minutes

Knowledge Check *(cont.)*

A registered nurse from the ICU can give propofol (Diprivan) IV push with a physician order, if the physician is present in the room, but is not intubating the patient.

- ○ True
- ◉ False

Reversal Agents

- Reversal agents may be indicated when:
  - The level of sedation is deeper than desired.
  - The patient's responsiveness or cardio-respiratory status is compromised.
  - An idiosyncratic reaction occurs.
- If a reversal agent is administered for the undesired effects, a **VOICE** file is required.
- A patient should be monitored for a minimum of two hours after giving a reversal agent.

Commonly Used Opioids

If a patient becomes difficult to arouse with verbal or physical stimuli related to sedation from an opioid, follow the Standing Order/Protocol for Adult Naloxone (Narcan) Protocol. The naloxone (Narcan) protocol can be located:

- Policy website on the Intranet
- Pharmacy website on the Intranet
- Side of the crash cart

Examples of commonly used opioids include:

Codeine	Morphine
Demerol (meperidine)	Norco (hydrocodone + acetaminophen)
Dilaudid (hydromorphone)	Oxycontin (oxycodone)
Dolophine (methadone)	Percocet (oxycodone + acetaminophen)
Duragesic (fentanyl patch)	Sublimaze (fentanyl injection)

naloxone (Narcan) Protocol

The naloxone protocol allows the registered nurse or RCIS to:

- Titrate oxygen to maintain an oxygen saturation of at least 92%.
- Perform further interventions, including the administration of naloxone depending on the patient's mental status and O_2 saturation.
- For patients with oxygen saturations ≥ to 80%, dilute the naloxone 0.4 mg in 9 ml of normal saline and administer in small, 1mL doses following the protocol. This allows for better titration of the dosing [so the patient doesn't over respond to the naloxone and end up in severe pain].
- Give naloxone 0.4 mg **undiluted** for an O_2 saturation below 80% or respiratory arrest.

NOTE: Click the button.

Review the naloxone (Narcan) Protocol

Show Changes

Tag Policy

Standing Order/Protocol for Adult Naloxone (Narcan)

Purpose

To provide a policy for Adult Naloxone (Narcan) standing orders/protocols.

Policy

A. The Protocol for Adult Naloxone (Narcan) shown below, is approved as a standing order and may be initiated by a Registered Nurse (RN) or Licensed Practical Nurse (LPN) without a provider order for any patient if:

1. Patient is difficult to arouse with verbal/physical stimuli ~**AND**~
2. Patient is on, or recently was on, opioids or suspected that the patient has consumed opioids

B. This protocol is not applicable for end of life/palliative or comfort care/hospice patients. Call provider to clarify if any questions.

C. If criteria above are met then the initiating [illegible] would enter by Physician Order Entry (POE) using

naloxone (Narcan) Points to Remember

- The onset of action for naloxone is within 2 minutes.
- The half-life of naloxone is 30-90 minutes.
- Many opioids have a longer half-life than naloxone, so it is important to monitor your patients closely. A repeat dose of naloxone may be required.

Knowledge Check

A 52-year-old female was admitted post-intervention to her right coronary artery. She received an initial dose of morphine sulfate 2 mg IV push prior to her sheath pull. She continued to complain of discomfort @ 8/10. An additional morphine sulfate 4 mg IV push was administered for discomfort. Respirations are now 5/minute; oxygen saturation is 82%. The patient is not arousable to verbal stimuli, but is arousable to a sternal rub.

Which dose of reversal agent should be initiated?

- [x] naloxone 0.4 mg diluted in 9 mL of normal saline, and give 1 mL IV push
- [ ] naloxone 0.4 mg diluted in 9 mL of normal saline, and give IV push
- [ ] naloxone 0.4 mg IV push (undiluted)
- [ ] naloxone 0.4 mg diluted in 9 mL of normal saline, and give 2 mL IV push

Treating Over Sedation from a Benzodiazepine

If a patient becomes difficult to arouse with verbal or physical stimuli related to sedation from a benzodiazepine, follow the flumazenil (Romazicon) protocol.

The flumazenil protocol can be located:

- Policy website on Intranet
- Pharmacy website on Intranet
- Side of the crash cart

Commonly Used Benzodiazepines

The most commonly used benzodiazepines are:

alprazolam (Xanax) ★	flurazepam (Dalmane)
chlordiazepoxide (Librium)	**lorazepam (Ativan)** ★
clonazepam (Klonopin)	**midazolam (Versed)** ★
clorazepate (Tranxene)	oxazepam (Serax)
diazepam (Valium) ★	**temazepam (Restoril)** ★
estazolam (Prosom)	triazolam (Halcion)

★ = MMC formulary benzodiazepines

flumazenil (Romazicon) Protocol

The flumazenil Protocol allows the registered nurse or RCIS to:

- Titrate oxygen to maintain an oxygen saturation of at least 92%.
- Perform interventions, including administering flumazenil if the patient is unarousable AND:
  - Oxygen saturation is less than 89% **OR**
  - Respiratory rate is less than 6.
- Initial dose: flumazenil 0.2 mg IV push over 30 seconds

NOTE: Click the button to review the flumazenil protocol; check for repeat dosing and the complete intervention sequence.

Review the flumazenil (Romazicon) Protocol

Show Changes

POMH)

Tag Policy

Flumazenil Protocol

Purpose

Flumazenil (Romazican) protocol for suspected Benzodiazepine overdose in adults.

Policy

Flumazenil Reversal Protocol (Physician Order Required)

Purpose: Flumazenil (Romazicon) protocol for suspected Benzodiazepine Overdose in Adults

Most Common Benzodiazepines
- Alprazolam (Xanax)
- Chlordiazepoxide (Librium)
- Clonazepam (Klonopin)
- Clorazepate (Tranxene)
- Diazepam (Valium)
- Estazolam (ProSom)

Difficult to arouse with verbal/physical stimuli or suspected benzodiazepine overdose

- Page respiratory therapy STAT
- STAT SpO2

flumazenil (Romazicon) Points to Remember

- The onset of action is 1-2 minutes.
- Duration:
  - Re-sedation occurs after approximately 1 hour (range: 19-50 minutes).
- Many benzodiazepines have a longer half-life than flumazenil, so it is important to monitor your patients closely. A repeat dose may be required.
- Avoid use of flumazenil in patients with chronic benzodiazepine use. Its use may precipitate seizures.

Knowledge Check

You are assigned to an 88-year-old man who arose from a sitting position and had a syncopal episode. He was placed on the stroke unit for telemetry monitoring. At the start of your evening shift, he becomes very agitated. An order is obtained to give him lorazepam (Ativan). He finally falls asleep after 0300. At the end of the shift (0700), you find him difficult to arouse to both verbal and physical stimuli. His respirations are 5/minute and his oxygen saturation is 86%.

Which reversal dosing agent is appropriate for this patient?

- ○ Undiluted naloxone (Narcan) 0.4 mg IV push STAT
- ○ Diluted naloxone (Narcan) 0.4 mg in 9 mL normal saline
- ◉ flumazenil (Romazicon) 0.2 mg IV push over 30 seconds
- ○ flumazenil (Romazicon) 0.4 mg IV push over 30 seconds

Selecting naloxone (Narcan) vs. flumazenil (Romazicon)

When a patient has received/taken both a benzodiazepine and an opioid, and a reversal agent is needed, **give the naloxone first**.

Reasons:

- Opioids are more likely to cause respiratory depression and other adverse effects, such as hypotension.
- flumazenil can cause seizures in patients with a history of long-term use of benzodiazepines.

Knowledge Check

A 21-year-old female patient has returned following endoscopy in the Medical Procedure Room. She received Demerol 75 mg and Versed 7.5 mg during the procedure.

She has a history of taking Xanax 0.25 mg three times per day for anxiety and Vicodin PRN for pain. She was discharged to B2 following an uneventful recovery with an Aldrete score of 8. Respirations are now 5/minute with an oxygen saturation of 85%. The patient is not arousable to verbal stimuli, but does arouse to a sternal rub.

Which reversal agent protocol should be used first?

- (●) naloxone (Narcan) Protocol
- ( ) flumazenil (Romazicon) Protocol

Knowledge Check *(cont.)*

A 21-year-old female patient has returned following endoscopy in the Medical Procedure Room. She received Demerol 75 mg and Versed 7.5 mg during the procedure.

She has a history of taking Xanax 0.25 mg three times per day for anxiety and Vicodin PRN for pain. She was discharged to B2 following an uneventful recovery with an Aldrete score of 8. Respirations are now 5 minute with an oxygen saturation of 85%. The patient is not arousable to verbal stimuli, but does arouse to a sternal rub.

Which dose of Narcan (naloxone) should be administered?

- ( ) naloxone 0.4 mg IV push (undiluted)
- ( ) naloxone 0.4 mg diluted in 9 mL of nomal saline, and give IV push
- ( ) naloxone 0.4 mg diluted in 9 mL of normal saline, and give 2 mL IV push
- (●) naloxone 0.4 mg diluted in 9 mL of normal saline, and give 1 mL IV push

Treating Patients Who Revert to a Deeper Level of Sedation

- Remember, the effects of opioids and benzodiazepines last longer than the effects of the reversal agents.
- Continue to monitor the patient for signs of progression to a deeper level of sedation for a minimum of 2 hours.
- Repeated dosing of the reversal agents may be needed.
- Create and submit a **VOICE** file.

Dissociative Sedation

Dissociative sedation is a trance state where the patient remains awake, but is unaware of pain and will have no memory of the event.

- In comparison to deep sedation, which causes the patient to:
  - Be unarousable, except with repeated or painful stimuli
  - Experience respiratory depression

Ketamine for Dissociative Sedation

Ketamine will be administered by providers credentialed for deep sedation.

1. A pharmacist, nurse, or non-credentialed provider may administer medications for dissociative sedation in the Emergency Department, as long as a provider credentialed for deep sedation, an RN, and a respiratory therapist are ***ALL*** present.
2. Respiratory adverse events, such as apnea or laryngospasm (although uncommon), may still occur, and providers must always be prepared to rescue the patient from a deep sedation state anytime ketamine is administered.
3. Ketamine (IM/IV) is used for dossociative sedation in both children and adults (including the mentally disabled) for medical procedures such as, but not limited to: fracture reduction, laceration repair, abscess drainage, foreign body removal.
4. If Ketamine is administered IM, IV access should be immediately available.

References

Lexicomp. (2023, November 29). *Flumazenil*. Retrieved December 5, 2023.

Munson Healthcare Policies and Procedures. (2021, April 20). *Flumazenil Protocol*. PolicyStat.

Munson Healthcare Policies and Procedures. (2022, February 21). *Standing Order/Protocol for Adult naloxone (Narcan)*. PolicyStat.

Munson Medical Center. (2023, October). *IV push/infusion chart - adult*.

Munson Medical Center Policies and Procedures. (2022, December 16). *Sedation*. PolicyStat.

Radial Artery Access and Care

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October 2025

MUNSON HEALTHCARE

Goal and Objectives

Goal

The goal for this course is to educate the nurse on radial access anatomy, care, and complications.

Objectives

1. Describe three benefits and limitations of radial artery access.
2. Differentiate three radial post-procedural complications and their treatments.
3. Explain radial artery patency in relation to radial artery occlusion.

Background, Benefits, and Limitations of Radial Access

- On August 14th, 1992, the first interventional coronary procedure was performed using the radial artery.
- **Radial artery access** is now the ***Gold Standard*** of practice in the Cath Lab and Interventional Radiology (IR).

Benefits	Limitations
Early ambulation	Prone to vasospasm
Fewer bleeding complications	Arterial vessel size limitations: Women have smaller vessels
Faster discharge rate	Difficult tortuosity
Collateral circulation prevents hand ischemia	Vessel accommodates up to 6fr sheath
Absence of major nerve structures minimizes neurological complications	Radial/brachial anatomical loops

Review of Radial Anatomy

The radial artery arises together with the ulnar artery from the bifurcation of the brachial artery just below the bend of the elbow.

It passes along the lateral side of the forearm from the neck of the radius to the styloid process in the wrist and is smaller than the ulnar artery.

The average diameter of the radial artery is:

- ***2.8mm in females***
- ***3.1mm in males***

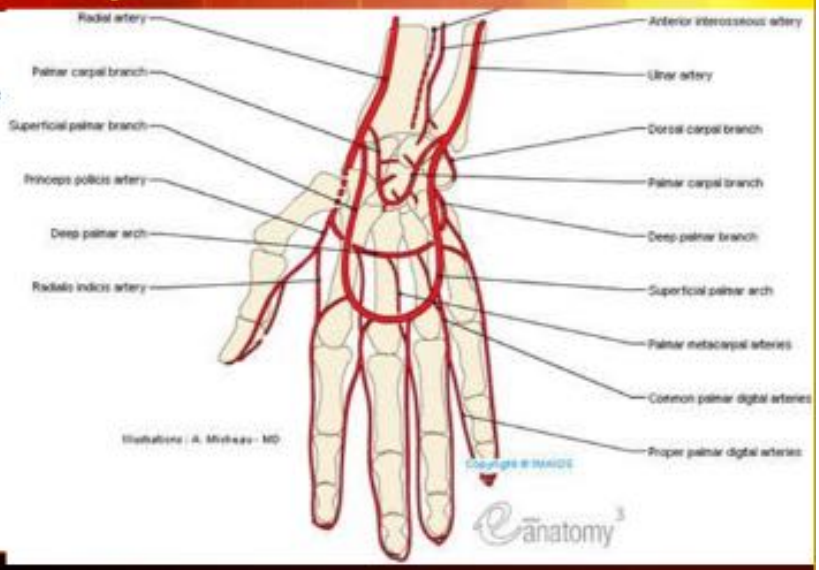
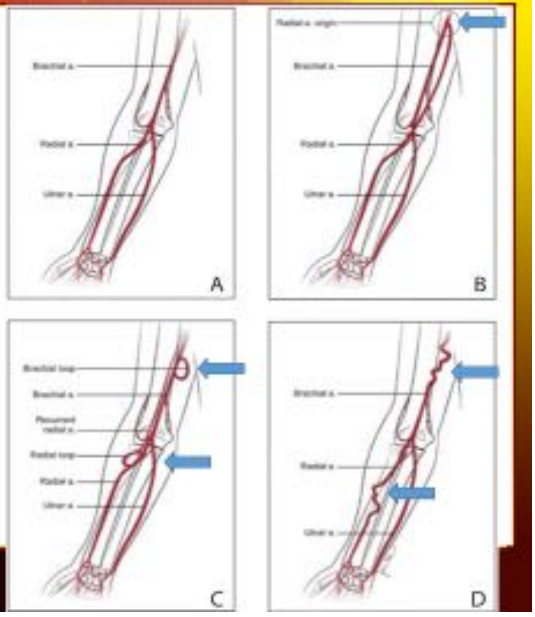


Image purchased from: https://www.imaios.com/en/e-anatomy/upper-limb/upper-extremity?mc=ms

Anatomical Considerations

Common radial artery anatomic variants

- **Normal (A)**
- **Other variants:**
  - High take-off radial artery **(B)**.
  - Radial and/or brachial loop **(C)**.
  - Vessel tortuosity **(D)**.
- *Consider abnormal variants as possible limitations to radial access which may increase risk of complications.*



Krishna, H., & Shroff, A. (2018). Ten Common (and Uncommon) Reasons for Unsuccessful Transradial Procedures. [Figure 1]. *Endovascular Today*, 17(11), 59. Retrieved from https://assets.bmctoday.net/evtoday/pdf/art1118_SF2_Shroff.pdf

Pre-procedural Considerations

Pre-procedural care includes:

- Assessment ***and*** documentation of the radial pulse bilaterally.
- **Clip the wrist** from the base of the thumb, approximately **15cm** towards the antecubital area.
- **Clip the right groin** (may need to use femoral approach, if radial limitations occur).
- Avoid starting an IV within **9cm** of the wrist area.



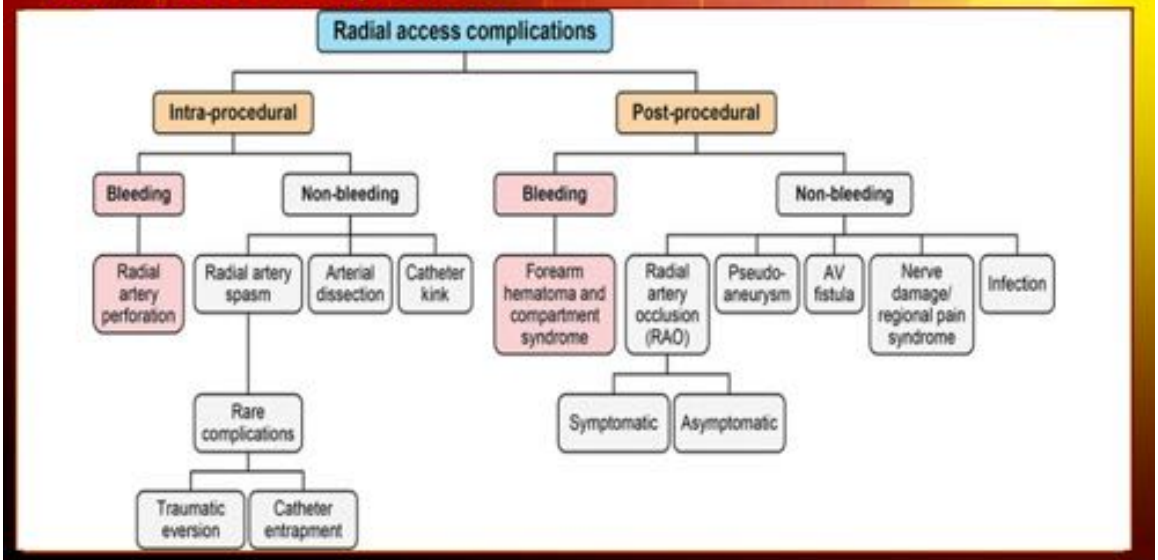
Radial Artery: Access Procedure

Radial Access Sheath Insertion



(1½ mins.)

Radial Access Complications



Radial Access Care

The compression device is used to apply direct pressure to the radial artery.

Upon receiving patient, verify the radial band is in the correct position (~2mm above the puncture site).

- **Elevate** the arm on a pillow with the site facing up.
- **Place** the limb-alert wrist band on the affected hand and leave it on for **2 days** post-procedure.
- Place the **Plethysmography/SpO_2** monitor on the ***affected*** hand (index finger or thumb).
  - **Verify patent hemostasis** by occluding the ulnar artery and ensuring blood flow to the hand (plethysmography wave form on monitor).
- **Assess** for signs and symptoms of bleeding, hematoma, pseudo-aneurysm, compartment syndrome, and radial artery occlusion.
- **Control** hypertension.
  - Place the blood pressure (BP) cuff on the ***non-procedural*** arm.
- **Verify** the type of procedure: Diagnostic vs Intervention
  - **Diagnostic procedure:** Remove 1-2cc of air, 1-hour post-procedure.
  - **Intervention (PCI, FFR, IVUS, OCT):** Remove 1-2cc of air, 2-hours post-procedure.
- Do not leave the radial compression band on the patient for an extended period of time.

Post-Procedural Complications: Re-bleed

Re-bleeding at the Access Site and Hematoma

- Bleeding can occur from the radial access site or from a small peripheral side branch of the radial artery.
- Local bleeding or hematomas may occur as a result of improper hemostatic device application, device failure, or vessel perforation.

What to do?

- **Compression of the radial artery**, ***both*** *proximal and distal* to the puncture site must be performed to control both antegrade and retrograde flow from the palmar arch collateral.
- **This can be achieved by** repositioning the hemostatic band or applying manual pressure.
- **If unable to control bleeding** or a growing hematoma at the access site, **occlude the brachial artery**, either manually or with a blood pressure cuff.

Post-Procedural Complications: Hematoma

Forearm Hematoma

- Bleeding may also rarely occur from a site on the radial artery remote from the puncture site. It can **occur from a perforation of a small side branch of the radial artery by a guide wire.**
- **If not controlled urgently** and appropriately, forearm hematomas can lead to the development of **compartment syndrome**. The forearm is anatomically susceptible to an increase in pressure, in case of a blood leak, as it has very little room for expansion.

Forearm Hematoma

What to do?

- Apply pressure to **occlude** the brachial artery by using the BP cuff to compress the brachial artery.
  - **Inflate the BP cuff** to **20mmHg above the systolic pressure.**
  - **Release the BP cuff pressure for 10-15 seconds every 10 minutes** to allow blood flow to the arm.
- **Assess** for pain, paresthesia, pallor, and pulselessness of the hand.
- **Protamine** can be used for Heparin reversal.
- **Control hypertension**, attain pain management, and closely monitor the distal perfusion bed with plethysmography.
- Assess the hematoma every 15 mins. by **measuring it with a measuring tape. Mark the borders with a marker** to check if the hematoma is growing.
- ***Suspect compartment syndrome?*** Consult a vascular surgeon.

Compartment Syndrome

This is a **rare** complication of radial artery catheterization. ***If not identified and treated emergently, it can lead to profound disability or limb loss.***

Compartment syndrome is an EMERGENCY!

Greater than expected **pain** is the earliest and most reliable indicator.

- Escalating pain unrelieved by immobilization and requiring increasing analgesics should illicit high suspicion.

A **swollen and tense** compartment is a direct manifestation of increased pressure.

An abnormal sensation, feeling like "pins and needles" and tingling, can be in the arm and hand.

Late indicators

- Decreased pulses.
- Absence of pain - due to tissue ischemia and necrosis or nerve injury.

Post-Procedural Complications - Pseudoaneurysm

Pseudoaneurysm

- Rarely occurs at the radial artery access site.
- Should be suspected in the presence of ***pulsatile swelling at the access site.***
- **Often painless**; however, some patients can have associated discomfort.
- ***Risk factors:*** systemic anticoagulation, inadequate compression post-procedure, infection, and multiple arterial punctures.

Diagnosis is confirmed by ultrasound.

What to do?

- Apply pressure to the brachial artery ***and*** notify the provider.
- Management options ordered by provider: compression with a radial hemostasis device, thrombin injection, ultrasound-guided compression, or surgical repair.

Post-Procedural Complications - Radial Artery Occlusion

Radial Artery Occlusion (RAO)

- Occurs in 1-12% of cases.
- **Often asymptomatic** and goes unnoticed.
- Limits use of the radial artery for: future cardiac catheterizations, use as a conduit in patients undergoing coronary artery bypass graft surgery, or for creation of an arteriovenous fistula in patients with end-stage renal disease.
- Hand ischemia is rare, but may occur.

Factors Impacting the Risk of RAO

Pre-procedural risk factors
- Elevated creatinine
- Female
- Low body weight
- Diabetes

Intra-procedural risk factors
- Artery to sheath ratio >1
- Vasospasm
- Longer procedure time

Post–procedural risk factors
- Longer compression
- Too much compression limiting blood flow through radial artery

Radial Artery Occlusion Risk Reduction

Factors that decrease the risk of RAO:
- Smaller catheters
- Heparin use during procedure
- Timely sheath removal
- **Patent hemostasis!!!**
- Short duration of compressive device

What is Patent Hemostasis?

Patent hemostasis is the technique of maintaining radial artery flow through guided artery compression during hemostasis.

- After the procedure is completed, the compression band is applied and 15-20cc of air is injected to exhibit pressure on the radial artery puncture site by the Cath Lab.
- The radial sheath is removed and no exterior bleeding should be observed at the arteriotomy (puncture) site.
- This volume of air typically creates radial artery total or partial collapse. At this point, slow balloon deflation (1cc/second) is performed until a small jet of bleeding is observed at the skin puncture site. In order to stop it, a quick insertion of 2cc of air is performed.

Radial Artery Patency (Patent Hemostasis)

Using a pulse oximetry waveform, radial artery patency should be assessed:

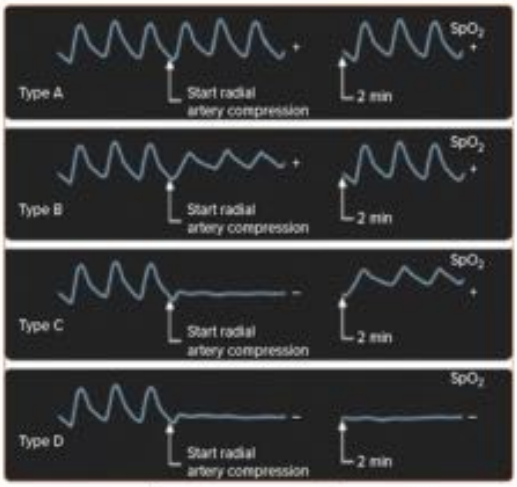
- Immediately after application of the compression device.
- On arrival to recovery room/inpatient unit.
- Whenever there is an increase in amount of air in the compression or adjustments to the compression band.
- After removal of the compression band.
- At the time of discharge.

How to Check Patent Hemostasis

- Patency of the radial artery is checked with a reversed Barbeau's test.
- Place the oximetry pulse detector on the patient's thumb or index finger on the affected hand. With the balloon inflated on the top of the radial artery, **simultaneous manual compression should be applied to collapse the ulnar artery.**
- If the inflated balloon has too much pressure, causing radial artery collapse, **the plethysmography pulse waveform will be flat**; in other words, there is no "flow" pulse/flow reaching the detector. In that case, an additional *1cc should be aspirated* from the balloon with the goal to reestablish flow through the radial artery.

What to Do for No-Flow on Pulse Oximetry

- If **no-flow** is identified, **remove 1-2cc of air** from the band until the flow is restored and patent hemostasis is achieved.
- **If bleeding occurs** and unable to maintain hemostatis, re-check in 15 minutes.
- **If *no-flow is* identified *after the band is removed*, immediately notify the provider.**
- **Document** patent hemostasis in IView.



A,B, and C show patent hemostasis

D indicates no flow

Site Assessment Post-Procedure

Thoroughly assess the radial access site for:

- Bleeding or oozing
- Hematoma formation
- Pain or tenderness
- Bruising/Discoloration

Perform neurovascular checks and document:

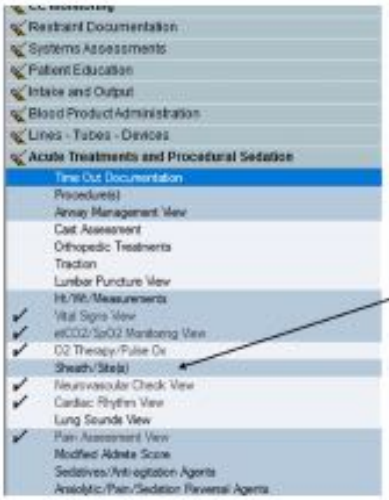
- Capillary refill
- Skin temperature and color: Compare with contralateral hand
- Radial and ulnar pulses: Presence, strength, and symmetry
- Sensation and motor function: Assess fingers for movement and any numbness/tingling
- Reversed Barbeau Test post-procedure to ensure collateral circulation

Post-Procedure Site Documentation

- Assess site immediately after arrival from the procedure.
- Verify the time and that the radial compression band was applied.
- Follow provider orders for frequency of site assessment.
- Assess site immediately before and immediately after any activity.
- Document the site assessment in PowerChart.



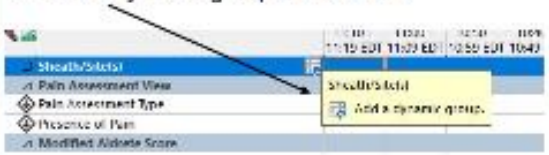
Sheath/Site Documentation



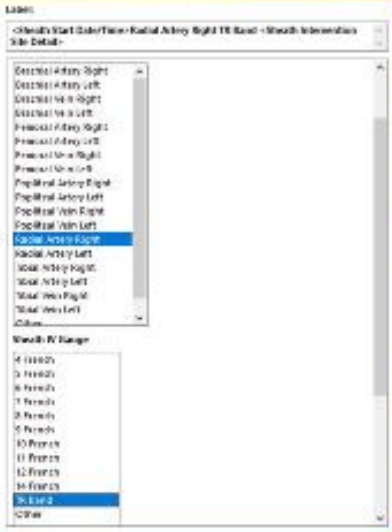
- Document sheath sites and neurovascular status in the Sheath/Site(s) section of the "Acute Treatments and Procedural Sedation" band in iView.

Sheath/Site Documentation (con't)

- Add a dynamic group for each site



- Select the correct site and choose "TR band" for a radial site with a band in place



Sheath/Site Documentation (con't)

- Document the assessment including:
  - Site condition
  - Presence of a closure device
  - Compression activity/band
  - Drainage
  - Site interventions
- **NOTE:** A TR band is NOT a closure device.
- With each site assessment, document a neurovascular check of the affected limb.



Summary

- Radial approach is the gold standard of practice in the Cath Lab.
- It allows for early mobilization, increases patient satisfaction, and decreases bleeding complications.
- Nursing interventions include awareness and prevention of complications.
- A rare complication of radial access is compartment syndrome.
- With the increase in radial use, RAO is a potential concern with permanent consequences.
- Patent hemostasis is considered best practice to prevent RAO.

For any questions or concerns, please contact the Cath Lab Clinical Nurse Specialist.

Case Study #1

Patient: John D., 67-year-old male

Procedure: Coronary angiography via right radial artery

Post-procedure orders:

- Radial compression band applied
- Vital signs Q15 minutes X 1 hour, then Q30 minutes X 2 hours
- Assess neurovascular status and site per protocol

Situation:

One hour post-procedure, the nurse notes that the patient's right hand is cooler than the left, and capillary refill is sluggish. The radial pulse is weak but present. The compression band is still inflated at the same pressure as it was post-procedure.

Case Study #1 Questions

Question 1:

What is the nurse's priority action in response to the assessment findings?

- ○ Document findings and continue monitoring
- ○ Notify the provider immediately
- ◉ Deflate the radial band slightly and reassess perfusion
- ○ Apply a warm compress to the affected hand

Question 2:

Which of the following is a critical nursing intervention during the first hour after radial artery procedures?

- ○ Encourage full mobility to prevent stiffness
- ◉ Frequently assess for signs of bleeding and neurovascular compromise
- ○ Apply ice packs to prevent inflammation
- ○ Encourage the patient to flex the wrist to promote circulation

Case Study #2

Patient: Maria L., 58-year-old female

Procedure: Subclavian artery stent via left radial access

Post-procedure orders:

- Radial compression band to be weaned off over 2 hours
- Monitor access site for bleeding, swelling, and hematoma
- Patient instructed to report tingling or numbness

Situation:

90 minutes post-procedure, the nurse begins deflating the radial band as per protocol. As air is released, the patient reports feeling a "warm, wet sensation" at her wrist. On inspection, there is oozing at the site.

Case Study #2 Questions

Question 1:

What is the most appropriate immediate response by the nurse?

- ○ Continue deflating the band
- ◉ Re-inflate the band slightly and apply direct pressure
- ○ Remove the band and apply a gauze dressing
- ○ Notify the provider and document the finding

Question 2:

Which patient complaint would be most concerning during radial band monitoring?

- ◉ "My hand feels cold and numb"
- ○ "This band is tight, but not painful"
- ○ "I feel tired and want to sleep"
- ○ "I'm feeling a little thirsty"

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Sandoval, Y., Bell, M. R., & Gulati, R. (2019). Transradial artery access complications. *Circulation: Cardiovascular Interventions*, *12*(11), e007386.

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MUNSON HEALTHCARE

Femoral Post Sheath Removal Care

Magdalena Stewart, DNP, AGPCNP-BC, AGCNS-BC, CCRC

December 2025

Goal and Objectives

Goal

To educate health care providers in the care of the patient femoral post sheath removal.

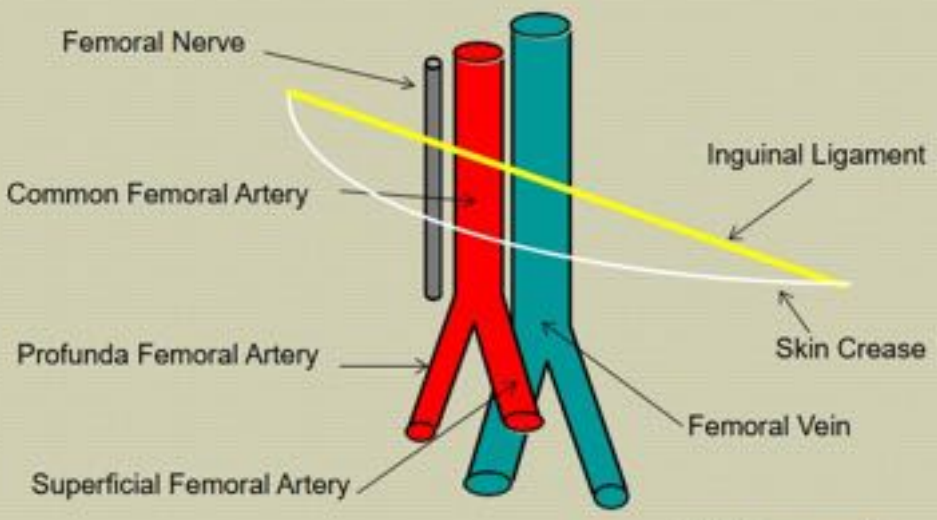
Objectives

1. Identify vascular anatomy.
2. State the process of hemostasis.
3. Define five complications that may occur femoral post sheath removal.
4. Identify potential complications associated with closure/compression devices.
5. State two nursing considerations for identified complications.

Progress

Vascular Anatomy

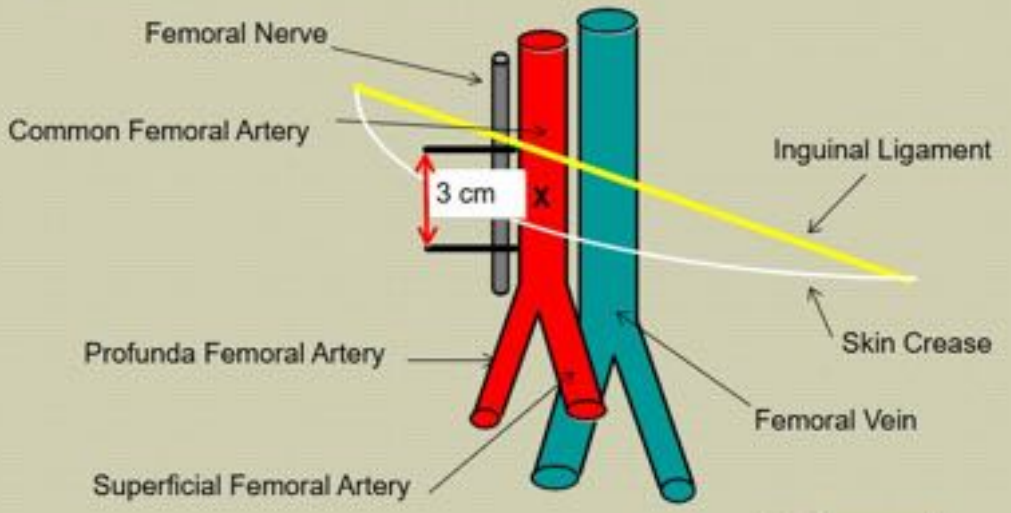
Identify the nerve, artery, vein, and ligament structures in the groin area.



Progress

Vascular Anatomy Relevant to the Sheath Insertion Site

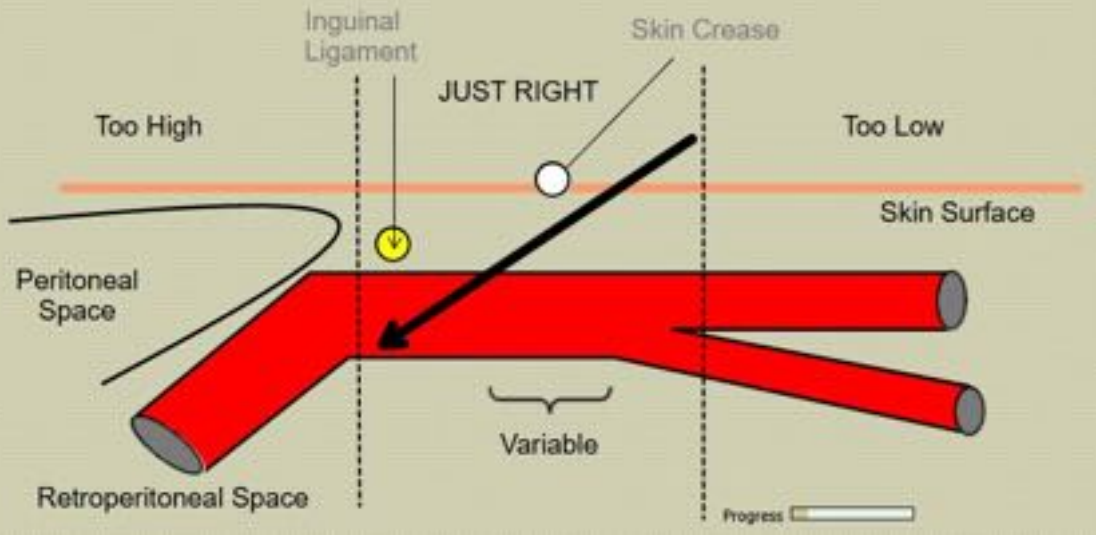
The arterial stick should be placed approximately 3 cm below the inguinal ligament and directly over the femoral artery pulse.



Progress

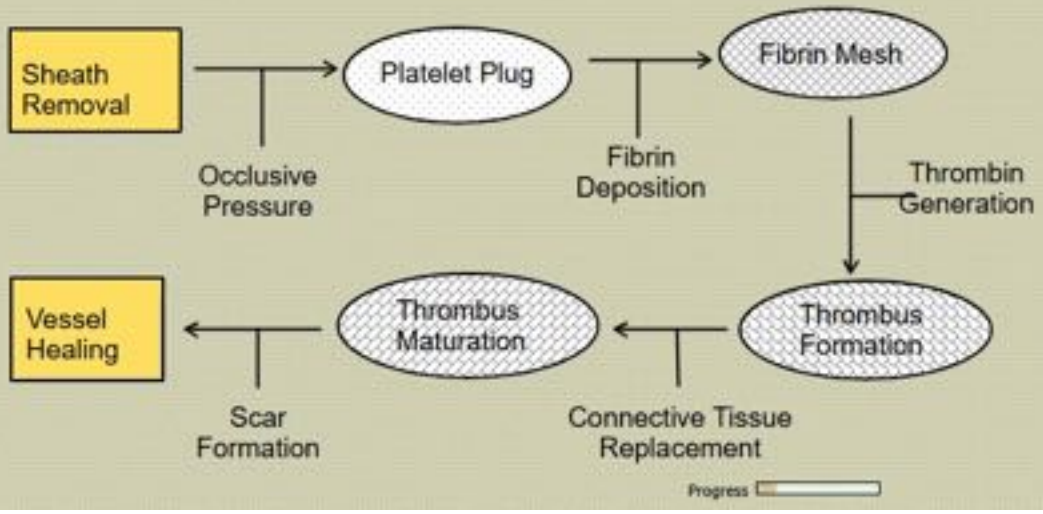
Arterial Puncture

If the arterial puncture is too high or too low, it may result in vascular complications. Review the correct position for puncture below.



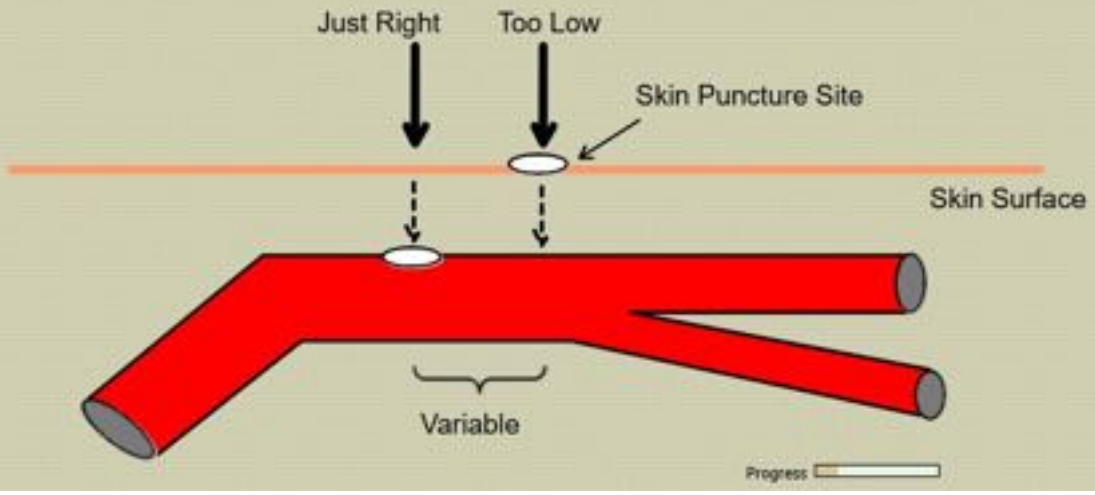
The Hemostasis Process

This is the normal hemostasis process. The process can be disrupted by certain drugs such as heparin and Integrilin.



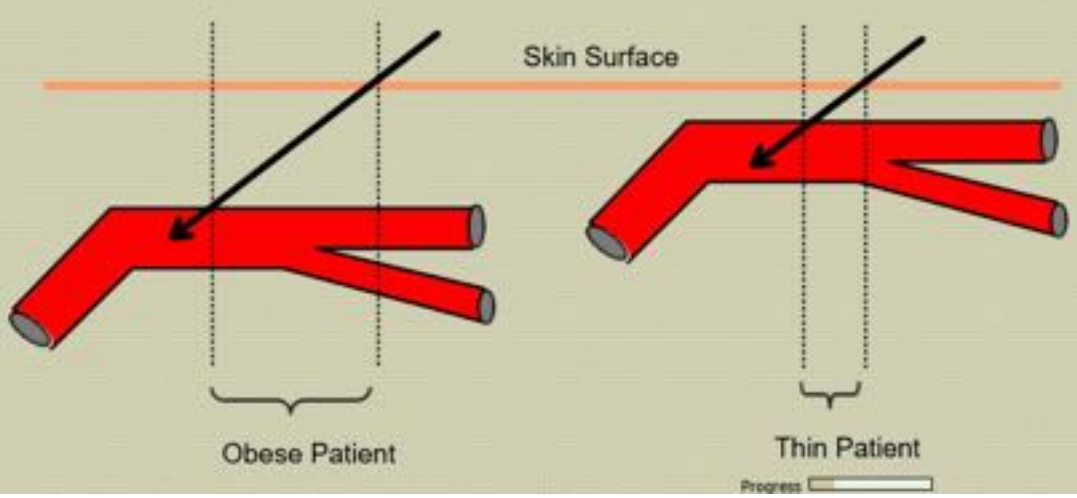
Hemostasis

Manual pressure should be applied 2-3 cm above the skin puncture to achieve hemostasis.



Hemostasis *(cont.)*

Vascular anatomy may be displaced depending on the weight of the patient.



Post Sheath Pull:
Potential Vascular Complications

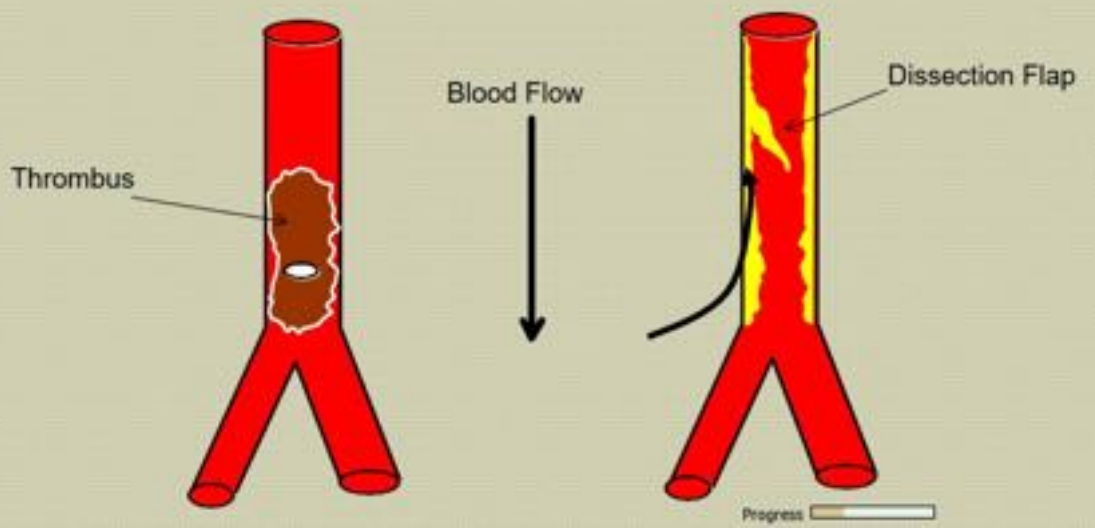
- Vessel thrombosis and dissection
- Bleeding
- Re-bleeding
- Femoral hematoma
- Retroperitoneal hemorrhage
- Pseudoaneurysm
- Arteriovenous fistula
- Atheroembolism

If any of the above complications occur, contact:
Cardiac Cath Lab - 231-935-9578
or the "neuro-on-call" if IR case

Progress

Vascular Complications:
Vessel Thrombosis and Dissection

Blood flow may be inhibited by a thrombus or dissection.



Progress

Vascular Complications: Vessel Thrombosis and Dissection *(cont.)*

Key Points

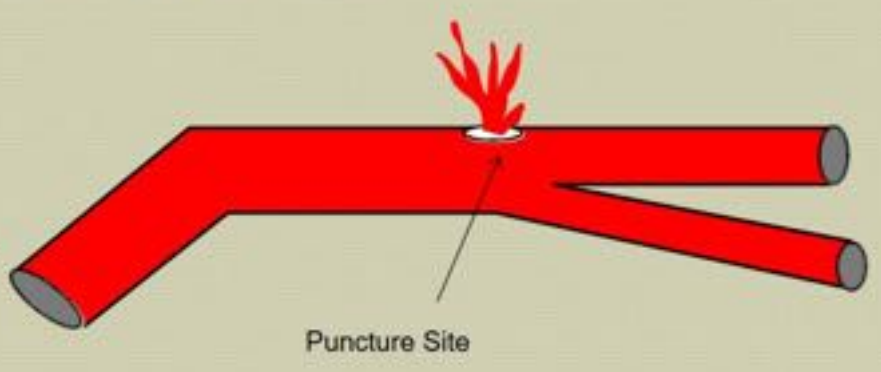
- Femoral artery thrombosis is rare and typically occurs in patients with small arterial lumens. Examples: peripheral vascular disease (PVD), diabetes mellitus (DM), and female gender.
- Dissection usually occurs in the setting of PVD or difficult arterial access.
- Patients commonly complain of leg pain or numbness.
- Physical exam reveals diminished or absent pulses.
- Rapid recognition is critical to avoid irreversible limb ischemia.
- Doppler ultrasound can be diagnostic.
- Urgent revascularization (surgical or percutaneous) is the treatment of choice.

Progress

Vascular Complications: Re-Bleeding

A re-bleed is uncontrolled bleeding from the puncture site.

- It is possible for the Hematocrit to drop by ≥ 10% and the hemoglobin to drop by ≥ 3 g/dL.
- The patient may require a transfusion.



Progress

Nursing Considerations: Re-Bleeding

- Assess distal pulse prior to compression.
- Apply gloves and palpate artery just superior to puncture site.
- **Apply manual pressure above the site for a minimum of 20 minutes. No peeking!**
- Compression should be forceful enough to prevent bleeding, oozing, and hematoma formation.
- Delegate someone to call the cardiology provider.
- After bleeding stops, assess for hematoma.
- After hemostasis, restart bed rest and site checks per protocol.
- Document in a Focus Note in PowerChart.
- Assess distal pulses.
- Check Hgb/Hct, if indicated.

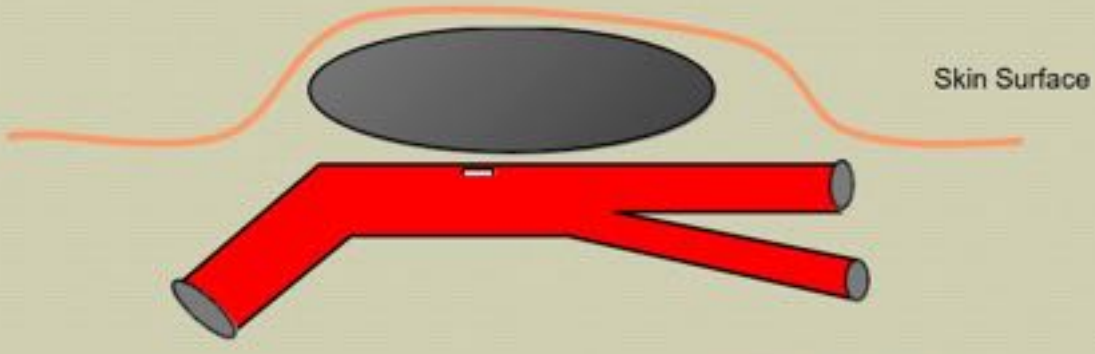


Progress

Vascular Complications: Hematoma

A hematoma is a collection of blood in the soft tissues of the upper thigh causing a tender mass of variable size.

- It is possible for the Hematocrit to drop by ≥ 10% and the hemoglobin to drop by ≥ 3 g/dL.
- The patient may require a transfusion.



Progress

Vascular Complications: Hematoma *(cont.)*

Risk Factors:

- Female gender
- Low platelet count
- Operator technique - inaccurate puncture of common femoral artery; number of arterial punctures
- Anticoagulation and/or platelet inhibitors
- Sheath size
- Delayed sheath pull
- Sheath pull technique
- Noncompliant patient or patient unable to comply with bed rest protocol

Progress

Vascular Complications: Hematoma *(cont.)*

Key Points:

- Hematomas can occur at any time before or after sheath removal.
- Measure (by palpation or imaging) and document the maximal dimension of the hematoma in centimeters.
- Immediate treatment includes correct manual compression. Do not "mash on" or massage the hematoma as this can cause damage to the vessel.
- Serial Hgb measurements and blood transfusions as needed. These are the treatments of choice.
- 1 - 2 weeks is required to reabsorb the hematoma and the patient should be warned about normal changes in the hematoma's appearance.
- Femoral nerve compression can occur from large hematomas.
- Surgical drainage is rarely needed.
- **Deaths do occur from hematomas - they must be respected.**

Progress

Nursing Considerations: Hematoma

- Assess distal pulse prior to compression.
- Apply gloves and palpate artery just superior to puncture site.
- **Apply manual pressure above the site for minimum of 20 minutes. No peeking!**
- Compression should be forceful enough to prevent increased hematoma formation, while maintaining distal pulses.
- Delegate someone to call the cardiology provider.
- Mark site: measure in centimeters.
- In PowerChart, document both a Focus Note and the hematoma size in Iview.
- Check Hgb/Hct, if indicated.



Progress

Nursing Considerations: Manual Compression Technique



Wrong Techniques



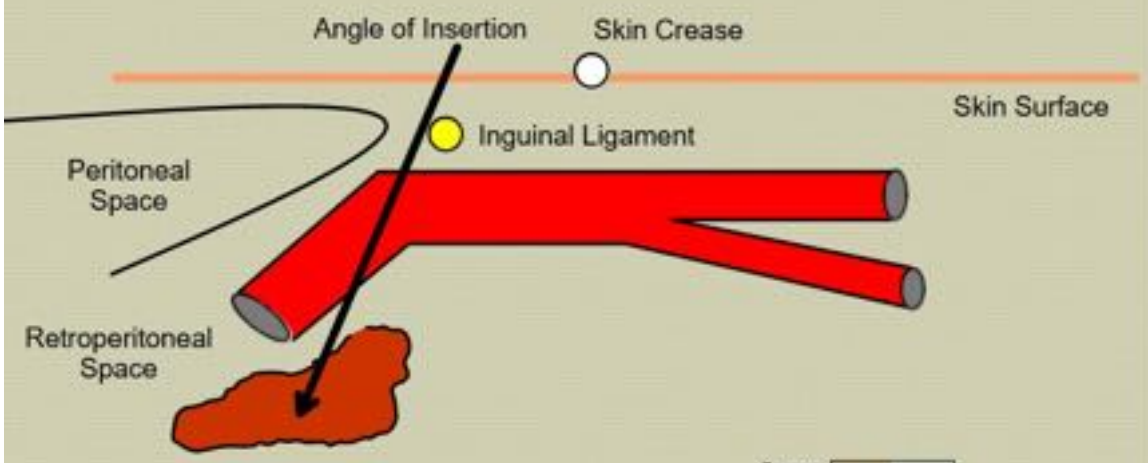
Correct Technique



Progress

Vascular Complications: Retroperitoneal Hemorrhage

A retroperitoneal hemorrhage is a hematoma extending into the retroperitoneal space that usually occurs from arterial puncture above the inguinal ligament.



Progress

Vascular Complications: Retroperitoneal Hemorrhage *(cont.)*

Risk Factors:

- Female gender
- Low platelet count
- Improper operator technique: a "high" stick above the inguinal ligament or a puncture through the back wall of the artery
- Anticoagulation and platelet inhibitors
- Sheath size
- Delayed sheath removal

Progress

Vascular Complications: Retroperitoneal Hemorrhage *(cont.)*

Key Points:

- This type of bleeding is not evident from the surface.
- Symptoms include hypotension, abdominal pain, and ipsilateral flank pain.
- Physical exam may reveal a palpable mass with discoloration over the flank or abdomen.
- Marked anemia can occur from blood loss.
- **This is a life-threatening situation!**
- CT scanning is the diagnostic test of choice.
- Treatment usually involves stopping anticoagulants, bed rest, and blood transfusion.

Progress

Vascular Complications: Pseudoaneurysm

A pseudoaneurysm is an interruption of the artery wall from the femoral artery puncture that does not thrombose when arterial sheaths are removed. This interruption in the arterial wall, caused by the original puncture, allows blood to jet back and forth from the bloodstream to the pouch. The aneurysm is termed "false." It does not involve any layers of the vessel wall as found with a true aneurysm.

"False" aneurysms can be masked by a hematoma and may rupture at any time. They continue to expand because they lack elastic fibers.



Progress

Vascular Complications: Pseudoaneurysm *(cont.)*

Risk Factors:

- Anticoagulation and platelet inhibitors.
- Obesity - causes difficulty in maintaining direct pressure.
- Advanced age - causes loss of tissue elasticity.
- Atherosclerotic occlusive disease.
- Increased sheath size - creates larger vascular interruption.
- Improper operator technique.
- Thrombolytic therapy - interrupts previously achieved hemostasis.
- Infection - impairs healing at the site of hemostasis.

Progress

Vascular Complications: Pseudoaneurysm *(cont.)*

Key Points:

- Physical exam reveals a pulsatile mass with a bruit auscultated superior to the puncture site. Bruits are heard when an artery is partially obstructed causing turbulent blood flow.
- Listen for bruits with the bell of the stethoscope held lightly against the skin.



Progress

Vascular Complications: Pseudoaneurysm *(cont.)*

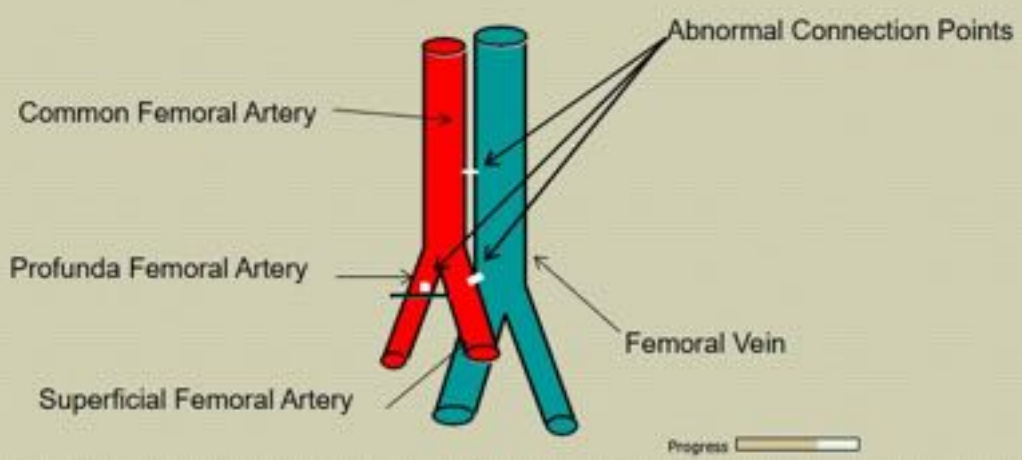
Key Points:

- Duplex ultrasound scanning allows a measure of size as well as distinction from intravenous fistula.
- There is a risk of enlargement and ultimate rupture if not detected and treated.
- Pseudoaneurysms smaller than 3 cm tend to close spontaneously or with compression.
- Those larger than 3 cm require alternative methods:
  - Ultrasound guided compression
  - Thrombin injection
  - Surgical repair

Progress

Vascular Complications: Arteriovenous Fistula

An arteriovenous fistula is an abnormal connection between an artery and a vein which forms when ongoing bleeding from the arterial puncture site decompresses into an adjacent venous structure.



Progress

Vascular Complications: Arteriovenous Fistula *(cont.)*

Risk Factors:

- Anticoagulation and platelet inhibitors.
- Female gender.
- Obesity - causes difficulty in maintaining direct pressure.
- Advanced age - causes loss of tissue elasticity.
- Atherosclerotic occlusive disease.
- Increased sheath size - creates larger vascular interruption.
- Improper operator technique.
- Poor sheath pull technique.
- Thrombolytic therapy - interrupts previously achieved hemostasis.
- Infection - impairs healing at the site of hemostasis.

Progress

Vascular Complications: Arteriovenous Fistula *(cont.)*

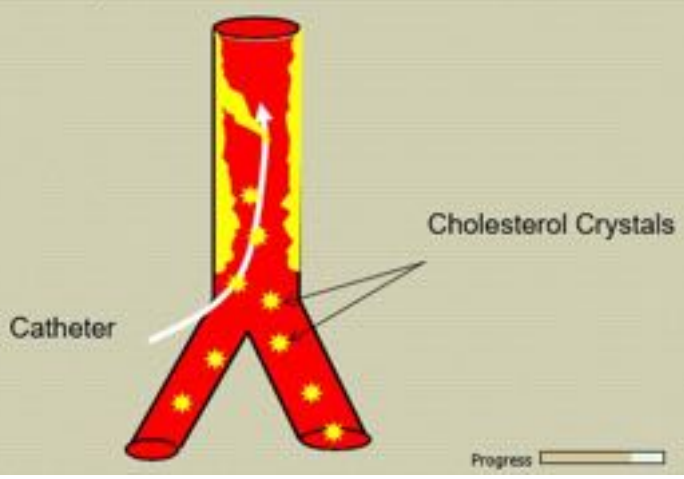
Key Points:

- AV fistulas may not present for days.
- Physical exam reveals a to-and-fro murmur or continuous bruit.
- AV fistulas tend to enlarge with time.
- If they do not close spontaneously after 2 - 4 weeks, surgical repair is indicated.

Progress

Vascular Complications: Atheroembolism

- The release of cholesterol crystals and other microscopic debris from the aorta after catheter manipulation results in mechanical trauma to friable atheromatous plaques.
- Distal embolization may occur to the lower extremities and abdominal viscera.



Progress

Vascular Complications: Atheroembolism *(cont.)*

Key Points:

- Physical exam may reveal a cyanotic foot in the case of microemboli and signs of limb ischemia in the case of macroemboli.
- Renal failure can occur if the renal arterial bed is involved.
- Distal gangrene and death can occur, in extreme cases.
- The onset is often insidious and can take days to months to become evident.
- Management is variable depending on the severity.

Progress

Compression and Closure Devices

Compression of an artery and the use of closure devices must be deployed correctly and appropriately to decrease the risks of vascular complications. You may need to perform manual pressure or utilize a Femostop if the patient re-bleeds.

Compression options:
- Manual pressure
- Femostop

Closure devices:
- Angioseal
- Perclose
- Vascade



Femostop

Note: Femostops should not be used on patients with peripheral vascular disease.

Progress

Compression and Closure Devices *(cont.)*

Key Points:

- Multiple studies have shown that the lowest complication rates occur with correctly applied manual pressure.
- Incorrect application of compression devices is a common error in post sheath removal care.
- Bleeding, despite a compression device (Femostop), mandates removal of the device and manual control of the hemorrhage.
- Closure devices are not a substitute for close observation and have their own set of possible complications.
- If a closure device fails, manual control of the hemorrhage is needed.

Progress

Nursing Considerations: Femoral Post Sheath Removal

- Post procedure checks per protocol (every 15 min x 4, every 30 min x 4, every 1 hour until stable, then prn).
- Document post procedure checks in IView.
- Per Interventional Order Set:
  - Bed rest and activity guidelines
  - PRN medications for back pain or discomfort
  - IV fluid discontinuation or restart
  - Ambulate at least 1 hour prior to discharge
- Patient education on re-bleeding and groin care.
- When receiving the patient, always check the site together with the recovery nurse before he/she leaves the room.

Progress

Nursing Considerations: Hypotension

Systolic BP < 90 mmHg:

- Increase IV fluids: Give 250 ml 0.9 NS bolus and call cardiologist for further orders.
- Give 0.5 mg – 1 mg Atropine IVP if suspect cause is due to vasovagal stimulation.
- Call cardiology provider if hypotension does not resolve quickly.
- Assess for signs of retroperitoneal bleeding (i.e., flank pain, increased heart rate, decreased blood pressure).
- Assess for signs of a pseudoaneurysm (i.e., auscultated bruit).

Progress

Nursing Considerations: Bradycardia Due to Vasovagal Stimulation

- Give 0.5 mg – 1 mg Atropine IVP.
- Treat cause of vasovagal response (i.e., anti-emetics for nausea/vomiting).
- Increase IV fluids for associated hypotension.
- Call cardiology provider if bradycardia does not resolve quickly or if ACLS treatment is required.
- Assess hand/Femostop positioning and adjust.

Progress

Nursing Considerations: Loss of Pedal Pulses

- Assess affected limb for pain, coolness, or mottling.
- Attempt to find pulse with a Doppler.
- Adjust amount of pressure to obtain a balance between hemostasis and adequate pulses.
- Call cardiology provider.

Progress

Patient Education: Femoral Post Procedure Instructions

- Can elevate HOB 30 degrees 1 hour post procedure. May log roll patient to affected side in 1 hour.
- Vital signs/groin assessment checks - every 15 minutes x 4, then every 30 minutes x 4, then every 1 hour until stable, and prn.
- Notify RN of any pain, change in sensation, warmth, or bleeding at the groin site.
- Notify RN of any signs and symptoms of angina: chest discomfort; jaw, neck, arm, or shoulder pain; shortness of breath; sweating; nausea; dizziness or lightheadedness.

Progress

Patient Education: Femoral Post Procedure Instructions *(cont.)*

- The RN may administer an anti-emetic agent to prevent vomiting which causes unnecessary strain at the groin site.
- Refrain from activities that will cause strain to the groin site; for example, do not lift head, raise up on elbows, or bend knees when repositioning.

Progress

References

American College of Cardiology Foundation. (2008). CathPCI Registry, NCDR CathPCI Registry v. 4.3.1. Coder's Data Dictionary. pp. 76-78.

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Progress

HEMOCHRON
Signature Elite



Kayla Barber, CLPT, MMC Lab Section Head
April 2024

MUNSON HEALTHCARE

Goal and Objectives

Goal

This course, in conjunction with direct observation of the Hemochron activated clotting time (ACT) procedure completion, will complete the annual competency requirement.

Objectives

1. List steps required in the completion of the Hemochron ACT procedure.
2. State procedure to follow if the instrument message says, 'ASSAY LOCKED'.
3. Obtain 80% or better on the Hemochron exam.

Clinical Significance

Anticoagulation is necessary during various medical and surgical procedures to counterbalance the natural thrombotic response of blood upon its exposure to a foreign surface, such as the bypass circuit or angioplasty guidewire.

Without optimal anticoagulant therapy, clot formation would occur within minutes. Close monitoring and control of anticoagulation is desirable to ensure clot-free blood flow, while minimizing bleeding complications following the procedure.

ACT testing is also useful for monitoring patients who are candidates for sheath removals following cardiac procedures.

Overview

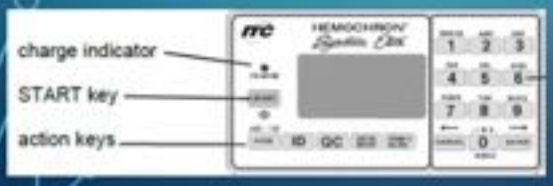
The Hemochron Signature Elite/Hemochron Jr. II Microcoagulation System utilizes a mechanical endpoint clotting mechanism in which testing occurs within the disposable ACT+ cuvette. Following whole blood sample introduction, the Hemochron Signature Elite/Hemochron Jr. II Microcoagulation System precisely measures 15 microliters of blood and automatically moves it into the test channel within the ACT+ cuvette.

The remainder of the blood sample, not needed for testing, is automatically drawn into the waste channel of the cuvette. Sample/reagent mixing and test initiation are performed automatically, requiring no operator interaction. After mixing with the reagent, the sample is then moved back and forth within the test channel and monitored for clot formation.

Clot Detection

The clot detection mechanism consists of two LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves back and forth between the two detectors is measured. As clot formation begins, blood flow is impeded and the movement slows.

The Hemochron Signature Elite/Hemochron Jr. II Microcoagulation instrument recognizes that a clot endpoint has been achieved when the movement decreases below a predetermined rate. The instrument's digital timer displays the correlated celite-ACT value in seconds.





Reagents and Materials

Each single-use cuvette contains a label, a sample well, a test channel containing reagents, an enclosed waste reservoir, and one or more optical detection windows.

Hemochron Signature Elite/ Hemochron Jr. II ACT test cuvette →



Storage & Stability

- Cuvettes should be stored at 2-8°C and are stable until the expiration date on the cuvette box.
- Cuvettes must be brought to room temperature before use.
  - You must date the cuvettes when room temperature is attained.
- Cuvettes may be kept at room temperature for up to 12 weeks, if kept in the sealed pouch.

Electronic Quality Control (EQC)

- The EQC is programmed to automatically run and perform two levels of EQC verification every 8hrs when plugged in.
- If you need to, you can also manually program the EQC to run by pressing the QC button and then 1=Run EQC.
- If the EQC fails for any reason, the instrument must be taken out of service and your POC coordinator contacted.

directCHECK
Whole Blood Quality Control

Liquid Quality Control (LQC)

LQC (normal level and abnormal level) is performed weekly and documented in the appropriate QC book.

QC control must be within the range established by the manufacturer for the two levels used. If the quality control is out of range and can not be corrected, you must take the instrument out of service and contact your POC coordinator.

If the screen states "Run LQX - Check QC Status" at any time, you must run the liquid QC before continuing with any patient testing.

Storage and Stability

- Controls are stable at 2-8°C until the expiration date on the box.
- Controls must be brought to room temperature before testing.
- Controls may be stored at room temperature for up to 4 weeks.

Patient Testing

- Insert cuvette into the cuvette opening of the instrument. The instrument will automatically identify the test cuvette and display the test type.
- During the pre-warm stage, observe the display for fault messages.
- When ready, the instrument will signal with an audible tone. The display will indicate the alternating messages "ADD SAMPLE" and "PRESS START".
  - The instrument will remain in the ready mode for 5 minutes before a "TIME OUT...FAULT" will occur, requiring a new cuvette to be placed in the instrument.

Patient Testing *(cont.)*

Obtain Sample

- If you are drawing from a line, make sure you flush until it is free from contamination before obtaining the patient test sample.
- Using a syringe, slowly draw the blood sample from a previously flushed line or via venipuncture.
- Immediately dispense blood into the sample well of the test cuvette.
  - This may be done with or without a needle.
  - Using a sufficient quantity of blood, directly fill the center sample well to the edge.
  - Should a large drop of blood extend above the center sample well, push it over into the outer sample well.

Patient Testing *(cont.)*

- Press the START key.
  - NOTE: The instrument displays a fault if an inadequate or excessive amount of sample has been provided.
- Test completion will indicate a fault condition.
  - NOTE: Two beeps indicate a fault condition.
- Upon clot detection, the ACT+ test result is automatically converted to a reference celite-ACT result. The correlated celite-ACT value will be displayed.
  - The test results will remain on the screen until the test cuvette is removed from the instrument and for 120 seconds following its removal.
  - NOTE: At any time during testing, if you receive any error codes that cannot be resolved, (e.g., "Assay Locked Out"), you must place a 'Do Not Use' sticker on the instrument, pull it out of service, and contact the POC coordinator at 56118 or 56405.

Reference

International Technidyne Corporation. (n.d.). Hemochron Signature Elite Manual. https://wexnermedical.osu.edu/-/media/files/wexnermedical/healthcare-professionals/clinical-labs/forms-policies-procedures/point-of-care/act/hemochron-signature-elite-user-manual.pdf?la=en&hash=6C636933E2522635380AA83D3033A281776A313

Instructions

The Evaluator will complete the checklist validation. You are responsible for ensuring you work with your manager, preceptor, or educator to have this checklist completed. Check with your manager for additional information.

Evaluator Guidelines

N/A – Not Assessed. If you choose Unmet or N/A, please add a comment to indicate the reason for the selection. The employee and manager or evaluator will develop an action plan for meeting the competency. The action plan should include 1) steps in the action plan, and 2) date to be completed.

See PolicyStat for complete information on Competency Assessment. Viewing Competency Assessment and Verification :: PolicyStat

Verification Methods Key:

CS	Case Study	E	Exemplar	PR	Qualified Peer Review	SA	Self Assessment
DR	Discussion/Reflection	MES	Mock Event/Survey	QI	Quality Improvement	TE	Test/Exam
EDW	Evidence of Daily Work	P	Presentation	RD/DO	Return Demo/Direct Observation		

Demonstrates process for activated clotting time (ACT) measurement according to Hemochron Signature Elite Competency criteria and manufacturer's instructions.

DR: Discusses how to problem solve issues with Hemochron Signature Elite analyzer

AND

RD/DO: Perform blind duplicate QC sample

OR

RD/DO: Performs ACT measurement and documentation.

Add Comment ▾

Met | Unmet

Status Active PolicyStat ID 15460185

MUNSON MEDICAL CENTER
MUNSON HEALTHCARE

Origination	12/18/2009
Last Approved	11/7/2025
Effective	11/7/2025
Last Revised	11/7/2025
Next Review	11/6/2028

Owner	Brendan Franklin: Dir Nursing Critical Care & Stroke
Area/ Department	Nursing
Applicability	MMC
Tags	Policy

Critical Care Standards

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Purpose

To provide a standard for nursing care in the critical care patient population and enhance coordination of care among the healthcare team.

Scope

Critically ill patients receiving care in A2, A3, and the Intensive Care Unit (ICU).

Policy

A. All Registered Nurses (RN) are prepared to:
   1. Utilize corresponding policies and procedures to implement nursing process for patient care.
   2. Respond to urgent and emergent situations.
   3. Perform specialized nursing procedures specific to critically ill patient needs.
   4. Administer care and specialized interventions in the critically ill patient population.
   5. Document care and specialized interventions.

B. Nursing care of critically ill patients in critical care units includes:
   1. Systems Assessments:
      a. Perform and document head-to-toe assessment every 4 hours, unless the patient's condition or physician order indicates alternative frequency.
      b. Including the following:

i. Recent and relevant events and patient outcomes.

ii. Device use, care and management and patient tolerance.

iii. Wound/skin care and management.

iv. Pain assessment and documentation unless patient condition requires a greater frequency. Pain reassessment will occur after treatment (per the Pain Management policy).

v. All individualized care needs for the critically ill patient.

2. Lines/Tubes/Devices
    a. Assessment is completed and documented every four hours including type, station, and status.

3. Vital signs:
    a. Blood pressure, heart rate, respiratory rate, and pulse oximetry with oxygen delivery method are monitored and recorded hourly, unless otherwise ordered or the patient's condition indicates alternative frequency.
    b. When titrating medications, vital signs are documented according to medication order titration guidelines.
    c. Temperatures are recorded at a minimum of every 4 hours unless otherwise ordered or the patient's condition indicates alternative frequency. Temperatures are recorded hourly when warming or cooling measures are used.
        i. All patients with abnormal temperatures are assessed for potential complications related to hypothermia or hyperthermia.
        ii. RN may initiate warm blankets, commercial warming devices, and/or fluid warmer on any patient with a rectal or core temperature of less than 35.6°C. Provider must be notified.
        iii. RN may initiate cooling blankets on any patient with a rectal or core temperature of greater than 38°C if antipyretics and other means of external cooling have been ineffective. Provider must be notified.
        iv. The fluid warmer may be used for any patient with a rectal or core temperature of less than 35.6°C.

4. Hemodynamic monitoring:
    a. Electrocardiogram (ECG) monitoring is established upon arrival and maintained throughout hospitalization.
    b. Invasive line pressures are documented every hour unless otherwise ordered or the patient's condition indicates alternative frequency. This includes but is not limited to: arterial blood pressure (ABP), central venous pressure (CVP), pulmonary artery pressure (PAP), pulmonary capillary wedge pressure (PCWP), Intracranial pressure (ICP), cerebral perfusion pressure (CPP).

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c. Arterial lines and pulmonary artery catheters must always be transduced. Exception: during magnetic resonance imaging (MRI) testing.

d. Transport monitoring: Minimum transport monitoring of critical care patients will include continuous ECG, blood pressure, and oxygen saturation monitoring. Arterial lines and pulmonary artery catheters must always be transduced, even during transport. Additional monitoring may be held or continued during transport.

5. Respiratory:
    a. Airway or endotracheal tube (ETT) station is documented every four hours.
    b. ETT is repositioned every four hours and prn in collaboration with Respiratory Therapy (RT).
    c. An RN may extubate a patient upon a physician's order or per protocol, with RT at the bedside.
6. Fluid volume status and intake & output (I&O):
    a. Patients require strict hourly I&O with daily weights unless otherwise ordered or the patient's condition indicates alternative frequency.
7. Nutrition:
    a. The goal is to start nutrition within 24 hours of admission, based on patient condition. Diet/nutrition is monitored daily, including type of nutrition, source and patient tolerance. RN may initiate dietary consult as needed.

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Document ID: 070.065

Approval Signatures

Step Description	Approver	Date
System Policy Oversight Committee	Terri Fries: Document Mgmt Spec	11/7/2025
CNO	Tamara Putney: VP and CNO Patient Care Services	11/7/2025
Mgr Nursing Services	Amber Bowers: Mgr Nursing Services	11/5/2025
Document Owner	Brendan Franklin: Dir Nursing Critical Care & Stroke	11/5/2025

Applicability

Munson Medical Center

Standards

No standards are associated with this document

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Status Active PolicyStat ID 17948440

Origination	12/13/2023
Last Approved	6/3/2025
Effective	6/3/2025
Last Revised	6/3/2025
Next Review	6/2/2028
Owner	Jennifer Standfest: CNO
Area/ Department	Nursing
Applicability	MMC, Cadillac, Charlevoix, Grayling, Otsego

Cardiac Telemetry Monitoring

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Purpose

To enhance patient safety and clinical consistency by outlining continuous cardiac monitoring guidelines, arrhythmia detections and overall alarm management.

Definitions

1. **Cardiac Monitoring/Telemetry Monitoring:** Continuous cardiac rhythm display at the bedside and/or transmitted to a central monitoring console that can provide alarms or print/save rhythm strips.
2. **Telemetry Technician:** Licensed or unlicensed staff member with training and competency in electrocardiogram (ECG) rhythm interpretation.
3. **Telemetry Observer:** An individual assigned to listen for and/or observe specific visual cues with the intention of escalating information to a resource trained to assess and/or intervene in a specific situation.

Policy

A. An order is needed to initiate and discontinue cardiac monitoring. Orders should specify any parameters and any circumstances in which the patient can be temporarily or permanently removed from monitoring.

B. When initiating cardiac monitoring, the following identifiers are used:

   1. 10-digit account number
   2. Last Name, First Name (NOTE: This will automatically pull through ADT feed if 10-digit account number is entered correctly)

C. The Registered Nurse (RN) is responsible to:
    1. Initiate and maintain continuous monitoring and to perform initial review and adjustment of settings and alarm parameters.
    2. Regularly review and interpret cardiac rhythm and document findings in the chart.
    3. Assess need for continued cardiac monitoring daily, using provider orders or protocol, where applicable.
    4. Report clinically relevant abnormalities identified on review or by alarm/event review to the provider. Abnormalities include but are not limited to:
        a. Any new dysrhythmia (i.e., tachy or brady arrhythmia exceeding alarm)
        b. Heart block
        c. New atrial fibrillation or flutter or inadequate rate control of these rhythms
        d. Ventricular tachycardia/fibrillation
        e. Supra-ventricular tachycardia
        f. Any symptomatic patient with a dysrhythmia
        g. Any dysrhythmia requiring immediate treatment
    5. Initiate code response or other facility specific rapid response protocols or appropriate emergency interventions
    6. The RN may delegate tasks to appropriately trained support personnel. These may include, but are not limited to: equipment preparation, skin preparation, electrode application/reapplication, application of monitoring equipment.

D. Where present, telemetry technicians may review and adjust specific settings and alarm parameters and may interpret cardiac rhythms, complete specific documentation, and shall report abnormalities to the RN.
    1. The technician will monitor each telemetry unit for ventricular tachycardia, ventricular fibrillation, asystole, tachycardia and bradycardia, low battery and lack of rhythm. The telemetry technician will contact the nurse with findings.
    2. A telemetry log may be kept on each unit with pertinent info such as the patient's name, dominant rhythm, assigned nurse and the direct phone number(s) for the assigned care team.

E. A telemetry technician and/or any RN not directly responsible for the patient's care who observes events or responds to alarms at the bedside or central monitoring station will notify the primary nurse of any changes in the patient's condition, monitor settings, or alarm parameters.

F. Where present, telemetry observers are identified 24 hours a day. The telemetry observer may perform other clerical duties that do not remove them from direct view or audio of the monitor. The observer will arrange for another trained observer or nurse to fill the role temporarily if needed for breaks or to perform other job duties away from the area.

G. Any support personnel should consult with/notify the appropriate individual (eg., telemetry observer or technician, RN, etc.) prior to removing a patient from monitoring for showering,

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procedures/testing or discharge.

Electrode and Lead Placement, Battery Replacement

A. Electrodes are applied according to Lippincott Procedures - Cardiac monitoring (lww.com) instructions found online. Electrodes shall be changed daily and as needed (PRN) or in accordance with manufacturer recommendations.

B. Lead placement should be confirmed at the beginning of each shift, along with verification the monitor / transmitter is functioning properly and that suitable battery life remains.

C. Battery change should occur minimally when “low battery” signal appears, or with approximately 25% battery life remaining.

Lead Selection

A. Lead II is generally selected as the standard monitoring lead.

B. For a standard 5 lead system, V1 is commonly selected as the second lead. An alternate lead may be selected based on which provides a clearer trace, more prominent or upright waves, or by which a particular area of the heart can be better monitored.

Cleaning

A. Upon discontinuation of telemetry monitoring, the telemetry unit and electrodes are cleaned per manufacturer instructions.

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Cardiac Rhythm Waveforms and Documentation

A. A rhythm strip will be measured, interpreted, and documented per the following guidelines:

1. Rhythm interpretation is ongoing and documented as part of the nursing assessment
2. Inpatient care (critical, intermediate, or telemetry care departments) at admission, each shift with initial RN assessment, and with any significant change in rhythm or significant symptoms
3. Emergency Department (ED) at admission and with any life-threatening rhythms or significant changes in patient condition
4. Rhythm waveform documentation should include the name of identified rhythm, heart rate, PR/QRS/QT intervals where applicable, and the name of the RN or Telemetry Technician performing the documentation.

Monitoring Guidelines

A. HR alarms will be set appropriately to the patient's baseline HR, rhythm, clinical condition or treatment plan by an RN or Telemetry Technician.

B. If a monitored patient has a pacemaker, the pacemaker detection function of the cardiac monitor must be turned ON

Refer to Munson Healthcare (MHC) entity specific intravenous (IV) Medication Guidelines and/or consult with pharmacy for information related to risk of prolonged QT interval and for IV medication administration and required monitoring.

C. QT interval monitoring functions of the cardiac monitors may be utilized by the RN/Tele Tech as an adjunct to patient / rhythm assessment. A patient with a baseline prolonged QT or on a medication that has the potential of prolonging the QT interval may have orders for more frequent QT measurements.

D. ST segment monitoring and ST mapping functions of the cardiac monitors may be utilized by the RN/Tele Tech as an adjunct to patient assessment. (Note: some clinical conditions make it difficult to achieve accurate ST monitoring i.e., atrial fib or flutter with an irregular baseline, ventricular pacing, left bundle branch block. Consider turning ST monitoring off in these conditions).

E. Silencing Alarms:

    1. A trained telemetry observer or technician or a registered nurse may silence clearly erratic/false alarms such as those caused by motion or artifact while requesting evaluation by clinical personnel.

    2. A lethal rhythm alarm may be silenced by a Telemetry Technician or RN after the RN evaluates the rhythm and/or patient condition.

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Alarm Settings and Clinical Management

A. The Clinical Engineering department has oversight for the testing and maintenance of clinical devices to ensure accurate settings, proper operation, and detectability of alarms.

B. Monitor settings are configured according to manufacturer recommendations to enhance patient safety. A copy of all configuration settings is maintained by the Clinical Engineering department. These settings may only be changed with approval of the Cardiac Monitoring Steering Committee or the Cardiac Monitoring Alarm Committee, with the endorsement of the Clinical Leadership Council.

C. Arrhythmia monitoring will be on and audible for all monitored patients, with the exception of patients who are receiving end of life care, where death is anticipated and an order for comfort care is present.

D. Alarm volume should be set audibly so that nursing staff is able to hear and respond appropriately to non-critical and critical alarms. It is the responsibility of the bedside nurses, the unit coordinator, and other clinical staff to maintain the appropriate alarm volume which decreases noise pollution for patients and visitors, while ensuring prompt staff notification of alarm situations.

E. Select alarm parameters are unlocked and able to be adjusted on an individual basis by the RN, Telemetry Technician, or other licensed clinician within their scope of service.

F. All monitor alarm settings should be adjusted to reflect patient or condition specific values and should be reviewed and adjusted (if indicated) at admission, each shift, and as needed by the RN and/or Telemetry Technician.

    1. The nursing staff member will determine the appropriate response to the alarm; however, the nurse is responsible to confirm findings, verify patterns, and evaluate

interpretations through patient assessment. The response to an alarm may include but is not limited to silencing the alarm, recording the strip, and/or initiating emergency interventions.

2. In the event of a Code Blue or Cardioversion, an event strip will be documented containing the initiation of the event and documentation of changes in rhythm continuing through termination of efforts. As an alternative, a strip from the defibrillator may be used to record the events of the Code Blue.

G. Patient care staff are familiar with alarm settings, policies and procedures.

Transfer/Discharge Procedure

A. At the time of transfer/discharge, the patient MUST be discharged from the bedside and/or central monitoring console, and when applicable, have their encounter be dissociated from the electronic health record (EHR).

B. Refer to manufacturer instructions for use for specific steps to transfer or discharge patient.

Transport Monitoring

A. An RN (or in some cases, a paramedic) shall accompany the patient for transport if the patient is in critical condition, hemodynamically unstable and/or on continuous vasoactive infusions.

B. Other monitored patients transported by unlicensed staff will be monitored remotely by the telemetry technician, telemetry observer, or RN. A portable phone will be assigned and in the possession of the staff member closest to/responsible for the patient at all times. Monitoring staff will use this phone to communicate emergency conditions and request immediate assistance for the patient.

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Reference

1. Wiegand, D. L. (Ed.). (2017). AACN Procedure Manual for High Acuity, Progressive, and Critical Care (7th ed., pp. 467-476). St. Louis, MO: Elsevier.

Keywords

Cardiac, Telemetry, Monitoring, Tele Tech

Approval Signatures

Step Description	Approver	Date
System Policy Oversight Committee	Terri Fries: Document Mgmt Spec	6/3/2025
CNO Council	Jennifer Standfest: CNO [AM]	6/2/2025

Document Owner	Jennifer Standfest: CNO [AM]	6/2/2025

Applicability

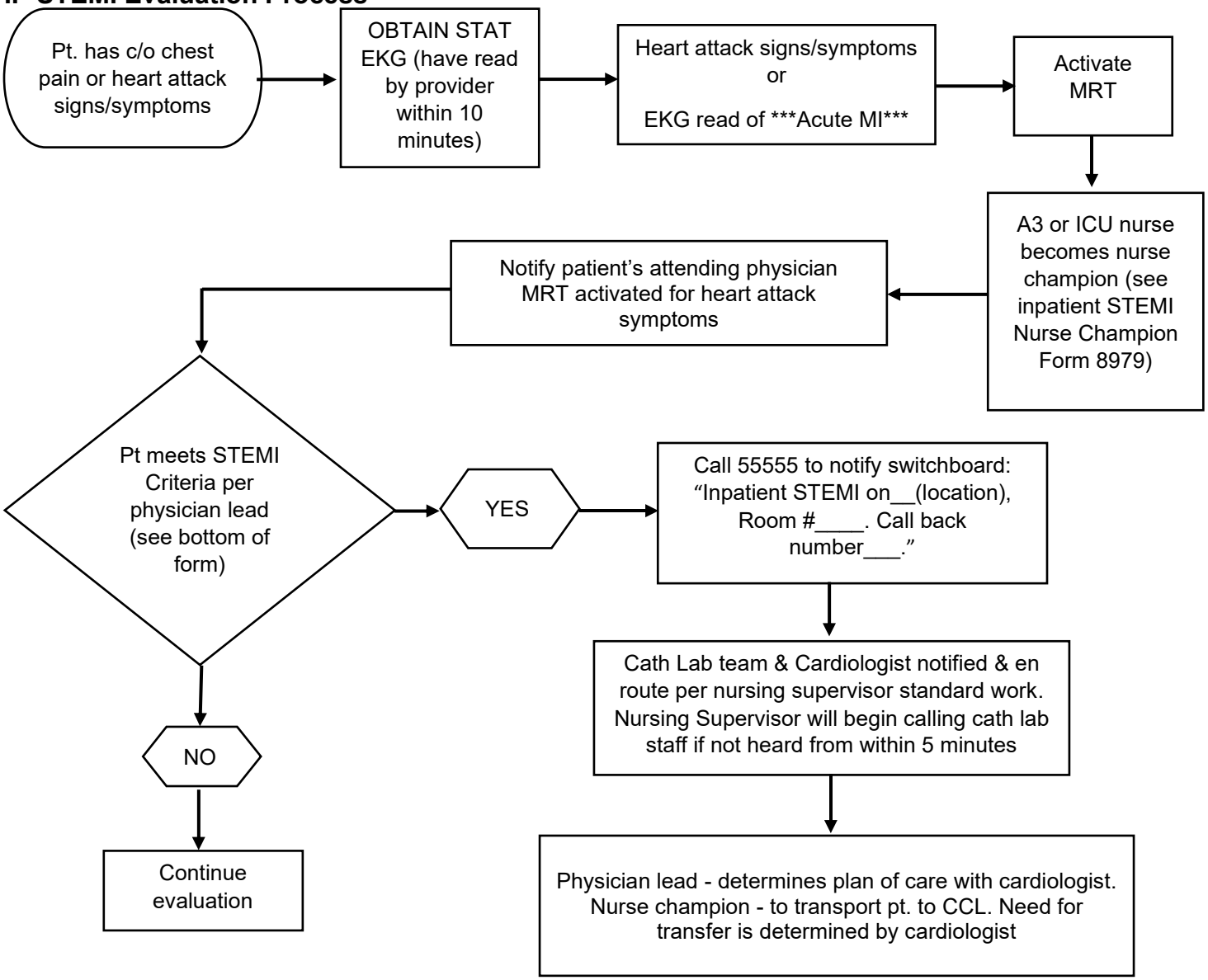
Cadillac Hospital, Charlevoix Hospital, Grayling Hospital, Munson Medical Center, Otsego Memorial Hospital

Standards

No standards are associated with this document

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IP STEMI Evaluation Process



Automatic STEMI Activation should occur:

IF

- ECG shows definite evidence of STEMI with 1 or more mm of ST elevation in 2 contiguous leads (or a new LBBB) and a story consistent with acute MI

And/or

- ECG machine algorithm interpretation of ***Acute MI*** (unless clearly an interpretation error)

Unless

- Diagnosis of STEMI uncertain
- Known DNR or DNR/DNI status AND patient unwilling to reverse

In these situations, it would be appropriate to consult a cardiologist prior to activation of STEMI page

Status Active PolicyStat ID 13648797

Origination	1/18/2011	Owner	Kerry Kole: Medical Director
Last Approved	5/15/2023	Area/ Department	Trauma Services
Effective	5/15/2023	Applicability	MMC
Last Revised	5/15/2023	Tags	Procedure
Next Review	5/14/2026		

Massive Transfusion Protocol

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Purpose

To provide a process in the case of a massive transfusion.

Policy

Indications

A. Massive blood loss and profound hemorrhagic/hypovolemic shock.

B. Triggers:

1. Greater than 6 units packed red blood cells (PRBC) transfused within 2 hours.
2. Hemodynamically unstable patient with identified or suspected coagulopathy of trauma or disseminated intravascular coagulopathy (DIC)
3. Any time at the discretion of the trauma surgeon / intensivist.
4. Assessment of blood consumption (ABC) score of greater than or equal to 3 (total possible score 4)
    a. Penetrating mechanism (no= 0; yes= 1)
    b. Emergency department (ED) systolic blood pressure less than 90 mmHg (no= 0; yes= 1)
    c. ED heart rate greater than 120 bpm (no= 0; yes= 1)
    d. Positive Ultrasound FAST Exam (no= 0; yes= 1)
5. Trauma patient who requires more than 1 liter crystalloid to maintain systolic blood pressure greater than 90mmHg.

Responsible Parties

A. Team leaders: depending on area in hospital
    1. Trauma surgeon (trauma bay, operating room (OR), intensive care unit (ICU))
    2. Intensivist (in ICU when trauma surgeon unavailable).
    3. ED physician (in ED when trauma surgeon unavailable)
    4. Anesthesiologist (in OR or Post Anesthesia Care Unit (PACU))
    5. Trauma advanced practice provider (APP)
    6. Obstetrician (OB)
    7. Sound hospitalist

B. Clinical pathologist

C. Lab blood bank / laboratory personnel

D. Pharmacy

E. Nursing supervisor / charge nurse

F. Clinical team:
    1. Trauma physician assistant (PA)/nurse practitioner (NP)
    2. ED registered nurse (RN)/paramedic
    3. ICU RN
    4. OR RN
    5. ED Technician / ICU technician / OR technician

G. Vascular Access

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Procedure

A. Initiation of the massive transfusion protocol (MTP):
    1. Trauma surgeon, intensivist, ED physician, trauma APP, anesthesiologist, Sound hospitalist, or OB initiate MTP.
        a. Staff member call switchboard to page out MTP overhead and to all responsible parties.
        b. Staff member enter order for Massive Transfusion in Cerner
            i. Initiate *Lab - every 30 minutes* immediately
        c. Blood bank and lab supervisor notified (by switchboard) of MTP initiation.
        d. Nursing/house supervisor to come to area if needed.
        e. Blood bank will notify clinical pathologist of MTP initiation
        f. Maintain communication with blood bank during the initiation and maintenance of MTP.

g. Consider the use of tranexamic acid (TXA) on patients greater than 18yrs old, initial 1g dose over 10 minutes and then a second 1g dose over the next 8 hours. **MUST BE USED WITHIN 3 HOURS OF INITIAL INJURY, IDEALLY less than 1 HOUR

h. Communicate with pharmacy the need for anticoagulation reversal agents.

2. Clinical pathologist or designee:
    a. Supervises procurement of lab tests.
    b. Tracks the use and available supply of blood and blood products.
    c. Advises the clinical team on the use of blood, blood products, and procoagulants
    d. Use of products based on lab results and available reserves.

3. Lab: confirm patient identification (ID) and medical record number (MR#) (actual or John Doe)
    a. Initial testing
        i. Type and cross (GTAB)
        ii. STAT coagulation profile: Prothrombin time (PT), partial thromboplastin time (PTT), fibrinogen, hemoglobin (HGB), platelet count
        iii. Basic metabolic panel (BMP), arterial blood gas (ABG), and lactate.
    b. Massive transfusion serial lab process.
        i. Repeat labs every 30 minutes until discontinued by clinical team.
        ii. Include complete blood count (CBC), PT/PTT, fibrinogen, lactate, BMP, and ionized calcium.

4. Blood bank:
    a. Prepares and releases
        i. First of five uncrossmatched PRBCs – O-negative or O-positive as indicated
        ii. 5 more units uncrossmatched, O-negative or O-positive PRBC as indicated (unless type specific available).
        iii. 5 single units of plasma
        iv. 5 units platelets
    b. Delivers the first trauma pack to the location of the MTP
    c. Prepares fresh frozen plasma (FFP) to stay 5 single units ahead.
    d. Prepares platelets to stay 5 units ahead.
    e. Ships components at temperatures appropriate for the product being

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delivered. This should prevent inappropriate temperature storage of a blood product, such as refrigeration of platelets.

f. Prepares trauma packs (see attached schedule). Trauma packs should be ready to be delivered every 20 minutes.

g. Updates to appropriate type-specific or crossmatched components once available.

h. Tracks results of labs as they become available.

i. Communicates with clinical pathologist and designated clinical team leader (usually the trauma surgeon, anesthesiologist, or intensivist depending on clinical area).

j. Access and maintenance of services:

i. Notifies blood center and requests urgent delivery as needed.

ii. Communicates status of reserves to clinical pathologist.

5. ED RN/paramedic and ICU RN respond to all MTPs

a. Maternity Unit: ED Brings Belmont and Maternity provides the MTP Cart

b. ED MTP: ICU brings the Belmont only (not the MTP cart)

c. All Other Units: ICU Brings MTP Cart and Belmont. ED also brings Belmont for backup.

6. Vascular Access ensure patient has large bore IV (unless physician inserting Cordis)

B. Maintenance of MTP:

1. Charge nurse/Patient Care Coordinator:

a. Checks for accuracy of specimens and verification of patient identity.

b. Expedites transfer of patient within the institution.

c. Expedites transfer of lab specimens in timely fashion.

d. Communicates with and assists clinical team to maintain accuracy and timeliness.

2. Clinical team:

a. Draws, labels and maintains serial labs every 30 minutes during MTP or until discontinued by team leader (see heading III, below).

b. Transfuses shipped trauma packs at regular intervals as needed

c. Documents Input/Output (I/O) and medication administration record (MAR) during MTP.

d. Accompany the patient to the OR or ICU.

e. Remain with the patient until the MTP is terminated.

3. Team leader:

a. Ensures timeliness of serial blood draws.

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b. Ensures timeliness of transfusions.

c. Supervises clinical team during the maintenance of MTP.

d. Designates alternate team leader when appropriate (e.g.: trauma surgeon designates anesthesiologist when operating).

e. Communicates with clinical pathologist regarding trend of lab results and transfusion needs.

i. Laboratory goals:

1. HGB 8-10 g/dL during the resuscitation and in the first 24 hours post stabilization. After 24 hour period of stabilization the HGB may be reduced to 7 g/dL if not actively bleeding.

2. Platelet count greater than 100,000 during resuscitation and in the first 24 hours post stabilization. After the 24 hour period of stabilization the goal is a platelet count greater than 50,000.

3. Coagulation testing goals: INR less than 2.0 and PTT less than 55 seconds. INR of 1.8 may be needed in TBI patients.

4. Fibrinogen greater than 150 mg/dL.

f. Terminates MTP (See heading III)

4. Clinical pathologist or designee:

a. Monitors coagulation and lab results

b. Advises team leader and clinical team of need for other blood components or specific alterations in transfusion needs (e.g. cryoprecipitate)

c. Notifies team leader of critical shortages in blood supply.

C. Termination of MTP:

1. Determined by team leader when either of the following are achieved

a. Achievement of endpoints of resuscitation ("stabilization").

i. Normalization of vital signs, including temperature.

ii. Normalization or improvement of coagulation parameters.

iii. Termination of bleeding/exsanguination.

b. Failure or Futility.

2. Call 55555 for switchboard to announce termination of MTP overhead.

3. Maintenance of hematologic function:

a. Serial hematologic assessments (CBC, PT/INR, PTT) every 6 hours for 24 hours, then twice daily (BID) or as needed.

b. Do not transfuse if there is no evidence of bleeding

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c. Transfuse FFP if there is evidence of oozing until INR less than 2.0.

d. Transfuse platelets if platelets less than 50 k/dL.

e. Transfuse red blood cells (RBC) to maintain HGB 8-10 g/dL in first 24 hours post stabilization; transfuse for HGB less than 7 g/dL after 24 hours (restrictive transfusion trigger) unless evidence of new bleeding.

f. Transfuse cryoprecipitate if fibrinogen less than 150 g/dL.

D. Review of case and debriefing:

1. What went well.
2. What did not.
3. Product wasted.

E. *If rotational thromboelastometry (ROTEM) is available, the following cut-points for transfusion triggers may also be used:

1. Plasma for CT exTEM greater than 100 seconds and/or CT inTEM greater than 230 seconds.
2. Cryoprecipitate (fibrinogen concentrate) and/or plasma for MCF fibTEM less than 8 mm.
3. Platelets for MCF exTEMless than 45 mm and MCF fibTEM greater than 10 mm.
4. Anti-fibrinolytics for ML exTEM greater than 15 percent.

Document ID: 038.P003

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Attachments

- ED Step-by-step instructions for using the Massive Transfusion Protocol Edits.doc
- Expected Response to Product
- MTP schedule.docx
- Step by step instructions for MTP in ICU 2019.pdf

Approval Signatures

Step Description	Approver	Date
System Policy Oversight Committee	Terri Fries: Document Mgmt Spec	5/15/2023

Mgr Trauma Program	Sarah Helveston: Mgr Trauma Program	5/15/2023
Document Owner	Kerry Kole: Medical Director	5/13/2023

Applicability

Munson Medical Center

Standards

No standards are associated with this document

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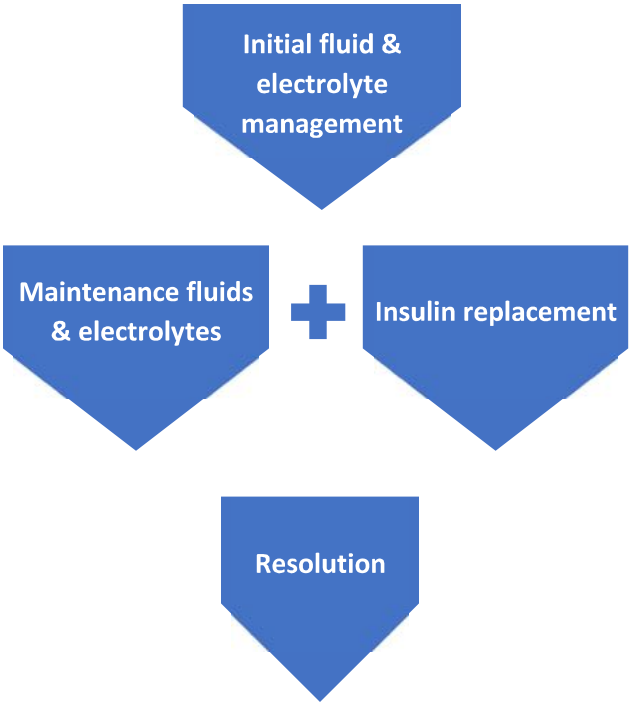
Reference Text:

Diabetic Ketoacidosis (DKA); Adult

This power plan is intended for use in individuals 22 years of age and up. It may also be used in individuals 18-21 years of age if care will not be primarily directed by a pediatric hospitalist (i.e. community hospital admissions, ICU-level care).

Last updated: 4/3/2024

I. DKA TREATMENT SUMMARY – QUICK REFERENCE



Initial Management
- Fluid resuscitation
- Electrolyte replacement

Acidosis Treatment
- **Two-bag method**
- Continuous insulin infusion

Transition to Subcutaneous Insulin
- **Requires 2-hr overlap with IV insulin**
- Upon DKA resolution
- Resumption of diet

Quick Reference for Nursing

Regular insulin (IV)

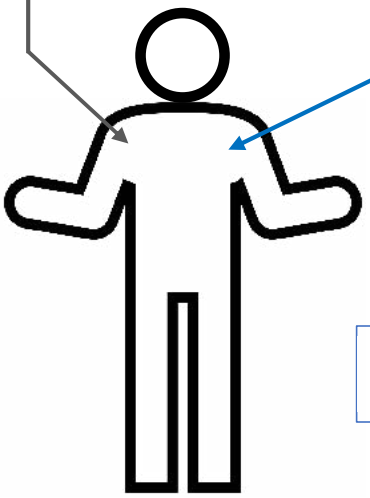
Q1H BG

0.9% NaCl or 0.45% NaCl ± 20 mEq/L KCL

D10 + 0.45% ± 20 mEq/L KCL

Clinical Scenario		Action Required
-	**...Default rate (no bolus, no titration)**	**Infuse at 0.1 unit/kg/hr**
IF	...BG 71-99 mg/dL	-PAUSE INSULIN- *Check BG Q15min until >100. To resume insulin, ensure Bag 2 is running at full rate*
IF	...BG ≤ 70 mg/dL or symptomatic HYPOglycemia	-PAUSE INSULIN- *Follow hypoglycemia protocol. To resume insulin, ensure Bag 2 is running at full rate*
IF	...Patient has persistent or recurrent HYPOglycemia	-CALL PROVIDER- *May consider decreasing insulin rate to 0.05 unit/kg/hr*
IF	...BG does NOT decrease by ≥100 mg/dL within the first two hours	-CALL PROVIDER- *May consider increasing insulin rate to 0.15 unit/kg/hr*
IF	...Potassium < 3.3 mmol/L	-PAUSE INSULIN & CALL PROVIDER- *Replace potassium per DKA electrolyte replacement protocol*

Blood glucose (mg/dL)	DKA Bag 1 rate (mL/hr)	DKA Bag 2 w/Dextrose rate (mL/hr)	TOTAL rate (mL/hr)
STANDARD			
BG >250	250	0 (zero)	250
BG 150-250	125	125	250
BG < 150	0 (zero)	250	250
FLUID RESTRICTED			
BG >250	125	0 (zero)	125
BG 150-250	75	125	200
BG < 150	0 (zero)	250	250



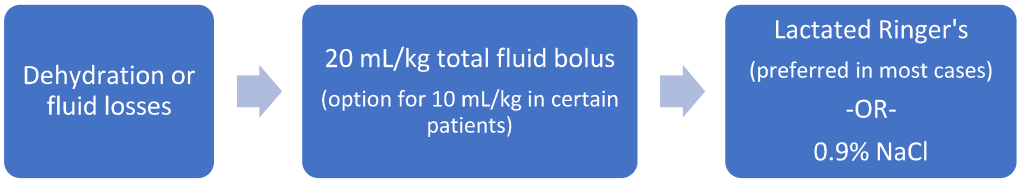
Potassium Level (mmol/L)	Parenteral (as potassium chloride IVPB)
< 3.3	Total dose: 80 mEq over minimum of 4 hours, *AND* 1. PAUSE insulin 2. Call provider to discuss before resuming
3.3 - 3.5	Total dose: 60 mEq over minimum of 3 hours
3.6 - 3.9	Total dose: 40 mEq over minimum of 2 hours
4 - 5.2	Total dose: 20 mEq over minimum of 1 hour
> 5.5	Call provider

Q4H BMP+ Mg + Phos

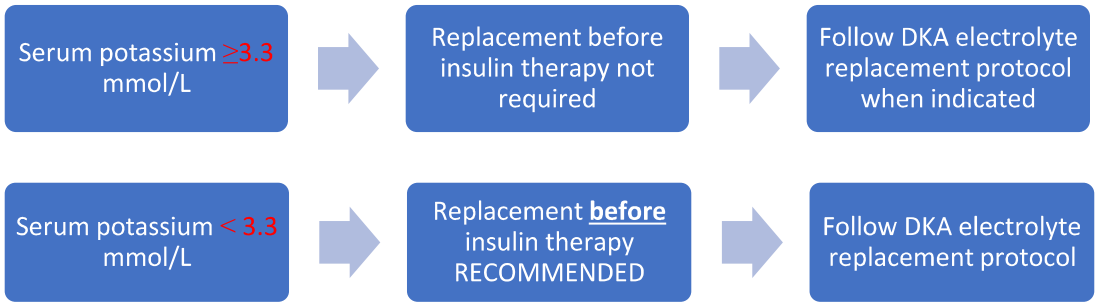
PLUS magnesium + phos replacement

II. DKA TREATMENT DETAILS

A. INITIAL FLUID MANAGEMENT:



B. INITIAL ELECTROLYTE REPLACEMENT:



C. IV INSULIN INFUSION

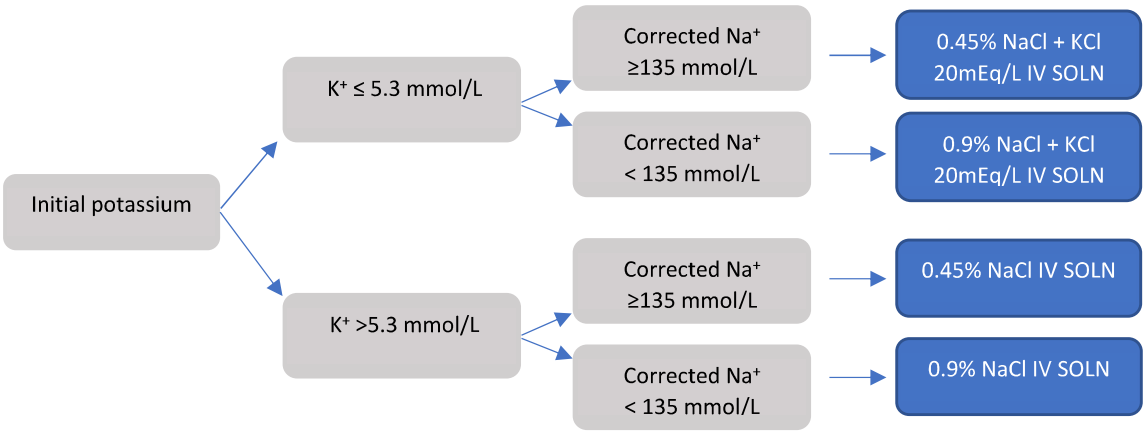
Clinical Scenario		Action Required
-	**…Default rate (no bolus, no titration)**	**Infuse at 0.1 unit/kg/hr**
IF	…BG 71-99 mg/dL	-PAUSE INSULIN- *Check BG Q15min until >100.* ***To resume insulin, ensure Bag 2 is running at full rate***
IF	…BG ≤ 70 mg/dL or symptomatic HYPOglycemia	-PAUSE INSULIN- *Follow hypoglycemia protocol.* ***To resume insulin, ensure Bag 2 is running at full rate***
IF	…Patient has persistent or recurrent HYPOglycemia	-CALL PROVIDER- *May consider decreasing insulin rate to 0.05 unit/kg/hr*
IF	…BG does NOT decrease by 100 mg/dL within the first two hours	-CALL PROVIDER- *May consider increasing insulin rate to 0.15 unit/kg/hr*
IF	…Potassium < 3.3 mmol/L	-PAUSE INSULIN & CALL PROVIDER- *Replace potassium per DKA electrolyte replacement protocol*

D. TWO-BAG MAINTENANCE FLUIDS:

DKA Bag 1 and DKA Bag 2 w/Dextrose are connected to two different IV pumps and connected to each other via Y-site to be administered through one IV line.

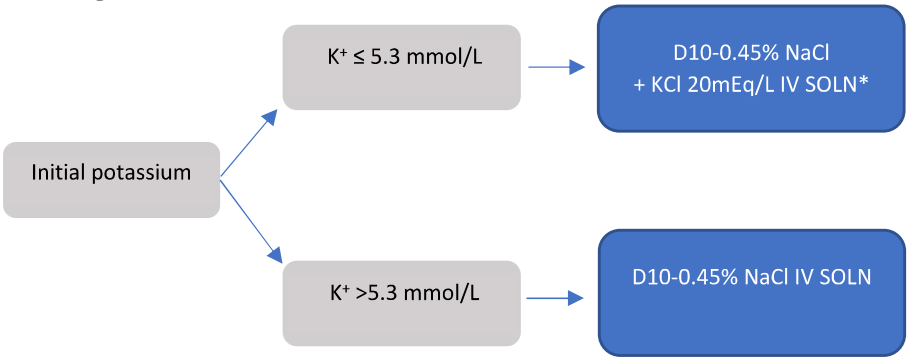
Provider to order bag 1 and bag 2 at same time as insulin drip, according to initial electrolytes:

DKA Bag 1



Corrected serum sodium = Na + 0.016(blood glucose – 100)*

DKA Bag 2 w/ Dextrose



***Solution requires compounding by pharmacy. If pharmacy unavailable to compound, may utilize D10/0.45 NaCl with electrolyte replacement per protocol.**

Bag 1 & 2 titration

1. Standard rate

Blood glucose (mg/dL)	DKA Bag 1 rate (mL/hr)	DKA Bag 2 w/Dextrose rate (mL/hr)	TOTAL rate (mL/hr)	Functional Dextrose
BG >250	250	0	250	0%
BG 150-250	125	125	250	5%
BG < 150	0	250	250	10%

2. Fluid restriction

Blood glucose (mg/dL)	DKA Bag 1 rate (mL/hr)	DKA Bag 2 w/Dextrose rate (mL/hr)	TOTAL rate (mL/hr)	Functional Dextrose
BG >250	125	0	125	0%
BG 150-250	75	125	200	6.25%
BG < 150	0	250	250	10%

E. ONGOING ELECTROLYTE REPLACEMENT (SEE **APPENDIX 1**)

1. Nurse to order and replace per *DKA Electrolyte Replacement Protocol using the Nursing – DKA Electrolyte Replacement care set*. **If patient not eligible for replacement protocol, provider to order all electrolyte replacement.**

F. TRANSITION TO SUBCUTANEOUS INSULIN

1. Patients will be transitioned from IV insulin to long-acting subcutaneous (basal) insulin when ALL of the following criteria are met:
    a. pH > 7.3
    b. Anion gap < 12
    c. Serum bicarbonate > 15
    d. Blood glucose < 200
    e. Beta-hydroxybutyrate < 5 or trending down
    f. Patient is tolerating PO and ready to resume full diet
2. Nurse to call provider when criteria are met to help facilitate transition to next step in DKA management.
3. **Continue insulin infusion and IV fluids for TWO hours after administration of subcutaneous long-acting (basal) insulin.**

III. DKA TREATMENT RATIONALE

A. Definitions

1. Diabetic ketoacidosis (DKA): An acute metabolic complication of diabetes. DKA is characterized by metabolic acidosis and ketone body derangements (e.g., ketosis) resulting from a profound or absolute lack of insulin in the body. Though hyperglycemia is usually associated with DKA, a minority of patients with DKA will have euglycemia (normal blood glucose).
2. Two-bag system: An approach to DKA management that uses two maintenance fluid solutions (one WITH and one withOUT dextrose), allowing insulin to run at a set rate. In clinical trials, the two-bag system has led to faster DKA resolution, less hypoglycemia, and faster anion gap closure compared to conventional (i.e., methods with insulin titration) approaches.

Table 1. Common diagnostic criteria for DKA. Adapted from *Diabetes Care*. 2009;32(7):1335-1343.

	DKA		
	Mild	***Moderate***	***Severe***
Glucose (mg/dL)*	>250	>250	>250
Arterial pH	7.3 to 7.25	7.24 to 7	<7
Serum bicarbonate (mEq/L)	18 to 15	15 to 10	<10
Urine ketones	Positive	Positive	Positive
beta hydroxybutyrate (mmol/L)	3 to 4	4 to 8	>8
Anion gap	>10	>12	>12
Mental Status	Alert	Alert/drowsy	Stupor/coma

*Blood glucose may be normal in patients with *euglycemic DKA.*

B. Initial fluid & electrolyte management

1. Fluid resuscitation: Patients with DKA frequently present with significant dehydration from GI losses and decreased oral intake. Many of these patients will require IV fluids prior to insulin initiation.
    a. Aggressive fluid resuscitation with 0.9% NaCl may cause renal tubular acidosis. In prospective clinical trials, this has been shown to cause or worsen acidemia and hyperkalemia, leading to increased incidence of AKI and need for renal replacement therapy.[1-4]
    b. The use of a balanced crystalloid such as Lactated Ringer's (LR) solution may be preferred for DKA management. *Prospective clinical data show that use of balanced crystalloids lead to faster time to DKA resolution and faster time to IV insulin discontinuation compared to 0.9% NaCl.*[5,6]
    c. Despite theoretical concerns, LR is NOT contraindicated in hyperkalemia, acute renal failure, or lactic acidosis, and is indeed preferred over 0.9% NaCl in these settings.
    d. Relevant contraindications to LR may include elevated intracranial pressure, metformin-associated lactic acidosis, overt liver failure, and severe hypercalcemia.
2. Electrolyte replacement: Correction of electrolyte derangements, especially hypokalemia, is recommended prior to the initiation of insulin. Since insulin therapy will decrease potassium further, the cutoffs for potassium replacement are *higher* in DKA compared to other diseases. *Serum potassium levels < 3.3 mmol/L should be repleted before insulin is started.* See **Appendix 1** for more information.

C. IV insulin infusion

1. IV insulin is required to correct the underlying pH abnormalities in DKA. Insulin secondarily lowers blood glucose when elevated.
2. As opposed to a one-bag system, *the two-bag system for DKA treatment does NOT require insulin titration.* Boluses of IV insulin are NOT recommended with the two-bag system.

D. Two-bag maintenance fluids

1. Treatment of DKA with the two-bag system has been tested in prospective, randomized clinical trials in adults.[7,8] Pertinent findings include:
    a. Faster normalization of blood pH
    b. Faster closure of the anion gap
    c. Fewer instances of significant hypoglycemia
    d. Less IV insulin administered in total
    e. No increase in length of hospital stay
2. Standard nomenclature will be adopted throughout MHC for the naming of Bag 1 and Bag 2 on labels and smart pump infusion devices:
    a. Bag 1: "DKA Bag 1"
    b. Bag 2: "DKA Bag 2 w/Dextrose"
3. ***DKA Bag 1 and DKA Bag 2 w/Dextrose are connected to two different IV pumps & connected to each other via Y-site, to be administered through one IV line.***
4. There are four (4) options for DKA Bag 1. The choice between these four options is dependent on:
    a. Initial serum potassium, **and**
    b. Corrected serum sodium
5. There are two (2) options for DKA Bag 2 w/Dextrose. The choice between the two may be dependent on either initial or subsequent serum potassium levels.
6. Maintenance fluid titration:
    a. Standard: the total, combined rate of DKA Bag 1 and DKA Bag 2 w/Dextrose is always equal to **250mL/hr.** The specific rates of Bag 1 or Bag 2 will be titrated by nursing per hourly glucose measurement.
    b. Fluid restriction: the total, combined rate of DKA Bag 1 and DKA Bag 2 w/Dextrose is NOT constant. The specific rates of Bag 1 or Bag 2 will vary between 125 and 250 mL/hr and will be titrated by nursing per hourly glucose measurement.

E. Ongoing electrolyte replacement

1. Prompt recognition and treatment of evolving hypokalemia and other electrolyte derangements is crucial in DKA management, as patients frequently present with electrolyte depletion and insulin therapy may have dramatic effects on serum electrolyte balance.
2. Electrolytes will be supplemented throughout the treatment window by the nursing-driven by the DKA Electrolyte Replacement Protocol and monitored with Q4H BMP laboratory measurement.
3. See **Appendix 1** for the *DKA Electrolyte Replacement Protocol*

F. Transition to subcutaneous insulin

1. Biochemical markers: DKA resolution is marked by normalization of blood pH, anion gap, and blood glucose.
2. Symptoms: Nausea, vomiting, and pertinent GI symptoms from presentation are resolved. Patients are able to tolerate meals.

3. Transition to SQ insulin: To prevent relapse, insulin therapy **MUST** continue after the acute treatment phase. **Continue insulin infusion and IV fluids for TWO hours after administration of subcutaneous long-acting (basal) insulin.**

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2. Self WH, Semler MW, Wanderer JP, et al. Balanced Crystalloids versus Saline in Noncritically Ill Adults. N Engl J Med 2018;378(9):819–28.
3. Hawkins WA, Smith SE, Newsome AS, Carr JR, Bland CM, Branan TN. Fluid Stewardship During Critical Illness: A Call to Action. J Pharm Pract 2020;33(6):863–73.
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5. Self WH, Evans CS, Jenkins CA, et al. Clinical Effects of Balanced Crystalloids vs Saline in Adults With Diabetic Ketoacidosis: A Subgroup Analysis of Cluster Randomized Clinical Trials. JAMA Netw open 2020;3(11):e2024596.
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7. Munir I, Fargo R, Garrison R, et al. Comparison of a 'two-bag system' versus conventional treatment protocol ('one-bag system') in the management of diabetic ketoacidosis. BMJ Open Diabetes Res Care 2017;5(1).
8. Haas NL, Gianchandani RY, Gunnerson KJ, et al. The Two-Bag Method for Treatment of Diabetic Ketoacidosis in Adults. J Emerg Med 2018;54(5):593–9.

APPENDIX 1: DKA ELECTROLYTE REPLACEMENT PROTOCOL

Purpose

To provide a plan for replacing potassium, magnesium, and phosphorus during the acute management of diabetic ketoacidosis in adults.

Criteria for use*

1. Patients must be monitored by continuous telemetry
2. To be used exclusively within the Adult DKA PowerPlan subsequent to a provider order
3. To be discontinued at the time of IV insulin discontinuation
4. Serum creatinine is ≤ 2.5 mg/dL and patient not on renal replacement therapy

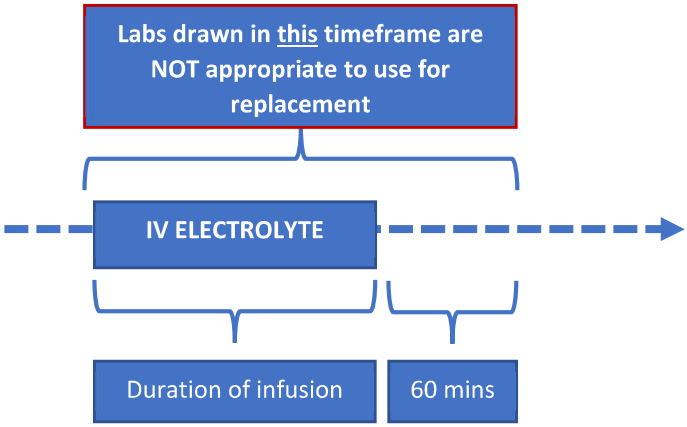
**If patient not eligible for replacement protocol, provider to order all electrolyte replacement.*

Process and Product Selection

1. Nurse to order electrolyte replacement in PowerChart based on potassium, magnesium, or phosphate protocol below.
    a. PowerChart search term: "Nursing - DKA Electrolyte Replacement"
    b. Ordering provider: "Nurse, per protocol"
2. Nurse to discontinue electrolyte replacement protocol when IV insulin is discontinued
3. Parenteral product selection will be guided by site formulary, availability, and MHC system electrolyte policies:
    a. MHC High-Alert Medications Policy
    b. Parenteral Potassium Supplementation Policy- Adult
4. Enteral administration is preferred where indicated

Monitoring

1. Scheduled BMP will be ordered for all patients every 4 hours
2. Nursing to order additional serum potassium levels as directed in *Potassium Replacement Protocol*
3. Replace electrolytes based only on appropriate serum measurements. To be an appropriate measurement, the lab draw must meet the following criteria:
    a. Lab NOT drawn during IV replacement of the electrolyte (electrolytes contained in maintenance IV fluids do not count)
    b. Lab drawn at least 60 minutes after administration of the electrolyte replacement, including oral (PO) replacement



Potassium Replacement Protocol

Replacement rate: 10 mEq/hr. If patient is monitored via continuous telemetry AND has a condition that requires more rapid supplementation, the administration rate shall not exceed 20 mEq/hr.

Potassium Level (mmol/L)	Enteral	Parenteral (as potassium chloride IVPB)	When to recheck level
< 3.3	Use IVPB replacement	Total dose: 80 mEq over minimum of 4 hours, *AND* 1. PAUSE insulin 2. Call provider to discuss before resuming	At next appropriate time until K >3.3 mmol/L *(see graphic above)*
3.3 – 3.5	Use IVPB replacement	Total dose: 60 mEq over minimum of 3 hours	At next appropriate time after replacement has finished *(see graphic above)*
3.6 – 3.9	40 mEq PO/NG x 1 dose Do not give both PO and IV replacement	Total dose: 40 mEq over minimum of 2 hours Do not give both PO and IV replacement	At next appropriate time after replacement has finished *(see graphic above)*
4 – 5.2	20 mEq PO/NG x 1 dose Do not give both PO and IV replacement	Total dose: 20 mEq over minimum of 1 hour Do not give both PO and IV replacement	At next appropriate time after replacement has finished *(see graphic above)*
> 5.5	Call provider		

Magnesium Replacement Protocol

Replacement rate: 1 gram/hour

Magnesium Level (mg/dL)	Parenteral (as magnesium sulfate IVPB)	When to recheck level
≤ 1.5	Total dose: 4 grams over minimum of 4 hours	At next appropriate time after replacement has finished *(see graphic above)*
1.6-1.9	Total dose: 2 grams over minimum of 2 hours	At next appropriate time after replacement has finished *(see graphic above)*

Phosphate Replacement Protocol

Replacement rate: 15 mmol over 1 hour

Phosphorus Level (mg/dL)	Enteral	Parenteral (as sodium phosphate IVPB)*	When to recheck level
< 1.5	K-Phos Neutral 2 tabs q2hr x3	15 mmol x3 doses	At next appropriate time after replacement has finished
1.5 – 1.9	K-Phos Neutral 2 tabs q2hr x2	15 mmol x2 doses	At next appropriate time after replacement has finished

*Solution requires compounding by pharmacy.

Owner: Pharmacy
Reviewed: 4/2024
Reference attached to: DKA IV Glucose Management order

Status **Active** PolicyStat ID **13403601**

Origination	12/11/2015
Last Approved	1/24/2024
Effective	1/24/2024
Last Revised	1/24/2024
Next Review	1/23/2026
Owner	Danielle Graber: Mgr Laboratory Services - Phlebotomy
Area/ Department	Laboratory
Applicability	Munson Healthcare Systemwide
Tags	Policy

LAB GEN: Patient Identification for Laboratory Specimen Collection

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Purpose

To provide accurate identification of patients, eliminating related medical errors and patient harm. Identification (ID) of the patient is an on-going process that begins when the patient enters the hospital and continues throughout the patient's stay. To maintain and facilitate patient care and safety and to ensure accurate and reproducible laboratory results, the labeling of laboratory samples will be consistently completed at the point of care.

Definition

1. **Point of Care:** within close proximity of the draw site; meaning at the patient's bedside or similar area (i.e. next to the drawing chair).

Policy

A. Patients are identified by two (2) identifiers at the point of care. All samples are adequately and permanently labeled immediately upon collection at the point of care.

Identification Guidelines

A. Two aspects of patient ID must be verified prior to specimen collection:
    1. **Inpatients (includes Emergency Room (ER) patients)**

a. Scan the patient's ID band located on the patients' wrist or ankle with the PDA system. Ask the patient to state their legal name (First & Last) and date of birth (DOB). Compare their response to the information on the PDA system & patient ID band.

b. If the PDA system is unavailable compare Sunquest label or chart sticker to the patient ID band located on the patients' wrist or ankle. Ask the patient to state their legal name (First & Last) and DOB. Compare their response to the information on the Sunquest label or chart sticker & patient ID band.

c. Note: For patients who are unable to verbalize two aspects of ID, verify ID with a caregiver or family member whenever practical.

2. **Outpatients**

    a. Ask patient to state the following information:

        i. Name: (First and Last legal)??

        ii. DOB

    b. Verify this information with that on all paperwork provided including the lab requisition(s).

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Labeling Guidelines

A. Immediately upon collection all samples must be permanently labeled with two patient-specific identifiers:

    1. Affix a sunquest label, chart sticker, or hand write full legal name and second unique ID number (medical record #). If the medical record # is unknown or is not available, acceptable 2nd identifiers are the patient's DOB, account number, office chart number, social security number.

    2. Affix labels vertically down blood tubes and horizontally across other collection containers.

B. If second label is required, the first permanent label may be covered but not removed. Double check full name and date of birth when applying second label.

C. Samples must be labeled in the patient's presence. Do not move samples or allow patient to leave the area before labeling the samples.

Pretransfusion Specimen Labeling Guidelines

A. Immediately upon collection pretransfusion blood specimens are labeled at the time of specimen collection in the presence of the patient with:

    1. Patient's first and last name

    2. Unique identification number (medical record #)

    3. Date and time of collection

    4. Initials of individual collecting the specimen if not Sunquest label

B. Sunquest Label, Chart Label, or hand labeled with black or blue ink is acceptable for labeling pretransfusion specimens.

C. Pretransfusion blood specimen collectors are recorded in the laboratory information system. All phlebotomists have a Tech ID code unique to employee. For non-laboratory staff collections, initials of collector are recorded in the laboratory information system as a comment.

Additional Information on Specimen Container(s) when Applicable

A. Specimen Source (such as cultures)

B. Collection Duration (12 or 24 hours for timed urine specimens)

C. Collection Time for Serial Draws (30 minutes, 1 hour, 2 hours, 3 hour)

D. Tube Number in Order of Draw (#1, #2, #3 for spinal fluid tubes)

E. Preservative Added (acetic acid preservative added to a 24-hour urine container)

Glass Slides

A. Glass slides must be labeled with the patient name. A second identifier is preferred, but the name only is acceptable.

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Approval Signatures

Step Description	Approver	Date
System Policy Oversight Committee	Terri Fries: Document Mgmt Spec	1/24/2024
Lab Medical Director	William Kanner	1/24/2024
Document Owner	Danielle Graber: Mgr Laboratory Services	10/20/2023

Applicability

Cadillac Hospital, Charlevoix Hospital, Grayling Hospital, Kalkaska Memorial Health Center, MHC Corporate (Home Health, Dialysis, NMSA, etc.), Manistee Hospital, Munson Medical Center, Otsego Memorial Hospital, Paul Oliver Memorial Hospital

Standards

No standards are associated with this document

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Peripheral nerve stimulation

Peripheral nerve stimulation

Revised: February 24, 2025

Introduction

Peripheral nerve stimulation assesses nerve impulse transmission at the neuromuscular junction of certain skeletal muscles to monitor the depth of neuromuscular blockade in patients who are receiving neuromuscular blocking drugs.[1] Neuromuscular blocking drugs produce paralysis to help synchronize breathing and mechanical ventilation in patients with severe lung injury; treat severe muscle spasms in patients with seizures, tetanus, or a drug overdose; and manage increased intracranial pressure in patients with head injuries.[1][2]

A peripheral nerve stimulator (PNS) helps evaluate the level of neuromuscular blockade and determine the lowest therapeutic dose of the neuromuscular blocking drug necessary to produce paralysis.[3] A PNS works by stimulating a peripheral nerve with a series of brief electrical pulses to produce a muscle response or twitch.

The train-of-four (TOF) method is the most common PNS method for monitoring neuromuscular blockade.[2] In this method, a PNS delivers a series of four electrical impulses to a particular peripheral nerve, and the practitioner then evaluates the muscle's response to the nerve stimulation. The most common and recommended location for the test is the ulnar nerve site, but you can also use the facial or posterior tibial nerves.[1] Four muscle twitches occur in response to the PNS indicates that less than 75% of the receptors are blocked. Three twitches occur when about 75% of the receptors are blocked. One or two twitches correspond to about 80% to 90% neuromuscular blockade.[1][4] Titration of the neuromuscular blocking drug ensures that each series of four electrical impulses produces one or two muscle twitches. The absence of twitches, which may indicate that 100% of the receptors are blocked, exceeds the desired level of neuromuscular blockade.[1]

Equipment

- Alcohol pads
- Facility-approved disinfectant
- Gloves
- PNS
- Pulse oximeter and probe
- Electrode gel patches
- Two leadwires
- Vital signs monitoring equipment
- Optional: arterial blood gas analysis supplies, battery, clippers, other personal protective equipment

Preparation of Equipment

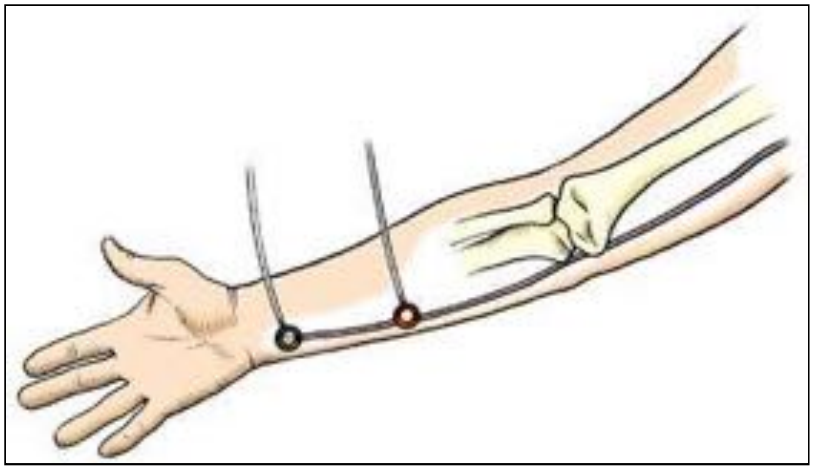
Inspect all equipment and supplies. If a product is expired, is defective, or has compromised integrity, remove it from patient use, label it as expired or defective, and report the expiration or defect as directed by your facility.

Implementation

- Verify the practitioner's order.
- Gather and prepare the necessary equipment and supplies.
- Perform hand hygiene.[5][6][7][8][9][10]
- Confirm the patient's identity using at least two patient identifiers.[11]
- Provide privacy.[12][13][14][15]
- Explain the procedure to the patient and family (if appropriate) according to their individual communication and learning needs *to increase their understanding, allay their fears, and enhance cooperation*.[16]
- Raise the bed to waist level before performing care *to prevent caregiver back strain.*[17]
- Perform hand hygiene.[5][6][7][8][9][10]
- Select a site for electrode placement that is accessible and without edema, wounds, catheters, or dressings *to ensure optimum placement for conducting stimulating current.* The preferred monitoring site is the ulnar nerve, but if this site isn't accessible, you may use another site.[18]
- If the patient has excessive hair at an electrode placement site, remove the hair with clippers *to improve electrode contact with the skin.*[1]
- Assess the patient's oxygen saturation level using pulse oximetry, vital signs, and neurovascular status *to obtain baseline data for later comparison*.

Performing ulnar nerve stimulation

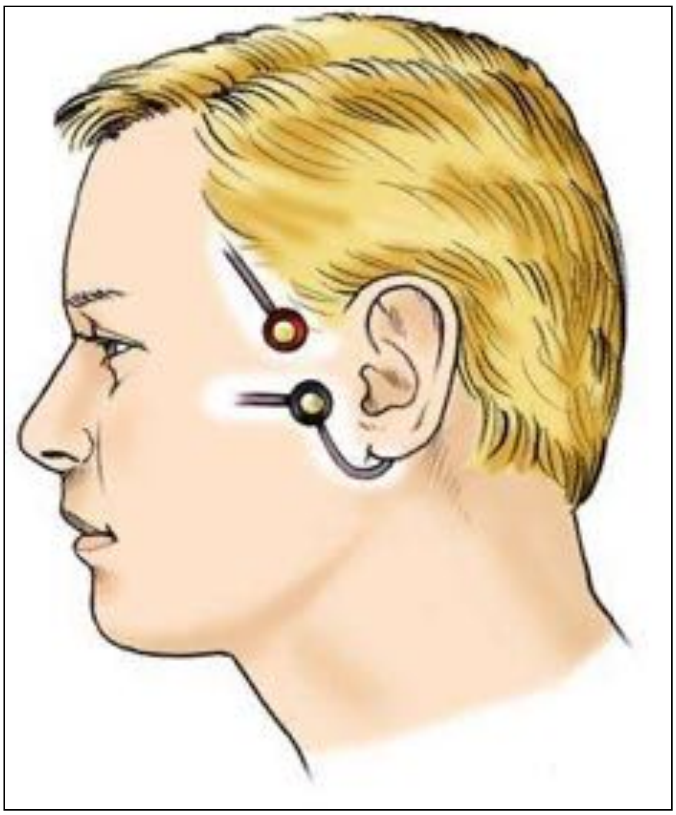
- Use an alcohol pad to clean the electrode placement sites on the patient's arm and then allow the sites to dry *to improve electrode contact with the skin.*
- Place the patient's arm in a relaxed position with the palm up *so that the ulnar nerve is easily accessible*.
- Place one electrode over the ulnar nerve at the crease of the wrist and the other electrode 0.4" to 0.8" (1 to 2 cm) away, parallel to the carpi ulnaris tendon (as shown below), *to ensure ulnar nerve stimulation.*



- Attach the leadwires to the PNS.
- Connect the black lead (negative) to the electrode nearest the wrist and the red lead (positive) to the electrode on the forearm.
- Turn on the PNS and choose a low amplitude (commonly 10 to 20 mA). *Higher current can overstimulate the nerve and result in rhythmic nerve firing.*[1]
- Press the TOF button to initiate the four impulses. Note thumb adductions or twitches that the stimulation produces and count them while lightly feeling for twitches. Don't count finger movement caused by muscle stimulation.
- Turn off the PNS.
- Perform hand hygiene.[5][6][7][8][9][10]

Performing facial nerve stimulation

- Use an alcohol pad to clean the electrode placement sites on the patient's face and then allow the sites to dry *to improve electrode contact with the skin.*
- Place one electrode near the outer canthus of the eye and the other electrode 0.8" (2 cm) below so that it's level with the tragus of the ear (as shown below) *to ensure facial nerve stimulation.*

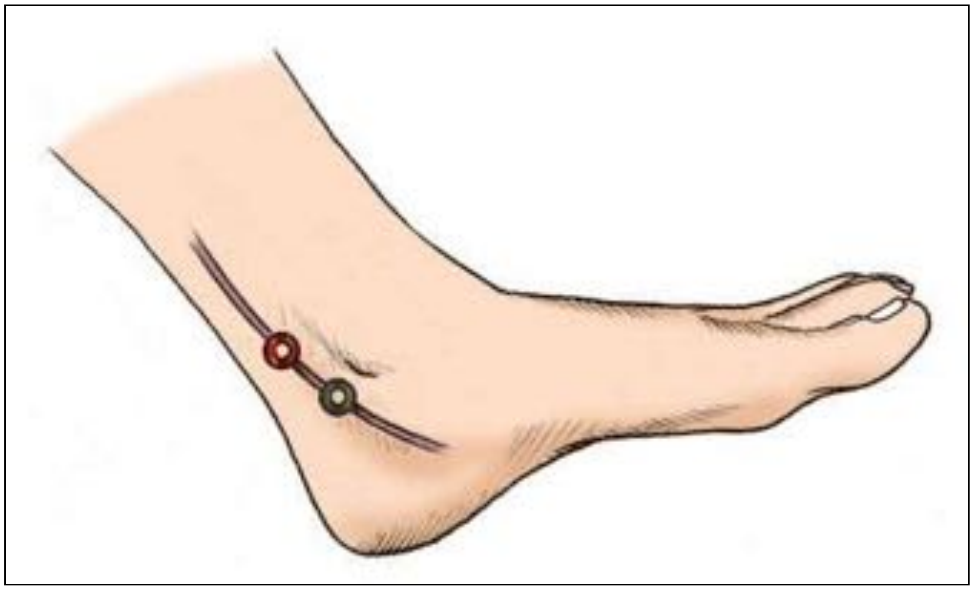


- Attach the leadwires to the PNS.
- Connect the black lead (negative) to the electrode nearest the tragus and the red lead (positive) to the electrode near the outer canthus of the eye.
- Turn on the PNS and choose a low amplitude (commonly 10 to 20 mA). *Higher current can overstimulate the nerve and result in rhythmic nerve firing.*[1]

- Press the TOF button to initiate the four impulses. Note eyebrow twitches that the stimulation produces and count them while lightly feeling for twitches.
- Turn off the PNS.
- Perform hand hygiene.[5][6][7][8][9][10]

Performing posterior tibial nerve stimulation

- Use an alcohol pad to clean the electrode placement sites on the patient's foot and then allow the sites to dry *to improve electrode contact with the skin.*
- Place one electrode 0.8" (2 cm) behind the medial malleolus and the other electrode 0.8" (2 cm) above the first electrode (as shown below) *to ensure posterior tibial nerve stimulation*.



- Attach the leadwires to the PNS.
- Connect the black lead (negative) to the electrode behind the medial malleolus and the red lead (positive) to the electrode above the first.
- Turn on the PNS and choose a low amplitude (commonly 10 to 20 mA). *Higher current can overstimulate the nerve and result in rhythmic nerve firing.*[1]
- Press the TOF button to initiate the four impulses. Note plantar flexion of the great toe and count the number of twitches that the stimulation produces.
- Turn off the PNS.
- Perform hand hygiene.[5][6][7][8][9][10]

Establishing supramaximal stimulation

- To determine the baseline amplitude setting for a patient who hasn't received neuromuscular blockade, set the amplitude to 5 mA and press the TOF button to initiate the stimulus.[1]

- Note the number of twitches produced.
- Increase the amplitude by 5 mA at a time until TOF stimulation produces four muscle twitches. *This step establishes the amount of current to use for peripheral nerve stimulation and enhances the reliability of testing.*[1]

- Once TOF stimulation produces four muscle twitches, increase the amplitude by 5 mA *to confirm this response level*.
    - If there is no increase in the intensity of the twitches, then the supramaximal stimulation is the level at which four vigorous twitches were observed.
    - If there is an increase in the intensity of the twitches, continue to increase by 5 mA until no increase in the intensity of the twitches is seen. Once there is no increase in intensity of the the twitches, then then supramaximal stimulation is the level at which four vigorous twitches were observed.[1]

Establishing TOF after neuromuscular blockade

- Determine the TOF 10 to 15 minutes after a bolus dose or any change in neuromuscular blocker administration *to assess the level of neuromuscular blockade.*[1]
- If no twitches occur, troubleshoot the equipment (replace the battery, check lead connections, or replace electrodes, as necessary).[1] Next, increase the stimulating current and then retest another nerve. If no response occurs, check the neuromuscular blocker infusion rate, concentration, and dose and then hold the bolus dose or reduce the infusion rate, as ordered. Retest the TOF in 10 to 15 minutes.[1]
- If one or two twitches occur, continue the current rate of the infusion.
- If three or four twitches occur, increase the rate of the neuromuscular blockade, as ordered, and then retest using TOF in 10 to 15 minutes.

Performing ongoing care

- Assess the oxygen saturation level (using pulse oximetry or arterial blood gas analysis), vital signs, and neurologic status before any increase in the level of neuromuscular blockade.[1]
- Change electrodes daily or more frequently if they become loose or if the gel dries out *to ensure optimum conduction.*[1]
- Assess the skin under the electrodes for signs of irritation and breakdown, which could impede conduction.
- Reevaluate the level of neuromuscular blockade every 4 to 8 hours during therapy with neuromuscular blocking drugs after the patient is stable and reaches an adequate level of neuromuscular blockade, as ordered or as directed by your facility.[1]
- Return the bed to the lowest position *to prevent falls and maintain the patient's safety.*[19]
- Discard used supplies in appropriate receptacles.[20]
- Perform hand hygiene.[5][6][7][8][9][10]
- Put on gloves and, as needed, other personal protective equipment.[20]
- Clean and disinfect reusable equipment according to the manufacturer's instructions *to prevent the spread of infection.*[21][22]
- Remove and discard your gloves and, if worn, other personal protective equipment.[20]
- Perform hand hygiene.[5][6][7][8][9][10]
- Document the procedure.[23][24][25][26]

Special Considerations

- *Because neuromuscular blocking drugs don't produce amnesia, sedation, or analgesia,* administration of sedative and analgesic drugs should always precede administration of a neuromuscular blocking drug.[1][2][3]
- Assess the patient's baseline electrolyte, blood urea nitrogen, and creatinine levels, *because imbalances may potentiate the effects of neuromuscular blocking drugs.*[1]

- Be aware that, *to avoid complications of neuromuscular blockade,* the patient will require frequent routine oral care and suctioning, deep vein thrombosis prophylaxis (as ordered), GI prophylaxis (as ordered), eye lubrication (as ordered), and footdrop prevention measures.[2]
- Be aware that PNS devices are unreliable for discerning the degree of neuromuscular recovery required for spontaneous ventilation and tracheal extubation. More precise medical devices, such as neuromuscular monitors that provide objective responses to nerve stimulation, are necessary *to assess readiness for tracheal extubation*. *Such monitors use different methods to measure the evoked muscle responses to electrical nerve stimulation.*[3]
- If the patient has hemiplegia, hemiparesis, or peripheral neuropathy (due to diabetes or another condition), keep in mind that the motor response to peripheral nerve stimulation may not be as pronounced, which can lead to the incorrect belief that a higher dose of neuromuscular blocking drugs is necessary. With a patient who has hemiplegia or hemiparesis, place the electrodes on the unaffected limb (if possible).
- Carefully check the electrode placement site, *because incorrect placement can lead to muscle, rather than nerve, stimulation.*[1]
- If no twitches are elicited at a level that previously elicited a response, troubleshoot the PNS before decreasing the level of neuromuscular blockade. Check the polarity of the leads, battery charge, electrode contact with the skin, condition of electrode gel pads, and leadwire connections.[1]
- Neuromuscular blockade should be discontinued as early as possible *to avoid drug metabolite accumulation and prolonged recovery.*[2]

Complications

Complications associated with peripheral nerve stimulation may include:

- cardiac arrhythmias (if PNS leadwires come in contact with an external pacing catheter or leadwire)[1]
- mild discomfort or tingling during TOF testing[1]
- pressure injury[1]
- protracted paralysis and muscle weakness (caused by excessive neuromuscular blockade)[3] [18]
- skin irritation.[1]

Documentation

Documentation associated with peripheral nerve stimulation includes:

- date and time of assessment
- initial TOF assessment
  - site used
  - amplitude used
  - dose of neuromuscular blocking drug administered
- each subsequent TOF assessment as a ratio of twitches per four stimulations (for example, 0/4, 1/4, 2/4, 3/4, 4/4)
- current used
- bolus doses or changes in the infusion rate of the neuromuscular blocking drug
- assessment findings
  - respiratory
  - cardiovascular
  - neurologic
  - neurovascular
- adverse effects
  - name of the practitioner notified
  - date and time of practitioner notification
  - prescribed interventions
  - response to those interventions

- teaching provided to the patient and family (if applicable)
    - understanding of that teaching
    - follow-up teaching needed.

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(Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions)

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Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions

The following leveling system is adapted from *Evidence-Based practice in nursing & healthcare: A guide to best practice,* Fifth edition, by Bernadette Mazurek Melnyk and Ellen Fineout-Overholt (2023).

Level I	Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs)
Level II	Evidence from well-designed single RCTs (experimental)
Level III	Evidence from well-designed nonrandomized controlled trials (quasi-experimental), systematic reviews of a complete body of evidence, and intervention studies using mixed methods
Level IV	Evidence from well-designed case-control and cohort studies (observational)
Level V	Evidence from systematic reviews of qualitative and descriptive studies

Level VI	Evidence from single descriptive and qualitative studies, evidence-based practice implementation, and quality improvement projects
Level VII	Evidence from expert opinion, expert committee reports, and literature reviews

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LIFEPAK® 15 MONITOR/DEFIBRILLATOR

OPERATING INSTRUCTIONS

Important Information

!USA Rx Only

!USA Device Tracking

The U.S. Food and Drug Administration requires defibrillator manufacturers and distributors to track the location of their defibrillators. If the device is located somewhere other than the shipping address or the device has been sold, donated, lost, stolen, exported, destroyed, permanently retired from use, or if the device was not obtained directly from Physio-Control, please do one of the following: register the device at http://www.physio-control.com, call the device tracking coordinator at 1.800.426.4448, or use one of the postage-paid address change cards located in the back of this manual to update this vital tracking information.

Text Conventions

Throughout these operating instructions, special text characters (for example, **CAPITAL LETTERS** such as **CHECK PATIENT** and **SPEED DIAL**) are used to indicate labels, screen messages, and voice prompts.

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1

PREFACE

This chapter provides a brief introduction to the LIFEPAK® 15 monitor/defibrillator and describes the product's intended use.

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Introduction

The LIFEPAK 15 monitor/defibrillator is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols.

These operating instructions include information and procedures related to *all* features of the LIFEPAK 15 monitor/defibrillator. Your LIFEPAK 15 monitor/defibrillator may not have all of these features.

These operating instructions describe the operation of the LIFEPAK 15 monitor/defibrillator when the factory default settings are used. The factory default settings for all setup options are identified in Table A-5 on page A-14. Your device may be set up with different default settings, based on your protocols. For information about changing default settings, see the *LIFEPAK 15 Monitor/ Defibrillator Setup Options* provided with your device.

IMPORTANT! Some LIFEPAK 15 monitor/defibrillator accessories are *not* interchangeable with accessories that are used with other LIFEPAK monitor/defibrillators. Specific accessory incompatibilities are noted in the related sections.

Intended Use

The LIFEPAK 15 monitor/defibrillator is intended for use by trained medical personnel in out-of-doors and indoor emergency care settings within the environmental conditions specified on page A-10. The LIFEPAK 15 monitor/defibrillator is designed to be used during ground transportation except when specified otherwise.

Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients. Automated external defibrillation mode is intended for use on patients eight years of age and older.

For additional intended use information, and information about the indications and contraindications of the monitoring and therapy functions, see the individual sections identified below.

• ECG Monitoring	See page 4-3	Standard feature
• 12-Lead Electrocardiography	See page 4-14	Optional
• SpO_2, SpCO, and SpMet Monitoring	See page 4-24	Optional
• Noninvasive Blood Pressure Monitoring	See page 4-35	Optional
• End-Tidal CO_2 Monitoring	See page 4-43	Optional
• Invasive Pressure Monitoring	See page 4-51	Optional
• Vital Sign and ST Segment Trends	See page 4-58	Optional

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• Automated External Defibrillation	See page 5-7	Standard feature
• Manual Defibrillation	See page 5-21	Standard feature
• Noninvasive Pacing	See page 5-31	Standard feature

Modes of Operation

The LIFEPAK 15 monitor/defibrillator has the following modes of operation:

- **AED mode**—for automated ECG analysis and a prompted treatment protocol for patients in cardiac arrest.
- **Manual mode**—for performing manual defibrillation, synchronized cardioversion, noninvasive pacing, and ECG and vital sign monitoring.
- **Archive mode**—for accessing stored patient information.
- **Setup mode**—for changing default settings of the operating functions. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.
- **Demo mode**—for simulated waveforms and trend graphs for demonstration purposes. For more information, see *LIFEPAK 15 Monitor/Defibrillator Demo Mode* at www.physio-control.com.
- **Service mode**—for authorized personnel to perform diagnostic tests and calibrations. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Service Manual*.

2

SAFETY INFORMATION

This chapter provides important information to help you operate the LIFEPAK 15 monitor/defibrillator. Familiarize yourself with all of these terms and warnings.

Terms . . . . . page 2-3
General Dangers and Warnings 2-3

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Terms

The following terms are used either in these operating instructions or on the LIFEPAK 15 monitor/defibrillator:

Danger: Immediate hazards that will result in serious personal injury or death.

Warning: Hazards or unsafe practices that may result in serious personal injury or death.

Caution: Hazards or unsafe practices that may result in minor personal injury, product damage, or property damage.

General Dangers and Warnings

The following are general danger and warning statements. Other specific warnings and cautions are provided as needed in other sections of these operating instructions.

DANGER!

EXPLOSION HAZARD

Do not use this defibrillator in the presence of flammable gases or anesthetics.

WARNINGS

SHOCK OR FIRE HAZARDS

SHOCK HAZARD

The defibrillator delivers up to 360 joules of electrical energy. Unless properly used as described in these operating instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this device unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

SHOCK HAZARD

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

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WARNINGS (CONTINUED)

SHOCK OR FIRE HAZARD

Do not immerse any portion of this defibrillator in water or other fluids. Avoid spilling any fluids on defibrillator or accessories. Spilled liquids may cause the defibrillator and accessories to perform inaccurately or fail. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this defibrillator or accessories unless otherwise specified.

POSSIBLE FIRE

Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

ELECTRICAL INTERFERENCE HAZARDS

POSSIBLE ELECTRICAL INTERFERENCE WITH DEVICE PERFORMANCE

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. RFI may result in distorted ECG, incorrect ECG lead status, failure to detect a shockable rhythm, cessation of pacing, or incorrect vital sign measurements. Avoid operating the device near cauterizers, diathermy equipment, or other portable and mobile RF communications equipment. Do not rapidly key EMS radios on and off. Refer to Appendix D for recommended distances of equipment. Contact Physio-Control Technical Support if assistance is required.

POSSIBLE ELECTRICAL INTERFERENCE

Using cables, electrodes, or accessories not specified for use with this defibrillator may result in increased emissions or immunity from electromagnetic or radio frequency interference (RFI) which could affect the performance of this defibrillator or of equipment in close proximity. Use only parts and accessories specified in these operating instructions.

POSSIBLE ELECTRICAL INTERFERENCE

This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. Verify the effects of defibrillator discharge on other equipment prior to using the defibrillator in an emergency situation, if possible.

IMPROPER DEVICE PERFORMANCE HAZARDS

POSSIBLE IMPROPER DEVICE PERFORMANCE

Using other manufacturers' cables, electrodes, or batteries may cause the device to perform improperly and may invalidate the safety agency certifications. Use only the accessories that are specified in these operating instructions.

WARNINGS (CONTINUED)

POSSIBLE IMPROPER DEVICE PERFORMANCE

Changing factory default settings will change the behavior of the device. Changes to the default settings must only be made by authorized personnel.

POSSIBLE DEVICE SHUTDOWN

Always have immediate access to a spare, fully charged, properly maintained battery. Replace the battery when the device displays a low battery warning.

SAFETY RISK AND POSSIBLE EQUIPMENT DAMAGE

Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage and affect the performance of the equipment. Skin burns will also occur due to heating of electrically conductive materials such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information.

Note: The LIFEPAK 15 monitor/defibrillator and its accessories that are intended for direct or casual contact with the patient are latex-free.

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BASIC ORIENTATION

This chapter provides a basic orientation to the LIFEPAK 15 monitor/defibrillator device and its controls, indicators, and connectors.

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Home Screen 3-16
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Front View

Figure 3-1 shows the front of the LIFEPAK 15 monitor/defibrillator. The front of the device is described in the following sections.



Figure 3-1 Front View

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Area 1

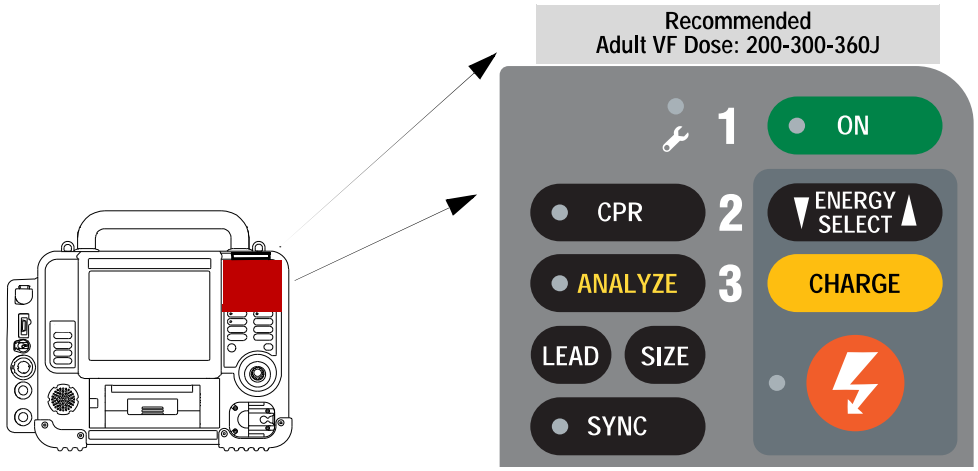


Figure 3-2 Area 1 Controls

Table 3-1 Area 1 Controls

	CONTROL	DESCRIPTION	FOR MORE INFORMATION
	VF dose label	Physio-Control recommended energy dose for adult Ventricular Fibrillation (VF)	See *Biphasic Clinical Summaries* at www.physio-control.com
1	ON	Turns device ON or OFF. LED illuminated when ON. Press and hold to turn device off.	
2	ENERGY SELECT	Increases or decreases energy level in Manual mode	See page 5-21
3	CHARGE	Charges the defibrillator in Manual mode	See page 5-21
		Shock button. Initiates discharge of defibrillator energy to patient. LED flashes when charging is complete.	See page 5-21
		Illuminated Service LED indicates a condition exists that prevents or could prevent normal defibrillator operation	See page 9-18
	CPR	Controls CPR metronome. LED illuminated when metronome function is active.	See page 5-24
	ANALYZE	Activates Shock Advisory System™ (AED mode). LED is illuminated when AED is analyzing the ECG, and flashes when user is prompted to push **ANALYZE**.	See page 5-7
	LEAD	Changes ECG lead	See page 4-4
	SIZE	Changes ECG size	See page 4-5
	SYNC	Activates Synchronized mode. LED is illuminated when Sync mode is active and flashes with detection of each QRS.	See page 5-26

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Area 2

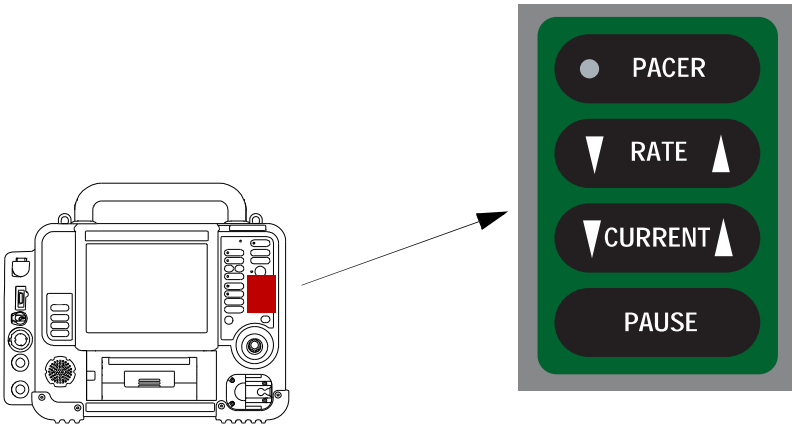


Figure 3-3 Area 2 Controls

Table 3-2 Area 2 Controls

CONTROL	DESCRIPTION	FOR MORE INFORMATION
PACER	Activates pacer function. LED illuminated when function is activated and flashes with each current pulse.	See page 5-31
RATE	Increases or decreases pacing rate	See page 5-31
CURRENT	Increases or decreases pacing current	See page 5-31
PAUSE	Temporarily slows pacing rate	See page 5-31

Area 3

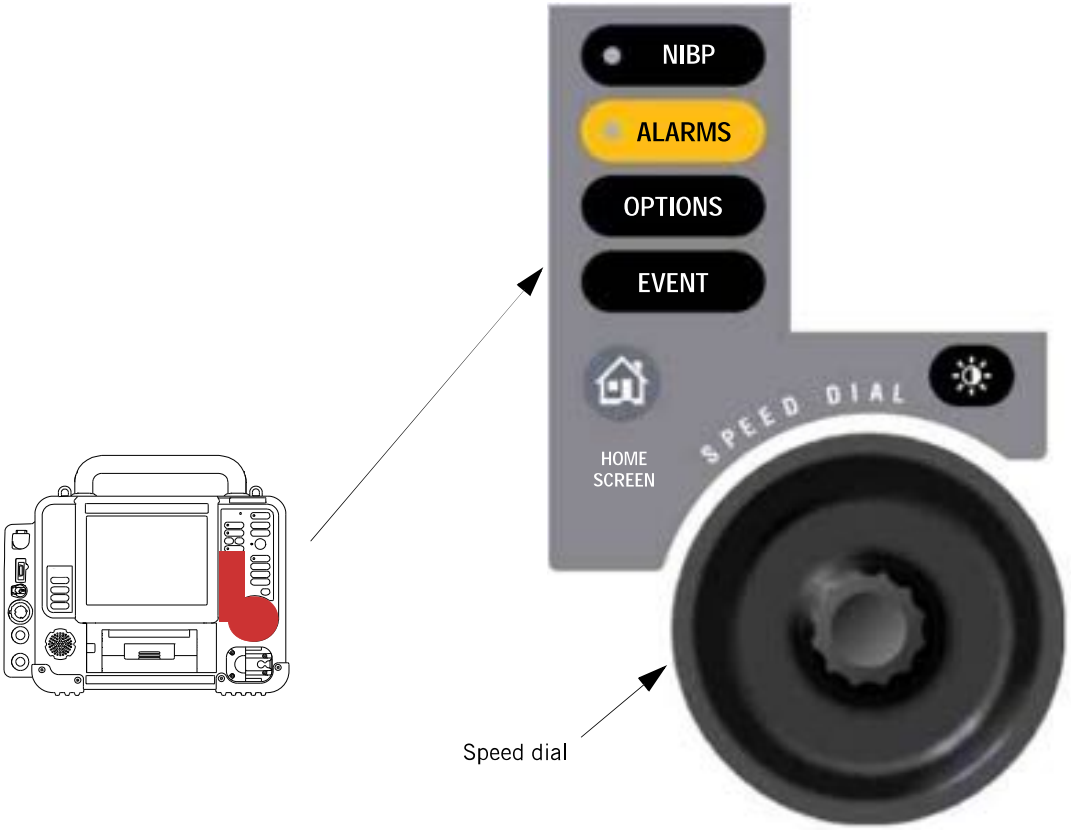


Figure 3-4 Area 3 Controls

Table 3-3 Area 3 Controls

CONTROL	DESCRIPTION	FOR MORE INFORMATION
NIBP	Initiates blood pressure measurement. LED illuminated when BP measurement is being obtained.	See page 4-35
ALARMS	Activates and silences alarms. LED illuminated when alarms are enabled and flashes when an alarm condition occurs.	See page 3-21
OPTIONS	Accesses optional functions	See page 3-23
EVENT	Accesses user-defined events	See page 3-25
HOME SCREEN	Returns to Home Screen display	See page 3-16
SPEED DIAL	Scrolls through and selects screen or menu items	See page 3-19
	Display mode button switches between color display and high contrast SunVue™ display	

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Area 4

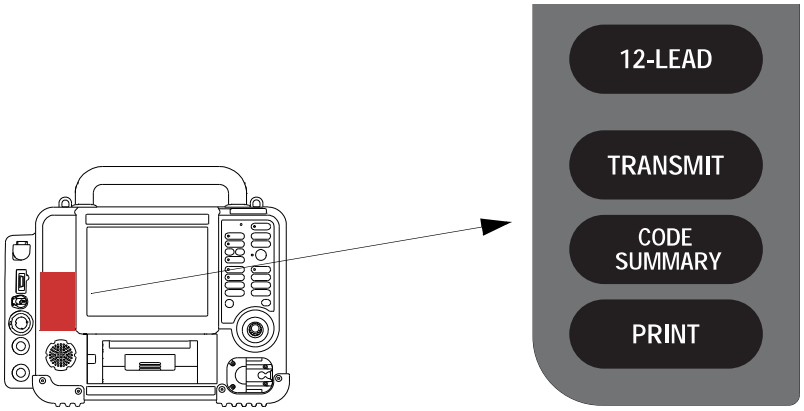


Figure 3-5 Area 4 Controls

Table 3-4 Area 4 Controls

CONTROL	DESCRIPTION	FOR MORE INFORMATION
12-LEAD	Initiates acquisition of 12-lead ECG	See page 4-14
TRANSMIT	Initiates transmission of patient data	See page 8-12
CODE SUMMARY	Prints CODE SUMMARY™ critical event record	See page 7-4
PRINT	Starts and stops printer	See page 7-10

Area 5

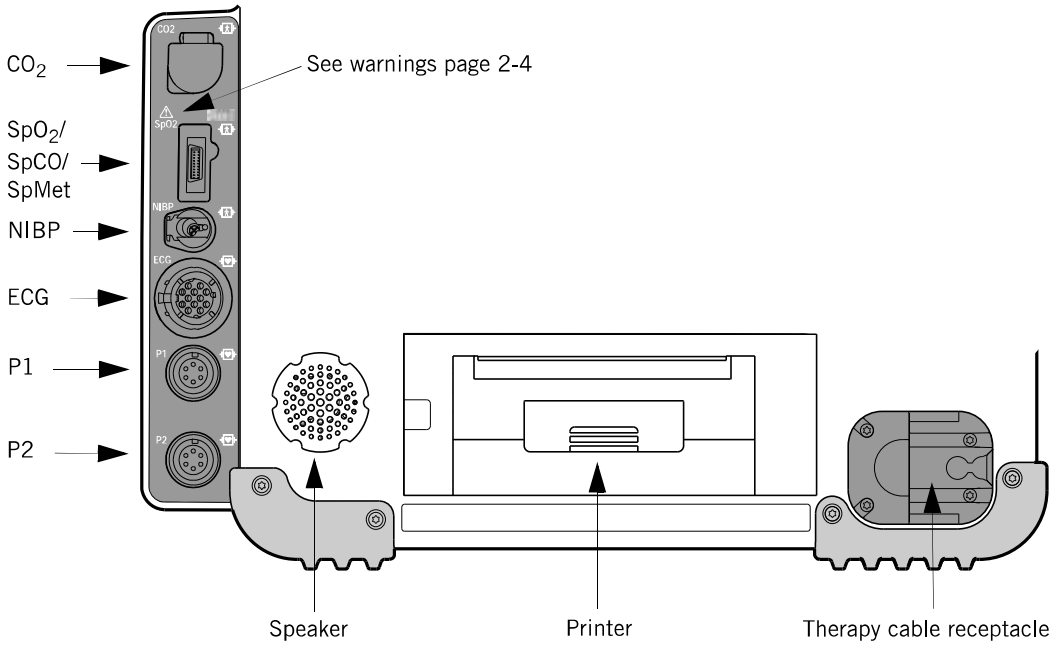


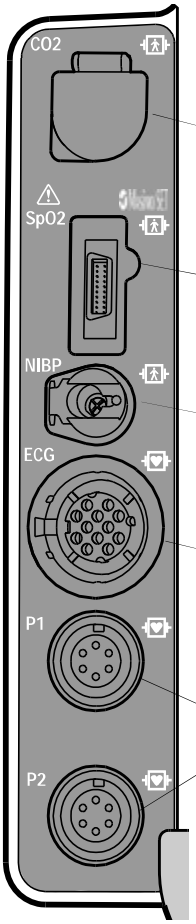
Figure 3-6 Area 5 Connectors, Speaker, and Printer

Table 3-5 Area 5 Connectors, Speaker, and Printer

LABEL	DESCRIPTION	FOR MORE INFORMATION
CO2	FilterLine® set port	See page 4-43
SpO2/SpCO/SpMet	Sensor cable port	See page 4-24
NIBP	Pneumatic tubing port	See page 4-35
ECG	Green electrically isolated ECG cable port	See page 4-3
P1	Invasive pressure cable port	See page 4-51
P2	Invasive pressure cable port	See page 4-51
Speaker	Projects device tones and voice prompts	
Printer	Door for 100 mm printer paper	See page 9-17
Therapy cable receptacle	QUIK-COMBO® therapy cable and standard (hard) paddles cable receptacle	See page 3-11

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Connectors



CONNECTOR	ACTION
CO2	**Connect:** Open CO_2 port door, insert FilterLine connector, and turn clockwise until connector is firmly seated. **Disconnect:** Rotate FilterLine connector counterclockwise and pull connector out.
SpO2/ SpCO/ SpMet	**Connect:** Align cable connector with SpO_2 port and push in until connector clicks into place. **Disconnect:** Press the gray buttons on each side of the cable connector simultaneously and pull connector out.
NIBP	**Connect:** Insert NIBP tubing connector into the NIBP port. **Disconnect:** Press the latch on the left side of the port and pull tubing connector out.
ECG	**Connect:** Align the green ECG connector with the ECG port; position the white line on the cable facing left. Insert the cable connector into the port until the connector is firmly seated. **Disconnect:** Pull the ECG connector straight out.
P1/P2	**Connect:** Align the IP (invasive pressure) cable connector with the P1 or P2 port; position the gap on the connector facing up. Insert the cable connector into the port until the connector is firmly seated. **Disconnect:** Grip the connector and pull straight out.

Connecting and Disconnecting the Therapy Cable

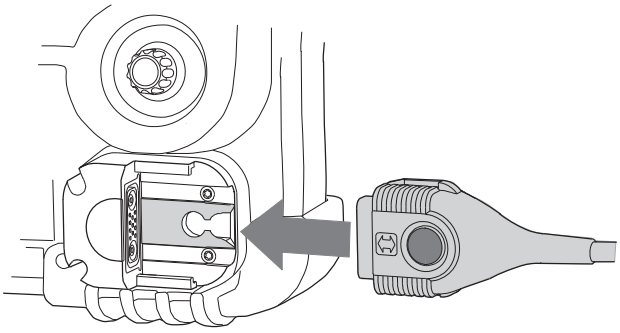
WARNING

POSSIBLE EQUIPMENT DAMAGE AND INABILITY TO DELIVER THERAPY

To help protect the therapy cable connector from damage or contamination, keep therapy cable connected to the defibrillator at all times. Inspect and test the therapy cable daily according to the Operator's Checklist in the back of this manual. Physio-Control recommends replacement of therapy cables every three years to reduce the possibility of failure during patient use.

IMPORTANT! The LIFEPAK 15 monitor/defibrillator QUIK-COMBO therapy cable and standard (hard) paddles have the same type of connector and connect to the defibrillator at the same location. These therapy cables are not compatible with other LIFEPAK defibrillator/monitors.

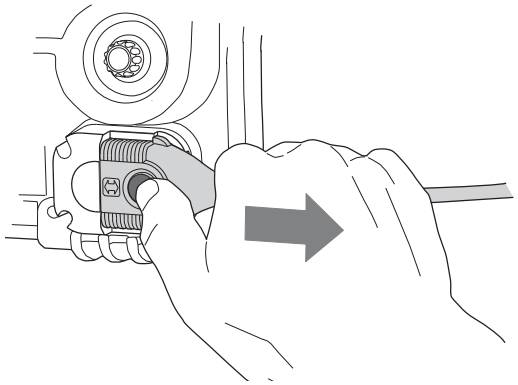
To connect a therapy cable to the defibrillator:



1. Align the therapy cable connector with the receptacle.
2. Slide the therapy cable until you feel the connector lock in place. You will also hear a "click."

Figure 3-7 Connect Therapy Cable

To disconnect the therapy cable from the defibrillator:



1. Press the release button on the therapy cable connector.
2. Slide the therapy cable connector out.

Figure 3-8 Disconnect Therapy Cable

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Back View

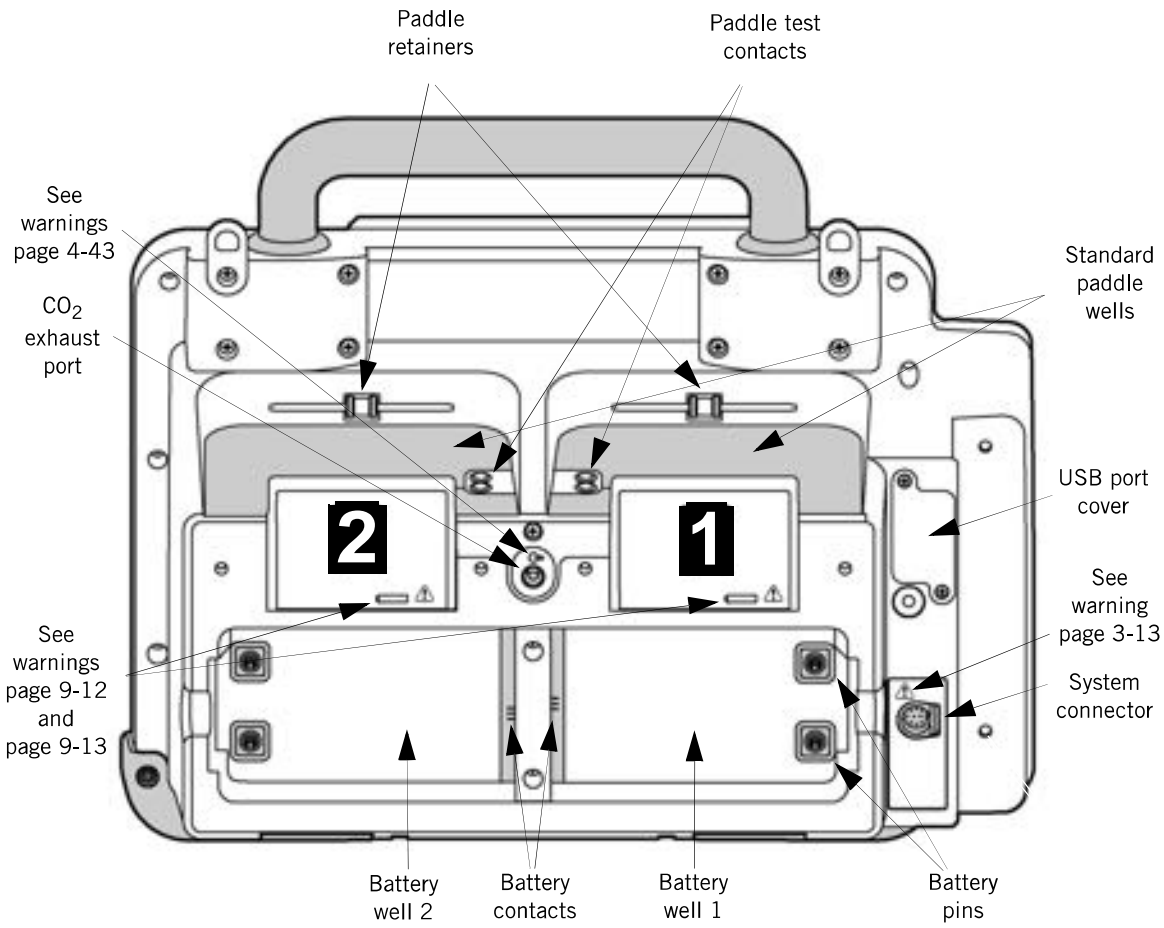


Figure 3-9 Back View

Table 3-6 Back View

LABEL	DESCRIPTION	FOR MORE INFORMATION
Battery wells, pins, and contacts	Each well holds one Lithium-ion battery. Two pins in each well transfer the battery power. Battery contacts transfer battery status information.	See page 9-12
CO_2 exhaust port	Connects to a scavenger system when monitoring $EtCO_2$ during use of anesthetics.	See page 4-43
Standard paddle wells, retainers, and test contacts	Paddle wells stow standard (hard) paddles. Retainers provide secure retention and quick removal of the paddles. Test contacts allow complete paddles defibrillation checks according to the Operator's Checklist.	See page 6-5 and Operator's Checklist in the back of this manual
USB port cover	Protects USB port from the environment.	For future use
System connector	Connects device to a gateway or external computer for transfer of patient reports. Also provides real-time ECG output.	See page 7-3

WARNING

SHOCK HAZARD

If you are monitoring a patient and using the system connector, all equipment connected to the system connector must be battery powered or electrically isolated from AC power according to EN 60601-1. If in doubt, disconnect the patient from the defibrillator before using the system connector. Only use Physio-Control recommended data transmission cables. For more information, contact Physio-Control Technical Support.

Note: To prevent inadvertent depletion of the defibrillator batteries, disconnect external devices from the system connector when not in use.

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Batteries

The LIFEPAK 15 monitor/defibrillator operates only on battery power using two Lithium-ion batteries, which must be removed from the device and charged in the Station or Mobile Li-ion Battery Charger.

IMPORTANT! The LIFEPAK 15 monitor/defibrillator Lithium-ion batteries are not interchangeable with batteries that are used in other LIFEPAK defibrillators.

Routinely inspect batteries for damage or leakage. Recycle or discard damaged or leaking batteries.

Each battery has a fuel gauge that indicates the approximate charge level in the battery. Press the gray button above the battery symbol to check the battery's charge level prior to installing it in the defibrillator. The four battery indicators shown here represent approximate charge—greater than 70%, greater than 50%, greater than 25%, and 25% or less, respectively.

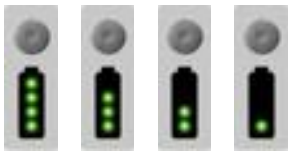


Figure 3-10 Battery Charge Indicators

Battery warning indicators are shown below. A single flashing LED indicates that the battery is very low and needs to be charged. Any two or more flashing LEDs indicate that the battery is faulty and should be returned to your authorized service personnel.

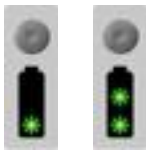


Figure 3-11 Battery Warning Indicators

Note: Older or heavily used batteries lose charge capacity. If a battery fuel gauge indicates fewer than four LEDs immediately after completing a charge cycle, the battery has reduced capacity. If the battery fuel gauge shows two or fewer LEDs after the battery completes a charge cycle, the battery should be replaced.

To install a battery:

1. Confirm that the battery is fully charged.
2. Inspect battery pins in the battery wells for signs of damage.
3. Align battery so battery clip is over the pins in the battery well.
4. Insert the end of the battery that is opposite the battery clip into the battery well.
5. Firmly press the clip end of the battery into the battery well until it clicks into place.
6. Repeat Step 1 through Step 5 to insert second battery.

To remove a battery, press the battery clip in and tilt the battery out of the battery well.

WARNING

POSSIBLE LOSS OF POWER DURING PATIENT CARE

Battery pins in the defibrillator may be damaged if batteries are dropped or forced into battery wells. Inspect pins routinely for signs of damage. Keep batteries installed at all times except when the device is removed from service for storage.

For information about battery maintenance, see "Battery Maintenance" on page 9-12.

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Home Screen

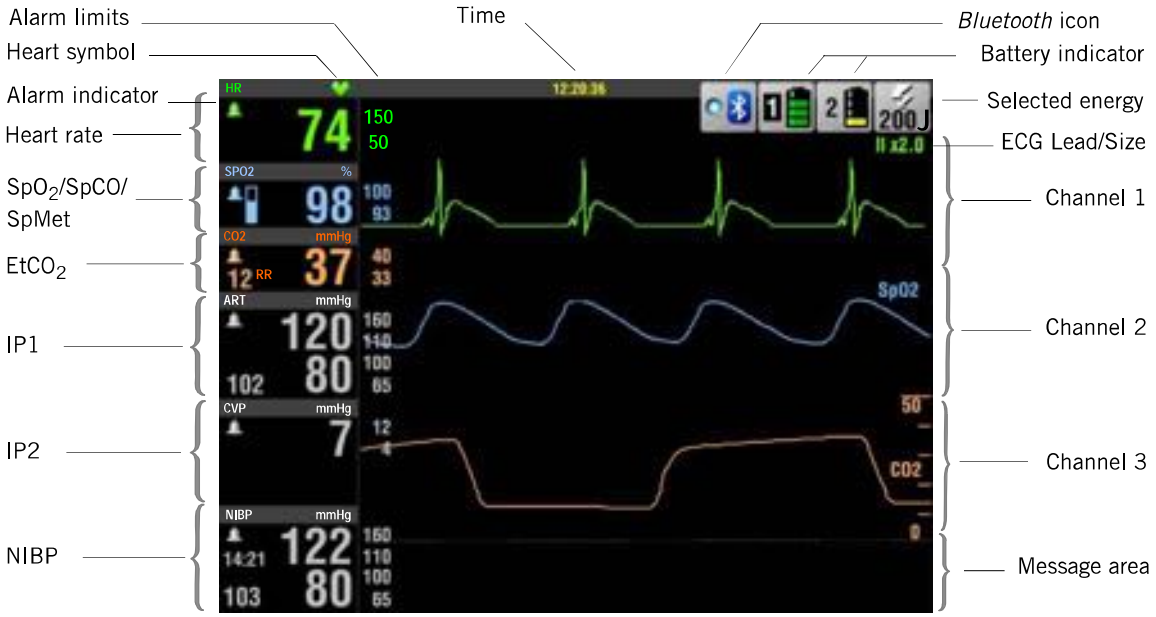


Figure 3-12 Home Screen

The Home Screen is the main screen that displays ECG and other information. When a monitoring cable is attached to the device, the corresponding monitoring area on the screen is activated and the current patient values for that function are displayed. For example, when you connect an SpO_2 cable, the SpO_2 area is activated on the screen. SpO_2 values for the patient appear after the patient is connected. When the cable is disconnected, the SpO_2 patient values are replaced by dashes (--). Separate controls do not activate the monitoring functions, except for NIBP.

Each vital sign monitoring area is colored to match its waveform. This color scheme aids in associating the displayed waveform with its vital sign value. When a function does not have a waveform displayed, the vital sign area is gray.

WARNINGS

FAILURE TO ACCURATELY COUNT HEART RATE

Patient heart rates above 300 bpm may not be counted accurately and may be displayed as dashes (---), a value near 300, or a value that is approximately one-half the actual patient heart rate. Increasing the ECG size to 2.0 or greater may improve the accuracy of the displayed heart rate value. Do not rely solely on the displayed heart rate for patient assessment. Use a printout of the ECG to calculate actual patient heart rate.

WARNINGS (CONTINUED)

FAILURE TO DETECT A CHANGE IN ECG RHYTHM

Heart rate meters may count internal pacing pulses during cardiac arrest or some arrhythmias. Do not rely entirely on heart rate meter alarms. Keep pacemaker patients under close surveillance.

IMPORTANT! Set the high heart rate alarm for patients who have heart rates above 300 bpm.

- For patient heart rates of 20 to 317 bpm, the device consistently sounds the alarm when ECG size is set to 1.0 or greater.
- For patient heart rates of 318 to 350 bpm, the device may intermittently silence the alarm for up to five seconds.

Table 3-7 Home Screen

AREA	DESCRIPTION	FOR MORE INFORMATION
Alarm limits	Limits display along the right side of the parameter.	See page 3-21
Heart symbol	Flashes with detected QRS signals.	
Alarm indicator	Indicates whether alarms are on or silenced. Absence of indicator means alarms are off.	See page 3-21
Heart rate	Device accurately detects and displays heart rates between 20 and 300 beats per minute (bpm). If heart rate is below 20 bpm or pacing is active, dashes (– – –) appear. If ECG is not active, the SpO_2 or NIBP monitor can display pulse rate, indicated by **PR (SPO_2)** or **PR (NIBP)**. If the patient's heart rate is above 300 bpm, dashes (---) may appear or the displayed rate may be less than the patient's heart rate.	
SpO2/SpCO/SpMet	Oxygen saturation level displays as a percentage from 50 to 100. Saturation below 50% displays as <50%. A fluctuating bar graph represents the pulse signal strength. When available and selected, the SpCO or SpMet value is displayed as a percent for 10 seconds, and then the SpO_2 area reverts to the SpO_2 reading.	See page 4-24
EtCO2	End-tidal CO_2 level displays in mmHg, Vol%, or kPa. Respiratory rate (RR) displays in breaths per minute.	See page 4-43

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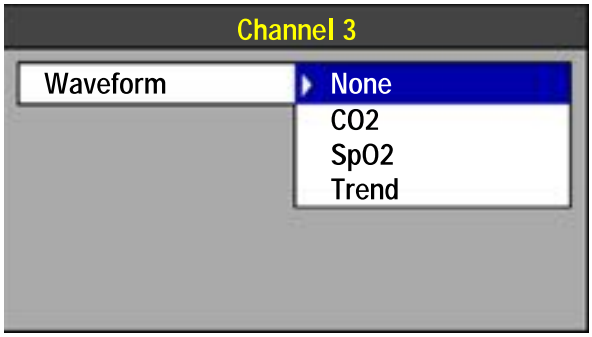
Table 3-7 Home Screen (Continued)

AREA	DESCRIPTION	FOR MORE INFORMATION
IP1/IP2	Displays systolic, diastolic, and mean invasive pressures in mmHg. Two channels are available; default labels are P1 and P2. User-selectable labels include the following: • ART (arterial pressure) • PA (pulmonary artery pressure) • CVP (central venous pressure) • ICP (intracranial pressure) • LAP (left atrial pressure)	See page 4-51
NIBP	Displays systolic, diastolic, and mean arterial pressures (MAP) in mmHg, and time to next BP, when interval is set.	See page 4-35
Time	Real or elapsed.	See *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.
Bluetooth icon	Indicates *Bluetooth* capability. The LED is illuminated when a *Bluetooth* connection is established. Select this icon to access the *Bluetooth* setup menu.	See page 8-3
Battery indicator	Indicates presence of battery in battery well 1 and 2, relative level of charge, and battery in use.	See page 3-20
Selected energy	Selected defibrillation energy.	
ECG Lead/Size	Lead and size for ECG.	See page 4-4
Channel 1	Displays the primary ECG waveform and is always visible.	See page 4-4
Channel 2	Displays an additional waveform, a continuation of the Channel 1 ECG (cascading ECG), or a trend graph.	See page 4-31
Channel 3	Displays an additional waveform or a trend graph.	See page 4-62
Message area	Displays up to two lines of status messages.	See Appendix B

Navigating the Home Screen

Use the **SPEED DIAL** to navigate around the Home Screen. As you rotate the **SPEED DIAL**, the individual vital sign areas and waveform channels on the Home Screen are outlined. If you outline a vital sign area or channel and then press the **SPEED DIAL**, a menu appears.

For example, rotate the **SPEED DIAL** to outline Channel 3, and then press the **SPEED DIAL**. The following menu appears.



1. Rotate the **SPEED DIAL** to the desired setting.
2. Press the **SPEED DIAL** to select the setting.

Whenever a menu is displayed, the ECG is always visible in Channel 1. To return to the Home Screen from any menu, press the **HOME SCREEN** button.

Rotate and press the **SPEED DIAL** to select an option in a menu.

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Battery Status Indicators

The Home Screen displays battery indicators that show the following information about the batteries installed in the defibrillator:

- Presence or absence of battery in battery well
- Battery in use
- Battery charge state

When two batteries are installed, the defibrillator uses the battery with the lowest level of charge first. The battery in use is indicated by a white battery number in a black box. When a battery reaches the replace battery state, the defibrillator automatically switches to the other battery. Table 3-8 provides a description of the various battery status indicators.

Table 3-8 Battery Status Indicators

INDICATOR	MEANING	DESCRIPTION
	Active battery	The defibrillator is using the battery in well 1 for power. Battery status indicators display up to four green bars. Each green bar represents approximately 25% remaining charge. For example, three green bars indicate about 75% remaining charge.
	Low battery	Battery in well 1 is in use and is low. One yellow bar indicates 5% to 10% remaining charge.
	Very low battery	Battery in well 1 is in use and is very low. One red flashing bar indicates 0 to 5% remaining charge. The defibrillator automatically switches to the other battery only if adequate charge is available. If both batteries show red bars, the **REPLACE BATTERY** voice prompt occurs.
	Unrecognized battery	Battery in well 2 is not in use. Battery communication failed or a non-Physio-Control battery is installed. The battery may power the defibrillator but the level of charge is unknown and low battery messages and prompts will not occur.
	No battery installed or fault detected	No battery is installed in battery well 1, or a fault was detected in the battery in well 1 and the device will not use the battery.

Note: Older or heavily used batteries lose charge capacity. If a fully charged battery is installed in the defibrillator and the battery status indicator shows less than four bars, the battery has reduced capacity. If a battery status indicator shows only one or two bars after a fully charged battery is installed, the battery has less than half the normal use time and should be recycled.

Alarms

LIFEPAK 15 monitor/defibrillator alarms can be set up to be ON or OFF when the defibrillator is turned on. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

When alarms are set up to be ON, default limits are set. The limits temporarily appear to the right of the active vital signs. For all vital sign default alarm limits, see Table A-3 on page A-12.

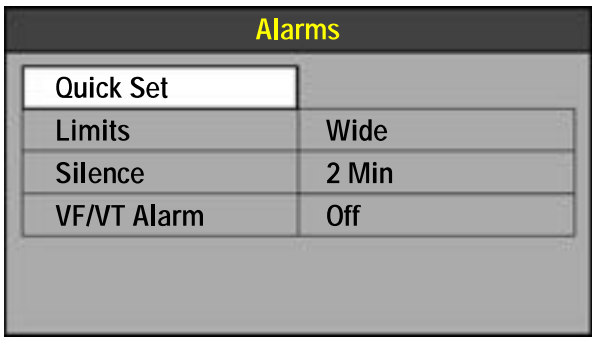
If alarms are set up to be OFF, press **ALARMS** to enable the alarms. Whether alarms are set up to be ON or are enabled by pressing **ALARMS**, they can only be turned off by pressing **ON** to turn off the device. If power is lost for less than 30 seconds, for example due to a system reset or changing the only active battery, alarm settings are restored automatically.

IMPORTANT! Set the high heart rate alarm for patients who have heart rates above 300 bpm.

- For patient heart rates of 20 to 317 bpm, the device consistently sounds the alarm when ECG size is set to 1.0 or greater.
- For patient heart rates of 318 to 350 bpm, the device may intermittently silence the alarm for up to five seconds.

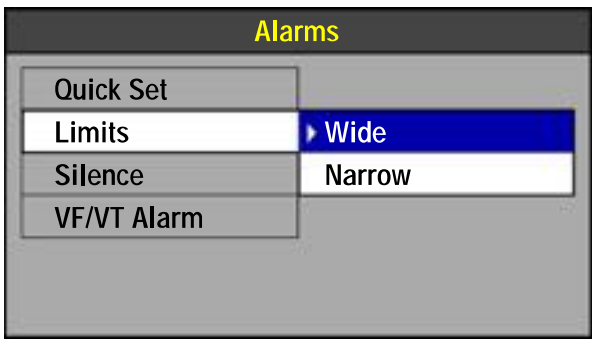
Setting Alarms

When you press **ALARMS**, the following menu appears:



Select **QUICK SET** to activate the alarms for all active monitoring functions.

The Quick Set limits automatically set high and low limits based on the patient's current vital sign values. For example, if the patient's HR is 70, selecting **WIDE** results in a high limit of 110 and a low limit of 45; selecting **NARROW** results in a high limit of 100 and a low limit of 50. The default is **WIDE**.



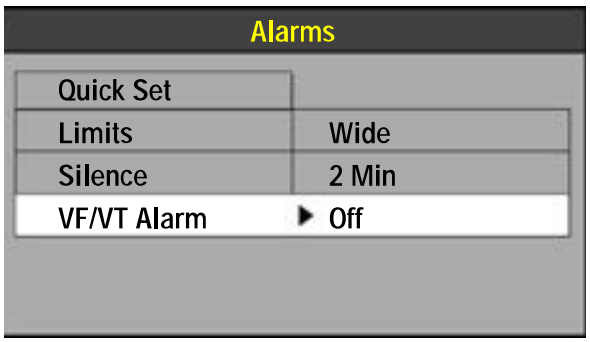
Select **LIMITS** to change alarm limits to **WIDE** or **NARROW**. See Table A-3 on page A-12.

Select **SILENCE** to turn off the audible alarm for up to 15 minutes. If an alarm limit is exceeded while the alarm is silenced, the violated vital sign flashes and an alarm message appears, but the alarm tone remains silent.

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Note: For patients with heart rates above 300 bpm, increasing the ECG size to 2.0 or greater may improve the performance of the heart rate alarm.

Note: The heart rate display and corresponding heart rate alarm should not be relied upon to provide an indication of ventricular fibrillation. Turn on the VF/VT alarm.



Select **VF/VT ALARM** to turn on continuous monitoring for ventricular fibrillation and ventricular tachycardia in Manual mode.

The VF/VT alarm indicator appears above the primary ECG when the alarm is ON.

When the alarm is silenced or suspended, a red X appears across the indicator.

Reselect **VF/VT** to turn off this alarm.

Note: When the **VF/VT ALARM** is ON, you are limited to **PADDLES** lead or Lead **II** in Channel 1. See "Selecting ECG Lead" on page 4-4.

Note: The VF/VT alarm is suspended when the metronome is active, the noninvasive pacemaker is on, or when standard paddles are attached and **PADDLES** lead is selected. The alarm is also suspended when the monitor/defibrillator is charging or is charged.

Managing Alarms

The alarm bell symbol indicates when alarms are ON or OFF. All alarms that are controlled by **QUICK SET** have equal priority. When alarms are ON and an alarm limit is exceeded, a tone sounds and the violated vital sign flashes.

To manage an alarm:

1. Press **ALARMS**. This silences the alarm for 2 minutes.
2. Assess the cause of the alarm.
3. Assess the appropriateness of the limits settings (**WIDE** or **NARROW**).

If the patient is unstable, consider silencing the alarm for up to 15 minutes while attending to the patient. Do NOT reselect **QUICK SET**.

WARNING

POSSIBLE FAILURE TO DETECT AN OUT OF RANGE CONDITION

Reselecting **QUICK SET** resets the alarm limits around the patient's current vital sign values, which may be outside the safe range for the patient.

4. After the patient is stable, reselect **QUICK SET**, if necessary.

When alarms are ON, you can silence them preemptively for up to 15 minutes.

To silence alarms preemptively:

1. Press **ALARMS**.
2. Select **SILENCE**.
3. Select **SILENCE** duration of 2, 5, 10, or 15 minutes.

The message **ALARMS SILENCED** appears in the message area at the bottom of the Home Screen.

Note: When you select **SILENCE**, the VF/VT alarm is not silenced.

Options

Press **OPTIONS** to display the Options menu. Rotate the **SPEED DIAL** to scroll through the choices. Press the **SPEED DIAL** to make a selection.

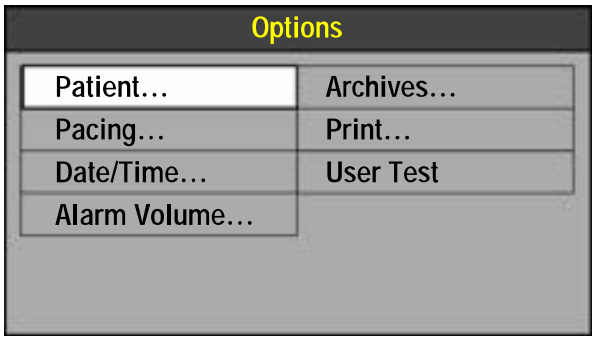


Table 3-9 Options Menu Selections

SELECTION	DESCRIPTION	FOR MORE INFORMATION
Patient	Enter patient name, patient ID, incident, age, and sex.	See "Entering Patient Data" in next section
Pacing	Select demand or nondemand pacing. Set internal pacer detection ON or OFF.	See page 5-31
Date/Time	Set date and time. Cycle power for change to take effect.	See *LIFEPAK 15 Monitor/Defibrillator Setup Options* for time display options.
Alarm Volume	Adjust volume for alarms, tones, voice prompts and CPR metronome.	
Archives	Access archived patient records.	See page 7-11

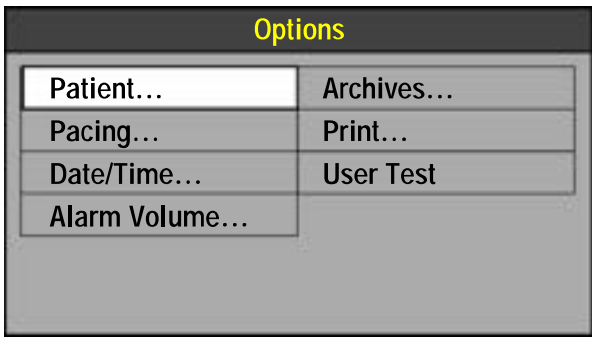
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Table 3-9 Options Menu Selections (Continued)

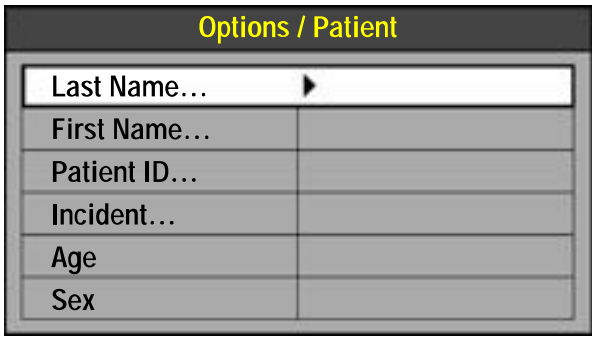
SELECTION	DESCRIPTION	FOR MORE INFORMATION
Print	Select report, format, mode, and speed for printing a current patient report.	See page 7-10
User Test	Initiate device self-test.	See page 9-5

Entering Patient Data

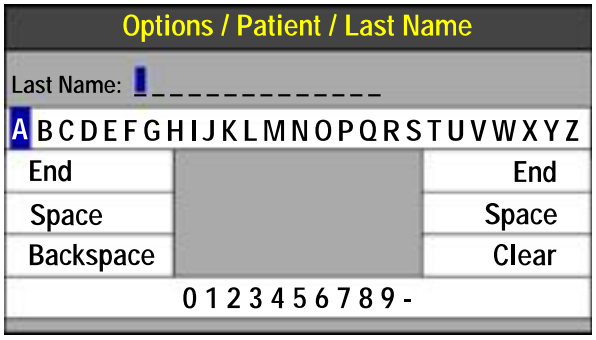
To enter patient data:



1. Press **OPTIONS**.
2. Use the **SPEED DIAL** to select **PATIENT**.



3. Select **LAST NAME**, **FIRST NAME**, **PATIENT ID**, **INCIDENT**, **AGE**, or **SEX**. (**LAST NAME** is selected in the example.)



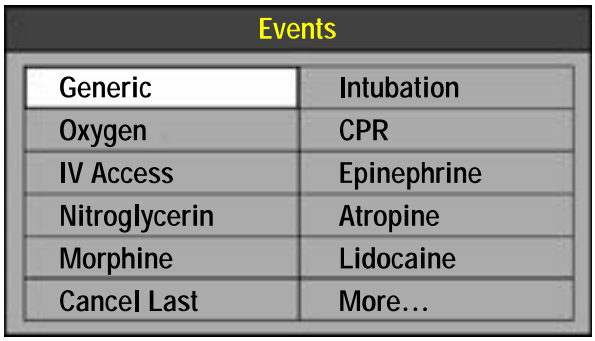
4. Rotate the **SPEED DIAL** to scroll through the characters and commands. Press the **SPEED DIAL** to make a selection. The selected character appears.
5. Repeat Step 4 until the name is complete.
6. Select **END**.

   Three additional commands are available:
   SPACE—inserts blank space.
   BACKSPACE—deletes last character and moves selection back one space.
   CLEAR—clears all characters.

Events

Use the Events menu to annotate patient events. A selected event appears in the Event log of the CODE SUMMARY critical event record. Events can be customized in Setup mode. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

To select an event:



1. Press **EVENT** to display the Events menu.
2. Rotate the **SPEED DIAL** to scroll through the choices. Press the **SPEED DIAL** to make a selection.
3. Select **MORE** to display additional event selections.



When an event is selected, the event and time stamp appear in the message area on the Home Screen.

Notes:

- If you highlight an event but do not select it and the menu times out, a Generic event and time stamp are annotated in the event log.
- If you highlight an event but do not select it and then press **HOME SCREEN**, a Generic event and time stamp are annotated in the event log.
- Select **CANCEL LAST** to indicate that an incorrect event was selected. A Cancel Last event and time stamp print in the event log.

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MONITORING

This chapter describes the monitoring features of the LIFEPAK 15 monitor/defibrillator.

Monitoring the ECG . . . . . page 4-3
Acquiring a 12-Lead ECG 4-14
Monitoring SpO2, SpCO, and SpMet 4-24
Monitoring Noninvasive Blood Pressure 4-35
Monitoring ETCO2 4-43
Monitoring Invasive Pressure 4-51
Vital Sign and ST Segment Trends 4-58

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Monitoring the ECG

Intended Use

The electrocardiogram (ECG) is a recording of the electrical activity of the heart. ECG monitoring allows for identification and interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate. The ECG is obtained by placing either electrodes or paddles on the patient and allows the heart's electrical activity to be monitored and recorded.

ECG monitoring is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times; do not rely solely on the ECG monitor.

ECG Monitoring Warning

WARNINGS

POSSIBLE MISINTERPRETATION OF ECG DATA

The frequency response of the monitor screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for diagnostic and ST segment interpretation. For diagnostic or ST segment interpretation, or to enhance internal pacemaker pulse visibility, attach the multi-lead ECG cable. Then print the ECG rhythm in diagnostic frequency response (DIAG) or obtain a 12-lead ECG.

FAILURE TO ACCURATELY COUNT HEART RATE

Patient heart rates above 300 bpm may not be counted accurately and may be displayed as dashes (---), a value near 300, or a value that is approximately one-half the actual patient heart rate. Increasing the ECG size to 2.0 or greater may improve the accuracy of the displayed heart rate value. Do not rely solely on the displayed heart rate for patient assessment. Use a printout of the ECG to calculate actual patient heart rate.

IMPORTANT! Set the high heart rate alarm for patients who have heart rates above 300 bpm.

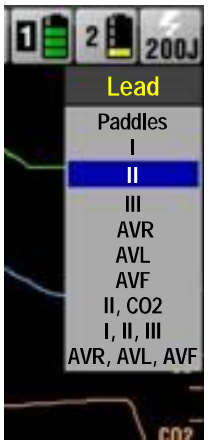
- For patient heart rates of 20 to 317 bpm, the device consistently sounds the alarm when ECG size is set to 1.0 or greater.
- For patient heart rates of 318 to 350 bpm, the device may intermittently silence the alarm for up to five seconds.

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Selecting ECG Lead

The LIFEPAK 15 monitor/defibrillator includes two methods for selecting or changing the ECG lead.

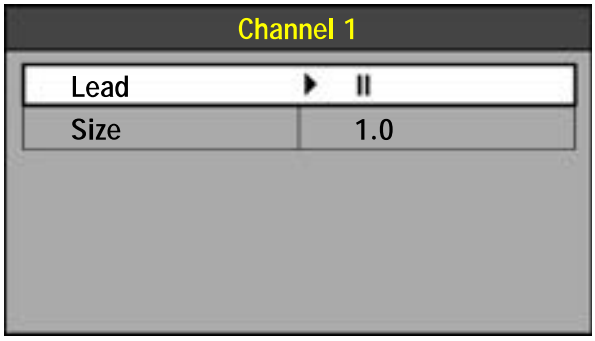
To select or change the displayed ECG lead using the **LEAD** button:



1. Press **LEAD**. If any ECG lead currently appears on the Home Screen, the lead changes to **PADDLES**. If **PADDLES** lead is currently displayed, the lead changes to Lead **II**.
2. While the **LEAD** menu is displayed, press **LEAD** again or rotate the **SPEED DIAL** to the desired lead.

Note: If lead sets are predefined for Channels 2 and 3, the lead sets show on the menu. The ECG cable that is connected to the device, such as 3-lead or 5-wire, determines the leads you can select. For information about defining lead sets, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

To select or change the displayed ECG lead using the **SPEED DIAL**:



1. For the primary ECG, outline and select **CHANNEL 1** and then select **LEAD**.
2. Rotate the **SPEED DIAL** to the desired ECG lead.
3. Press the **SPEED DIAL** to select the ECG lead.
4. Repeat this procedure to select or change displayed ECG waveforms for Channels 2 and 3.

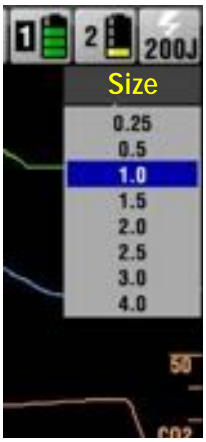
Note: The ECG shows dashed lines until the electrodes are connected to the patient.

Note: When the **VF/VT ALARM** is ON, you are limited to **PADDLES** lead or Lead **II** in Channel 1. See "Setting Alarms" on page 3-21.

Changing ECG Size

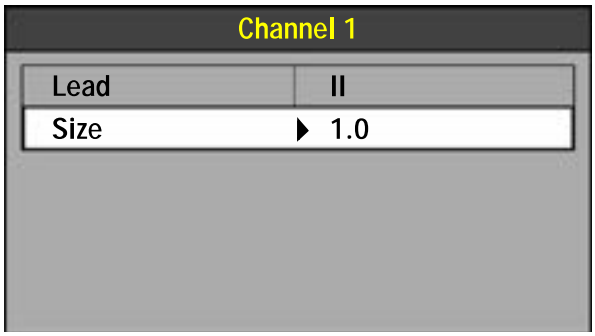
The LIFEPAK 15 monitor/defibrillator includes two methods for selecting or changing ECG size.

To select or change the displayed ECG size using the **SIZE** button:



1. Press **SIZE**.
2. While the **SIZE** menu is displayed, press **SIZE** again or rotate the **SPEED DIAL** to the desired size.

To select or change the displayed ECG size using the **SPEED DIAL**:



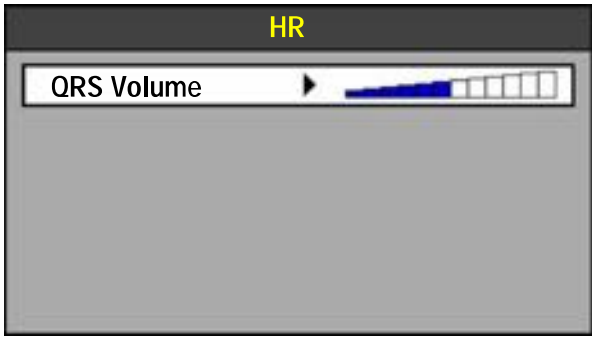
1. For the primary ECG, outline and select **CHANNEL 1** and then select **SIZE**.
2. Rotate the **SPEED DIAL** to the desired ECG size.
3. Press the **SPEED DIAL** to select the ECG size.

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Adjusting the Systole Volume

To adjust the systole beep volume, use the **SPEED DIAL** to outline and select the **HR** area on the Home Screen.

The following menu appears:



1. Press the **SPEED DIAL** to select **QRS VOLUME**.
2. Rotate the **SPEED DIAL** to the desired volume.
3. Press the **SPEED DIAL** to set the volume.

Note: The volume is reset to OFF each time the device is turned off.

Monitoring Using Paddle Accessories

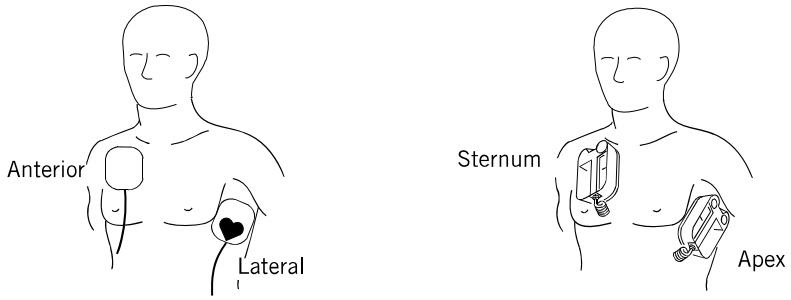
To monitor ECG using paddles, you can use either QUIK-COMBO therapy electrodes or standard (hard) paddles. For more information about paddle accessories, see Chapter 6, "Paddle Accessory Options."

Anterior-Lateral Placement

Anterior-lateral placement is the only placement that should be used for ECG monitoring using paddle accessories.

To place the therapy electrodes or paddles:

1. Place either the ♥ therapy electrode or **APEX** paddle lateral to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible (see Figure 4-1).



QUIK-COMBO Therapy Electrodes **Standard Paddles**

Figure 4-1 Anterior-Lateral Placement

2. Place the other therapy electrode or **STERNUM** paddle on the patient's upper right torso, lateral to the sternum and below the clavicle as shown in Figure 4-1.

Special Situations for Electrode or Paddle Placement

When placing therapy electrodes or standard paddles, be aware of the special requirements in the following possible situations:

Obese Patients or Patients with Large Breasts

Apply therapy electrodes or standard paddles to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.

Thin Patients

Follow the contour of the ribs and spaces when pressing the therapy electrodes or standard paddles onto the torso. This limits air spaces or gaps under the electrodes and promotes good skin contact.

Patients with Implanted Devices Such as Pacemakers or Defibrillators

If possible, place therapy electrodes or standard paddles away from implanted device.

Paddles ECG Monitoring Procedure

To monitor using standard paddles or therapy electrodes:

1. Press **ON**.
2. Prepare the patient's skin:
   - Remove all clothing from the patient's chest.
   - Remove excessive chest hair as much as possible. Avoid nicking or cutting the skin if using a shaver or razor. If possible, avoid placing electrodes over broken skin.
   - Clean and dry the skin, if necessary. Remove any medication patches and ointment on the patient's chest.
   - Briskly wipe the skin dry with a towel or gauze. This mildly abrades the skin and removes oils, dirt, and other debris for better electrode adhesion to the skin.
   - Do not use alcohol, tincture of benzoin, or antiperspirant to prep the skin.
3. Apply the standard paddles or therapy electrodes in the anterior-lateral position. For therapy electrodes, confirm that the package is sealed and the Use By date is not passed. For standard paddles, apply conductive gel over the entire electrode surface.
4. Connect the therapy electrodes to the therapy cable.
5. Select **PADDLES** lead.

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Monitoring Using ECG Cable Accessories

The following ECG cables, shown in Figure 4-2, are available for ECG monitoring with the LIFEPAK 15 monitor/defibrillator:

- 12-lead
- 3-lead
- 5-wire

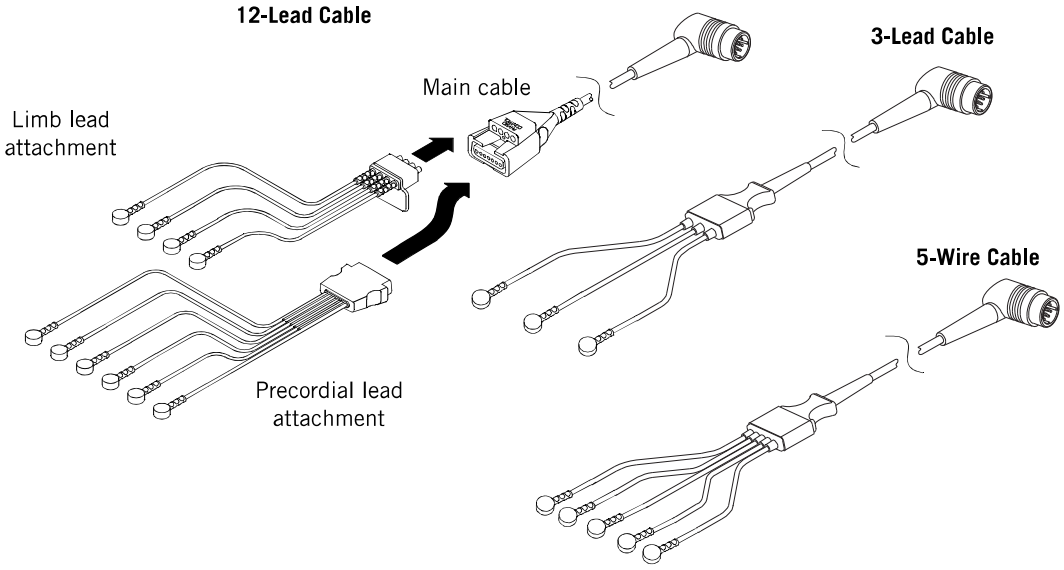
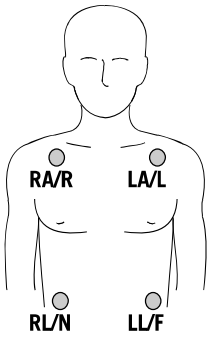


Figure 4-2 12-Lead, 3-Lead, and 5-Wire ECG Cables

ECG Monitoring Procedure

To perform ECG monitoring:

1. Press **ON**.
2. Attach the ECG cable to the green connector on the monitor.
3. Identify the appropriate electrode sites on the patient as shown in Figure 4-3.



AHA Labels		IEC Labels	
RA	Right Arm	**R**	Right
LA	Left Arm	**L**	Left
***RL**	Right Leg	**N**	Negative
LL	Left Leg	**F**	Foot

***Note:** Not used for 3-lead cable.

Figure 4-3 Limb Lead Electrode Placement

4. Prepare the patient's skin for electrode application:
   - Shave excessive hair at electrode site.
   - For oily skin, clean skin with alcohol pad.
   - Gently scrape skin to remove surface layer of dead cells and improve conduction of electrical signals.
   - Avoid locating electrodes over tendons and major muscle masses.
   - Clean and dry the skin.
5. Apply ECG electrodes:
   - Confirm that the package is sealed and the Use By date is not passed.
   - Attach an electrode to each of the lead wires.
   - Grasp electrode tab and peel electrode from carrier.
   - Inspect electrode gel and make sure gel is intact (discard electrode if gel is not intact).
   - Hold electrode taut with both hands. Apply the electrode flat to the skin. Smooth tape outwardly. Avoid pressing the center of the electrode.
   - Secure the trunk cable clasp to the patient's clothing.

   Note: Electrode quality is critical for obtaining an undistorted ECG signal. Always check the date code on electrode packages for expiration date before using on a patient. Do not use electrodes that have expired. Disposable electrodes are intended for a single use.
6. Select the desired ECG lead on the monitor screen.
7. If necessary, adjust ECG size for accurate heart rate counting.
8. Press **PRINT** to obtain an ECG printout.

Precordial Lead ECG Monitoring

The precordial (chest) leads (see ECG Leads Color Codes on page 4-10) can be used for monitoring when using the 12-lead cable or 5-wire cable.

To perform precordial lead ECG monitoring:

1. Insert the precordial lead attachment into the main cable as shown in Figure 4-2 on page 4-8.
2. Place the precordial lead electrodes on the chest as described in the 12-lead ECG procedure and shown in Figure 4-5 on page 4-15.

Note: When using a 5-wire cable, attach the limb leads as described in "ECG Monitoring Procedure" on page 4-8, and place the C-lead electrode on the chest in the precordial position desired. Note that the LIFEPAK 15 monitor labels the ECG for this lead as V1 on the screen and printout, regardless of the location of the C-lead electrode.

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Leads Off

If an electrode or lead wire disconnects during ECG monitoring, the monitor emits an audible alarm and displays a **LEADS OFF** message. The ECG trace becomes a dashed line. The alarm and messages continue until the electrode or lead wire is replaced.

Color Coding for ECG Leads

The lead wires and the electrode snaps for the patient ECG cable are color coded according to American Heart Association (AHA) or International Electrotechnical Commission (IEC) standards as listed in Table 4-1.

Table 4-1 ECG Leads Color Codes

LEADS	AHA LABEL	AHA COLOR	IEC LABEL	IEC COLOR
Limb Leads	RA	White	R	Red
	LA	Black	L	Yellow
	RL	Green	N	Black
	LL	Red	F	Green
	C	Brown	C	Brown
Precordial Leads	V1	Red	C1	Red
	V2	Yellow	C2	Yellow
	V3	Green	C3	Green
	V4	Blue	C4	Brown
	V5	Orange	C5	Black
	V6	Violet	C6	Violet

Monitoring Patients Who Have Internal Pacemakers

The LIFEPAK 15 monitor/defibrillator internal pacemaker detection feature can be used to help identify internal pacemaker pulses on the printed ECG. When enabled, this feature uses lead V4 to detect internal pacemaker pulses. If V4 is not available because it is not attached or is too noisy, Lead II is used.

When the internal pacemaker detection feature is ON, the LIFEPAK 15 monitor/defibrillator annotates a hollow arrow ⇧ on the printed ECG if internal pacemaker pulses are detected. Patient history and other ECG waveform data, such as wide QRS complexes, should be used to verify the presence of an internal pacemaker. False annotations of this arrow may occur if ECG artifacts mimic internal pacemaker pulses. If false annotations occur frequently, deactivate the detection feature using the **OPTIONS / PACING / INTERNAL PACER** menu (see "Options" on page 3-23).

The LIFEPAK 15 monitor/defibrillator typically does not use internal pacemaker pulses to calculate the heart rate. However, when using therapy electrodes or standard paddles to monitor in **PADDLES** lead, the monitor may detect internal pacemaker pulses as QRS complexes, resulting in an inaccurate heart rate.

Large amplitude pacemaker pulses may overload the QRS complex detector circuitry so that no paced QRS complexes are counted. To help minimize ECG pickup of large unipolar pacemaker pulses, place ECG electrodes so the line between the positive and negative electrodes is perpendicular to the line between the pacemaker generator and the heart.

Smaller amplitude internal pacemaker pulses may not be distinguished clearly in **PADDLES** lead. For improved detection and visibility of internal pacemaker pulses, turn on the internal pacemaker detector function using the **OPTIONS / PACING / INTERNAL PACER** menu or connect the ECG cable, select an ECG lead, and print the ECG in diagnostic frequency response. For information about configuring internal pacemaker detection, see the Pacing Setup menu in the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

Troubleshooting Tips

If problems occur while monitoring the ECG, check Table 4-2 for aid in troubleshooting. For basic troubleshooting problems, such as no power, see General Troubleshooting Tips on page 9-18.

Table 4-2 Troubleshooting Tips for ECG Monitoring

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Any of these messages displayed: **CONNECT ELECTRODES** **CONNECT ECG LEADS** **ECG LEADS OFF** **XX LEADS OFF**	Therapy electrodes not connected	• Connect therapy electrode.
	One or more ECG electrodes disconnected	• Connect ECG electrode.
	ECG cable is not connected to monitor	• Connect ECG cable.
	Poor electrode-skin contact	• Reposition cable or lead wires to prevent electrodes from pulling away from patient. • Secure trunk cable clasp to patient's clothing. • Prepare skin and apply new electrodes.
	PACER was pressed. The monitor automatically switched to Lead II, but ECG leads are not connected.	• Connect ECG leads and initiate pacing.
	Broken ECG cable lead wire	• Select another lead. • Select **PADDLES** lead, and use standard paddles or therapy electrodes for ECG monitoring. • Check ECG cable continuity.
Screen blank and **ON** LED illuminated	Screen not functioning properly	• Print ECG on recorder as backup. • Contact service personnel for repair.

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Table 4-2 Troubleshooting Tips for ECG Monitoring (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Systole beeps not heard or do not occur with each QRS complex	Volume too low	• Adjust volume.
	QRS amplitude too small to detect	• Adjust ECG size.
Displayed heart rate (HR) different than pulse rate	ECG size set too high or too low	• Adjust ECG size up or down.
	Monitor detecting the patient's internal pacemaker pulses	• Change monitor lead to reduce internal pacemaker pulse size.
	Patient's heart rate greater than 300 bpm	• Adjust ECG size to 2.0 or greater.
Displayed heart rate (HR) different from displayed ECG waveform	ECG size set too high or too low	• Adjust ECG size up or down.
	Monitor detecting the patient's internal pacemaker pulses	• Change monitor lead to reduce internal pacemaker pulse size.
	Patient's heart rate greater than 300 bpm	• Adjust ECG size to 2.0 or greater. • Use printout of the ECG to calculate actual patient heart rate.
Poor ECG signal quality	Poor electrode-skin contact	• Reposition cable or lead wires to prevent electrodes from pulling away from patient. • Secure trunk cable clasp to patient's clothing. • Prepare skin and apply new electrodes.
	Outdated, corroded, or dried-out electrodes	• Check Use By date on electrode packages. • Use only unexpired silver/silver chloride electrodes. Leave electrodes in sealed pouch until time of use.
	Loose connection. Damaged cable or connector/ lead wire	• Check or reconnect cable connections. • Inspect ECG and therapy cables. Replace if damaged. • Check cable with simulator and replace if malfunction observed.
	Noise because of radio frequency interference (RFI)	• Check for equipment causing RFI (such as a radio transmitter) and relocate or turn off equipment power.

Table 4-2 Troubleshooting Tips for ECG Monitoring (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Baseline wander (low frequency/high amplitude artifact)	Inadequate skin preparation	• Prepare skin and apply new electrodes.
	Poor electrode-skin contact	• Check electrodes for proper adhesion.
	Diagnostic frequency response	• Print ECG in monitor frequency response.
Fine baseline artifact (high frequency/low amplitude)	Inadequate skin preparation	• Prepare skin and apply new electrodes.
	Isometric muscle tension in arms/legs	• Confirm that limbs are resting on a supportive surface. • Check electrodes for proper adhesion.
ECG amplitude too small	Poor electrode-skin contact	• Prep skin, apply new electrodes.
	ECG lead selected	• Increase ECG gain or change ECG lead.
	Patient condition (for example, significant myocardial muscle loss or tamponade)	• Increase ECG gain or change ECG lead.
Monitor displays dashed lines with no ECG **LEADS OFF** messages	**PADDLES** lead selected but patient connected to ECG cable	• Select one of the limb or precordial leads.
Monitor shows isoelectric (flat) line and **PADDLES** lead selected	The Test Load is connected to therapy cable	• Remove the Test Load and connect therapy electrodes to cable. • Connect ECG cable and select another lead.
Internal pacemaker pulses difficult to see	Pacemaker pulses are very small	• Turn on internal pacemaker detector (see "Monitoring Patients Who Have Internal Pacemakers" on page 4-10).
	Monitor frequency response limits visibility	• Connect ECG cable and select a lead other than **PADDLES**. • Print ECG in Diagnostic mode (see "How to Print a Current Report" on page 7-10).

For general troubleshooting tips, see Table 9-2 on page 9-18.

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Acquiring a 12-Lead ECG

Intended Use

The 12-lead ECG offers paramedics and emergency physicians significant advantages over the single lead ECG trace typically available in EMS. The 12-lead ECG not only provides a diagnostic quality ECG for use in the detection of ST elevation myocardial infarction (STEMI), but also allows the knowledgeable paramedic to determine the area of myocardial injury, anticipate associated potential complications, and implement treatment strategies accordingly. In addition, the 12-lead ECG provides a baseline for serial ECG evaluations.

The 12-lead ECG transmission to the emergency department (ED) is recommended by the AHA and ERC for patients with Acute Coronary Syndrome (ACS). When transmitted from the field, 12-lead ECG has been shown to shorten time to in-hospital treatment by an estimated 10 to 60 minutes. Patients may also benefit from triage and transport to the most appropriate facility. Documentation of transient or intermittent arrhythmias and other electrophysiologic events that occur in the prehospital setting can assist in diagnosis and treatment decisions in the ED.

Indications

The 12-lead electrocardiogram is used to identify, diagnose, and treat patients with cardiac disorders and is useful in the early detection and prompt treatment of patients with acute ST-elevation myocardial infarction (STEMI).

Contraindications

None known.

12-Lead ECG Warning

WARNING

POSSIBLE INABILITY TO OBTAIN A DIAGNOSTIC 12-LEAD ECG

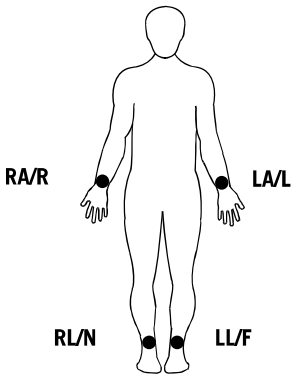
Using previously unpackaged electrodes or electrodes past the Use By date may impair ECG signal quality. Remove electrodes from a sealed package immediately before use and follow the procedure for applying the electrodes.

Identifying Electrode Sites

To obtain a 12-lead ECG, place the electrodes on the limbs and the chest (precordium) as described in the following paragraph.

Limb Lead Electrode Sites

When acquiring a 12-lead ECG, limb lead electrodes are typically placed on the wrists and ankles as shown in Figure 4-4. The limb lead electrodes can be placed anywhere along the limbs. Do not place the limb lead electrodes on the torso when acquiring a 12-lead ECG.

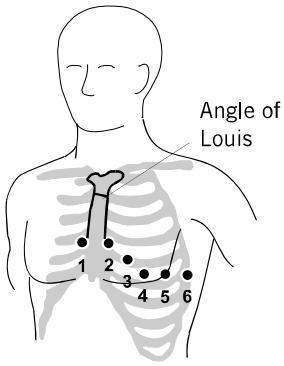


AHA Labels		IEC Labels	
RA	Right Arm	**R**	Right
LA	Left Arm	**L**	Left
RL	Right Leg	**N**	Negative
LL	Left Leg	**F**	Foot

Figure 4-4 Limb Lead Electrode Placement for 12-Lead ECG

Precordial Lead Electrode Sites

The six precordial (chest) leads are placed on specific locations as shown and summarized in Figure 4-5. Proper placement is important for accurate diagnosis and should be identified as follows: leads are V1 through V6 for AHA, or C1 through C6 for IEC. See ECG Leads Color Codes on page 4-10 for color codes.



LEAD		LOCATION
V1	C1	Fourth intercostal space to the right of the sternum
V2	C2	Fourth intercostal space to the left of the sternum
V3	C3	Directly between leads V2/C2 and V4/C4
V4	C4	Fifth intercostal space at midclavicular line
V5	C5	Level with V4/C4 at left anterior axillary line
V6	C6	Level with V5/C5 at left midaxillary line

Figure 4-5 Precordial Lead Electrode Placement

Locating the V1/C1 position (fourth intercostal space) is critically important, because it is the reference point for locating the placement of the remaining V/C leads.

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To locate the V1/C1 position:

1. Place your finger at the notch in the top of the sternum.
2. Move your finger slowly downward about 3.8 centimeters (1.5 inches) until you feel a slight horizontal ridge or elevation. This is the Angle of Louis where the manubrium joins the body of the sternum.
3. Locate the second intercostal space on the patient's right side, lateral to and just below the Angle of Louis.
4. Move your finger down two more intercostal spaces to the fourth intercostal space, which is the V1/C1 position.
5. Continue locating other positions from V1/C1 (see Figure 4-5).

Other important considerations:

- When placing electrodes on female or obese patients, always place leads V3-V6 and C3-C6 *under* the breast rather than *on* the breast.
- Never use the nipples as reference points for locating the electrodes for men or women patients, because nipple locations vary widely.

12-Lead ECG Procedure

To acquire a 12-lead ECG:

1. Press **ON**.
2. Insert the limb lead and the precordial lead attachments into the main cable as shown in Figure 4-6.

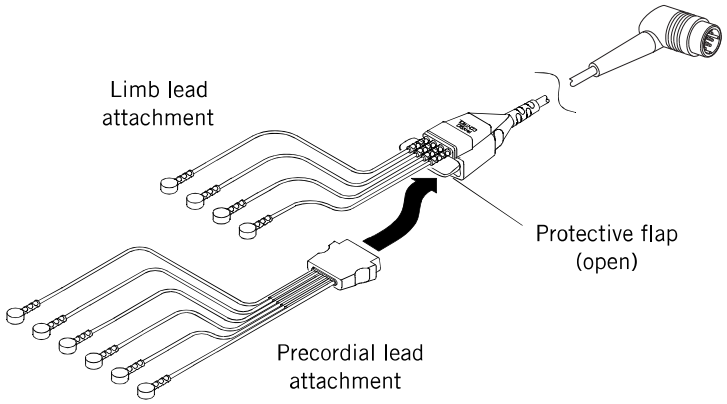


Figure 4-6 12-Lead ECG Cable

3. Insert the cable connector into the green ECG connector on the monitor.
4. Prepare patient's skin for electrode application (see page 4-9).
5. Apply ECG electrodes (see page 4-15).

6. Encourage the patient to remain as still as possible.

WARNING

POSSIBLE INACCURATE DIAGNOSIS

If age and sex are not entered when a 12-lead ECG is obtained, the interpretive statements are based on a default of a 50-year-old male and may provide incorrect analysis for that patient.

7. Press **12-LEAD**. The **12-LEAD / AGE** menu appears, prompting you to enter the patient's age.

   Use the **SPEED DIAL** to select the age. Always enter the patient's age if the patient is 15 years old or younger. If you do not enter an age, the default value of 50 years is used by the interpretive analysis program and annotated on the 12-lead ECG report.

8. The **12-LEAD / SEX** menu appears, prompting you to enter the patient's sex.

   Use the **SPEED DIAL** to select the patient's sex. If you do not enter the sex, the default of male is used by the interpretive analysis program and is annotated on the 12-lead ECG report.

The monitor acquires, analyzes, and automatically prints the 12-lead ECG. An ECG leads-off condition for any lead is indicated on the report by a dashed line.

Note: If 15 years or less is entered for patient age, the 12-lead ECG prints at diagnostic frequency response of 0.05–150 Hz, even when 0.05–40 Hz is set up as the print default.

Note: When **12-LEAD** is pressed, internal pacemaker detection is automatically enabled, even if the function is set up to be OFF.

ECG Override

If the monitor detects signal noise while acquiring data (such as patient motion or a disconnected electrode), the screen displays the message: **NOISY DATA! PRESS 12-LEAD TO ACCEPT**. The message remains and 12-lead ECG acquisition is interrupted until noise is eliminated. Take appropriate action to eliminate the signal noise. This message remains as long as signal noise is detected. When signal noise is eliminated, the monitor resumes acquiring data. To override the message and acquire the 12-lead ECG in spite of the signal noise, press **12-LEAD** again. The 12-lead ECG will be acquired and printed with no interpretive statements. Any 12-lead ECG report acquired in this way is annotated with the following statement: **ECG OVERRIDE: DATA QUALITY PROHIBITS INTERPRETATION**.

If the signal noise persists for longer than 30 seconds, 12-lead ECG acquisition stops. The screen displays **EXCESSIVE NOISE–12-LEAD CANCELLED**. You must then press **12-LEAD** to restart 12-lead ECG acquisition.

Note: If **12-LEAD** is pressed immediately after ECG electrodes are applied, the message **NOISY DATA** may occur. This message is due to the temporary instability between the electrode gel and the patient's skin that is not viewable on the ECG monitor screen, but is detected as noisy data. In

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general, it is best to wait at least 30 seconds after applying the last electrode before pressing the **12-LEAD** button, to allow for electrode/skin stabilization. Also, good skin preparation shortens the stabilization time.

Computerized ECG Analysis

Computerized ECG analysis statements are automatically printed on 12-lead ECG reports. Printing of the interpretive statements is a setup option and may be turned off in Setup mode. For information on how to change this setup option, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

The interpretative statements pertaining to myocardial injury, infarct, and ischemia are derived from measurements made on a signal-averaged beat (median beat) formed for each of the 12 leads. The computerized ECG analysis selects three representative beats from the ten seconds of data for each lead and averages the three beats to derive the median beat for that lead. The ECG analysis is always based on ECG data obtained at 0.05–150 Hz frequency response.

The analysis program is adjusted for patient age and sex. The 12-lead ECG interpretive algorithm used by the LIFEPAK 15 monitor/defibrillator is the University of Glasgow 12-Lead ECG Analysis Program. For more information, contact your Physio-Control representative for a copy of the *Physio-Control Glasgow 12-Lead ECG Analysis Program Physician's Guide*.

WARNING

POSSIBLE INCORRECT TREATMENT WITH REPERFUSION THERAPY

Computerized ECG interpretive statements should not be used to withhold or prescribe patient treatment without review of the ECG data by qualified medical personnel. All 12-lead ECG interpretation statements provided by the LIFEPAK 15 monitor/defibrillator include the printed message **UNCONFIRMED**. Always confirm interpretive statements by over-reading the ECG data.

Printed 12-Lead ECG Report Formats

Two 12-lead ECG report formats are available for printing: 3-channel or 4-channel. In addition, each of those formats can be printed in standard and cabrera styles.

The 3-Channel Format

The 3-channel format prints 2.5 seconds of data for each lead. Figure 4-7 is an example of a 12-lead ECG report printed in the 3-channel format, standard style. Figure 4-8 is an example of a 12-lead ECG report printed in the 3-channel format, cabrera style. The sequence in which the limb leads are presented differs between the standard and cabrera styles, as shown. The default format for printing 12-lead ECG reports is 3-channel standard. To change the printed format of

12-lead ECG reports, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device. Alternatively, press **OPTIONS**, select **PRINT**, select **REPORT: 12-LEAD**, and then select **FORMAT**.

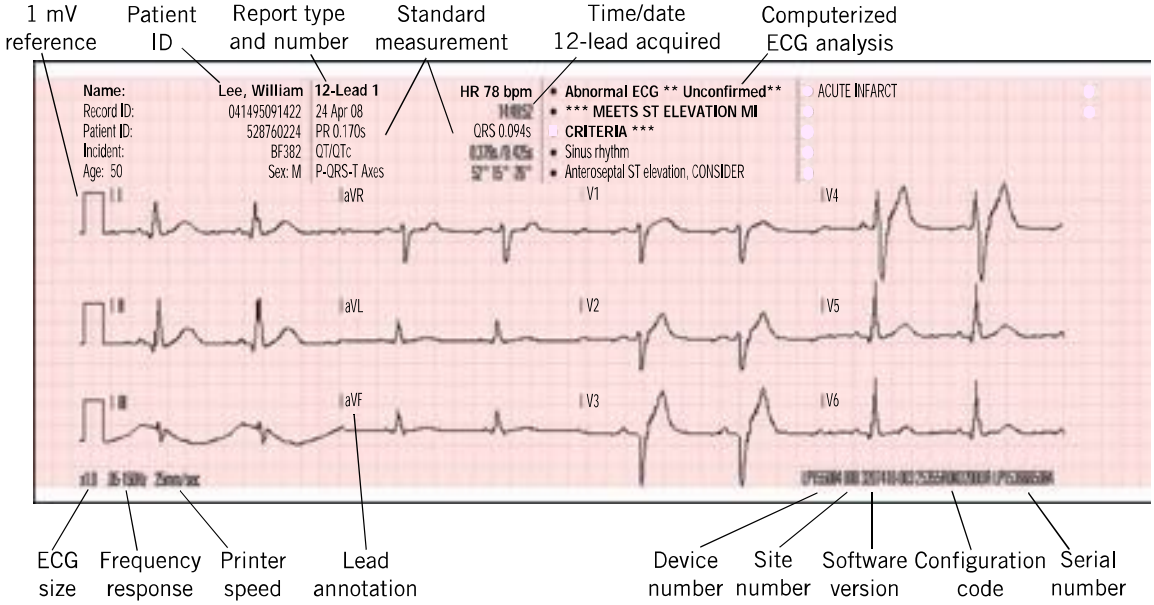


Figure 4-7 Example of Printed 3-Channel, Standard 12-Lead ECG Report

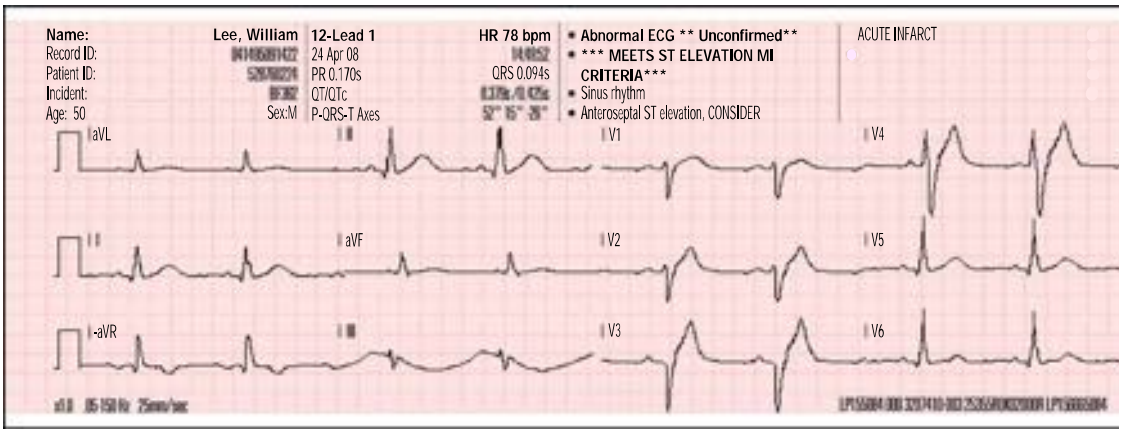


Figure 4-8 Example of Printed 3-Channel, Cabrera 12-Lead ECG Report

The 4-Channel Format

Figure 4-9 and Figure 4-10 are examples of 12-lead ECG reports printed in the 4-channel format. The 4-channel format consists of the median complex (or median beat) derived for each of the 12 leads and 10 seconds of data for Lead II.

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Note: The fiducial marks displayed in the 4-channel format identify the measurement intervals used for the interpretive statements of the analysis program. These marks are part of the analysis program and cannot be turned off.

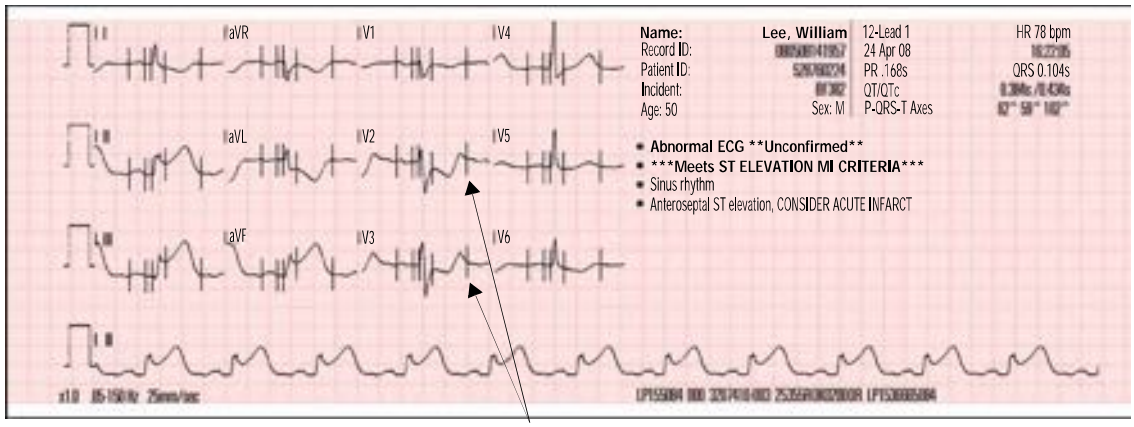


Figure 4-9 Example of Printed 4-Channel, Standard 12-Lead ECG Report

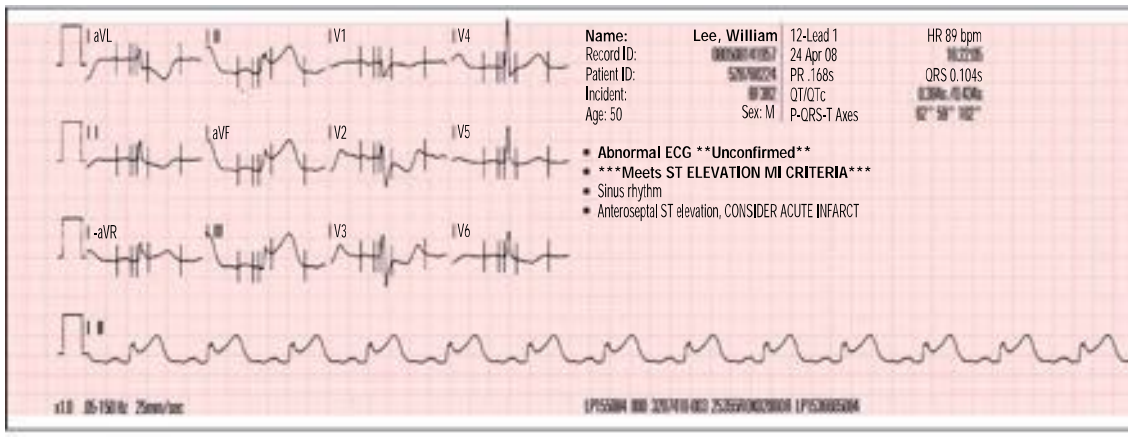


Figure 4-10 Example of Printed 4-Channel, Cabrera 12-Lead ECG Report

Printed 12-Lead ECG Frequency Response

The 12-lead ECG can be printed in two diagnostic frequency responses (or bandwidths): 0.05–40 Hz and 0.05–150 Hz. The frequency response of 0.05–150 Hz is the Association for the Advancement of Medical Instrumentation (AAMI) standard for diagnostic ECGs. The 0.05–40 Hz setting preserves the low frequency limit that is needed for the diagnosis of myocardial ischemia and infarction while reducing high frequency artifact (in particular from patient muscle tension) to help make the diagnostic printout less noisy and more readable.

Note: The LIFEPAK 15 monitor/defibrillator acquires ECG data and performs the interpretive analysis based on the full frequency of 0.05–150 Hz. The 0.05–40 Hz bandwidth affects only the printed appearance of the ECG data.

The 12-lead ECG printed in the 0.05–40 Hz setting can be used to diagnose acute myocardial ischemia and ST-segment elevation myocardial infarction (STEMI). This is because the low frequency limit of 0.05 Hz is not changed from the standard diagnostic setting of 0.05–150 Hz. The 0.05 Hz frequency provides accurate representation of low frequency signals, that is, the P, ST segment, and T waves. The presence or absence of ST segment changes indicative of myocardial ischemia or infarction will be accurately reproduced. In addition, the criteria for visual analysis and interpretation of cardiac rhythm and PR, QRS, and QT intervals are preserved, as is true with hospital cardiac monitors that have an upper frequency limit of 40 Hz.

However, in some adult patients, the amplitude (that is, voltage) of the QRS may be reduced when 12-lead ECGs are printed at the upper limit of 40 Hz rather than at 150 Hz. Therefore, certain diagnoses, which depend on R wave amplitude (for example, ventricular hypertrophy), should not be made using this setting. In the pediatric patient, this effect on R wave amplitude is particularly noticeable because QRS durations in children are typically quite narrow. Because R wave amplitude reduction is more likely with pediatric patients, the 12-lead ECG automatically prints at 0.05–150 Hz, overriding the 40 Hz limit, when a patient age of 15 years or younger is entered.

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Troubleshooting Tips

Table 4-3 Troubleshooting Tips for the 12-Lead ECG

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Any of these messages displayed: **CONNECT ECG LEADS** **ECG LEADS OFF** **XX LEADS OFF**	One or more ECG electrodes disconnected	• Confirm ECG electrode connections.
	ECG cable is not connected to monitor	• Confirm ECG cable connections.
	Poor electrode-skin contact	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. • Secure trunk cable clasp to patient's clothing. • Prepare skin and apply new electrodes.
	Broken lead wire	• Select another lead. • Select **PADDLES** lead and use standard paddles or therapy electrodes for ECG monitoring. • Check ECG cable continuity.
Noisy signal and/or message displayed: **NOISY DATA! PRESS 12-LEAD TO ACCEPT**	Noise in a lead other than the displayed lead	• Press **12-LEAD** again to override the message. Examine the printout to determine leads affected by noise. Replace or reposition the affected electrodes and lead wires.
	Poor electrode-skin contact	• Reposition cable or lead wires to prevent electrodes from pulling away from patient. • Secure trunk cable clasp to patient's clothing. • Prepare skin and apply new electrodes.
	Loose connection	• Check or reconnect cable connections.
	Patient motion	• Encourage patient to lie quietly. • Support patient's limbs.
	Vehicle motion	• Stop vehicle while acquiring 12-lead ECG data.
	Outdated, corroded, or dried-out electrodes	• Check Use By date on electrode packages. • Use only unexpired silver/silver chloride electrodes. Leave electrodes in sealed pouch until time of use.
	Radio Frequency Interference (RFI)	• Check for equipment causing RFI (such as a radio transmitter) and relocate or turn off equipment power.
	Damaged cable or connector/lead wire	• Inspect main cable and attachments. Replace if damaged.

Table 4-3 Troubleshooting Tips for the 12-Lead ECG (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Monitor does not complete 12-lead ECG operation sequence	Operator pressed another function button (such as **PRINT**) before 12-lead ECG sequence completed	• Press **12-LEAD** to acquire another 12-lead ECG. Allow enough time for sequence to complete.
Noisy signal and message displayed: **EXCESSIVE NOISE– 12-LEAD CANCELLED**	Signal noise for more than 30 seconds	• Press **12-LEAD** to acquire another 12-lead ECG.
Baseline wander (low frequency/high amplitude artifact)	Inadequate skin preparation	• Prepare skin as described on page 4-8 and apply new electrodes.
	Poor electrode-skin contact	• Check electrodes for proper adhesion.
Fine baseline artifact (high frequency/low amplitude)	Inadequate skin preparation	• Prepare skin as described on page 4-9 and apply new electrodes.
	Isometric muscle tension in arms/legs	• Confirm that limbs are resting on a supportive surface. • Check electrodes for proper adhesion.

For general troubleshooting tips, see Table 9-2 on page 9-18.

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Monitoring SpO2, SpCO, and SpMet

SpO_2, SpCO™, and SpMet™ are optional features for the LIFEPAK 15 monitor/defibrillator. When all three options (SpO_2, SpCO, and SpMet) are installed, the pulse oximeter measures functional oxygen saturation (SpO_2), carboxyhemoglobin concentration (SpCO), and methemoglobin concentration (SpMet) in the blood.

IMPORTANT! SpO_2-only sensors and combination SpO_2, SpCO, and SpMet sensors are available for use. Masimo® SpO_2-only sensors that have a red connector are compatible with the LIFEPAK 15 monitor. Masimo Rainbow™ sensors are necessary to monitor SpO_2, SpCO, and SpMet. These sensors are not compatible with other LIFEPAK defibrillator/monitors.

For a list of Masimo sensors and connector cables that are intended for use with the LIFEPAK 15 monitor/defibrillator, see the Physio-Control web site. Carefully read the Directions for Use that are provided with the sensors and connector cables for a complete description, instructions, warnings, cautions, and specifications. To order sensors and connector cables, contact your Physio-Control representative or order online at store.physio-control.com.

Intended Use

A pulse oximeter is a noninvasive device that continuously measures functional oxygen saturations (SpO_2), carboxyhemoglobin concentration (SpCO), and methemoglobin concentration (SpMet) in the blood. Continuously monitoring SpO_2 can provide an early warning when oxygen saturation is decreasing and can help the clinician act rapidly before the patient develops the later signs of hypoxemia. Previously, the blood parameters SpCO and SpMet could only be obtained from invasive blood gas samples. This new technology assists in identifying the often hidden conditions of carboxyhemoglobinemia (carbon monoxide poisoning) and methemoglobinemia (a condition that impedes delivery of oxygen to the tissues). Low levels of both SpCO and SpMet are normally found in the blood; however, early detection of significantly high levels can lead to proper diagnosis and treatment, and can help improve patient outcome.

Pulse oximetry is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times; do not rely solely on the SpO_2, SpCO, and SpMet measurements. If a trend toward patient deoxygenation is evident or carbon monoxide poisoning or methemoglobinemia is suspected, blood samples should also be analyzed using laboratory instruments to completely understand the patient's condition.

Do not use the pulse oximeter to monitor patients for apnea.

Indications

Pulse oximetry is indicated for use in any patient who is at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglobinemia. SpO_2 monitoring may be used during no motion and motion conditions, and in patients who are well or poorly perfused. SpCO and SpMet accuracies have not been validated under motion or low perfusion conditions.

Contraindications

None known.

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SpO2, SpCO, and SpMet Warnings and Cautions

WARNINGS

SHOCK OR BURN HAZARDS

SHOCK OR BURN HAZARD

Before use, carefully read these operating instructions, the sensor and cable directions for use, and precautionary information.

SHOCK OR BURN HAZARD

Using other manufacturers' sensors or cables may cause improper oximeter performance and invalidate safety agency certifications. Use only sensors and cables that are specified in these operating instructions.

INACCURATE READINGS HAZARDS

INACCURATE PULSE OXIMETER READINGS

Do not use a damaged sensor or cable. Do not alter the sensor or cable in any way. Alterations or modification may affect performance and/or accuracy. Never use more than one cable between the pulse oximeter and the sensor to extend the length.

INACCURATE PULSE OXIMETER READINGS

Sensors exposed to ambient light when incorrectly applied to a patient may exhibit inaccurate saturation readings. Securely place the sensor on the patient and check the sensor's application frequently to help ensure accurate readings.

INACCURATE PULSE OXIMETER READINGS

Severe anemia, methemoglobin, intravascular dyes that change usual blood pigmentation, excessive patient movement, venous pulsations, electrosurgical interference, exposure to irradiation and placement of the sensor on an extremity that has a blood pressure cuff, intravascular line, or externally applied coloring (such as nail polish) may interfere with oximeter performance. The operator should be thoroughly familiar with the operation of the oximeter prior to use.

INACCURATE PULSE OXIMETER READINGS

The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.

POSSIBLE SKIN INJURY

Prolonged, continuous use of a sensor may cause irritation, blistering, or pressure necrosis of the skin. Check the sensor site regularly based on patient condition and type of sensor. Change the sensor site if skin changes occur. Do not use tape to hold the sensor in place as this may cause inaccurate readings or damage to the sensor or skin.

WARNINGS (CONTINUED)

POSSIBLE STRANGULATION

Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTIONS

EQUIPMENT HAZARDS

POSSIBLE EQUIPMENT DAMAGE

To avoid damage to the cable, always hold by the connector rather than the cable, when connecting or disconnecting either end.

POSSIBLE EQUIPMENT DAMAGE

Do not soak or immerse the sensors or cables in any liquid solution. Do not attempt to sterilize.

No Implied License

Possession or purchase of the pulse oximeter does not convey any expressed or implied license to use the pulse oximeter with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

How a Pulse Oximeter Works

A pulse oximeter sensor directs light through a patient's fleshy body site (usually a finger or toe). The sensor sends wavelengths of light from the emitter to the receiving detector as shown in Figure 4-11.

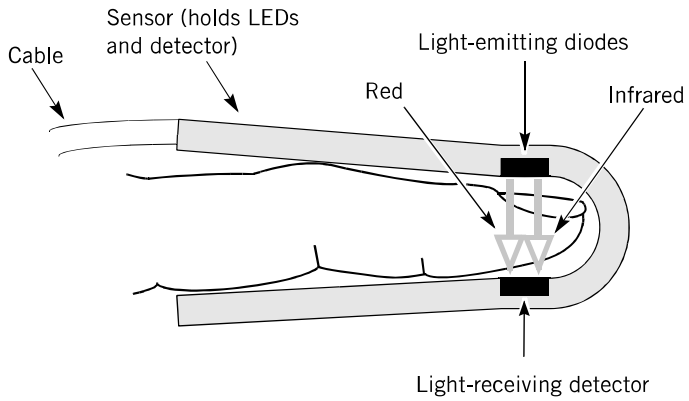


Figure 4-11 How a Pulse Oximeter Works

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The pulse oximeter translates the amount of light received by the detector to the various forms of hemoglobin saturation levels and displays them as SpO_2, SpCO, and SpMet percentages. Normal values for SpO_2 typically range from 95% to 100%. Normal values for SpCO are typically less than 9% (the higher range of normal is often seen in smokers). Normal values for SpMet are typically less than 2% and may be caused by exposure to some pharmaceuticals including local anesthetic agents and chemical agents such as nitrites.

SpO2, SpCO, and SpMet Monitoring Considerations

The quality of the SpO_2, SpCO, and SpMet readings depends on correct sensor size and placement, adequate blood flow through the sensor site, and limiting patient motion and sensor exposure to ambient light. For example, with very low perfusion at the sensor site, readings may be lower than core arterial oxygen saturation. Test methods for accuracy are available by contacting your local Physio-Control representative.

Use the following criteria to select the appropriate pulse oximeter sensor:

- Patient size (adult, pediatric, infant) and weight
- Patient perfusion to extremities
- Patient activity level
- Available application sites on the patient's body
- Sterility requirements
- Anticipated duration of monitoring

To help ensure optimal performance:

- Use a dry and appropriately sized sensor.
- Choose a site that is well perfused. The ring finger is preferred.
- Choose a site that least restricts patient movement, such as finger of the non-dominant hand.
- Be sure the fleshy part of the digit completely covers the detector.
- Keep the sensor site at the same level as the patient's heart.
- Apply the sensor according to the Directions for Use provided with the sensor.
- Observe all warnings and cautions noted in the sensor's Directions for Use.

Sensor Application

The preferred site for sensor application is the ring finger of the non-dominant hand. To position the sensor:

1. Orient the sensor so the cable is on the back of the patient's hand.
2. Place the finger in the sensor until the tip of the finger touches the "raised digit stop."

3. The hinged tabs of the sensor should open to evenly distribute the grip pressure of the sensor along the length of the finger. Check the arrangement of the sensor to verify correct positioning. Complete coverage of the detector window is needed to ensure accurate data.

The sensors are sensitive to light. If excessive ambient light is present, remove or reduce lighting, cover the sensor site with an opaque material to block the light, and check appropriateness of sensor site. Failure to do so could result in inaccurate measurements.

If excessive movement presents a problem during SpCO/SpMet monitoring, consider the following possible solutions:

- Be sure the sensor is secure and properly aligned.
- Use a disposable adhesive sensor.
- If possible, move the sensor to a less active site.

Note: Wrapping the sensor too tightly or using supplemental tape to hold the sensor in place may cause inaccurate oximeter readings.

Note: Circulation distal to the sensor site should be checked routinely.

IMPORTANT! Masimo Rainbow sensors are necessary to monitor SpCO and SpMet and are not compatible with other LIFEPAK defibrillator/monitors.

Oximeter Monitoring Procedure

Power to the pulse oximeter is controlled by the LIFEPAK 15 monitor/defibrillator. When the defibrillator is turned on, the oximeter turns on and performs a calibration and self-test that requires approximately 20 seconds. During the calibration and self-test, the screen does not display SpO_2, SpCO, or SpMet information.

To conserve battery power, the pulse oximeter goes into “sleep mode” when not in use. Sleep mode is activated within 10 seconds of disconnecting the sensor. During sleep mode, the screen does not display SpO_2, SpCO, or SpMet information. When a sensor or patient signal is detected, the oximeter performs a self-test and then returns to normal mode.

The pulse oximeter measures and displays SpO_2 levels between 50 and 100%. SpO_2 levels less than 50% are displayed as <50. When SpO_2 levels are between 70 and 100%, oximeter measurements are accurate ±3 digits. The pulse oximeter measures and displays SpCO in the range of 0–40% with accuracy of ±3 digits. The pulse oximeter measures and displays SpMet in the range of 0–15% with accuracy of ± 1 digit.

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To monitor SpO_2:

1. Press **ON**.
2. Connect the pulse oximeter cable to the monitor and sensor.
3. Attach the sensor to the patient.
4. Observe the pulse bar for fluctuation. Amplitude of the pulse bar indicates relative signal quality.
5. Confirm that the SpO_2 reading appears and is stable.
6. Use the **SPEED DIAL** to adjust volume, sensitivity, and averaging time, as necessary.

To monitor SpCO or SpMet:

1. Perform Step 2 through Step 5 above.
2. Verify that an SpCO/SpMet sensor is in use. Only Rainbow sensors are capable of reading SpCO/SpMet.
3. Encourage the patient to remain still.
4. To quickly obtain SpCO or SpMet value, press **PRINT**. If dashes (---) appear on printout instead of values for SpCO or SpMet, allow a few more seconds for measurement to be obtained.

   or

   To display SpCO or SpMet:

   - Use the **SPEED DIAL** to select the SpO_2 area.
   - Select **PARAMETER** from menu.
   - Select **SPCO** or **SPMET**. Selected value displays for 10 seconds.

Note: SpCO and SpMet monitoring are not intended for use under patient motion or low perfusion conditions.

SpCO/SpMet Advisory

If the SpCO or SpMet reading is above normal limits, indicating a dangerous amount of carboxyhemoglobin or methemoglobin, an Advisory occurs.

During an Advisory:

- The elevated SpCO or SpMet value is displayed instead of SpO_2.
- The elevated value flashes and the alarm tone sounds.
- One of the following Advisory messages appears in the message area:

  Advisory: SpCO > 10%

  Advisory: SpMet > 3%

To cancel the Advisory, press **ALARMS**. The SpO_2 area reverts to the SpO_2 reading. The Advisory message remains on the screen until the elevated value returns to within normal limits or the device is turned off.

WARNING

INACCURATE SPO_2 READINGS

Carboxyhemoglobin and methemoglobin may erroneously increase SpO_2 readings. The amount that SpO_2 increases is approximately equal to the amount of carboxyhemoglobin or methemoglobin that is present.

The Pleth Waveform

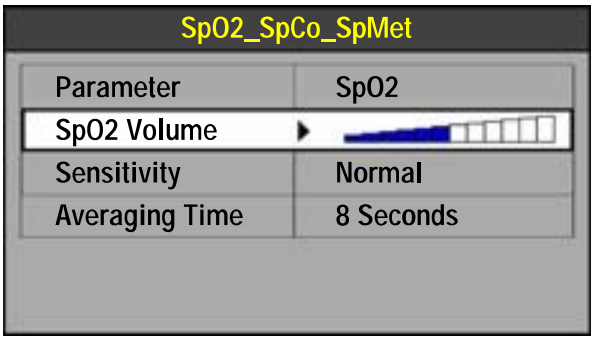
You can display the plethysmographic (pleth) waveform in Channel 2 or 3.

To display the pleth waveform:

1. Rotate the **SPEED DIAL** to outline waveform **CHANNEL 2** or **3**.
2. Press the **SPEED DIAL**. The Channel menu appears.
3. Select **WAVEFORM** and then select **SPO2**. The SpO_2 waveform appears in the selected channel. The waveform is automatically sized for optimum waveform viewing.

Volume

To adjust the pulse tone volume:



1. Rotate the **SPEED DIAL** to outline the SpO_2 area on the Home Screen.
2. Press the **SPEED DIAL**.
3. Highlight and select **SPO2 VOLUME**.
4. Rotate the **SPEED DIAL** to the desired volume.
5. Press the **SPEED DIAL** to set the volume.

Sensitivity

The sensitivity setting allows you to adjust the oximeter to either **NORMAL** or **HIGH** for differing perfusion states.

To adjust sensitivity:

1. Outline and select the SpO_2 area on the Home Screen.
2. Select **SENSITIVITY** and then select **NORMAL** or **HIGH**.

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Note: **NORMAL** sensitivity is recommended for most patients. The **HIGH** sensitivity setting allows SpO_2 monitoring under low perfusion states, such as the severe hypotension of shock. However, when SpO_2 sensitivity is set to **HIGH**, the signal is more susceptible to artifact. Monitor the patient closely when using the **HIGH** sensitivity setting.

Averaging Time

Averaging time allows you to adjust the time period that is used to average the SpO_2 value.

To adjust averaging time:

1. Outline and select the SpO_2 area on the Home Screen.
2. Select **AVERAGING TIME** and then select one of the following:
   - 4 Seconds
   - 8 Seconds
   - 12 Seconds
   - 16 Seconds

Note: Averaging time of 8 seconds is recommended for most patients. For patients with rapidly changing SpO_2 values, 4 seconds is recommended. Use a 12- or 16-second time period when artifact is affecting the performance of the pulse oximeter.

Cleaning

Pulse oximetry sensors may be adhesive (single-patient use) or reusable.

To clean the reusable sensor and connector cable:

1. Disconnect the sensor and cable from the monitor. Inspect the cable for damage.
2. Use a clean, soft cloth dampened with 70% isopropyl alcohol to wipe clean.
3. Allow to dry thoroughly before placing the sensor on a patient or reconnecting the cable to the monitor.

Note: Do not attempt to sterilize. Do not soak or immerse in any liquid solution. For information about cleaning the device, see "Cleaning the Device" on page 9-15.

Troubleshooting Tips

Table 4-4 Troubleshooting Tips for SpO_2, SpCO, and SpMet

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
The monitor measures a pulse, but there is no oxygen saturation or pulse rate	Excessive patient motion	• Keep patient still. • Check that sensor is secure. • Relocate sensor. • Apply adhesive sensor.
	Patient perfusion may be too low	• Check patient. • Increase sensitivity.
SpO_2 or pulse rate changes rapidly, pulse amplitude is erratic	Excessive patient motion	• Keep patient still. • Check that sensor is secure. • Relocate sensor. • Apply adhesive sensor. • Increase sensitivity.
	An electrosurgical unit (ESU) may be interfering with performance	• Move the monitor as far as possible from the ESU. • Plug the ESU and monitor into different circuits. • Move the ESU ground pad as close to the surgical site as possible.
	Sensor may be damp	• Replace sensor.
SPO2: NO SENSOR DETECTED message appears	Sensor not connected to patient or cable disconnected from monitor/defibrillator	• Check that sensor and cable are connected properly. • Check that appropriate sensor is in use.
	Damaged cable or sensor	• Replace damaged cable or sensor.
No SpO_2, SpCO, or SpMet value (---) is displayed	Oximeter may be performing self-calibration or self-test	• Wait for completion. • If values do not display within 30 seconds, disconnect and reconnect sensor. If values do not display within another 30 seconds, replace sensor.
	Defibrillator shock just delivered	• None. If values do not display within 30 seconds, disconnect and reconnect sensor. If values do not display within another 30 seconds, replace sensor.
	High intensity lights (such as pulsating strobe lights) may be interfering with performance	• Cover sensor with opaque material, if necessary.

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Table 4-4 Troubleshooting Tips for SpO_2, SpCO, and SpMet (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
	Damaged cable or sensor	• Replace damaged cable or sensor.
Different SpCO or SpMet measurements on same patient	Every measurement, even on the same patient, can be different	• Confirm by taking three measurements: ring finger, middle finger, and then index finger; average the results.
XXX appears in place of SpO_2 reading	SpO_2 module failed. Internal cable failed.	• Contact qualified service personnel.
SPO2: CHECK SENSOR message appears	Sensor is disconnected from patient or cable	• Attach the sensor. • Check that sensor is secure.
	Excessive ambient light	• Remove or block light source, if possible. • Cover sensor with opaque material, if necessary.
	Faulty or defective sensor	• Replace sensor.
	Patient has a weak pulse or low blood pressure, or the sensor is not properly placed	• Change sensor location. • Check if patient perfusion is adequate for sensor location. • Check that sensor is secure and not too tight. • Check that sensor is not on extremity with blood pressure cuff or intravascular line. • Test sensor on someone else.
SPO2: UNKNOWN SENSOR message appears	A sensor that is not Physio-Control approved is connected to the device.	• Check that the sensor is an approved Physio-Control sensor.
SPO2: SEARCHING FOR PULSE message appears	A sensor is connected to the patient and is searching for a pulse	• Wait for completion.
SPO2: LOW PERFUSION message appears	Patient has a weak pulse	• Change sensor location.

Table 4-4 Troubleshooting Tips for SpO_2, SpCO, and SpMet (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
SPO2: POOR QUALITY SIGNAL message appears	When the signal quality is low, the accuracy of the measurement may be compromised	• Check that sensor and cable are connected properly. • Move sensor to a better perfused site.
SPO2: SENSOR DOES NOT SUPPORT SPCO OR SPMET message appears	SpO_2-only sensor used with SpCO/SpMet capable device	• None necessary, or use Rainbow sensor to measure SpCO or SpMet.

Note: Rainbow sensor messages (SpO_2, SpCO, and SpMet) are reported as **SPO2: (MESSAGE)**.

For general troubleshooting tips, see Table 9-2 on page 9-18.

Monitoring Noninvasive Blood Pressure

Intended Use

The LIFEPAK 15 noninvasive blood pressure (NIBP) monitor measures blood pressure (BP) using the oscillometric measurement technique to determine systolic, diastolic, and mean arterial pressures, and pulse rate. The measurement can be initiated manually or set to recur automatically at predetermined intervals.

Blood pressure measurements determined using this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard *Electronic or automated sphygmomanometers* (AAMI SP-10).

NIBP is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times; do not rely solely on the NIBP monitor.

Indications

Noninvasive blood pressure monitoring is intended for detection of hypertension or hypotension and monitoring BP trends in patient conditions such as, but not limited to, shock, acute dysrhythmia, or major fluid imbalance.

Contraindications

None known.

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NIBP Monitoring Warnings and Caution

WARNINGS

POSSIBLE LOSS OF INTRAVENOUS ACCESS AND INACCURATE INFUSION RATE

Do not apply the blood pressure cuff on an extremity that is used for an intravenous infusion. Patency of the intravenous infusion may be affected by blood pressure measurement due to the occlusion of blood flow.

INACCURATE READINGS HAZARDS

POSSIBLE INACCURATE BLOOD PRESSURE READINGS

Do not alter the NIBP monitor's pneumatic tubing. Altering NIBP tubing may cause improper performance and may void the warranty. Avoid compression or restriction of pressure tubes.

POSSIBLE INACCURATE BLOOD PRESSURE READINGS

Using NIBP accessories not recommended by Physio-Control may cause the device to perform improperly and invalidate the safety agency certifications. Use only the accessories that are specified in these operating instructions.

POSSIBLE INACCURATE OXYGEN SATURATION READINGS

Do not perform NIBP measurement on an extremity used for oxygen saturation monitoring. Oxygen saturation measurement is affected by blood pressure measurement due to the occlusion of blood flow.

CAUTION

EQUIPMENT DAMAGE

Do not inflate a cuff unless it is placed on an extremity.

How NIBP Monitoring Works

The NIBP monitor uses the oscillometric measurement technique. The oscillometric technique does not use Korotkoff sounds to determine blood pressure; rather, it monitors the changes in pressure pulses that are caused by the flow of blood through the artery. The NIBP monitor inflates the cuff around the patient's arm to a value that occludes the artery, and then deflates the cuff in steps. When blood starts to flow through the artery, the increasing blood flow causes the amplitude of the pressure pulses in the cuff to increase. As the NIBP monitor steps the pressure down, the pulses reach a peak amplitude and then start to decrease. The rising and falling amplitude values form a curve that is analyzed to yield systolic pressure, diastolic pressure, and mean arterial pressure (MAP).

The NIBP monitor measures the pulse rate by tracking the number of pulses over time. The NIBP monitor uses artifact rejection techniques to provide accurate results under most operating conditions. When a patient is experiencing arrhythmias during a measurement, the accuracy of the pulse determination may be affected or the time needed to complete a measurement may be extended. In shock conditions, the low amplitude of blood pressure waveforms makes it difficult for the monitor to accurately determine the systolic and diastolic pressures.

NIBP Monitoring Considerations

As with any noninvasive oscillometric blood pressure monitor, clinical conditions can affect the accuracy of the measurements obtained, including the following:

- The patient's physiological condition. For example, shock may result in a blood pressure waveform that has a low amplitude, making it difficult for the monitor to accurately determine the systolic and diastolic pressures.
- The position of the patient.
- Motion may prolong the measurement process since motion artifacts have to be rejected in the data stream. Motion that affects measurement can include patient movement, patient seizure, bumping the cuff, and flexing the extremity under the cuff.
- The presence of other medical devices. The NIBP monitor does not operate effectively if the patient is connected to a heart/lung machine.
- When a patient is experiencing arrhythmias, pulse rate accuracy may be affected or the time needed to complete an NIBP measurement may be extended. The device automatically deflates if a blood pressure measurement cannot be obtained in 120 seconds.
- Blood pressure and pulse can fluctuate greatly between measurements; the monitor cannot alert the operator of changes in vital signs that occur between measurement cycles.
- There may be some difference between readings taken manually and readings from the NIBP monitor due to the differing sensitivity of the two methods. The NIBP monitor meets the ANSI/SP10 AAMI standard that requires a mean difference of ±5 mmHg, with a standard deviation no greater than 8 mmHg, compared to auscultatory readings.
- When using the NIBP monitor during defibrillation, the NIBP monitor is not available when the defibrillator is being charged. Upon shock, the monitor resets and dashes (– – –) appear in place of pressure readings. After defibrillation, you can resume blood pressure measurement according to "NIBP Monitoring Procedure" on page 4-38.
- If the blood pressure cuff fails to deflate for any reason or causes undue discomfort to the patient, remove the cuff from the arm or disconnect the tubing from the defibrillator.

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Cuff Selection

The use of properly designed and sized cuffs is essential for the accurate measurement of blood pressure. The cuff must fit snugly around the extremity to occlude the artery. For a list of BP cuffs that are intended for use with the LIFEPAK 15 monitor/defibrillator, see the LIFEPAK 15 Monitor/Defibrillator Accessories Catalog at store.physio-control.com.

NIBP Monitoring Procedure

The NIBP monitor inflates an occluding cuff and determines systolic and diastolic pressures, mean arterial pressure (MAP), and pulse rate. Pressure measurements are reported in mmHg and pulse rate in beats per minute (bpm).

Both single-measurement and specified-interval (timer-controlled) methods of blood pressure reading are available.

The NIBP monitor draws power from the defibrillator. When the defibrillator is turned on, the NIBP monitor conducts a self-test that takes approximately three seconds.

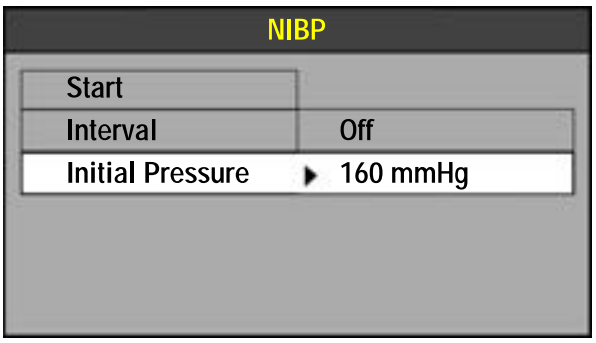
IMPORTANT! The LIFEPAK 15 monitor NIBP port and tubing are not compatible or interchangeable with the NIBP tubing that is used with other LIFEPAK monitor/defibrillators.

Changing the Initial Inflation Pressure

The initial cuff pressure should be set approximately 30 mmHg higher than the patient's anticipated systolic pressure. The factory default initial inflation pressure for the first measurement is 160 mmHg. For pediatric patients, the initial cuff pressure may need to be lowered. Initial inflation settings are 80, 100, 120, 140, 160, or 180 mmHg.

Caution should be taken not to lower the initial pressure below the adult patient's systolic measurement. Doing so may cause the cuff to reinflate and cause patient discomfort. For subsequent measurements, the monitor inflates approximately 30 mmHg higher than the previously determined systolic pressure.

To select an initial pressure:



1. Rotate the **SPEED DIAL** to outline the NIBP area.
2. Press the **SPEED DIAL**. The NIBP menu appears.
3. Select **INITIAL PRESSURE**.
4. Rotate the **SPEED DIAL** to the desired pressure.
5. Press the **SPEED DIAL** to set the initial pressure.

Note: Measurement data is recorded in the LIFEPAK 15 monitor/defibrillator Vital Sign Log. For more information about the Vital Sign Log and its use, see Chapter 7, "Data Management."

Manual Single-Measurement Procedure

The NIBP measurement typically takes 40 seconds to complete. If the measurement is not completed within 120 seconds, the cuff automatically deflates.

To obtain a manual single measurement:

1. Press **ON**.
2. Select the appropriately-sized cuff and apply it snugly to the extremity.
3. Connect the tubing to the cuff and to the NIBP port on the monitor.
4. Change the initial inflation pressure, if necessary.
5. Position the extremity in a relaxed and supported position at approximately the same level as the patient's heart. Inform the patient that the cuff will inflate and cause a "big squeeze" around the arm and that the patient's fingers may tingle.
6. Press **NIBP** to start the measurement, and check that the patient's arm is not moving. When the measurement is complete, systolic, diastolic, and mean arterial pressures are displayed.

To cancel a measurement, press **NIBP** again.

Note: NIBP pulse rate is displayed only when ECG or SpO_2 is not active.

Timer-Controlled Measurement Procedure

When the timer is set, the monitor performs recurring measurements at a fixed interval. When using timer-controlled measurement, the interval is counted from the start of the measurement to the start of the next measurement. Choices are **OFF** (factory default), **2**, **3**, **5**, **10**, **15**, **30**, and **60** minutes.

To take a manual measurement between timer-controlled measurements, press **NIBP**. The next interval is counted from the beginning of the manual measurement.



Figure 4-12 NIBP Measurements and Timer

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To set timer-controlled measurements:

1. Press **ON**.
2. Select the appropriately-sized cuff and apply it snugly to the extremity.
3. Connect the tubing to the cuff and to the NIBP port on the monitor.
4. Rotate the **SPEED DIAL** to outline the **NIBP** area.
5. Press the **SPEED DIAL**. The NIBP menu appears.
6. Select **INTERVAL** and then select the desired time interval.
7. Position the extremity in a relaxed and supported position at approximately the same level as the patient's heart. Inform the patient that the cuff will inflate and cause a "big squeeze" around the arm and that the patient's fingers may tingle.
8. Press **NIBP** to start the measurement, and check that the patient's arm is not moving. When the measurement is complete, systolic, diastolic, and mean arterial pressures are displayed. The countdown timer shows the time to the next automatic NIBP measurement.

To cancel a measurement in progress, press **NIBP** again.

Note: If at any time the cuff pressure exceeds 290 mmHg or there is a system failure of the NIBP module, timer-controlled NIBP is terminated. To reactivate, follow the Timer-Controlled Measurement Procedure.

Cleaning

To clean the cuff and pneumatic tubing:

1. Disconnect the tubing from the cuff and monitor. Use a clean, soft cloth dampened with a germicidal solution to wipe clean.
2. Inspect the tubing for cracks or kinks. If any damage is noted, replace the tubing.
3. Inspect the cuff for damage or excessive wear. If any damage is noted, replace the cuff.
4. Allow both to dry before placing the cuff on a patient or reconnecting the tubing to the monitor.

For information about cleaning the device, see "Cleaning the Device" on page 9-15.

Troubleshooting Tips

Table 4-5 Troubleshooting Tips for NIBP Monitoring

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
NIBP AIR LEAK message appears	Cuff applied too loosely. Leak in cuff/monitor pneumatic system.	• Check cuff for snug fit on patient. • Check that the cuff/monitor connection is secure. • Check cuff for leaks. Do not use a cuff that exhibits a leak.
NIBP FLOW ERROR message appears	The pneumatic system is not maintaining stable cuff pressure	• Deflate or remove cuff. • Check tubing for leaks. • Replace cuff.
NIBP FAILED message appears	The monitor cannot establish zero-pressure reference	• Check tubing for kink or blockage. • If this message persists, remove monitor from use and obtain service. Use another method to measure the patient's blood pressure.
NIBP INITIALIZING message appears	NIBP is requested and is not successful due to a 30-second reset	• Wait until message disappears and request NIBP.
NIBP MOTION message appears	The patient extremity moved too much for the monitor to accurately complete the measurement	• Have patient lie quietly with extremity relaxed and supported. • Check that patient's arm does not move during NIBP measurement.
NIBP OVERPRESSURE message appears	Cuff pressure exceeded 290 mmHg	• Disconnect tubing or remove cuff. • Avoid very rapid squeezing of the cuff. • If this message persists, remove the cuff from use and obtain service.
NIBP TIME OUT message appears	The monitor did not complete a measurement in 120 seconds	• Check cuff for snug fit on patient. • Repeat measurement. • Try a higher initial pressure. • If this message persists, use another method to measure the patient's blood pressure.

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Table 4-5 Troubleshooting Tips for NIBP Monitoring (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
NIBP WEAK PULSE message appears	The monitor did not detect any pulses	• Check pulses distal to the cuff. • Check cuff for snug fit on patient.
XXX appears in place of NIBP readings	NIBP module failed. NIBP module failed to calibrate successfully.	• Contact qualified service personnel.
NIBP CHECK CUFF message appears	The cuff is not connected to patient or device	• Check cuff for snug fit on patient. • Check cuff tubing connection to device.
Unable to connect NIBP tubing to device	The LIFEPAK 12 NIBP tubing connector is not compatible with the LIFEPAK 15 NIBP port	• Obtain correct NIBP tubing that is compatible with LIFEPAK 15 monitor/ defibrillator.
Cuff not deflating	Internal valves fail to open	• Disconnect NIBP tubing. • Remove cuff from patient.
Cuff not inflating	Cuff is not connected to the device	• Check tubing connection to device and cuff.
	Leak in tubing, cuff, or connector	• Replace NIBP tubing or cuff.

For general troubleshooting tips, see Table 9-2 on page 9-18.

Monitoring ETCO2

Intended Use

The end-tidal CO_2 ($EtCO_2$) monitor is a capnometric device that uses non-dispersive infrared spectroscopy to continuously measure the amount of CO_2 during each breath and report the amount present at the end of exhalation ($EtCO_2$). The sample is obtained by the side stream method and can be used with intubated or nonintubated patients. Respiration rate is also measured and displayed in breaths per minute.

The $EtCO_2$ monitor is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times; do not rely solely on the $EtCO_2$ monitor.

Indications

$EtCO_2$ monitoring is used to detect trends in the level of expired CO_2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.

Contraindications

None known.

EtCO2 Monitoring Warnings

WARNINGS

FIRE HAZARDS

FIRE HAZARD

Before use, carefully read these operating instructions, the FilterLine® tubing directions for use, and precautionary information.

FIRE HAZARD

The FilterLine tubing may ignite in the presence of O_2 when directly exposed to laser, electrosurgical devices, or high heat. Use with caution to prevent flammability of the FilterLine tubing.

FIRE HAZARD

Flammable anesthetics become mixed with the patient's air that is sampled by the capnometer. When using the $EtCO_2$ monitor in the presence of flammable gases, such as nitrous oxide or certain other anesthetics, connect the $EtCO_2$ gas port to a scavenger system.

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WARNINGS (CONTINUED)

INACCURATE READINGS HAZARDS

POSSIBLE INACCURATE PATIENT ASSESSMENT

The $EtCO_2$ monitor is intended only as an adjunct in patient assessment and is not to be used as a diagnostic apnea monitor. An apnea message appears if a valid breath has not been detected for 30 seconds and indicates the time elapsed since the last valid breath. It must be used in conjunction with clinical signs and symptoms.

POSSIBLE INACCURATE CO2 READINGS

Using other manufacturers' CO_2 accessories may cause the device to perform improperly and invalidate the safety agency certifications. Use only the accessories that are specified in these operating instructions.

HEALTH HAZARDS

POSSIBLE STRANGULATION

Carefully route the patient tubing (FilterLine) to reduce the possibility of patient entanglement or strangulation.

INFECTION HAZARD

Do not reuse, sterilize, or clean Microstream® CO_2 accessories as they are designed for single-patient one-time use.

How Capnography Works

An $EtCO_2$ sensor continuously monitors carbon dioxide (CO_2) that is inspired and exhaled by the patient. The sensor employs Microstream non-dispersive infrared (IR) spectroscopy to measure the concentration of CO_2 molecules that absorb infrared light.

The CO_2 FilterLine system delivers a sample of the exhaled gases directly from the patient into the LIFEPAK 15 monitor for CO_2 measurement. The low sampling flow rate (50 ml/min) reduces liquid and secretion accumulation and prevents obstruction, which maintains the shape of the CO_2 waveform.

The CO_2 sensor captures a micro sample (15 microliters). This extremely small volume allows for fast rise time and accurate CO_2 readings, even at high respiration rates.

The Microbeam IR source illuminates the sample cell and the reference cell. This proprietary IR light source generates only the specific wavelengths characteristic of the CO_2 absorption spectrum. Therefore, no compensations are required when concentrations of O_2, anesthetic agent, or water vapor are present in the exhaled breath.

You can set up the LIFEPAK 15 monitor/defibrillator to use the capnography Body Temperature Pressure Saturated (BTPS) conversion method. This option corrects for the difference in temperature and moisture between the sampling site and alveoli. The correction formula is 0.97 × the measured $EtCO_2$ value. See the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

EtCO2 Monitoring Waveform Analysis

Valuable information concerning the patient's expired CO_2 can be acquired by examination and interpretation of the waveform.

The Phases of the Waveform

Figure 4-13 is a graphic representation of a normal capnograph waveform. Four phases of the waveform require analysis. The flat I–II baseline segment (Respiratory Baseline) represents continued inhalation of CO_2-free gas. This value normally is zero. The II–III segment (Expiratory Upstroke), a sharp rise, represents exhalation of a mixture of dead space gases and alveolar gases from acini with the shortest transit times. Phase III–IV (Expiratory Plateau) represents the alveolar plateau, characterized by exhalation of mostly alveolar gas. Point IV is the end-tidal ($EtCO_2$) value that is recorded and displayed by the monitor. Phase IV–V (Inspiratory Downstroke), a sharp fall, reflects the inhalation of gases that are CO_2-free. Alterations of the normal capnograph or $EtCO_2$ values are the result of changes in metabolism, circulation, ventilation, or equipment function.

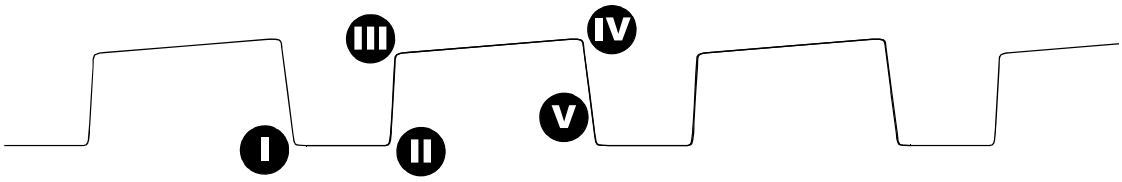


Figure 4-13 Phases of the Respiratory Waveform

Respiratory Baseline Elevation of the waveform baseline (I–II segment) usually represents rebreathing CO_2. This elevation usually is accompanied by gradual increases in the $EtCO_2$ value. Rebreathing CO_2 is common in circumstances of artificially produced increased dead space and hypoventilation. Precipitous rises in both baseline and $EtCO_2$ values usually indicate contamination of the sensor.

Expiratory Upstroke In the normal waveform, the rising phase (II–III segment) is usually steep. When this segment becomes less steep, CO_2 delivery is delayed from the lungs to the sampling site. The causes of this delay can be physiologic or mechanical and include bronchospasm, obstruction of the upper airway, or obstruction (or kinking) of an endotracheal tube (ETT).

Expiratory Plateau The plateau of the waveform, which represents the remainder of expiration (III-IV segment), should be nearly horizontal. The end of the plateau represents the $EtCO_2$ value. Upward slanting of the expiratory plateau occurs when there is uneven emptying of the alveoli.

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Similar to the diminished slope of the Expiratory Upstroke, this pattern can occur in asthma, chronic obstructive pulmonary disease (COPD), partial upper-airway obstruction, or partial mechanical obstruction such as a partially kinked ETT.

Inspiratory Downstroke The fall to baseline (IV-V segment) is a nearly vertical drop. This slope can be prolonged and can blend with the expiratory plateau in cases of leakage in the exhale portion of the breathing circuit. The peak $EtCO_2$ value (IV) is often not reached. Relying on the numeric end-tidal value without observing the breathing waveform may obscure the presence of a leak.

EtCO2 Monitoring Procedure

When activated, the $EtCO_2$ monitor draws power from the defibrillator. The LIFEPAK 15 monitor/defibrillator activates the $EtCO_2$ monitor when it senses the attachment of the FilterLine set. Initialization, self-test, and warm up of the $EtCO_2$ monitor is typically less than 30 seconds, but may take up to two-and-one-half minutes.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Failure to replace a broken or missing CO_2 port door may allow water or particulate contamination of the internal CO_2 sensor. This may cause the CO_2 module to malfunction.

To monitor $EtCO_2$:

1. Press **ON**.
2. Select the appropriate $EtCO_2$ accessory for the patient.
3. Open the CO_2 port door and insert the FilterLine connector; turn connector clockwise until tight.
4. Verify that the CO_2 area is displayed. The $EtCO_2$ monitor performs the autozero routine as part of the initialization self-test.

   Note: If you use a ventilation system, do not connect the FilterLine set to the patient/ventilation system until the $EtCO_2$ monitor has completed its self-test and warm-up.
5. Display CO_2 waveform in Channel 2 or 3.
6. Connect the CO_2 FilterLine set to the patient.
7. Confirm that the $EtCO_2$ value and waveform are displayed. The monitor automatically selects the scale for the best visualization of the waveform. You can change the scale, if desired, as described in the next section.

Note: It is possible for the FilterLine set to become loose at the device connection and still have an $EtCO_2$ value and CO_2 waveform, but they may be erroneously low. Make sure the FilterLine connection is firmly seated and tight.

Note: The capnography module performs self-maintenance within the first hour of monitoring and once an hour during continuous monitoring. The self-maintenance includes "auto-zeroing." Self-maintenance is also initiated when the surrounding temperature changes 8°C (14.4°F) or more, or the surrounding pressure changes greater than 20 mmHg. The CO_2 module detects this change and attempts to purge the tubing. To clear the **CO2 FILTERLINE PURGING** or **CO2 FILTERLINE BLOCKAGE** messages, remove the FilterLine tubing and reconnect it to the monitor.

CO2 Display

The following scales are available to display the CO_2 waveform. The LIFEPAK 15 monitor/defibrillator automatically selects the scale based on the measured $EtCO_2$ value. To change the CO_2 scale, outline and select the CO_2 area using the **SPEED DIAL** and then select the desired scale from the scale menu.

- Autoscale (default)
- 0–20 mmHg (0–4 Vol% or kPa).
- 0–50 mmHg (0–7 Vol% or kPa).
- 0–100 mmHg (0–14 Vol% or kPa).

The CO_2 waveform is compressed (displayed at 12.5 mm/sec sweep speed) to provide more data in the 4-second screen. There is a slight delay between when the breath occurs and when it appears on the screen. Printouts are at 25 mm/sec. Continuous print may be changed to 12.5 mm/sec, if desired.

The monitor shows the maximum CO_2 value over the last 20 seconds. If the $EtCO_2$ values are increasing, the change can be seen with every breath. However, if the values are continually decreasing, it will take up to 20 seconds for a lower numerical value to be displayed. Because of this, the $EtCO_2$ value may not always match the level of the CO_2 waveform.

CO2 Alarms

The $EtCO_2$ monitor provides:

- $EtCO_2$ high and low alarms controlled by activating **ALARMS** (see "Alarms" on page 3-21)
- $FiCO_2$ (inspired CO_2) alarm (automatic and not adjustable)
- Apnea alarm (automatic and not adjustable)

Note: The apnea alarm occurs when a breath has not been detected for 30 seconds. The message **ALARM APNEA** appears in the message area along with the time since the last detected breath.

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CO2 Detection

A CO_2 waveform appears when any CO_2 is detected, but CO_2 must be greater than 3.5 mmHg for a numerical value to be displayed. However, the CO_2 module will not recognize a breath until the CO_2 is at least 8 mmHg (1.0% or kPa). Valid breaths must be detected in order for the apnea alarm to function and to count the respiratory rate (RR). The RR represents an average over the last eight breaths.

When CO_2 is not detected in the cardiac arrest situation—for example, the CO_2 waveform is either dashes "---" or a flat solid line at or near zero—several factors must be quickly evaluated. Assess for the following causes:

Equipment issues

- Disconnection of the FilterLine set from the endotracheal tube (ETT)
- System is purging due to fluid in the patient/sensor connection from ET administration of medications
- System is auto-zeroing
- Shock was delivered and system is resetting
- Loose FilterLine set to device connection

Loss of airway function

- Improper placement of ETT
- ETT dislodgment
- ETT obstruction

Physiological factors

- Apnea
- Massive pulmonary embolism
- Loss of perfusion
- Inadequate CPR
- Exsanguination

Cleaning

Accessories for CO_2 monitoring are disposable and are intended for single-patient use. Do not clean and reuse a FilterLine set. Dispose of the contaminated waste according to local protocols.

For information about cleaning the device, see "Cleaning the Device" on page 9-15.

Troubleshooting Tips

Table 4-6 Troubleshooting Tips for $EtCO_2$ Monitoring

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
ALARM APNEA message appears and waveform is solid line at or near zero	No breath has been detected for 30 seconds since last valid breath	• Check the patient.
	FilterLine connection to device is loose	• Twist FilterLine connector clockwise until tight and firmly seated.
	FilterLine set is disconnected from patient or ETT	• Check ventilation equipment (if used) for leaks or disconnected tubing.
CO2 FILTERLINE OFF message appears and waveform is "---"	FilterLine set disconnected or not securely connected to device	• Connect FilterLine set to device port. • Twist FilterLine connector clockwise until tight and firmly seated.
CO2 FILTERLINE PURGING message appears and waveform is "---"	FilterLine set is kinked or clogged with fluid, or rapid altitude change occurred	• Disconnect and then reconnect the FilterLine set. • Twist FilterLine connector clockwise until tight and firmly seated.
CO2 FILTERLINE BLOCKAGE message appears and waveform is "---"	The message appears after 30 seconds of unsuccessful purging	• Disconnect and then reconnect the FilterLine set. • Change the FilterLine set.
	FilterLine set is kinked or clogged	• Twist FilterLine connector clockwise until tight and firmly seated.
CO2 INITIALIZING message appears and waveform is "---"	FilterLine set just connected to device	• None.
	Defibrillation shock delivered	• None. System resets automatically within 20 seconds.
AUTO ZEROING message appears and waveform is "---"	Module is performing self-maintenance	• None.
	Defibrillation shock delivered	• None. System resets automatically within 20 seconds.

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Table 4-6 Troubleshooting Tips for $EtCO_2$ Monitoring (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
$EtCO_2$ values are erratic	FilterLine connection to device is loose	• Twist FilterLine connector clockwise until tight and firmly seated.
	A leak in the FilterLine set	• Check for connection leaks and line leaks to patient, and correct, if necessary.
	A mechanically ventilated patient breathes spontaneously or patient is talking	• No action required.
$EtCO_2$ values are consistently higher than expected	Physiological cause such as COPD	• None.
	Inadequate ventilation	• Check ventilator, increase ventilatory rate/bagging.
	Patient splinting during breathing	• Supporting measures such as pain relief.
	Improper calibration	• Contact qualified service personnel.
$EtCO_2$ values are consistently lower than expected	FilterLine connection to device is loose	• Twist FilterLine connector clockwise until tight and firmly seated.
	Physiological cause	• See Physiological factors in "CO2 Detection" on page 4-48.
	Hyperventilation	• Check ventilator, decrease ventilatory rate/bagging.
	Improper calibration	• Contact qualified service personnel.
CO_2 waveform stays elevated for several seconds	Expiration is prolonged due to bagging technique	• Release bag reservoir completely with expiration. Observe that elevated baseline returns to normal level.
Sudden extreme increase in $EtCO_2$	Fluid has entered CO_2 module	• Contact qualified service personnel.
XXX appears instead of $EtCO_2$ value	CO_2 module malfunction	• Contact qualified service personnel.
There is no $EtCO_2$ value and the CO_2 waveform is flat	Measured CO_2 is less than 3.5 mmHg	• See "CO2 Detection" on page 4-48.

Note: To decrease the likelihood of the FilterLine connection coming loose during use, hand-straighten the tubing after removal from the package before connecting to patient or device.

For general troubleshooting tips, see Table 9-2 on page 9-18.

Monitoring Invasive Pressure

Intended Use

The LIFEPAK 15 invasive pressure (IP) monitor is intended for measuring arterial, venous, intracranial, and other physiological pressures using an invasive catheter system with a compatible transducer.

The IP monitor is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times; do not rely solely on the IP monitor.

Indications

Invasive pressure monitoring is indicated for use in patients who require continuous monitoring of physiological pressures in order to rapidly assess changes in the patient's condition or response to therapy. It may also be used to aid in medical diagnosis.

Contraindications

None known.

IP Monitoring Warnings

WARNINGS

INACCURATE READINGS HAZARDS

POSSIBLE INACCURATE PRESSURE READINGS, AIR EMBOLISM, BLOOD LOSS, OR LOSS OF STERILITY

Before use, carefully read these operating instructions, and the transducer and infusion set instructions for use and precautionary information.

INACCURATE PRESSURE READINGS

Pressure readings should correlate with the patient's clinical presentation. If readings do not correlate, verify that the zeroing stopcock is positioned at the patient's zero reference, rezero the transducer, and/or check the transducer with a known or calibrated pressure. Manually check cuff blood pressure.

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WARNINGS (CONTINUED)

INACCURATE PRESSURE READINGS

Changing the patient's position changes the zero reference level. Relevel the transducer's zeroing stopcock any time the patient's position is changed.

HEALTH HAZARDS

POSSIBLE LETHAL ARRHYTHMIA

Ventricular fibrillation may be induced if the isoelectric barrier of the transducer is disrupted. The isoelectric barrier within the transducer may be disrupted if the transducer body is damaged. Do not use a transducer that is visibly damaged or leaking fluid.

INCREASED INTRACRANIAL PRESSURE

Do not use a continuous flush device with transducers used for intracranial monitoring.

IP Monitoring

Two channels are available for invasive pressure monitoring, with default labels P1 and P2 and the user-selectable labels shown in Table 4-7.

Table 4-7 IP Labels and Descriptions

LABEL	DESCRIPTION
ART	Arterial Pressure
PA	Pulmonary Artery Pressure
CVP	Central Venous Pressure
ICP	Intracranial Pressure
LAP	Left Atrial Pressure

When the default labels P1 and P2 are used, the IP monitoring area displays systolic, diastolic, and mean pressures. When ICP, LAP, or CVP labels are used, the IP monitoring area displays mean pressure in large type. Systolic and diastolic pressures are not displayed.



Figure 4-14 IP Labels

Because pressures can change in a short time, data should be checked regularly during vital sign monitoring.

How IP Monitoring Works

IP monitoring involves the conversion of fluid pressure into an electrical signal. The conversion is accomplished with a pressure transducer. The transducer is connected to a patient's indwelling pressure catheter using a special assembly of tubing, stopcocks, adapters, flush valves, and fluids, commonly known as a flush system. The transducer translates the pressure wave into an electrical signal. A well-functioning flush system is essential for obtaining undistorted waveforms and accurate information.

IP monitoring is available on either Channel 2 or 3. The IP connector (6-pin type 3102A-14S-6S) is compatible with industry standard (60601-2-34 and AAMI-BP22) pressure transducers with 5µV/V/mmHg sensitivity. For a list of IP transducers that are compatible with the LIFEPAK 15 monitor/defibrillator, see the LIFEPAK 15 Monitor/Defibrillator Accessory Catalog at www.physio-control.com. If the use of other transducers is desired, the customer must be responsible for determining if the transducers comply with standards and are compatible with the monitor.

The IP connector pinout has the following configuration, counterclockwise from 12 o'clock, viewed from the front of the LIFEPAK 15 monitor/defibrillator.

A pin = - signal	B pin = + excitation	C pin = + signal
D pin = - excitation	E pin = shield	F pin = unlabeled

An invasive pressure adapter cable is used to connect the transducer to the monitor.

IP Monitoring Procedure

Prepare a flush system according to local protocols. Position the transducer at the patient's phlebostatic axis (zero-reference level).

To avoid offset errors, a zero reference must be established before any meaningful pressure readings are obtained. This is done by opening the transducer stopcock to air so that atmospheric pressure becomes the reference.

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The P1 or P2 connector and Channel 2 or 3 can be used for IP monitoring. P1 and Channel 2 are used in these instructions.

To monitor IP:

1. Prepare the transducer system according to the operating instructions provided with the transducer and your local protocol.
2. Press **ON**.
3. Connect the IP cable to the transducer and to the P1 port on the monitor.
4. Use the default label **P1** or select **ART**, **PA**, **CVP**, **ICP**, or **LAP**. To change the label, select the P1 area. From the menu, select **P1**. Select a label from the list.
5. Use the **SPEED DIAL** to outline and select **CHANNEL 2** on the Home Screen. From the Channel 2 menu, select **WAVEFORM** and then select the label that is desired for the waveform.
6. Open the transducer's stopcock to air to zero the transducer and remove stopcock cap. Select the **P1** area. Select **ZERO** from the menu. The message **P1 ZEROED** appears when zeroing is complete and the pressure values are displayed as zeros.
7. Close the stopcock to air. The patient's pressure waveform should be displayed. A scale is automatically selected to display the pressure. Confirm that pressure amplitude correlates with the digital readout.

   Note: If you place a cap on an open port before you close the port to air, an error message may appear. You will be required to zero the transducer again.

If pressure alarms are desired, set the alarms after you obtain a satisfactory waveform. Error or alarm messages appear in the message area at the bottom of the screen. For more information, see "Alarms" on page 3-21.

IP Scale Options

The IP monitor can display pressures from -30 to 300 mmHg. After zeroing the transducer pressure, the monitor automatically selects one of the following scales based on the patient's measured pressure:

- -30 to 30 mmHg
- 0 to 60 mmHg
- 0 to 120 mmHg
- 0 to 150 mmHg
- 0 to 180 mmHg
- 0 to 300 mmHg

You can also manually select one of these scales or autoscale to readjust the waveform within the channel.

To change the scale:

1. Use the **SPEED DIAL** to outline and select the P1 area. The P1 menu appears.
2. From the menu, select **SCALE** and then choose a scale from the list.

Cleaning

IP transducers are disposable and are intended for single-patient use. Do not clean and reuse transducers. Dispose of the contaminated waste according to local protocols.

IP cables are reusable and may be cleaned. To clean the reusable IP cable:

1. Disconnect the cable from the monitor.
2. Use a clean, soft cloth dampened with a germicidal solution to wipe clean.
3. Allow to dry before reconnecting the cable to the monitor.

For information about cleaning the device, see "Cleaning the Device" on page 9-15.

Troubleshooting Tips

The error messages in Table 4-8 use the text **PX** to represent any of the labels for invasive pressure, including P1, P2, and the user-selectable labels ART, PA, CVP, ICP, and LAP.

Table 4-8 Troubleshooting Tips for IP Monitoring

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Invasive pressure value is blank	No transducer is connected	• Connect the transducer to the cable, and the cable to the monitor.
No scale appears next to the waveform	The zero reference has not been established	• Zero the transducer.
PX NOT ZEROED message appears	The zero reference has not been established	• Zero the transducer.
PX ZERO FAILED message appears	An unsuccessful attempt has been made to set a zero reference value	• Make sure that the transducer is open to air and repeat the attempt to zero.
Dampened waveform	Loose connection	• Check the entire system for leaks. Tighten all connections. Replace any defective stopcocks.
	Tubing too long or too compliant	• Use short, stiff tubing with a large diameter.
	Thrombus formation, air bubbles, or blood left in catheter after blood draw	• Use syringe to draw back air or particles in catheter, and then flush system.

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Table 4-8 Troubleshooting Tips for IP Monitoring (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
	Kinked catheter, catheter tip against vessel wall, arterial spasm	• Reposition catheter. Anchor catheter to skin at insertion site.
Resonating waveform	Tubing too long	• Use short, stiff tubing with large diameter.
No waveform. No pressure reading.	Transducer closed to patient	• Check patient. Check stopcock positions and monitor setup.
	Defibrillator shock just delivered	• None.
Invasive BP lower than cuff BP	Transducer level higher than the heart	• Reposition transducer to correct height.
	Loose connection	• Tighten all connections.
	Thrombus formation, air bubbles, or blood in catheter, kinking, or arteriospasm	• Use syringe to draw back air or particles in catheter, and then flush system.
	Improper zero reference	• Open stopcock to air and rezero transducer.
	Defective transducer	• Replace transducer.
Invasive BP higher than cuff BP	Transducer level lower than the heart	• Reposition transducer to correct height.
	Improper zero reference	• Rezero.
	Catheter whip artifact	• Change catheter tip position. • Use mean pressure values (mean pressure is less affected by extremes and will therefore reflect a more accurate reading).
Inability to flush system	Pressure bag leaking	• Keep positive pressure in flush bag at all times. • Remove dressing to check for external kinking.
	Partially kinked or obstructed catheter	• Replace catheter, if clotted.
Inability to zero system	Stopcock not open to air or defective	• Check stopcock position. Replace any defective stopcocks.
	Defective transducer	• Replace transducer.

Table 4-8 Troubleshooting Tips for IP Monitoring (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
System has been zeroed but continues to indicate zero reference required	Steps to zero system performed in wrong order	• Close stopcock to air before placing cap on port.
Catheter whip (fling) artifact Pulmonary Artery	Excessive catheter movement. Motion of the catheter tip within the vessel accelerates fluid movement in the catheter, causing artifact to be superimposed on the pressure wave, increasing readings by 10–20 mmHg.	• Change catheter tip position. • Use mean pressure values (mean pressure is less affected by extremes and therefore reflects a more accurate reading).
Permanent Pulmonary Wedge Pressure (PWP) tracing (wedge tracing persists after balloon deflation)	Catheter tip partially clotted	• Use syringe to aspirate, and then flush.
	Catheter migrated distally in pulmonary artery	• Observe PA waveform before balloon inflation. Flattening of the waveform could indicate wedging with balloon deflated. Turn patient side to side in Trendelenburg position, or stimulate cough in attempt to dislodge catheter. • Retract catheter with balloon deflated until proper position is obtained. • Minimize chances of catheter advancement by firmly anchoring catheter at insertion site.
Failure to obtain PWP	Malposition of catheter tip	• Reposition catheter.
	Leak in balloon. Ruptured balloon.	• Replace catheter.
Progressive elevation of PWP	Overinflation	• Inflate balloon in small increments while watching scope for confirmation of wedging. Use only enough air to wedge. Do not use more than the volume recommended by the manufacturer.
	Catheter migrated distally in pulmonary artery	• Reposition catheter.

For general troubleshooting tips, see Table 9-2 on page 9-18.

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Vital Sign and ST Segment Trends

Intended Use

The trends feature of the LIFEPAK 15 monitor/defibrillator provides the ability to graphically display and document the patient's vital signs (VS) and ST segment measurements for up to eight hours. VS trending is intended for use with any patient who requires continuous monitoring of vital signs over an extended period of time to identify changes in patient condition and to document patient response to therapy. ST trending is intended for use with patients suspected of having acute ischemic events, such as unstable angina, and for patients during treatment of an acute ischemic event. ST segment measurement is initiated using a 12-lead ECG and is derived using the University of Glasgow 12-Lead ECG Analysis Program.

VS and ST Trends Warning

WARNING

INACCURATE INTERPRETATION OF PATIENT STATUS

Vital sign and ST graphs are tools to be used in addition to patient assessment. Artifact and noise may produce spurious data. Ensure artifact-free monitoring as much as possible and assess the patient frequently to confirm the appropriateness of monitor data.

How VS Trends Work

Each active vital sign can be displayed graphically for time ranges of 30 minutes, and 1, 2, 4, and 8 hours. The vital signs are HR, SpO_2, SpCO, SpMet, CO_2, and RR; and systolic, diastolic, and mean pressures. Data is sampled every 30 seconds. If valid data is not available, a blank space is substituted on the graph. NIBP values are plotted only when an NIBP measurement is obtained. VS measurements are not averaged or filtered. No messages or alarms occur based on changes in VS measurements.



Figure 4-15 EtCO2 Trend Graph



Figure 4-16 Pressure Trend Graph

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How ST Trends Work

ST measurements can be displayed graphically for time ranges of 30 minutes, and 1, 2, 4, and 8 hours. ST trending is initiated by obtaining the patient's first 12-lead ECG. The ST J-point (STJ) is the part of the ST segment that is measured (see Figure 4-17). The STJ measurement is plotted on the ST trend graph (see Figure 4-18).

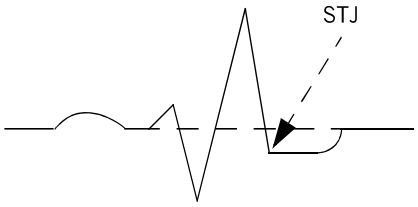


Figure 4-17 STJ Measurement

When all leads of the 12-lead ECG cable are attached to the patient, STJ measurements are obtained automatically every 30 seconds. If a lead is off, or the ECG data is too noisy, ST measurements are not obtained and the graph shows a blank for that time period. If an STJ measurement in any lead deviates from the initial measurement by 1 mm (0.1 mV) or more and the deviation persists for 2.5 minutes, the monitor automatically prints another 12-lead ECG.

Interpreting the ST Trend Graph

Using the first 12-lead ECG, the monitor identifies the presence of any STJ displacement, either negative or positive, and the lead that has the most STJ displacement. When **AUTO** is selected, the lead that has the most STJ displacement is shown on the graph. The STJ is measured every 30 seconds thereafter.

Figure 4-18 shows an example of an ST trend graph. The elapsed time goes from right to left across the screen. The most current STJ measurement is on the far right. Each time an STJ measurement is obtained, it is compared to the first STJ or baseline measurement. The bars represent the change in the STJ compared to the first measurement.



Figure 4-18 ST Trend Graph

This ST trend graph depicts the changes in STJ from a patient's first 12-lead ECG over 10 minutes of monitoring time. The patient's initial ECG showed no ST elevation in any lead. Then the patient developed 3 mm elevation in Lead II. This change in ST elevation is represented by the vertical bars and lasted approximately 5 minutes. (Each vertical bar represents a 30-second interval). After treatment was initiated, the ST decreased to the current STJ measurement of 1.0, but is still positive compared to the initial ECG.

The annotation (1.0/1.0) means that the current STJ measurement is elevated 1.0 mm and represents a change of 1.0 mm from the initial ECG. To confirm the value of the initial 12-lead ECG STJ measurement, subtract the STJ change from the current STJ measurement, for example, 1.0 – 1.0 = 0. You can display the ST graph of other leads.

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Displaying and Printing Trend Graphs

The trend graph for any active vital sign or ST measurement can be displayed in Channel 2 or 3. The example in Figure 4-18 shows the trend graph in Channel 3. Only two trend graphs can be displayed at a time, but the device collects trend data on all active vital sign values.

To display trend graphs:

1. Rotate the **SPEED DIAL** to outline Channel 2 or 3, and then press the **SPEED DIAL** to select the channel. The Channel menu appears.
2. Select **WAVEFORM**, and then select **TREND**.
3. Select **SOURCE**, and then select the desired VS or ST.
4. The default setting for **SCALE** and **RANGE** is **AUTO**. When **AUTO** is used, the monitor automatically updates the scale so that all values are displayed and all data from Power On to the present time is visible. If you change scale or range, some data may not be visible because it is off scale or out of range.
5. Press **HOME SCREEN**. The graph for the selected VS or ST appears in the channel.

Note: To initiate ST trends, you must obtain a 12-lead ECG. The initial ECG provides the baseline ST measurement and initiates the ST trends feature.

To print trend graphs:

1. Press **OPTIONS**. The Options menu appears.
2. Rotate and then press the **SPEED DIAL** to select **PRINT**.
3. Select **REPORT**, and then select **TREND SUMMARY**.
4. Select **PRINT**. The Trend Summary Report prints graphs of all actively monitored VS and ST trends.

VS and ST Monitoring Considerations

For best results, consider the following:

- The ability of the patient to cooperate and be relaxed. Patients who are restless can produce noisy physiological signals. Noisy signals can result in inaccurately high or low data measurements.
- The quality of the physiological signal. If the ECG has significant artifact, the HR may have spurious measurements. Noisy 12-lead ECGs may need to be overridden, and ST measurements will not be obtained.
- The expected length of time the patient is to be monitored. VS graphs of the patient monitored for only a short time (for example, 15 minutes) may not provide enough data to identify gradual changes in patient condition.
- The patient ECG rhythm. Diagnosis of ST associated ischemia is inhibited by certain ECG findings such as left bundle branch block and ventricular pacing.

THERAPY

This chapter describes patient therapy.

General Therapy Warnings and Cautions . . . . . page 5-3
Therapy Electrode and Standard Paddle Placement 5-4
Automated External Defibrillation (AED) 5-7
Manual Defibrillation 5-21
Synchronized Cardioversion Procedure 5-26
Noninvasive Pacing 5-31
Pediatric ECG Monitoring and Manual Mode Therapy Procedures 5-38

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General Therapy Warnings and Cautions

WARNINGS

SHOCK HAZARDS

SHOCK HAZARD

The defibrillator delivers up to 360 joules of electrical energy. When discharging the defibrillator, do not touch the paddle electrode surfaces or disposable therapy electrodes.

SHOCK HAZARD

If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Clear everyone away from contact with the patient, bed, and other conductive material before discharging the defibrillator.

SHOCK HAZARD

Do not discharge the defibrillator into the open air. To remove an unwanted charge, change the energy selection, select disarm, or turn off the defibrillator.

BURN AND INEFFECTIVE ENERGY DELIVERY HAZARDS

POSSIBLE FIRE, BURNS, AND INEFFECTIVE ENERGY DELIVERY

Do not discharge standard paddles on top of therapy electrodes or ECG electrodes. Do not allow standard paddles (or therapy electrodes) to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

POSSIBLE SKIN BURNS AND INEFFECTIVE ENERGY DELIVERY

Therapy electrodes that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use therapy electrodes that have been removed from foil package for more than 24 hours. Do not use electrodes beyond expiration date. Check that electrode adhesive is intact and undamaged. Replace adult therapy electrodes after 50 shocks or pediatric therapy electrodes after 25 shocks.

POSSIBLE SKIN BURNS

During defibrillation or pacing, air pockets between the skin and therapy electrodes may cause patient skin burns. Apply therapy electrodes so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new electrodes.

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WARNINGS (CONTINUED)

DEVICE PERFORMANCE HAZARD

POSSIBLE DEFIBRILLATOR SHUTDOWN

The large current draw required for defibrillator charging may cause the defibrillator to reach a shutdown voltage level with no low battery indication. If the defibrillator shuts down without warning or if a replace battery warning occurs, immediately replace the battery with another fully charged battery.

POSSIBLE INTERFERENCE WITH IMPLANTED ELECTRICAL DEVICE

Defibrillation may cause implanted devices to malfunction. Place standard paddles or therapy electrodes away from implanted devices if possible. Check implanted device function after defibrillation.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Prior to using this defibrillator, disconnect from the patient all equipment that is not defibrillator-protected.

Therapy Electrode and Standard Paddle Placement

The following paragraphs describe therapy electrode and standard paddle skin preparation and placement, including special placement situations.

Patient Skin Preparation

Prepare the patient's skin:

- Remove all clothing from the patient's chest.
- Remove excessive chest hair as much as possible. Avoid nicking or cutting the skin if using a shaver or razor. If possible, avoid placing electrodes over broken skin.
- Clean and dry the skin, if necessary. Remove any ointment on the patient's chest.
- Briskly wipe the skin dry with a towel or gauze. This mildly abrades the skin and removes oils, dirt, and other debris for better electrode adhesion to the skin.
- Do not use alcohol, tincture of benzoin, or antiperspirant to prep the skin.

Anterior-Lateral Placement

Anterior-lateral placement is used for ECG monitoring, defibrillation, synchronized cardioversion, and noninvasive pacing.

To perform anterior-lateral placement:

1. Place either the ♥ therapy electrode or **APEX** paddle lateral to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. See Figure 5-1.

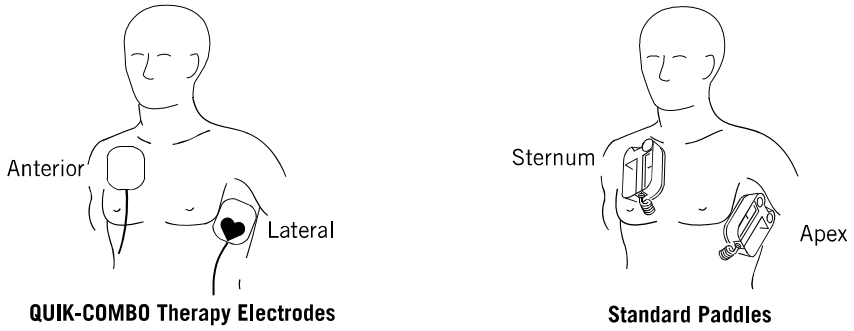


Figure 5-1 Anterior-Lateral Placement

2. Place the other therapy electrode or **STERNUM** paddle on the patient's upper right torso, lateral to the sternum and below the clavicle as shown in Figure 5-1.

Anterior-Posterior Placement

Anterior-posterior is an alternative position for noninvasive pacing, manual defibrillation, and synchronized cardioversion, but not for ECG monitoring or AED mode. The ECG signal obtained through electrodes in this position is not a standard lead.

To perform anterior-posterior placement:

1. Place either the ♥ or **+** therapy electrode over the left precordium as shown in Figure 5-2. The upper edge of the electrode should be below the nipple. Avoid placement over the nipple, the diaphragm, or the bony prominence of the sternum, if possible.
2. Place the other electrode behind the heart in the infrascapular area as shown in Figure 5-2. For patient comfort, place the cable connection away from the spine. Do not place the electrode over the bony prominences of the spine or scapula.

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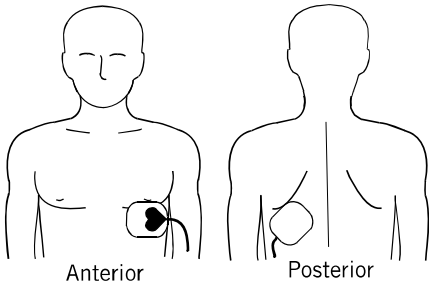


Figure 5-2 Anterior-Posterior Placement

Special Situations for Electrode or Paddle Placement

When placing therapy electrodes or standard paddles, be aware of the special requirements in the following possible situations.

Synchronized Cardioversion

Alternative placements for cardioversion of atrial fibrillation include a) place the ♥ therapy electrode over the left precordium and the other electrode on the patient's right posterior infrascapular area; or b) place the ♥ therapy electrode to the right of the sternum and the other electrode on the patient's posterior left infrascapular area.

Obese Patients or Patients with Large Breasts

Apply therapy electrodes or standard paddles to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.

Thin Patients

Follow the contour of the ribs and spaces when pressing therapy electrodes onto the torso. This action limits air spaces or gaps under the electrodes and promotes good skin contact.

Patients with Implanted Devices

Implanted devices such as cardiac defibrillators, pacemakers, or other devices may absorb energy from a LIFEPAK 15 defibrillator shock or be damaged by the shock. If possible, place therapy electrodes or standard paddles in the standard placements but away from the implanted device. Treat the patient like any other patient who requires care. If defibrillation is unsuccessful, it may be necessary to try alternate electrode placement (anterior-posterior).

Automated External Defibrillation (AED)

Intended Use

When used in AED mode, the LIFEPAK 15 monitor/defibrillator is a semiautomatic defibrillator that provides a prompted treatment protocol and ECG analysis using a patented Shock Advisory System™ (SAS). This software algorithm analyzes the patient's electrocardiographic (ECG) rhythm and indicates whether or not a shockable rhythm is detected. AED mode requires operator interaction in order to defibrillate the patient.

AED mode is intended for use by personnel who are authorized by a physician or medical director and have, at a minimum, the following skills and training:

- CPR training
- AED training equivalent to that recommended by the American Heart Association (AHA) or the European Resuscitation Council (ERC)
- Training in the use of the LIFEPAK 15 monitor/defibrillator in AED mode

Indications

AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 15 monitor/defibrillator is not intended for use on pediatric patients less than eight years old.

Contraindications

None known.

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AED Warnings

WARNINGS

MISINTERPRETATION OF DATA HAZARDS

POSSIBLE MISINTERPRETATION OF DATA

Do not analyze in a moving vehicle. Motion artifact may affect the ECG signal resulting in an inappropriate **SHOCK** or **NO SHOCK ADVISED** message. Motion detection may delay analysis. Stop vehicle and stand clear of patient during analysis.

POSSIBLE ECG MISINTERPRETATION

Do not place therapy electrodes in the anterior-posterior position when operating this defibrillator in AED mode. A **SHOCK** or **NO SHOCK** decision may be inappropriately advised. The shock advisory algorithm requires the electrodes to be placed in the anterior-lateral (Lead II) position.

PEDIATRIC PATIENT SAFETY RISK

In AED mode, this defibrillator is not designed or tested to interpret pediatric rhythms or administer energy at pediatric joule settings for children under eight years old.

AED Mode

The LIFEPAK 15 monitor/defibrillator is set up to operate in Manual mode when it is turned on (factory default setting). The device can be set up to power on in AED mode by changing the Setup Options. The factory default settings for AED mode are identified in Table A-5 on page A-14. The energy settings and other AED setup options can be changed according to medical protocol. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

The ECG is continuously displayed in AED mode; however, access to other functions such as **OPTIONS** is not allowed in AED mode. The CPR metronome automatically sounds during CPR times, but it can only be silenced and un-silenced in AED mode.

You can exit AED mode's prompted protocol and enter Advisory Monitoring or Manual Mode. For more information about Advisory Monitoring, see "Advisory Monitoring" on page 5-18. Access to Manual mode may be direct, require confirmation or a passcode, or not allowed, depending on how your defibrillator is set up. For more information, see "CPR Time and Metronome" on page 5-14. It is important to be thoroughly familiar with your monitor/defibrillator settings and operation before use.

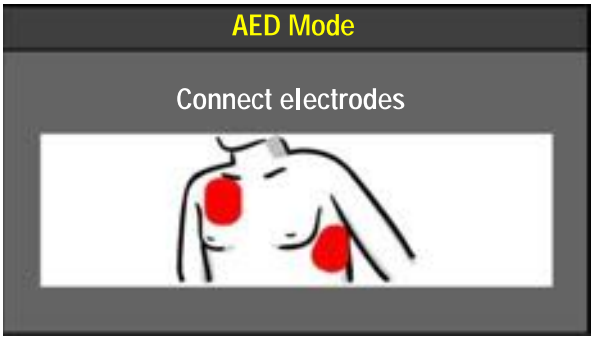
AED Procedure

The following descriptions of AED prompts (voice and text) are based on the factory default settings for AED mode. The settings are consistent with the 2005 American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines. Changing the setup options may result in different AED behavior.

The CPR metronome automatically sounds during CPR times and can only be silenced and un-silenced.

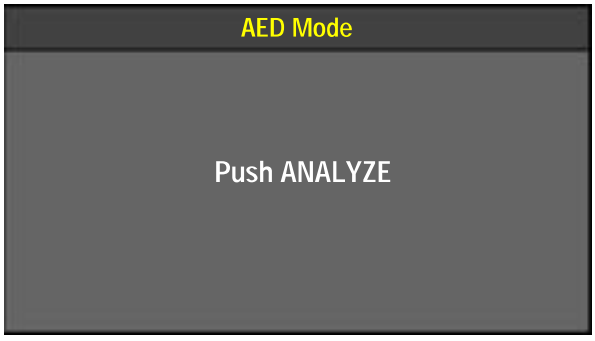
To perform automated external defibrillation:

1. Verify that the patient is in cardiopulmonary arrest (unconscious, pulseless, not breathing normally).
2. Press **ON**.
3. Prepare the patient for electrode placement (see "Patient Skin Preparation" on page 5-4).



The **CONNECT ELECTRODES** prompts occur until the patient is connected to the AED. If possible, place the patient on a hard surface away from standing water.

4. Connect the therapy electrodes to the therapy cable and confirm cable connection to the defibrillator.
5. Apply the therapy electrodes to the patient's chest in the anterior-lateral position (see "Anterior-Lateral Placement" on page 5-5).



The **PUSH ANALYZE** prompts occur when the patient is properly connected to the AED.

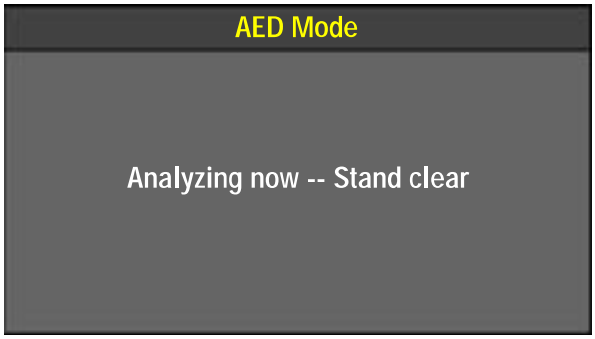
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6. Press **ANALYZE** to initiate the analysis. Stop CPR.

WARNING

POSSIBLE MISINTERPRETATION OF DATA

Do not move the AED during analysis. Moving the AED during analysis may affect the ECG signal resulting in an inappropriate **SHOCK** or **NO SHOCK ADVISED** decision. Do not touch the patient or the AED during analysis.

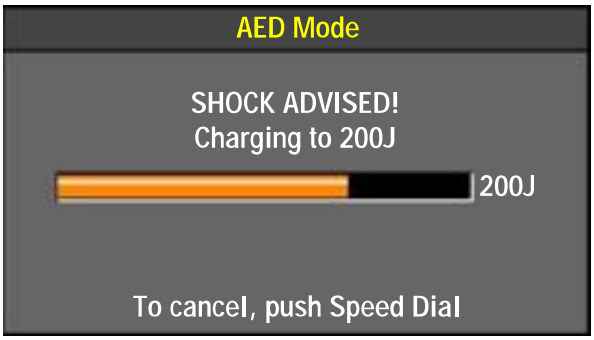


The **ANALYZING NOW—STAND CLEAR** prompts occur. The SAS analyzes the patient's ECG in approximately 6 to 9 seconds and advises either **SHOCK ADVISED** or **NO SHOCK ADVISED**.

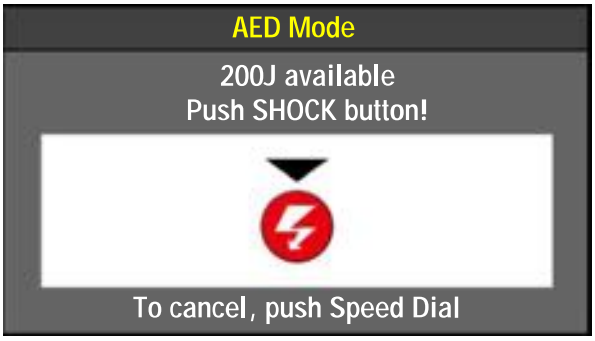
7. Continue to follow the screen messages and voice prompts provided by the AED.

Shock Advised

The following prompts occur when shock is advised:



If the AED detects a shockable rhythm, the **SHOCK ADVISED** prompts occur. Charging to the joule setting for Shock #1 begins. A charging bar appears and a ramping tone sounds.

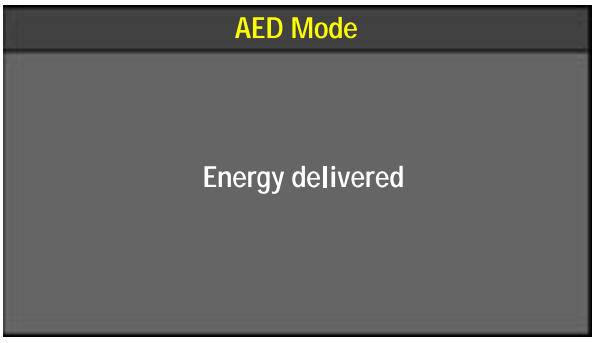


When charging is complete, the available energy is displayed.

The **STAND CLEAR, PUSH SHOCK BUTTON!** ( ) message occurs, followed by a "Shock ready" tone.

Clear everyone away from touching the patient, bed, or any equipment that is connected to the patient.

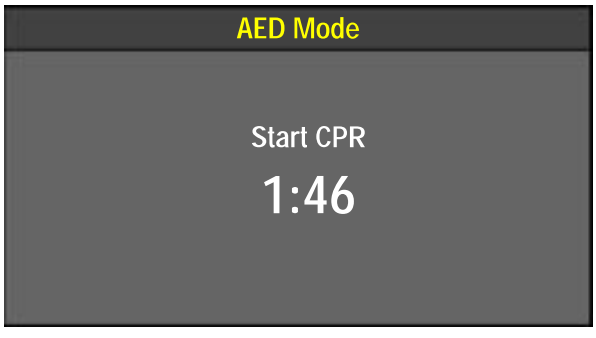
Press (shock) to deliver energy to the patient.



When the (shock) button is pressed, the **ENERGY DELIVERED** message occurs indicating that the energy transfer was completed.



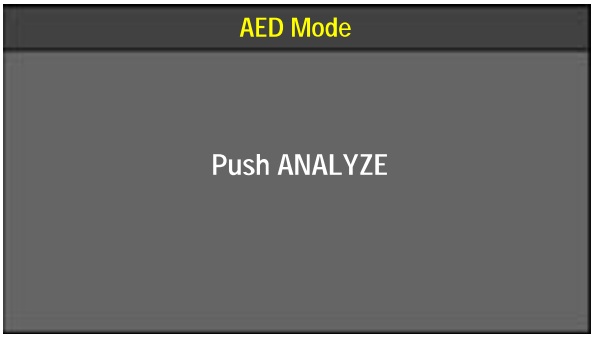
Note: If you do not press the (shock) button within 60 seconds, or the **SPEED DIAL** is pressed to cancel charging, the defibrillator disarms and the **DISARMING** message appears.



After a shock is delivered, the **START CPR** prompts occur. A countdown timer (min:sec format) continues for the duration specified in the **CPR TIME 1** setup option.

Note: The CPR metronome automatically provides audible compression "tocks" and ventilation prompts or tones only during CPR intervals at a ratio of 30:2. To silence the metronome, press **CPR**. To un-silence the metronome, press **CPR** again.

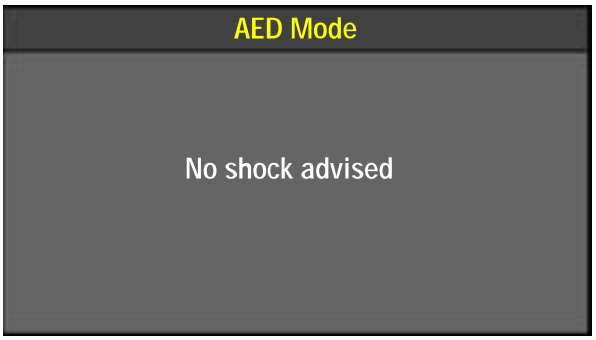
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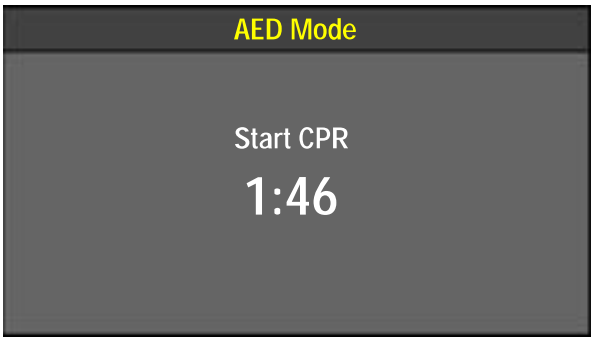
When the CPR countdown time ends, the **PUSH ANALYZE** prompts occur. These prompts repeat every 20 seconds until you press **ANALYZE**.

No Shock Advised

The following prompts occur if no shock is advised:

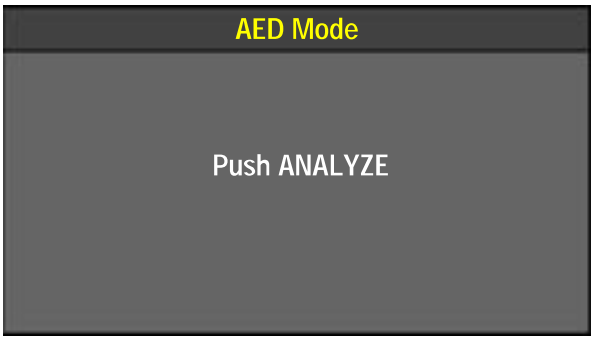


If the AED detects a nonshockable rhythm, the **NO SHOCK ADVISED** prompts occur. The defibrillator does not charge, and no shock can be delivered.



After **NO SHOCK ADVISED**, the **START CPR** prompts occur. A countdown timer (min:sec format) continues for the duration specified in the **CPR TIME 2** setup option.

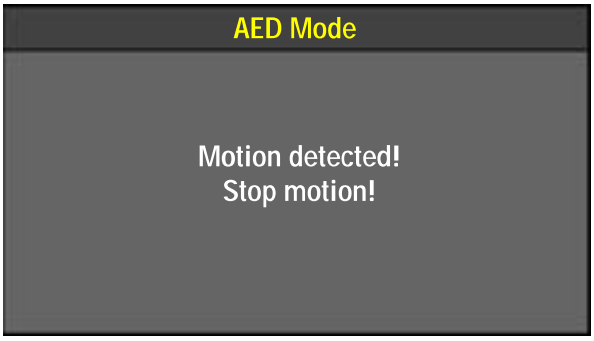
Note: The CPR metronome automatically provides audible compression "tocks" and ventilation prompts or tones only during CPR intervals. To silence the metronome, press **CPR**. To un-silence the metronome, press **CPR** again.



When the CPR countdown time ends, the **PUSH ANALYZE** prompts occur. These prompts repeat every 20 seconds until you press **ANALYZE**.

Subsequent analysis for **SHOCK ADVISED** and **NO SHOCK ADVISED** sequences are the same as described above. The energy level for Shock 2, 3, and greater depends on the **ENERGY PROTOCOL** setup and the analysis decision. When a **NO SHOCK ADVISED** decision follows a shock, the energy level does not increase for the next shock. When a **SHOCK ADVISED** decision follows a shock, the energy level increases for the next shock.

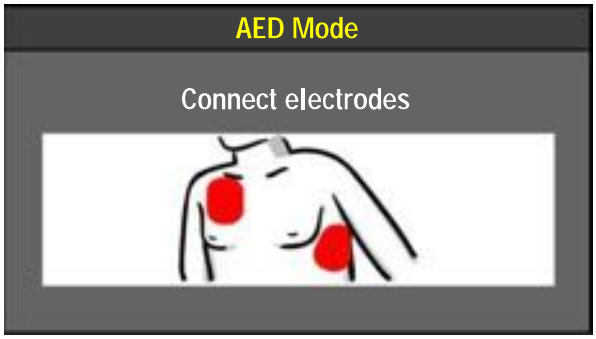
Motion Detected



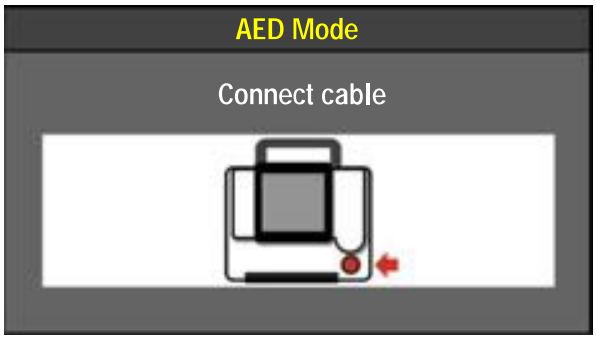
If the AED detects motion during the ECG analysis, the **MOTION DETECTED, STOP MOTION** prompts occur, followed by a warning tone.

Analysis is inhibited until the motion stops or for up to 10 seconds. After the motion ceases or 10 seconds have elapsed, analysis continues to completion even if motion is still present. For possible causes of motion detection and suggested solutions, see Table 5-1.

Electrodes or Therapy Cable Off



If therapy electrodes are not connected, the **CONNECT ELECTRODES** prompts occur until the patient is connected.



If the therapy cable is not connected to the defibrillator, the **CONNECT CABLE** message appears until the cable is connected.

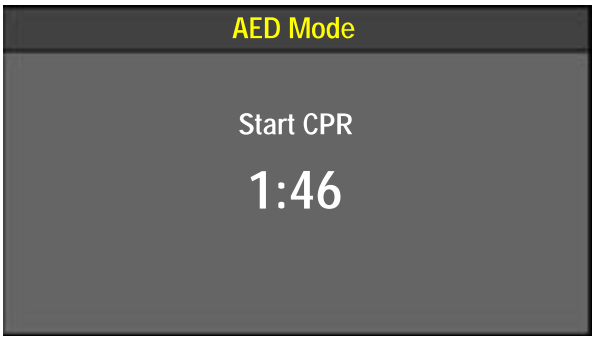
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Shock Counter



The shock counter (x) indicates how many shocks have been delivered to the patient. The shock counter resets to zero whenever the defibrillator is turned off for longer than 30 seconds.

CPR Time and Metronome



During use, CPR time shown on the countdown timer will vary slightly due to the metronome. When the CPR metronome is active during use, CPR times are adjusted to end CPR compression "tocks" on a compression cycle. As a result, the CPR countdown timer shows CPR times that approximate the seconds selected in Setup mode.

Even if the metronome is off or silent during CPR time, the CPR time displayed will vary slightly from the time set up in Setup mode. This is because the metronome keeps track of compression "tocks" and ventilation prompts in the background so that if the metronome is activated, the CPR time ends with compressions.

Switching from AED Mode to Manual Mode

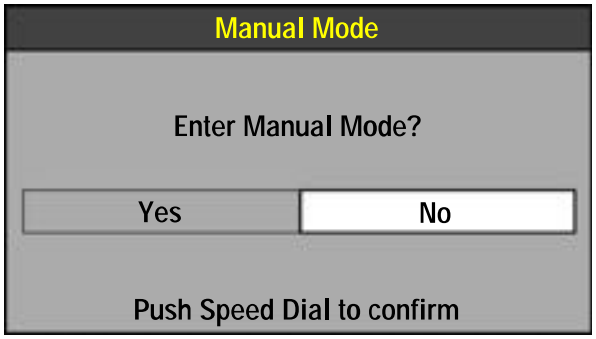
When in AED mode, Manual mode may be accessed directly, require confirmation or a passcode, or not be accessible at all depending on how your defibrillator has been set up.

To switch from AED mode to Manual mode, press **ENERGY SELECT** one time. You can also press **PACER** or **CHARGE** to switch from AED mode to Manual mode.

Note: If the metronome is active (providing compression "tocks" and ventilation prompts) when you switch from AED mode to Manual mode, the metronome stays active upon entering Manual mode.

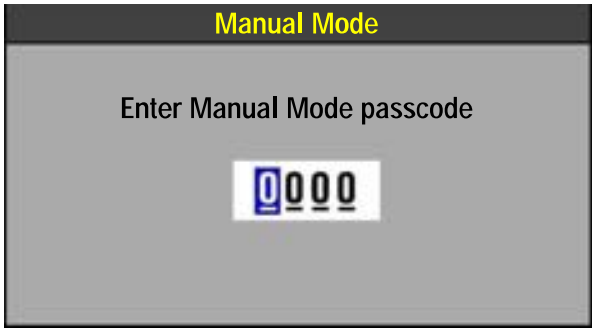
Depending on how manual access is set up, continue to Manual mode as follows:

- **AED/Direct**—No restrictions to Manual mode access.
- **AED/Confirmed**—A confirmation screen appears.



Select **YES** to enter Manual mode.

- **AED/Passcode**—A passcode screen appears:



Rotate and press the **SPEED DIAL** to enter the passcode.

The code changes to dots to protect the passcode, and the defibrillator enters Manual mode.

You have three opportunities to enter the correct password. After an incorrect attempt, the message **INCORRECT--TRY AGAIN** appears. After three incorrect attempts, the message **ACCESS DENIED** appears, and the defibrillator returns to AED mode.

- **Restricted**—A **MANUAL MODE DISABLED** message appears, an alert tone sounds, and the LIFEPAK 15 monitor/defibrillator returns to AED mode.

It is important that all users of the LIFEPAK 15 monitor/defibrillator be thoroughly familiar with the monitor/defibrillator settings and operation before use.

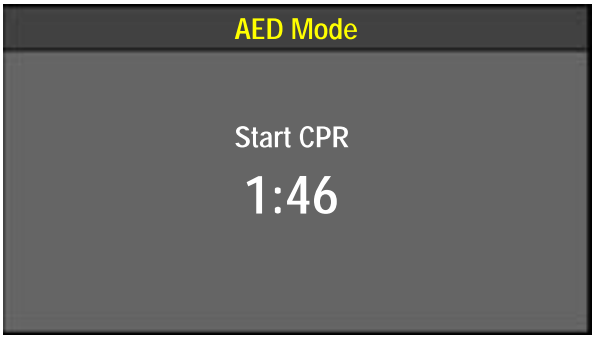
Special AED Setup Options

The following descriptions of AED prompts (voice and text) explain special setup options.

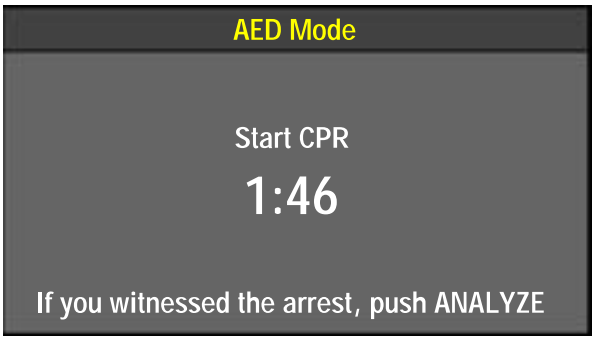
Initial CPR - CPR First

When the **INITIAL CPR** option is set to **CPR FIRST**, you are prompted to **START CPR** immediately after the AED is turned on, and before an analysis.

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The **START CPR** prompts occur.



After 3 seconds, a countdown timer appears and the **IF YOU WITNESSED THE ARREST, PUSH ANALYZE** prompts occur. These prompts provide an opportunity to end the initial CPR early and proceed directly to analysis.

Note: The decision to end CPR early is based on your protocol and if you witnessed the arrest.

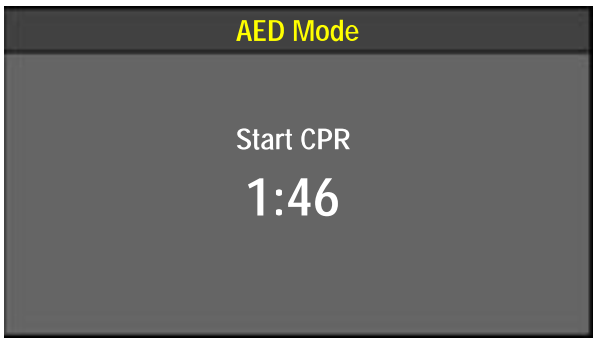
- If you did witness the arrest, press **ANALYZE.** The CPR period ends, and the **ANALYZING NOW, STAND CLEAR** prompts occur.
- If you did not witness the arrest, perform CPR and do not press **ANALYZE.** The Initial CPR countdown timer continues for the duration specified in the **INITIAL CPR TIME** setup option, for example, 90 seconds. When initial CPR time ends, the **PUSH ANALYZE** prompts occur.

Initial CPR - Analyze First

When the **INITIAL CPR** option is set to **ANALYZE FIRST**, you are prompted to perform analysis after the AED is turned on. CPR is prompted after the AED completes the analysis.

If the electrodes are not attached to the patient, the **CONNECT ELECTRODES** prompts occur before you are prompted to perform analysis.

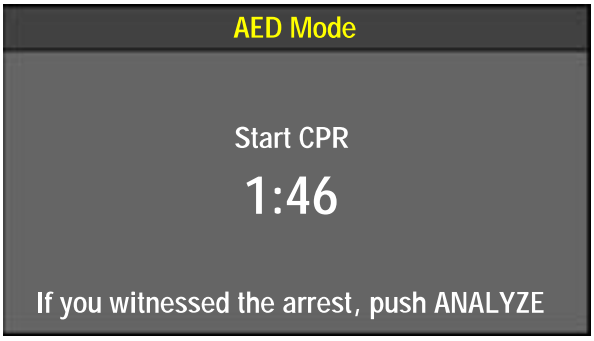
No Shock Advised If the AED detects a nonshockable rhythm, the **START CPR** prompts occur.



A countdown timer (min:sec format) continues for the duration specified in the **INITIAL CPR TIME** setup option.

When initial CPR time ends, the **NO SHOCK ADVISED** prompts occur, followed by **PUSH ANALYZE.**

Shock Advised If the AED detects a shockable rhythm, the **START CPR** prompts occur, followed by **IF YOU WITNESSED THE ARREST, PUSH ANALYZE.**



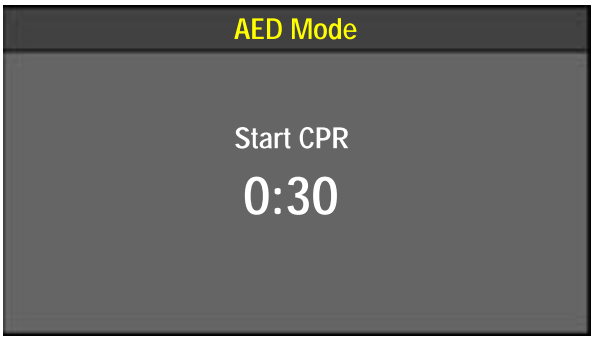
These prompts provide an opportunity to end the initial CPR early and proceed directly to delivering a shock.

Note: The decision to end CPR early is based on your protocol and if you witnessed the arrest.

- If you did witness the arrest, press **ANALYZE.** This ends the initial CPR period and the **SHOCK ADVISED** and **STAND CLEAR, PUSH SHOCK BUTTON!** (⚡) prompts occur. Proceed according to your training with the AED for delivering the shock.
- If you did not witness the arrest, perform CPR and do not press **ANALYZE** to end CPR early. The Initial CPR countdown timer continues for the duration specified in the **INITIAL CPR TIME** setup option, for example, 90 seconds. Near the end of CPR time, the defibrillator silently charges to prepare for the shock. CPR continues up to shock delivery. When initial CPR time ends, the **SHOCK ADVISED** and **STAND CLEAR, PUSH SHOCK BUTTON!** (⚡) prompts occur. Proceed according to your training with the AED for delivering a shock.

Pre-shock CPR Time

When **PRE-SHOCK CPR** time is set to 15 seconds or more, you are prompted to start CPR immediately after a shockable rhythm is detected, before the shock is delivered.



After analysis is complete, the **START CPR** prompts occur. A countdown timer (min:sec format) continues for the duration specified in the **PRE-SHOCK CPR** time setup option.

The defibrillator silently charges in preparation for the shock.

When CPR time ends, the **SHOCK ADVISED** and **STAND CLEAR, PUSH SHOCK BUTTON!** (⚡) prompts occur. Proceed according to your training with the AED for delivering a shock.

Note: The ⚡ (shock) button is disabled during the pre-shock CPR interval to avoid accidental shock delivery while the defibrillator is charged and a responder is performing CPR.

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Advisory Monitoring

Advisory Monitoring is a special way to set up AED mode that allows the use of all the monitoring functions without initiating the AED prompted protocol when the device is turned on. When needed, the AED mode prompted protocol can be initiated by pressing **ANALYZE**. In addition, access to Manual mode therapies—that is, manual defibrillation, synchronized cardioversion, or pacing—by unauthorized users can be restricted, if necessary.

Certain setup options must be changed for the device to operate in Advisory Monitoring when it is turned on. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

When set up for Advisory Monitoring and the monitor is turned on, the **ADVISORY MODE-MONITORING** message appears continuously in the message area on the Home Screen. Monitor functions such as NIBP, SpO_2 and 12-lead ECG can be used. Lead II and dashes are shown in the top ECG trace (Channel 1) unless or until the patient is connected to the ECG cable. If therapy electrodes (pads) and the therapy cable are connected to the patient, press **LEAD** to change to **PADDLES** lead and view the ECG.

In Advisory Monitoring, **LEAD II** and **PADDLES** lead are the only ECG monitoring leads allowed in Channel 1. The Continuous Patient Surveillance System (CPSS) is active and automatically evaluates the patient ECG. However, CPSS is evaluating only for a potentially shockable rhythm. If a shockable ECG rhythm such as VF is detected, the **PUSH ANALYZE** prompt occurs.

Pressing **ANALYZE** causes the device to enter AED Mode. Prior to pressing **ANALYZE**, confirm that the patient is in cardiac arrest. Motion artifact, a low amplitude ECG, and other causes of poor ECG signal may cause false CPSS alerts. If the patient is not in cardiac arrest, do not press **ANALYZE**. Troubleshoot the cause of the false CPSS alert.

If the patient is in cardiac arrest, press **ANALYZE**. The defibrillator begins the AED prompted protocol and analyzes the patient's ECG when therapy electrodes are applied to the patient. For more information about defibrillator behavior in AED mode, see "Automated External Defibrillation (AED)" on page 5-7.

Note: CPSS only evaluates for shockable ECG rhythms. If the ECG rhythm is nonshockable, for example asystole, no prompting occurs. Users who are not trained to interpret ECGs or are trained only to use AED mode must always press **ANALYZE** when using this special setup function to initiate ECG analysis and AED prompting.

To switch back to Advisory Monitoring from AED prompted protocol, press **LEAD**.

For information about limiting access to Manual mode by unauthorized users, see "CPR Time and Metronome" on page 5-14, or see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

Troubleshooting Tips

Table 5-1 Troubleshooting Tips for AED Mode

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
CONNECT ELECTRODES message appears	Therapy electrodes are not connected to the therapy cable	• Check for electrode connection.
	Electrodes do not adhere properly to the patient	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended. • Replace the electrodes.
	Electrodes are dry, damaged, or out of date	• Apply new electrodes.
	Therapy cable damaged	• Replace therapy cable and perform daily checks per Operator's Checklist.
CONNECT CABLE message appears	Therapy cable is disconnected during charging	• Reconnect cable and press **CHARGE** again.
	Therapy cable damaged	• Replace therapy cable and perform daily checks per Operator's Checklist.
MOTION DETECTED and **STOP MOTION** messages appear during analysis	Patient movement	• Stop CPR during analysis. • When patient is being manually ventilated, press **ANALYZE** after complete exhalation.
	Patient movement because of agonal respirations	• Allow analysis to proceed to completion—analysis is delayed no more than 10 seconds due to motion detection.
	Electrical/radio frequency interference	• Move hand-held communication devices or other suspected devices away from the defibrillator, when possible.
	Vehicle motion	• Stop vehicle during analysis. • Move patient to stable location, when possible.

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Table 5-1 Troubleshooting Tips for AED Mode (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
DISARMING message appears (energy charge removed)	(shock) button not pressed within 60 seconds after charge complete	• Recharge the defibrillator, if desired.
	SPEED DIAL pressed	• Recharge the defibrillator.
	Therapy electrodes or cable disconnected	• Reconnect electrode or cable.
Energy did not escalate	After a shock, the next analysis was **NO SHOCK ADVISED**	• No action needed. Defibrillator does not escalate energy when a **NO SHOCK ADVISED** decision follows a shock.
Charge time to 360 joules exceeds 10 seconds	Battery low	• Replace battery with fully charged battery.
	Operating temperature is too low	• Move patient and device to warmer environment, if necessary.
REPLACE BATTERY prompt occurs	Both batteries are very low	• Replace one or both batteries immediately.
Voice prompts sound faint or distorted	Low battery power	• Replace the battery immediately.
CPR time shown (minutes/seconds) is different than expected	Function of metronome	• None. The metronome adjusts the CPR time to ensure CPR cycle ends with compressions. (See page 5-14.)
	Incorrect setup option selected	• Change CPR time setup option. See *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.
Press **CPR** and metronome does not activate	In AED mode, and not in CPR interval	• Wait until CPR interval (audible "tocks") to silence or activate metronome.
Home Screen is blank but **ON** LED is illuminated	Screen not functioning properly	• Press **ANALYZE** and follow voice prompts to treat patient.
Analysis result is **NO SHOCK ADVISED** and ECG shows a perfectly flat, isoelectric line.	The Test Load is connected to therapy cable	• Remove the Test Load and connect therapy electrodes to the cable.

For general troubleshooting tips, see Table 9-2 on page 9-18.

Manual Defibrillation

The LIFEPAK 15 monitor/defibrillator provides manual defibrillation using adult and pediatric QUIK-COMBO pacing/defibrillation/ECG electrodes, adult standard paddles, or pediatric paddles. For more information, see "Paddle Accessory Options" on page 6-1.

The LIFEPAK 15 monitor/defibrillator is capable of providing intra-operative direct defibrillation and synchronized cardioversion with the internal paddles accessory designed for the LIFEPAK 15 defibrillator. For more information, see the Instructions for Use for the internal handles and paddles with discharge control.

Intended Use

When used in Manual mode, the LIFEPAK 15 monitor/defibrillator is a direct current defibrillator that applies a brief, intense pulse of electricity to the heart muscle. Manual mode requires operator interpretation of the ECG rhythm and interaction with the device in order to defibrillate the patient.

Manual mode defibrillation and synchronized cardioversion are intended for use by personnel who are authorized by a physician or medical director and have, at a minimum, the following skills and training:

- Arrhythmia recognition and treatment
- Advanced resuscitation training equivalent to that recommended by the AHA or ERC
- Training on the use of the LIFEPAK 15 monitor/defibrillator

Defibrillation is only one aspect of the medical care required to resuscitate a patient who has a shockable ECG rhythm. Depending on the situation, other supportive measures may include:

- Cardiopulmonary resuscitation (CPR)
- Administration of supplemental oxygen
- Drug therapy

Indications

Manual defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia and, in relatively stable patients, ventricular tachycardia.

Contraindications

Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

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Manual Defibrillation Warnings

WARNINGS

SHOCK HAZARD

Conductive gel (wet or dry) on the paddle handles can allow the electrical energy to discharge through the operator during defibrillation. Completely clean the paddle electrode surfaces, handles, and storage area after defibrillation.

BURNS AND INEFFECTIVE ENERGY DELIVERY HAZARDS

POSSIBLE FIRE, BURNS, AND INEFFECTIVE ENERGY DELIVERY

Precordial lead electrodes and lead wires may interfere with the placement of standard paddles or therapy electrodes. Before defibrillation, remove any interfering precordial lead electrodes and lead wires.

POSSIBLE BURNS AND INEFFECTIVE ENERGY DELIVERY

A gel pathway on the skin between the standard paddles will cause defibrillating energy to arc between paddles and divert energy away from the heart muscle. Do not allow conductive gel (wet or dry) to become continuous between paddle sites.

POSSIBLE PATIENT SKIN BURNS

During defibrillation, air pockets between the skin and standard paddles can cause patient skin burns. Completely cover paddle electrode surfaces with fresh conductive gel and apply 25 lb of pressure per paddle during discharge.

POSSIBLE PADDLE DAMAGE AND PATIENT SKIN BURNS

Discharging the defibrillator with the standard paddle surfaces shorted together can pit or damage the paddle electrode surface. Pitted or damaged paddle surfaces may cause patient skin burns during defibrillation. Discharge the defibrillator only as described in these operating instructions.

POSSIBLE INCORRECT ENERGY DELIVERY

The defibrillator does not automatically adjust energy when using pediatric therapy electrodes or pediatric standard paddles. Manually select the appropriate energy prior to defibrillating the patient.

Manual Mode

The LIFEPAK 15 monitor/defibrillator is set up to operate in Manual mode when it is turned on (factory default setting). If required by your protocols, the defibrillator can be set up to power on in the automated external defibrillator (AED) mode. For information on switching from AED mode to Manual mode, see "CPR Time and Metronome" on page 5-14.

Manual Defibrillation Procedure

To perform manual defibrillation:

1. Verify that the patient is in cardiopulmonary arrest (unconscious, pulseless, not breathing normally).
2. Press **ON**.
3. Identify the electrode or paddle sites on the patient and prepare the patient's skin. (See "Patient Skin Preparation" on page 5-4.) Use either the anterior-lateral or anterior-posterior position.
4. Connect the therapy electrodes to the therapy cable and confirm cable connection to the defibrillator.
5. Apply therapy electrodes to the patient in anterior-lateral or anterior-posterior position. If using standard paddles, apply conductive gel to the paddles and place paddles on the patient's chest in the anterior-lateral position.
6. Confirm desired energy is selected, or press **ENERGY SELECT** or rotate the **SPEED DIAL** to select the desired energy. On the standard (hard) paddles, rotate the **ENERGY SELECT** dial.
7. Press **CHARGE.** While the defibrillator is charging, a charging bar appears and a ramping tone sounds, indicating the charging energy level. When the defibrillator is fully charged, the screen displays available energy.
8. Make certain all personnel, including the operator, stand clear of the patient, stretcher, bed, and any equipment connected to the patient.
9. Confirm ECG rhythm requires defibrillation. Confirm available energy.
10. Press the ⚡ (shock) button on the defibrillator or the ⚡ (shock) buttons on the standard paddles to discharge energy to the patient. For standard paddles, apply firm pressure with both paddles to the patient's chest, and press both paddle buttons simultaneously to discharge energy to the patient. For safety reasons, the ⚡ (shock) button on the defibrillator front panel is disabled when using standard paddles.

    Note: To disarm (cancel the charge), press the **SPEED DIAL.** The defibrillator disarms automatically if shock buttons are not pressed within 60 seconds, or if you change the energy selection after charging begins.

    Note: To interrupt defibrillation and initiate pacing, press **PACER**. If charged, the defibrillator disarms.
11. Start CPR according to your protocol. To activate the metronome, press **CPR** at any time.
12. At the end of your CPR period, observe the patient and the ECG rhythm. If an additional shock is necessary, repeat the procedure beginning at Step 6.

Successful resuscitation is related to the length of time between the onset of a heart rhythm that does not circulate blood (ventricular fibrillation, pulseless ventricular tachycardia) and defibrillation. The physiological state of the patient may affect the likelihood of successful defibrillation. Thus, failure to resuscitate a patient is not a reliable indicator of defibrillator

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performance. Patients often exhibit a muscular response (such as jumping or twitching) during an energy transfer. The absence of such a response is not a reliable indicator of actual energy delivery or device performance.

Using the CPR Metronome

When CPR is required during cardiac arrest, the CPR metronome provides audible prompts that guide the user to deliver CPR with proper timing in accordance with the 2005 American Heart Association and European Resuscitation Council CPR guidelines.

CPR Metronome Warnings

WARNING

CPR DELIVERED WHEN NOT NEEDED

The metronome sounds do not indicate information regarding the patient's condition. Because patient status can change in a short time, the patient should be assessed at all times. Do not perform CPR on a patient who is responsive or is breathing normally.

Note: The CPR metronome is a tool to be used as a timing aid during CPR. Assess the patient at all times and provide CPR only when indicated. Provide CPR according to your training and protocols.

How the CPR Metronome Works

The metronome provides audible "tocks" at a rate of 100/minute to guide the rescuer in performing chest compressions. The metronome also provides audible ventilation prompts (either a tone or verbal "ventilate") to cue the rescuer when to provide ventilations. The metronome prompts the rescuer to perform CPR at the selected compression to ventilation (C:V) ratio.

Age-Airway Considerations

The default C:V ratio for the metronome (in both AED and Manual modes) is Adult - No Airway (30:2) because most patients in cardiac arrest are adults who have an initially unsecured airway. In Manual mode, the user can choose the most appropriate C:V ratio based on the patient's age and current airway status. The Age-Airway selection determines the C:V ratio of the metronome sounds. The default C:V ratios are shown in Table 5-2.

Table 5-2 Default Age-Airway C:V Ratios in Manual Mode

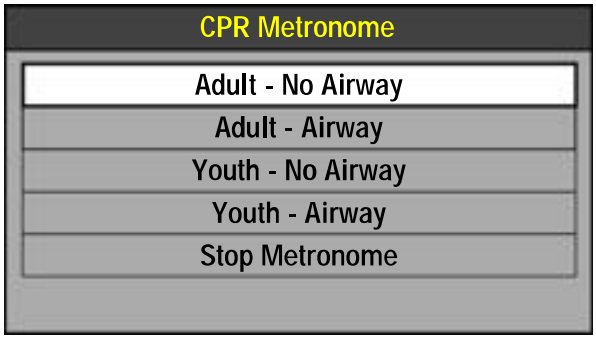
AGE-AIRWAY	C:V RATIO
Adult - No Airway*	30:2
Adult - Airway**	10:1
Youth - No Airway***	15:2
Youth - Airway	10:1

* No Airway = No artificial airway in place
** Airway = Advanced artificial airway in place
*** Youth = Pre-pubescent child

Note: The compression-to-ventilation ratio selections can be set up according to local medical protocols. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

Activating and Deactivating the Metronome

To activate the CPR metronome in Manual mode:



1. Press **CPR**. The CPR Metronome menu appears and the metronome is activated using the Adult-No Airway default setting.
2. Use the **SPEED DIAL** to highlight and select the desired Age-Airway setting.



When the metronome is on, a message appears in the message area that indicates the current Age-Airway selection.

Note: If the VF/VT alarm is on, it is suspended when the metronome is on to prevent false VF/VT alarms. If other vital sign alarms activate when the metronome is on, the visual indicators occur, but the alarm tone is suppressed until the metronome is deactivated.

The metronome provides "tocks" and ventilation prompts continuously until it is deactivated. To stop the metronome, select **STOP METRONOME** in the CPR Metronome menu. An event is recorded in the CODE SUMMARY Event Log when CPR metronome is turned ON or OFF and when the Age-Airway setting is changed. To adjust the volume of the metronome, press **OPTIONS**, select **ALARM VOLUME**, and change the **VOLUME**.

Note: If all Age-Airway selections are set to the same C:V ratio (for example, Adult - No Airway, Adult - Airway, Youth - No Airway, and Youth - Airway all set to 10:1), the CPR metronome always provides "tocks" and ventilation prompts at the set ratio for both AED mode and Manual

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mode. In this situation, the CPR Metronome menu does not appear when **CPR** is pressed during use—pressing the **CPR** button only activates and deactivates the metronome at the fixed C:V ratio.

Synchronized Cardioversion Procedure

The LIFEPAK 15 monitor/defibrillator can be set up to remain in Sync mode or to return to Asynchronous mode after a shock is delivered. The factory default setting is to return to Asynchronous mode after a shock. It is important that you know how your defibrillator is set up. For information about changing the setup option, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

To perform synchronized cardioversion:

1. Press **ON**.
2. Attach patient ECG cable and ECG electrodes as previously described (see "Monitoring the ECG" on page 4-3). ECG electrodes and cable must be used to monitor the ECG when standard paddles are used for cardioversion.
3. Select Lead **II** or lead with greatest QRS complex amplitude (positive or negative).

   Note: To monitor the ECG using therapy electrodes, place the electrodes in anterior-lateral position and select **PADDLES** lead.

WARNING

POSSIBLE LETHAL ARRHYTHMIA

Ventricular fibrillation may be induced with improper synchronization. DO NOT use the ECG from another monitor (slaving) to synchronize the monitor/defibrillator's discharge. Always monitor the patient's ECG directly through the defibrillator's ECG cable or therapy cable. Confirm proper placement of the sense markers on the ECG.

4. Press **SYNC.** The **SYNC MODE** message appears in the message area when Sync is active.

   Note: Press **SYNC** again to deactivate Sync mode.
5. Observe the ECG rhythm. Confirm that a triangle sense marker (▼) appears near the middle of each QRS complex. If the sense markers do not appear or are displayed in the wrong locations (for example, on the T-wave), adjust **ECG SIZE** or select another lead. (It is normal for the sense marker location to vary slightly on each QRS complex.)
6. Connect the therapy electrodes to the therapy cable and confirm cable connection to the defibrillator.

7. Prepare the patient's skin and apply therapy electrodes to the patient in the anterior-lateral position. (See "Therapy Electrode and Standard Paddle Placement" on page 5-4.) If using standard paddles, apply conductive gel to the paddles and place paddles on the patient's chest.
8. Press **ENERGY SELECT** or rotate the **SPEED DIAL** to select the desired energy. On the standard (hard) paddles, rotate the **ENERGY SELECT** dial.
9. Press **CHARGE**. While the defibrillator is charging, a charging bar appears and a ramping tone sounds, indicating the charging energy level. When the defibrillator is fully charged, the screen displays available energy.
10. Make certain all personnel, including the operator, stand clear of the patient, bed, and any equipment connected to the patient.
11. Confirm ECG rhythm. Confirm available energy.
12. Press and *hold* the (shock) button on the defibrillator until the **ENERGY DELIVERED** message appears on the screen. For standard paddles, press and hold both (shock) buttons on the paddles simultaneously until the **ENERGY DELIVERED** message appears on the screen. Release buttons. For safety reasons, the (shock) button on the defibrillator front panel is disabled when using standard paddles.

    Note: To disarm (cancel a charge), press the **SPEED DIAL**. The defibrillator disarms automatically if shock buttons are not pressed within 60 seconds, or if you change the energy selection after charging begins.
13. Observe patient and ECG rhythm. Repeat procedure starting from Step 4, if necessary.

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Troubleshooting Tips

Table 5-3 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Charge time to 360 joules exceeds 10 seconds	Battery low	• Replace battery with fully charged battery.
	Operating temperature is too low	• Move patient and device to warmer environment, if necessary.
Energy not delivered to patient when ⚡ (shock) buttons are pressed	Device is in Sync mode and QRS complexes are not detected	• Adjust ECG size for optimum sensing QRS or deactivate **SYNC** if rhythm VF/VT.
	SYNC accidentally pressed and rhythm is VF/VT	• Press **SYNC** to turn off Sync. • Press ⚡ (shock) buttons.
	Device in Sync mode and ⚡ (shock) buttons not pressed and held until next detected QRS	• Hold ⚡ (shock) buttons until discharge occurs or next detected QRS and **ENERGY DELIVERED** message appears.
	⚡ (shock) buttons pressed before full charge reached	• Wait for tone and message indicating full charge.
	Standard paddles connected and ⚡ (shock) button on defibrillator front panel pressed	• Simultaneously press ⚡ (shock) buttons on standard paddles to discharge.
	Sixty seconds elapsed before ⚡ (shock) buttons were pressed after full charge. Energy was internally removed.	• Press ⚡ (shock) buttons within 60 seconds of full charge.
	Energy selection changed	• Press **CHARGE** again.
CONNECT CABLE message appears	Therapy cable is disconnected during charging	• Reconnect cable and press **CHARGE** again.
	Therapy cable damaged	• Replace therapy cable and perform daily checks per Operator's Checklist.
ENERGY FAULT message appears (selected and available energy)	Defibrillator out of calibration	• Attempt to transfer energy. • Contact a qualified service technician.

Table 5-3 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
DISARMING message appears	⚡ (shock) button not pressed within 60 seconds after charge complete	• Recharge the defibrillator, if desired.
	Energy selected after charge complete	• Recharge the defibrillator.
	SPEED DIAL pressed	• Recharge the defibrillator.
	PACER pressed	• Recharge, if necessary, or no action, if pacing desired.
	Therapy electrodes or cable disconnected	• Reconnect electrode or cable.
Energy did not escalate automatically per energy protocol	**ENERGY SELECT** pressed and disabled automatic protocol	• Continue to select energy manually to treat patient. For more information about energy protocol, see *LIFEPAK 15 Monitor/ Defibrillator Setup Options* provided with your device.
SYNC mode will not activate	**PACER** is on. Pacing and Sync are separate functions and are not allowed at the same time.	• Discontinue pacing, if appropriate for the patient, and press **SYNC**.
	ECG electrodes not attached to patient and standard paddles connected to defibrillator	• Connect ECG electrodes to patient.
Patient did not "jump" (no muscle response) during defibrillator discharge	Patient muscle response is variable and depends on patient condition. Lack of visible response to defibrillation does not necessarily mean the discharge did not occur.	• No action needed.
	The Test Load is connected to therapy cable	• Remove the Test Load and connect therapy electrodes to cable.

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Table 5-3 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
ABNORMAL ENERGY DELIVERY message appears and Shock XJ Abnormal annotated on printout	Open air discharge with standard paddles	• Press paddles firmly on patient's chest when discharging.
	Standard paddles placed face-to-face when ⚡ (shock) button pressed	• Perform test discharges per Operator's Checklist. • See "Manual Defibrillation Warnings" on page 5-22.
	Patient impedance is out of range	• Increase energy or repeat shocks as needed. • Consider replacing disposable therapy electrodes with new ones.
	Internal fault occurred	• Repeat shock. • Perform CPR and obtain another defibrillator, if necessary.
CONNECT ELECTRODES message appears	Therapy electrodes are not connected to the therapy cable	• Check for electrode connection.
	Electrodes do not adhere properly to the patient	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended. • Apply new electrodes.
	Electrodes are dry, damaged, or out of date	• Apply new electrodes.
	Therapy cable damaged	• Replace therapy cable and perform daily checks per Operator's Checklist.
REPLACE BATTERY prompt occurs	Both batteries are very low	• Replace one or both batteries immediately.
CPR time shown (minutes/seconds) is different than expected	Metronome is on	• None. The metronome adjusts the CPR time to ensure CPR cycle ends with compressions.
	Incorrect setup option selected	• Change CPR time setup option. See *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

Table 5-3 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Home Screen is blank but **ON** LED is illuminated	Screen not functioning properly	• Print ECG strip to assess rhythm and other active vital signs. • Press **ANALYZE** and use AED mode, if necessary.

For general troubleshooting tips, see Table 9-2 on page 9-18.

Noninvasive Pacing

The LIFEPAK 15 monitor/defibrillator provides noninvasive pacing using adult or pediatric QUIK-COMBO pacing/defibrillation/ECG electrodes. For more information, see Chapter 6, "Paddle Accessory Options."

Intended Use

A noninvasive pacemaker is a device that delivers an electrical stimulus to the heart causing cardiac depolarization and myocardial contraction. The energy is delivered through large adhesive electrodes placed on the chest. In addition to noninvasive pacing, other supportive measures may be necessary.

Noninvasive pacing is intended for use by personnel who are authorized by a physician or medical director and have, at a minimum, the following skills and training:

- Arrhythmia recognition and treatment
- Advanced resuscitation training equivalent to that recommended by the AHA or ERC
- Training on the use of the LIFEPAK 15 monitor/defibrillator

Indications

Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications

Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

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Noninvasive Pacing Warnings

WARNING

POSSIBLE INABILITY TO PACE

Using other manufacturers' combination therapy electrodes with this device could cause a decrease in pacing efficacy or the inability to pace because of unacceptably high impedance levels and invalidate the safety agency certifications. Use only the therapy electrodes that are specified in these operating instructions.

Demand and Nondemand Pacing

The LIFEPAK 15 monitor/defibrillator can be used for either demand or nondemand (asynchronous or "fixed rate") pacing.

Demand mode is used for most patients. In demand mode, the LIFEPAK 15 pacemaker inhibits pacing output when it "senses" the patient's own beats (intrinsic QRSs). In demand mode, if the ECG SIZE is set too low to detect the patient's beats, or if an ECG lead becomes detached so that the ECG rhythm is not present, the pacemaker generates pacing pulses asynchronously. This means that the pacemaker generates pacing pulses at the selected rate regardless of the patient's ECG rhythm.

Nondemand mode can be selected if noise or artifact interferes with proper sensing of QRS complexes. Press **OPTIONS** to access nondemand mode. For more information, see "Options" on page 3-23.

Noninvasive Pacing Procedure

ECG monitoring during pacing is performed with the ECG electrodes and patient ECG cable. Therapy electrodes are not capable of monitoring ECG and delivering pacing current at the same time.

Be sure to place the QUIK-COMBO therapy electrodes in the proper locations. Improper placement of the electrodes may make a difference in the capture threshold. For example, if the electrode placement is reversed, more pacing current may be needed to achieve capture.

WARNING

POSSIBLE INTERRUPTION OF THERAPY

Observe the patient continuously while the pacemaker is in use. Patient response to pacing therapy (for example, capture threshold) may change over time.

To perform noninvasive pacing:

1. Press **ON**.
2. Connect the patient ECG cable, apply ECG electrodes to the ECG cable and patient, and select Lead **I**, **II**, or **III**. To receive the best monitoring signal, make sure there is adequate space between the ECG electrodes and the therapy electrodes.
3. Identify the QUIK-COMBO therapy electrode sites on the patient. Use either the anterior-lateral or anterior-posterior position and prepare the patient's skin. (See "Therapy Electrode and Standard Paddle Placement" on page 5-4.)
4. Apply therapy electrodes to the patient.
5. Connect the therapy electrodes to the therapy cable.
6. Press **PACER**.

WARNING

POSSIBLE INEFFECTIVE PACING

The ECG size must be properly adjusted so that the patient's own beats are detected. If ECG size is set too high or too low, pacing pulses may not be delivered when required. Adjust ECG size so that sense markers are placed on the patient's QRS complexes.

7. Observe the ECG rhythm. Confirm that a triangle sense marker (▼) appears near the middle of each QRS complex. If the sense markers do not appear or are displayed in the wrong location (for example, on the T-wave), adjust **ECG SIZE**, or select another lead. (The sense marker location may vary slightly on each QRS complex.)
8. Press **RATE** or rotate the **SPEED DIAL** to select the desired pacing rate.
9. Press **CURRENT** or rotate the **SPEED DIAL** to increase current until electrical capture occurs. Electrical capture is indicated by a wide QRS complex and a T-wave following the pace marker. For each delivered pacing stimulus, a positive pace marker displays on the ECG waveform.

   Note: Dashes (---), not heart rate, are displayed on the Home Screen during noninvasive pacing, and heart rate alarms are disabled.

10. Palpate patient's pulse or check blood pressure to assess for mechanical capture. Consider use of sedation or analgesia if patient is uncomfortable.

    Note: To change rate or current during pacing, press **RATE** or **CURRENT**. The **RATE** and **CURRENT** buttons allow changes in increments of 10; the **SPEED DIAL** allows changes in increments of 5.

    Note: To interrupt pacing and view the patient's intrinsic rhythm, press and hold **PAUSE**. This causes the pacer to pace at 25% of the set rate. Release **PAUSE** to resume pacing at the set rate.

11. To stop pacing, reduce current to zero or press **PACER**.

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Note: To defibrillate and stop noninvasive pacing, press **CHARGE**. Pacing automatically stops. Proceed with defibrillation.

The physiologic state of the patient may affect the likelihood of successful pacing or of skeletal muscle activity. The failure to successfully pace a patient is not a reliable indicator of pacemaker performance. Similarly, the patient's muscular response to pacing is not a reliable indicator of current delivered.

WARNING

POSSIBLE PATIENT SKIN BURNS

Prolonged noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Discontinue noninvasive pacing if skin becomes burned and another method of pacing is available. For additional information about therapy electrodes, see "QUIK-COMBO Therapy Electrodes" on page 6-3.

If the monitor detects **ECG LEADS OFF** during pacing, pacing automatically switches to nondemand and continues at a fixed rate until the ECG lead is reattached. During nondemand pacing, the pacemaker delivers pulses at the set pace rate regardless of any intrinsic beats that the patient may have. The monitor continues to display the pacing rate (ppm) and the current (mA). To reestablish demand pacing, reattach the ECG lead.

While pacing, visually monitor the patient at all times—*do not* rely on the **ECG LEADS OFF** warning to detect changes in pacing function. Routinely assess for proper ECG sensing, pace pulse delivery, electrical capture, and mechanical capture.

If pacing electrodes detach during pacing, you see **CONNECT ELECTRODES** and **PACING STOPPED** messages and hear an alarm. The pacing rate is maintained and the current resets to 0 mA. Reattaching the pacing electrodes silences the alarm and removes the **CONNECT ELECTRODES** message. The current remains at 0 mA until you increase the current manually.

To turn off the LIFEPAK 15 monitor/defibrillator, pacing must be stopped. If the **ON** button is pressed when **PACER** is active, an alert tone sounds and the **PACING IN PROGRESS** message appears.

Troubleshooting Tips

Table 5-4 Troubleshooting Tips for Noninvasive Pacing

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Device does not function when **PACER** is pressed	Power off	• Check if power is **ON**.
	Low battery	• Replace battery with fully charged battery.
PACER LED is on, but **CURRENT (mA)** will not increase	Therapy electrodes off	• Check for message displayed. • Inspect therapy cable and electrode connections.
PACER LED on, **CURRENT (MA) >0,** but pace markers absent (not pacing)	Pacing rate set below patient's intrinsic rate	• Increase **PPM**.
	Pacer oversensing (ECG artifact, ECG size too high)	• Establish clean ECG; decrease ECG size. • Select nondemand pacing.
Monitor screen displays distortion while pacing	ECG electrodes not optimally placed with respect to pacing electrodes	• Reposition electrodes away from pacing electrodes. • Select another lead (I, II, or III).
Pacing stops spontaneously	**PACER** pressed off	• Press **PACER** and increase the current.
	Internal error detected. Service message indicates an internal failure.	• Check for service indicator. • Cycle power and start pacing again. • Obtain service by a qualified service technician.
	Therapy electrode off	• Check for message. Check pacing cable and electrode connections.
	CHARGE pressed	• Press **PACER** and increase current, if pacing desired. Otherwise, proceed with defibrillation.
	Radio frequency interference	• Move radio equipment away from pacemaker.

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Table 5-4 Troubleshooting Tips for Noninvasive Pacing (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
No muscle response to pacing	Patient's heart rate may be greater than noninvasive pacer ppm	• No action needed.
	The Test Load is connected to therapy cable	• Remove the Test Load and connect therapy electrodes to cable.
	Patient muscle response is variable and depends on patient condition. Muscular response to pacing is not a reliable indicator of current delivered.	• No action needed.
Capture does not occur with pacing stimulus	Current (mA) set too low	• Increase pacing current. (Administer sedation or analgesia as needed.)
CONNECT CABLE or **PACING STOPPED** message appears	Therapy cable damaged	• Replace therapy cable and perform daily checks per Operator's Checklist.
CONNECT ELECTRODES message appears	Pacing cable or electrode disconnected	• Reconnect and set current.
	Electrodes not adhering to skin	• Prepare skin.
	Therapy cable damaged	• Replace therapy cable and perform daily checks per Operator's Checklist.
	Electrodes outdated	• Replace electrodes and set current.
PACING IN PROGRESS message appears	**CPR** pressed	• Press **PACER** to stop pacing, if appropriate, and then press **CPR**.
Pacing stops spontaneously and **PACER FAULT** message appears	Internal error detected	• Cycle power and start pacing again. • Obtain service by a qualified service technician.
Intrinsic QRS complexes not sensed when pacing	ECG size too low	• Increase ECG size or select another lead.
	Intrinsic QRS complexes are occurring during pacemaker's refractory period	• Adjust PPM.

Table 5-4 Troubleshooting Tips for Noninvasive Pacing (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Pacing starts spontaneously	Patient's heart rate falls below set pacing rate	• Appropriate pacemaker function; assess patient.
	During standby pacing, ECG lead disconnects and pacing begins asynchronously	• Reconnect ECG lead.
Set pacing rate (ppm) and ECG paced rate do not appear to match	Internal error detected	• Print ECG and calculate the pace rate.
Improper sensing (for example, sensing on T-waves)	QRS complex too small	• Select another lead.
	T-wave too large	• Adjust ECG size.
SYNC mode will not activate	**PACER** is on. Pacing and Sync are separate functions and are not allowed at the same time.	• Discontinue pacing, if appropriate for the patient, and press **SYNC**.
Defibrillator will not turn off	Pacemaker is on	• Turn off **PACER** and then press and hold **ON** for at least 2 seconds.

For general troubleshooting tips, see Table 9-2 on page 9-18.

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Pediatric ECG Monitoring and Manual Mode Therapy Procedures

WARNINGS

BURN HAZARDS

POSSIBLE PATIENT SKIN BURNS

Do not use pediatric QUIK-COMBO electrodes on adults or larger children. Delivery of defibrillation energies equal to or greater than 100 joules (typically used on adults) through these smaller electrodes increases the possibility of skin burns.

POSSIBLE PEDIATRIC PATIENT SKIN BURNS

Noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Inspect underlying skin of the ♥ electrode frequently after 30 minutes of continuous pacing. Discontinue noninvasive pacing if skin burn develops and another method of pacing is available. On cessation of pacing, immediately remove or replace electrodes with new ones.

For pediatric patients, follow the procedures for ECG monitoring, manual defibrillation, synchronized cardioversion, and pacing except for the following:

- Use the appropriate paddle accessory based on the weight of the child.
- Select the appropriate defibrillation energy for the weight of the child according to the American Heart Association (AHA) recommendations or local protocol. Using energy levels of 100 joules or greater is likely to cause burns.
- When pacing, inspect the patient's skin under the heart electrode frequently for signs of burns.

Note: The amount of pacing current needed for capture is similar to the pacing current needed for adults. For more information about pediatric paddles and electrodes, see Chapter 6, "Paddle Accessory Options."

6

PADDLE ACCESSORY OPTIONS

This chapter provides information about the paddle accessory options that may be used with the LIFEPAK 15 monitor/defibrillator.

QUIK-COMBO Therapy Electrodes . . . . . page 6-3
Standard Paddles. 6-5

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QUIK-COMBO Therapy Electrodes

Physio-Control QUIK-COMBO therapy electrodes are pre-gelled, self-adhesive therapy electrodes used for defibrillation, synchronized cardioversion, ECG monitoring, and pacing (see Figure 6-1).

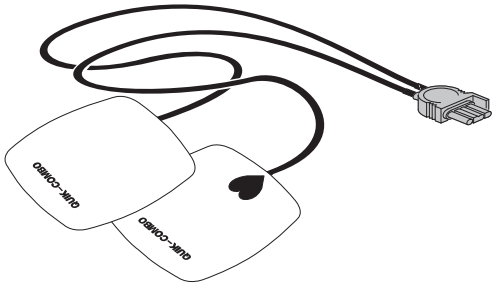


Figure 6-1 QUIK-COMBO Therapy Electrodes

A QUIK-COMBO therapy electrode set:

- Is a substitute for standard paddles.
- Provides Lead II monitoring signal when placed in the anterior-lateral position.
- Quickly restores the ECG trace on the monitor following defibrillation.

Always have immediate access to a spare set of therapy electrodes.

To help prevent therapy electrode damage:

- Only open electrode package immediately prior to use.
- Do not trim therapy electrodes.
- Do not crush, fold, or store the electrodes under heavy objects.
- Store therapy electrodes in a cool, dry location. These electrodes are designed to withstand environmental temperature fluctuations between -40° to 50° C (-40° to 122° F). Continuous exposure to temperatures above 23° C (73° F) reduces the shelf life of electrodes.

Several types of QUIK-COMBO therapy electrodes are available as described in Table 6-1.

IMPORTANT! Infant/Child Reduced Energy Defibrillation Electrodes are not compatible with the LIFEPAK 15 monitor/defibrillator.

Table 6-1 QUIK-COMBO Electrodes

TYPE	DESCRIPTION
QUIK-COMBO	Electrodes, with 61 cm (2 ft) of lead wire, designed for patients weighing 15 kg (33 lb) or more
QUIK-COMBO RTS	Electrodes, providing a radio-transparent electrode and lead wire set, designed for patients weighing 15 kg (33 lb) or more

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Table 6-1 QUIK-COMBO Electrodes (Continued)

TYPE	DESCRIPTION
QUIK-COMBO with REDI-PAK™ preconnect system	Electrodes designed for patients weighing 15 kg (33 lb) or more and that allow preconnection of the electrode set to the device while maintaining electrode shelf life and integrity
Pediatric QUIK-COMBO RTS	Electrodes designed for patients weighing 15 kg (33 lb) or less

Connecting Therapy Electrodes

To connect QUIK-COMBO therapy electrodes to the QUIK-COMBO therapy cable:

1. Open the protective cover on the therapy cable connector (see Figure 6-2).
2. To insert the QUIK-COMBO electrode connector into the therapy cable connector, align the arrows and press the connectors firmly together.

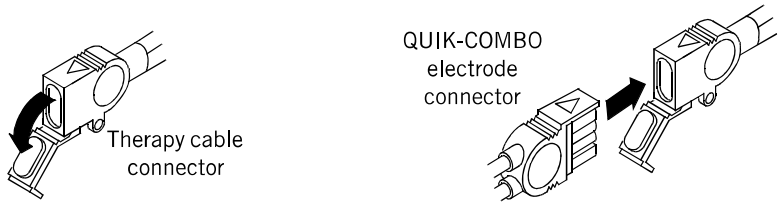


Figure 6-2 Connect QUIK-COMBO Electrodes to Therapy Cable

Replacing and Removing Therapy Electrodes

Replace adult QUIK-COMBO electrodes with new electrodes after one of the following occurs:

- 50 defibrillation shocks
- 24 hours on the patient's skin
- 8 hours of continuous pacing

Replace pediatric QUIK-COMBO electrodes with new electrodes after one of the following occurs:

- 25 defibrillation shocks
- 24 hours on the patient's skin
- 8 hours of continuous pacing

To remove QUIK-COMBO therapy electrodes from the patient:

1. Slowly peel back the therapy electrode from the edge, supporting the skin as shown in Figure 6-3.

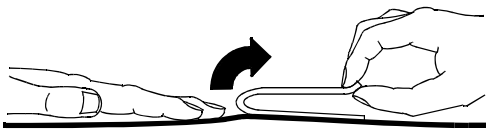


Figure 6-3 Removing Therapy Electrodes from Skin

2. Clean and dry the patient's skin.
3. When applying new electrodes, adjust the positions slightly to help prevent skin burns.
4. Close the protective cover on the therapy cable connector when the cable is not in use.

Cleaning

QUIK-COMBO electrodes are not sterile or sterilizable. They are disposable and are for a single patient application. Do not autoclave, gas sterilize, immerse in fluids, or clean electrodes with alcohol or solvents.

Include daily inspection of the QUIK-COMBO therapy electrode package as part of your defibrillator test routine. Daily inspection helps ensure that the therapy electrode has not exceeded the electrode package Use By date and is ready for use when needed. For more information about daily inspection and test, see the Operator's Checklist in the back of this manual.

Standard Paddles

Adult Standard Paddles

Standard paddles are hard, hand-held paddles that are applied to the patient's chest to briefly monitor the ECG or to deliver defibrillation shocks. Figure 6-4 describes the features of the standard paddles.

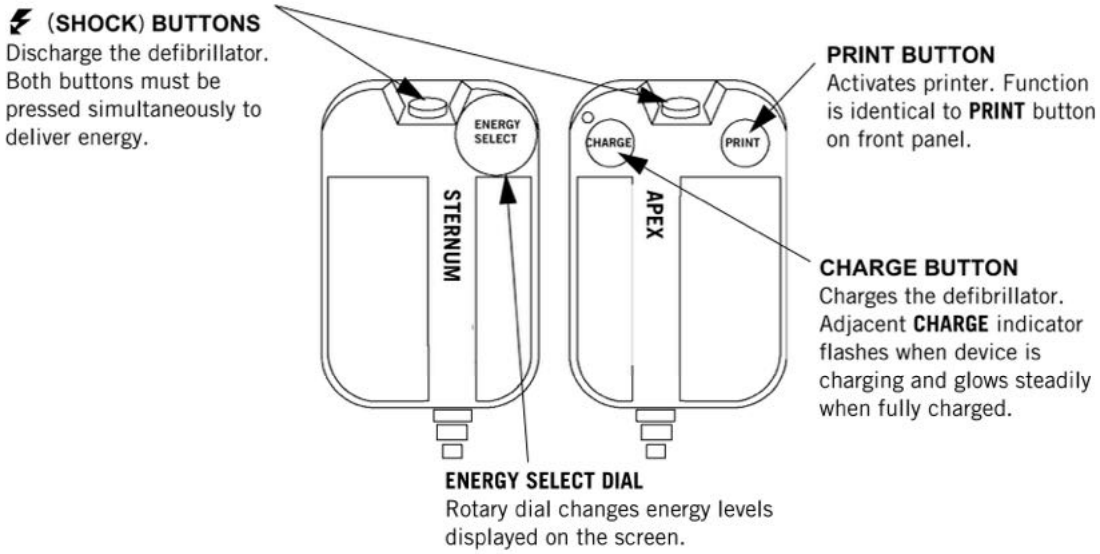


Figure 6-4 Standard Paddles

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A standard paddle set:

- Can be used instead of QUIK-COMBO therapy electrodes.
- Provides Lead II monitoring signal when held in the anterior-lateral position.
- Is used for defibrillation, synchronized cardioversion, and QUIK-LOOK® ECG checks.

To help prevent standard paddles damage:

- Handle with care to prevent damage to paddle surfaces.
- Store in paddle wells on the device to protect the electrode surface.
- Clean dried or wet gel from the electrode surface after each use.

Cleaning Standard Paddles

After each use:

1. Wipe standard paddle electrodes, handles, paddle wells, cables, and connector with mild disinfectant or soap and water solution. Do not immerse or soak.
2. Dry thoroughly.
3. Examine paddle surfaces, handles, cables, and connectors for damage or signs of wear.
   - Cables that show signs of wear such as loose cable connections, exposed wires, or cable connector corrosion must be removed from use immediately.
   - Paddles that have rough or pitted electrodes should be removed from use immediately.

Note: Standard paddles are not sterile or sterilizable. Do not autoclave, gas sterilize, immerse in fluids, or clean with alcohol or solvents.

Testing Standard Paddles

Include inspecting and testing of the standard paddles as part of your defibrillator test routine. Daily inspection and testing helps ensure that the standard paddles are in good operating condition and are ready for use when needed. For more information about inspection and testing, see the Operator's Checklist at the back of this manual.

Pediatric Paddles

Pediatric paddles slide onto adult paddles (see Figure 6-5). Pediatric paddles should be used for patients weighing less than 10 kg (22 lb) or for patients whose chest size cannot accommodate the adult hard paddles.

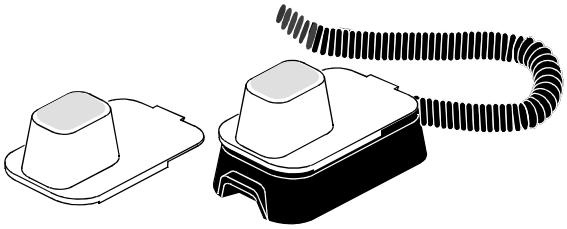


Figure 6-5 Pediatric Paddles

Use the adult paddle controls for selecting energy and charging. Each pediatric paddle attachment has a metal spring plate with a contact on it that transfers defibrillation energy from the adult paddle electrode to the pediatric paddle. This solid cadmium-silver contact will not scratch the adult paddle electrode.

Note: Inspect the spring plates and the contacts routinely to make sure that they are clean and intact.

Attaching Pediatric Paddles

To attach the pediatric paddles:

1. Slide the paddles onto clean adult paddles, starting at the front of the adult paddle (see Figure 6-6).
2. Slide the pediatric paddle until you feel the paddles lock in place.

Note: Do not use conductive gel *between* adult and pediatric paddles.

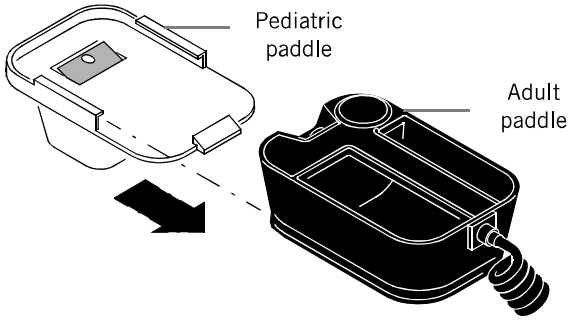


Figure 6-6 Attaching a Pediatric Paddle

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Removing Pediatric Paddles

To remove pediatric paddles:

1. Press down on the rear tab.
2. Slide the pediatric paddle off (see Figure 6-7).

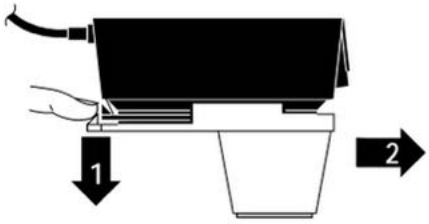


Figure 6-7 Removing a Pediatric Paddle

Placing Pediatric Paddles

Adult paddles are recommended if the paddles fit completely on the child's chest. Allow at least 2.5 cm (1 in) of space between the paddles.

For infants with very small chests, pediatric paddles may be too large to place in the anterior-lateral position. In this situation, place paddles in the anterior-posterior position. Holding the paddles against the chest and back supports the patient on his or her side.

Do not use the pediatric paddles on adults or older children. Delivery of recommended adult energies through this relatively small electrode surface increases the possibility of skin burns.

Anterior-Lateral Placement Standard pediatric paddle placement includes (see Figure 6-8):

- **STERNUM** paddle to the patient's right upper torso, lateral to the sternum and below the clavicle.
- **APEX** paddle lateral to the patient's left nipple in the midaxillary line, with the center of the paddle in the midaxillary line, if possible.



Figure 6-8 Anterior-Lateral Paddle Position

Anterior-Posterior Placement Place the **STERNUM** paddle anteriorly over the left precordium and the **APEX** paddle posteriorly behind the heart in the infrascapular area (see Figure 6-9).

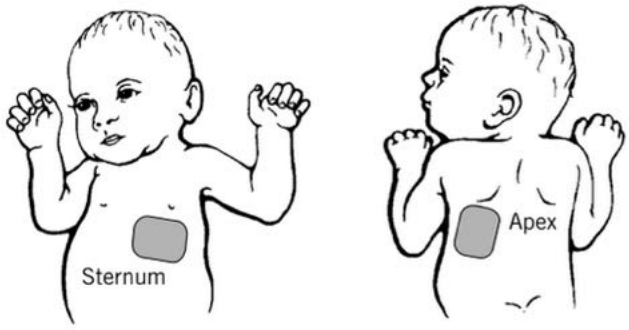


Figure 6-9 Anterior-Posterior Paddle Position

Cleaning Pediatric Paddles

Individually protect paddles before and after cleaning to prevent damage to paddle surfaces. After each use:

1. Wipe or rinse paddle electrodes, cable connector, paddle handles, and cables with mild soap and water or disinfectant using a damp sponge, towel, or brush. Do not immerse or soak.
2. Dry thoroughly.
3. Examine paddle surfaces, connector, handles, and cables for damage or signs of wear.
   - Cables that show signs of wear such as loose cable connections, exposed wires, or cable connector corrosion should be removed from use immediately.
   - Paddles that have rough or pitted electrodes should be removed from use immediately.

If necessary, sterilize this accessory according to the sterilization instructions provided with the accessory.

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7

DATA MANAGEMENT

This chapter describes how to manage current and archived Patient Records when using the LIFEPAK 15 monitor/defibrillator.

Patient Records and Reports . . . . . page 7-3
Memory Capacity 7-9
Managing Current Patient Records 7-10
Managing Archived Patient Records 7-11

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Patient Records and Reports

When you turn on the LIFEPAK 15 monitor/defibrillator, a new Patient Record is created and stamped with the current date and time. All events and associated waveforms are digitally stored in the Patient Record as reports, which you can print, transmit, or download to the LIFENET® Cardiac Care System, or to post-event review products such as CODE-STAT™ or DT EXPRESS™ software. For information on how to print a report, see "How to Print a Current Report" on page 7-10. For information on how to transmit or download a report, see Chapter 8, "Data Transmission." When you turn off the device, the current Patient Record is saved in the archives.

You can also print, transmit, download, or delete any Patient Records that are stored in the archives. To access the archives, press **OPTIONS** and then select **ARCHIVES**. When you enter Archive mode, patient monitoring ends and the current Patient Record is saved and closed. Turn off the device to exit Archive mode. For more information, see "Managing Archived Patient Records" on page 7-11.

Report Types

The reports that are available in a Patient Record depend on the features in your device and how your device is set up. For information on setting up your device, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device. Table 7-1 describes the various report types that may exist in a Patient Record and how they can be accessed.

Table 7-1 Report Types

REPORT TYPE	DESCRIPTION	PRINT FROM MONITOR	TRANSMIT
12-Lead ECG Report	The diagnostic 12-lead ECG report. For more information, see "Printed 12-Lead ECG Report Formats" on page 4-18.	X	X[1]
CODE SUMMARY™ Critical Event Record	Includes patient information, event and vital sign log, and waveforms associated with events (for example, defibrillation). For more information, see "CODE SUMMARY Report" on page 7-4.	X	X
Vital Signs Summary	Includes patient information, event and vital sign log.	X	X
Trend Summary	Includes patient information, vital sign log, and vital sign graphs.	X	X

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Table 7-1 Report Types (Continued)

REPORT TYPE	DESCRIPTION	PRINT FROM MONITOR	TRANSMIT
Snapshot Report	Includes patient information and 8 seconds of waveform data captured at the time of transmission.		X
Continuous ECG Report[2]	Provides real-time lead ECG data, acquired when the device is powered on and electrodes are connected to the patient. Only for post-event review with CODE-STAT or DT EXPRESS software.		X

[1] Transmission of a 12-lead ECG report automatically includes transmission of the Vital Signs Summary.
[2] To obtain CPR analytics using CODE-STAT software, the patient's ECG must be monitored using **PADDLES** lead in Channel 1.

CODE SUMMARY Report

The LIFEPAK 15 monitor/defibrillator automatically stores a CODE SUMMARY report as part of the Patient Record for each patient. The CODE SUMMARY report can be set up to always print in a particular format. The available formats are shown in Table 7-2. For CODE SUMMARY setup information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

To generate a CODE SUMMARY report, press **CODE SUMMARY**. If you interrupt printing of a CODE SUMMARY report, the entire CODE SUMMARY report is reprinted when printing is resumed. "Code Summary Complete" prints immediately following the last waveform event.

Table 7-2 CODE SUMMARY Formats

FORMAT	ATTRIBUTES
Long format	• Preamble • Event/vital sign log • Event waveforms • 12-lead ECG reports • Trend Summary
Medium format	• Preamble • Event/vital sign log • Event waveforms • Trend Summary
Short format	• Preamble • Event/vital sign log • Trend Summary

Note: When CODE SUMMARY reports are transmitted, they are always sent in the long format.

The CODE SUMMARY report always contains the Preamble and the Event/Vital Sign Log. See Figure 7-1 for an example.

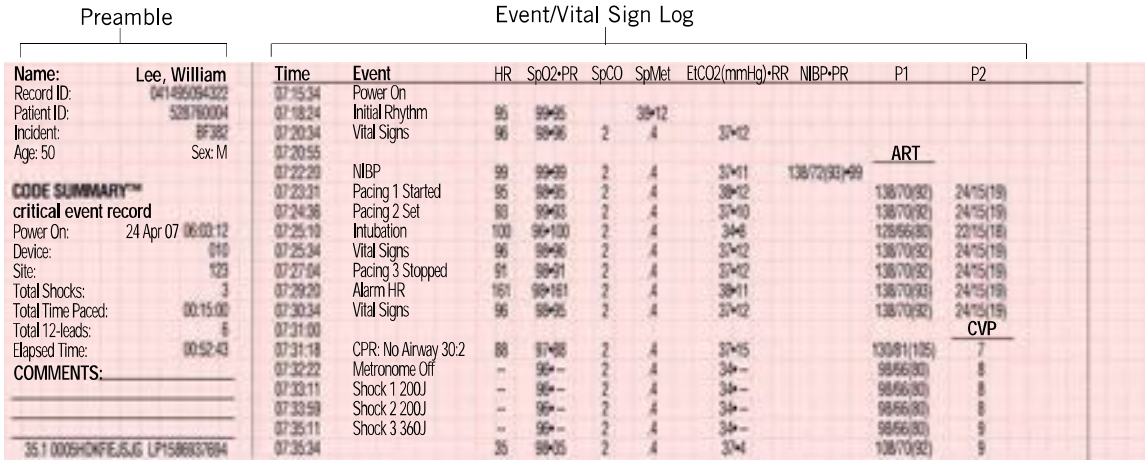


Figure 7-1 CODE SUMMARY Report

Preamble

The preamble consists of patient information (name, patient ID, age, and sex) and device information (date, time, and therapy information) as shown in Figure 7-1. The defibrillator automatically enters a unique identifier in the ID field for each Patient Record. This identifier is composed of the date and time that the defibrillator is turned on. The Incident field allows you to enter up to 14 alpha-numeric characters to link the device to other documents such as an EMS Run Report.

Event/Vital Sign Log

The LIFEPAK 15 monitor/defibrillator documents events and vital signs in chronological order. Events are operator or device actions, such as actions that are related to monitoring, pacing, AED therapy, or data transmission. Values for each active vital sign are entered into the log automatically every 5 minutes and for each event. Figure 7-2 lists events that may be found in the Event Log.

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Figure 7-2 Possible Event Log Entries

Monitoring

- Check patient
- Initial rhythm
- Replace battery
- 12-lead
- NIBP
- Alarm events
- IP label change
- Vital signs
- 5-wire on/off
- SpCO/SpMet Advisory

AED

- Connect electrodes
- Motion
- Analysis
- Analysis stopped
- Shock advised
- No shock advised

CPR Metronome

- On/Off
- Age-Airway changed

Defibrillation

- Manual mode
- Charge removed
- Shock X, XXXJ
- Shock X, Abnormal

Operator Initiated

- Event
- Alarms on/off
- Print
- VF/VT alarm on/off
- Sync on/off
- Snapshot
- Internal pacer detection on/off

Pacing

- Started
- Set
- Changed
- Stopped
- Paused

Transmission

- Transmission complete
- Transmission failed
- Transmission cancelled

Memory Status

- Out of waveform memory (memory low)
- Out of event memory (memory full)

Waveform Events

In addition to being documented in the Event Log, therapy and other selected events also capture waveform data that are printed with the long and medium CODE SUMMARY report. The waveform events and the characteristics of waveform data are described in Table 7-3.

Table 7-3 Waveform Events

EVENT NAME	WAVEFORM DATA (WHEN CAPTURED)
INITIAL RHYTHM	8 seconds after leads on
CHECK PATIENT	8 seconds prior to alert
SHOCK or NO SHOCK ADVISED	2-3 segments of analyzed ECG. Each segment is 2.7 seconds
ANALYSIS X STOPPED	8 seconds of data prior to cessation of analysis

Table 7-3 Waveform Events (Continued)

EVENT NAME	WAVEFORM DATA (WHEN CAPTURED)
SHOCK X	3 seconds prior to shock and 5 seconds after shock
PACING X STARTED	8 seconds prior to increase of current from 0
PACING X SET	8 seconds after ppm and mA are stable for 10 seconds
PACING X CHANGED	8 seconds after pacing rate, current, or mode is changed
PACING X STOPPED	3 seconds prior to pacing current is zero and 5 seconds after
PACING X PAUSED	Initial 8 seconds while **PAUSE** is pressed
ALARM*	3 seconds prior to violated parameter and 5 seconds after
EVENT*	3 seconds prior to event selection and 5 seconds after
PRINT	3 seconds prior to pressing **PRINT** and 5 seconds after
12-LEAD	10 seconds after **12-LEAD** is pressed
SNAPSHOT	3 seconds prior to and 5 seconds after SNAPSHOT requested
VITAL SIGNS	3 seconds prior to and 5 seconds after vital signs are acquired

*To reduce the length of the CODE SUMMARY report, storing waveform data with these events can be set to OFF (see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device).

Waveform events are preceded by a header that includes the following information:

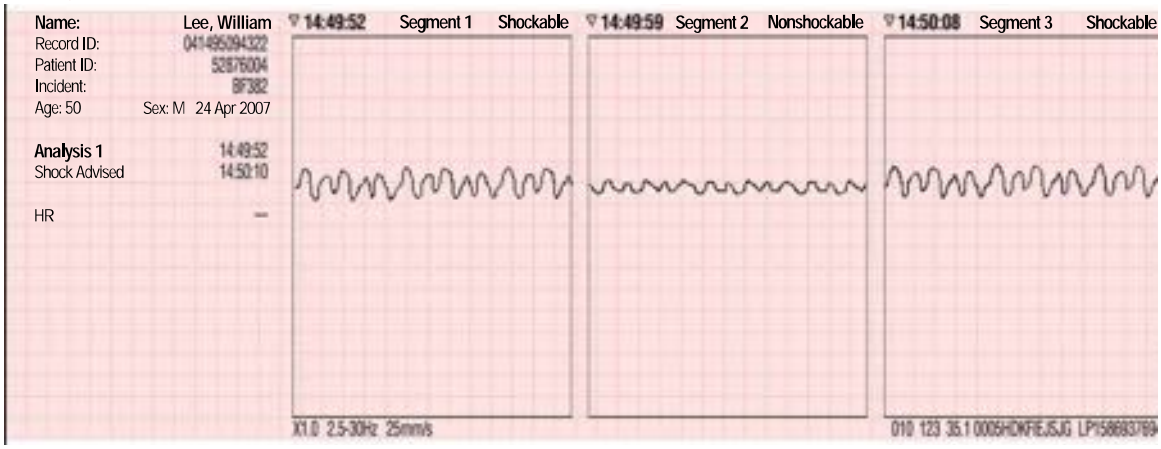
- Patient data
- Event name
- Therapy data*
- Vital signs
- Device configuration information

*Patient impedance (in ohms) appears on shock reports when using disposable defibrillation electrodes. This impedance is measured just prior to the shock and is used to determine voltage compensation.

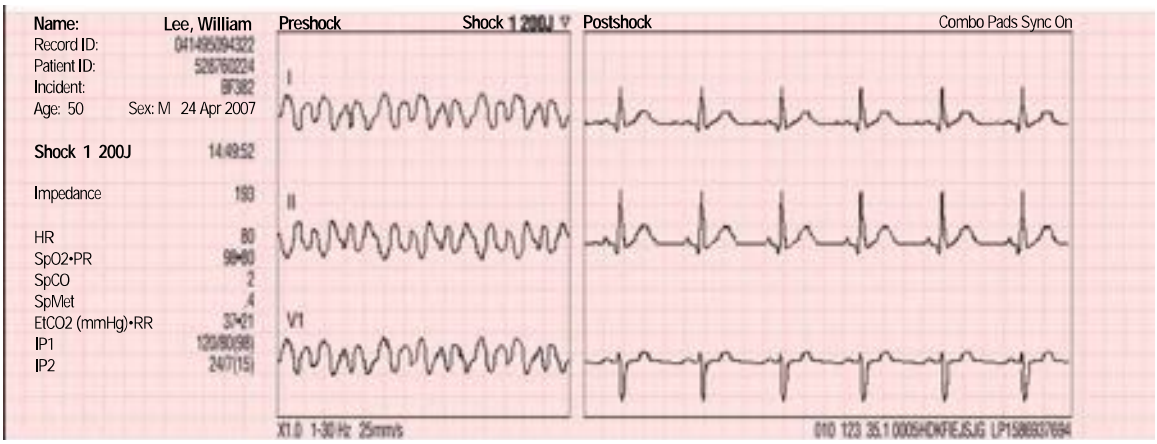
Figure 7-3 shows four examples of waveform events as they would appear in the CODE SUMMARY report.

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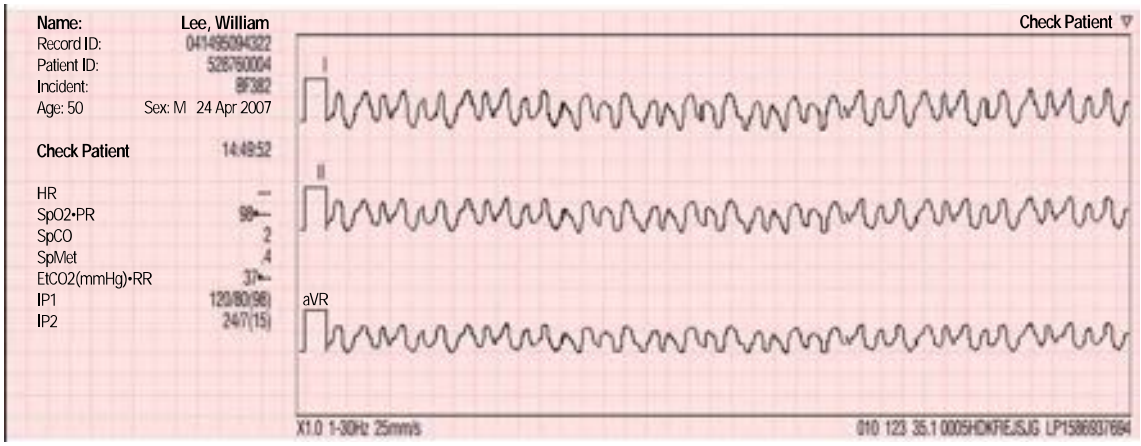
Analysis Event



Shock Event



Check Patient Event



Pacing Event

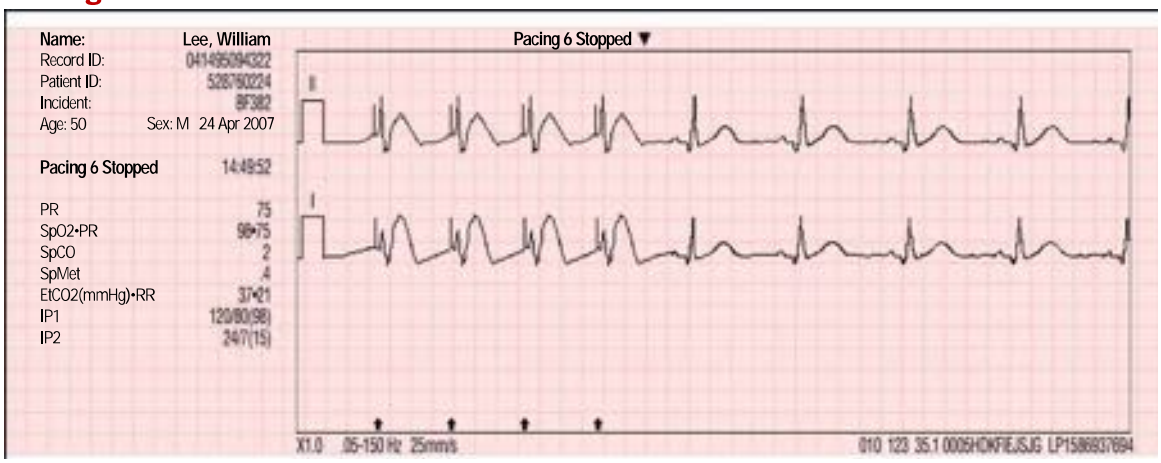


Figure 7-3 Waveform Event Printout Examples

Memory Capacity

The LIFEPAK 15 monitor/defibrillator retains data for two or more patients when you switch power off or remove the batteries. The number of patient reports that the LIFEPAK 15 monitor/defibrillator can store depends on various factors, including the number of displayed waveforms, the duration of each use, and the type of therapy. The total capacity is 360 minutes of continuous ECG or 400 single waveform events. The maximum memory capacity for a single patient includes up to 200 single waveform reports and 90 minutes of continuous ECG. When the defibrillator reaches the limits of its memory capacity, the defibrillator deletes an entire Patient Record using a "first in, first out" priority to accommodate a new Patient Record. Deleted Patient Records cannot be retrieved.

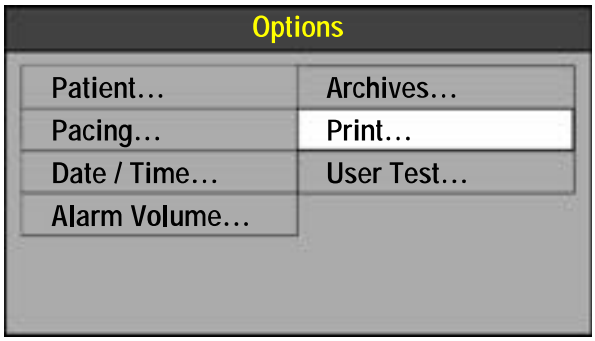
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Managing Current Patient Records

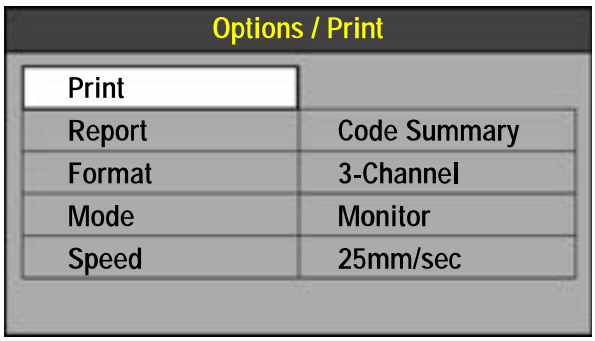
You can add specific patient information to a current Patient Record. For more information, see "Entering Patient Data" on page 3-24.

How to Print a Current Report

To print a current report:



1. Press **OPTIONS**. The Options menu appears.
2. Select **PRINT**. The Options/Print menu appears.



3. If the **REPORT**, **FORMAT**, and **MODE** settings are correct, select **PRINT**. Otherwise, make changes as desired.

   Select a **REPORT**:
   - **CODE SUMMARY**
   - **TREND SUMMARY**
   - **VITAL SIGNS**
   - **12-LEAD**

   Note: A check next to a 12-lead report indicates that the report was previously printed.

   Select a **FORMAT** (for 12-Lead ECG only):
   - **3-CHANNEL**
   - **4-CHANNEL**

   Select a **MODE** to change the frequency response of ECG reports:
   - **MONITOR**
   - **DIAGNOSTIC** (12-Lead reports always print in Diagnostic mode)

Select the **SPEED** option on this menu to change the speed of the continuous printout when the **PRINT** button is pressed. Note that this **SPEED** option does not affect reports that are printed from this menu. Available printing speeds for the **PRINT** button are:

- **12.5 MM/SEC**
- **25 MM/SEC**

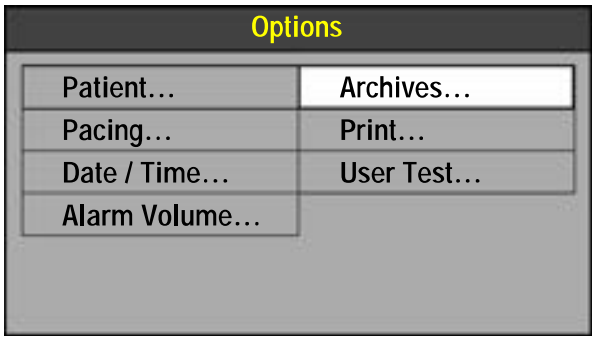
Managing Archived Patient Records

When you turn off the LIFEPAK 15 monitor/defibrillator, the current Patient Record is saved in the archives. You can print, edit, delete, or download archived records. For information about downloading to CODE-STAT software, see Chapter 8, "Data Transmission." You can also transmit individual reports from an archived Patient Record. For information about transmitting an archived report, see Chapter 8, "Data Transmission."

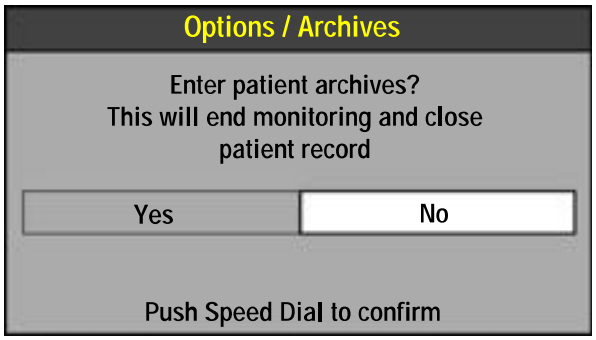
Note: When you enter Archive mode, patient monitoring ends (for example, no ECG, no alarms) and the current Patient Record is saved and closed.

Accessing Archive Mode

To enter Archive mode:



1. Press **OPTIONS**. The Options menu appears.
2. Select **ARCHIVES**. The Options/Archives menu appears.

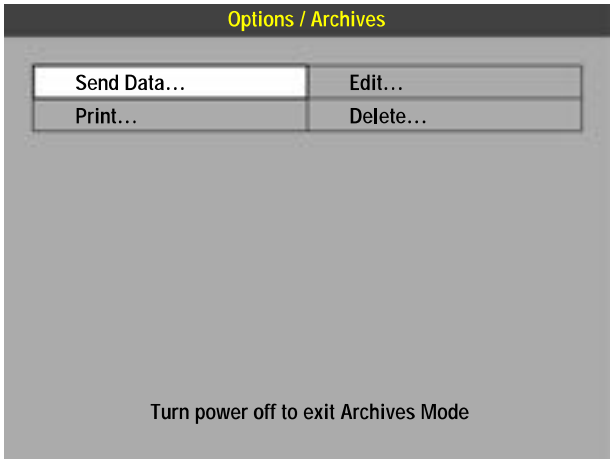


3. Select **YES**. The device enters Archive mode and the Options/Archives menu appears.

   Note: Your device may be set up so that you must enter a password to enter Archive mode.

Note: To exit Archive mode, power off the device.

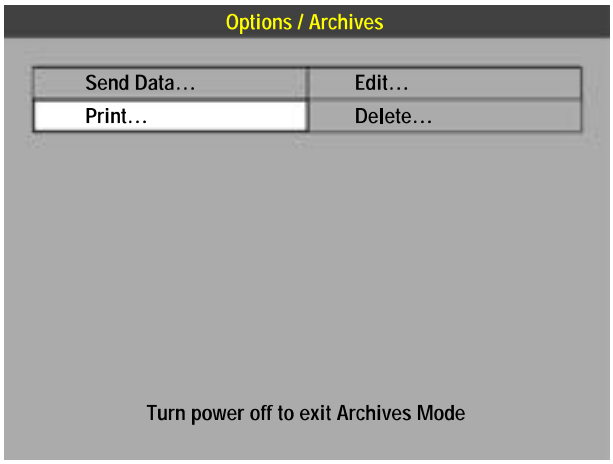
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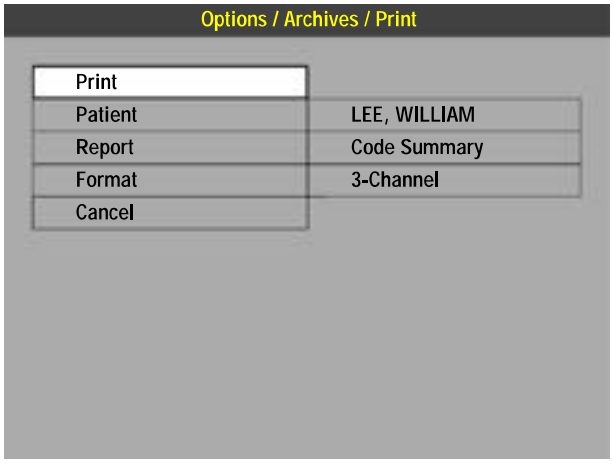
You can send, print, edit, or delete an archived record. For information about sending an archived record, see Chapter 8, "Data Transmission."

Printing Archived Patient Reports

To print archived patient reports:



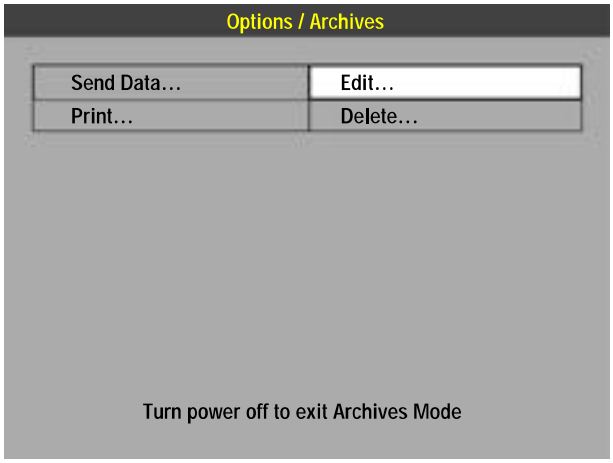
1. In Archive mode, select **PRINT**. The Options/Archives/Print menu appears showing the current patient.



2. If the **PATIENT**, **REPORT**, and **FORMAT** settings are correct, go to Step 6.
3. To select a different patient, select **PATIENT** and then select the desired patient from the list.
4. To select a different report, select **REPORT** and then select one of the following:
   - **CODE SUMMARY**
   - **TREND SUMMARY**
   - **VITAL SIGNS**
   - **12-LEAD**
5. To select a different format, select **FORMAT** and then select one of the following (for 12-Lead ECG only):
   - **3-CHANNEL**
   - **4-CHANNEL**
6. Select **PRINT**. The archived report is printed.

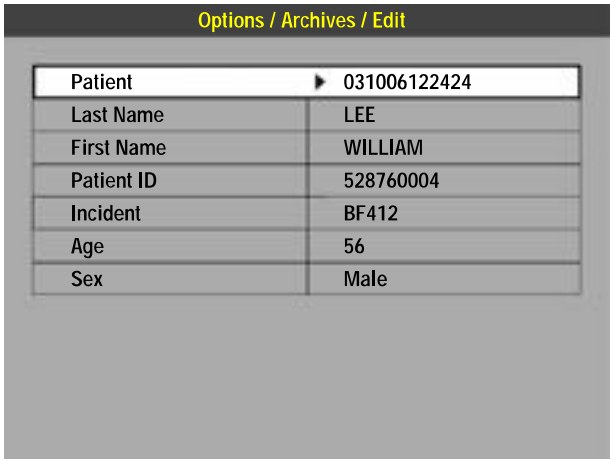
Editing Archived Patient Records

To edit archived patient records:



1. In Archive mode, select **EDIT**. The Options/Archives/Edit menu appears.

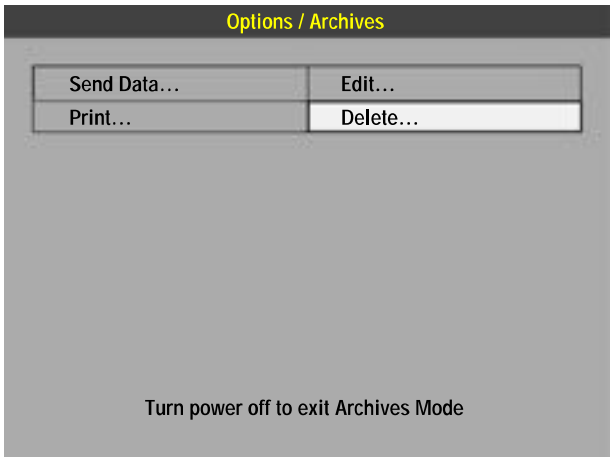
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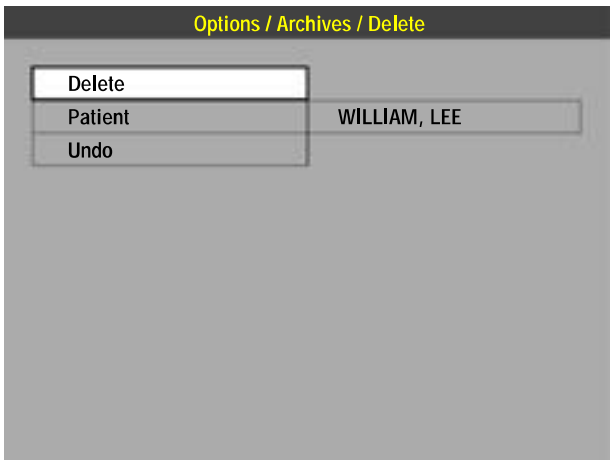
2. Select **PATIENT**.
3. Add the necessary patient information. Only blank fields may be edited.
4. Press **HOME SCREEN** and then turn off the device.

Deleting Archived Patient Records

To delete archived patient records:



1. In Archive mode, select **DELETE**. The Options/Archives/Delete menu appears.



2. To permanently remove the Patient Record that is displayed, select **DELETE**.
3. To see the list of all patient records, select **PATIENT**. The patient list appears. Select the Patient Record you want to delete.
4. To undo the delete operation, immediately select **UNDO**. If you continue with other device operations, you cannot undo the deletion.
5. Press **HOME SCREEN** and then turn off the device.

DATA TRANSMISSION

This chapter describes how to transmit Patient Records and reports from the LIFEPAK 15 monitor/defibrillator.

About Transmitting Patient Records and Reports. . . page 8-3
Preparing the Monitor for Transmission 8-4
Using Bluetooth Wireless Communication. 8-5
Using a Direct Connection. 8-10
Transmitting Reports 8-12
Considerations When Transmitting Data 8-14
Troubleshooting Tips 8-15

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About Transmitting Patient Records and Reports

You can transmit current and archived data from the LIFEPAK 15 monitor/defibrillator to the LIFENET® Cardiac Care System or to post-event review products such as CODE-STAT™ or DT EXPRESS™ software.

The LIFEPAK 15 monitor can transmit patient reports using the following methods:

- *Bluetooth*® wireless connection—If your LIFEPAK 15 monitor has the *Bluetooth* feature installed and enabled, you can transmit data using a wireless connection.
- Direct cable connection—You can use a special cable to establish a direct connection from the LIFEPAK 15 monitor to a PC or gateway, and transmit data using this wired connection.

Figure 8-1 represents an overview of the data transmission process.

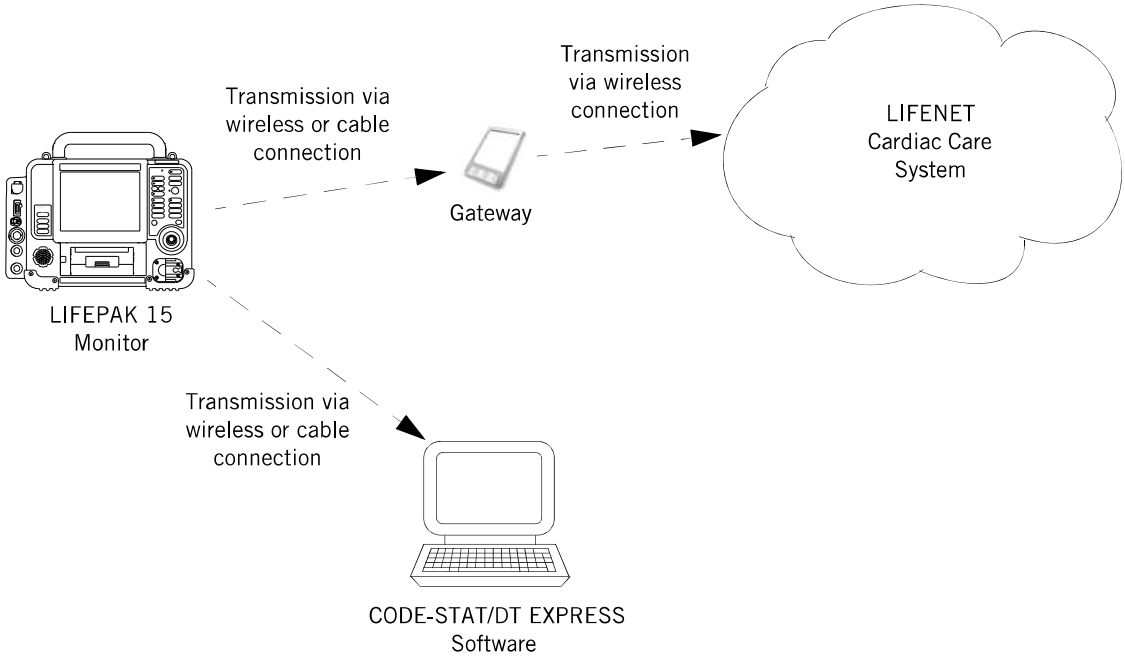


Figure 8-1 Transmitting Data from the LIFEPAK 15 Monitor/Defibrillator

For information about configuring your LIFEPAK 15 monitor to work in the LIFENET Cardiac Care System, see the LIFENET system help documentation or contact your Physio-Control representative.

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Preparing the Monitor for Transmission

Before you can transmit using a wireless or direct connection, you must define transmission sites and output ports in the LIFEPAK 15 monitor Setup mode.

For each transmission site, select an output port:

- For wireless transmission, set **OUTPUT PORT** to **BLUETOOTH WIRELESS**.
- For a direct connection, set **OUTPUT PORT** to **DIRECT CONNECT**.
- Set **OUTPUT PORT** to **BOTH** if you normally transmit using a *Bluetooth* connection but you need a direct cable backup. (If you set **OUTPUT PORT** to **BOTH**, make sure the *Bluetooth* LED is not illuminated before you attempt to transmit using a direct connection. The device will not transmit using the direct connection when a wireless connection is available.)

For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

Using Bluetooth Wireless Communication

Bluetooth technology is a short-range wireless communication technology that is available as an option on the LIFEPAK 15 monitor/defibrillator. When *Bluetooth* technology is installed, the *Bluetooth* icon appears on the Home Screen. See Figure 8-2.

For more information about supported *Bluetooth* technologies, see www.physio-control.com.

A *Bluetooth* connection between the LIFEPAK 15 monitor and a target device is always initiated from the LIFEPAK 15 monitor.

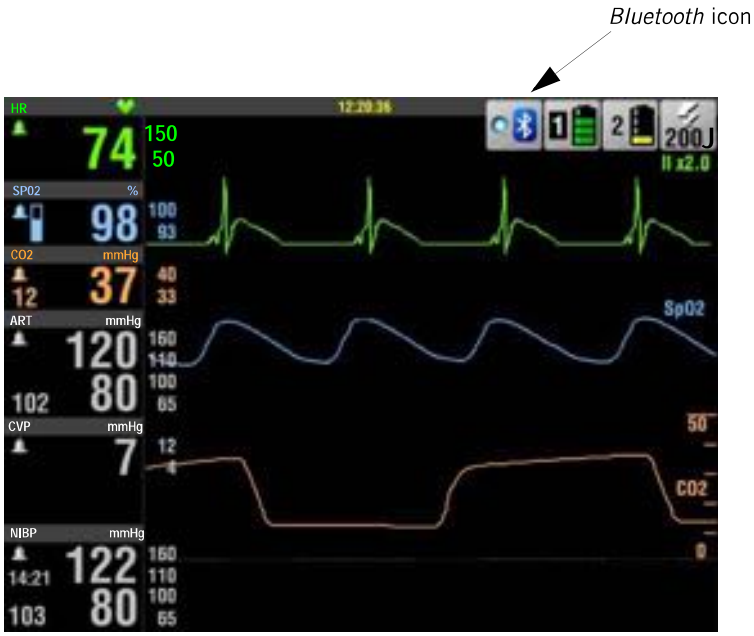


Figure 8-2 *Bluetooth* Icon on the Home Screen

The *Bluetooth* icon shows the status of the wireless connectivity in the device.

Table 8-1 *Bluetooth* Status

BLUETOOTH ICON	DESCRIPTION
	The *Bluetooth* LED is illuminated when the *Bluetooth* feature is enabled in this device and this device is connected to another *Bluetooth*-enabled device.
	The *Bluetooth* icon appears but the LED is not illuminated when the *Bluetooth* feature is enabled in this device, but this device is currently not connected to another *Bluetooth*-enabled device.
	A red X appears when the *Bluetooth* feature is installed in this device, but wireless communication is currently set to **OFF** or there is a *Bluetooth* malfunction. See Table 8-3 on page 8-15.

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Preparing for a Wireless Transmission

Before you can send wireless transmissions from the LIFEPAK 15 monitor, you must prepare the monitor and target devices for communication.

The target device must:

- Be *Bluetooth*-enabled, turned on, and discoverable.
- Have the LIFENET PC Gateway application or the patient care reporting software CODE-STAT or DT EXPRESS installed and running.
- Have a *Bluetooth* COM port configured for incoming data.
- Have an established friendly name.

The LIFEPAK 15 monitor must:

- Have at least one transmission site defined that has **OUTPUT PORT** set to **BLUETOOTH WIRELESS**.
- Have a *Bluetooth* passcode that matches the passcode in the target device, if the target device requires a passcode.
- Have **SEARCH FILTER** set to **ON** if you are using the Physio Service Class. For information about the Physio Service Class, see "Bluetooth Search Filter" later in this chapter.

Bluetooth Passcodes

The LIFEPAK 15 monitor has a *Bluetooth* passcode that you define.

To transmit from the LIFEPAK 15 monitor to a headless gateway (a device that has no user interface), the *Bluetooth* passcode that you enter in the LIFEPAK 15 monitor must match the *Bluetooth* passcode that is preconfigured in the gateway. For information about the *Bluetooth* passcode in the headless gateway, see the documentation that ships with the gateway, or consult your system administrator or equipment technician.

To transmit from the LIFEPAK 15 monitor to a PC, you need to set a *Bluetooth* passcode in the LIFEPAK 15 monitor, and then enter that passcode on the PC, if prompted.

Bluetooth Search Filter

A *Bluetooth*-enabled LIFEPAK 15 monitor may discover numerous *Bluetooth* devices that are within range. To help filter out extraneous devices and find the specific target device that you want to transmit to, Physio-Control developed the Physio Service Class (PSC).

The PSC is a prefix that you can add to the friendly name of your target devices. Then when you set the **SEARCH FILTER** to **ON** in the LIFEPAK 15 monitor, only target devices that have the PSC prefix in their names appear in the list of discovered devices (if they are powered on and discoverable).

The various PSC prefixes correspond to LIFEPAK 15 monitor modes of operation. Table 8-2 lists the LIFEPAK 15 monitor modes and the service class and friendly name prefix that is discoverable in each mode. For example, when the LIFEPAK 15 monitor is in Archive mode and the filter is on, it can discover devices whose friendly names begin with A_ or B_.

Table 8-2 Physio Service Class Prefixes

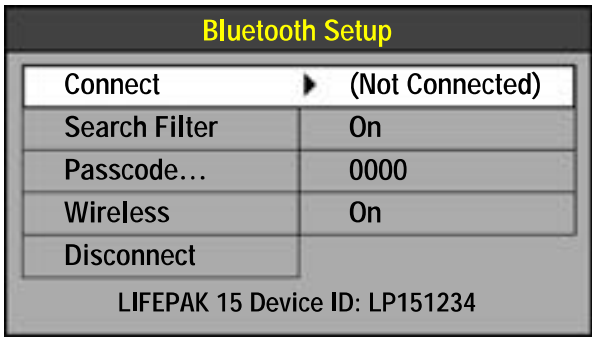
LIFEPAK 15 MONITOR/DEFIBRILLATOR MODE	SERVICE CLASS	FRIENDLY NAME PREFIX
LIFEPAK 15 monitor must be in Archive mode	Archive	A_
LIFEPAK 15 monitor can be in AED, Manual, or Archive mode	Both Cardiac Care and Archive	B_
LIFEPAK 15 monitor can be in AED or Manual mode	Cardiac Care	C_

For information about configuring the friendly name in your target devices, see the documentation provided with those devices.

Bluetooth Setup

Use the *Bluetooth* Setup menu to set up the *Bluetooth* transmission on the LIFEPAK 15 monitor.

To access the *Bluetooth* Setup menu:



1. On the **HOME SCREEN**, rotate the **SPEED DIAL** to outline the *Bluetooth* icon.
2. Press the **SPEED DIAL**. The *Bluetooth* Setup menu appears.
3. Set **SEARCH FILTER** to **ON** if you want to find only devices that include the PSC in their friendly name; otherwise, set **SEARCH FILTER** to **OFF**.
4. Set a *Bluetooth* passcode.
   - To transmit to a headless gateway, enter the passcode that is preconfigured in the gateway.
   - To transmit to a PC, you may need to enter a passcode or acknowledge the connection.
5. Ensure that **WIRELESS** is set to **ON**.

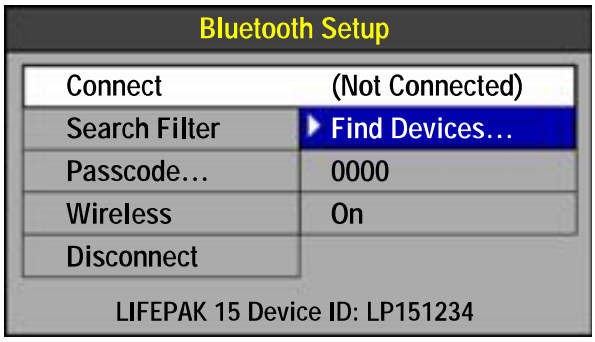
Note: The default setting for **WIRELESS** is **ON**, and the default setting for **SEARCH FILTER** is **ON**. Use the **WIRELESS** setting to turn off the wireless signal when operating the LIFEPAK 15 monitor in an environment where transmission is not desirable.

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Establishing a Bluetooth Connection

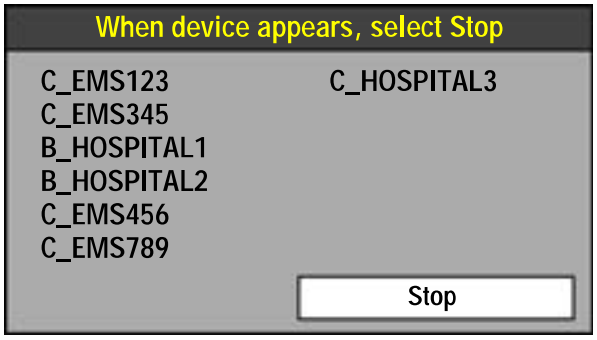
You must know the friendly name of the target device that you want to connect to.

To establish a *Bluetooth* connection:



1. On the LIFEPAK 15 monitor, use the **SPEED DIAL** to select the *Bluetooth* icon and access the *Bluetooth* Setup menu.
2. Select **CONNECT** and then select **FIND DEVICES**. This will disconnect any existing connections.

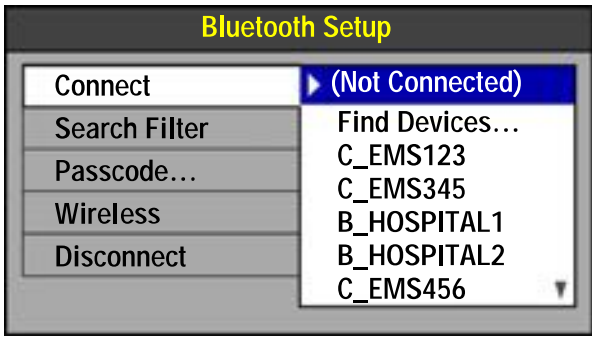
   Note: If the LIFEPAK 15 monitor is set to **WIRELESS OFF**, wireless status changes to **WIRELESS ON**.



- The Find Devices menu appears. The monitor begins searching for *Bluetooth* devices that are in the area and that meet the search filter criteria.
- Devices are displayed in the order found—the most recently found device appears at the top of the list.

3. When the desired device appears, press the **SPEED DIAL** to select **STOP** and end the search. You return to the *Bluetooth* Setup menu.
4. Use the **SPEED DIAL** to scroll through the list and select the desired device.
5. If you are connecting to a PC, you may be prompted to acknowledge the connection. Enter the passcode, if requested, and then accept the connection.

   When the connection is made, an alert tone sounds, the *Bluetooth* LED on the Home Screen is illuminated, and **CONNECTED TO (*DEVICE NAME*)** briefly appears in the message area.



After you establish a *Bluetooth* connection, you are ready to transmit patient data. Proceed to "Transmitting Reports" on page 8-12.

Re-establishing a Bluetooth Connection

The LIFEPAK 15 monitor retains in its memory two last-connected devices, limited to one in each mode—one for cardiac care (AED or Manual mode) and one for Archive mode. When the LIFEPAK 15 monitor is powered on and the wireless feature is set to **WIRELESS ON**, the monitor automatically searches for the last connected device. If the last connected device in that mode is turned on and within range, a connection is established automatically. When a connection is established, the *Bluetooth* LED is illuminated and **CONNECTED TO (*DEVICE NAME*)** appears in the message area.

Note: If **RESET DEFAULTS** is selected in Setup mode, the *Bluetooth* passcode is not reset, However, connections to the last-connected devices are reset (terminated). To re-establish a connection, use **FIND DEVICES**.

Terminating a Bluetooth Connection

When the *Bluetooth* LED is illuminated, the LIFEPAK 15 monitor has a wireless connection established with another *Bluetooth* device.

To terminate a *Bluetooth* connection:

1. Use the **SPEED DIAL** to select the *Bluetooth* icon and access the *Bluetooth* Setup menu.
2. Select **DISCONNECT**. The *Bluetooth* connection is terminated and is not retained as the last connected device.

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Using a Direct Connection

A special cable can be used to create a direct connection between the LIFEPAK 15 monitor and a gateway or PC. Figure 8-3 shows the equipment connections to send reports directly to a computer using a direct cable connection.

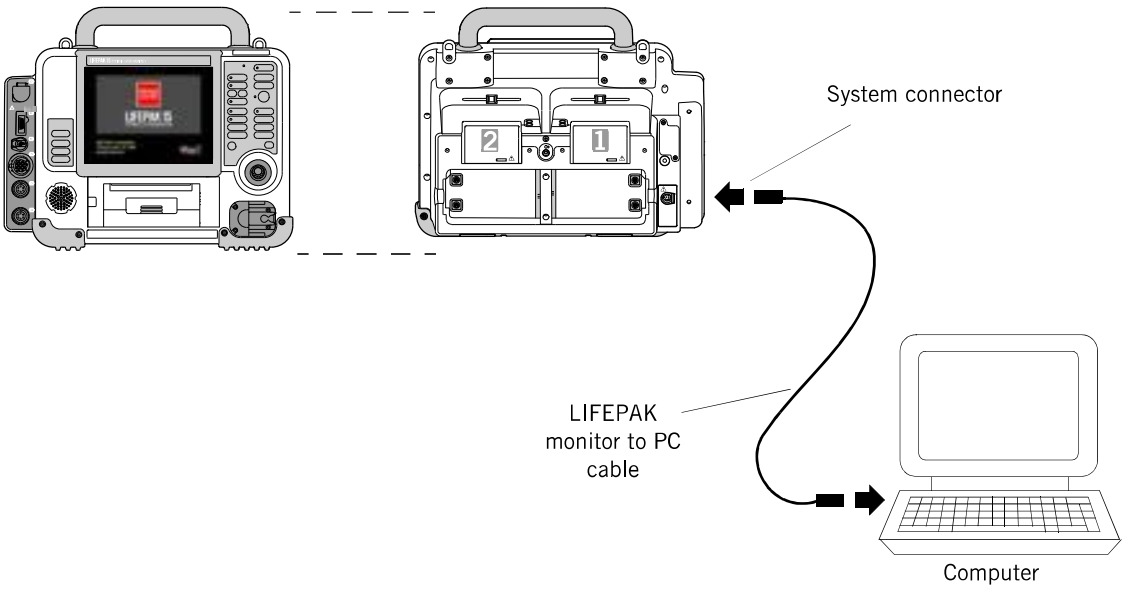


Figure 8-3 Data Transmission using a Direct Connection

WARNING

SHOCK HAZARD

If you are monitoring a patient and using the system connector, all equipment connected to the system connector must be battery powered or electrically isolated from AC power according to EN 60601-1. If in doubt, disconnect the patient from the defibrillator before using the system connector. Only use Physio-Control recommended data transmission cables. For more information, contact Physio-Control Technical Support.

To establish a direct connection:

1. Position the PC or gateway within reach of the LIFEPAK 15 monitor.
2. Configure a COM port on the PC for incoming data.
3. Connect the cable to the system connector on the monitor and to the PC.
4. If using CODE-STAT or DT EXPRESS software, open the download wizard on the PC and select the LIFEPAK 15 monitor.

After you establish a direct connection, you are ready to transmit patient data. Proceed to "Transmitting Reports" on page 8-12.

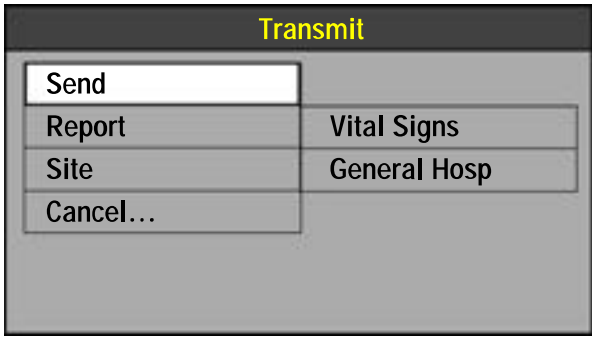
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Transmitting Reports

After you have established a wireless or direct connection, you can transmit Patient Records and reports. All patient reports can be transmitted real time during patient monitoring (Manual or AED mode), or reports can be transmitted post event (Archive mode).

How to Transmit a Current Patient Report

To transmit a current patient report:

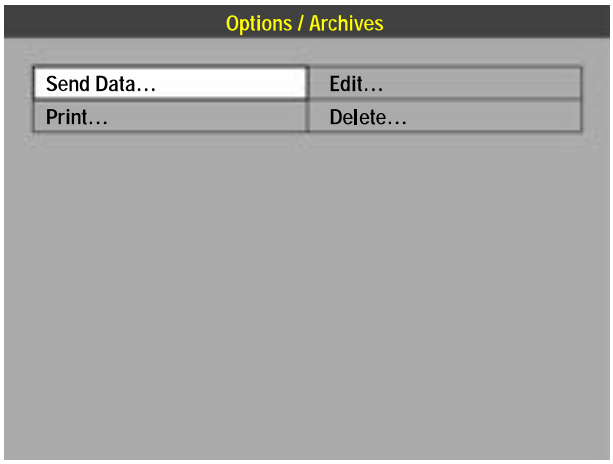


1. Press **TRANSMIT**. The Transmit menu appears.
2. Use the **SPEED DIAL** to select the desired **REPORT** and **SITE**, if necessary.
3. Select **SEND**. The patient report is transmitted. The status of the transmission appears in the message area.

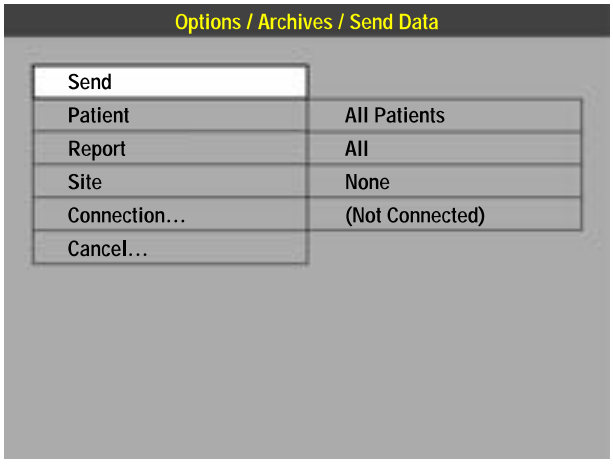
How to Transmit an Archived Patient Report

When you turn off the LIFEPAK 15 monitor/defibrillator, the current Patient Record is saved in the archives. For information about accessing Archive mode, see Chapter 7, "Data Management."

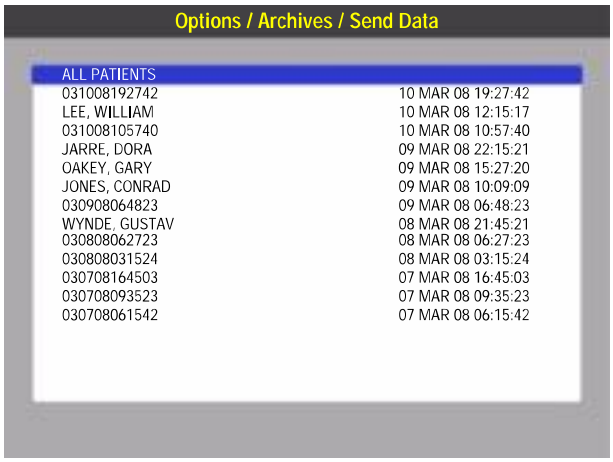
To transmit an archived patient report:



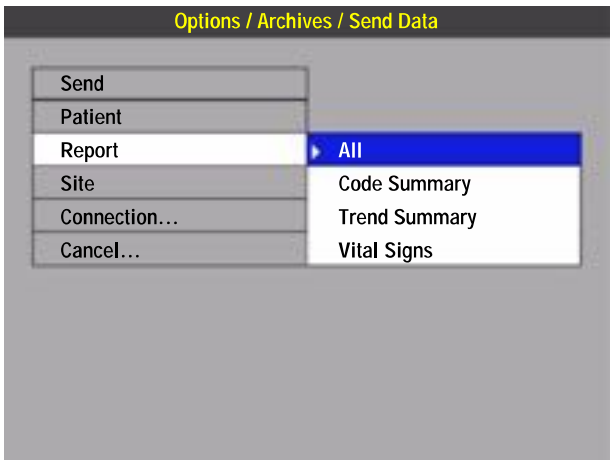
1. In the Options/Archives menu, select **SEND DATA**. The Options/Archives/Send Data menu appears.



2. If the **PATIENT**, **REPORT**, and **SITE** are correct, proceed to Step 7.



3. To transmit records for a particular patient, select **PATIENT**. A list of patients appears.
4. Select the patient.



5. To transmit a specific report, select **REPORT** and then select the report.
6. To select a transmission site, select **SITE** and then select the site. Make sure you specify a site whose **OUTPUT PORT** is configured for the transmission method you are using.
7. To transmit using a wireless transaction, select **CONNECTION** and proceed with establishing a *Bluetooth* connection. For more information, see "Establishing a Bluetooth Connection" on page 8-8.
8. Select **SEND**. The patient report is transmitted. The status of the transmission appears in the message area.

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Transmission Status Report

Whenever you attempt to transmit a record, a transmission report is automatically printed at the completion of the transmission attempt. The transmission report indicates the date and time of the transmission attempt and the final status of the transmission.

Cancelling a Transmission

You can cancel a transmission that is in process. To cancel a transmission, select **CANCEL** on the Transmit menu if you are transmitting a current record, or select **CANCEL** on the Options/Archives/ Send Data menu if you are transmitting an archived record.

Considerations When Transmitting Data

When considering any treatment protocol that involves transmitting patient data, be aware of possible limitations. Successful transmission depends on access to public or private network services that may or may not always be available. This fact is especially true for wireless communication, which is influenced by many factors, such as:

- Geography
- Location
- Weather
- Number of wireless devices in the area

Treatment protocol must always take into account the fact that data transfer *cannot be assured* using wireless communication. Your treatment protocol must include contingency planning for interrupted data transmission.

Periodically test your device transmission function to ensure that the device and transmission accessories are ready for use.

Troubleshooting Tips

Table 8-3 Troubleshooting Tips for Data Transmission

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Bluetooth icon on LIFEPAK 15 monitor has red X across it	**WIRELESS** is set to **OFF** in the *Bluetooth* Setup menu	• Set **WIRELESS** to **ON**. • If red X remains, *Bluetooth* module in LIFEPAK 15 monitor may be faulty. Contact qualified service representative.
	WIRELESS is set to **OFF** in the setup options, so the **WIRELESS** default is **OFF** each time the LIFEPAK 15 monitor is turned on	• Change **WIRELESS** setup option. See *LIFEPAK 15 Monitor/ Defibrillator Setup Options* provided with your device. • If red X remains, *Bluetooth* module in LIFEPAK 15 monitor may be faulty. Contact qualified service representative.
	Bluetooth module in LIFEPAK 15 monitor may be faulty	• Contact qualified service representative.
Bluetooth LED is not illuminated	Target device is off or cannot communicate with the LIFEPAK 15 monitor	• Confirm that target device is on and discoverable. • See the operating instructions for your target device.
	Bluetooth module in LIFEPAK 15 monitor may be faulty	• If other troubleshooting is unsuccessful, contact qualified service representative.
LIFEPAK 15 monitor does not automatically connect to last connected device	Target device is off or cannot communicate with the LIFEPAK 15 monitor	• Confirm that target device is on and discoverable.
	Last connection to target device may have occurred when the LIFEPAK 15 monitor was in a different mode	• Confirm that **OUTPUT PORT** is set to **BLUETOOTH WIRELESS**. • Select **FIND DEVICES** and establish a new connection.
Device does not connect to last connected device after **WIRELESS** is set to **ON**	*Bluetooth* menu is displayed, which prevents discovery of devices	• Press **HOME SCREEN** to exit menu and allow LIFEPAK 15 monitor to find last connected device.
UNABLE TO CONNECT message appears	LIFEPAK 15 monitor cannot establish wireless connection. Target device may not have the necessary software application or cannot accept data.	• Verify target device is ready to receive transmissions. • Attempt to retransmit.

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Table 8-3 Troubleshooting Tips for Data Transmission (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to find a particular *Bluetooth* device, or **BLUETOOTH DEVICE NOT FOUND** message appears	Search filter may be on and target device does not have a PSC prefix	• Confirm that target device is on and discoverable. • Confirm friendly name of target device. • Set **SEARCH FILTER** to **OFF** and then select **FIND DEVICES** again.
	Target device is not functioning	• Confirm that target device is on and discoverable. • Confirm friendly name of target device. • If message still appears, contact the service provider for your target device.
	Bluetooth module in LIFEPAK 15 monitor may be faulty	• Contact qualified service representative.
Unable to transmit data for post-event review using either direct connection or *Bluetooth* connection	Post-event review software is not installed on target device	• Install CODE-STAT or DT EXPRESS post-event review software on target device.
	Post-event review software is not open and running on target device	• Make sure the target device is running Device Communications or the download wizard.
	COM port is not configured for incoming data on target device	• Configure COM port on target device.
	LIFEPAK 15 monitor not selected in download wizard on target device	• Open download wizard on target device and select the LIFEPAK 15 monitor.
BLUETOOTH UNAVAILABLE message appears	*Bluetooth* module in LIFEPAK 15 monitor not responding	• Turn LIFEPAK 15 monitor off and back on. • If message still appears, *Bluetooth* module may be faulty. Contact qualified service representative.
BLUETOOTH DEVICE NOT FOUND message appears	Unable to locate *Bluetooth* device	• Verify target device is ready to receive transmissions. • Set **SEARCH FILTER** to **OFF** and then select **FIND DEVICES** again.
UNKNOWN DEVICE message appears	*Bluetooth* name discovery failed or timed out before the device name was obtained	• Verify name of target device. • Verify target device is ready to receive transmissions. • Attempt to retransmit.

Table 8-3 Troubleshooting Tips for Data Transmission (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to transmit using a gateway device that has a functioning direct connection or *Bluetooth* connection	Transmission sites are not set up in LIFEPAK 15 monitor	• Define transmission sites. Each site name must exactly match the name of the target device. See *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.
	Transmission site names in LIFENET system do not match site names in LIFEPAK 15 monitor	• Check site names in LIFENET system.
	Cellular communication is not working between the gateway and transmission sites	• Use alternate method to communicate patient data.
UNABLE TO TRANSMIT message appears	The LIFEPAK 15 monitor cannot connect to the device name selected	• Verify target device is ready to receive transmissions. • Verify target device setup. • Attempt to retransmit.
	The output port on the LIFEPAK 15 monitor is not configured for the transmission method you are using	• Make sure the transmission site **OUTPUT PORT** is configured for the type of transmission you are attempting. • Attempt to retransmit.
	Target device unable to connect or unable to connect within timeout interval	• Verify target device is ready to receive transmissions. • Verify target device setup. • Attempt to retransmit.
	The target device requires you to "accept" incoming communications	• Check your target device for a required acknowledgment to connect. • Enter passcode, when prompted. • Set to "Always allow" if possible. • Attempt to retransmit.
	Direct connection was disrupted	• Verify cable connections. • Attempt to retransmit.
TRANSMISSION FAILED message appears	Computer application program is not ready or is not available to receive transmission	• Verify target device is running necessary software. • Attempt to retransmit.

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Table 8-3 Troubleshooting Tips for Data Transmission (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
LOST DIRECT CONNECTION message appears	Direct connection was interrupted	• Verify cable connections between LIFEPAK 15 monitor and gateway or PC. • Attempt to retransmit.
LOST BLUETOOTH CONNECTION message appears	Connection with *Bluetooth* target device was interrupted	• Verify target device is ready to receive transmissions. • Attempt to retransmit.
TRANSMISSION CANCELLED message appears	LIFEPAK 15 operator cancelled transmission	• Attempt to retransmit if cancelled in error.

MAINTAINING THE EQUIPMENT

This chapter describes how to perform operator-level maintenance, testing, and troubleshooting for the LIFEPAK 15 monitor/defibrillator and selected accessories. For additional information about accessories, refer to specific accessory operating instructions.

General Maintenance and Testing . . . . . page 9-3
Battery Maintenance 9-12
Cleaning the Device 9-15
Storing the Device 9-15
Loading Paper 9-17
General Troubleshooting Tips 9-18
Service and Repair 9-20
Product Recycling Information. 9-21
Warranty 9-21
Accessories 9-22

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General Maintenance and Testing

Periodic maintenance and testing of the LIFEPAK 15 monitor/defibrillator and accessories are important to help prevent and detect possible electrical and mechanical discrepancies. If testing reveals a possible discrepancy with the defibrillator or accessories, see "General Troubleshooting Tips" on page 9-18. If the discrepancy cannot be corrected, immediately remove the LIFEPAK 15 monitor/defibrillator from service and contact a qualified service technician. For testing information regarding accessories, see the accessory operating instructions.

A **MAINTENANCE DUE** message can be set up to appear at selected intervals (3, 6, or 12 months) to remind you that the LIFEPAK 15 monitor/defibrillator is due for maintenance. The factory default is **OFF**, but it can be activated by service personnel.

An Operator's Checklist is included in the back of this manual. You may reproduce the checklist and use it to inspect and test the LIFEPAK 15 monitor/defibrillator. Daily inspection and test is recommended.

Maintenance and Testing Schedule

Table 9-1 lists the recommended maintenance and testing schedule. This schedule may be used in conjunction with the internal quality assurance program of the hospital, clinic, or emergency medical service where the defibrillator is used.

Cables and paddles are a critical part of therapy delivery and suffer wear and tear. Therapy cable testing as described in the Operator's Checklist is recommended on a daily basis. The Test Load ships with the device and is necessary for testing the QUIK-COMBO cable. Physio-Control recommends replacement of therapy cables every three years to reduce the possibility of failure during patient use.

The 12-lead ECG cable is a critical part of diagnosis and suffers wear and tear. Inspect the 12-lead cable as described in the Operator's Checklist, and test it as described in "Patient ECG Cable Check" on page 9-6.

Additional periodic preventive maintenance and testing—such as electrical safety tests, performance inspection, and required calibration—should be performed regularly by qualified service technicians. See the *LIFEPAK 15 Monitor/Defibrillator Service Manual* for more information.

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Table 9-1 Recommended Maintenance Schedule for Clinical Personnel

OPERATION	DAILY	AFTER USE	AS REQUIRED	6 MONTHS	12 MONTHS
Complete Operator's Checklist. Includes QUIK-COMBO therapy cable check and Standard Paddles Monitoring and User Test	X				
Inspect defibrillator	X	X			
Check that all necessary supplies and accessories are present (for example, fully charged batteries, gel, electrodes, ECG paper, etc.)	X	X	X		
Function Checks:					
Patient ECG Cable Check				X	
Standard Paddles Synchronized Cardioversion Check				X	
Therapy Cable Monitoring and Synchronized Cardioversion Check				X	
Therapy Cable Pacing Check				X	
Clean defibrillator		X	X		
Preventive Maintenance and Testing					X

Self-Tests

Each time you turn on the LIFEPAK 15 monitor/defibrillator, it performs internal self-tests to check that internal electrical components and circuitry work properly. The defibrillator stores the results of all user-initiated self-tests in a test log.

When the defibrillator is on and a problem is detected that requires immediate service, such as a malfunctioning charging circuit, the Service LED is illuminated.

For more information, see Table 9-2 on page 9-18.

Auto Tests

The defibrillator performs an automatic self-test daily at 03:00 (3:00 A.M.), if not in use. During the automatic self-test, the defibrillator turns itself on (**ON** LED illuminates) briefly and completes the following tasks:

- Performs a self-test
- Stores the self-test results in the test log
- Turns itself off

If the defibrillator detects a problem during an auto test, it annotates the fault condition on the printed test report.

The automatic self-test is not performed if the defibrillator is already turned on at 03:00 or if batteries are not installed. If the defibrillator is manually turned on while a self-test is in progress, the self-test is halted and the defibrillator turns on normally.

For more information, see Table 9-2 on page 9-18.

User Tests

The User Test is a functional test of the LIFEPAK 15 monitor/defibrillator. The User Test should be performed only as a test and not while using the defibrillator during patient care. Perform the User Test as a part of completing the daily Operator's Checklist.

Note: The defibrillator must be in Manual mode to perform the User Test.

To perform a User Test separate from completing the Operator's Checklist:

1. Press **ON** to turn on the LIFEPAK 15 monitor/defibrillator.
2. Press **OPTIONS**. The Options menu appears.
3. Select **USER TEST**. The defibrillator performs the following tasks:
   - Self-tests to check the device.
   - Charges to 10 joules and discharges internally (this energy is not accessible at the therapy connector).
   - Prints a Pass/Fail report.

If the LIFEPAK 15 monitor/defibrillator detects a failure during the User Test, the Service LED is illuminated and the printed report indicates that the test failed. Remove the defibrillator from use and contact a qualified service technician.

If you must interrupt the User Test, turn the power off and then on again. The test stops and the defibrillator operates normally. A Pass/Fail report does not print.

Note: During the User Test, all front panel controls (except **ON**) and standard paddle controls are disabled. Routinely testing the defibrillator consumes battery power; maintain all batteries as described in "Battery Warnings" on page 9-12.

Note: The last 40 User and Auto Test results are transmitted with all reports to the CODE-STAT Suite data management system.

Note: It is important to understand defibrillator operation. For suggested procedures to help keep personnel acquainted with normal defibrillator operation, see the function checks that are provided in this chapter. The function checks used may vary according to your local protocols. To test the defibrillator by performing the function checks, you need a simulator. To troubleshoot device performance, see Table 9-2 on page 9-18.

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Standard Paddles User Test

Perform the Standard Paddles User Test as a part of completing the daily Operator's Checklist that is provided in the back of this manual.

Function Checks

The following function checks are provided to help personnel keep acquainted with normal operating procedures and to troubleshoot LIFEPAK 15 monitor/defibrillator performance.

Note: If your organization downloads device electronic patient records for post-event review, consider entering "TEST" as the patient's name to distinguish simulator function tests from actual patient uses.

Patient ECG Cable Check

Equipment Needed:

- LIFEPAK 15 monitor/defibrillator
- Fully charged batteries
- Patient ECG cable (3-lead, 12-lead, or 5-wire)
- 3-lead or 12-lead simulator

To check the patient ECG cable:

1. Press **ON**.
2. Connect the ECG cable to the defibrillator.
3. Connect all cable leads to the simulator.
4. Turn on the simulator and select a rhythm.
5. Confirm that Lead **II** is selected.
6. After a few seconds, confirm that the screen displays a rhythm and that no **LEADS OFF** or **SERVICE** message appears.
7. For 12-lead cable, press **12-LEAD** and wait for printout. Confirm that a rhythm prints for each lead.

Standard Paddles Synchronized Cardioversion Check

WARNING

SHOCK HAZARD

The defibrillator delivers up to 360 joules of electrical energy. Unless discharged properly as described in this test, this electrical energy may cause serious personal injury or death. Do not attempt to perform this test unless you are qualified by training and experience and are thoroughly familiar with these operating instructions.

Equipment Needed:

- LIFEPAK 15 monitor/defibrillator
- Standard paddles
- Defibrillator checker
- Patient ECG cable
- 3-lead or 12-lead patient simulator
- Fully charged batteries

To check standard paddles synchronized cardioversion:

1. Press **ON**.
2. Connect the ECG cable to the monitor and to the patient simulator.
3. Turn on the simulator and select any rhythm except asystole or ventricular fibrillation.
4. Select Lead **II**.
5. Press **SYNC**. Confirm that the **SYNC** LED lights. Adjust ECG size until the sense markers appear on the QRS complexes. Confirm that the **SYNC** LED blinks off with each detected QRS complex and that the heart rate is displayed.
6. Select **100 JOULES**.
7. Press **CHARGE** and confirm that the tone indicating full charge sounds within 10 seconds or less.
8. Remove the standard paddles from the paddle wells and place the standard paddles on the defibrillator checker plates.

Note: This test is not intended to be performed with the paddles in the wells. Discharging 100 joules in the paddle wells may damage the defibrillator.

9. Press the **APEX** (shock) button, confirm that the defibrillator does not discharge, and then release the button.
10. Press the **STERNUM** (shock) button, confirm that the defibrillator does not discharge, and then release the button.

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11. Press **PRINT**.

WARNING

POSSIBLE PADDLE DAMAGE AND PATIENT BURNS

Press paddles firmly onto the defibrillator checker plates when discharging to prevent arcing and formation of pits on paddle surfaces. Pitted or damaged paddles may cause patient skin burns during defibrillation.

12. Apply firm pressure with both paddles on the defibrillator checker paddle plates, and simultaneously press and hold both ⚡ (shock) buttons while observing the screen.
13. Confirm that the defibrillator discharges on the next sensed QRS complex.
14. Press **PRINT** again to stop the printer.
15. Confirm that the defibrillator returns to Asynchronous mode (sense markers are no longer displayed and **SYNC** LED is off).

    Note: Defibrillator may be set up to remain in Sync mode after discharge.
16. Confirm that the printer annotates the time, date, Sync On, sense markers prior to energy delivered, energy selected, no sense markers after Shock 1, and Sync Off on the ECG strip.
17. Turn off the defibrillator.

Note: If a **CONNECT CABLE**, **PADDLES LEADS OFF**, or any other warning message appears, replace the paddle assembly with a new paddle assembly and repeat the test. If the problem cannot be corrected, remove the device from active use and contact a qualified representative.

Therapy Cable Monitoring and Synchronized Cardioversion Check

CAUTION

POSSIBLE SIMULATOR DAMAGE

Do not discharge more than 30 shocks within an hour, or 10 shocks within a five-minute period, or pace continually into Physio-Control patient simulators. Simulators may overheat.

Equipment Needed:

- LIFEPAK 15 monitor/defibrillator
- QUIK-COMBO therapy cable
- Patient ECG cable
- 3-lead or 12-lead patient simulator with QUIK-COMBO connector
- Fully charged batteries

To check therapy cable monitoring and synchronized cardioversion:

1. Press **ON**.
2. Connect the ECG cable to the defibrillator and to the simulator.
3. Connect the therapy cable to the simulator.
4. Turn on the simulator and select any rhythm except asystole or ventricular fibrillation.
5. Select **PADDLES** lead.
6. Confirm that the screen displays an ECG and that the **PADDLES LEADS OFF** message does not appear.

   Note: If the screen displays dashed lines, artifact (irregular noise signals), or any warning message, replace the therapy cable and repeat the test. If the problem cannot be corrected, remove the defibrillator from active use and contact a qualified service representative.
7. Select Lead **II**.
8. Press **SYNC**. Confirm that the **SYNC** LED lights and the Sync mode message appears. Adjust ECG size until sense markers appear on the QRS complexes. Confirm that the **SYNC** LED blinks off with each detected QRS complex and that the heart rate is displayed.
9. Select **50 JOULES**.
10. Press **CHARGE**.

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11. Press **PRINT**.

WARNING

SHOCK HAZARD

During defibrillation checks, the discharged energy passes through the cable connectors. Securely attach cable connectors to the simulator.

12. After the tone sounds indicating full charge, press and hold (shock) while observing the Home Screen.
13. Confirm that the defibrillator discharges on the next sensed QRS complex.
14. Press **PRINT** again to stop the printer.
15. Confirm that the defibrillator returns to Asynchronous mode (sense markers are no longer displayed and **SYNC** LED is off).

    Note: Defibrillator may be set up to remain in Sync mode after discharge.
16. Select **PADDLES** lead.
17. Disconnect the therapy cable from the simulator. Confirm that the **PADDLES LEADS OFF** message appears and that an audible tone occurs.
18. Confirm that the printer annotates the time, date, Sync On, sense markers prior to energy delivered, energy selected, no sense markers after Shock 1, and Sync Off on the ECG strip.
19. Turn off the defibrillator.

Therapy Cable Pacing Check

Equipment Needed:

- LIFEPAK 15 monitor/defibrillator
- QUIK-COMBO therapy cable
- Patient ECG cable
- 3-lead or 12-lead patient simulator with QUIK-COMBO connector
- Fully charged batteries

To check therapy cable pacing:

1. Press **ON**.
2. Connect the QUIK-COMBO therapy cable to the QUIK-COMBO simulator.
3. Turn on the simulator and select **BRADY**.
4. Connect the ECG cable to the defibrillator and to the simulator.
5. Select Lead **II**.
6. Press **PACER**.

7. Confirm that sense markers appear on each QRS complex. If sense markers do not appear, or appear elsewhere on the ECG, press the **SELECTOR** on waveform Channel 1 and adjust ECG size from the menu.
8. Confirm that the **RATE** menu appears.
9. Press **CURRENT** and increase the current to 80 mA.
10. Observe the screen for captured complexes. Confirm the **PACER** LED flashes with each delivered pacing pulse.
11. Disconnect the QUIK-COMBO therapy cable from the simulator. Confirm that the pacemaker stops pacing, the **CONNECT ELECTRODES** message appears, and an audible alarm sounds.
12. Reconnect the QUIK-COMBO therapy cable to the simulator. Confirm that the audible alarm stops, the **PACING STOPPED** message is displayed, and current is 0 mA.
13. Wait approximately 30 seconds and confirm that an audible alarm occurs.
14. Increase current to 80 mA. Confirm that audible alarm stops.
15. Press **CHARGE**. Confirm that the **PACER** LED goes off and that heart rate and available energy are displayed.

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Battery Maintenance

This section provides information about the Physio-Control Lithium-ion batteries that are specifically designed for use in the LIFEPAK 15 monitor/defibrillator. Lithium-ion batteries are low maintenance and require no scheduled cycling to prolong battery life.

IMPORTANT! The LIFEPAK 15 monitor/defibrillator Lithium-ion batteries, battery chargers, and power cords are not interchangeable with batteries, battery chargers, and power cords that are used in other LIFEPAK defibrillators.

Battery Warnings

WARNINGS

POSSIBLE FIRE, EXPLOSION, AND BURNS

Do not disassemble, puncture, crush, heat above 100°C (212°F), or incinerate the battery.

LOSS OF POWER HAZARDS

POSSIBLE LOSS OF POWER AND DELAY OF THERAPY DURING PATIENT CARE

Using an improperly maintained battery to power the defibrillator may cause power failure without warning. Use the appropriate Physio-Control battery charger to charge batteries.

POSSIBLE LOSS OF POWER DURING PATIENT CARE

Physio-Control has no information regarding the performance or effectiveness of its LIFEPAK monitor/defibrillators if other manufacturers' batteries or battery chargers are used. Using other manufacturers' batteries or battery chargers may cause the device to perform improperly and invalidate the safety agency certifications. Use only Physio-Control LIFEPAK 15 monitor/defibrillator batteries (PN 3206735) and the appropriate Physio-Control LIFEPAK 15 monitor/defibrillator battery charger.

POSSIBLE LOSS OF POWER DURING PATIENT CARE

Battery pins in the defibrillator may be damaged if batteries are dropped or forced into battery wells. Inspect pins routinely for signs of damage. Keep batteries installed at all times except when device is removed from service for storage.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

When storing the LIFEPAK 15 monitor/defibrillator for an extended period of time, the battery should be removed from the device.

Receiving New Batteries

New batteries do not arrive fully charged. Charge each new battery in the LIFEPAK 15 Station or Mobile Li-ion Battery Charger before use. For information about charging batteries, see the *Instructions For Use* that ships with the battery charger.

Storing Batteries

Li-ion batteries self-discharge during storage.

If you store the battery:

- Do not remove the Charge Before Use label to indicate that the battery has not yet been charged.
- Store batteries at temperatures between 20° to 25°C (68° to 77°F).
- Charge the battery fully within one year of when you receive it. Fully recharge the battery once per year thereafter.

WARNING

POSSIBLE LOSS OF POWER DURING PATIENT CARE

Stored batteries lose charge. Failure to charge a stored battery before use may cause device power failure without warning. Always charge a stored battery before placing it in active use.

Charging the Battery

- Charge the battery before use.
- Remove the Charge Before Use label prior to placing the battery in the charger.
- Charge the battery using the LIFEPAK 15 Monitor/Defibrillator Station Li-ion Battery Charger or the Mobile Li-ion Battery Charger.
- The battery fuel gauge does not function until the battery is charged.
- For information about how to charge the battery, see the *Station and Mobile Lithium-ion Battery Charger Instructions for Use*.

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Replacing Batteries

Physio-Control recommends that batteries be replaced approximately every two years. Properly maintained batteries may last longer. A battery has reached the end of useful life if *one or more* of the following circumstances occur:

- Physical damage occurs to the battery case, for example, cracks or a broken clip.
- The battery is leaking.
- The battery charger indicates **FAULT**.
- The battery fuel gauge indicates two or fewer LEDs (bars) after the battery completes a charge cycle.

Dispose of used batteries promptly. Keep batteries away from children.

Recycling Batteries

To promote awareness of battery recycling, Physio-Control batteries are marked with one of these symbols:



When a battery has reached the end of its useful life, recycle the battery as described below.

Battery Recycling in the USA

Recycle batteries by participating with Physio-Control in a national recycling program. Contact your Physio-Control representative to obtain shipping instructions and shipping containers. Do not return your batteries to the Physio-Control offices in Redmond, Washington, unless instructed to do so.

Battery Recycling Outside the USA

Recycle batteries according to national and local regulations. Contact your local Physio-Control representative for assistance.

Cleaning the Device

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Do not clean any part of this device or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this device or any accessories unless otherwise specified in accessory operating instructions.

Clean the LIFEPAK 15 monitor/defibrillator, therapy and ECG cables, and batteries with a damp sponge or cloth. Use only the cleaning agents listed below:

- Quaternary ammonium compounds
- Isopropyl alcohol
- Peracetic (peroxide) acid solutions

Note: Carefully clean the connector ports. Do not allow cleaning fluids to penetrate the exterior surfaces of the device.

Clean the carrying case accessory as follows and as described on its instruction tag:

- Hand wash using mild soap or detergent and water. A scrub brush may be useful for heavily soiled spots. Cleaners such as Formula 409® are helpful for grease, oil, and other tough stains.

For information about cleaning the reusable monitoring sensors and cables, see the individual monitoring section.

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Storing the Device

To take the LIFEPAK 15 monitor/defibrillator out of service and store it for an extended period of time, follow these guidelines:

- Remove the batteries.
- Store the defibrillator and batteries at room temperature.

For more information about storage and operating specifications, see the Environmental section in Table A-1.

To return the LIFEPAK 15 monitor/defibrillator to service, perform the following tasks:

- Complete the tasks listed in the Operator's Checklist located at the end of this manual. If the Operator's Checklist can not be located, a copy is available at www.physio-control.com.
- Consider having the device serviced by a qualified service technician.

Loading Paper

Check the amount of paper in the printer as part of the daily check according to the Operator's Checklist provided in the back of this manual.

CAUTION

POSSIBLE PRINTER MALFUNCTION

Using other manufacturers' printer paper may cause the printer to function improperly or damage the print head. Use only Physio-Control printer paper.

The printer is equipped with an out-of-paper sensor to protect the printer printhead. The sensor automatically turns off the printer if paper runs out or the printer door is open.

To load paper:

1. Lift the printer door latch to release the door (see Figure 9-1).
2. Pull out the printer door.
3. Remove the empty paper spool, if present.
4. Insert a new paper roll with the graph side facing up. Make sure the end of the paper extends outward so it is exposed when the printer door is closed.
5. Close the printer door and press down on the latch until the door clicks shut.

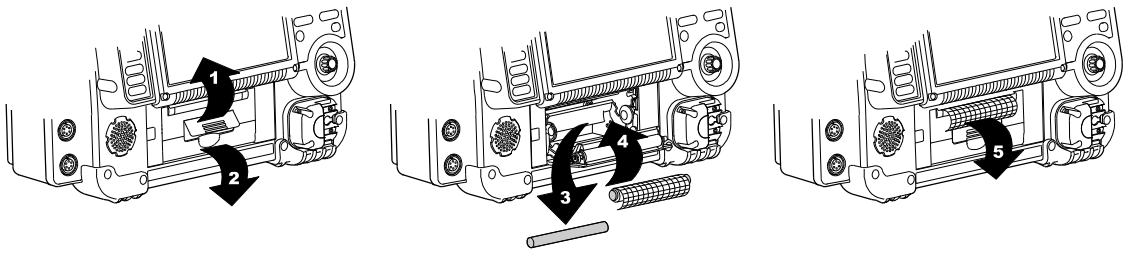


Figure 9-1 Loading Paper

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General Troubleshooting Tips

If a problem is detected with the LIFEPAK 15 monitor/defibrillator during operation or testing, refer to the troubleshooting tips in Table 9-2. If the problem cannot be corrected, remove the LIFEPAK 15 monitor/defibrillator from active use and contact a qualified service technician for service and repair.

Table 9-2 General Troubleshooting Tips

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
No power when monitor/ defibrillator is turned **ON**	Low battery voltage	• Replace with fully charged, properly maintained battery.
	Battery connector pin loose, covered with foreign substance, or damaged	• Remove battery and inspect pins. Clean if foreign substance present. Contact a qualified service technician to replace if bent, cracked, or loose.
Device won't turn off	**ON** not pressed long enough to turn off device	• Press and hold **ON** for at least two seconds.
Monitor/defibrillator operates, but screen is blank	Operating temperature is too low or too high	• Replace the battery immediately.
	Screen not operating properly	• Contact qualified service technician.
Monitor/defibrillator operates, but screen not readable	Screen in direct sunlight	• Change screen from color to black and white. • Reposition or shield device. • Print ECG strip to assess rhythm and other active vital signs. • Press **ANALYZE** and use AED mode, if necessary.
CHECK PRINTER message appears	Printer paper jams, slips, or misfeeds	• Reinstall paper. • If problem persists, contact qualified service technician.
	Printer is out of paper	• Add new paper.

Table 9-2 General Troubleshooting Tips (Continued)

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Service LED illuminates	Device self-test circuitry detects service condition	• Continue to use defibrillator or pacemaker, if needed. • Turn device off and then on again. Note that this creates a new "patient." If Service LED does not clear, remove device from active use. • Report occurrence of Service LED to qualified service personnel. • Obtain another defibrillator, if necessary.
ECG monitoring problems		• See "Troubleshooting Tips" on page 4-11.
Problems with AED operation		• See "Troubleshooting Tips" on page 5-19.
Problems with defibrillation/synchronized cardioversion		• See "Troubleshooting Tips" on page 5-28.
Problems with pacing		• See "Troubleshooting Tips" on page 5-35.
Displayed time is incorrect	Time is incorrectly set	• Change the time setting. See "Options" on page 3-23.
Date printed on report is incorrect	Date is incorrectly set	• Change the date setting. See "Options" on page 3-23.
Displayed messages are faint or flicker	Low battery power. Out of temperature range.	• Replace the battery immediately.
Low speaker volume	Moisture in speaker grill holes	• Wipe moisture from speaker grill and allow device to dry.
MAINTENANCE DUE message appears	Maintenance prompt is set to display at a selected interval in Service mode	• Continue to use device, if needed. • Contact service personnel to perform routine maintenance. • Contact Physio-Control Technical Support for instructions on how to reset or turn off this prompt.

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Service and Repair

WARNINGS

SHOCK HAZARD

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact a qualified service technician for repair.

INEFFECTIVE ENERGY DELIVERY HAZARD

Service mode is for authorized personnel only. Improper use of Service mode may inappropriately alter the device's configuration and may change energy output levels. Contact qualified service technician for assistance or information about device configuration.

If the LIFEPAK 15 monitor/defibrillator requires service as indicated by testing, troubleshooting, or a service message, contact a qualified service technician. In the USA, call Physio-Control Technical Support at 1.800.442.1142.

When calling Physio-Control to request service, identify the model and serial number and describe the observation. If the device must be shipped to a service center or the factory, pack the device in the original shipping container, if possible, or in protective packing to prevent shipping damage.

The *LIFEPAK 15 Monitor/Defibrillator Service Manual* provides detailed technical information to support service and repair by a qualified service technician.

Product Recycling Information

Recycle the device at the end of its useful life.

Recycling Assistance

The device should be recycled according to national and local regulations. Contact your local Physio-Control representative for assistance.

Preparation

The device should be clean and contaminant-free prior to being recycled.

Recycling of Disposable Electrodes

After using disposable electrodes, follow your local clinical procedures for recycling.

Packaging

Packaging should be recycled according to national and local regulations.

Warranty

Refer to the warranty statement included with the product. For duplicate copies, contact your local Physio-Control representative. In the US, call 1.800.442.1142. Outside the USA, contact your local Physio-Control representative.

Using defibrillation electrodes, adapter devices, or other parts and supplies from sources other than Physio-Control is not recommended. Physio-Control has no information regarding the performance or effectiveness of its LIFEPAK defibrillators if they are used in conjunction with defibrillation electrodes or other parts and supplies from other sources. If device failure is attributable to defibrillation electrodes or other parts or supplies not manufactured by Physio-Control, this may void the warranty.

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Accessories

Table 9-3 lists accessories that are available for the LIFEPAK 15 monitor/defibrillator. To order, contact your Physio-Control representative or order online at store.physio-control.com.

Note: The LIFEPAK 15 monitor/defibrillator and its accessories that are intended for direct or casual contact with the patient are latex-free.

Table 9-3 Accessories for the LIFEPAK 15 Monitor/Defibrillator

CATEGORY	RELATED ACCESSORY
Power	Lithium-ion battery
	Station Lithium-ion Battery Charger
	Mobile Lithium-ion Battery Charger
Therapy	QUIK-COMBO pacing/defibrillation/ECG electrodes
	QUIK-COMBO RTS pacing/defibrillation/ECG electrodes
	Pediatric QUIK-COMBO RTS pacing/defibrillation/ECG electrodes
	QUIK-COMBO pacing/defibrillation/ECG electrodes with REDI-PAK preconnect system
	QUIK-COMBO Therapy cable
	Standard paddles
	Pediatric paddles
Monitoring:	
ECG	3-lead ECG cable
	5-wire ECG cable
	12-lead ECG cable (includes main cable, limb lead attachment, and precordial lead attachment)
SpO_2	Patient extension cables LNOP® and LNCS™
	Reusable LNOP and LNCS sensors
	Disposable LNOP and LNCS sensors
	Disposable LNOP and LNCS sensors sample kits
SpCO and SpMet	Rainbow patient extension cables
	Rainbow reusable sensors
	Rainbow disposable sensors
NIBP	NIBP blood pressure cuffs
	NIBP hoses
$EtCO_2$	$EtCO_2$ FilterLine sets
	$EtCO_2$ Smart CapnoLine lines

Table 9-3 Accessories for the LIFEPAK 15 Monitor/Defibrillator (Continued)

CATEGORY	RELATED ACCESSORY
IP	Transducers (5 µV/V/mm Hg, IEC 60601-2-34 and AAMI BP-22 compliant)
Other accessories	Wireless modem/gateway
	LIFEPAK monitor to PC cable (serial communication cable)
	PC-based configuration tool
	Test Load

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A

SPECIFICATIONS AND PERFORMANCE CHARACTERISTICS

This appendix contains the specifications and performance characteristics for the LIFEPAK 15 monitor/defibrillator and the LIFEPAK 15 monitor/defibrillator batteries. It also lists high and low alarm limits, alarm performance characteristics, and factory default settings.

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A

Specifications and Performance Characteristics

Table A-1 lists the LIFEPAK 15 monitor/defibrillator specifications for the device.

Table A-2 lists the specifications for the LIFEPAK 15 monitor/defibrillator batteries.

Table A-3 lists the high and low limits for alarms when either the wide or narrow alarm setting is selected on the LIFEPAK 15 monitor/defibrillator.

Table A-4 lists the alarm performance characteristics.

Table A-5 lists the factory default settings for the LIFEPAK 15 monitor/defibrillator setup options.

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications

CHARACTERISTIC	DESCRIPTION
All specifications are at 20°C unless otherwise stated.	
GENERAL	
Modes	AED mode—for automated ECG analysis and a prompted treatment protocol for patients in cardiac arrest. Manual mode—for performing manual defibrillation, synchronized cardioversion, noninvasive pacing, and ECG and vital sign monitoring. Archive mode—for accessing stored patient information. Setup mode—for changing default settings of the operating functions. Service mode—for authorized personnel to perform diagnostic tests and calibrations. Demo mode—for simulated waveforms and trend graphs for demonstration purposes.
Self-test	When powered on, the device performs a self-test to check internal electrical components and circuitry. A service indicator is illuminated if an error is detected. The device also performs an auto test daily. Results are stored in the device log.
Continuous Patient Surveillance System (CPSS)	In Advisory Monitoring, CPSS monitors the patient ECG, via QUIK-COMBO® electrodes or Lead II, for a potentially shockable rhythm.
Voice Prompts	Manual mode: Used for selected prompts (selectable ON/OFF) AED mode: Used for entire AED protocol
Analog ECG Output	Output: 1 volt/mV Frequency Response: 0.67 to 32 Hz (except 2.5 to 25 Hz for Paddles ECG and 1.3 to 23 Hz for 1–30 Hz Monitor Frequency Response)
Notch Filter	50 or 60 Hz

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Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC		DESCRIPTION		
POWER				
Batteries		Rechargeable Lithium-ion battery, 11.1V typical		
		Dual battery capability with automatic switching		
		Low battery indication and message: Low battery fuel gauge indication and low battery message in status area for each battery		
		Replace battery indication and message: Replace battery fuel gauge indication, audio tones, and replace battery message in the status area for each battery. When replace battery is indicated, device auto-switches to second battery. When both batteries reach replace battery condition, a voice prompt instructs user to replace battery.		
		Input voltage range is between +8.8 and +12.6 VDC		
		5.7 Ah rated capacity		
Battery Capacity		For two, new fully-charged batteries, 20°C (68°F):		
Operating Mode		Monitoring Minutes	Pacing (minutes)	Defibrillation (360J discharges)
Total Capacity to Shutdown	Typical	360	340	420
	Minimum	340	320	400
Capacity After Low Battery	Typical	21	20	30
	Minimum	12	10	6
PHYSICAL				
Weight		Basic monitor/defibrillator with new roll paper and two batteries installed: 8.6 kg (18.9 lb)		
		Fully featured monitor/defibrillator with new roll paper and two batteries installed: 9.1 kg (20.1 lb)		
		Lithium-ion battery: 0.59 kg (1.3 lb)		
		Accessory bags and shoulder strap: 1.77 kg (3.9 lb)		
		Standard (hard) paddles: 0.95 kg (2.1 lb)		
Height		31.7 cm (12.5 in)		
Width		40.1 cm (15.8 in)		
Depth		23.1 cm (9.1 in)		
DISPLAY				
Size (active viewing area)		212 mm (8.4 in) diagonal; 171 mm (6.7 in) wide x 128 mm (5.0 in) high		

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
Display Type	640 dot x 480 dot color backlit LCD
	User selectable display mode (full color or SunVue™ high contrast)
	Displays a minimum of 4 seconds of ECG and alphanumerics for values, device instructions, or prompts
	Displays up to three waveforms
	Waveform display sweep speed: 25 mm/sec for ECG, SpO_2, IP, and 12.5 mm/sec for CO_2
DATA MANAGEMENT	
The device captures and stores patient data, events (including waveforms and annotations), and continuous waveform and patient impedance records in internal memory.	
The user can select and print reports, and transfer the stored information via supported communication methods.	
Report Types	Three format types of CODE SUMMARY™ critical event record: short, medium, and long
	12-lead ECG with STEMI statements
	Continuous ECG (transfer only)
	Trend Summary
	Vital Sign Summary
	Snapshot
Memory Capacity	Total capacity is 360 minutes of continuous ECG or 400 single waveform events.
	Maximum memory capacity for a single patient includes up to 200 single waveform reports and 90 minutes of continuous ECG.
COMMUNICATIONS	
The device is capable of transferring data records by wired or wireless connection. This device complies with Part 15 of the FCC rules, and its operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.	
Serial Port	RS232 communication +12V available Limited to devices drawing maximum 0.5 A current
Bluetooth® technology	*Bluetooth* technology provides short-range wireless communication with other *Bluetooth*-enabled devices.
MONITOR	
ECG	ECG is monitored via several cable arrangements. A 3-wire cable is used for 3-lead ECG monitoring. A 5-wire cable is used for 7-lead ECG monitoring. A 10-wire cable is used for 12-lead ECG acquisition. When the chest electrodes are removed, the 10-wire cable functions as a 4-wire cable. Standard paddles or QUIK-COMBO pacing/defibrillation/ECG electrodes are used for paddles lead monitoring.

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Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
Frequency Response	Monitor—0.5 to 40 Hz or 1 to 30 Hz Paddles—2.5 to 30 Hz 12-lead ECG diagnostic—0.05 to 150 Hz
Lead Selection	Leads I, II, III (3-wire ECG cable)
	Leads I, II, III, AVR, AVL, and AVF acquired simultaneously (4-wire ECG cable)
	Leads I, II, III, AVR, AVL, AVF, and C lead acquired simultaneously (5-wire ECG cable)
	Leads I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, and V6 acquired simultaneously (10-wire ECG cable)
ECG Size	4, 3, 2.5, 2, 1.5, 1, 0.5, 0.25 cm/mV (fixed at 1 cm/mV for 12-lead)
Heart Rate Display	20–300 bpm digital display
	Accuracy: ±4% or ±3 bpm, whichever is greater
QRS Detection Range	Duration: 40 to 120 msec Amplitude: 0.5 to 5.0 mV
Common Mode Rejection (CMRR)	ECG Leads: 90 dB at 50/60 Hz
SpO_2/SpCO/SpMet	
Sensors	Masimo® sensors including Rainbow™ sensors
SpO_2	
Displayed Saturation Range	"<50" for levels below 50%; 50 to 100%
Saturation Accuracy	70–100% (0–69% unspecified)
Adults/Pediatrics	±2 digits (during no motion conditions) ±3 digits (during motion conditions)
Dynamic signal strength bar graph	
Pulse tone as SpO_2 pulsations are detected	
SpO_2 Update Averaging Rate	User selectable: 4, 8, 12 or 16 seconds
SpO_2 Sensitivity	User selectable: Normal, High
SpO_2 Measurement	Functional SpO_2 values are displayed and stored
Pulse Rate Range	25 to 240 bpm
Pulse Rate Accuracy	
Adults/Pediatrics	±3 digits (during no motion conditions) ±5 digits (during motion conditions)
Optional SpO_2 waveform display with autogain control	
SpCO™	
SpCO Concentration Display Range	0 to 40%

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION	
SpCO Accuracy	±3 digits	
SpMet™		
SpMet Saturation Range	0 to 15.0%	
SpMet Display Resolution	0.1% up to 10%	
SpMet Accuracy	±1 digit	
NIBP		
Blood Pressure	Systolic Pressure Range: 30 to 255 mmHg	
	Diastolic Pressure Range: 15 to 220 mmHg	
	Mean Arterial Pressure Range: 20 to 235 mmHg	
	Units: mmHg	
	Blood Pressure Accuracy: ±5 mmHg	
	Blood Pressure Measurement Time: 20 seconds, typical (excluding cuff inflation time)	
Pulse Rate	Pulse Rate Range: 30 to 240 pulses per minute Pulse Rate Accuracy: ±2 pulses per minute or ±2%, whichever is greater	
Operation Features	Initial Cuff Pressure: User selectable, 80 to 180 mmHg Automatic Measurement Time Interval: User selectable	
Automatic Cuff Deflation	Excessive Pressure: If cuff pressure exceeds 290 mmHg Excessive Time: If measurement time exceeds 120 seconds	
CO_2		
CO_2 Range	0 to 99 mmHg (0 to 13.2 kPa) Units: mmHg, %, or kPa	
CO_2 Accuracy	CO_2 partial pressure at sea level:	Accuracy:
(0–80 bpm)*	0 to 38 mmHg (0 to 5.1 kPa)	±2 mmHg (0.27 kPa)
	39 to 99 mmHg (5.2 to 13.2 kPa)	±5% of reading + 0.08% for every 1 mmHg (0.13 kPa) above 38 mmHg (5.1 kPa)
(>80 bpm)*	0 to 18 mmHg (0 to 2.4 kPa)	±2 mmHg (0.27 kPa)
	19 to 99 mmHg (2.55 to 13.3 kPa)	±4 mmHg (0.54 kPa) or ±12% of reading, whichever is higher
	*For RR > 60 bpm, to achieve specified CO_2 accuracy, the Microstream® FilterLine® H Set for infant must be used.	
Respiration Rate Accuracy	0 to 70 bpm: ±1 bpm 71 to 99 bpm: ±2 bpm	
Respiration Rate Range	0 to 99 breaths/minute	
Rise Time	190 msec	
Response Time	3.3 seconds (includes delay time and rise time)	

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Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
Initialization Time	30 seconds (typical), 10-180 seconds
Ambient Pressure	Automatically compensated internally
Optional Display Waveform	CO_2 pressure
Scale factors	Autoscale, 0–20 mmHg (0–4 Vol%),0–50 mmHg (0–7 Vol%), 0–100 mmHg (0–14 Vol%)
INVASIVE PRESSURE	
Transducer Type	Strain-gauge resistive bridge
Transducer Sensitivity	5μV/V/mmHg
Excitation Voltage	5 VDC
Connector	Electro Shield CXS 3102A 14S-6S
Bandwidth	Digital filtered, DC to 30 Hz (< -3db)
Zero Drift	1 mmHg/hr without transducer drift
Zero Adjustment	±150 mmHg including transducer offset
Numeric Accuracy	±1 mmHg or 2% of reading, whichever is greater, plus transducer error
Pressure Range	-30 to 300 mmHg, in six user selectable ranges
Invasive Pressure Display	Display: IP waveform and numerics Units: mmHg Labels: P1 or P2, ART, PA, CVP, ICP, LAP (user selectable)
TREND	
Time Scale	Auto, 30 minutes, 1, 2, 4, or 8 hours
Duration	Up to 8 hours
ST	After initial 12-lead ECG analysis, automatically selects and trends ECG lead with the greatest ST displacement
Display	Choice of HR, PR (SpO_2), PR (NIBP), SpO_2(%), SpCO(%), SpMet(%), CO_2 ($EtCO_2$/$FiCO_2$), RR (CO_2), NIBP, IP1, IP2, ST
ALARMS	
Quick Set	Activates alarms for all active vital signs
VF/VT Alarm	Activates continuous CPSS monitoring in Manual mode
Apnea Alarm	Occurs when 30 seconds has elapsed since last detected respiration
Heart Rate Alarm Limit Range	Upper, 100–250 bpm; lower, 30–150 bpm
INTERPRETIVE ALGORITHM	12-Lead Interpretive Algorithm: University of Glasgow 12-Lead ECG Analysis Program, includes AMI and STEMI statements
PRINTER	
Prints continuous strip of the displayed patient information and reports	
Paper Size	100 mm (3.9 in)
Print Speed	25 mm/sec or 12.5 mm/sec Optional 50 mm/sec time base for 12-lead ECG reports

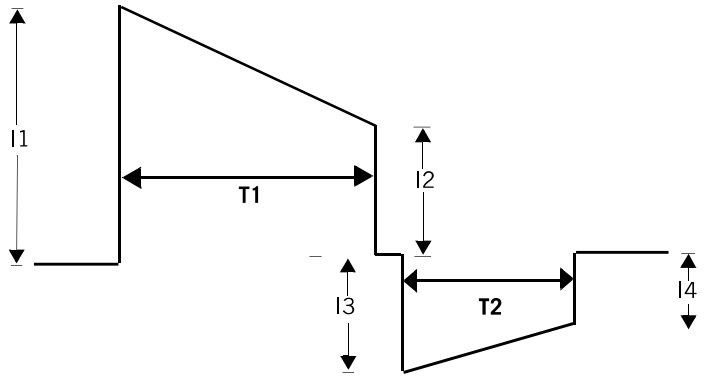
Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
Delay	8 seconds
Autoprint	Waveform events print automatically
Frequency Response	Diagnostic—0.05 to 150 Hz or 0.05 to 40 Hz Monitor—0.67 to 40 Hz or 1 to 30 Hz
DEFIBRILLATOR	
Manual Mode	
Energy Select	2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, and 360 joules
Charge time	Charge time to 360 joules in less than 10 seconds, typical
Synchronous cardioversion	Energy transfer begins within 60 msec of the QRS peak
Paddles Lead Off Sensing	The transition point at which device changes from assuming that QUIK-COMBO electrodes are properly connected to patient to assuming that electrodes are not connected is 300±50Ω.
Biphasic Waveform	Biphasic Truncated Exponential
	The following specifications apply from 25 to 200Ω, unless otherwise specified: Energy Accuracy: ±1 joule or 10% of setting, whichever is greater, into 50Ω; ±2 joules or 15% of setting, whichever is greater, into 25-175Ω.
	Voltage Compensation: Active when disposable therapy electrodes are attached. Energy output within ±5% or ±1 joule, whichever is greater, of 50Ω value, limited to the available energy which results in the delivery of 360 joules into 50Ω.

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Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION

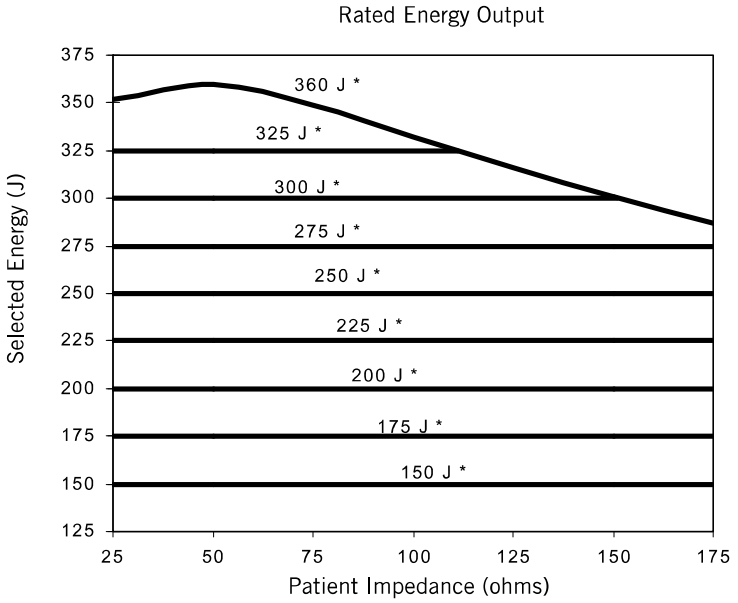


Biphasic Waveform

Patient Impedance (Ω)	Phase 1 Duration (ms)		Phase 2 Duration (ms)		Tilt (%)	
	Min	**Max**	**Min**	**Max**	**Min**	**Max**
25	5.1	6.0	3.2	4.2	69.9	85.2
50	6.8	7.9	4.4	5.5	57.0	74.7
75	7.6	9.4	4.9	6.5	49.3	67.6
100	8.7	10.6	5.6	7.3	43.0	62.2
125	9.5	11.2	6.2	7.7	39.0	56.6
150	10.1	11.9	6.6	8.2	36.8	52.6
175	10.6	12.5	6.9	8.6	33.8	49.3

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
	Rated energy output is the nominal delivered energy based on the energy setting and patient impedance as defined in the following chart.



* Energy setting selected

Paddle Options	QUIK-COMBO pacing/defibrillation/ECG electrodes (standard) Standard paddles (optional)
Cable Length	8 foot long (2.4 m) QUIK-COMBO cable (not including electrode assembly)
AED Mode	Shock Advisory System (SAS) is an ECG analysis system that advises the operator if the algorithm detects a shockable or nonshockable ECG rhythm. SAS acquires ECG via therapy electrodes only.
Shock Ready Time (AED mode)	Using a fully charged battery at normal room temperature, the device is ready to shock within 20 seconds if the initial rhythm finding is **SHOCK ADVISED**
Biphasic Output Energy	Shock levels ranging from 150–360 joules with same or greater energy level for each successive shock
cprMAX™ Technology	In AED mode, cprMAX technology provides a method of maximizing the CPR time that a patient receives, with the overall goal of improving the rate of survival of patients treated with AEDs
Setup Options:	
Auto Analyze	Allows for auto analysis. Options are **OFF, AFTER 1ST SHOCK**
Initial CPR	Allows the user to be prompted for CPR for a period of time prior to other activity. Options are **OFF**, **ANALYZE FIRST**, **CPR FIRST**

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Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
Initial CPR Time	Time interval for Initial CPR. Options are **15**, **30**, **45**, **60**, **90**, **120**, and **180** seconds
Pre-Shock CPR	Allows the user to be prompted for CPR while the device is charging. Options are **OFF**, **15**, **30** seconds
Pulse Check	Allows the user to be prompted for a pulse check at various time. Options are **ALWAYS**, **AFTER SECOND NSA**, **AFTER EVERY NSA**, **NEVER**
Stacked Shocks	Allows for CPR after 3 consecutive shocks or after a single shock. Options are **OFF**, **ON**
CPR Time 1 or 2	User selectable times for CPR. Options are **15**, **30**, **45**, **60**, **90**, **120, 180** seconds and **30** minutes
PACER	
Pacing Mode	Demand or nondemand Rate and current defaults
Pacing Rate	40 to 170 PPM
Rate Accuracy	±1.5% over entire range
Output Waveform	Monophasic, truncated exponential current pulse (20 ±1.5 msec)
Output Current	0 to 200 mA
	Pause: Pacing pulse frequency reduced by a factor of 4 when activated
Refractory Period	180 to 280 msec (function of rate)
ENVIRONMENTAL—Unit meets functional requirements during exposure to the following environments unless otherwise stated.	
Operating Temperature	0° to 45°C (32° to 113°F) -20°C (-4°F) for 1 hour after storage at room temperature 60°C (140°F) for 1 hour after storage at room temperature
Storage Temperature	-20° to 65°C (-4° to 149°F) except therapy electrodes and batteries
Relative Humidity, Operating	5 to 95%, non-condensing NIBP: 15 to 95%, non-condensing
Relative Humidity, Storage	10 to 95%, non-condensing
Atmospheric Pressure, Operating	-382 to 4,572 m (-1,253 to 15,000 ft) NIBP: -152 to 3,048 m (-500 to 10,000 ft)
Water Resistance, Operating	IP44 (splash and dust resistance) per IEC 529 and EN 1789 (without accessories except for 12-lead ECG cable, hard paddles, and battery pack)
Vibration	MIL-STD-810E Method 514.4 Propeller Aircraft - category 4 (figure 514.4-7 spectrum a) Helicopter - category 6 (3.75 Grms) Ground Mobile - category 8 (3.14 Grms)
	EN 1789: Sinusoidal Sweep, 1 octave/min, 10-150 Hz, ±0.15 mm/2 g
Shock (drop)	5 drops on each side from 18 inches onto a steel surface EN 1789: 30-inch drop onto each of 6 surfaces

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION
Shock (functional)	Meets IEC 60068-2-27 and MIL-STD-810E shock requirements 3 shocks per face at 40 g, 6 ms half-sine pulses
Bump	1000 bumps at 15 g with pulse duration of 6 msec
Impact, Non-operating	IEC 60601-1 0.5 + 0.05 joule impact UL 60601-1 6.78 Nm impact with 2-inch diameter steel ball Meets IEC62262 protection level IK 04
EMC	EN 60601-1-2:2001 Medical Equipment - General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
	EN 60601-2-4:2003: (Clause 36) Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator-Monitors
Cleaning	Cleaning 20 times with the following: Quaternary ammonium, isopropyl alcohol, hydrogen peroxide
Chemical Resistance	60 hour exposure to specified chemicals: Betadine (10% Povidone-Iodine solution) Coffee, Cola Dextrose (5% Glucose solution) Electrode Gel/Paste (98% water, 2% Carbopol 940) HCL (0.5% solution, pH=1) Isopropyl Alcohol NaCl solution (0.9% solution) Cosmetic discoloration of the paddle well shorting bar shall be allowed following exposure to HCL (0.5% solution).

Table A-2 Battery Specifications

CHARACTERISTIC	DESCRIPTION
Battery Type	Lithium-ion
Weight	0.59 kg (1.3 lb)
Voltage	11.1V typical
Capacity (rated)	5.7 amp hours
Charge Time (with fully depleted battery)	4 hours and 15 minutes (typical)
Battery indicators	Each battery has a fuel gauge that indicates its approximate charge. A fuel gauge that shows two or fewer LEDs after a charge cycle indicates that the battery should be replaced.
Charging Temperature Range	0° to 50°C (32° to 122°F)
Operating Temperature Range	0° to 50°C (32° to 122°F)
Short Term (<1 week) Storage Temperature Range	-20° to 60°C (-4° to 140°F)
Long Term (>1 week) Storage Temperature Range	20° to 25°C (68° to 77°F)
Operating and Storage Humidity Range	5 to 95% relative humidity, non-condensing

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Table A-3 Alarm Limits

VITAL SIGN (VS)	PATIENT VS VALUE	WIDE LIMITS*		NARROW LIMITS*		LIMITS RANGE		DEFAULT LIMITS**	
		LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH
Heart Rate	<60	-20	+35	-10	+25	30–150	100–250	50	150
(HR)	60–79	-25	+40	-20	+30				
Pulse Rate (PR)	80–104	-30	+40	-30	+30				
(bpm)	≥105	-35	+45	-25	+25				
SpO_2	≥90	-5	+3	-5	+3	50	90–100	85	100
(%)	<90	-5	+3	-5	+3				
Systolic BP (mmHg)	<90	-20	+35	-10	+25	30	245	50	200
	90–114	-20	+35	-10	+25				
	115–140	-25	+35	-10	+20				
	>140	-25	+35	-10	+20				
Diastolic BP (mmHg)	<65	-15	+25	-10	+25	12	210	20	150
	65-90	-15	+15	-15	+10				
	>90	-15	+15	-15	+10				
$EtCO_2$ (mmHg/%)	>40/5.3	-10/-1.3	+15/+2.0	-10/-1.3	+15/+2.0	5/0.7	70/9.2	15/2.0	50/6.6
	≤40/5.3	-10/-1.3	+15/+2.0	-10/-1.3	+15/+2.0				
Inspired CO_2 (mmHg/%)	—	n/a	+5/+0.7	n/a	+3/+0.4	n/a	0/0–10/1.3	—	8/1.1
Respiration	<15	-8	+8	-4	+4	5-15	10–60	5	30
Rate (RR)	≥15	-15	+15	-8	+8				
Systolic PA (mmHg)	<15	-6	+12	-4	+6	10	100	10	40
	15–35	-8	+16	-6	+8				
	>35	-12	+16	-8	+10				
Diastolic PA (mmHg)	<5	-4	+12	-4	+8	0	50	0	18
	5–13	-4	+16	-6	+6				
	>13	-6	+16	-6	+6				
CVP (mmHg)	≥9	-10	+10	-5	+5	0	25	0	15
ICP, LAP (mmHg)	<15	-6	+6	-4	+4	0	40	0	18
	≥15	-6	+8	-4	+6				

*Numbers are ± from patient's VS value when the alarms are set.

**Default limits are established when alarms are set up to be ON.

Table A-4 Alarm Performance Characteristics

CHARACTERISTIC	DESCRIPTION
Heart Rate Alarm Time	For a 1 mV, 206 bpm tachycardia, the average detection time was 4.6 seconds. For a test signal half as large, the average was 4.1 seconds. In this case the device sensitivity was increased to 5mV/cm. For a test signal twice as large, the average was 3.1 seconds. For a 2 mV, 195 bpm tachycardia, the average detection time was 2.5 seconds. For a test signal half as large, the average was 2.2 seconds. In this case the device sensitivity was increased to 5mV/cm. For a test signal twice as large, the average was 1.5 seconds.
Audible Alarms	This is a standalone device. All alarm tones are internal to the LIFEPAK 15 monitor/defibrillator.
	Alarm violations are manifested by tones, voice prompts, and visual indications.
	Alarm manifestation occurs within 1 second after a displayed parameter violates its alarm limit. User selectable alarm volume adjustment is provided. This adjustment does not allow alarm volume to attain/reach a zero level.
	SAS tones reinforce SAS messages provided on the product display.
	The following identifies the tone assignments for each type of alarm: • The priority 1 tone is used to alert the user to the possibility of death. This tone is a 440 Hz and 880 Hz alternating tone with a 50% duty cycle and a 4 Hz alternation frequency. This tone has a volume of 70 ±5 dB (A) as measured at a distance of 1 meter from the display. • The priority 2 tone (the Quick Set alarm tone) is used to alert the user that a possible life-threatening condition exists. This tone is a continuous 698 Hz tone. • The priority 3 tone is used to alert the user that an abnormal condition exists. Three beeps at 1046 Hz for 100 ms duration each with a 150 ms silence between the first and second and the second and third, followed by a 200 ms silence. • Priority 3 tones come in single and repeating types: for a single tone, the 3-beep sequence sounds only once. For a repeating tone, the 3-beep sequence sounds every 20 seconds. • The priority 4 tone is a momentary tone between 500 and 1500 Hz. Specific characteristics are: • QRS and Volume Setting Tone—100 msec duration at 1397 Hz—4 msec duration at 1319 Hz.
	The alert tone shall consist of one set of two tones to precede voice prompts and to draw attention to the display. Specific characteristics consist of: • 1000 Hz square wave, 100 ms duration. • Silence, 100 msec duration. • Silence, 140 msec duration (when preceding a voice prompt). • Voice prompt, when used.

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Table A-4 Alarm Performance Characteristics (Continued)

CHARACTERISTIC	DESCRIPTION
Visual Alarms	Alarms are indicated visually by: • The violated parameter flashes in inverse video with a message in the message area of the display. • These visual indications remain on the display until the alarm is corrected. Visual indication of alarms continue even when the tones have been silenced.

Table A-5 Setup Options Factory Default Settings

MENU	MENU/ITEM	FACTORY DEFAULT SETTINGS	
General	Language	(Country Specific)	
	Code Summary	Long	
	Trend Summary	Off	
	Site Number	000	
	Device ID	"LP15" + last 4 digits of serial number, for example, LP151234	
	Auto Log	On	
	Line Filter	60 Hz	
	Timeout Speed	30 seconds	
Manual mode	Sync After Shock	Off	
	Pads Default	200 (joules)	
	Energy Protocol	Inactive	
	Internal Default	10 (joules)	
	Voice Prompts	On	
	Shock Tone	On	
	Manual Access	Manual / Direct	
	Set Passcode	0000	
AED mode	Energy Protocol	200–300–360	
	Auto Analyze	Off	
	Motion Detection	On	
	Pulse Check	Never	
	CPR	CPR Time 1	120 seconds
		CPR Time 2	120 seconds
		Initial CPR	Off
		Initial CPR Time	120 seconds
		Preshock CPR	Off
CPR Metronome	Metronome	On	
	Adult - No Airway	30:2	
	Adult - Airway	10:1	
	Youth - No Airway	15:2	
	Youth - Airway	10:1	

Table A-5 Setup Options Factory Default Settings (Continued)

MENU	MENU/ITEM	FACTORY DEFAULT SETTINGS	
Pacing	Rate	60 PPM	
	Current	0 mA	
	Mode	Demand	
	Internal Pacer	Detection Off	
Monitoring	Channels	Default Set	Set 1
	Set 1	Channel 1	ECG Lead II
		Channel 2	None
		Channel 3	None
	Continuous ECG	On	
	SpO2 Tone	Off	
	CO2	Units	mmHg
		BTPS	Off
	NIBP	Initial Pressure	160 mmHg
		Interval	Off
	Trends	On	
12-Lead	Auto Transmit	Off	
	Auto Print	On	
	Print Speed	25 mm/sec	
	Interpretation	On	
	Format	3-Channel Standard	
Events	Events Page 1	Event 2	Oxygen
		Event 3	IV Access
		Event 4	Nitroglycerin
		Event 5	Morphine
		Event 6	Cancel Last
		Event 7	Intubation
		Event 8	CPR
		Event 9	Epinephrine
		Event 10	Atropine
		Event 11	Lidocaine
	Events Page 2	Event 12	ASA
		Event 13	Heparin
		Event 14	Thrombolytic
		Event 15	Glucose
		Event 16	Naloxone
		Event 17	Transport
		Event 18	Adenosine
		Event 19	Vasopressin
		Event 20	Amiodarone

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Table A-5 Setup Options Factory Default Settings (Continued)

MENU	MENU/ITEM	FACTORY DEFAULT SETTINGS	
		Event 21	Dopamine
		Event 22	Bicarb
Alarms	Volume	5	
	Alarms	Off	
	VF/VT Alarm	Off	
Printer	Auto Print	Defibrillation	On
		Pacing	Off
		Check Patient	Off
		SAS	Off
		Patient Alarms	Off
		Events	Off
		Initial Rhythm	Off
	ECG Mode	Monitor	
	Monitor Mode	1–30 Hz	
	Diagnostic Mode	.05–40 Hz	
	Alarm Waveforms	On	
	Event Waveforms	On	
	Vitals Waveforms	Off	
Transmission	Sites	Site 1 / Output Port / Direct Connect	
	Default Site	None	
	Default Report	12-Lead	
	Wireless	On	
	Search Filter	On	
Clock	Date/Time	Current date/time PST	
	Clock Mode	Real Time	
	DST	Off	
	Time Zone	None	
Service	Maintenance Prompt Interval	Off	

B

SCREEN MESSAGES

This appendix describes the screen messages that the LIFEPAK 15 monitor/defibrillator may display during normal operation.

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Table B-1 Summary of Screen Messages

MESSAGE	DESCRIPTION
12-LEAD ECG UNAVAILABLE	A 12-lead was requested but the necessary ECG data is not available.
ABNORMAL ENERGY DELIVERY	A discharge occurred when the paddles were shorted together, when hard paddles did not have adequate contact with the patient or were discharged in the air, or patient impedance was out of range. Message may also appear in certain types of internal faults.
ACCESS DENIED	Three consecutive incorrect passcode attempts were made to enter Manual mode.
ACQUIRING 12-LEAD	Monitor is acquiring data for 12-lead ECG report.
ACQUIRING SNAPSHOT	A snapshot report of current vital signs has been requested.
ADVISORY MODE-MONITORING	The device is monitoring the patient ECG for a shockable rhythm.
ADVISORY: SPCO > 10%	SpCO advisory alert activated. SpCO value is greater than 10%.
ADVISORY: SPMET > 3%	SpMet advisory alert activated. SpMet value is greater than 3%.
ALARM APNEA	No valid breath has been detected for 30 seconds.
ALARMS SILENCED	Alarms are silenced. An alert tone with status message **ALARMS SILENCED** occurs periodically as a reminder.
ANALYZING 12-LEAD	The data for 12-lead ECG report is being analyzed.
ANALYZING NOW-STAND CLEAR	The AED is analyzing the patient ECG rhythm.
ATTEMPTING TO TRANSMIT	The device is processing a transmission request.
AUTO NIBP CANCELLED	The automatic initiation of NIBP measurements has been cancelled.
BATTERY X LOW	The specified battery has a low energy condition.
BLUETOOTH DEVICE NOT FOUND	*Bluetooth* device has not been detected.
BLUETOOTH UNAVAILABLE	Unable to locate or connect to target device.
CANNOT CHARGE	**CHARGE** is pressed and the synchronize source is missing for synchronized cardioversion, the therapy cable is not connected, or QUIK-COMBO electrodes are not attached to the therapy cable.
CHARGING TO XXX J	Appears when **CHARGE** is pressed on the front panel or standard paddles.
CHECK FOR PULSE	AED prompt after each standard 3-shock sequence or **NO SHOCK ADVISED** message.
CHECK PATIENT!	A potentially shockable rhythm has been detected when the VF/VT alarm is on.

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Table B-1 Summary of Screen Messages (Continued)

MESSAGE	DESCRIPTION
CHECK PRINTER	The printer door is open, there is no paper in the printer, or another printer malfunction exists.
CO2 AUTOZERO	$EtCO_2$ monitor is automatically performing a zero-point calibration.
CO2 FILTERLINE BLOCKAGE	$EtCO_2$ FilterLine tubing is kinked or clogged; the message appears after 30 seconds of unsuccessful purging.
CO2 FILTERLINE OFF	$EtCO_2$ FilterLine tubing is disconnected or is not securely connected to the device.
CO2 FILTERLINE PURGING	$EtCO_2$ FilterLine tubing is kinked or clogged with liquid.
CO2 INITIALIZING	$EtCO_2$ monitor is performing a self-check.
CONNECT CABLE	Therapy cable is not connected when you press **CHARGE**, **PACER**, or **ANALYZE**.
CONNECT CHEST LEADS	A 12-lead ECG analysis was requested and precordial leads are not connected to the patient.
CONNECT ECG LEADS	ECG electrodes or leads are disconnected.
CONNECT ELECTRODES	Therapy electrodes are disconnected.
CONNECTED TO	The device is connected via *Bluetooth* technology to another *Bluetooth*-enabled device. The name of the connected device follows this message.
CONNECTING TO	The device is establishing communication with another *Bluetooth*-enabled device. The name of the target device follows this message.
CPR: ADULT-AIRWAY X:Y	An option for CPR metronome. The patient is an adult for whom an advanced airway has been established. The specified C:V ratio will be used.
CPR: ADULT-NO AIRWAY X:Y	An option for CPR metronome. The patient is an adult for whom an advanced airway has not been established. The specified C:V ratio will be used.
CPR: YOUTH-AIRWAY X:Y	An option for CPR metronome. The patient is a youth (younger than the age of puberty) for whom an advanced airway has been established. The specified C:V ratio will be used.
CPR: YOUTH-NO AIRWAY X:Y	An option for CPR metronome. The patient is a youth (younger than the age of puberty) for whom an advanced airway has not been established. The specified C:V ratio will be used.
CURRENT FAULT	The comparison between delivered and selected pacing current is out of tolerance.
DEMAND	Pacemaker is in Demand mode.

Table B-1 Summary of Screen Messages (Continued)

MESSAGE	DESCRIPTION
DEMO MODE	The device is in Demo mode and simulated patient data is displayed.
DISARMING...	The energy charge is being removed internally.
ECG CABLE OFF	The device is printing and the ECG cable is removed.
ECG LEADS OFF	Multiple ECG electrodes are disconnected.
ENDING DEVICE SEARCH	The request for finding a *Bluetooth* device was stopped.
ENERGY DELIVERED	Energy transfer is complete.
ENERGY FAULT	The comparison between stored and selected energy is out of tolerance.
ENTER MANUAL MODE?	One of the Manual mode access buttons was pressed and the confirmation screen is set up to appear.
EXCESSIVE NOISE - 12-LEAD CANCELLED	Noise is detected for longer than 30 seconds that is too great to record a 12-lead ECG report.
IF NO PULSE, PUSH ANALYZE	Follows a CPR interval, if a **PULSE CHECK** setup option other than **NEVER** is selected.
IF NO PULSE, START CPR	Follows delivery of a shock or **NO SHOCK ADVISED** prompt, if a **PULSE CHECK** setup option other than **NEVER** is selected.
IF YOU WITNESSED THE ARREST, PUSH ANALYZE	Initial CPR message that follows **START CPR** prompt, to remind user to deliver a shock immediately if the user witnessed the arrest.
LA LEADS OFF	ECG electrode "LA" is disconnected.
LAST CONNECTED TO	When *Bluetooth* connectivity is installed and this device previously connected to a target device, the name of the target device appears after this message.
LL LEADS OFF	ECG electrode "LL" is disconnected.
LOST BLUETOOTH CONNECTION	Communication with *Bluetooth* device has been interrupted.
LOST DIRECT CONNECTION	Communication via direct connection has been interrupted.
MAINTENANCE DUE	Reminder message that appears at the interval that is set in Service mode. Message continues to appear until reset or turned off.
MANUAL MODE DISABLED	Access to Manual mode from AED mode has been restricted.
MOTION DETECTED!/STOP MOTION!	Motion was detected during ECG analysis.
NIBP AIR LEAK	NIBP cuff applied too loosely or there is a leak in cuff/monitor pneumatic system.
NIBP CHECK CUFF	NIBP cuff is not connected to patient or device.

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Table B-1 Summary of Screen Messages (Continued)

MESSAGE	DESCRIPTION
NIBP FAILED	NIBP monitor cannot establish zero-pressure reference.
NIBP FLOW ERROR	NIBP pneumatic system is not maintaining stable cuff pressure.
NIBP INITIALIZING	NIBP is requested and is unable to be successful due to a 30 second reset.
NIBP MOTION	Patient extremity moved too much for the NIBP monitor to accurately complete the measurement.
NIBP OVERPRESSURE	NIBP cuff pressure exceeded 290 mmHg.
NIBP TIME OUT	NIBP monitor did not complete a measurement in 120 seconds.
NIBP WEAK PULSE	The monitor did not detect any pulses.
NO SHOCK ADVISED	The defibrillator did not detect a shockable rhythm.
NO SITES DEFINED	Device is attempting to transmit using *Bluetooth* connection, but no associated destinations have been defined.
NOISY DATA! PRESS 12-LEAD TO ACCEPT	Monitor detects excessive signal interference while acquiring data. Press **12-LEAD** to override the message and acquire 12-lead ECG with noise.
NON-DEMAND	Pacemaker is in Nondemand (asynchronous) mode.
OBTAINING DEVICE NAMES	Device is obtaining names of available *Bluetooth*-enabled devices.
PACER FAULT	Internal error detected during pacing.
PACING IN PROGRESS	The requested action is not available because the device is currently performing pacing.
PACING STOPPED	Pacing has stopped—for example, due to disconnection of therapy electrodes.
PASSCODE INCORRECT - TRY AGAIN	Incorrect passcode entered.
PAUSED	The pacing **PAUSE** button is pressed and held. Current pulses are applied at reduced frequency while the MA and PPM settings are maintained.
PUSH ANALYZE	Press **ANALYZE** to begin ECG analysis.
PUSH SHOCK BUTTON!	The defibrillator is fully charged and ready to provide therapy.
PX NOT ZEROED	Transducer is connected or reconnected and is not zeroed.
PX TRANSDUCER NOT DETECTED	IP transducer is disconnected from the monitor/defibrillator.
PX ZERO FAILED	The device was unable to zero the pressure transducer.
PX ZEROED	Transducer successfully zeroed.
PX ZEROING	Monitor is establishing a zero reference.

Table B-1 Summary of Screen Messages (Continued)

MESSAGE	DESCRIPTION
RA LEADS OFF	ECG electrode "RA" is disconnected.
REPLACE BATTERY X	Power loss for the battery in well X is imminent.
SEARCHING FOR DEVICES	Device is attempting to identify available *Bluetooth* devices.
SELECT BIPHASIC ENERGY / XXX J	**ENERGY SELECT** was pressed on front panel or on standard paddles.
SELF TEST FAILED	Device detected internal error; remove device from service.
SELF TEST IN PROGRESS	Device is performing a self test after turning on.
SELF TEST PASSED	Device passed internal test and is available for use.
SHOCK ADVISED!	The defibrillator has analyzed the patient ECG rhythm and detected a shockable ECG rhythm.
SPO2: CHECK SENSOR	The SpO_2 sensor connection to device or application to patient needs checked.
SPO2: LOW PERFUSION	Patient has a weak pulse.
SPO2: NO SENSOR DETECTED	A sensor is disconnected from the monitor.
SPO2: POOR QUALITY SIGNAL	Device is not receiving sufficient input from sensor.
SPO2: SEARCHING FOR PULSE	A sensor is connected to the patient and is searching for a pulse.
SPO2: SENSOR DOES NOT SUPPORT SPCO OR SPMET	The sensor in use only measures SpO_2.
SPO2: UNKNOWN SENSOR	A sensor that is not Physio-Control approved is connected to the device.
STAND CLEAR/PUSH SHOCK BUTTON	Prompts you to stand clear and push (shock).
START CPR	Prompts you to begin providing CPR to the patient.
SWITCHING PRIMARY TO LEAD II	Pacing is turned on while **PADDLES** is the primary lead.
SWITCHING PRIMARY TO PADDLES	Device was in Lead II when **ANALYZE** was pressed. **PADDLES** becomes the primary lead.
SYNC MODE	Device is currently in Sync mode.
TO CANCEL, PUSH SPEED DIAL	The defibrillator is charging or charged and the device may be disarmed by pressing the Speed Dial.
TRANSMISSION CANCELLED	Data transmission has been cancelled.
TRANSMISSION COMPLETED	Data transmission completed successfully.
TRANSMISSION FAILED	Data transmission was not successful.

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Table B-1 Summary of Screen Messages (Continued)

MESSAGE	DESCRIPTION
TRANSMITTING TO <SITE>	Connection is established to <site> and transmission of requested report is occurring.
UNABLE TO CONNECT	Unable to establish connection with *Bluetooth* device.
UNABLE TO TRANSMIT	Unable to send data.
UNKNOWN DEVICE	*Bluetooth* connection failed or timed out before obtaining target device name.
USE ECG LEADS	Sync mode attempted, but ECG electrodes are not attached to patient, **PADDLES** lead is displayed, and standard paddles are connected to defibrillator.
USER TEST FAILED	Unsuccessful User Test.
USER TEST IN PROGRESS	**USER TEST** selected on the **OPTIONS** menu and test is in process.
USER TEST PASSED	Successful User Test completed.
VX LEADS OFF	ECG electrode such as “V1” is disconnected.
X DEVICES FOUND	Shows number of *Bluetooth*-enabled devices found.
XX LEADS OFF	ECG electrode such as “RA” is disconnected.
XX% TRANSMITTED	Specified percent of the transmission is completed.

C

SHOCK ADVISORY SYSTEM

This appendix describes the basic function of the Shock Advisory System™ (SAS) algorithm.

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Overview of the Shock Advisory System

The Shock Advisory System (SAS) is an ECG analysis system built into the biphasic LIFEPAK 15 monitor/defibrillator that advises the operator as to whether it detects a shockable or nonshockable rhythm. This system makes it possible for individuals who are not trained to interpret ECG rhythms to provide potentially lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia.

The Shock Advisory System contains the following features:

- Electrode Contact Determination
- Automated Interpretation of the ECG
- Operator Control of Shock Therapy
- Continuous Patient Surveillance System (CPSS)
- Motion Detection

The Shock Advisory System is active when the LIFEPAK 15 monitor/defibrillator is used as an automated external defibrillator (AED). CPSS may be activated during monitoring.

When the LIFEPAK 15 monitor/defibrillator is in AED mode, the device recommends and advises defibrillation shocks for patients who have heart rates up to 350 bpm if all other shockable ECG criteria are met. Upon the user pressing the (shock) button, the LIFEPAK 15 device delivers the shock therapy to the patient.

Electrode Contact Determination

The Shock Advisory System measures the patient's transthoracic impedance through the therapy electrodes. If the baseline impedance is higher than a maximum limit, it determines that the electrodes do not have sufficient contact with the patient or are not properly connected to the AED. When this occurs, ECG analysis and shock delivery are inhibited. The AED advises the operator to connect electrodes when there is insufficient electrode contact.

Automated Interpretation of the ECG

The Shock Advisory System recommends a shock if it detects the following:

- Ventricular fibrillation—with a peak-to-peak amplitude of at least 0.08 mV.
- Ventricular tachycardia—defined as having a heart rate of at least 120 beats per minute, QRS width of at least 0.16 seconds, and no apparent P waves.

Pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm. The Shock Advisory System recommends no shock for all other ECG rhythms including asystole, pulseless electrical activity, idioventricular rhythms, bradycardia, supraventricular tachycardias, atrial fibrillation and flutter, heart block, premature ventricular

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complexes, and normal sinus rhythms. These rhythms are specifically mentioned in the AHA recommendations. The SAS does not continue analyzing the ECG after a **SHOCK ADVISED** decision is reached.

Shock Advisory System Performance

ECG analysis by the Shock Advisory System (SAS) in the LIFEPAK 15 monitor/defibrillator was tested by playing ECG waveforms from the Physio-Control database through the electrode connector. For each test ECG, the decision **SHOCK** or **NO SHOCK** of the SAS was recorded and compared to the rhythm classification and treatment recommendation by clinical experts. A report of test results is available on request.

SAS Test Set

The SAS Test Set consists of 989 ECG samples recorded during pre-hospital use of the LIFEPAK 5 defibrillator. The ECG was recorded using cassette tape recorders connected to the LIFEPAK 5 defibrillator. Selected ECG segments were sampled and the ECG rhythm was classified by clinical experts. The SAS Test Set contains the following ECG samples:

- 168 each coarse ventricular fibrillation (VF) (≥200 µV peak-to-peak amplitude)
- 29 each fine ventricular fibrillation (<200 and ≥80 µV peak-to-peak amplitude)
- 65 each shockable ventricular tachycardia (VT) (HR >120 bpm, QRS duration ≥160 ms, no apparent P waves, patient reported to be pulseless by the paramedics)
- 43 each asystole (<80 µV peak-to-peak amplitude)
- 144 each normal sinus rhythm (NSR) (sinus rhythm, heart rate 60-100 bpm)
- 531 each other organized rhythm (includes all rhythms except those in other listed categories)
- 2 each transitional (transition occurs within the sample from nonshockable to nonshockable or vice versa)
- 5 each shockable rhythms with pacemaker artifact (the pacemaker artifact is spread over time by the filtering in the LIFEPAK 5 defibrillator)
- 2 each nonshockable rhythms with pacemaker artifact (the pacemaker artifact is spread over time by the filtering in the LIFEPAK 5 defibrillator)

Table C-1 LIFEPAK 15 Monitor/Defibrillator Overall SAS Performance

SAS OVERALL PERFORMANCE	
Sensitivity	>90%
Specificity	>95%
Positive Predictive Value	>90%
False Positive Rate	<5%

Table C-2 LIFEPAK 15 Monitor/Defibrillator SAS Performance by Rhythm Category

RHYTHM CLASS	ECG TEST[1] SAMPLE SIZE	PERFORMANCE GOAL	OBSERVED PERFORMANCE
Shockable: Coarse VF	168	>90% sensitivity	LIFEPAK 15 monitor/defibrillator meets the AAMI[2] DF80 requirements and AHA[3] recommendations.
Shockable: VT	65	>75% sensitivity	LIFEPAK 15 monitor/defibrillator meets the AAMI DF80 requirements and AHA recommendations.
Nonshockable: NSR	144	>99% specificity for NSR (AHA)	LIFEPAK 15 monitor/defibrillator meets the AHA recommendations.
Nonshockable: asystole	43	>95% specificity	LIFEPAK 15 monitor/defibrillator meets the AAMI DF80 requirements and AHA recommendations.
Nonshockable: all other rhythms	531	>95% specificity	LIFEPAK 15 monitor/defibrillator meets the AAMI DF80 requirements and AHA recommendations.
Intermediate: fine VF	29	Report only	>75% sensitivity

[1]Each sample is run 10 times asynchronously.
[2]Association for the Advancement of Medical Instrumentation. DF80: 2003 Medical electrical equipment-Part2-4, Section 6.8.3 aa) 3) essential performance data of the rhythm recognition detector. Arlington, VA: AAMI, 2004.
[3]Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. American Heart Association (AHA) Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation*, 1997: Vol. 95: 1677-1682.
VF = ventricular fibrillation
VT = ventricular tachycardia
NSR = normal sinus rhythm

Operator Control of Shock Therapy

The Shock Advisory System causes the AED to charge automatically when it detects the presence of a shockable rhythm. When a shock is advised, the operator presses the **SHOCK** button to deliver the energy to the patient.

Continuous Patient Surveillance System

The Continuous Patient Surveillance System (CPSS) automatically monitors the patient's ECG rhythm for a potentially shockable rhythm while the electrodes are attached and the AED is turned on. CPSS is not active during ECG analysis or when the AED is in a CPR cycle.

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Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. A motion detector is designed into the LIFEPAK 15 monitor/defibrillator. **MOTION DETECTION** can be set up to be **ON** or **OFF**. For more information, see the *LIFEPAK 15 Monitor/Defibrillator Setup Options* provided with your device.

A number of activities can create motion, including CPR, rescuer movement, patient movement, and some internal pacemakers. If variations in the transthoracic impedance signal exceed a maximum limit, the Shock Advisory System determines that patient motion of some kind is present. If motion is detected, the ECG analysis is inhibited. The operator is advised by a displayed message, a voice prompt, and an audible alert. After 10 seconds, if motion is still present, the motion alert stops and the analysis always proceeds to completion. This limits the delay in therapy in situations where it may not be possible to stop the motion. However, the rescuer should remove the source of motion whenever possible to minimize the chance of artifact in the ECG.

There are two reasons why ECG analysis is inhibited when the motion alert occurs, and why the rescuer should remove the source of the motion whenever possible:

1. Such motion may cause artifact in the ECG signal. This artifact can cause a nonshockable ECG rhythm to look like a shockable rhythm. For example, chest compressions during asystole can look like shockable ventricular tachycardia. Artifact can also cause a shockable ECG rhythm to look like a nonshockable rhythm. For example, chest compressions during ventricular fibrillation can look like an organized, and therefore nonshockable, rhythm.
2. The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

D

ELECTROMAGNETIC COMPATIBILITY GUIDANCE

This appendix provides guidance and manufacturer's declaration of electromagnetic compatibility.

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Electromagnetic Emissions

Table D-1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The LIFEPAK 15 monitor/defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 15 monitor/defibrillator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The LIFEPAK 15 monitor/defibrillator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LIFEPAK 15 monitor/defibrillator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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Essential Performance

The LIFEPAK 15 monitor/defibrillator maintains safe and effective performance of the defibrillation therapy and patient monitoring functions when operated in the electromagnetic environment specified in Table D-2 through Table D-4.

Table D-2 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The LIFEPAK 15 monitor/defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 15 monitor/defibrillator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LIFEPAK 15 monitor/defibrillator requires continued operation during power mains interruptions, it is recommended that the LIFEPAK 15 monitor/defibrillator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC Mains voltage prior to application of the test level.

Table D-3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The LIFEPAK 15 monitor/defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 15 monitor/defibrillator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the LIFEPAK 15 monitor/defibrillator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

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[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LIFEPAK 15 monitor/defibrillator is used exceeds the applicable RF compliance level above, the LIFEPAK 15 monitor/defibrillator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LIFEPAK 15 monitor/defibrillator.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table D-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the LIFEPAK 15 Monitor/Defibrillator

The LIFEPAK 15 monitor/defibrillator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LIFEPAK 15 monitor/defibrillator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LIFEPAK 15 monitor/defibrillator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
Note: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

E

SYMBOLS

This appendix provides information about the symbols that are used in these operating instructions, or on the LIFEPAK 15 monitor/defibrillator, its accessories, packaging, or training tools.

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Symbols

The symbols in Table E-1 may be found in these operating instructions or on the LIFEPAK 15 monitor/defibrillator, its accessories, packaging, or training tools.

Table E-1 Symbols

SYMBOL	DESCRIPTION
Device or User Interface	
	Attention, consult accompanying documents
	Alarm on
	Alarm off
	VF/VT alarm on
	VF/VT alarm is on, but is silenced or suspended
	Battery in well, fully charged. For a description of all battery indicators, see "Battery Status Indicators" on page 3-20.
	Heart rate/pulse rate indicator
	*Bluetooth* wireless technology
 (x)	Shock count (x) on screen
	Shock button on front panel or hard paddles
	Service indicator
>	Greater than
<	Less than
J	Joules
	Display mode button
	Home Screen button

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Table E-1 Symbols (Continued)

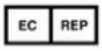
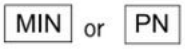
SYMBOL	DESCRIPTION
	CO_2 exhaust
	Input/output
	Defibrillation-proof type CF patient connection
	Defibrillation protected, type BF patient connection
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on disposing of this product.
	Mark of conformity to applicable European Directives
	Canadian Standards Association certification for Canada and the United States
	Date of manufacture. Date may appear before, after, or below the figure.
	Authorized EC representative
	Manufacturer's identification number (part number)
	Serial number
	Reorder number
	By prescription only
	For USA audiences only
	Catalog number
	Manufacturer
	Indicates that a product complies with applicable ACA standards
	Positive terminal

Table E-1 Symbols (Continued)

SYMBOL	DESCRIPTION
	Negative terminal
	Fuse
	Battery
	Static-sensitive device. Static discharge may cause damage.
Reports	
	Biphasic defibrillation shock
	Pace arrow, noninvasive pacing
	Pace arrow, internal pacing detection
	QRS sense marker
	Event marker
Accessories	
	Mark of conformity to applicable European Directives
	Recognized component mark for the United States
	Recognized component mark for Canada and the United States
	Complies with (USA) Federal Communications Commission regulations
	Type BF patient connection
LOT YYWW	Lot number (batch code). YY (year) and WW (week) of manufacture.
IP44	Enclosure ingress protection code per IEC 60529
	Warning, high voltage

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Table E-1 Symbols (Continued)

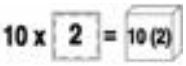
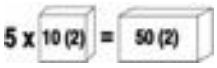
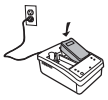
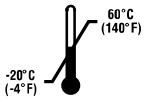
SYMBOL	DESCRIPTION
	CAUTION - FIRE HAZARD Do not disassemble, heat above 100°C (212°F), or incinerate battery
	CAUTION - FIRE HAZARD Do not crush, puncture, or disassemble battery
	Use By date shown: yyyy-mm-dd or yyyy-mm
	Indoor use only
	Item is latex free
	Lead free
	Dispose of properly
	Store in a cool, dry location (0° to 50°C, 32° to 122°F)
	Single use only
	2 electrodes in 1 pouch
	10 pouches in 1 shelf-pak
	5 shelf-paks in 1 case
	Shave patient skin
	Clean patient skin
	Treatment

Table E-1 Symbols (Continued)

SYMBOL	DESCRIPTION
	Press electrode firmly onto patient
	Connect QUIK-COMBO cable
	Remove release liner
	Do not use this pediatric QUIK-COMBO electrode on LIFEPAK 500, LIFEPAK 1000, LIFEPAK CR® Plus, or LIFEPAK EXPRESS® defibrillators
	For use on adults
	Not for use on adults
	For use on children up to 15 kg (33 lb)
	Not for use on children under 15 kg (33 lb)
	Remove label from battery
	Charge battery
	Insert battery in LIFEPAK 15 monitor/defibrillator
	Rechargeable battery
	DC voltage
	AC voltage

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Table E-1 Symbols (Continued)

SYMBOL	DESCRIPTION
Shipping carton	
	This end up
	Fragile/breakable Handle with care
	Protect from water
	Recommended storage temperature -20°–60°C (-4°–140°F)
	Relative humidity range 10 to 95%
 or	Recycle this item

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PHYSIO CONTROL

LIFEPAK® 20e DEFIBRILLATOR/MONITOR

OPERATING INSTRUCTIONS



LIFEPAK® 20e DEFIBRILLATOR/MONITOR

OPERATING INSTRUCTIONS

Important Information

!USA Rx Only

!USA Device Tracking

The U.S. Food and Drug Administration requires defibrillator manufacturers and distributors to track the location of their defibrillators. If the device is located somewhere other than the shipping address or the device has been sold, donated, lost, stolen, exported, destroyed, permanently retired from use, or if the device was not obtained directly from Physio-Control, please do one of the following: register the device at http://www.physio-control.com, call the device tracking coordinator at 1.800.426.4448, or use one of the postage-paid address change cards located in the back of this manual to update this vital tracking information.

Text Conventions

Throughout these operating instructions, special text characters are used to indicate labels, screen messages, and voice prompts:

- Operating control labels: **CAPITAL LETTERS** such as **ON/OFF** and **SHOCK**.
- Screen messages and voice prompts: ***CAPITAL ITALICIZED LETTERS*** such as ***CONNECT ELECTRODES***.

Version History

These operating instructions describe LIFEPAK 20e defibrillator/monitor devices with software version 3202609-084 or later.

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ABOUT AUTOMATED EXTERNAL DEFIBRILLATION

The following considerations and guidelines apply when using the LIFEPAK® 20e defibrillator/monitor as an automated external defibrillator (AED).

Operator Considerations

The LIFEPAK 20e defibrillator/monitor, when in AED mode, is a semiautomatic defibrillator that uses a patented Shock Advisory System™. This software algorithm analyzes the patient's electrocardiographic (ECG) rhythm and indicates whether or not it detects a shockable rhythm. The LIFEPAK 20e defibrillator/monitor in AED mode requires operator interaction to defibrillate the patient.

The LIFEPAK 20e defibrillator/monitor in AED mode is intended for use by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training.
- AED training equivalent to that recommended by the American Heart Association.
- Training in the use of the LIFEPAK 20e defibrillator/monitor in AED mode.

Indications

The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm.

In AED mode, the LIFEPAK 20e defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.

Contraindications

None known.

ABOUT DEFIBRILLATION THERAPY

Operator Considerations

A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. The LIFEPAK 20e defibrillator/monitor delivers this energy through disposable electrodes, standard paddles or internal paddles applied to the patient's chest.

Defibrillation is only one aspect of the medical care required to resuscitate a patient with a shockable ECG rhythm. Depending on the situation, other supportive measures may include:

- Cardiopulmonary resuscitation (CPR)
- Administration of supplemental oxygen
- Drug therapy

Successful resuscitation is related to the length of time between the onset of a heart rhythm that does not circulate blood (ventricular fibrillation, pulseless ventricular tachycardia) and defibrillation. The American Heart Association has identified the following as critical links in the chain of survival from cardiac arrest:

- Early access
- Early CPR by first responders or bystanders
- Early defibrillation
- Early advanced life support

The physiological state of the patient may affect the likelihood of successful defibrillation. Thus, failure to resuscitate a patient is not a reliable indicator of defibrillator performance. Patients will often exhibit a muscular response (such as jumping or twitching) during an energy transfer. The absence of such a response is not a reliable indicator of actual energy delivery or device performance.

Indications

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia and, in relatively stable patients, ventricular tachycardia.

The biphasic defibrillation waveform used in this defibrillator has only been clinically tested on adults; it has not been tested on pediatric patients.

Contraindications

Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA) such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

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ABOUT NONINVASIVE PACING

A noninvasive pacemaker is a device that delivers an electrical stimulus to the heart, causing cardiac depolarization and myocardial contraction. The energy is delivered through large adhesive electrodes placed on the chest. In addition to noninvasive pacing, other supportive measures may be necessary.

Among other factors, it is recognized that successful pacing of a patient is related to the length of time between the onset of a dysrhythmia and the initiation of pacing. Rapid pacing and prompt follow-up care are essential. The physiologic state of the patient may affect the likelihood of successful pacing or of skeletal muscle activity. The failure to successfully pace a patient is not a reliable indicator of pacemaker performance. Similarly, the patient's muscular response to pacing is not a reliable indicator of energy delivered. Refer to the booklet, *Noninvasive Pacing: What You Should Know* for further information.

Indications

Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications

Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

ABOUT SPO2 MONITORING

A pulse oximeter is a noninvasive device that checks the saturation of oxygen in arterial blood (SpO2). It uses an optical sensor that directs light through the patient's finger and then measures the received light with a detector. This received light is translated into a saturation percentage and is displayed as an SpO2 reading.

Indications

A pulse oximeter is indicated for use in any patient who is at risk of developing hypoxemia.

Contraindications

None known.

ABOUT ECG MONITORING

The ECG (electrocardiogram) is a recording of the electrical activity of the heart. ECG monitoring allows for identification and interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate. The ECG is obtained by placing either electrodes or paddles on the patient and allows the heart's electrical activity to be monitored and recorded.

SAFETY INFORMATION

This section provides important information to help you operate the LIFEPAK 20e defibrillator/monitor. Familiarize yourself with all of these terms, warnings, and symbols.

Terms	page 1-2
General Warnings and Cautions	1-2
Symbols	1-3

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TERMS

The following terms are used either in these operating instructions or on the LIFEPAK 20e defibrillator/monitor:

Danger: Immediate hazards that will result in serious personal injury or death.

Warning: Hazards or unsafe practices that may result in serious personal injury or death.

Caution: Hazards or unsafe practices that may result in minor personal injury, product damage, or property damage.

GENERAL WARNINGS AND CAUTIONS

The following are general warning and caution statements. Other specific warnings and cautions are provided as needed in other sections of these operating instructions.

WARNINGS!

Shock hazard.

The defibrillator delivers up to 360 J of electrical energy. Unless properly used as described in these operating instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this device unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

Shock hazard.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

Shock or fire hazard.

Do not immerse any portion of this defibrillator in water or other fluids. Avoid spilling any fluids on defibrillator or accessories. Spilled liquids may cause the defibrillator and accessories to perform inaccurately or fail. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this defibrillator or accessories unless otherwise specified.

Possible fire or explosion.

Do not use this device in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

Possible electrical interference with device performance.

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this defibrillator. RFI may result in improper defibrillator operation, distorted ECG, failure to detect a shockable rhythm, or cessation of pacing. Avoid operating the defibrillator near cauterizers, diathermy equipment, cellular phones, or other portable and mobile RF communications equipment. Maintain equipment separation of at least 1.2 m (4 ft) and do not rapidly key EMS radios on and off. Contact a technical support representative if assistance is required.

Possible electrical interference.

Using cables, electrodes, or accessories not specified for use with this device may result in increased emissions or decreased resistance to electromagnetic interference which could affect the performance of this device or of equipment in close proximity. Use only parts and accessories specified in these operating instructions.

WARNINGS! (CONTINUED)

Possible electrical interference.

This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. Verify the effects of defibrillator discharge on other equipment prior to using defibrillator in an emergency situation, if possible.

Possible defibrillator shutdown.

When operating on battery power, adhere to battery maintenance and replacement intervals discussed in the Battery Performance and Life section to prevent possible defibrillator shutdown. If the defibrillator shuts down without warning, or if a ***LOW BATTERY: CONNECT TO AC POWER*** message appears on the monitor screen, immediately connect the AC power cord to an outlet.

Possible improper defibrillator performance.

Changing factory default settings will change the behavior of the device. Changes to the default settings must only be made by authorized personnel.

Possible improper defibrillator performance.

Using other manufacturers' cables, electrodes, or batteries may cause the device to perform improperly and invalidates the safety agency certification. Use only the accessories specified in these operating instructions.

Possible failure to detect an out of range condition.

Reselecting QUICK SET will reset the alarm limits around the patient's current vital sign values. This may be outside the safe range for the patient.

Safety risk and possible equipment damage.

Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment and affect the performance of the equipment. Skin burns will also occur due to heating of electrically conductive materials such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information.

SYMBOLS

The symbols below may be found in these operating instructions or on various configurations of LIFEPAK 20e defibrillator/monitor and accessories:



Defibrillation-proof type CF terminal

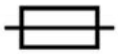


Defibrillation protected, type BF patient connection



Attention, consult accompanying documents

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	Warning, high voltage
	Type BF patient connection
	Static sensitive device (SSD)
	Safety ground. Protective earth connection
	Fuse
	Equipotential connector
	Positive terminal
	Negative terminal
	Lot number (batch code)
	Use by date shown: yyyy-mm-dd
	Reorder number
	Date of manufacture
	Single use only
	Indoor use only
	Alarm on
	Alarm off
	VF/VT alarm on
	VF/VT alarm silenced
>	Greater than
<	Less than

J	Joules
	Contrast
	Adult defibrillation paddle
	Infant defibrillation paddle
	Home screen button
	Battery status indicator (refer to page 2-17)
	Heart rate/pulse rate indicator
	Shock count (x) on screen
	Mark of conformity to applicable European Directives
	Canadian Standards Association certification for Canada and the United States
	Recognized component mark for Canada and the United States
	DC voltage
	AC voltage
	On (power: connection to the AC Mains)
	Off (power: disconnection from the AC Mains)
	Power on/off
	[signal] Input
	[signal] Output

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This end up



Fragile/breakable
Handle with care



Protect from water



Recycle this item



System connector/Data in



Sync in/ECG out



LIFEPAK 20e defibrillator/monitor to LIFEPAK 20e defibrillator/monitor cable
(refer to Send Configuration Setup Menu, page 8-13)



Turn counterclockwise to unlock



Switch on



Switch off



Pace arrow, noninvasive pacing



Pace arrow, internal pacing



R-wave sense marker



Event marker



Biphasic defibrillation shock



Shock button

!USA

For USA audiences only

CAT

Catalog number used for placing orders

MIN	Manufacturer's Identification Number (part number)
Rx Only	Federal law restricts this device to sale by or on the order of a physician
	Manufacturer
EC REP	Authorized EC representative

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BASIC ORIENTATION

This section provides a basic orientation to the LIFEPAK 20e defibrillator/monitor.

Introduction	page 2-2
Unpacking and Inspecting	2-2
Controls, Indicators, and Connectors	2-3
Entering Patient Data	2-12
Setting Alarms	2-13
Managing Alarms	2-15
Connecting to Power	2-16

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INTRODUCTION

The LIFEPAK 20e defibrillator/monitor with enhanced battery technology is an acute cardiac care response system used by authorized healthcare providers in hospital and clinic settings.

The LIFEPAK 20e defibrillator/monitor offers the following optional features:

- Semiautomatic defibrillator
- Noninvasive pacemaker
- Pulse oximeter
- Paddle accessories

Note: These operating instructions include information and procedures related to all features of the LIFEPAK 20e defibrillator/monitor. Your LIFEPAK 20e defibrillator/monitor may not have all of these features. For more information, contact your Physio-Control representative or call the number listed on the back cover of these operating instructions.

The LIFEPAK 20e defibrillator/monitor is available only with the biphasic defibrillation waveform. For a description of the defibrillation waveform, refer to Appendix A.

The LIFEPAK 20e defibrillator/monitor uses QUIK-COMBO® pacing/defibrillation/ECG electrodes or FAST-PATCH® disposable defibrillation/ECG electrodes for ECG monitoring and patient therapy. The therapy cable connects the QUIK-COMBO or FAST-PATCH electrodes to the defibrillator. For more information about QUIK-COMBO or FAST-PATCH electrodes, refer to Section 3 of these operating instructions.

The standard paddle set is an accessory for the LIFEPAK 20e defibrillator/monitor and includes adult and pediatric defibrillator (hard) paddles. The standard paddles can be used for QUIK-LOOK® ECG monitoring, defibrillation, and synchronized cardioversion therapies. When using standard paddles, a conductive interface designed for defibrillation, such as defibrillation gel or gel pads, must be used between the paddle electrode surface and the skin.

The adult standard paddles can be used for any pediatric patient weighing approximately 10 kg (22 lb) or more as long as the paddles fit completely on the chest and there is at least 2.5 cm (1 in.) of space between the paddle electrodes. Pediatric paddles should be used for patients weighing 10 kg (22 lb) or less or those whose chests are too small to accommodate the adult paddles.

Optional internal paddles are also available.

For more information about using paddle accessories, refer to Section 5 of these operating instructions.

UNPACKING AND INSPECTING

After you have removed the LIFEPAK 20e defibrillator/monitor from the shipping container, make sure you have all the required supplies and accessories including cables and ECG paper. Examine the defibrillator and all accessories for any sign of damage that may have occurred during shipping. If possible, save the shipping container and foam inserts in case you have to ship the defibrillator at a later date.

Note the label located to the right of the screen (Figure 2-1). Before the defibrillator/monitor's first use, plug the power cord into an AC outlet for 3 hours to charge the internal battery.



Figure 2-1 Initial Battery Charge

CONTROLS, INDICATORS, AND CONNECTORS

The following figures provide a brief description of the controls, indicators, and connectors for the LIFEPAK 20e defibrillator/monitor. Figure 2-2 shows the front view of the LIFEPAK 20e defibrillator/monitor and Figure 2-3 shows the front view divided into six areas. Figure 2-4 through Figure 2-13 show details of each area. Figure 2-14 shows the back view of the defibrillator. Additional information about areas 3, 4, and 6 follow the applicable figures. The light emitting diode (LED) illuminates (turns on) indicating when the corresponding function is active. For example, the **ANALYZE** button LED is on when the advisory function is active.



Figure 2-2 Front View with Door

The door on the LIFEPAK 20e defibrillator/monitor hides the manual defibrillation and noninvasive pacing buttons. When the door is closed, the appearance and operation of the device is simplified for the automated external defibrillator (AED) user.

To enter manual mode, press the **MANUAL** button located on the lower left corner of the door. This opens the door and automatically takes the device out of AED mode and allows access to manual mode defibrillation and pacing. After entering manual mode, closing the door does not affect operation.

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Figure 2-3 Front View without Door

Area 1

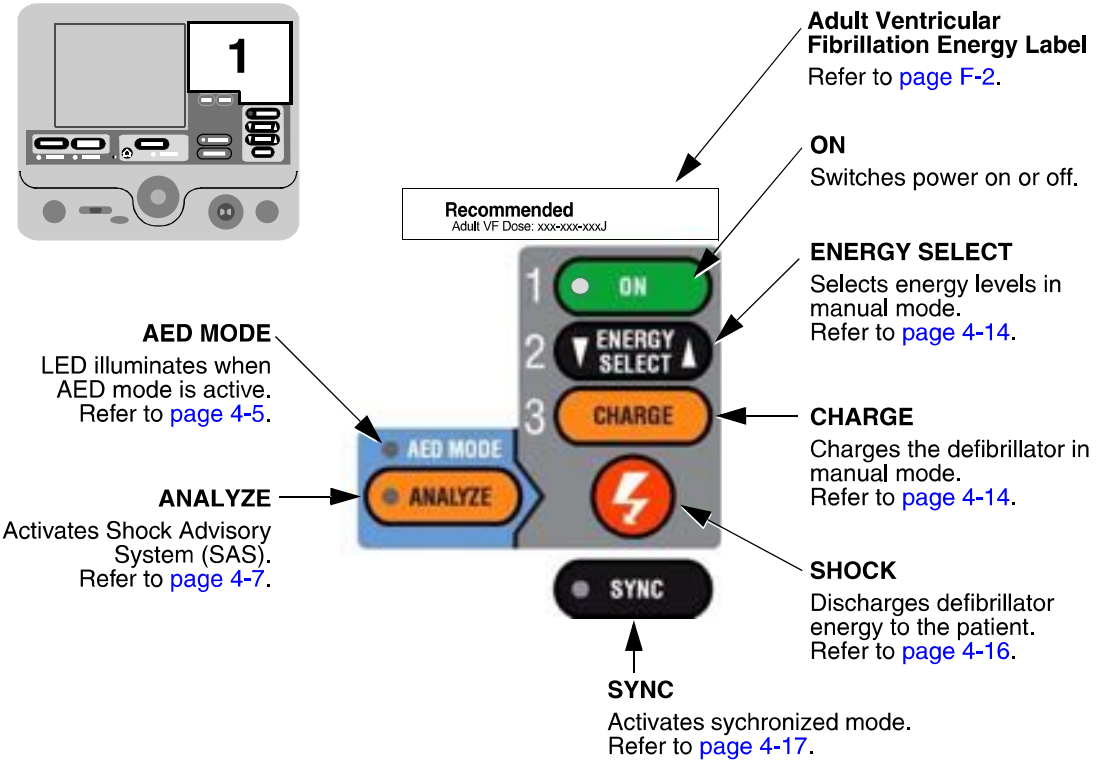
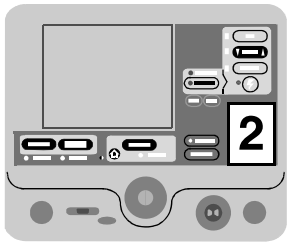


Figure 2-4 Area 1

Area 2





PACER
Activates the pacing function.
Refer to page 4-22.

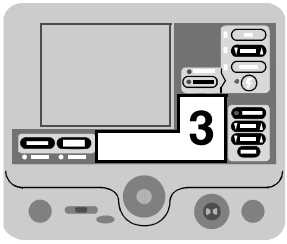
CURRENT
Adjusts pacing current.
Refer to page 4-22.

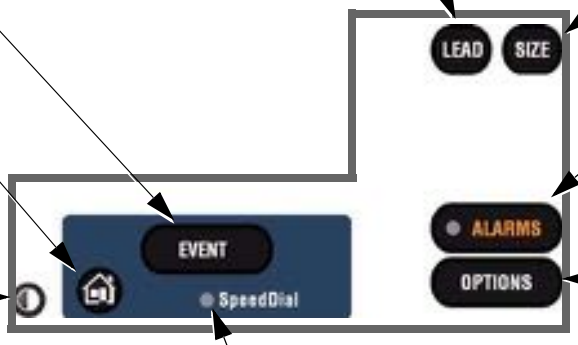
RATE
Selects pacing rate.
Refer to page 4-22.

PAUSE
Temporarily slows pacing rate.
Refer to page 4-22.

Figure 2-5 Area 2

Area 3





LEAD
Changes ECG lead.
Refer to page 3-2.

SIZE
Changes ECG size.
Refer to page 3-2.

EVENT
Activates user-defined events.
Refer to page 2-6.

HOME SCREEN
Returns immediately to Home Screen.
Refer to page 2-6.

ALARMS
Activates and silences alarms.
Refer to page 2-13.

CONTRAST
Adjusts screen contrast.
Refer to page 2-6.

OPTIONS
Accesses optional functions.
Refer to page 2-6.

LED
Illuminates when the Speed Dial is active.
Refer to page 2-7.

Figure 2-6 Area 3

Area 3

The following paragraphs provide additional information about the controls shown in "Area 3," page 2-5.

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Contrast

Press the **CONTRAST** button and rotate the Speed Dial to adjust the screen contrast/brightness. When the defibrillator is turned on, the contrast setting defaults to the previously adjusted setting.

Home Screen

The home screen is the background screen that displays during ECG monitoring. Pressing **HOME SCREEN** returns you to the home screen from any menu screen or overlay, except during AED analysis or during manual defibrillation charging and shocking.

Event

After pressing **EVENT**, the screen displays the following overlay.



Use the Speed Dial to scroll through and select menu choices.

Generic is automatically selected when **EVENT** is pressed and no other selection is made. The selected event and time stamp appear in the message/status area on the screen. Events are printed in the CODE SUMMARY™ Event Log. Refer to page 8-10 for information about configuring events.

Options

After pressing **OPTIONS**, the screen displays the overlay shown in Figure 2-7. Use the Speed Dial to scroll through and select menu choices.

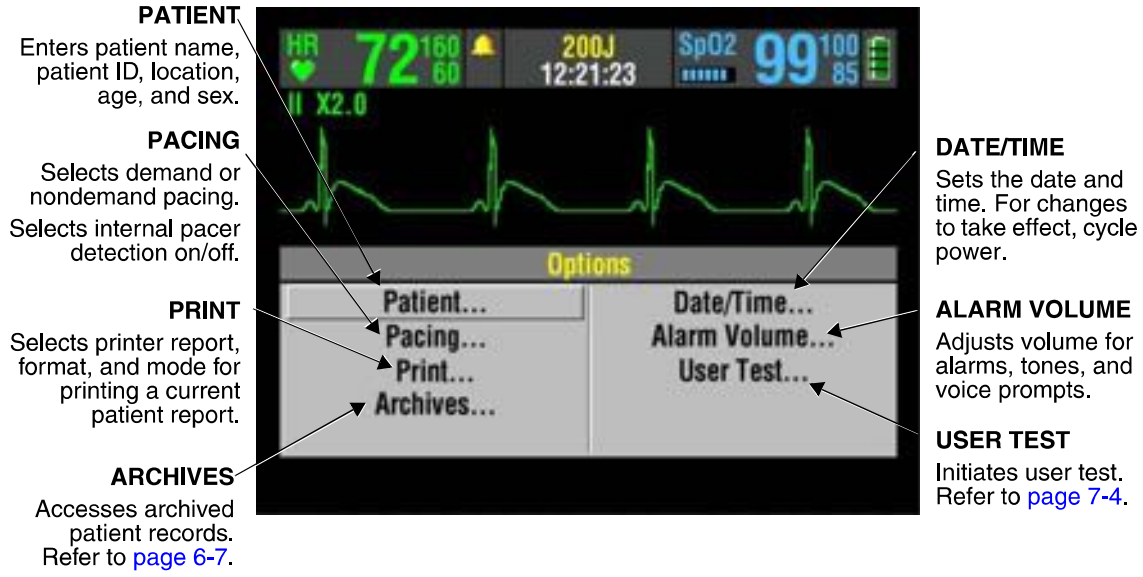


Figure 2-7 Options

Alarms

Refer to page 2-13 for information about setting alarms.

Speed Dial LED

The indicator LED for the Speed Dial illuminates when the Speed Dial is active.

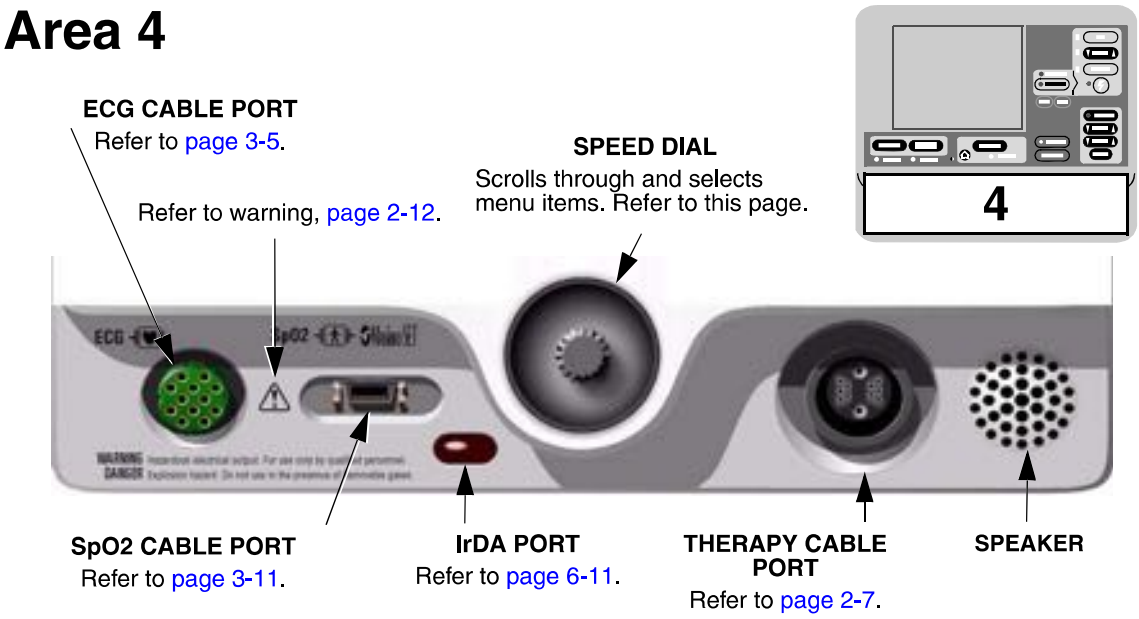


Figure 2-8 Area 4

Area 4

The following paragraphs provide additional information about the Speed Dial and the therapy cable connector shown in Area 4.

Speed Dial

Use the Speed Dial to scroll through and select the desired menu item either while viewing the monitor screen or while in Options mode. Press the Speed Dial to activate the highlighted menu item. Default menu items are highlighted with a gray background; after a menu item is selected, the background is black.

Therapy Cable Connector

WARNING!

Possible equipment damage and inability to deliver therapy.

To protect the therapy cable connector from damage or contamination, keep the therapy cable connected to the defibrillator at all times.

Connecting the Therapy Cable

To connect a therapy cable connector to the therapy cable port:

1 Orient the therapy cable so that the arrow is on top with the cable angled to the right (refer to Figure 2-9).
2 Insert the therapy cable into the therapy cable connector on the defibrillator until a “click” is sensed.

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3 Pull gently on the locking ring to check that the cable is locked in place.

Disconnecting the Therapy Cable

To disconnect a therapy cable connector from the therapy cable port:

1 Rotate the locking ring on the therapy cable in the direction of the arrow (counterclockwise) until it stops (refer to Figure 2-10).
2 Gently pull out the cable connector.

Note: LIFEPAK 20e defibrillator/monitors with hardwired standard paddles do not have this feature.

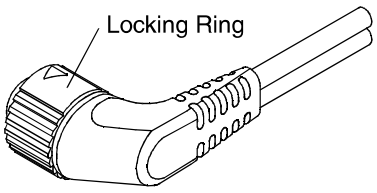


Figure 2-9 Therapy Cable Orientation

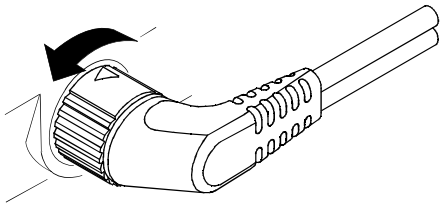


Figure 2-10 Disconnecting the Therapy Cable

Area 5

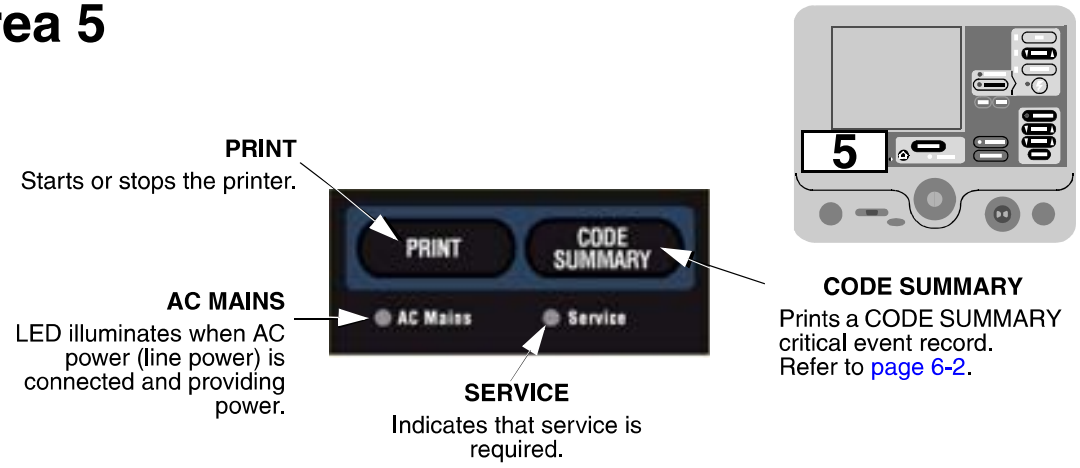
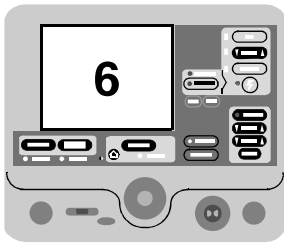


Figure 2-11 Area 5

Area 6



MONITORING AREA

Displays heart rate, time, SpO2, battery status indicator, indicators for VF/VT alarm and selected energy. Refer to page 2-10.



WAVEFORM CHANNEL AREA

Displays up to two waveform channels. Refer to page 2-10.

STATUS MESSAGE AREA

Displays status and alarm messages.

Figure 2-12 Area 6

Area 6

The following paragraphs provide additional information about Area 6.

Monitoring Area—Heart Rate

The LIFEPAK 20e defibrillator/monitor displays a heart rate between 20 and 300 beats per minute (bpm). A heart rate symbol flashes with each beat. If the heart rate is below 20 bpm or pacing is enabled, the screen displays dashes (– – –). Heart rates above 300 bpm do not yield valid systole tones and the displayed heart rate will not be valid. The heart rate indicator is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times and to not rely solely on the displayed heart rate.

WARNING!

Failure to detect a change in ECG rhythm.

Heart rate meters may continue to count the internal pacing pulses during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely on heart rate meter alarms. Keep pacemaker patients under close surveillance.

QRS detection is essential for using the digital heart rate display, systole tone, synchronized cardioversion, and noninvasive demand pacing. The QRS detector in the LIFEPAK 20e defibrillator/monitor selectively detects QRS complexes. It discriminates against most noise, muscle artifact, T-waves, and other spurious signals.

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The QRS detect algorithm automatically adjusts itself to the amplitude of the QRS complexes. Changing the gain of the ECG has no effect on QRS detection. For optimum QRS detection performance, use the lead with the greatest QRS amplitude.

Monitoring Area—Pulse Rate. If the ECG is not active, the SpO2 monitor can display pulse rate. The pulse rate source is indicated by **PR (SPO2)**.

Monitoring Area—SpO2 (pulse oximeter). The oxygen saturation level is shown as a percentage from 50 to 100. Saturation below 50% is shown as <50%. A fluctuating bar graph represents the pulse signal strength.

Monitoring Area—Battery Status Indicator. The battery status indicator shows the approximate amount of battery charge remaining in the internal Lithium-ion rechargeable battery. (Refer to page 2-16 for further information.)

Waveform Channel Area

Channel 1.This is the top channel. It displays the primary ECG waveform and is always visible when ECG is displayed.

Channel 2.This is the bottom channel. It can display an additional waveform or a continuation of the Channel 1 ECG.

Selecting Waveform Channels

The monitor power must be turned on.



1 At the home screen, rotate the Speed Dial to highlight Channel 1 or 2.
2 Press the Speed Dial. An overlay appears with the monitoring choices for the selected channel.
3 Rotate and press the Speed Dial to select monitoring choices for that channel.

Changing Printer Paper

CAUTION!

Possible printer malfunction.

Using other manufacturers' printer paper may cause the printer to function improperly and/or damage the print head. Use only the printer paper specified in these operating instructions.

Loading 50 mm Paper

The printer is equipped with an out-of-paper sensor to protect the printhead. The sensor automatically turns off the printer if paper runs out or if the printer door is open.

To load the paper:

1 Press the black button to open the printer door.
2 Remove the empty paper roll.
3 Insert the new paper roll, grid facing upward.
4 Pull out a short length of paper.
5 Push the printer door in to close.

Figure 2-13 illustrates the steps for loading 50 mm paper.

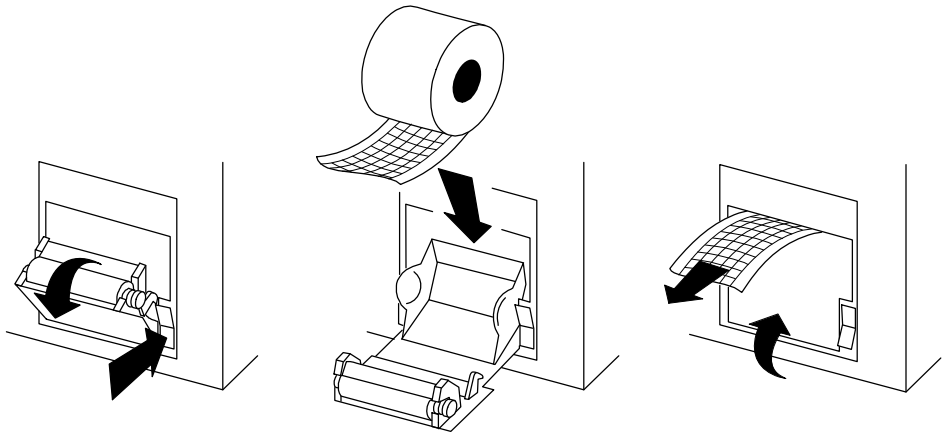


Figure 2-13 Printer

Back View

The following paragraphs provide additional information about the back view (see Figure 2-14).

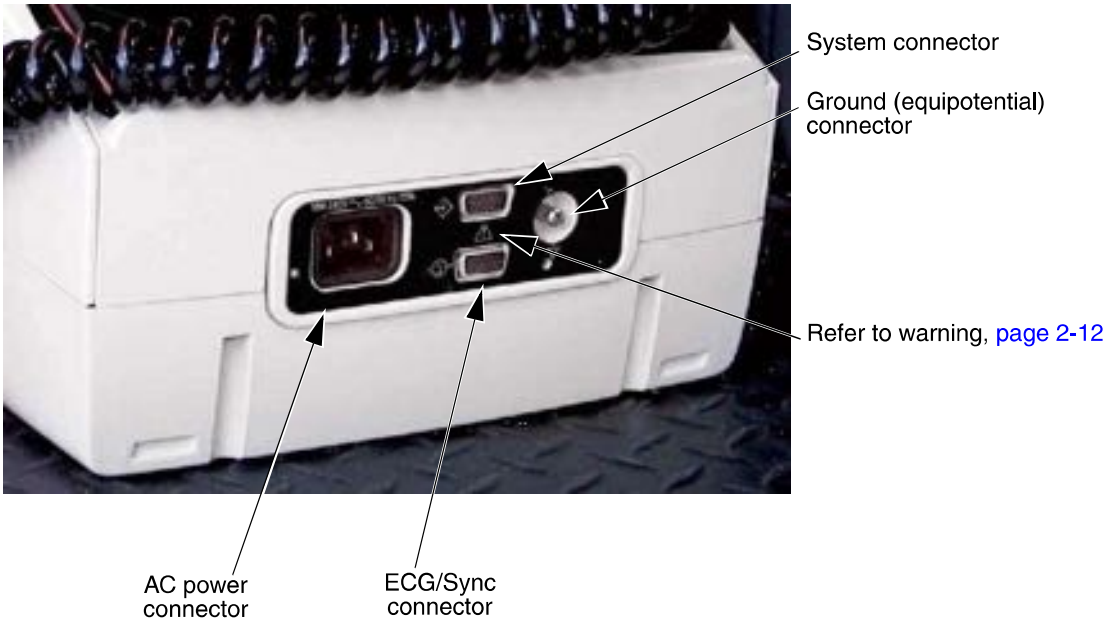


Figure 2-14 Back View

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WARNING!

Shock hazard.

If you are monitoring a patient and using the system connector, all equipment connected to the system connector must be battery powered or electrically isolated from AC power according to EN 60601-1. If in doubt, disconnect the patient from the monitor before using the system connector. For more information, contact Physio-Control Technical Support.

System Connector

The system connector provides access to another LIFEPAK 20e defibrillator/monitor, so that setup information can be transferred between defibrillators.

ECG/Sync Connector

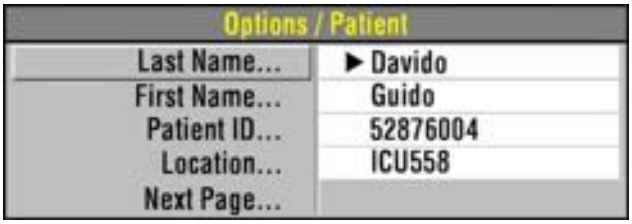
The ECG/Sync connector provides remote synchronization and real-time ECG output to a third party monitor.

ENTERING PATIENT DATA

The following paragraphs describe how to enter or edit a patient's name, identification (ID), age, or sex.

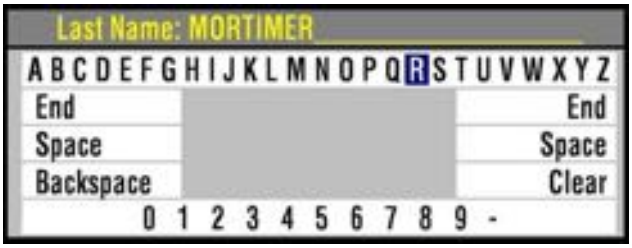


1 Press **OPTIONS**.
2 Select **PATIENT**.



To enter or edit a patient's name or ID:

1 Select **LAST NAME**, **FIRST NAME**, or **ID**. **LAST NAME** is used as an example (for this procedure).

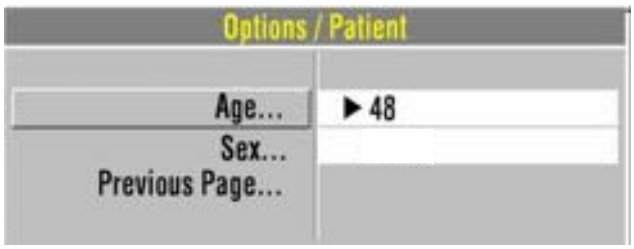


2 Rotate the Speed Dial to scroll through the alphabet.
3 Press the Speed Dial to select the desired character. The character appears in the highlighted area.
4 Repeat Step 2 and Step 3 until the name is complete.
5 Scroll and select **END** to return to the Options/Patient screen as shown previously.

There are three additional commands:

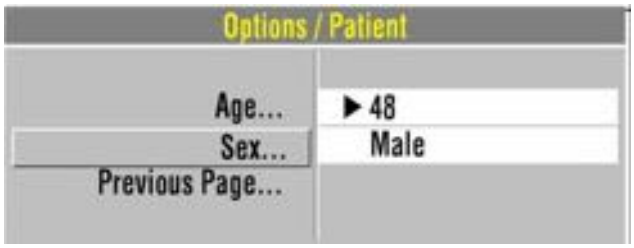
- **BACKSPACE –** moves highlight bar left one space
- **CLEAR –** clears all characters in the name field
- **SPACE –** inserts a blank space

6 To exit, press the **OPTIONS** or **HOME SCREEN** button.



To enter or edit a patient's age:

1 Select **AGE**.
2 Rotate the Speed Dial to scroll to the desired age.
3 Press the Speed Dial.



To enter or edit a patient's sex:

1 Select **SEX**.
2 Rotate the Speed Dial to highlight **MALE** or **FEMALE**.
3 Press the Speed Dial.

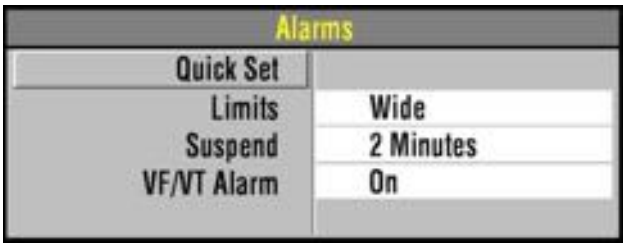
SETTING ALARMS

Alarms for the LIFEPAK 20e defibrillator/monitor can be set to **ON** or **OFF**, and are enabled when the monitor is turned on. When the alarms are set to **ON**, predetermined limits are set. To view these limits, press the **ALARMS** button. The limits will appear to the right of the parameter value. To change the limits, select **QUICK SET**.

When the alarms are set to **OFF**, you must press the **ALARMS** button and select **QUICK SET** to enable the alarms.

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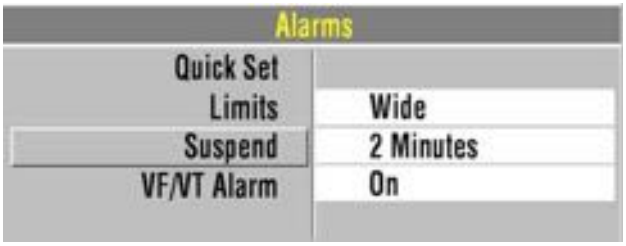
When you press the **ALARMS** button, the following Alarms overlay appears:



1 Select **QUICK SET** to activate the alarms for all active parameters. The quick set limits are set automatically based on the patient's current vital sign values (refer to Table 2-1). The alarm limits default to the setting (**WIDE** or **NARROW**) displayed on the overlay.



2 Select **LIMITS** to change the alarm limits to **WIDE** or **NARROW** (refer to Table 2-1).



3 Select **SUSPEND** to turn off the audible alarm for up to 15 minutes. If an alarm limit is exceeded while the alarm is silenced, the violated parameter flashes, an alarm message appears, but the alarm tone remains silent.



Select **VF/VT ALARM** to turn on continuous monitoring for ventricular fibrillation and ventricular tachycardia in manual mode.
A symbol appears above the primary ECG when the alarm is on .
Reselect **VF/VT ALARM** to turn off this alarm.
Note: When the VF/VT alarm is on, you are limited to **PADDLES** lead or lead II. Refer to "Selecting ECG Lead and Size," page 3-2.
Note: The VF/VT alarm will be suspended when the noninvasive pacemaker is on and when standard paddles are attached and **PADDLES** lead is selected. The alarm is also suspended when the defibrillator is charging or is fully charged.

Table 2-1 Wide and Narrow Alarm Limits

Parameter	Range	Wide Limits[1]		Narrow Limits*		Limits Range†	
		Low	High	Low	High	Low	High
Heart Rate (bpm)	<60	-20	+35	-10	+25	30–150	100–250
	60–79	-25	+40	-20	+30		
	80–104	-30	+40	-30	+30		
	≥105	-35	+45	-25	+25		
SpO2 (%)	≥90	-5	+3	-5	+3	50	90–100
	<90	-5	+3	-5	+3		

*.Numbers are ± from patient's initial value

†.Numbers are absolute range values

MANAGING ALARMS

The alarm bell symbol indicates when alarms are on or off. When alarms are on and an alarm limit is exceeded, a tone sounds, the violated parameter flashes, and an alarm message appears on the screen.

To manage an alarm:

1 Press **ALARMS**. This silences the alarm for 2 minutes.
2 Assess the cause of the alarm.
3 Assess the appropriateness of the limits setting (**WIDE** or **NARROW**).
4 If the patient is unstable, consider silencing the alarm for up to 15 minutes while attending to the patient. Do **not** reselect **QUICK SET.**
5 Once the patient is stable, reselect **QUICK SET** if necessary.

WARNING!

Possible failure to detect an out of range condition.

Reselecting QUICK SET will reset the alarm limits around the patient's current vital sign values. This may be outside the safe range for the patient.

When alarms are on, you can silence them preemptively for up to 15 minutes.

To silence alarms preemptively:

1 Press **ALARMS**.
2 Select **SUSPEND**.
3 Select a silence duration of 2, 5, 10, or 15 minutes.
4 The message ***ALARMS SUSPENDED*** appears at the bottom of the screen.

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CONNECTING TO POWER

The LIFEPAK 20e defibrillator/monitor operates on AC (line) power or its internal Lithium-ion battery. You can switch from battery to AC power or AC power to battery while the device is on and in use by plugging in or unplugging the AC power cord.

WARNING!

Possible defibrillator shutdown.

When operating on battery power, adhere to battery maintenance and replacement intervals discussed in the Battery Performance and Life section to prevent possible defibrillator shutdown. If the defibrillator shuts down without warning, or if a ***LOW BATTERY: CONNECT TO AC POWER*** message appears on the monitor screen, immediately connect the AC power cord to an outlet.

AC Operation

When the LIFEPAK 20e defibrillator/monitor operates on AC power, the AC Mains LED illuminates. When the defibrillator is not in use, the battery charge is best maintained if the power cord is connected to an AC outlet and the defibrillator is turned off.

Battery Operation

The internal Lithium-ion battery is rechargeable and is intended for use when AC power is unavailable or when the device is being used in a portable manner, such as in transport. The defibrillator automatically switches to battery power when the power cord is disconnected from an AC outlet or from the defibrillator.

A new, fully charged battery provides approximately 140 360-joule discharges, 110 minutes of pacing, or approximately 210 minutes of continuous monitoring before the defibrillator turns off. When one flashing red bar appears in the battery status indicator and the ***LOW BATTERY: CONNECT TO AC POWER*** message appears on the screen, immediately plug the power cord into an AC outlet to continue use and begin recharging the battery. If low battery messages frequently appear, the battery may need to be replaced. Contact Physio-Control Technical Support or qualified service personnel for assistance.

Connect the defibrillator to AC power after each use to recharge the battery. Typically, new fully depleted batteries recharge for 4 hours to regain full capacity. Partially depleted batteries recharge for a time period equivalent to the time the defibrillator was in use. For example, if the defibrillator was used one hour, the required recharge time will be approximately one hour.

New batteries or batteries that have been stored for an extended time should be recharged before they are used. Connect the defibrillator to an AC power outlet to bring the battery to full charge.

Note: The LIFEPAK 20e defibrillator/monitor is intended to operate with the internal battery installed. In the event of a missing or faulty battery, when plugged into AC power, the device will still operate and the service light will illuminate at power on. Contact Physio-Control Technical Support or qualified service personnel for assistance.

Battery Performance and Life

Several factors can contribute to the Lithium-ion battery's performance and life cycle, including:

1 The defibrillator's use for assisting patients ("on time" and shocks).
2 The defibrillator's use when the battery is at minimum capacity (low battery condition).
3 The battery's normal self-discharge rate and the energy used by defibrillator self-tests.

To maximize battery performance and life, plug the defibrillator/monitor into an AC outlet to recharge the battery whenever the defibrillator/monitor is not in use. As a reminder, you can set up the LIFEPAK 20e defibrillator/monitor to sound a series of warning beeps, identified as ***AC LOSS ALERT***, whenever the defibrillator is turned off and not plugged into an AC outlet (refer to the "General Setup Menu," page 8-4).

Note: While the defibrillator is plugged into AC power, the battery condition is periodically checked. If the battery is missing or is unable to charge, a service LED illuminates the next time the defibrillator is turned on. To check the battery capacity, perform the defibrillation function test (refer to "Maintenance and Testing Schedule," page 7-2).

Note: Even when properly maintained, the internal rechargeable Lithium-ion battery should be replaced every two years.

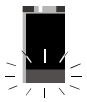
Battery Status Indicator

The battery status indicator approximates the amount of operating time available under battery power for the LIFEPAK 20e defibrillator/monitor. The battery status indicator appears on the screen after the defibrillator is turned on. (See Figure 2-12, page 2-9.) The number of illuminated bars indicates the battery capacity and how long the battery will provide power to the defibrillator.

A new, fully charged battery will show four green bars, indicating the battery is charged to 100% capacity. As battery charge and battery capacity decreases, the indicator bars decrease incrementally. One flashing red bar indicates a very low or empty battery. Refer to Table 2-2.

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Table 2-2 Battery Status Indicator

Battery Indicator	Battery Status	Messages and Tones	Battery Capacity (percentage)
	Four **green** bars	None	76–100
	Three **green** bars	None	51–75
	Two **green** bars	None	26–50
	One **green** bar	None	16–25
	One **yellow** bar	***LOW BATTERY*** Three beeps (one time). Message remains in message area, cycling with others if necessary.	11–15
	One flashing **red** bar	***LOW BATTERY: CONNECT AC POWER*** Three beeps (every 20 seconds). Message remains in message area, cycling with others if necessary.	0–10

It is important to note that both charge (voltage) and capacity are factors contributing to the battery status indicator's display. For example, the battery status indicator displays two green bars when a new battery has 100% capacity and has been charged to 50%. However, an older battery that is 100% charged and only has 50% capacity also displays two green bars. The following demonstrates this example.



This battery may either be low in capacity or low in charge as follows:

- For a new battery with 100% capacity, this symbol indicates 50% charged (low in charge).
- For an older battery with 50% capacity, this symbol indicates 100% charged (low in capacity).

MONITORING

This section describes the monitoring features of the LIFEPAK 20e defibrillator/monitor.

Monitoring the ECG	page 3-2
Monitoring SpO2	3-9

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MONITORING THE ECG

The following subsections describe:

- ECG Monitoring Warning
- Selecting ECG Lead and Size
- Adjusting the Systole Tone Volume
- Monitoring ECG with Paddles Accessories
- Monitoring with the Patient ECG Cable
- Troubleshooting Tips for ECG Monitoring

ECG Monitoring Warning

WARNING!

Possible misinterpretation of ECG data.

The frequency response of the monitor screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for diagnostic and ST segment interpretation. For diagnostic or ST segment interpretation, or to enhance internal pacemaker pulse visibility, attach the ECG cable. Then print the ECG rhythm in diagnostic frequency response (DIAG).

Selecting ECG Lead and Size

There are two methods for selecting or changing the ECG lead. Both methods are available on your LIFEPAK 20e defibrillator/monitor. The leads available depend on the ECG cable (3-wire or 5-wire) connected to the device.

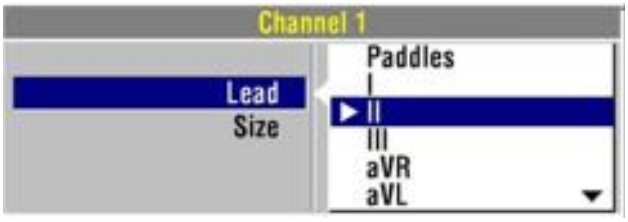


To change the ECG lead using the **LEAD** button:

1. Press the **LEAD** button. If ECG lead appears, the lead automatically changes to paddles. If **PADDLES** lead appears, the lead automatically changes to lead II.
2. When the Lead menu appears, press the **LEAD** button again or rotate the Speed Dial to select another lead. The highlighted selection shows the ECG lead.

   Note: When the VF/VT alarm is on, you are limited to **PADDLES** lead or lead II in Channel 1. Refer to "Setting Alarms," page 2-13.

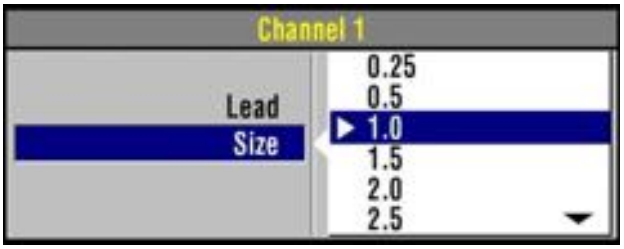
Note: If one or more lead sets are preconfigured, the menu displays the lead sets. Refer to page 8-9 for information about configuring lead sets.



To select or change the ECG lead using the Speed Dial:

1 Highlight and select **CHANNEL 1**, and then select **LEAD** to obtain the primary ECG lead choices.
2 Change the ECG lead by rotating the Speed Dial. The highlighted selection shows the ECG lead.
3 Repeat Step 1 and Step 2 to select or change displayed waveforms for Channel 2.

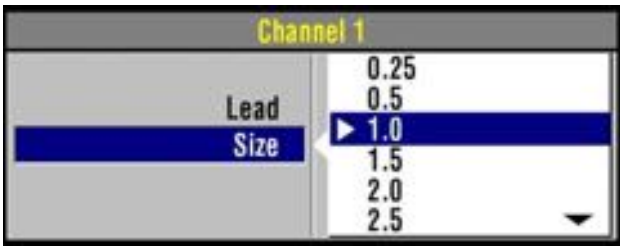
You can select or change the ECG size by using the **SIZE** button or the Speed Dial. If an ECG is in Channel 2, the size is automatically changed to match the Channel 1 size.



To select or change the ECG size using the **SIZE** button:

1 Press the **SIZE** button.
2 When the Size menu appears, press the **SIZE** button again. The highlighted selection shows the current ECG size.

To select or change the ECG size using the Speed Dial:

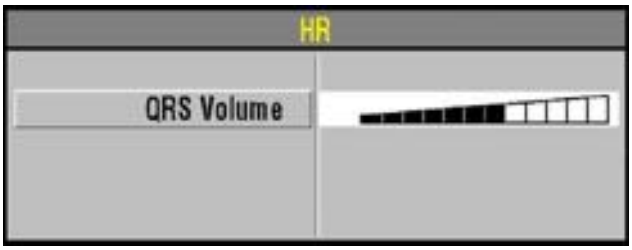


1 To obtain the primary ECG, highlight and select **CHANNEL 1**, and then select **SIZE**.
2 Change ECG size by rotating the Speed Dial. The highlighted selection shows the current ECG size.

Adjusting the Systole Tone Volume

To adjust the systole tone volume, highlight and select heart rate (HR) in the monitoring area of the screen.

The following overlay appears:



1 Rotate the Speed Dial to the desired volume.
2 Press the home screen to exit.

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Monitoring ECG with Paddles Accessories

Anterior-lateral Placement

Anterior-lateral placement is the only placement that should be used for ECG monitoring with paddles accessories.

1 Place either the ♥ or + therapy electrode or the apex paddle lateral to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. Refer to Figure 3-1.

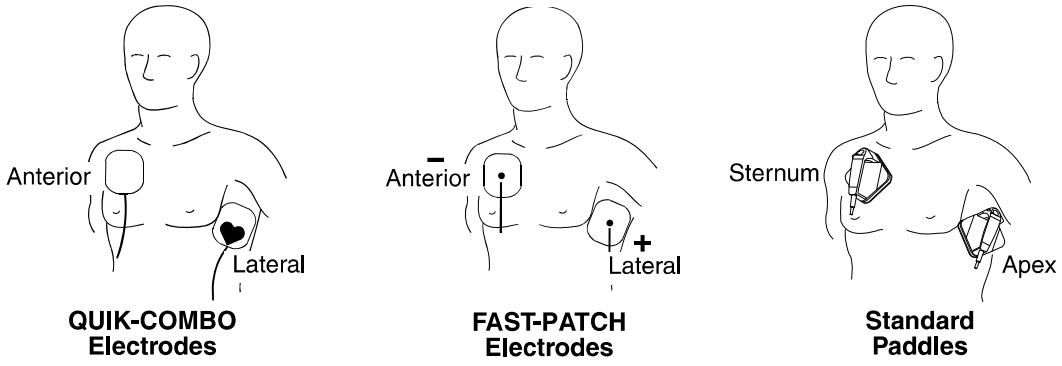


Figure 3-1 Anterior-lateral Placement

2 Place the other therapy electrode or sternum paddle on the patient's upper right torso, lateral to the sternum and below the clavicle as shown in Figure 3-1.

Special Placement Situations

When placing therapy electrodes or standard paddles, be aware of the special requirements in the following possible situations.

- **Obese Patients or Patients with Large Breasts —** Apply therapy electrodes or standard paddles to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.
- **Thin Patients —** Follow the contour of the ribs and spaces when pressing the therapy electrodes or standard paddles onto the torso. This limits air spaces or gaps under the electrodes and promotes good skin contact.
- **Patients with Implanted Pacemakers** — If possible, place therapy electrodes or standard paddles away from internal pacemaker generator.
- **Patients with Implanted Defibrillators —** Apply therapy electrodes or standard paddles in the anterior-lateral position and treat this patient as any other patient requiring emergency care.

Paddles Monitoring Procedure

To monitor using therapy electrodes or standard paddles:

1 Press **ON**. Adjust contrast if necessary.
2 Prepare the patient's skin:
   - Remove excessive chest hair as much as possible. Avoid nicking or cutting the skin. If possible, avoid placing therapy electrodes or standard paddles over broken skin.
   - Clean and dry the skin.
   - Do not use alcohol, tincture of benzoin, or antiperspirant to prep the skin.

3 Apply the therapy electrodes or standard paddles in the anterior-lateral position.
For therapy electrodes, confirm that the package is sealed and the Use By date has not passed. For standard paddles, apply conductive gel over the entire electrode surface.
4 Connect the disposable therapy electrodes to the therapy cable.
5 Select **PADDLES** lead.

Monitoring with the Patient ECG Cable

There are two ECG cables available for ECG monitoring as shown in Figure 3-2: the 3-wire and 5-wire cables.

Connecting the Patient ECG Cable

Connect the cable by inserting the main cable connector into the green electrically isolated ECG connector on the monitor.

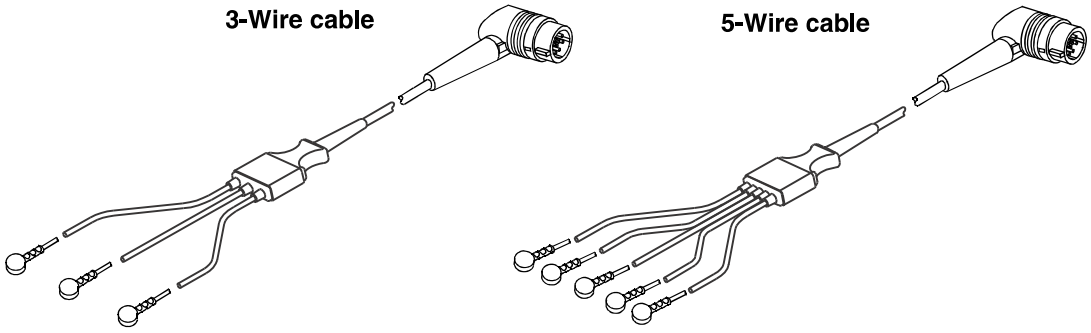
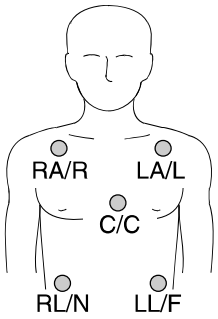


Figure 3-2 3-wire and 5-wire ECG Cables

ECG Monitoring Procedure

1 Press **ON**. Adjust contrast if necessary.
2 Attach the ECG cable to the monitor.
3 Identify the appropriate electrode sites on the patient as shown in Figure 3-3.



AHA Labels		IEC Labels	
RA	Right Arm	**R**	Right
LA	Left Arm	**L**	Left
RL*	Right Leg	**N**	Negative
LL	Left Leg	**F**	Foot
C*	Chest	**C**	Chest

***Note**: Not used for 3-wire cable.

Figure 3-3 Electrode Placement for ECG monitoring

4 Prepare the patient's skin for electrode application:
- Shave excessive hair at electrode site. Avoid locating electrodes over tendons and major muscle masses.
- For oily skin, clean skin with an alcohol pad.
- Dry the site with a brisk rub.

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5 Apply ECG electrodes:
   - Confirm package is sealed and Use By date has not passed.
   - Attach an electrode to each of the lead wires.
   - Grasp electrode tab and peel electrode from carrier.
   - Inspect electrode gel and ensure the gel is intact (discard electrode if gel is not intact).
   - Hold electrode taut with both hands. Apply the electrode flat to the skin. Smooth tape outwardly. Avoid pressing the center of the electrode.
   - Secure the trunk cable clasp to the patient's clothing.
6 Select the lead on the monitor screen.
7 If necessary, adjust ECG size.
8 Press **PRINT** to obtain an ECG printout.

ECG Electrode Requirements

Electrode quality is critical for obtaining an undistorted ECG signal. Always check the date code on electrode packages for the Use By date before applying the electrodes to a patient. Do not use electrodes with expired Use By date codes. Disposable electrodes are intended for a single use.

For best ECG monitoring results, use silver/silver chloride (Ag/AgCl) electrodes. These electrodes provide a rapid display of post-defibrillation ECG.

Leads Off Messages

If an electrode or lead wire disconnects during ECG monitoring, the monitor emits an audible alarm and displays a leads off message. The ECG trace becomes a dashed line. The alarm and messages continue until the electrode or lead wire is replaced.

Color Coding for ECG Leads

The lead wires and the electrode snaps for the patient ECG cable are color coded according to AHA or IEC standards as listed in Table 3-1.

Table 3-1 ECG Leads Color Codes

Leads	AHA Label	AHA Color	IEC Label	IEC Color
Limb Leads	RA	White	R	Red
	LA	Black	L	Yellow
	RL	Green	N	Black
	LL	Red	F	Green
	C	Brown	C	Brown

Monitoring Patients with Internal Pacemakers

The LIFEPAK 20e defibrillator/monitor typically does not use internal pacemaker pulses to calculate the heart rate. However, the monitor may detect internal pacemaker pulses as QRS complexes. This may result in an inaccurate heart rate display.

Smaller amplitude internal pacemaker pulses may not be distinguished clearly. For improved detection and display of internal pacemaker pulses, turn on the internal pacemaker detector, and/or connect the ECG cable, select an ECG lead, and print the ECG in diagnostic frequency response.

Large amplitude pacemaker pulses may overload the QRS complex detector circuitry so that no paced QRS complexes are counted. To help minimize ECG pickup of large unipolar pacemaker pulses when monitoring patients with internal pacemakers, place ECG electrodes so the line

between the positive and negative electrodes is perpendicular to the line between the pacemaker generator and the heart.

The LIFEPAK 20e defibrillator/monitor annotates internal pacemaker pulses with a hollow arrow ⇧ on the display and the printed ECG if this feature is configured or selected **ON**. False annotations of this arrow may occur if ECG artifacts mimic internal pacer pulses. If false annotations occur, you may deactivate the detection feature using the Options/Pacing/Internal Pacer menu (refer to Figure 2-7). Also refer to the "Pacing Setup Menu" in Table 8-8. Patient history and other ECG waveform data, such as wide QRS complexes, should be used to verify the presence of an internal pacemaker.

Troubleshooting Tips for ECG Monitoring

If problems occur while monitoring the ECG, check the list of observations in Table 3-2 for aid in troubleshooting. For basic troubleshooting problems such as no power, refer to "General Troubleshooting Tips" in Section 7.

Table 3-2 Troubleshooting Tips for ECG Monitoring

Observation	Possible Cause	Corrective Action
1 Screen blank and **ON** LED lighted.	Screen not functioning properly.	• Print ECG on recorder as backup. • Contact service personnel for repair.
2 Any of these messages displayed: ***CONNECT ELECTRODES*** ***CONNECT ECG LEADS*** ***ECG LEADS OFF*** ***XX LEADS OFF***	Therapy electrodes are not connected.	• Confirm therapy electrode connections.
	One or more ECG electrodes are disconnected.	• Confirm ECG electrode connections.
	ECG cable is not connected to monitor.	• Confirm ECG cable connections.
	Poor electrode-to-patient adhesion.	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. • Prepare skin and replace electrode(s). • Select another lead.
	Broken ECG cable lead wire.	• Select **PADDLES** lead and use standard paddles or therapy electrodes for ECG monitoring. • Check ECG cable continuity.
3 Poor ECG signal quality.	Poor electrode-skin contact.	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. Secure trunk cable clasp to patient's clothing. • Prepare skin and replace electrode(s).
	Outdated, corroded, or dried-out electrodes.	• Check date codes on electrode packages. • Use only silver/silver chloride electrodes with Use By dates that have not passed. • Leave electrodes in sealed pouch until time of use.

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Table 3-2 Troubleshooting Tips for ECG Monitoring (Continued)

Observation	Possible Cause	Corrective Action
	Loose connection. Damaged cable or connector/ lead wire.	• Check/reconnect cable connections. • Inspect ECG and therapy cables. • Replace if damaged. • Check cable with simulator and replace if malfunction observed.
	Misplaced electrodes/lead wire.	• Confirm correct placement. • Select lead view with optimal QRS detection.
	Noise because of radio frequency interference (RFI).	• Check for equipment causing RFI (such as a radio transmitter) and relocate or turn off equipment power.
4 Baseline wander (low frequency/high amplitude artifact).	Inadequate skin preparation. Poor electrode-skin contact. Diagnostic frequency response.	• Prepare skin and apply new electrodes. • Check electrodes for proper adhesion. • Print ECG in monitor frequency response.
5 Fine baseline artifact (high frequency/low amplitude).	Inadequate skin preparation. Isometric muscle tension in arms/legs.	• Prepare skin and apply new electrodes. • Confirm that limbs are resting on a supportive surface. • Check electrodes for proper adhesion.
6 Systole beeps not heard or do not occur with each QRS complex.	Volume too low. QRS amplitude too small to detect.	• Adjust volume. • Change ECG lead.
7 Monitor displays dashed lines with no ECG leads off messages.	**PADDLES** lead selected but patient connected to ECG cable.	• Select one of the limb leads.
8 Heart rate (HR) display different than pulse rate.	Monitor is detecting the patient's internal pacemaker pulses.	• Prepare skin and apply new electrodes in different location. • Select lead view with optimal QRS detection.
9 Internal pacemaker pulses difficult to see.	Pulses from pacemaker are very small. Monitor the visibility of frequency response limits.	• Turn on internal pacemaker detector (refer to page 3-6). • Connect ECG cable and select ECG lead instead of paddles. • Print ECG in diagnostic mode (refer to page 3-5).

MONITORING SpO2

The following paragraphs describe:

- SpO2 Warnings and Cautions
- When to Use a Pulse Oximeter
- How a Pulse Oximeter Works
- SpO2 Monitoring Considerations
- SpO2 Monitoring Procedure
- SpO2 Waveform
- SpO2 Volume
- Sensitivity
- Averaging Time
- Pulse Oximeter Sensors
- No Implied License
- Cleaning
- Troubleshooting Tips for SpO2

SpO2 Warnings and Cautions

WARNINGS!

Shock or burn hazard.

Before use, carefully read these operating instructions, the sensor and extension cable directions for use, and precautionary information.

Shock or burn hazard.

Other manufacturers' oxygen transducers may cause improper oximeter performance and invalidate safety agency certification. Use only oxygen transducers approved for this product.

Inaccurate pulse oximeter readings.

Do not use a damaged extension cable or one with exposed electrical contacts. Never use more than one extension cable between the pulse oximeter and the sensor.

Inaccurate pulse oximeter readings.

Do not use a damaged sensor. Do not alter the sensor in any way. Alterations or modifications may affect performance and/or accuracy.

Inaccurate pulse oximeter readings.

Sensors exposed to ambient light (such as sunlight, surgical lights, or bilirubin lamp) when incorrectly applied to a patient may exhibit inaccurate saturation readings. Securely place the sensor on the patient and check the sensor's application frequently to help ensure accurate readings.

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WARNINGS! (CONTINUED)

Inaccurate pulse oximeter readings.

Severe anemia, significant blood levels of carboxyhemoglobin or methemoglobin, elevated levels of total bilirubin, intravascular dyes that change usual blood pigmentation, excessive patient movement, venous pulsations, electrosurgical interference, exposure to irradiation and placement of the sensor on an extremity that has a blood pressure cuff, intravascular line or externally applied coloring (such as nail polish) may interfere with oximeter performance. The operator should be thoroughly familiar with the operation of the oximeter prior to use.

Inaccurate pulse oximeter readings.

The pulsations from intra-aortic balloon support can be additive to the pulse rate. Verify patient's pulse rate against the ECG heart rate.

Skin injury.

Prolonged, continuous use of a sensor may cause irritation, blistering, or pressure necrosis of the skin. Check the sensor site regularly based on patient condition and type of sensor. Change the sensor site if skin changes occur. Do not use tape to hold the sensor in place, as this may cause inaccurate readings or damage to the sensor or skin.

Possible strangulation.

Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTION!

Possible equipment damage.

To avoid damaging the extension cable or the sensor, hold the connectors, rather than the cables, when disconnecting.

When to Use a Pulse Oximeter

A pulse oximeter is a noninvasive tool that checks the saturation of oxygen in arterial blood (SpO2) and is not to be used as an apnea monitor or as a replacement or substitute for ECG based arrhythmia analysis. It is used for monitoring patients who are at risk of developing hypoxemia. If a pulse oximeter is not used, the only indications of hypoxemia are a patient's dusky skin, nail beds, and mucous membranes, accompanied by restlessness and confusion. These indications are not conclusive, however, and do not appear until after the patient has developed hypoxemia. Pulse oximetry is to be used in addition to patient assessment. Care should be taken to assess the patient at all times and to not solely rely on the SpO2 reading. If a trend toward patient deoxygenation is indicated, blood samples should be analyzed using laboratory instruments to completely understand the patient's condition.

How a Pulse Oximeter Works

A pulse oximeter sensor directs light through a fleshy body site (usually the finger or earlobe). The sensor sends light from the emitting diodes to the receiving detector as shown in Figure 3-4. Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The pulse oximeter translates the amount of light received into a saturation percentage and displays an SpO2 reading. Normal values typically range from 95% to 100% at sea level.

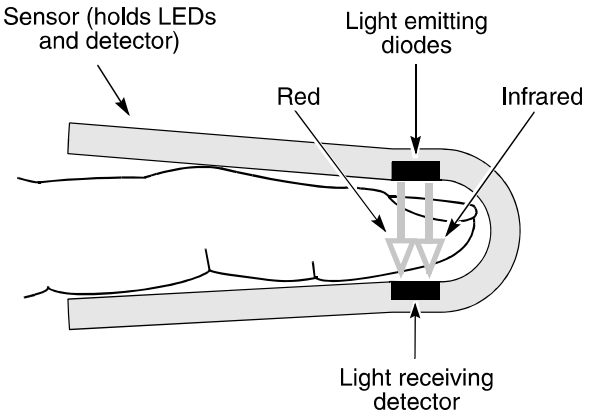


Figure 3-4 How a Pulse Oximeter Works

The quality of the SpO2 reading depends on correct sensor size and placement, adequate blood flow through the sensor site, patient motion, and exposure to ambient light. For example, with very low perfusion at the monitored site, readings may read lower than core arterial oxygen saturation. Test methods for accuracy are available by contacting your local Physio-Control representative.

SpO2 Monitoring Considerations

Each oximeter sensor is applied to a specific site on the patient. Use the following criteria to select the appropriate sensor:

- Patient weight
- Patient perfusion to extremities
- Patient activity level
- Available application sites on the patient's body
- Sterility requirements
- Anticipated duration of monitoring

To help ensure optimal and accurate performance:

- Use a dry and appropriately sized sensor.
- Keep the sensor site at the same level as the patient's heart.
- Apply the sensor according to the Directions for Use provided with the sensor.
- Observe all warnings and cautions noted in the sensor's Directions for Use.

The sensors are sensitive to light. If excessive ambient light is present (such as sunlight, surgical lights, or bilirubin lamp), cover the sensor site with an opaque material to block the light. Failure to do so could result in inaccurate measurements.

If patient movements present a problem, consider the following possible solutions:

- Be sure the sensor is secure and properly aligned.
- Use a new sensor with fresh adhesive backing.
- If possible, move the sensor to a less active site.

Note: Wrapping the sensor too tightly or using supplemental tape to hold the sensor in place may cause inaccurate measurements.

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SpO2 Monitoring Procedure

The defibrillator controls power to the pulse oximeter. When the defibrillator is turned on, the oximeter turns on and performs a self-test that requires up to 10 seconds. When the defibrillator is turned off, the oximeter also turns off.

To conserve battery power, the pulse oximeter goes into “sleep mode” when not in use. Sleep mode is activated within 10 seconds of disconnecting the sensor. During sleep mode, the screen does not display SpO2 information. The oximeter returns to normal mode after detecting a sensor or a patient signal. The oximeter performs the self-test when it returns from sleep mode to active mode.

The pulse oximeter measures SpO2 levels between 1% and 100%. When SpO2 levels are between 70% and 100%, oximeter measurements are accurate within ±3 digits. When the pulse oximeter measures SpO2 levels less than 50%, the display shows < 50%.

To measure the patient’s SpO2 levels:

1 Connect the SpO2 cable to the monitor.
2 Attach the sensor to the SpO2 cable and the patient.
3 Press **ON.**
4 Observe the pulse bar for fluctuation. Amplitude of the pulse bar indicates relative signal quality.
5 Adjust sensitivity, averaging time, and SpO2 volume as necessary.

SpO2 Waveform

The SpO2 waveform can be displayed on waveform Channel 2 by selecting waveform Channel 2 and then selecting SpO2 from the Waveform menu. The SpO2 waveform automatically sizes itself to provide optimum waveform viewing.

SpO2 Volume

To adjust the pulse tone volume, highlight and select **SPO2** on the home screen.
The following overlay appears:



1 Highlight and select **SPO2 VOLUME**.
2 Rotate the Speed Dial to the desired volume.
3 Press the Speed Dial to set the volume.

Sensitivity

The sensitivity setting allows you to adjust the oximeter for differing perfusion states. To adjust the sensitivity to either normal or high, highlight and select **SPO2** on the home screen and then select **SENSITIVITY**.

The normal sensitivity setting is the recommended setting for most patients. The high sensitivity setting allows for SpO2 monitoring under low perfusion states such as the severe hypotension of shock. However, when the SpO2 sensitivity is set to high, the signal is more susceptible to artifact. It is recommended that the patient be monitored closely when the high sensitivity setting is in use.

Averaging Time

The averaging time setting allows you to adjust the time period used to average the SpO2 value. Four time periods are provided for averaging: 4, 8, 12, and 16 seconds. To adjust the averaging time, highlight and select **SPO2** on the home screen and select **AVERAGING TIME**.

The averaging time of 8 seconds is recommended for most patients. For patients with rapidly changing SpO2 values, the 4-second time is recommended. The 12- and 16-second periods are used when artifact is affecting the performance of the pulse oximeter.

Pulse Oximeter Sensors

The Accessory Catalog describes the sensors that can be used with the LIFEPAK 20e defibrillator/monitor. To order compatible sensors and extension cables, refer to the accessories catalog or contact your local Physio-Control sales representative.

Masimo Sp02 Sensors

Carefully read the directions for use provided with sensors and cables for complete descriptions, instructions, warnings, cautions, and specifications.

Compatibility with Nellcor Sensors

The LIFEPAK 20e defibrillator/monitor can be ordered to have compatibility with Nellcor sensors. To use the Nellcor sensor with the LIFEPAK 20e defibrillator/monitor, the Masimo MNC-1 adapter cable must be used. Carefully read the directions for use provided with the Nellcor sensors and the Masimo MNC-1 adapter cable for complete description, instructions, warnings, cautions, and specifications.

No Implied License

Possession or purchase of this oximeter does not convey any express or implied license to use the oximeter with replacement parts which would, alone or in combination with the oximeter, fall within the scope of one or more of the patents relating to this device.

Cleaning

To clean the sensors, first remove them from the patient and disconnect them from the connector cable. Clean LNC and LNOP DCI sensors by wiping them with a 70% isopropyl alcohol pad. Allow the sensors to dry before placing them on a patient. Do not attempt to sterilize.

To clean the connector and adapter cables, first remove them from the defibrillator and then wipe them with a 70% isopropyl alcohol pad. Allow them to dry before reconnecting them to the defibrillator. Do not attempt to sterilize.

Note: Do not soak or immerse the cables in any liquid solution.

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Troubleshooting Tips for SpO2

Table 3-3 Troubleshooting Tips for SpO2

Observation	Possible Cause	Corrective Action
1 The oximeter measures a pulse, but there is no oxygen saturation or pulse rate.	Excessive patient motion.	• Keep patient still. • Check that sensor is secure. • Relocate sensor. • Replace sensor.
	Patient perfusion may be too low.	• Check patient. • Increase sensitivity.
2 SpO2 or pulse rate changes rapidly; pulse amplitude is erratic.	Excessive patient motion.	• Keep patient still. • Check that sensor is secure. • Relocate sensor. • Replace sensor. • Increase sensitivity.
	An electrosurgical unit (ESU) may be interfering with performance.	• Move the monitor as far as possible from the ESU. • Plug the ESU and monitor into different circuits. • Move the ESU ground pad as close to the surgical site as possible. • Sensor may be damp, replace it. • Remove sensor extension cable and connect the sensor directly.
3 No SpO2 value is displayed.	Oximeter may be performing a self-test (requires 10 seconds).	• Wait for completion.
4 ***SPO2: NO SENSOR DETECTED*** message appears.	Sensor is not connected to patient or cable disconnects from device.	• Check that sensor and cable are connected properly.
5 ***SPO2: CHECK SENSOR*** message appears.	Sensor is disconnected from patient or cable.	• Attach the sensor. • Check that sensor is secure.
	Excessive ambient light.	• Remove or block light source if possible. • Cover sensor with opaque material, if necessary.
	Patient has a weak pulse or low blood pressure.	• Test sensor on someone else. • Check if patient perfusion is adequate for sensor location. • Check if sensor is secure and not too tight. • Check that sensor is not on extremity with blood pressure cuff or intravascular line. • Change sensor location.
6 ***SPO2: UNKNOWN SENSOR*** message appears.	A sensor is connected to the device that is not compatible with the Masimo Sp02 module.	• Refer to "Pulse Oximeter Sensors," page 3-13 for sensor compatibility.

Table 3-3 Troubleshooting Tips for SpO2 (Continued)

Observation	Possible Cause	Corrective Action
7 ***SPO2: SEARCHING FOR PULSE*** message appears.	A sensor is connected to the patient and is searching for a pulse.	• Wait for completion.
8 ***SPO2: LOW PERFUSION*** message appears.	Patient has a weak pulse.	• Change sensor location.

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THERAPY

This section describes patient therapy.

General Therapy Warnings and Cautions	page 4-2
Therapy Electrode and Standard Paddle Placement	4-3
Automated External Defibrillation	4-5
Manual Defibrillation	4-14
Pediatric Defibrillation	4-19
Noninvasive Pacing	4-22

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GENERAL THERAPY WARNINGS AND CAUTIONS

WARNINGS!

Shock hazard.

The defibrillator delivers up to 360 J of electrical energy. When discharging the defibrillator, do not touch the paddle electrode surfaces or disposable therapy electrodes.

Shock hazard.

If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Clear everyone away from contact with the patient, bed, and other conductive material before discharging the defibrillator.

Shock hazard.

Do not discharge the defibrillator into the open air. To remove an unwanted charge, change the energy selection, select disarm, or turn off the defibrillator.

Possible fire, burns, and ineffective energy delivery.

Do not discharge standard paddles on top of therapy electrodes or ECG electrodes. Do not allow standard paddles (or therapy electrodes) to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

Possible defibrillator shutdown.

When operating on battery power, adhere to battery maintenance and replacement intervals discussed in the Battery Performance and Life section to prevent possible defibrillator shutdown. If the defibrillator shuts down without warning, or if a ***LOW BATTERY: CONNECT TO AC POWER*** message appears on the monitor screen, immediately connect the AC power cord to an outlet.

Possible skin burns.

During defibrillation or pacing, air pockets between the skin and therapy electrodes may cause patient skin burns. Apply therapy electrodes so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new electrodes.

Possible skin burns and ineffective energy delivery.

Therapy electrodes that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use therapy electrodes that have been removed from foil package for more than 24 hours. Do not use electrodes beyond expiration date. Check that electrode adhesive is intact and undamaged. Replace therapy electrodes after 50 shocks.

Possible interference with implanted electrical device.

Defibrillation may cause implanted devices to malfunction. Place standard paddles or therapy electrodes away from implanted devices if possible. Check implanted device function after defibrillation.

CAUTION!

Possible equipment damage.

Prior to using this defibrillator, disconnect all equipment from the patient that is not defibrillator-protected.

THERAPY ELECTRODE AND STANDARD PADDLE PLACEMENT

The following paragraphs describe therapy electrodes and standard paddles placement, including special placement situations.

Anterior-lateral Placement

Anterior-lateral placement allows for ECG monitoring, defibrillation, synchronized cardioversion, and noninvasive pacing.

1 Place either the ♥ or + therapy electrode, or apex paddle lateral to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. Refer to Figure 4-1.

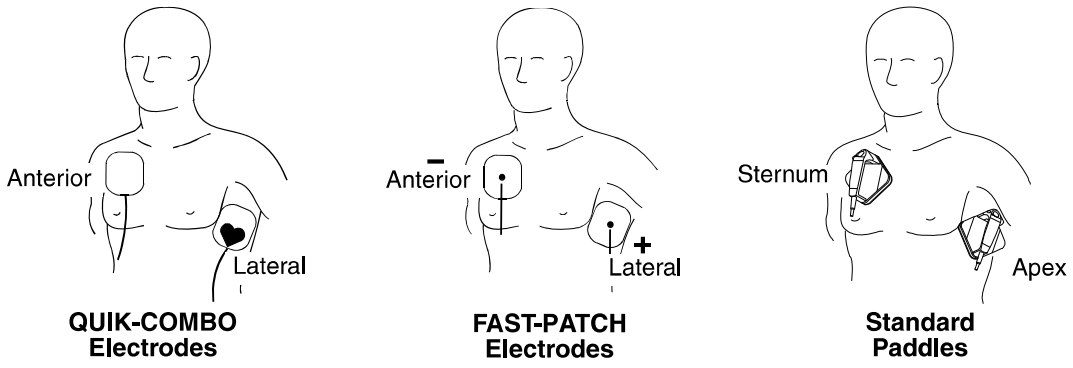


Figure 4-1 Anterior-lateral Placement

2 Place the other therapy electrode or sternum paddle on the patient's upper right torso, lateral to the sternum, and below the clavicle as shown in Figure 4-1.

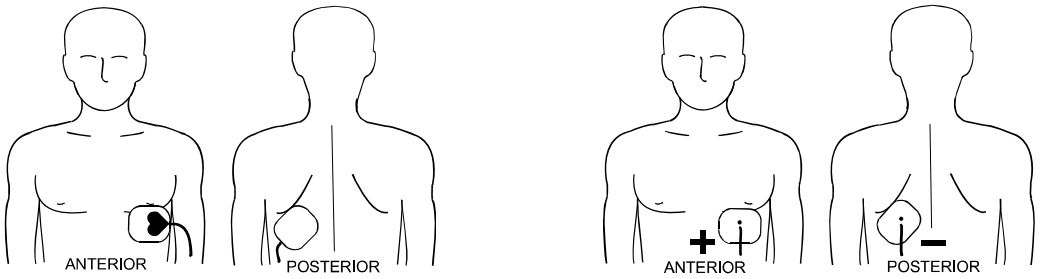
Anterior-posterior Placement

Anterior-posterior is an alternative position for noninvasive pacing, manual defibrillation, and synchronized cardioversion, but not for ECG monitoring or automated defibrillation. The ECG signal obtained through electrodes in this position is not a standard lead. (For pediatric applications, see "Pediatric Defibrillation," page 4-19.)

1 Place either the ♥ or + therapy electrode over the left precordium as shown in Figure 4-2. The upper edge of the electrode should be below the nipple. Avoid placement over the nipple, the diaphragm, or the bony prominence of the sternum if possible.

2 Place the other electrode behind the heart in the infrascapular area as shown in Figure 4-2. For patient comfort, place the cable connection away from the spine. Do not place the electrode over the bony prominences of the spine or scapula.

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QUIK-COMBO Electrodes **FAST-PATCH Electrodes**

Figure 4-2 Anterior-posterior Placement for Noninvasive Pacing or Defibrillation

Special Placement Situations

When placing therapy electrodes or standard paddles, be aware of the special requirements in the following possible situations.

Synchronized Cardioversion

Alternative anterior-posterior placements for cardioversion of supraventricular arrhythmias include:

- Place the ♥ or + therapy electrode over the left precordium and the other electrode on the patient's right posterior infrascapular area

  – or –

- Place the ♥ or + therapy electrode to the right of the sternum and the other electrode on the patient's posterior left infrascapular area.

Obese Patients or Patients with Large Breasts

Apply therapy electrodes or standard paddles to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.

Thin Patients

Follow the contour of the ribs and spaces when pressing the therapy electrodes onto the torso. This limits air spaces or gaps under the electrodes and promotes good skin contact.

Patients with Implanted Pacemakers

If possible, place therapy electrodes or standard paddles away from the internal pacemaker generator to help prevent damage to the pacemaker. Treat the patient like any other patient requiring care. When operating the defibrillator in AED mode, pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm.

Patients with Implanted Defibrillators

Apply therapy electrodes or standard paddles in the anterior-lateral position and treat this patient as any other patient requiring emergency care. If defibrillation is unsuccessful, it may be necessary to try alternate electrode placement (anterior-posterior) due to the insulative properties of implanted defibrillator electrodes.

AUTOMATED EXTERNAL DEFIBRILLATION

The following paragraphs include:

- AED Warnings
- AED Setup
- AED Procedure
- Special AED Setup Options
- Troubleshooting Tips for AED Mode
- Switching from AED to Manual Mode

AED Warnings

WARNING!

Possible misinterpretation of data.

Do not analyze while patient is moving or being transported. Motion artifact may affect the ECG signal resulting in an inappropriate ***SHOCK*** or ***NO SHOCK ADVISED*** message. Motion detection may delay analysis. Stop motion and stand clear of patient during analysis.

Pediatric patient safety risk.

In AED mode, the LIFEPAK 20e defibrillator/monitor is not intended for use on pediatric patients less than eight years old.

AED Setup

You can set up the LIFEPAK 20e defibrillator/monitor to turn on in AED mode before placing the defibrillator in use (refer to Section 8).

When illuminated, the AED mode LED indicates that the Continuous Patient Surveillance System (CPSS) is active. CPSS automatically monitors the patient ECG for a potentially shockable rhythm.

When the **ANALYZE** button is pressed, the Shock Advisory System (SAS) is activated. SAS is an ECG analysis system that advises the user if it detects a shockable or nonshockable rhythm.

The LIFEPAK 20e defibrillator/monitor can be setup to display the ECG waveform in AED mode or to not display a waveform. The operation in AED mode remains the same whether or not the ECG waveform is displayed.



When the ECG waveform is set to **ON** in the setup options (refer to Section 8), the ECG appears with all of the AED messages and prompts, as shown in the screen to the left.

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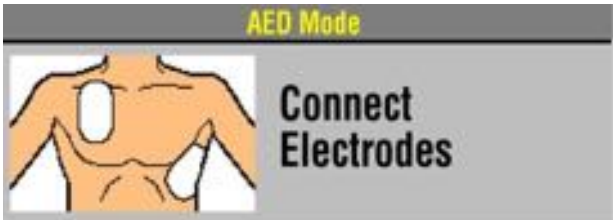


When the ECG waveform is set to **OFF** in the setup options, the messages and prompts fill the screen as shown in the screen to the left.

AED Procedure

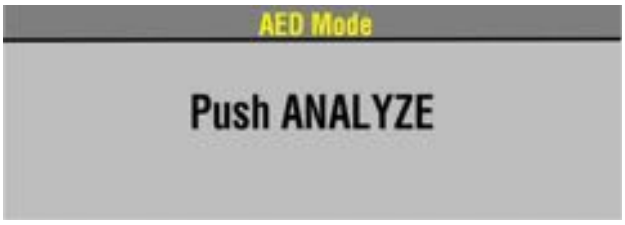
The following descriptions of voice prompts and messages are based on the factory default settings for AED mode. The default settings are consistent with 2005 American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines. Changing the setup options may result in different AED behavior. Refer to Section 8 for setup option choices.

1 Verify that the patient is in cardiopulmonary arrest (unresponsive, not breathing normally, and showing no signs of circulation.
2 Press **ON**.
3 Prepare the patient for electrode placement (refer to "Paddles Monitoring Procedure" on page 3-4).



The ***CONNECT ELECTRODES*** message and voice prompt occur until the patient is connected to the AED.

4 Connect the therapy electrodes to the therapy cable, and confirm cable connection to the defibrillator.
5 Apply the electrodes to the patient's chest in the anterior-lateral position (refer to "Anterior-lateral Placement," page 4-3).
6 Press the **ANALYZE** button to initiate analysis. Stop CPR.



The ***PUSH ANALYZE*** message and voice prompt occur when the patient is properly connected to the AED. The ***PUSH ANALYZE*** message will stay on the screen and the analyze LED flashes until **ANALYZE** is pressed.

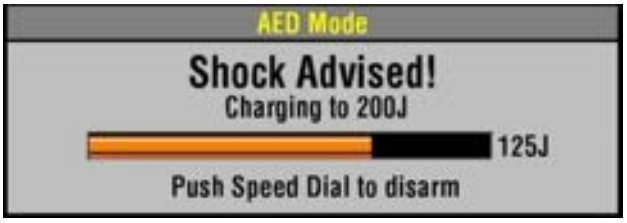
7 Follow screen messages and voice prompts provided by the AED.



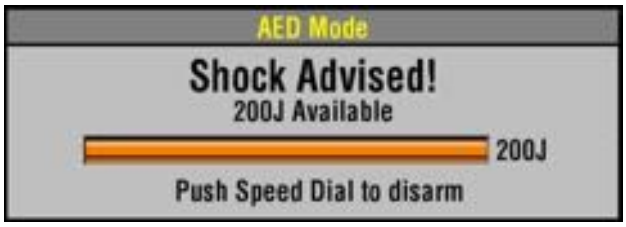
You will see and hear ***ANALYZING NOW, STAND CLEAR***. Do not touch or move the patient or therapy cable during analysis. ECG analysis requires approximately 6 to 9 seconds. The analyze LED illuminates during analysis.

The SAS analyzes the patient's ECG and advises either ***SHOCK ADVISED*** or ***NO SHOCK ADVISED***.

Shock Advised



If the AED detects a shockable ECG rhythm, you will see and hear ***SHOCK ADVISED***. The AED begins charging to the setup joule setting for shock #1. A rising tone indicates that the AED is charging.



When charging is complete, the AED displays the available energy.

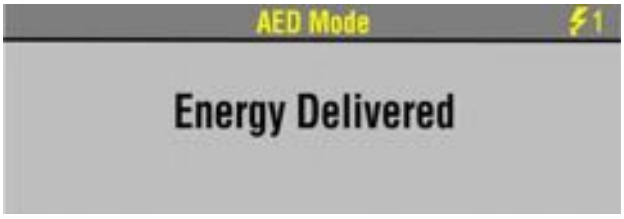


You will see and hear ***STAND CLEAR, PUSH TO SHOCK*** (⚡) followed by a "shock ready" tone. The shock LED flashes.
Clear everyone away from the patient, bed, or any equipment connected to the patient.

Press the ⚡ button to discharge the AED.



Note: If you do not press the ⚡ button within 60 seconds, the AED disarms the shock button, and the ***DISARMING*** message appears.



When the ⚡ button is pressed you will see the message ***ENERGY DELIVERED*** indicating energy transfer was completed.

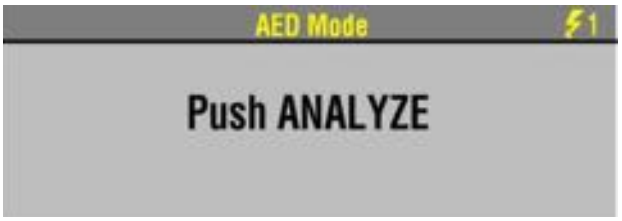
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When energy transfer is complete the shock counter increases by 1. This will continue to increase incrementally with every energy transfer.



After a shock is delivered you will see and hear ***START CPR***. A countdown timer (min:sec format) continues for the duration specified in the **CPR TIME 1** setup option.



When the CPR countdown time ends, you will see and hear ***PUSH ANALYZE***. This message stays on the screen and the voice prompt will repeat every 20 seconds until you press the **ANALYZE** button.

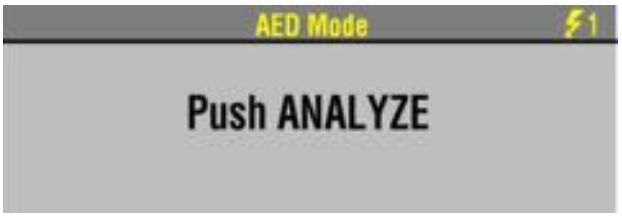
No Shock Advised



If the AED detects a nonshockable rhythm, you will see and hear ***NO SHOCK ADVISED***. The AED will not charge, and a shock can not be delivered.

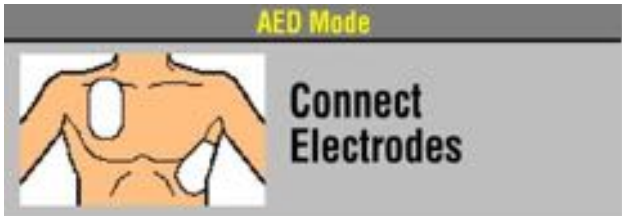


After a ***NO SHOCK ADVISED*** prompt you will see and hear ***START CPR***. A countdown timer (min:sec format) continues for the duration specified in the **CPR TIME 2** setup option. (Refer to Section 8).



When the CPR countdown time ends, you will see and hear ***PUSH ANALYZE***. This message stays on the screen and the voice prompt will repeat every 20 seconds until you press the **ANALYZE** button.

Proper Connection



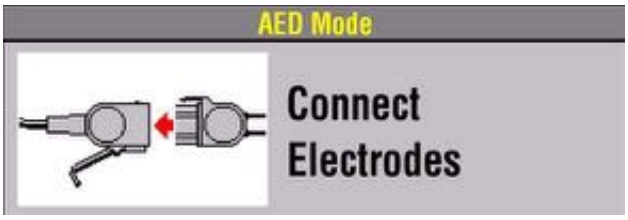
If therapy electrodes are not connected to the therapy cable or not placed on the patient's chest, the ***CONNECT ELECTRODES*** message and voice prompt occur until the patient is connected to the AED.



If the therapy cable is not connected to the defibrillator, you will see the ***CONNECT CABLE*** message until the cable is connected.

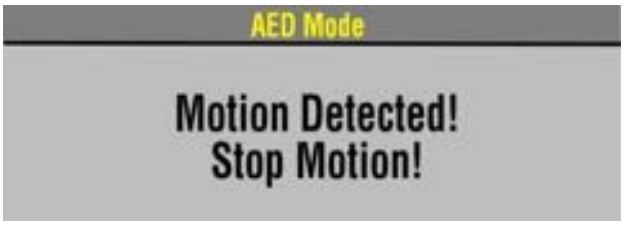


If the test plug is connected to the therapy cable when analysis is initiated, the ***REMOVE TEST PLUG*** message and voice prompt occurs.



After you remove the test plug from the therapy cable, the message and voice prompt ***CONNECT ELECTRODES*** occurs until the patient is connected to the AED.

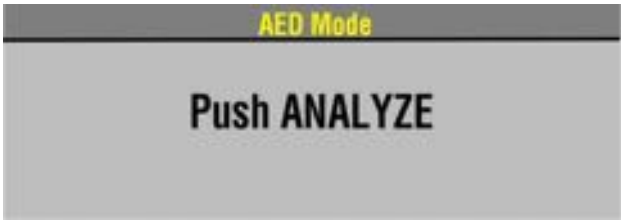
Motion Detected



If motion is detected during the ECG analysis, you will see and hear ***MOTION DETECTED, STOP MOTION*** followed by a warning tone. Analysis is inhibited up to 10 seconds. After 10 seconds, even if motion is still present, the analysis proceeds to completion. Refer to Table 4-1 for possible motion causes and suggested solutions.

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Continuous Patient Surveillance System



When the device is not analyzing the ECG and is not in CPR Time, the Continuous Patient Surveillance System (CPSS) actively monitors the ECG for a potentially shockable rhythm.

If a shockable rhythm is detected, you will see and hear ***PUSH ANALYZE***.

You should:

1 Confirm the patient is unconscious, pulseless, and not breathing normally.
2 Confirm no motion is present. Stop CPR.
3 Press **ANALYZE**.

The AED begins to analyze the patient's ECG.

For information about changing the defibrillation mode, refer to Section 8.

Special AED Setup Options

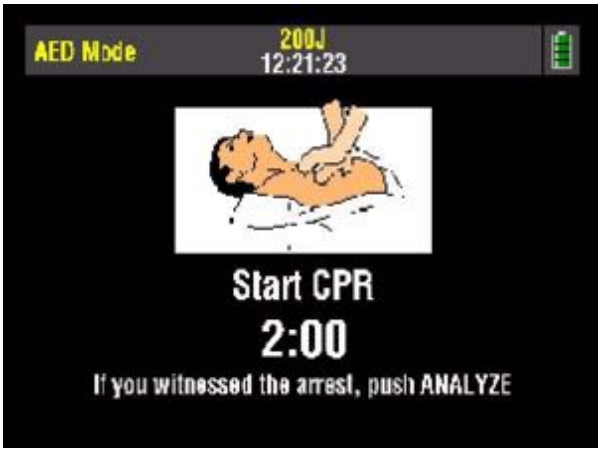
The following descriptions of voice prompts and messages explain special cprMAX technology setup options (refer to Appendix F).

Initial CPR - CPR First

When the **INITIAL CPR** option is set to **CPR FIRST**, you will be prompted to ***START CPR*** immediately after the AED is turned on.



You will see and hear ***START CPR***.



After 3 seconds, a countdown timer continues for the duration specified in the initial CPR period and you will see and hear ***IF YOU WITNESSED THE ARREST, PUSH ANALYZE***. This provides an opportunity to end the initial CPR early and proceed to analysis.

- If you did witness the arrest, you should press **ANALYZE** and proceed directly to analysis. This will end the CPR period and you will see and hear ***ANALYZING NOW, STAND CLEAR***.

  Note: The decision to end CPR early is based on your hospital protocol.
- If you did not witness the arrest, you should perform CPR and not press **ANALYZE**. The **INITIAL CPR** countdown timer continues for the duration specified in the **INITIAL CPR TIME** setup option, for example, 90 seconds. When **INITIAL CPR TIME** ends, you will see and hear ***PUSH ANALYZE***.

Initial CPR - Analyze First

When the **INITIAL CPR** option is set to **ANALYZE FIRST**, you will be prompted to perform analysis after the AED is turned on. CPR is prompted after the AED completes the analysis.

If the electrodes are not attached to the patient, you will see and hear ***CONNECT ELECTRODES*** before you are prompted to perform analysis.

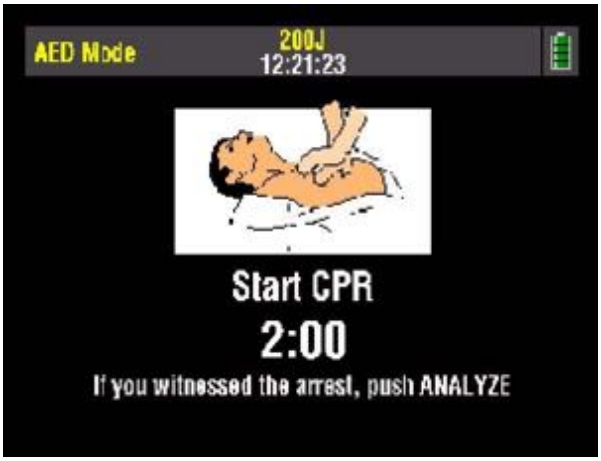
No Shock Advised



If the AED detects a nonshockable rhythm, you will be prompted to ***START CPR.*** A countdown timer (min:sec format) continues for the duration specified in the **INITIAL CPR TIME** setup option. (Refer to Section 8).

When initial CPR time ends, you will see and hear ***NO SHOCK ADVISED*** followed by ***PUSH ANALYZE***.

Shock Advised



If the AED detects a shockable rhythm, you will see and hear ***START CPR*** followed by ***IF YOU WITNESSED THE ARREST, PUSH ANALYZE***. This provides an opportunity to end the initial CPR early and proceed directly to delivering a shock.

- If you did witness the arrest, you should press **ANALYZE** and proceed directly to shock. This will end the CPR period and you will see and hear ***SHOCK ADVISED*** and ***STAND CLEAR, PUSH TO SHOCK*** ( ). Proceed according to your training with the AED for delivering the shock.

  Note: The decision to end CPR early is based on your hospital protocol.
- If you did not witness the arrest, you should perform CPR and not press **ANALYZE**. The **INITIAL CPR** countdown timer continues for the duration specified in the **INITIAL CPR TIME** setup option, for example, 90 seconds. When initial CPR time ends, you will see and hear ***SHOCK ADVISED***. Proceed according to your training with the AED for delivering a shock.

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PreShock CPR Time

When **PRESHOCK CPR** time is set to 15 seconds or more, you are prompted to start CPR immediately after a shockable rhythm is detected, before the shock is delivered.



After analysis is complete, you will see and hear ***START CPR***. A countdown timer (min:sec format) continues for the duration specified in the **PRESHOCK CPR** time setup option (for example, 15 seconds).

When CPR time ends you will then see and hear ***SHOCK ADVISED***. Proceed according to your training with the AED for delivering a shock.

The **SHOCK** button is disabled during the preshock CPR interval to avoid accidental shock delivery while the defibrillator is charged and a responder is performing CPR.

Troubleshooting Tips for AED Mode

Table 4-1 Troubleshooting Tips for AED Mode

Observation	Possible Cause	Corrective Action
1 ***CONNECT ELECTRODES*** message appears.	Inadequate connection to defibrillator.	• Check for electrode connection.
	Electrodes do not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out of date.	• Replace the electrodes.
2 ***REMOVE TEST PLUG*** message appears.	Test plug connected to therapy cable.	• Disconnect test plug from therapy cable. • Connect electrodes to therapy cable.
3 ***MOTION DETECTED*** and ***STOP MOTION*** messages appear during analysis.	Patient movement.	• Stop CPR during analysis. • When patient is being manually ventilated, press **ANALYZE** after complete exhalation. • Move patient to stable location when possible.
	Patient movement because of agonal respirations.	• Press **ANALYZE** immediately after exhalation or wait until agonal respirations are slower or absent.
	Electrical/radio frequency interference.	• Move hand-held communication devices or other suspected devices away from the defibrillator when possible.
4 ***DISARMING*** message appears.	Therapy cable or electrodes disconnected from AED or patient.	• Confirm secure connection and press **ANALYZE**.
	Shock button not pressed within 60 seconds or door is open.	• Press **ANALYZE** again. • Press **SHOCK** immediately when directed.
5 Voice prompts sound faint or distorted.	Low battery power.	• Connect to AC power.
6 ***LOW IMPEDANCE–RECHARGING*** message appears.	Patient impedance <15 ohms detected.	• No action required.

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Switching from AED to Manual Mode

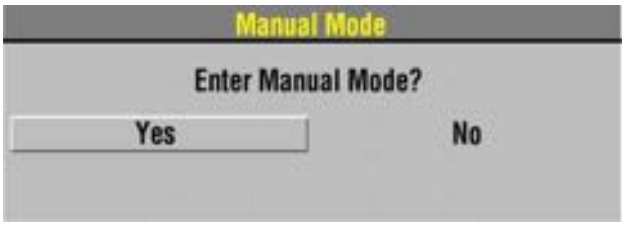
If the front console door is closed, you can enter manual mode by pressing the **MANUAL** button located in the lower left corner of the door. This opens the door and automatically takes the defibrillator out of AED mode, allowing you to access manual mode defibrillation and pacing.

Note: Closing the door again will not place the defibrillator in AED mode. Pressing **ANALYZE** while the defibrillator is in manual mode will place the defibrillator in AED mode.

If the door is not installed, or to manually switch to manual mode, press one of the following keys: **ENERGY SELECT, CHARGE, PACER, LEAD.**

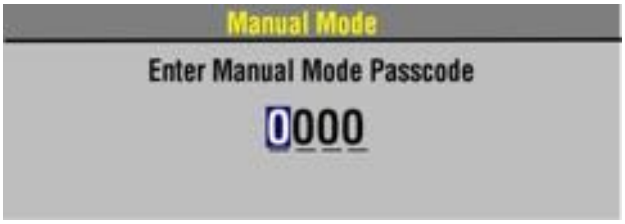
Depending on the defibrillator's configuration, continue to manual mode as follows:

- **Direct**. No restrictions to manual mode - access is immediate.
- **Confirm**. A confirmation overlay appears:



Select **YES** to change to manual mode.

- **Passcode**. A passcode overlay appears:



Enter the passcode to change to manual mode.

Refer to Section 8 for information about changing the defibrillation mode.

MANUAL DEFIBRILLATION

The following paragraphs describe:

- Manual Defibrillation Warnings
- Impedance
- Defibrillation Procedure
- Synchronized Cardioversion Procedure
- Remote Synchronization Procedure

Manual Defibrillation Warnings

WARNINGS!

Possible fire, burns, and ineffective energy delivery.

Precordial lead electrodes and lead wires may interfere with the placement of standard paddles or therapy electrodes. Before defibrillation, remove any interfering precordial lead electrodes and lead wires.

Shock hazard.

Conductive gel (wet or dry) on the paddle handles can allow the electrical energy to discharge through the operator during defibrillation. Completely clean the paddle electrode surfaces, handles, and storage area after defibrillation.

Possible patient skin burns.

During defibrillation, air pockets between the skin and standard paddles can cause patient skin burns. Completely cover paddle electrode surfaces with fresh conductive gel and apply 11.3 kg (25 lb) of pressure per paddle during discharge.

Possible paddle damage and patient skin burns.

Discharging the defibrillator with the standard paddle surfaces shorted together can pit or damage the paddle electrode surface. Pitted or damaged paddle surfaces may cause patient skin burns during defibrillation. Discharge the defibrillator only as described in these operating instructions.

Possible burns and ineffective energy delivery.

A gel pathway on the skin between the standard paddles will cause defibrillating energy to arc between paddles and divert energy away from the heart muscle. Do not allow conductive gel (wet or dry) to become continuous between paddle sites.

Possible damage to defibrillator and defibrillator shutdown.

When used in conjunction with another defibrillator to deliver more than 360J, one or both defibrillators may be damaged and shutdown may occur due to excessive currents. Avoid simultaneous discharge from both defibrillators and maintain a backup defibrillator in case one or both defibrillators shut down. If the defibrillator shuts down, take the defibrillator out of service and contact a qualified service technician.

To use the LIFEPAK 20e defibrillator/monitor primarily as a manual defibrillator, configure the defibrillator before placing the defibrillator in use. To configure the defibrillator, refer to Section 8.

Impedance

LIFEPAK biphasic defibrillators measure the patient's transthoracic impedance and automatically adjust the defibrillation waveform voltage and current duration to meet the needs of the individual patient.

Impedance is measured whenever the defibrillator is charged. To ensure correct patient impedance readings, you should always charge the defibrillator when the standard paddles (hard paddles) or QUIK-COMBO electrodes are in contact with the patient's chest.

If the standard paddles are in the paddle wells or touching face to face (shorted paddles) when the defibrillator is charged, the defibrillator limits the available energy to 79 joules This prevents damage to the internal circuits, in the event the energy is discharged while the hard paddles are still in the paddle wells or shorted together. If the defibrillator is charged to 80 joules or more and energy is discharged when the hard paddles are seated in the paddle wells, the display indicates the selected energy available and the automatic printout annotates time, date and Shock 1 79 J.

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If the defibrillator is charged to 80 joules or more with paddles in the paddle wells, and then the paddles are removed and placed on a patient, the defibrillator continues charging to the selected energy and defibrillation may be completed as usual. When charging the defibrillator with the paddles on the patient's chest, the defibrillator automatically adjusts the waveform voltage and current duration based on the patient's impedance. It is important to understand that this automatic adjustment does not occur when the defibrillator is charged with the paddles seated in the paddle wells.

When the paddles or QUIK-COMBO electrodes are on the patient's chest when the defibrillator is charged and the defibrillator measures an impedance of 15 ohms or less, the defibrillator disarms the capacitor and automatically recharges to a lower energy setting. When this condition occurs, the ***LOW IMPEDANCE-RECHARGING*** message appears on the display. When charging is complete, defibrillation may be completed as usual.

Defibrillation Procedure

You can configure the LIFEPAK 20e defibrillator/monitor to automatically sequence energy levels. Refer to "Manual Mode Setup Menu," page 8-5.

1 Press **ON**.
2 Identify the electrode or paddle sites on the patient. Use either the anterior-lateral or anterior-posterior position as described on page 4-3.
3 Prepare the patient's skin for electrode application:
   - If possible, place the patient on a firm surface away from standing water.
   - Remove clothing from the patient's upper torso.
   - Remove excessive hair from the electrode sites; if shaving is necessary, avoid cutting the skin.
   - Clean the skin and dry it briskly with a towel or gauze.
   - Do not apply alcohol, tincture of benzoin, or antiperspirant to the skin.
4 Connect the therapy electrodes to the therapy cable, and confirm cable connection to the defibrillator.

   Note: When in **PADDLES** lead, if the ***REMOVE TEST PLUG*** message appears, disconnect test plug and connect therapy electrodes to QUIK-COMBO therapy cable.
5 Apply therapy electrodes to the patient in anterior-lateral or anterior-posterior position. If using standard paddles, apply conductive gel to the paddles and place paddles on the patient's chest.
6 Press **ENERGY SELECT**.
7 Press **CHARGE.** While the defibrillator is charging, a charging bar appears and a ramping tone sounds, indicating the charging energy level. When the defibrillator is fully charged, an overlay appears (refer to "Defibrillation Procedure," page 4-16).
8 Make certain all personnel, including the operator, stand clear of the patient, bed, and any equipment connected to the patient.
9 Confirm ECG rhythms and available energy.
10 Press the **SHOCK** button(s) to discharge energy to the patient or press the Speed Dial to remove the charge. If the **SHOCK** button(s) are not pressed within 60 seconds, stored energy is internally removed.

   Note: If you change the energy selection after charging has started, the energy is removed. Press **CHARGE** to restart charging.
11 Observe the patient and the ECG rhythm. If an additional shock is necessary, repeat the procedure beginning at Step 6.

   Note: If the ***ABNORMAL ENERGY DELIVERY*** message appears and the shock is not effective, increase energy, if necessary, and repeat shock. (Also refer to page 4-21.)

Synchronized Cardioversion Procedure

Note: The LIFEPAK 20e defibrillator/monitor can be configured to remain in synchronous mode or to return to asynchronous mode after discharge. It is important that you know how your defibrillator is configured. Refer to "Manual Mode Setup Menu," page 8-5.

1 Press **ON**.

2 Attach patient ECG cable and ECG electrodes as described previously on page 3-5.

3 Select lead II or the lead with greatest QRS complex amplitude (positive or negative).

Note: To monitor the ECG through therapy electrodes, place the electrodes in the anterior-lateral position and select **PADDLES** lead.

WARNING!

Possible lethal arrhythmia.

Ventricular fibrillation may be induced with improper synchronization. DO NOT use the ECG from another monitor (slaving) to synchronize the LIFEPAK 20e defibrillator/monitor discharge. Always monitor the patient's ECG directly through the ECG cable, therapy cable or use the remote synchronization procedure. Confirm proper placement of the sense markers on the ECG.

4 Press **SYNC**. Confirm the sync LED blinks with each detected QRS complex.

Note: Press **SYNC** again to deactivate synchronous mode.

5 Observe the ECG rhythm. Confirm that a triangle sense marker appears near the middle of each QRS complex. If the sense markers do not appear or are displayed in the wrong locations (for example, on the T-wave), select another lead. (It is normal for the sense marker location to vary slightly on each QRS complex.)

6 Prepare the patient's skin for therapy electrode application as described in Step 3 of Defibrillation Procedure, page 4-16.

7 Connect the therapy electrodes to the therapy cable, and confirm cable connection to the defibrillator.

8 Apply therapy electrodes to the patient in the anterior-lateral or anterior-posterior position. If using standard paddles, apply conductive gel to the paddles and place paddles on the patient's chest.

9 Press **ENERGY SELECT**.

10 Press **CHARGE**.

Note: If the ***REMOVE TEST PLUG*** message appears, disconnect test plug and connect therapy electrodes to QUIK-COMBO therapy cable and press **CHARGE**.

11 Make certain all personnel, including operator, stand clear of the patient, bed, and any equipment connected to the patient.

12 Confirm ECG rhythm. Confirm available energy.

13 Press and **hold SHOCK** button(s) until discharge occurs with next detected QRS complex and then release **SHOCK** button(s). If **SHOCK** buttons are not pressed within 60 seconds, stored energy is internally removed.

Note: If you change the energy selection after charging has started, the energy is removed internally. Press **CHARGE** to restart charging.

14 Observe patient and ECG rhythm. Repeat procedure from Step 4, if necessary.

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Remote Synchronization Procedure

WARNINGS!

Possible lethal arrhythmia.

Ventricular fibrillation may be induced with improper synchronization. The hospital's biomedical engineering staff should perform synchronization delay measurements on the system, as a whole, to ensure that the 60 ms limit for synchronization delay is not exceeded, per requirements as specified in AAMI DF2 (1996). Always confirm proper placement of the sense markers on the ECG.

Possible monitor incompatibility

If the R-wave synchronization markers do not appear to be nearly simultaneous with the R-waves on the remote monitor display or are not present, do not proceed with synchronized cardioversion.

The LIFEPAK 20e defibrillator/monitor can be configured to receive an ECG source from a remote monitor (such as a bedside ECG monitoring system) by means of the ECG/Sync connector on the back of the defibrillator/monitor. Refer to "Manual Mode Setup Menu," page 8-5. The remote monitor must have a sync out connector and a cable must be provided to make this connection. Refer to the *LIFEPAK 20e Defibrillator/Monitor Service Manual* for more details.

Note: The LIFEPAK 20e defibrillator/monitor can be configured to remain in synchronous mode or to return to asynchronous mode after discharge. It is important that you know how your defibrillator is configured. Refer to "Manual Mode Setup Menu," page 8-5.

To perform the synchronized cardioversion using a remote monitoring ECG source:

1 Ensure defibrillator/monitor is connected to AC power.
2 Connect the sync cable to the defibrillator/monitor ECG/Sync connector and the remote monitor.
3 Press **ON**.
4 Attach the ECG cable from the remote monitor to the patient.
5 Press **SYNC** on the defibrillator/monitor.
6 Select **REMOTE SYNC** from the menu.

Note: The screen on the defibrillator/monitor will display the message ***REMOTE SYNC*** in place of any waveforms.

7 Observe the ECG rhythm on the remote monitor. Confirm that a sense marker appears above each QRS complex.
8 Confirm that the sync LED on the defibrillator/monitor blinks with each detected QRS on the remote monitor.
9 Follow Step 6 through Step 14 from "Synchronized Cardioversion Procedure" provided previously.

PEDIATRIC DEFIBRILLATION

Pediatric paddles are part of the standard paddle set (refer to page 5-7).

Pediatric Paddle Placement

Pediatric paddles should be used for patients weighing less than 10 kg (22 lb) or for patients whose chest size cannot accommodate the adult therapy electrodes.

Adult paddles are recommended if the paddles will fit completely on the patient's chest. Allow at least 2.5 cm (1 in.) of space between the paddles.

For neonates with very small chests, pediatric paddles may be too large to place in the anterior-lateral position. In this situation, place paddles in the anterior-posterior position. Holding the paddles against the chest and back will support the patient on his/her side.

Do not use the pediatric paddles on adults or older children. Delivery of recommended adult energies through this relatively small electrode surface increases the possibility of skin burns.

Anterior-Lateral

The following is the standard pediatric paddle placement (refer to Figure 4-3):

- Sternum paddle to the patient's right upper torso, lateral to the sternum and below the clavicle.
- Apex paddle lateral to the patient's left nipple in the midaxillary line, with the center of the paddle in the midaxillary line if possible.



Figure 4-3 Anterior-lateral Paddle Position

Anterior-Posterior

Place the sternum paddle anteriorly over the left precordium and the apex paddle posteriorly behind the heart in the infrascapular area (refer to Figure 4-4)

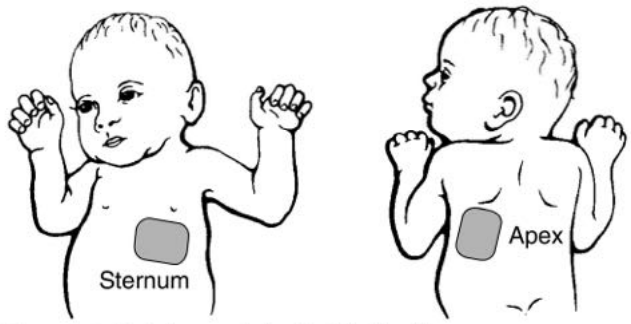


Figure 4-4 Anterior-posterior Paddle Position

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Defibrillation Procedure

To defibrillate the patient:

1 Press **ON** to turn on the defibrillator.
2 To access the pediatric paddles, slide the adult paddle forward until it releases.
3 Apply defibrillation gel to the pediatric paddle electrode surfaces.
4 Select the appropriate energy for the weight of the child according to American Heart Association recommendations (or equivalent guidelines).
5 Place the paddles firmly on the patient's chest.
6 Press **CHARGE**.
7 Make certain all personnel, including the operator, are clear of the patient, the bed, and any equipment connected to the patient.
8 Confirm ECG rhythm and available energy.
9 Press the **SHOCK** button(s) to discharge energy to the patient or press the Speed Dial to remove the charge. If **SHOCK** buttons are not pressed within 60 seconds, stored energy is internally removed.

   Note: If you change the energy selection after charging has started, the energy is removed. Press **CHARGE** to restart charging.

Note: If the ***ABNORMAL ENERGY DELIVERY*** message appears and the shock is not effective, increase energy, if necessary, and repeat shock. (Also refer to page 4-21.)

Troubleshooting Tips for Defibrillation and Synchronized Cardioversion

Table 4-2 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion

Observation	Possible Cause	Corrective Action
1 Charge time to 360 J exceeds 10 seconds.	Battery low.	• Connect to AC power. • Defibrillator operating in low temperature environment (<25°C or 77°F).
2 Energy not delivered to patient when **SHOCK** button(s) are pressed.	Defibrillator in sync mode and QRS complexes are not detected.	• Change ECG lead for optimum sensing QRS or deactivate **SYNC**.
	Defibrillator in sync mode; **SHOCK** button(s) not pressed and held until next detected QRS.	• Hold shock buttons until discharge occurs or next detected QRS.
	SHOCK button(s) pressed before full charge reached.	• Wait for tone and message indicating full charge.
	Sixty seconds elapsed before **SHOCK** button(s) pressed after full charge. Energy internally removed.	• Press **SHOCK** button(s) within 60 seconds of full charge.
	ENERGY selection changed.	• Press **CHARGE** again.
	Test plug connected to QUIK-COMBO therapy cable.	• Disconnect test plug and connect electrodes to QUIK-COMBO therapy cable.

Table 4-2 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion (Continued)

Observation	Possible Cause	Corrective Action
3 ***REMOVE TEST PLUG*** message appears.	Test plug connected to QUIK-COMBO therapy cable.	• Disconnect test plug and connect electrodes to QUIK-COMBO therapy cable.
4 ***CONNECT CABLE*** or ***ENERGY NOT DELIVERED*** message appears.	Therapy cable became disconnected and energy was removed internally.	• Reconnect cable and press **CHARGE** again.
5 ***ENERGY FAULT*** message appears (selected and available energy).	Defibrillator is out of calibration.	• May still transfer energy. • Contact qualified service personnel.
6 ***DISARMING*** message appears.	Discharge button not pressed within 60 seconds after charge complete.	• Recharge the defibrillator if desired.
	Energy selected after charge complete.	• Recharge the defibrillator.
	Therapy cable disconnects.	• Reconnect electrode/cable.
7 Patient didn't jump (no muscle response) during defibrillator discharge.	Patient muscle response is variable and depends on patient condition. Lack of visible response to defibrillation does not necessarily mean the discharge did not occur.	• No action needed.
	Therapy cable not connected to therapy electrodes.	• Connect electrodes to therapy cable.
8 ***ABNORMAL ENERGY DELIVERY*** message appears and Shock XJ Abnormal annotated on printout.	Open air discharge with standard paddles.	• Press paddles firmly on patient's chest when discharging. • Perform test discharges with defibrillation checker.
	Discharge occurs with standard paddles shorted together.	• Refer to warning, page 4-15.
	Patient impedance out of range.	• Increase energy and/or repeat discharges as needed. • Consider replacing disposable therapy electrodes with new.
9 ***CONNECT ELECTRODES*** message appears.	Inadequate connection to defibrillator.	• Check for electrode connection.
	Electrodes do not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out of date.	• Replace the electrodes.

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Table 4-2 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion (Continued)

Observation	Possible Cause	Corrective Action
10 ***CONNECT TO AC POWER*** message appears.	Remote sync is selected and the defibrillator is not connected to AC power.	• Connect to AC power. • Press **SYNC** to turn off remote sync.
11 ***CONNECT SYNC CABLE TO REMOTE MONITOR*** message appears.	Remote sync is selected and the defibrillator is not connected to the remote monitor.	• Connect to remote monitor. • Press **SYNC** to turn off remote synchronization.
12 ***LOW IMPEDANCE–RECHARGING*** message appears.	Patient impedance of <15 ohms detected.	• No action required.
13 ***SEARCHING FOR SIGNAL*** message appears.	Remote sync is selected and the defibrillator is qualifying the input signal.	• No action required.

NONINVASIVE PACING

The LIFEPAK 20e defibrillator/monitor provides noninvasive pacing using QUIK-COMBO electrodes.

The following paragraphs include:

- Noninvasive Pacing Warnings
- Demand and Nondemand Pacing
- Noninvasive Pacing Procedure
- Troubleshooting Tips for Noninvasive Pacing

For information about noninvasive pediatric pacing, refer to the Physio-Control *Therapy Electrodes Operating Instructions*.

Noninvasive Pacing Warnings

WARNINGS!

Possible inducement of ventricular fibrillation.

Sinus bradycardia may be physiologic in severe hypothermia (i.e., appropriate to maintain sufficient oxygen delivery when hypothermia is present), and cardiac pacing is usually not indicated.

Possible interruption of therapy.

Observe the patient continuously while the pacemaker is in use. Patient response to pacing therapy, e.g., capture threshold, may change over time.

Possible inability to pace.

Using other manufacturers' combination therapy electrodes with this device could cause a decrease in pacing efficacy or the inability to pace because of unacceptably high impedance levels.

WARNINGS! (CONTINUED)

Possible patient skin burns.

Prolonged noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Discontinue noninvasive pacing if skin becomes burned and another method of pacing is available.

Demand and Nondemand Pacing

The noninvasive pacemaker can be used for either demand (synchronous) or nondemand (asynchronous) pacing modes.

The demand mode is used for most patients. In the demand mode, the LIFEPAK 20e defibrillator/monitor/pacemaker inhibits pacing when it senses the patient's own beats (intrinsic QRSs). In demand mode, if the ECG amplitude is too low to detect the patient's beats, or if an ECG lead becomes detached so that the ECG rhythm is not present, the pacemaker generates pacing pulses asynchronously. This means that the pacemaker generates pacing pulses at the selected rate, regardless of the patient's ECG rhythm.

Asynchronous or nondemand mode can be selected if noise or artifact interferes with proper sensing of QRS complexes. Press the **OPTIONS** button to access the nondemand mode. (Refer to page 2-6.)

The LIFEPAK 20e defibrillator/monitor has an integrated pulse oximeter that can be used in conjunction with a noninvasive pacemaker to help confirm capture. To confirm capture, compare the pulse rate measured by the oximeter to the set pacing rate of the pacemaker.

Noninvasive Pacing Procedure

ECG monitoring during pacing must be performed with the ECG electrodes and patient ECG cable. Pacing therapy electrodes cannot be used to monitor ECG rhythm and deliver pacing current at the same time. Be sure to place the therapy electrodes in the proper locations as described in the pacing procedure. Improper electrode placement may make a difference in the capture threshold.

To pace, perform the following:

1 Press **ON**.
2 Connect the patient ECG cable, apply ECG electrodes to the ECG cable and patient, and select Lead I, II, or III. To receive the best monitoring signal, ensure there is adequate space between the ECG electrodes and the therapy electrodes.
3 Identify the QUIK-COMBO electrode sites on the patient. For pacing, use either the anterior-lateral or anterior-posterior position (refer to page 4-3).
4 Prepare patient's skin for electrode application as described in Step 3 of the Defibrillation Procedure.
5 Apply QUIK-COMBO electrodes to the patient.
6 Connect the therapy electrodes to the therapy cable.
7 Press **PACER**. Confirm the LED illuminates, indicating that the power is on.

   Note: If the ***REMOVE TEST PLUG*** message appears, disconnect test plug and connect therapy electrodes to QUIK-COMBO therapy cable.
8 Observe the ECG rhythm. Confirm that a triangle sense marker appears near the middle of each QRS complex. If the sense markers do not appear or are displayed in the wrong location (for example, on the T-wave), select another lead. (It is normal for the sense marker location to vary slightly on each QRS complex.)

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9 Press **RATE** or rotate the SPEED DIAL to select the desired pacing rate.

Note: The **RATE** button changes the rate in 10 pulse per minute (ppm) increments; the Speed Dial changes the rate in 5 ppm increments.

10 Press **CURRENT** or rotate the Speed Dial to increase current until electrical capture occurs. For each delivered pacing stimulus, the **PACER** indicator flashes off and a positive pace marker displays on the ECG waveform.

11 Palpate the patient's pulse or check blood pressure and compare the SpO2 pulse rate with the set pacing rate to assess for mechanical capture. Consider use of sedation or analgesia if patient is uncomfortable.

Note: The **CURRENT** button changes the current in 10 mA increments; the Speed Dial changes the current in 5 mA increments.

Note: To change rate or current during pacing, press **RATE** or **CURRENT**, and then rotate the Speed Dial.

Note: To interrupt pacing and view the patient's intrinsic rhythm, press and hold the **PAUSE** button. This causes the pacer to pace at 25% of the set rate. Release the **PAUSE** button to resume pacing at the set rate.

12 To stop pacing, reduce current to zero or press **PACER**.

Note: To defibrillate and stop noninvasive pacing, press **ENERGY SELECT** or charge the defibrillator. Pacing automatically stops. Proceed with defibrillation.

If the monitor detects ECG leads off during pacing, pacing continues at a fixed rate until the ECG lead is reattached. During fixed-rate pacing, the pacemaker delivers pulses at the set pace rate regardless of any intrinsic beats that the patient may have. The monitor continues to display the pacing rate (ppm) and the current (mA). To reestablish demand pacing, reattach the ECG lead.

While pacing, visually monitor the patient at all times, *do not* rely on the ***ECG LEADS OFF*** warning to detect changes in pacing function. Routinely assess the ECG for proper sensing, pace pulse delivery, electrical capture, and mechanical capture.

If pacing electrodes detach during pacing, the ***CONNECT ELECTRODES*** and ***PACING STOPPED*** messages appear and an alarm sounds. The pacing rate is maintained and the current resets to 0 mA. Reattaching the pacing electrodes silences the alarm and removes the ***CONNECT ELECTRODES*** message. The current remains at 0 mA until you increase the current manually.

Troubleshooting Tips for Noninvasive Pacing

Table 4-3 Troubleshooting Tips for Noninvasive Pacing

Observation	Possible Cause	Corrective Action
1 Device does not function when **PACER** is pressed.	Power off.	• Check if power is **ON**.
	Low battery.	• Connect to AC power.
2 **PACER** LED on, but **CURRENT (MA)** will not increase.	Therapy electrodes off.	• Check for message displayed. • Inspect therapy cable and electrode connections.
3 **PACER** LED on, **CURRENT (MA) >0,** but pace markers absent (not pacing).	Pacing rate set below patient's intrinsic rate.	• Increase pacing rate.
	Pacer oversensing (ECG artifact, ECG size too high).	• Establish clean ECG; decrease ECG size. • Select nondemand pacing.

Table 4-3 Troubleshooting Tips for Noninvasive Pacing (Continued)

Observation	Possible Cause	Corrective Action
4 Pacing stops spontaneously.	**PACER** button pressed off.	• Press **PACER** and increase the current.
	Internal error detected. Service message indicates an internal failure.	• Check for service indicator. • Cycle power and start pacing again. • Obtain service by qualified service personnel.
	Therapy electrode off.	• Check for message. Check pacing cable and electrode connections.
	ENERGY SELECT or **CHARGE** pressed.	• Press **PACER** and increase current. • Check for service message. • Cycle power and start pacing again.
	Radio frequency interference.	• Move radio equipment away from pacemaker.
5 Monitor screen displays distortion while pacing.	ECG electrodes not optimally placed with respect to pacing electrodes.	• Reposition electrodes away from pacing electrodes.
	Patient response to pacing is highly variable with respect to capture threshold and ECG distortion.	• Select another lead (I, II, or III). • Consider changing pacing rate.
6 Capture does not occur with pacing stimulus.	Current (mA) set too low.	• Increase pacing current. (Administer sedation/ analgesia as needed.)
7 ***CONNECT ELECTRODES*** message appears.	Pacing cable or electrode disconnected.	• Reconnect and set current.
	Electrodes not adhering to skin.	• Prepare skin.
	Electrodes outdated.	• Apply new electrodes and set current.
8 Pacing stops spontaneously and ***PACER FAULT*** message appears.	Internal error detected.	• Cycle power and start pacing again. • Obtain service by qualified service personnel.
9 ***REMOVE TEST PLUG*** message appears.	Test plug connected to therapy cable.	• Disconnect test plug from therapy cable. • Connect electrodes to therapy cable.
10 Intrinsic QRS complexes not sensed when pacing.	ECG amplitude too low to be sensed.	• Select another lead.
	Intrinsic QRS complexes are occurring during pacemaker's refractory period.	• Adjust pacing rate.

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Table 4-3 Troubleshooting Tips for Noninvasive Pacing (Continued)

Observation	Possible Cause	Corrective Action
11 Pacing starts spontaneously.	Patient's heart rate falls below set pacing rate.	• Appropriate pacemaker function assess patient.
	During standby pacing, ECG lead disconnects.	• Reconnect ECG lead.
12 Set pacing rate (ppm) and ECG paced rate do not appear to match.	Internal error detected.	• Print ECG and calculate the pace rate.
13 Improper sensing (for example, sensing on T-waves).	QRS complex too small. T-wave too large.	• Select another lead.

PADDLE ACCESSORY OPTIONS

Therapy Electrodes	page 5-2
Standard Paddle Set (Optional)	5-7
Internal Handles with Discharge Control	5-9

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THERAPY ELECTRODES

The following paragraphs describe:

- About Therapy Electrodes
- Electrode Placement
- Cable Connection
- ECG Monitoring and Therapy Procedures
- Replacing and Removing Electrodes
- Testing
- Cleaning and Sterilizing

About Therapy Electrodes

There are two pre-gelled, self-adhesive therapy electrodes available: QUIK-COMBO pacing/defibrillation/ECG electrodes and FAST-PATCH defibrillation/ECG electrodes (Figure 5-1). QUIK-COMBO electrodes are used for defibrillation, synchronized cardioversion, ECG monitoring, and pacing. FAST-PATCH electrodes can be used for defibrillation, synchronized cardioversion, and ECG monitoring, but not for pacing. To use FAST-PATCH electrodes with the LIFEPAK 20e defibrillator/monitor requires the addition of a FAST-PATCH defibrillation adapter cable.

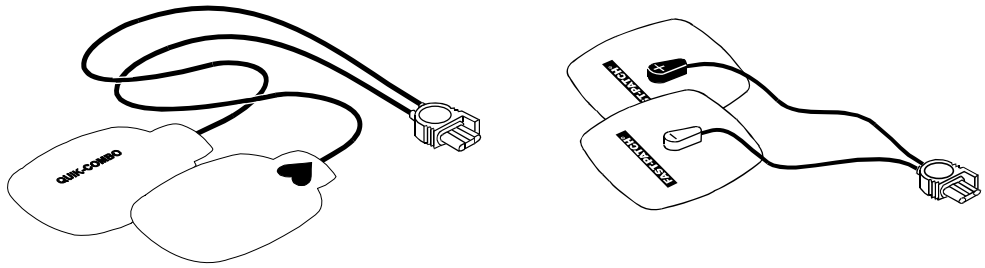


Figure 5-1 QUIK-COMBO and FAST-PATCH Electrodes

A QUIK-COMBO or FAST-PATCH electrode set:

- Is a substitute for standard paddles.
- Provides a Lead II monitoring signal when placed in the anterior-lateral position.
- Quickly restores the ECG trace on the monitor following defibrillation.

To help prevent electrode damage:

- Do not fold the electrodes.
- Do not trim the electrodes.
- Do not crush, fold, or store the electrodes under heavy objects.
- Store therapy electrodes in a cool, dry location. These electrodes are designed to withstand environmental temperature fluctuations between -40° to 50°C (-40° to 122°F). Continuous exposure to temperatures above 23°C (73°F) reduces the shelf life of electrodes.

There are several types of QUIK-COMBO electrodes available as described in Table 5-1.

Table 5-1 QUIK-COMBO Electrodes

Type	Description
QUIK-COMBO	Electrodes, with .6 m (2 ft) of lead wire, designed for patients weighing 15 kg (33 lb) or more.
QUIK-COMBO - RTS	Electrodes, providing a radio-transparent electrode and lead wire set, designed for patients weighing 15 kg (33 lb) or more.
QUIK-COMBO with REDI-PAK™ preconnect system	Electrodes designed for patients weighing 15 kg (33 lb) or more and allow preconnection of the electrode set to the device while maintaining electrode shelf life and integrity.
Pediatric QUIK-COMBO	Electrodes designed for patients weighing 15 kg (33 lb) or less.

FAST-PATCH electrodes can be used on pediatric patients if the placement meets conditions noted in the following paragraphs. Usually, these conditions can be met by patients weighing 15 kg (33 lb) or more.

Electrode Placement

When using QUIK-COMBO or FAST-PATCH electrodes, ensure that the electrodes:

- Fit completely on the chest as described on page 3-4 or page 4-3.
- Have at least 2.5 cm (1 in.) of space between electrodes.
- Do not overlap bony prominences of sternum or spine.

To place the electrodes:

1 Prepare the patient for electrode placement:
   - Remove all clothing from the patient's chest.
   - Remove excessive chest hair as much as possible. Avoid nicking or cutting the skin if using a shaver or razor. If possible, avoid placing the electrodes over broken skin.
   - Clean and dry the skin. If there is ointment on the patient's chest, use soap and water to clean the skin. Briskly wipe the skin dry with a towel or gauze. This mildly abrades the skin and removes oils, dirt, and other debris for better electrode adhesion to the skin. Do not use alcohol, tincture of benzoin, or antiperspirant to prepare the skin.
2 Slowly peel back the protective liner on the electrodes, beginning with the cable connection end (refer to Figure 5-2).

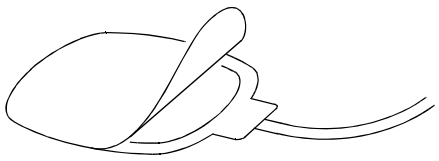


Figure 5-2 Peeling the Liner from the Electrode

3 Place the electrodes in the anterior-lateral or anterior-posterior position, as described on page 3-4 or page 4-3, depending on the therapy to be provided and special placement considerations.
4 Starting from one edge, firmly press the electrode on the patient's chest to eliminate air pockets between the gel surface and the skin. Firmly press all adhesive edges to the skin.

   Note: Once applied, therapy electrodes should not be repositioned.

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Cable Connection

To connect QUIK-COMBO electrodes to the QUIK-COMBO therapy cable:

1 Open the protective cover on the QUIK-COMBO therapy cable connector (refer to Figure 5-3).
2 Insert the QUIK-COMBO electrode connector into the therapy cable connector by aligning the arrows and pressing the connectors firmly together for proper attachment.

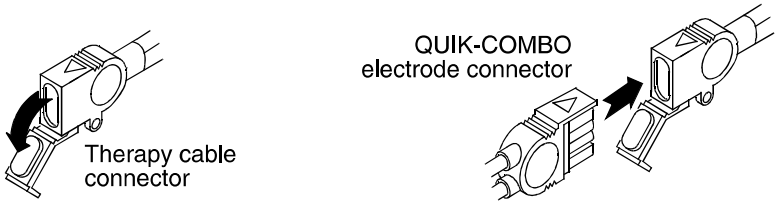


Figure 5-3 Connecting QUIK-COMBO Electrodes to Therapy Cable

To properly connect FAST-PATCH electrodes to the FAST-PATCH defibrillation adapter cable and ensure energy delivery:

1 Attach the defibrillation cable to the electrode post (before applying electrodes to the patient, when possible).
2 Support the electrode post when attaching the defibrillation cable (refer to Figure 5-4). Firmly press the cable onto the electrode until a click is heard or felt.



Figure 5-4 Connecting FAST-PATCH Electrodes to Defibrillation Cable

3 Pull up gently on the connector to confirm that the defibrillation cable is securely connected to the electrode.

Note: If you are reattaching the defibrillation cable to an electrode that is already on the patient, lift the adhesive edge under the electrode post slightly and place your finger under the post. Connect the cable as described in the preceding steps.

ECG Monitoring and Therapy Procedures

WARNINGS!

Possible patient skin burns.

Do not use Pediatric QUIK-COMBO electrodes on adults or larger children. Delivery of defibrillation energies equal to or greater than 100 joules (typically used on adults) through these smaller electrodes increases the possibility of skin burns.

Possible pediatric patient skin burns.

Noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Inspect underlying skin of the ♥ electrode frequently after 30 minutes of continuous pacing. Discontinue noninvasive pacing if skin burn develops and another method of pacing is available. On cessation of pacing, immediately remove or replace electrodes with new ones.

For adult patients, follow the procedures for ECG monitoring, AED defibrillation, manual defibrillation, synchronized cardioversion, and pacing described in Section 3 or Section 4.

For pediatric patients, follow the procedures for ECG monitoring, manual defibrillation, synchronized cardioversion, and pacing except for the following:

- Select the appropriate defibrillation energy for the weight of the pediatric patient according to the American Heart Association (AHA) recommendations or local protocol. Using energy levels of 100 joules or greater is likely to cause burns.
- When pacing, frequently inspect the patient's skin under the heart electrode for signs of burns.

Note: The amount of pacing current needed for capture is similar to the pacing current needed for adults.

Replacing and Removing Electrodes

Replace QUIK-COMBO, QUIK-COMBO RTS, QUIK-COMBO REDI-PAK, or FAST-PATCH Plus electrodes with new electrodes after 50 defibrillation shocks or 24 hours on the patient's skin, or after 8 hours of continuous pacing. Replace pediatric QUIK-COMBO electrodes after 25 defibrillation shocks or 24 hours on the patient's skin, or after 8 hours of continuous pacing.

To remove QUIK-COMBO or FAST-PATCH electrodes from the patient:

1 Slowly peel back the electrode from the edge, supporting the skin as shown in Figure 5-5.

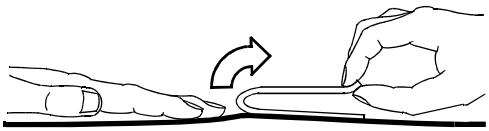


Figure 5-5 Removing Therapy Electrodes from Skin

2 Clean and dry the patient's skin.
3 When replacing electrodes, adjust the electrode positions slightly to help prevent skin burns.
4 Close the protective cover on the QUIK-COMBO therapy cable connector when the cable is not in use.

To disconnect the defibrillation cable from the FAST-PATCH electrodes:

1 Press down around the electrode post.
2 Pinch the snap connector with the fingers of the other hand and pull straight up (refer to Figure 5-6).

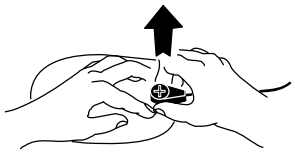


Figure 5-6 Disconnecting Defibrillation Cable from FAST-PATCH Electrodes

WARNING!

Possible cable damage and ineffective energy delivery or loss of monitoring.

Improper disconnection of the defibrillation cable may damage the cable wires. This can result in failure to deliver energy or loss of ECG signal during patient care. Position the cable so that it will not be pulled, snagged, or tripped over. Do not disconnect the defibrillation cable snap connectors from electrode posts or posts on testing devices by pulling on the cable. Disconnect the cable by pulling each cable connector straight out (refer to Figure 5-8).

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Figure 5-7 Disconnecting Defibrillation Cable from Test Post

Testing

As part of your defibrillator test routine, inspect and test the QUIK-COMBO therapy cable or FAST-PATCH defibrillation adapter cable. Daily inspection and testing will help ensure that the defibrillator and therapy cables are in good operating condition and are ready for use when needed. (Refer to "Maintaining the Equipment," page 7-1 and the "LIFEPAK® 20e Defibrillator/ Monitor Operator's Checklist," page D-1.)

Note: During the daily auto test and the user test, energy is discharged through the therapy cable, testing the defibrillation component of the therapy cable. Performing the therapy cable test on the Operator's Checklist checks the sensing component of the therapy cable. Complete therapy cable integrity is checked when both tests are performed.

If you detect any discrepancy during inspection and testing, remove the therapy cable from use and immediately notify a qualified service technician.

Cleaning and Sterilizing

QUIK-COMBO and FAST-PATCH electrodes are not sterile or sterilizable. They are disposable and are to be used for a single patient application. Do not autoclave, gas sterilize, immerse in fluids, or clean electrodes with alcohol or solvents.

STANDARD PADDLE SET (OPTIONAL)

The following paragraphs describe:

- About the Standard Paddle Set
- Accessing the Pediatric Paddles
- Replacing the Adult Paddle Attachment
- Cleaning the Standard Paddle Set

Figure 5-8 illustrates the standard paddles' features.

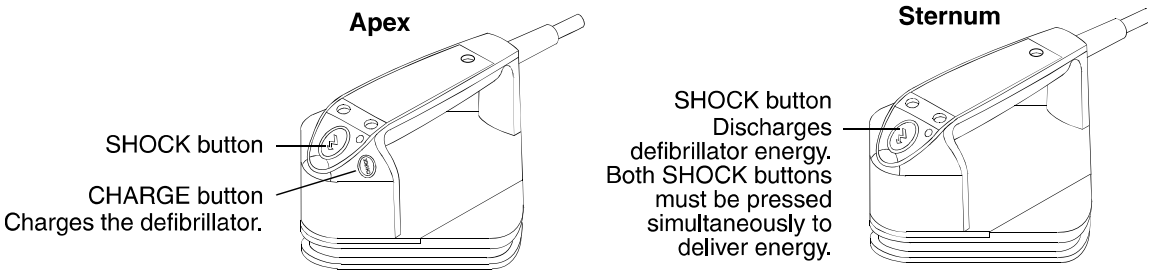


Figure 5-8 Standard Paddles

About the Standard Paddle Set

A standard paddle set:

- Can be used instead of QUIK-COMBO therapy electrodes.
- Provides Lead II monitoring signal when held in the anterior-lateral position.
- Is used for defibrillation, synchronized cardioversion, and QUIK-LOOK® ECG checks.

To help prevent standard paddles damage:

- Handle with care to prevent damage to paddle surfaces.
- Store in paddle wells on the device to protect the electrode surface.
- Clean dried or wet gel from the electrode surface after each use.

The standard paddle set consists of two parts:

1 The handle assembly, which includes the pediatric paddle
2 The adult paddle attachment

Features of the QUIK-LOOK defibrillation paddles can be used with both the pediatric paddle and adult paddle attachment.

Accessing the Pediatric Paddles

To access the pediatric paddles:

1 Grasp the standard paddle handle with one hand and the bottom of the adult paddle electrode with the other hand.
2 Slide the paddle handle back until you hear a click (refer to Figure 5-9).
3 Lift the paddle handle away from the adult attachment.

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4 The pediatric paddle is now exposed and ready for use (refer to Figure 5-10).

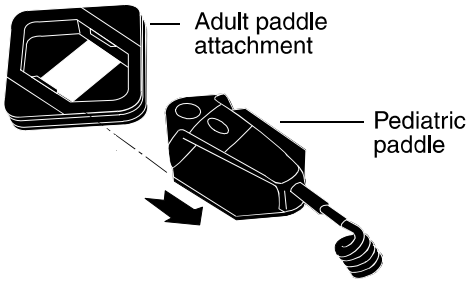


Figure 5-9 Accessing a Pediatric Paddle

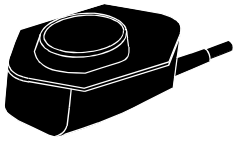


Figure 5-10 Pediatric Paddle (Bottom)

Replacing the Adult Paddle Attachment

To replace the adult paddle attachment:

1 Hold the adult paddle attachment with one hand and the standard handle with the other hand.
2 Fit the pediatric paddle onto the adult paddle attachment.
3 Slide the paddle handle forward until you hear a click. (Refer to Figure 5-11.)

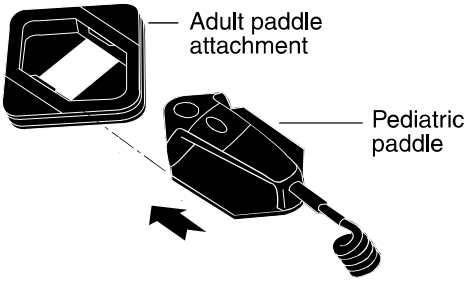


Figure 5-11 Replacing a Pediatric Paddle

Each adult paddle attachment has a contact spring plate that transfers energy from the pediatric paddle to the adult paddle. Routinely inspect the spring plates and pediatric paddle surfaces to make sure that they are clean and intact.

Cleaning the Standard Paddle Set

Individually protect paddles before and after cleaning to prevent damage to paddle surfaces. After each use:

1 Separate the adult and pediatric paddles.
2 Wipe or rinse paddle electrodes, cable connector, handles, and cables with mild soap and water or disinfectant using a damp sponge, towel, or brush. Do not immerse or soak.
3 Dry all parts thoroughly.
4 Examine paddles (including electrode surfaces), cables, and connectors for damage or signs of wear.

Note: Cables showing signs of wear, such as loose cable connections, exposed wires, or cable connector corrosion, should be removed from use immediately.

Note: Paddles with rough or pitted electrodes should be removed from use immediately.

INTERNAL HANDLES WITH DISCHARGE CONTROL

The following paragraphs describe:

- About Internal Handles with Discharge Control
- Inserting the Paddles
- Removing the Paddles
- Internal Defibrillation Procedure
- Internal Paddles Synchronized Cardioversion Procedure
- Handling Internal Paddles
- Cleaning and Sterilizing
- Testing

About Internal Handles with Discharge Control

Internal handles with discharge control (Figure 5-12) are specifically designed for open chest cardiac defibrillation and connect directly to the LIFEPAK 20e defibrillator/monitor.

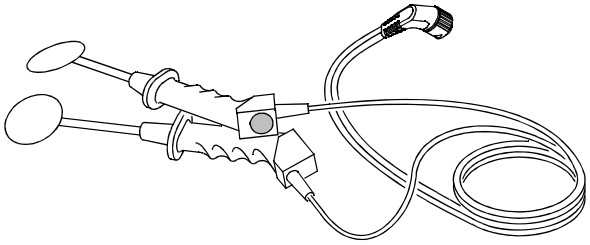


Figure 5-12 Internal Handles with Discharge Control

Internal handles with discharge control are designed to be used only with internal paddles that have the cam locking end as shown in Figure 5-13. No other paddles are compatible with these handles.

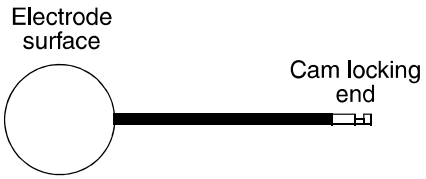


Figure 5-13 Internal Paddle

The internal paddles are available in the sizes listed in Table 5-2.

Table 5-2 Internal Paddle Options

Diameter		Shaft Length	
Centimeters	Inches	Centimeters	Inches
2.5	1.0	15.9	6.25
3.8	1.5	15.2	6.00
3.8	1.5	22.9	9.00
3.8	1.5	36.2	14.25

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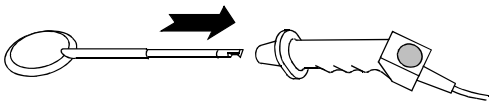
Table 5-2 Internal Paddle Options (Continued)

Diameter		Shaft Length	
Centimeters	Inches	Centimeters	Inches
5.1	2.0	14.6	5.75
5.1	2.0	22.2	8.75
6.4	2.5	14.0	5.50
6.4	2.5	21.6	8.50
8.9	3.5	12.7	5.00
8.9	3.5	20.3	8.00

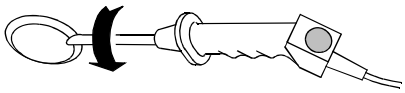
Inserting the Paddles

To insert the paddles:

1 Using a sterile technique, insert paddle fully into handle until a positive stop is reached.



2 Press and rotate the paddle as shown (clockwise) until a second stop is reached.



3 Release the paddle to lock in place. A correctly installed and locked paddle cannot be directly withdrawn or rotated.

Removing the Paddles

To remove the paddles:

1 Push the paddle into the handle until a positive stop is reached.
2 Rotate the handle counterclockwise until a second stop is reached.
3 Slide the paddle out of the handle.

Internal Defibrillation Procedure

When internal handles are connected, energy selection is automatically limited to 50 joules because of possible cardiac damage from higher energies. To initiate internal defibrillation:

1 Press **ON**. The Joules Selected symbol appears on the screen.
2 Press **ENERGY SELECT** if energy other than 10 joules is desired.
3 Press **CHARGE**.
4 Place conductive surface of paddles against the right atrium and left ventricle.
5 Make certain that all personnel, including the operator, are clear of the patient, operating table or bed, or any other equipment connected to the patient.
6 Press the discharge control located on the internal handle when the defibrillator has reached the selected energy level. The defibrillator will not discharge until it completes charging to the selected energy level. If discharge control is not pressed within 60 seconds, stored energy is removed automatically.
7 Press the Speed Dial to manually remove an unwanted charge.

Internal Paddles Synchronized Cardioversion Procedure

When internal handles are connected, the energy selection is automatically limited to 50 joules. To use internal paddles for synchronized cardioversion:

1 Connect the internal paddles to the defibrillator.
2 Turn on the defibrillator, and then select **PADDLES** lead.
3 Change the ECG size (gain) to the lowest setting, 0.25.
4 Place the conductible surface of the paddles against the patient's atrium and ventricle.
5 Select the desired energy setting.
6 Press **SYNC**.
7 Confirm that a stable ECG signal is present and that triangle sense markers appear near the middle of each QRS complex.

   Note: The patient's ECG acquired through internal paddles may be unreliable for synchronized cardioversion due to excessive noise or artifact, causing inappropriate R-wave detection. If the sense markers do not appear or are displayed in the wrong location (for example, on the T-wave), acquire the patient's ECG through standard ECG electrodes and cable.
8 Press **CHARGE**.
9 Make certain that all personnel, including the operator, are clear of the patient, operating table or bed, or any other equipment that is connected to the patient.
10 When the defibrillator reaches the selected energy level, press and hold the discharge control located on the internal handle. Discharge will occur with the next detected QRS complex.
11 Observe the patient's ECG rhythm.
12 If necessary, repeat Step 4 through Step 11.

Handling Internal Paddles

Observe the following precautionary measures to avoid damage to the coating on internal paddles.

- Immediately following surgery and after removing the handle(s), cover each paddle to help protect the paddles from impact to each other, other instruments, or hard surfaces.
- Use caution while handling the paddles during and after cleaning and before the sterilization wrapping process.
- Inspect the paddles for chips and scratches after each use. If any damage is found, remove the paddle(s) from use immediately.

Cleaning and Sterilizing

Product shipped non-sterile. Clean and sterilize prior to use. Clean and sterilize this accessory according to the sterilization instructions provided with the accessory.

Testing

Perform 20 J defibrillation test using a defibrillator analyzer no less than quarterly or after ten sterilization cycles, whichever comes first.

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DATA MANAGEMENT

This section describes data management functions.

Overview of Data Storage and Retrieval	page 6-2
CODE SUMMARY Report	6-2
Managing Archived Patient Records	6-7
Entering Archives Mode	6-7
Printing Archived Patient Reports	6-7
Editing Archived Patient Records	6-9
Deleting Archived Patient Records	6-10
Overview of Connections for Transmitting Reports	6-11

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OVERVIEW OF DATA STORAGE AND RETRIEVAL

The following paragraphs describe patient data storage and retrieval using the LIFEPAK 20e defibrillator/monitor.

Data Storage

When you turn on the LIFEPAK 20e defibrillator/monitor, you create a new Patient Record stamped with the current date and time. All events and associated waveforms are digitally stored in the Patient Record as patient reports, which you can print. When you turn off the device, the current Patient Record data is saved in the patient archives.

To access the patient archives, press **OPTIONS** and select **ARCHIVES**. You can print or delete patient records stored in the archived Patient Record. When you enter the archives mode, patient monitoring ends and the current Patient Record is saved and closed. Turn off the device to exit the archives mode.

Report Types

Patient reports within a Patient Record are stored as a CODE SUMMARY Critical Event Record, which includes patient information, event and vital signs logs, and waveforms associated with events (for example, defibrillation) as described on page 6-4.

Memory Capacity

The LIFEPAK 20e defibrillator/monitor retains data for two or more patients when you switch power off or remove the batteries. The number of patient reports that the defibrillator can store depends on various factors, including the number of displayed waveforms, the duration of each use, and the type of therapy. Typically, memory capacity includes up to 100 single waveform reports. When the defibrillator reaches the limits of its memory capacity, the defibrillator deletes an entire Patient Record using a “first in, first out” priority to accommodate a new Patient Record. Deleted Patient Records cannot be retrieved.

CODE SUMMARY REPORT

The LIFEPAK 20e defibrillator/monitor automatically stores a CODE SUMMARY report as part of the Patient Record for each patient. The report consists of the following:

- Preamble
- Event/vital signs log
- Waveforms associated with certain events

Figure 6-1 is an example of a CODE SUMMARY report. Press **CODE SUMMARY** to print the report.

Preamble

Name:	**DAVIDO, GUIDO**	**CODE SUMMARY™**	
ID	041495094322	**critical event record**	
Patient ID:	52876004	Power On:	24 April 09 06:03:12
Location:	L483	Device:	100
Age: 45	Sex: M	Site:	ABCD
		Total Shocks:	3
		Total time paced	00:15:00
		Elapsed Time:	00:52:43
	35.1 3434 LP20PRB005		

Event/Vital Signs Log

Time	Event	HR	SpO2•PR	COMMENTS:
07:15:34	Power On			
07:16:34	Initial Rhythm	95	99•95	
07:20:34	Vital Signs	92	98•94	
07:22:14	Pacing 1 Started	95	98•95	
07:24:34	Pacing 2 Set	99	98•99	
07:25:34	Vital Signs	92	98•93	
07:26:36	Alarm HR	152	99	

Figure 6-1 CODE SUMMARY Report

Preamble

The preamble contains patient information (name, event identification, patient identification, location, age, and sex) and device information (date, time, and therapy information) as shown in Figure 6-1. The event identification is a unique identifier that the defibrillator automatically enters in the ID field for each Patient Report. This identifier includes the date and time that the defibrillator is turned on. The location field allows you to enter up to 25 alpha-numeric characters to identify where the device was used. You can link the data you enter to other patient information.

Event/Vital Signs Log

The LIFEPAK 20e defibrillator/monitor documents events and vital signs in chronological order. Events are operator or device actions that are related to monitoring, pacing, AED therapy, data transmission, and more. Table 6-1 shows a complete listing of events that can be found in the event log.

Vital signs (or active parameters) are entered into the log automatically every 5 minutes (or for each event) and when alarm limits are exceeded. Refer to **AUTO LOG** in Table 8-1 for more information.

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Table 6-1 Event Types

Event Types	Events			
Monitoring	• Initial rhythm	• Alarm events	• Vital signs	
Operator initiated	• Event	• Print	• Sync On/Off	• Internal Pacer Detection On/Off
	• Alarms On	• VF/VT Alarm On/ Off		
Therapy AED	• AED mode	• Connect electrodes	• Analysis	• Shock advised
	• Check patient	• Motion	• Analysis stopped	• No shock advised
Defibrillation	• Manual mode	• Charge removed	• Shock X Delivered	• Shock X Not Delivered
Pacing	• Started	• Set	• Changed	• Stopped
	• Paused			
Memory Status	• Out of Waveform Memory [memory low]	• Out of Event Memory [memory full]		

Waveform Events

In addition to being documented in the Event Log, therapy and other selected events also capture waveform data as described in Table 6-2.

Table 6-2 Waveform Events

Event Name	Waveform Data
INITIAL RHYTHM	• 8 seconds after leads on.
CHECK PATIENT	• 8 seconds prior to alert.
SHOCK **or** NO SHOCK ADVISED	• 2–3 segments of analyzed ECG. Each segment may be 2.7 seconds.
ANALYSIS X STOPPED	• 8 seconds of data prior to cessation of analysis.
SHOCK X	• 3 seconds prior to shock and 5 seconds after shock.
PACING X STARTED	• 8 seconds prior to increase of current from 0.
PACING X SET	• 8 seconds after ppm and mA are stable for 10 seconds.
PACING X CHANGED	• 8 seconds after pacing rate, current, or mode is changed.
PACING X STOPPED	• 3 seconds prior to pacing current is zero and 5 seconds after.
PACING X PAUSED	• Initial 8 seconds while **PAUSE** is pressed.
ALARM*	• 3 seconds prior to violated parameter and 5 seconds after.
EVENT*	• 3 seconds prior to event selection and 5 seconds after.
PRINT	• 3 seconds prior to pressing **PRINT** and 5 seconds after.

*To reduce the length of the CODE SUMMARY report, storing waveform data with these events can be configured **OFF** (refer to page 8-11).

Waveform events are preceded by a header that includes the following information:

- Patient data
- Event name
- Therapy data
- Vital signs
- Device configuration information
- Transthoracic impedance measured during the shock (defibrillation events only)

CODE SUMMARY Format

You can configure the LIFEPAK 20e defibrillator/monitor to print a CODE SUMMARY report in one of the formats described in Table 6-3. CODE SUMMARY reports are always stored in the medium format.

Table 6-3 CODE SUMMARY Formats

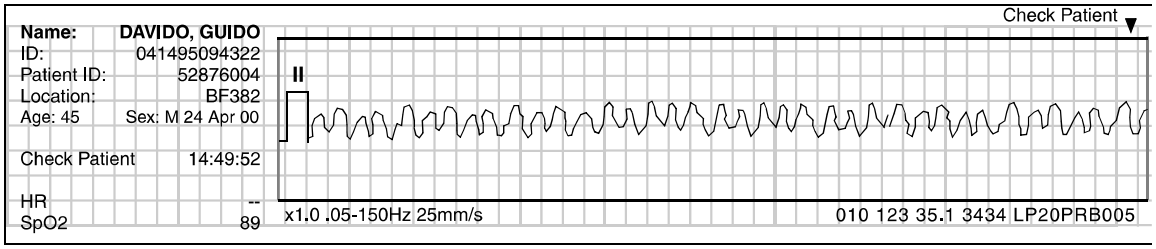
Format	Attributes	
Medium format	• Preamble • Event/vital signs log	• Event waveforms
Short format	• Preamble	• Event/vital signs log

The format determines only which reports are printed when the **CODE SUMMARY** button is pressed. If you interrupt printing of a CODE SUMMARY report, the entire CODE SUMMARY report will be reprinted when printing is resumed.

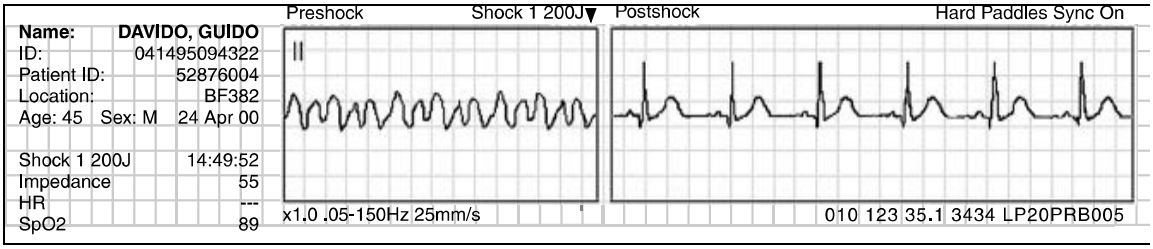
CODE SUMMARY Complete is printed immediately following the last waveform event.

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Refer to Figure 6-2 for examples of waveform data event printouts in the CODE SUMMARY report.



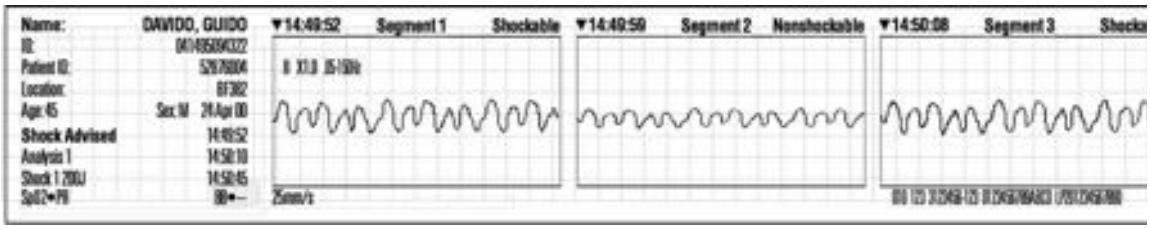
Check Patient Event



Defibrillation Event



Pacing Event



SAS Event



Parameter Alarm Event

Figure 6-2 Waveform Event Printout Examples

MANAGING ARCHIVED PATIENT RECORDS

When you turn off the LIFEPAK 20e defibrillator/monitor, the current Patient Record is saved in the archives. There are three options for managing archived Patient Records:

- Print archived patient reports
- Edit archived patient records
- Delete archived patient records

To perform any or all of these options, you must first enter the archives mode and then proceed with the desired option.

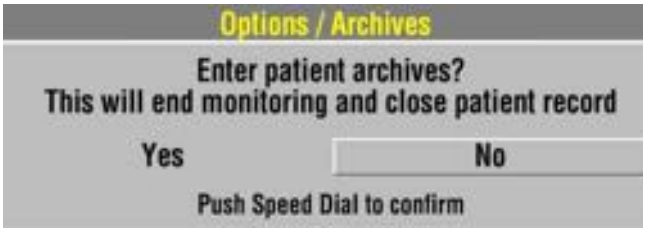
ENTERING ARCHIVES MODE



To enter the archives mode:

1 Press **OPTIONS**.

2 Select **ARCHIVES**.



3 Select **YES** to enter the patient archives.

YES closes and saves the current Patient Record and ends patient monitoring.

–or–

SELECT **NO** to clear the overlay and return to the previous screen.

Note: When you enter the archives mode, patient monitoring ends (for example, no ECG, no alarms) and the current Patient Record is saved and closed.

PRINTING ARCHIVED PATIENT REPORTS

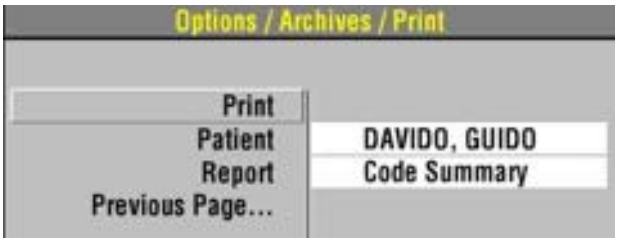


To print:

1 Be sure that you are in the archives mode (refer to "Entering Archives Mode," page 6-7).

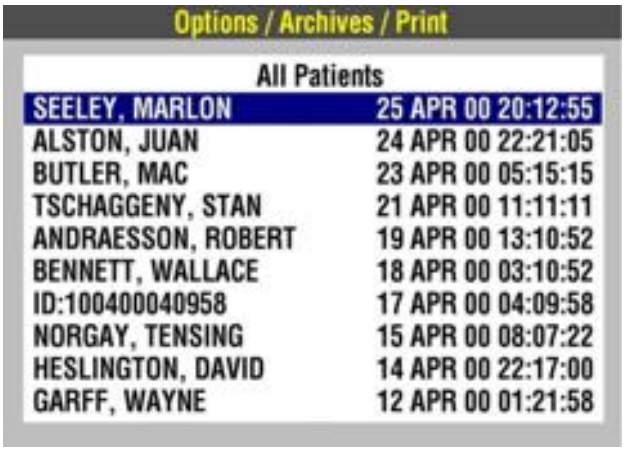
2 Select **PRINT**.

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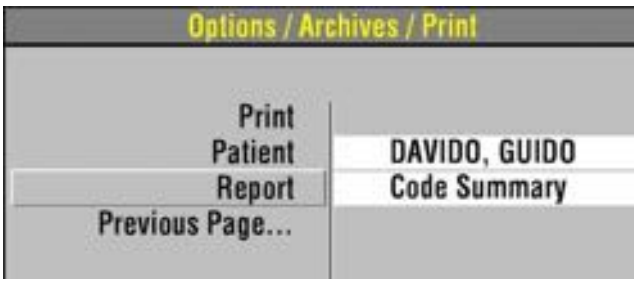


3 If the **PATIENT** and **REPORT** settings are correct, select **PRINT** to print the report.

Otherwise, select **PATIENT** and proceed to the next step.

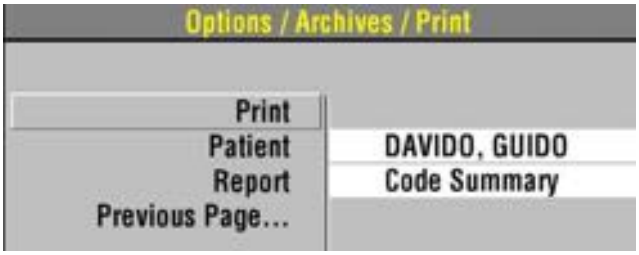


4 Select a patient from the list of Patient Records or select **ALL PATIENTS** to print a list of all Patient Records in the archives.



5 Select **REPORT** to display the report list:

CODE SUMMARY – Prints the CODE SUMMARY report (medium format).
A check mark indicates that a report was previously printed.



6 Select **PRINT**.

To return to the Options/Archives menu, press **HOME SCREEN**.
–or–
To exit the archives mode, turn off the device.

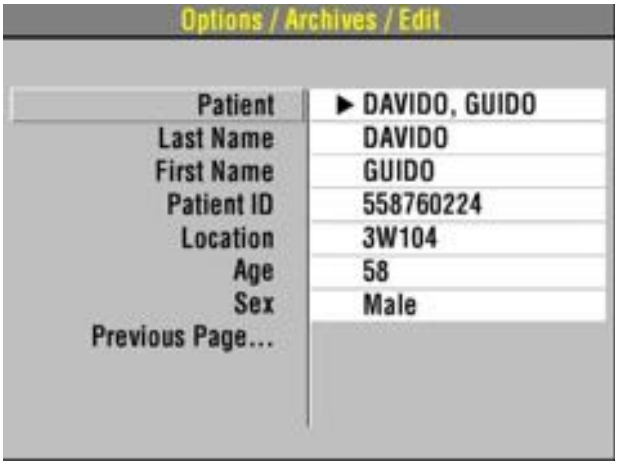
EDITING ARCHIVED PATIENT RECORDS



To edit:

1 Be sure that you are in the archives mode (refer to "Entering Archives Mode," page 6-7).

2 Select **EDIT.**



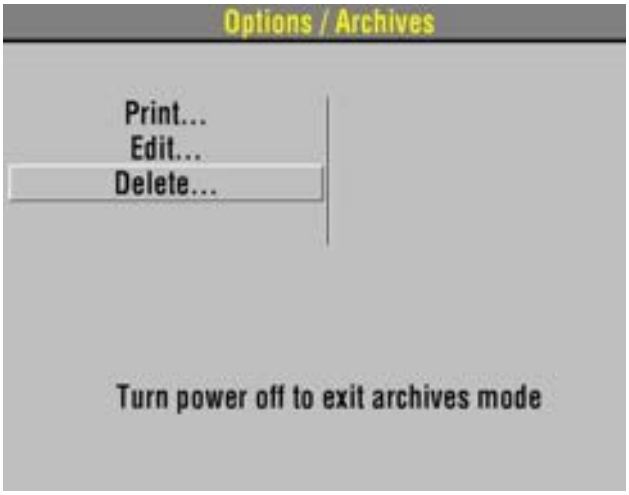
3 Select **PATIENT**.

4 Add or change the necessary patient information.

5 Press **HOME SCREEN**, then turn off the device.

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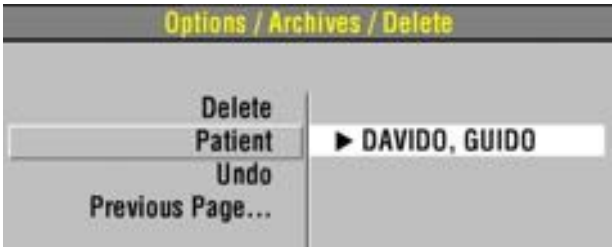
DELETING ARCHIVED PATIENT RECORDS



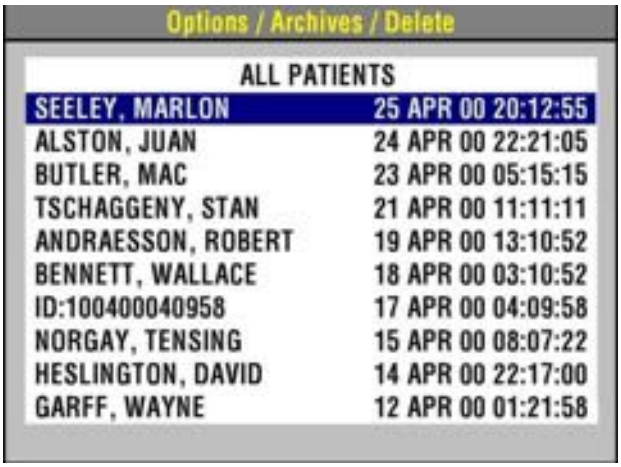
To delete:

1 Be sure that you are in the archives mode (refer to "Entering Archives Mode," page 6-7).

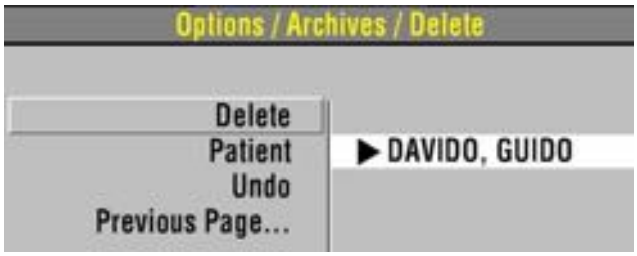
2 Select **DELETE**.



3 Select **PATIENT**.



4 Select a patient from the list.



5 Select **DELETE** to permanently remove the selected Patient Record from the archives.

Note: If, after you select **DELETE**, you decide you do not want to remove the patient record, immediately select **UNDO**. If you continue operations, you cannot reverse the **DELETE** selection.

6 Press **HOME SCREEN** and then turn off the device.

OVERVIEW OF CONNECTIONS FOR TRANSMITTING REPORTS

Patient reports can be transmitted from the LIFEPAK 20e defibrillator/monitor to compatible LIFENET® System data management tools.

An IrDA port, located on the front of the LIFEPAK 20e defibrillator/monitor (refer to page 2-7), supports wireless, infrared communications for transmitting reports from the defibrillator to your computer. To receive the transmission, your computer must have an operational IrDA port.

If your computer does not have an IrDA port, you can install an IrDA adapter to provide the needed interface. Physio-Control recommends installing an IrDA adapter on all computers to ensure successful communication connections and data transmissions.

IrDA adapters are available for serial or USB computer ports. Follow the installation and usage instructions provided with the adapter, ensuring that the adapter mount (receiving end) is positioned on a stable surface. Figure 6-3 provides guidelines to follow for positioning the defibrillator and the IrDA adapter before initiating a transmission.

Note: The shaded cone in Figure 6-3 represents the approximate parameters for positioning the defibrillator's IrDA port opposite the IrDA adapter. As the distance between the two increases, so does the possible range for aligning them.

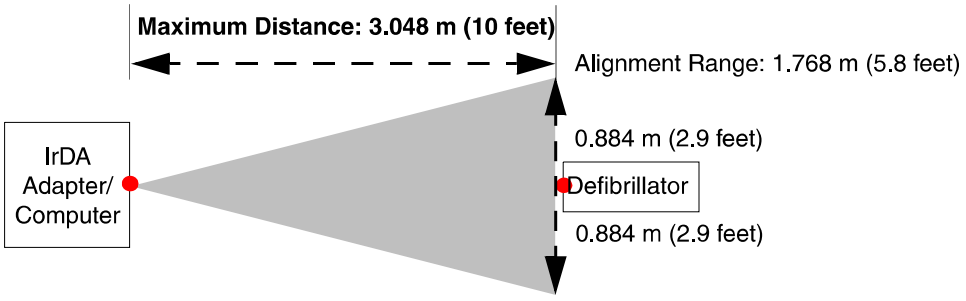


Figure 6-3 IrDA Connections

You initiate and control transmission of device data at your computer using LIFENET Post Event Review tools. This includes entering patient information, selecting reports to be transmitted, and monitoring transmission progress. More information about configuring LIFENET Post Event Review tools and instructions for gathering device data can be found in the documentation and online help of the LIFENET Post Event Review products.

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MAINTAINING THE EQUIPMENT

This section describes how to perform operator-level maintenance, testing, and troubleshooting for the LIFEPAK 20e defibrillator/monitor and selected accessories. For additional information about accessories, refer to specific accessory operating instructions.

General Maintenance and Testing	page 7-2
General Troubleshooting Tips	7-10
Service and Repair	7-12
Product Recycling Information	7-12
Warranty	7-12
Accessories, Supplies, and Training Tools	7-13

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GENERAL MAINTENANCE AND TESTING

Periodic maintenance and testing of the LIFEPAK 20e defibrillator/monitor and accessories will help detect and prevent possible electrical and mechanical discrepancies. If testing reveals a possible discrepancy with the defibrillator or accessories, refer to "General Troubleshooting Tips," page 7-10. If the discrepancy cannot be corrected, immediately remove the defibrillator from service and contact qualified service personnel. For testing information regarding accessories, refer to the accessory operating instructions.

Each time you turn on the defibrillator/monitor, it performs self tests. If the defibrillator/monitor detects a failure, the service LED illuminates.

A ***MAINTENANCE DUE*** message can be configured to appear on the screen at selected intervals (3, 6 or 12 months) to remind you that the device is due for maintenance. The factory default is **OFF**, but it can be activated by service personnel.

Maintenance and Testing Schedule

Table 7-1 lists the recommended maintenance and testing schedule. This schedule may be used in conjunction with the internal quality assurance program of the hospital, clinic, or emergency medical service where the defibrillator is used. An Operator's Checklist is included in these operating instructions (refer to Appendix D). Cables and paddles are a critical part of therapy delivery and suffer wear and tear. Physio-Control recommends replacement of these accessories every three years to reduce the possibility of failure during patient use.

Additional periodic preventive maintenance and testing, such as electrical safety tests, performance inspection, and required calibration should be performed regularly by qualified service personnel.

Table 7-1 Recommended Maintenance Schedule

Operation	Daily	After Use	As Required	6 Months	12 Months
Daily auto test – performed automatically by defibrillator.	X				
Complete Operator's Checklist (refer to Appendix D).	X				
Inspect defibrillator.		X	X		
Clean defibrillator.		X	X		
Check that all necessary supplies and accessories are present (for example, gel, electrodes, ECG paper, etc.).		X	X		
Perform user test.			X		
Perform function checks:					
Standard paddles monitoring check				X	
Standard paddles defibrillation and synchronized cardioversion check on battery power				X	
Therapy cable monitoring check				X	
Therapy cable defibrillation and synchronized cardioversion check on battery power				X	
Therapy cable pacing check				X	
Preventive maintenance and testing.					X

Daily Auto Test

For routine testing and inspection, the user can rely on the daily auto test and the checks completed using the Operator's Checklist (refer to Appendix D).

Each day at approximately 0300 (3:00am), the LIFEPAK 20e defibrillator/monitor automatically completes the following tasks:

- Turns itself on
- Performs self-test
- Charges to a low energy level (approximately 1-3 joules) and then discharges through a test plug or hard paddles
- Tests the pacing circuitry (if noninvasive pacing installed)
- Prints the results, if configured **ON**
- Turns itself off

The daily auto test is not performed if the LIFEPAK 20e defibrillator/monitor is already turned on at 0300. If you must use the defibrillator while the daily auto test is in progress, press **ON** to turn the defibrillator off and press **ON** again. The test is halted and the LIFEPAK 20e defibrillator/monitor resumes normal operation.

The daily auto test is a functional test, which checks the defibrillator and pacer circuitry and the defibrillation component of the therapy cables. This test may take the place of your daily defibrillator charging and discharging protocol.

It is important that the standard paddles set is securely seated in the paddle wells or that the QUIK-COMBO therapy cable is connected to the QUIK-COMBO test plug (refer to Figure 7-1) for the daily auto test to perform properly. There are two reasons why the daily auto test may not complete. The first is if the standard paddles set is not securely seated in the paddle wells or the QUIK-COMBO therapy cable is not connected to the QUIK-COMBO test plug (refer to Figure 7-1). The second is when there is a problem with the therapy cable or the defibrillator. When the daily auto test does not complete, a report prints (if configured ON) and a momentary message appears on the screen indicating the self test did not complete. In the event of an incomplete daily auto test, confirm proper cable connection and perform the manual user test in the **OPTIONS** menu. While attempting to perform the user test, if the message ***CONNECT TO TEST PLUG*** appears, contact a qualified service representative.

If connected to AC power and the defibrillator detects a problem during the auto test, it remains on and the service LED illuminates. If the defibrillator is not connected to AC power and the defibrillator detects a problem during the auto test, the defibrillator will turn off after the auto test. The service LED illuminates the next time the defibrillator is turned on. If the setup option for auto print is on, a test report will automatically print at completion of the auto test. Refer to "General Troubleshooting Tips," page 7-10.

Note: Integrity of the Standard Paddles and the QUIK-COMBO therapy cable is tested when both the daily auto test is properly performed and section 8 on the Operator's Checklist is completed (refer to Appendix D).

Note: The daily auto test cannot be relied on if REDI-PAK electrodes are connected to the therapy cable. For daily testing, you must manually perform the user test in the Options menu (refer to the User Test section).

Note: The factory setting for printed test reports is **OFF**. To obtain printed test reports, set the self test to **ON** in the auto print menu (refer to the "Defining Setup Options" section).

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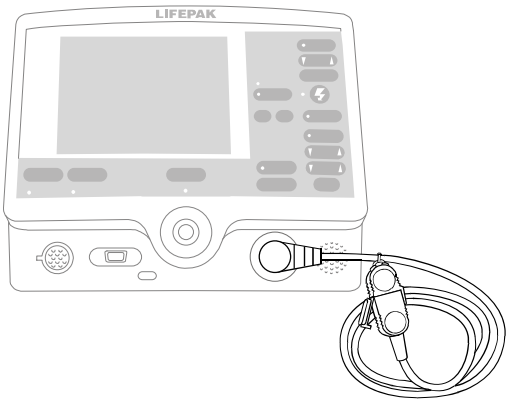


Figure 7-1 QUIK-COMBO Test Plug

User Test

The LIFEPAK 20e defibrillator/monitor user test performs the same functions as the daily auto test (refer to the "Daily Auto Test" section). The manual user test is recommended if the daily auto test was not completed, if a test failure was reported, or if REDI-PAK electrodes are preconnected to the therapy cable as part of defibrillator readiness. This test may also be performed to meet more frequent defibrillator testing requirements.

To perform the user test, the standard paddles set must be securely seated in the paddle wells or the QUIK-COMBO therapy cable must be connected to the QUIK-COMBO test plug (see Figure 7-1). For REDI-PAK electrodes, disconnect the REDI-PAK electrodes from the QUIK-COMBO therapy cable and connect the QUIK-COMBO test plug to the therapy cable.

Perform User Test

Procedure:

1 Press **ON**.

Note: To perform the user test, ignore all ***REMOVE TEST PLUG*** prompts and keep the test plug connected.

2 Press **OPTIONS**. If the defibrillator is in AED mode, switch to manual mode and then press **OPTIONS**. Refer to "Switching from AED to Manual Mode," page 4-14.

3 Select **USER TEST**.

Note: If the message ***CONNECT TEST PLUG*** appears and the standard paddles set is securely seated in the paddle wells or the QUIK-COMBO therapy cable is correctly connected to the QUIK-COMBO test plug, contact a qualified service representative.

4 Select **YES** to initiate user test.

After selecting **YES**, the user test automatically performs the following tasks:

- Performs self-tests.
- Charges to a low energy level (approximately 1-3 joules) and then discharges through a test plug or hard paddles.
- Tests the pacing circuitry (if noninvasive pacing installed).
- Prints the results.
- Turns itself off.

Note: During the user test, all front panel controls and standard paddles controls are disabled. Pressing the **ON** button will power off the defibrillator.

If the LIFEPAK 20e defibrillator/monitor detects a problem during the user test, the service LED lights and a printed report indicates that the test failed. Turn off the defibrillator and contact qualified service personnel. Refer to "General Troubleshooting Tips," page 7-10.

If it is necessary to interrupt the user test, turn the power off and then on again. The test will stop and the defibrillator will operate normally. A Pass/Fail test report will not print.

Note: It is important to understand defibrillator operation. Refer to page 7-2 through page 7-10 for suggested procedures to help ensure that personnel are acquainted with normal defibrillator operation and to troubleshoot device performance. The procedures used may vary according to your local protocols. To test the defibrillator by performing the function checks requires the use of an optional test load simulator.

Cleaning

CAUTION!

Possible equipment damage.

Do not clean any part of this device or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this device or any accessories unless otherwise specified in accessory operating instructions.

Clean the LIFEPAK 20e defibrillator/monitor, cables, and accessories with a damp sponge or cloth. Use only the cleaning agents listed below:

- Quaternary ammonium compounds
- Isopropyl alcohol
- Peracetic (peroxide) acid solutions

Function Checks

CAUTION!

Possible simulator damage.

Do not discharge more than 30 shocks within an hour or 10 shocks within a five-minute period, or pace continually into Physio-Control patient simulators. Simulators may overheat.

The following function checks are provided to help personnel keep acquainted with normal operating procedures and to troubleshoot device performance.

Older Physio-Control simulators and testers respond differently to defibrillators configured with a biphasic defibrillation waveform. Older QUIK-COMBO simulators require a 275 joules biphasic shock to change simulated VF rhythm to NSR. Sometimes no amount of energy can change the simulated VF rhythm. The pace LED flashes when the shock does not change the simulated rhythm.

Newer QUIK-COMBO simulators, described in the Physio-Control accessories catalog and on the Web site, respond appropriately to defibrillators with a biphasic defibrillation waveform. For further information, in the USA, call 1.800.442.1142. Outside the USA, contact your local Physio-Control representative.

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Patient ECG Cable Check

Equipment needed:

- LIFEPAK 20e defibrillator/monitor
- Fully charged batteries
- Patient ECG cable (3-wire or 5-wire)
- 3-lead or 12-lead simulator

Procedure:

1 Press **ON**.
2 Connect the ECG cable to the defibrillator.
3 Connect all cable leads to the simulator.
4 Turn on the simulator and select a rhythm.
5 After a few seconds confirm that the screen displays a rhythm and no ***LEADS OFF*** or ***SERVICE*** messages appear.

Standard Paddles Monitoring Check

Equipment needed:

- LIFEPAK 20e defibrillator/monitor
- Standard paddles

Procedure:

1 Press **ON**.
2 Select **PADDLES** lead.
3 Press the paddle electrode surfaces together and confirm that a flat line appears.
4 Shake each paddle in the air and confirm that irregular noise signals appear.
5 Install the paddles in the paddle wells.

Standard Paddles Defibrillation and Synchronized Cardioversion Check on Battery Power

WARNING!

Shock hazard.

When discharged as described in this test, the defibrillator delivers up to 360 J of electrical energy. Unless discharged properly as described in this test, this electrical energy may cause serious personal injury or death. Do not attempt to perform this test unless you are qualified by training and experience and thoroughly familiar with these operating instructions.

Equipment needed:

- LIFEPAK 20e defibrillator/monitor with fully charged internal battery
- Standard paddles
- Defibrillator checker
- Patient ECG cable
- 3-lead or 12-lead patient simulator

Procedure:

Ensure the defibrillator is connected to AC power 4 hours prior to performing this test. The battery should be fully charged.

1 Disconnect the defibrillator from AC power.
2 Press **ON**.
3 Connect the ECG cable to the monitor and the patient simulator.
4 Turn on the simulator and select any rhythm except asystole or ventricular fibrillation.
5 Select Lead II.
6 Press **SYNC**.
7 Confirm the sync LED lights. Adjust ECG size until the sense markers appear on the QRS complexes. Confirm that the sync LED blinks off with each detected QRS complex and the heart rate is displayed.
8 Place the standard paddles on the defibrillator checker paddle plates.
9 Select 200 J.
10 Press **CHARGE**.

Note: If the defibrillator takes more than 10 seconds to charge to 200 joules, the battery may need to be replaced. Contact qualified service personnel.

11 Confirm that the tone indicating full charge sounds within 10 seconds or less.
12 Press only the apex **SHOCK** button and confirm that the defibrillator does not discharge. Release the apex **SHOCK** button.
13 Press only the sternum **SHOCK** button and confirm that the defibrillator does not discharge. Release the sternum **SHOCK** button.
14 Press **PRINT**.

WARNING!

Possible paddle damage and patient burns.

Press paddles firmly onto test load plates when discharging to prevent arcing and formation of pits on paddle surfaces. Pitted or damaged paddles may cause patient skin burns during defibrillation.

15 Apply firm pressure with both paddles on the defibrillator checker and hold both **SHOCK** buttons while observing the screen.
16 Confirm the defibrillator discharges on the next sense QRS complex.
17 Confirm the defibrillator returns to asynchronous mode (sense markers are no longer displayed and sync LED is off).
18 Confirm that the printer annotates the time, date, sync **ON**, sync sense markers prior to energy delivered, energy selected, no sense markers after **SHOCK** 1, and sync **OFF** on the ECG strip.
19 Connect defibrillator to AC power and power off.

Note: The the defibrillator may be configured to remain in synchronous mode after discharge.

Note: To perform a defibrillation check with standard paddles *seated in the paddle wells*, perform the user test (page 7-4), not the standard paddles defibrillation check.

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Therapy Cable Monitoring Check

Equipment needed:

- LIFEPAK 20e defibrillator/monitor
- QUIK-COMBO® (or FAST-PATCH®) therapy cable
- QUIK-COMBO 3-lead or 12-lead patient simulator, or posted patient simulator
- Fully charged batteries

Procedure:

1 Press **ON**.
2 Turn on the simulator and select normal sinus rhythm.
3 Connect the therapy cable to the patient simulator.
4 Select **PADDLES** lead.
5 Confirm that the screen shows a normal sinus rhythm and that no ***PADDLES LEADS OFF*** or ***SERVICE*** message appears.
6 Disconnect the therapy cable from the simulator. Confirm the ***PADDLES LEADS OFF*** message appears and an audible alarm sounds.

Therapy Cable Defibrillation and Synchronized Cardioversion Check on Battery Power

Equipment needed:

- LIFEPAK 20e defibrillator/monitor with fully charged internal battery
- QUIK-COMBO or FAST-PATCH therapy cable
- QUIK-COMBO 3-lead or 12-lead patient simulator, or posted patient simulator
- Patient ECG cable

Procedure:

Note: Ensure the defibrillator is connected to AC power 4 hours prior to performing this test. The battery should be fully charged.

1 Disconnect the defibrillator from AC power.
2 Press **ON**.
3 Connect the ECG cable to the monitor and the patient simulator.
4 Connect the therapy cable to the simulator.
5 Turn on the simulator and select any rhythm except asystole or ventricular fibrillation.
6 Select Lead II.
7 Press **SYNC**.
8 Confirm the sync LED lights. Adjust ECG size until the sense markers appear on the QRS complexes. Confirm that the sync LED blinks off with each detected QRS complex and the heart rate is displayed.
9 Select 200 J.
10 Press **CHARGE**.

Note: If the defibrillator takes more than 10 seconds to charge to 200 joules, the battery may need to be replaced. Contact qualified service personnel.

11 Confirm that the tone indicating full charge sounds within 10 seconds or less.
12 Press **PRINT.**

WARNING!

Shock hazard.

During defibrillation checks, the discharged energy passes through the cable connectors. Securely attach cable connectors to the simulator.

13 After the tone sounds, indicating full charge, press and hold **SHOCK** while observing the monitor screen.

14 Confirm the defibrillator discharges on the next sense QRS complex.

15 Confirm the defibrillator returns to asynchronous mode (sense markers are no longer displayed and sync LED is off).

16 Confirm that the printer annotates the time, date, sync **ON**, sync sense markers prior to energy delivered, energy selected, no sense markers after **SHOCK** 1, and sync **OFF** on the ECG strip.

17 Connect defibrillator to AC power and power off.

Note: The defibrillator may be configured to remain in synchronous mode after discharge.

Therapy Cable Pacing Check

Equipment needed:

- LIFEPAK 20e defibrillator/monitor
- QUIK-COMBO therapy cable
- Patient ECG cable
- QUIK-COMBO 3- or 12-lead patient simulator
- Fully charged batteries

Procedure:

1 Press **ON**.

2 Connect the QUIK-COMBO therapy cable to the QUIK-COMBO simulator.

3 Turn on the simulator and select **BRADY**.

4 Connect the ECG cable to the defibrillator and the simulator.

5 Select **LEAD II**.

6 Press **PACER**.

7 Confirm that sense markers appear on each QRS complex. If sense markers do not appear, or appear elsewhere on the ECG, press the selector on waveform Channel 1 and adjust ECG size on the overlay.

8 Confirm that the Rate overlay appears.

9 Press **CURRENT** and increase the current to 80 mA.

10 Observe the screen for captured complexes. Confirm the pacer LED flashes with each delivered pacing pulse.

11 Disconnect the QUIK-COMBO therapy cable from the simulator. Confirm that the pacemaker stops pacing, the ***CONNECT ELECTRODES*** message appears, and an audible alarm sounds.

12 Reconnect the QUIK-COMBO therapy cable to the simulator. Confirm that the audible alarm ceases, the ***PACING STOPPED*** message displays, and that the current is 0 mA.

13 Increase current to 80 mA.

14 Press **CHARGE**. Confirm the pacer LED turns off and the heart rate and available energy appear on the screen.

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GENERAL TROUBLESHOOTING TIPS

If a problem with the defibrillator/monitor is detected during operation or testing, refer to the troubleshooting tips in Table 7-2. If the problem cannot be corrected, remove the defibrillator/monitor from use and contact qualified service personnel.

Table 7-2 General Troubleshooting Tips

Observation	Possible Cause	Corrective Action
1 No power when defibrillator/monitor is turned **ON.**	Low battery voltage.	• Connect to AC power.
2 Defibrillator/monitor operates, but screen is blank.	Operating temperature is too low or too high.	• Connect to AC power.
	Screen is not displaying properly.	• Contact qualified service personnel.
3 ***CHECK PRINTER*** message appears.	Printer paper jams, slips, or misfeeds.	• Reinstall paper.
	Printer is out of paper.	• Add new paper. • If problem persists, contact qualified service personnel.
4 No power when connected to AC power.	Loose or improper connection between defibrillator and power source.	• Check power connections and cables.
5 Service LED illuminates.	Device self-test circuitry detects service condition.	• Continue to use defibrillator or pacemaker if needed. • Turn device off and then on again. Note that this creates a new Patient Record. • If service LED does not clear, remove device from active use. • Report occurrence of service LED to qualified service personnel.
6 ECG monitoring problems.		• Refer to Section 3, page 3-5.
7 Problems with AED operation.		• Refer to Section 4, page 4-6.
8 Problems with defibrillation/ synchronized cardioversion.		• Refer to Section 4, page 4-20.
9 Problems with pacing.		• Refer to Section 4, page 4-22.
10 Displayed time is incorrect.	Time is incorrectly set.	• Change the time setting. Refer to Section 2, page 2-6.
11 Date printed on report is incorrect.	Date is incorrectly set.	• Change the date setting. Refer to Section 2, page 2-6.
12 Displayed messages are faint or flicker.	Low battery power. Out of temperature range.	• Connect to AC power immediately.

Table 7-2 General Troubleshooting Tips (Continued)

Observation	Possible Cause	Corrective Action
13 Low speaker volume.	Moisture in speaker grill holes.	• Wipe moisture from speaker grill and allow device to dry.
14 ***MAINTENANCE DUE*** message appears.	Maintenance prompt is set to display at a selected interval in service mode.	• Continue to use device if needed. • Contact service personnel to reset or turn off the maintenance prompt. • Contact Physio-Control Technical Support for instructions on how to reset or turn off this prompt.
15 ***SELF TEST DID NOT COMPLETE*** message appears.	Test plug not connected to QUIK-COMBO therapy cable during daily auto test.	• Connect test plug to QUIK-COMBO therapy cable. • Perform manual user test.
	Standard paddles not seated in paddle wells during daily auto test.	• Make sure standard paddles are securely seated in the paddle wells for daily auto test.
	Defective therapy cable or a problem with the defibrillator.	• Contact qualified service personnel.
16 ***SELF TEST FAILED*** message appears.	Device self-test circuitry detects service condition during daily auto test.	• Use defibrillator or pacemaker if needed in an emergency. • Report occurrence of self-test failure to qualified service personnel.
17 ***USER TEST DID NOT COMPLETE*** message appears.	Test plug not connected to QUIK-COMBO therapy cable during user test.	• Connect test plug to QUIK-COMBO therapy cable for user test.
	Standard paddles not seated in paddle wells during user test.	• Make sure standard paddles are securely seated in the paddle wells for user test.
	Defective therapy cable or a problem with the defibrillator.	• Contact qualified service personnel.
18 ***USER TEST FAILED*** message appears.	Device self-test circuitry detects service condition during user test.	• Use defibrillator or pacemaker if needed in an emergency. • Report occurrence of user-test failure to qualified service personnel.
19 Printout annotated 79 J, but > 79 J was selected.	Paddles discharged when seated in the paddle wells or shorted together.	• Refer to "Standard Paddles Defibrillation and Synchronized Cardioversion Check on Battery Power," page 7-6. • Perform User Test.
20 Defibrillator does not charge to 200 J within 10 seconds while on battery power.	Low battery condition.	• Connect the defibrillator to AC power.
	Defective battery.	• Contact qualified service personnel.

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SERVICE AND REPAIR

WARNINGS!

Shock hazard.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact qualified service personnel for repair.

Possible ineffective energy delivery.

Service mode is for authorized personnel only. Improper use of service mode may inappropriately alter the device's configuration and may change energy output levels. Contact qualified service personnel for assistance or information about device configuration.

If testing, troubleshooting, or a service message indicates the LIFEPAK 20e defibrillator/monitor requires service, contact qualified service personnel. In the USA, call 1.800.442.1142. Outside the USA, contact your local Physio-Control representative.

When calling Physio-Control to request service, identify the model and serial number and describe the observation. If the device must be shipped to a service center or the factory, pack the device in the original shipping container, if possible, or in protective packing to prevent shipping damage.

The *LIFEPAK 20e Defibrillator/Monitor Service Manual* provides detailed technical information to support service and repair by qualified service personnel.

PRODUCT RECYCLING INFORMATION

All materials should be recycled according to national and local regulations. Contact your local Physio-Control representative for assistance or refer to http://recycling.medtronic.com for instructions on disposing of this product.

Recycling Assistance

The defibrillator and its accessories should be recycled according to national and local regulations. Contact your local Physio-Control representative for assistance.

Preparation

The device should be clean and contaminant-free prior to being recycled.

Recycling of Disposable Electrodes

After using disposable electrodes, follow your local clinical procedures for recycling.

Packaging

Packaging should be recycled according to national and local regulations.

WARRANTY

Refer to the warranty statement included in the accessory kit shipped with this product. For duplicate copies, contact your local Physio-Control representative. In the USA, call 1.800.442.1142. Outside the USA, contact your local Physio-Control representative.

ACCESSORIES, SUPPLIES, AND TRAINING TOOLS

The following accessories are approved for use with the LIFEPAK 20e defibrillator/monitor. To order, contact your Physio-Control representative or order online at store.physio-control.com. For non-CE marked accessories, see the LIFEPAK 20 Accessory Catalog.

Note: The LIFEPAK 20e defibrillator/monitor and its accessories that are intended for direct or casual contact with the patient are latex-free.

Therapy	• QUIK-COMBO® pacing/defibrillation/ECG electrodes • QUIK-COMBO RTS pacing/defibrillation/ECG electrodes • Pediatric QUIK-COMBO pacing/defibrillation/ECG electrodes • QUIK-COMBO pacing/defibrillation/ECG electrodes with REDI-PAK™ preconnect system • QUIK-COMBO defibrillation cable • FAST-PATCH® Plus defibrillation/ECG electrodes • FAST-PATCH adapter cable • Standard paddles with built-in pediatric paddles • Internal handles with discharge controls • Internal paddles (used with internal handles)
Monitoring	
ECG	• 3-wire ECG cable • 5-wire ECG cable
SpO_2 - Masimo®	• Patient extension cables LNOP® (4, 8, and 12 ft) • Patient extension cables LNCS™ (4, 10, 14 ft) • Extension cable LNCS (4 ft) • Reusable LNOP and LNCS sensors • Disposable LNOP and LNCS sensors • Disposable LNOP and LNCS sample kits
SpO_2 - Nellcor™	• Reusable Oximax™ DS-100A Adult sensor • Disposable Oximax sensors (Max-A Adult, Max-R Adult Nasal, Max-P Pediatric, Max-I Infant, Max-N Neonatal/Adult) • Disposable Oxisensor® II sensors (D-25 Adult, D-20 Pediatric, I-20 Infant, N-25 (Neonatal/Adult) • MNC-1 Adapter cable (4, 10 ft)
Other accessories	• QUIK-COMBO Test Plug • Docking Station • Serial Cable (system connector)

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DEFINING SETUP OPTIONS

This section describes how to define setup options for the LIFEPAK 20e defibrillator/monitor.

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SETUP OPTIONS

Setup options allow you to define operating features for the LIFEPAK 20e defibrillator/monitor such as device identification numbers and default settings. Table 8-1 through Table 8-19 list all setup options along with the factory default settings.

WARNING!

Possible improper defibrillator performance.

Changing factory default settings will change the behavior of the device. Changes to the default settings must only be made by authorized personnel.

Print Configurations Before Service or Repair

If the defibrillator receives service or repair that affects the internal memory components, such as replacement of the main printed circuit board, any changes previously made to the option definitions may be lost from memory. Before allowing service or repair, be sure to print the current user setup defaults so the customized definitions may be reentered after service or repair. (Refer to "Print Defaults," page 8-12.)

Passcode Security

To prevent unauthorized access, a security passcode is required for access to the Setup menu and service mode (refer to page 8-13). The LIFEPAK 20e defibrillator/monitor allows you to change both of these passcodes. The passcode definition is part of the device identification option.

Note: To use the defibrillator with any new settings, you must turn the defibrillator off and on again.

WARNING!

Possible ineffective energy delivery.

Service mode is for authorized personnel only. Improper use of service mode may inappropriately alter the defibrillator's configuration and may change energy output levels. Contact service personnel for assistance or information about defibrillator configuration.

ENTERING SETUP OPTIONS



To enter the Setup menu:

1 Press **ON** while holding down **OPTIONS** and **EVENT.** Continue to hold these controls down until the passcode screen appears.

2 Enter the passcode by scrolling through the digits in the highlighted fields.

3 Select the digit. The digit changes to a dot to protect the passcode. If you enter the correct digit, the next number in line highlights automatically.

When you have entered the correct passcode, the setup overlay appears.
If you enter the passcode incorrectly, the message ***PASSCODE INCORRECT—TRY AGAIN*** appears in the status message area. You have three chances to enter the passcode correctly. Turn the power off and on to start again.

Pressing **HOME SCREEN** after selecting a menu item returns you to the Setup screen.



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GENERAL SETUP MENU

The General Setup menu allows you to define general purpose settings. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-1 General Setup Menu

Menu Item	Help Message	Options
LANGUAGE	Language used for all messages and prompts	Options are: **ENGLISH**, **FRENCH, GERMAN, SPANISH, SWEDISH, ITALIAN, DUTCH, FINNISH, DANISH, NORWEGIAN, POLISH, PORTUGUESE, BRAZILIAN, JAPANESE, CHINESE MANDARIN, CZECH, RUSSIAN, HUNGARIAN,** and **KOREAN**.
CODE SUMMARY	CODE SUMMARY Format	Options are: **SHORT** and **MEDIUM** (refer to page 6-2).
SITE NUMBER	Site ID Number	Prints on reports. **0-9, A-Z** available**.** Maximum 25 digits.
DEVICE NUMBER	Defibrillator ID Number	Prints on reports. **0-9, A-Z** available. Maximum 25 digits.
AUTO LOG	Auto vital sign event capture every 5 minutes	**ON**: Vital sign data entered into event/vital sign log every 5 minutes. **OFF**: Vital sign entered only when events occur.
LINE FILTER	Line filter center frequency	**50** or **60 HZ**.
TIMEOUT SPEED	Delay before a menu is dismissed	Time that menus stay on screen (**30**, **10**, or **5 SECONDS**). (Pacing and Transmit menus are fixed at 30 seconds.)
AC LOSS ALERT	A series of warning beeps if the defibrillator is turned off and not connected to AC power.	Options are: **5**, **15**, or **30 MINUTES**, or **NEVER ALERT**.
PREVIOUS PAGE		Go back to previous page.

MANUAL MODE SETUP MENU

The Manual Mode Setup menu allows you to define defibrillation and synchronized cardioversion settings. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-2 Manual Mode Setup Menu

Menu Item	Help Message	Options
SYNC	Set up sync defaults	Refer to Table 8-3.
PADDLES DEFAULT	Default energy for paddles or QUIK-COMBO electrodes	Power-on energy setting for standard paddles and therapy electrodes: **2, 5, 10, 50, 100, 125, 150, 175, 200, 300** (joules), or **ENERGY PROTOCOL**.
ENERGY PROTOCOL...	Energies for energy protocol	Refer to Table 8-4.
INTERNAL DEFAULT	Default energy for internal paddles	Power-on energy setting for internal paddles: **2**, **5, 10, 20, 30,** or **50**.
VOICE PROMPTS	Voice prompts active in manual mode	**ON**: Voice prompts active. **OFF**: Voice prompts inactive.
SHOCK TONE	Tone when defibrillator is fully charged	**ON**: A tone sounds. **OFF:** No tone.
MANUAL ACCESS	Means for accessing manual mode	**MANUAL / DIRECT:** No restrictions to manual mode. **AED / DIRECT:** No restrictions to AED mode. **AED / CONFIRM**: Confirmation required to gain manual access. **AED / PASSCODE**: Passcode required to enter manual mode.
SET PASSCODE...	Passcode required to enter manual mode	If configured for passcode access: None: Default passcode enabled. New: User-defined 4-digit code enabled.

Table 8-3 Synchronization Defaults

Menu Item	Help Message	Options
SYNC AFTER SHOCK	Resume sync after energy transfer	**ON**: Defibrillator returns to synchronous mode after energy transfer. **OFF**: Defibrillator returns to asynchronous mode.
REMOTE SYNC	Allow sync with remote monitor	**ON**: Remote synchronization active with connection to a compatible remote monitor. **OFF**: No remote monitor connection active.

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Table 8-4 Manual Mode Energy Protocol Setup Menu

Menu Item	Help Message	Options
PRESET PROTOCOL	Select preset energy protocol	**FULL RANGE**, **PEDIATRIC**.
ENERGY 1	Select energy level for shock 1	Full range: **100, 125, 150, 175, 200, 225, 250, 275, 300, 325, 360**. Pediatric: **2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100**.
ENERGY 2*	Select energy level for shock 2	Full range: **100, 125, 150, 175, 200, 225, 250, 275, 300, 325, 360**. Pediatric: **2**, **3**, **4**, **5**, **6**, **7**, **8**, **9**, **10**, **15**, **20**, **30**, **50**, **70**, **100**.
ENERGY 3*	Select energy level for shock 3	Full range: **100, 125, 150, 175, 200, 225, 250, 275, 300, 325**, **360**. Pediatric: **2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150**.

*__ENERGY 2__ cannot be less than __ENERGY 1__. __ENERGY 3__ cannot be less than __ENERGY 2__.

To activate, select **ENERGY PROTOCOL** in the Paddle Default menu. Auto energy sequences are disabled if you press the **ENERGY SELECT** control or change to or from AED mode during use.

AED MODE SETUP MENU

The AED Mode Setup menu allows you to define automated external defibrillator (AED) settings. When you select a menu item, the screen displays a help message describing the option. The underlined options are factory default settings and are consistent with 2005 American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines. Refer to Appendix F for a more detailed description of CPR setup options.

Table 8-5 AED Mode Setup Menu

Menu Item	Help Message	Options
ENERGY PROTOCOL...	Sequence of defibrillation energies	Refer to Table 8-7.
VOICE PROMPTS	Voice prompts on in AED Mode	**ON:** Voice prompt active. **OFF**: Voice prompt inactive.
AUTO ANALYZE	Select Auto Analyze options	**AFTER 1ST SHOCK**: The second and third rhythm analyses of each three-shock stack start automatically. (Stacked Shocks must be set to **ON**.) **OFF**: Auto analyze inactive.
MOTION DETECTION	Alert when motion is detected	**ON** or **OFF**.
ECG DISPLAY	Display ECG waveform in AED Mode.	**ON** or **OFF**.
CPR...	Set CPR options for AED Mode	
PULSE CHECK	Enable Pulse Check prompt	**ALWAYS**: After every stack of shocks and every NSA finding. **AFTER EVERY NSA**: Only after ***NO SHOCK ADVISED.*** **AFTER SECOND NSA**: After every NSA except for first analysis NSA result. **NEVER:** Never prompt for ***PULSE CHECK***.

Table 8-6 AED Mode CPR Setup Mode

Menu Item	Help Message	Options
CPR TIME 1	Set CPR interval after shocks	**15**, **30**, **45**, **60**, **90**, **120**, **180 SECONDS**, or **30 MINUTES**
CPR TIME 2	Set CPR interval after **NO SHOCK ADVISED**	**15**, **30**, **45**, **60**, **90**, **120**, **180 SECONDS**, or **30 MINUTES**
INITIAL CPR	Enable Initial CPR	**OFF**, **ANALYZE FIRST**, **CPR FIRST**
INITIAL CPR TIME	Set CPR interval for initial CPR	**15**, **30**, **45**, **60**, **90**, **120**, **180 SECONDS**

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Table 8-6 AED Mode CPR Setup Mode (Continued)

Menu Item	Help Message	Options
PRESHOCK CPR	Set CPR interval after shock advised decisions	**OFF, 15, 30 SECONDS**

Table 8-7 AED Mode Energy Protocol Setup Menu

Menu Item	Help Message	Options
PRESET PROTOCOLS	Select a preset energy protocol	Energy 1: **150**, **175**, **200**, **225**, **250**, **275**, **300**, **325**, **360** Energy 2: **150**, **175**, **200**, **225**, **250**, **275**, **300**, **325**, **360** Energy 3: **150**, **175**, **200**, **225**, **250**, **275**, **300**, **325**, **360** Energy 2 cannot be less than Energy 1. Energy 3 cannot be less than Energy 2.
FLEXIBLE PROTOCOLS	Repeat previous energy after ***NO SHOCK ADVISED***	**ON** or **OFF**.
STACKED SHOCKS	Enable consecutive shocks without CPR	**ON** or **OFF**.

PACING SETUP MENU

The Pacing Setup menu allows you to define noninvasive pacemaker settings. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-8 Pacing Setup Menu

Menu Item	Help Message	Options
RATE	Default pacing rate	**40–170**, **60 PPM**.
CURRENT	Default pacing current	**0–200 mA**.
MODE	Default pacing mode	**DEMAND** or **NON-DEMAND**.
INTERNAL PACER	Detect internal pacemaker and print arrows	**DETECTION OFF** or **DETECTION ON**.

MONITORING MENU

Use the Monitoring menu to define settings for the ECG and SpO2 monitoring. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-9 Monitoring Menu

Menu Item	Help Message	Options
CHANNELS...	Set up default channel waveforms	Refer to Table 8-10.
CONTINUOUS ECG	Continuously store ECG waveform	**ON** or **OFF**.
SPO2 TONE	SpO2 pulse tone	**ON** or **OFF**.

Channels Setup Menu

To define the default set and up to five optional waveform sets for Channels 1 and 2, select an item from the Channels Setup menu.

Table 8-10 Channels Setup Menu

Menu Item	Help Message	Options
Default **SET**	Select default waveform set	**SET 1**, **SET 2**, **SET 3**, **SET 4**, or **SET 5**.
SET 1	Select channel waveforms for Set 1	Refer to Table 8-11.
SET 2	Select channel waveforms for Set 2	Refer to Table 8-11.
SET 3	Select channel waveforms for Set 3	Refer to Table 8-11.
SET 4	Select channel waveforms for Set 4	Refer to Table 8-11.
SET 5	Select channel waveforms for Set 5	Refer to Table 8-11.

Waveform Sets Setup Menu

Table 8-11 Waveform Sets Setup Menu

Menu Item	Help Message	Options*
CHANNEL 1	Select waveform for Channel 1	**PADDLES, ECG LEAD I, ECG LEAD II, ECG LEAD III, (AVR, AVL, AVF, C)**
CHANNEL 2	Select waveform for Channel 2	**NONE, CASCADING ECG, PADDLES, ECG LEAD I, ECG LEAD II, ECG LEAD III, (AVR, AVL, AVF, C), SPO2**

*Only available leads appear as options.

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EVENTS SETUP MENU

Use the Events Setup menu to configure or create user-annotated events. When you select a menu item, the screen displays a help message.

Table 8-12 Events Setup Menu

Menu Item	Help Message	Options
EVENTS PAGE 1	Select events for Page 1	Select events 2 to 9 from a preset list.
EVENTS PAGE 2	Select events for Page 2	Select events 10 to 18 from a preset list.
CUSTOM EVENTS	Create custom events to use in event screen	Create up to 16 event names to include in the preset list. Resetting to defaults will delete the custom list.

ALARMS SETUP MENU

The Alarms Setup menu allows you to define alarms and set the alarm volume level. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-13 Alarms Setup Menu

Menu Item	Help Message	Options
VOLUME	Set volume for alarms, tones, and voice prompts	Select volume level from gradient display. The minimum setting reduces but does not silence alarms.
ALARMS	Enable alarms at power up	**ON**: Enables alarms for Heart Rate and SpO2, whenever defibrillator power is turned on. **OFF**: Alarms available through **ALARMS** button.
VF/VT ALARM	Alarms when VF or VT detected	**ON**: Enables VF/VT alarm whenever defibrillator power is turned on. **OFF**: VF/VT alarm available through **ALARMS** button.

PRINTER SETUP MENU

The Printer Setup menu allows you to define automatic event printing and ECG frequency response. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-14 Printer Setup Menu

Menu Item	Help Message	Options
AUTO PRINT	Specify Auto Print Event	Refer to Table 8-15.
ECG MODE	Default ECG frequency response	**MONITOR** or **DIAGNOSTIC**
MONITOR MODE	Default monitor frequency response for printer and display	**1–30 HZ** or **.5–40 HZ**.
DIAGNOSTIC MODE	Default diagnostic frequency response for printer	**.05–40 HZ** or **.05–150 HZ**.
ALARM EVENTS	Print waveforms with alarm events and print with CODE SUMMARY report	**ON** or **OFF**.
EVENT WAVEFORMS	Print waveforms with user-entered events and print with CODE SUMMARY report	**ON** or **OFF**.

Auto Print Setup Menu

Table 8-15 Auto Print Setup Menus

Menu Item	Help Message	Options
DEFIBRILLATION	Auto print defibrillation events	**ON** or **OFF**.
PACING	Auto print pacing events	**ON** or **OFF**.
CHECK PATIENT	Auto print check patient events	**ON** or **OFF**.
SAS	Auto print SAS events	**ON** or **OFF**.
PATIENT ALARMS	Auto print patient alarms	**ON** or **OFF**.
EVENTS	Auto print operator annotated events	**ON** or **OFF**.
INITIAL RHYTHM	Auto print initial rhythm	**ON** or **OFF**.
SELF TEST	Auto print self test result	**ON** or **OFF**.

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CLOCK SETUP MENU

Use the Clock Setup menu to define settings for the time to be displayed. When you select a menu item, the screen displays a help message. The underlined options are factory default settings.

Table 8-16 Clock Setup Menu

Menu Item	Help Message	Options
TIME ZONE	Select time zone for this device	**NONE**, 74 time zone settings.
DATE/TIME	Set current date and time	Current date will be active next time device is turned on.
CLOCK MODE	Real or elapsed time on display	**REAL TIME** or **ELAPSED TIME**.
DST	Daylight savings time	**ON** or **OFF**.

RESET DEFAULTS SETUP MENU

Use the Reset Defaults menu to configure the defibrillator for all factory default settings.

Table 8-17 Reset Defaults Setup Menu

Menu Item	Help Message	Options
CANCEL	Cancel and return to Setup screen	Cancels reset operation.
RESET	Reset to factory configuration settings	Resets setup parameters to the factory default settings, except for transmission sites, output ports, initialization strings, and the maintenance interval, which remain unchanged.

PRINT DEFAULTS

Use the Print Defaults menu to print the current device configuration.

SEND CONFIGURATION SETUP MENU

Use the Send Configuration Setup menu to transfer the setup in one device to overwrite the setup in another device. You can send setup configurations between devices with different features because all devices have identical setup menus, regardless of features.

To send the setup from one device to another:

1 Connect the transport configuration cable to the system connector port on both devices.
2 Turn on the sending defibrillator and enter setup mode (refer to page 8-2).
3 Select the **SEND CONFIG...** menu option.
4 Turn on the receiving defibrillator.
5 On the sending defibrillator, click **SEND** and then follow the screen prompts.

Table 8-18 Send Configuration Setup Menu

Menu Item	Help Message	Options
SEND	Send device configuration to another device.	Connect devices with a cable, display this screen on both defibrillators, and then select **SEND**.
PREVIOUS PAGE	Go back to previous page.	Cancels the operation.

SET PASSCODES SETUP MENU

Use the Set Passcodes menu to change the factory default passcode of 0000 to some other number. If you lose the setup passcode, contact the factory for assistance.

Table 8-19 Set Passcodes Setup Menu

Menu Item	Help Message	Options
SETUP MODE	(The current passcode appears.) Set passcode to enter setup mode	Rotate the Speed Dial to select digits.
ARCHIVES ACCESS	Select passcode access for archives mode	**NO PASSCODE, ARCHIVES ONLY, DELETE ONLY, ARCHIVES/DELETE.**
ARCHIVES MODE	Set passcode to enter archives mode.	Rotate the Speed Dial to select digits.
DELETE RECORDS	Set passcode to delete records in archives mode.	Rotate the Speed Dial to select digits.

SERVICE MODE

The service mode contains tests and logs intended for service personnel. For specific information concerning access to the service mode, refer to the *LIFEPAK 20e Defibrillator/ Monitor Service Manual*.

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APPENDIX A
SPECIFICATIONS AND PERFORMANCE CHARACTERISTICS

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All specifications are at 20°C (68°F) unless otherwise stated.

GENERAL

The LIFEPAK 20e defibrillator/monitor has seven main operating modes:

Manual Mode	Provides normal operating capability for ALS users
AED Mode	Provides normal operating capability for BLS users
Archive Mode	Allows operator to print, edit or delete previous patient records
Setup Mode	Allows operator to configure the instrument
Service Mode	Allows operator to execute device diagnostic tests and calibrations
Inservice Mode	Provides simulated waveforms for demonstration purposes
Auto Test Mode	Provides daily automatic tests of critical circuits

POWER

AC Powered	100-120 VAC 50/60 HZ, 220-240 VAC 50/60 HZ, total power draw less than 120 Volt-Amperes (VA)

Operating Time

A new, fully charged, internal backup battery provides a minimum of the following prior to shutdown:

	---total--	--after low battery--
Monitoring plus SpO2 (minutes)	210	5
Defibrillation (360 J discharges):	140	3
Monitoring Plus Pacing (minutes at 100 mA, 60 ppm) Plus SpO2:	110	2

Battery Charging Time	Battery charges while defibrillator operates from AC power. Typical battery charge time of less than four hours when defibrillator is powered off and AC power is applied.
Low Battery Indication	Low battery message in status area and warning tone sounds.
Battery Status Indicator	Indicates available battery capacity.
A Service Indicator	When Error Detected.

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PHYSICAL CHARACTERISTICS

Weight (maximum)	Basic defibrillator/monitor with Hard Wired Hard Paddles: 6.17 kg (13.6 lb)
	Fully featured defibrillator/monitor (Pacing, SpO2, and door) without paper or cables: 5.58 kg (12.3 lb)
	QUIK-COMBO cable, add: 0.20kg (0.43 lb) For Standard (Hard) Paddles, add: 0.88 kg (1.95 lb)
Size (maximum)	
Height	21.3 cm (8.4 in.)
Width	26.2 cm (10.3 in.)
Depth	26.2 cm (10.3 in.)

DISPLAY

Size (active viewing area)	115.18 mm (4.53 in.) wide x 86.38 mm (3.4 in.) high
Display Type	320 dot x 240 dot color active or passive (base unit only) LCD
	User selectable display contrast for LCD (passive only)
	Displays a minimum of 4 seconds of ECG and alphanumerics for values, device instructions, or prompts
	Option to display one additional waveform
	Waveform display sweep speed: 25mm/sec for ECG

DATA MANAGEMENT

	The device captures and stores patient data, events (including waveforms and annotations), and continuous ECG waveform records in internal memory
	The user can select and print reports
Report Types	Two format types of CODE SUMMARY critical event record (short and medium)
	• Initial ECG (except short format)
	• Auto vital sign measurements every 5 minutes
Memory Capacity	Two full-capacity patient records that include CODE SUMMARY critical event records - up to 100 single waveform events

MONITOR

ECG	ECG is monitored via several cable arrangements. A 3-wire cable is used for 3-lead ECG monitoring. A 5-wire cable is used for 3-lead ECG plus AVR, AVL, AVF, and C. Standard paddles or therapy electrodes (QUIK-COMBO pacing/ defibrillation/ECG electrodes or FAST-PATCH disposable defibrillation/ECG electrodes) are used for Paddles lead monitoring. Compatible with LIFEPAK 12 ECG and Therapy Cables.
Lead Selection	Leads I, II, III (3-wire ECG cable)
	Leads I, II, III, AVR, AVL, AVF, and C acquired simultaneously (5-wire ECG cable)
ECG Size	4, 3, 2.5, 2, 1.5, 1, 0.5, 0.25 cm/mV

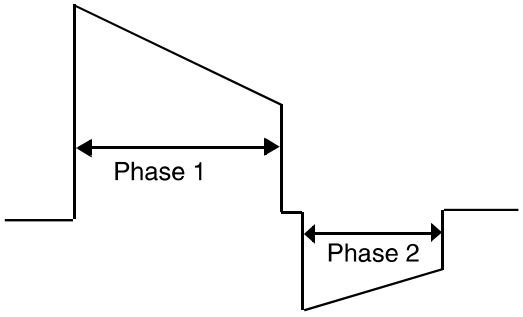
Heart Rate Display	20–300 bpm digital display
	Out of range indication: Display symbol "---"
	Heart symbol flashes for each QRS detection
Continuous Patient Surveillance System (CPSS)	In AED mode, while Shock Advisory System is not active, CPSS monitors the patient, via QUIK-COMBO paddles or Lead II ECG, for potentially shockable rhythms.
Voice Prompts	Used for selected warnings and alarms (configurable on/off).
Analog ECG Output	1 V/mV x 1.0 gain <35 msec delay
Common Mode Rejection	90 dB at 50/60 Hz
SpO2	Masimo® sensors
Saturation range	1 to 100%
Saturation Accuracy	70–100% (0–69% unspecified)
Adults/Pediatrics	±2 digits (during no motion conditions) ±3 digits (during motion conditions)
Neonates	±3 digits (during no motion conditions) ±3 digits (during motion conditions)
Dynamic signal strength bar graph	
Pulse tone at the onset of the pleth waveform	
SpO2 Update Averaging Rate	User selectable 4, 8, 12 or 16 seconds
SpO2 measurement	Functional SpO2 values are displayed and stored
Pulse rate range	25 to 240 pulses per minute
Pulse rate accuracy	
Adults/Pediatrics/ Neonates	±3 digits (during no motion conditions) ±5 digits (during motion conditions)
SpO2 waveform with autogain control	
Alarms	
Quick Set	Activates alarms for all parameters
VF/VT Alarm	Activates continuous CPSS monitoring in Manual Mode

PRINTER

	Prints continuous strips of the displayed patient information
Paper Size	50 mm (2.0 in.)
Print Speed	Continuous ECG 25 mm/sec ±5% (measured in accordance with AAMI EC-11 (1991), 4.2.5.2)
	25 mm/sec print speed for CODE SUMMARY Reports
Delay	8 seconds
Autoprint	Waveform events print automatically (user configurable)

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FREQUENCY RESPONSE	
Diagnostic Frequency Response	0.05 to 150 Hz or 0.05 to 40 Hz (user configurable)
Monitor Frequency Response	0.67 to 40 Hz or 1 to 30 Hz (user configurable)
Paddles Frequency Response	2.5 to 30 Hz
Analog ECG Output Frequency Response	0.67 to 32 Hz (except 2.5 to 30 Hz for Paddles ECG)
DEFIBRILLATOR	
Manual	
Energy Select	2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, and 360 J or one of two user configurable protocols of three sequential shock levels
Full Range	100–360, 100–360, 100–360 J
Pediatric	2–100, 2–100, 2–150 J
Charge Time	Charge time to 200 J in less than 5 seconds with fully charged battery Charge time to 360 J in less than 7 seconds with fully charged battery Charge time to 360 J in less than 10 seconds while not in low battery operations
Synchronous Cardioversion	Energy transfer begins within 60 msec of the QRS peak Energy transfer begins with 25 msec of the External Sync Pulse External Sync Pulse: 0-5V (TTL Level) Pulse, active High, > 5 msec in duration, no closer than 200 msec apart and no further than 1 sec apart
Waveform	Biphasic Truncated Exponential
	The following specifications apply from 25–200Ω, unless otherwise specified.
	Energy Accuracy: ±1 J or 10% of setting, whichever is greater, into 50Ω; ±2 J or 15% of setting, whichever is greater, into any impedance from 25–100Ω.
	Voltage Compensation: Active when disposable therapy electrodes are attached. Energy output within ±5% or ±1 J, whichever is greater, of 50Ω value limited to the available energy which results in the delivery of 360 J into 50Ω.



Patient Impedance (Ω)	Phase 1 Duration (ms) Min	Phase 1 Duration (ms) Max	Phase 2 Duration (ms) Min	Phase 2 Duration (ms) Max	Tilt (%) Nominal
25	5.1	6.0	3.4	4.0	77.5
50	6.8	7.9	4.5	5.3	65.8
100	8.7	10.6	5.8	7.1	52.6
125	9.5	11.2	6.3	7.4	47.8

Note: Tilt is the amount of slope in waveform, expressed as the amount the current or voltage drops before truncation. A 100% tilt waveform would be termed nontruncated.

Paddle Options	QUIK-COMBO pacing/defibrillation/ECG electrodes (standard)
	FAST-PATCH disposable defibrillation/ECG electrodes (optional)
	Standard Paddles (optional)
	Internal Handles with discharge control (optional)
Cable Length	2.4 m (8 ft) long QUIK-COMBO cable (not including electrode assembly)
AED Mode	
Shock Advisory System (SAS)	ECG analysis system that advises the operator if the algorithm detects a shockable or nonshockable ECG rhythm. SAS acquires ECG via therapy electrodes only.
Shock Ready Time (AED Mode)	Using a fully charged battery at normal room temperature, the defibrillator is ready to shock within 16 seconds of power on, if the initial rhythm finding is **SHOCK ADVISED**.
Output Energy	One user configurable protocol with three sequential shock levels
Full Range	150–360, 150–360, 150–360 J

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PACER	
Pacing Mode	Demand or non-demand Rate and current defaults (user configurable)
Pacing Rate	40 to 170 ppm
Rate Accuracy	±1.5% over entire range
Output Waveform	Monophasic, amplitude stable to ±5% relative to leading edge for currents greater than or equal to 40 mA, Duration 20 ±1 msec, Rise/Fall times <= 1 msec [10-90% levels]
Output Current	0 to 200 mA
Pause	Pacing pulse frequency reduced by a factor of 4 when activated
Refractory Period	200 to 300 msec ±3% (function of rate)

ENVIRONMENTAL	
Temperature, Operating	5° to 40°C (41° to 104°F)
Temperature, Non-Operating	-20° to 60°C (-4° to 140°F) except therapy electrodes
Relative Humidity, Operating	5 to 95%, non-condensing
Atmospheric Pressure, Operating	Ambient to 522 mmHg (0 to 3048 meters) (0 to 10,000 ft)
Water Resistance, Operating (without accessories except for ECG Cable and Hard Paddles)	IPX1 (spillage) per IEC 60601-1 clause 44.6
EMC	IEC 60601-1-2:2001/EN 60601-1-2:2001, Medical Equipment-General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests. IEC 60601-2-4:2002; Clause 36/EN 60601-2-4:2003: Clause 36, Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator monitors.
Shock (drop)	1 drop on each side from 45.7 cm (18 in.) onto a steel surface
Vibration	MIL-STD-810E Method 514.4, Cat 1

CHARACTERISTIC	
Respiration, Leads Off Sensing, Noise Cancellation Current, and Voltage	6 The ECG leads off function uses AC current for sensing leads off, the disposable defibrillation electrodes use AC current for leads off, and the ECG leads use a noise cancellation signal which ranges from DC to approximately 5k Hz. The amplitude of these signals conforms to AAMI EC-11 3.2.10 and AAMI EC-13 (1992) 3.2.5.

CHARACTERISTIC	
Heart Rate Averaging Method	The heart rate average is formed by a weighted average of approximately 8 seconds duration. When the input rate is trending rapidly, the rate meter will track more quickly. refer to heart rate response time disclosure. The display update interval is every heartbeat or every 2 seconds, whichever is shorter.
Heart Rate Response Time	Heart rate meter response time: For an 80 to 120 bpm step change, the response time is 5.5 seconds average with a range of 4.9 to 6.2 seconds when tested per AAMI EC-13 4.1.2.1 f. For an 80 to 40 bpm step change, the response time is 5.6 seconds with a range of 5.0 to 6.4 seconds.
Heart Rate With Irregular Rhythm	All complexes are detected. The rate meter output can range from the heart rate associated with the shortest R-R interval to the heart rate associated with the longest R-R interval. When present, intermediate length R-R intervals are favored as the basis for the rate.
Waveform	Biphasic Truncated Exponential.

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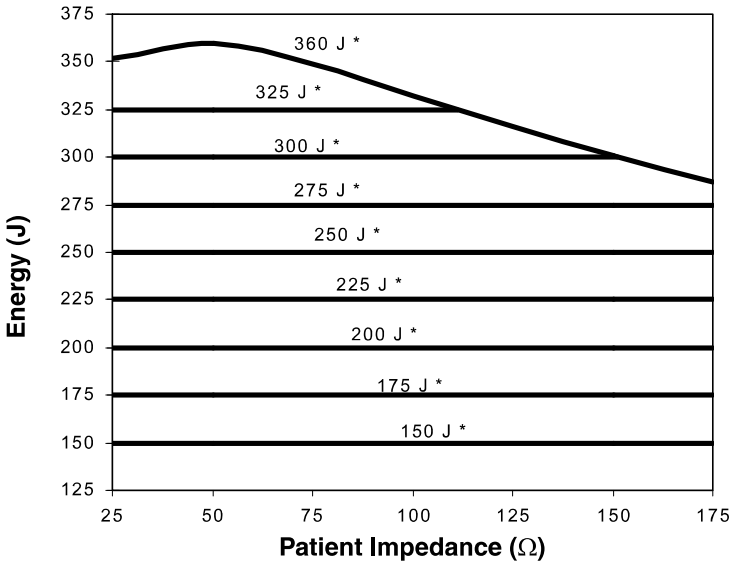
CHARACTERISTIC

The following characteristics apply from 25-175Ω, unless otherwise specified.

Energy Accuracy: +1 J or 10% of setting, whichever is greater, into 50Ω; +2 J or 15% of setting, whichever is greater, into any impedance from 25-175Ω.

Voltage Compensation: Active when disposable therapy electrodes are attached. Energy output within +5% or +1J, whichever is greater, of 50Ω value limited to the available energy, which results in the delivery of 360 J into 50Ω.

Rated Energy Output



* Energy setting selected

Patient Impedance (Ω)	Phase 1 Duration (ms) Nominal	Phase 2 Duration (ms) Nominal	Tilt (%) Nominal
75	8.8	6.0	57.4
150	11.3	7.6	42.2
175	11.8	8.0	39.1

CHARACTERISTIC	
Heart Rate Alarm Time	In five trials for a 1 mV, 206 bpm tachycardia, the average detection time was 7.1 seconds. The maximum detection time was 7.9 seconds. The minimum time was 5.6 seconds. For a test signal half as large, the average was 6.1 seconds, the maximum was 6.4, and the minimum was 5.7. In this case the device sensitivity was increased to 5 mV/cm. For a test signal twice as large, the average was 5.7 seconds, the maximum was 6.3, and the minimum was 5.1. In five trials for a 2 mV, 195 bpm tachycardia, the average detection time was 6.2 seconds. The maximum detection time was 7.1 seconds. The minimum time was 5.8 seconds. For a test signal half as large, the average was 6.0 seconds, the maximum was 6.7, and the minimum was 5.4. In this case the device sensitivity was increased to 5 mV/cm. For a test signal twice as large, the average was 6.0 seconds, the maximum was 6.4, and the minimum was 5.8.
Accuracy Of Signal Reproduction	The device is a digital sampled data system. It meets requirements for both test methods for diagnostic frequency response described in EC11 section 3.2.7.2.
Audible Alarms	This is a standalone device. All alarm tones are internal to the biphasic LIFEPAK 20e defibrillator/monitor. Alarm violations are manifest by tones, voice prompts, and visual indications. Alarm manifestation occurs within 1 second after a displayed parameter violates its alarm limit. User selectable alarm volume adjustment is provided. This adjustment does not allow alarm volume to attain/reach a zero level. SAS tones reinforce SAS messages provided on the product display.

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CHARACTERISTIC	
	The following identifies the tone assignments for each type of alarm: • The priority 1 tone is used to alert the user to the possibility of imminent death. This tone is a 440 Hz and 880 Hz alternating tone with a 50% duty cycle and a 4 Hz alternation frequency. • The priority 2 tone is used to alert the user that a possible life-threatening condition exists. This tone is a continuous 698 Hz tone. • The priority 3 tone is used to alert the user that an abnormal condition exists. Three beeps at 1046 Hz for 100 msec duration each with a 150 msec silence between the first and second and the second and third, followed by a 200 msec silence. • Priority 3 tones come in single and repeating types: for a single tone, the 3-beep sequence sounds only once. For a repeating tone, the 3-beep sequence sounds every 20 seconds. • The priority 4 tone is a momentary tone between 500 and 1500 Hz. Specific characteristics are: – QRS and Volume Setting Tone - 100 msec duration at 1397 Hz. – Key click - 4 msec duration at 1319 Hz. The alert tone shall consist of one set of two tones to precede voice prompts and to draw attention to the display. Specific characteristics shall be: • 1000 Hz square wave, 100 msec duration. • Silence, 100 msec duration. • Silence, 140 msec duration (when preceding a voice prompt). • Voice prompt, when used.
Visual Alarms	Alarms are indicated visually by: The violated parameter flashes in inverse video with a message in the status region of the display. These visual indications remain on the display until the alarm is corrected. Visual indication of alarms continue even when the tones have been silenced.
Alarm Silencing	If a violated parameter alarms, the tone may be silenced for two minutes by pressing the Alarms button. A preemptive alarm silence is provided with selectable settings of 2, 5, 10, and 15 minutes. Visual alarms remain on at all times.

CHARACTERISTIC

VF/VT Alarm	Automatically monitors the patient's ECG rhythm for a potentially shockable rhythm using the Continuous Patient Surveillance System (CPSS). The VF/VT alarm requires that the patient's ECG be monitored in Lead II or Paddles lead using therapy electrodes. The VF/VT alarm will be suspended if pacing is enabled or Standard paddles are connected and Paddles is the displayed lead.
Energy Shunting	If the paddles input is connected in parallel with a second defibrillator, energy delivery to the patient is reduced by less than 10 percent.
Tall T-wave Rejection	T-waves that are 1 mV high are not detected by the monitor when the R-wave size is 1 mV and input rate is 80 ppm.
Displayed SpO2	The LIFEPAK 20e defibrillator/monitor is calibrated to display functional saturation, which is the standard for SpO2.

Charge Time

AC Operation Only:

Typical Time from Charge to Shock Ready

Voltage	Manual Mode		AED Mode	
110V (Nominal)	360 J	6 seconds	200 J	4 seconds
220V (Nominal)	360 J	6 seconds	200 J	4 seconds
90V (90% of Nominal -100)	360 J	6 seconds	200 J	4 seconds
198V (90% of Nominal -220)	360 J	6 seconds	200 J	4 seconds

Typical Time from Power-on to Shock Ready

Voltage	Manual Mode		AED Mode	
90V (90% of Nominal -100)	360 J	11 seconds	200 J	15 seconds
198V (90% of Nominal -220)	360 J	11 seconds	200 J	15 seconds

Battery-only Operation:

Typical Time from Charge to Shock Ready

Battery	Manual Mode		AED Mode	
Fully charged	360 J	6 seconds	200 J	4 seconds
Fully charged battery, followed with 15 full energy	360 J	6 seconds	200 J	4 seconds

Typical Time from Power-on to Shock Ready

Battery	Manual Mode		AED Mode	
Fully charged battery, followed with 15 full energy	360 J	11 seconds	200 J	15 seconds

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APPENDIX B
CLINICAL SUMMARIES

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DEFIBRILLATION OF VENTRICULAR FIBRILLATION AND VENTRICULAR TACHYCARDIA

Background

Physio-Control conducted a multi-centered, prospective, randomized and blinded clinical trial of biphasic truncated exponential (BTE) shocks and conventional monophasic damped sine wave (MDS) shocks. Specifically, the equivalence of 200 J and 130 J BTE shocks to 200 J MDS shocks[1] was tested.

Methods

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a customized defibrillator delivered an automatically randomized shock. Efficacy was based on success of this shock. To demonstrate equivalence of test shocks to control shocks, the 95% upper confidence limit of the difference in efficacy (95UCLD), control minus test, was required to be less than 10%.

Results

Ventricular Fibrillation

The efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks (95UCLD=2%). The difference in success rates of 200 J MDS minus 200 J BTE shocks was -10% (exact 95% confidence interval from -27% to 4%). The 130 J BTE shocks were not demonstrated equivalent to 200 J MDS shocks (95UCLD=22%). However, neither was their efficacy significantly lower than that of the 200 J MDS shocks (statistical power limited by small sample sizes). For all shock types, hemodynamic parameters (oxygen saturation and systolic and diastolic blood pressure) were at or near their pre-induction levels by 30 seconds after successful shocks.

Shock	Ventricular Fibrillation 1st Shock Success	Exact 95% Confidence Interval
200 J MDS	61/68 (90%)	80-96%
200 J BTE	39/39 (100%)	91-100%
130 J BTE	39/47 (83%)	69-92%

[1] S.L. Higgins et al., "A comparison of biphasic and monophasic shocks for external defibrillation," *Prehospital Emergency Care*, 2000, 4(4):305-13.

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Ventricular Tachycardia

Seventy-two episodes of ventricular tachycardia (VT), induced in 62 patients, were treated with randomized shocks. High rates of conversion were observed with biphasic and monophasic shocks. Sample sizes were too small to statistically determine the relationship between success rates of the waveforms tested.

Shock	Ventricular Tachycardia 1st Shock Success	Exact 95% Confidence Interval
200 J MDS	26/28 (93%)	77-99%
200 J BTE	22/23 (96%)	78-100%
130 J BTE	20/21 (95%)	76-100%

Conclusions

In this double-blinded study, the efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks for defibrillation of short duration, electrically-induced VF. However, the comparison of efficacy of 130 J biphasic and 200 J monophasic shocks for VF was inconclusive. All waveforms tested provided a high rate of termination of VT. The VT sample sizes were too small to statistically determine the relationship between VT success rates of the waveforms tested.

Compared to conventional shocks for VF, we found no positive or negative effect of biphasic shocks for VF on hemodynamic parameters following the defibrillating shock. It is possible that, compared to 200 J monophasic shocks, 200 J biphasic shocks will in some cases enable earlier termination of VF. Therefore, we conclude that biphasic shocks for VF delivered at conventional energy levels have the potential to improve outcome in resuscitation of patients with cardiac arrest.

EXTERNAL CARDIOVERSION OF ATRIAL FIBRILLATION

Overview

The performance of the Physio-Control biphasic truncated exponential (BTE) waveform was compared to the conventional monophasic damped sine (MDS) waveform in an international, multi-center, prospective, randomized clinical study of adult patients undergoing elective cardioversion of atrial fibrillation (AF). A total of 80 patients were enrolled in the study and were treated with one or more study shocks. The primary dataset consisted of 72 enrolled patients confirmed to have been in AF. Data from seven patients with atrial flutter were analyzed separately. One patient who did not satisfy all protocol criteria was excluded from analysis.

Subjects were randomized to receive biphasic or monophasic shocks from LIFEPAK 12 defibrillator/monitors. Progressive shocks of 70, 100, 200 and 360 J of the assigned waveform, and a 360 J crossover shock of the other waveform, were delivered if AF persisted. Shocks were delivered using EDGE System QUIK-COMBO® Pacing/Defibrillation/ECG electrodes applied in the standard anterior-lateral position. Successful cardioversion was defined as the confirmed removal of AF after delivery of a shock, as determined by ECG over-read by two cardiologists with no knowledge of the shock waveform. Patients rated skin pain on a scale from 0 to 8 after the procedure.

This study showed that these biphasic shocks provide higher efficacy for cardioversion of atrial fibrillation, requiring fewer shocks, 65% less current and 65% less energy to cardiovert atrial fibrillation. Patients undergoing elective cardioversion with the biphasic protocol, as compared to those receiving the monophasic protocol, reported significantly less post-procedure pain.

Objectives

The primary objective of the study was to compare the cumulative efficacy of biphasic and monophasic shocks of 200 J or less for cardioversion of atrial fibrillation. A triangular sequential design was used to test for a statistically significant difference between groups of patients treated with these two waveforms.

Secondary objectives included 1) providing an estimation of the dose response relationship for the two waveforms which would allow clinicians to make well-informed selections of energy doses for cardioversion with biphasic shocks and 2) comparing the pain experienced by patients following treatment with monophasic and biphasic shocks.

Results

Seventy-two of the patients enrolled were in atrial fibrillation and 7 were in atrial flutter. On average, patients had been in atrial fibrillation for 88 days, were 66 years old, weighed 81 kg and had 72 ohms of transthoracic impedance. Sixty-three percent were male and 46% had been previously cardioverted. There were no significant differences between the groups of patients treated with monophasic and biphasic shocks, either in these baseline characteristics or in left atrial dimension, cardiac medications or diagnosis.

The cumulative success rates for cardioversion of atrial fibrillation are presented in Table B-1 and Figure B-1. These data provide a reasonable estimate of the expected probability of cardioversion success for a single shock at any given energy level within the range studied. Energy and peak current delivered for all shocks at each energy setting are presented in Table B-2.

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Table B-1 Cumulative Success Rates and Crossover Results for Cardioversion of AF

Energy Setting	70 J	100 J	200 J	360 J	360 J Crossover Successes
MDS: *n* = 37	5.4%	19%	38%	86%	4 of 5 pts succeeded with 360 J BTE shock
BTE: *n* = 35	60%	80%	97%	97%	0 of 1 pts succeeded with 360 J MDS shock

Cumulative percentages of successes for cardioversion of AF with shocks of 200 J or less, the primary endpoint of the study, was significantly higher in the biphasic group than the monophasic group ($p<0.0001$). The observed cumulative percentage of successes at 360 J was also higher for biphasic shocks than for monophasic shocks, but did not attain statistical significance.

Table B-2 Energy Settings, Delivered Energy and Peak Current for Shocks Delivered to Patients in AF

Energy Setting	Number of Patients	Delivered Energy	Peak Current, Amps
Monophasic shocks			
70 J	37	73±3	21.0±3.5
100 J	35	105±4	24.6±4.3
200 J	30	209±7	34.6±5.9
360 J	23	376±13	46.8±8
360 J crossover shocks	1	380	44.7
Biphasic shocks*			
70 J	35	71±0	11.9±2.5
100 J	14	102±0	14.9 ±3.5
200 J	7	203±1	20.6±3.5
360 J	1	362	28.5
360 J crossover shocks	5	361±6	32.4±8.5

* Peak current and delivered energy are not available for two of the patients treated with biphasic shocks.

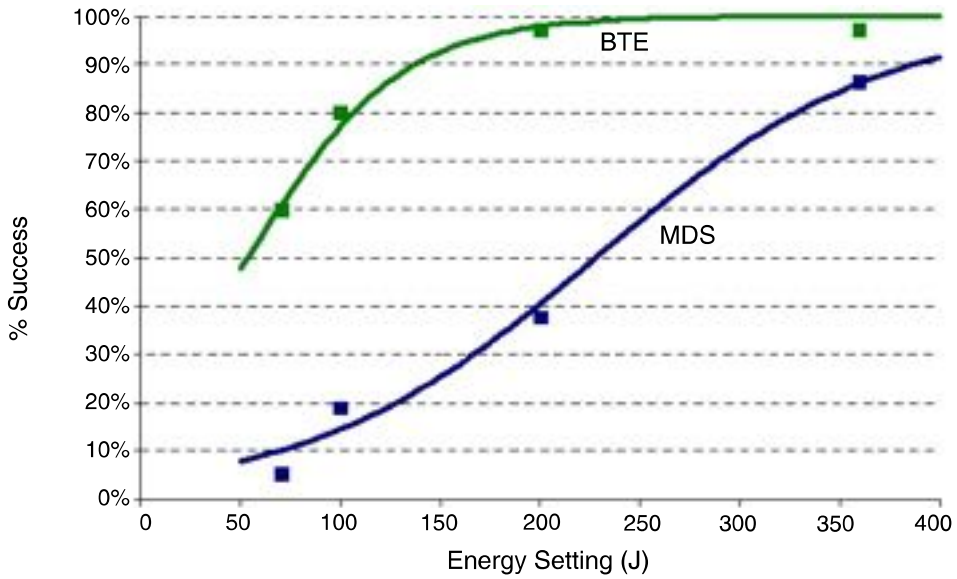


Figure B-1 Cumulative Shock Success for Cardioversion of Atrial Fibrillation with Monophasic (MDS) and Biphasic (BTE) Shocks: Observed Rates (*n*) Plotted with Estimated Dose Response Curves

Compared to monophasic shocks, biphasic shocks cardioverted atrial fibrillation with less peak current (14.0 ± 4.3 vs. 39.5 ± 11.2 A, p<0.0001), less energy (97 ± 47 vs. 278 ± 120 J, p<0.0001), fewer shocks (1.7 vs. 3.5 shocks, p < 0.0001) and less cumulative energy (146 ± 116 vs. 546 ± 265 J, p<0.0001). Patients treated with the biphasic protocol, as compared to those treated with the monophasic protocol, reported significantly less post-procedure pain just after (0.4 ± 0.9 vs. 2.5 ± 2.2, p<0.0001) and 24 hours after the procedure (0.2 ± 0.4 vs. 1.6 ± 2.0, p<0.0001).

All patients with atrial flutter were cardioverted with the first shock (70 J), whether that shock was monophasic (n=4) or biphasic (n=3).

Anterior-lateral electrode placement was used for treatment of most (96%) of the patients studied. Reports in the literature differ on whether anterior-posterior electrode placement provides better shock efficacy than anterior-lateral placement. If there is a benefit to anterior-posterior electrode placement, it may be possible to obtain modestly higher cardioversion success rates with both waveforms than those observed in this study. However, placement is not likely to affect the observed relationship *between* the efficacies of monophasic and biphasic waveforms.

Conclusions

The data demonstrate the Physio-Control biphasic waveform is clinically superior to the conventional monophasic damped sine waveform for cardioversion of atrial fibrillation. Specifically, compared to monophasic shocks, biphasic shocks cardioverted atrial fibrillation with less peak current, less energy, fewer shocks and less cumulative energy. Patients undergoing elective cardioversion with the biphasic protocol, as compared to those receiving the monophasic protocol, reported significantly less post-procedure pain just after and 24 hours after the procedure. This may be due to fewer required shocks, less cumulative energy, less delivered peak current or other characteristics of this biphasic waveform.

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Guidance for Selection of Shock Energy

Biphasic waveform technology is a standard in cardiac defibrillators. The study summarized here[1] provides the best information available on which to base energy selections for cardioversion with this waveform.

For cardioversion of atrial fibrillation, the results of this study provide specific guidance for three possible strategies in selection of shock energy levels.

- To optimize for more rapid cardioversion and fewer shocks, select the same biphasic energy levels used previously with monophasic defibrillators (e.g., use 200 J biphasic instead of 200 J monophasic). This can be expected to increase the success rate yet decrease the peak current of the first and subsequent shocks.
- To maintain shock efficacy equivalent to that previously observed with monophasic shocks, select a biphasic energy level of about one-third the energy previously used for monophasic shocks (e.g., use 100 J biphasic instead of 300 J monophasic).
- To optimize for low initial and cumulative energy using a step-up protocol, select 70 J for the first shock and use small increases in energy if further shocks are needed.

Each of these strategies should provide effective cardioversion therapy while substantially reducing the amount of peak current to which the heart is exposed.

For cardioversion of atrial arrhythmias other than atrial fibrillation, the data available to guide the selection of energy settings is very limited. It is likely that biphasic doses below 50 J will provide high success rates when treating atrial flutter and paroxysmal supraventricular tachycardia. However, until more clinical data becomes available, it may be advisable to use the same energy settings for biphasic shocks as are customarily used for monophasic shocks.

Arrhythmias may persist for a variety of reasons unrelated to the type of waveform used for cardioversion. In persistent cases, clinicians continue to have the option to either increase shock intensity or switch to an alternate electrode placement.

[1]Koster R, Dorian P., et al. A randomized trial comparing monophasic and biphasic waveform shocks for external cardioversion of atrial fibrillation. *American Heart Journal*, 2004;147(5):K1-K7.

INTRA-OPERATIVE VENTRICULAR DEFIBRILLATION

Overview

The defibrillation efficacy of the Physio-Control biphasic truncated exponential (BTE) waveform was compared to the standard monophasic damped sine waveform (MDS) in a prospective, randomized multi-center study of patients undergoing intra-operative, direct defibrillation for ventricular fibrillation (VF). A total of 251 adult patients were enrolled in the study; 98 of these developed VF that was treated with one or more study shocks. Seven patients who did not satisfy all protocol criteria were excluded from analysis.

Subjects were randomized to receive BTE or MDS shocks from LIFEPAK 12 defibrillator/monitor. Those who developed VF after removal of the aortic clamp received progressively stronger shocks of 2, 5, 7, 10 and 20 joules (J) using 2-inch paddles until defibrillation occurred. A 20 J crossover shock of the alternate waveform was given if VF persisted.

This study showed that these biphasic shocks have higher defibrillation efficacy, requiring fewer shocks, less threshold energy and less cumulative energy than monophasic damped sine shocks.

Objectives

The primary objective of the study was to compare the cumulative efficacy of BTE shocks to MDS shocks at 5 J or less. A triangular sequential design was used to test for a difference between waveform groups.

The secondary objective was to provide an estimation of the dose response relationship for the two waveforms that would allow physicians to make well-informed selections of energy doses for intra-operative defibrillation with biphasic shocks.

Results

Thirty-five male and 15 female subjects were randomized to the BTE group; 34 and 7 to the MDS group. Mean age was 66 and 68 years, respectively. There were no significant differences between BTE and MDS treatment groups for cardiac etiology, arrhythmia history, current cardiac medications, American Society of Anesthesiology (ASA) risk class, left ventricular wall thickness, cardiopulmonary bypass time, core temperature or blood chemistry values at the time of aortic clamp removal.

Cumulative defibrillation success at 5 J or less, the primary endpoint of the study, was significantly higher in the BTE group than in the MDS group (p=0.011). Two of the 91 patients included in this primary endpoint analysis could not be included in more comprehensive analyses due to protocol variances that occurred in the shock sequence after the 5 J shock. Thus, the cumulative success rates for intra-operative defibrillation in the remaining 89 patients are presented in Table B-3 and Figure B-2. These data provide a reasonable estimate of the expected probability of defibrillation success for a single shock at any given energy level within the range studied.

Compared to the MDS group, the BTE group required, on average, fewer shocks (2.5 vs. 3.5: p=0.002), less threshold energy (6.8 J vs. 11.0 J: p=0.003) and less cumulative energy (12.6 J vs. 23.4 J: p=0.002). There was no significant difference between success rates for BTE versus MDS crossover shocks.

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Table B-3 Cumulative Shock Success Rates and Crossover Shock Results for Intra-operative Defibrillation

Energy Setting	2 J	5 J	7 J	10 J	20 J	20 J Crossover Successes
MDS: n = 41	7%	22%	34%	51%	76%	3 of 8 pts succeeded with 20 J BTE shock
BTE: n = 48*	17%	52%	67%	75%	83%	3 of 8 pts succeeded with 20 J MDS shock

*Two subjects randomized to the BTE group were unable to be included in the cumulative success rates shown in the table and figure due to protocol deviations occurring after the 5 J shock.

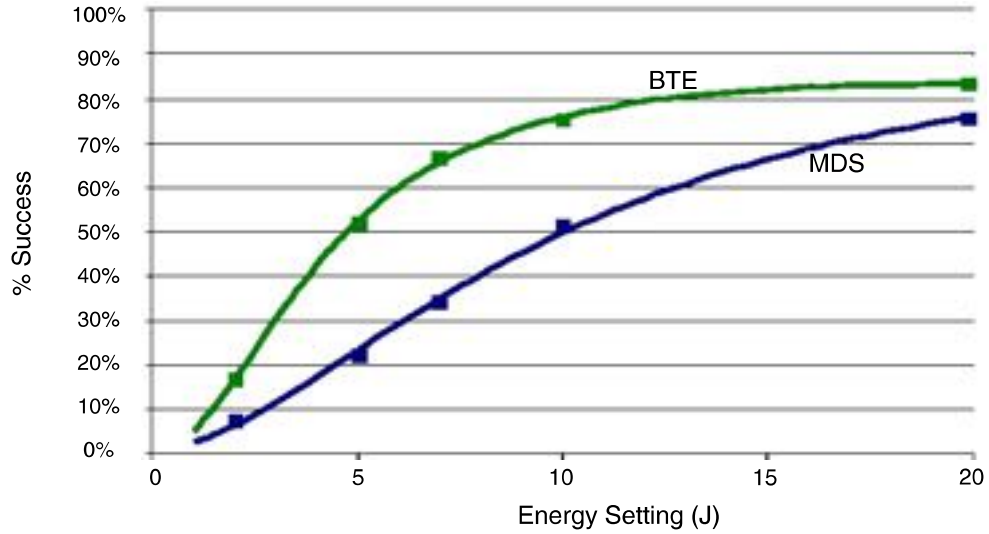


Figure B-2 Cumulative Shock Success for Intra-operative Defibrillation with Monophasic (MDS) and Biphasic (BTE) Shocks: Observed Rates (*n*) Plotted with Estimated Dose Response Curves

Conclusions

The data demonstrate the Physio-Control biphasic waveform is clinically superior to the conventional monophasic damped sine waveform for intra-operative internal defibrillation of VF. Specifically, these biphasic shocks have higher defibrillation efficacy, while requiring fewer shocks, less threshold energy and less cumulative energy than monophasic damped sine shocks. There were no unsafe outcomes or adverse effects from the use of the biphasic waveform.

Guidance for Selection of Shock Energy

Biphasic waveform technology is a standard in cardiac defibrillators. The results of this study[1] provide specific guidance for three possible strategies in developing a dosing regimen.

- To optimize for lower initial and cumulative energy using a step-up protocol, select 5 J for the first shock and use small incremental increases in energy if further shocks are needed. In this study, biphasic shocks of 5 J were successful in approximately half of the patients.
- To optimize for more rapid defibrillation and fewer shocks, select the same BTE energy level used previously with MDS (e.g., 20 J BTE instead of 20 J MDS), which can be expected to increase the success rate yet decrease by approximately 30% the peak current of the first and subsequent shocks.
- To maintain an equivalent degree of efficacy as previously observed with MDS shocks, a BTE energy level one-half of that previously used for MDS shocks (e.g., 10 J BTE instead of 20 J MDS) would be an appropriate choice.

Each of these strategies should provide effective defibrillation therapy while substantially reducing the amount of peak current to which the heart is exposed.

Fibrillation may persist for a variety of reasons unrelated to the type of waveform used for defibrillation. In cases where fibrillation is persistent, physicians continue to have the option to either increase shock intensity or switch to a larger paddle size. Larger paddle size is known to decrease energy requirements for successful defibrillation.[2]

[1]B. Schwarz et al., Biphasic shocks compared with monophasic damped sine wave shocks for direct ventricular defibrillation during open heart surgery. *Anesthesiology.* 2003;98(5):1063-1069.

[2]Y. Zhang et al., "Open chest defibrillation: biphasic versus monophasic waveform shocks," *J Am Coll Cardiol*, 2001, 37(2 supplement A):320A.

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APPENDIX C
SCREEN MESSAGES

This appendix provides the Summary of Screen Messages table and describes screen messages that the LIFEPAK 20e defibrillator/monitor may display during operation.

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Table C-1 Summary of Screen Messages

Message	Description
ABNORMAL ENERGY DELIVERY	A discharge occurred when the paddles were shorted together (refer to warning, page 4-15); an open air discharge occurred; or, the patient impedance is out of range. This message may also appear in certain types of internal faults.
ACCESS DENIED	Three consecutive incorrect passcode attempts were entered.
AED MODE	The device is monitoring the patient condition and functioning as a semiautomatic external defibrillator.
ALARMS SILENCED	The alarms are silenced. An alert tone and this message appear periodically to remind you that alarms have been silenced.
ANALYZING NOW–STAND CLEAR	The AED is analyzing the patient ECG rhythm.
C LEAD OFF	The ECG electrode “C” is disconnected.
CHARGING TO XXX J	The front panel or the standard paddles **CHARGE** button was pressed.
CHECK FOR PULSE	The AED prompt that appears after each standard 3-shock sequence or ***NO SHOCK ADVISED*** message.
CHECK PATIENT!	A potentially shockable rhythm is detected when the VF/VT alarm is on.
CHECK PRINTER	The printer door is open; there is no paper in the printer; or, there is another printer malfunction.
CONNECT CABLE	In manual mode, the therapy cable was not connected when you pressed **CHARGE**. In pacing mode, the QUIK-COMBO cable was not connected when you increased current. In AED advisory mode, the QUIK-COMBO cable was not connected when you pressed **ANALYZE.**
CONNECT ELECTRODES	The defibrillator detects that the therapy electrodes are disconnected.
CONNECT SYNC CABLE TO REMOTE MONITOR	Remote sync is selected and the device is not connected to the remote monitor.
CONNECT TO AC POWER	Remote sync is selected and the device is not connected to AC power.
CONNECT TO TEST PLUG	Test plug not connected to QUIK-COMBO therapy cable or standard paddles not seated in paddle wells during user test.
CURRENT FAULT	The comparison between delivered and selected pacing current is out of tolerance.
DEMAND	The pacemaker is in the demand mode.
DISARMING...	The decision was made to remove the energy charge.
ECG CABLE OFF	The ECG cable was removed during printing.

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Table C-1 Summary of Screen Messages (Continued)

Message	Description
ECG LEADS OFF	Multiple ECG electrodes were disconnected either when the device was turned on or during monitoring.
ENERGY DELIVERED	Energy transfer was completed.
ENERGY NOT DELIVERED	An open air discharge is detected with standard paddles. Usually this is because the electrodes are not in contact with a patient or test load when the shock is initiated.
ENERGY SELECT/XXX J	The front panel or standard paddles **ENERGY SELECT** button was pressed.
IF NO PULSE, PUSH ANALYZE	This message appears following a CPR interval (if activated in setup configuration).
IF NO PULSE, START CPR	Initiate CPR if no pulse and continue with CPR until completion tone.
IF YOU WITNESSED THE ARREST, PUSH ANALYZE	Initial CPR message following **START CPR** prompt to remind user to deliver a shock immediately, if the user witnessed the arrest.
LA LEADS OFF L LEADS OFF	ECG electrode LA is disconnected. ECG electrode L is disconnected.
LL LEADS OFF F LEADS OFF	ECG electrode LL is disconnected. ECG electrode F is disconnected.
LOW BATTERY	Battery status indicator shows one yellow segment; low battery condition exists.
LOW BATTERY: CONNECT TO AC POWER	Battery status indicator shows one flashing red segment; very low battery condition exists.
LOW IMPEDANCE–RECHARGING	Patient impedance of <15 ohms detected.
MOTION DETECTED!/ STOP MOTION!	The defibrillator detected motion during ECG analysis, thereby inhibiting analysis.
NO SHOCK ADVISED	The defibrillator does not detect a shockable rhythm.
NON-DEMAND	The pacemaker is in nondemand (asynchronous) mode.
PACER FAULT	The pacemaker detects a pacing fault condition due to high pacing rate or loss of interprocessor communication. Pacing function stops.
PACING STOPPED	Pacing stops and this message appears whenever any of the following occur: pacer electrodes off, pacer cable disconnected, or pacer failure due to high pacing rate or high impedance.
PAUSED	The pacing **PAUSE** button was pressed and held. Current pulses are applied at reduced frequency while the mA and ppm settings are maintained.

Table C-1 Summary of Screen Messages (Continued)

Message	Description
PUSH ANALYZE	Press **ANALYZE** to begin ECG analysis.
PUSH SPEED DIAL TO DISARM	An instruction on the charging screen overlays for disarming the charge.
PUSH PADDLE BUTTON TO SHOCK!	The front panel **SHOCK** button is disabled if internal paddles are attached. This message appears if you attempt to transfer energy by pressing the front panel **SHOCK** button.
PUSH PADDLE BUTTONS TO SHOCK!	If standard paddles are attached, the front panel **SHOCK** button is disabled. Message appears if you attempt to transfer energy by pressing the front panel **SHOCK** button.
PUSH SHOCK BUTTON!	The defibrillator is fully charged and ready to provide therapy (a therapy cable or internal paddles must be connected).
RA LEADS OFF R LEADS OFF	ECG electrode RA is disconnected. ECG electrode R is disconnected.
RL LEADS OFF N LEADS OFF	ECG electrode RL is disconnected. ECG electrode N is disconnected.
REMOVE TEST PLUG	The QUIK-COMBO test plug is connected to the QUIK-COMBO therapy cable.
SEARCHING FOR SIGNAL	Remote sync is selected and the device is qualifying the input signal.
SELF TEST DID NOT COMPLETE	Test plug not connected to QUIK-COMBO therapy cable, standard paddles not seated in paddle wells, possible defective therapy cable, or a problem with the defibrillator during daily auto test.
SELF TEST DID NOT COMPLETE – CONNECT TO TEST PLUG	Test plug not connected to QUIK-COMBO therapy cable, standard paddles not seated in paddle wells, possible defective therapy cable, or a problem with the defibrillator during daily auto test.
SELF TEST FAILED	An unsuccessful self test has occurred.
SELF TEST IN PROGRESS	Confirms that the self test is in progress.
SELF TEST SUCCEEDED	A successful self test was completed.
SHOCK ADVISED!	The defibrillator detected a shockable rhythm.
SPO2: CHECK SENSOR	The SpO2 sensor detached from the patient after a measurement was obtained.
SPO2: LOW PERFUSION	Patient has a weak pulse.
SPO2: NO SENSOR DETECTED	A sensor was disconnected from the monitor.

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Table C-1 Summary of Screen Messages (Continued)

Message	Description
SPO2: SEARCHING FOR PULSE	Confirms the pulse oximetry sensor is connected to the defibrillator.
SPO2: UNKNOWN SENSOR	A sensor is connected to the device that is not compatible with the Masimo SpO2 module.
STAND CLEAR/PUSH SHOCK BUTTON	Stand clear of the patient and push the **SHOCK** button.
START CPR	Initiate CPR in AED mode.
SWITCHING PRIMARY TO LEAD II	**PADDLES** lead is not available and you pressed the **ANALYZE** button.
SWITCHING PRIMARY TO PADDLES	**PADDLES** lead is available and you pressed the **ANALYZE** button.
USE ECG LEADS	The device is attempting synchronized cardioversion and **PADDLES** lead was selected.
USER TEST DID NOT COMPLETE	Test plug not connected to QUIK-COMBO therapy cable, standard paddles not seated in paddle wells, possible defective therapy cable, or a problem with the defibrillator during user test.
USER TEST DID NOT COMPLETE – CONNECT TO TEST PLUG	Test plug not connected to QUIK-COMBO therapy cable, standard paddles not seated in paddle wells, defective therapy cable, or a problem with the defibrillator during user test.
USER TEST FAILED	An unsuccessful user test has occurred.
USER TEST IN PROGRESS	Confirms that the user test is in progress.
USER TEST SUCCEEDED	A successful user test was completed.

APPENDIX D
OPERATOR'S CHECKLIST

This Operator's Checklist may be reproduced.

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LIFEPAK® 20e Defibrillator/Monitor Operator's Checklist

Unit Serial No.:_____

Location: _____

Daily inspection and testing of the defibrillator/monitor using this Operator's Checklist is recommended. This form may be reproduced.

Instruction	Recommended Corrective Action	Date / Initials

Insert a ✔ in the box after completing each instruction.

1 Check printed result of 3 A.M. daily auto test. (If no self-test results have printed, refer to Step 10.) If:

SELF-TEST FAILED	Contact qualified service personnel.
SELF-TEST DID NOT COMPLETE – CONNECT TO TEST PLUG	Connect test plug or secure paddles in well, and perform manual User Test. If ***CONNECT TO TEST PLUG*** message appears, contact qualified service personnel.

2 Inspect physical condition for:

Foreign substances	Clean the defibrillator.
Damage or cracks	Contact qualified service personnel.

3 Inspect power source for:

AC power connector plugged into unit and AC power source; AC Mains LED is lit	If AC Mains LED is not lit, contact qualified service personnel.
Broken, loose, or worn power cable	Replace damaged or broken parts.

4 Check therapy and ECG electrodes for:

Use By date	Replace if past expiration date.
Spare electrodes available	Obtain spare electrodes.

5 Examine accessory cables for:

Cracking, damage, broken or bent parts or pins, and paddle surfaces for pitting	Replace damaged or broken parts.

6 Disconnect the defibrillator from AC power, wait 2 seconds, press ON and look for:

Momentary ***SELF-TEST*** messages and momentary illumination of LEDs	If absent, contact qualified service personnel.
Service LED is lit	If lit, power off device, then power back on. If service LED stays lit, contact qualified service personnel.

7 Check ECG printer for:

Adequate paper supply	Replace if necessary.
Ability to print	If not working, contact qualified service personnel.

8 Confirm therapy cable connected to defibrillator and perform cable check:

<u>If QUIK-COMBO® therapy cable is connected:</u>

• Confirm test plug connected to therapy cable.	
• Press **ANALYZE** button.	
• After ***ANALYZING NOW*** message, look for ***REMOVE TEST PLUG*** message.	If ***CONNECT CABLE*** or ***CONNECT ELECTRODES*** message appears, contact qualified service personnel.

<u>If HARD PADDLES are connected:</u>

• Confirm paddles properly seated in wells.	
• Select 10 J and press the **CHARGE** button.	If ***CONNECT CABLE*** or ***CONNECT ELECTRODES*** message appears, contact qualified service personnel.
• When fully charged, press the **SHOCK** button on the paddles and look for the ***ENERGY DELIVERED*** message.	If no energy delivered and shock tone continues, press Speed Dial to disarm, and contact qualified service personnel.

9 Reconnect to AC power and then power off the device.

10 *Perform manual User Test if:

User Test Performed

• Hospital protocol requires more frequent device testing than the recommended daily auto test	If User Test fails, contact qualified service personnel.
• Daily auto test did not complete or did not print	
• REDI-PAK™ electrodes pre-connected to therapy cable	**Note**: Reconnect electrodes to therapy cable after user test is completed.

APPENDIX E
SHOCK ADVISORY SYSTEM

This appendix describes the basic function of the Shock Advisory System (SAS).

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OVERVIEW OF THE SHOCK ADVISORY SYSTEM

The Shock Advisory System™ (SAS) is an ECG analysis system built into the LIFEPAK 20e defibrillator/monitor that advises the operator as to whether it detects a shockable or nonshockable rhythm. This system makes it possible for individuals who are not trained to interpret ECG rhythms to provide potentially lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia. The Shock Advisory System contains the following features:

- Electrode Contact Determination
- Automated Interpretation of the ECG
- Operator Control of Shock Therapy
- Continuous Patient Surveillance System (CPSS)
- Motion Detection

The Shock Advisory System is active when the LIFEPAK 20e defibrillator/monitor is used as an automated external defibrillator (AED). CPSS may be activated during monitoring.

Electrode Contact Determination

The Shock Advisory System measures the patient's transthoracic impedance through the therapy electrodes. If the baseline impedance is higher than a maximum limit, it determines that the electrodes do not have sufficient contact with the patient or are not properly connected to the AED. When this occurs, ECG analysis and shock delivery are inhibited. The AED advises the operator to connect electrodes when there is insufficient electrode contact.

Automated Interpretation of the ECG

The Shock Advisory System recommends a shock if it detects the following:

- Ventricular fibrillation - with a peak-to-peak amplitude of at least 0.08 mV.
- Ventricular tachycardia - defined as having a heart rate of at least 120 beats per minute, QRS width of at least 0.16 seconds, and no apparent P waves.

Pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm. The Shock Advisory System recommends no shock for all other ECG rhythms including asystole, pulseless electrical activity, idioventricular rhythms, bradycardia, supraventricular tachycardias, atrial fibrillation and flutter, heart block, premature ventricular complexes and normal sinus rhythm. These rhythms are specifically mentioned in the AHA recommendations.

Shock Advisory System Performance

ECG analysis by the Shock Advisory System (SAS) in the LIFEPAK 20e defibrillator/monitor (AED) series was tested by playing ECG waveforms from the Physio-Control database through the electrode connector. For each test ECG, the decision shock or no shock, of the SAS was recorded and compared to the rhythm classification and treatment recommendation by clinical experts.

SAS Test Set

The SAS Test Set consists of 989 ECG samples recorded during pre-hospital use of the LIFEPAK 5 defibrillators. The ECG was recorded using cassette tape recorders connected to the LIFEPAK 5 defibrillators. Selected ECG segments were sampled and the ECG rhythm was classified by clinical experts. The SAS Test Set contains the following ECG samples:

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- 168 each coarse ventricular fibrillation (VF) (>= 200 µV peak-to-peak amplitude)
- 29 each fine ventricular fibrillation (< 200 and >= 80 µV peak-to-peak amplitude)
- 65 each shockable ventricular tachycardia (VT) (HR > 120 bpm, QRS duration >= 160 ms, no apparent P waves, patient reported to be pulseless by the paramedics)
- 43 each asystole (< 80 µV peak-to-peak amplitude)
- 144 each normal sinus rhythm (NSR) (sinus rhythm, heart rate 60-100 bpm)
- 531 each other organized rhythm (includes all rhythms except those in other listed categories)
- 2 each transitional (transition occurs within the sample from nonshockable to nonshockable or vice versa)
- 5 each shockable rhythms with pacemaker artifact (the pacemaker artifact is spread over time by the filtering in the LIFEPAK 5 defibrillator)
- 2 each nonshockable rhythms with pacemaker artifact (the pacemaker artifact is spread over time by the filtering in the LIFEPAK 5 defibrillator)

Table E-1 LIFEPAK 20e Series Overall SAS Performance

SAS Overall Performance	
Sensitivity	>90%
Specificity	>95%
Positive Predictive Value	>90%
False Positive Rate	<5%

Table E-2 LIFEPAK 20e Series SAS Performance by Rhythm Category

Rhythm Class	ECG Test[1] Sample Size	Performance Goal	Observed Performance
Shockable: Coarse VF	168	>90% sensitivity	LIFEPAK 20e meets the AAMI[2] DF80 requirements and AHA[3] recommendations
Shockable: VT	65	>75% sensitivity	LIFEPAK 20e meets the AAMI DF80 requirements and AHA recommendations
Nonshockable: NSR	144	>99% specificity	LIFEPAK 20e meets the AHA recommendations
Nonshockable: asystole	43	>95% specificity	LIFEPAK 20e meets the AAMI DF80 requirements and AHA recommendations
Nonshockable: all other rhythms	531	>95% specificity	LIFEPAK 20e meets the AAMI DF80 requirements and AHA recommendations
Intermediate: fine VF	29	Report only	>75% sensitivity

1 Each sample is run 10 times asynchronously.

2 Association for the Advancement of Medical Instrumentation. DF80: 2003 Medical electrical equipment-Part2-4. Arlington, VA: AAMI, 2004

3 Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. American Heart Association (AHA) Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation. 1997: Vol. 95: 1677-1682.

VF = ventricular fibrillation
VT = ventricular tachycardia
NSR = normal sinus rhythm

Operator Control of Shock Therapy

The Shock Advisory System causes the AED to charge automatically when it detects the presence of a shockable rhythm. When a shock is advised, the operator presses the **SHOCK** button to deliver the energy to the patient.

Continuous Patient Surveillance System

The Continuous Patient Surveillance System (CPSS) automatically monitors the patient's ECG rhythm for a potentially shockable rhythm while the electrodes are attached and the AED is turned on. CPSS is not active during ECG analysis or when the AED is in a CPR cycle.

Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. A motion detector is designed into the LIFEPAK 20e defibrillator/monitor. **MOTION DETECTION** can be configured in the setup mode to be **ON** or **OFF**.

A number of activities can create motion, including CPR, rescuer movement, patient movement, and some internal pacemakers. If variations in the transthoracic impedance signal exceed a maximum limit, the Shock Advisory System determines that patient motion of some kind is present. If motion is detected, the ECG analysis is inhibited. The operator is advised by a displayed message, a voice prompt, and an audible alert. After 10 seconds, if motion is still present, the motion alert stops and the analysis always proceeds to completion. This limits the delay in therapy in situations where it may not be possible to stop the motion. However, the rescuer should remove the source of motion whenever possible to minimize the chance of artifact in the ECG.

There are two reasons why ECG analysis is inhibited when the motion alert occurs, and why the rescuer should remove the source of the motion whenever possible:

1 Such motion may cause artifact in the ECG signal. This artifact can cause a nonshockable ECG rhythm to look like a shockable rhythm. For example, chest compressions during asystole can look like shockable ventricular tachycardia. Artifact can also cause a shockable ECG rhythm to look like a nonshockable rhythm. For example, chest compressions during ventricular fibrillation can look like an organized and, therefore, nonshockable rhythm.
2 The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

The motion detection feature can be set to off. When this option is off, analysis of the ECG is allowed to proceed uninhibited even in the presence of motion, which may or may not cause artifact in the ECG as described previously. Artifact in the ECG can sometimes cause an erroneous shock advisory decision.

The skill and training level of the care providers should be taken into consideration when deciding whether or not to turn off the motion detection feature. How readily do the users respond to the AED voice prompt? For example, do they immediately stop CPR upon hearing the **STAND CLEAR, ANALYZING NOW** prompt?

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APPENDIX F
About cprMAX Technology

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ABOUT cprMAX TECHNOLOGY

Physio-Control cprMAX™ technology is designed to allow resuscitation protocols to maximize the quantity of CPR administered during treatment with an AED, consistent with the 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care [1] (AHA Guidelines) and the European Resuscitation Council Guidelines for Resuscitation 2005 [2].

Setup options should be changed only under the direction of a physician knowledgeable in cardiopulmonary resuscitation who is familiar with the literature in this area.

The cprMAX technology includes the following setup options:

- **INITIAL CPR**. Prompts the user to perform an initial period of CPR. Applies only to immediately after turning on the AED or after the first analysis.
- **PRESHOCK CPR** time. Prompts for CPR after a shockable ECG rhythm is detected, before the shock is delivered. If **INITIAL CPR** is set to **OFF**, then **PRESHOCK CPR** applies to all shock advised decisions (including the first analysis).
- **CPR TIME 1** and **2**. CPR time periods after shocks or no shock advised decisions respectively.
- **STACKED SHOCKS**. Eliminates the analysis after each shock and inserts prompting for CPR after each shock. This eliminates the three-shock stack.
- **PULSE CHECK**. Indicates when, if ever, the device is to prompt for pulse checks.

AED protocols are aligned with the AHA and ERC Guidelines when the setup options are set as follows:

- Initial CPR: **OFF**
- PreShock CPR time: **OFF**
- CPR Times 1 & 2: **120 SECONDS**
- Stacked Shocks: **OFF**
- Pulse Check: **NEVER**

The above options are the factory default settings for cprMAX technology. Your hospital procedures should determine whether or not to change the options and should ensure that you receive training.

The adult ventricular fibrillation (VF) energy label is also provided as the recommended energy for treating VF [3][4]. Refer to the label on your defibrillator for recommended doses.

1 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation 2005;112 (Supplement IV).
2 European Resuscitation Council Guidelines for Resuscitation 2005. J. Resuscitation 2005; 67 (Supplement 1).
3 2005 AHA Guidelines, IV-40.
4 ERC Guidelines 2005, S31.

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AED OPERATION WITH cprMAX TECHNOLOGY

The following paragraphs describe AED operation with cprMAX technology setup options.

Initial CPR

The **INITIAL CPR** option prompts the user to perform an initial period of CPR. The choices are: **OFF, ANALYZE FIRST** and **CPR FIRST**. The factory default is **OFF**.

- The **OFF** setting has no prompting for an initial CPR period.
- The **ANALYZE FIRST** setting prompts for analysis and then CPR. If the analysis determines that a shock is needed, the AED will prompt, ***IF YOU WITNESSED THE ARREST, PUSH ANALYZE***, which provides the opportunity to end CPR early and proceed directly to delivering a shock.
- The **CPR FIRST** setting prompts the user to perform CPR immediately after the defibrillator is powered on. The AED will also prompt, ***IF YOU WITNESSED THE ARREST, PUSH ANALYZE,*** which provides the opportunity to end CPR early and proceed directly to analysis.

Hospitals that choose to implement this option should develop a protocol and provide training to responders instructing them when to end the initial CPR interval early. Potential situations for instructing responders to end CPR early include:

- The patient's collapse was witnessed by the responder.
- The responder ascertains that fewer than four or five minutes have elapsed since the patient's collapse.
- The patient exhibits agonal breathing, an indicator of a short downtime.
- The responder ascertains that CPR of adequate quality and duration has already been provided before attaching the AED electrodes.

Refer to Continuous Patient Surveillance System for a more detailed description of the AED prompting sequence for each **INITIAL CPR** option.

Initial CPR Time

The **INITIAL CPR TIME** option applies when **INITIAL CPR** is set to **ANALYZE FIRST** or **CPR FIRST**. It sets the CPR time for that CPR period. The time choices for **INITIAL CPR TIME** are: **15**, **30**, **45**, **60**, **90**, **120**, and **180 SECONDS**. The default setting is **120 SECONDS**.

PreShock CPR Time

The **PRESHOCK CPR** time option inserts prompting for CPR when a shockable ECG rhythm is detected and during the time the AED is charging. It applies only when analysis results in ***SHOCK ADVISED*** decisions. When **INITIAL CPR** is set to **OFF** or **CPR FIRST**, **PRESHOCK CPR** time applies to the first and all subsequent shocks. When **INITIAL CPR** is set to **ANALYZE FIRST**, **PRESHOCK CPR** time apples to the second and all subsequent shocks. The choices for **PRESHOCK CPR** time are: **OFF, 15,** and **30 SECONDS**. To prompt for CPR only for the time the capacitor is charging, select the 15-seconds CPR interval. The **SHOCK** button is not enabled until charging and CPR time are completed. The default setting for **PRESHOCK CPR** time is **OFF**.

Note: Although the **SHOCK** button is disabled during the **PRESHOCK CPR** interval, it becomes active as soon as the **PRESHOCK CPR** interval ends. To minimize the interval between the final chest compression and shock delivery (while maintaining responder safety), hospital protocols that select this option should provide specific training and protocols to address the rapid transition from **PRESHOCK CPR** to shock delivery.

Stacked Shocks

When set to **OFF**, the **STACKED SHOCKS** option inserts prompting for CPR after each (a single) shock. This eliminates the three-shock stack. CPR is prompted after the shock regardless of the ECG rhythm. The CPR time following the shock is determined by the **CPR TIME 1** setting selected. Choices for the **STACKED SHOCKS** option are **ON** or **OFF**. The default setting is **OFF**.

When this option is set to **ON**, the defibrillator follows the previously traditional stacked shock protocol and delivers up to three consecutive shocks, as necessary, without interposed CPR.

Pulse Check

The **PULSE CHECK** option inserts prompting to check for a pulse or check the patient, depending on the **PULSE PROMPT** setting. The choices for **PULSE CHECKS** are: **ALWAYS, AFTER EVERY NSA, AFTER SECOND NSA**, and **NEVER**. The default setting is **NEVER**.

- The **ALWAYS** option prompts for a pulse check after CPR Times 1 and 2, after a ***NO SHOCK ADVISED*** decision, after a single ***SHOCK ADVISED*** decision with **STACKED SHOCKS OFF**, or after three consecutive ***SHOCK ADVISED*** decisions if **STACKED SHOCKS** is **ON**.
- The **AFTER EVERY NSA** option prompts for a pulse check after every ***NO SHOCK ADVISED*** decision.
- The **AFTER SECOND NSA** option prompts for a pulse check after the second analysis if the second analysis results in a ***NO SHOCK ADVISED*** decision, regardless of the first analysis decision (***SHOCK ADVISED*** or ***NO SHOCK ADVISED***).
- The **NEVER** option eliminates all **PULSE CHECK** prompts.

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APPENDIX G
DOCKING STATION

This appendix describes how to install and use the LIFEPAK 20e defibrillator/monitor docking station.

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LIFEPAK 20E DEFIBRILLATOR/MONITOR DOCKING STATION

The LIFEPAK 20e defibrillator/monitor docking station allows you to secure your defibrillator to an emergency cart or other flat surface. The docking station provides a 360-degree turning radius for the viewing of the LIFEPAK 20e defibrillator/monitor display from any angle.

To insert the LIFEPAK 20e defibrillator/monitor into the docking station:

1 Hold the LIFEPAK 20e defibrillator/monitor by the handle over the docking station (refer to Figure G-1, arrow 1).
2 Tilt the LIFEPAK 20e defibrillator/monitor backward into the docking station, aligning slots in the rear of the defibrillator to rollers on the docking station (refer to Figure G-1, arrow 2).
3 Align recess in lower front panel of the LIFEPAK 20e defibrillator/monitor with the front roller on the docking station and press down on the front of the LIFEPAK 20e defibrillator/monitor until you hear a click (refer to Figure G-1, arrow 3).
4 Check to make sure that the LIFEPAK 20e defibrillator/monitor is securely locked into position.

To turn the LIFEPAK 20e defibrillator/monitor while in the docking station:

1 Grasp the LIFEPAK 20e defibrillator/monitor by the handle, or by its sides.
2 Turn to the correct position. You will hear clicking sounds as the defibrillator locks into place.

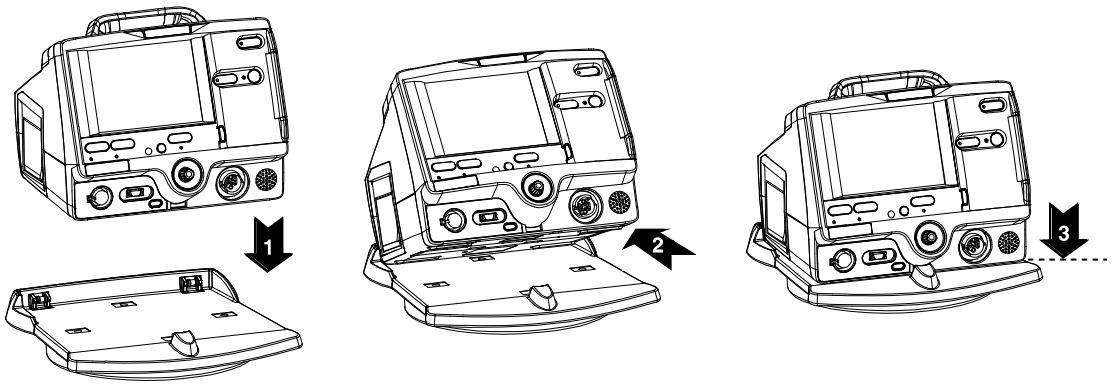


Figure G-1 Docking Station

To remove the LIFEPAK 20e defibrillator/monitor from the docking station:

1 Grasp the LIFEPAK 20e defibrillator/monitor by the handle.
2 Pull briskly on the LIFEPAK 20e defibrillator/monitor until it releases from the docking station.

Note: To install the docking station to a flat surface or wall mount (GCX) bracket, refer to the docking station installation instructions or consult the *LIFEPAK 20e Defibrillator/Monitor Service Manual*.

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APPENDIX H
ELECTROMAGNETIC COMPATIBILITY GUIDANCE

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Table 1

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The LIFEPAK 20e defibrillator/monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 20e defibrillator/monitor should ensure that the defibrillator/monitor is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The LIFEPAK 20e defibrillator/monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LIFEPAK 20e defibrillator/monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Essential Performance

The LIFEPAK 20e defibrillator/monitor maintains safe and effective performance of the defibrillation therapy and patient monitoring functions when operated in the electromagnetic environment specified in Tables 2 through 4.

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Table 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The LIFEPAK 20e defibrillator/monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 20e defibrillator/monitor should ensure that the defibrillator/monitor is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LIFEPAK 20e defibrillator/monitor requires continued operation during power mains interruptions, it is recommended that the LIFEPAK 20e defibrillator/monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC Mains voltage prior to application of the test level.			

Table 3

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The LIFEPAK 20e defibrillator/monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 20e defibrillator/monitor should ensure that the defibrillator/monitor is used in such an electromagnetic environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the LIFEPAK 20e defibrillator/monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1]	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[1]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[2] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[3] should be less than the compliance level in each frequency range.[4] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LIFEPAK 20e defibrillator/monitor is used exceeds the applicable RF compliance level above, the LIFEPAK 20e defibrillator/monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LIFEPAK 20e defibrillator/monitor.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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Table 4

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the LIFEPAK 20e Defibrillator/Monitor Series

The LIFEPAK 20e defibrillator/monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LIFEPAK 20e defibrillator/monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LIFEPAK 20e defibrillator/monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Philips Monitoring System (MUNSON)

Philips Monitoring System (MUNSON)

Introduction

Central Monitoring System

The Philips Patient Information Center is a regulated medical IT system that:

- Provides continuous monitoring of patient vital signs from admission to discharge.
- Consolidates and communicates vital signs data from monitors and third-party devices to caregivers and to the Electronic Medical Record (EMR) for a complete patient record.

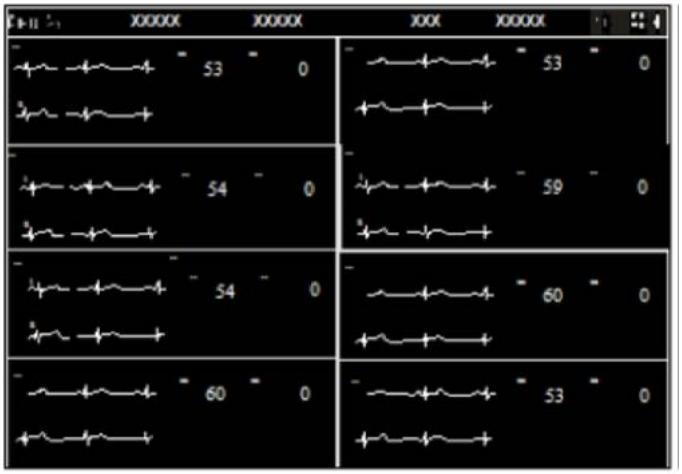
- Supports industry standard interfaces to integrate into existing hospital IT infrastructure and EMR systems while meeting requirements for manageability, serviceability, and security.
- Meets the needs of caregivers on the go by means of remote access to patient vital signs for information anywhere.

Through a combination of advanced alarm management, mobility, and clinical decision support, Philips Patient Monitoring Systems enable reduction of non-actionable alarms, improve workflow efficiency, and facilitate early intervention of patient deterioration to improve patient care and outcomes.

The Information Center software runs on a PC workstation with one or two displays for viewing patient data and accessing clinical applications. A mouse and keyboard are provided for entering and changing patient data and other information. If you position the cursor on a labeled application button and click, the application is immediately displayed on the screen. Note that an on-screen keyboard is not available.

With a touchscreen, you can access patient data by either using the mouse or by touching the item on the screen with your finger or a stylus. The mouse is best for making precise selections and measurements, such as using calipers. The touchscreen is best for actions such as acknowledging alarms, accessing application windows, or recording strips. When using a touchscreen, keep the area free of items that can inadvertently touch the screen. If the touchscreen becomes unavailable for any reason, you can access patient data by using the mouse and keyboard.

The Main Screen displays real-time waves, numerics, and alarms from multiple patients. It can be configured to show up to 64 waves, and contains the following elements:



1 Caption Bar

2 Patient Sectors

 Select the Patient Window button to open the Patient window to Display a real-time view of the current patient's data. You also can choose to do an ECG analysis to view all available ECG leads. The Patient Window provides a real-time view of the patient's waves and numerics. You can view patient data and perform all tasks in the Patient Window. In addition to the waves and numerics, the Patient Window contains the following items:

- The Bed Label Pane - Displays the bed label and ID for the currently selected patient. Select the down arrow to select another patient to view.
- The Print Icon to start a printout of the Patient summary report.
- The Help Icon.
- Alarm message areas – All active alarms and technical alarms display on the top right of the patient window. Status messages are color-coded to indicate the message severity. Orange background indicates high severity. Black background indicates low severity. Select the status message to open System Help in the application window. The Help contains a list of status messages with the possible causes and recommended actions for each message.
- Patient Name - Displays the patient's name. Depending on the length of the complete string and the amount of available space, a minimum number of characters is shown, ending with an ellipsis (...). Three question marks (???) precede the patient's name when there is a problem identifying the patient. For example: Patient data between the Information Center and the bedside does not match. All required information was not entered when the patient was admitted.

Buttons in the sector become visible when you move the cursor into the sector or, if using a touch screen display, when you first touch the sector with a stylus or the tip of your finger. When you place the cursor inside a patient sector, the sector is outlined in an orange border. You can minimize the buttons by moving the cursor into the sector and holding down the **Ctrl** key. While the cursor is inside the sector, the buttons remain minimized until you press the **Ctrl** key again. If you move the cursor out of the active sector and move it back in, the buttons become visible.

 Select the Manage Patient icon, which will allow you to:

- Admit, discharge, and transfer patients.
- Enter or update patient demographic information.
- Manage the equipment associated with the patient.
- Temporarily place the bed in standby.
- Enter a temporary transport location, and/or select the patient's equipment to place in standby.
- Export ECG waveform data to a Philips Holter system for analysis.

To Admit a Patient: Use one of the following methods:

- Manually enter new patient information in the fields in the **Patient Demographics** section by typing a 1-30 character first and last name in the appropriate fields. You can use the TAB key to move from field to field. You can also admit a new patient by entering the MRN.
- Use the **Find Patient...** option to find a patient who is being monitored in another Information center or who has been recently discharged.

You can then choose the patient's gender from a drop-down list. It will default to Male while performing a 12-lead if not assigned. It will default to Female while measuring STE if not assigned. Specify the patients birth date by entering it on the calendar. This will update the age field. Enter the patient's height in the appropriate field. This can be in inches or centimeters according to your policy. Enter the Patient's weight using pounds or kilograms according to your policy. Select "Apply" after verifying all information is correct.

Read all confirmation messages and check patient alarms, settings, and paced status when automatic admission, discharge, or transfer is complete.

Viewing and Adjusting Waves:

When the ECG measurement is on, the first wave displayed is the primary ECG wave. The primary wave is always used for ECG analysis. A rhythm status message displays in the upper right corner of the wave, and an arrhythmia status message displays above and in the center of the wave.

Pleth waves on an Efficia monitor are labeled as SpO2.

Wave Adjustments

You can adjust waves in the patient sector or Patient Window layout by selecting a wave then selecting one or more options described below.

- Change Wave – Select a wave from the list. You cannot select the primary ECG wave.
- ECG Analysis – Available if you select an ECG wave. Select to access the ECG Analysis application.
- Primary Lead – Available if you select the primary ECG wave. Select the primary led from the list.
- Size up or Size down - Select to increase or decrease the size (gain) of the wave (if available).
- Set up ECG – Available if you select an ECG wave. Select to access the **Measurements** application ECG page, where you can change heart rate limits and asystole thresholds.

Manually Transferring a Patient to a New Bed: Transfer data for a patient by performing the following steps:

- Use one of the following methods to open the **Manage Patient** In the sector for the bed that you want to transfer, select the name field or select the **Manage Patient** shortcut button. In the application window task bar, select the **Manage Patient** button.
- Select the **..** button. The **Transfer Patient** dialog box displays a list of available beds in the institutions and units.
- To transfer this patient to another bed within this unit, select the bed from the list of beds in your unit. To transfer this patient to a bed in another unit, first select the unit name, then select a bed from the list.
- Specify whether to clear the sector (remove the bed from the sector) upon transfer by selecting or clearing the **Clear Sector** check box. The system can be configured so that the check box is selected by default. Depending on your unit practices, you may want to clear the check box so the sector is not cleared and the equipment remains assigned to the sector.
- Select "OK".
- Confirm the transfer by selecting the orange "TRANSFER" button.

To Discharge a Patient: Use one of the following methods to discharge a patient.

- Manually discharge a patient in the **Manage Patient** application.
- Discharge a patient directly from the hospital information system or bed management system.

Considerations

Before discharging a patient, note the following:

- Discharging the patient at the Information Center also discharges the patient from the bedside monitor. All monitor and MMS settings (including arrhythmia settings) reset to their defaults.
- When you discharge a patient, the Information Center saves the patient data for all admitted patients. The system stores seven days of data and purges the stored data seven days after discharge.

You can search discharged patient data without readmitting for up to seven days.

- If you readmit a patient, the discharge data is overwritten by new monitoring data as it occurs, and you will only see the full disclosure amount of data.
- Monitoring devices may be set up with predefined configurations called *profiles*. When you discharge a patient, the profile reverts to the default profile configured for the device. Refer to your monitoring device documentation for details. When

you discharge an admitted patient at the Patient Monitor, the Information Center discharges the patient and saves the data.

- *Important* — For MRx monitors, turning off the bedside monitor for more than 10 seconds discharges the patient at the MRx monitor and resets defaults, but it does not discharge the patient from the Information Center; the patient is still admitted at the Information Center. It is important to discharge the patient before turning the monitor off to avoid data being associated with the wrong patient.
- Patients that are discharged while the Information Center is in Local/Disconnected mode will be synchronized upon connection to the primary server.

Warning

Read all confirmation messages and check patient alarms, settings, and paced status when automatic admission, discharge, or transfer is complete.

Measuring ECG:

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the

Information Center as a waveform and a numeric. In order to compare measured ECG signals, the electrodes are placed in standardized positions, forming "leads". To obtain ECG signals optimized for use in diagnosis and patient management in different care environments, different lead placements can be used.

Selecting the Primary and Secondary ECG Leads

The telemetry device or patient monitor uses the primary and secondary lead selected at the

Information Center to compute HR and to analyze and detect cardiac arrhythmias.

You should choose a primary and (if using multi-lead monitoring) secondary lead that have the

following characteristics:

- the QRS complex should be either completely above or below the baseline and it should not be biphasic
- the QRS complex should be tall and narrow
- the T-wave should be less than 1/3 the R-wave height
- the P-wave should be less than 1/5 the R-wave height

Documenting Patient Events

Documentation of patient events and procedures is a necessary element of patient care. You can print reports from the PIC iX to paper, electronically via PDF, or both.

Create a Saved Strip

You can create a saved strip with the PIC iX electronic caliper (eCaliper) measurements and comments in any strip tile in Alarm Review, General Review, or specialty review applications.

Note —You must have Full Permission Access to annotate and save a strip to the database.

- Select the strip that you want to annotate.
- Select the Annotate icon. The Saved strip dialog box opens. You can move the dialog box as needed.
- Select a label from the drop-down list to add labels. This field can be customized as needed in Alarm Review.
- Enter text in the second field, up to 30 characters. This value displays in the Comment field for the strip.
- Add eCaliper measurements. Consider changing the wave speed to 50 mm/sec. (Select the speed on the bottom right of the strip, then select a speed from the list.) Click and drag in the strip to and from the desired location in the wave. The measurement is displayed between the vertical lines. In the dialog box, click the measurement label to add the measured value. *Note* — Double-click the measurement to see the caliper bars at any time.
- Select another strip and repeat these steps as needed.
- When you are done, select Save. The measurements are saved to the strip.

Reviewing ECG Waves

Depending on the number of ECG leads and licensing, 3 to 12 waves are available for review. These waves can be reviewed with the other data tiles, such as with events and alarms.

Alarms:

Quickly Viewing Target Events - When reviewing patient data, it is often helpful to quickly view specific types of alarms or events.

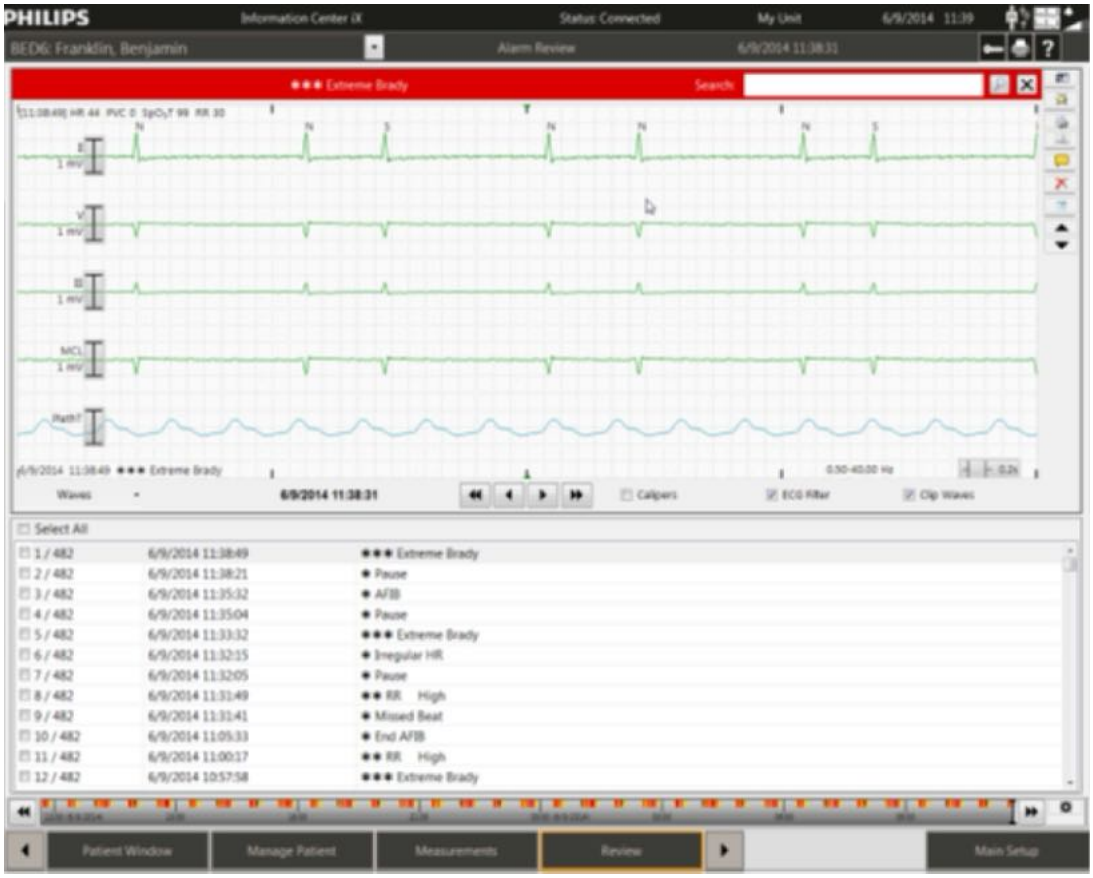
Fast Alarm Review - Select either the Acknowledge key, or the alarm banner in the sector to see alarming waves prior to being available in other applications. Alarm strips can be printed, annotated, or discarded. If you are using secondary notifications, such as with Philips CareEvent, you can manually page an alarm from this application.

Note — The Silence key is called the Acknowledge key.

Alarm Review

Alarm Review always opens with the most recent alarm strip. To review alarms, open Alarm Review from the Review sector button, if configured, or you can open Alarm Review from the main Setup menu or from the Review application menu in any open application. Use the toggle icon to switch between the three different tiles. The tile you prefer can be set up as a default on each host.

- **Tabular** tile – shows a detailed strip with multiple waves and a tabular list of alarms. Use the up and down arrow keys to quickly view alarm strips. This is the factory default tile.
- **Compressed** tile – shows 30 seconds of compressed waves for all strips.
- **Strip Window** tile – a combination of Compressed and Strip tiles.



Reviewing Alarms and Events in Other Applications

Within the factory default review applications (as well as custom applications that were created for your unit), there is a data type called the Event tile. You can use the Event tile to review alarms with other associated data, such as compressed wave storage or graphical trends. Arrhythmia events are also shown, even when a specific alarm is off, such as for yellow level ventricular alarms. The length of the colored box indicates the duration of the event.

- Open the review application. If opened from Alarm Review, the time focus is the selected alarm. If opened from another application, it opens at the current time minus the one minute for storage.
- The Event tile is highlighted below. Note the displayed number of events shown on the right. Alarms are shown with the corresponding color, and arrhythmia events are shown in cyan.



- Clear the check box next to the events you do not want to see. If licensed, specific events can be customized for each review application.
- Move the cursor over any alarm or event to see text that contains the details.
- Select the event to examine its associated waves, trends, and numerics.
- Use the arrow keys in the middle of the tile to quickly navigate to next or previous events.

 Alarms off. Displays next to the numeric when alarms are turned off for the numeric.

 Pause Alarms (Red and/or yellow). **PRESS THIS BUTTON AGAIN TO RESUME ALARMS!**

 Acknowledge/Review Button. Turns off the alarm sound and the sector background changes from blue to black.

 Volume icon. Select to adjust the alarm volume.

Physiological alarms are red and yellow alarms. A red alarm indicates a high priority patient alarm such as a potentially life-threatening situation (for example, asystole). A yellow alarm indicates a lower priority physiological alarm (for example, a respiration alarm limit violation). Additionally, there are short yellow alarms, most of which are specific to arrhythmia-related patient conditions (for example, ventricular bigeminy). Alarm message areas. All active alarms and technical alarms/INOPs display on the top right of the patient sector. A RED warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient. A YELLOW caution alerts you to where special care is necessary for the safe and effective use of the

product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury. Technical alarms, or INOPs indicate that the monitoring device cannot measure or detect alarm conditions reliably. If a technical alarm interrupts monitoring and alarm detection (for example, LEADS OFF), the numeric is replaced by a question mark in the sector and Patient Window, and an audible indicator sounds. Technical alarms without this audible indicator indicate that there may be a problem with the reliability of the data, but that monitoring is not interrupted. Most technical alarms are light blue, however there are a small number of technical alarms that are always yellow or red to indicate a severity corresponding to red and yellow alarms.

There can be only one alarm sound annunciating at the Information Center at one time.

- If there is an unacknowledged red level alarm in the presence of any other level alarm, the sound for the red alarm annunciates.
- If there is no unacknowledged red level alarm condition and there is an unacknowledged long yellow alarm in the presence of any other yellow technical alarm (acknowledged or unacknowledged) the sound for the long yellow alarm annunciates.
- If there is no unacknowledged red level alarm or long yellow level alarm condition and there is an arrhythmia or nurse call event, the short yellow (*) alarm sound annunciates.
- If there are no unacknowledged red or long/short yellow alarm conditions and there is any bed with an unacknowledged technical alarm condition, the sound for the technical alarm annunciates.
- If multiple sectors are in alarm, once the highest level alarm is acknowledged in a sector the next highest alarm annunciates.
- An alarm tone indicates the alarm type. There is no sound for soft INOPs/technical alarms.

Other Buttons and Icons:

 **Battery icon.** If there is at least one battery-operated device assigned to this patient, the battery icon indicates the device with the least amount of battery strength. Move your cursor over the icon to view a list of equipment for this patient sorted from the lowest to highest battery charge. The battery icon has five levels: approximately 100% to 80%, 80% to 60%, 60% to 40%,40% to 20%, or -Replace Battery strength. The number of segments indicates the approximate power level.

 **Help icon**. Select to view the online Help application. The Help application is always available and provides context-specific information on using the Information Center applications.

 **Manage Patient icon**. Available in sectors not currently monitoring a patient. Select the icon to access the **Manage Patient** application where you can assign a monitoring device.

The Measurements Button: Provides access to the **Measurements** application, which allows you to:

- Change alarm limits for a patient.
- Turn specific alarms on or off for a patient.
- Adjust measurement settings within a profile.
- Set up telemetry devices.
- Designate which alarms will generate a recording or report or initiate a page.
- View or print an Alarm Summary.
- Configure criteria to trigger alarm advisor notifications.
- View active notifications.

Your choices in the application depend on how your unit is set up and the equipment assigned to the patient.

Paced Mode icon. Indicates the patient's current paced status.

-  On – The icon is white when **Paced Mode** is turned on.
-  Off – The icon is green with an X over it when **Paced Mode** is turned off.
-  Unconfirmed – A red question mark displays over the icon when the patient's paced mode is unknown or in conflict.

The pacer spike color is always white unless the ECG wave is white. If the ECG wave is white, then the pacer spike color is green. Pacer spikes may be configured to display with fixed amplitude for increased visibility.

Important — If **Paced Mode** is set to **Unconfirmed**, the ST/AR algorithm acts as though **Paced mode** is turned on. Select the icon to display a menu where you can turn **Paced Mode** on or off.

Warning - If the patient has a pacemaker, **Paced Mode** must be turned on, enabling the ST/AR algorithm to detect and reject pace pulses (spikes) from the HR count. Otherwise, pace pulses could be detected as beats and the monitor may not alarm for an asystole condition. If the patient does not have a pacemaker, turn **Paced Mode** off to allow the ST/AR algorithm to work most effectively.

 **Print/record Icon**. Depending on your system setup, select this icon to do the following:

- **Record All** — make a delayed recording for all sectors that currently have patient data.
- **Print All** — print a strip for all patients in the unit.
- **Save Strips —** create saved strips for all patients in the unit.

If you select this icon, a message asks you to confirm that you want to proceed with the action. Select **Yes** to confirm. Your system may be set up to just record, record and save a strip, or to just save a delayed strip.

Resuscitation Status Icons:

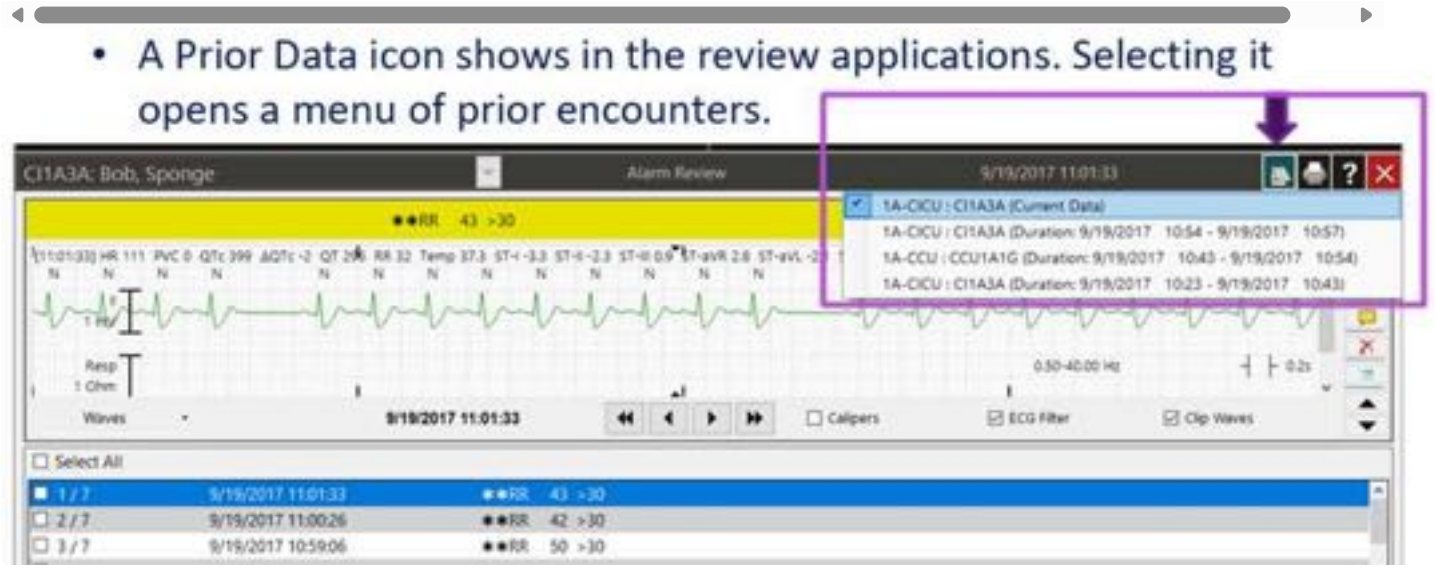
 Do Not Resuscitate. Resuscitation icon. Indicates the patient's current resuscitation status.

 Modified. The icon is solid white when the patient's resuscitation status is set to **DNR** (Do Not Resuscitate). The icon is a white outline when the patient's status is set to **Modified**. The icon does not display if the patient's resuscitation status is set to **Full**. Select the icon to access the **Manage Patient** application where you can change the resuscitation status.

<u>Prior Data:</u>

Patient data can be stored up to 7 days for each patient of Retrospective Review at Central Station. Data stored upon discharge, or from another unit with a transfer, will be shown separately from current data.

« SCROLL »



Once you are into this window –

- The Information Bar at the top turns teal green (states 'Prior Data')
- The only smart key on the bottom task bar will be 'Review'
- Main Screen button becomes 'Current Unit'
- To close the application, use the red X in the upper right or choose the Current Unit button

« SCROLL »



References:

- MX Series QR Codes
- Central Monitoring Station PICiX
  - IFU_-_PIC_iX_Rel_C.03_-_English.pdf- Central station user manual
  - PIICiX Rev C.03 Patient Data Review
- MX40 Telemetry box
  - the MX40 IFU manual link
  - the MX40 quick card reference
- MX400 Large Mounted Monitor
  - IFU MX400-800_IVPM_N0x)Mar2019.pdf User manual
- Invasive pressure Guide
  - Invasive Pressure PDF
- Capnography
  - Capnography Application Guide

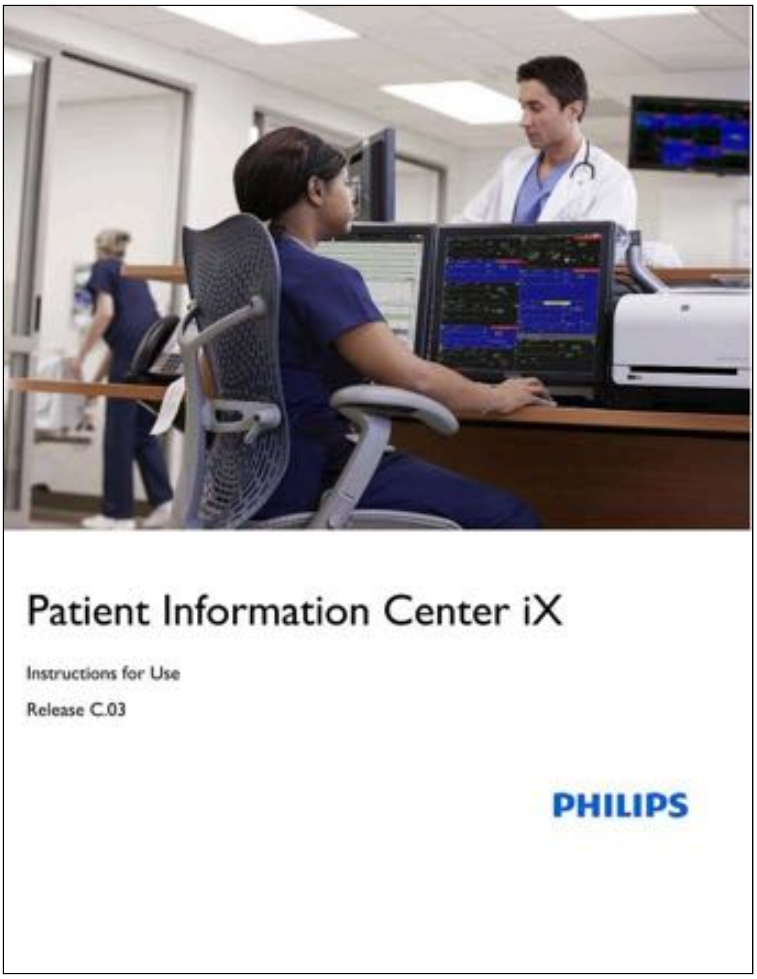
Notes

MX Series QR Codes



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Philips Monitoring System Manual



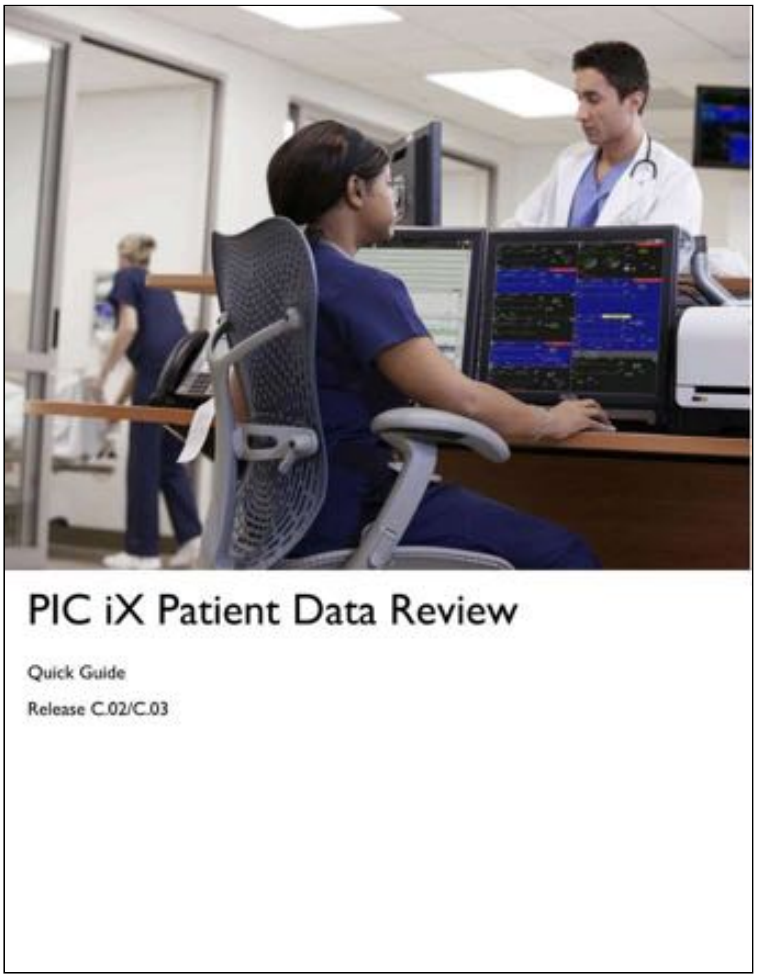
Patient Information Center iX

Instructions for Use

Release C.03

PHILIPS

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Car Seat Quick Guide

Car Seat Assessment Record (CAR)
Quick Guide

1. Place baby in car seat.
2. Change Screen to **CAR SEAT TEST.**



3. Touch SmartKey – **START CAR.**
4. Select amount of time for Test Duration *(based on hospital protocol)*



5. Touch **CONFIRM** key.

*****CAR is now in progress*****
Monitoring is continued during CAR.

6. If at any time during CAR you need to exit or stop – press the SmartKey **STOP CAR** and **CONFIRM**.

   At any time you can also switch back to your default monitoring screen by touching **Change Screen**, then touch the back arrow at the top of that menu. *CAR will continue to run in the back ground.*

7. When CAR is complete, the countdown timer (to the far right in the CAR Screen) will turn **RED**.



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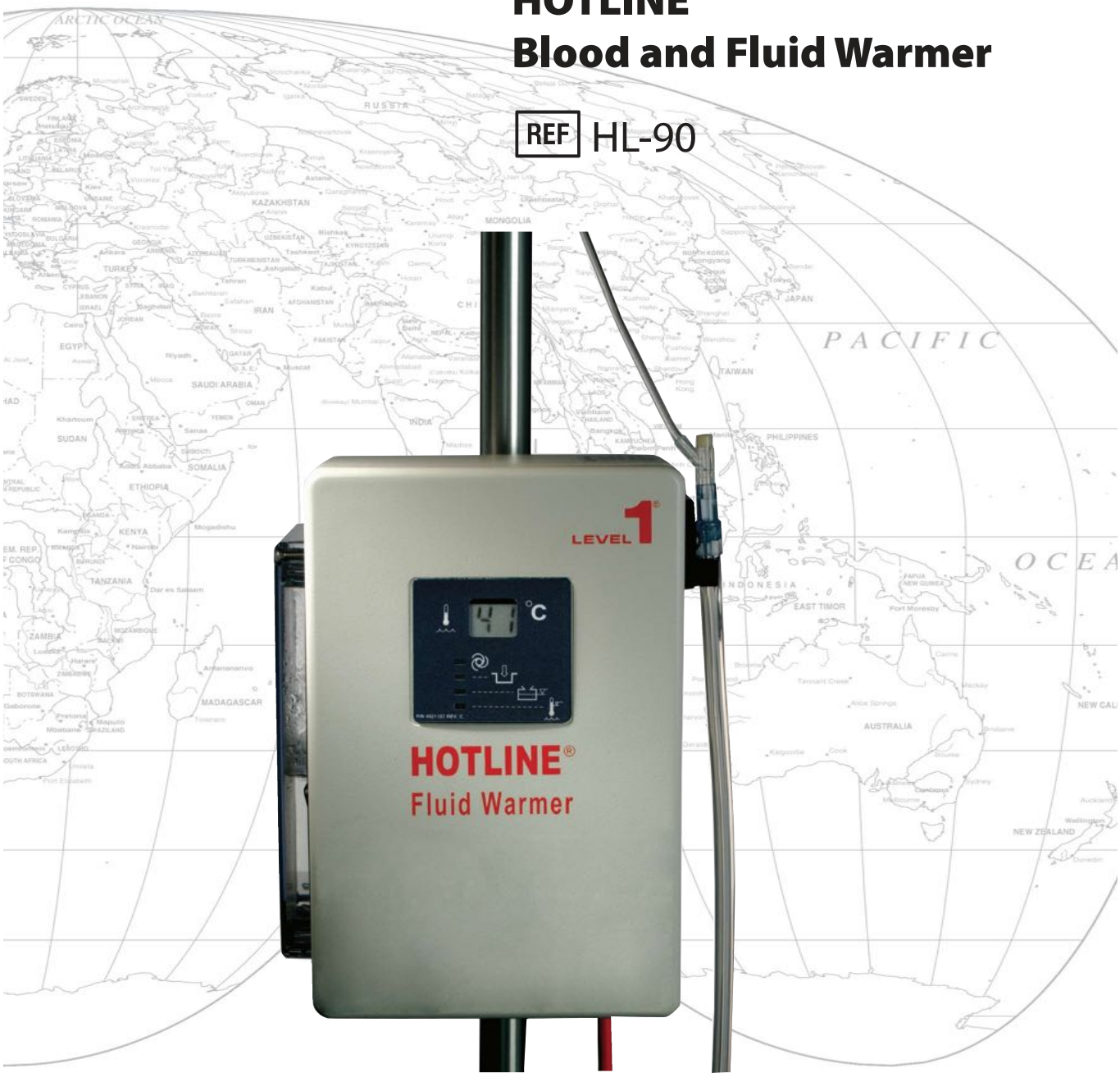
LEVEL 1®

OPERATOR'S MANUAL

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HOTLINE®
Blood and Fluid Warmer

REF HL-90



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LEVEL 1®

HOTLINE®
Blood and Fluid Warmer

REF HL-90`

OPERATOR'S MANUAL

PN 10011022-003

smiths medical

HOTLINE® Blood and Fluid Warmer

Part Number: 10011022-003

This revision supercedes all previous revisions.

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SECTION 1

About this Manual

This operator's manual describes the assembly, use, and maintenance of the HOTLINE® Blood and Fluid Warmer. This manual is intended for use by individuals trained in the healthcare and biomedical professions.

WARNING: These instructions contain important information for safe use of the product. Read the entire contents of this operator's manual, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.

Indications for Use

The HOTLINE® Blood and Fluid Warmer is designed for use with the HOTLINE® Fluid Warming Set to warm blood and intravenous (I.V.) fluids and deliver them to the patient's intravenous access site at normothermic temperatures under gravity flow conditions. The HOTLINE® Warmer is intended for use by trained medical personnel to provide routine flow of warmed I.V. fluid.

Conventions Used in this Manual

- The HOTLINE® Blood and Fluid Warmer will be referred to as the HOTLINE® Warmer.
- The L Series Fluid Warming Sets (L-70, L-70NI, L-80) will be referred to as the HOTLINE® Fluid Warming Set or Disposable Set.

Convention	Description
CONTRAINDICATION	A Contraindication statement alerts the operator to conditions when the device should not be used.
CAUTION	A Caution statement alerts the operator to conditions that may cause malfunction, failure, or damage to the device.
WARNING	A Warning statement alerts the operator to conditions that may cause death or serious injury to the patient or operator.

SECTION 2

Description

The HOTLINE® Warmer delivers blood and intravenous fluid at normothermic temperatures by surrounding the sterile intravenous line with a layer of warmed recirculating solution. An onboard recirculating solution supply is heated to 41.5°C ± 0.5 and circulated through the outer lumen of the HOTLINE® Fluid Warming Set, which surrounds the intravenous line.

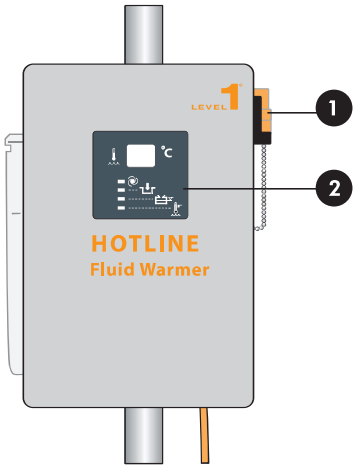
The HOTLINE® Warmer employs a safe, recirculating solution heating system, inherently free of "hot spots," to actively warm the patient line. Electronic circuitry continuously monitors the recirculating solution temperature. The primary temperature control circuit limits the recirculating solution to 42°C maximum. In the unlikely event of a malfunction of this circuit, a second "watchdog" circuit will visually and audibly alarm and stop the recirculating solution pump if the temperature reaches 43.1°C. Fluid in the HOTLINE® Fluid Warming Set is never exposed to any damaging or dangerous temperatures while the HOTLINE® Warmer is operating.

The recirculating solution temperature and visual alarms are indicated on the Display Panel on the front of the HOTLINE® Warmer. A green Operating light illuminates on this panel when the HOTLINE® Warmer is set up and operating correctly.

Components

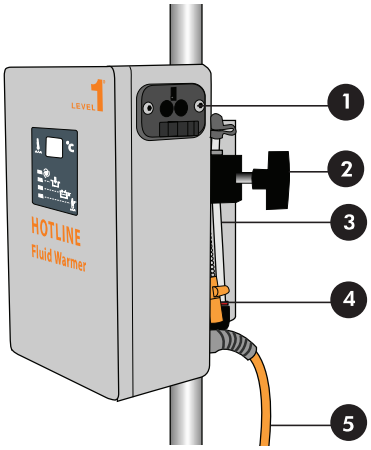
The HOTLINE® components are called-out in the following series of figures.

Front View



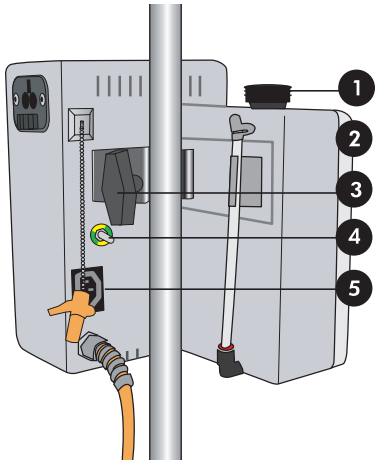
1 Socket for HOTLINE® Fluid Warming Set with the reflux plug in place

2 Display Panel



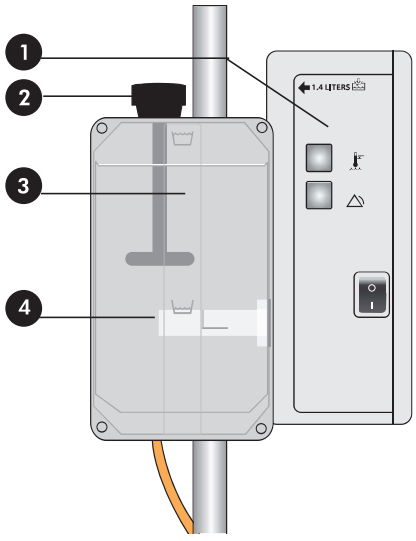
Right Side View

1. Socket with the reflux plug removed
2. Clamp for I.V. pole
3. Drain tube in tube holder
4. Reflux plug
5. Power cord



Rear View

1. Fill-port plug
2. Drain tube in tube holder
3. Clamp for I.V. pole
4. Protective earth terminal
5. Auxiliary electrical outlet (uncovered)



Left Side View

1. Power and Alarm Test Panel
2. Fill-port plug
3. Reservoir, contains recirculating solution
4. Float switch (inside reservoir)

HOTLINE® Fluid Warming Set

HOTLINE® Fluid Warming Sets (L-70, L-70NI, L-80) are individually packed, single-use disposables with a Sterile Fluid Path. The priming volume is 20 ml for the L-70 and L-70NI, and 21 ml for the L-80. The HOTLINE® Fluid Warming Set has a Twin-Tube Connector that plugs into the socket on the right side of the HOTLINE® Warmer. This is the only connection necessary to provide the warming function. The HOTLINE® Fluid Warming Set is easily unplugged from the HOTLINE® Warmer and discarded.

SECTION 3

Important Safety Information

This section covers information for prescribers and guidelines for safe use of the HOTLINE® Warmer.

CONTRAINDICATION

Not for use in warming platelets, cryo-precipitates, or granulocyte suspensions.

WARNINGS

Death or serious injury may occur to the patient or operator if these warnings are not followed.

- **These instructions contain important information for safe use of the product. Read the entire contents of this operator's manual, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.**
- **The HOTLINE® Fluid Warming Set, L-10, PC-8, and YC-8 are single-use devices and are not intended for re-sterilization.**
- **Do not use HOTLINE® Fluid Warming Set, L-10, PC-8, and YC-8 if the caps are not securely in place, else the I.V. flow path may not be sterile.**
- **The HOTLINE® Warmer is for use only with Smiths Medical supplied or approved parts, accessories, and Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, or Disposable Sets.**
- **Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens.**
- **Set-up, priming, and use require aseptic technique as per applicable institutional policies and procedures.**

WARNINGS *[continued]*

- **Prime the recirculating solution path before connecting to the intravenous extension set. This is to confirm that there is not a breach between the recirculating solution path and intravenouspath. If fluid exits the patient end of the HOTLINE® Fluid Warming Set before connecting to the intravenous administration set, remove and replace HOTLINE® Fluid Warming Set.**

- **Remove all air from the HOTLINE® Fluid Warming Set, L-10, PC-8, and YC-8 before connecting to the patient. Failure to do so may result in introduction of air to the patient.**

- **To reduce the risk of outgassed microbubbles entering patient vasculature, an L-10 Gas Vent may be used with the HOTLINE® Fluid Warming Set.**

- **Not for use with pressure devices generating over 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of the HOTLINE® Fluid Warming Set.**

- **To prevent a breach between the recirculating solution path and intravenous path, do not use needles greater than 38 mm (1.5") in length when accessing the injection port. If there is a breach between the recirculating solution path and intravenous path, patient illness may occur because of the HOTLINE® Warmer's recirculating solution entering the patient's bloodstream.**

- **Do not stick the HOTLINE® Fluid Warming Set with needles, as this will breach the I.V. path and compromise the integrity of the patient intravenous line. If a Disposable Set with a breached recirculating solution path/intravenous path is used, then patient illness may occur because of the HOTLINE® Warmer's recirculating solution entering the patient's bloodstream.**

- **Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required to clear the over temperature condition or to remove the device from service.**

- **If any visual indicator does not illuminate or the audible signal does not sound, do not use the HOTLINE® Warmer. Remove the device from service immediately.**

- **Do not operate the HOTLINE® Warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The risk of explosion exists if the HOTLINE® Warmer is operated in a potentially explosive environment.**

WARNINGS *[continued]*

- **Do not use the HOTLINE® Warmer in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The HOTLINE® Warmer may act as a projectile in a strong magnetic field, cause image artifacts, or not function as intended.**
- **Exposed conductor on MAINS power cord can cause an electrocution hazard. Remove device from service if the MAINS power cord has exposed wires.**
- **Grounding reliability can only be achieved when the MAINS power cord is connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.**
- **Do not mount the HOTLINE® Warmer more than 107 cm (42") above the floor. For convenience, 107 cm (42") is indicated on the HOTLINE® Warmer power cord by a black mark. Mounting the HOTLINE® Warmer above 107 cm (42") may result in instability of the pole and tipping.**
- **Ensure that the HOTLINE® Warmer clamp is screwed tightly onto the I.V. pole. Failure to securely mount the HOTLINE® Warmer onto the I.V. pole may cause the HOTLINE® Warmer to slide down the I.V. pole.**
- **Do not use the HOTLINE® Warmer if equipment or Disposable Set malfunction is evident.**
- **No operator-serviceable parts. All service must be performed bySmiths Medical or competent personnel.**
- **No modification of this equipment is allowed.**
- **The HOTLINE® Warmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you should verify normal operation of the HOTLINE® Warmer in the configuration in which it is to be used.**
- **Common portable and mobile consumer electronic devices may cause interference with the HOTLINE® Warmer. Observe the HOTLINE® Warmer to verify normal operation.**
- **Facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord.**

CAUTIONS

Malfunction, failure, or damage to the device may occur if these cautions are not followed.

- **Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.**
- **Do not autoclave or immerse any part of the HOTLINE® Warmer in liquids, which may cause damage and improper functioning.**
- **Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the HOTLINE® Warmer.**
- **Do not place the HOTLINE® Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the HOTLINE® Warmer or into the external connectors.**
- **This device is cooled by convection. Be sure the air vents on the bottom and the back of the device are kept clear.**
- **Do not fill the HOTLINE® Warmer reservoir with a HOTLINE® Fluid Warming Set in place. Failure to remove the HOTLINE® Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE® Warmer.**
- **Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.**

Additional WARNINGS and CAUTIONS for Accessories

WARNINGS for the L-10 Gas Vent and L-80 Fluid Warming Set

- Do not tape over vents, else air will not be vented.
- Not for use with volumetric infusion pumps, hand pumps, or syringes. These may compromise the integrity of the L-10 Gas Vent or HOTLINE® Fluid Warming Set.
- When the L-10 Gas Vent is in use, it should be placed at or below the heart level. Do not raise the gas vent above the patient's heart level. If the gas vent is raised above heart level, air may be entrained into the infusion line, possibly causing air embolism, resulting in serious injury or death.

CAUTIONS for the L-10 Gas Vent and L-80 Fluid Warming Set

- This product contains natural rubber latex, which may cause allergic reactions.

SECTION 4

Assembly Instructions

Read through the instructions completely prior to setting up the HOTLINE® Warmer.

Step 1 - Unpack the HOTLINE® Warmer

1. Open the shipping carton and remove the HOTLINE® Warmer.
2. Check the contents of the package to verify the following components are present:
   - HOTLINE® Warmer
   - Operator's Manual
   - HOTLINE® Inspection/Test Form
3. Examine the HOTLINE® Warmer for damage. If any components appear damaged, do not use the HOTLINE® Warmer. Contact Smiths Medical for a replacement.

Note: *After unpacking the HOTLINE® Warmer, recycle packaging material according to hospital policy for recyclable materials.*

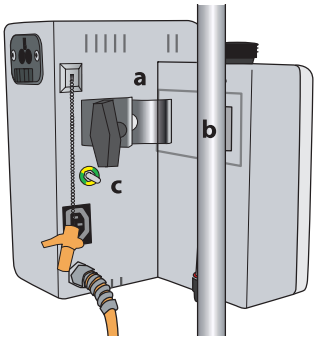
Step 2 - Clamp the HOTLINE® Warmer to the I.V. Pole

WARNINGS

- **Ensure that the HOTLINE® Warmer pole clamp is screwed tightly onto the I.V. pole. Failure to securely mount the HOTLINE® Warmer onto the I.V. pole may cause the HOTLINE® Warmer to slide down the pole and may injure the patient or operator.**
- **Do not mount the HOTLINE® Warmer more than 107 cm (42") above the floor. For convenience, 107 cm (42") is indicated on the HOTLINE® Warmer line cord by a black mark. Mounting the HOTLINE® Warmer above 107 cm (42") may result in instability of the pole and tipping that may injure the patient or operator.**

CAUTION

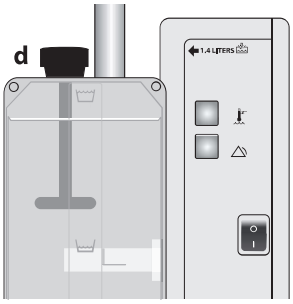
This device is cooled by convection. Be sure the air vents on the bottom and the back of the device are kept clear.



1 Slide the clamp **(a)** on the HOTLINE® Warmer over the I.V. pole **(b)** and tighten the clamp screw **(c)** firmly.

2 Check the tightness of the HOTLINE® Warmer to ensure it is securely clamped to the pole.

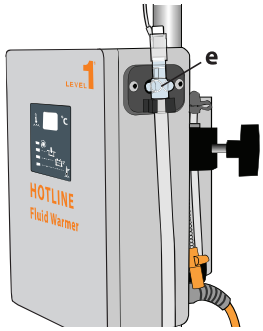
Step 3 - Disinfect the Reservoir



1 Prepare a 0.3% hydrogen peroxide solution by mixing 140 ml of 3% hydrogen peroxide solution and 1,260 ml of distilled water.

2 Remove the reflux plug from the socket if required, and then remove the fill-port plug **(d)** and fill the reservoir with 1.4 liters of 0.3% hydrogen peroxide solution.

3 Replace the fill-port plug **(d)**.

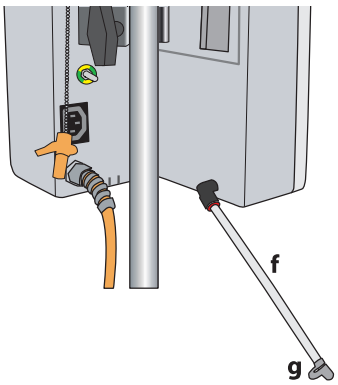


4 Insert a HOTLINE® Fluid Warming Set **(e)** (L-70, L-70 NI, L-80) into the socket.

5 Plug the HOTLINE® Warmer into properly grounded power outlet.

6 Turn the HOTLINE® Warmer ON and let the solution circulate for a 30-minute disinfection period.

7 Turn the HOTLINE® Warmer OFF.



8 Invert the drain tube **(f)** and place a container under the end of the tube. Remove the end cap **(g)** and drain the recirculating solution into the container.

9 When all the recirculating solution has drained from the reservoir, replace the end cap and insert the drain tube back in the holder.

10 Remove the HOTLINE® Fluid Warming Set and discard according to established hospital procedures.

Step 4 - Fill the Reservoir With Recirculating Solution

WARNING

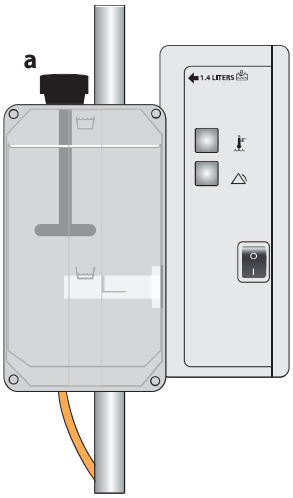
Do not fill the HOTLINE® Warmer reservoir with a HOTLINE® Fluid Warming Set in place. Failure to remove the HOTLINE® Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE® Warmer.

Recirculating Solution Protocols

Use one of the following solutions for the reservoir.

Recirculating Solution	Preparation	Maintenance
0.3% Hydrogen Peroxide Solution	Mix 140 ml of 3% hydrogen peroxide with 1,260 ml of distilled water.	Replace solution and disinfect reservoir every 12 months.
Distilled Water	Use distilled water.	Replace solution and disinfect reservoir every 30 days.
35% Isopropyl Alcohol Solution	Mix 700 ml of 70% isopropyl alcohol with 700 ml of distilled water.	Replace solution and disinfect reservoir every 30 days.

Note: *Use distilled water only, not tap water. Failure to do so may cause build-up of mineral deposits in the recirculating solution path, which may impair heater performance.*



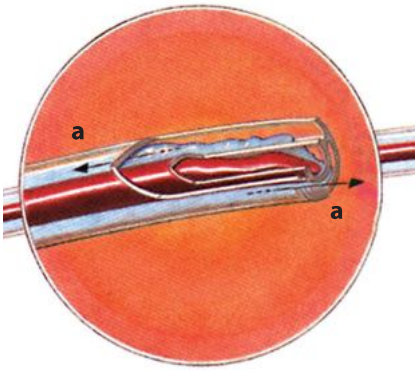
1. Prepare the recirculating solution.
2. Remove the fill-port plug **(a)**.
3. Fill the reservoir with 1.4 liters of recirculating solution.
4. Replace the fill-port plug.

Step 5 - Perform the Electrical Safety Tests

Perform all applicable electrical safety tests as required per institutional procedure. Refer to Section 9, *"Testing"*, for more information about electrical safety testing.

SECTION 5

Principle of Operation



HOTLINE® Warmer delivers blood and intravenous fluid at normothermic temperatures under routine, gravity flow rates. Conventional fluid warming systems suffer from cool-down between the warmer and the patient connection. HOTLINE® Warmer overcomes this problem by providing active warming of the patient line all the way to the patient connection.

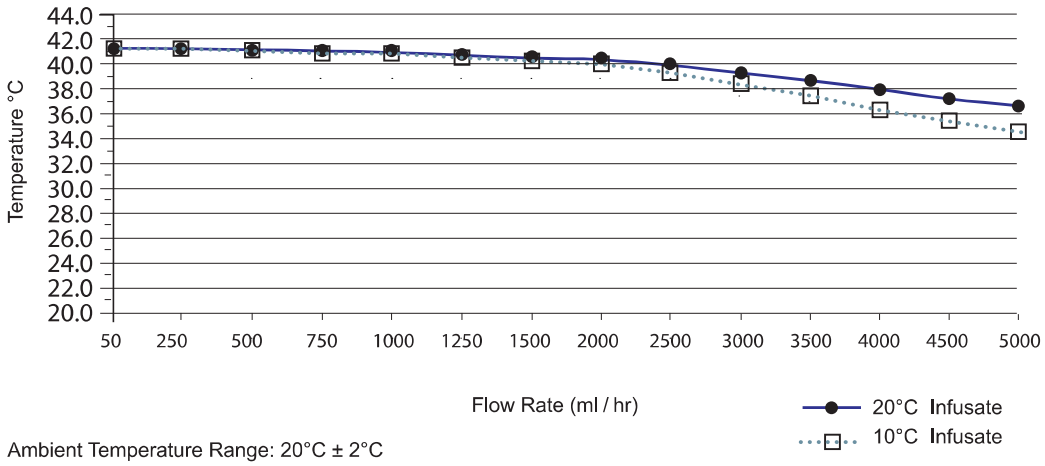
Active warming is achieved by surrounding the sterile intravenous line with a layer of precisely controlled warm recirculating solution **(a)**, thereby protecting the patient line against exposure to cold and eliminating patient line cool-down.

The unique design of the HOTLINE® Fluid Warming Set allows blood and intravenous fluid to be delivered to the patient at normothermic temperature at gravity flow rates to 50-5,000 ml/hr.

Infusate Delivery Temperatures

The following table shows the typical infusate delivery temperatures at the patient end of an L-70 HOTLINE® Fluid Warming Set.

Note: *The setpoint temperature of the recirculating solution is 41.9°C.*



Ambient Temperature Range: 20°C ± 2°C

SECTION 6

Operation

This section describes the controls and displays that monitor and control the HOTLINE® Warmer, and the modes of operation.

Controls and Displays

- Display Panel
- Power and Alarm Test Buttons
- Reservoir Level Display

Display Panel

The Display Panel is located on the front of the HOTLINE® Warmer and provides continuous information about the operation of the HOTLINE® Warmer. A liquid crystal display (LCD) indicates recirculating solution temperature. Just below the LCD, four light-emitting diodes (LEDs) indicate operation modes for the HOTLINE® Warmer.

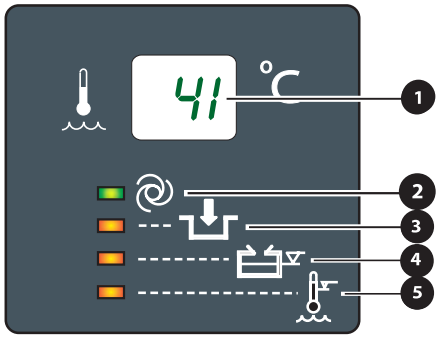
1 **Recirculating Solution Temperature -** The temperature is displayed in degrees Celsius.

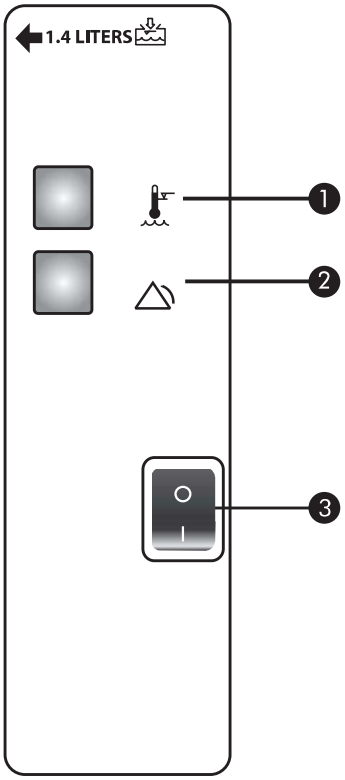
2 **ON/Operation -** The green LED illuminates when the power is turned on and the HOTLINE® Fluid Warming set is properly installed.

3 **Check Disposables -** The red LED illuminates and an audible attention signal beeps when the HOTLINE® Fluid Warming Set is not properly installed.

4 **Add Recirculating Solution -** The red LED illuminates and an audible attention signal beeps when the level in the reservoir is low and additional recirculating solution must be added.

5 **Over Temperature -** The red LED illuminates and an audible warning signal beeps when the recirculating solution is over the acceptable temperature for safe use.





Power and Alarm Test Panel

The Power and Alarm Test Panel is located on the left side of the HOTLINE® Warmer next to the reservoir. This panel contains two pressure-sensitive buttons that are activated when pressed, and the ON/OFF switch.

1 **Over Temperature Alarm Test Button -** The Over Temperature Alarm Test is used to confirm the proper operation of the Over Temperature circuitry.

2 **Alarm Test Button -** The Alarm Signal Test is used to confirm proper operation of the visual and audible alarms.

3 **Power ON/OFF Switch -** The black switch toggles to turn power ON and OFF.



Reservoir Level Display

The reservoir for the recirculating solution is located on the left side of the HOTLINE® Warmer, next to the Power and Alarm Test Panel. The level of the recirculating solution is visible in the reservoir. Two symbols indicate the maximum **(a)** and minimum **(b)** solution level requirements.

Modes of Operation

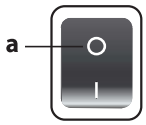
The HOTLINE® Warmer operation is defined in the following modes:

- OFF Mode
- ON/Operating Mode
- Check Disposables Mode
- Add Recirculating Solution Mode
- Over Temperature Alarm Mode

The description of each mode includes a definition of the mode, activation and/or monitoring of the mode, mode characteristics, and method to clear the mode state.

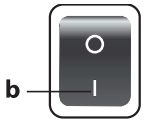
OFF Mode

The power switch is in the OFF position **(a)** and the HOTLINE® Warmer is turned off.



ON/Operating Mode

The power switch is in the ON position **(b)** and the HOTLINE® Fluid Warming Set has been properly installed.



Mode characteristics

- The green Operating LED **(c)** illuminates.
- The reservoir temperature display will begin to increase.
- The recirculating solution path in the HOTLINE® Fluid Warming Set will automatically prime.



Check Disposables Mode

The Check Disposables mode indicates a missing or improperly installed HOTLINE® Fluid Warming Set.

Mode characteristics

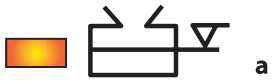
- The green Operating LED on the Display Panel turns off.
- The red Check Disposables LED **(d)** on the Display Panel illuminates.
- The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
- The recirculating solution stops circulating.



To clear this mode, check that the Twin-Tube Connector on the HOTLINE® Fluid Warming Set is firmly inserted in the socket.

Add Recirculating Solution Mode

The Add Recirculating Solution mode indicates that the solution level in the reservoir is below its minimum level.



Mode characteristics

- The green Operating LED on the Display Panel turns off.
- The red Add Solution LED **(a)** on the Display Panel illuminates.
- The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
- The recirculating solution stops circulating.

To clear this mode, add recirculating solution to the reservoir.

Over Temperature Alarm Mode

The Over Temperature Alarm mode indicates that the temperature of the recirculating solution is at or above 43.1°C.



Mode characteristics

- The green Operating LED on the Display Panel turns off.
- The red Over Temperature LED **(b)** on the Display Panel illuminates.
- The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
- The recirculating solution stops circulating.

For instructions to clear this mode, see Section 8, *"Troubleshooting"*.

SECTION 7

Operating Instructions

The Operating Instructions are grouped into five segments. Read through each segment BEFORE performing a procedure.

WARNINGS

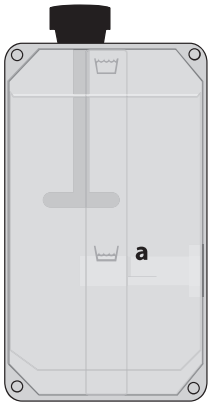
- **Set-up, priming, and use require aseptic technique as per applicable institutional policies and procedures. Death or serious injury may occur to the patient or operator if this warning is not followed.**
- **Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.**
- **Do not fill the HOTLINE® reservoir with a HOTLINE® Fluid Warming Set in place. Failure to remove the HOTLINE® Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE® Warmer.**

Step 1 - Set Up the HOTLINE® Warmer

1 Check that the level is above the minimum level mark **(a)** on the reservoir. Add recirculating solution to the reservoir through the fill-port if required.

2 Check the condition of the HOTLINE® Warmer with a visual inspection before using. Remove from service any HOTLINE® Warmer that shows physical damage.

3 Plug the HOTLINE® Warmer into properly grounded power outlet.



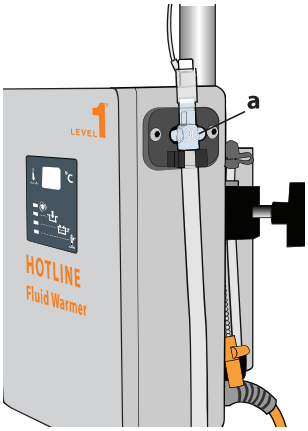
Step 2 - Set Up the HOTLINE® Fluid Warming Set

WARNINGS

- **The HOTLINE® Fluid Warming Set is a single-use device and is not intended for re-sterilization. Death or serious injury may occur to the patient or operator if this warning is not followed.**
- **Do not use HOTLINE® Fluid Warming Set, L-10, PC-8, and YC-8 if the caps are not securely in place, else flow path may not be sterile and may cause death or serious injury.**
- **Prime the recirculating solution path before connecting to the intravenous extension set. This is to confirm that there is not a breach between the recirculating solution path and intravenous path. If fluid exits the patient end of the HOTLINE® Fluid Warming Set before connecting to the intravenous extension set, remove and replace HOTLINE® Fluid Warming Set. Death or serious injury may occur to the patient or operator if this warning is not followed.**

To set up the HOTLINE® Fluid Warming Set, you will need the following:

- HOTLINE® Warmer
- Intravenous administration set
- Intravenous fluid or blood
- Extension Set, 20 cm (8") or less in length (optional)



1. Remove the reflux plug (if present) from the socket on the right side of the HOTLINE® Warmer.
2. Plug the Twin-Tube Connector on the HOTLINE® Fluid Warming Set **(a)** into the socket.
3. Turn ON the power switch.
   - The green Operating LED on the Display Panel illuminates.
   - The recirculating solution temperature display will begin to increase.
   - The recirculating solution path in the HOTLINE® Fluid Warming Set will automatically prime.
4. Remove the end cap and inspect the patient end of the HOTLINE® Fluid Warming Set for leaks to confirm the integrity of the intravenous pathway.

Step 3 - Connect the Intravenous Administration Set

WARNINGS

- **Remove all air from the HOTLINE® Fluid Warming Set, L-10, PC-8, and YC-8 before connecting to the patient. Failure to do so may result in introduction of air to the patient, which may contribute to serious patient injury or death.**

- **To prevent a breach between the recirculating solution path and intravenous path, do not use needles greater than 38 mm (1.5") in length when accessing the injection port. If there is a breach between the recirculating solution path and intravenous path, patient illness may occur because of the HOTLINE® Warmer's recirculating solution entering the patient's bloodstream.**

- **Do not stick the HOTLINE® Fluid Warming Set with needles, as this will breach the I.V. path and compromise the integrity of the patient intravenous line. If a Disposable Set with a breached recirculating solution path/intravenous path is used, then patient illness may occur because of the HOTLINE® Warmer's recirculating solution entering the patient's blood stream.**

1. Connect the I.V. fluid and the intravenous administration set to the HOTLINE® Fluid Warming Set.
2. Fully prime the intravenous administration set, the HOTLINE® Fluid Warming Set, and patient extension set (if used).
3. Connect the distal end of the HOTLINE® Fluid Warming Set to the patient's intravenous access site without entrapping air.

Step 4 - Using the HOTLINE® Warmer

WARNINGS

- **Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required to clear the over temperature condition or to remove the device from service. Death or serious injury may occur to the patient or operator if this warning is not followed.**

- **If any visual indicator does not illuminate or the audible signal does not sound, do not use the HOTLINE® Warmer. Remove the device from service immediately. Death or serious injury may occur to the patient or operator if this warning is not followed.**

WARNINGS *[continued]*

- **Not for use with pressure devices generating over 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of the HOTLINE® Fluid Warming Set.**

1 Wait until the recirculating solution temperature display reaches 41°C, which indicates the HOTLINE® Warmer is ready for use.

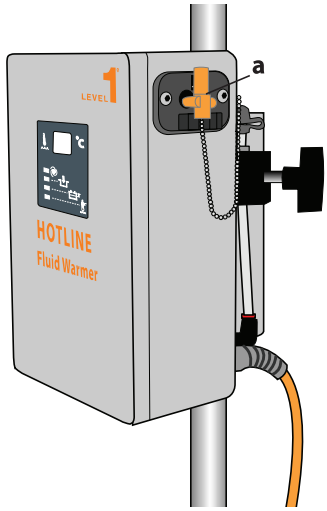
2 Adjust the rate of I.V. flow using the clamp on the intravenous administration set.

Note: *Do not kink the Disposable Set. Do not restrict the circulation of the solution through the tubing.*

Step 5 - After Use

WARNING

Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens.



1 Turn OFF the power switch.

2 Remove the HOTLINE® Fluid Warming Set, and insert the reflux plug **(a)** into the socket.

3 After use, handle and dispose of the HOTLINE® Fluid Warming Set in a safe manner according to local guidelines for disposal of contaminated medical waste.

4 Wipe down the external surfaces of the HOTLINE® Warmer with mild liquid detergent soap and warm tap water mixture and a soft cloth or sponge. See Section 10, *"Maintenance"*, for more details about cleaning and external disinfection.

Storage

Store the HOTLINE® Warmer in a cool, dry place. Do not expose to extreme temperatures. See Section 13, *"Specifications and Accessories"*, for more details.

SECTION 8

Troubleshooting

Only competent personnel should perform any routine maintenance and repairs to the HOTLINE® Warmer.

Problem	Check the following
No power	1 Confirm that the HOTLINE® Warmer is plugged in properly. 2 Confirm that the power switch is in the ON position. **Note:** *If the HOTLINE® Warmer is plugged in and the power switch is turned ON, the green or red LED will illuminate.*
Check Disposables alarm	Confirm that the HOTLINE® Fluid Warming Set is properly installed. 1 Push the Twin-Tube Connector firmly into the socket on the right side of the HOTLINE® Warmer. **Note:** *Turn OFF the power switch before replacing the HOTLINE® Fluid Warming Set.* 2 If the alarm is not cleared, replace the HOTLINE® Fluid Warming Set. Turn ON the power switch and verify that the alarm has cleared. 3 If the alarm is not cleared, remove the HOTLINE® Warmer from service.
Add Recirculating Solution alarm	Check the level in the reservoir • Turn OFF the power switch, remove the HOTLINE® Fluid Warming Set if installed, and add recirculating solution to the maximum level.
Over Temperature alarm	1 Check the HOTLINE® Fluid Warming Set for kinks or other restrictions. 2 Check for air lock: a Turn the power switch OFF, remove the HOTLINE® Fluid Warming Set, and gently shake HOTLINE® Warmer to dislodge air. b Plug in the HOTLINE® Fluid Warming Set and turn power switch ON. c If the alarm is not cleared, remove the HOTLINE® Warmer from service and return it for repair or replacement.
Hot cabinet	Check for blocked air vents on the bottom or the back of the HOTLINE® Warmer. **Note:** *Room temperature above 42°C may cause the HOTLINE® Warmer to shut down and the Over Temperature alarm to activate. In this situation, turn the power switch OFF and allow the HOTLINE® Warmer to cool down before returning it to service.*

Problem	Check the following
Difficult to install the HOTLINE® Fluid Warming Set	Lubricate O-rings in the socket. Refer to Section 10, *"Maintenance"*, for the procedure.
Recirculating solution leaks at the socket where the HOTLINE® Fluid Warming Set plugs into the HOTLINE® Warmer	Replace O-rings. Use the O-ring Replacement Kit: P/N 80-04-001. Refer to Section 10, *"Maintenance"*, for the procedure.
Electrical interference - receiving or transmitting	1 Move the HOTLINE® Warmer away from the device in question. 2 Plug the HOTLINE® Warmer into a separate electrical circuit. • If the problem continues, notify Smiths Medical or your local Smiths Medical distributor.

SECTION 9

Testing

The HOTLINE® Warmer should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by competent personnel. If competent personnel are not available, contact Smiths Medical or your local Smiths Medical distributor.

If the HOTLINE® Warmer and any installed accessories do not pass any of the listed tests, discontinue use of the HOTLINE® Warmer and remove from service. Contact Smiths Medical or your local Smiths Medical distributor.

WARNING

If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Death or serious injury may occur to the patient or operator if this warning is not followed.

Note: *Alarm testing requires a HOTLINE® Fluid Warming Set to be installed and that the HOTLINE® Warmer be turned ON and in the Operating mode.*

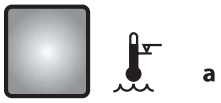
Alarm Signal Test

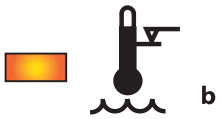
The Alarm Signal Test is used to confirm proper operation of the visual and audible alarm indicators.



1. Press and hold the Alarm Test button **(a)**.
2. Observe the following:
   - The green Operating LED turns off.
   - Three red LEDs (Check Disposables, Add Solution, and Over Temperature) illuminate.
   - The audible alarm sounds (54-59dB) and repeats approximately every two seconds.

Over Temperature Alarm Test



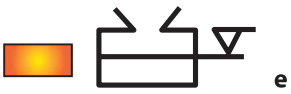


The HOTLINE® Warmer should be running at an operating temperature of approximately 41°C to 42°C.

1. Press and hold the Over Temperature Alarm Test button **(a)**.
2. Observe the following:
   - The recirculating solution Over Temperature Alarm activates at 43°C.
   - The green Operating LED turns off.
   - The red Over Temperature LED **(b)** illuminates.
   - The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
3. Stop pressing the Over Temperature Alarm Test button to stop the test.

Add Recirculating Solution Test



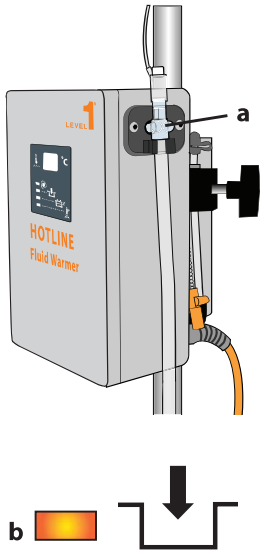


The HOTLINE® Warmer is equipped with a float switch, which senses the recirculating solution level in the reservoir. When the recirculating solution is too low, the Add Recirculating Solution Alarm will activate.

1. Remove the fill-port plug **(c)** on the reservoir.
2. Gently depress the float switch **(d)**. (This action will simulate the low solution condition.)

   Note: *Use a non-metal tool to depress the float switch because the float switch contains a magnet.*
3. Observe the following:
   - The green Operating LED turns off.
   - The red Add Recirculating Solution LED **(e)** illuminates.
   - The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.

Check Disposables Test

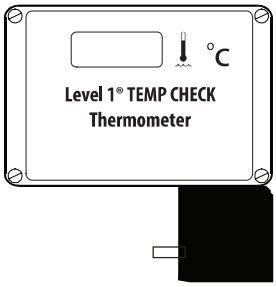


An interlock switch/sensor, located in the socket on the right side of the HOTLINE® Warmer, senses a properly installed HOTLINE® Fluid Warming Set. When the switch does not sense a HOTLINE® Fluid Warming Set, the Check Disposables alarm activates.

1. Slowly remove the HOTLINE® Fluid Warming Set **(a)** from the HOTLINE® Warmer socket.
2. Observe the following actions:
   - The green Operating LED turns off.
   - The red Check Disposables LED **(b)** illuminates.
   - The audible alarm sounds (54-59dB) and repeats approximately every two seconds.

Note: *In any alarm condition, the pump should not be running. A small amount of solution dripping from the disconnection is normal and should stop in a few seconds.*

Temperature Verification of the Recirculating Solution



Use the Level 1® TEMP CHECK Thermometer (HLTA-40) to verify the displayed recirculating solution temperature. Other methods of temperature verification may be inaccurate.

TEMP CHECK provides an accurate reading of the highest temperature of the recirculating solution. Because the temperature of the reservoir is typically 0.5°C to 2.0°C lower than the temperature from the heater, and the temperature of the recirculating solution begins to drop due to the effect of ambient temperature on the HOTLINE® Fluid Warming Set, the highest temperature of the solution is just after it leaves the heater. During the temperature verification test, the TEMP CHECK is positioned on the right side of the HOTLINE® Warmer attached to the socket and senses the solution just after it leaves the heater and before it enters the HOTLINE® Fluid Warming Set.

Refer to the TEMP CHECK HLTA-40 Thermometer Operator's Manual for complete Temperature Verification and Calibration Instructions.

To verify the recirculating solution temperature, you will need the following:

- TEMP CHECK (HLTA-40)
- HOTLINE® Warmer
- HOTLINE® Fluid Warming Set

To Verify the Recirculating Solution Temperature:

1. Plug the HOTLINE® Warmer into a power outlet.
2. Place the TEMP CHECK on the top right corner of the HOTLINE® Warmer and plug it into the socket on the right side of the HOTLINE® Warmer.
3. Plug the Twin-Tube Connector on the HOTLINE® Fluid Warming Set into the socket on the right side of the TEMP CHECK.
4. Remove the black label from the auxiliary outlet on the back of the HOTLINE® and plug in the TEMP CHECK power cord.

   Note: *The auxiliary outlet is for use only with Smiths Medical accessories.*
5. Turn ON the HOTLINE® Warmer. Allow 15 minutes for the temperature to stabilize.
6. If the TEMP CHECK display indicates a temperature between 41°C and 42°C, and the HOTLINE® Warmer display equals the TEMP CHECK display, recirculating solution verification is complete. Refer to the TEMP CHECK Manual for OVERTEMP ALARM verification.
7. If the TEMP CHECK display does not indicate a temperature between 41°C and 42°C, refer to the TEMP CHECK Manual for calibration instructions.

Periodic Electrical Testing

Electrical Safety Tests must be performed by competent personnel authorized by the institution to perform such testing. The Safety Tests must be performed and documented at least once per year, or according to institutional policy. These tests include but are not limited to:

- Leakage current
- Ground bond test

Note: *All equipment connecting to the device must conform to IEC or ISO standards for requirements for medical electrical systems (e.g., IEC 60601-1 or clause 16 of IEC 60601-1 3Ed.). Any persons connecting additional equipment to the device, is responsible that the device system created as a result complies with the standard requirements for medical electrical systems.*

Leakage Current

Leakage current must be tested according to methods and pass/fail criteria described in IEC 60601-1. Leakage current must be performed with the heater circuit in the full ON condition. To achieve this condition, perform the test when the reservoir is at room temperature. When the HOTLINE® Warmer is first turned on and the temperature is rapidly rising, but still below 41°C, the heater circuit is in a full ON condition.

Note: *The HOTLINE® Warmer is equipped with sensing interlocks. A HOTLINE® Fluid Warming Set is required to correctly operate the HOTLINE® Warmer and perform leakage current testing. Do not defeat the sensing interlocks or try to operate the HOTLINE® without a HOTLINE® Fluid Warming Set in place.*

Ground Bond Test

Ground bond test must be tested according to methods and pass/fail criteria described in IEC 60601-1.

SECTION 10

Maintenance

Only competent personnel should perform any routine maintenance and repairs to the HOTLINE® Warmer. Maintenance is scheduled with each use, every 30 days, and every 12 months. The tasks are described below.

Maintenance Performed with Every Use

CAUTION

Do not autoclave or immerse any part of the HOTLINE® Warmer in liquids, which may cause damage and improper functioning.

Clean and inspect the HOTLINE® Warmer.

Clean the Exterior

Clean the entire HOTLINE® Warmer after every use.

CAUTIONS

- **Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the HOTLINE® Warmer**
- **Do not place the HOTLINE® Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the HOTLINE® Warmer or into the external connectors.**

1. To isolate equipment from MAINS, unplug the HOTLINE® Warmer before servicing.
2. Visually inspect the HOTLINE® Warmer to ensure there is no visible damage or deterioration of the enclosure such as cracks, or deterioration of the labels and power cord. Do not clean if there is a defect. Contact Smiths Medical or your local Smiths Medical distributor.
3. Immerse a soft cloth or sponge as an applicator into the cleaning solution consisting of mild liquid detergent soap and warm tap water mixture. Squeeze out excess solution so that the applicator is not dripping. Wipe or scrub the entire surface of the enclosure and control panels. Use a soft brush to clean the power cord if necessary.

4 Rinse a separate soft cloth or sponge in room temperature running potable water. Squeeze out excess water so that the applicator is not dripping. Wipe all of the aforementioned surfaces. Repeat rinsing the cloth or sponge several times with fresh running water during this process to insure all visible residue is removed.

5 Dry the item with a hand towel or soft cloth.

6 Visually inspect the HOTLINE® Warmer and its components to insure that they have been thoroughly cleaned. Repeat cleaning procedure if necessary.

7 After thoroughly cleaning the HOTLINE® Warmer, perform disinfection if required.

8 If it is hospital policy to perform disinfection as part of reprocessing, then follow your institution's guidelines for disinfecting of the surfaces of non-critical medical devices. The list below includes low-level disinfectants that are commonly used in the medical community and high-level disinfectants that are claimed by the manufacturer. The effectiveness of these listed disinfectants should be validated using the hospital procedures.

   The following disinfectant agents can be used without causing damage to the enclosure:

   Low Level Disinfectants:

   - fantastik® All Purpose Cleaner

   High Level Disinfectants:

   - 1.56% Phenol (e.g., Sporicidin®)
   - 3.4% Glutaraldehyde (e.g., CIDEX® Plus)
   - 10% Bleach solution
   - 1% Ammonia solution
   - Surface disinfectants compatible with plastic materials.

9 Rinsing of the disinfectant residue should be done using a soft cloth or sponge as the applicator.

General Inspection

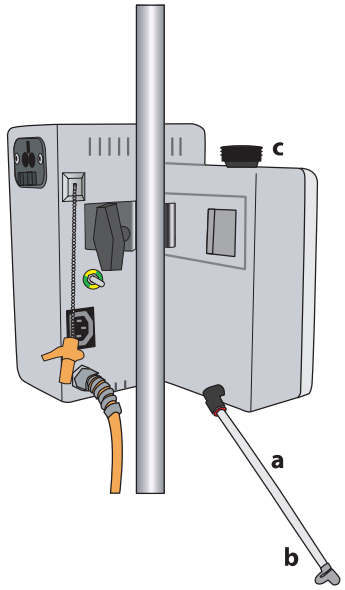
- Check the condition of the HOTLINE® Warmer with a visual inspection before using. Remove from service any HOTLINE® Warmer that shows physical damage.
- If the HOTLINE® Fluid Warming Set does not install easily, lubricate the O-Rings as directed in the following section.

Disinfect the Reservoir and Change the Recirculating Solution

Disinfect the reservoir and change the recirculating solution every 30 days or every 12 months based on the recirculating solution used for the HOTLINE® Warmer. Refer to the following table for the maintenance schedule.

Recirculating Solution	Preparation	Maintenance
0.3% Hydrogen Peroxide Solution	Mix 140 ml of 3% hydrogen peroxide with 1,260 ml of distilled water.	Replace solution and disinfect reservoir every 12 months.
Distilled Water	Use distilled water.	Replace solution and disinfect reservoir every 30 days.
35% Isopropyl Alcohol Solution	Mix 700 ml of 70% isopropyl alcohol with 700 ml of distilled water.	Replace solution and disinfect reservoir every 30 days.

Note: *Use distilled water only, not tap water. Failure to do so may cause build-up of mineral deposits in the recirculating solution path, which may impair heater performance.*



Disinfect the Reservoir

1. To isolate equipment from MAINS, unplug the HOTLINE® Warmer before servicing.
2. Remove the drain tube from the holder on the rear of the HOTLINE® Warmer.
3. Invert the drain tube **(a)** and place a container under the end of the tube. Remove the end cap **(b)** and drain the recirculating solution into the container.
4. When all the recirculating solution has drained from the reservoir, replace the end cap and insert the drain tube back in the holder.
5. Prepare a 0.3% hydrogen peroxide solution by mixing 140 ml of

3% hydrogen peroxide solution and 1,260 ml of distilled water.

6 Remove the fill-port plug **(c)**, fill the reservoir with the hydrogen peroxide solution, and replace the fill-port plug.

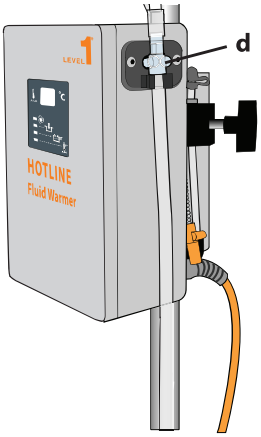
7 Remove the reflux plug from the socket if required, and insert a HOTLINE® Fluid Warming Set **(d)** (L-70, L-70NI, L-80) into the socket.

8 Turn the HOTLINE® Warmer ON, and let the recirculating solution circulate for a 30-minute disinfection period.

9 Turn the HOTLINE® Warmer OFF and to isolate equipment from MAINS, unplug the power cord.

10 Empty the reservoir.

11 Remove the HOTLINE® Fluid Warming Set and discard according to established hospital procedures.



These suggested instructions are designed to be used in conjunction with established hospital procedures.

Add Recirculating Solution

CAUTION

Do not fill the HOTLINE® Warmer reservoir with a HOTLINE® Fluid Warming Set or a TEMP CHECK in place. Failure to remove the HOTLINE® Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE® Warmer.

1 Prepare the recirculating solution.

2 Remove the fill-port plug.

3 Fill the reservoir with 1.4 liters of recirculating solution.

4 Replace the fill-port plug.

Maintenance Performed Every 30 Days

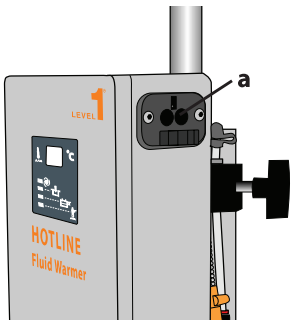
Disinfect the Reservoir and Change Recirculating Solution for Distilled Water and 35% Isopropyl Alcohol Solution

Refer to *Disinfect the Reservoir and Change the Recirculating Solution* procedure in this section.

Lubricate O-Ring Seals

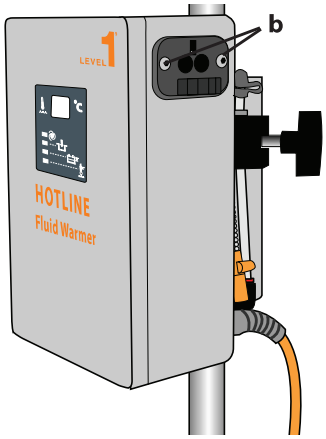
1 Place a small amount of silicone lubricant on a cotton swab.

2 Apply silicone lubricant along the O-Rings inside the socket **(a)** located on the right side of the HOTLINE® Warmer.



Silicone lubricant is available from Smiths Medical, (Silicone lubricant P/N 80-04-002).

Maintenance Performed Every 12 Months



Disinfect the Reservoir and Change Recirculating Solution for 0.3% Hydrogen Peroxide Solution

Refer to *Disinfect the Reservoir and Change the Recirculating Solution* procedure in this section.

Replace O-Rings (O-Ring Kit: P/N 80-04-001)

1. To isolate equipment from MAINS, unplug the HOTLINE® Warmer before servicing.
2. Remove the socket head screws **(b)** with a 0.31 cm (1/8") hex wrench.
3. Remove the face plate, being careful not to damage the micro-switch lever.
4. Remove the old O-rings and clean the sockets with a cotton swab.
5. Apply silicone lubricant to two new O-rings and install into the sockets.
6. Reassemble in reverse order, being careful not to damage the micro-switch lever.
7. Insert HOTLINE® Fluid Warming Set and power on HOTLINE® Warmer to verify that there are no leaks around the face plate.

Testing HOTLINE® Warmer Operation

Perform all the tests described in the testing section of this manual. See Section 9, *"Testing"*. The Scheduled Maintenance Checklist below also lists the tests.

Maintenance Log

All maintenance and testing should be done by competent personnel. Regularly scheduled maintenance ensures proper functioning of the equipment. Refer to the table below for required tasks and frequency of routine maintenance.

Maintenance Checklist

Task	Every Use	Every 30 Days	Every 12 Months
Clean the Exterior	☐		
General Inspection	☐		
Disinfect the Reservoir and Change Distilled Water or Isopropyl Alcohol solution		☐	
Lubricate the O-Rings		☐	☐
Disinfect the Reservoir and Change the Hydrogen Peroxide Solution			☐
Replace the O-Rings			☐
Alarm Signal Test			☐
Add Recirculating Solution Test			☐
Check Disposables Test			☐
Over Temperature Alarm Test			☐
Verify Temperature Calibration			☐
Electrical Safety Tests			☐

SECTION 11

Limited Warranty

Smiths Medical ASD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the HOTLINE® Blood and Fluid Warmer (the "HOTLINE® Warmer"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and excludes any accessory items or equipment used with the HOTLINE® Warmer.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any HOTLINE® Warmer (not including accessories) which is defective if a claim is made during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This warranty extends only to the Original Purchaser of the HOTLINE® Warmer. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases HOTLINE® Warmers for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, Smiths Medical ASD, Inc., 6000 Nathan Lane North, Minneapolis, MN 55442, (800) 258-5361. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE HOTLINE® WARMER. If authorized, the HOTLINE® Warmer must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty: The warranty is void if the HOTLINE® Warmer has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected; 3) misused; or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the HOTLINE® Warmer's serial number will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the HOTLINE® Warmer or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.
2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE HOTLINE® WARMER FOR ANY PARTICULAR PURPOSE.
3. The HOTLINE® Warmer can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the HOTLINE® Warmer for any particular medical treatment.
4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the HOTLINE® Warmer for any particular medical treatment or for any medical complications resulting from the use of the HOTLINE® Warmer. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the HOTLINE® Warmer.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

SECTION 12

Service

WARNING

No operator-serviceable parts. All service must be performed by Smiths Medical or competent personnel. Death or serious injury may occur if this warning is not followed.

All service must be performed by Smiths Medical or competent personnel. Service by any other person or organization voids the warranty and transfers liability for malfunctions of the device to the servicing organization.

Non-Warranty Work

Devices received that are no longer under warranty can be returned for repair at a cost. The device will be promptly inspected and a verbal estimate of the repair cost will be provided. A purchase order will be required from the original purchaser consistent with the verbal estimate. A written estimate will be provided upon request.

Before returning the HOTLINE® Warmer for service, contact Smiths Medical for Returned Goods Authorization. Be sure that ALL recirculating solution is drained from the device before packing the HOTLINE® Warmer for shipment.

Note: *The HOTLINE® Warmer must be cleaned and disinfected for repair shipment or it will be immediately returned as received.*

Additional Documentation

Upon request Smiths Medical will provide the following documentation:

- Circuit diagrams
- Components parts list(s)
- Description of function
- Service and calibration instructions

Disposal Information

Observe national and local codes or requirements for disposal of contaminated materials and for recycling of solid waste materials that may impact the environment.

Service Contacts

Contact your Smiths Medical Technical Service Department or Smiths Medical distributor at:

USA/Canada

Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA
Tel: 1 800 258 5361 (US/CA)
Tel: + 1 614 210 7300

European Representative

Smiths Medical Czech Republic a. s.
Olomoucká 306, Hranice 1 - Město,
753 01 Hranice, Czech Republic
Tel: +44 (0)1233 722100

www.smiths-medical.com

SECTION 13

Specifications and Accessories

System Specifications

Standard Compliance	Guidelines		
Product Safety	IEC 60601-1		
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class A		
Enclosure Protection	IEC 60529 IP Code: IPX1		
Fluid Warmers	ASTM F2172-02		
Physical	**Dimensions**		
Height, Overall	24.1 cm	(9.5 inches)	
Width, Overall	21.0 cm	(8.3 inches)	
Depth, Overall	17.8 cm	(7.0 inches)	
Weight, Dry	3.5 Kg	(7.6 lbs)	
Weight, Wet (with recirculating solution)	5.0 Kg	(11.0 lbs)	
Weight, Shipping	3.6 Kg	(7.95 lbs)	
Recirculating Solution Capacity	1.4 L	(0.37 gallons)	
Maximum Height on I.V. Pole	107 cm	(42 inches)	
Environmental	**Temperature**	**Humidity [%]**	**Atmospheric Pressure**
Operation	10°C to 45°C	10 to 95	70kPa to 106kPa
Transportation	-18°C to 60°C	5 to 90	70kPa to 106kPa
Storage	-18°C to 60°C	5 to 90	70kPa to 106kPa
Thermal	**Temperature**		
Temperature Set Point	41.9°C ± 0.1°C		
Over Temperature Set Point	43.1°C		
Electrical	**Type**		
MAINS Power Input:			
100V	100VAC, 50/60 Hz, 3.8 Amps		
115V	115VAC, 50/60 Hz, 3.0 Amps		
230V	230VAC, 50/60 Hz, 1.5 Amps		

Electrical	**Type**
MAINS Auxiliary Supply Power Output:	
100V	100VAC, 50/60 Hz, 1.0 Amps
115V	115VAC, 50/60 Hz, 1.0 Amps
230V	230VAC, 50/60 Hz, 0.6 Amps
Protection Against Electrical Shock	Class 1 Equipment, Type BF Applied Part (Disposable set)
Mode of Operation	Continuous
Type of Current	Alternating
Ingress Protection Rating	IPX1
Performance	
Recirculating Solution Temperature	Recirculating solution temperature reaches 37°C from ambient in about 4 minutes
Normothermic Flow Rates	At gravity flow rates to 5,000 ml per hour

Electromagnetic Compliance

HOTLINE® Warmer is certified to be in compliance with the European Communities Council Directive relating to Electromagnetic Compatibility (EMC): (89/336/EEC). Test methods and acceptance criteria as specified in EN 60601-1-2 demonstrate conformance.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The HOTLINE® Warmer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The operator might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Note: Compliance using 100-240V 50/60Hz with AC power cord of 3.8 m (12.5 ft.).		

WARNINGS:

- **The HOTLINE® Warmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you should verify normal operation of the HOTLINE® Warmer in the configuration in which it is to be used.**
- **Common portable and mobile consumer electronic devices may cause interference with the HOTLINE® Warmer. Observe the HOTLINE® Warmer to verify normal operation.**
- **Facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord.**

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines No input/output lines tested	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV for line to line ± 0.5 kV, ±1 kV, ±2 kV for line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% drop, 0.5 periods, 0^{o}, 45^{o}, 90^{o}, 135^{o}, 180^{o}, 225^{o}, 270^{o}, 315^{o} 100% dip, 250/300 period 30% dip, 25/30 periods	100% drop, 0.5 periods, 0^{o}, 45^{o}, 90^{o}, 135^{o}, 180^{o}, 225^{o}, 270^{o}, 315^{o} 100% dip, 250/300 period 30% dip, 25/30 periods	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Radiofrequency Electromagnetic Immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [1.2]\sqrt{P}$
	6 Vrms ISM bands 150 kHz to 80 MHz	6 Vrms 150 kHz to 80 MHz	$d = [0.58]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = [0.35]\sqrt{P}$ 80 MHz to 800 MHz $d = [0.7]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF Proximity Fields	Per 60601-1-2:2014 section 8.10 Table 9.	Per 60601-1-2:2014 section 8.10 Table 9.	$d = [6/E]\sqrt{P}$ *E is the immunity test level in V/m. Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Environmental Recommendations

Recommended separation distances between portable and mobile RF communications equipment and the HOTLINE® Warmer			
The HOTLINE® Warmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the HOTLINE® Warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HOTLINE® Warmer as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power or transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=[3.5/V1]\sqrt{P}$	80 MHz to 800 MHz $d=[3.5/E1]\sqrt{P}$	800 MHz to 2.5 GHz $d=[7/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note 2 *The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.*

Note 3 *An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.*

Note 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Accessories

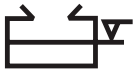
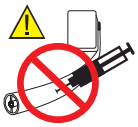
REF	Product Description
L-70	HOTLINE® Fluid Warming Set with Injection Port
L-70NI	HOTLINE® Fluid Warming Set without Injection Port
L-80	HOTLINE® Warming Set with L-10 Gas Vent
L-10	Gas Vent
PC-8	T-Connector, 20.3 cm (8") Patient Lead with Injection Port
YC-8	Y-Connector, 20.3 cm (8") Patient Lead with Injection Port

SECTION 14

Symbols

Symbol	Meaning
	**Caution**
	Follow Instructions for Use
	Do not re-use
	Catalog Number
	Serial Number
	Batch Code
	Part Number
	Date of Manufacture
	Use by
	Manufacturer
	Authorized Representative in the European Community
	Contains or Presence of Natural Rubber Latex
	Not made with natural rubber latex
	Contains or Presence of Phthalate: bis(2-ethylhexyl) phthalate (DEHP)
	Sterile Fluid Path, Ethylene oxide gas sterilized
	Type BF Applied Part (Disposable Sets)
	Alternating Current
	Protective earth; protective ground
	Equipotentiality
	Temperature Limitation

Symbol	Meaning
	Humidity Limitiation
	Atmospheric pressure limitation
	Quantity
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Collect separately
Rx ONLY	**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
	Electrical Shock Hazard
IPX1	Protected Against Dripping Water
CLASS 1	Device is a class type 1 equipment
	Protective earth terminal, for maintenance only
	Recyclable Product
	Alarm Test
	Power switch in the ON position
	Power switch in the OFF position.
	Reservoir Temperature Display
	Automatic Operation
	Recirculating Solution Temperature

Symbol	Meaning
	Over Temperature Test (Recirculating Solution Over Temperature)
	Add Recirculating Solution
	Check Disposables, Check Tubing
	Maximum Reservoir Level
	Minimum Reservoir Level
	Device has been tested by TÜV SÜD America, a nationally recognized technical laboratory, to meet all requirements for safety.
	Device has been tested by National Technical Systems, a nationally recognised technical lab, to meet U.S. requirements for safety.
	Warning: Do not stick HOTLINE® tubing wiht needles. Patient injury or death result.

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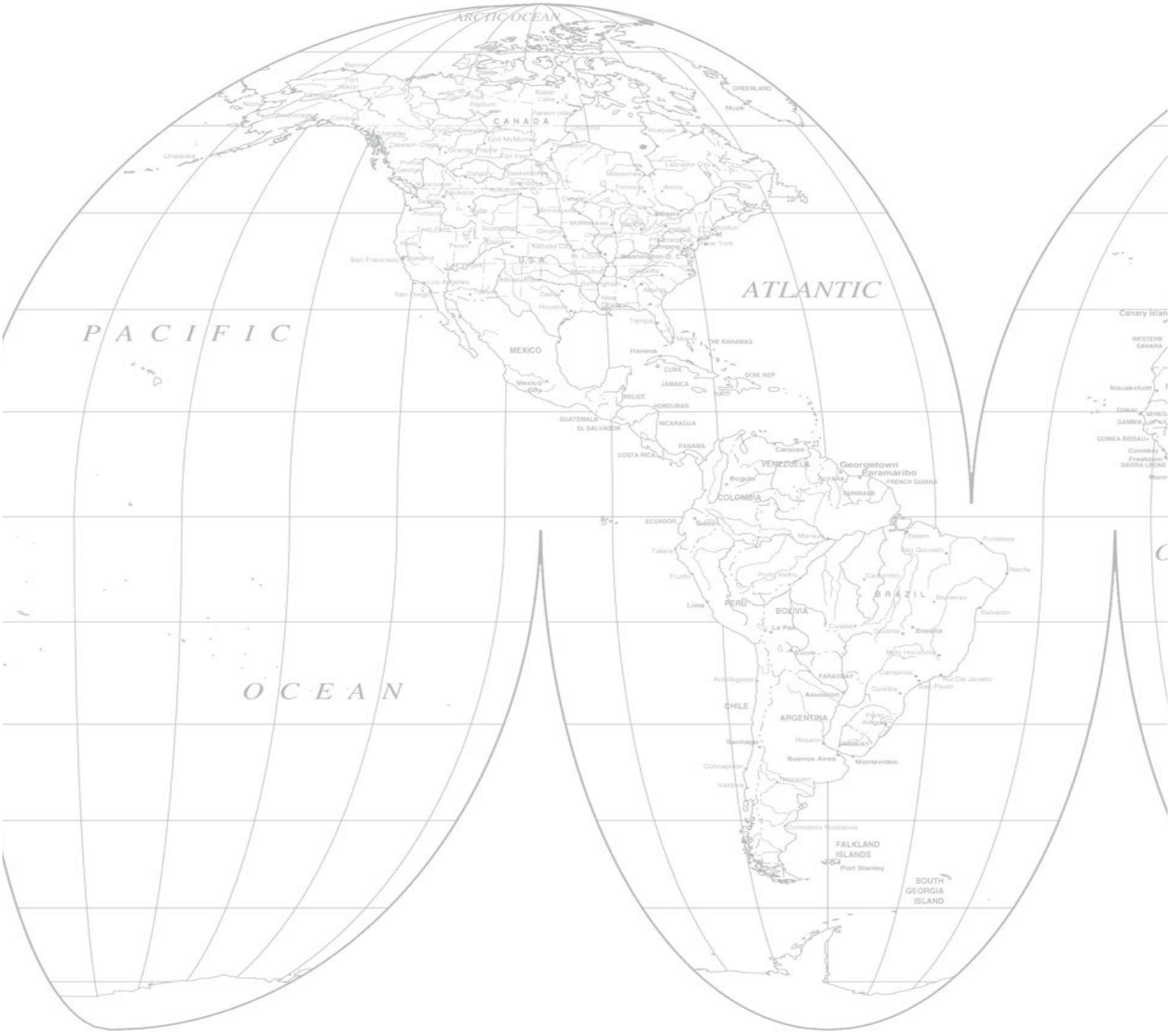
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LEVEL 1®



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Procedure: Massive infusion device use

Checklist: Massive infusion using a Belmont infuser device

Evaluator's Name: _____ **Examinee's Name:** _____

Evaluator's ID: _____ **Examinee's ID:** _____

Evaluator's Dept: _____ **Examinee's Dept:** _____

Date: _____ **Meets criteria/Does not meet criteria:** _____

Select Evaluation Method:

☐ Clinical Observation ☐ Documentation Review

☐ Demonstration ☐ Verbalization

Massive infusion using a Belmont infuser device

Objective: To administer a massive IV fluid or blood infusion using a Belmont infuser device according to the standard of care.

Checklist Step	Comments
Y- Meets; N- Does not meet; I- Not Applicable	

__ Verify the practitioner's order.

__ Review the practitioner's order to make sure that the prescribed infusion solution, rate, and administration route are appropriate for the patient's age, condition, and access device and that the infusion or medication is compatible with other solutions or medications. Make sure the order includes any test results that require monitoring. Address concerns about the order with the practitioner, the pharmacist, your supervisor, the risk management department, or as directed by your facility.

__ Verify the patient's baseline hematocrit, electrolyte and hemoglobin levels, and results of coagulation and other studies, as ordered.

__ Review the patient's medical record for history of allergies, as indicated.

__ Gather and prepare the necessary equipment and supplies.

__ Perform hand hygiene.

__ Confirm the patient's identity using at least two patient identifiers.

__ Provide privacy.

__ Explain the procedure to the patient and family (if appropriate) according to the patient's and family's individual communication and learning needs.

__ Raise the bed to waist level before providing care.

__ Perform a baseline physical assessment. Assess for conditions that can increase the risk of adverse effects of therapy.

__ Insert an indwelling urinary catheter, as ordered, if the patient doesn't already have one.

__ Perform hand hygiene.

__ Put on gloves and, as needed, other personal protective equipment.

__ Make sure that the patient has two patent large-bore IV catheters. If not, insert two IV catheters. If you can't establish venous access, initiate intraosseous access if indicated.

__ Assist the practitioner as needed with insertion of a central venous or pulmonary artery catheter.

__ Assist the practitioner as needed with insertion of an arterial catheter.

__ If you're infusing blood products, perform a pretransfusion blood verification with another qualified health care provider.

__ Remove the administration set from its packaging and inspect it.

__ Install the appropriate administration set into the infusion device according to the manufacturer's instructions.

__ Confirm that the heat exchanger is properly secured.

__ As necessary for infusion of larger volumes of fluid, replace the reservoir chamber with the larger-capacity reservoir. Using sterile technique, remove the reservoir chamber from the administration set by disconnecting the luer connectors.

__ Attach the reservoir holder onto the IV pole and place the larger reservoir into the holder.

__ Attach the three fluid supply tails onto the top of the larger reservoir you plan to use.

__ Connect the larger reservoir to the administration set. Adjust the reservoir holder so that the connection leads underneath the reservoir aren't stretched or kinked.

__ Hang the fluid bag on the IV pole.

__ Close the bag clamps, remove the bag spike cap, vigorously scrub the port with an antiseptic pad, and allow it to dry. Then spike the fluid bag.

__ Repeat the process with additional fluid lines you'll use.

__ Open the bag clamps.

__ Prime the main system by pressing the PRIME button to recirculate 100 mL of fluid at 500 mL/minute.

__ Prime the remainder of the administration tubing: Open the IV fluid bag roller clamp and remove the male luer cap at the distal end of the tubing. Press the PT. LINE PRIME button once to prime at 50 mL/minute and press and hold the button to prime at 200 mL/minute. Press the STOP button after inspecting the tubing for air bubbles. Press the PT. LINE PRIME button again.

__ Perform a vigorous mechanical scrub of the needleless connector on the vascular access device for at least 5 seconds using an antiseptic pad. Allow it to dry completely.

__ While maintaining the sterility of the syringe tip, attach a prefilled syringe containing preservative-free normal saline solution to the needleless connector. Unclamp the catheter and slowly aspirate for a blood return (if not contraindicated) that's the color and consistency of whole blood. If you don't obtain a blood return, take steps to locate an external cause of obstruction.

__ If you obtain a blood return, inject preservative-free normal saline solution slowly into the catheter.

Don't forcibly flush the device; further evaluate the device if you meet resistance.

__ Clamp the catheter and remove and discard the syringe in a puncture-resistant sharps disposal container.

__ Carefully remove the needleless connector from the vascular access device. Perform a vigorous mechanical scrub of the catheter hub for at least 5 seconds using an antiseptic pad. Allow it to dry completely.

__ Trace the IV tubing from the patient to its point of origin.

__ Connect the distal end of the tubing to the patient's vascular access catheter. Route the tubing in a standardized direction if the patient has other tubing and catheters that have different purposes. Label the tubing at both the distal and proximal ends if multiple IV lines will be used.

__ Unclamp the catheter, press INFUSE, and adjust the flow rate, as necessary.

__ Monitor the patient's vital signs every 5 to 15 minutes, as indicated. As the patient's condition stabilizes, monitor vital signs less frequently.

__ Monitor core temperature every 15 to 30 minutes and maintain a core temperature of no lower than 96.8° F (36° C).

__ Assess the patient's hemodynamic parameters every 15 to 30 minutes and urine output every 30 to 60 minutes, as ordered.

__ Inspect the IV sites every 15 minutes.

__ If the patient is receiving blood products, monitor closely for signs of a transfusion reaction.

__ Obtain an arterial blood gas sample, as ordered.

__ When the infusion is complete, change the IV fluid or blood bag.

__ Discard the empty infusion bag in a proper receptacle or, if required by your facility, return it to the blood bank.

__ Obtain blood samples, as ordered, to check hemoglobin level, hematocrit, lactic acid level, and electrolyte levels and for coagulation studies and thromboelastography.

__ Notify the practitioner of critical test results within your facility's established time frame.

__ Return the bed to the lowest position.

__ Discard used supplies in appropriate receptacles.

__ Provide warming measures, such as blankets.

__ Remove and discard your gloves and, if worn, other personal protective equipment.

__ Perform hand hygiene.

__ Clean and disinfect your stethoscope with a disinfectant pad.

__ Perform hand hygiene.

__ Document the procedure.

Pericardial catheter management

Pericardial catheter management

Reviewed: September 15, 2025

Introduction

A practitioner may leave an indwelling pericardial catheter in place after pericardiocentesis to drain excess pericardial fluid. The pericardial catheter may also be used to administer antibiotics or chemotherapeutic agents into the pericardial space, if necessary. The catheter typically remains in place for up to 5 days or until the patient's drainage is less than 25 mL per day.[1] Prolonged dwell time increases the risk of infection; however, a catheter may need to remain in place for a longer period depending on the indication for placement and the patient's condition.[2]

While the pericardial catheter remains in place, a specially trained nurse should maintain the catheter to prevent such complications as infection, catheter occlusion, and reaccumulation of fluid in the pericardial sac.[1][3]

Equipment

- Antiseptic pad
- Antiseptic swab (alcohol-based chlorhexidine preferred)
- Cardiac monitor with leads and electrodes
- Disinfectant pads
- Emergency equipment (code card with emergency medications, defibrillator, handheld resuscitation bag with mask, intubation equipment)
- Facility-approved pain assessment tool
- Gloves
- Gown
- Label
- Mask with a face shield or mask and goggles
- Prefilled syringe of sterile normal saline solution or other prescribed flush solution
- Sterile 4″ × 4″ (10- × 10-cm) gauze pad
- Sterile drape
- Sterile gloves
- Sterile nonvented end caps
- Sterile occlusive dressing
- Stethoscope
- Tape
- Vital signs monitoring equipment
- Optional: pericardial drainage bag and tubing, prescribed analgesic

Preparation of Equipment

Inspect all equipment and supplies. If a product is expired, is defective, or has compromised integrity, remove it from patient use, label it as expired or defective, and report the expiration or defect as

directed by your facility. Make sure that emergency equipment is functioning properly and readily available.

Implementation

- Verify the practitioner's order.
- Review the patient's medical record *to determine the indication and date of insertion.* Check for allergies.[2]
- Gather and prepare the necessary equipment and supplies.
- Perform hand hygiene.[4][5][6][7][8][9]
- Confirm the patient's identity using at least two patient identifiers.[10]
- Provide privacy.[11][12][13][14]
- Explain the procedure to the patient and family (if appropriate) according to their individual communication and learning needs *to increase their understanding, allay their fears, and enhance cooperation.*[15]
- Raise the bed to waist level before providing care *to prevent caregiver back strain.*[16]
- Perform hand hygiene.[4][5][6][7][8][9]
- Assess the patient's cardiac and hemodynamic status *to evaluate the effectiveness of therapy and promptly recognize signs of cardiac tamponade, cardiac injury, or hemodynamic instability.*[2] (See *Watching for signs of cardiac tamponade.*)

WATCHING FOR SIGNS OF CARDIAC TAMPONADE

An occluded pericardial catheter can lead to cardiac tamponade. Therefore, monitoring the patient for these signs of cardiac tamponade is important:

- dyspnea
- tachypnea
- tachycardia
- hypotension
- increased jugular vein distention
- pulsus paradoxus
- muffled heart sounds
- pericardial rub
- precordial dullness on percussion
- altered level of consciousness
- equalization of right atrial pressure, pulmonary artery diastolic pressure, and pulmonary artery occlusion pressure
- cardiac index less than 2.5 L/minute/m^2.[2][17]

- Screen for and assess the patient's pain using facility-defined criteria that are consistent with the patient's age, condition, and ability to understand.[18]
- Treat the patient's pain, as needed and ordered, using nonpharmacologic, pharmacologic, or a combination of approaches. Base the treatment plan on evidence-based practices and the patient's clinical condition, past medical history, and pain management goals.[18] If you're administering pain medication, follow safe medication administration practices.[19][20][21][22]
- Monitor closely if the patient is at high risk for adverse outcomes related to opioid treatment, if prescribed.[18]
- Perform hand hygiene.[4][5][6][7][8][9]

- Put on a gown, gloves, and a mask with a face shield or a mask and goggles *to comply with standard precautions*.[23] [24] [25]
- Establish a sterile field for the sterile supplies using a sterile drape.[2]
- Remove the existing dressing and discard it in an appropriate receptacle.[2] [23]
- Assess the catheter insertion site for signs of infection (such as pain, redness, or drainage), catheter migration, and loose sutures. Notify the practitioner if you note any of these complications.[2]
- Remove and discard your gloves.[23]
- Perform hand hygiene.[4] [5] [6] [7] [8] [9]
- Put on sterile gloves.[2] [23] [24]
- Clean around the catheter insertion site using an antiseptic swab, following the manufacturer's instructions. Allow the area to dry completely.[2]
- Make sure that the catheter and stopcock are anchored securely to the patient's chest using tape and sterile gauze pads and that the pericardial catheter, stopcock, tubing, and drainage bag connections are tight *to prevent dangerous disconnections.*[2] [26]
- Apply a sterile occlusive dressing over the catheter insertion site. Label the dressing as directed by your facility.[2]
- Maintain the drainage bag lower than the patient's chest *to facilitate drainage.*[2]
- Turn the stopcock off to the infusion port and open between the patient and the drainage bag to facilitate drainage when indicated *because the practitioner may order continuous or intermittent pericardial fluid drainage.* You'll typically perform intermittent drainage every 4 to 6 hours or as clinically indicated by echocardiography.[2]
- Assess the pericardial fluid drainage for color, amount, and consistency every hour and as needed or prescribed.[2]
- If the patient is prescribed intermittent drainage, flush the pericardial catheter, if prescribed:
    - Turn the stopcock off to the patient.[2]
    - Thoroughly disinfect the infusion port with an antiseptic pad for 15 seconds and allow it to dry.[2]
    - Connect the syringe containing the flush solution to the injection port and open the stopcock to the patient. Monitor the patient's vital signs and electrocardiogram while flushing the catheter.[2]
    - Gently flush the catheter with 2 to 5 mL of sterile normal saline solution or other prescribed solution (such as heparinized solution).[2]
    - Turn the stopcock off to the patient.[2]
    - Disconnect the flush syringe.[2]
    - Replace the end cap on the infusion port with a new, sterile nonvented end cap.[2]
- Troubleshoot the device if drainage lessens or ceases, and you suspect that the pericardial catheter is occluded:
    - Make sure the drainage bag is positioned lower than the insertion site. Reposition the drainage bag, if needed.[2]
    - Determine whether there's an external mechanical cause, such as compressed or kinked tubing. Change the tubing or unkink it, as needed. Turn or reposition the patient, if necessary.[2]
    - Trace the tubing from the patient to its point of origin *to assess for loose tubing connections and tighten any loose connections.*[2] [26] [27]
    - Check the stopcock *to make sure that it's in the correct position to facilitate drainage.*[2]
    - If the previous steps don't relieve the occlusion, thoroughly disinfect the infusion port, allow it to dry, flush the catheter, turn the stopcock off to the infusion port, and allow the

flush solution to passively drain. Alternatively, gently attempt to aspirate the flush solution through the attached syringe.[2]
    - Consider changing the tubing and drainage bag using sterile technique if the catheter itself is patent.[2]
    - Immediately notify the patient's practitioner *because fluid may accumulate in the pericardium, causing tamponade*.[2]
- Return the bed to the lowest position *to prevent falls and maintain the patient's safety.*[28]
- Reassess and respond to the patient's pain by evaluating the response to treatment and progress toward pain management goals. Assess for adverse reactions and risk factors for adverse events that may result from treatment.[18]
- Discard used supplies in appropriate receptacles.[23]
- Remove and discard your gloves and other personal protective equipment.[23]
- Perform hand hygiene.[4][5][6][7][8][9]
- Clean and disinfect your stethoscope with a disinfectant pad.[29][30]
- Perform hand hygiene.[4][5][6][7][8][9]
- Document the procedure.[31][32][33][34]

Special Considerations

- Change the pericardial catheter insertion site dressing every 24 hours or immediately if it becomes damp, soiled, or loosened or when inspection of the site is necessary.[2]
- Change the pericardial tubing and drainage bag (if in use) every 72 hours using sterile technique. Assess the system for patency after the tubing and drainage bag change.[2]
- Regularly assess the patient for readiness for pericardial catheter removal (less than 25 mL drainage during the past 24 hours, hemodynamic stability, or absence of pericardial effusion on an echocardiogram) *because early catheter removal reduces the risk of infection*.[1][2]
- The Joint Commission issued a sentinel event alert related to managing risk during transition to new International Organization for Standardization tubing standards that were designed to prevent dangerous tubing misconnections, which can lead to serious patient injury and death. During the transition, make sure to trace the tubing and catheter from the patient to the point of origin before connecting or reconnecting any device or infusion, at any care transition (such as a new setting or service), and as part of the handoff process; route tubes and catheters having different purposes in different standardized directions; when there are different access sites or several bags hanging, label the tubing at both the distal and proximal ends; use tubing and equipment only as intended; and store medications for different delivery routes in separate locations.[27]

Complications

Complications associated with pericardial catheter management may include:

- infection
    - infective pericarditis
    - death
- catheter occlusion
    - reaccumulation of fluid in the pericardial sac
    - pericardial tamponade.[1][2][3]

Documentation

Documentation associated with pericardial catheter management includes:

- assessment findings

- amount, color, and consistency of pericardial drainage
- date and time of pericardial catheter dressing, tubing, and drainage bag change
- troubleshooting measures needed
    - interventions
    - response to those interventions
- complications associated with the pericardial catheter
    - name of the practitioner notified
    - date and time of practitioner notification
    - prescribed interventions
    - response to those interventions
- results of the pain assessment
    - interventions performed
    - response to those interventions
- teaching provided to the patient and family (if applicable)
    - understanding of that teaching
    - follow-up teaching needed.

Related Procedures

- Cardiac tamponade, emergency patient care, oncology
- Pericardial catheter insertion, assisting
- Pericardiocentesis (Advanced practice)
- Pericardiocentesis, assisting

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(Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions)

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Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions

The following leveling system is adapted from *Evidence-Based practice in nursing & healthcare: A guide to best practice,* Fifth edition, by Bernadette Mazurek Melnyk and Ellen Fineout-Overholt (2023).

Level I	Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs)
Level II	Evidence from well-designed single RCTs (experimental)
Level III	Evidence from well-designed nonrandomized controlled trials (quasi-experimental), systematic reviews of a complete body of evidence, and intervention studies using mixed methods
Level IV	Evidence from well-designed case-control and cohort studies (observational)
Level V	Evidence from systematic reviews of qualitative and descriptive studies
Level VI	Evidence from single descriptive and qualitative studies, evidence-based practice implementation, and quality improvement projects
Level VII	Evidence from expert opinion, expert committee reports, and literature reviews

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Ventricular assist device (VAD) management



Ventricular assist device (VAD) management

Revised: September 15, 2025

Introduction

Implantation of a ventricular assist device (VAD) provides support to a failing heart by assisting with the pumping function. VADs are designed to decrease the heart's workload and increase cardiac output in patients with ventricular failure. They're commonly used as a bridge to cardiac transplantation in patients who are at risk for death from refractory end-stage left ventricular heart failure, as a bridge to recovery after cardiogenic shock, or as destination therapy for patients who don't qualify for or desire cardiac transplantation.[1] [2] Other indications for VAD therapy include an inability to be weaned from cardiopulmonary bypass and heart failure that doesn't respond to optimal medical therapy.[1] [2] VADs are associated with improved secondary organ function, reduced pulmonary hypertension, and improved nutritional status. These benefits may also give time for health improvement to patients who previously received a VAD as destination therapy so that they can become eligible for cardiac transplantation.[3] [4]

Inserting a VAD involves a specific surgical procedure in which an artificial pump diverts blood flow from a ventricle. The HeartMate VADs are currently the only available VADs for implant. The HeartWare VAD is no longer implanted because of safety concerns but may still be present in patients in whom it was implanted before 2021.[3] HeartMate II and HeartMate 3 VADs have been recalled (but not removed from the market) because of a reported issue called extrinsic outflow graft obstruction, in which the device becomes obstructed by buildup. This buildup causes the device to be less effective, possibly resulting in serious injury or patient death. Low-flow alarms may be the first sign of this issue and should be investigated promptly.[5] The HeartWare and HeartMate 3 VADs use a centrifugal blood pump that's implanted in the pericardial space with left ventricular apex to ascending aorta cannulation to provide left ventricular support.[6] The inflow conduit is integrated with the pump, and an outflow graft with a strain relief is attached to the pump. A percutaneous driveline connects the pump to an external controller, powered by batteries or electricity from an outlet. The monitor displays system performance and changes controller operating parameters.[1] The HeartMate II Left Ventricular Assist System (LVAS), an axial-flow, rotary ventricular assist system, generates blood flow at a rate of up to 10 L/minute. One end of the VAD is attached to the apex of the left ventricle; the other end connects to the ascending aorta. The VAD draws blood at high speeds from the weakened left ventricle and ejects it into the ascending aorta.[7] A small external computer monitors the system's operation. A driveline, which passes through the patient's abdomen, connects the implanted pump to the system controller. The system is powered by two lithium batteries or a power module that connects to an electrical outlet.[8]

VAD use is contraindicated in patients who can't tolerate anticoagulation therapy as well as in patients who are pregnant because of the need for anticoagulation. Because VADs have limited use in patients with artificial mitral or aortic valves, the risks of use in these patients are currently unknown.[1] Other relative contraindications include body surface area less than 1.2 m^2, irreversible end-stage organ damage, unrepairable ventricular septal defect, comorbidities that limit life expectancy to less than 3 years, active infection, diabetes-related retinopathy, poor glycemic control, severe nephropathy,

peripheral neuropathy, active long-term institutionalized psychiatric illness, and conditions that limit the patient's ability to care for the device (such as neuromuscular disease, psychosocial or cognitive conditions, lack of a caregiver or increased caregiver burden, active substance abuse, and medical nonadherence).[2]

Equipment

- AC or DC adapter
- Battery charger
- Cardiac monitor with leads and electrodes
- Cap
- Disinfectant pad
- Dressing supplies
- Electronic infusion device (preferably a smart pump with dose-error reduction software and interoperability with electronic health records)
- Emergency equipment (code cart with emergency medications, defibrillator, handheld resuscitation bag with mask, intubation equipment)
- Facility-approved pain assessment tool
- Gloves
- Hemodynamic monitoring equipment
- IV administration set
- Mask
- Mild antiseptic soap or cleaning agent (preferably chlorhexidine)
- Oral care supplies
- Other prescribed medications
- Prescribed analgesics
- Prescribed IV fluid
- Pulse oximeter and probe
- Sterile gauze pad
- Sterile gloves
- Sterile normal saline solution
- Stethoscope
- Suction equipment
- System controller
- System monitor
- VAD
- VAD batteries
- Vital signs monitoring equipment
- Optional: 12-lead electrocardiography (ECG) machine, antiembolism stockings, arterial catheter monitoring supplies, blood glucose monitoring supplies, customized percutaneous lead immobilization binder or belt, Doppler ultrasound device, gown, IV dextran, mask with face shield or mask and goggles, Montgomery strap, scale, sequential compression device, specialized clip, sterile gown, ultrasound gel

Preparation of Equipment

Inspect all equipment and supplies. If a product is expired, is defective, or has compromised integrity, remove it from patient use, label it as expired or defective, and report the expiration or defect as directed by your facility. Make sure emergency equipment is functioning properly and readily available. Have a backup controller available and programmed identically to the primary controller *in case the primary controller fails or malfunctions. Using a backup controller with settings different from the patient's current system may result in diminished support and patient harm.* Ensure that fully charged batteries are available at all times.[1]

Implementation

- Review the patient's medical record for medical and surgical history, allergies, and current medications.
- Verify the practitioner's orders.
- Perform hand hygiene.[9][10][11][12][13][14]
- Confirm the patient's identity using at least two patient identifiers.[15]
- Provide privacy.[16][17][18][19]
- Explain the procedure to the patient and family (if appropriate) according to their individual communication and learning needs *to increase their understanding, allay their fears, and enhance cooperation.*[20]
- Provide emotional support to the patient and family.
- Raise the patient's bed to waist level before providing care *to prevent caregiver back strain.*[21]
- Perform hand hygiene.[9][10][11][12][13][14]
- Put on gloves and, as needed, other personal protective equipment *to comply with standard precautions.*[22][23][24]
- Receive handoff communication from the person who was responsible for the patient's care. Ask questions, as needed, *to avoid miscommunication that could lead to patient care errors during transitions of care.* As part of the handoff process, trace each tubing and catheter from the patient to its point of origin; a standardized line reconciliation process should be used.[25]
- Make sure that the VAD, controller, monitor, and power sources are set up according to the device manufacturer's instructions for use.
- Attach the patient to a continuous cardiac monitor and pulse oximeter, and attach hemodynamic monitoring equipment to the monitor modules, if present.[26] Make sure that alarm limits are set appropriately for the patient's current condition and that alarms are turned on, functioning properly, and audible to staff.[27][28][29][30]
- Closely monitor the patient's vital signs at an interval determined by your facility and the patient's condition. Manually auscultate the patient's blood pressure *to ensure accurate results.* If you can't manually auscultate blood pressure, use a Doppler ultrasound device.[1] Consider using an arterial catheter for blood pressure monitoring if blood flow is pulseless or hypotension precludes use of the manual and Doppler methods.[6][8] To measure blood pressure using a Doppler ultrasound device, follow these steps:
    - Place an appropriately sized blood pressure cuff around the patient's upper arm so that the end of the cuff is ¾" to 1" (2 to 2.5 cm) above the antecubital fossa. Align the cuff so that the mark on the cuff for "artery" is positioned over the artery.[31] Alternatively, place the cuff on the patient's forearm for radial artery measurement or the ankle for tibial artery measurement.[32]
    - Apply ultrasound gel to the general location of the artery intended for blood pressure measurement.[32]
    - Locate the vessel by turning on the Doppler ultrasound device and placing the probe over the area until you locate audible blood flow.[32]
    - Hold the probe still over the artery; don't press down too hard, or you'll compress the vessel and be unable to hear the blood flow.[32]
    - Inflate the blood pressure cuff until the flow sounds disappear and then add 30 mm Hg.[32]
    - Release the bulb and slowly deflate the cuff while watching the pressure manometer.[32]
    - Note the pressure at the point where flow returns to the artery, as indicated by continuous flow or a mildly pulsatile sound.[32]
    - Document this pressure as *XX/Doppler* or *XX/D* (for example, *88/Doppler* or *88/D*); note the location where you measured the pressure.[32]

- Monitor the patient's cardiovascular, respiratory, and neurologic status *to promptly recognize changes in the patient's condition.* Assess the exit site and monitor the mediastinal and chest tube sites and drainage.[8] Immediately report bleeding from the exit site, a sudden increase in or cessation of chest or mediastinal tube drainage, and other associated complications.
- Screen for and assess the patient's pain using facility-defined criteria that are consistent with the patient's age, condition, and ability to understand.[33]
- Treat the patient's pain, as needed and ordered, using nonpharmacologic, pharmacologic, or a combination of approaches. Base the treatment plan on evidence-based practices and the patient's clinical condition, past medical history, and pain management goals.[33] Administer analgesics, as needed and ordered, following safe medication administration practices.[34] [35] [36] [37]
- Monitor closely if the patient is at high risk for adverse outcomes related to opioid treatment, if prescribed.[33]
- If the patient requires endotracheal intubation and mechanical ventilation during the immediate postoperative period, confirm the ventilator settings and keep the head of the bed elevated at least 30 degrees, if tolerated. Assess the patient's readiness for extubation. Extubate the patient as soon as clinically indicated *to reduce the risk of ventilator-associated pneumonia.*[1]
- Weigh the patient and record the weight in kilograms *to ensure accurate medication dosing.*[38]

HeartWare HVAD System

- Confirm the controller settings on the monitor, including the pump speed, hematocrit setting, VAD identification, pump serial number, suction response setting, controller date and time, low-flow alarm limit, high-power alarm limit, and patient identification.[1] Make sure that the connections to the power, monitor, and driveline are secure.[1] Make sure that the alarms are turned on, functioning properly, and audible to staff.[27] [28] [29]
- Monitor the VAD parameters completely *to promptly recognize changes in the patient's condition.*
- Monitor the patient's cardiac index *because pump speeds are adjusted according to a calculated cardiac index; guidelines recommend pump speeds of 2,400 to 3,200 revolutions per minute (RPM).* Unless there's a clear clinical need for higher flows, the cardiac index should be set at or above 2.2 L/minute/m^2.[1]
- Administer IV fluid, as prescribed, to maintain a pump flow index (pump flow ÷ body surface area) greater than 2 L/minute/m^2 with central venous pressure and left atrial pressure less than 20 mm Hg. Maintain mean arterial pressure at less than 85 mm Hg, as tolerated. *The VAD pump is sensitive to preload and afterload.*[1]
- Administer a vasopressor or vasodilator, as prescribed and needed, following safe medication administration practices *to adjust vasomotor tone.*[1] [34] [35] [36] [37]
- Administer an inotropic agent, as ordered and needed, following safe medication administration practices *to improve right ventricular function.*[1] [34] [35] [36] [37]
- Administer anticoagulant therapy, as prescribed, following safe medication administration practices *to reduce the risk of stroke and other thromboembolic events.*[1] [34] [35] [36] [37] Anticoagulation therapy should be individualized for each patient.
    - Before starting anticoagulation, make sure that chest tube drainage is less than 40 mL/hour for about 3 hours, hematocrit is stable without the need for blood transfusion, and coagulation factors are approaching normal.[1]
    - Administer low-dose heparin at 10 units/kg/hour on postoperative day 1 to a target partial thromboplastin time (PTT) of 40 to 50 seconds, as ordered.[1]
    - Gradually increase the heparin dosage, as prescribed, to maintain the PTT between 50 and 60 seconds.[1]

- Monitor platelet reactivity, as ordered, *to assess for aspirin resistance;* administer aspirin monotherapy or combination therapy with dipyridamole or clopidogrel, as prescribed, within 24 hours after implantation if the patient experiences no postoperative bleeding complications *to reduce the risk of stroke.*[1] For a patient who has a sensitivity to or other intolerance of aspirin, administer clopidogrel as ordered.[1]
- Begin warfarin within 4 days postoperatively and titrate to maintain the patient's International Normalized Ratio (INR) at 2 to 3 for long-term therapy, as ordered.[1]

◆ ***Clinical alert:*** Anticoagulant medications are considered high-alert medications *because they can cause significant patient harm when used in error.*[39] [40] ◆

- If required by your facility, before administering an anticoagulant, have another nurse perform an independent double-check *to verify the patient's identity and make sure that you have the correct medication in the prescribed strength or concentration, the medication's indication corresponds with the patient's diagnosis, the dosage calculations and formula used to derive the final dose are correct, the prescribed route of administration is safe and proper for the patient, the prescribed time and frequency of administration are safe and proper for the patient, and, if an infusion, the pump settings are correct and the infusion line is attached to the correct port.*[39] [40]
- Administer systemic antibiotics, as ordered, for 48 to 72 hours, following safe medication administration practices *to reduce the risk of infection.*[1] [34] [35] [36] [37]
- Turn the patient from side to side at least every 2 hours as soon as the patient is clinically stable. Begin physical therapy and range-of-motion (ROM) exercises on the first postoperative day, if possible, *to reduce the risk of pressure injuries and other complications of immobility.*[1] [2] As soon as the patient is able, assist the patient to a chair. Progress to ambulation in the hallways within a few days of VAD implantation.[1]
- Perform driveline exit site care routinely, as ordered, following strict sterile technique:[41]
  - Perform hand hygiene.[9] [10] [11] [12] [13] [14]
  - Put on a cap, a mask, and sterile gloves.[1] [2] [22] [23] Also put on a sterile gown and use maximal barrier precautions, if required in your facility.[32] [41]
  - Remove and discard the dressing in an appropriate receptacle.[22]
  - Remove and discard your gloves.[22]
  - Perform hand hygiene.[9] [10] [11] [12] [13] [14]
  - Put on a new pair of sterile gloves.[2] [22] [23]
  - Inspect the driveline for kinks, tears, punctures, breakdown of material, and other damage. Notify the practitioner if you see blood within the driveline lumen or the driveline is damaged.[1]
  - Clean the exit site with an antiseptic cleaning agent (preferably, diluted chlorhexidine scrub solution), and dry the site with a sterile gauze pad *to avoid tissue injury.*[1] [2] [41]
  - Immobilize the percutaneous lead with a sterile occlusive dressing and, if necessary, a specialized clip, Montgomery strap, or customized percutaneous lead immobilization binder or belt.[41] Keep the extra external length of the driveline under a binder or clothing.[1]
- If the patient requires defibrillation, use an external defibrillator to deliver shocks, as indicated, according to Advanced Cardiac Life Support (ACLS) protocols. Note that you can leave the VAD intact and don't need to turn it off.[1] If internal defibrillation is necessary, you can also leave the VAD intact and don't need to turn it off as the practitioner delivers the shocks.[1]
- Promptly respond to alarms and troubleshoot the device, as permitted and necessary. Always refer to the manufacturer's instructions for use. (See *Responding to HeartWare system alarms*.)

TROUBLESHOOTING

RESPONDING TO HEARTWARE SYSTEM ALARMS

The table below lists high-, middle-, and low-priority HeartWare ventricular assist device (VAD) system alarms along with their symbols and tones, display messages, possible causes, and interventions. Always refer to the manufacturer's instructions for use.

High-priority, critical alarms

Alarm symbol and tone	*Display messages*	*Possible causes*	*Interventions*
No symbol Continuous loud tone that can't be muted	No message	• No power to pump • Pump stopped functioning	• Connect two new power sources. • Replace the controller. • Contact the HeartWare clinical support team.[1]
Flashing red Loud, two-toned alarm that can't be muted	VAD stopped Connect driveline	• Driveline disconnected • Driveline fracture • Connector malfunction or breakage • VAD electrical failure	• Reconnect the driveline. • Contact the HeartWare clinical support team. • Download and email the patient log files as directed by your facility.[1]
	VAD stopped Change controller	• Controller failure • VAD failure • Thrombus or other materials (such as tissue fragments) in the device	• Exchange the controller. • Contact the HeartWare clinical support team. • Download and email the patient log files as directed by your facility.[1]
	Controller failed Change controller	• Controller component failed	• Exchange the controller. • Contact the HeartWare clinical support team.[1]
	Critical battery 1 Replace battery 1	• Limited battery 1 time remaining • Battery malfunction	• Replace the critical battery with a fully charged battery or an AC or DC adapter. • Change the controller if the new power sources don't correct the alarm.[1]
	Critical battery 2	• Limited battery 2 time remaining • Battery malfunction	• Replace the critical battery with a fully charged battery or an AC or DC adapter.

	Replace battery 2		• Change the controller if the new power sources don't correct the alarm.[1]
Medium-priority alarms			
Alarm symbol and tone	*Display messages*	*Possible causes*	*Interventions*
Flashing yellow Intermittent beep that gradually increases in volume over time if not muted	Controller fault Call	• Controller component malfunction, but pump is still working	• Confirm the frequency and the duration of the alarm, concurrent alarms, and pump flow, speed, and power. • Assess the patient for such complaints as shortness of breath, chest pain, palpitations, and dizziness. • Monitor the isolated alarm and download the information at the next patient visit.[1]
	Controller fault Call: Alarms off	• Controller component malfunction • Suction detection disabled • Low-flow alarm disabled • VAD connect alarm possibly disabled • High-power alarm possibly disabled	• For multiple alarms within 24 hours without other issues, assess the patient at a nonemergent practitioner visit. • For multiple alarms within 1 hour with other alarms or patient signs and symptoms, replace the controller and assess the device at the next emergent visit. • Download and email the patient log files from the original (alarming) controller and new controller. • Contact the HeartWare clinical support team.[1]

High watts Call	• VAD pump watts that exceeded high-power alarm threshold • Alarm threshold set too close to the average power • Thrombus or other materials (such as tissue fragments) in the device • High revolutions per minute (RPM) • High flow • VAD electrical fault	• Confirm the correct settings for the high-power alarm and pump speed. • Monitor blood coagulation studies, as ordered. • Assess the patient for signs of hemolysis. • Download and email the patient log files as directed by your facility. • Assess for signs of aortic insufficiency, thrombus, or another cause. • Contact the HeartWare clinical support team.[1]
Electrical fault Call	• Fault in continuity of pump-to-controller electrical connections • Partial driveline fracture • Connector malfunction • Controller component failure • VAD malfunction	• Check driveline cover and ensure that the driveline connector is engaged. • Inspect the driveline for defects. • Download and email the patient log files as directed by your facility. • Contact the HeartWare clinical support team.[1]
Low flow Call	• Average flow below low-flow alarm threshold • Alarm threshold set too close to average flow • Suction detected • RPM too high or too low • Poor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, or other cause) • High blood pressure • Outflow graft kink	• Confirm the VAD parameters. • If possible, confirm the correct settings for the low-flow alarm limit and viscosity. • Confirm that the patient's mean arterial pressure is less than 85 mm Hg. • Evaluate the cause of poor left ventricular filling; attach the patient to the monitor *to evaluate the pump waveform and administer volume resuscitation, if indicated and ordered.* • If you can't identify a potential patient cause, download and email the patient log files as directed by your facility. • Arrange for echocardiography, if ordered. • Contact the HeartWare clinical support team.[1]

	Suction Call	• RPM too high • Poor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, or other cause) • Thrombus or other materials (such as tissue fragments) in the device	• Confirm pump flow trends to evaluate a decrease in mean flow. • Download and email the patient log files as directed by your facility. • Administer volume resuscitation or institute measures to correct the cause of poor left ventricular filling, as ordered. • Decrease the pump speed, if ordered. • Contact the HeartWare clinical support team. • Arrange for echocardiography, if ordered.[1]

Low-priority alarm			
Alarm symbol and tone	*Display message*	*Possible causes*	*Interventions*
Solid yellow Intermittent beep that gradually increases in volume over time if not muted	Low battery 1 Replace battery 1	• Battery power low	• Replace low battery.[1]
	Low battery 2 Replace battery 2	• Battery power low	• Replace low battery.[1]
	Power Disconnect Reconnect power 1	• Power source disconnected or malfunctioning	• Reconnect the power source. • Replace the power source. • Replace the controller.[1]
	Power Disconnect Reconnect power 2	• Power source disconnected or malfunctioning	• Reconnect the power source. • Replace the power source. • Replace the controller.[1]

- If a red or high-priority alarm signals because of controller failure, change the controller.[1] (See *Changing the HeartWare controller*.)



EQUIPMENT

CHANGING THE HEARTWARE CONTROLLER

If a controller failure or serious malfunction generates a red or high-priority alarm and the HeartWare controller display tells you to change the controller, follow these steps:[1]

- Perform hand hygiene.[9] [10] [11] [12] [13] [14]
- Instruct the patient to lie or sit down if the patient isn't already doing so.
- Position the new controller within easy reach.
- Connect one backup power source to the new controller. (*Note:* The new controller may alarm after 10 seconds; this is expected).
- Pull back the white driveline cover from the original controller's silver connector.
- Disconnect the driveline from the original controller; don't disconnect by pulling on the driveline cable.
- Connect the driveline to the new controller. The pump should restart, and the revolutions per minute, liters per minute, and watts should appear on the controller display. If the pump doesn't restart, check the driveline and power connections. If the pump still doesn't start, call for medical assistance immediately.
- If a red alarm adapter is available, insert it into the data connector on the original controller *to prevent the controller alarm from sounding after power removal.* If an alarm adapter isn't available, press and hold the Alarm Mute and Scroll buttons simultaneously on the original controller until you hear a beep or for at least 5 seconds and then release the buttons.
- Disconnect both power sources from the original controller.
- Connect a second power source to the new controller.
- Slide the white driveline cover up over the new controller's silver connector, and ensure that the data port is covered by the cap. If the controller running the pump has the red alarm adapter connected, remove it and cover the data port with the cap.
- Contact the HeartWare manufacturer to obtain a new backup controller.

HeartMate II or HeartMate 3 LVAS

- Assess the system settings and parameters, including:
  - pump flow: estimate of blood flow out of the pump, which is based on pump speed and the amount of power provided to the pump motor
  - pump speed: speed of the pump in RPM
  - pulsatility index: displayed as pulse index, a calculation related to the amount of assistance that's provided by the pump, which typically ranges from 1 to 10 (higher values indicate higher pulsatility, which means the pump is providing less support and the heart is providing more support)
  - pump power: amount of power provided by the pump motor, which ranges from 0 to 25.5 watts.[8]
- Make sure that alarm limits are set appropriately for the patient's current condition and that alarms are turned on, functioning properly, and audible to staff.[27] [28] [29]
- Suspect thrombus formation if you note an increase in the VAD system power requirement and a reduction in the pulse index. Notify the practitioner of your findings *because pump replacement may be necessary.*[8]
- Monitor the patient for signs and symptoms of blood leakage from any system component (unexplained internal bleeding possibly with painful abdominal distention or tamponade, blood draining from the driveline exit site, or decreased hemoglobin level and hematocrit).[6] [8]
- Closely monitor the patient's hemodynamic status. Small increases in afterload (systemic vascular resistance) and small decreases in preload (left ventricular filling) can result in diminished pump flow, a reduction that may result in a clinically significant decrease in

perfusion.[8] Assess the patient for signs and symptoms of decreased perfusion with changes in preload and afterload. Monitor mixed venous oxygen saturation levels as ordered.[8]

- If the patient's condition changes, auscultate over the pump pocket *to verify that the pump is running*.[8]
- Administer IV fluid as prescribed.
- Administer medications, as prescribed, following safe medication administration practices *to maintain mean arterial pressure at less than 90 mm Hg.*[8][34][35][36][37]
- Administer 10% low-molecular-weight dextran at 25 mL/hour, if prescribed, following safe medication administration practices.[6][34][35][36][37]
- Administer anticoagulant therapy, as prescribed, following safe medication administration practices *to reduce the risk of stroke and other thromboembolic events.*[8][34][35][36][37] Expect anticoagulation therapy to be specific for each patient.
    - Begin IV heparin therapy 12 to 24 hours after surgery or when chest tube drainage is less than 50 mL/hour for a period of 2 to 3 hours, as ordered.[6]
    - Initially, titrate the heparin dose to maintain a PTT of 45 to 50 seconds for 24 hours, as ordered.[6]
    - After 24 hours, increase the heparin dose and titrate to a PTT of 50 to 60 seconds, as ordered.[6]
    - After another 24 hours, increase the heparin dose and titrate to a PTT of 55 to 65 seconds, as ordered.[6]
    - Days 2 to 3 postoperatively, administer aspirin, as prescribed.[6]
    - Days 3 to 5 postoperatively, after chest tube removal with no evidence of bleeding, begin warfarin (overlapping with heparin) as ordered.[6]
    - Discontinue heparin, as ordered, after the patient's INR stabilizes to a range of 2 to 3 on warfarin therapy.[6]
- If the patient requires defibrillation, use an external defibrillator to deliver shocks, as indicated, according to ACLS protocols. Leave the pump running and don't disconnect the system controller from the percutaneous lead before delivering the shock. If internal defibrillation is necessary, disconnect the VAD from the controller *because the paddles will be in close proximity to the device. Because retrograde flow may occur through the pump when it's off,* you may have to clamp the outflow graft while the device is stopped.[6][8]
- Administer prophylactic antibiotics postoperatively, as prescribed, following safe medication administration practices *to reduce the risk of infection.*[6][8][34][35][36][37]
- If the patient reports dizziness, immediately assess the patient and evaluate the system.[8]
- Turn the patient from side to side at least every 2 hours as soon as the patient is clinically stable. Begin physical therapy and ROM exercises on the first postoperative day, if possible, *to reduce the risk of pressure injuries and other complications of immobility.*[1][2][8] As soon as possible, assist the patient to a chair. Progress to ambulation in the hallways within a few days of VAD implantation.[1][8]
- Promptly respond to alarms and troubleshoot the device, as permitted and necessary. Always refer to the manufacturer's instructions for use. (See *Responding to HeartMate system alarms*.)

TROUBLESHOOTING

RESPONDING TO HEARTMATE SYSTEM ALARMS

The table below lists the different HeartMate Left Ventricular Assist System alarms along with their screen message and meaning as well as appropriate interventions for each.[6][8]

Hazard alarms		
System controller screen message	*Alarm meaning*	*Intervention*
Low flow Call hospital contact	The pump is off and the pump running symbol is black. May indicate significant outflow obstruction.[5]	• Check to see whether the fixed speed setting is below 8,000 revolutions per minute (RPM) for HeartMate II (HM II) or 4,000 RPM for HeartMate 3 (HM 3) and the system controller's backup battery isn't installed. In these conditions, you can only start the pump from the system monitor's clinical or settings screen by pressing the pump START button. Otherwise, press any button on the system controller to attempt to start the pump. • Switch to the backup system controller and attempt to restart the pump. • Assess the patient's clinical status.
Connect driveline	The driveline is disconnected and the pump running symbol is black.	• Immediately reconnect the driveline to the system controller and move the driveline safety tab on the system controller to the locked position. • If the alarm persists after reconnecting the driveline, press any button on the system controller to attempt to start the pump. Otherwise, check to see if the fixed speed setting is below 8,000 RPM for HM II or 4,000 RPM for HM 3 and whether the system controller's backup battery isn't installed. In these conditions, you can only start the pump from the system monitor's clinical or settings screen by pressing the pump start button. • If the driveline is connected and the alarm persists, replace the system controller with the preprogrammed backup system controller.
Backup battery Connect power immediately	Both power cables are disconnected.	• Immediately connect to a working power source (power module or two fully charged HeartMate 14-volt lithium-ion batteries).
Low flow Call hospital contact	Flow is less than 2.5 L/minute.	• Ensure that the driveline is connected to the system controller. • Ensure that a power source is connected to the system controller. • Assess the patient's clinical status.
Replace power immediately Low battery	Low battery, power input is extremely low with less than 5 minutes remaining.	• Immediately connect to a working power source (power module or two fully charged HeartMate 14-volt lithium-ion batteries).

Advisory alarms		
System controller screen message	*Alarm meaning*	*Intervention*
Connect power	One of the two power cables is disconnected.	• Promptly connect the disconnected power cable to the power source (functioning power module or two fully charged HeartMate 14-volt lithium-ion batteries).
Replace power Low battery	Low battery, power input is low with less than 15 minutes remaining	• Promptly connect the system controller to a working or different power source (power module or two fully charged HeartMate 14-volt lithium-ion batteries).
Call hospital contact Controller fault	System controller hardware fault	• Switch to the backup system controller. • Obtain a new system controller for the patient.
Call hospital contact Comm fault	Communication fault (HM 3)	• Contact the manufacturer to determine the steps to take next. • Use the system monitor to silence the alarm while awaiting resolution, if needed. (*Note:* The alarm must be active to access the alarm silence for this situation.)
Call hospital contact Backup battery fault	System controller backup battery fault	• Replace the 11-volt lithium-ion backup battery. (*Note:* If replacing the battery doesn't resolve the alarm, the system controller may need replacement or require additional steps. Call the manufacturer with questions.)
Call hospital contact Low speed	Low-speed advisory warning	• Use the system monitor to check that the fixed-speed and low-speed limits have been set appropriately. • Replace the system controller. • Assess the patient's clinical status.
None	Driveline fault	• Contact the manufacturer to determine the steps to take next. • Use the system monitor to silence the alarm while awaiting resolution, if needed. (*Note:* The alarm must be active to access the alarm silence for this situation.)
Image of the controller and	System controller backup battery not	• Install the 11-volt lithium-ion backup battery in the system controller.

a battery appears	installed	• Obtain a new backup battery replacement kit. (*Note:* If replacing the battery doesn't resolve the alarm, the system controller may need replacement or require additional steps. Call the manufacturer with questions.)

- If an alarm signals controller failure, change the controller. (See *Changing the HeartMate II controller*.)



EQUIPMENT

CHANGING THE HEARTMATE II CONTROLLER

If a controller failure or serious malfunction generates an alarm indicating that the HeartMate II controller needs replacement, follow these steps:[8]

- Perform hand hygiene.[9][10][11][12][13][14]
- Place the backup system controller within reach.
- Instruct the patient to sit or lie down if the patient isn't already doing so *to avoid dizziness if the pump briefly stops.*
- Unlock the driveline safety tab on the running system controller.
- Replace the system controller.
  - If only an in-use power source is available, move the white connector's power source from the running controller to the backup system controller. Promptly move the driveline from the running controller to the backup system controller, aligning the mark on the driveline with the arrow on the system controller. Move the black connector's power source from the running controller to the backup system controller.
  - If multiple power sources are available, keep the running system controller connected to power. Connect the white and black connectors on the backup system controller to power. Promptly move the driveline from the running controller to the backup system controller, aligning the mark on the driveline with the arrow on the system controller. Disconnect the old, replaced system controller from power.
- Keep in mind that, when the driveline is connected to the backup system controller, the controller will alarm and then clear, which is normal. The pump will start, the running symbol will illuminate in green, and you can access system information by pressing the display button. If the pump running symbol is black, take these steps:
  - Inspect the driveline *to make sure it's fully inserted into the controller.* Tug on the metal end of the driveline *to ensure that it's connected.*
  - Check that the system controller's black-and-white power cables are connected to the working power source.
- Lock the driveline safety tab on the backup system controller; the safety tab can't move into the locked position without full, proper insertion of the driveline. If the driveline safety tab won't lock, align the driveline and firmly press it into the system controller until it snaps into place.
- Put the old, replaced system controller into sleep mode by pressing and holding the battery button for 5 seconds.
- Don't use the old, replaced system controller. Contact the manufacturer to request a new backup system controller and instructions on returning the old one.

- Perform percutaneous lead exit site care daily, using strict sterile technique.

    - Perform hand hygiene.[9][10][11][12][13][14]
    - Put on a cap, a mask, and sterile gloves.[6][8][22][23] Also put on a sterile gown and use maximal barrier precautions if required in your facility.[32]
    - Remove and discard the dressing in an appropriate receptacle.[22]
    - Remove and discard your gloves.[22]
    - Perform hand hygiene.[9][10][11][12][13][14]
    - Put on sterile gloves.[6][8][22][23]
    - Gently clean the site with a mild antiseptic soap (preferably, chlorhexidine solution) and then dry the clean site with a sterile gauze pad.[8]
    - Inspect the percutaneous lead *to make sure it's free from bending and kinking.*
    - Cover the site with a dry sterile dressing.[6][8]
    - Immobilize the percutaneous lead with a stabilization belt or abdominal binder *to reduce trauma to the exit site.* Keep the stabilization belt or abdominal binder in place at all times, except when the patient showers (if permitted) or for replacement of the belt or binder with a newly cleaned belt or binder.[8]
- Arrange for echocardiography, if ordered, to perform a ramped speed study *to determine the patient's appropriate fixed-speed setting.* A ramped speed study is intended for hemodynamically stable, euvolemic patients in the postoperative period or later.[8]

Completing the procedure

- Monitor the patient's intake and output closely *for prompt detection of changes in the patient's condition.*[2]
- Closely monitor the patient for signs of right-sided heart failure. When this condition occurs, it typically develops within 24 hours after left VAD implantation. Warning signs include increasing right atrial pressure (RAP) with concurrent decreases in pulmonary artery occlusion pressure (PAOP) and left VAD flow. Systemic hypotension, tachycardia, and a decrease in urine output soon follow. Administer IV fluids, as prescribed, to increase RAP to 15 to 18 mm Hg. After optimizing intravascular fluid volume, administer inotropic therapy and a pulmonary vasodilator, such as nitric oxide, as prescribed.[1][8]
- Monitor the patient for signs of cardiac tamponade, such as unexplained low VAD flow or cardiac output despite adequate intravascular fluid volume (RAP or PAOP of 10 to 15 mm Hg), narrowed pulse pressure beyond what's expected from a device recipient, elevated RAP or PAOP despite inadequate pump or cardiac output, reduced mixed venous oxygen saturation, tachycardia, reduced urine output, sudden cessation of chest tube drainage, decreased electrical voltage on the ECG, and enlargement of the cardiac silhouette or widened mediastinum on chest X-ray. Notify the practitioner immediately if such signs occur.[32]
- If the patient suffers cardiac arrest and needs cardiopulmonary resuscitation, compressions may pose a risk *because of the pump location and position of the outflow graft on the aorta.* Collaborate with the patient's practitioner in advance, and be familiar with your facility's guidelines for which ACLS measure to follow in the event of cardiac arrest. If the patient undergoes chest compressions, be sure to confirm function and positioning of the VAD after the patient's condition stabilizes. Cardiac massage under direct vision performed by a skilled surgeon may be effective for a patient who has had recent device implantation (before mediastinal healing).[1][32][42]
- Obtain a 12-lead ECG, as ordered, if the patient complains of "feeling different" *to determine an underlying cause.*[8] (See the "12-lead electrocardiogram [ECG]" procedure.)
- Provide oral nutrition, as ordered, as soon as the patient's condition warrants *to correct nutritional deficiencies and reduce the risk of infection.* Alternatively, if the patient remains intubated, begin enteral tube feeding, as ordered.[1][8]

- Remove invasive monitoring lines and catheters, as ordered, as soon as the patient's condition allows *to reduce the risk of infection.*[1][8]
- Monitor laboratory test results (electrolyte and lactate levels, complete blood count, prothrombin time, INR, and PTT), as ordered.[1][8] Notify the practitioner of critical test results within your facility's established time frame, *so the patient can be treated promptly.*[43]
- Monitor the patient's blood glucose levels and administer antidiabetic agents, as prescribed, following safe medication administration practices *to maintain strict blood glucose control, which helps reduce the risk of infection.*[8][34][35][36][37] (See the "Blood glucose monitoring" procedure.)
- Avoid situations and use of devices that can cause strong electrostatic discharges *because electrostatic discharges can damage the electrical parts of the VAD system and cause the VAD to stop or perform improperly.*[1][8]
- Provide oral care *to reduce oral bacterial colonization, which helps reduce the risk of health care–associated pneumonia.*
    - Gently brush the patient's teeth, gums, and tongue at least twice daily using a soft-bristle toothbrush, toothpaste, and sterile water.[44]
    - Moisturize the oral mucosa and lips every 2 to 4 hours *to reduce oral inflammation and improve oral health.*[44]
    - Use a chlorhexidine mouth rinse twice daily during the perioperative period, as prescribed, *to prevent ventilator-associated pneumonia.*[44] (See the "Oral care" or "Oral care for an intubated patient" procedure.)
- Use antiembolism prevention strategies, such as applying antiembolism stockings or a sequential compression device, as ordered, *to promote venous return and prevent venous thromboembolism.* (See the "Antiembolism stocking application, knee-length" or "Antiembolism stocking application, thigh-length" or "Antiembolism stocking with a waist belt application" procedure.) (See the "Sequential compression therapy" procedure.)
- If the patient was receiving a beta-adrenergic blocker before surgery, collaborate with the patient's practitioner *to make sure that the patient receives it during the perioperative period, as appropriate.*[45]
- If the patient had an indwelling urinary catheter inserted for surgery, remove the catheter on postoperative day 1 or 2 (with the day of surgery considered day 0) or as soon as the patient no longer needs it *to reduce the risk of catheter-associated urinary tract infection.*[45][46] (See the "Indwelling urinary catheter [Foley] removal" procedure.)

◆ ***Hospital-acquired condition alert:*** Keep in mind that the Centers for Medicare and Medicaid Services considers catheter-associated urinary tract infection (CAUTI) a hospital-acquired condition *because it can be reasonably prevented using a variety of best practices*. Make sure to follow evidence-based CAUTI prevention practices—such as performing hand hygiene before and after any catheter manipulation; maintaining a sterile, continuously closed drainage system; maintaining unobstructed urine flow; emptying the collection bag regularly; replacing the catheter and drainage system using sterile technique when breaks in sterile technique, disconnection, or leakage occurs; and discontinuing the catheter as soon as it's no longer clinically indicated—when caring for a patient with an indwelling urinary catheter *to reduce the risk of CAUTI.*[46][47][48][49] ◆

- Return the bed to the lowest position *to prevent falls and maintain the patient's safety.*[50]
- Maintain the device according to the manufacturer's instructions for use.
- Remove and discard your gloves and other personal protective equipment.[22]
- Perform hand hygiene.[9][10][11][12][13][14]
- Clean and disinfect your stethoscope with a disinfectant pad.[51][52]
- Perform hand hygiene.[9][10][11][12][13][14]

- Reassess and respond to the patient's pain by evaluating the response to treatment and progress toward pain management goals. Assess for adverse reactions and risk factors for adverse events that may result from treatment.[33]
- Perform hand hygiene.[9][10][11][12][13][14]
- Document the procedure.[53][54][55][56]

Special Considerations

- Don't subject the patient to magnetic resonance imaging (MRI), *because the VAD contains magnetic components; MRI can cause device failure or patient injury.*[1][6][8]
- Keep cell phones at least 20" (50 cm) from the controller *because phones can interfere with the device function.*[1][8]
- Don't expose the patient to therapeutic levels of ultrasound energy, *because lithotripsy and other procedures that use high-intensity ultrasound can cause harm if the implanted device inadvertently concentrates the ultrasound field.*[1][8]
- Don't expose the patient to high-power electrical treatments, such as diathermy.[1][8]
- Keep in mind that therapeutic ionizing radiation may damage the device, although the damage may not be immediately detectable.[1][8]

◆ ***Clinical alert:*** Electrostatic discharge, such as from walking across carpet and taking clothes out of a dryer, can interfere with electrical parts of the HeartMate 3 and cause it to stop functioning. In addition, the device can interfere with implantable cardiac defibrillators, requiring adjustment of device sensitivity or repositioning of the lead.[6] ◆

- The Joint Commission issued a sentinel event alert concerning medical device alarm safety *because alarm-related events have been associated with permanent loss of function and death.* Among the major contributing factors were improper alarm settings, alarm settings turned off inappropriately, and alarm signals that were inaudible to staff. Make sure alarm limits are appropriately set and that alarms are turned on, functioning properly, and audible to staff. Follow facility guidelines for preventing alarm fatigue.[27]
- The Joint Commission issued a sentinel event alert concerning inadequate handoff communication *because of the potential for patient harm that can result when a receiver receives inaccurate, incomplete, untimely, misinterpreted, or otherwise inadequate information*. To improve handoff communication, standardize the critical information communicated by the sender. At a minimum, include the sender contact information, illness assessment, patient summary (including events leading up to the illness or admission, hospital course, ongoing assessment, and plan of care), to-do action list, contingency plans, allergy list, code status, medication list, and dated laboratory test results and vital signs. Provide face-to-face communication whenever possible in an interruption-free location. Use facility-approved, standardized tools and methods (for example, forms, templates, checklists, protocols, and mnemonics). Provide ample time and opportunity for questions, and include the multidisciplinary team members and the patient and family when appropriate.[57]

Patient Teaching

The patient and family must receive extensive training and be able to teach back VAD care and maintenance. Provide the patient with written materials for reference after discharge. At a minimum, teach about:

- concept of ventricular assistance
- way in which the VAD assists the heart
- control modes
- battery power versus other power sources

- battery use regimen
- importance of recognizing and responding to alarms
- use of a medical alert identification bracelet
- maintenance and safety checks
- anticoagulation therapy
- system components
- use of accessories to hold and carry system components
- identification of emergencies
- steps to take in an emergency
- emergency transportation plan
- preparation and practice for emergency procedures
- diagnosis of power and connector problems
- emergency telephone contacts
- procedure for replacing the running system controller with the backup system controller
- exit site care
- activities of daily living
- showering
- travel
- warnings and cautions.[1][6][8]

Complications

Complications associated with VADs may include:

- bleeding (perioperative or late)
- cardiac arrhythmias
- hypovolemia[6][8]
- local infection
- respiratory failure
- device malfunction
- sepsis
- right-sided heart failure
- driveline infection
- kidney failure
- stroke
- neurologic event
- psychiatric episodes
- peripheral thromboembolism
- hemolysis
- liver dysfunction
- device thrombosis
- myocardial infarction[8]
- air embolism
- aortic insufficiency
- driveline perforation
- erosion and other tissue damage
- GI bleeding
- arteriovenous malformations
- hypertension
- multiorgan failure
- pericardial effusion or tamponade
- platelet dysfunction
- worsening heart failure
- wound dehiscence
- death.[1][8][58]

Documentation

Documentation of VAD management includes:

- vital signs
    - use of Doppler ultrasound
- cardiac rhythm
- pulse oximetry
- hemodynamic parameters
- assessment findings
    - cardiovascular
    - respiratory
        - chest tube drainage
        - suction settings
    - neurologic
- pain scores
    - interventions performed
    - response to those interventions
- oxygen delivery type and settings
- patient positioning
- ROM
- oral care
- system parameters
- pump adjustments
- medications administered
    - medication name
    - medication strength
    - dose
    - route of administration
    - date and time of administration
    - access site used (if applicable)
    - administration device used
    - rate of administration (if applicable)
- intake and output
    - oral nutrition
    - urinary catheter drainage
- laboratory test results
- 12-lead ECG findings (if done)
- complications
    - date and time of practitioner notification
    - name of the practitioner notified
    - prescribed interventions
    - response to those interventions.
- dressing changes
- condition of the insertion site
- teaching provided to the patient and family (if applicable)
    - understanding of that teaching
    - follow-up teaching needed.

Related Procedures

- Ventricular assist device (Impella), percutaneous, management

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(Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions)

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Rating System for the Hierarchy of Evidence for Intervention/Treatment Questions

The following leveling system is adapted from *Evidence-Based practice in nursing & healthcare: A guide to best practice,* Fifth edition, by Bernadette Mazurek Melnyk and Ellen Fineout-Overholt (2023).

Level I	Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs)
Level II	Evidence from well-designed single RCTs (experimental)
Level III	Evidence from well-designed nonrandomized controlled trials (quasi-experimental), systematic reviews of a complete body of evidence, and intervention studies using mixed methods
Level IV	Evidence from well-designed case-control and cohort studies (observational)
Level V	Evidence from systematic reviews of qualitative and descriptive studies
Level VI	Evidence from single descriptive and qualitative studies, evidence-based practice implementation, and quality improvement projects
Level VII	Evidence from expert opinion, expert committee reports, and literature reviews

Data from Gyatt, G., & Rennie D. (2002). Users' guides to the medical literature. American Medical Association; Harris, R. P., et al. (2001). Current methods of the U.S. Preventative Services Task Force: A review of the process. American Journal of Preventative Medicine, 20, 21-35.

Procedure: Bilevel positive airway pressure (BiPAP) use

Checklist: Bilevel positive airway pressure (BiPAP) use

Evaluator's Name: _____ **Examinee's Name:** _____

Evaluator's ID: _____ **Examinee's ID:** _____

Evaluator's Dept: _____ **Examinee's Dept:** _____

Date: _____ **Meets criteria/Does not meet criteria:** _____

Select Evaluation Method:

☐ Clinical Observation ☐ Documentation Review

☐ Demonstration ☐ Verbalization

Bilevel positive airway pressure (BiPAP) use

Objective: To use bilevel positive airway pressure (BiPAP) according to the standard of care.

Checklist Step	Comments
Y- Meets; N- Does not meet; I- Not Applicable	
__ Verify the practitioner's order.	
__ Review the patient's medical record for history, indication for BiPAP use, and contraindications to BiPAP use.	
__ Gather and prepare the necessary equipment and supplies.	
__ Perform hand hygiene.	
__ Confirm the patient's identity using at least two patient identifiers.	
__ Provide privacy.	
__ Explain the procedure to the patient and family (if appropriate) according to their individual communication and learning needs.	
__ Raise the bed to waist level before providing care.	
__ Perform hand hygiene.	
__ Put on gloves and, as needed, other personal protective equipment.	
__ Obtain the patient's vital signs.	

__ If not already in use, attach a pulse oximeter to the patient. Make sure that alarms are turned on, functioning properly, and audible.

__ Obtain the patient's oxygen saturation level using pulse oximetry, and assess the patient's respiratory status.

__ Adjust the inspiratory positive airway pressure, expiratory positive airway pressure, breaths/minute (if applicable), inspiratory time, and fraction of inspired oxygen, as ordered. The initial setting for inspiratory positive airway pressure is usually 10 cm H_2O; for expiratory positive airway pressure, 5 cm H_2O. Titrate pressures, as ordered, and according to the patient's condition.

__ Adjust the sensitivity as low as possible without causing autocycling.

__ Confirm the settings by comparing them with the practitioner's order. Confirm that the BiPAP device is functioning properly.

__ Apply the patient interface to the patient's face, secure it with the headgear, and tighten the straps. Avoid tightening the straps more than necessary.

__ Set the alarm limits on the BiPAP device and make sure that alarms are turned on, functioning properly, and audible.

__ Monitor the patient's vital signs, oxygen saturation level, and respiratory status, observing for chest expansion and auscultating for bilateral breath sounds.

__ Obtain an arterial blood sample for arterial blood gas analysis if ordered. Notify the practitioner of critical test results within your facility's established time frame.

__ Maintain the head of the patient's bed at 30 to 45 degrees unless contraindicated. If the patient can't bend at the hip, use the reverse Trendelenburg position.

__ Regularly assess the patient's skin for signs of skin breakdown under the patient interface. If redness persists after removing the interface, apply a liquid skin barrier or hydrocolloid patch.

__ Assist the patient with oral care, including brushing the teeth, tongue, and gums at least twice per day using a soft toothbrush and moisturizing the patient's oral mucosa and lips every 2 to 4 hours.

__ Return the bed to the lowest position.

__ Remove and discard your gloves and, if worn, other personal protective equipment.

__ Perform hand hygiene.

__ Place the call light within the patient's reach, and establish an alternative method of communication such as a communication board if necessary.

__ Clean and disinfect your stethoscope with a disinfectant pad.

__ Perform hand hygiene.

__ Put on gloves and, as needed, other personal protective equipment.

__ Clean and disinfect other reusable equipment according to the manufacturer's instructions.

__ Remove and discard your gloves and, if worn, other personal protective equipment.

__ Perform hand hygiene.

__ Document the procedure.