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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PREFACE

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

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

• 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*.

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

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.

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.

BASIC ORIENTATION

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

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.

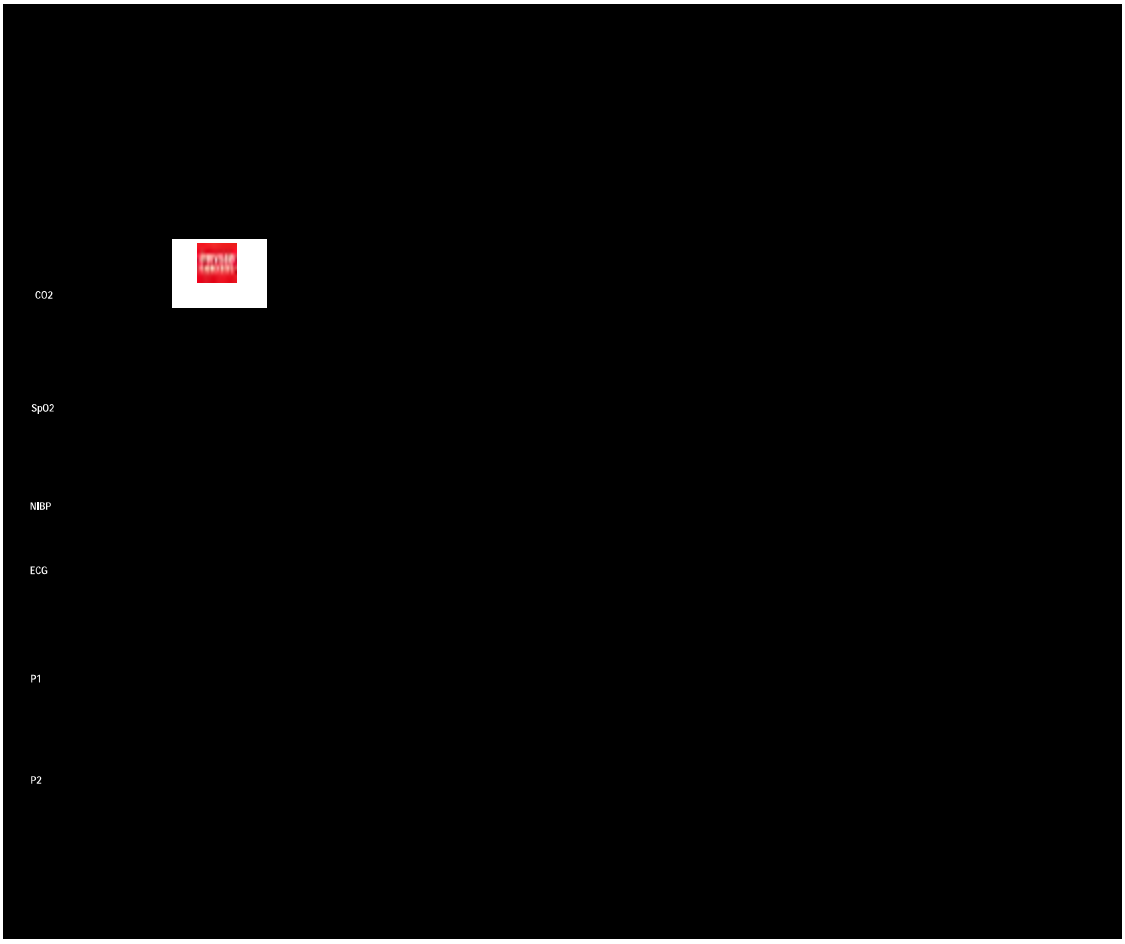


Figure 3-1 Front View

Area 1

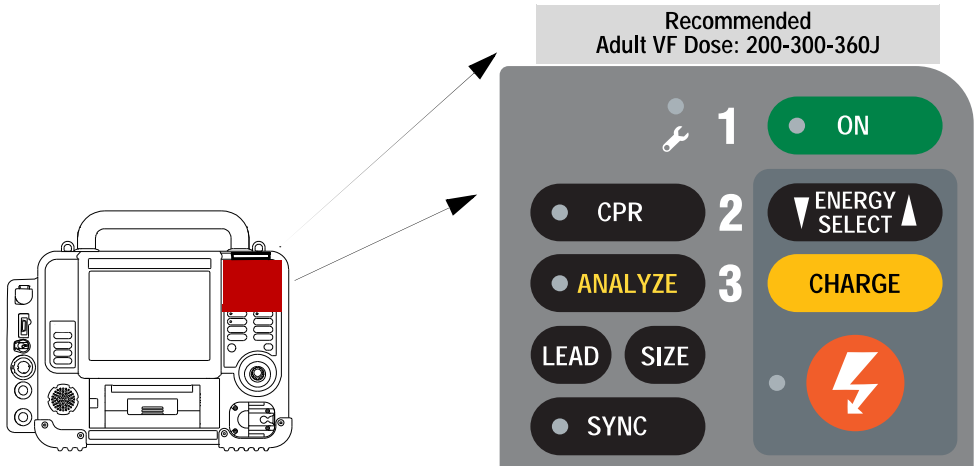


Figure 3-2 Area 1 Controls

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

Area 2

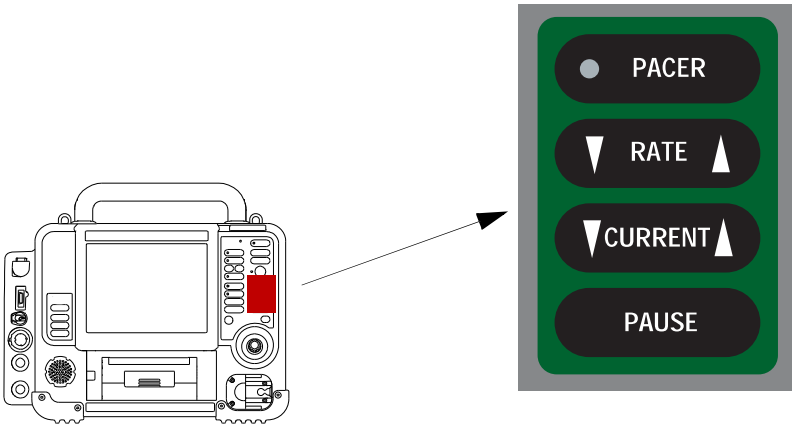


Figure 3-3 Area 2 Controls

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

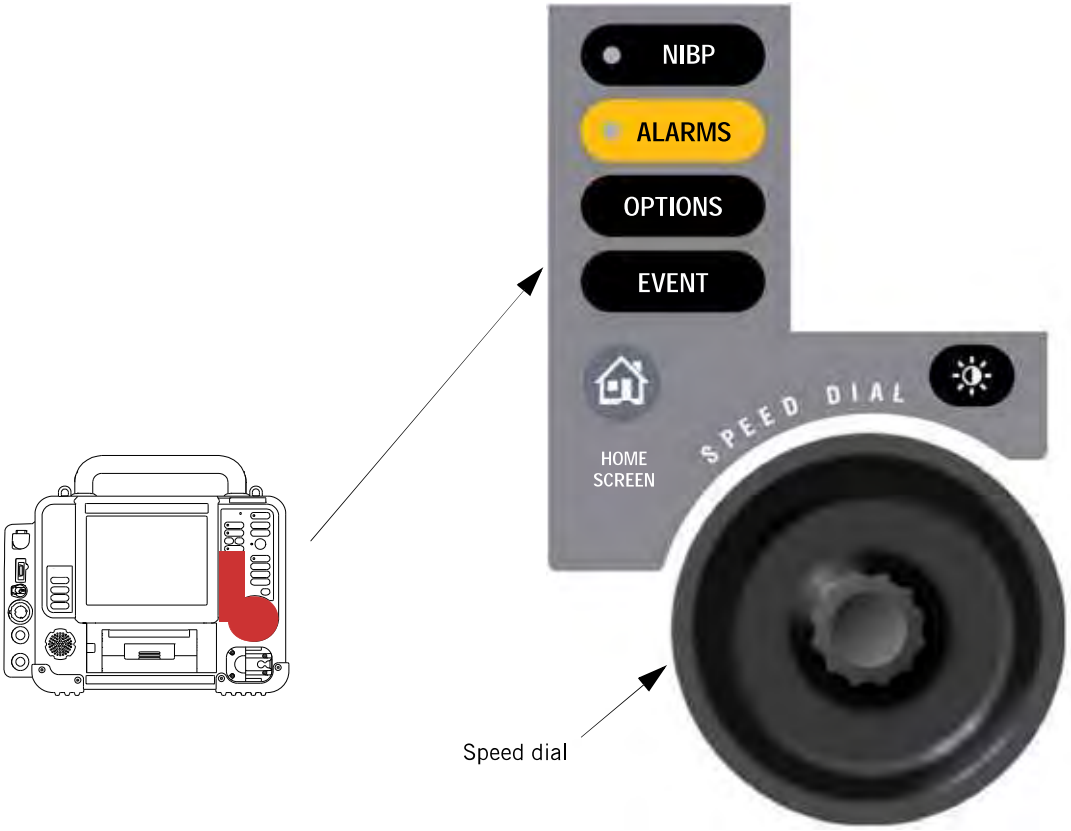


Figure 3-4 Area 3 Controls

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	

Area 4

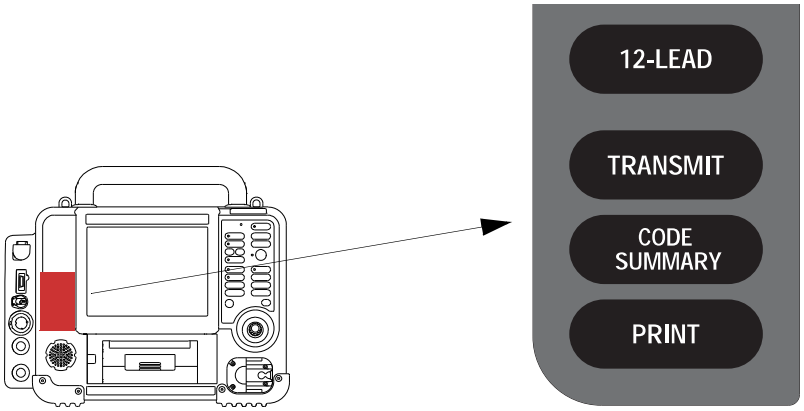


Figure 3-5 Area 4 Controls

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

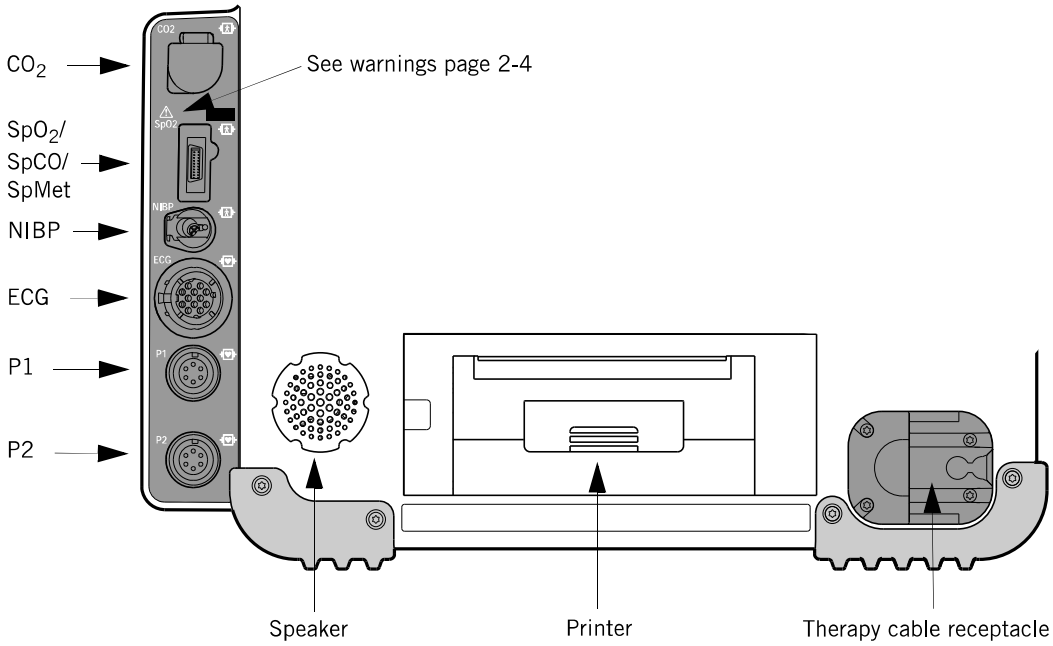
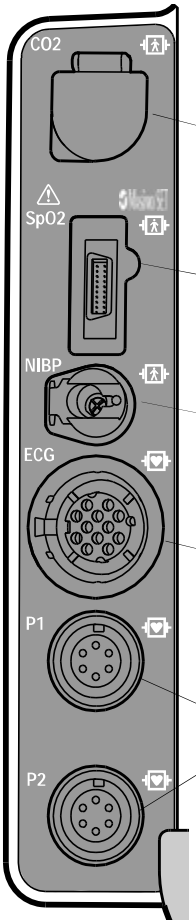


Figure 3-6 Area 5 Connectors, Speaker, and Printer

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

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

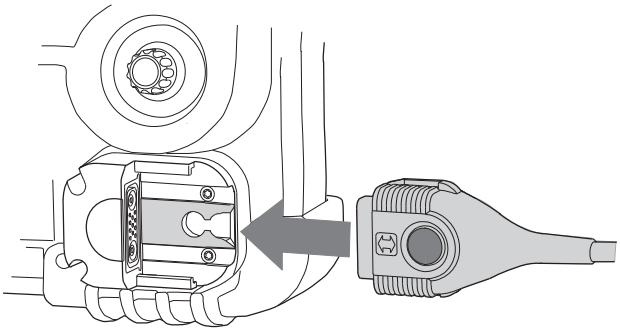
WARNING

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.

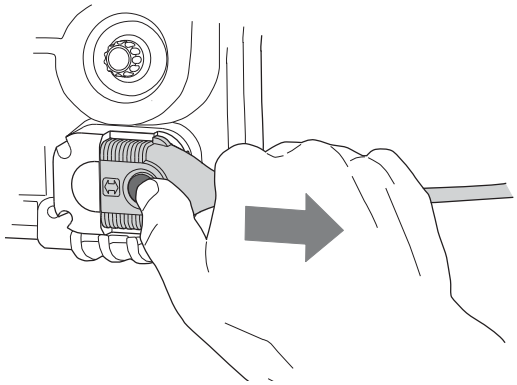
To connect a therapy cable to the defibrillator:



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

Back View

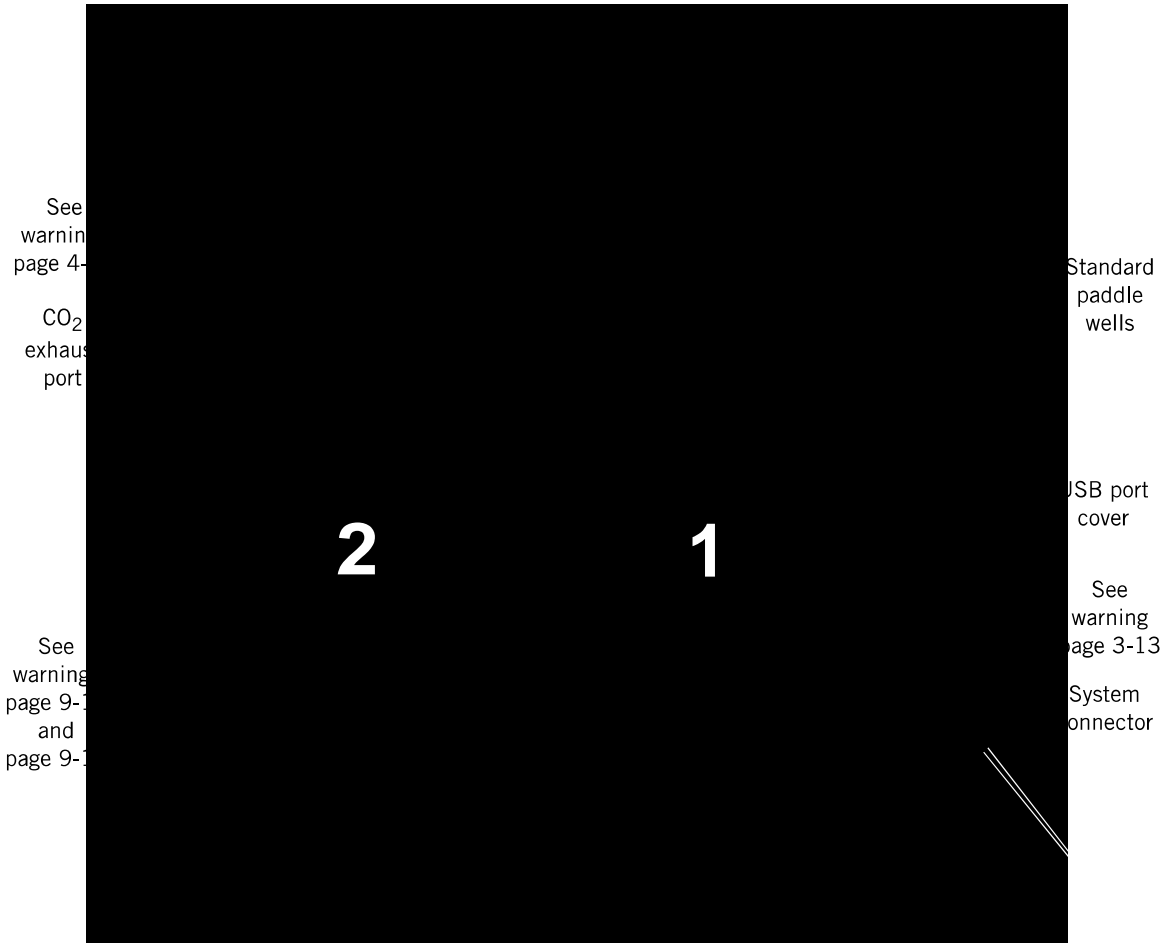


Figure 3-9 Back View

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.

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.

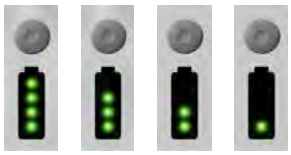


Figure 3-10 Battery Charge Indicators

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.

Home Screen

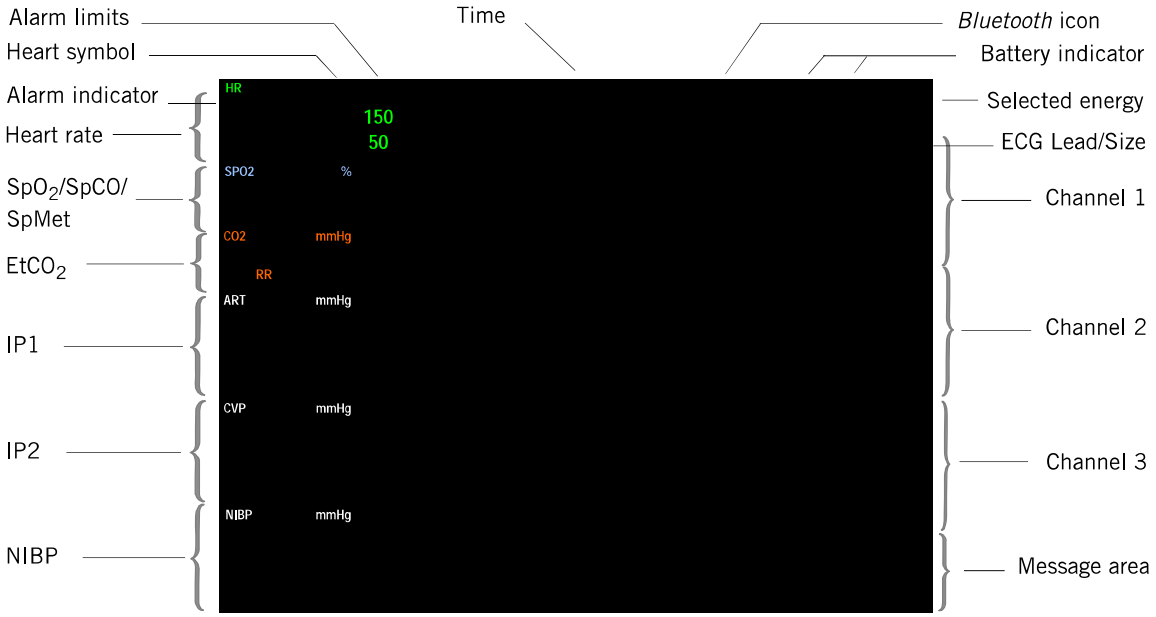


Figure 3-12 Home Screen

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

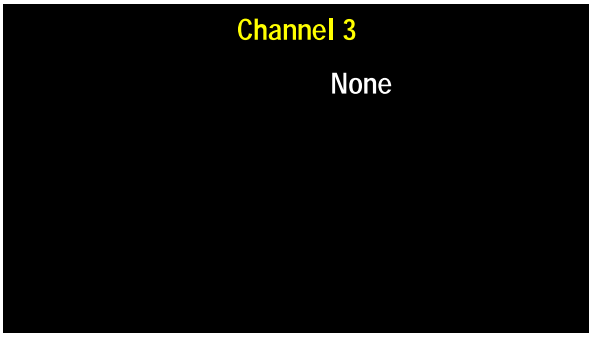
Table 3-7 Home Screen (Continued)

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.

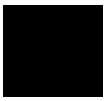
Battery Status Indicators

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.

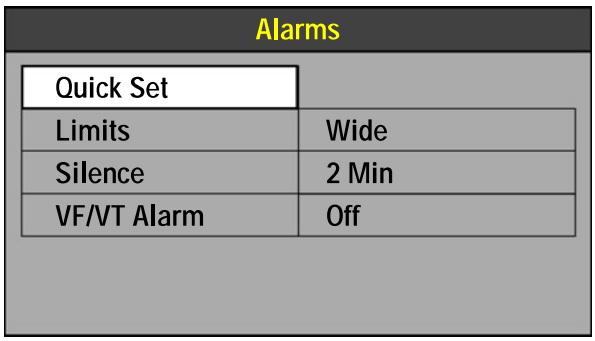
If alarms are set up to be OFF, press **ALARMS** to enable the alarms. Whether alarms are set up to be ON or are enabled by pressing **ALARMS**, they can only be turned off by pressing **ON** to turn off the device. If power is lost for less than 30 seconds, for example due to a system reset or changing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

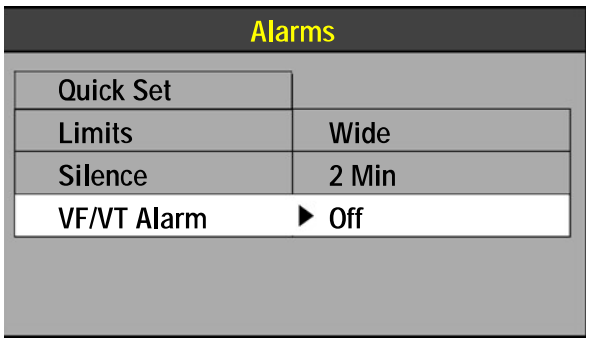
The Quick Set limits automatically set high and low limits based on the patient's current vital sign values. For example, if the patient's HR is 70, selecting **WIDE** results in a high limit of 110 and a low limit of 45; selecting **NARROW** results in a high limit of 100 and a low limit of 50. The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

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.

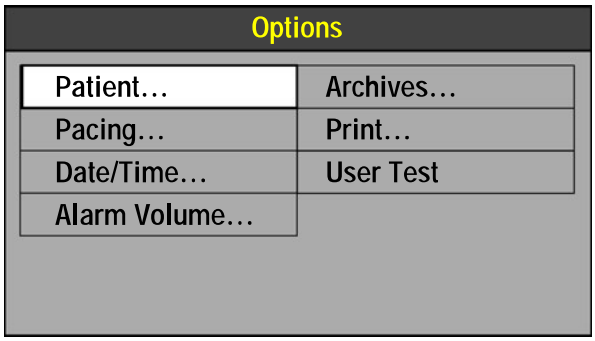


Table 3-9 Options Menu Selections

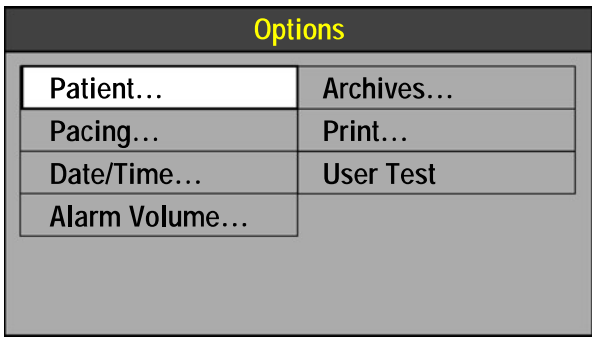
SELECTION	DESCRIPTION	FOR MORE INFORMATION
Patient	Enter patient name, patient ID, incident, age, and sex.	See "Entering Patient Data" in next section
Pacing	Select demand or nondemand pacing. Set internal pacer detection ON or OFF.	See page 5-31
Date/Time	Set date and time. Cycle power for change to 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

Table 3-9 Options Menu Selections (Continued)

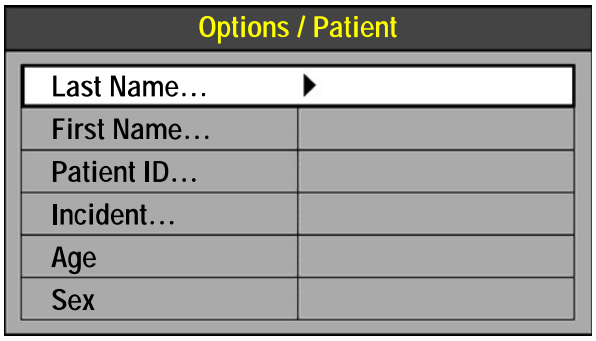
SELECTION	DESCRIPTION	FOR MORE INFORMATION
Print	Select report, format, mode, and speed for printing a current patient report.	See page 7-10
User Test	Initiate device self-test.	See page 9-5

Entering Patient Data

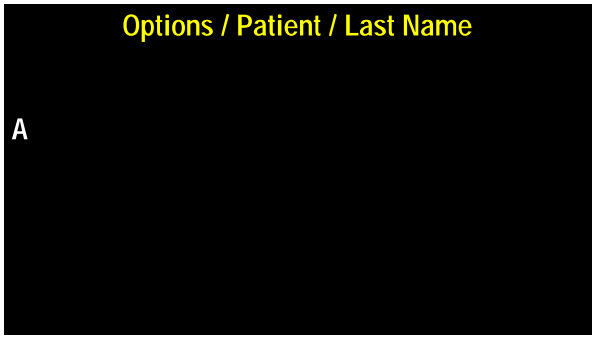
To enter patient data:



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.)



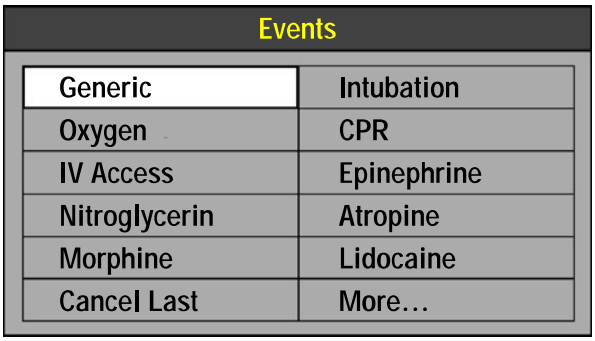
4. Rotate the **SPEED DIAL** to scroll through the characters and commands. Press the **SPEED DIAL** to make a selection. The selected character appears.
5. Repeat Step 4 until the name is complete.
6. Select **END**.

   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.

4

MONITORING

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

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.

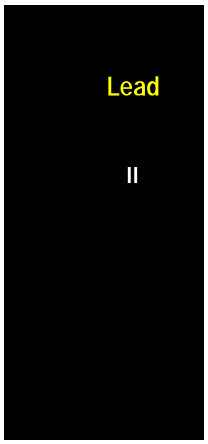
IMPORTANT! Set the high heart rate alarm for patients who have heart rates above 300 bpm.

- 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.

Selecting ECG Lead

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

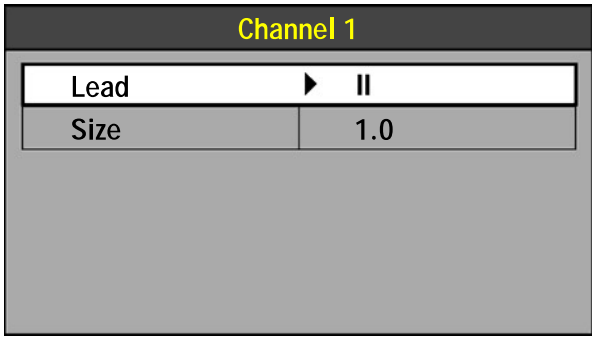
To select or change the displayed ECG lead using the **LEAD** button:



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.

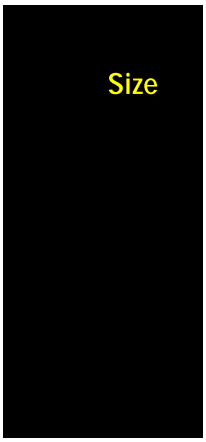
Note: The ECG shows dashed lines until the electrodes are connected to the patient.

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

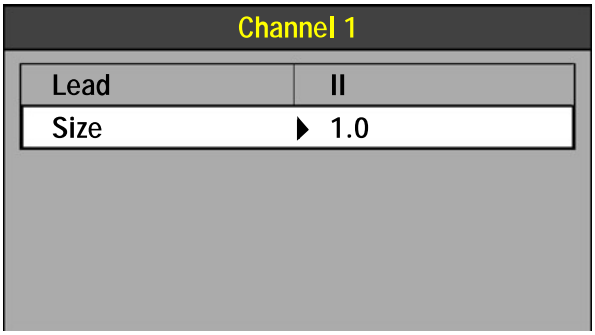
The LIFEPAK 15 monitor/defibrillator includes two methods for selecting or changing ECG size.

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.

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

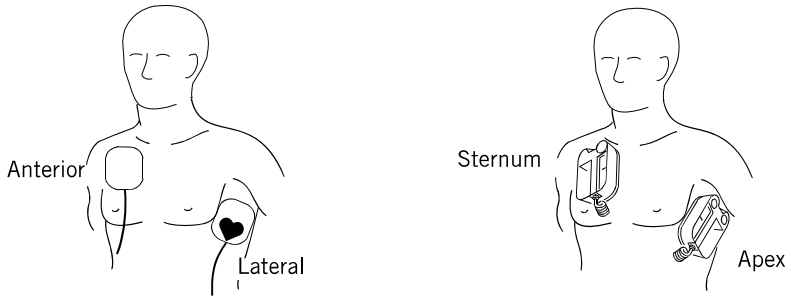
To monitor ECG using paddles, you can use either QUIK-COMBO therapy electrodes or standard (hard) paddles. For more information about paddle accessories, see Chapter 6, "Paddle Accessory Options."

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.

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

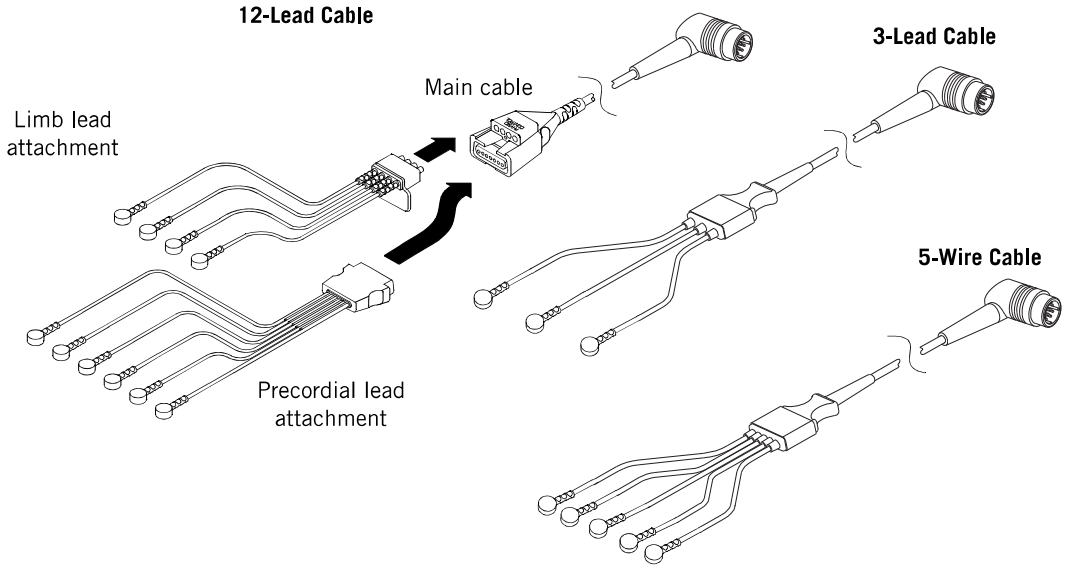
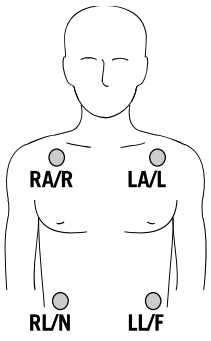


Figure 4-2 12-Lead, 3-Lead, and 5-Wire ECG Cables

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.

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.

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.

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

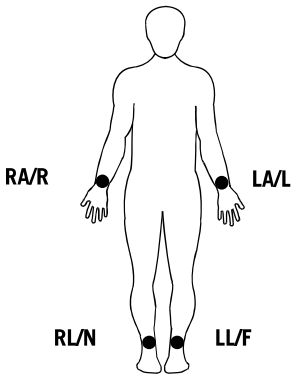
Using previously unpackaged electrodes or electrodes past the Use By date may impair ECG signal quality. Remove electrodes from a sealed package immediately before use and follow the procedure for applying the electrodes.

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.

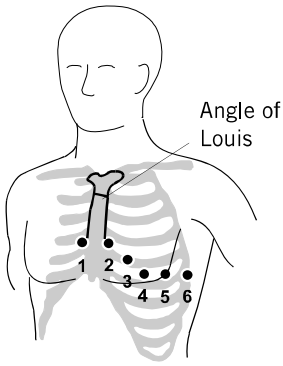


AHA Labels		IEC Labels	
RA	Right Arm	**R**	Right
LA	Left Arm	**L**	Left
RL	Right Leg	**N**	Negative
LL	Left Leg	**F**	Foot

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.

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.

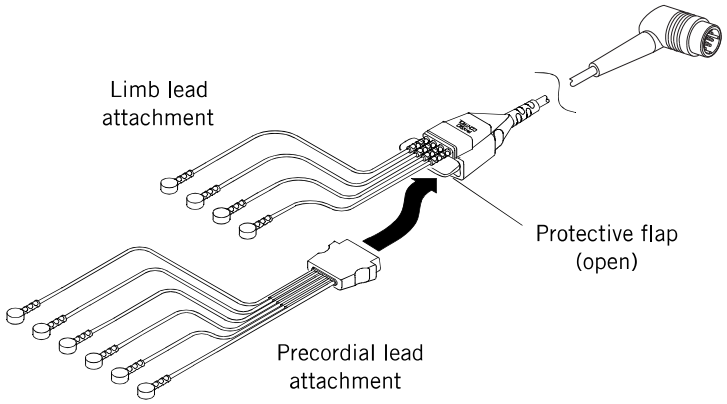


Figure 4-6 12-Lead ECG Cable

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

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**.

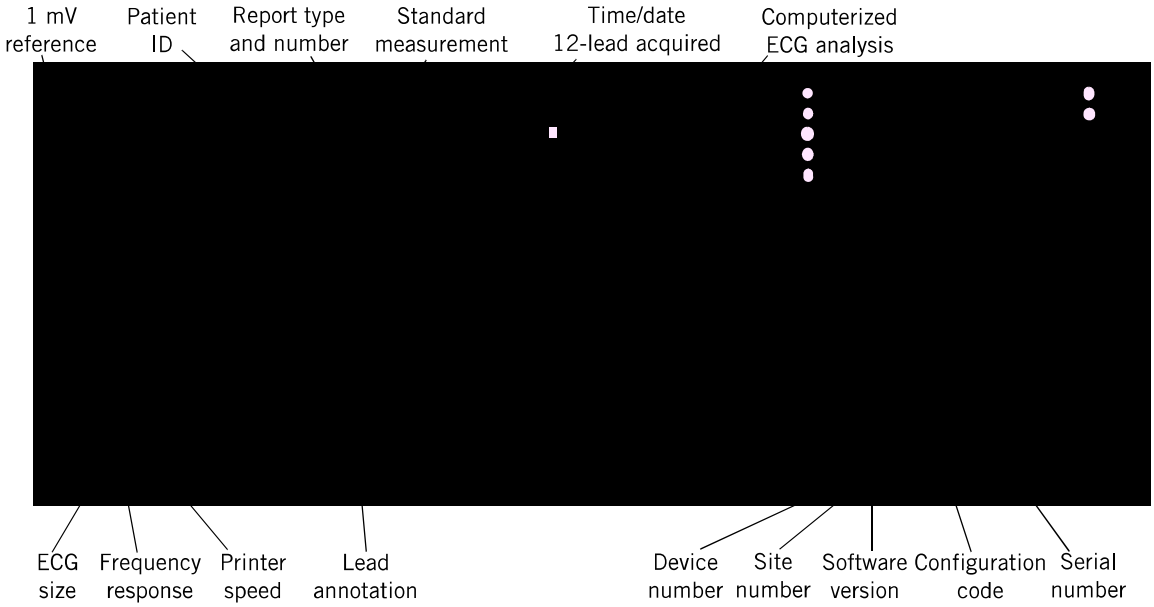


Figure 4-7 Example of Printed 3-Channel, Standard 12-Lead ECG Report

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.

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.

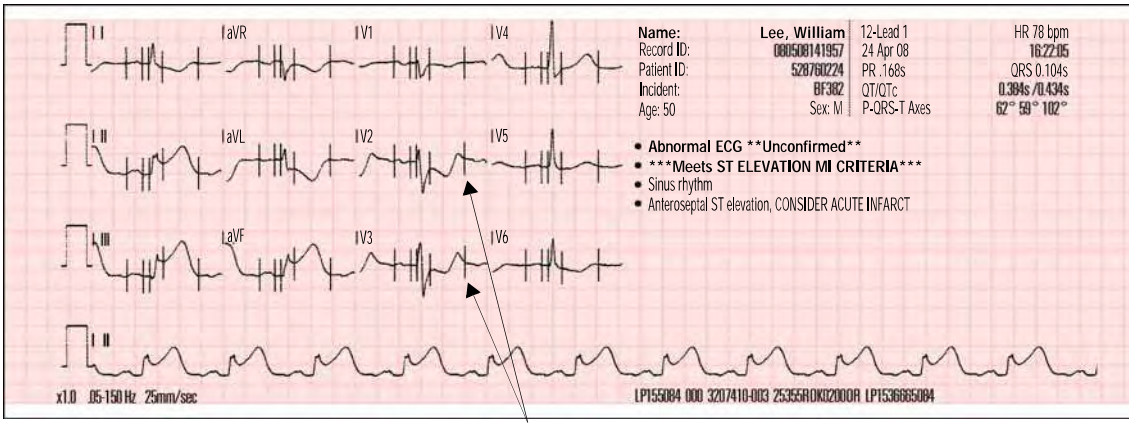


Figure 4-9 Example of Printed 4-Channel, Standard 12-Lead ECG Report

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.

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.

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.

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.

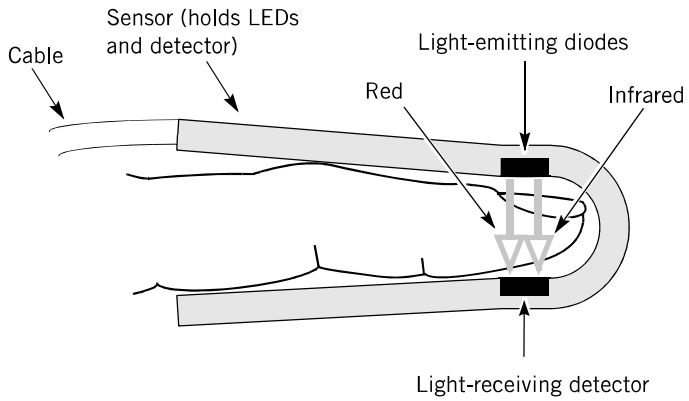


Figure 4-11 How a Pulse Oximeter Works

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.

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**.

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.

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.

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.

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.

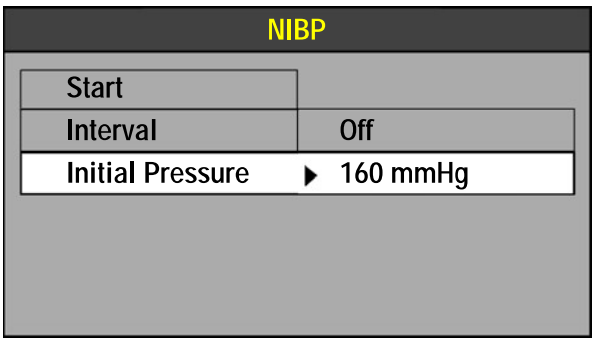
IMPORTANT! The LIFEPAK 15 monitor NIBP port and tubing are not compatible or interchangeable with the NIBP tubing that is used with other LIFEPAK monitor/defibrillators.

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.

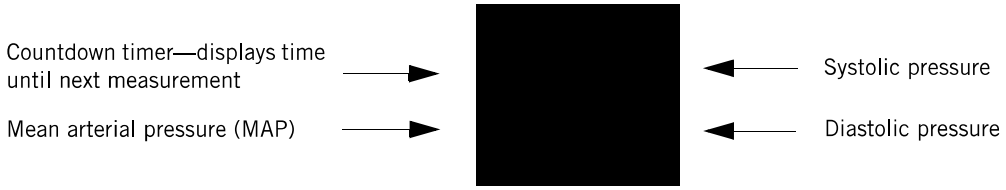


Figure 4-12 NIBP Measurements and Timer

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.

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.

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.

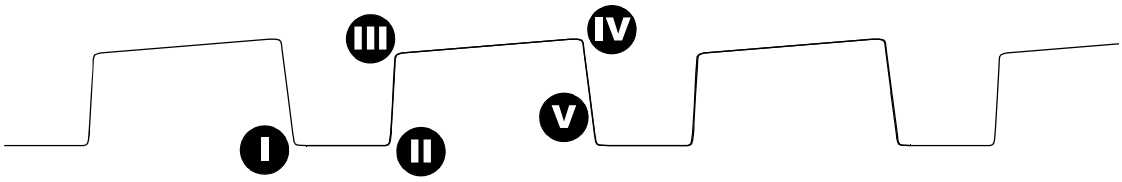


Figure 4-13 Phases of the Respiratory Waveform

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.

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.

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.

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.

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.

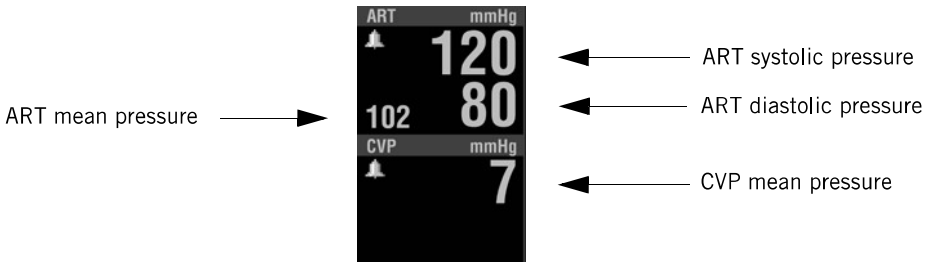


Figure 4-14 IP Labels

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.

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.

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.

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

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).

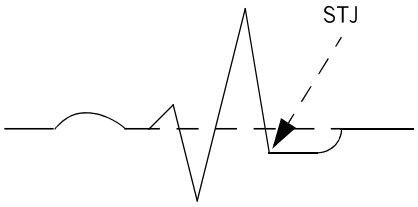


Figure 4-17 STJ Measurement

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.

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

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.

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.

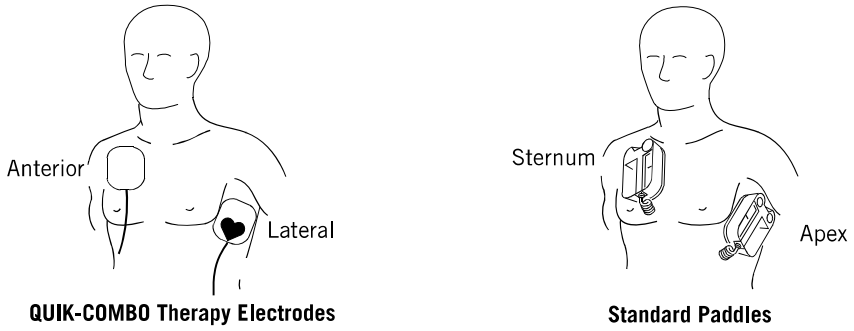


Figure 5-1 Anterior-Lateral Placement

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.

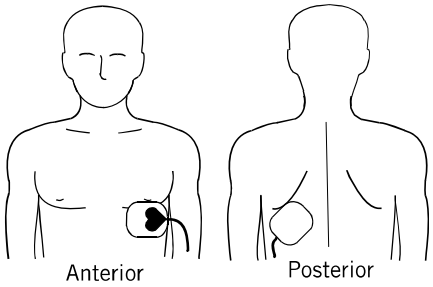


Figure 5-2 Anterior-Posterior Placement

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.

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.

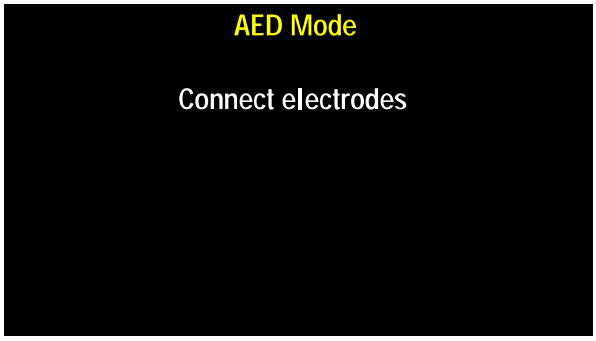
AED Procedure

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.

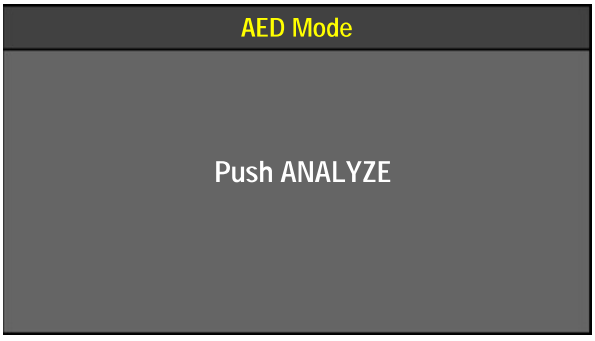
To perform automated external defibrillation:

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).



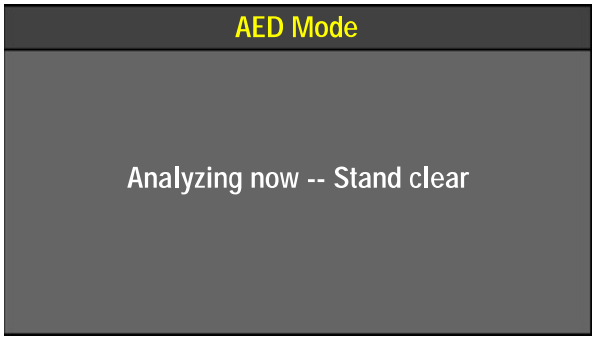
The **PUSH ANALYZE** prompts occur when the patient is properly connected to the AED.

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.

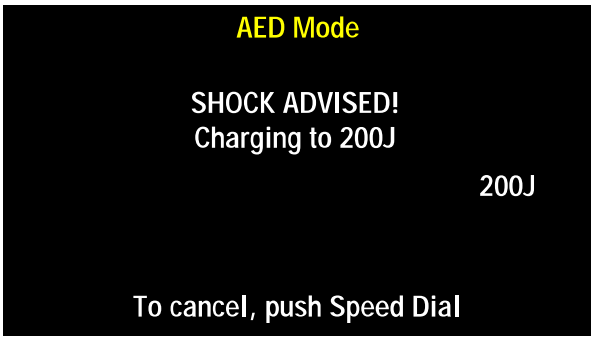


The **ANALYZING NOW—STAND CLEAR** prompts occur. The SAS analyzes the patient's ECG in approximately 6 to 9 seconds and advises either **SHOCK ADVISED** or **NO SHOCK ADVISED**.

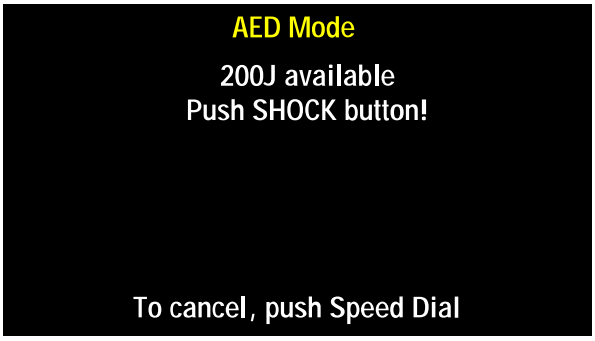
7. Continue to follow the screen messages and voice prompts provided by the AED.

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.

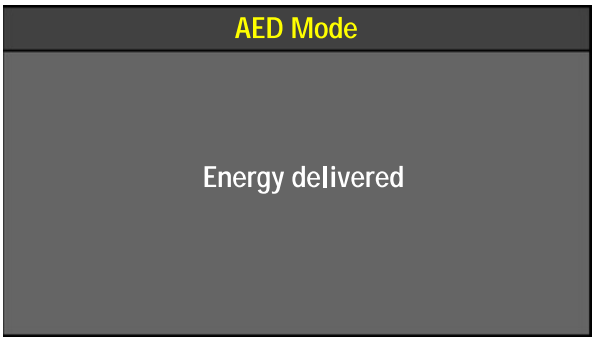


When charging is complete, the available energy is displayed.

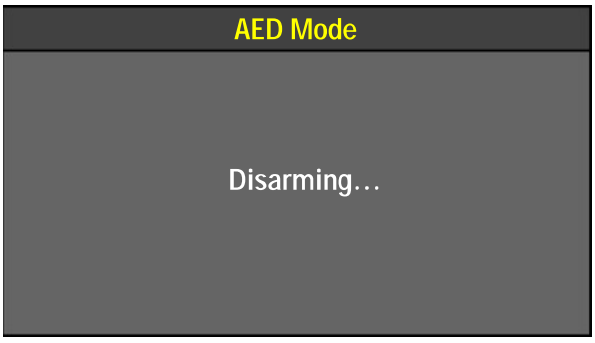
The **STAND CLEAR, PUSH SHOCK BUTTON!** ( ) message occurs, followed by a "Shock ready" tone.

Clear everyone away from touching the patient, bed, or any equipment that is connected to the patient.

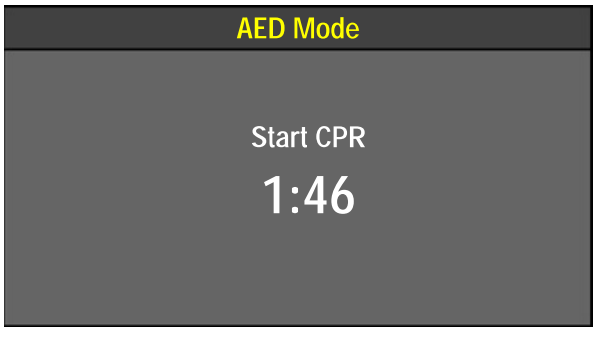
Press (shock) to deliver energy to the patient.



When the (shock) button is pressed, the **ENERGY DELIVERED** message occurs indicating that the energy transfer was completed.

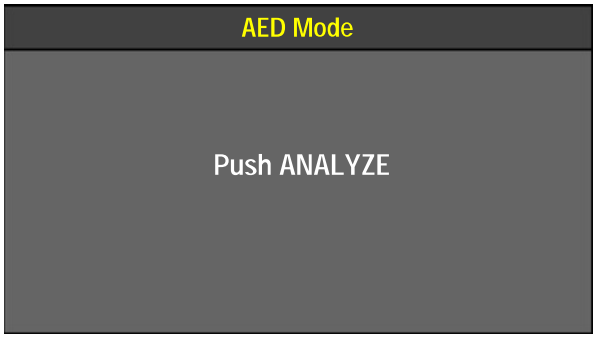


Note: If you do not press the (shock) button within 60 seconds, or the **SPEED DIAL** is pressed to cancel charging, the defibrillator disarms and the **DISARMING** message appears.



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.

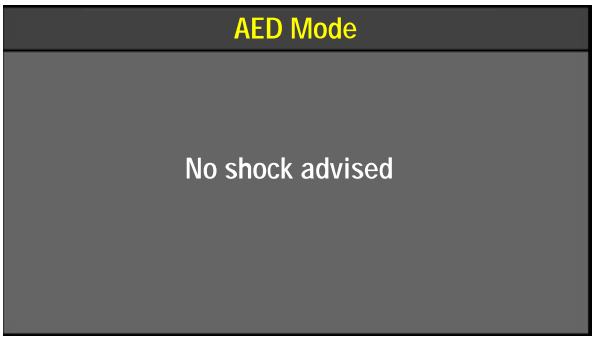
Note: The CPR metronome automatically provides audible compression "tocks" and ventilation prompts or tones only during CPR intervals at a ratio of 30:2. To silence the metronome, press **CPR**. To un-silence the metronome, press **CPR** again.



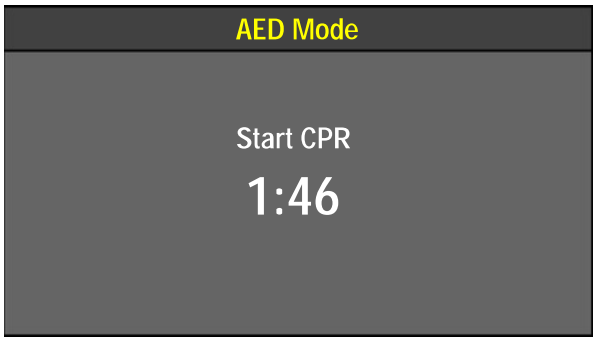
When the CPR countdown time ends, the **PUSH ANALYZE** prompts occur. These prompts repeat every 20 seconds until you press **ANALYZE**.

No Shock Advised

The following prompts occur if no shock is advised:

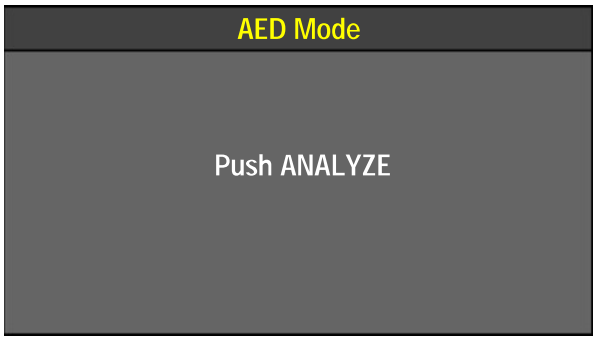


If the AED detects a nonshockable rhythm, the **NO SHOCK ADVISED** prompts occur. The defibrillator does not charge, and no shock can be delivered.



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.

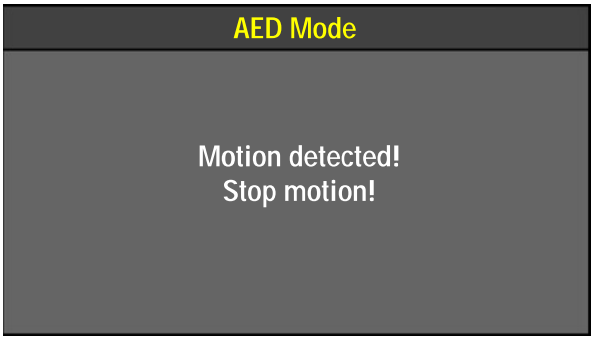
Note: The CPR metronome automatically provides audible compression "tocks" and ventilation prompts or tones only during CPR intervals. To silence the metronome, press **CPR**. To un-silence the metronome, press **CPR** again.



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.

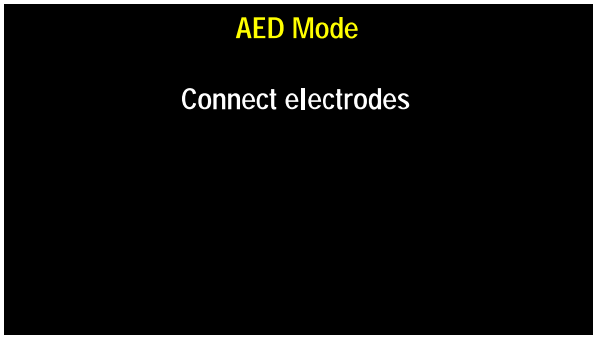
Motion Detected



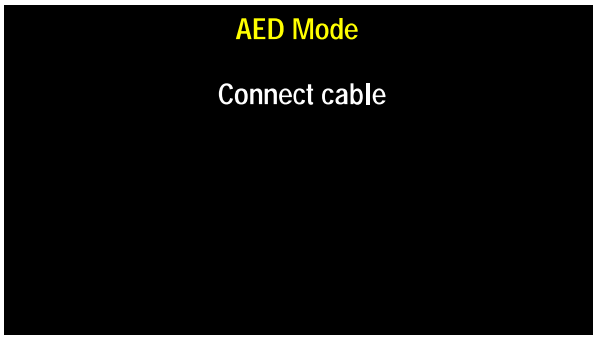
If the AED detects motion during the ECG analysis, the **MOTION DETECTED, STOP MOTION** prompts occur, followed by a warning tone.

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.

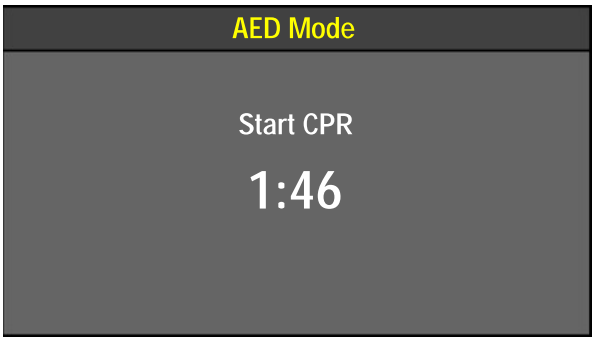


If the therapy cable is not connected to the defibrillator, the **CONNECT CABLE** message appears until the cable is connected.

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

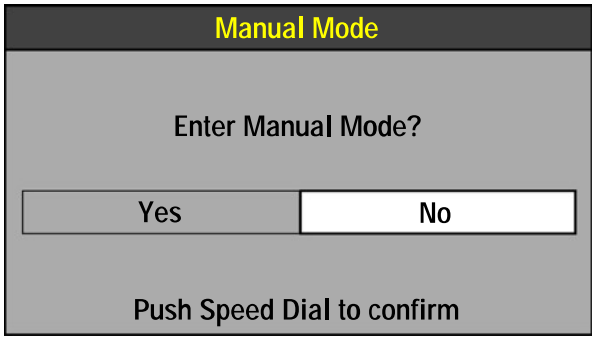
When in AED mode, Manual mode may be accessed directly, require confirmation or a passcode, or not be accessible at all depending on how your defibrillator has been set up.

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.

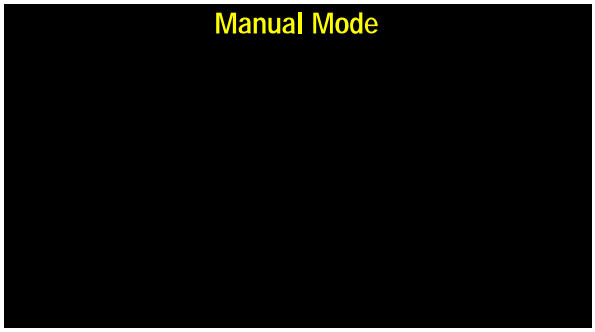
Depending on how manual access is set up, continue to Manual mode as follows:

- **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.

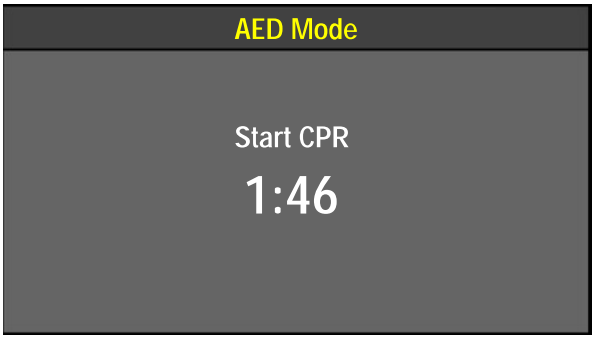
It is important that all users of the LIFEPAK 15 monitor/defibrillator be thoroughly familiar with the monitor/defibrillator settings and operation before use.

Special AED Setup Options

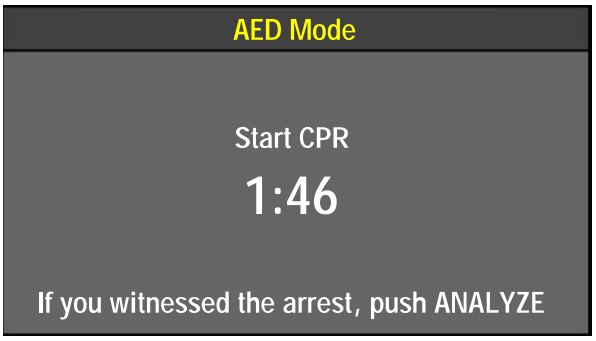
The following descriptions of AED prompts (voice and text) explain special setup options.

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.



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.

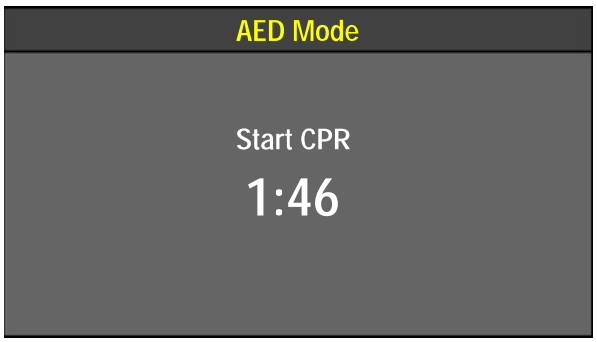
- If you did witness the arrest, press **ANALYZE.** The CPR period ends, and the **ANALYZING NOW, STAND CLEAR** prompts occur.
- If you did not witness the arrest, perform CPR and do not press **ANALYZE.** The Initial CPR countdown timer continues for the duration specified in the **INITIAL CPR TIME** 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.

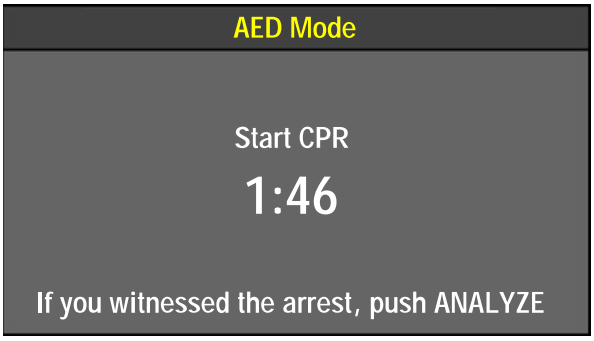
No Shock Advised If the AED detects a nonshockable rhythm, the **START CPR** prompts occur.



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.**



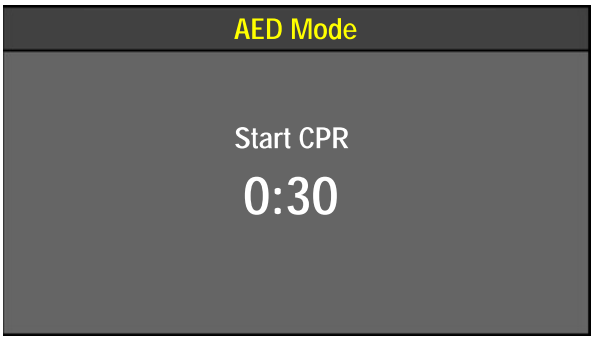
These prompts provide an opportunity to end the initial CPR early and proceed directly to delivering a shock.

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.

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.

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.

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

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

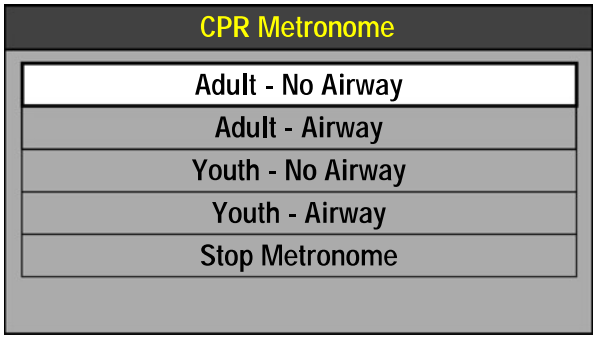
AGE-AIRWAY	C:V RATIO
Adult - No Airway*	30:2
Adult - Airway**	10:1
Youth - No Airway***	15:2
Youth - Airway	10:1

* 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

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.

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.

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.

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**.

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.

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.

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."

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

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).

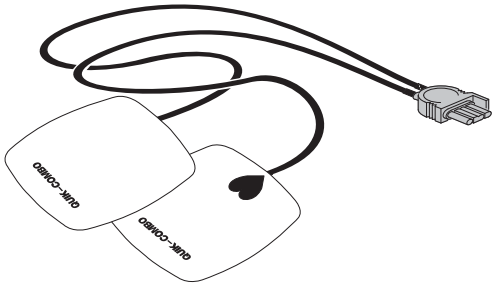


Figure 6-1 QUIK-COMBO Therapy Electrodes

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

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.

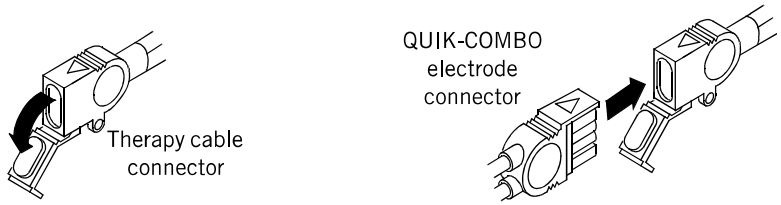


Figure 6-2 Connect QUIK-COMBO Electrodes to Therapy Cable

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.

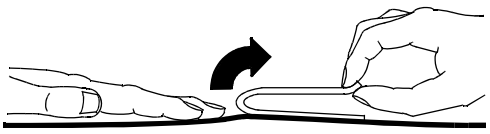


Figure 6-3 Removing Therapy Electrodes from Skin

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.

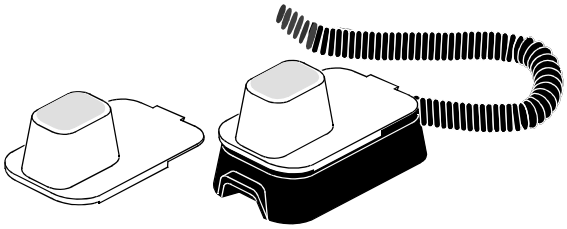


Figure 6-5 Pediatric Paddles

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.

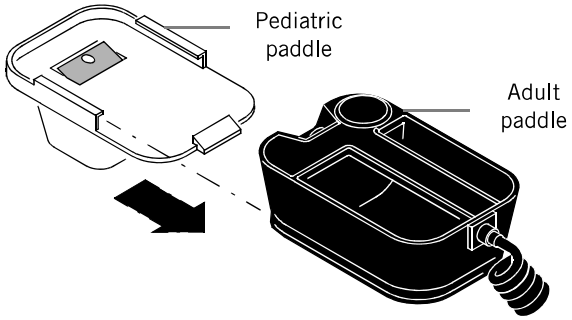


Figure 6-6 Attaching a Pediatric Paddle

DATA MANAGEMENT

This chapter describes how to manage current and archived Patient Records when using the LIFEPAK 15 monitor/defibrillator.

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

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.

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

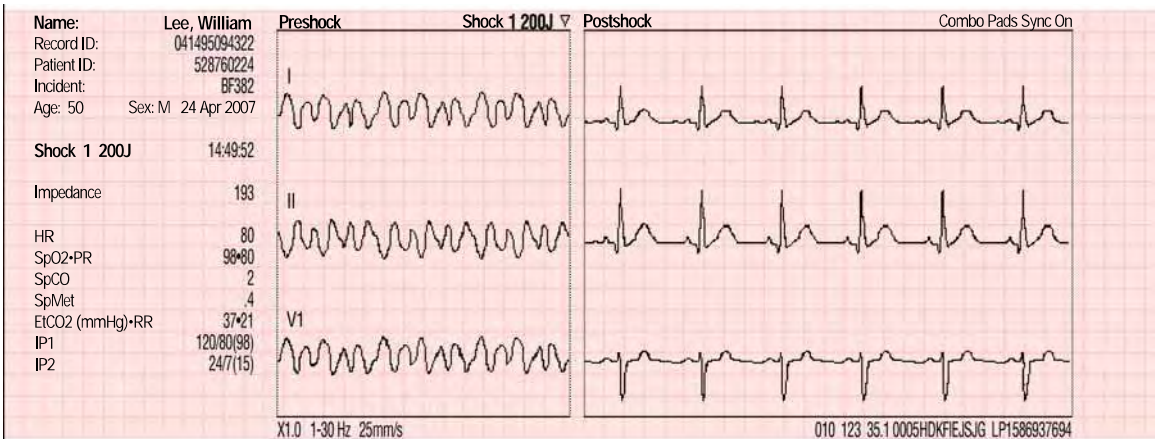
*Patient impedance (in ohms) appears on shock reports when using disposable defibrillation electrodes. This impedance is measured just prior to the shock and is used to determine voltage compensation.

Figure 7-3 shows four examples of waveform events as they would appear in the CODE SUMMARY report.

Analysis Event

[redacted]

Shock Event



Check Patient Event

[redacted]

Pacing Event

Figure 7-3 Waveform Event Printout Examples

Memory Capacity

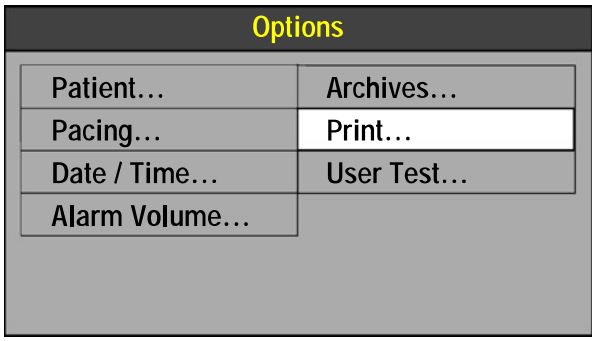
The LIFEPAK 15 monitor/defibrillator retains data for two or more patients when you switch power off or remove the batteries. The number of patient reports that the LIFEPAK 15 monitor/defibrillator can store depends on various factors, including the number of displayed waveforms, the duration of each 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.

Managing Current Patient Records

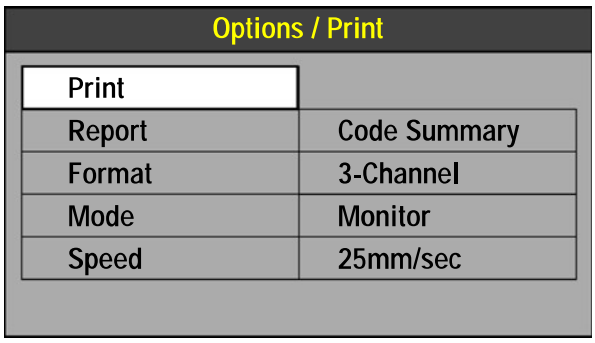
You can add specific patient information to a current Patient Record. For more information, see "Entering Patient Data" on page 3-24.

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**

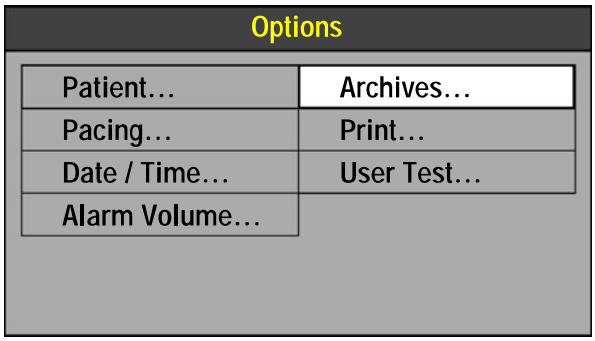
Managing Archived Patient Records

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."

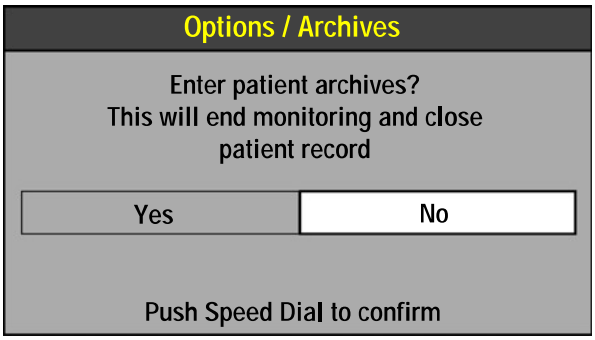
Note: When you enter Archive mode, patient monitoring ends (for example, no ECG, no alarms) and the current Patient Record is saved and closed.

Accessing Archive Mode

To enter Archive mode:



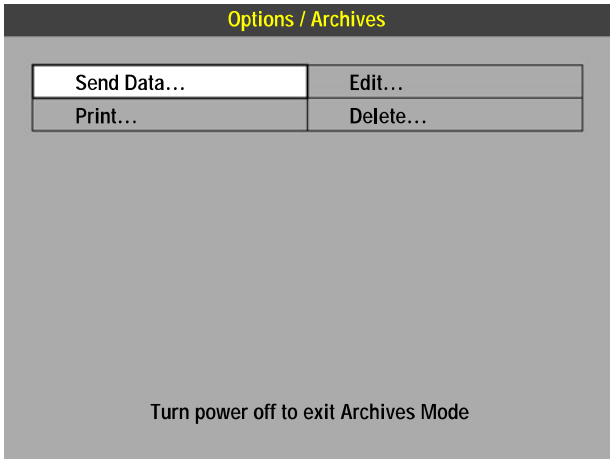
1. Press **OPTIONS**. The Options menu appears.
2. Select **ARCHIVES**. The Options/Archives menu appears.



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.

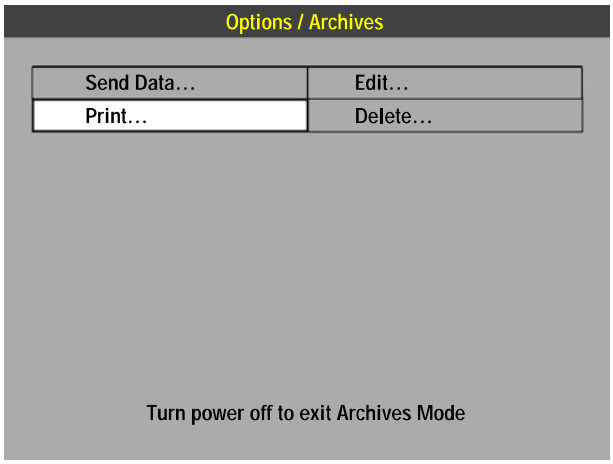
Note: To exit Archive mode, power off the device.



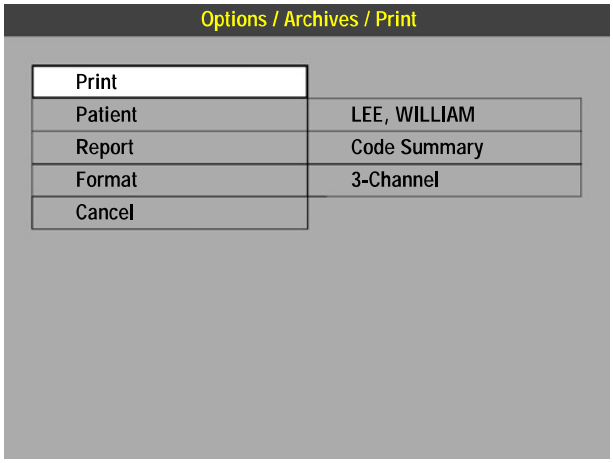
You can send, print, edit, or delete an archived record. For information about sending an archived record, see Chapter 8, "Data Transmission."

Printing Archived Patient Reports

To print archived patient reports:



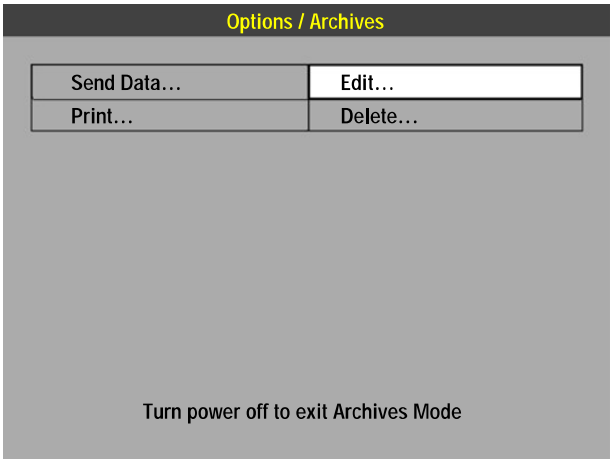
1. In Archive mode, select **PRINT**. The Options/Archives/Print menu appears showing the current patient.



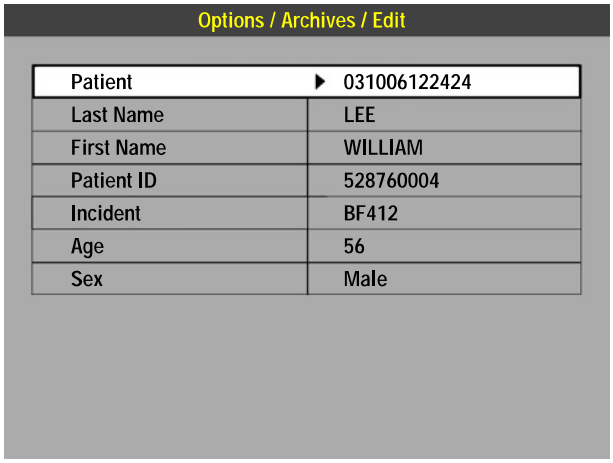
2. If the **PATIENT**, **REPORT**, and **FORMAT** settings are correct, go to Step 6.
3. To select a different patient, select **PATIENT** and then select the desired patient from the list.
4. To select a different report, select **REPORT** and then select one of the following:
   - **CODE SUMMARY**
   - **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:



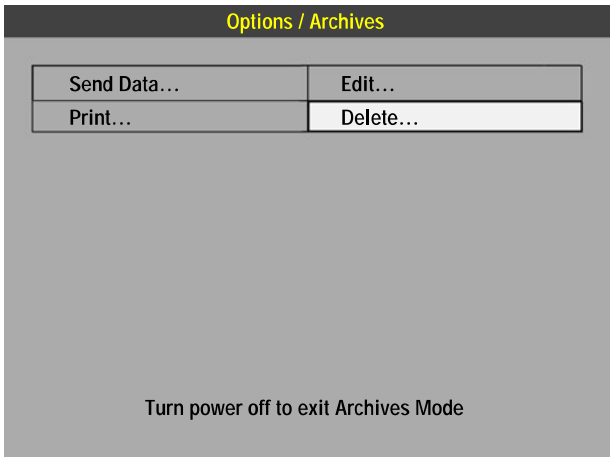
1. In Archive mode, select **EDIT**. The Options/Archives/Edit menu appears.



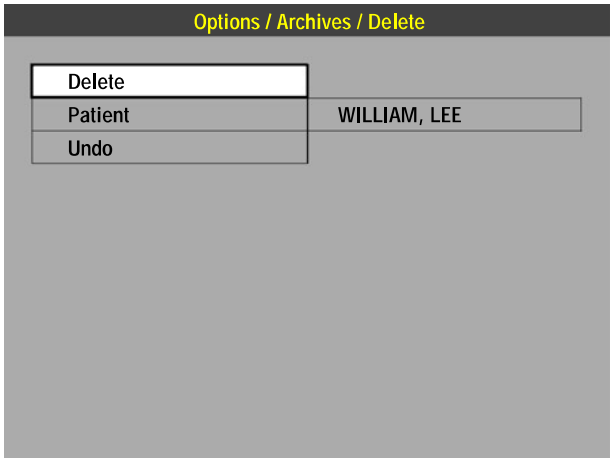
2. Select **PATIENT**.
3. Add the necessary patient information. Only blank fields may be edited.
4. Press **HOME SCREEN** and then turn off the device.

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

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.

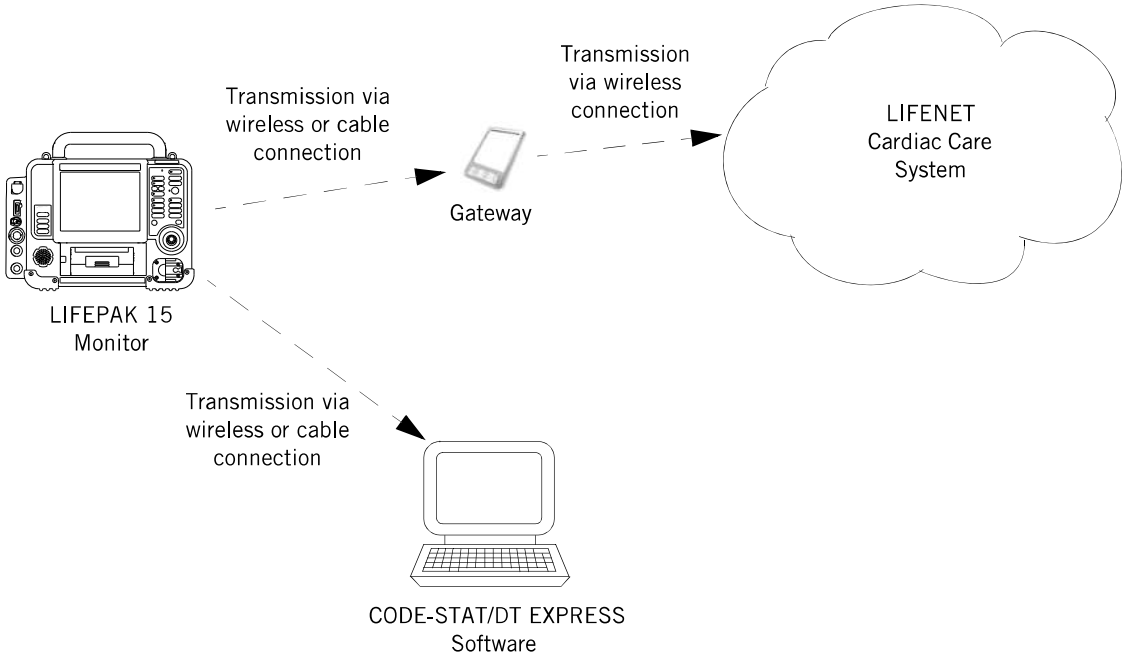


Figure 8-1 Transmitting Data from the LIFEPAK 15 Monitor/Defibrillator

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.

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.

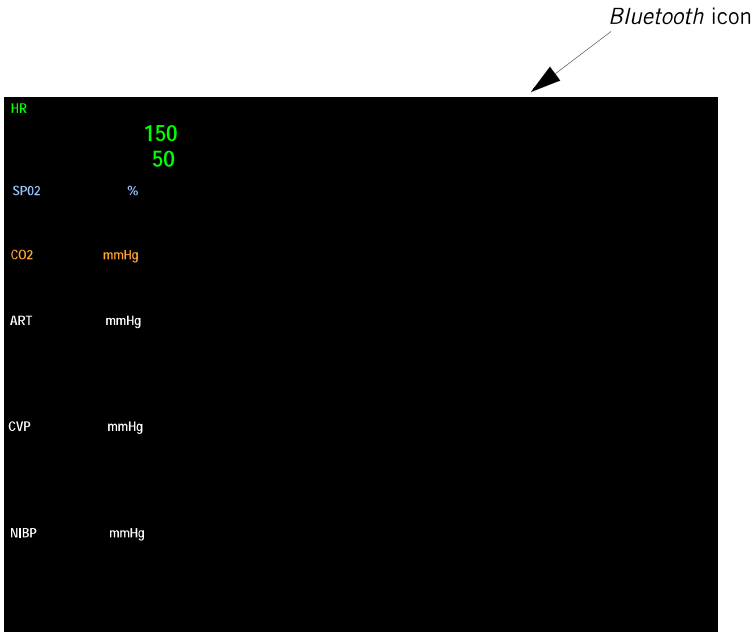


Figure 8-2 *Bluetooth* Icon on the Home Screen

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.

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

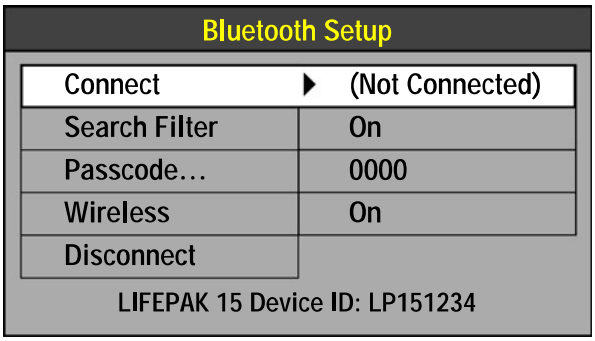
LIFEPAK 15 MONITOR/DEFIBRILLATOR MODE	SERVICE CLASS	FRIENDLY NAME PREFIX
LIFEPAK 15 monitor must be in Archive mode	Archive	A_
LIFEPAK 15 monitor can be in AED, Manual, or Archive mode	Both Cardiac Care and Archive	B_
LIFEPAK 15 monitor can be in AED or Manual mode	Cardiac Care	C_

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:



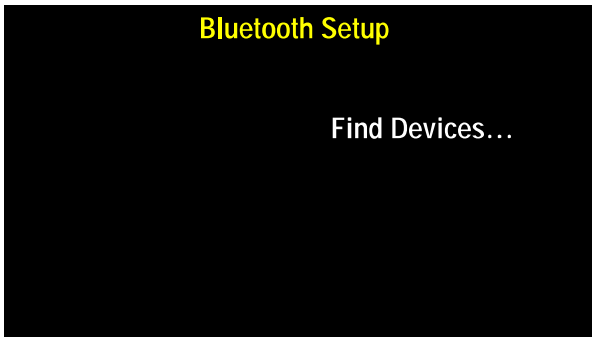
1. On the **HOME SCREEN**, rotate the **SPEED DIAL** to outline the *Bluetooth* icon.
2. Press the **SPEED DIAL**. The *Bluetooth* Setup menu appears.
3. Set **SEARCH FILTER** to **ON** if you want to find only devices that include the PSC in their friendly name; otherwise, set **SEARCH FILTER** to **OFF**.
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.

Establishing a Bluetooth Connection

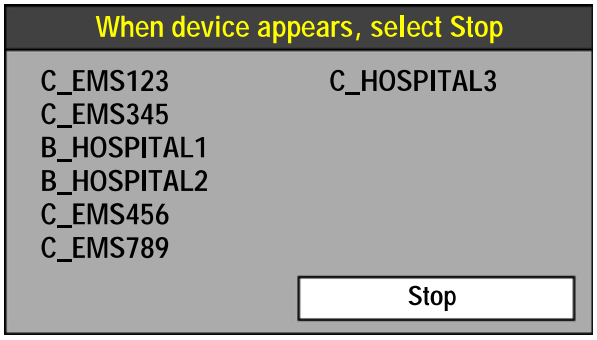
You must know the friendly name of the target device that you want to connect to.

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.

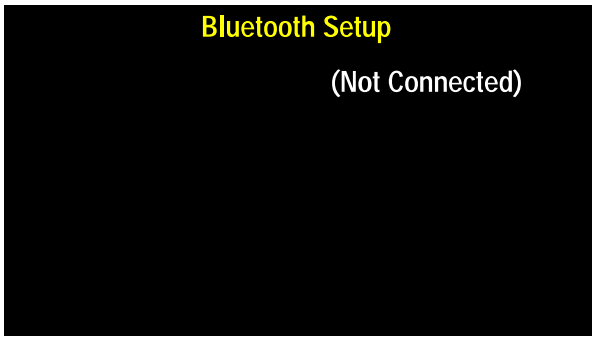
   Note: If the LIFEPAK 15 monitor is set to **WIRELESS OFF**, wireless status changes to **WIRELESS ON**.



- 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.

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.

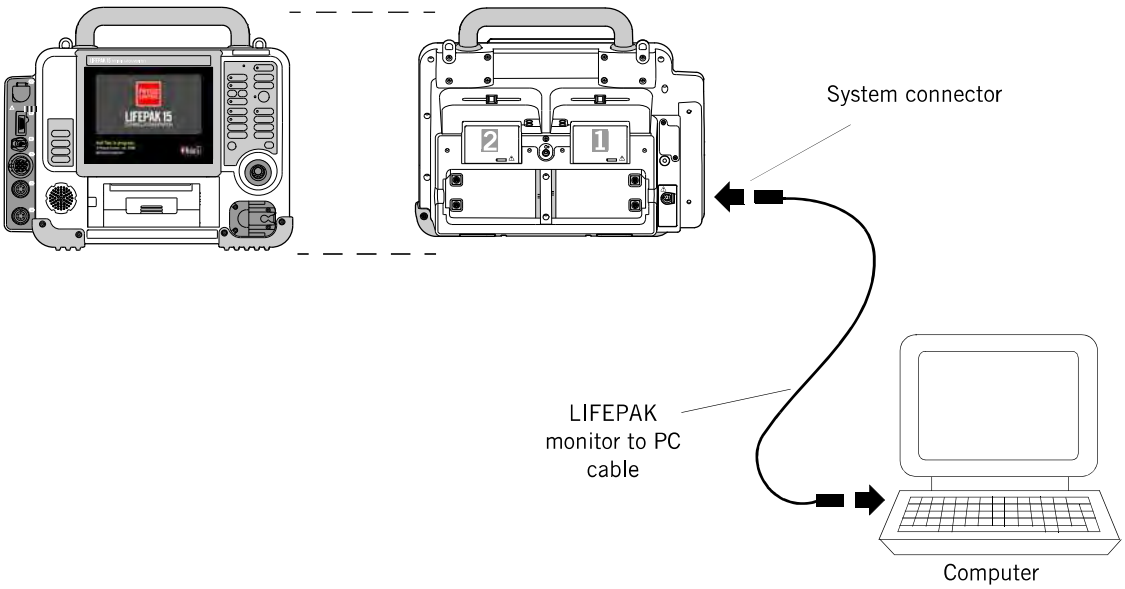


Figure 8-3 Data Transmission using a Direct Connection

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.

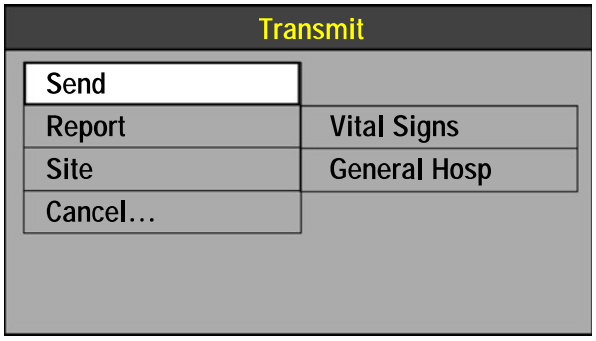
After you establish a direct connection, you are ready to transmit patient data. Proceed to "Transmitting Reports" on page 8-12.

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:

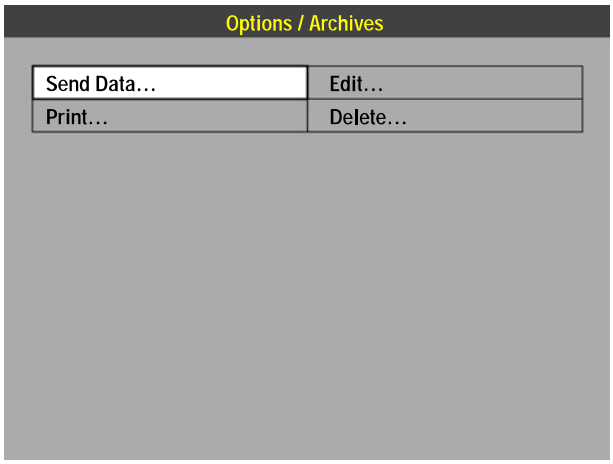


1. Press **TRANSMIT**. The Transmit menu appears.
2. Use the **SPEED DIAL** to select the desired **REPORT** and **SITE**, if necessary.
3. Select **SEND**. The patient report is transmitted. The status of the transmission appears in the message area.

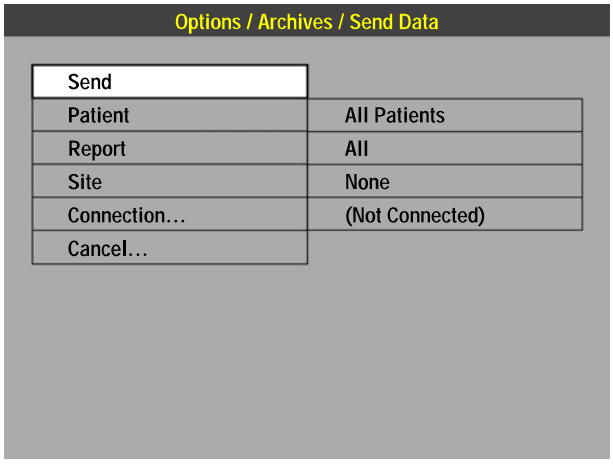
How to Transmit an Archived Patient Report

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."

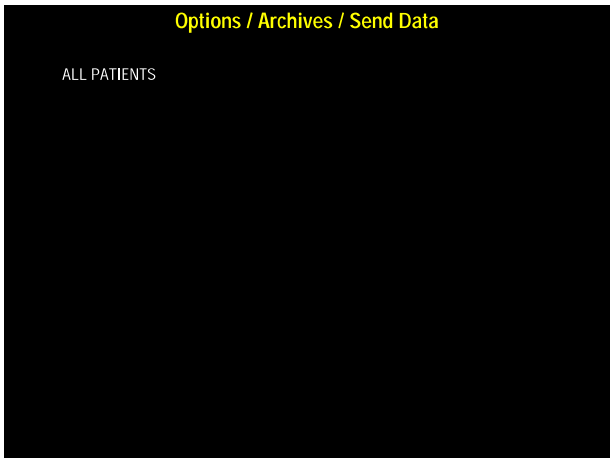
To transmit an archived patient report:



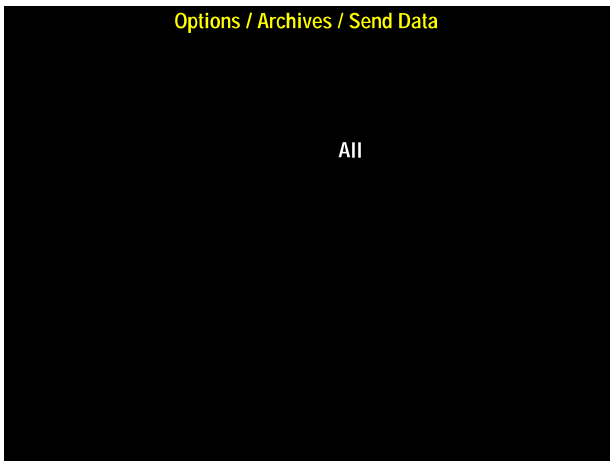
1. In the Options/Archives menu, select **SEND DATA**. The Options/Archives/Send Data menu appears.



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.

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.

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.

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

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.

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.

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.

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**.

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.

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*.

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.

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.

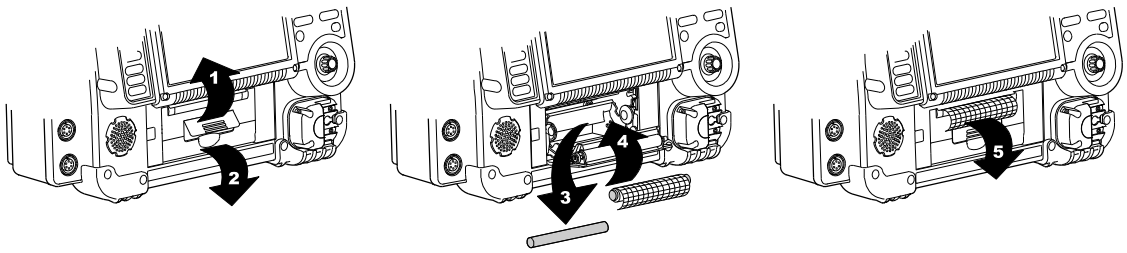


Figure 9-1 Loading Paper

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.

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.

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

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.

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

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.

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)	

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

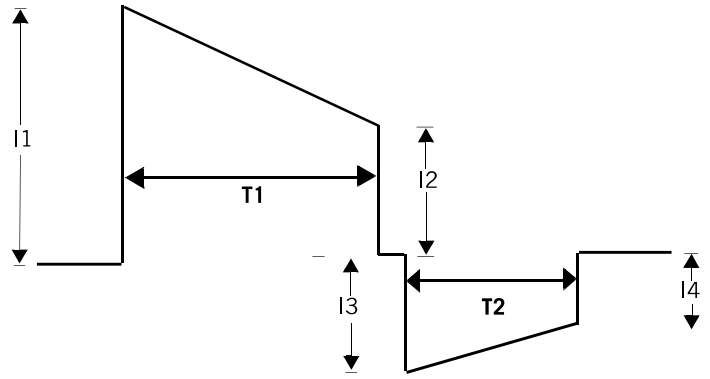
CHARACTERISTIC	DESCRIPTION
Initialization Time	30 seconds (typical), 10-180 seconds
Ambient Pressure	Automatically compensated internally
Optional Display Waveform	CO_2 pressure
Scale factors	Autoscale, 0–20 mmHg (0–4 Vol%),0–50 mmHg (0–7 Vol%), 0–100 mmHg (0–14 Vol%)
INVASIVE PRESSURE	
Transducer Type	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.

Table A-1 LIFEPAK 15 Monitor/Defibrillator Specifications (Continued)

CHARACTERISTIC	DESCRIPTION

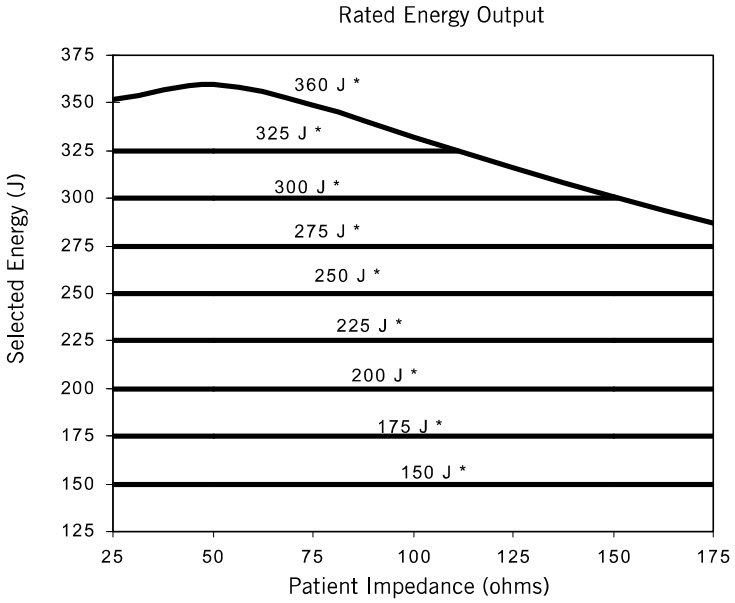


Biphasic Waveform

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**

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

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.

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

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.

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.

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.

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.

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.

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

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.

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.

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	

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.

[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.

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.

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

Table E-1 Symbols (Continued)

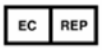
SYMBOL	DESCRIPTION
	CO_2 exhaust
	Input/output
	Defibrillation-proof type CF patient connection
	Defibrillation protected, type BF patient connection
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com 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
MIN or PN	Manufacturer's identification number (part number)
SN	Serial number
REF	Reorder number
Rx Only or Rx Only	By prescription only
!USA	For USA audiences only

Table E-1 Symbols (Continued)

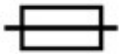
SYMBOL	DESCRIPTION
	Negative terminal
	Fuse
	Battery
	Static-sensitive device. Static discharge may cause damage.
Reports	
	Biphasic defibrillation shock
	Pace arrow, noninvasive pacing
	Pace arrow, internal pacing detection
	QRS sense marker
	Event marker
Accessories	
	Mark of conformity to applicable 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

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)

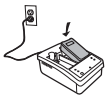
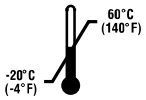
SYMBOL	DESCRIPTION
	Press electrode firmly onto patient
	Connect QUIK-COMBO cable
	Remove release liner
	Do not use this pediatric QUIK-COMBO electrode on LIFEPAK 500, LIFEPAK 1000, LIFEPAK CR® Plus, or LIFEPAK EXPRESS® defibrillators
	For use on adults
	Not for use on adults
	For use on children up 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

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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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:

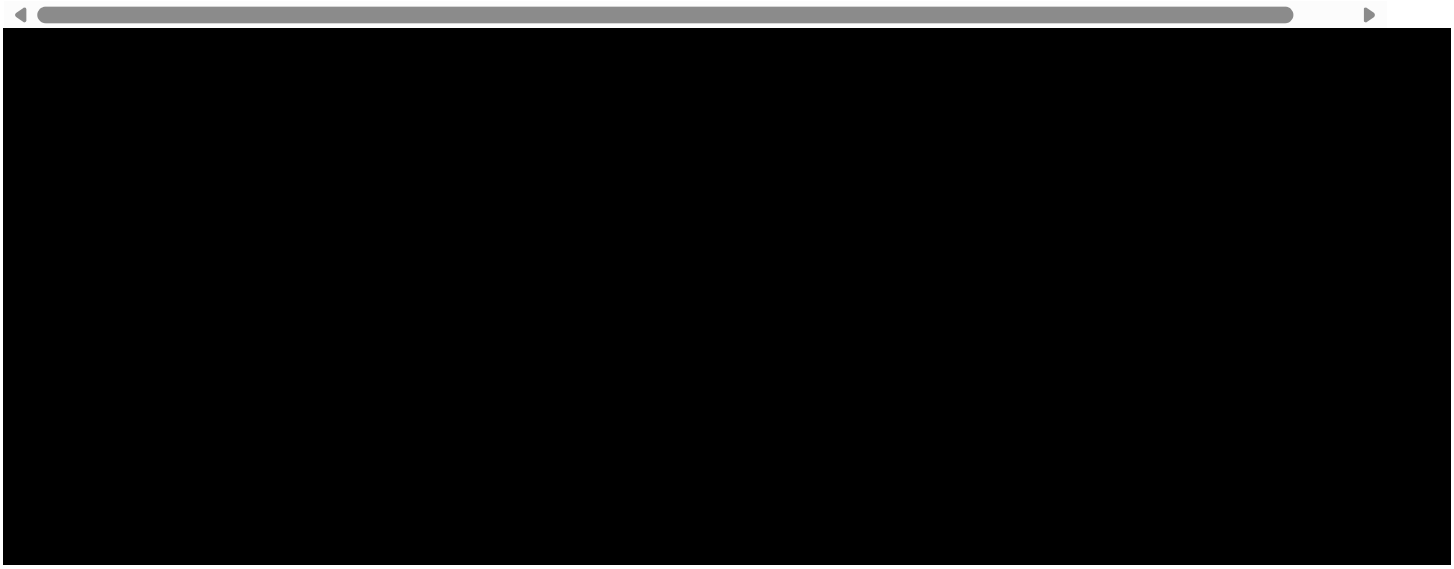
 Do Not Resuscitate. Resuscitation icon. Indicates the patient's current resuscitation status.

 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

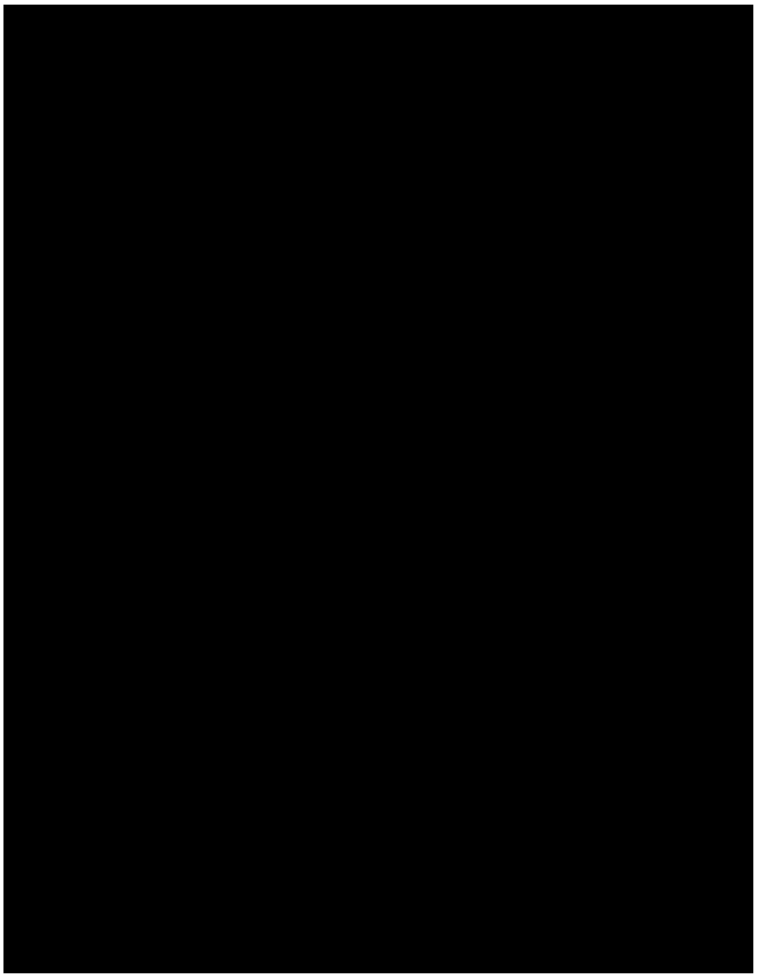
« SCROLL »

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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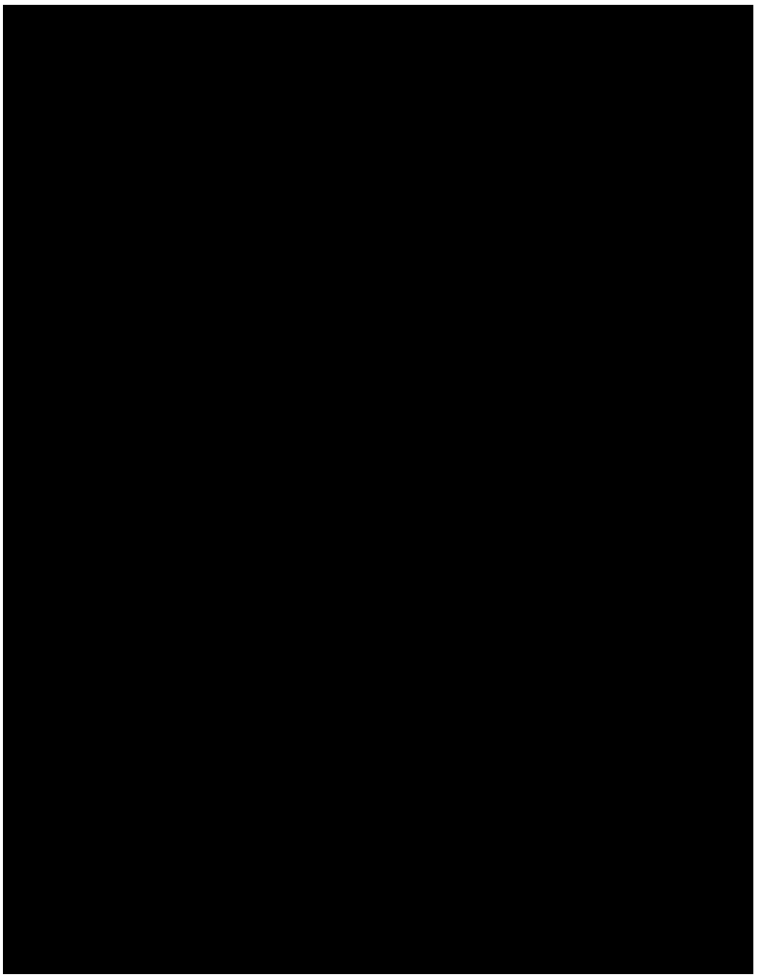
Philips Monitoring System Manual



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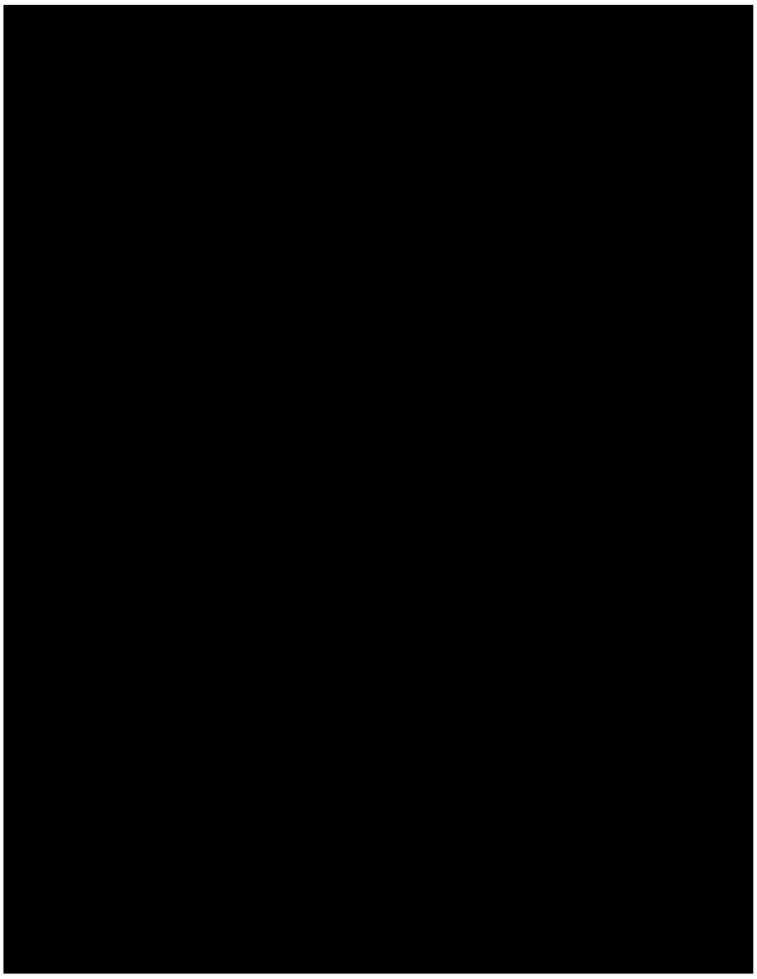

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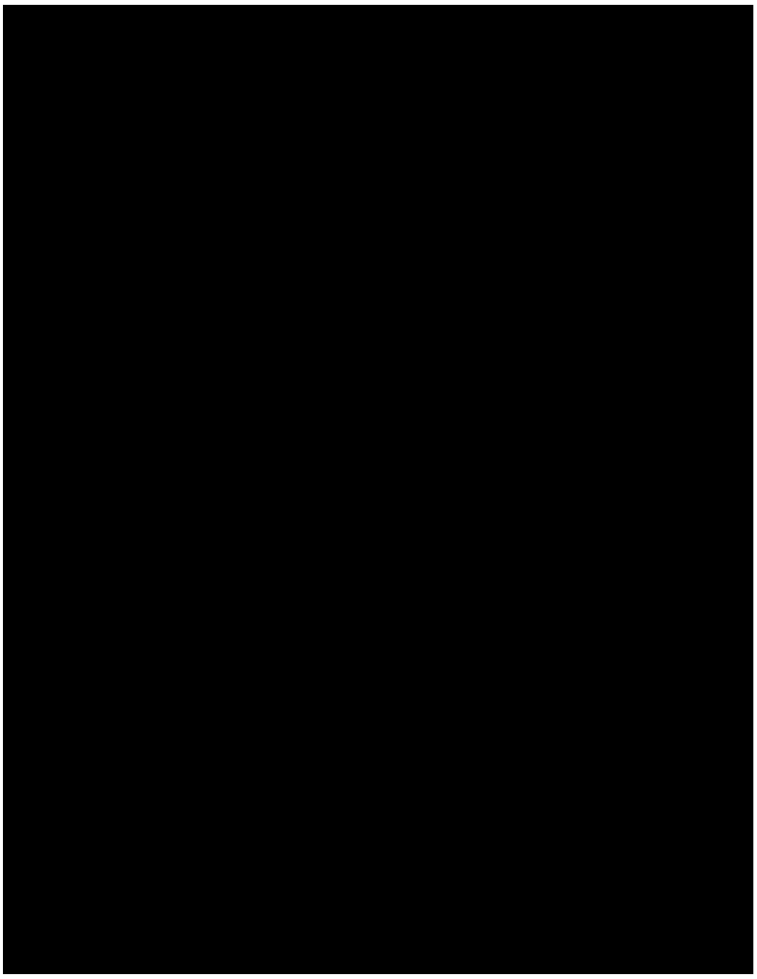
Car Seat Quick Guide



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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.

LEVEL 1®

OPERATOR'S MANUAL

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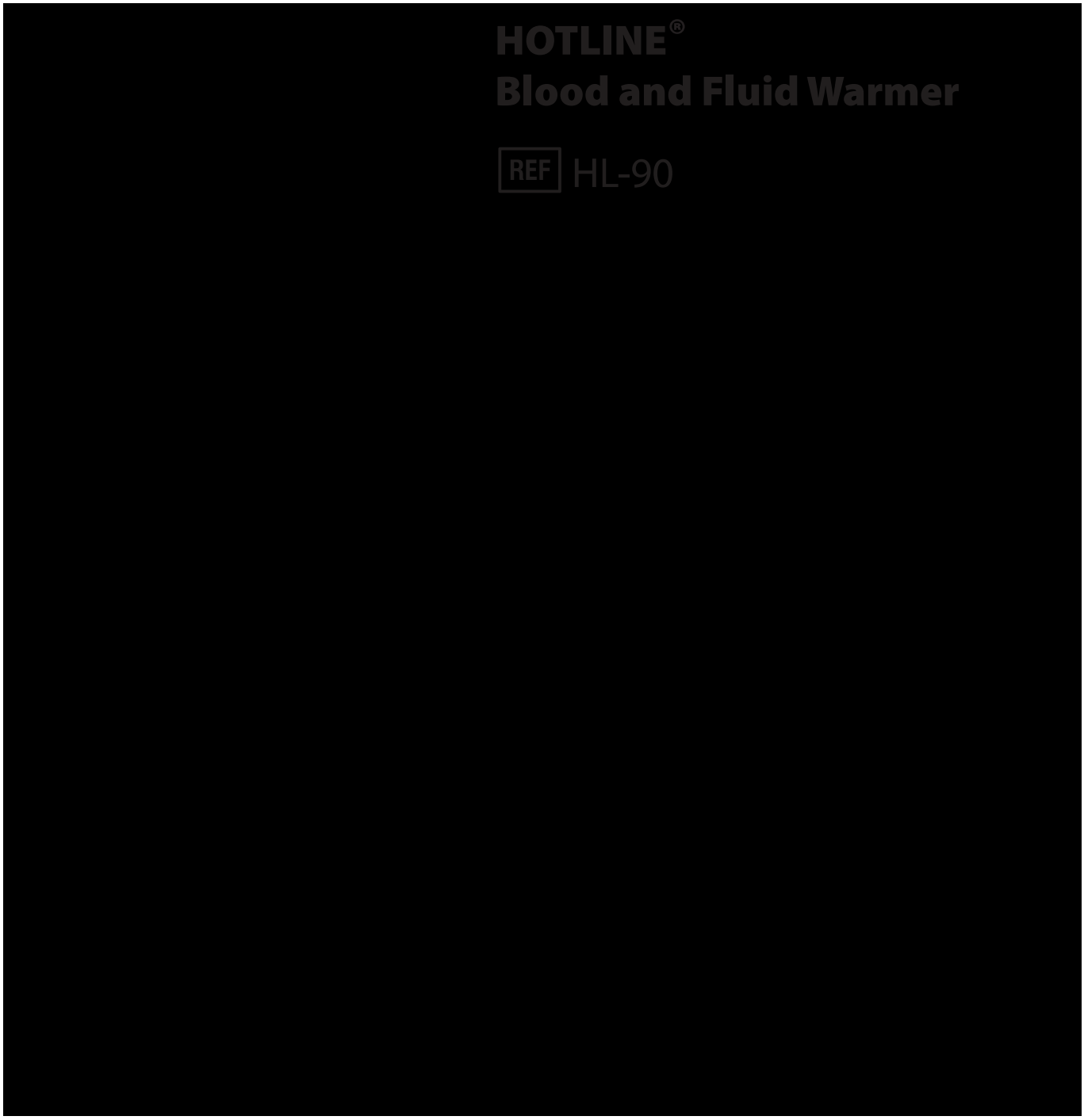

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HOTLINE®
Blood and Fluid Warmer

REF HL-90`

OPERATOR'S MANUAL

PN 10011022-003

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HOTLINE® Blood and Fluid Warmer

Part Number: 10011022-003

This revision supercedes all previous revisions.

Every effort has been made to ensure that the information in this manual is accurate and details provided are correct at the time of printing. The company, however, reserves the right to improve the equipment shown. Mention of third-party products is for informational purposes only and constitutes neither an endorsement nor a recommendation. Smiths Medical ASD, Inc. ("Smiths Medical") assumes no responsibility with regard to the performance or use of these products.

For further information, please call your local Smiths Medical distributor or Smiths Medical direct at 1 800 258 5361 or +1 614 210 7300.

Contents

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.

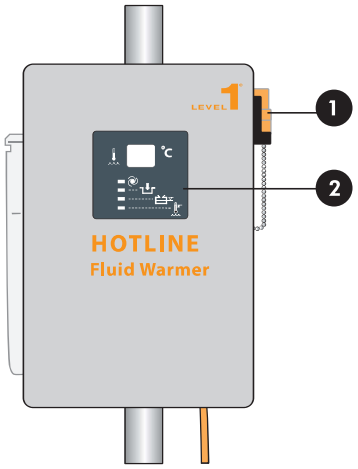
The HOTLINE® Warmer employs a safe, recirculating solution heating system, inherently free of "hot spots," to actively warm the patient line. Electronic circuitry continuously monitors the recirculating solution temperature. The primary temperature control circuit limits the recirculating solution to 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.

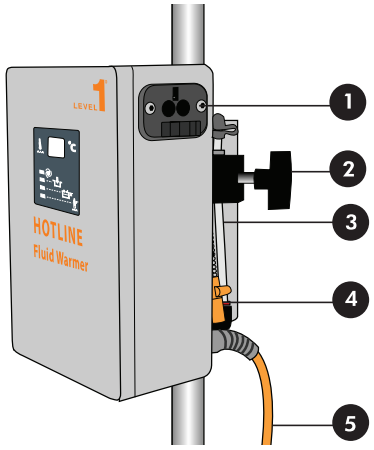
Components

The HOTLINE® components are called-out in the following series of figures.

Front View

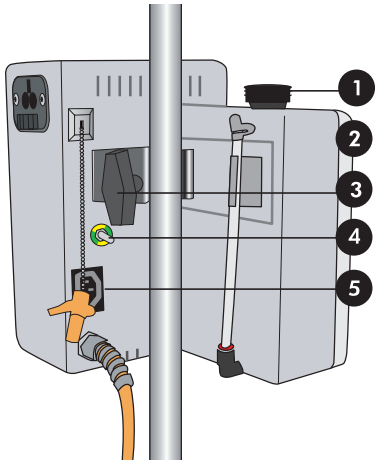


1. Socket for HOTLINE® Fluid Warming Set with the reflux plug in place
2. Display Panel



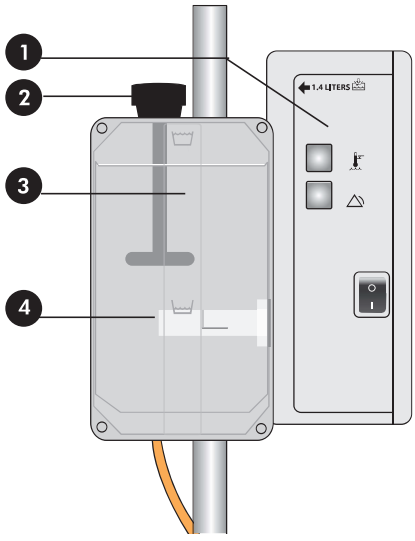
Right Side View

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.*

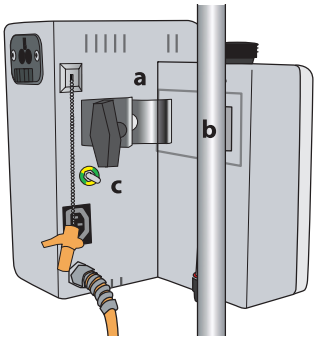
Step 2 - Clamp the HOTLINE® Warmer to the I.V. Pole

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

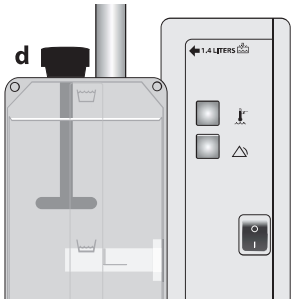
This device is cooled by convection. Be sure the air vents on the bottom and the back of the device are kept clear.



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.

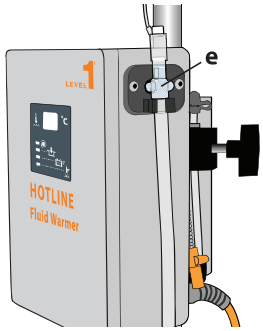
Step 3 - Disinfect the Reservoir



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)**.

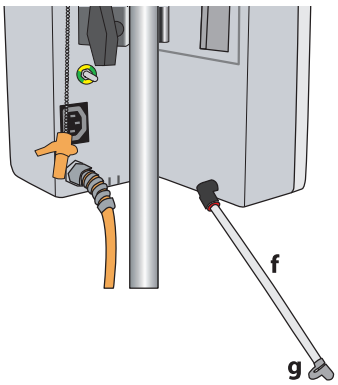


4 Insert a HOTLINE® Fluid Warming Set **(e)** (L-70, L-70 NI, L-80) into the socket.

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

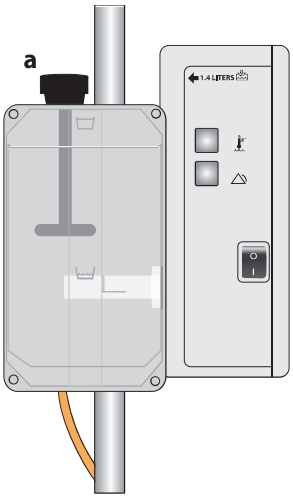
Do not fill the HOTLINE® Warmer reservoir with a HOTLINE® Fluid Warming Set in place. Failure to remove the HOTLINE® Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE® Warmer.

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.*



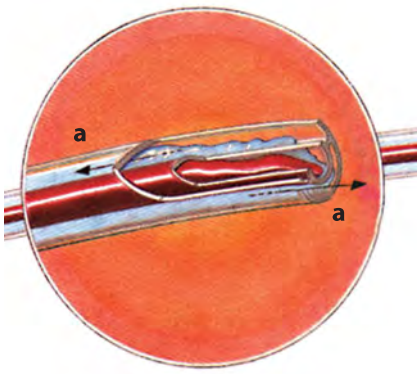
1. Prepare the recirculating solution.
2. Remove the fill-port plug **(a)**.
3. Fill the reservoir with 1.4 liters of recirculating solution.
4. Replace the fill-port plug.

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.

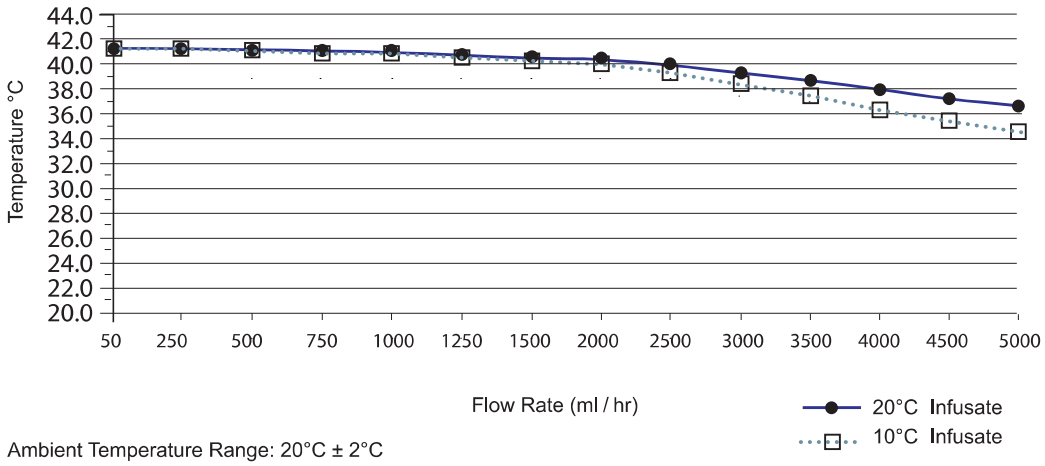
Active warming is achieved by surrounding the sterile intravenous line with a layer of precisely controlled warm recirculating solution **(a)**, thereby protecting the patient line against exposure to cold and eliminating patient line cool-down.

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.

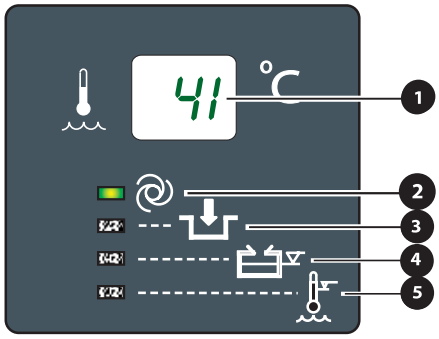
1 **Recirculating Solution Temperature -** The temperature is displayed in degrees Celsius.

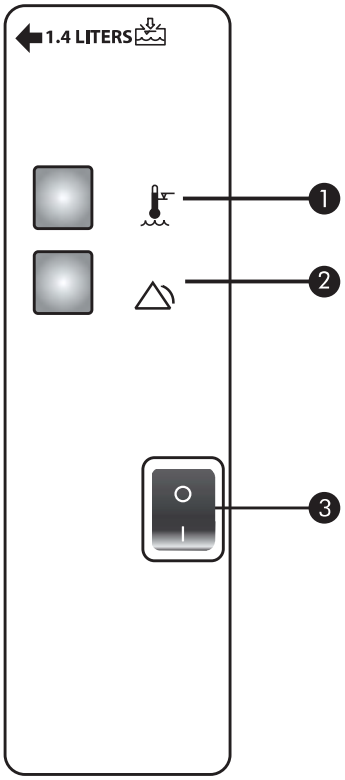
2 **ON/Operation -** The green LED illuminates when the power is turned on and the HOTLINE® Fluid Warming set is properly installed.

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.





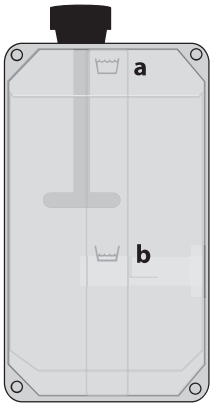
Power and Alarm Test Panel

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

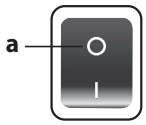
The HOTLINE® Warmer operation is defined in the following modes:

- 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.

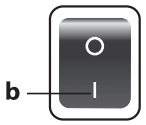
OFF Mode

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.

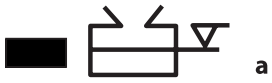
Mode characteristics

- 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

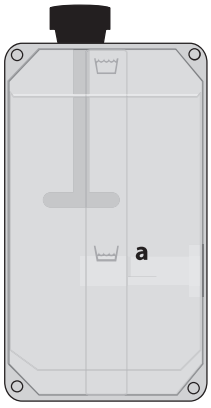
Operating Instructions

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.

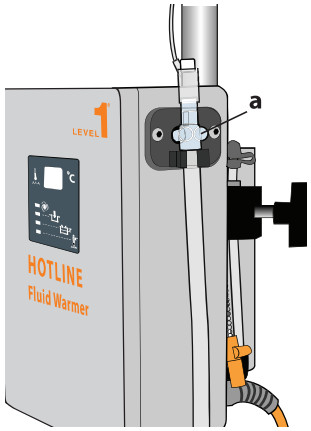
Step 2 - Set Up the HOTLINE® Fluid Warming Set

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.

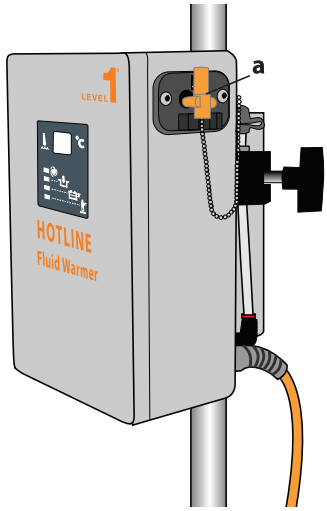
2 Adjust the rate of I.V. flow using the clamp on the intravenous administration set.

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.

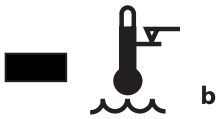
Note: *Alarm testing requires a HOTLINE® Fluid Warming Set to be installed and that the HOTLINE® Warmer be turned ON and in the Operating mode.*

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.

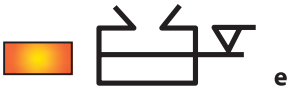
1. Press and hold the Over Temperature Alarm Test button **(a)**.
2. Observe the following:
   - The recirculating solution Over Temperature Alarm activates at 43°C.
   - The green Operating LED turns off.
   - The red Over Temperature LED **(b)** illuminates.
   - The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
3. Stop pressing the Over Temperature Alarm Test button to stop the test.

Add Recirculating Solution Test

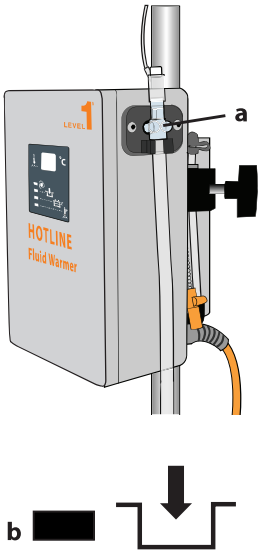
The HOTLINE® Warmer is equipped with a float switch, which senses the recirculating solution level in the reservoir. When the recirculating solution is too low, the Add Recirculating Solution Alarm will activate.

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

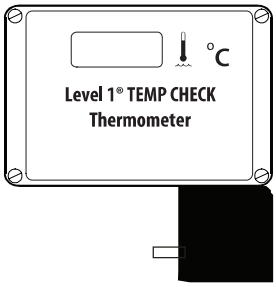


An interlock switch/sensor, located in the socket on the right side of the HOTLINE® Warmer, senses a properly installed HOTLINE® Fluid Warming Set. When the switch does not sense a HOTLINE® Fluid Warming Set, the Check Disposables alarm activates.

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

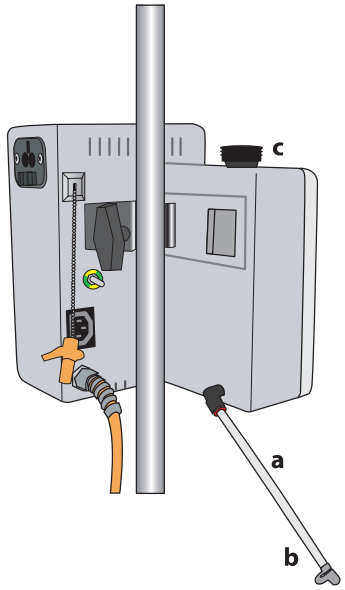
- Check the condition of the HOTLINE® Warmer with a visual inspection before using. Remove from service any HOTLINE® Warmer that shows physical damage.
- If the HOTLINE® Fluid Warming Set does not install easily, lubricate the O-Rings as directed in the following section.

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.

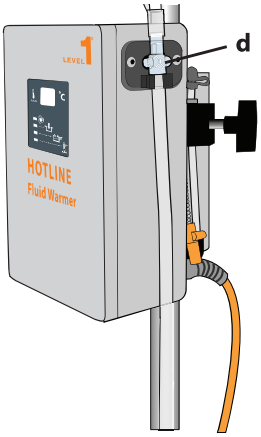
7 Remove the reflux plug from the socket if required, and insert a HOTLINE® Fluid Warming Set **(d)** (L-70, L-70NI, L-80) into the socket.

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

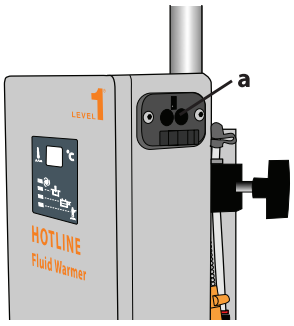
Disinfect the Reservoir and Change Recirculating Solution for Distilled Water and 35% Isopropyl Alcohol Solution

Refer to *Disinfect the Reservoir and Change the Recirculating Solution* procedure in this section.

Lubricate O-Ring Seals

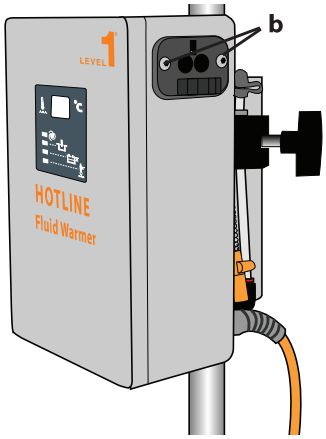
1 Place a small amount of silicone lubricant on a cotton swab.

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, 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0, 315^0 100% dip, 250/300 period 30% dip, 25/30 periods	100% drop, 0.5 periods, 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0, 315^0 100% 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]√P	80 MHz to 800 MHz d=[3.5/E1]√P	800 MHz to 2.5 GHz d=[7/E1]√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

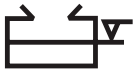
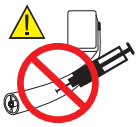
REF	Product Description
L-70	HOTLINE® Fluid Warming Set with Injection Port
L-70NI	HOTLINE® Fluid Warming Set without Injection Port
L-80	HOTLINE® Warming Set with L-10 Gas Vent
L-10	Gas Vent
PC-8	T-Connector, 20.3 cm (8") Patient Lead with Injection Port
YC-8	Y-Connector, 20.3 cm (8") Patient Lead with 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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LEVEL 1®

Manufacturer:
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6000 Nathan Lane North
Minneapolis, MN 55442 USA
Tel: 1 800 258 5361 (USA/CA)
Tel: +1 614 210 7300

www.smiths-medical.com

EC REP European Representative:
Smiths Medical Czech Republic a. s.
Olomoucká 306, Hranice 1 - Město,
753 01 Hranice, Czech Republic
Tel: +44 (0)1233 722100

Rx ONLY CE 2797

smiths medical

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.

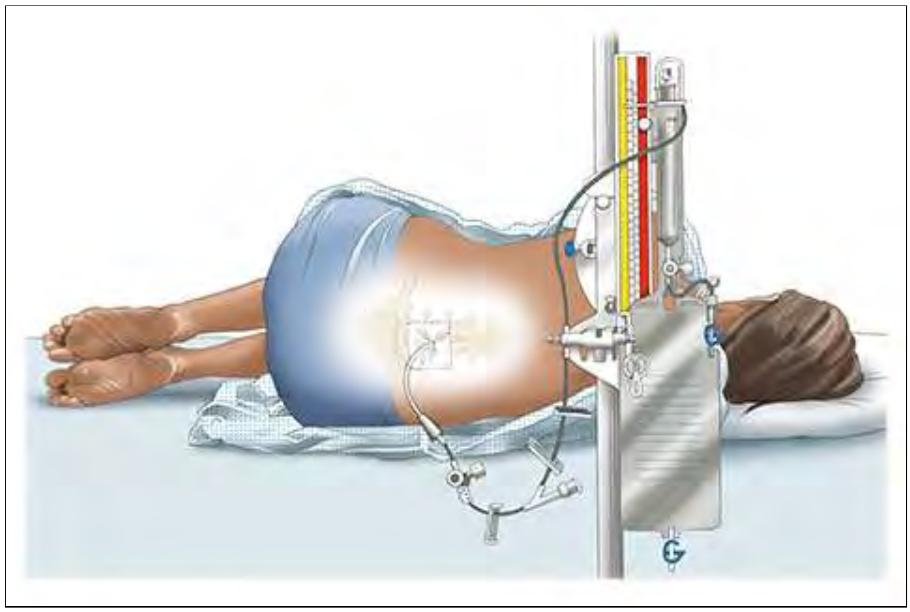
__ Document the procedure.

Lumbar drain management after thoracoabdominal aortic aneurysm repair

Lumbar drain management after thoracoabdominal aortic aneurysm repair
Reviewed: December 15, 2025

Introduction

A lumbar drainage device (shown below) is a closed sterile system that enables the drainage of cerebrospinal fluid (CSF) from the subarachnoid space, which is located between the arachnoid and pia mater. A practitioner inserts the device through a special spinal needle, known as a *Tuohy needle*, into the lumbar subarachnoid space at the L2 to L3 level or below. When inserted for patients undergoing thoracoabdominal aortic aneurysm repair, the device helps prevent paralysis by maintaining spinal perfusion pressure through CSF drainage when the aorta is cross-clamped for the operative procedure. Lumbar drainage may continue after surgery to prevent postoperative spinal cord ischemia.[1] When lumbar drainage continues postoperatively after thoracoabdominal aortic aneurysm repair, the practitioner may order a specific pressure parameter for when drainage should occur, typically around 10 mm Hg.[2][3] Alternatively, the practitioner may elect to limit lumbar drainage by keeping the drain closed unless a neurologic deficit occurs.[4]



Relative contraindications to lumbar drainage include coagulopathy, active bleeding, brain abscess, and a history of lumbar spine surgery or lumbar vertebral fracture. Absolute contraindications to lumbar drainage include increased intracranial pressure, unequal pressures between the supratentorial and infratentorial compartments as evidenced by computed tomography findings, infected skin over the intended drain insertion site, spinal epidural abscess, intracranial mass, obstructive noncommunicating hydrocephalus, and spinal arteriovenous malformation.

Special considerations when caring for a patient with a lumbar drain device include minimizing device handling. When device handling is necessary, the health care provider must perform hand hygiene, put on gloves, and maintain the sterility of the drainage system.

Equipment

- Closed (nonvented) cap or luer-lock adapter
- Gloves
- IV pole
- Lumbar drainage system and tubing
- Pole clamp or cord attachment
- Vital signs monitoring equipment
- Optional: 30-mL syringe containing sterile preservative-free normal saline solution, bedside monitor, drainage bag, graduated burette, labels, leveling device (carpenter's level or laser), other personal protective equipment, pressure cable, sterile occlusive dressing, stopcock, transducer system

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

- Receive handoff communication from the person who was responsible for the patient's care. Ask questions, as necessary, *to avoid miscommunications that may cause 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.[5]
- Verify the practitioner's order.
- Review the patient's medical record for a history of allergies to tape, antiseptic solutions, or latex.
- Gather and prepare the necessary equipment and supplies.
- Perform hand hygiene.[6][7][8][9][10][11]
- Confirm the patient's identity using at least two patient identifiers.[12]
- Provide privacy.[13][14][15][16]
- 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.*[17]
- Perform hand hygiene.[6][7][8][9][10][11]
- Put on gloves and, as needed, other personal protective equipment *to comply with standard precautions*.[18][19][20]
- Make sure that the lumbar drainage system is clamped before changing the patient's position *so that CSF overdrainage doesn't occur.*[21]
- Assist the patient to a side-lying position *to expose the lumbar drain exit site*.
- Assess the condition of the dressing and lumbar drainage system exit site. Make sure that the sterile occlusive dressing is intact and that the drainage system is free from kinks. Change the dressing immediately using sterile technique if it becomes wet or soiled or is no longer intact.[21][22]
- After assessing the dressing and lumbar drainage system exit site, reposition the patient as ordered.
- Make sure that the lumbar drainage system is secured to an IV pole at the patient's bedside using the cord attachment or a pole clamp and cord attachment. Make sure that the drainage system is positioned so that minor patient position changes won't put pressure on the tubing or let the drainage unit fall, causing CSF overdrainage.
- Trace the lumbar drainage system tubing from the patient to its point of origin *to make sure that it's attached to the proper port*.[23][24] Make sure that all ports on the drainage system have a closed cap or luer-lock adapter *to prevent leakage and reduce the risk of infection.*

- Set the zero reference level by raising or lowering the system so that the zero reference mark on the lumbar drainage system is set to the appropriate anatomic landmark, as ordered.[21] Examples of anatomic landmarks include the external auditory meatus, shoulder height, and the level of the catheter insertion.[21] If you're using a laser level to level the device, make sure that the laser light doesn't shine in the patient's eyes or the eyes of anyone else in the room.
- Unclamp the lumbar drainage system.
- If the practitioner orders a pressure parameter for CSF drainage, set the pressure level on the graduated burette of the lumbar drainage system as ordered *so that CSF will drain into the graduated burette when the pressure in the lumbar space is higher than the prescribed pressure level.*
- If the practitioner prescribes intraspinal pressure monitoring, assemble a fluid-filled transducer system with a stopcock and closed cap as follows:[21]
    - Using sterile technique, prime the transducer system with preservative-free normal saline solution. Don't attach a pressurized bag of IV fluid to the transducer system.[21]
    - Maintaining the sterility of the system, attach the fluid-filled transducer system to the lumbar drainage system.[21] Trace the tubing from the patient to the point of origin *to make sure that you're connecting the tubing to the proper port.*[23][24] Make sure that all connections are secure *to prevent dangerous disconnections.*[23] Route the tubing in a standardized direction if the patient has other tubing and catheters having different purposes. Label the tubing at both the distal (near the patient connection) and proximal (near the source container) ends *to reduce the risk of misconnection if multiple tubes will be used.*[24]
    - Connect the transducer system to the pressure cable and bedside monitor.
    - Level and zero the transducer to the prescribed anatomic reference point.[21]
    - 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.[25][26][27]
- Assess the patient's vital signs and neurologic status hourly *to promptly identify changes in condition.* Notify the practitioner immediately of changes in the patient's neurologic status, such as decreased level of consciousness, focal deficit, pupillary or vision changes, headache, photophobia, nuchal rigidity, and irritability. Any change in level of consciousness, new headache, confusion, or irritability could indicate CSF overdrainage and require immediate notification of the practitioner and clamping of the drainage system. Neurologic checks should also include checking the lower extremities for sensory and motor function.[3]
- Assess the patient hourly for signs of infection or CSF leakage from the insertion site.
    - Monitor the CSF amount, clarity, and color hourly or as ordered.[21] Also monitor the level and security of the lumbar drainage system. Change the drainage system bag when it becomes three-quarters full. (See *Changing the drainage bag*.)[28]

EQUIPMENT

CHANGING THE DRAINAGE BAG

Follow these steps to change a drainage bag when it becomes three-quarters full:

- Perform hand hygiene.[6][7][8][9][10][11]
- Put on sterile gloves.[18][19][20]
- Turn the stopcock on the drainage system to stop CSF flow from the patient.
- Disconnect the drainage bag from the system using strict sterile technique.
- Place a closed cap over the exposed port on the three-quarters-full bag.
- Connect the replacement drainage bag to the lumbar drainage device system using strict sterile technique.
- Make sure that the connections are tight and that the stopcocks and clamps are in the correct position to enable drainage (if ordered).

- Discard the old drainage bag in an appropriate receptacle as directed by your facility.[20]
- Remove and discard your gloves.[20]
- Perform hand hygiene.[6][7][8][9][10][11]
- Document the procedure.[29][30][31]

- When the drain is open to drainage, instruct the patient to avoid coughing, sneezing, and straining, when possible, *to prevent overdrainage caused by increased thoracic pressure.*
- Assist the patient with turning from side to side at least every 2 hours *to prevent skin breakdown.* If the drain is positional, monitor which positions cause variances in the drainage rate from the lumbar drainage device. Plan patient care and positioning as indicated. Instruct the patient and family members about restrictions in patient positioning. Advise them to call the nurse for assistance with position changes.
- Discard used supplies in appropriate receptacles.[20]
- Remove and discard your gloves and, if worn, other personal protective equipment.[20]
- Perform hand hygiene.[6][7][8][9][10][11]
- Document the procedure.[29][30][31][32]

Special Considerations

- 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 or death.* Among the major contributing factors were improper alarm settings, alarms settings turned off inappropriately, and alarm signals that were inaudible to staff. Make sure that alarm limits are set appropriately and that alarms are turned on, functioning properly, and audible to staff. Follow facility guidelines for preventing alarm fatigue.[27]
- Note that data are insufficient to recommend a specific dressing and dressing change frequency for lumbar drainage devices. Therefore, the recommendations of the Centers for Disease Control and Prevention in the "Guidelines for the Prevention of Intravascular Catheter-Related Infections" are widely accepted for maintenance of lumbar drainage devices.[22]
- Be sure to keep the head of the bed in the prescribed position *to prevent CSF overdrainage or underdrainage*.[21]
- For a patient with a cognitive impairment and for the safety of all patients, use the lockout control on the bed to prevent the patient from changing the bed height or head-of-the-bed elevation. An observer may also be necessary in the patient's room *to prevent complications from lumbar drainage for a patient with cognitive impairment.*
- 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.[24]
- 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. Include the multidisciplinary team members and the patient and family, when appropriate.

Patient Teaching

Teach the patient and family (if applicable) about the reason for the drain and the importance of restricting the patient's activity level. Instruct the patient to avoid straining, coughing, and sneezing.

Complications

Complications associated with lumbar drain management after thoracoabdominal aortic aneurysm repair may include:

- infection[21]
- excessive drainage at the puncture site[21]
- change in neurologic status[21]
  - decreased level of consciousness
  - pupillary changes
  - motor or sensory impairment
- bladder or bowel dysfunction[21]
- overdrainage[21]
- headache[21]
- meningeal irritation
- nerve root irritation
- tension pneumocranium
- central herniation
- subdural hemorrhage
- spinal hematoma[21]
- intracranial venous thrombosis
- retained catheter.

Documentation

Documentation associated with lumbar drain management after thoracoabdominal aortic aneurysm repair includes:

- vital signs
- neurologic assessment findings
- abnormal findings
  - name of practitioner notified
  - date and time of notification
  - prescribed interventions
  - response to those interventions
- color, clarity, and amount of CSF drainage every hour for a patient on an intensive care unit and every 2 hours for a patient on a regular patient unit
- condition of the dressing
- teaching provided to the patient and family (if applicable)
  - understanding of that teaching
  - follow-up teaching needed.

Related Procedures

- External ventriculostomy device management, pediatric

References

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

1. Uchino, G., et al. (2017). Spinal cord protection during thoracoabdominal aortic replacement: Spinal cord perfusion maintenance. *Interactive Cardiovascular and Thoracic Surgery, 24*(5), 708–713. Retrieved October 2025 from https://doi.org/10.1093/icvts/ivw450 (Level VI)
   Abstract | Complete Reference

2. Keith, C. J., et al. (2012). Protocol implementation of selective postoperative lumbar spinal drainage after thoracic aortic endograft. *Journal of Vascular Surgery, 55*(1), 1–8. Retrieved October 2025 from https://doi.org/10.1016/j.jvs.2011.07.086 (Level IV)
Abstract | Complete Reference | Full Text
3. Hiratzka, L. F., et al. (2010). ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM guidelines for the diagnosis and management of patients with thoracic aortic disease. *Circulation, 121*(13), e266–e369. Retrieved October 2025 from https://doi.org/10.1161/cir.0b013e3181d4739e (Level VII)
4. Estrera, A. L., et al. (2009). Cerebrospinal fluid drainage during thoracic aortic repair: Safety and current management. *Annals of Thoracic Surgery, 88*(1), 9–15. Retrieved October 2025 from https://doi.org/10.1016/j.athoracsur.2009.03.039 (Level IV)
Abstract | Complete Reference
5. The Joint Commission. (2025). Standard PC.02.02.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
6. Centers for Disease Control and Prevention. (2002). Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recommendations and Reports, 51*(RR-16), 1–45. Retrieved October 2025 from https://www.cdc.gov/mmwr/pdf/rr/rr5116.pdf (Level VII)
7. World Health Organization (WHO). (2009). *WHO guidelines on hand hygiene in health care: First global patient safety challenge, clean care is safer care.* Retrieved October 2025 from https://iris.who.int/bitstream/handle/10665/44102/9789241597906_eng.pdf (Level VII)
8. The Joint Commission. (2025). Standard NPSG.07.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
9. Accreditation Commission for Health Care. (2025). Standard 07.02.05. *Accreditation requirements for acute care hospitals.* (Level VII)
10. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Infection prevention and control and antibiotic stewardship programs. 42 C.F.R. § 482.42.
11. DNV GL-Healthcare USA, Inc. (2024). IC.1.SR.3f. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
12. The Joint Commission. (2025). Standard NPSG.01.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
13. Accreditation Commission for Health Care. (2025). Standard 15.01.07. *Accreditation requirements for acute care hospitals.* (Level VII)
14. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Patient's rights. 42 C.F.R. § 482.13(c)(1).
15. The Joint Commission. (2025). Standard RI.01.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
16. DNV GL-Healthcare USA, Inc. (2024). PR.2.SR.5. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
17. The Joint Commission. (2025). Standard PC.02.01.21. *Comprehensive accreditation manual for hospitals.* (Level VII)
18. Siegel, J. D., et al. (2007, revised 2024). *2007 guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Retrieved October 2025 from https://www.cdc.gov/infection-control/media/pdfs/Guideline-Isolation-H.pdf (Level VII)
19. Accreditation Commission for Health Care. (2025). Standard 07.02.04. *Accreditation requirements for acute care hospitals.* (Level VII)
20. Occupational Safety and Health Administration. (2019). *Bloodborne pathogens, standard number 1910.1030.* Retrieved October 2025 from https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030 (Level VII)
21. American Association of Critical-Care Nurses (AACN). (2024). *AACN procedure manual for progressive and critical care* (K. L. Johnson, Ed.;8th ed.). Elsevier.
22. Centers for Disease Control and Prevention. (2011, revised 2017). *Guidelines for the prevention of intravascular catheter-related infections.* Retrieved October 2025 from https://www.cdc.gov/infection-control/media/pdfs/Guideline-BSI-H.pdf (Level I)

23. U.S. Food and Drug Administration. (2023). *Examples of medical device misconnections.* Retrieved October 2025 from https://www.fda.gov/medical-devices/medical-device-connectors/examples-medical-device-misconnections
24. The Joint Commission. (2014). *Sentinel event alert 53: Managing risk during transition to new ISO tubing connector standards.* Retrieved October 2025 from https://digitalassets.jointcommission.org/api/public/content/df1ada467ed147518c77827f35acd1ea (Level VII)
25. Graham, K. C., & Cvach, M. (2010). Monitor alarm fatigue: Standardizing use of physiological monitors and decreasing nuisance alarms. *American Journal of Critical Care, 19*(1), 28–37. Retrieved October 2025 from https://doi.org/10.4037/ajcc2010651
Abstract | Complete Reference | Full Text
26. The Joint Commission. (2025). Standard NPSG.06.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
27. The Joint Commission. (2013). *Sentinel event alert 50: Medical device alarm safety in hospitals.* Retrieved October 2025 from https://digitalassets.jointcommission.org/api/public/content/f65e5c9df2b94000a99445e0a7877007 (Level VII)
28. Leverstein-van Hall, M. A., et al. (2010). A bundle approach to reduce the incidence of external ventricular and lumbar drain-related infections. *Journal of Neurosurgery, 112*(2), 345–353. Retrieved October 2025 from https://doi.org/10.3171/2009.6.JNS09223
Abstract | Complete Reference
29. Accreditation Commission for Health Care. (2025). Standard 10.00.03. *Accreditation requirements for acute care hospitals.* (Level VII)
30. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Medical record services. 42 C.F.R. § 482.24(b).
31. The Joint Commission. (2025). Standard RC.01.03.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
32. DNV GL-Healthcare USA, Inc. (2024). MR.2.SR.1. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)

Additional References

- Khan, N. R., et al. (2016). The use of lumbar drains in preventing spinal cord injury following thoracoabdominal aortic aneurysm repair: An updated systematic review and meta-analysis. *Journal of Neurosurgery, 25*(3), 383–393. Retrieved October 2025 from https://doi.org/10.3171/2016.1.SPINE151199 (Level I)
- Petroff, D., et al. (2019). Paraplegia prevention in aortic aneurysm repair by thoracoabdominal staging with 'minimally invasive staged segmental artery coil embolisation' (MIS2ACE): Trial protocol for a randomised controlled multicentre trial. *BMJ Open, 9*(3), Article e025488. Retrieved October 2025 from https://doi.org/10.1136/bmjopen-2018-025488

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.

Pericardial catheter management

Pericardial catheter management

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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

References

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

1. Hoit, B. D. (2024). Pericardial effusion: Approach to management. In: *UpToDate,* LeWinter, M. M. (Ed.).
   UpToDate Full Text
2. American Association of Critical-care Nurses (AACN). (2024). *AACN procedure manual for progressive and critical care* (K. L. Johnson, Ed.; 8th ed.). Elsevier.
3. Kumar, R., et al. (2015). Complications of pericardiocentesis: A clinical synopsis. *International Journal of Critical Illness & Injury Science, 5*(3), 206–212. Retrieved July 2025 from https://doi.org/10.4103/2229-5151.165007 (Level V)
4. Centers for Disease Control and Prevention. (2002). Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recommendations and Reports, 51*(RR-16), 1–45. Retrieved July 2025 from https://www.cdc.gov/mmwr/pdf/rr/rr5116.pdf (Level VII)
5. World Health Organization (WHO). (2009). *WHO guidelines on hand hygiene in health care: First global patient safety challenge, clean care is safer care.* Retrieved July 2025 from https://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf?sequence=1 (Level VII)
6. The Joint Commission. (2025). Standard NPSG.07.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
7. Accreditation Commission for Health Care. (2025). Standard 07.02.05. *Accreditation requirements for acute care hospitals.* (Level VII)
8. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Infection prevention and control and antibiotic stewardship programs. 42 C.F.R. § 482.42.
9. DNV GL-Healthcare USA, Inc. (2024). IC.1.SR.3f. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
10. The Joint Commission. (2025). Standard NPSG.01.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
11. Accreditation Commission for Health Care. (2025). Standard 15.01.07. *Accreditation requirements for acute care hospitals.* (Level VII)
12. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Patient's rights. 42 C.F.R. § 482.13(c)(1).

13. DNV GL-Healthcare USA, Inc. (2024). PR.2.SR.5. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
14. The Joint Commission. (2025). Standard RI.01.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
15. The Joint Commission. (2025). Standard PC.02.01.21. *Comprehensive accreditation manual for hospitals.* (Level VII)
16. Waters, T. R., et al. (2009). *Safe patient handling training for schools of nursing.* Retrieved July 2025 from https://www.cdc.gov/niosh/docs/2009-127/pdfs/2009-127.pdf (Level VII)
17. Hoit, B. D. (2024). Cardiac tamponade. In: *UpToDate,* Gersh, B. J., & Hoekstra, J. (Eds.). UpToDate Full Text
18. The Joint Commission. (2025). Standard PC.01.02.07. *Comprehensive accreditation manual for hospitals.* (Level VII)
19. Accreditation Commission for Health Care. (2025). Standard 16.01.03. *Accreditation requirements for acute care hospitals.* (Level VII)
20. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Nursing services. 42 C.F.R. § 482.23(c).
21. DNV GL-Healthcare USA, Inc. (2024). MM.1.SR.3. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
22. The Joint Commission. (2025). Standard MM.06.01.01. *Comprehensive accreditation manual for hospitals*. (Level VII)
23. Occupational Safety and Health Administration. (2019). *Bloodborne pathogens, standard number 1910.1030.* Retrieved July 2025 from https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030 (Level VII)
24. Siegel, J. D., et al. (2007, revised 2024). *2007 guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Retrieved July 2025 from https://www.cdc.gov/infection-control/media/pdfs/guideline-isolation-h.pdf (Level VII)
25. Accreditation Commission for Health Care. (2025). Standard 07.02.04. *Accreditation requirements for acute care hospitals*. (Level VII)
26. U.S. Food and Drug Administration. (2023). *Examples of medical device misconnections.* Retrieved July 2025 from https://www.fda.gov/medical-devices/medical-device-connectors/examples-medical-device-misconnections
27. The Joint Commission. (2014). *Sentinel event alert 53: Managing risk during transition to new ISO tubing connector standards*. Retrieved July 2025 from https://digitalassets.jointcommission.org/api/public/content/df1ada467ed147518c77827f35acd1ea?v=101e5070 (Level VII)
28. Ganz, D. A., et al. (2013). *Preventing falls in hospitals: A toolkit for improving quality of care* (AHRQ Publication No. 13-0015-EF). Agency for Healthcare Research and Quality. Retrieved July 2025 from https://www.ahrq.gov/sites/default/files/publications/files/fallpxtoolkit.pdf (Level VII)
29. Rutala, W. A., et al. (2008, revised 2024). *Guideline for disinfection and sterilization in healthcare facilities, 2008.* Retrieved July 2025 from https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf (Level I)
30. Accreditation Commission for Health Care. (2025). Standard 07.04.01. *Accreditation requirements for acute care hospitals.* (Level VII)
31. The Joint Commission. (2025). Standard RC.01.03.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
32. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Medical record services. 42 C.F.R. § 482.24(b).
33. Accreditation Commission for Health Care. (2025). Standard 10.00.03. *Accreditation requirements for acute care hospitals.* (Level VII)
34. DNV GL-Healthcare USA, Inc. (2024). MR.2.SR.1. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)

Additional References

- Hoit, B. D. (2024). Pericardial effusion: Approach to diagnosis. In: *UpToDate*, LeWinter, M. M., & Sexton, D. J. (Eds.).
  UpToDate Full Text
- Webner, C. (2021). Electrocardiogram findings associated with malignant pericardial effusion and cardiac tamponade. *ACCN Advanced Critical Care, 32*(2), 227–232. Accessed July 2025 from https://doi.org/10.4037/aacnacc2021887

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.

THORAGUARD

SURGICAL DRAINAGE SYSTEM

RESOURCE GUIDE

IFU-2128 Ver 5
09-09-2022

Scope of Resource Guide

The Thoraguard Resource Guide is a supplement to the Thoraguard Operator's Manual and not to be used in place of the Operator's Manual. The information and figures contained within the Resource Guide are an abbreviated version of those found in the Operator's Manual. For a complete description of Thoraguard's operation or a comprehensive list of instructions, please refer to the Thoraguard Operator's Manual.

Intended Use

The Thoraguard System is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. The Thoraguard System is indicated for all situations where chest drains are applied – especially for thoracic drainage in the pleural and mediastinal cavity in situations such as pneumothorax, after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions. The Thoraguard System is intended for use on patients in appropriate care settings.

CAUTION: The Thoraguard System is only intended for use by or on the order of a physician.

Centese, Inc.
4156 S 52nd St
Omaha, NE 68117
402-300-3150
www.centese.com

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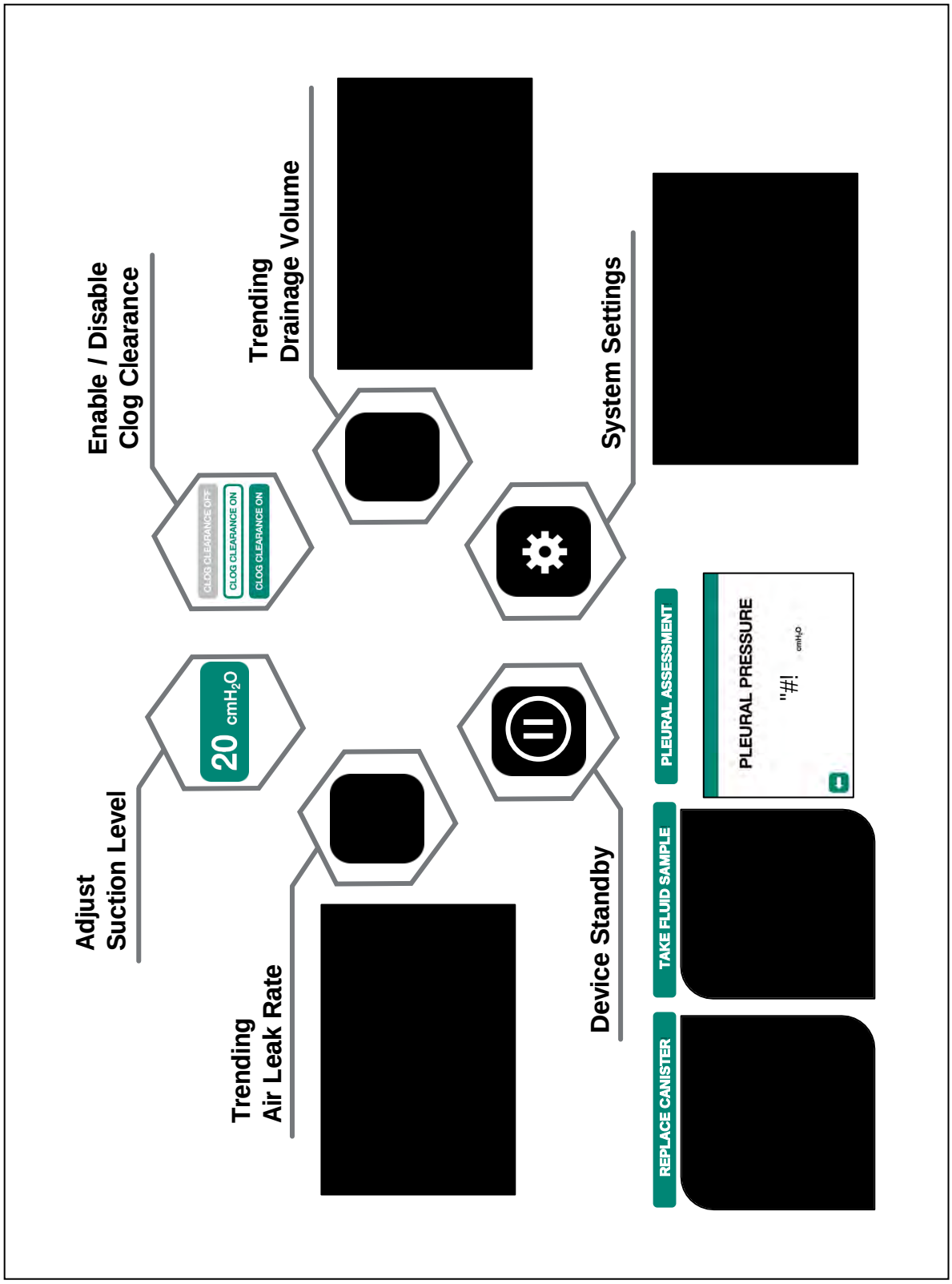
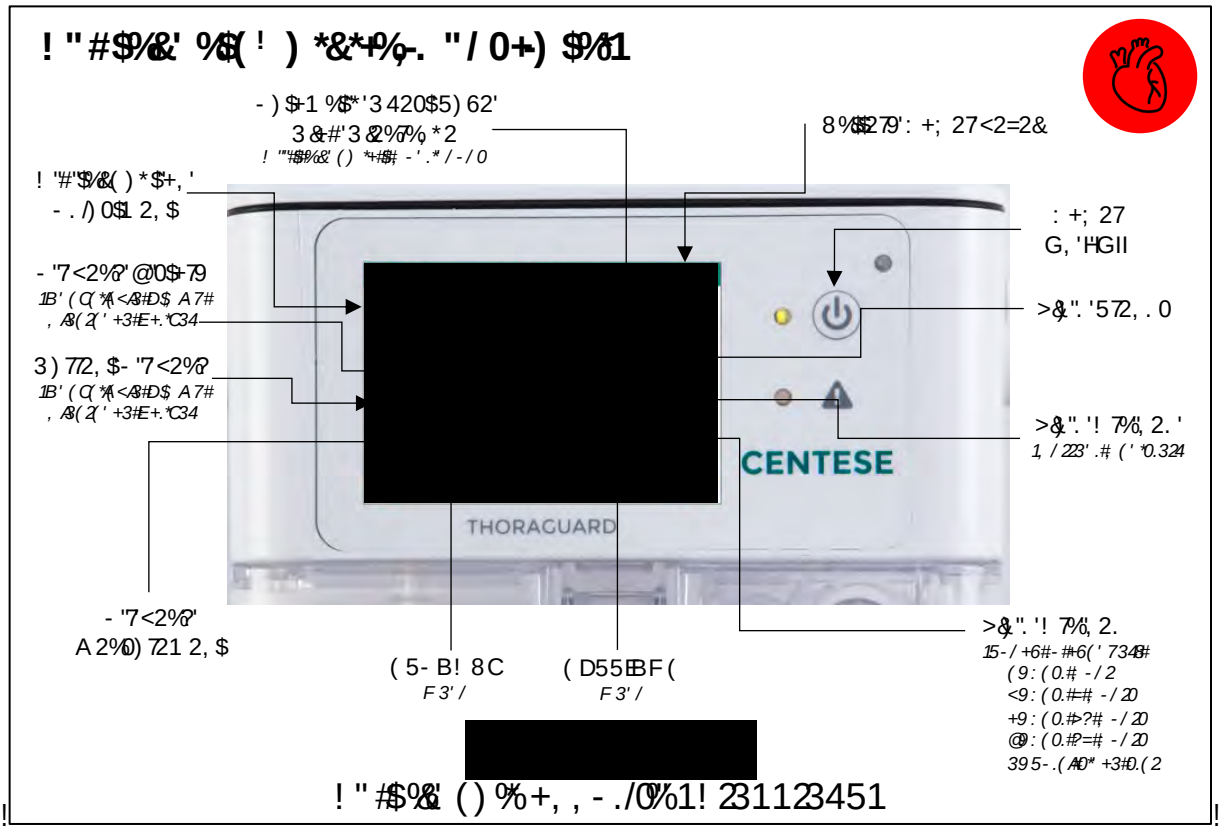
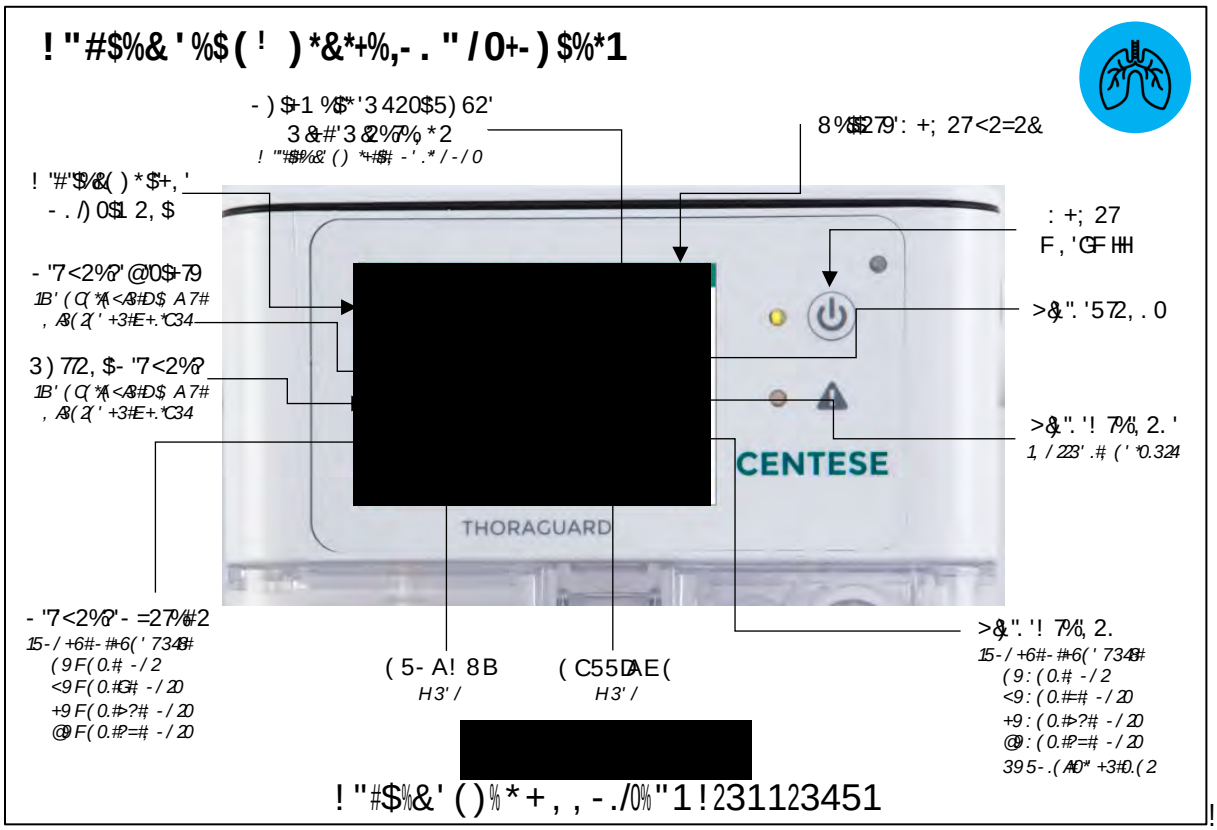
Thoraguard Home Screen Navigation

!



4” x 6” Reference Cards





Thoraguard Chest Tube OR Tips

The Thoraguard Chest Tube is a proprietary chest tube for use only with the Thoraguard Drainage System. Due to the unique design and to ensure proper functionality of the Clog Clearance feature, the following tips may help optimize results:

Submerge Thoraguard Chest Tube in saline or sterile water for at least 10 seconds prior to use

Position drainage holes for optimal access to draining fluid

Ensure all chest tubes and connectors are free from blood / fluid build-up or other surgical materials prior to connecting to Thoraguard Drainage System!

Do not cut or create additional holes in the chest tube

Surgical Sealants and Hemostatic Agents should not come in contact with chest tubes

Do not over-tighten sutures on chest tubes during securement

Do not apply direct suction to the relief (small) lumen of the chest tube

Clog Clearance Settings

[!] Clog clearance mode should only be used in combination with the Thoraguard Chest Tube Kit.

When clog clearance is enabled and dynamic mode is selected, Thoraguard automatically monitors for the completeness of the clog clearance cycle. If the system cannot detect the completion of the clog clearance cycle, Thoraguard will alarm.

Although the clog clearance incomplete alarm is not necessarily an indicator of an obstructed chest tube, always check the chest tube and SmartValve for potential obstructions when the alarm activates. During this time, the system will continue to provide suction at the pre-determined setting, including ongoing activation of the clog clearance functionality.

The alarm also prompts the user to consider updating the clog clearance settings. Selecting “YES” takes the user to the clog clearance setting screen, where continuous clog clearance may be selected for a set period of time, after which dynamic clog clearance will resume and Thoraguard will again monitor for completeness of the clog clearance cycle. Clog clearance may also be turned off.

Dynamic Clog Clearance

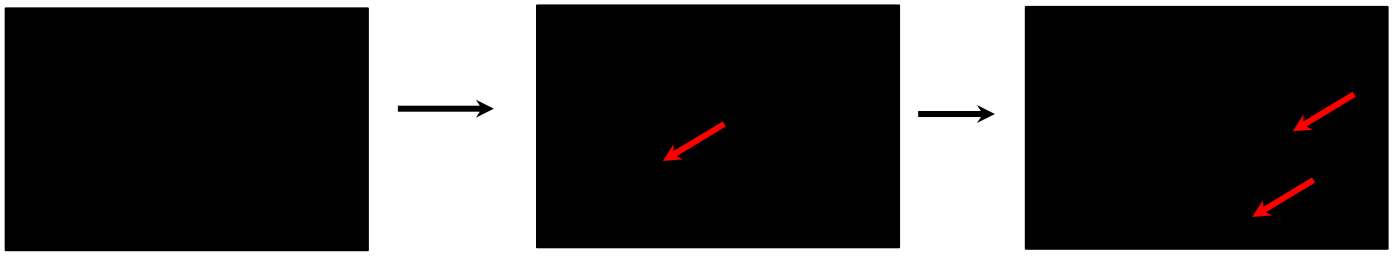
Dynamic clog clearance is the standard clog clearance mode, whereby cycles will intermittently run and last from 30 seconds to 5 minutes, with time between cycles ranging from 5 seconds to 1 minute, based on the pressure response of the system during the last cycle.

Continuous Clog Clearance

Continuous clog clearance maintains suction at -100 cmH_2O to clear the tube continuously. To enable this mode, press “CONTINUOUS” — the user will be asked for confirmation before progressing to time selection. When continuous clog clearance is selected, the user must also select whether to enable this mode for 1 hour, 2 hours, 4 hours, or 8 hours. Once the selected period of time has passed, Thoraguard will automatically resume operation in dynamic mode.

[!] Continuous clog clearance maintains suction at -100 cmH_2O. Clog clearance incomplete alarms are unavailable in this mode.

Example Clog Clearance Incomplete Workflow



2nd Alarm (within 60 minutes of Alarm 1)	Continuous Mode 1-hour	Continuous Mode 1-hour	Continuous Mode 1-hour (2x with each additional alarm) or Disable Clog Clearance if clinically appropriate
Alarm 3+	Continuous Mode 2-hour (2x with each additional alarm)	Continuous Mode 2-hour (2x with each additional alarm) or Disable Clog Clearance if clinically appropriate	

Clamping Chest Tubes with Thoraguard

In certain clinician directed scenarios, it may be desirable to purposely seal off a patient's chest tube(s). To properly clamp a Thoraguard Chest Tube, the clamp should span both the drainage lumen and relief lumen as shown in Figure 1. To clamp a non-Thoraguard chest tube, the clamp should be placed on the chest tube as shown in Figure 2. The drainage tube should not be clamped (Figure 3). Thoraguard does not need to be powered down.

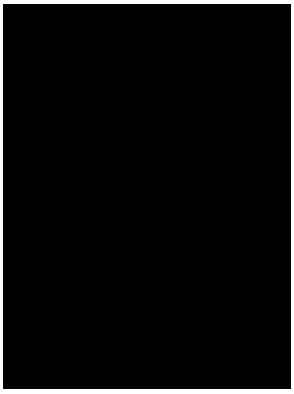


Figure 1: Clamped Thoraguard Chest Tube

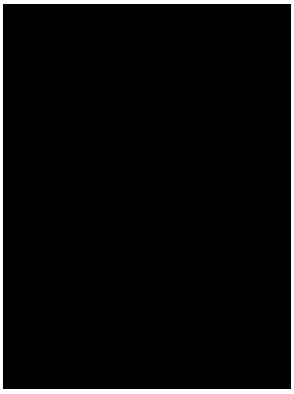


Figure 2: Clamped Traditional Chest Tube

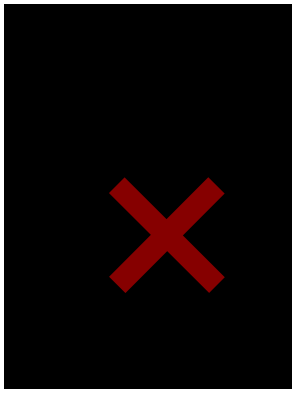


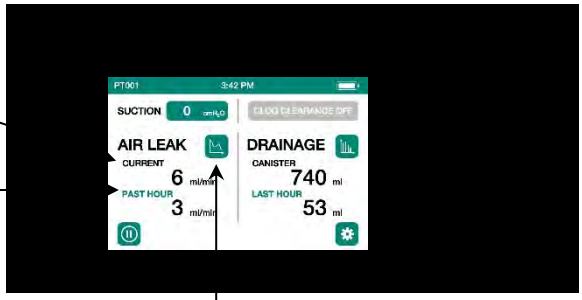
Figure 3: Incorrect Clamp location

Air Leak Assessment with Thoraguard

Thoraguard's digital air leak displays current and historical data to assess patient air leak and to inform clinical decisions. The information supports a comprehensive clinical assessment.!

CURRENT:!

A real-time measurement patient air leak.
Measured as the volume of air removed in mL/min.!



AVERAGE AIR LEAK!

The average air leak measured over the specified time period. Default display is PAST HOUR (prior 60-minutes). Touch to display PAST 6 HOURS, PAST 12 HOURS, or PAST 24 HOURS.!

AIR LEAK TRENDS GRAPHS!

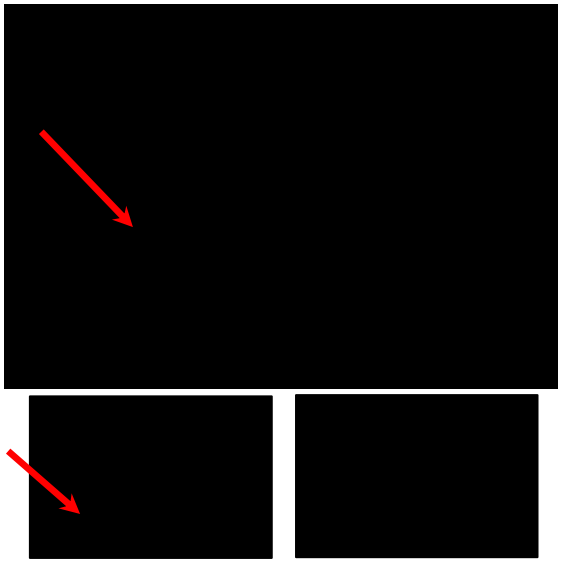
Displays patient air leak rate over 6-hour, 12-hour, and 24-hour time periods. This may be used to identify trends in a patient's air leak over time and the incidence of recent air leak fluctuations.!

6-hour!

12-hour!

24-hour!

Air leak graphs update with incremental bars that represent the average air leak value over a 5-minute period. Note that the "Air Leak Rate" axis of the graph automatically adjusts.!



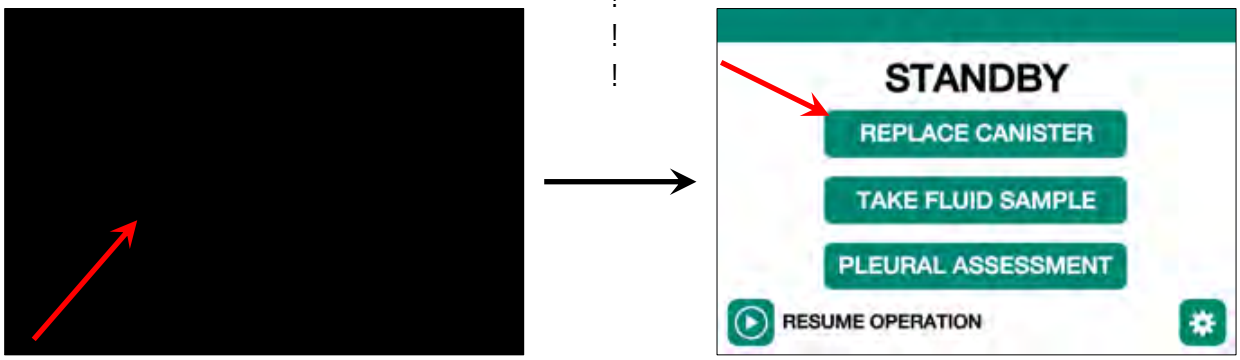
PLEURAL ASSESSMENT:!

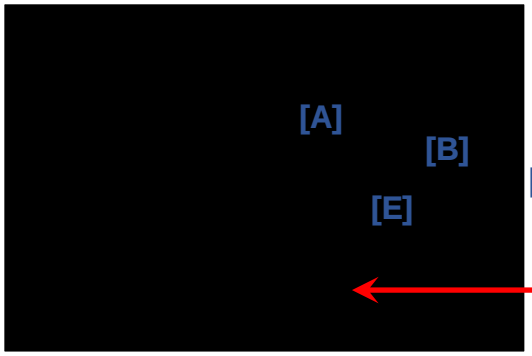
Note: this functionality only works with a chest tube in the intrapleural space.!

A digital surrogate for patient tidaling. Pleural Assessment provides a real-time measurement of pressure at the drainage tubing barb as a proxy for pleural pressure. !

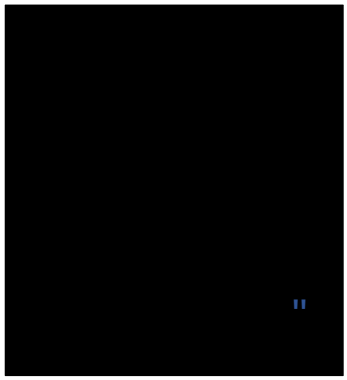
The pleural assessment can be accessed at any point in therapy and may be useful if the clinician desires to monitor for tidal oscillations or pressure fluctuations generated by patient maneuvers such as a Cough or Valsalva, or to check that the chest tube is not occluded. !

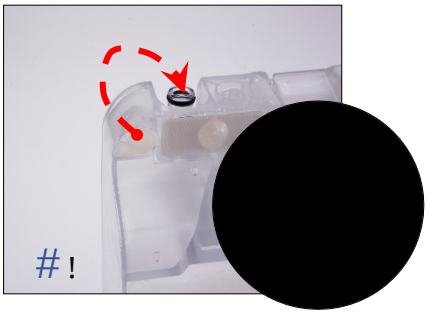
Thoraguard Canister Replacement Sequence





Complete A – E then press **PROCEED**



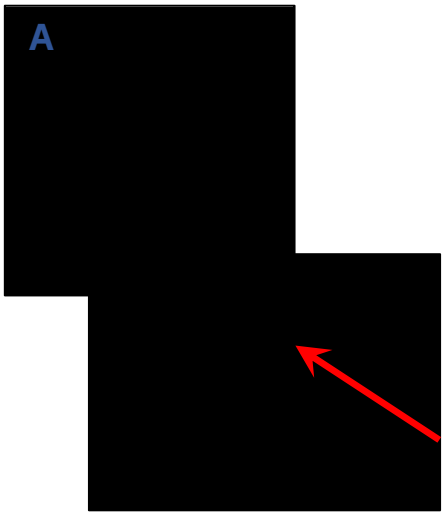


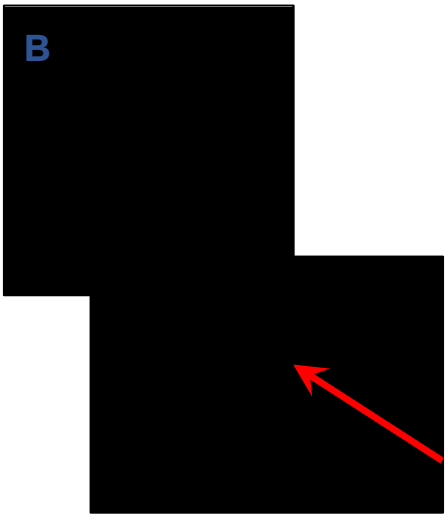
PROCEED: Complete System Check Sequence* (next page)

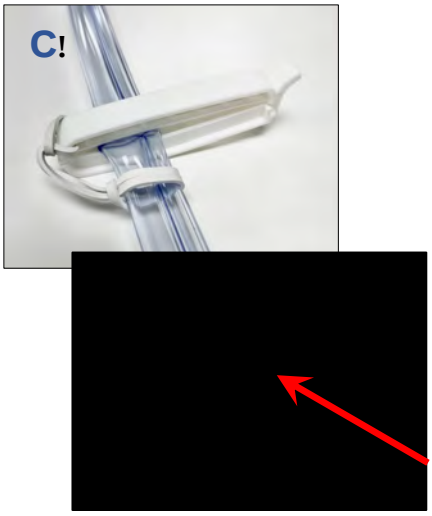
*Failure to complete System Check Sequence after Canister Replacement will result in inaccurate data readings

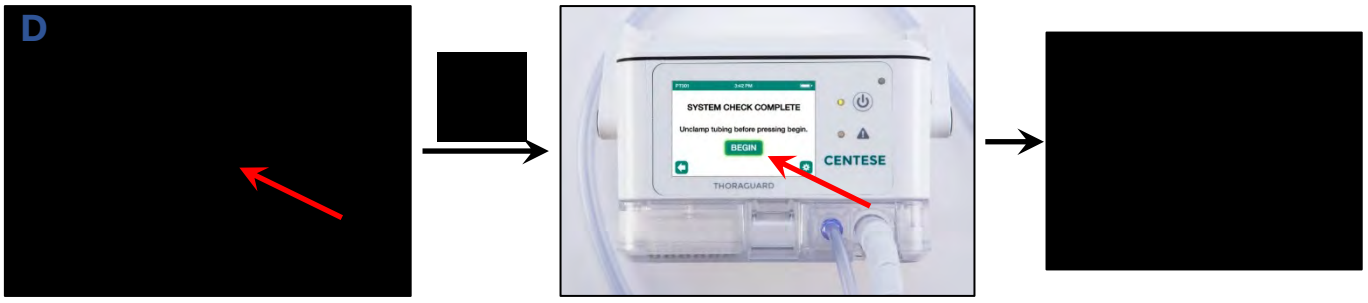
Thoraguard System Check Sequence

"# Confirm the canister is firmly attached and check off on screen. **[A]**!
$# Confirm all tubing is properly connected and check off on screen. **[B]**!
%# Properly clamp drainage tube and check off on screen. **[C]** !
&# Press “BEGIN SYSTEM CHECK” to continue. **[D]**!









SYSTEM CHECK FAILED Warning:!

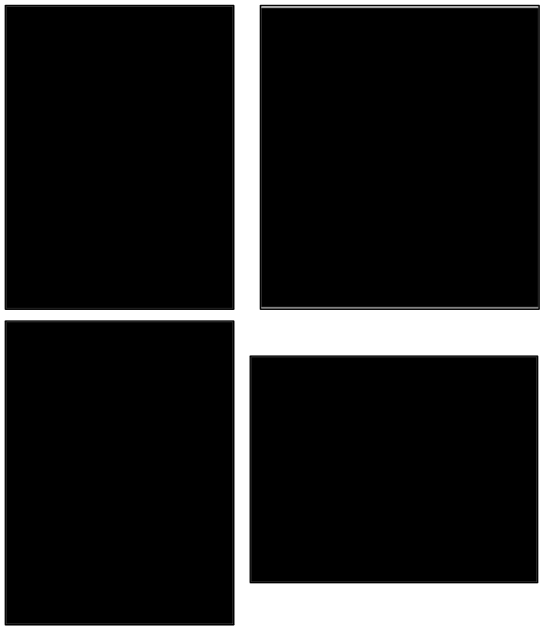
$% Check canister connection.!
&% Confirm tubing connection.!
'% Unclamp tubing and re-clamp – ensuring clamp is fully engaged and tubing is fully sealed.!
(% Press RESUME.!
)% Re-try System Check Sequence.!

System Check Fail Troubleshooting

SYSTEM CHECK FAILED
Move to **Troubleshooting Stage 1**

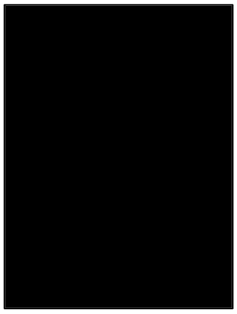
Troubleshooting Stage 1:
A. Ensure canister is properly connected.
B. Confirm canister latch is fully engaged
C. Confirm drainage lines are securely attached.
D. Clamp tubing prior to system check
    1. Consider using additional clamp (double clamp)
E. Re-try system check sequence

IF **SYSTEM CHECK FAILED**
Move to **Troubleshooting Stage 2**



Troubleshooting Stage 2:
A. Canister may be damaged
    1. Replace canister (retain drainage line)

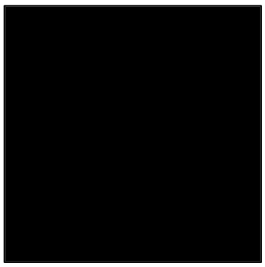
IF **SYSTEM CHECK FAILED**
Move to **Troubleshooting Stage 3**



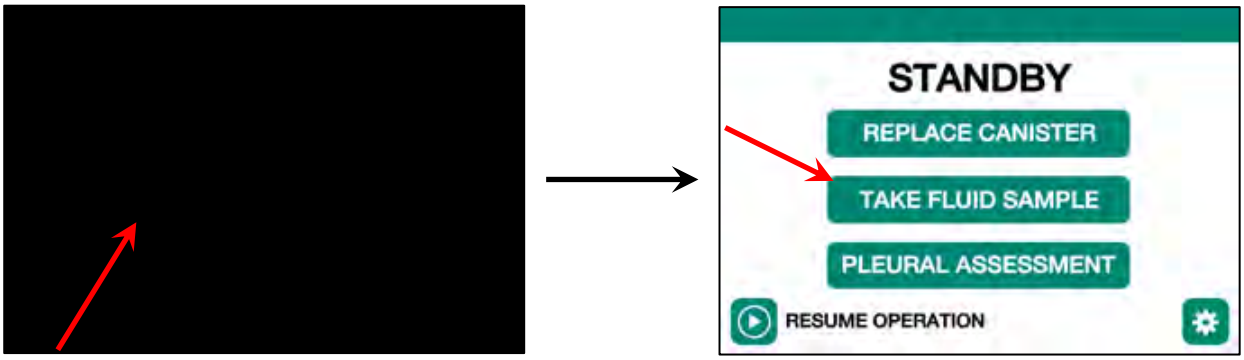
Troubleshooting Stage 3:
A. Drainage line may be damaged
    1. Replace drainage line

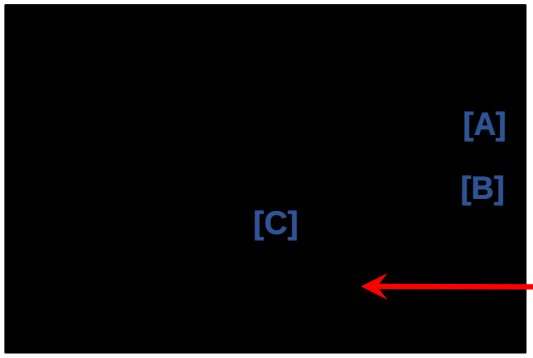
IF **SYSTEM CHECK FAILED**
Move to **Troubleshooting Stage 4**

Troubleshooting Stage 4:
A. Control Module may be damaged
    1. Replace Control Module
    2. Tag Control Module for service inspection



Thoraguard Fluid Sample Guide





Complete A – C!
then **RESUME**!

Multi-Step Alarm Troubleshooting

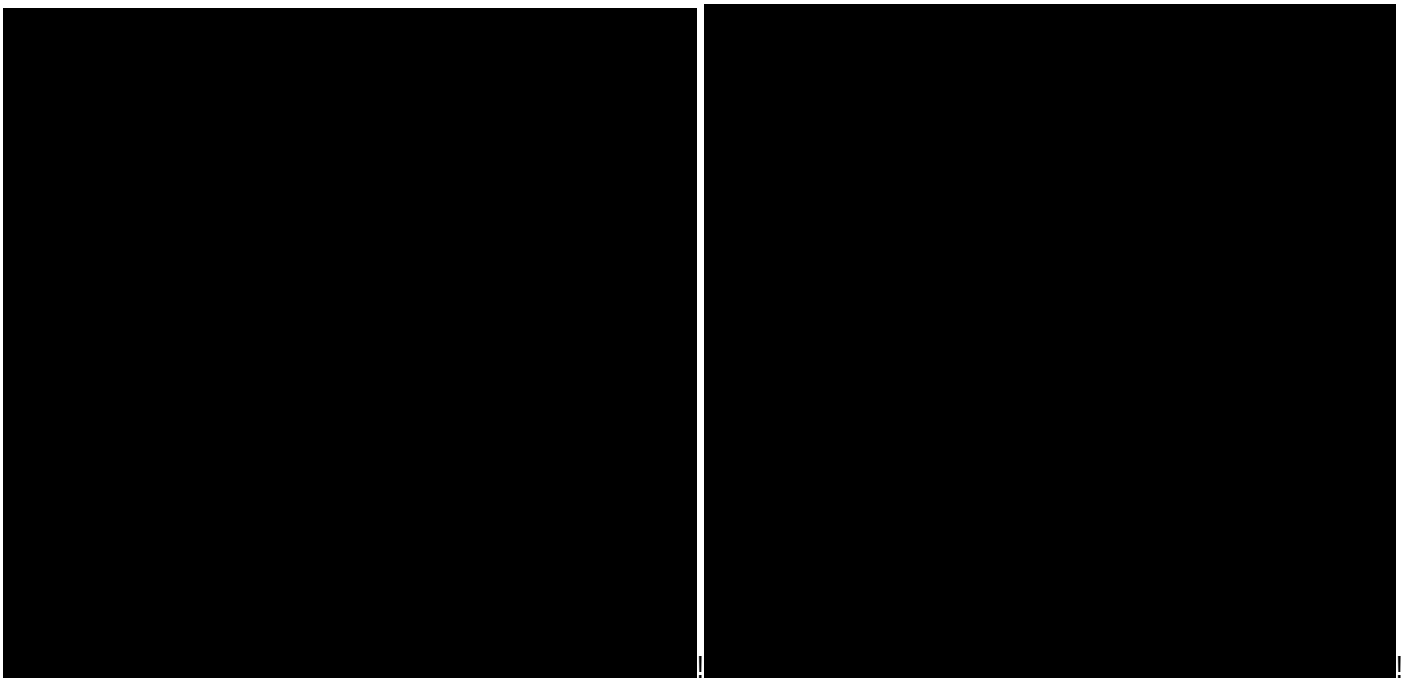
A selected list of alarms and troubleshooting steps is provided below. “What to Do” with multiple troubleshooting steps should be followed sequentially. Should a step yield a resolved alarm condition further progression is not necessary.

Displayed Message	Description	Alarm Level	What to Do
Use Warnings			
CANISTER DISCONNECTED 0035	The canister has become disconnected.	**High**	1) Re-connect canister. 2) Ensure canister latches properly. 3) Replace canister. 4) If alarm persists despite canister firmly attached and no visible damage, consider replacing Control Module.
DRAINAGE LINE OBSTRUCTED 0040	A clog has been detected in the drainage tubing.	**High**	1) Check tubing for clogs. 2) Confirm clamp is unclamped. 3) Inspect chest tube connector for build-up. 4) Replace drainage line.
CANISTER FILTER CLOGGED 0050	The filter in the drainage canister is clogged.	**High**	1) Replace canister. 2) Replace Control Module.
EXCESSIVE AIR LEAK 0055	A large air leak (over 5000 ml/min) has been detected.	**High**	1) Check all connections for leaks. 2) Inspect all tubing for damage. 3) Ensure canister is securely attached to Control Module. 4) Replace canister and drainage line.
Control Module System Faults			
CONTROL MODULE FAULT 0210	Internal error with Control Module during startup.	**Medium**	1) Restart Control Module 2) Replace Control Module and return unit to Centese for repair
CONTROL MODULE FAULT 0215	Internal error with Control Module during use.	**High**	1) Restart Control Module 2) Replace Control Module and return unit to Centese for repair

24/7 Tech Support: 402-300-3150

Using the Drainage Tubing Clamp

When clamping the drainage tubing, clamp perpendicularly across the tubing with the large tube facing the inside hinge. Position the tube near the inside hinge and clamp without overlapping the tubing as shown below:



Frequently Asked Questions (FAQs)

1.! Canister drainage reading displays "NOT LEVEL"

Thoraguard has integrated leveling sensors in the control module which improve the accuracy of digital measurements. When in use, if the control module is not held upright or placed on a level surface the words "NOT LEVEL" appear under "CANISTER" drainage measurement section of the Home Screen. To resolve this, place the control module on a level surface and wait for the system to stabilize-this may take a few moments.

Note, if Thoraguard has less than 200 mL of drainage, the control module must be level within ±5°. If greater than 200 mL of drainage has accumulated, the control module must be level within ±10°. This notification is different than the "Device Tipped Over" Alarm.

2.! Canister drainage reading is higher than actual amount of fluid in canister

When Thoraguard has been calibrated properly, the accuracy of the drainage volume measurement is ±5% of the total volume of fluid in the canister. This applies to volumes greater than 100 mL. If the digital display of Canister exceeds the actual volume amount by more than approximately 5%, this may be a caused by specific scenarios:

a)! Excessive fluid sloshing or foaming during movement or ambulation – this can cause digital readings to skew high due to fluid movement in the canister. Once increased, the digital readings do not return lower. If no further sloshing occurs, normal fluid accumulation will cause the total amount of fluid to match the digital reading, at which point the measurements will once again begin to correlate accurately. Alternatively, the canister may be replaced with a new canister and completion of the Canister Replacement sequence.

b)! If the canister is tipped over this may result in the fluid measurement sensors incorrectly detecting an increase in fluid volume. This can result in a discrepancy between the digitally displayed fluid drainage levels and actual fluid levels. If this occurs, Thoraguard should be kept in a stable and upright position until normal fluid accumulation will cause the total amount of fluid to match the digital reading, at which point the measurements will once again begin to correlate accurately. Alternatively, the canister may be replaced with a new canister and completion of the Canister Replacement sequence.

c)! The canister was replaced, but system check was not completed correctly. When the Canister Replacement sequence is performed completely, the drainage reading under canister resets to -- mL. If this scenario occurred, the Canister Replacement sequence can be re-run with the existing canister if less than 50 mL of fluid is in the canister. If there is greater than 50 mL of fluid in the canister a new replacement canister should be connected and Cannister Replacement with System Check should be completed correctly.

3.! Canister Full Alarm continues despite canister being recently replaced

If the canister is replaced, but system check is not completed correctly, the Canister Full Alarm may continue to trigger. If the Canister Replacement sequence is performed correctly, the canister drainage reading displayed resets to -- mL. If this occurred and there is <50 mL of fluid is in the canister, the Canister Replacement sequence can be re-run with the existing canister. If there is >50 mL of fluid in the canister a new replacement canister should be connected and the full Canister Replacement sequence performed.

4.! The Control Module is not charging despite being plugged in

Troubleshooting steps:

a)! Confirm that the correct power supply is being used. The words "Centese Thoraguard" should be prevalent on the black power transformer.

b)! Ensure that the connection between the gray power cord and black transformer is secure and the green light on the black transformer is illuminated when the power cord is plugged.

c)! The power plug is fully inserted into the power port on the side of the Control Module. In some cases, the connection may feel snug, but the system requires additional force to engage the final 1/8". Rotating the plug while pushing into the power port may help.

The charging battery icon will appear when the control module and power supply are properly connected.

5.! Can the Clog Clearance feature be used with any chest tube?

No. The Clog Clearance feature is for use with the Thoraguard Chest Tube Kit only. The Thoraguard Control Module and Drainage Kit can be used with any standard chest tube. However, activating the Clog Clearance feature with a chest tube other than a Thoraguard Chest Tube will not provide active clearance and may trigger a Clogged Chest Tube alarm.

6.! If a Control Module needs to be replaced while on a patient, can I use the same canister?

No. If a Control Module needs to be replaced while providing therapy to a patient, a new canister should be used and the New Patient set-up sequence should be followed. Re-use of an existing canister will cause errors in the drainage readings. If the drainage tubing connected to the chest tube is intact, this may be reused.

7.! The System will not pass system check, what do I do now?

For Thoraguard to pass system check, the Control Module must have 3 core steps in place during the entire system check process:

A.! The canister must be firmly attached to the Control Module with both feet (located at the base of the system) engaged and the canister securely latched.

B.! Both drainage lines must be securely connected. Note, over-tightening of the connectors may result in damage to the canister.

C.! The drainage line must be entirely clamped so that no airflow can occur during the entire system check sequence.

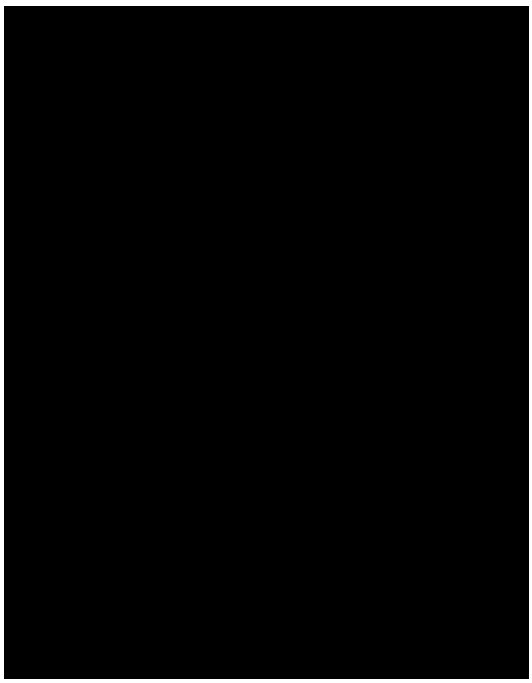
The first step of troubleshooting should be to re-try the system check sequence confirming A–C above. Additional troubleshooting steps can be found on Page 13 of this Resource Guide.

8.! Does Centese have Technical Support?

Yes. Technical Support via phone is available 24/7. Call: 402-300-3150.

Thoraguard After Use Processing

Thoraguard Control Module and Power Supply should be cleaned and reused following standard hospital wipe down protocols.



Thoraguard Control Module
TGCM1000

Thoraguard Power Supply
TGPS0100

Location of soiled units after use: _____

Contact number for pick-up of soiled units: _____

Storage location for cleaned units: _____

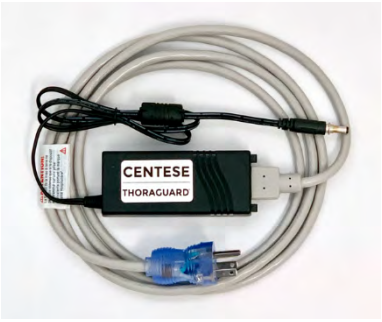
Contact for storage cleaned units: _____

Note: The Thoraguard Control Module is intended to be used and stored in a hospital environment between 50°F and 104°F (10°C to 40°C), relative humidity of 10-90%, non-condensing, altitude within 0 to 2,000 meters (6,560 feet), and pressure of 101 kPa to 81 kPa. **Do not use Thoraguard near active HF Surgical Equipment or MRI.**

Thoraguard Cleaning Instructions

Thoraguard Control Module!
TGCM1000!

Thoraguard Power Supply!
TGPS0100!



The exterior surfaces of the Control Module may be cleaned with a soft, non-abrasive cloth dampened with warm water / mild detergent, alcohol, or a non-staining chemical disinfectant. Always dilute cleaning agents according to manufacturer's instructions, or lowest possible concentration. Clean by spraying cleanser directly onto a soft lint-free cloth and then wiping surfaces dry.!

!

Take extra care when cleaning the screen of the Control Module because it may be damaged by aggressive cleaning methods. Wipe around, not over, connector sockets when possible. Clean around the barbs where the drainage canister connects, but pay special attention not to leave dirt or lint inside the barbs.!

!

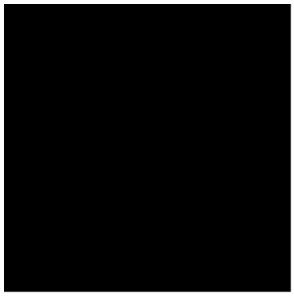
Recommended cleaning and disinfecting agents are listed below. In addition, follow your institution's guidelines for cleaning and disinfecting of devices. !

Recommended Cleaning Agents	Mild soaps
	Common bleach 10% solution diluted with water
	Mild detergent mixed with water
	Isopropyl alcohol 70% solution[1]
Recommended Disinfecting Agents	Alcohol based (E.g. Ethanol 70%[1], Isopropyl 70%[1], Cutasept®, Hospisept®, Kodan® Tinktur Forte, Sagrosept®, Spitacid®, Sterilium®)
	Aldehyde based (E.g. Dilution of formaldehyde (3-5%), Cidex®, Gigasept®)
	Bleach (E.g. Dilution of sodium hypochlorite (laundry bleach): concentration ranging from 500 ppm (1:100 dilution of household bleach), Hydrogen peroxide 3%[1], Clorox (1:10 dilution), Dakin's Solution)
	Phenol based (E.g. Wofasept®, Sporicidin®)

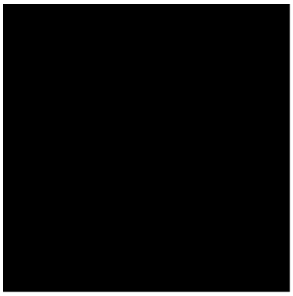
Acceptable Common Cleaning Wipes:!

Thoraguard

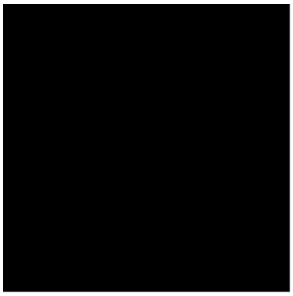
Instructional Videos



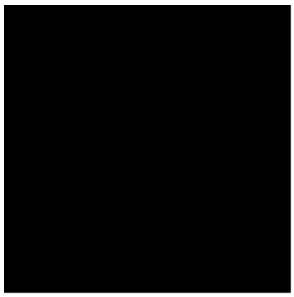
Thoraguard Instructional Video – Full Length (19:39)



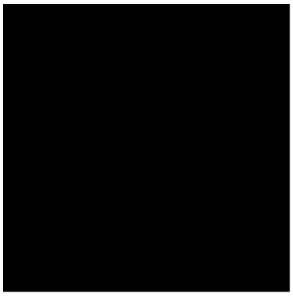
Thoraguard – Canister Replacement Guide (2:16)



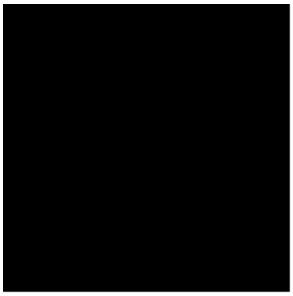
Thoraguard – Power Down & Disconnection Guide (1:21)



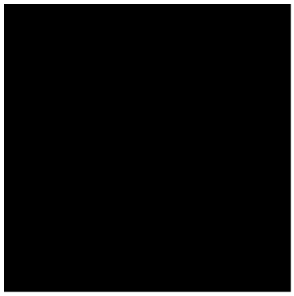
Thoraguard – Set-up in the OR Guide (3:29)



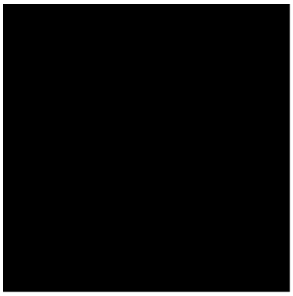
Thoraguard – Taking a Fluid Sample Guide (0:46)



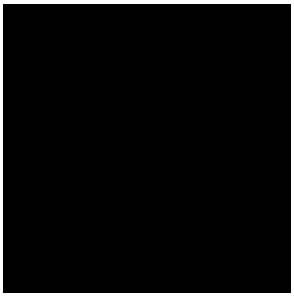
Thoraguard – Chest Tube Set-up Guide (3:06)



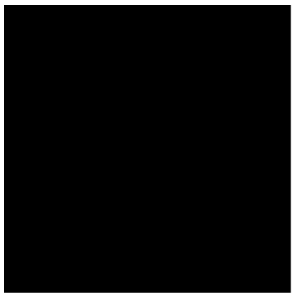
Thoraguard – System Operation Overview (1:32)



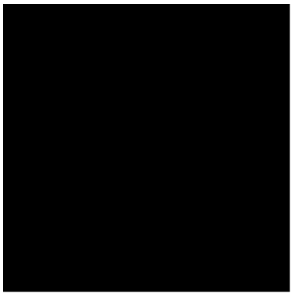
Thoraguard – Pleural Assessment Overview (0:36)



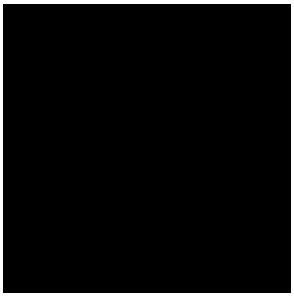
Thoraguard – Set-up Outside of the OR Guide (2:07)



Thoraguard – Data Trends Overview (1:54)



Thoraguard – Settings Menu Overview (1:12)



Thoraguard – Clog Clearance Incomplete Guide (1:03)

Suggested Competencies Training Form: **Bio-Engineering Team**

THORAGUARD COMPETENCY	**YES**	**NO**	**N/A**
Opening shipment packaging and removing components			
Identification of serial number location			
Location and storage of IFU / Operator's Manual			
Review of product specifications			
Attaching power cord and charging			
Powering on and off			
Setting date and time for user location			
Confirming set-up / calibration			
Cleaning instructions			
Location of spare power cords			
Transfer to charging / use locations			
Location of Centese service / repair information			
Location of Centese main contact information			

Name: _____ Date: _____

Print Name: _____

Location: _____ Shift: _____

Confirmed by: _____ Date: _____

Suggested Competencies Training Form: **OR Team**

THORAGUARD COMPETENCY	**YES**	**NO**	**N/A**
Location of disposables and Control Modules			
Control module power cord and charging / status			
Opening Drainage and Chest Tube Kits while maintaining sterility			
Presentation of Kits to the Sterile Field			
Location of Thoraguard Drainage Kit Set-up Instructions			
Location of Thoraguard Chest Tube Kit Set-up Instructions			
Correct removal and hydration of Thoraguard Chest Tube			
Maintenance of SmartValve in a dry location			
Flush Thoraguard Chest Tube with sterile water / saline			
Attaching SmartValve to Thoraguard Chest Tube			
Correct attachment of the canister and drainage tube set			
Correct placement and use of set up clamp			
Turning Control Module power on / off			
Set-up positioning of Control Module outside of sterile field			
Performing System Check set up			
Connection to Thoraguard SmartValve and Chest Tube			
Connection to a standard chest tube			
Changing suction level setting			
Setting to SmartSeal - Zero Suction Mode			
Set-up of Clog Clearance feature			
Use of Clog Clearance Incomplete workflow			
Configuring Drainage Alarm			
Disable Air Leak Display			
Pleural Assessment feature			
Assessing initial drainage and air leak			
Understanding and managing Alarms and Notifications			
Transport from OR with power charging cord			
Control Module handle / hook adjustment			
Location of Centese contact information			
Review of Thoraguard Warnings and Precautions in Operator’s Manual			

Name: _____ Date: _____

Print Name: _____

Location: _____ Shift: _____

Confirmed by: _____ Date: _____

Suggested Competencies Training Form: **Patient Care Location Team(s)**

THORAGUARD COMPETENCY	**YES**	**NO**	**N/A**
Location of Thoraguard Operator's Manual			
Location of replacement Thoraguard Disposables and Control Modules			
How to ambulate or transport patients with Thoraguard			
Control Module handle / hook adjustment			
Control Module Power Supply connection and charging status			
Maintaining aseptic technique during canister replacement			
Correct replacing a canister			
Replacement of drainage tube			
Correct performance of system check			
Changing suction setting			
Setting to SmartSeal - Zero Suction Mode			
Understanding and resolving Alarms and Notifications			
How to check for air leak			
Monitoring fluid drainage			
Using Pleural Assessment feature			
Identifying necessary patient data for documentation			
Historical data review (ex. Last Hour, Past Hour, Trends, etc.)			
How to draw a fluid sample			
When to use Clog Clearance feature			
Activating Clog Clearance			
Use of Clog Clearance Incomplete Workflow			
Disposal of single-use materials			
Power down / turning off			
Restart after unintentional power down			
Thoraguard Control Module and power cord cleaning			
Destination of Control Module and power cord after removal			
Location of Centese contact information			
Review of Thoraguard Warnings and Precautions in Operator's Manual			

Name: _____ Date: _____

Print Name: _____

Location: _____ Shift: _____

Confirmed by: _____ Date: _____

Suggested Competencies Training Form: **Materials Management / Supply Team**

THORAGUARD COMPETENCY	**YES**	**NO**	**NA**
Centese part numbers loaded			
Centese shipment / case and order quantities confirmed			
Centese warranty and return policies reviewed			
Cleaning instructions reviewed			
Return Control Module and Power Cord to storage location			
Location of spare power cords			
Location of Centese service / repair information			
Location of Centese main contact information			

Name: _____ Date: _____

Print Name: _____

Location: _____ Shift: _____

Confirmed by: _____ Date: _____

Objectives

1. Identify the purpose for the chest tube.
2. Identify set-up for chest tube and drainage system.
3. Describe management and troubleshooting of a chest tube.

Suction Set-up

Do not connect suction tubing to suction canister.

Click to see the correct set-up.

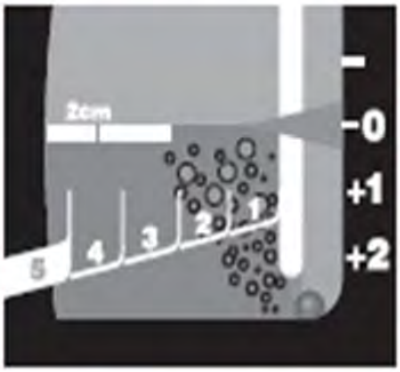
Set at -20cmH2O

1. Review patient orders.
   - Example shows suction ordered at -20cmH2O.
2. If suction is ordered:
   - Ensure dial is adjusted to correct setting.
   - Suction tubing is attached to chest tube drainage system and wall suction at adaptor, **not** the suction canister.

Suction tubing connection points on drainage system and wall suction.

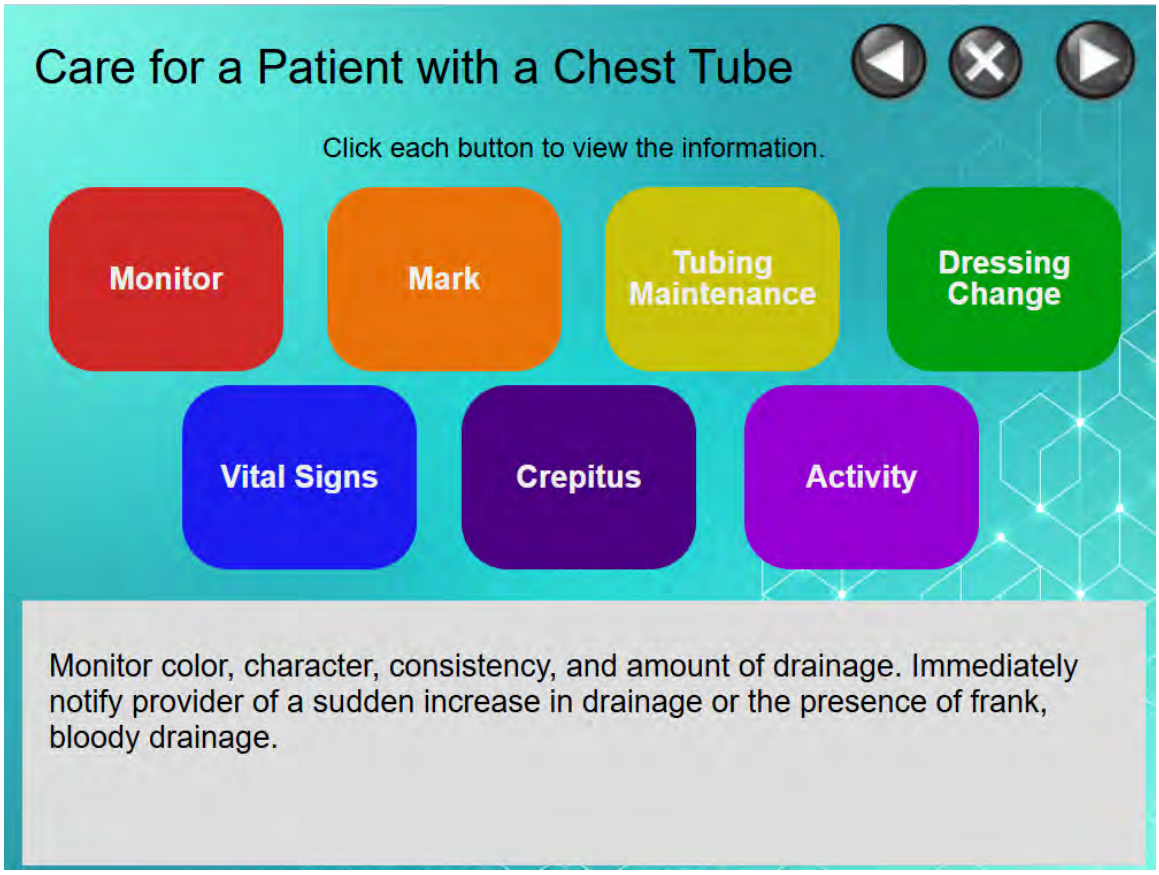
Troubleshooting Air Leaks

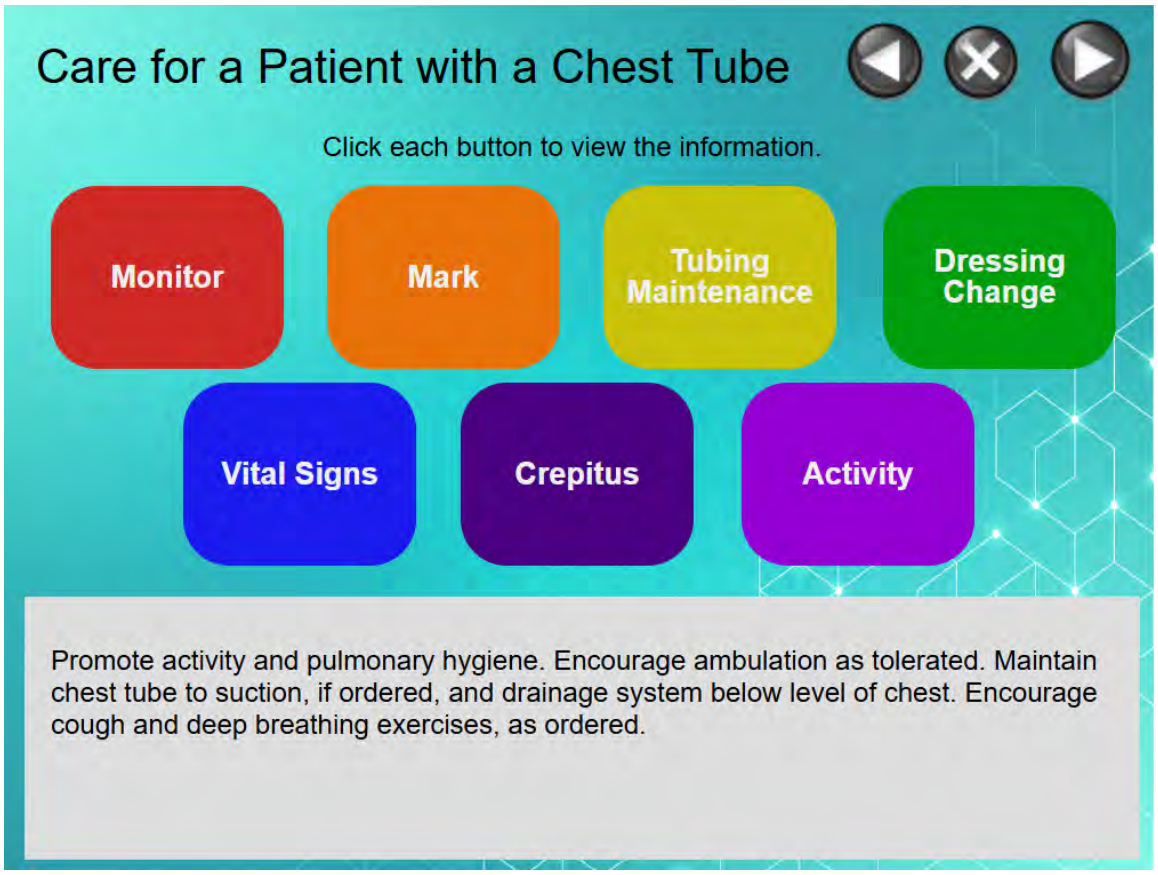
- Observe water seal for bubbling. This may be expected if the patient has a pneumothorax.
- For new, worsening, or constant bubbling:
  - Attempt to determine the source of an air leak.
  - *Momentarily* clamp the chest tube close to the drainage container. If the bubbling:



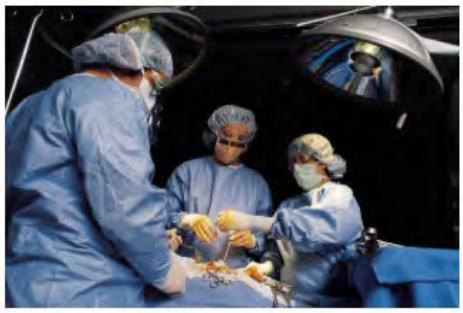
Stops **Continues**

The air leak may be from the catheter connection tubing or the patient's chest. Check the tubing, connection points, and the patient's dressing for possible dislodgement. Notify provider accordingly.


Care for a Patient with a Chest Tube
Click each button to view the information.
Monitor
Mark
Tubing Maintenance
Dressing Change
Vital Signs
Crepitus
Activity
Monitor color, character, consistency, and amount of drainage. Immediately notify provider of a sudden increase in drainage or the presence of frank, bloody drainage.


Care for a Patient with a Chest Tube
Click each button to view the information.
Monitor
Mark
Tubing Maintenance
Dressing Change
Vital Signs
Crepitus
Activity
Promote activity and pulmonary hygiene. Encourage ambulation as tolerated. Maintain chest tube to suction, if ordered, and drainage system below level of chest. Encourage cough and deep breathing exercises, as ordered.

Preparing A Patient For Surgery



Molly Gallagher, BSN, RN, CAPA
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.

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.

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.

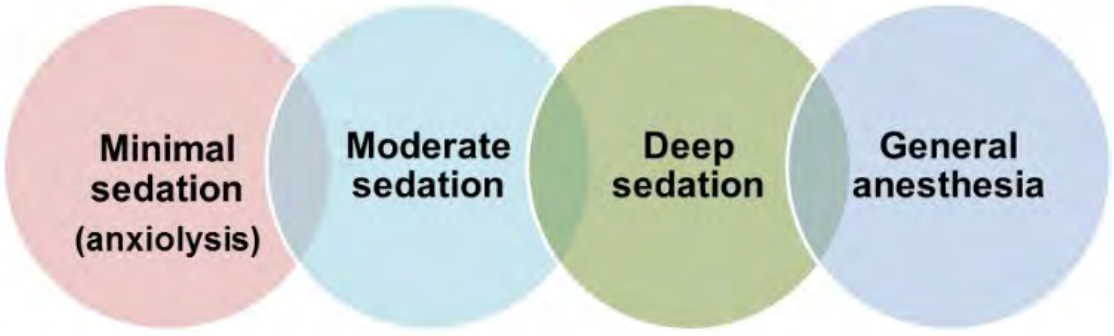
What if the patient is admitted the night before surgery?

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

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

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:



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.

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

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:

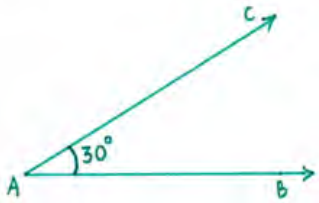
A score < 8 indicates the patient should be closely monitored with interventions applied as indicated.

Nausea and Vomiting

<u>Aspiration is a major concern with the patient receiving sedation</u>.

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.



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

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

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.

[redacted]

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

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?

- (●) 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 nomal 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

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 *(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

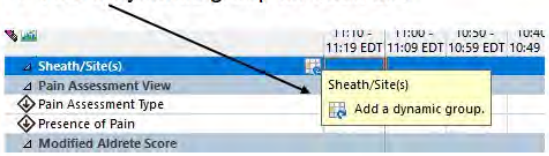
Post-Procedural Complications: Hematoma

Forearm Hematoma

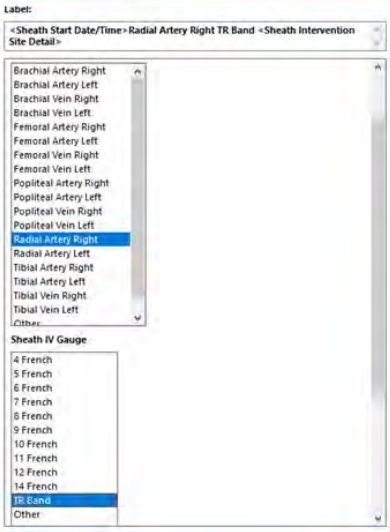
- Bleeding may also rarely occur from a site on the radial artery remote from the puncture site. It can **occur from a perforation of a small side branch of the radial artery by a guide wire.**
- **If not controlled urgently** and appropriately, forearm hematomas can lead to the development of **compartment 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.

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



References

Bourassa M. G. (2005). The history of cardiac catheterization. *The Canadian journal of cardiology*, *21*(12), 1011–1014.

Fischman D, et al. (2021) "Up in Arms" Making the Argument for Broadening the Use of the Radial Artery. *Journal of American College of Cardiology Interventions*. (8) 917–918. https://doi.org/10.1016/j.jcin.2021.02.023

Krishna, H., & Shroff, A. (2018). Ten Common (and Uncommon) Reasons for Unsuccessful Transradial Procedures: Understanding the limitations of radial access is key to optimal application. [Review of *Ten Common (and Uncommon) Reasons for Unsuccessful Transradial Procedures Understanding the limitations of radial access is key to optimal application*.]. Figure 1., *Endovascular Today*, *17*(11), 50. https://assets.bmctoday.net/evtoday/pdfs/et1118_SF2_Shroff.pdf

Mitchell, M. D., Hong, J. A., Lee, B. Y., Umscheid, C. A., Bartsch, S. M., & Don, C. W. (2012). Systematic review and cost–benefit analysis of radial artery access for coronary angiography and intervention. *Circulation: Cardiovascular Quality and Outcomes*, *5*(4), 454-462.

Pristipino, C., Trani, C., Nazzaro, M. S., Berni, A., Patti, G., Patrizi, R., ... & Richichi, G. (2009). Major improvement of percutaneous cardiovascular procedure outcomes with radial artery catheterization: results from the PREVAIL study. *Heart*, *95*(6), 476-482.

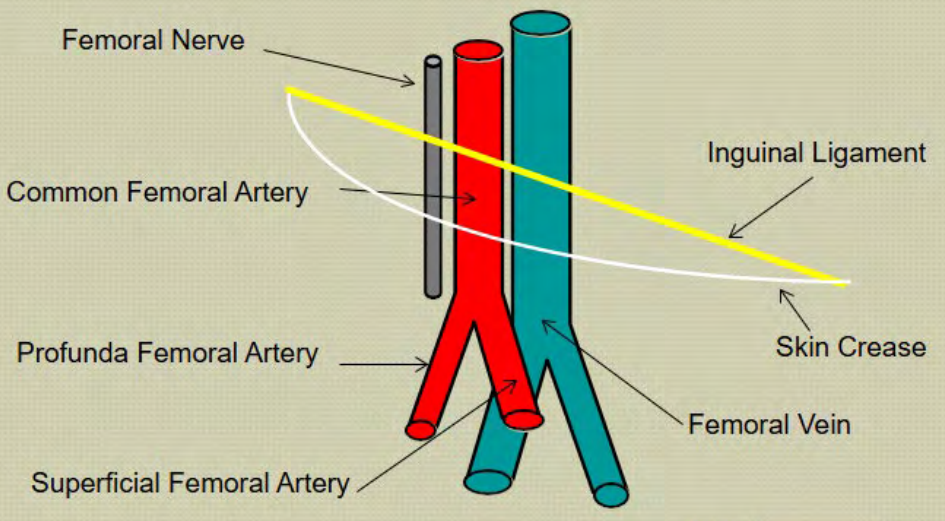
Roy, S., Kabach, M., Patel, D. B., Guzman, L. A., & Jovin, I. S. (2022). Radial artery access complications: prevention, diagnosis and management. *Cardiovascular Revascularization Medicine*, *40*, 163-171.

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

Shroff, A., Pinto, D. (2021). Vascular access, management and closure. Best practices. The Society for Cardiovascular Angiography and Interventions (SCAI)

Vascular Anatomy

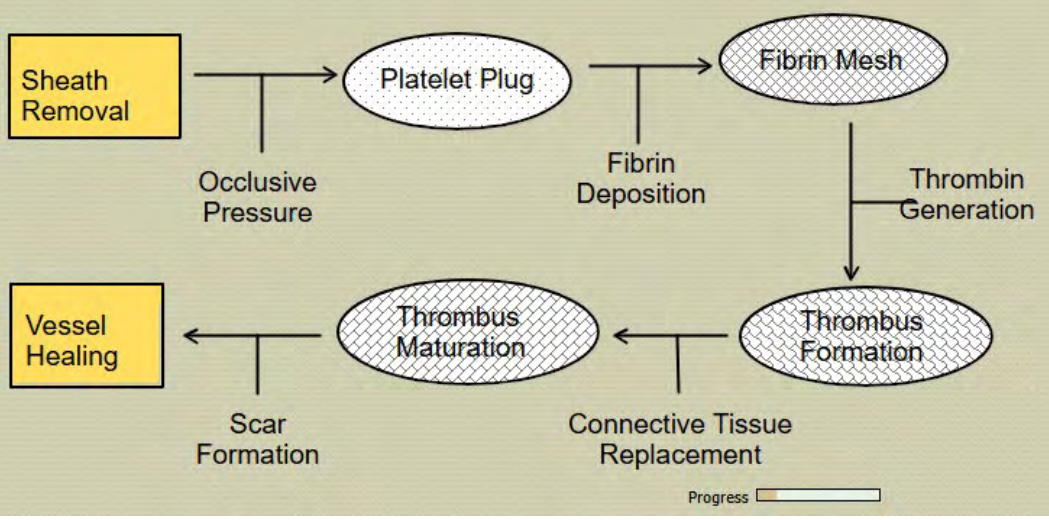
Identify the nerve, artery, vein, and ligament structures in the groin area.



Progress

The Hemostasis Process

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



Progress

Post Sheath Pull:
Potential Vascular Complications

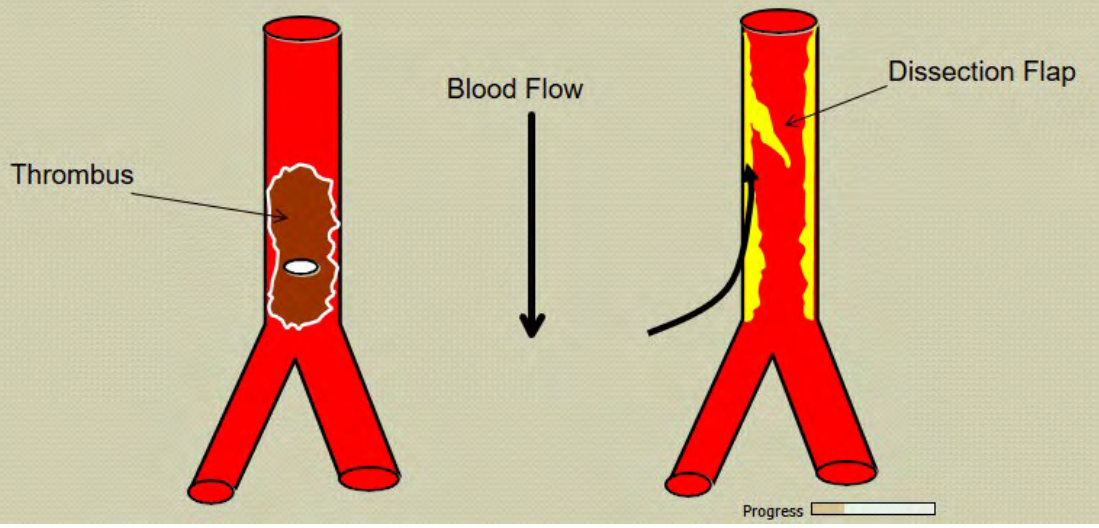
- Vessel thrombosis and dissection
- Bleeding
- Re-bleeding
- Femoral hematoma
- Retroperitoneal hemorrhage
- Pseudoaneurysm
- Arteriovenous fistula
- Atheroembolism

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

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

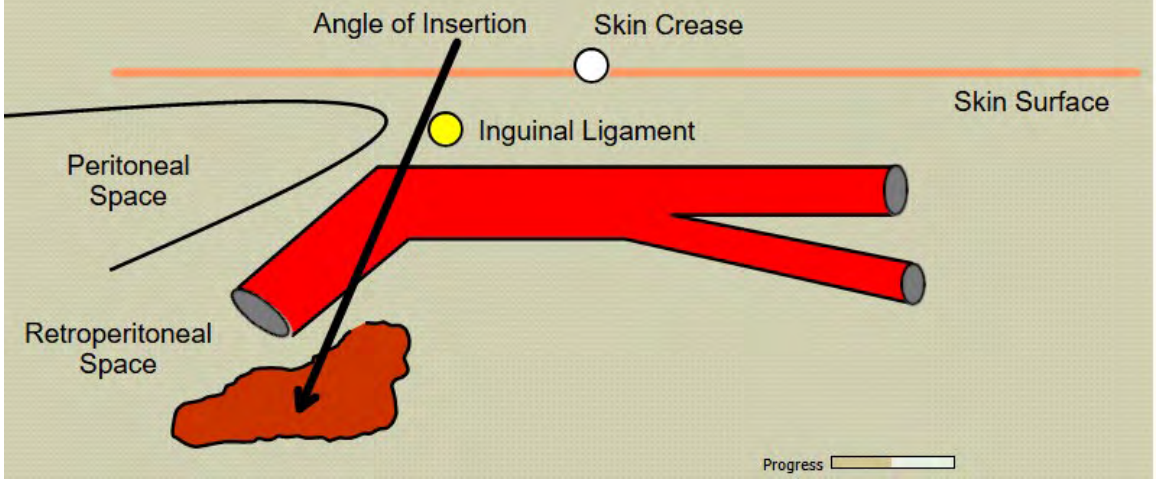
Nursing Considerations: Hematoma

- 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

Vascular Complications: Retroperitoneal Hemorrhage

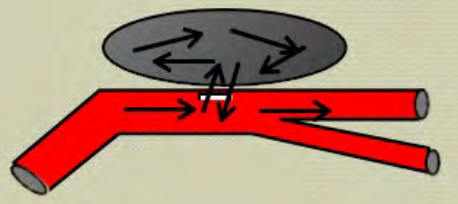
A retroperitoneal hemorrhage is a hematoma extending into the retroperitoneal space that usually occurs from arterial puncture above the inguinal ligament.



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

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

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: 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

Landing a Heart on A2 + HemoSphere/Philips Monitors

Room Preparation (NAs):

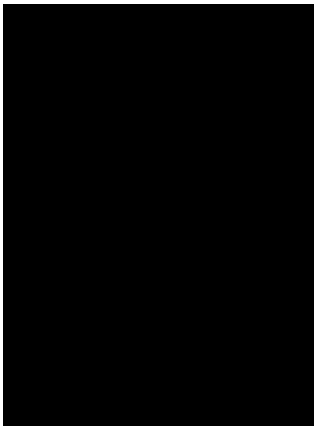
Bed: After open heart surgery, the patient will be transported from OR to A2 on a bed (Versa Care bed with blue mattress). The OR tech will pick the bed up in the AM (for planned procedures) or for emergent cases, when the patient is boarding.

- *To prepare the bed:*
  1. Make bed with a flat sheet. A pillow, pillow case and patient gown should be placed on the bed and the bed should be "zeroed" prior to being picked up.
  2. Set aside pillow, pillowcase and gown within the room for future use.
  3. Secure oxygen tank in a holder to the foot of the bed. The tank should contain at least 500 PSI on the dial, or be almost FULL.

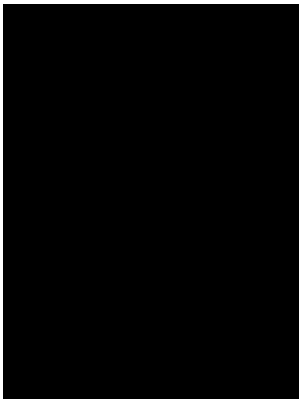
Equipment: These pieces of equipment are the necessary components the nursing staff will need to monitor and treat the patient following open heart surgery. Please ensure the heart pole and other equipment is placed in the room ready for room set up.

1. A Bair Hugger: the warming blanket used to rewarm the patient after the cold environment in the OR.
2. An IV pole with four IV pumps attached. The IV pole should also have the following monitoring cables and a Philips Module. See photos below. There should be one cable with two pressure monitoring ports (one for CVP and one for PA pressures) and a cable with a single port (for Arterial BP monitoring).
3. Two wall suction units with 10' tubing available and ready for connection.
4. A 20' suction tubing for low wall suction for the chest tube/s.

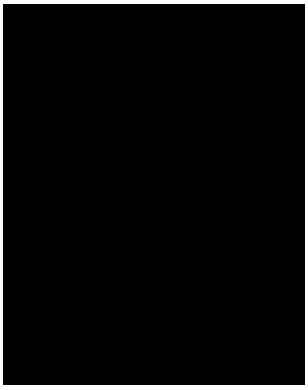
Single Port Pressure Cable (1)



Double Port Pressure Cable (1)



Philips Module Extension



Supplies: Our stock representative from NMSA prepares “heart boxes” that contain the necessary equipment to prepare the room for the patients arrival. See photo below:

Medications: Under the cardiothoracic open heart immediate post-operative order set, the following medications will be available in the Pyxis located in the Med Room under the patient’s name: albumin 5% (250 mL x4), Potassium Chloride 20 mEq IVPB, Magnesium Sulfate 2 gm IVPB, and an Insulin pen.

Monitor Setup: <u>DO NOT admit patient to the Philips monitor until patient lands.</u> The nurse admits the patient to the HemoSphere monitor before they arrive on A2 to minimize delays in monitoring when they arrive from the OR. You will verify that the HemoSphere is plugged in to a red hospital outlet and complete the following steps:

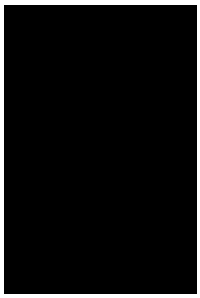
Ensure you have the additional Philips Module for extra monitoring port (for PA/CVP lines) and that it is attached to the back of the main Philips Monitor. Attach all other necessary cords:

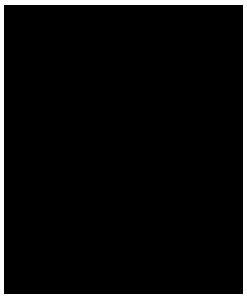
a. Bifurcated pigtail with dual pressure cable
b. Single pressure cable
c. Temperature cable

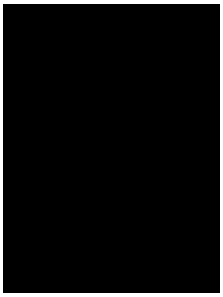
d. SpO2, EKG, and NIBP should already be present in the room.

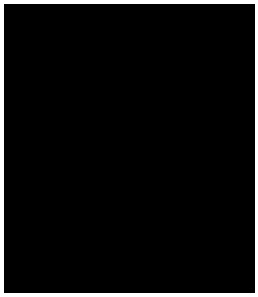

Dual Pressure Cable

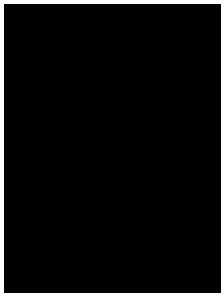

Single Pressure Cable


Temperature Cable

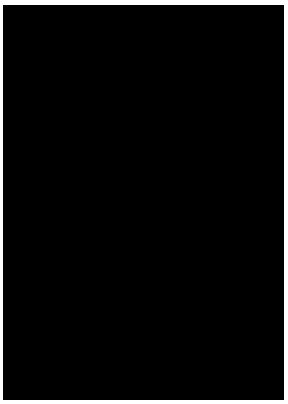

SpO2 Cable

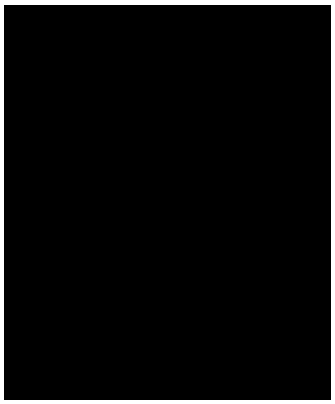

EKG Cable

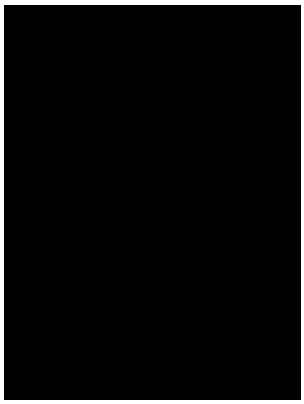

NIBP Cable


EtCO2 Box

2. Ensure that the Intellibridge EC10 module is connected into the Philips Monitor. Plug the ethernet cable with this module into the back of the HemoSphere monitor. This will ensure that the data pulls into PowerChart.





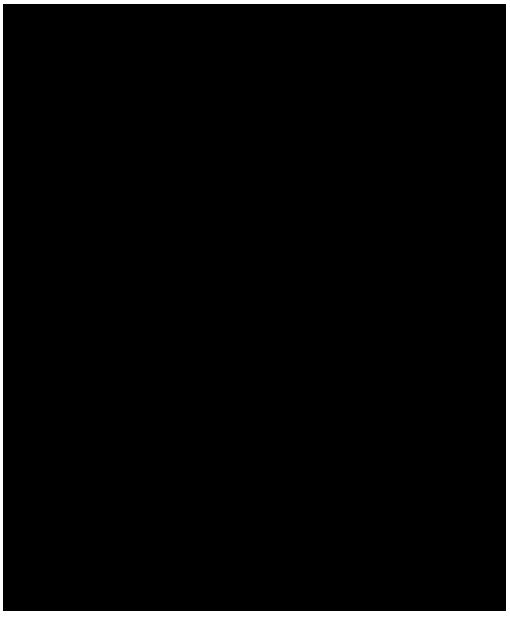


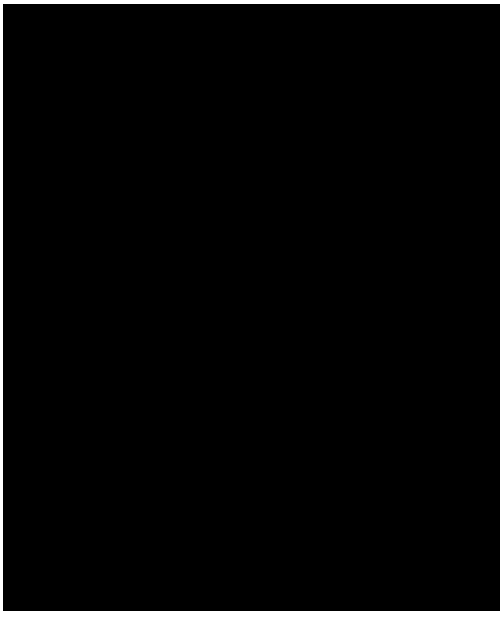
3. Confirm that the following cables are attached to the HemoSphere:
    a. Two gray Edwards pressure cables with pigtails that connect to the Philips cables. HemoSphere pressure cable that will connect to the Acumen.

HemoSphere Pressure Cable for Acumen

Gray Edwards Cables (x2)

4. Connect the two Philips cables (those that will be prepared on the heart poles) into the HemoSphere pressure cables. The HemoSphere cables are bifurcated and will only connect one way into the Philips pressure cables. This will leave you with three Edwards ports to connect when the patient arrives (gray bifurcated cords for the PA and CVP, and white for the Arterial Line/Acumen).

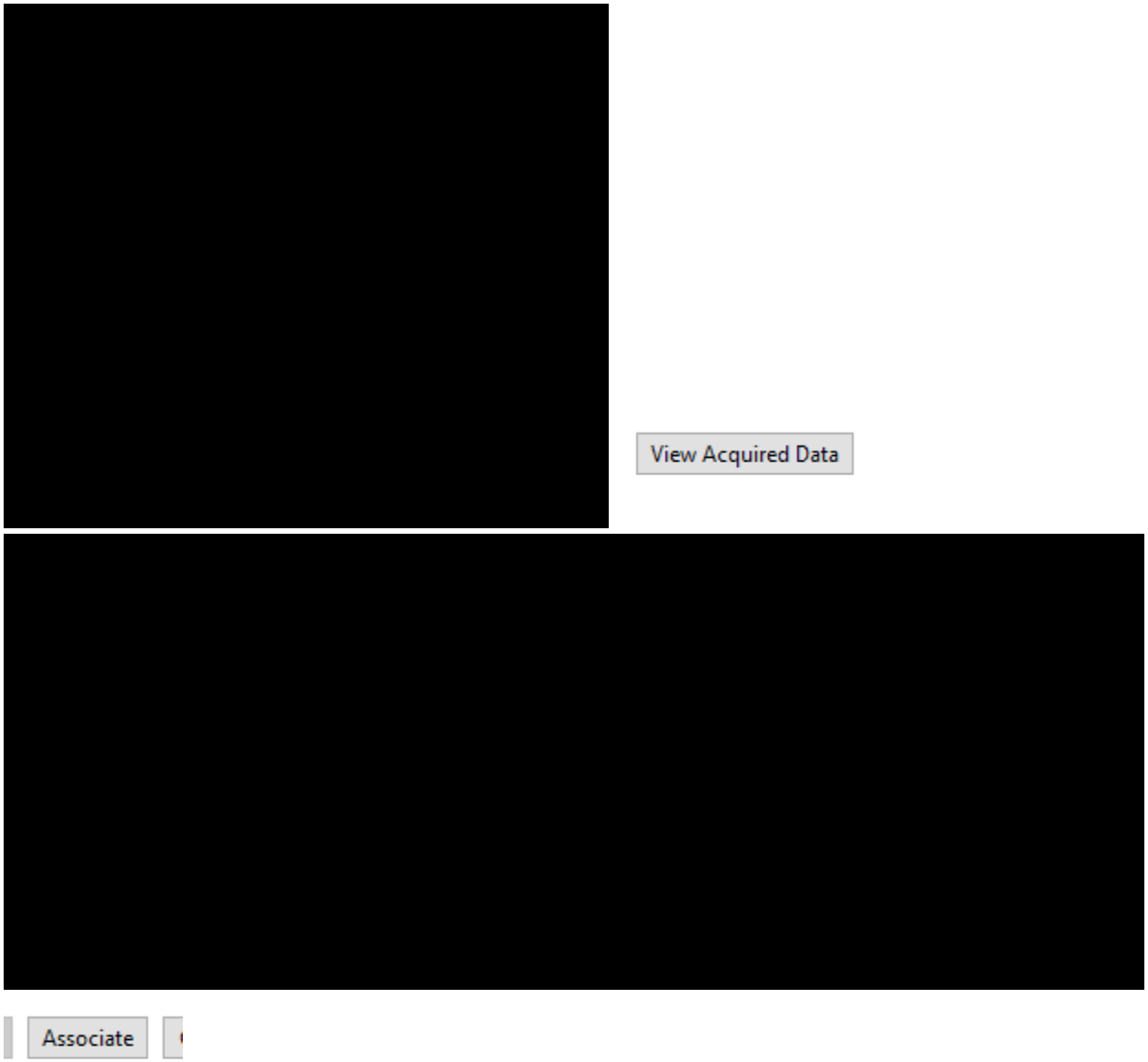




5. Power HemoSphere on (this has a delay) via center power button.
    i. Enter patient data: height, weight, gender and age, into the HemoSphere.
    ii. Select “next”
    iii. Select Minimally Invasive as the default monitoring option > start session > proceed to setup.

Cerner/PowerChart Association: The nurse associates the bedside monitor with the patients medical record number. Open the patient encounter and choose the “associate patient” icon  from the IVIEW menu bar. If this step is not completed, the vital signs and other data will not pull through into the chart. If you have forgotten to do this step please try the following, or you will have to manually enter the data: Open the patient encounter and

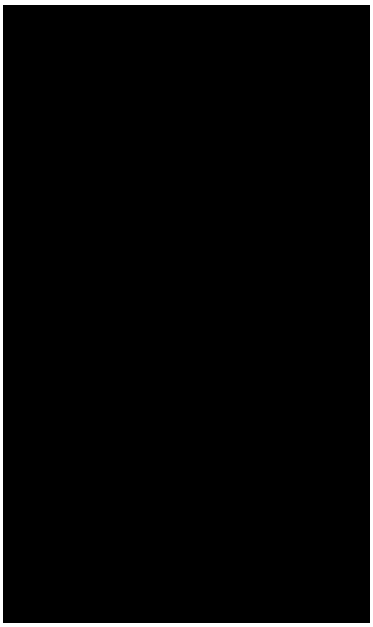
choose the “associate patient” icon in IVIEW, Click on the patient room you need to associate the patient to then click “View Acquired Data,” click back to the timeframe you would like to capture, press “OK” in the bottom right hand corner, and then click on “Associate.”

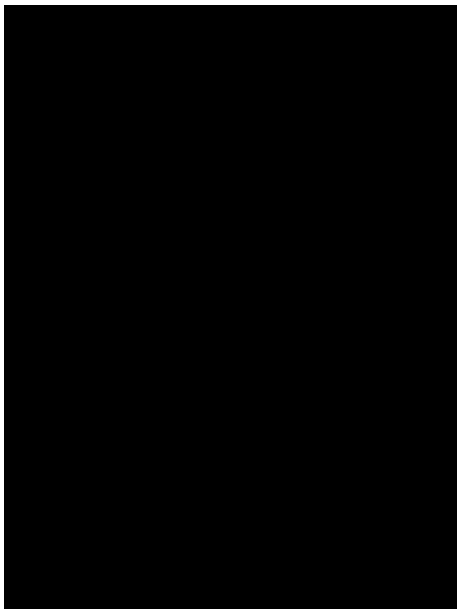


Room Set-Up:

The Philips Monitor side of the bed is where the primary nurse (aka the “A” nurse) will work when the patient lands. Supplies set up on this side of the bed include:

1. Monitor cables as well as SpO2 pleth and temperature cable.
2. Hemosphere and associated cables.





3. IV pole with 4 pumps.
4. D50.45NS and 0.9NS primed on pumps and ready to attach to the patient.

The ventilator side of the bed is where another nurse (aka the "B" nurse) will work while they assist with landing the patient. Supplies set up on this side of the bed include:

1. EKG electrode patches attached to the EKG wires. Hang these up on the ceiling IV pole for easy access on admission.
2. OG supplies (Salem-Sump one way valve and Toomey syringe).
3. Two suction canisters connected to the wall (lower suction canister is for the OG and the upper suction canister is for respiratory suctioning).
4. Long suction near floor for the chest tubes.
5. Plastic bags for the temporary epicardial pacemaker wires.
6. Yankauer suction
7. Graduated cylinder

- Depending on the room set up, the lab supplies may be located on either side of the patient bed. This will include two specimen bags, two needless med prep cannulas, a vacutainer, two CHG swabs, an ABG syringe and a blue and purple top lab tube.

Unit notification: The OR calls the unit clerk with "warming" and "closing." It is their responsibility to notify the primary RN, the charge RN and respiratory therapy. The primary RN will notify their chosen "B" nurse.

- Warming: As they begin to rewarm the patient, there is roughly an hour until the patient will be admitted to the unit.
- Closing: This signifies the case is wrapping up and the patient will usually be admitted between 20-30 minutes.

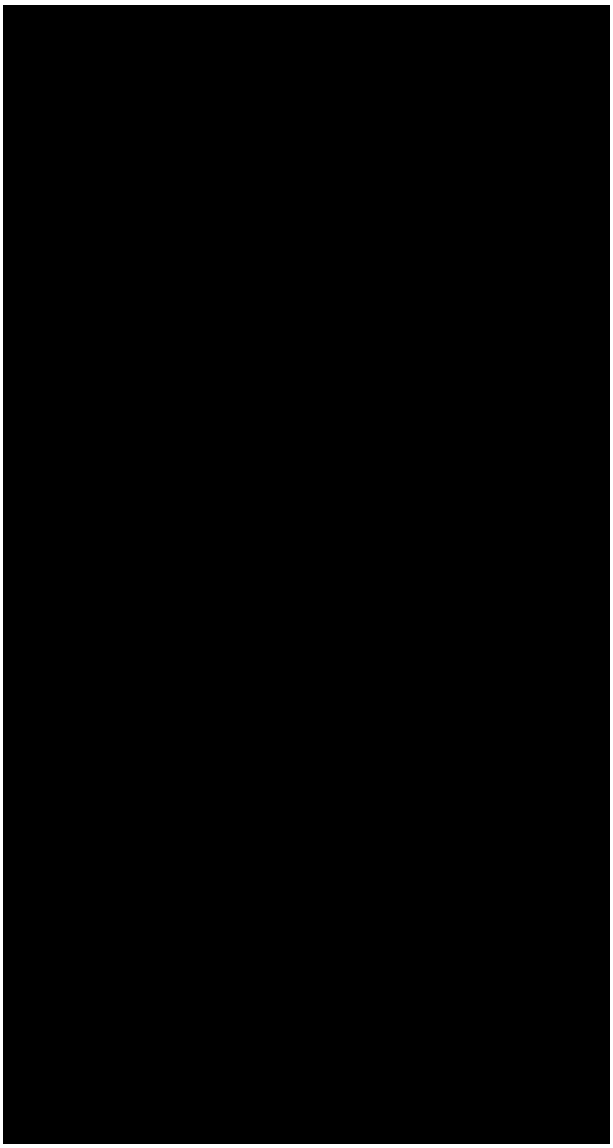
Admission/Landing Team Roles:

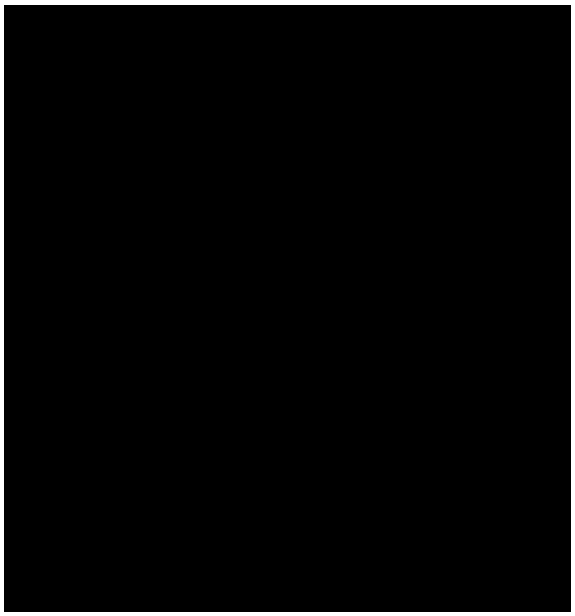
Primary Nurse ("A" nurse):

1. As the patient arrives with anesthesia and perfusion, assess if any immediate intervention is needed for bleeding, blood pressure, heart rhythm, etc.
2. Connect the pleth.
3. Transfer patient from the X3 transport monitor to the in-room Philips Monitor.
    a. The admission will need to take place within the Philips Monitor at the central monitoring station.
4. Attach the CVP and PA transducer cables from the Philips Monitor to the gray Edwards Cables connected to the HemoSphere, if not already done in advance.
5. Attach the Arterial Line transducer cable to the white Acumen Cable (GREEN to MACHINE).
6. Attach the Red arterial line cable to the single Philips cable (RED to BED).
7. Zero all transducers on both the HemoSphere and the Philips Monitor.
8. Attach the Venous Oximetry cable from the PA catheter to the HemoSphere gray port.
    a. Hit Water Drop symbol (or select venous oximetry) > recall oximetry data to see the previous data.
9. View hemodynamics and associated calculations on the Philips Monitor and HemoSphere.
10. Receive report from anesthesiologist, and give special attention to bleeding and blood products given, arrhythmias, hemodynamic measurements and IV medications given.
11. Monitor vital signs and chest tube output q15 minutes x1 hour, then every hour if stable.
12. Complete head to toe assessment (include all systems: check pulses, dressings, neuro status, foley output, etc.) and document in PowerChart.
13. Initiate/continue fluids and vasoactive drips per orders/parameters when needed.
14. Ensure chest x-ray is obtained ASAP – page through PerfectServe Clinical Collaboration > Directory > MMC Radiology Port Tech.
15. Give initial magnesium dose, manage electrolytes and blood glucose.

Secondary Nurse (“B” Nurse):

1. Place EKG patches to patient using standard lead placement. Ensure good connection and note patients rhythm.
2. Attach ForeSight Tissue Oximetry box to Port A on HemoSphere (lime green port). Connect lime green cables to sensors on the head.
    a. Lime green cable #1 = Left sensor
    b. Lime green cable #2 = Right sensor
    c. Calibrate total hemoglobin when prompted.





Connect temporary pacemaker wires (A-wires from right side of chest and V-wires from left side of chest). Cardiac wire is negative and sutured in placed, ground wire is positive and is stapled to the skin. Program pacemaker as needed.

3. Check placement of OG or place OG as indicated. Attach to low intermittent suction. Tape the ETT and OG together and note station.
4. Administer albumin or gather other medications as indicated or required by the primary RN.
5. Print lab stickers if not already done and draw from the arterial line.
6. Attach chest tubes to suction, if not already completed by perfusionist.
7. Place Bair Hugger if indicated and turn on.
8. Empty foley and record output.

Post-Operative Recovery:

Call physician if:

a. Chest tube output >150 mL/hr
b. Vital signs outside acceptable ranges
c. Heart rate >120 or < 60
d. Cardiac Index <2.0
e. Dysrhythmias
f. Urine output < 100 mL/hr in first 8 hours post-operative or <0.5mL/kg/hr after that

Immediate Post-operative Patient Care:

a. Ensure adequate pain control or sedation with Precedex gtt, especially if not meeting parameters to extubate.
b. Bring family in to see patient as soon as x-ray is completed and patient is stabilized.
c. Watch for lab results to come back and cover abnormal electrolytes. Call provider with abnormal values especially anticoags:
    i. PTT >36
    ii. INR >1.4
    iii. Fibrinogen <220
d. Watch for chest x-ray to come back and verify placement of ETT, OG and PA catheter.
e. If shivering, medicate with Demerol as needed.
f. Begin oral care per orders. Suction ETT as needed.
g. Document and monitor cardiac profiles at least q4 hours and PRN.

h. Recalibrate SvO2 as needed if questionable reading (too high, too low, or no correlation with CO/CI). Calibrate q24 hours if PA catheter remains in patient.
i. Continue D50.45NS at 50 mL/hr and NS at 20 mL/hr until stepdown orders placed on POD1 AM.
j. Remove Bair Hugger blanket once patient temperature reaches 37.0 Celsius.
k. Elevate HOB to 30 degrees as soon as blood pressure will tolerate to facilitate chest tube drainage and prevent ventilator associated pneumonia.
l. Turn the patient q2 hours and PRN when warm and stable.

Afternoon/Evening and into POD 1 AM patient care:

a. Ensure adequate pain control.
b. Bathe patient once they reach temp, reinforce sternal and leg dressings if needed.
c. Wean and extubate patient according to extubation protocol. Goal is to extubate within 6 hours post-op. Apply oxygen via nasal cannula at 4L. After extubation, use IS every 1-2 hours. Patient may have ice chips after extubation if no nausea.
d. Turn the patient every 2 hours and PRN.
e. Wean drips as tolerated/ordered.
f. Discontinue PA catheter and arterial line in early AM if patient meets parameters.
g. If able to de-line, discontinue ForeSight monitoring.
h. Weigh patient in AM with standing scale (only use bed scale if patient remains vented or unstable).
i. Remove ACE wraps from legs and JP drains if present and meeting removal requirements.
j. Ensure chest x-ray is obtained.
k. Isolate epicardial wires as appropriate.

Post-Operative Day 1 Patient Care:

a. Ensure adequate pain control and hourly use of IS.
b. Discontinue PA cath, arterial line if not already done and per provider order.
c. Ensure step-down orders are placed as appropriate.
d. Switch patient to portable telemetry box.
e. Discontinue D50.45NS and KVO fluids and saline lock if appropriate.
f. Up in chair and full liquid breakfast. Advance diet to Diabetic Diet, No Caffeine with Supplements as tolerated. All meals should be consumed up in the chair.
g. Begin ambulation and work up to 4 walks daily.

HEMOSPHERE HOW-TOs:

Recalibrate SvO2:

Click on Venous Oximetry > In vivo calibration

Wait for Hemosphere to allow you to draw. When ready, the “draw” button will appear.

Tap draw button and collect sample. Sample is collected from the PA line of the PA catheter.

Send BOTH a mixed venous sample and an H&H or CBC, as both are required for recalibration.

You MUST leave the Hemosphere on the recalibration screen until all labs come back. At this point you will update the data (Hemoglobin, Hematocrit and SvO2) and then press “start monitoring.” The HemoSphere will initialize and calibration will be complete. All data is still visible on the left side of the screen while completing a calibration and alarms are still active.

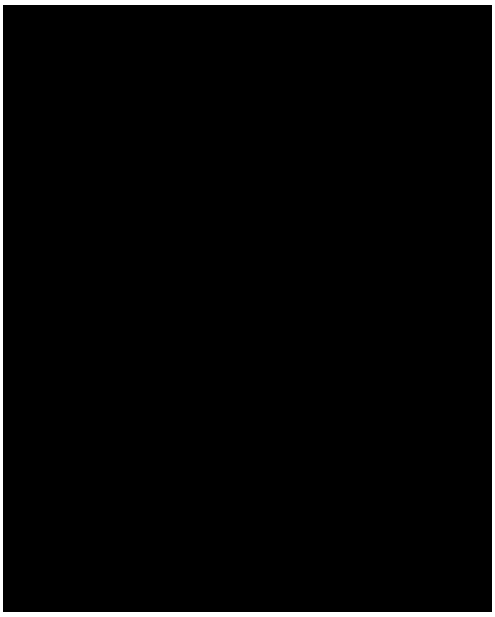
** Recalibration needs to occur every 24 hours if the patient is remaining lined. Night shift will draw a mixed venous with the AM labs. To do this, pick Venous Gas from the Cardiothoracic labs.

**IF the SvO2 cable becomes unplugged when the HemoSphere has been turned off, the data is gone, so in-vivo calibration will need to be completed again.

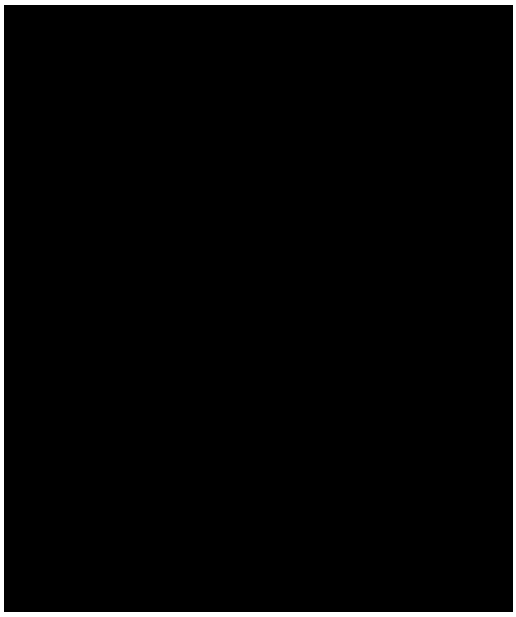
Changing from Non-Invasive to Invasive Monitoring:

- We are defaulting to use of the Arterial line (non-invasive) monitoring for the HemoSphere when a patient lands from the OR. However, if the arterial line is not reading appropriately then you may need to change to invasive mode, which uses the PA catheter as the primary measurement for our hemodynamic data. This means we may lose some of the numbers provided through the HemoSphere device.
- Change monitor to PA mode or Invasive mode by clicking on the Swan-Ganz icon on the bottom of the HemoSphere screen.

- Connect the CCO cables, located on the side of the HemoSphere.
- Connect the cable with the yellow tip to the yellow port on the side of the HemoSphere.
- Plug the blue port of the cable into the blue port of the PA catheter
- Plug the white port of the cable into the white port of the PA catheter



Pressure Cable



Blue and White Ports from PA Cath

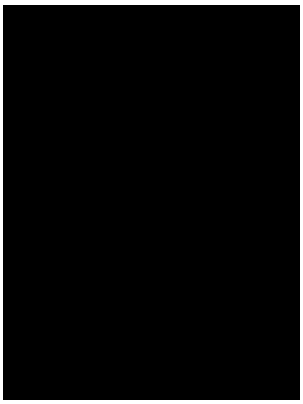
Activating Non-Pulsatile Mode (if patient leaves the room – Road Trips):

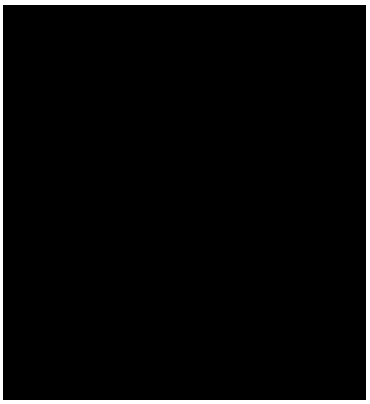
1. Unplug the SvO2 cable from the monitor. Keep everything else intact.
2. Place HemoSphere Alta into Non-pulsatile mode by holding down red alarm button > select pause > enter.
3. To return to monitoring, touch the gray non-pulsatile mode icon > exit.

Use with an IABP/Loss of Art line:

- In addition to connecting the SvO2 cable, you must also connect the gray and yellow patient Swan CCO cables.
    - Plug the blue port of the cable into the blue port of the PA catheter
    - Plug the white port of the cable into the white port of the PA catheter
    - Plug the yellow magnetic hub into the Hemosphere
    - DO NOT TOUCH THE RED CAP
    - Change monitor from non-invasive mode to PA mode or Invasive mode by clicking on the Swan-Ganz icon on the bottom of the HemoSphere screen.

- Add speaker cable (Dark gray Maguire enterprises cable) to Philips Monitor and connect to the back of the HemoSphere. This pulls EKG data as priority over arterial IABP waveform data in HemoSphere.


Maguire Cable


HemoSphere Port (on back)


Phillips Port (left hand side)

Use with an Impella: no changes.

Shooting a Cardiac Index (if needed – RARE):

- Change monitor to Invasive mode.
- Touch clinical tools >iCO thermodilution
- Should default to injectate and catheter size. May need to adjust this.
- Use of the same injectate device located in stock room, if needed.

CentriMag:

- HemoSphere/PA Cath/Acumen will NOT be accurate.
    - ONLY Foresight will work. Place 2 Foresight stickers on forehead (channel A), and one on each leg (channel B).

ForeSight IQ Sensor Attachment:

- Clean forehead with alcohol swab and dry.
- Place on sensor on each side of the forehead.
- If needing to overlap, then only the black outline portion can be touching.
- STICK IT BEFORE YOU CLICK IT.

Status Active PolicyStat ID 15460185

[redacted]

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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

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).

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.

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

Status Active PolicyStat ID 17948440

[redacted]

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Next Review	6/2/2028
Owner	Jennifer Standfest: CNO
Area/ Department	Nursing
Applicability	MMC, Cadillac, Charlevoix, Grayling, Otsego

Cardiac Telemetry Monitoring

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,

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.

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.

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.

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

Status Active PolicyStat ID 13403601

[redacted]

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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

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).

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.

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

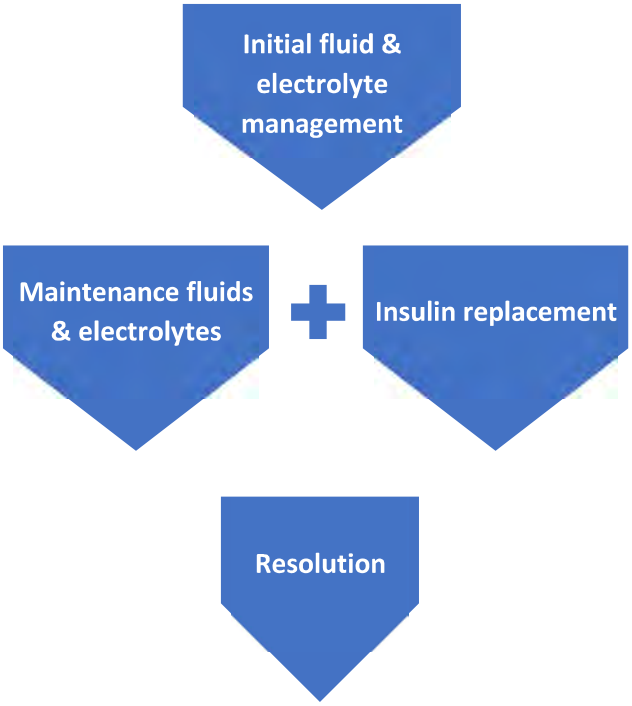
Reference Text:

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)

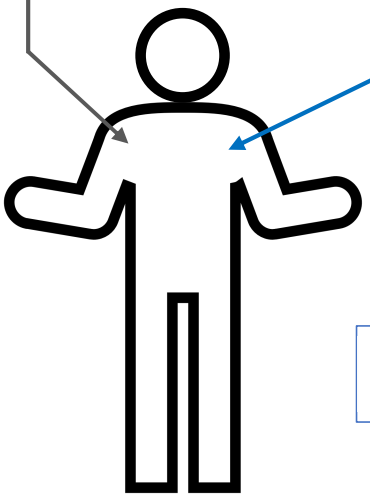
Q1H BG

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



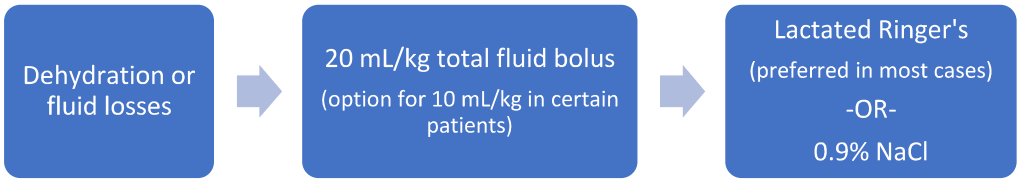
Potassium Level (mmol/L)	Parenteral (as potassium chloride IVPB)
< 3.3	Total dose: 80 mEq over minimum of 4 hours, *AND* 1. PAUSE insulin 2. Call provider to discuss before resuming
3.3 - 3.5	Total dose: 60 mEq over minimum of 3 hours
3.6 - 3.9	Total dose: 40 mEq over minimum of 2 hours
4 - 5.2	Total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

Q4H BMP+ Mg + Phos

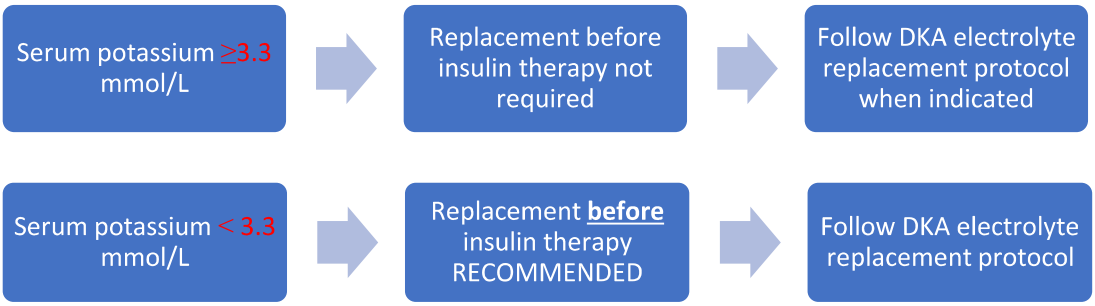
PLUS magnesium + phos replacement

II. DKA TREATMENT DETAILS

A. INITIAL FLUID MANAGEMENT:



B. INITIAL ELECTROLYTE REPLACEMENT:



C. IV INSULIN INFUSION

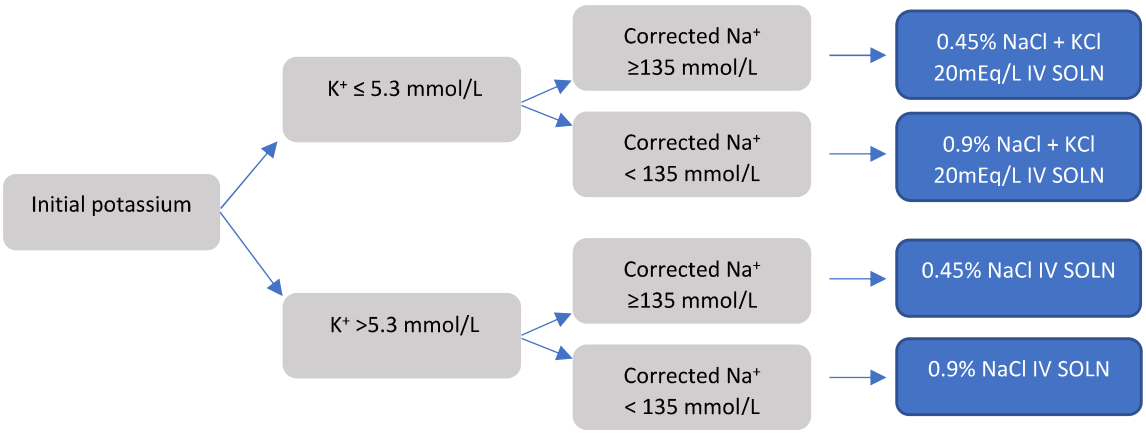
Clinical Scenario		Action Required
-	**…Default rate (no bolus, no titration)**	**Infuse at 0.1 unit/kg/hr**
IF	…BG 71-99 mg/dL	-PAUSE INSULIN- *Check BG Q15min until >100.* ***To resume insulin, ensure Bag 2 is running at full rate***
IF	…BG ≤ 70 mg/dL or symptomatic HYPOglycemia	-PAUSE INSULIN- *Follow 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.

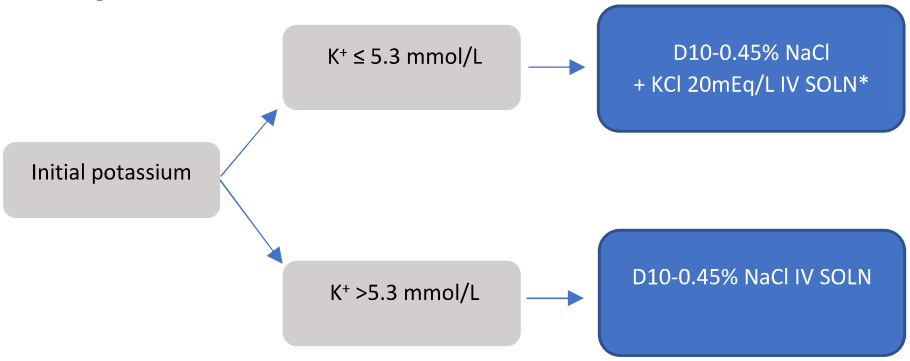
Provider to order bag 1 and bag 2 at same time as insulin drip, according to initial electrolytes:

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.**

REFERENCES

1. Astapenko D, Navratil P, Pouska J, Cerny V. Clinical physiology aspects of chloremia in fluid therapy: a systematic review. Perioper Med 2020;9(1).
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.
4. Magee CA, Bastin MLT, Laine ME, et al. Insidious Harm of Medication Diluents as a Contributor to Cumulative Volume and Hyperchloremia: A Prospective, Open-Label, Sequential Period Pilot Study. Crit Care Med 2018;46(8):1217–23.
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.
6. Ramanan M, Attokaran A, Murray L, et al. Sodium chloride or Plasmalyte-148 evaluation in severe diabetic ketoacidosis (SCOPE-DKA): a cluster, crossover, randomized, controlled trial. Intensive Care Med 2021;47(11):1248–57.
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

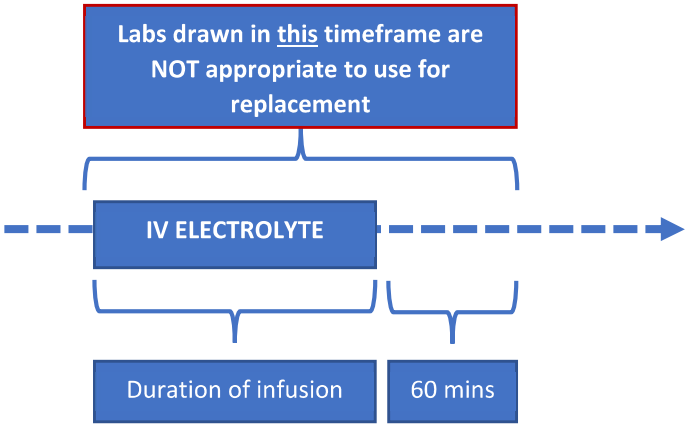
**If patient not eligible for replacement protocol, provider to order all electrolyte replacement.*

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 13648797

[redacted]

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

Massive Transfusion Protocol

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

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

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.

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

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

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

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

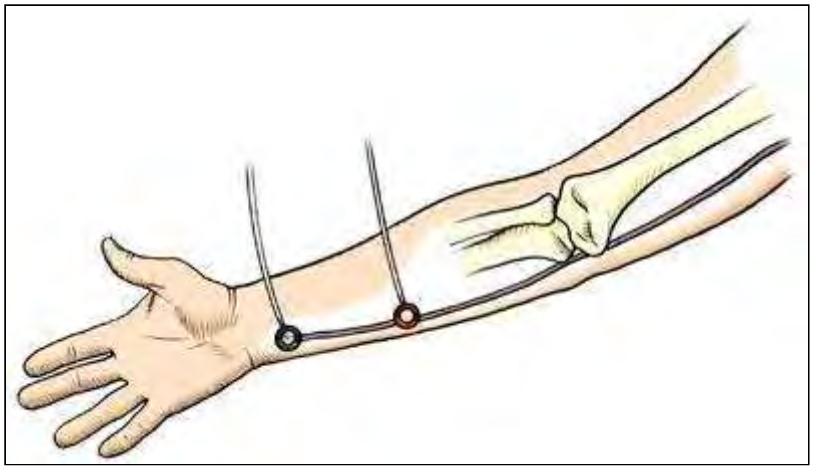
Inspect all equipment and supplies. If a product is expired, is defective, or has compromised integrity, remove it from patient use, label it as expired or defective, and report the expiration or defect as directed by your facility.

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

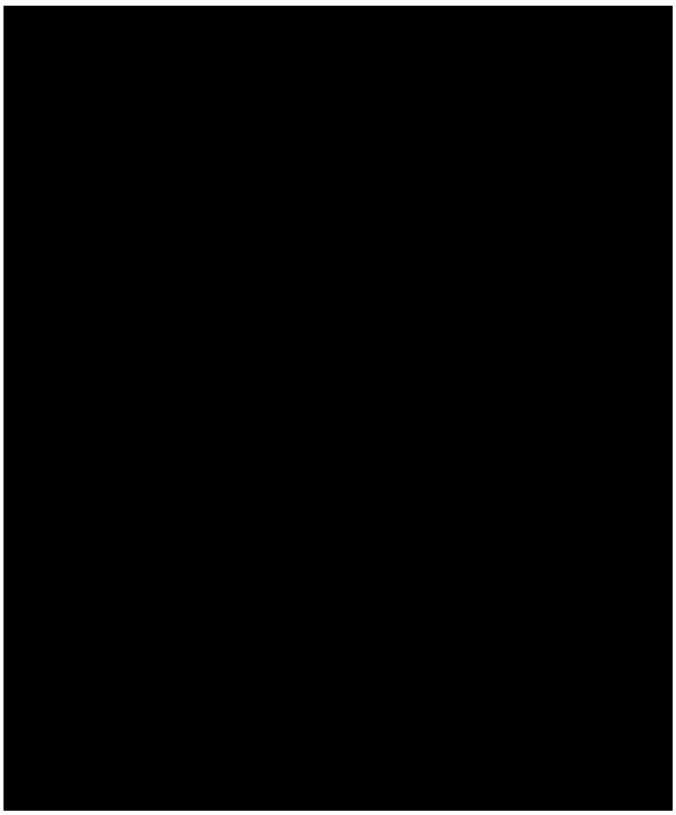
- Use an alcohol pad to clean the electrode placement sites on the patient's arm and then allow the sites to dry *to improve electrode contact with the skin.*
- Place the patient's arm in a relaxed position with the palm up *so that the ulnar nerve is easily accessible*.
- Place one electrode over the 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.*

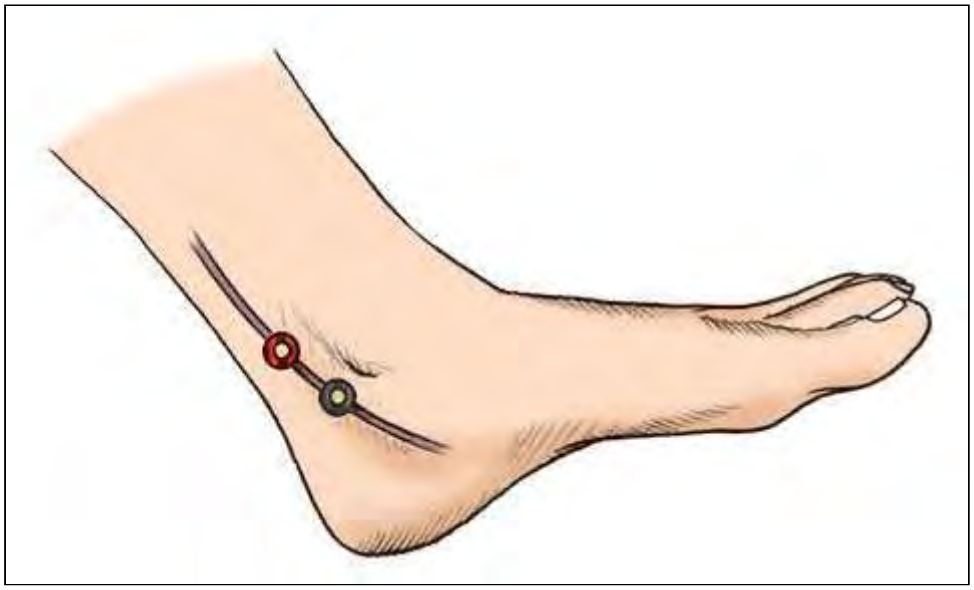


- Attach the leadwires to the PNS.
- Connect the black lead (negative) to the electrode nearest the tragus and the red lead (positive) to the electrode near the outer canthus of the eye.
- Turn on the PNS and choose a low amplitude (commonly 10 to 20 mA). *Higher current can overstimulate the nerve and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

References

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

1. Johnson, K. L. (2024). *AACN procedure manual for progressive and critical care* (8th ed.). Elsevier.
2. Bittner, E. A. (2024). Neuromuscular blocking agents in critically ill patients: Use, agent selection, administration, and adverse effects. In: *UpToDate,* Parsons, P. E. (Ed.). UpToDate Full Text
3. Brull, S. J., & Kopman, A. F. (2017). Current status of neuromuscular reversal and monitoring: Challenges and opportunities. *Anesthesiology, 126*(1), 173–190. Retrieved January 2025 from https://doi.org/10.1097/ALN.0000000000001409 Abstract | Complete Reference
4. Saenz, A. D., et al. (2019). Peripheral nerve stimulator--Train of four monitoring. *Medscape.* Retrieved January 2025 from https://emedicine.medscape.com/article/2009530-overview#a3
5. The Joint Commission. (2025). Standard NPSG.07.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
6. Centers for Disease Control and Prevention. (2002). Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recommendations and Reports, 51*(RR-16), 1–45. Retrieved January 2025 from https://www.cdc.gov/mmwr/pdf/rr/rr5116.pdf (Level VII)
7. World Health Organization (WHO). (2009). *WHO guidelines on hand hygiene in health care: First global patient safety challenge, clean care is safer care.* Retrieved January 2025 from https://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf?sequence=1 (Level VII)
8. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Infection control. 42 C.F.R. § 482.42.
9. Accreditation Commission for Health Care. (2023). Standard 07.02.05. *Healthcare Facilities Accreditation Program: Accreditation requirements for acute care hospitals.* (Level VII)
10. DNV GL-Healthcare USA, Inc. (2024). IC.1.SR.3f. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
11. The Joint Commission. (2025). Standard NPSG.01.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
12. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Patient's rights. 42 C.F.R. § 482.13(c)(1).
13. Accreditation Commission for Health Care. (2023). Standard 15.01.07. *Healthcare Facilities Accreditation Program: Accreditation requirements for acute care hospitals.* (Level VII)
14. The Joint Commission. (2025). Standard RI.01.01.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
15. DNV GL-Healthcare USA, Inc. (2024). PR.2.SR.5. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)
16. The Joint Commission. (2025). Standard PC.02.01.21. *Comprehensive accreditation manual for hospitals*. (Level VII)
17. Waters, T. R., et al. (2009). *Safe patient handling training for schools of nursing.* Retrieved January 2025 from https://www.cdc.gov/niosh/docs/2009-127/pdfs/2009-127.pdf (Level VII)
18. Renew, J. R. (2024). Monitoring neuromuscular blockade. In: *UpToDate*, Joshi, G. P. (Ed.). UpToDate Full Text
19. Ganz, D. A., et al. (2013). *Preventing falls in hospitals: A toolkit for improving quality of care* (AHRQ publication no. 13-0015-EF). Agency for Healthcare Research and Quality. Retrieved

January 2025 from https://www.ahrq.gov/patient-safety/settings/hospital/fall-prevention/toolkit/index.html (Level VII)
20. Occupational Safety and Health Administration. (2019). *Bloodborne pathogens, standard number 1910.1030.* Retrieved January 2025 from https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030 (Level VII)
21. Accreditation Commission for Health Care. (2023). Standard 07.04.01. *Healthcare Facilities Accreditation Program: Accreditation requirements for acute care hospitals.* (Level VII)
22. Rutala, W. A., et al. (2008, revised 2024). *Guideline for disinfection and sterilization in healthcare facilities, 2008.* Retrieved January 2025 from https://www.cdc.gov/infection-control/media/pdfs/guideline-disinfection-h.pdf?CDC_AAref_Val=https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf (Level I)
23. The Joint Commission. (2025). Standard RC.01.03.01. *Comprehensive accreditation manual for hospitals.* (Level VII)
24. Centers for Medicare and Medicaid Services. (2024). Condition of participation: Medical record services. 42 C.F.R. § 482.24(b).
25. Accreditation Commission for Health Care. (2023). Standard 10.00.03. *Healthcare Facilities Accreditation Program: Accreditation requirements for acute care hospitals.* (Level VII)
26. DNV GL-Healthcare USA, Inc. (2024). MR.2.SR.1. *NIAHO® accreditation requirements, interpretive guidelines and surveyor guidance – revision 24.* (Level VII)

Additional References

- Naguib, M., et al. (2018). Consensus statement on perioperative use of neuromuscular monitoring. *Anesthesia and analgesia, 127*(1), 71–80. Retrieved January 2025 from https://doi.org/10.1213/ANE.0000000000002670(Level VII)
- Ong Sio, L. C., et al. (2023). Mechanism of action of peripheral nerve stimulation for chronic pain: A narrative review. *International Journal of Molecular Sciences, 24*(5), Article 4540. Retrieved January 2025 from https://doi.org/10.3390/ijms24054540
- Rezaiguia-Delclaus, S., et al. (2021). Neuromuscular blockade monitoring in acute respiratory distress syndrome: Randomized controlled trial of clinical assessment alone or with peripheral nerve stimulation. *Anesthesia and Analgesia, 132*(4), 1051–1059. Retrieved January 2025 from https://doi.org/10.1213/ANE.0000000000005174 (Level II)

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.