Important Information – Please Read Before Use

CAUTION

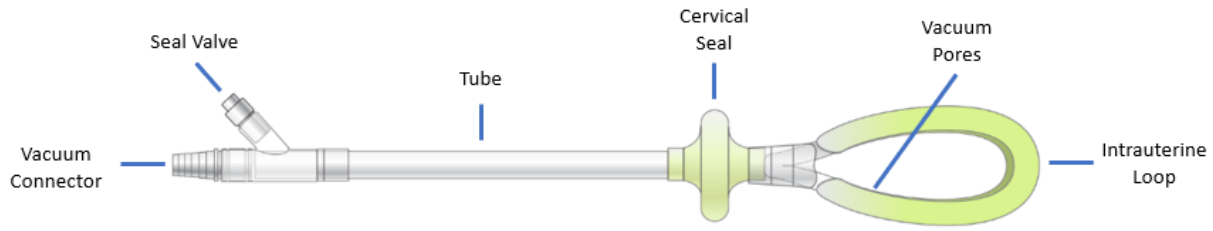
Federal law (USA) restricts this device to sale by or on the order of a physician. This medical device is intended for use by healthcare providers trained and experienced in obstetrics and gynecological techniques.

INDICATIONS FOR USE

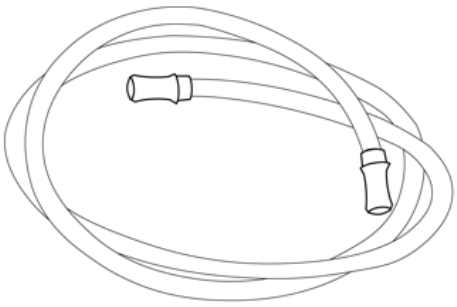
The Jada® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted.

DESCRIPTION

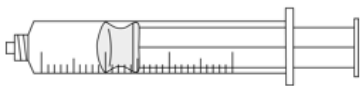
The Jada System is a 41 cm long intrauterine device made of silicone. Jada consists of an Intrauterine Loop on the distal end of a Tube. The proximal end of the Tube has a Vacuum Connector for connection to sterile vacuum tubing. The Cervical Seal proximal to the Intrauterine Loop is filled and emptied with a sterile luer tapered syringe filled with sterile fluid via the Seal Valve. The Intrauterine Loop consists of a loop tube with 20 Vacuum Pores oriented toward the inside diameter of the Intrauterine Loop. The outer surface of the Intrauterine Loop is covered by a Shield which overhangs the Vacuum Pores to protect tissue from vacuum and the Vacuum Pores from plugging with tissue and blood clots. A sterile luer tapered 60 mL syringe and a sterile 12’ vacuum tubing are supplied with the Jada System.



Jada System



12’ Vacuum Tubing



Luer Tapered 60 mL Syringe

CONTRAINDICATIONS

The following are contraindications to Jada use:

- Ongoing intrauterine pregnancy
- Untreated uterine rupture
- Unresolved uterine inversion
- Current cervical cancer
- Known uterine anomaly
- Current purulent infection of vagina, cervix, or uterus
- For C-sections: Cervix < 3 cm dilated before use of Jada

WARNINGS

- Avoid excessive force when inserting the Jada into the uterus or trauma to uterine wall may occur, including perforation.
- The safety and effectiveness of the Jada System in delivery at a gestational age < 34 weeks or, if multiples, uterus judged < 34 weeks size, have not been established. With smaller uterine size, there is potential for increased risk of perforation and expulsion.
- Signs of patient deterioration or failure to improve indicate the need for reassessment and possibly more aggressive treatment and management of postpartum hemorrhage (PPH)/abnormal postpartum uterine bleeding.
- Jada is not a substitute for surgical management and fluid resuscitation of life-threatening PPH/abnormal postpartum uterine bleeding.
- Remove air from Cervical Seal prior to device use to minimize risk of air embolism if Cervical Seal bursts.
- Always fill the Cervical Seal with sterile fluid. Never inflate with air, carbon dioxide, or any other gas to minimize risk of air embolism if Cervical Seal bursts.

PRECAUTIONS

- The safety and effectiveness of the use of Jada in patients with placenta accreta have not been evaluated.
- Use care when suturing any lacerations to avoid puncturing or damaging the material of the Cervical Seal.
- The maximum vacuum pressure is 90 mm Hg. Do not increase the vacuum pressure higher than 90 mm Hg. (90 mm Hg = 1.7 psi = 12.0 kPa = 3.5 in Hg = 120.0 mbar) or tissue trauma may occur.
- After initiation of vacuum, blood flow into Jada or the vacuum tubing and/or improvement in uterine tone should be noted. If this does not occur, the Cervical Seal and/or the vacuum may not be effective. If so, refer to Troubleshooting section.
- During treatment, the presence of intermittent or continuous air flow through Jada and vacuum tubing may indicate an issue with the Cervical Seal location or Cervical Seal coverage. If so, refer to the Troubleshooting section.

- Jada should not be left within the uterus for longer than 24 hours due to the possibility of an adverse tissue reaction or infection.
- The safety and effectiveness of the use of Jada in patients with Disseminated Intravascular Coagulation (DIC) have not been evaluated.

SUMMARY OF CLINICAL DATA

The safety and effectiveness of the Jada System was evaluated in the PEARLE study (**P**rospectiv**e**, Single Arm, Pivotal Clinic**a**l T**r**ia**l** D**e**signed to Assess the Safety and Effectiveness of the Jada System In Treating Primary Postpartum Hemorrhage "PPH") under an approved IDE from the U.S. Food and Drug Administration (FDA).

Study Design

PEARLE was a prospective, single-arm, literature-controlled, multi-center treatment study where each enrolled subject was treated with the Jada System. The primary endpoints of the study were:

- Primary Effectiveness Endpoint: control of postpartum hemorrhage, defined as the avoidance of non-surgical, second line or surgical intervention to control uterine hemorrhage after the use of the Jada System per the Instructions for Use.
- Primary Safety Endpoint: incidence, severity and seriousness of adverse events related to Jada.

The following Secondary Endpoints were evaluated in the PEARLE study:

- Time to hemorrhage control.
- Rate of non-surgical intervention required to control PPH after Jada use.
- Rate of surgical intervention required to control PPH after Jada use.
- Assessment of device usability.
- Rate of blood product transfusion required after Jada use, and number of transfusion units when administered.

Use of the Jada System occurred after failure of first line uterotonics and uterine massage.

The comparator to the Jada System was a literature meta-analysis of the Bakri® Postpartum Balloon. Based on a random effects model used in the meta-analysis, the estimated pooled proportion of subjects who reached control of uterine hemorrhage following Bakri Postpartum Balloon treatments was 82.0% (95% CI: 73.4% to 89.2%). By this definition, the study was considered a success if the lower bound of the two-sided Exact Clopper-Pearson mid-p 95% Confidence Interval for the Study Treatment Success was greater than or equal to 73.4%.

A total of 107 subjects were enrolled in PEARLE at 12 investigational centers in the United States.

Cohort	Subjects (N)
Total Subjects Enrolled*	107
Safety/Intent to Treat (ITT)**	106
Modified Intent to Treat (mITT)***	104
Per Protocol (PP)****	97

*All subjects in whom Jada insertion was attempted.
** All subjects in whom treatment was attempted with Jada (device inserted and vacuum turned on).
***All subjects in whom treatment was attempted with Jada (device inserted and vacuum turned on) and whose treatment was not aborted early for non-Jada reasons.
**** All subjects who completed Jada treatment per Jada's Instructions for Use, and who completed their 6-week visit without any major protocol deviations.

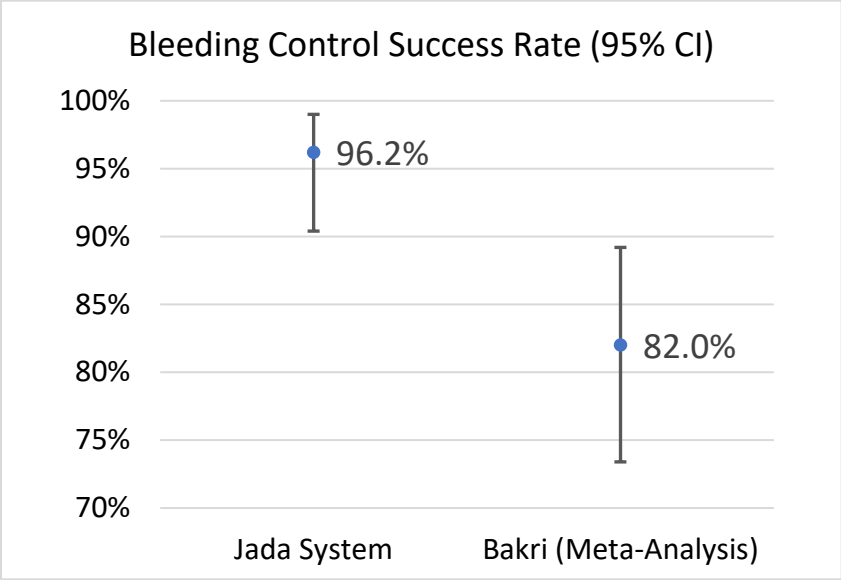
Primary Endpoints

Effectiveness

The analysis of effectiveness was based on the 106 subjects in the ITT Cohort. Results from the 104 subjects in the mITT and 97 subjects in the PP Cohort are also presented. The treatment success rate in the ITT Cohort was 94.3% (100/106, p<0.001), with a lower bound 95% confidence limit of 88.1%. One subject counted as a success in the study was treated with uterine balloon tamponade (UBT) prior to meeting the minimum EBL threshold. The UBT treatment was unsuccessful and continued blood loss occurred. After meeting the EBL threshold, the subject was treated with Jada which controlled hemorrhage without requiring further treatment. The treatment success rate of the comparator, the Bakri Postpartum Balloon, was 82.0% (95% CI: 73.4% to 89.2%). The treatment success rate in the mITT Cohort was 96.2 (95% CI: 90.4%, 98.9%). The confidence intervals for the mITT cohort and the meta-analysis of the comparator do not overlap.

Primary Effectiveness			
Cohort (N)	**Treatment Success**	**95% Confidence Limit (2-sided)**	***P* value**
ITT (N=106)	94.3% (100/106)	88.1%, 97.9%	<0.001
mITT (N=104)	96.2% (100/104)	90.4%, 98.9%	<0.001
PP (N=97)	99.0% (96/97)	94.4%, 100%	<0.001

Jada Success Rate Compared to Bakri Postpartum Balloon (mITT Cohort).



Safety

The analysis of safety was based on the 106 subjects in the Safety / ITT Cohort. There were no adverse events judged definitely related to the device or the procedure and there was a low rate of possibly related adverse events, all of which were anticipated in this patient population and with introduction of an intrauterine device. Five possibly device-related adverse events were rated as “mild” and three were rated as “moderate” without any event in this group rated “severe”. The three moderate events were cases of endometritis, which is a known risk of long labor, vaginal exam, and PPH.

Secondary Endpoints

Control of hemorrhage was defined in the protocol as the time from connecting the vacuum source to Jada to the time the first of any of the following occurs: there is no blood being collected in the tubing or canister, or the blood loss is observed as leveled off in the canister, or blood loss is at a rate of < 500 mL in 24 hours. The median time to control of PPH in the ITT, mITT and PP population was 3 minutes.

Timing of the procedure and duration of treatment was tracked from diagnosis through treatment and patient discharge for subjects enrolled in PEARLE. Jada was used most often within one hour after delivery. Bleeding was controlled quickly from the time of connection of vacuum, with a median control in three minutes. The duration of treatment with active vacuum connected was a median of 2 hours and 24 minutes with total in-dwelling time median of 3 hours and 11 minutes.

Duration of Treatment (ITT Cohort (N=106*))				
Procedural Steps	**Time (minutes)**			
	Mean	**SD**	**Median**	**Min, Max**
Time to control of hemorrhage	4.2	5.3	3.0	0, 35.0

Duration of Vacuum Treatment (Protocol: ≥ 60 minutes)	248.8	261.1	144.0	57, 1276
Total in-dwelling time (Treatment + Verification)	306.0	274.9	191.0	70, 1400

*Timing of steps was available in 100 subjects in whom bleeding was successfully controlled with Jada alone.

The median hospital length of stay from delivery time was 2.2 days.

The need for non-surgical intervention after use of Jada was rare, with only 2 subjects receiving non-surgical intervention in the ITT Cohort.

Surgical intervention after Jada treatment was reported in three subjects: one subject received a B-Lynch compression suture in conjunction with Jada, one subject received B-Lynch compression suture followed by hysterectomy, and one subject underwent hysterectomy.

Rate of Non-surgical and Surgical Intervention After Jada Use			
Cohort	**Non-Surgical Intervention**	**Surgical Intervention**	**No Intervention Needed**
ITT	2/106 (1.9%) (95% CI: 0.2%, 6.7%)	3/106 (2.8%) (95% CI: 0.6%, 8.1%)	101*/106 (95.3%)
mITT	1/104 (0.9%) (95% CI: 0%, 5.2%)	3/104 (2.9%) (95% CI: 0.6%, 8.2%)	100/104 (96.2%)
PP	0/97 (0%)	1/97 (1.0%)	96/97 (99%)

*One subject who did not meet the success criteria in the ITT Cohort did not have any further intervention for uterine bleeding post Jada use.

The device usability was notably positive by investigators on all measurements.

Investigators Experience with Jada Use (N=107)	
Category Evaluated	**Response (Agreed or Strongly Agreed)**
IFU and device training clearly explained use	100%
Jada was easy to insert and position	96.3%
Jada was easy to remove	98.1%
Jada use did not inhibit other care	98.1%
Jada was easy to use	98.1%
Would recommend Jada to treat PPH	97.2%

In the study, 40 subjects (37.7%) in the ITT Cohort, 38 subjects (36.5%) in the mITT Cohort and 33 subjects (34.0%) in the PP Cohort received any blood product replacement. Transfusion of four or more units of packed red blood cells (PRBC) occurred in five subjects (4.7%) in the ITT Cohort, five subjects (4.8%) in the mITT Cohort and four subjects (4.1%) in the PP Cohort. No subject developed disseminated intravascular coagulation (DIC) on the study.

Additional Treatment

A subset of subjects received tranexamic acid (TXA) along with uterotonics and uterine massage for treatment of PPH. TXA was used in 41/106 (39%) subjects in the ITT cohort.

Summary of TXA Usage in Study Subjects (ITT Cohort (N=106))	
Timing of TXA Usage	**Number of Subjects (%)**
Any use of TXA in Study Subject	41/106 (39%)
Before Jada Use	22/106 (21%)
During Jada Use	10/106 (9%)
After Jada Use	3/106 (3%)
Before and During Jada Use	4/106 (4%)
Before and After Jada Use	2/106 (2%)

The safety data evaluation showed there were no device deficiencies or adverse events reported related to use of TXA in study subjects.

Summary of Effectiveness Results for Subjects With and Without TXA (ITT Cohort (N=106))	
TXA Usage Timing	**Success Rate per Primary Effectiveness Endpoint % (n/N)**
No TXA Use	100% (65/65)
Any TXA Use	85% (35/41)
Before Jada Use	96% (21/22)
During Jada Use	80% (8/10)
After Jada Use	33% (1/3)
Before and During Jada Use	100% (4/4)
Before and After Jada Use	50% (1/2)

Additional Analyses by Delivery Mode

Sub-group analysis of effectiveness rate was evaluated by mode of delivery, vaginal or c-section. For the ITT population of 106 subjects, there were 91 vaginal deliveries with three failures, and 15 c-sections with three failures. One subject counted as a success in the study was treated after vaginal delivery with uterine balloon

tamponade (UBT) prior to meeting the minimum EBL threshold. The UBT treatment was unsuccessful and continued blood loss occurred. After meeting the EBL threshold, the subject was treated with Jada which controlled hemorrhage without requiring further treatment. The success rates in the ITT Cohort were 96.7% and 80.0% after vaginal and c-section birth, respectively. In the mITT Cohort, success rates were 98.9% and 80.0%, respectively. In the PP Cohort, the success rates were 100.0% and 91.7%, respectively.

Effectiveness of Jada by Delivery Type/Cohort						
	Vaginal Delivery			**C-Section**		
Primary Effectiveness	**ITT (N=91)**	**mITT (N=89)**	**PP (N=85)**	**ITT (N=15)**	**mITT (N=15)**	**PP (N=12)**
	88/91 (96.7%)	88/89 (98.9%)	85/85 (100.0%)	12/15 (80.0%)	12/15 (80.0%)	11/12 (91.7%)
Time to Hemorrhage Control with Jada Success (minutes)	**ITT (N=88)**	**mITT (N=88)**	**PP (N=85)**	**ITT (N=12)**	**mITT (N=12)**	**PP (N=11)**
Mean	3.8	3.8	3.8	7.1	7.1	7.2
SD	4.6	4.6	4.6	8.7	8.7	9.1
Median	3.0	3.0	3.0	4.0	4.0	3.0
Min, Max	0, 35	0, 35	0, 35	0, 29	0, 29	0, 29

Summary

The results of the PEARLE study demonstrated that the Jada System is safe with an effectiveness rate of 94.3% for its intended use. The effectiveness rates in the mITT and PP Cohorts were 96.2% and 99.0%, respectively. There were no adverse events judged definitely related to the device or the procedure, and there was a low rate of possibly related adverse events, all of which were anticipated in this patient population and with introduction of an intrauterine device.

The secondary endpoints were also overwhelmingly positive. Bleeding was controlled in 3 minutes in the ITT, mITT and PP populations. The rate of further surgical or non-surgical intervention after Jada was very low. The rate of blood transfusion was expected in this patient population, treated at U.S. hospitals with ready access to these resources. The median reported total time for Jada treatment with vacuum in this study was 2 hours and 24 minutes, and total in-dwelling time was 3 hours and 11 minutes.

Additional clinical data collected outside the United States

First-in-Woman Study Results

A First-in-Woman (FIW) feasibility study with Ethics Committee oversight was conducted at two clinical sites in Indonesia. The purpose of the study was to demonstrate the placement, function, and operation of the Jada System to meet its intended use.

Ten subjects were enrolled in the feasibility study. None of the subjects presented with a retained placenta, uterine lacerations, uterine scarring, or for any conditions other than atonic postpartum hemorrhage. Bleeding

was controlled within two minutes for all ten subjects. Evaluation of the primary clinical data safety endpoints determined that: 1) no safety issues were observed relative to the placement, insertion, or removal of the Jada, 2) there were no complications related to delayed arrest of blood loss, 3) there was no damage to the uterus, cervix, or vagina, and 4) no uterine inversion or folding events were observed during the Jada procedure.

Case Series Outside the United States

Thirteen subjects were enrolled at the clinical trial site at St. Francis Hospital Nsambya, in Kampala, Uganda under an earlier iteration of the PEARLE study protocol with similar inclusion/exclusion criteria.

Jada was effective at treating PPH in all 13 subjects, including three subjects who were enrolled despite estimated blood loss (EBL) at study entry significantly higher than allowed per study inclusion criterion. Hemorrhage was controlled in each subject but two subjects subsequently died due to lack of blood product supply for transfusion to treat their severe blood loss. There were no adverse events designated definitely related to the device or the procedure.

INSTRUCTIONS FOR USE

Pre-Jada Patient Evaluation

Precaution: The safety and effectiveness of the use of Jada in patients with placenta accreta have not been evaluated.

1. Evaluate for lacerations, retained products of conception, or other causes of bleeding, and remove any organized clots prior to using Jada.

Note: Prioritization of laceration repair and placement of Jada for atony-related bleeding is up to the judgment of the provider. Repair of vaginal and external genital lacerations can be performed with the Jada in place.

Precaution: Use care when suturing any lacerations to avoid puncturing or damaging the material of the Cervical Seal.

Jada Preparation

2. Inspect the packaging and Jada before use.
3. Ensure that the bladder is empty (straight cath or place Foley) in order to facilitate palpation and contraction of the uterus.
4. Connect a vacuum canister and sterile standard vacuum tubing to a regulated vacuum source.
5. Attach a sterile luer tapered syringe to remove any air that is in the Cervical Seal.
6. Fill sterile luer tapered syringe with 60 mL of sterile fluid.

Jada Placement: Post Vaginal Delivery or Post Cesarean Section After Closure of Hysterotomy

7. Secure visualization of the cervix to confirm it is dilated ≥ 3 cm to allow for placement of Jada.
8. Using a hand, compress the Intrauterine Loop near the distal tip for support and insert Jada transvaginally, leading with the Intrauterine Loop (**See Figure 1**). Avoid excessive force. Use gentle traction on the

anterior cervical lip to stabilize the cervical opening, if needed. An instrument can be placed on the anterior cervical lip, but do not grasp Jada with an instrument to facilitate intrauterine insertion.

9. Place Jada such that the Intrauterine Loop is located in the uterus and is oriented in the frontal plane of the body by assuring the Seal Valve is oriented at either 3 or 9 o'clock. Ultrasound may be used to confirm proper placement of the Intrauterine Loop within the uterus.

10. After insertion, the Intrauterine Loop should be within the uterus while the Cervical Seal should be located within the vagina at the external cervical os (**See Figure 2**).

Note: If clinically relevant, a B-Lynch compression suture may be used in conjunction with Jada.

Filling of Cervical Seal and Connection of Vacuum

11. While securely holding the Seal Valve and avoiding unintentional proximal or distal movement of the Cervical Seal away from the external cervical os, attach a sterile luer tapered syringe to fill the Cervical Seal with 60 mL of sterile fluid. If needed, add up to another 60 mL of sterile fluid to achieve coverage of the external cervical os and create a seal for vacuum (**See Figure 3**).

12. Set the vacuum source to 80 mm Hg +/- 10 mm Hg while occluding the end of the tubing (80 mm Hg = 1.5 psi = 10.7 kPa = 3.2 in Hg = 106.7 mbar) (**See Figure 4**).

Precaution: The maximum vacuum pressure is 90 mm Hg. Do not increase the vacuum pressure higher than 90 mm Hg. (90 mm Hg = 1.7 psi = 12.0 kPa = 3.5 in Hg = 120.0 mbar) or tissue trauma may occur.

13. After the vacuum pressure has been set and confirmed, connect Jada to the sterile vacuum tubing (**See Figure 5**). Blood flow into the vacuum tubing and/or improvement in uterine tone should be noted after initiation of vacuum.

Note: Confirm that the Cervical Seal is positioned at the external cervical os after the system is in place (Cervical Seal is filled and the vacuum is connected). Reposition Jada if required to facilitate a seal.

14. After initial evacuation of any pooled blood, presentation may vary during treatment: there may be no further blood evacuation, or additional blood moving into the tubing, or accumulation of blood in the canister. If blood flow does not stop or slow sufficiently, consider increasing the vacuum pressure in accordance with your clinical judgment, not to exceed a maximum pressure of 90 mm Hg.

15. Tape Jada to the patient's inner thigh without tension.

Precaution: Ensure Jada is secured with tape to avoid unintentional dislodgement.

16. Leave Jada in place with the vacuum applied until:

    - PPH/abnormal postpartum uterine bleeding is controlled for at least 1 hour,
    - The uterus is firm,
    - Patient is stable.

17. Consider prophylactic antibiotics for prolonged use.

Verify and End Treatment

18. Before disconnecting vacuum, assess the patient to confirm that treatment is no longer needed.

19. Disconnect vacuum tubing from Jada while vacuum is on to collect any blood from the tubing into the canister. Secure tubing in case re-application of vacuum is needed.

20. Attach a luer tapered syringe to remove the fluid from the Cervical Seal and keep the Jada System in place for at least 30 minutes while monitoring for any recurrent uterine bleeding.

Jada Removal

Precaution: to avoid uterine inversion, do not remove the Jada while vacuum is applied. Always disconnect Jada from vacuum tubing before removal.

Precaution: remove all fluid from the Cervical Seal prior to removing Jada to avoid disruption of the vaginal mucosa or any sutured lacerations.

21. If PPH/abnormal postpartum uterine bleeding remains controlled and the uterus remains firm for a minimum of 30 minutes after vacuum is disconnected, remove Jada.
22. Place one hand on the abdomen to secure the uterine fundus while the other hand slowly withdraws the device.

TROUBLESHOOTING

SITUATION	**RECOMMENDED ACTION**
Vacuum is not detected at the end of the vacuum tubing.	a) Check connection on all system components: • Confirm vacuum source is functional, including regulator. • Confirm lid of vacuum canister is fully seated and that canister is not cracked. • Confirm vacuum tubing is securely connected at both ends and any connection in between. b) Confirm desired vacuum level is regulated in the appropriate units (i.e. mm Hg vs. cm Hg).
Vacuum system is connected and working but uterus does not collapse and/or bleeding does not stop.	a) Increase vacuum pressure to maximum (90 mm Hg). b) Disconnect the vacuum tubing from Jada and occlude the end of the tubing to check vacuum. c) Confirm appropriate Jada placement, with ultrasound if needed: • Confirm proper placement of Intrauterine Loop in uterus (vs. misplacement in posterior vaginal fornix). • Confirm proper placement of Cervical Seal outside of the cervical os (vs. misplacement into uterus). • Ensure Cervical Seal is sufficiently filled with sterile fluid to create adequate seal at the cervix. d) Re-evaluate patient for other sources of bleeding.

HOW SUPPLIED

Jada, luer tapered 60 mL syringe and vacuum tubing are supplied sterile. Jada and other components are sterile if package is unopened or undamaged. Do not use Jada or other components if there is doubt as to whether the devices are sterile.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Sterile fluids
- Vacuum canister
- Regulated vacuum source
- Tape

STORAGE

Handle with care. Store in original packaging in a clean, cool, and dry location. Avoid exposure to temperature and humidity extremes.

RE-STERILIZATION/RE-USE

Jada, luer tapered 60 mL syringe and vacuum tubing are for single-patient use only. Do not reuse, reprocess, or re-sterilize. Reuse of Jada, luer tapered 60 mL syringe or vacuum tubing may lead to cross contamination, infection, or patient death.

SYMBOL GLOSSARY

Sources: **21 CFR 801** Labeling and **ISO 15223-1:2016** *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.*

Symbol	Title	Meaning/Definition	Standard/ Ref. Number
	Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 5.1.5
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 5.1.4
	Prescription Only	"CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN."	21 CFR 801.109
	Consult instructions for use or consult	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 5.4.3

Symbol	Title	Meaning/Definition	Standard/ Ref. Number
	electronic instructions for use		
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1 5.4.4
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1 5.3.2
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 5.2.4
	Sterilized using ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 5.2.3
	Does not contain natural rubber latex	Indicates the absence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	ISO 15223-1 5.4.5
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 5.3.4
	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1 5.4.2
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1 5.2.8
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 5.2.6
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1 5.1.1

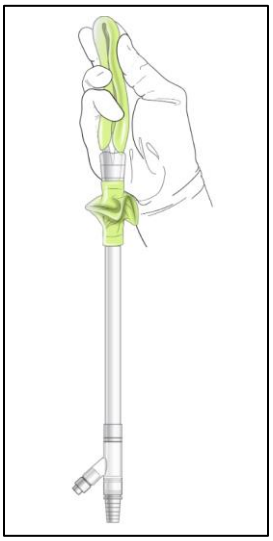


Figure 1

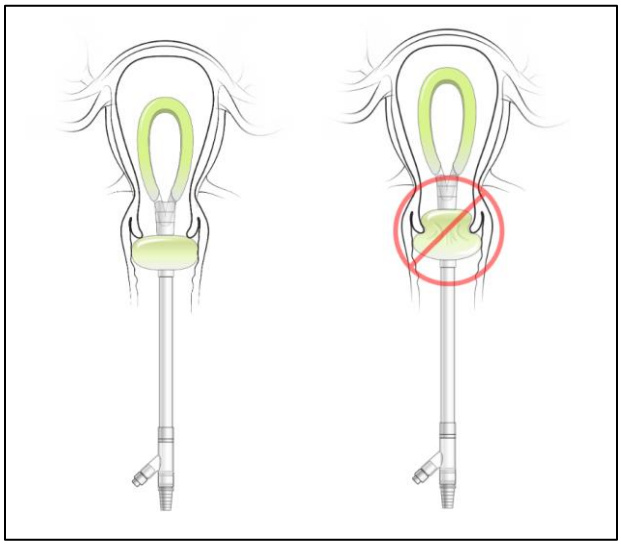


Figure 2

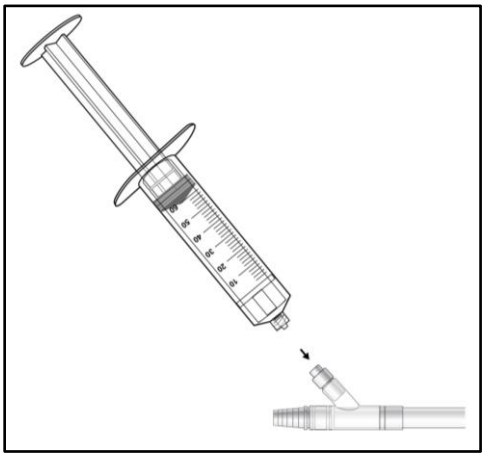


Figure 3

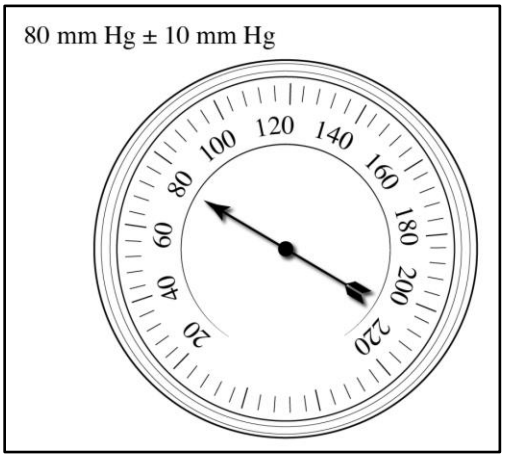


Figure 4

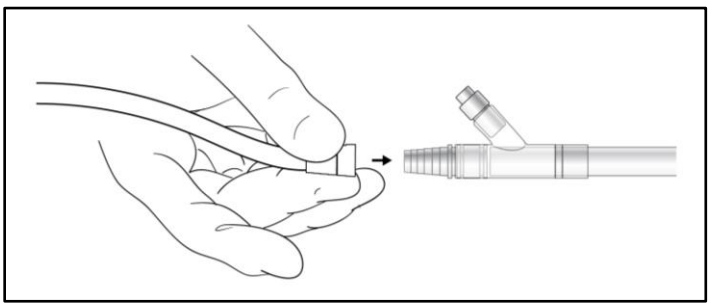


Figure 5

Organon LLC
30 Hudson Street, Floor 33
Jersey City, NJ 07302 USA
Tel: 844-JADAMOM
844-523-2666
www.organon.com

For patent information: www.organon.com/our-solutions/patent/

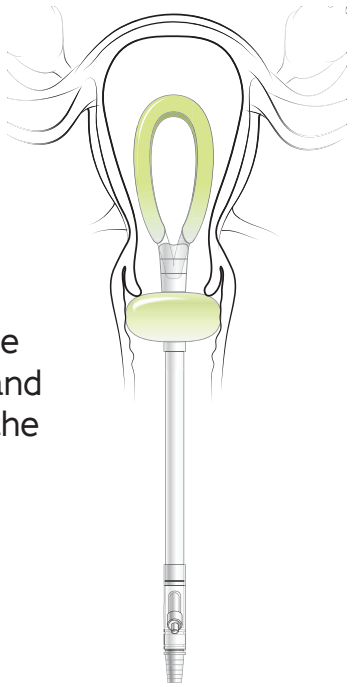
LBL-24 v3.0 | Effective 10/31/2022

Bakri® Postpartum Balloon is a registered trademark of Cook Incorporated.

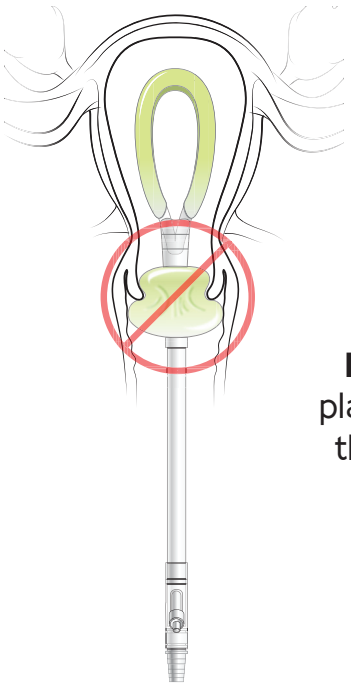
Jada® Placement

The Jada System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative managment is warranted.

Place inside the vagina and up against the cervix

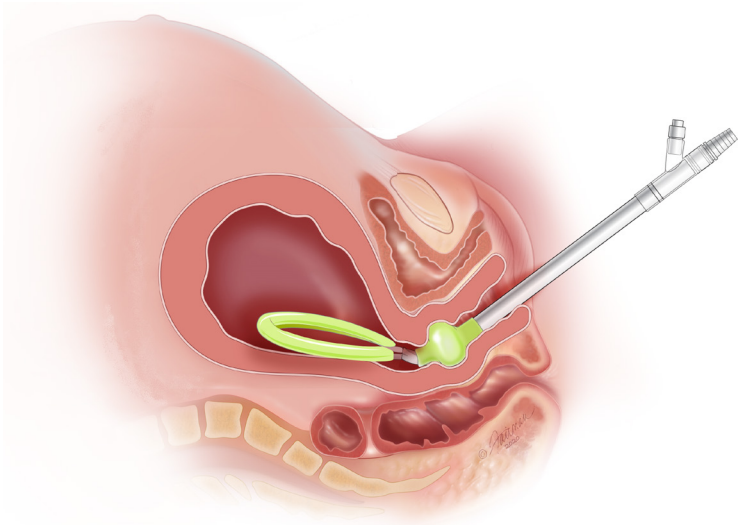


Correct Placement



Incorrect Placement

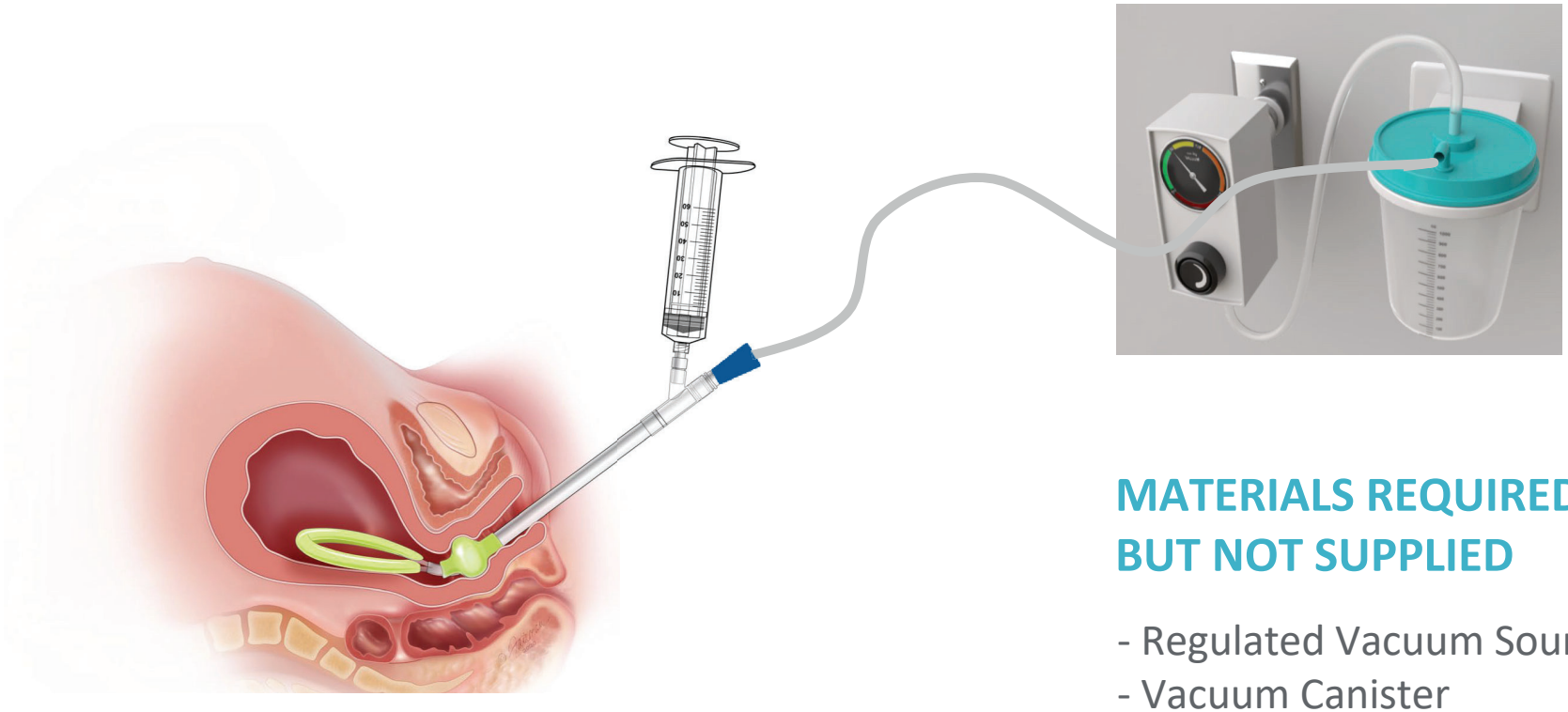
DO NOT place inside the cervix



Jada correctly placed inside the vagina with Cervical Seal inflated

Please see the Instructions for Use for the indications, contraindications, warnings, precautions, and other important information available at thejadasystem.com/ifu

The **Jada**® System: Set-Up



MATERIALS INCLUDED IN JADA KIT

- Jada Device (with blue seal valve)
- Vacuum Tube (12 ft)
- 60-mL Syringe

MATERIALS REQUIRED BUT NOT SUPPLIED

- Regulated Vacuum Source
- Vacuum Canister
- Tape
- 60-120 mL Sterile Fluid

ORGANON

Jada SYSTEM

1. **Along with the Jada® System, also bring:**
   - **60-120 mL Sterile fluids (saline, water)**
   - **Tape**

2. **In the room, check working order of:**
   - **Regulated vacuum source**
   - **Vacuum canister**

3. **Vacuum setting: 80 mm Hg ± 10 mm Hg** (not to exceed 90 mm Hg)

Please consult the product's Instructions for Use (IFU) prior to use for detailed product information, including indications for use, contraindications, warnings, precautions, and other important information.

Jada SYSTEM

Status Active PolicyStat ID 17112177

MUNSON MEDICAL CENTER
MUNSON HEALTHCARE

Origination	5/9/2013
Last Approved	10/21/2025
Effective	10/21/2025
Last Revised	10/21/2025
Next Review	10/20/2028
Owner	Angela Simmonds: Resource Clinician
Area/ Department	Women & Children Services
Applicability	MMC
Tags	Guideline

Magnesium Sulfate Administration - Maternity

Purpose

To promote the safe use of intravenous (IV) magnesium sulfate in the pregnant or postpartum woman.

Definitions

1. **Magnesium sulfate:** is a smooth muscle relaxant. Excess magnesium:
    a. Decreases neuromuscular irritability and blocks the release of acetylcholine at neuromuscular junctions. (Acetylcholine is the excitatory substance that transmits nerve messages across the synapse).
    b. Depresses the vasomotor center by acting on the peripheral vascular system (causes vasodilation, which increases blood flow to the uterus and can cause transient episodes of decreased blood pressure [BP] for 30 - 45 minutes after administration).
    c. Depresses central nervous system irritability.
2. **Indications:** for magnesium sulfate therapy may include**:**
    1. Prevention and treatment of seizures in women with preeclampsia or eclampsia.
    2. Fetal neuroprotection before anticipated early preterm (less than 32 weeks of gestation) delivery within 12 hours.
    3. Short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal corticosteroids in pregnancy women who are at risk of preterm delivery within 7 days.

Guidelines

Contraindications/ Cautions

A. Hypocalcemia

B. Myasthenia gravis

C. Renal failure

Additional Precautions

A. Magnesium sulfate used with terbutaline may increase potential for pulmonary edema.

B. Contributing risk factors associated with pulmonary edema include anemia, fluid overload, and multiple gestation pregnancy.

Safety Mechanisms

A. Because magnesium sulfate is a high-alert medication, certain safety mechanisms must be in place during administration:

1. An infusion pump must be used for the bolus and maintenance magnesium sulfate infusions.
2. The bolus dose should be from a separate IV bag (not from the maintenance IV). Both bags are premixed and are checked by two nurses before administration.
3. IV tubing is labeled and traced from the patient to the bag with each hand-off or shift change.

Equipment Needed

A. Two infusion pumps (for the primary infusion and the magnesium sulfate infusion) (or 3 infusion pumps if also on Oxytocin or other continuous infusion).

B. Magnesium sulfate loading (bolus) dose as ordered.

C. Magnesium sulfate maintenance infusion as ordered.

Process

A. Verify the absence of contraindications to magnesium sulfate administration, including hypocalcemia, myasthenia gravis or renal failure.

B. Educate patient about common transient side effects of magnesium sulfate (maternal flushing, lethargy, headache, muscle weakness, neonatal hypotonia), and safety measures used to avoid potentially serious adverse drug reactions.

C. Obtain the premixed magnesium sulfate IV bolus and maintain bags from the Pyxis once orders are placed in the electronic health record (EHR):

1. Magnesium sulfate is supplied in pre-mixed bags of 2 gram and 4 gram. When administering a 6 gram loading dose, one 2 gram and one 4 gram pre-mixed bags

are used.

D. Perform a baseline assessment and document before administration:
    1. BP
    2. Respiratory rate (RR)
    3. Deep tendon reflexes (DTRs)
    4. Presence/absence of clonus
    5. Level of consciousness
    6. Pulse oximeter reading
    7. Breath sounds
    8. Intake and output
    9. Fetal heart rate (FHR)

E. Establish primary IV line with infusion pump. To avoid mix-up of the IV lines, do not prepare the magnesium sulfate line until the primary line is infusing via the pump.

F. Connect the magnesium sulfate bolus IV into the primary IV line at the closest port (*either the Y site on the extension tubing or the lowest Y port on the primary IV tubing*) to the primary venipuncture site.

G. Program an infusion pump to run the bolus dose as ordered *(typically 6 grams total over 30 minutes)*. A second Registered Nurse (RN) must verify the correct medication, dose, and infusion rate, and check all pump settings and tubing connections before administration.

H. Remain at the bedside during the administration of the bolus dose to monitor the patient for side effects, adverse drug reactions, and to continuously assess fetal status.

I. At the completion of the bolus dose, connect the maintenance magnesium sulfate solution into the primary IV line at the closest port (*either the Y site on the extension tubing or the lowest Y port on the primary IV tubing*) to the primary venipuncture site. Prepare the infusion pump to administer the maintenance magnesium sulfate infusion as ordered (*typically 2 grams/hour*). Only program the infusion pump with the volume required for 2 hours of therapy. A second RN must verify the correct medication, dose, and infusion rate, and check all pump settings and tubing connections prior to administration.

J. If the drug is discontinued, the infusion bag and tubing should be removed immediately from the patient's access site, pump, and IV pole to prevent later accidental infusion.

Monitoring/Assessment

A. Record BP, pulse, respirations, and oxygen saturations every 15 minutes for the first hour of therapy (from the start of loading dose) and every 30 minutes during the second hour.

B. Record BP, pulse, respirations, and oxygen saturation at least hourly for the duration of magnesium sulfate infusion.

C. Assess and document the following at least every 2 hours:
    1. Level of consciousness

2. DTRs and clonus
3. Breath sounds
4. Intake and output (urine output should exceed 30 mL/hr). If using a Foley, use an urometer.
    a. Magnesium sulfate circulates largely unbound to protein and is excreted in the urine. Therefore, safe clinical practice requires an accurate record of intake and output when patients are receiving magnesium sulfate. With normal renal function, the half-life for magnesium excretion is approximately 4 hours; women with preeclampsia may not have normal renal function, increasing the risk for toxicity (Simpson & Knox, 2004, p. 162).

D. Laboratory testing:
    1. In the Obstetrics (OB) Hypertensive Disorders of Pregnancy Powerplan, appropriate lab tests are to be ordered by the care provider with magnesium sulfate administration for preeclampsia (i.e. complete blood count (CBC), GTABS, coagulation studies, Urinalysis (UA), protein/creat ratio, liver function studies, electrolytes, etc.)
    2. Collect laboratory specimens for serum magnesium levels as ordered (reported as mg/dL)
        a. Bolus/loading dose: Magnesium sulfate level drawn and analyzed 2 hours after infusion
        b. Maintenance therapy: Magnesium sulfate level drawn every 6 hours as ordered

E. Notify care provider immediately about:
    1. Magnesium sulfate levels less than 4.8 mg/dL or greater than 8.4 mg/dL
    2. Significant change in BP or heart rate
    3. Absent deep tendon reflexes
    4. Urine output less than 30 mL/hr over 4 hours
    5. Respirations less than 12 breaths per minute
    6. Shortness of breath or breath sounds suggestive of pulmonary edema
    7. Oxygen saturation less than 95%
    8. Changes in level of consciousness
    9. Visual disturbances

F. Monitor for magnesium toxicity. Magnesium toxicity results in loss of DTRs, and progressive muscle weakness, including the diaphragm and other respiratory muscles, and depression of the respiratory center in the brain. Monitor for signs of toxicity such as severe respiratory depression, decreased level of consciousness, respiratory arrest, and cardiac arrest. If present:
    1. Discontinue magnesium sulfate
    2. Notify physician immediately

3. Draw a stat serum magnesium level
4. Obtain calcium gluconate for immediate administration (antidote for magnesium sulfate toxicity).
    a. Indication: reversal of respiratory depression. Medication to be kept in locked medication drawer in patient room.
    b. Calcium gluconate 1 gram (10 mL) IVPush over 3 minutes

G. Monitor postpartum mother for signs of uterine atony, such as boggy uterus, elevated fundal level or excessive lochia

H. After magnesium sulfate infusion is discontinued, record BP, pulse, respirations, and oxygen saturation every 4 hours for 24 hours, then record BP, pulse, and respirations once a shift thereafter (not to exceed a period greater than 8 hours) until discharge.

Nursing Standard of Care Interventions

A. Resuscitation equipment readily available for both mother and infant

B. Electronic fetal monitoring as ordered to assess fetal well-being

C. Recommended nothing by mouth (NPO) or minimal ice chips until stabilized as ordered

D. Bed rest with lateral positioning preferred

E. Limit environmental stimuli as appropriate for patient condition

F. Preeclampsia/ Gestational Hypertension
    1. Foley catheter with urometer is preferred for severe preeclampsia until stabilized
    2. Fluids restrictions: less than 3000 mL total IV and by mouth (PO) intake per 24 hrs or per care provider's orders

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Document ID: 088.G004

Approval Signatures

Step Description	Approver	Date
System Policy Oversight Committee	Terri Fries: Document Mgmt Spec	10/21/2025
VP and CNO Patient Care Services	Tamara Putney: VP and CNO Patient Care Services	10/20/2025
P&T Committee	Heather Tolfree: Mgr Pharmacy - CPS	10/17/2025
Mgr Nursing Services	Sarah McClure: Mgr Nursing Services	10/16/2025
Document Owner	Angela Simmonds: Resource Clinician	10/16/2025

Applicability

Munson Medical Center

Standards

No standards are associated with this document

MUNSON HEALTHCARE

Malignant Hyperthermia

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April 2025

Goals and Objectives

Goals

To assist staff in recognizing signs and symptoms of malignant hyperthermia (MH) to be able to implement treatment options.

To increase awareness of the Malignant Hyperthermia Association of United States (MHAUS).

Objectives

1. List the signs of malignant hyperthermia (MH).
2. State which patients are more conducive to the development of this crisis.
3. Demonstrate knowledge and understanding of administering dantrolene sodium (Ryanodex).
4. Describe management of an MH crisis to include cooling measures, electrolyte imbalances, and dysrhythmias.

Course contains videos - use  or 

Page n of nn

What is Malignant Hyperthermia?

MH is a genetically inherited disorder of skeletal muscle that predisposes susceptible individuals to a life-threatening adverse reaction upon exposure to some anesthetic agents.

It leads to a hypermetabolic crisis manifesting as metabolic and respiratory acidosis, tachycardia, cardiac arrhythmias, skeletal muscle rigidity, and heat production.

Although the occurrence of an MH crisis is rare, incidence varies per geographic location which includes Michigan.

Malignant Hyperthermia

While most cases of MH occur during general anesthesia, the one-hour period immediately following surgery (including the recovery room) is also a critical time.

In addition, MH can occur if trigger anesthetics and/or succinylcholine are used in any location, such as EDs, dental surgeries, surgeon's offices, or ICUs.

Malignant Hyperthermia *(cont.)*

Triggers for MH include:

- Inhaled general anesthetics (e.g. desflurane, enflurane, halothane, isoflurane, sevoflurane)
- Succinylcholine
- Exertional heat or exercise (rare)

MH Susceptible Patients

Currently, no simple diagnostic test is available for screening the general public.

Patients with a history of MH, family history, or even possible history are treated as though they are MH susceptible.

Screening:

- Scheduled cases will be screened prior to surgery.
- Emergent cases will be screened prior to induction when patient condition or family presence allows.
- Screening should include family or personal history of MH and/or complications from anesthesia.

Pre-Procedure Prep

During the preprocedural screening, if a patient has been identified as MH susceptible, the following preparation is needed:

- Anesthesia/providers create a detailed plan considering alternative anesthetic agents.
- When possible, schedule the patient as a first case.
- Notify all post-procedure destinations.
- Place the MH cart outside of the procedure room.

Clinical Features

The sequence and timing of clinical manifestations may vary from patient to patient.

- Unexplained tachycardia or arrhythmias (usually ventricular tachycardia and premature ventricular contractions) - **Early Sign**
- Unexplained increase in end-tital carbon dioxide ($EtCO_2$) - **Early Sign**
- Tachypnea or breathing over the ventilator - **Early Sign**
- Sinus tachycardia - **Early Sign**
- Masseter muscle or generalized muscle rigidity - **Early Sign**
- Hyperkalemia - mixed metabolic/respiratory acidosis - **Early Sign**
- Rapidly rising body temperature (hyperthermia) - **Late Sign**
- Myoglobinuria - **Late Sign**
- Rhabdomyolysis - **Late Sign**
- Disseminated intravascular coagulation (DIC) - **Late Sign**

Pediatric patients

- Sinus tachycardia, hypercarbia, rapid temperature increase, and skin mottling; may not see muscle rigidity in pediatrics

Response to an MH Crisis

Please complete the activity before moving on.

If a MH crisis is suspected, immediately take the following steps:
(Click each arrow to view the information.)

- Call/page anesthesia provider STAT if not present.
- Discontinue volatile agents (inhaled general anesthetics and/or Succinylcholine).
- Obtain the MH Cart/Bag and dantrolene (Ryanodex or Dantrium).
- Obtain MH Crisis Checklist from MH Cart/Bag and follow the guidelines on the checklist.
  1. Master copies of hospital specific MH crisis checklists are attached to the MHC PolicyStat - Malignant Hyperthermia Guidelines.
- Contact the Malignant Hyperthermia Association of the United States (MHAUS) for additional support.
- Contact Pharmacy & Phlebotomy to assist, as needed.

Page n of nn

MH Initial Treatment

- Hyperventilate with 100% oxygen at flows of 10ml/min.
  - If available, insert activated charcoal filters into the anesthesia breathing circuit.
- Administer initial dose of dantrolene (Ryanodex or Dantrium) 2.5 mg/kg IVP
- Establish large bore IV access (avoid hands), infuse Dextrose 5% (D5W) or 0.9% sodium chloride.
  - Avoid Lactated Ringer's and Normasol, which contain calcium.
- Continue patient monitoring of ECG, pulse oximetry, capnometry, and core body temperature.

MH Crisis Medications

- Dantrolene sodium IV (Ryanodex, Dantrium)
- Preservative-free sterile water for injection (in vials)
- 8.4% sodium bicarbonate
- 10% calcium chloride
- 50% dextrose
- 2% lidocaine (amiodarone is also acceptable)
- Regular insulin, 100 unit/mL (refrigerated)
- Normal saline solution (at least 3,000 mL, refrigerated)
- D5W

Dantrolene Sodium

Dantrolene sodium is available as a solution (Dantrium), or as a suspension (Ryanodex) once reconstituted, for treatment of MH.

Product Comparison

	Dantrium	Ryanodex
Vial strength	Each vial 20 mg	Each vial 250 mg
Reconstitution per vial	60 ml of sterile water preservative free yields 0.33 mg/ml	5 ml of sterile water preservative free yields 50 mg/ml
Time to reconstitute	15-20 minutes for 13 vials	<1 minute for 1 vial
# Vials/per dose	13-18 vials	1-2 vials
Color	**Shaken until solution is clear**	**Uniform orange color**
Dose	**2.5 mg/kg**	**2.5 mg/kg**

You must watch the video to advance.

Dantrolene Sodium (Ryanodex)

Mixing and Administration Instructions:

- Each vial is to be reconstituted with 5 mL of sterile water (NO preservative/NO bacteriostatic agent).
- Mix thoroughly.
- Draw up patient-specific, weight-based dose (2.5 mg/kg).
- Administer IVP into a large bore IV (avoid hand) of 0.9% normal saline or D5W solution; flush line after dose is given.
- Has potential for tissue necrosis with extravasation.

Ryanodex Video

Click here to watch a 4½ minute video on how to mix and administer Ryanodex.

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Dantrolene Sodium (Ryanodex) *(cont.)*

Dosing chart is on the MH cart, and also comes with the vial of Ryanodex.

Maximum cumulative dose is 10 mg/kg

DOSAGE SCHEDULE TO TREAT MH

- Based on recommended loading dose of 2.5 mg per kg[1]
- Chart calculated using 250 mg vials of RYANODEX® (dantrolene sodium) for injectable suspension reconstituted with 5 mL of sterile water for injection USP (without a bacteriostatic agent)[3]
- In case of emergency, contact the 24-hour MHAUS Hotline at 800.644.9737

RYANODEX® DOSAGE CHART[3]

Patient's weight in kg	Patient's weight in pounds	Number of 250 mg vials to open	mg dosage needed	mL of reconstituted RYANODEX® to administer
5	11	1	12.5 mg	0.25 mL
10	22	1	25.0 mg	0.50 mL
15	33	1	37.5 mg	0.75 mL
20	44	1	50.0 mg	1.00 mL
25	55	1	62.5 mg	1.25 mL
30	66	1	75.0 mg	1.50 mL
35	77	1	87.5 mg	1.75 mL
40	88	1	100.0 mg	2.00 mL
45	99	1	112.5 mg	2.25 mL
50	110	1	125.0 mg	2.50 mL
55	121	1	137.5 mg	2.75 mL
60	132	1	150.0 mg	3.00 mL
65	143	1	162.5 mg	3.25 mL
70	154	1	175.0 mg	3.50 mL
75	165	1	187.5 mg	3.75 mL
80	176	1	200.0 mg	4.00 mL
85	187	1	212.5 mg	4.25 mL
90	198	1	225.0 mg	4.50 mL
95	209	1	237.5 mg	4.75 mL
100	220	1	250.0 mg	5.00 mL
105	231	2	262.5 mg	5.25 mL
110	242	2	275.0 mg	5.50 mL
115	253	2	287.5 mg	5.75 mL
120	264	2	300.0 mg	6.00 mL
125	275	2	312.5 mg	6.25 mL
130	286	2	325.0 mg	6.50 mL
135	297	2	337.5 mg	6.75 mL
140	308	2	350.0 mg	7.00 mL
145	319	2	362.5 mg	7.25 mL
150	330	2	375.0 mg	7.50 mL

Labeled dose range of 1 to 10 mg/kg with a maximum cumulative dose of 10 mg/kg. If the physiologic and metabolic abnormalities of MH continue, administer additional doses.[1]

Dantrolene Sodium (Ryanodex) Locations

Cadillac
MH Cart

Charlevoix
- MH Cart
- Pharmacy

Grayling
MH Cart

Manistee
MH Cart

Otsego Memorial Hospital
- Anesthesia Pyxis
- ICU Pyxis

Paul Oliver Memorial Hospital
MH Cart

MMC
- 2 vials: OR 2nd floor in the MH Cart
- 2 vials: OB (Recovery Room) Pyxis
- 2 vials: Basement Pharmacy

MH Crisis Checklist

Please refer to your facility-specific MH Crisis Checklist and policy for Malignant Hyperthermia treatment and management.

Web Window

https://mobile.mhc.net/Malignant Hyperthermia Crisis Checklist 2022.pdf

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Recommended MH Supplies

Important - Know the location of your hospital's MH supplies.

- Charcoal filters
- Variety of syringes, including (3) 5mL syringes and (3) 60 mL syringes
- IV catheter supplies (large bore)
- Central venous access catheter kits (appropriate sizes for patient population)
- Transducer kits for arterial and central venous catheters
- Arterial blood gas (ABG) kits and syringes (3 mL) for blood gas analysis or point of care monitors
- Pressure bag
- Core temperature probes
- Bucket for ice and cold packs
- Large Steri-Drape™ to cover surgical wound
- Urinary catheter kit
- Urine collection container for myoglobin level
- Small and large plastic bags
- Test strips for urine hemoglobin
- Variety of blood collection tubes

Additional Equipment

- Capnography
- Cooling blanket
- Emergency equipment:
  - Crash cart
  - Defibrillator
  - Intubation supplies
  - Mechanical ventilator
  - Handheld resuscitation bag with mask

MH Supportive Therapy

- Cool patient, as needed, based on body temperature using ice packs to neck, axilla or groin, cooling blankets, chilled intravenous solution, or lavage.
- Obtain lab work, including blood gas.
- Re-dose dantrolene based on patient response.
- Treat respiratory and metabolic acidosis, hyperkalemia, and dysrhythmias, as needed (avoid calcium channel blockers).
- Monitor renal function and treat myoglobinuria, if needed.
- Provider should consider insertion of an arterial line, central venous catheter, and/or a pulmonary artery catheter.

Transferring a MH Suspected or Confirmed Patient

- The anesthesia provider will determine the location to best manage patient care during the acute phase (e.g., inpatient facility Post Anesthesia Care Unit (PACU) or critical care unit).
- Notify house supervisor/admitting for bed placement needs, as applicable.
- The anesthesia provider will arrange the transfer and accompany the patient, as needed.

Post-MH Crisis

- Observe the patient for at least 24 hours on a critical care unit.
- Monitor ABGs, electrolytes, calcium, clotting studies, myoglobin, urine output and color, and other studies as ordered.
- Key indicators of stability include:
  - $EtCO_2$ is declining or normal
  - Heart rate is stable
  - Hyperthermia is resolving
  - Generalized muscle rigidity has resolved
  - Restock MH cart or bag
- Ensure additional vials of dantrolene (Ryanodex or Dantrium) are readily available.

Post-MH Crisis Complications

- Dantrolene sodium (Ryanodex) is associated with flushing, drowsiness, voice disorders, dysphagia, and nausea.
  - Symptoms may persist up to 48 hours post-dose.
- Rhabdomyolysis
  - Urine becomes cola-colored (dark red or brown).
  - Patient may c/o muscle pain.
  - **Immediately** notify attending provider and anesthesia provider.
- Paralysis, blindness, renal failure, reoccurrence of syndrome, muscle weakness, multi-organ failure, and/or death
  - Patients should not ambulate without assistance until normal strength and balance has returned.
- Obstetrical cases
  - Dantrolene sodium (Ryanodex) readily crosses placenta - may lead to side effects in unborn child.
  - Notify the obstetrician and pediatrician of dantrolene sodium (Ryanodex) administration.

Documentation and Reporting

A. Notify the unit manager and director of the event.
B. Document event on unit-based patient care records (EMR).
C. Complete a facility occurrence report (e.g., VOICE) under "adverse medication event".
D. Anesthesia Services should review each case and consider contributing information to the MHAUS.

MH Guidelines

Web Window

https://munsonhealthcare-all.policystat.com/policy/14063752/latest

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Malignant Hyperthermia Association of the United States (MHAUS)

Mission: To promote optimum care and scientific understanding of MH and related disorders.

The MHAUS Association provides:

- Resources for healthcare professionals
  - Education and research
- Patient/family teaching re: MH precautions, susceptibility, and testing centers

Visit **http://www.mhaus.org** for healthcare provider and public education materials.

For support during an MH crisis,

call the 24-hour **MH Hotline**

1-800-644-9737

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Massive Transfusion Protocol

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May 2023

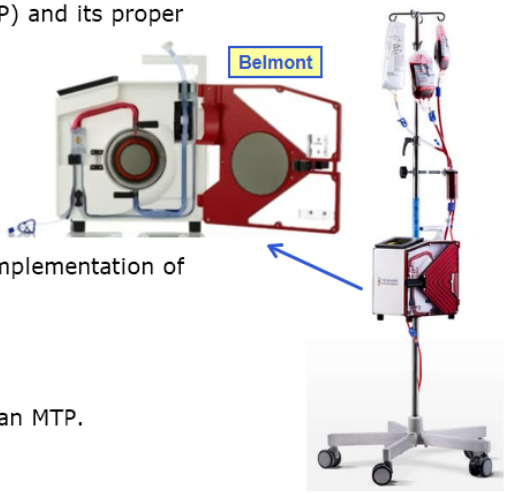
MUNSON HEALTHCARE

Goal

This course will familiarize the learner with the indications for the initiation of the Massive Transfusion Protocol (MTP) and its proper implementation.

Objectives

1. State indications for initiation of the MTP.
2. State the process to initiate MTP.
3. Identify the members of the MTP team.
4. State each MTP team member's role during implementation of the MTP.
5. Verbalize how Trauma Packs are obtained.
6. Identify end points of the MTP.
7. State the process and rationale for canceling an MTP.

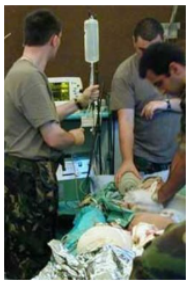


Indications for Initiation

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

B. Triggers:

1. Greater than 6 units packed red blood cells (PRBC's) 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 systolic blood pressure less than 90 mmHG (no=0; yes=1)
   c. Emergency department 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 90 mmHG.



MTP Team

Click each button to identify the MTP team members.

MTP Team Leaders

- Trauma surgeon
- Intensivist
- Emergency department (ED) physician
- Anesthesiologist [in OR or Post Anesthesia Care Unit (PACU)]
- Trauma advance practice providers (APP)
- Obstetrician (OB)
- Hospitalist

MTP Clinical Team

MTP Team

Exit

Click each button to identify the MTP team members.

MTP Team Leaders

MTP Clinical Team

- Clinical team:
  - Trauma physician assistant (PA)/nurse practition (NP)
  - ED nurse/ED tech
  - ICU RN
- Clinical pathologist
- Lab blood bank/laboratory personnel
- Pharmacy
- Nursing supervisor/charge nurse
- Vascular Access

How to Initiate the Massive Transfusion Protocol

Exit

Please click each step below:

1. The Team Leader initiates the Massive Transfusion Protocol.
2. A designated staff member calls **55555** to page out MTP overhead and to all responsible parties.
3. A designated staff member enters an order for Massive Transfusion in Cerner.
   - Initiates *Lab - Q 30 min.* immediately
4. A designated staff member locates the MTP supplies. The MTP packet contains MTP specific blood slips and the MTP policy.
5. A designated staff member locates the Belmont. If the MTP is in Maternity, an ED nurse will bring the Belmont.

Responsibilities

Exit

There are 3 areas of responsibility. Please click each area.

General Nursing | **Clinical Pathologist (or Designee)** | **Laboratory Personnel**

- Coordinates Trauma Packs from the Blood Bank at regular intervals and infuse per MTP flowsheet.
- Maintains documentation of transfusions, using the MTP form #10104.
- **Designates one staff member** to maintain communication with Blood Bank personnel during initiation and maintenance of the MTP.

Responsibilities

Exit

There are 3 areas of responsibility. Please click each area.

General Nursing | **Clinical Pathologist (or Designee)** | **Laboratory Personnel**

- Tracks the use and available supply of blood products.
- Advises the clinical team on the use of blood products and pro-coagulants.
- Assists with interpretation of thromboelastography (ROTEM).

Responsibilities

Exit

There are 3 areas of responsibility. Please click each area.

General Nursing | **Clinical Pathologist (or Designee)** | **Laboratory Personnel**

- Confirms patient identity, using two patient identifiers (name, date of birth, or medical record number), before drawing labs.
- If the patient's identity is not known, they will be a John/Jane Doe until the patient's identity is established.
- Labs are repeated every 30 minutes until discontinued by the Clinical Team Leader.

Labs Drawn

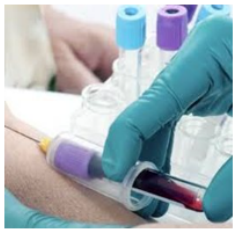
Exit

Click each button below:

Labs Drawn upon Initiation of the MTP

- Type and cross (GTAB)
- STAT coagulation profile (PT INR, PTT, fibrinogen, hemoglobin, platelet count)
- STAT Quantitative D-Dimer (requires special tube only be obtained from the lab)
- STAT Basic metabolic profile
- POC ABG's*
- STAT Lactate

***Can be done at the bedside, with the I-STAT.**



Labs Drawn Every Half Hour

Labs Drawn

Exit

Click each button below:

Labs Drawn upon Initiation of the MTP

Labs Drawn Every Half Hour

These labs are drawn every half hour and sent to the lab:

- CBC
- PT, PTT
- Fibrinogen
- Basic metabolic profile
- Ionized calcium
- Lactate

Nursing Roles While Caring for the MTP Patient

Exit

There are 2 roles for the RN while caring for the patient on the MTP.
Click each button to find out more.

MTP Nurse 1 **MTP Nurse 2**

Responsibilities of MTP Nurse 1:

- Document on the MTP Flowsheet: Massive Transfusion Protocol Documentation form #10104.
- Ensure Trauma Pack Blood Slips are filled out.
  - If uncrossmatched unit, provider must sign the form.
- **Designate one person** to communicate with the Blood Bank.

Nursing Roles While Caring for the MTP Patient

There are 2 roles for the RN while caring for the patient on the MTP.
Click each button to find out more.

MTP Nurse 1 **MTP Nurse 2**

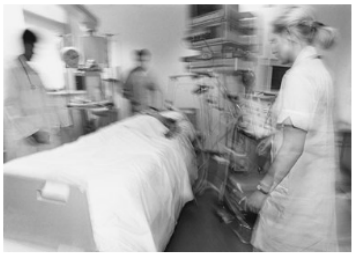
Responsibilities of MTP Nurse 2:

- Maintain transfusions with the Belmont.
- Troubleshoot problems with the Belmont.
- Maintain goal transfusion of 1:1 PRBC to Plasma.
- Clearly communicate time up and time down of each blood product to the documenting nurse.

Transferring the Patient Undergoing MTP to the Next Level of Care

Responsibilities of the MTP team:

- Accompany the patient to the OR or ICU.
- Maintain documentation on the MTP flowsheet or assist with the Belmont.
- Continue with patient care in the ICU or provide hand-off to the next caregiver.
- Remain with the patient until the MTP is canceled.



Cryoprecipitate is available with Pack 1:

Trauma Pack	Products
1	5 u PRBCs, 5 u plasma, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
2	5 u PRBCs, 5 u plasma, 5-pk platelets, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
3	5 u PRBCs, 5 u plasma, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
4	5 u PRBCs, 5 u plasma, 5-pk platelets, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
5	5 u PRBCs, 5 u plasma, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
6	5 u PRBCs, 5 u plasma, 5-pk platelets, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
7	5 u PRBCs, 5 u plasma, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
8	5 u PRBCs, 5 u plasma, 5-pk platelets, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
9	5 u PRBCs, 5 u plasma, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)
10	5 u PRBCs, 5 u plasma, 5-pk platelets, OPTION for cryo (5 u for fibrinogen <150, 10 u for <100)

* For OB: 10 unites cryoprecipitate (for fibrinogen <200) is available for order on every trauma pack.

Lethal Trauma Triad

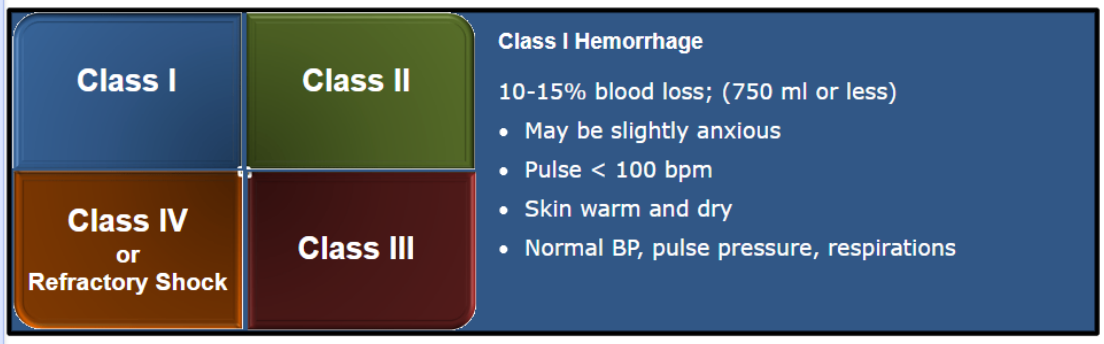
Hypothermia	Coagulopathy	Acidosis
• Reduces enzymatic activity of plasma coagulation proteins, preventing activation of platelets; disrupts coagulation cascade [1] • Onset at core temp of 34°C (93.2°F) and below [1]	• May occur due to activation and consumption of coagulation factors (acute DIC) [1] • Secondary to hemodilution from red cell & crystalloid infusions [1]	• Interferes with assembly of coagulation factor complexes involving calcium & negatively charged phospholipids [1] • Delayed thrombin production → delayed fibrin production → increased risk of fibrinolysis → increased bleeding [1]

1. Cohen, M. & Kutcher, M. (2021, May 28). Coagulopathy associated with trauma. UpToDate. Waltham, MA. Retrieved May 3, 2023, from https://www.uptodate.com/contents/coagulopathy-in-trauma-patients

Classes of Hemorrhagic Shock

Exit

There are 4 classes of hemorrhagic shock.
Please click the button for each class below:



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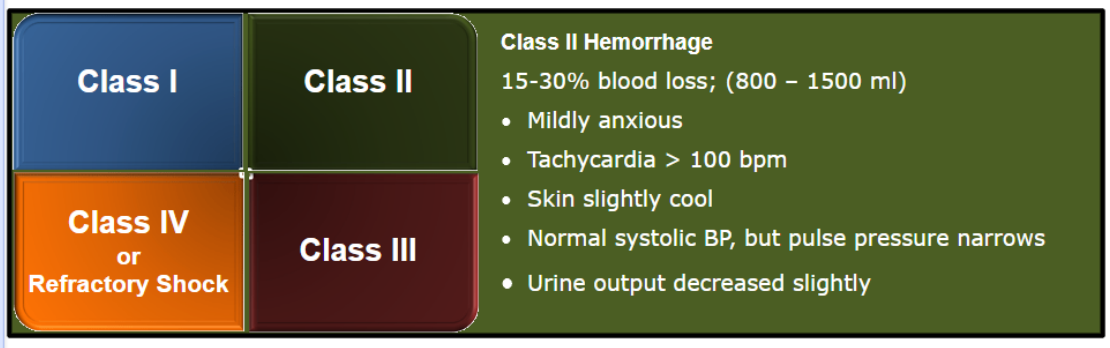

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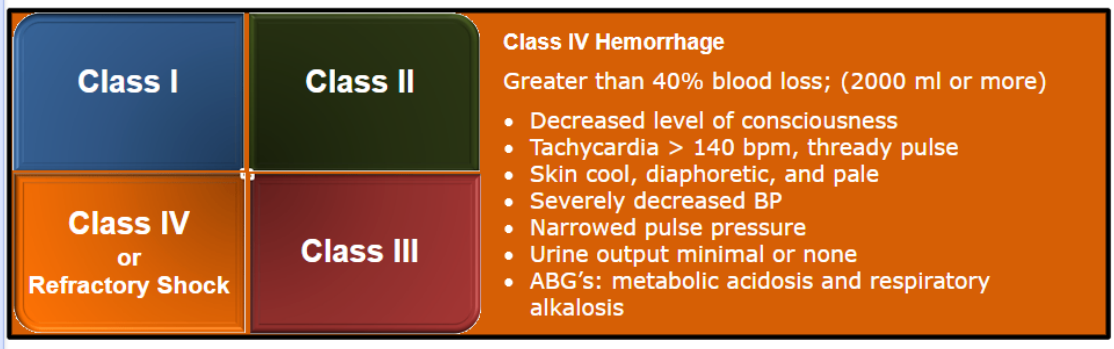

Classes of Hemorrhagic Shock

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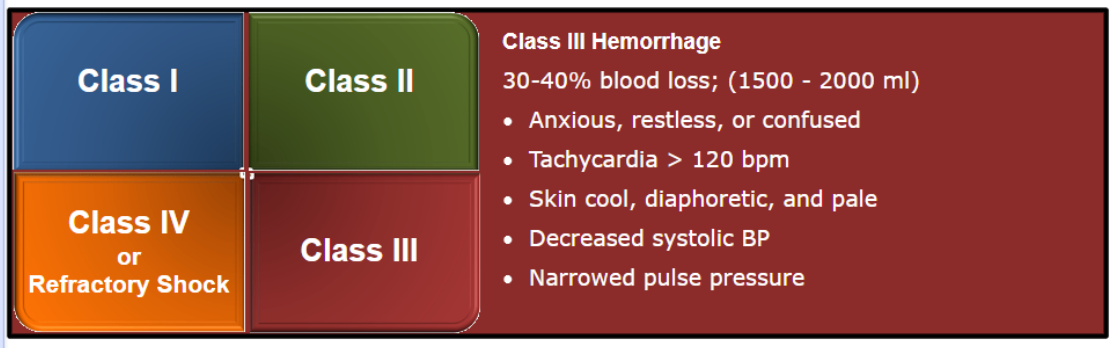
There are 4 classes of hemorrhagic shock.
Please click the button for each class below:



Termination of the Massive Transfusion Protocol

The Physician Team Leader is the only one who can make the decision to terminate the Massive Transfusion Protocol.

Endpoints for termination include:

- Normalization of vital signs
- Normalization/improvement of coagulopathy
- Termination of bleeding
- Failure/futility

When the MTP is terminated, it is essential to call 55555 to announce the status change.

- Various providers and staff are involved, and vital blood products are being prepared and delivered. This announcement is essential for proper allocation and workflow.

Review and Debriefing

- All MTP cases will be reviewed and data collected.
- In certain situations, a follow-up debriefing may occur.
  - Staff can also request a debriefing.
- All staff involved with the case should attend this debriefing.

Cosgriff, N., Moore, E.E., Sauia, A., et al. Predicting life-threatening coagulopathy in the massively transfused trauma patient: hypothermia and acidoses revisited. *J Trauma* 1997; 42: 857-61.

Hess, J.R., Lawson, J.H. The coagulopathy of trauma vs. disseminated intravascular coagulation. *J Trauma* 2006; 60: S12-S19.

Hirshberg, A., Dugas, M., Banez, E., et al. Minimizing dilutional coagulopathy in exsanguinating hemorrhage: a computer simulation. *J Trauma* 2003; 54: 454-61.

Malone, D.L., Hess, J.R., Fingerhut, A. Massive transfusion practices around the globe and a suggestion for a common massive transfusion protocol. *J Trauma* 2006; 60: S91-S96.

Munson Medical Center Policies and Procedures. (2022, November). *Massive Transfusion Protocol.* PolicyStat.

OB Guidelines for Care of Women with Diabetes Complicating Pregnancy

Refer to orders for individualized patient care. Patient's orders supersede any information contained within the reference text.

	Antepartum/ Latent Labor	**Intrapartum**	**Postpartum**
Preadmission	Usual dose of intermediate-acting or long-acting insulin is given at bedtime. Morning dose of insulin is withheld or reduced based upon the timing of admission or delivery.		
Admission	• Obtain POC BG • Document time of last insulin dose or oral medication • Document time and description of last oral intake • Patient on insulin pump: consult pharmacy to complete medication history. Ensure patients has replacement supplies available.		
PowerPlan	OB Diabetic Antepartum-Intrapartum	• OB Diabetic Antepartum-Intrapartum • OB Diabetic Insulin Continuous Infusion – Type 1, Type 2, Gestational DM	• OB Diabetic Postpartum
Diet	• If taking meals, use diabetic diet • In early labor, clear NON CALORIC liquids maybe taken. If carbohydrates are needed, use IV dextrose (Dextrose 5%) as a carb source as ordered, maintained by an infusion. This equals 5 grams dextrose per 100 mL of Dextrose 5%. • If epidural or in labor, clear, non-caloric liquids or NPO per OB and anesthesia		
Target Blood Glucose (BG) Range	When taking meals, BG target is less than 95 mg/dL fasting/premeal; less than 140 mg/dL, 1 hour after meal	BG target **90-110 mg/dL** to optimize fetal oxygenation during labor and prevent newborn hypoglycemia	**GDM:** less than 100 mg/dL fasting/ premeal; less than 140 mg/dL, 1 hr after meal **Type 2 DM and Type 1 DM:** less than 130 mg/dL fasting/premeal

Point of Care (POC) BG Checks	See provider orders, not to exceed more than 4 hours in latent labor	Diabetic women in labor should have BG check **every hour in active labor** (>6 cm and actively contracting). If BG is greater than or equal to 110 mg/dL, check BG every 30 minutes. Notify provider if: **BG is greater than or equal to 110 mg/dL X 2 or 140 mg/dL x1** If on insulin infusion, see *Insulin Infusion Management of the Pregnant Woman with Diabetes*	**GDM**: Check BG once before transfer to PP. If greater than targets100 mg/dL, continue BG checks premeal until they are in the target range. **Type 2 DM**: When taking food, check BG AC & HS; and at 3 AM if taking bedtime basal insulin. **Type 1 DM**: When taking food, check BG AC & HS and 3 AM. • Additionally, check BG just before and 1 hour after breastfeeding begins for the first 3 days postpartum. • If BG is less than 100 mg/dL prior to breastfeeding, a 15-gram carbohydrate snack is. advised to prevent hypoglycemia.

Insulin Infusion Management of the Pregnant Woman with Diabetes

Goal: Target blood glucose (BG) range 90-110 mg/dL to optimize fetal oxygenation during labor and prevent newborn hypoglycemia

DM Type	Gestational DM	Type 2 DM -- insulin alone or with metformin	Type 1 DM -- always needs insulin
IV Therapy *Insulin infusion requires a dedicated IV site and line; must be administered by an infusion pump and label line.* ***A second RN must verify the correct medication, dose, and infusion rate, and check all pump settings and tubing connections before administration.***	• If BG is greater than or equal to 200 mg/dL, Lactated Ringers or 0.9% Sodium Chloride at 125 mL/hr • If BG less than 200 mg/dL, Dextrose 5% Lactated Ringers or Dextrose 5% with 0.45% Sodium Chloride at 125 mL/hr • Notify provider if not already ordered		
Point of Care (POC) BG Checks during Insulin Infusion	BG every 1 hour. If in target range (90-110mg/dL) x 3 consecutive hours, may change to BG every 2 hours. If at any time BG falls outside of target range, resume hourly BG.	BG every 1 hour. If in target range (90-110mg/dL) x 3 consecutive hours, may change to BG every 2 hours. If at any time BG falls outside of target range, resume hourly BG.	BG every 1 hour.
Hypoglycemia *(see protocol)*	Implement orders at BG less than 70 mg/dL Avoid glucagon unless the patient is losing consciousness and IV access is lost		
Managing Hyperglycemia	Call provider to initiate insulin infusion when BG is greater than 110 mg/dL X 2 or greater than 140 mg/dL x1.		
IV Insulin Algorithm *Insulin attaches to the IV tubing therefore, 30 mL of the insulin solution must be flushed through the tubing prior to beginning the insulin infusion.*	See protocol: Insulin Infusion OB Type 2 DM and GDM	See protocol: Insulin Infusion OB Type 2 DM and GDM	See protocol: Insulin Infusion OB Type 1 DM

Initial Postpartum	D/C IV insulin infusion and Dextrose 5% (if any) after delivery of the infant and placenta	Post-delivery: 1. Following delivery of infant and placenta – discontinue IV insulin infusion and dextrose 5% OR decrease current infusion rate by half, per provider order 2. Discontinue OB Insulin Infusion Titration Protocol - Intrapartum Type 2 DM order 3. Obtain BG and then call ordering provider If insulin drip not discontinued at delivery, when able to have a meal, discontinue IV dextrose and IV insulin. Give **1/2** the pregnancy premeal insulin dose (as ordered by provider).	Post-delivery: 1. Following delivery of infant and placenta - decrease current infusion rate by half 2. Discontinue OB Insulin Infusion Titration Protocol - Intrapartum Type 1 DM order 3. Obtain BG and then call ordering provider When able to have a meal, discontinue IV dextrose and IV insulin. Give **½** the pregnancy premeal insulin dose (as ordered by provider). Long-acting insulin should be given 1-2 hours prior to discontinuing drip (50% of pregnancy dose)

References

American College of Obstetricians and Gynecologists. (2018). Practice Bulletin No. 201: Pregestational diabetes mellitus. *Obstetrics and Gynecology, 132*(6):e228-e248. doi: 10.1097/AOG.0000000000002960.

Dude A, Niznik CM, Szmuilowicz ED, Peaceman AM, Yee LM. Management of Diabetes in the Intrapartum and Postpartum Patient. Am J Perinatol. 2018; 35(11): 1119-1126. doi:10.1055/s-0038-1629903.

Owner: OB Section. Prior versions exist.
Updated/reviewed: OB section Aug. 2024; MMC P&T Committee Aug. 2025
Reference text attached to: OB Diabetic Antepartum-Intrapartum and OB Diabetic Postpartum

Nursing – OB Antepartum/Intrapartum/Postpartum Insulin Monitoring Instructions

General Information

- These plans are used for patients who have Gestational, Type 1 or Type 2 diabetes.
    - Gestational
    - Type 1: Diabetes with no insulin production, these patients need to be on insulin immediately. Oral medications are not used in Type 1 diabetes.
    - Type 2: Diabetes in which insulin is made by the pancreas but there is insulin resistance
- For blood glucose less than 70 mg/dL, follow Hypoglycemia Management Protocol – Adult (unless on intravenous insulin infusion, then follow instructions in continuous infusion protocol).

Target Blood Glucose Levels

- Antepartum
    - Target range for blood glucose less than 95 mg/dL (fasting) and less than 140 mg/dL one hour after meals
    - Call Provider if blood glucose is greater than 200 three times in 24 hours
- Intrapartum
    - Target blood glucose range 90-110 mg/dL
- Postpartum
    - For Type 1 and Type 2 Diabetes, target range for blood glucose less than 130 mg/dL (fasting) and less than 180 mg/dL one hour after meals
    - For Gestational Diabetes, target range for blood glucose less than 100 mg/dL (fasting) and less than 140 mg/dL one hour after meals
    - Call Provider if blood glucose is greater than 300 mg/dL or less than 70 mg/dL

Insulin Instructions

- **Basal Insulin** - Long acting insulin to reproduce endogenous insulin that is normally produced by the pancreas 24 hours per day in those without diabetes
    - Basal insulin is still GIVEN even if the patient is NPO, on clear liquids, or eating less than 50% of meal
    - Basal insulin is still GIVEN regardless of blood glucose level
- **Nutritional /Meal-Time Insulin** - Short acting insulin to balance the carbohydrate intakewith meals. Sole purpose of nutritional insulin is to prevent postprandial hyperglycemia.
    - Nutritional insulin should be HELD if the patient is NPO or not eating for any reason
    - Fixed dose nutritional insulin should be held or adjusted per provider order if patient is eating less than 50% of a meal. Carbohydrate based insulin can still be given based on the actual carbohydrates consumed.
    - Administer as close to the meal as possible. If meal intake is uncertain, may consider administering immediately after the meal.
    - Nutritional and Correctional insulin doses should be added together so that the patient receives ONE injection
    - Basal Insulin and Nutritional/Meal time (bolus) Insulin mimic the natural pattern of endogenous insulin secretion
- **Correctional Insulin** - Additional short acting insulin used to make small corrections and bring blood glucose back to target, if needed

- The provider will order the appropriate correctional scale at the desired frequency. The nurse should check a fingerstick blood glucose to determine the correctional insulin dose per the correctional scale, even if patient uses a continuous glucose monitor (CGM).
- Nutritional and Correctional insulin doses should be added together so that the patient receives ONE injection
- Correctional insulin should still be GIVEN if patient is NPO or refusing food for any reason
- ***Postpartum insulin doses should be decreased 50% from the antepartum dose***

Fingerstick Blood Glucose Instructions

- The frequency of the Correctional Insulin order will determine the frequency of the fingerstick blood glucose checks that are to be covered with the correctional insulin. The Correctional scale frequency will drive the fingerstick blood glucose check
- The provider may order additional fingerstick blood glucose to be checked but not covered. These glucose checks with no coverage may occur at HS or 3 am if ordered.
- The provider should be notified if the blood glucose is greater than 300 mg/dL. Follow thehypoglycemia protocol and notify provider if less than 70 mg/dL.

Owner: Maternity Section

Reference Text created on 05/03/2012; reviewed and updated on 03/16/2020, 9/9/2024

Reference Text attached to the following Order:
Nursing - OB Antepartum/Intrapartum/Postpartum Insulin Monitoring Instructions

Obstetric Hemorrhage Guidelines

	Assessments	Meds/Procedures	Blood Bank
Stage 0	**All births- Every woman in labor/giving birth**		
• Risk assessment • Active management of 3rd stage	• Prepare for every patient according to hemorrhage risk factors • Measure quantitative cumulative blood loss for every birth	• **Active Management of 3rd Stage** • **Oxytocin** IV infusion or 10u IM • **Fundal massage**	• **Medium Risk:** GTABS, 0 units • **High Risk:** GTABS, 2 units • **Positive Antibody Screen** (prenatal or current, exclude low level anti-D from RhoGam): GTABS, 2 units
Stage 1	**Triggers: CBL ≥ 500mL vaginal / ≥ 1000 mL cesarean with *continued bleeding* or Signs of concealed hemorrhage: VS abnormal or trending (HR ≥ 110, BP ≤ 85/45, O2 sat < 95%, shock index 0.9) or Confusion**		
• Activate hemorrhage protocol • Rule out hemorrhage causes besides atony	• Nurse to enter per **protocol OB Postpartum Hemorrhage: Stage 1 Protocol PowerPlan** • Notify charge nurse, OB/ CNM, anesthesiologist • VS q5 min • Continuous O2 Sats • Record quantitative cumulative blood loss q5-15 min • Careful inspection with good exposure of vaginal walls, cervix, uterine cavity, placenta. If intra-op, inspect broad ligament, posterior uterus and placenta.	• **IV Access: Minimum 18 gauge** • Increase IV fluid (LR) and **oxytocin** rate • **Fundal/bimanual massage** **MOVE ON** to 2nd level uterotonic if no response (see Stage 2 meds below) • Empty bladder: Straight cath or Foley with urometer • Keep patient warm	• **Convert to High Risk and take appropriate precautions** Consider GTABS, 2 Units PRBCs *where clinically appropriate if not already done*

Important Phone Numbers:	Anesthesia: Switchboard	Lab: 56100
Blood Bank: 56115	Pharmacy: 56581	MRT: 55555
Massive Transfusion Protocol Team: 55555	ICU PCC/Charge RN: 33001 OB Charge RN: 33320	ED Charge RN: 33420 Nursing Supervisor: 56203

Adapted from CMQCC Appendix C Obstetric Hemorrhage Care Guidelines 7/2022. Approved by P&T and OB Section. 2023
Updated 11/15/2023

Stage 2	Triggers: ***Continued bleeding*** **w/ CBL < 1500 mL or VS remain abnormal**		
• Sequentially advance through medications and procedures • Mobilize team and blood bank support • Keep ahead with volume and blood products • Determine source of bleeding **including concealed hemorrhage**	• **OB provider to bedside** • OB provider to order or give VO for **OB Postpartum Hemorrhage: Stage 2 PowerPlan** • **Extra help:** 2nd OB, OB Rapid Response, assign roles • Continue VS & record **cumulative** quantitative blood loss q5-15 min • Weight bloody materials • **Complete evaluation** of vaginal wall, cervix, placenta, uterine cavity • Send additional labs including DIC panel • Evaluate for special cases: - Uterine inversion - Amniotic fluid embolism	• **2nd Level Uterotonic, *with order from provider:*** - **Methylergonovine** 0.2mg IM every 2hr: max of 5 doses(*if no HTN)* or - **Carboprost** 250 mcg IM every 20 mins: max of 8 doses (*if no asthma*) or *Only if hypertensive and asthmatic* - **Misoprostol** 800 mcg SL or 600 mcg PO or 1000 mcg PR • **Tranexamic Acid** 1gm- may repeat in 30mins • **2nd IV access** (minimum 18 gauge) • Oxygen 5-7 LPM via tight face mask • Bimanual/uterine massage • **Vaginal:** (typical order) - Move to OR - Repair any tears - D&C: r/o retained placenta - Place intrauterine balloon - Place intrauterine vacuum induced hemorrhage control device - Selective Embolization (Interventional Radiology) • **Intra-op Cesarean:** (typical order) - Inspect broad ligament, posterior uterus, and placenta - Uterine sutures - Place intrauterine balloon - Place intrauterine vacuum induced hemorrhage control device - Uterine artery ligation	• **Notify Blood Bank of OB hemorrhage, 56115** • Bring 2 Units PRBCs to bedside, consider use of **Emergency Release products** (un-crossmatched) and transfuse per clinical signs **–** *do not wait for lab values* • PT, PTT, Fibrinogen STAT • Consider thawing 2 FFP (takes 35+mins), use if transfusing >2u PRBC's • Determine availability of additional RBCs and other Coag products • Use blood warmer for transfusion • Consider activating MTP if there is ***continued bleeding*** ***Blood Bank Location:*** Go past cafeteria, to D elevators, turn to your left and take the stairs to the second floor. Exit stairwell and turn right, past elevators, through glassed-in lab area entrance door. Inside, blood bank is first door on right. Bring patient stickers w you.

Adapted from CMQCC Appendix C Obstetric Hemorrhage Care Guidelines 7/2022. Approved by P&T and OB Section. 2023
Updated 11/15/2023

Stage 3	Triggers: ***Continued bleeding*** **with CBL > 1500mL or > 2 units PRBCs given or abnormal VS or Suspicion of DIC**		
• Initiate Massive Transfusion Protocol • Invasive surgical approaches	• **Expand team,** *may include:* - Advanced GYN surgeon - 2nd anesthesia provider - OR staff (56301) - Adult intensivist • **Repeat** coags & ABGs, electorlytes (included in MTP PowerPlan) • Central line • Family support/MSW • **Primary nurse:** - - Announce VS and QBL q 5-10mins - -Upper body warming if feasible - SCD's - Circulate in OR • Second nurse and/or anesthesiologist: - Continue to administer meds, blood products and draw labs as ordered • Third Nurse (or charge): - Recorder	• Activate Massive Transufion Protocol, enter **MTP for Traumatic Injury PowerPlan** - Call switchboard for **Massive Transfusion Protocol** team page at 55555 - Trauma provider/anesthesia to run MTP. ED and ICU RN to run rapid infuser. • Selective embolization (IR) • Laparotomy - Uterine sutures - Uterine artery ligation - Hysterectomy • Patient support - Warmer for IV fluids - Upper body warming device - SCDs	• **Transfuse aggressively** • MTP pack, lab brings first pack - Near 1:1 PRBC: FFP - 1 PLT apheresis pack per 4-6 units PRBCs • **Unresponsive Coagulopathy**: After 8-10 units PRBCs and coagulation factor replacement with ongoing hemorrhage, may consider risk/benefit of rFactor VIIa in consultation with hematologist or trauma surgeon
Once Stabilized: Modified Postpartum Management with increased surveillance; consider ICU			

Step-by-Step Instructions for use of the Massive Transfusion Protocol: Maternity

1. **Anesthesia or OBGYN** initiates the MTP
    a. **Anesthesia or Trauma APP** supervises the clinical team during the MTP
    b. Anesthesia/ RN *(identify one person to be contact person)* maintains communication with blood bank during the initiation and maintenance of MTP
    c. Anesthesia communicates with the Pharmacy regarding the need for NOVO-Seven
    d. Anesthesia/ OBGYN will communicate the need to go to the ICU with the staff within those areas
2. OB RN puts in the verbal order for the MTP Powerplan titled *Massive Transfusion for Traumatic Injury*
    a. RN notifies the blood bank
    b. OB RN remains primary nurse and documents on Powerchart and/ or SurgiNet
    c. RN notifies the OB Charge Nurse of the initiation of the MTP
        i. Charge RN calls switchboard (dial "55555") for MTP burst page and states **"Massive Transfusion Protocol Team to Maternity"**
            1. MTP page sent to: ED RN, ICU RN, OR charge RN, trauma team, lab, pharmacy, nursing supervisor, blood bank
        ii. Charge RN notifies Unit Clerk who will watch for the MTP team to arrive and direct them where to get coveralls for the OR and which room to go to
        iii. NA in OB brings the spacelab monitor to the room, if MTP occurs in the patient room
3. ED and ICU RN prepares for rapid fluid and blood administration – **ED RN to bring Level One Rapid Infuser to OB**
    a. ED and ICU RNs maintain the documentation on the MTP flow record (*located in blue packet on top of cart*) and maintain blood product and fluid transfusions
4. Blood bank delivers the 1st trauma pack/cooler to OB. All subsequent blood product pick-ups, OB Unit Assistant/ Runner to obtain from blood bank. Runner to bring signed (by the Physician or designee) trauma lab slip, found in pocket of MTP folder. If an OB Unit Assistant is not available, OB Charge Nurse will designate a runner.
    a. OB Unit Assistant, or designated runner, remains in OB OR for further instruction
5. OB Charge Nurse
    a. OB Charge Nurse will communicate the need for extra resources to the Nursing Supervisor
    b. OB Charge Nurse will ensure the transfer of the blood products from the tube station to the OB OR
6. Process for Lab Techs
    a. Confirm patient ID# (Actual or Doe)
    b. STAT coagulation profile: PT, PTT, Fibrinogen, Hemoglobin, Platelet count, quantitative D-Dimer, Fibrin degradation product
    c. Type and Cross (GTAB)
    d. Basic Metabolic Profile, ABG's, and lactate
7. Serial Lab Process
    a. Repeat every 30 minutes until discontinued by clinical team
    b. Include CBC, PT, PTT, Fibrinogen, Lactate, BMP, and ionized calcium

Updated 6/29/2023

MUNSON MEDICAL CENTER
MUNSON HEALTHCARE

Newborn Hypoglycemia Screening and Management Protocol

Who to Screen:

- Any symptomatic infant
- Small for gestational age (SGA); less than 10th percentile (WHO growth chart) term infants, Fenton for <37wks
- Large for gestational age (LGA); greater than 90th percentile (WHO growth chart) term infants, Fenton for <37wks
- If unknown dates, infants weighing <2500 grams or >4500 grams
- Infant born to mothers with any diabetic condition
- Late preterm (born at 34 – 36 6/7 weeks gestation)

Birth to 4 hours

Symptomatic

Irritability, tremors, jitteriness, exaggerated Moro reflex, high- pitched cry, seizures, lethargy, floppiness, cyanosis, apnea, poor feeding, hypothermia

Check STAT glucose and call the provider; IV glucose indicated if **< 40 mg/dL** and symptomatic, direct admission to NICU

Asymptomatic, at risk infant

INITIAL FEED WITHIN 1 hour: at least 15-30 mL*, or 10 minutes observed vigorous breastfeeding
**May be mother's pumped breast milk, donor breast milk with parent consent, or formula.*
Initiate pumping if donor milk given.
Screen glucose 30 minutes after conclusion of 1st feed

If initial screen **less than 25:**

- Give 40% glucose gel per infant weight
- Order stat serum glucose; OB RN Lab Superuser to draw
- **Call provider with bedside glucose level**
- Refeed **at least 15-30 mL*, or 10 minutes observed vigorous breastfeeding**
  - **May be mother's pumped breast milk, donor breast milk with parent consent, or formula. Initiate pumping if donor milk given.*
- Check blood glucose 1 hour after glucose gel
  - **If rescreen is:**

< 25 mg/dL
Direct admit to NICU. RN to call NICU provider.

25-40 mg/dL

- Give 40% glucose gel per infant weight
- Refeed **at least 15-30 mL***
  - **May be mother's pumped breast milk, donor breast milk with parent consent, or formula*
- Check blood glucose 1 hour after glucose gel

See 4-24 hours algorithm**

If initial screen is **≥ 25:**

- Encourage skin-to-skin
- Ensure frequent feedings, not to exceed 3 hours between feedings. Feeding time starts at beginning of feed.
- Check AC chem before next feeding

See 4-24 hours algorithm

40% Glucose Gel Administration

Scan 40% glucose gel. Draw up weight based dose from medicine cup using oral syringe. Dry buccal mucosa with 3x3 gauze. Place portion of gel on a latex-free gloved finger and then massage into the buccal mucosa. Repeat process, alternating sides, until the complete weight based dose is administered. Dispose of remaining glucose gel.

Infant's weight*	40% glucose gel dose
1.50-1.74 kg	0.75 mL
1.75- 2.24 kg	1 mL
2.25- 2.74 kg	1.25 mL
2.75- 3.24 kg	1.5 mL
3.25- 3.74 kg	1.75 mL
3.75- 4.24 kg	2 mL
4.25- 4.74 kg	2.25 mL
4.75- 5.24 kg	2.5 mL
5.25- 5.74 kg	2.75 mL

Infant's weight*	40% glucose gel dose
1.50-1.74 kg	0.75 mL
1.75- 2.24 kg	1 mL
2.25- 2.74 kg	1.25 mL
2.75- 3.24 kg	1.5 mL
3.25- 3.74 kg	1.75 mL
3.75- 4.24 kg	2 mL
4.25- 4.74 kg	2.25 mL
4.75- 5.24 kg	2.5 mL
5.25- 5.74 kg	2.75 mL

Newborn Hypoglycemia Screening and Management Protocol

4-24 hours

Symptomatic

Irritability, tremors, jitteriness, exaggerated Moro reflex, high-pitched cry, seizures, lethargy, floppiness, cyanosis, apnea, poor feeding, hypothermia

Check STAT glucose and call the provider; IV glucose indicated if **< 40 mg/dL** and symptomatic, direct admission to NICU

Asymptomatic, at risk infant

Continue feeds every 2-3 hours at least 15-30 mL*, or 10 minutes observed vigorous breastfeeding
**May be mother's pumped breast milk, donor breast milk with parent consent, or formula. Initiate pumping if donor milk given.*
*** If one hour post glucose gel administration, proceed to results below:*
Screen glucose prior to each feed

< 35 mg/dL

- Give 40% glucose gel per infant weight
- Order stat serum glucose; OB RN Lab Superuser to draw
- **Notify provider, may consider IV glucose**
- Refeed **at least 15-30 mL*, or 10 minutes observed vigorous breastfeeding**
  - **May be mother's pumped breast milk, donor breast milk with parent consent, or formula*
- Recheck blood glucose 1 hour after glucose gel
  - If glucose level remains less than 45 mg/dL, **notify provider**

If recheck is **<35 mg/dL**, admit to NICU

If recheck is **35-45 mg/dL**, refeed or admit to NICU per provider order

≥ 35

- **Feed at least 15-30 mL*, or 10 minutes observed vigorous breastfeeding**
- Encourage skin-to-skin
- Ensure frequent feedings, not to exceed 3 hours between feedings. Feeding time starts at beginning of feed.
- Check AC chem before next feeding

- **Continue pre-feed screening until:**

IDM or LGA Infant

- Continue pre-feed screening every 2-3 hours until 3 consecutive glucose ≥ 45 mg/dL and over 12 hours of age
- If infant has not met above criteria by 12 hours of age, notify provider who may consider NICU consult

SGA or Late Preterm Infant

- Continue pre-feed screening every 2-3 hours until 3 consecutive glucose ≥45 mg/dL and over 12 hours of age
- Reassess pre-feed glucose ~24 hours of age.
- If infant has not met above criteria by 24 hours of age, notify provider who may consider NICU consult

May administer max of three doses of 40% glucose gel in 24 hours. If infant requires third dose of glucose gel, administer gel and notify provider for further orders.

If greater than 24 hours and infant unable to maintain glucose ≥45 mg/dL, notify provider for further orders.

Approved by Pharmacy & Therapeutics 4/8/2019; updates approved by Pediatric Section 5/2024

Status Active PolicyStat ID 16540943

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Origination	6/3/2013
Last Approved	11/8/2024
Effective	11/8/2024
Last Revised	11/8/2024
Next Review	11/8/2027
Owner	Angela Simmonds: Resource Clinician
Area/ Department	Women & Children Services
Applicability	MMC
Tags	Guideline

Newborn Hypoglycemia Screening and Management Guideline

Purpose

Identification and management of newborns at risk for hypoglycemia.

Definition

A. **Glucose Gel Background:** Glucose gel mobilizes the newborn's own glucose stores together with breastfeeding, expressed breast milk or formula which increase blood glucose levels. Glucose gel is used for the management of asymptomatic hypoglycemia in newborns of diabetic mothers, large for gestational age, late preterm and small for gestational age newborns.

Guideline

A. See attachment for *Newborn Hypoglycemia Screening and Management Protocol*

B. All well newborns will be fed within 1 hour of birth. Sustained skin-to-skin contact with the mother is recommended for all newborns to support bonding, breastfeeding, and newborn thermoregulation.

C. All newborns will be weighed shortly after birth, after allowing time for feeding and skin-to-skin. Using the WHO Growth Chart for term, the newborn will be determined to be small, appropriate, or large for gestational age based on percentile. The Fenton Growth Chart will be used for infants less than 37 weeks.

D. Careful monitoring for the symptoms of neonatal hypoglycemia is required for all newborns. These symptoms are not specific to hypoglycemia, however, and may be present in newborns

with other clinical conditions (e.g., infection). Any newborn displaying symptoms should have a glucose level immediately checked with a bedside monitor. These symptoms include: irritability, tremors, jitteriness, exaggerated Moro reflex, high-pitched cry, seizures, lethargy, floppiness, cyanosis, apnea, poor feeding, hypothermia.

E. The following newborns are considered at risk for neonatal hypoglycemia, and will receive bedside blood glucose checks regardless of symptoms. At-risk newborns include those who are:
    1. Small for gestational age (SGA), less than the 10th percentile, based on the WHO growth chart
    2. Large for gestational age (LGA), greater than the 90th percentile, based on the WHO growth chart
        a. If unknown dates , less than 2500 grams or greater than 4500 grams
    3. Born to mother with any diabetic condition
    4. Late preterm (born at 34 – 36 6/7 weeks gestation)

F. Newborns who are asymptomatic and not at risk do not require routine blood glucose checks

Procedure for At-Risk Newborns

Symptomatic Newborn

A. If the newborn is symptomatic at any time, immediately check glucose with a bedside monitor. **If the level is less than 40 mg/dL,** feed infant and immediately contact Neonatologist or Neonatal Nurse Practitioner for a direct admit to the neonatal intensive care unit (NICU), and anticipate orders for intravenous (IV) glucose (to be started in NICU).

Asymptomatic Newborn, Birth to 4 Hours of Age

A. If the at-risk newborn is asymptomatic, perform an initial glucose screen 30 minutes after conclusion of the initial feeding

B. If initial screen is **less than 25 mg/dL**, nurse to administer weight-based dose of 40% glucose gel to the neonate's buccal cavity, order stat serum glucose, call provider with bedside glucose level, refeed infant at least 15-30 mL (may be mother's pumped breast milk, donor breast milk with parent consent, or formula), or 10 minutes observed vigorous breastfeeding. Recheck glucose level 1 hour after gel administration. Initiate pumping if donor breast milk given.
    1. If the **second glucose** result is **less than 25 mg/dL**, immediately contact the NICU provider for direct admission to the NICU
    2. If the **second glucose** is **25 to 40 mg/dL**, nurse to administer weight-based dose of 40% glucose gel to the neonate's buccal cavity and refeed infant at least 15-30 mL (may be mother's pumped breast milk, donor breast milk with parent consent, or formula). Recheck glucose level 1 hour after gel administration.
        a. Move to 4-24 hours algorithm

C. If initial screen is **25 mg/dL or greater**: encourage skin-to-skin positioning, ensure frequent

feedings not to exceed 3 hours between feedings, and check AC glucose level before next feeding

Asymptomatic Newborn, 4 to 24 Hours of Age

A. Continue to feed the at-risk newborn every 2 to 3 hours, at least 15-30 mL (may be mother's pumped breast milk, donor breast milk with parent consent, or formula), or 10 minutes observed vigorous breastfeeding. Check glucose levels prior to each feed. The target glucose level before routine feedings is 45 mg/dL or greater.

B. If the glucose level is **less than 35 mg/dL**, nurse to administer weight-based dose of 40% glucose gel to the neonate's buccal cavity, order stat serum glucose, notify provider who may consider IV glucose, refeed infant at least 15-30 mL (may be mother's pumped breast milk, donor breast milk with parent consent, or formula), or 10 minutes observed vigorous breastfeeding. Recheck glucose level 1 hour after gel administration.

    1. If the repeat glucose level remains **less than 45 mg/dL**, notify the newborn's care provider.

C. If the glucose level is **35 mg/dL or greater**, encourage skin-to-skin positioning, ensure frequent feedings not to exceed 3 hours between feedings, and check AC glucose level before next feeding

D. Continue pre-feed glucose screenings every 2-3 hours for the at-risk newborn until a target value of **45 mg/dL or greater** is obtained at least 3 times consecutively and until at least 12 hours of age. **In addition**, for newborns who are SGA or late preterm, reassess a pre-feed glucose at approximately 24 hours of age.

40% glucose gel administration

A. Scan 40% glucose gel.

B. Squirt glucose gel into medicine cup.

C. Draw up weight based dose from medicine cup using oral syringe (see dosing chart located on the *Newborn Hypoglycemia Screening and Management Protocol*).

D. Dry buccal mucosa with 3x3 gauze. Place portion of gel on a latex-free gloved finger and then massage into the buccal mucosa.

E. Repeat process, alternating sides, until the complete weight based dose is administered.

F. Dispose of remaining glucose gel.

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A. Association of Women's Health, Obstetric and Neonatal Nurses. (2018). Newborn Blood Glucose Monitoring. *Templates for protocols and procedures for maternity services* (4th ed.). Washington, DC: AWHONN.

B. Bennett, C., Fagan, E., Chaharbakhshi, E., Zamfirova, I., & Flicker, J. (2016). Implementing a protocol using glucose gel to treat neonatal hypoglycemia. *Nursing for Women's Health, 20*(1), p.64-74.

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Approvals
Pediatric Section 09/17/2021
Pharmacy & Therapeutics 04/08/2019

Document ID: 088.G001

Attachments

Newborn Hypoglycemia Screening and Management Guideline

Approval Signatures

Step Description	Approver	Date
System Policy Oversight Committee	Terri Fries: Document Mgmt Spec	11/8/2024
VP and CNO Patient Care Services	Tamara Putney: VP and CNO Patient Care Services	11/4/2024
Mgr Nursing Services	Nicole Matters: Dir Nursing Women & Children's & Acute Care	11/4/2024
Document Owner	Angela Simmonds: Resource Clinician	10/8/2024

Applicability

Munson Medical Center

Standards

No standards are associated with this document

Nitronox Plus

50/50 Oxygen/Nitrous Oxide System Training

Parker

PORTER
The Trusted Name In Nitrous

Presented by:
Linde Gas & Equipment, Inc.,
an authorized distributor

Training Agenda

- NitroNox Plus Set Up
  - Equipment
  - 6-Step Set Up Process
- Post Use
- Cylinder Maintenance
  - Cylinder Maintenance
  - Safety Features
- Nitrous Oxide Use

Equipment Setup

- Nitronox Plus
  - Includes cart, regulators, and hoses
  - Cylinder or wall-supplied gas
- Keys
- Disposable circuit and mask

6-Step Set Up Process

1. Obtain, insert, and turn keys
2. Connect nitrous oxide source
3. Connect oxygen source
4. Connect vacuum/WAGD source
5. Assemble disposable patient circuit
6. Check pressure gauges

Step 1 - Insert key and turn to on

- Off position
  - No N2O
  - Yes 100% O2
- On position
  - Yes 50% N2O
  - Yes 50% O2

Step 2 - Connect Nitrous Oxide

- Suggested to use two nitrous oxide cylinders: primary and backup
- Open primary or in-use cylinder
- To open a closed cylinder, place cylinder wrench on top of cylinder and turn to the left (counterclockwise)
  - “righty tighty/lefty loosey”
- Nitrous oxide tank pressure on regulator should read 750 psi

If using wall-supplied nitrous oxide, utilize appropriate gas hose and quick connect.

Step 3- Connect to Oxygen

- Connect green oxygen hose to wall source oxygen

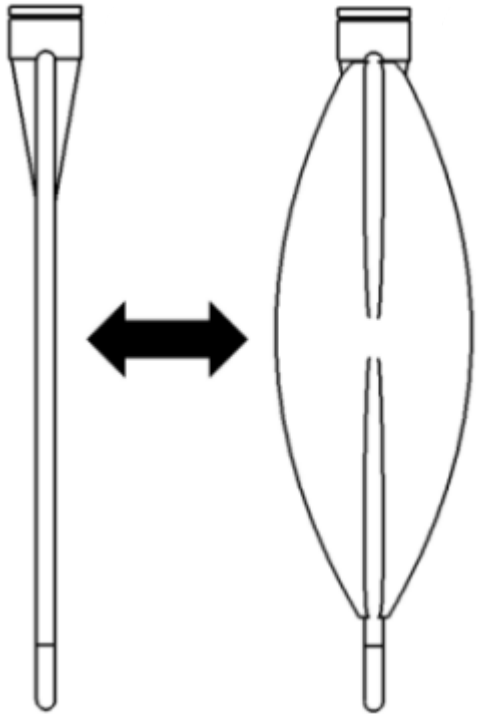
Step 4 - Connect to Vacuum Source

- Connect gray vacuum hose from the barbed outlet connector on the scavenger interface to the wall source vacuum (or WAGD)
- Confirm grey reservoir bag is hanging off correct port

Scavenger System Use

- Turn Flow Control Knob on Scavenger System until the pressure is within vacuum gauge
  - (-3 to -8 inHg)

- Reservoir bag will slightly inflate upon <u>exhalation</u>
  - Pressure should be at the lowest setting to allow complete deflation between breaths.
  - If bag accumulates gas, adjust vacuum flow.



Disposable Circuit

- Ideal infection control – single patient use disposable
- Packaged ready for use
- Dual limb circuit – standard use in anesthesia
- 4 mask size options

Step 5 - Connect Disposable Patient Circuit

Attach blue hose to mixed gas output

Connect pink hose of the disposable breathing circuit to scavenger interface

Attach mask to “tee” piece

Step 6 Check Pressure Gauges

Pressure Gauges

O_2 Mixed N_2O

- Oxygen and Nitrous Oxide should both be into the green zone 45-60 psi
  - Outside of the green zone? Pull the system from use
- Mixture Pressure should read in the green zone 30-40 psi
  - In red zone? Pull the system from use

NitroNox Plus
Ready for Patient Use

Post Use

- Close “in-use” cylinder first
  - Turn cylinder wrench to the right (clockwise) until met resistance
- Discard breathing circuit
- Disconnect wall sources
- Wipe down equipment
- Lock and store the equipment in locked area
- Return key to locked area

Post Use Cont.

- N_20 cylinder pressure gauge will stay at 750 psi
- N_20 line pressure gauge will stay up into the green zone 45-60psi
- No natural bleed
- Holding pressure = airtight equipment

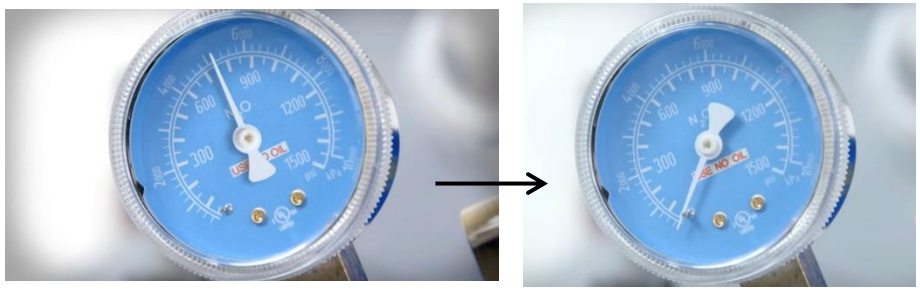
Cylinder Maintenance

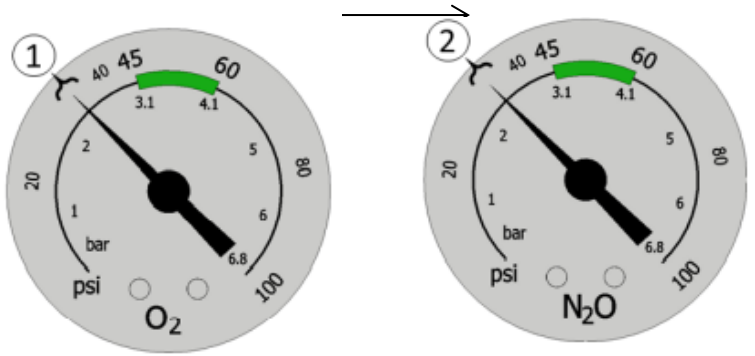
Emptying Nitrous Oxide Cylinder

Two (2) Visual Cues

1. Nitrous Oxide Tank Pressure gauge drops from 750 to 0 in < 5 minutes

2. Alarm sounds when either O_2 or N_2O line pressure drops below 35 psi





Cylinder Safety

- Close cylinders after every use
  - “Righty tighty” until you meet resistance
- Ensure cylinder is closed before removing from regulator

Removing Regulator

Twist T-handle until you can slide the regulator up and off of the empty cylinder.

Yoke Washers

Evaluate the rubber yoke washers. Damaged? Replace.
Intact? Reusable.
Only use rubber yoke washer.

Yoke Valve
Pin Index Connection

Gas Specific

Safety Features

- Fail safe
  - Nitrous oxide will not flow without oxygen
- Diameter Index hoses
  - Prevents cross connection of gases
- PIN index e-cylinder cart
  - Prevents cross connection of gases
- Emergency Air Entrainment Valve
  - Anti-suffocation valve

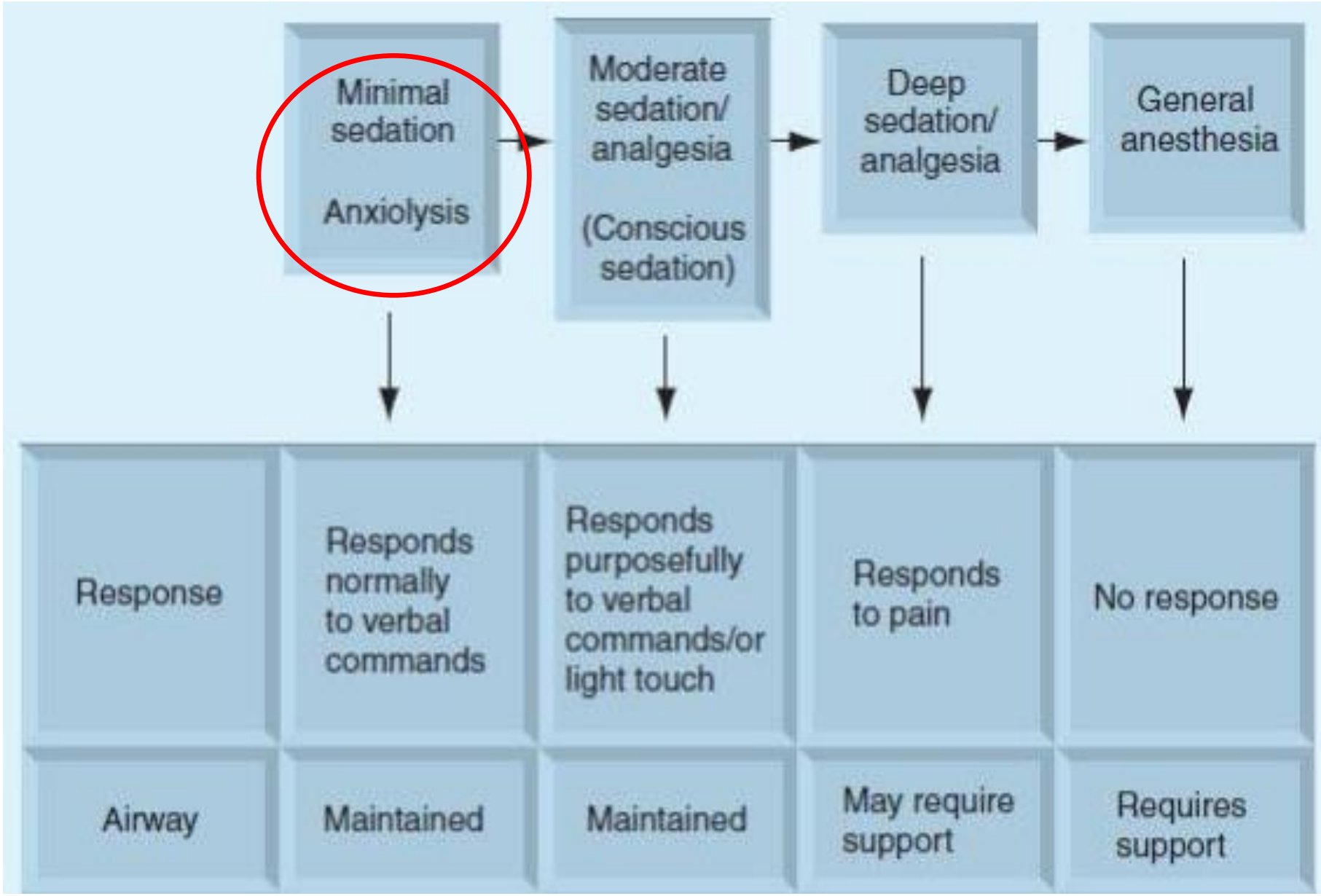
Nitrous Oxide Use

What is Nitrous Oxide (N_20)?

- Colorless, odorless gas
  - *Some will say "sweet smelling"*
- Non-Flammable
- Absorbed by Inhalation – Fast Onset
  - ***Not Metabolized – 0.04%***
- Eliminated via lungs – Exhalation – Short Half Life
- Mild Analgesic with Amnestic Properties
  - ***<u>Will not eliminate pain</u>***
- Helps patient disassociate from pain
  - *Floating, tingling, heavy, etc…*
- Adverse Reactions – dizziness, nausea, vomiting, headache

Benefits of Using N_2O / O_2

- Analgesia, Pain Management, Minimal Sedation
  - *Additional Option / "Tool"*
- Long track record of use and safety
- Easy to Administer
  - *Equipment Safe and Simple To Use*
- Fast Acting
  - *<1-2 minutes*
- Short Duration of Effect: <3-5 minutes
  - *Doesn't stay in system for "hours"*
- Few Contraindications and *Few Side Effects*


Minimal sedation
Anxiolysis
Moderate sedation/ analgesia
(Conscious sedation)
Deep sedation/ analgesia
General anesthesia
Response
Responds normally to verbal commands
Responds purposefully to verbal commands/or light touch
Responds to pain
No response
Airway
Maintained
Maintained
May require support
Requires support

NitroNox Plus

Manufactured by Porter Instrument, a division of Parker Hannifin

Linde Gas & Equipment, Inc. is an authorized distributor

Contacts

Sales & Education: Jackie Krall
Jackie.Krall@linde.com

Customer Service:
LG.US.infohealtheast@linde.com

NITRONOX PLUS®

Demand Flow Nitrous Oxide & Oxygen Systems

50/50 Fixed O_2/N_2O

0-50% Adjustable N_2O

0-70% Adjustable N_2O

PORTER

The Trusted Name In Nitrous

The next generation of Nitronox® features a sleek new design and a choice of fixed or adjustable nitrous oxide, PLUS so much more!

The solution you have been asking for is here.

The Nitronox® name is synonymous with quality and the ability to effectively reduce patient pain and anxiety during minimally invasive medical procedures. Nitronox Plus builds on decades of that success and is the culmination of years of gathering user feedback to design a device that offers healthcare professionals the functionality they've asked for.

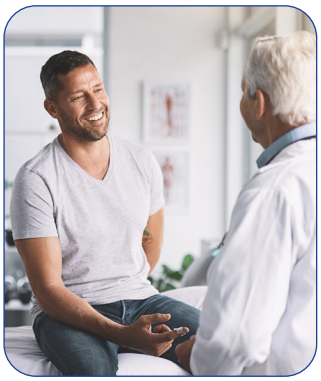
Adjustable nitrous oxide in a demand flow system now available.

Previously, demand flow systems only offered a fixed 50/50 mixture while continuous flow systems offered the ability to adjust the percentage of nitrous oxide. Porter has taken the benefits of an adjustable continuous flow system and combined them into a new demand flow system that allows for a predictable patient experience. Now available are options that offer 0-50% or 0-70% adjustable nitrous oxide along with a new 50/50 fixed system. These 3 new models allow you to choose the system that best fits your needs. Regardless of application, Nitronox Plus has the right option for you.

Demand flow system wtih enhanced features.

Nitronox Plus provides healthcare professionals with features not available in other demand flow systems.

- Designed for use with children and adults
- Available in fixed or adjustable mixture concentration models
- Key lock mechanism for safety and security
- Audible low gas pressure alarm
- Internal, but accessible demand valve
- Safety function test button



Designed to meet infection control standards.

- One way directional flow of inhaled and exhaled gas
- Single-use, disposable breathing circuits
- Single-use masks and mouthpieces
- Front panel user interfaces designed to prevent surface cleaners and disinfectants from entering the device

NITRONOX PLUS® Features

Emergency air intake valve – allows patient to pull in room air through breathing circuit should gas supply run out

3 visual gas pressure gauges – real time confirmation of gas supply and gas mixture pressure

Built-in oxygen failsafe – prevents the flow of nitrous oxide without oxygen

Mixed gas outlet – breathing circuit connects here

Single adjustable nitrous oxide knob – easily control the percentage of nitrous oxide (adjustable models only)

On/off key lock for security – nitrous oxide will only flow in the on position, oxygen flows in either position

Audible low gas pressure alarm – alert indicates either low oxygen or nitrous oxide gas pressure

Diameter indexed safety system (DISS) connections – prevents crossing of gas lines

Demand valve access panel – offers quick access for in-field servicing

Built in demand valve – designed for both pediatric and adult patients

Function test button – easy access to perform periodic safety and function tests

NITRONOX PLUS®

Applications & Procedures

Nitronox Plus® is ideal to help reduce patient pain and anxiety for minimally invasive medical procedures including:

Hospital Use

- Labor and Delivery
- Emergency Departments
  - > Laceration repair
  - > Setting broken bones/dislocations
  - > IV placement
- Radiology
  - > Catheter insertion
  - > CT Scans
  - > PICC lines
- Oncology
  - > Biopsies
  - > Infusion Therapy
  - > Tumor ablation
- Burn Units
  - > Wound debridement

In-Office Procedures

- Medical Aesthetics
  - > Dermal filler injections
  - > Body contouring
- Dermatology
  - > Biopsies
  - > Microdermabrasion
- Plastic Surgery
  - > Non-invasive fat reduction
  - > Neurotoxin injections
- Urology
  - > Vasectomy
  - > BPH treatment
- OB/GYN
  - > Endometrial ablation
  - > IUD insertion/removal

Why Nitronox Plus?

- Choice of fixed or adjustable demand flow system
- Combined benefits of continuous and demand flow systems
- Simple to use
- Designed to meet infection control standards
- Multiple system configurations available
- Manufactured and serviced in the USA
- Porter has been manufacturing nitrous oxide and oxygen systems for over 50 years
- 3-year warranty

Nitronox Plus on 2-Cylinder Stand

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FM #1460

Novii Wireless Patch System

Operation and Maintenance Manual

Declaration

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This Operations and Maintenance Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures.

GE Healthcare only considers itself responsible for any effects on safety, reliability, and performance of the equipment if:

1. Assembly operations, re-adjustments, modifications, or repairs are carried out by persons authorized by GE Healthcare, and
2. The electrical installation complies with national standards, and
3. The equipment is used in accordance with the Operations and Maintenance Manual
4. Only parts issued and approved by GE Healthcare can be used with the device
5. There are no user serviceable parts inside the Novii POD and the Novii Interface. Contact your local GE distributor when the Novii System requires servicing.

Conventions Used in This Operator Manual

WARNING: A 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.

CAUTION: A caution alerts you to situations 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.

Definition of Terms Used

Term	Definition
ECG	Electrocardiogram
MECG	Maternal Electrocardiogram
FHR	Fetal Heart Rate
UA	Uterine Activity
TOCO	Non-invasive method of measuring uterine activity
IUPC	Intra-Uterine Pressure Catheter
FSE	Fetal Scalp Electrode
BPM	Beats Per Minute
FECG	Fetal Electrocardiogram
US	Ultrasound (Doppler)
ESD	Electrostatic Discharge
PSU	Power Supply Unit

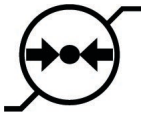
Contents

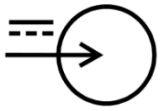
Section 1 - Symbols and Standards

This section describes symbols displayed on the Novii Wireless Patch System and the standards that it complies with.

1.1 Symbols associated with standards

Symbol	Description	Standard reference Number	Standards Title
	Refer to instruction manual/booklet (blue background)	ISO 7010-M002	ISO 7010: Graphical symbols - Safety colors and safety signs - Registered safety signs
	Do Not Use If Package is Damaged	ISO 7000-2506	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Use By Date (YYYY-MM-DD)	ISO 7000-2607	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Catalog number	ISO 7000-2493	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Batch code	ISO 7000-2492	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Serial Number	ISO 7000-2498	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Date of Manufacture (in “YYYY-MM-DD” format)	ISO 7000-2497	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Manufacturer	ISO 7000-3082	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	WEEE logo: This symbol indicates that the waste of electrical and electronic equipment including battery must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).

	for information concerning the decommissioning of your equipment.		
	WEEE logo: This symbol indicates that the battery in this product must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).
	Non-ionizing electromagnetic radiation To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	IEC 60417-5140	IEC 60417: Graphical symbols for use on equipment
	Class II Insulation	IEC 60601-1	IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
	TYPE BF EQUIPMENT: Type BF equipment is suitable for intentional external and internal application to the patient, excluding direct cardiac application. Type BF equipment has an F-type applied part. The applied Parts of the Novii System are the five electrodes of the Novii Patch that are placed on the patient abdomen. This applied part connects to the pins at the bottom of the Novii Pod.	IEC 60417-5333	IEC 60417: Graphical symbols for use on equipment
	Do not reuse	ISO 7000-1051	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Pressure limitation	ISO 7000-2621	ISO 7000: Graphical symbols for use on equipment – Registered symbols

	Humidity limitation	ISO 7000-2620	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	Temperature limitation	ISO 7000-0632	ISO 7000: Graphical symbols for use on equipment – Registered symbols
	MR unsafe MRI not compatible (red circle and slash)	ASTM F2503 Clause 7.3.3	ASTM F2503: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
	The device has been certified to OSHA requirements in the US and Canada. ANSI/AAMI ES 60601-1:2005 +C1(2009) +A1(2012) +A2(2010) CAN/CSA C22.2 No.60601-1:14	Not applicable	Not applicable
IP20	Protected from touch by fingers and objects greater than 12 millimeters. Not protected from liquids.	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code).
IPX0 (IP57)	• IPX0 - When device is not in use (Pod separate from Patch) the Ingress Protection Rating is IPX0 - Not protected from solid particles or liquids. • IP57 - When device is in use (Pod connected to Patch) the Ingress Protection Rating is IP57 - Protected from limited dust ingress. Protected from immersion between 15 centimeters and 1 meter in depth.	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code).
	To indicate a d.c. rated power input	IEC 60417	Graphical Symbols for Use on Equipment

1.2 Symbols not associated with standards

Symbol	Description
℞ ONLY	Federal Law restricts this device to sale by or on the order of a licensed health practitioner
CE	Signifies European technical conformity for Class 1 devices, no Notified Body number is required.
CE 0197	Signifies European technical conformity for Class 2 devices, the Number is the Notified Body number.
FCC ID: YOM-6960-MON	Novii Pod Federal Communication Commission identification number.
FCC ID: YOM-6961-MON	Novii Interface Federal Communication Commission identification number.
	Complies with Australian and New Zealand Radio communications requirements.
	Contains the following serialized items
	Not made with natural rubber latex
	No Polyvinyl chloride (PVC) used
	Unique Device Identifier

1.3 Standards

The Novii Interface complies with the following standards

Medical Device Standards	Description
IEC 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
EN 60601-1 ANSI/AAMI ES 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance including deviations for US
CAN/CSA-C22.2 No. 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance with Canadian deviations
KS C IEC 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance with Korean deviations
IEC 60601-1-2 EN60601-1-2	Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62304	Medical device software — Software life-cycle processes Include Danish and Swedish language deviations
IEC 62366	Medical devices – Application of usability engineering to medical devices
ISO 1041	Information supplied by the manufacturer with medical devices
ISO 10993-5	Biological Evaluation of Medical Devices Part 5: In Vitro Cytotoxicity
ISO 10993-10	Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization
ISO 15223-1	Graphical Symbols for use in the labelling of medical devices

Wireless Standards	Description
ETSI EN 301 489-17 V3.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17 Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
ETSI EN 301 489-1 V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1 Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and article 6 of Directive 2014/30/EU
FCC CFR 47 (Part 15)	Federal Communications Rules & Regulations for title 47: Part 15 - Radio Frequency Devices
FCC CFR 47 (Part 18)	Federal Communications Rules & Regulations for title 47: Part 18 - Industrial, Scientific and Medical Equipment

Section 2 - Safety

2.1 Indications for Use

The Novii Pod is an intrapartum Maternal/Fetal Monitor that non-invasively measures and displays fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). The Novii Pod acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the Pod also acquires and displays the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG). The Pod is indicated for use on women who are at >36 completed weeks (37.0), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The Novii Patch is an accessory to the Novii Pod that connects directly to the Novii Pod and contains the surface electrodes that attach to the abdomen.

The Novii Interface is an accessory to the Novii Pod which provides a means of interfacing the wireless output of the Novii Pod to the transducer inputs of a Maternal/Fetal Monitor. The Novii Interface enables signals collected by the Novii Pod to be printed and displayed on a Maternal/Fetal Monitor and sent on to a central network, if connected.

The Novii Pod maternal-Maternal/Fetal Monitor and its accessories are intended for use by healthcare professionals in a clinical setting.

2.2 Contraindications

The Novii Interface is contraindicated for use in preterm gestation (≤36 completed weeks). The uterine contraction trace generated by the Novii Pod and monitored by the Maternal/Fetal Monitor via the Novii Interface may show deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.

IMPORTANT NOTE: The Novii system is contra-indicated for use with: Magnetic Resonance Imaging (MRI) scanners, Computer Tomography (CT) scanners, Diathermy / electro surgery, Metal Detectors, Transcutaneous Electrical Nerve Stimulation (TENS) machines, Cardiac Pacemakers, Cardiac Defibrillators.

2.3 Warnings and Cautions

2.3.1 Clinical

WARNING: The Novii Wireless Patch does not replace observation and evaluation of the mother and fetus at regular intervals, by a qualified care provider, who will make diagnoses and decide on treatments and interventions. Clinical assessment of the Maternal/Fetal Monitor's display or trace when using the Novii Wireless Patch solution must be combined with knowledge of patient history and risk factors to properly care for the mother and fetus.

WARNING: If you are concerned with the clinical data provided by GE Healthcare, it should be verified by an alternative method, such as palpation of the maternal pulse to exclude MHR/FHR confusion or hand-held Doppler to confirm the FHR.

WARNING: The safety and effectiveness of Novii FHR, MHR and UA have NOT been cleared by the FDA for the following patient populations:

- Preterm gestation (i.e. ≤ 36 completed weeks gestation)
- Antepartum (i.e. at term, but not in labor)
- Multiple gestations

WARNING: A labor monitor is intended for use by clinical professionals who are trained in the medical procedures, practices, and the terminology required when monitoring obstetric patients. The monitor is only one clinical indicator of labor progress and fetal/maternal well-being. The monitor is designed to assist the clinical staff in assessing the status of the patient and her unborn baby.

WARNING: GE Healthcare recommends establishing the presence of the fetal heartbeat by auscultation before starting continuous monitoring by either using a Pinard stethoscope or hand-held Doppler.

WARNING: If the signal quality indicator on the Novii Interface display is red for an extended period, use an alternative method to confirm FHR.

WARNING: Novii UA provides information on the frequency and timing of the contraction peak. Interpretation of the Novii UA pattern should be done in the clinical context of the patient. It is always good practice to use manual palpation, maternal perception of UA and observation in conjunction with the UA trace. It is important to note that there will be a delay of 10 seconds or more from maternal perception and/or manual palpation when compared to the display on the Maternal/Fetal Monitor and trace paper.

WARNING: MHR/FHR confusion. When the FHR is tracking close to the MHR you should always confirm the FHR using another modality.

WARNING: **GE Healthcare does not recommend or support mixing Novii UA with US/FSE FHR monitoring.**

There is a 10-second delay (5mm on the tracing) in the Novii UA trace with respect to the US/FSE FHR trace; late decelerations could appear as early decelerations masking a potential fetal compromise.

Using the US transducer in addition to Novii FHR, MHR and UA to confirm the FHR, for short periods, during gaps or suspected artifact can be used, but the potential for missing a fetal compromise remains, due to US FHR and Novii UA desynchronization.

WARNING: **GE Healthcare does not recommend or support mixing Novii FHR/MHR with TOCO/IUPC UA monitoring.**

If the Novii UA cable is disconnected and the TOCO/IUPC is used (against this recommendation), it is clinically important to understand that the FHR/MHR shift will have changed from a 10 second to a 6 second delay (3 mm). Early decelerations may appear as 'subtle' late decelerations. This could lead to an unnecessary intervention.

CAUTION: US law restricts this device to sale by, or on the order of, a physician

CAUTION: The 10 second (or 6 second, if the Novii UA cable is disconnected) MHR delay should be taken into consideration when monitoring the patient's response to a test dose during epidural placement. There is a 6 or 10 second MHR delay in reporting the MHR with respect to real time events.

CAUTION: The 10 second (or 6 second, if the Novii UA cable is disconnected) FHR shift should be taken into consideration during prolonged FHR decelerations when resuscitative measures are being used, the impact of any maneuver will not be seen for 10 seconds.

CAUTION: The 10-second UA delay should be taken into consideration when coaching patients to push during the second stage. The patient may sense the contraction before it appears on the monitor tracing - the contraction has already been building for 10 seconds.

CAUTION: When the patient is moving and/or the fetus is active caution should be exercised in interpreting the UA trace. If the interpretation of uterine contractile pattern(s) is uncertain, another modality to monitor uterine contractions should be considered and clinical management of the patient adjusted appropriately. The Novii Pod monitors uterine activity by measuring the electrical signals (EMG) generated by the uterine muscle when it contracts, as opposed to the tocodynamometer (TOCO transducer) which monitors uterine activity as measured by the displacement of a plunger or button with respect to a guard ring caused by the tightening of the uterus during a contraction. Small relative changes in the electrode positions used to monitor the uterine EMG resulting from maternal or fetal movement cause electrical signals that can look like uterine activity.

CAUTION: The Novii Pod when attached to the Novii Patch can remain on the patient while taking a bath or shower (rated IP57), but monitoring will not work when the woman is in the bathtub and the Pod **is fully submerged under water** (restricting the Bluetooth signal) and cannot be guaranteed during a shower. However, the Pod needs to remain attached to the patch while exposed to water to maintain the integrity of the Patch**.**

CAUTION: We recommend that the Novii fetal/maternal ECG waveform is not displayed on Corometrics 259cx monitor by manually turning this option off. No diagnostic information can be inferred from waveform sent from Novii Interface to the Maternal/Fetal Monitor. It is a pulse that can be used by the monitor to accurately calculate the FHR and MHR.

CAUTION: Only touch the UA zero reference button on the Maternal/Fetal Monitor when prompted by the Novii Interface at the start of the monitoring. Do not touch the UA reference button during a monitoring session since it could result in masking contractions, unless it is confirmed by palpation of the uterus that no contraction is present.

CAUTION: If the Maternal/Fetal Monitor UA reference button is accidently touched during monitoring wait until you are confident the woman is not having a contraction (by using palpation) and then re-touch the UA reference button on the Maternal/Fetal Monitor.

CAUTION: Any unexpected data from the Novii Interface as shown on the Maternal/Fetal Monitor display or trace must result in further examination of the mother and fetus in a hospital environment.

CAUTION: The Novii Pod transmits FHR, UA and MHR data to the Maternal/Fetal Monitor with a short delay of 10 seconds. Data is synchronized allowing accurate interpretation of decelerations in relation the peak of contractions. Duration of Novii Wireless Patch contractions can be shorter than mechanical contractions, hence when palpating the uterus there will be a delay between manual detection of a contraction and the display of the contraction on the Maternal/Fetal Monitor.

CAUTION: It may prove difficult to use the Novii UA to coach patients to commence contraction pain coping strategies or actively push in the second stage of labor. Its value lies in providing an accurate picture of the pattern of uterine contractions over time.

CAUTION: High and Low UA sensitivity gives the user the choice to best conform with the clinical situation; the Low UA sensitivity setting is less sensitive to UA and removes some of the small deflections that may represent artifacts or inconsequential contractions. It is, however, important to switch to High sensitivity once the patient is in established labor. Novii will automatically switch back to High UA sensitivity after 60 min of Low UA sensitivity monitoring. No warning is given.

CAUTION: Prior to the connection of the Novii Pod, the Novii Patch must not come in contact with water; any water trapped in the Pod connection area may damage the Pod. An example of this situation could be when a bed bath is given after the Patch has been fitted, but before the Pod has been connected.

2.3.2 Uterine EMG Activity; Potential Problems with Clinical Interpretation

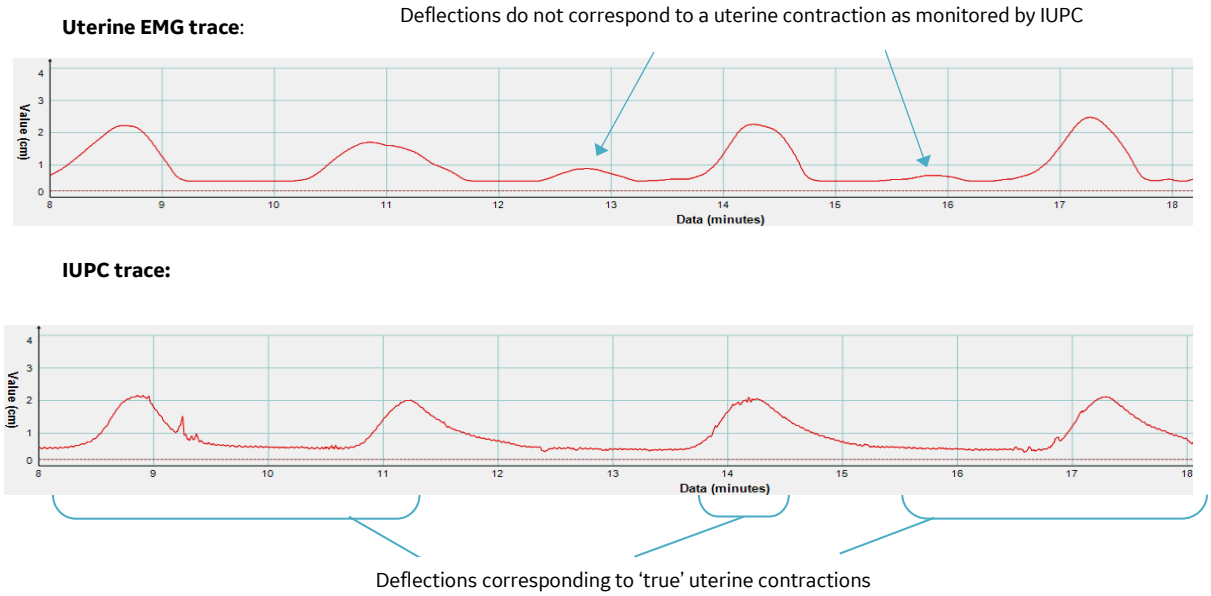
WARNING: The Novii Pod may monitor UA deflections from baseline that do not represent uterine contractions that cause an increase in intra-uterine pressure. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. When this occurs, the "false contraction" often does not attain the amplitude of true uterine contractions. If the interpretation of uterine contractile pattern(s) is uncertain, another modality to monitor uterine contractions should be considered and clinical management of the patient adjusted appropriately.

WARNING: The Novii Pod monitors uterine contractions by measuring electrical activity (EMG) of the uterus as opposed to a tocodynamometer (TOCO transducer) which monitors uterine activity as measured by the movement of a button with reference to a guard-ring. The button is pressed in by a tightening of the uterine muscle as measured on the abdominal wall. Occasionally, low amplitude electrical activity insufficient to cause a contraction detected by a TOCO transducer is displayed as a deflection above baseline on the Novii Interface Maternal/Fetal Monitor tracing. These deflections from baseline may represent electrical activity in myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. Thus, caution should be used in interpreting as contractions deflections from baseline that have relatively lower amplitude compared to contractions characteristic of the overall uterine activity pattern. False positive UC could also occur from maternal activity or vigorous fetal movement. Any movement that changes the maternal abdominal surface contours can produce, what appears on the trace to be, a UC. This is caused by small changes in the electrode positions in relation to each other and to the underlying skin. This may create confusion particularly during early induction monitoring, when regular true contractions are not present. Before any definitive clinical interpretation of UC information generated by Novii is made, ensure, if possible that the patient is not moving and is in a comfortable and relaxed position. If there is concern about false positive contractions during early labor or induction, it can be helpful to have the patient use the event marker on the GE Corometrics 259cx and 174 Maternal/Fetal Monitor to indicate when she feels a contraction and/or the fetus move.

Irregular high amplitude 'ragged' looking contractions that are coincidental with fetal or maternal movements with no other clinical indication of UC should be discounted. They are unlikely to be real contractions. As such, they should not

influence medical intervention unless corroborated by another device or clinical assessment.

For example, in the following sample Maternal/Fetal Monitor tracing using uterine EMG, there are deflections above the baseline in the tracing that does not correspond to uterine contractions in the simultaneously monitored IUPC tracing (e.g., deflections identified by arrows). IUPC is considered the gold standard for monitoring uterine contractions.



WARNING: Users should not use the low sensitivity setting during active labor; the onset of the contraction trace will be further delayed and the amplitude will be reduced. The peak will remain synchronized with the FHR trace.

2.3.3 Safety

WARNING: Only use the Novii Interface with the GE Corometrics 259cx and 174 Maternal/Fetal Monitor with the specific interface cable for that monitor, see Section 13.1.

WARNING: Do not position the Novii Interface so as to make it difficult to disconnect its AC/DC adapter. Position the Interface on a stable surface more than 20 cm from the patient or user during normal use.

WARNING: The Novii Interface power cable and other interconnecting cables must be positioned and/or restrained to avoid users and patients tripping over them.

WARNING: The operator should not touch the unearthed metal parts of the Novii Interface and the patient at the same time. In particular do not touch the metal shielding of the connectors at the back of the Novii Interface and the patient at the same time.

WARNING: Novii is not suitable for use in an Oxygen rich environment.

WARNING: The Novii Interface is not explosion-proof and must not be used in the presence of flammable anesthetic gases.

WARNING: SHOCK HAZARD. Do not attempt to connect the power cable with wet hands. Make certain that your hands are clean and dry before touching a power cable or plug.

WARNING: USE ONLY THE POWER SUPPLY SUPPLIED WITH THE DEVICE.

The Novii interface could be damaged if a power supply not issued by GE Healthcare is attached to the interface.

WARNING: Unplug the Novii Interface from the AC power supply before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the Novii Interface and accessories periodically to ensure that the cables, connectors and the device itself do not have visible evidence of damage that may affect performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: DO NOT attempt to service the Novii system yourself.

WARNING: There are no user serviceable parts inside the Novii POD and the Novii Interface. Please contact GE Healthcare or your local distributor when the Novii System requires servicing.

WARNING: The Novii Interface is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operations and Maintenance Manual.

WARNING: Novii should not be used for primary monitoring in applications where any loss of the FHR and UA signal is unacceptable.

WARNING: No Modification of this equipment is allowed.

WARNING: Do not use a new Novii Patch if the Package is damaged or open.

WARNING: The Novii Pod contains a Li-ion battery. Do not throw the Novii Pod into a fire or other heat source. Do not put the Novii Pod into any liquid (except when attached to the Patch and used during a shower or bath). Do not put the Novii Pod into a pocket or bag without protection. Do not disassemble the Novii Pod. Do not crush or pierce the Novii Pod. Do not leave the Novii Pod close to a fire or heat source above 30 °C. Do not use the Novii Pod if there are any signs of visible damage. Do not discharge the Novii Pod in any way other than it's intended use.

Do not use the Novii Pod if there is any discoloration, unusual heat, odor or discharge. Do not put the Novii Pod into a microwave or pressurized container.

If liquid leaks from the Novii Pod onto your clothes or skin wash well immediately with fresh water.

If liquid leaks from the Novii Pod and comes into contact with your eye, do not rub your eye, wash well with clean edible oil and see a doctor immediately.

WARNING: Do not charge the Pods on an external wireless charger, only charge via the Novii Interface. External wireless chargers will cause uncontrolled charging of the Pod, reducing the lifespan and efficiency of the battery.

WARNING: During monitoring, do not charge a 'third' Pod on the Interface when one Pod is already charging and the second Pod is monitoring the patient. This will result in uncontrolled charging.

WARNING: There is no ON/Off switch included with the Novii Interface so it is terminated by unplugging the power cable from the back of the unit.

WARNING: There is no ON/Off switch included with the Novii Interface so it is terminated by disconnecting the power supply from the mains.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature. The Novii Interface and all cable connectors should be kept clean and free of electrode gel and other substances.

CAUTION: The Novii Interface is rated IP20. Do not operate the Novii Interface if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: The Novii Pod on its own is rated IPX0. The Novii Pod is rated IP57 when mated with the Novii Patch. Do not submerse the Novii Pod in any liquid if not mated to a patch.

CAUTION: Never use sharp or pointed objects to operate the touch screen display. Do not exert excessive pressure when operating the touch screen.

CAUTION: The Pod gold connection pins need to be kept clean, and should be protected at all times; only keep your Pods in the Interface charging bays or clipped to a Patch. Placing it down anywhere else could result in damage to the gold pins.

2.4 Electromagnetic Compatibility (EMC)

2.4.1 Electromagnetic Interferences

The Novii System has been designed to minimize the impact of electromagnetic interference from other electrical equipment and also to minimize the interference caused to other electrical equipment by the Novii System. The Novii system has been tested and found to comply with the Medical Electrical Equipment - General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility, IEC 60601-1-2 2014 and FCC Part 15. Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care environment, it is possible that high levels of such interference due to proximity or strength of the source may result in degradation to the performance of the Novii system.

Risks and Characterization associated with Electro Magnetic Interferences:

Risk	EMI characterization
High EMI interrupting the Bluetooth transmission between the Novii Pod and Novii Interface	This will present as a simultaneous gap in the FHR, MHR and UA data to the user The Bluetooth connection can be interrupted intermittently or constantly. The Bluetooth communication interruptions will create gaps on the tracing of the Maternal/Fetal Monitor attached to the Novii System. In the event of such interference these gaps will typically occur simultaneously on the FHR, MHR and Uterine Activity tracing even if the patient is in close proximity of the Novii Interface.
High EMI present on the inputs of the Novii Pod	This will present to the user as gaps in FHR data only On some occasions, the electromagnetic interference will not disrupt the Bluetooth transmission of all signals simultaneously, but gaps will occur in the FHR tracing only since the Novii System will stop detecting the FHR if the noise in the abdominal recording is too high to detect signals accurately.
Electrostatic Discharge (ESD) present on the Novii System (either Pod or Interface)	ESD present on the Novii System could create artifacts. Specifically, this artifact will present as transient changes to the FHR trace, appearing as deflections on the FHR trace of 35 BPM maximum (e.g. from a reading of 120 BPM down to 85 BPM). These FHR deflections are very short in duration and would appear to the user as a spike on the FHR trace. Once the source of ESD interference has been removed the Novii System will go on working as normal, there will be no permanent damage to the system.

If you suspect your Novii System is affected by electromagnetic interference from another electrical device, it may be necessary to take mitigating actions, such as re-orienting or relocating the Novii Interface or the device creating the interference. In general, the further away the Novii System is from the interfering device, the lower the interference will be (please follow guide lines

of Warning G below for minimum distances with other electrical equipment). If the device creating interference is not in use, it is advised to turn it off. Turning equipment in the vicinity off and on, can help to isolate the offending equipment.

WARNING: A) Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: B) Use of accessories and cables other than those specified in Section 13.1 of this manual may result in increased EMC emissions and/or decreased immunity of the Novii system to other electrical equipment.

WARNING: C) The Novii Interface connects to the GE Corometrics 259cx and 174 Maternal/Fetal Monitor; hence it will be adjacent to, or stacked on top of the monitor. It should be verified that the Novii Interface is correctly connected and calibrated with the maternal / fetal monitor. To confirm correct calibration the TEST function of the Novii Interface should be used. When connected together, both Novii and the Maternal/Fetal Monitor should be observed to function in normal operation, in the configuration in which it will be used.

WARNING: D) For Electromagnetic Compatibility the Novii Interface has been tested to IEC 60601-1-2. The Essential Performance for that test is the Recording Mode when the Novii Interface collects via Bluetooth the patient data from a Novii Pod and transfers the data to a Maternal/Fetal Monitor through the connecting cables. Essential performance in Transmission Mode was defined as “no FHR/UA gaps greater than 30s, no FHR error greater than 15 BPM for 15s, no UA error larger than 20% of full scale for more than 30s and no interruption of the transmission mode”.

WARNING: E) This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Novii or shielding the location.

WARNING: F) The Novii Interface may suffer from interference by other equipment, even if that other equipment complies with CISPR emission requirements.

Guidance and manufacturer's declaration – electromagnetic emissions Table 1 of IEC 60601-1-2		
The Novii system is intended for use in the electromagnetic environment specified below. The customer or the user of Novii system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
Radiated emissions CISPR 11	Class B	The Novii™ system 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.
Harmonic emissions IEC 61000-3-2	Class B	The Novii™ system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity Table 2 of IEC 60601-1-2			
The Novii™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Novii™ Interface 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	± 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 %.
Transient/burst IEC 61000-4-4	± 2 kV Live and neutral simultaneously	± 2 kV Live and neutral simultaneously	AC power should meet the standards of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV AC supply line differential mode	± 1 kV AC supply line differential mode	AC power should meet the standards of a typical commercial or hospital environment.
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100 % reduction for 10ms/Half Cycle 30 % reduction for 500ms/25 Cycles 100 % reduction for 20 ms/1Cycle 100 % reduction for 5 s	100 % reduction for 10ms/Half Cycle 30 % reduction for 500ms/25 Cycles 100 % reduction for 20 ms/1Cycle 100 % reduction for 5 s	AC power should meet the standards of a typical commercial or hospital environment. If the user of the Novii system requires continued operation during power mains interruptions, it is recommended that the Novii Interface 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: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity Table 4 of IEC 60601-1-2			
Novii™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Novii™ Interface should assure that it is used in such an environment.			
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 V	Portable and mobile RF communications equipment should be used no closer to any part of Novii™ 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√P 150 kHz to 80 MHz d= 1.2 √P 80MHz to 800MHz d = 2.3 √P 800MHz to 6GHz
Radiated RF	3 V/m 80 MHz to 6 GHz	3 V/m	

IEC 61000-4-3			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 strengths 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 reflection 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 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 Novii™ system is used exceeds the applicable RF compliance level above, the Novii™ 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 Novii™ system [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Novii™ system Table 6 of EN60601-1-2			
The Novii™ system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Novii™ system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Novii™ system 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 d = 1.2√P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2,5 GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.3
10	3.80	3.80	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

WARNING: G) The Novii system may be interfered with Radiofrequency identification (RFID) systems (tag and reader). Ensure RFID reader is placed as far as possible from the Novii Interface. If an RFID tag is placed on the Novii Pod or Novii Interface and you experience poor quality data (Data transmission loss, gaps in FHR data, Gaps in MHR data, uninterpretable uterine activity) please remove the RFID tag and RFID reader and check again the Novii System data quality. If the presence of the RFID correlates with the poor performance of the Novii System, please report the issue to your distributor or to GE Healthcare and do not use the RFID system in conjunction with the Novii System.

2.5 Electrostatic Discharge (ESD) precautions

ESD present on the Novii System could create artifacts. Specifically, this artifact will present as transient changes to the FHR trace, appearing as deflections on the FHR trace of 35 BPM maximum (e.g. from a reading of 120 BPM down to 85 BPM). These FHR deflections are very short in duration and would appear to the user as a spike on the FHR trace.

Once the source of ESD interference has been removed the Novii System will go on working as normal, there will be no permanent damage to the system.

WARNING: A) Although precautions have been taken to ensure otherwise, static electricity could cause damage to the pins of the Novii Pod or the pins of all three connectors located at the back of the Novii Interface and render the system inoperable. Pins of the Novii Pod or pins of the Novii Interface connectors should not be touched, and connection to these connectors should not be made unless ESD precautionary measures are used.

WARNING: B) ESD precautionary measures should be taken to minimize the risk of damage to the Novii system. More specifically:

- The pins of all connectors at the back of the Novii Interface and the pins of the Novii Pod should not be touched by any part of the body, including the fingers.
- Do not touch any metallic parts of the Novii Interface or Pod and the patient at the same time.

2.6 Magnetic Resonance Environment (MRE)

WARNING*:* The Novii Wireless Patch System cannot be used or placed in a MR Environment. This could result in serious injuries and death of patients and other individuals.

2.7 Wireless Technology

The Novii System uses Wireless Technology to perform four main functions, specifically:

- to communicate patient monitoring data from the Pod/Patch to the Interface via Bluetooth, and;
- to charge the battery in the Novii Pods when docked to the Interface using wireless induction charging (WPC 1.1). The Interface has two charging bays allowing two Pods to be charged at the same time
- to initiate the Bluetooth communication between the Pod and Interface using wireless infrared communication (IrDA).

2.7.1 Novii Bluetooth wireless characteristics:

During patient monitoring the Novii Interface and Pod communicate wirelessly via two Bluetooth Transceivers. Bluetooth uses a radio technology called frequency-hopping spread spectrum, which chops up the data being sent and transmits chunks of it on up to 79 frequency bands of 1 MHz each in the range 2,400-2,483.5 GHz (allowing for guard bands). This helps to ensure the performance and accuracy of transmitted data. The Bluetooth module is Class 1.5 (with transmit power control) with a maximum transmit power of 10.5dBm.

The Bluetooth set up and configuration is fully automatic and does not require any user set up (Bluetooth Address is automatically exchanged via an IrDA connection which is initiated by a Pod proximity detector, see Section 2.7.2. A key characteristic of the Novii wireless system is that it uses a very low power transmission setting (100 times less than a mobile phone) to mitigate any risks from harmful radio frequencies. Another key characteristic of the Novii system is that it is designed to communicate over a short distance and if the patient goes out of range (typically greater than 100 feet / 30 meters) there will be a visual alert.

The Novii Interface can only connect to a Pod that is placed in the charging bay.

The Bluetooth characteristics of the Novii system are as follow:

FFC ID of Novii Pod	FCC ID: YOM-6960-MON
FFC ID of Novii Interface	FCC ID: YOM-6961-MON
Radio Technology	Bluetooth: Frequency-hopping spread spectrum
RF frequencies	79 bands (1 MHz each; centered from 2.402 to 2.480 GHz) in the range 2,400-2,483.5 GHz (allowing for guard bands).
Bluetooth Class / Power	Class 1.5 Bluetooth module. Software controllable power. Max power 10.5 dBm. Typical power 4dBm
Sensitivity	-93 dBm

Data rate	Up to 2,178 kilo bit per second (kbps). The Novii Pod sends data by packet of 80 bytes every 2 seconds
Protocol	Bluetooth HCI via ACL data packets including Forward Error Correction scheme. CRC mechanism for error detection.
Distance	Up to 100 feet / 30 meters line of sight
Alert	Bluetooth out of range alert on the Novii Interface
Pairing process	Automatic pairing process using a separate IrDA to transmit the Pod Bluetooth address to the Interface. This is initiated only when prior to monitoring the Pod is placed in an Interface charging bay.
Quality of service	The Novii Interface and Novii Pod do not allow multiple connections to the Bluetooth Interface. The connection between the Pod and Interface is one to one and the full bandwidth is dedicated to transmitting the patient data. The Bluetooth interface allow data transmission up to 2,178 kilo bit per second(kbps). However only a bandwidth of 320kbps is required to transmit the patient data (80 bytes every 2 seconds)

2.7.2 Wireless charging technology characteristics:

The charging of the Novii Pods on the interface uses 'Qi Near Field Magnetic Induction'. The wireless charging is compliant to WPC 1.1. The wireless charging is only activated when a Novii Pod is detected on one of the two charging bays of the Novii Interface. Detection is made via polarized Hall effect sensors. The Novii Interface and Pod are fitted with magnets so that when the Pod is placed on the charging bay, the Pod is automatically positioned correctly. The wireless induction charger also features a Foreign Object Detection (FOD) scheme to protect the Interface from overheating in the presence of a metallic foreign object.

The wireless charging characteristics of the Novii system are as follows:

Wireless Induction technology	Conforms to WPC 1.1 "Qi" near-field magnetic induction. Closed-Loop Power Transfer Control with full bridge inverter
Power	Max transmitted power on Pod: 5W: 5V/1A
Protection	Over temperature protection and proprietary FOD Proprietary Foreign Object Detection
RF frequencies	Power transfer by modulating the switching frequency of the full-bridge inverter from 110kHz to 205kHz at a fixed 50% duty cycle specified by the WPC specification.
Quality of service	One to one connection. The full bandwidth is dedicated to transmitting the pairing data.

2.7.3 Wireless infrared communication (IrDA) characteristics:

The Novii Pod and Interface are each fitted with an Infrared Transceiver complaint with the IrDA physical layer IrPHY 1.4. Before an active Bluetooth communication between the Pod and the Interface can be established, an initial communication is carried out using the IrDA wireless protocol to transmit the Pods Bluetooth address to the Interface. The IrDA communication is only initiated once the Pod is placed on the Interfaces charging bay. This forms the automatic pairing process required before any other Bluetooth communication can take place between the Pod and Interface.

The wireless infrared communication characteristics of the Novii system are as follows:

Wireless infrared communication specification	Conforms to the IrDA® specification.
Power	Low power IrDA. MAX. 150 mW/sr
Data Rate	Up to 115 kilo bit per second (kbps). The Novii system utilizes 9.6 kilo bit per second.
Distance	Up to 30 cm/20 cm. The Novii Pod transceiver is tuned so that it can only be detected 1 cm away from it.
Quality of service	The IrDA transceivers of the Novii Pod continuously send the Bluetooth address when placed on the Interface charging bay up until the Interface can connect to the Pod via Bluetooth before the transceiver turns off.

2.8 FCC Information (USA)

This Declaration confirms that Novii Wireless Patch System complies with to all the requirements of FCC 47 CFR Part 15 & Part 18.

- FCC 47 CFR Part 15B Clause 15.107
- FCC 47 CFR Part 15B Clause 15.109
- FCC 47 CFR Part 15C:2016
    - FCC 47 CFR Part 15C Clause 15.205 (b)
    - FCC 47 CFR Part 15C Clause 15.247 (b) (1) (4)
    - FCC 47 CFR Part 15C Clause 15.247 (d)
- FCC 47 CFR Part 18:2016
    - FCC 47 CFR Part 18 Clause 18.305 (b)
    - FCC 47 CFR Part 18 Clause 18.307

Technology	**Frequency Band**	**Channel Frequency**
Wireless Charging	100 kHz to 300kHz	172 kHz
Bluetooth (GFSK/DH5)	2400 MHz to 2483.5 MHz	2441 MHz

	FCC Rule Parts	Frequency Range	Output Watts
Novii POD FCC ID: YOM-6960-MON	Part 15C	2402.0 – 2480.0 MHz	0.01
	Part 18	0.11 – 0.205 MHz	NA
Novii Interface FCC ID: YOM-6961-MON (S/N ≥ TA2354) FCC ID: T7V1315 (S/N < TA2354)	Part 15C	2400.0 – 2483.5 MHz	0.01
	Part 18	0.11 – 0.205 MHz	NA

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.

FCC Service Information

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Grant of Equipment Authorization

Certification Issued Under the Authority of the Federal Communications Commission

2.9 RE-Directive

Novii Wireless Patch System complies with Radio Equipment Directive (RED) 2014/53/EU for Class I (unrestricted devices).

2.10 CE Marking Information Compliance

CE
0197

The Novii System bears CE mark CE 0197 indicating conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. The product is radio-interference protection class B in accordance with IEC 60601-1-2

The country of manufacture can be found on the equipment labelling.

First year of CE mark was 2014

2.11 Classification of Medical equipment and marking

Protection against Electrical Shock	Novii Interface: Class II ME Equipment Novii Pod: Internally Powered ME Equipment with Type BF applied parts.
IP rating	The Novii Interface is rated IP20 The Novii Pod is rated IPX0, when connected to the Patch it becomes IP57
Suitability for use in an OXYGEN RICH ENVIRONMENT	Not suitable for use in an oxygen rich environment
Mode of Operation	Continuous Operation

Section 3 - Device Description

3.1 Components

The Novii Wireless Patch System should contain (but not limited to) the following items:

- Novii Interface device
- Power Supply for Interface device
- Cables to connect the Novii Interface to your GE Corometrics Fetal Monitor (FECG, TOCO and optional MECG input cables).
- Novii Pods
  Some package variations include an additional Pod as a backup/replacement device for loss, damage or breakdown. This spare Pod should remain in the box and placed in a secure location that does not see extremes in temperature e.g. a locked cabinet/drawer in the nurse Manager's office
- 3M red Dot 2236 skin prep tape
- Operations and Maintenance Manual

3.2 General description

The Novii Interface is a device that allows a Novii Pod to send fetal, maternal and UA data to the GE Corometrics 259cx and 174 Maternal/Fetal Monitor. The Novii Pod is a wearable, battery-powered device for surveillance of fetal and maternal well-being. The Novii Pod is designed to passively monitor Fetal Heart Rate (FHR), Uterine Activity (UA) and Maternal Heart Rate (MHR) during pregnancy. The Novii Wireless Patch system is cleared for use from 36 completed week's gestation (37.0) for intrapartum use in singleton pregnancies. The Novii Pod is attached via a magnetic clip directly on to the Novii Patch which locates 5 ECG electrodes on the abdomen of a pregnant woman, using the umbilicus as reference location point (when the umbilicus has been displaced the midpoint between the fundus and the edge of symphysis pubis should be used, see section 7.4). The Novii Pod then monitors the electrical signals present at the electrode sites: fetal ECG, maternal ECG and Uterine EMG (Electromyography) plus noise and interference signals. The acquired signals are then converted by the Novii Pod into a digital format and processed in real-time to extract clinically relevant information, such as Fetal Heart Rate, Uterine Activity and Maternal Heart Rate.

The Novii Pod sends the FHR, UA and MHR data along with maternal movement from the on-board three axis accelerometer, signal quality and Pod battery status signals to the Novii Interface. This digital data is sent wirelessly via Bluetooth. The Novii Interface receives the Bluetooth data and converts the FHR, MHR and UA data into an analogue signal before feeding it to a Maternal/Fetal Monitor via the external FECG (FHR), TOCO (UA) and MECG inputs (analogue signals). The plugs and cables are specific to the

Maternal/Fetal Monitor being connected. The Maternal/Fetal Monitor will display, print, and connect to a central station the data from the Novii Interface as if it was acquired from traditional transducers.

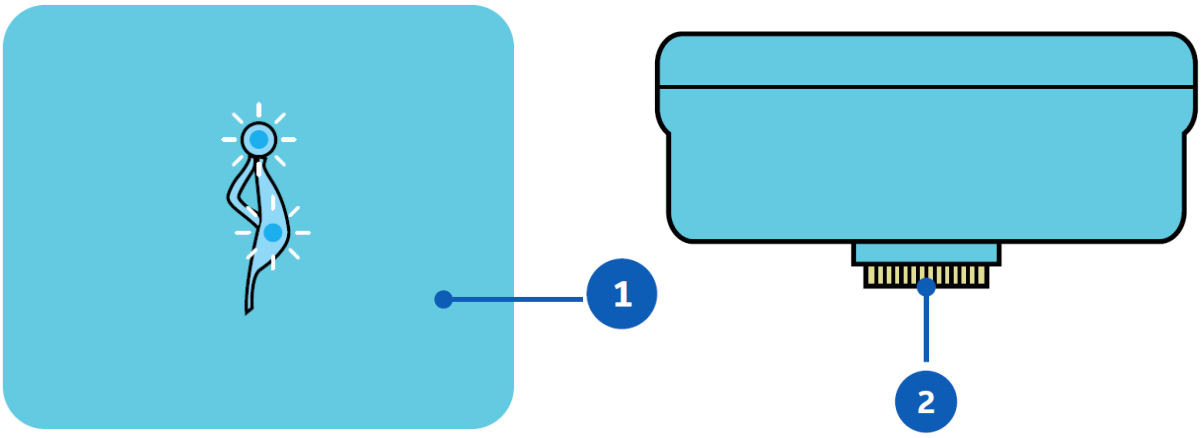
The Novii Pod has no controls only an LED to indicate when it is on and working. Placing the Pod in a free Novii Interface charging bay that is switched on will allow it to wirelessly connect with the Novii Interface and for its battery to be charged inductively. The Pod will then be automatically activated when removed from the charging bay. Set-up and operation instructions are communicated to the user via the Novii Interface display as described in Section 6.

3.3 Novii Pod

The Novii Pod processes the fECG, mECG & EMG signals and communicates via Bluetooth with the Novii Interface.

Novii Pod Features include:

- Up to 11 hours battery life[1]
- 2 Hour charge time
- Monitors FHR, MHR & UA
- Communicates signals to Novii Interface via Bluetooth
- Bluetooth wireless range 100 ft / 30 m
- Attached by magnets to Novii Interface charging bay or Patch while in use
- Waterproof only when Pod is attached[2]



[1] Varies per use depending on Bluetooth range

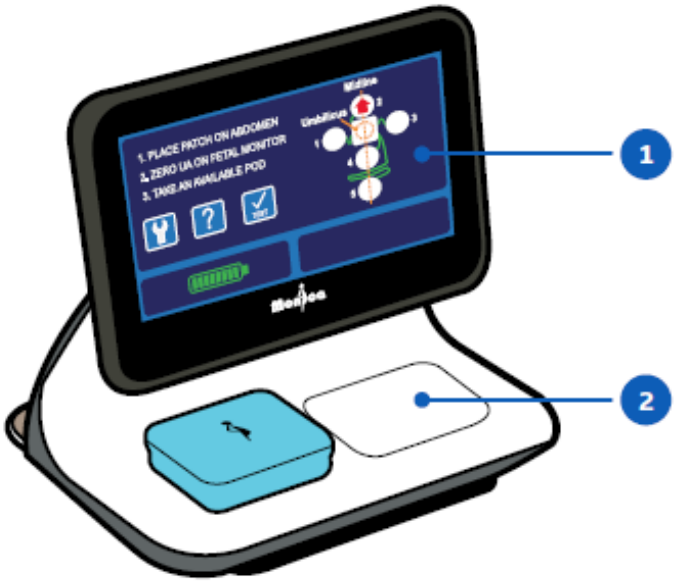
[2] Novii works well in shower with splashing, but Bluetooth signal cannot transmit and all signals will be lost if Pod is submerged under water in a tub

1. Two blue LED lights located on the Novii Pod indicate:
    - Charging: Single LED flashes slowly
    - Fully Charged: Single LED on constant, then turns off in stand-by mode
    - Pod On/Active: Both LEDs flash, alternately
    - Connected to Patch: Both LEDs on constant
    - Monitoring: Both LEDs flash slowly in unison
    - Pod off / Fully Charged: Both LEDs are off
2. Connection pins (avoid contact to prevent damage or debris)

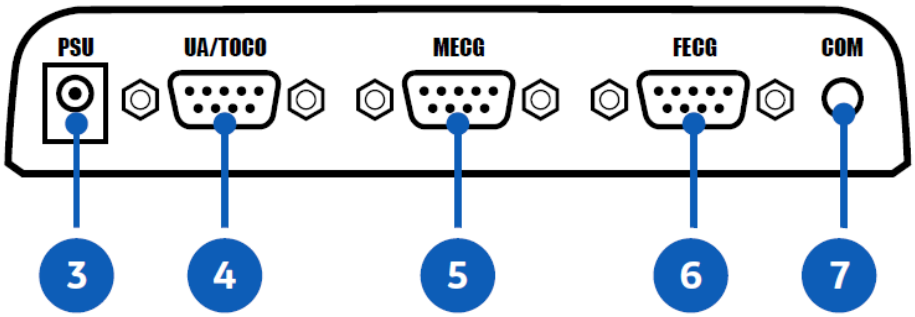
3.4 Novii Interface

The Novii Interface is an accessory to the Novii Pod which provides a means of interfacing the wireless output of the Novii Pod to the transducer inputs of a compatible Maternal/Fetal Monitor. The Novii Interface enables signals collected and processed by the Novii Pod to be printed and displayed on a compatible Maternal/Fetal Monitor and sent on to a central network, if connected.

No data is stored by the Novii Interface; the screen provides user feedback on the signal quality, Bluetooth status and other settings with help information when appropriate. There is an option to display a digital value of the maternal heart rate when MECG is not available as a monitoring option on the Maternal/Fetal Monitor or the MHR cable has not been connected, see Section 4.3.2.



1. Touch Screen Display
2. Wireless Charging Bays (x2)
3. Power Supply Connection
4. UA/TOCO Cable Connection
5. mECG Cable Connection
6. fECG Cable Connection
7. COM Port [Service Use Only]

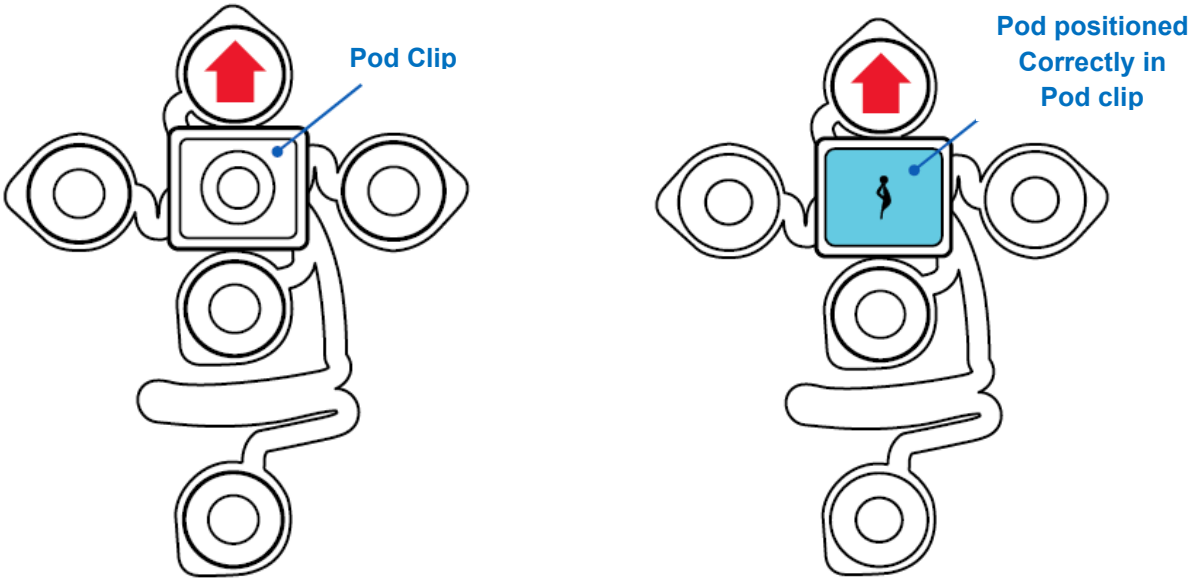


There is no power button on the Novii Interface, removing the power supply will turn the Interface off. If the Interface if switched on and there has been no activity for 10 minutes, the Interface will go into the 'power-save' standby mode, this will allow the Pod(s) to fully charge and then automatically turn off when full, with minimal power consumption.

3.5 Novii Patch

The Novii Patch is an accessory to the Novii Pod and contains the surface electrodes that attach to the maternal abdomen. The Novii Pod connects directly to the Novii Patch via the Pod Clip while in use. Features include:

- Single patient use
- Maximum 12-month shelf life. Store flat, no more than 10 high, at +10°C to 30°C (+50°F to 86°F)
- Hypoallergenic
- No latex used in manufacturing
- Can be worn for up to 48 hours
- Pod Clip magnetically holds Pod in place
- Waterproof when only Pod is attached[3]
- May reinforce electrodes with medical tape or transparent adhesive dressing



[3] Novii works well in shower with splashing, but Bluetooth signal cannot transmit and all signals will be lost if Pod is submerged under water in a tub

Section 4 - Installation & Settings

Installation of the Novii Wireless Patch System should be performed by a trained healthcare professional.

Novii Interface settings allow the audio alerts and MHR display to be adjusted to the hospital requirements.

Factory default settings are:

- Language –English
- Display MHR on Novii Interface - Disabled
- Audio alerts – Disabled

In a typical situation:

- The Novii Interface will be located on the same cart or furniture as the Maternal/Fetal Monitor (either using a VESA mount or on the top of the cart) allowing the operator to use both devices conveniently. Cable connection of the Novii Interface to the Maternal/Fetal Monitor and to the AC power supply is described below, Section 4.2.

- After setup and the Patient is wearing the Novii Pod and Patch, the patient can be positioned anywhere within the room and, depending on the construction of the L&D floor and interference from other Bluetooth and Wi-Fi transmitting devices, can be up to 100 feet away (the Bluetooth Class 1.5 connection allows distances up to 100 feet / 30 meters between patient and the Novii Interface under ideal line of sight situations).

4.1 Installation

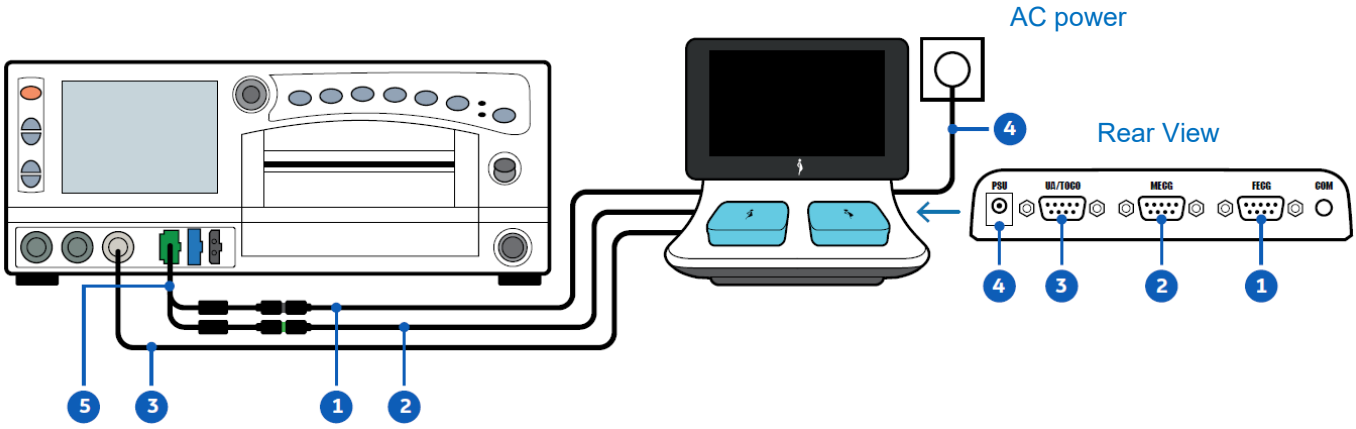
4.1.1 Power on/off

When the Novii Interface is switched on, by connecting the power supply (there is no on/off switch) the following splash display will be shown, indicating the Interface program version number, for around 5 seconds while the device starts and internal checks are performed.

4.1.2 Select Language

To select language, see Section 4.3 and 4.3.1.

4.2 Cable Connection



1. fECG Interface Connection Cable

2. mECG Interface Connection Cable

3. UA Interface Connection Cable

4. Power Supply Cable

5. Y Adapter Cable – needed for GE 259cx monitors only

The Novii Interface will be supplied with specific interface cables and calibrated only for use with GE Corometrics 259cx and 174 Maternal/Fetal Monitor, see section 13.1

When connecting to the GE Corometrics 259cx Maternal/Fetal Monitor it must be equipped with GE Y-adapter cable (part# 1442AA0), shown below:

The Interface Cables are permanently connected by using a Screwdriver to secure them to the back of the Interface. Cable Connection is as follows:

a. Connect Novii FECG interface cable (105-PT-102) to the FECG (Fetal Scalp Electrode) port on the Fetal Monitor first (using the already connected GE Y adaptor if using the Corometrics 259cx), then into the port labelled FECG on the rear of the Novii Interface, tighten screw with a screwdriver.
b. Connect Novii UA interface cable (105-PT-106) to the TOCO port on the Fetal Monitor first and then into the port labelled TOCO on the rear of the Novii Interface, tighten screw with a screwdriver.
c. If available on the Maternal/Fetal Monitor being used, connect Novii MHR interface cable (105-PT-104) to the MECG port on the Maternal/Fetal Monitor first (using the already connected GE Y adaptor if using the Corometrics 259cx) and then into the port labelled MECG on the rear of the Novii Interface, tighten screw with a screwdriver.

1. Connect the cable of the Novii power supply (2111623-001) to the power socket on the rear of the Novii Interface (socket labelled PSU), and then connect the power supply to the AC power source.

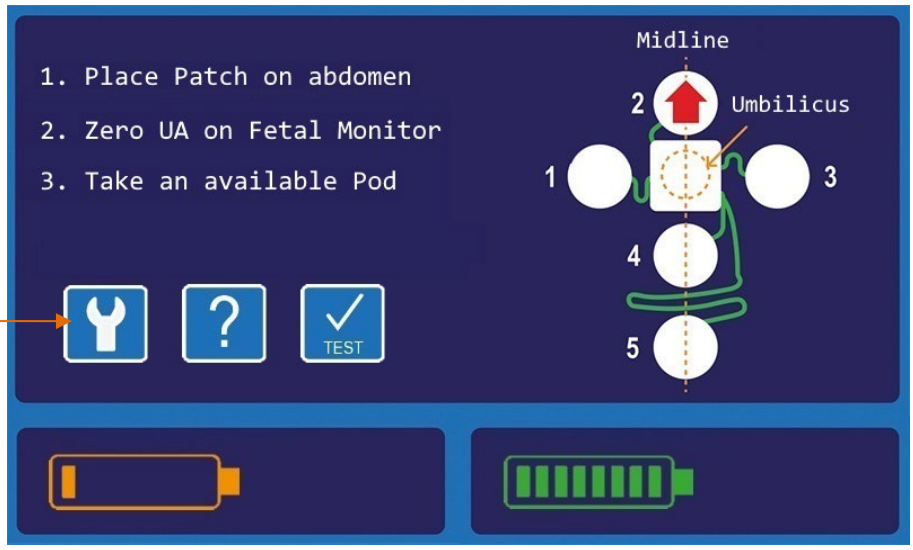
2. The Power Supply of the Novii Interface is regarded as part of the Medical Equipment.

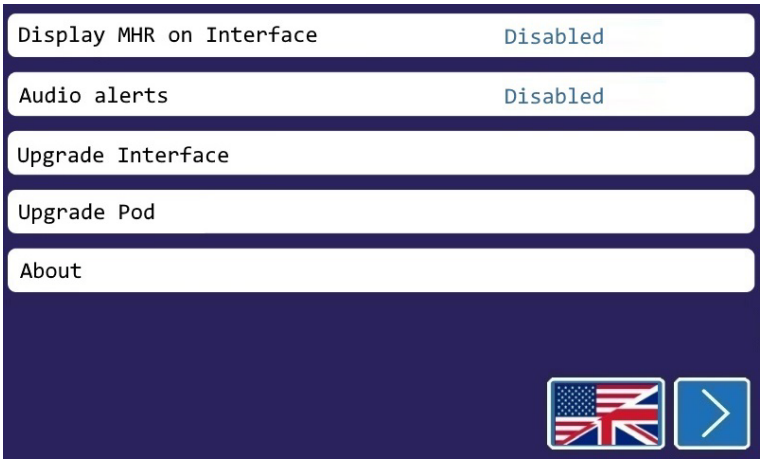
CAUTION: It is important to run the Novii TEST sequence after installation to ensure that the Interface, cables, 'Y' cable adaptor and Maternal/Fetal Monitor are working correctly, Section 5. It is important that during the test the 'Y' cable is moved around to ensure there are no intermittent connection problems. If you see FHR or MHR errors please quarantine the 'Y' cable and advise your GE Healthcare representative.

4.3 Settings

From the Start screen, Section 6.4, enter set up by selecting the SETUP button 

To access the settings, touch the SETUP icon



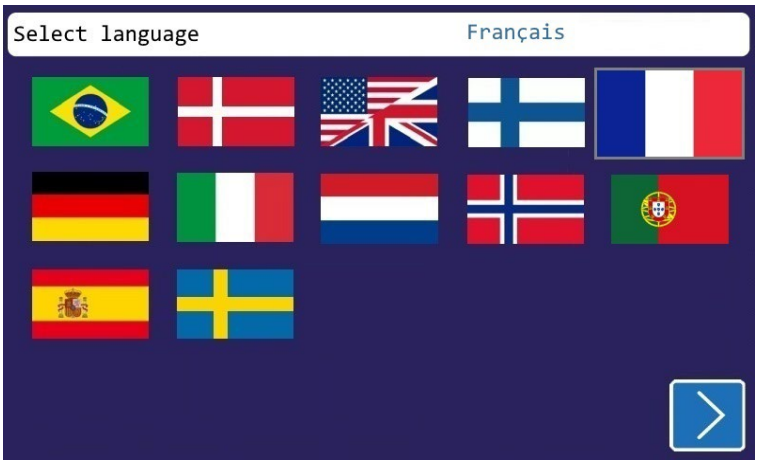


There is only one 'SETUP' screen, touch 'NEXT/EXIT' forward arrow key  to accept changes if any made and exit.

Touching the item 'bar' will scroll the user through the available options or take the user to another screen with a list to select from or more information/options e.g. ABOUT

4.3.1 SELECT LANGUAGE

Touching the language Flag  will display the 'Select Language' screen, select the flag relevant to the language that you want to use. Once the selected flag is highlighted, then press the forward arrow key  to save and exit. The Interface will automatically restart.



4.3.2 DISPLAY MHR ON INTERFACE

Touching this item 'bar' will Enable or Disable the MHR display on the Novii Interface.

Selecting to display the MHR on the Novii Interface will automatically turn on the "MHR/FHR coincidence Alert". The default is not to display the MHR on the Novii Interface. As well as a visual alert there is also an audio alert and this will be enabled if the AUDIO ALERTS are turned ON, see Section 4.3.3 below.

4.3.3 AUDIO ALERTS

The factory default is AUDIO ALERTS DISABLED and can only be changed in the SETUP. By touching the AUDIO ALERTS item 'bar' in SETUP the audio alerts can be ENABLED, providing an audible alert to supplement the visual alert for the following situations:

i. Low Pod battery - Audio alert is always enabled
ii. Pod not returned to Interface charging bay - Audio alert is always enabled
iii. MHR coincident with FHR (only if the DISPLAY MHR ON INTERFACE has been Enabled) and Audio Alerts have been enabled
iv. Electrode(s) detached from abdomen. Audio alerts need to be enabled
v. Patch not genuine - Audio alert is always enabled

Once an alert sounds it can be silenced by touching the SOUND button which will be flashing or by following on screen instructions. If the alert condition continues the alert will repeat according to the schedule below:

Alert Condition	**Initial Alert Condition**	**Once acknowledged Audio Alert will repeat if the condition does not resolve after**
Low battery	Up to 60 minutes battery life left	15 minutes
MHR coincident with FHR	MHR is within ±10 bpm of FHR for 60 seconds	60 minutes
Pod left in Patch and Novii Patch electrode/skin preparation check is not passed or bypassed	After 10 min	Will not be repeated once alert has been cancelled
Pod not returned after removed from Patch	2 minutes after end of 2 minute count down	Will not repeat after Pod is docked or alarm condition is acknowledged on display screen
Pod not attached to Patch	After 2 minute count down has finished	Will not repeat after Pod is docked or alarm condition is acknowledged on display screen
Electrode(s) detached from abdomen	When electrode(s) detached	Will not repeat after audio alert has been silenced

4.3.4 UPGRADE INTERFACE

A confirmation screen shows that the Novii Interface is in Bluetooth upgrade mode with instructions. This should only be carried out by a trained bio-med engineer or a trained GE Healthcare authorized person, who has access to the upgrade instructions.

4.3.5 UPGRADE Pod

A confirmation screen shows that the Novii Pod placed in left charging bay is in Bluetooth upgrade mode with instructions. This should only be carried out by a trained bio-med engineer or a trained GE Healthcare nominated person, see the service manual for instructions.

4.3.6 ABOUT

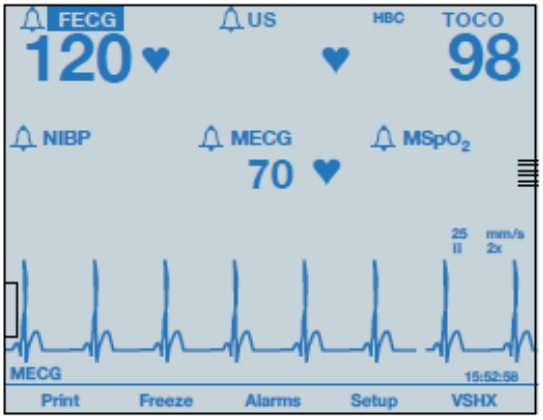
Touching the About item 'bar' will display the Novii Interface firmware version and serial number along with the firmware version and serial number of any Pods docked.

Section 5 - TEST function

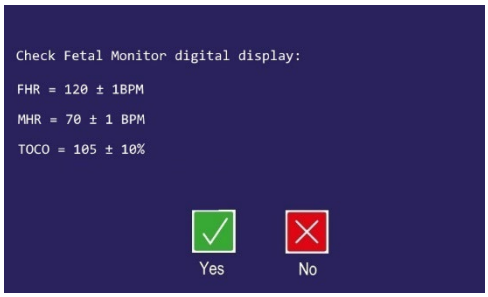
Test Function is used to confirm that the Novii Interface is correctly connected to fetal monitor and that there are no problems with the cables. A signal will be sent to the Maternal/Fetal Monitor to check correct functionality. GE Healthcare recommends that whenever the user requires evidence to demonstrate the correct operation of the Interface and Maternal/Fetal Monitor e.g. after installation, or to confirm that there are no breaks in the cables or a fault has developed; the TEST button on the Start screen should be used. The GE Y adaptor should always be moved, shaken, to ensure there are no intermittent problems.

1. On Novii Interface Start Screen press 

2. Zero UA (press the UA Reference) on Fetal Monitor  then press 



3. FHR, MHR and UA test signals are sent from Novii Interface to Fetal Monitor

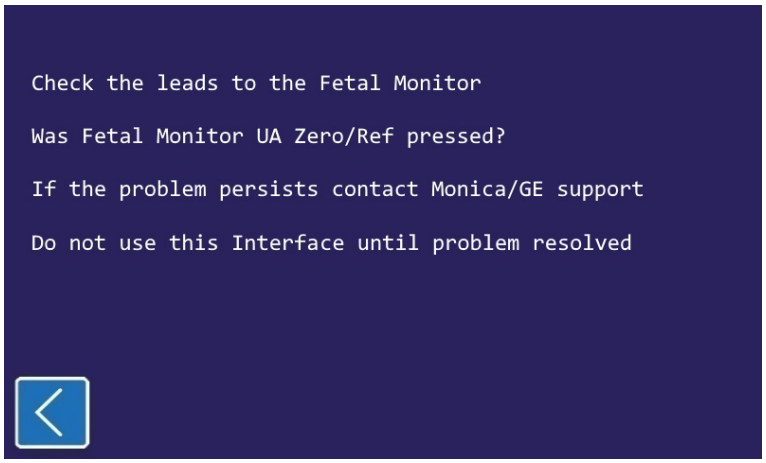


4. Check that all signals are displayed and parameters are in range. Shake Interface cables to test for intermittent breaks in signal and replace cable if needed. If signals are missing, check that connections are secure.

The FHR digital display should read 120±1bpm, the MHR digital display should read 70±1bpm and the TOCO should read 105±10% full scale deflection. If the values are not in the expected range, contact your GE Representative or Distributor and do not use this Novii Interface until the problem has been resolved.

The test values shown on the digital Maternal/Fetal Monitor display should be continuous and stable. If not, check the GE Y adaptor and if faulty, quarantine and contact your local GE Healthcare representative.

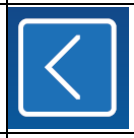
Answering YES will end the TEST process and take the user back to the Start screen, (Section 6.4). If the user answers NO the following instruction will be displayed:



Section 6 - Operating Novii

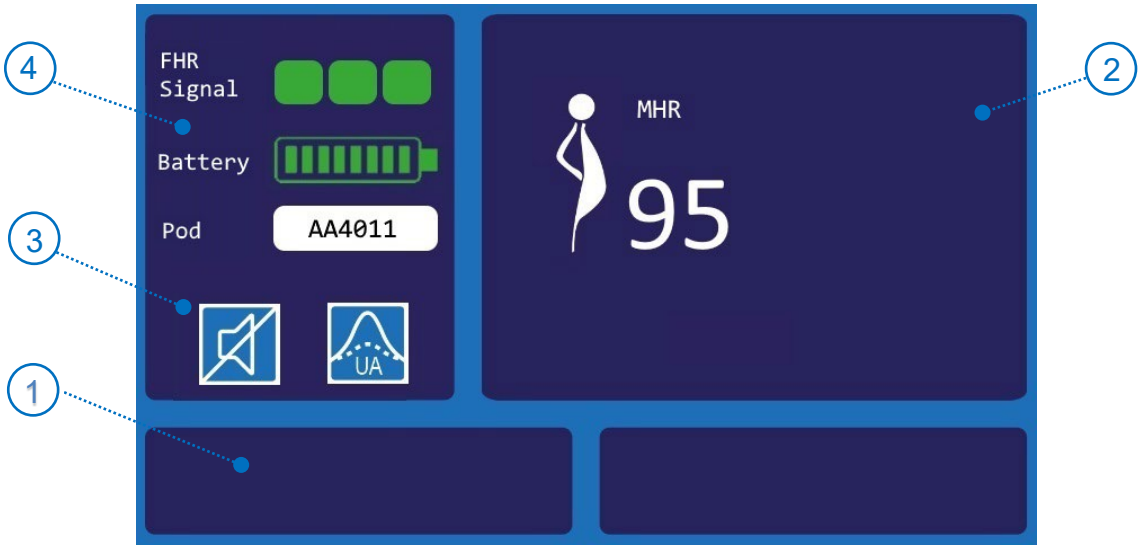
6.1 Introduction

To help set-up the Novii Interface and provide status information of how the Pod and Patch are operating; a touch color screen is used. There is no on/off switch; the Novii Interface will always be on when connected to a live power source. The Novii Interface follows a number of simple rules and convections:

Warning, Alerts and Actions:	Are always displayed in ORANGE		
Touch Buttons:	Active controls to change the status of a function or select a new function are displayed with a white icon in a blue box showing the status or function. For example:		
		Used as back/cancel instruction	 Used as a next/exit instruction
Novii Pod Status:	The battery charging levels and status of a Novii Pod placed in the right or left charging bay (2) is shown in lower left or right of the display.		

6.2 Monitoring Screen

The screen on the Novii Interface guides the user when starting a monitoring session and then helps the user achieve the best signal quality, through status alerts and control options. The format of the main monitoring screen is shown below:



1. Status of the Novii Pod positioned in the charging bay directly below (left or right bay)
2. This area reserved for help/support information, alert messages and Novii MHR display when enabled
3. User controls: SOUND (on/off) and UA SENSITIVITY (high/low) Touching these buttons will toggle between the two states.
4. During monitoring this area provides Novii Pod performance/status information: Battery life, fECG signal quality and serial number of the monitoring Pod. When not monitoring, this area is combined with area 2 to extend region for help/support information/messages.

6.3 Initial Screen and Standby Screen

6.3.1 Power on/off

When Novii Interface is switched on, by connecting the power supply (there is no on/off switch) the following splash display will be shown, indicating the Interface program version number, for around 5 seconds while the device starts and internal checks are performed.

If the Novii Interface has been inactive for 10 minutes and there is no monitoring, no Bluetooth connection and no other event activity, the Standby screen below will be displayed:

Monitoring cannot be started when the Standby screen is display, if a Pod is removed it will not power on.

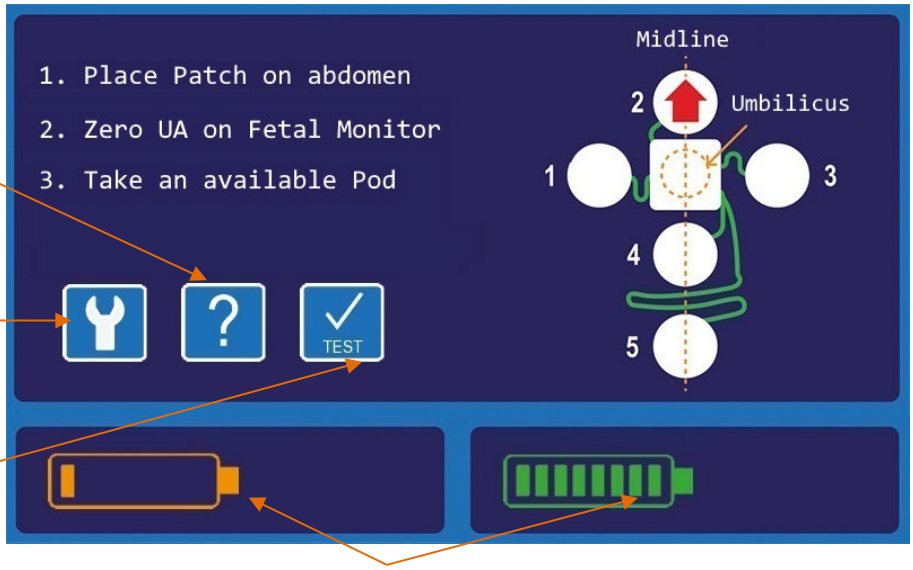
Touching the Standby button  , or removing and redocking a Pod will take the user to the 'start-screen ', Section 6.4.

To power off the Interface, remove the power supply from the back of the Interface or wall socket.

6.4 Start Screen

The Start Screen will be displayed if the following conditions are met:

- Novii Interface and Pods have been registered
- One or more Pods have been placed in the charging bays
- A Pod has sufficient battery life (>4.0hrs) to commence monitoring (it takes up to 2hrs to fully charge a Pod from empty):



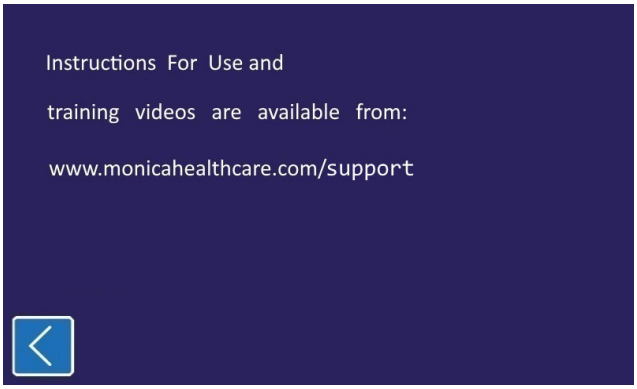
For additional support and help touch the HELP icon

To access the settings, touch the SETUP icon, section 4.3

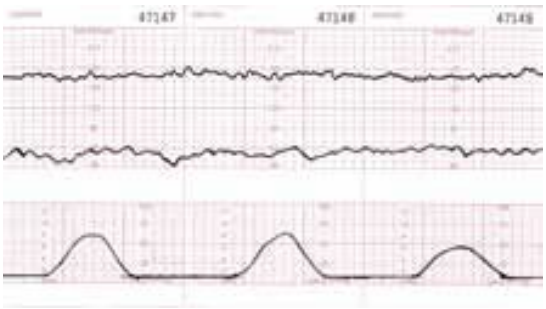
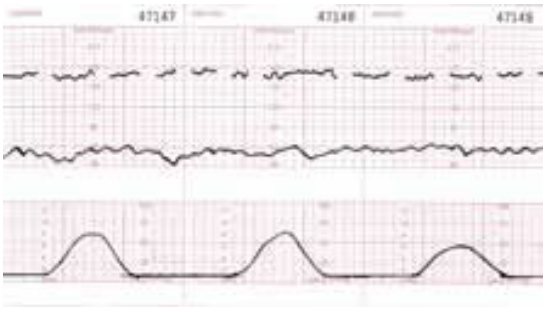
To check the connection to the fetal monitor touch the TEST icon, section 5

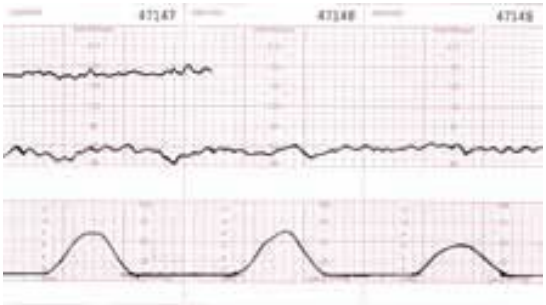
The status of the Novii Pod(s) placed in the two charging bays is shown here

When the help button is selected from the start screen, the user will be guided on how to access further support and instructions.



6.5 Novii Interface Icons and Status Messages

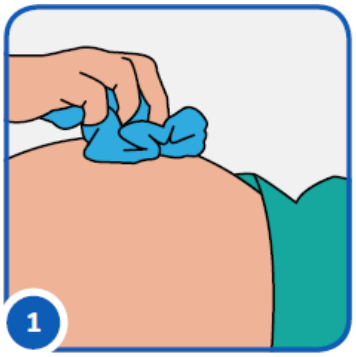
Symbol	Description
	Digital display of the maternal heart rate (MHR). Needs to be enabled in the settings, Section 4.3.2. **Note – MHR is not shown when alert or help messages are being shown**
	When the MHR is shown on the Novii screen. This alert symbol is displayed when the MHR and FHR are within 10 bpm of each other for longer than 60 seconds. If enabled, an audible alert will also be heard until the user silences it by touching the audio alert sound icon which will be flashing. The audio alert will be silenced for 60 minutes. The visual alert will disappear when the FHR and MHR diverge with a greater than 10 bpm difference for a cumulative time of 60 seconds.
	Good FHR Signal Quality – Expect continuous FHR tracing. 
	Poor FHR Signal Quality – FHR extraction may be compromised, with possible FHR gapping and/or artifact. Be cautious in interpretation and seek confirmation, 

	Bad FHR Signal Quality – No fECG can be extracted and FHR gapping or artifact is to be expected. Use ultrasound transducer to obtain/confirm FHR for short durations. Consider troubleshooting (section 18) if bad signal is frequent or continuous. Increased noise or poor Patch placement may cause poor/bad signal quality. 
	Novii Pod battery status - all 8 segments displayed green indicates the Novii Pod battery is fully charged with a life of up to 11 hours.
	Novii Pod battery status - Pod battery life has dropped to around 60 minutes and the user should be prepared to replace the Pod. When this occurs an alert/help message will be displayed, see Section 9.1.
	Novii Pod battery status – Pod battery is fully discharged
AAXXXX	Serial number of the Pod connected to the Patch
	Uterine Activity is set high and this is the correct setting for active Labor. Touching the button will change the mode to low sensitivity as shown below. The default start-up setting is high.
	Uterine Activity is set low and many users find this low sensitivity setting better for pre/early induction Labor. In low sensitivity artifact produced by fetal and maternal movement is suppressed. Touching the button will change the mode to high sensitivity as shown above, which is the default start-up setting. When using the Low UA sensitivity setting the Interface will automatically switch back to High UA sensitivity after 60 min. There is no audio or visual alert/help message, other than a change to the UA sensitivity button when this happens.
	Sound alerts enabled. Factory default setting is OFF During an audio alert, touching the SOUND ON button will disable audio.
	All sound alerts disabled except for Battery Low, Return Pod to charging bay and Patch not genuine

Section 7 - Applying the Novii Patch

7.1 Good Practice

- The Novii Patch is Latex Free, however ask if the patient has any other allergies or skin sensitivities that might prevent the Patch from being used.
- Place the Novii Patch before connecting Novii Interface to fetal monitor, to allow gel time to absorb in to the skin.
- Check Patch expiration date. If Patch is opened but not used, may reseal, date and use within 30 days.

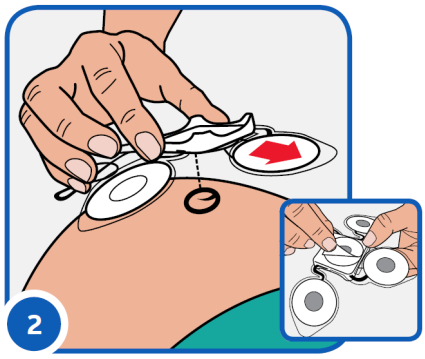


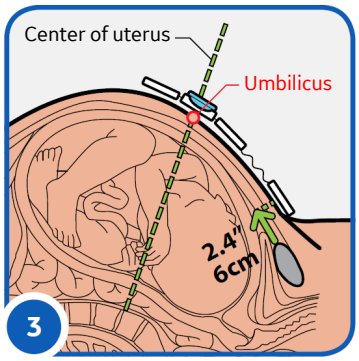
7.2 Before Placing Novii Patch

1. Wash the area where the Patch will be placed with mild soapy water, rinse and ensure the area is dry. Do not use hospital grade anti-microbial soaps which may contribute to adverse skin reactions.

7.3 Standard Patch Placement

2. Remove backing from Pod Clip. Place the Pod Clip on the midline over the umbilicus (center of the uterus). Arrow pointing towards patient's head
3. Center of bottom electrode is placed on the midline, approximately 2.4" / 6cm above (towards the patient's head), the symphysis pubis. Typically, this is just above the hairline.





Do not place the Novii Patch on skin with any lesions.

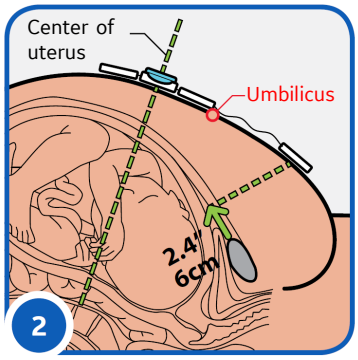
7.4 Patients with Displaced Umbilicus and/or Pannus

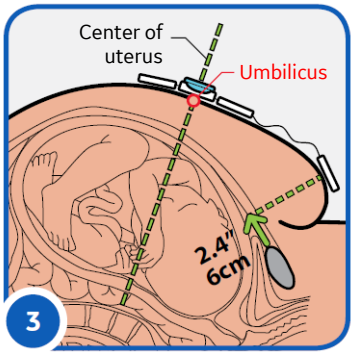
2. Displaced Umbilicus – Where the umbilicus is displaced downwards by more than 3cm from the center of the uterus, with the patient supine or semi supine, you will need to estimate where the center of the uterus is. DO NOT place Pod Clip over the umbilicus.
Find the centre of the uterus and place Pod Clip at this point on the midline. The following approaches can be used to find the centre of the uterus:
    a. Position Pod clip along the mid-line where it intersects the horizontal line passing over the iliac crests

    b. Position Pod clip along the mid-line at the mid-point between the fundus and symphysis pubis).

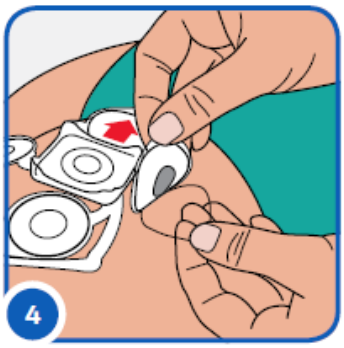
    c. Position Pod clip so that the top edge of electrode #2 is 5” / 12cm below the fundus.

3. If there is a large Pannus covering the pubic area, place bottom electrode on top of pannus approximating to the point 2.4” / 6cm above the estimated symphysis pubic bone. This is difficult to estimate and if the FHR signal is poor, reposition this electrode lower down on abdomen to maximize FHR signal and consider placing under the pannus just below turn ensuring the electrode is not folded.



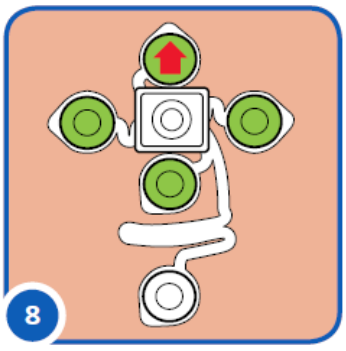


7.5 Applying Electrodes/Skin Preparation

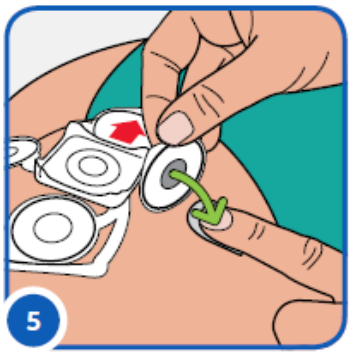


4. Lift up one of the electrodes around Pod Clip and remove the protective cover. (Do not exfoliate skin under center Pod Clip).

6. Exfoliation technique: using controlled gentle pressure do 3x vertical and 3x horizontal strokes (creating a '+' shape). Keep exfoliation area to a minimum. (Hold skin taught if required).

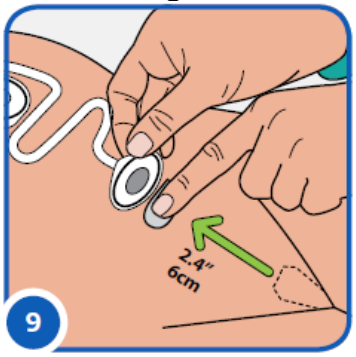


8. Repeat steps 4–7 for the remaining 3 electrodes around the clip.



5. Focusing on the area of skin below black foam, use skin prep tape to exfoliate (remove dead skin cells). Use one piece of 1" / 2cm skin prep tape for every 2–3 electrodes.

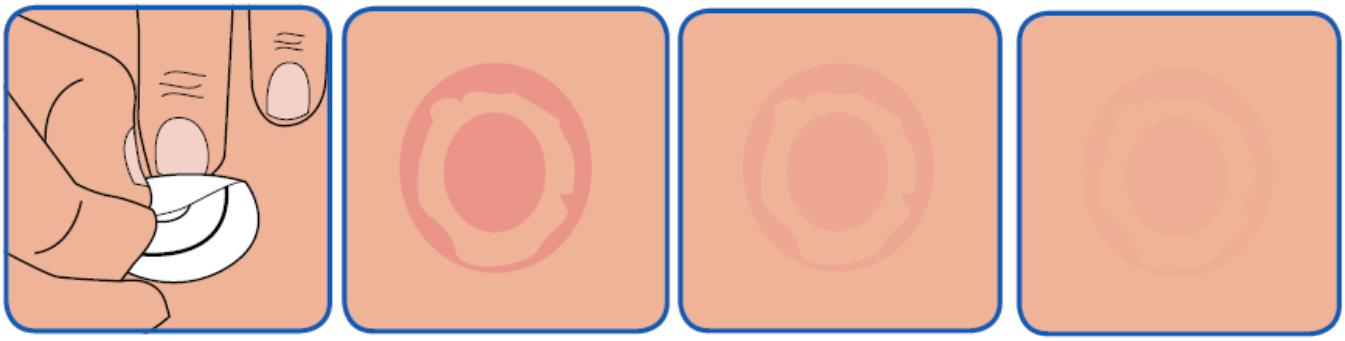
7. To accurately place the electrode - place the centre of the black foam over the center of the exfoliated area (+). Press on outer adhesive edge to secure in place.



9. Repeat steps 4–7 for bottom electrode, ensuring center of electrode placement is 2.4" / 6cm above symphysis pubic bone. (See pictures in steps 2 and 3).

7.6 Avoiding Skin Redness/Reaction

Application of electrodes on patients may result in some skin irritation or redness upon removal, but usually subsides within 24 hours and will leave no permanent marks.



Assess patient for skin allergies and sensitivities. Inform them that redness can occur and there is a low risk for an adverse skin reaction.

Patient may report a tingling sensation or itching when the Patch is first applied, but this should subside in 15-30 minutes.

If this worsens, assess for an allergic reaction by lifting an electrode. The electrode directly below the Patch Clip will have minimal interference with monitoring if lifted. Remove Patch immediately if allergic reaction is noted. Avoid use of alcohol or strong soaps which dries patient's skin and may increase susceptibility to reactions.

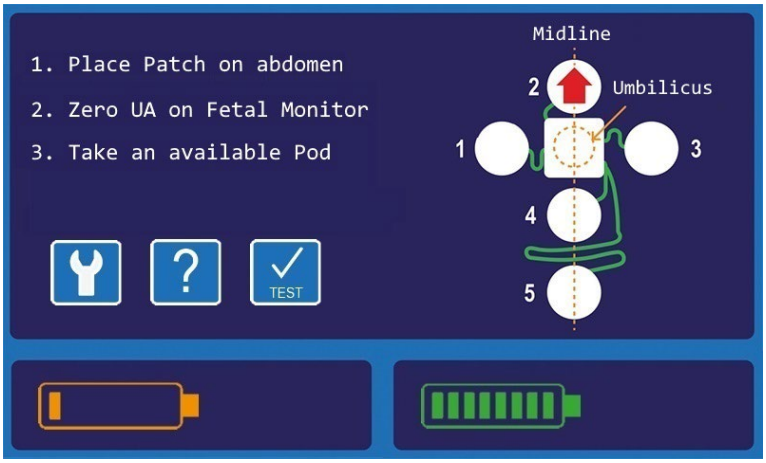
Correct Patch removal will help reduce skin irritation: To remove, gently peel each electrode back slowly at a low profile (<45°), while supporting the skin.

Do not leave the Patch on for >48 hours.

Section 8 - Monitoring

8.1 Starting Monitoring

To start monitoring follow the three instructions on the Start Screen

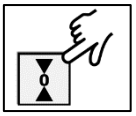


Instruction 1: Place the Patch on the abdomen

See section 7

Instruction 2: Zero UA on Maternal/Fetal Monitor

Press the UA zero reference button on the Fetal Monitor.

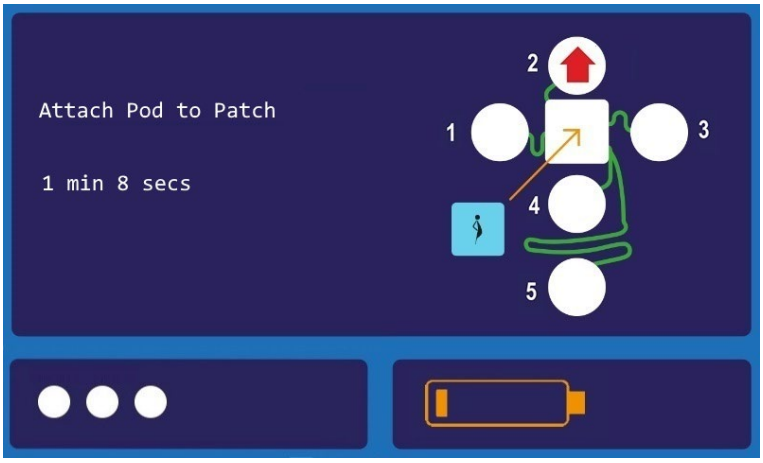


Instruction 3: Select a Charged Pod

1. Remove any Novii Pod from one of the Novii Interface charging bays as long as the Pod battery status icon is **GREEN**. Once it is removed the blue lights on the front of the Novii Pod will flash alternately, to indicate that the Pod is now 'active' and paired to the Novii Interface.

2. The Interface display will change to a countdown as shown below. The Novii Pod must now be clipped to the Patch, within 2 minutes. The Pod is attached to the Patch with the Novii symbol facing up. Magnets in both **the Patch clip and Pod ensure correct placement and, no force is required.**

3. The battery charging icon on the Interface will be replaced by a 'busy' icon (1, 2, 3 white dots), indicating that the Pod is preparing to establish communication with the Patch. The busy icon will remain until the MHR is detected when it will stop.



4. If the Pod is not attached to the Novii Patch within the 2-minute countdown it will switch off and the blue lights will go out and an audio/visual alert will be generated immediately after the countdown finishes.

5. If the 2nd Pod is removed from the charging bay whilst the 1st Pod is monitoring a patient, it will not turn on.

CAUTION: If the Pod is removed to start monitoring before the TOCO zero on the Fetal Monitor has been pressed; the user will have either re-dock the Pod and start again, or, palpate the uterus and when confident that the patient is not having a contraction press the zero TOCO button on the Maternal/Fetal Monitor.

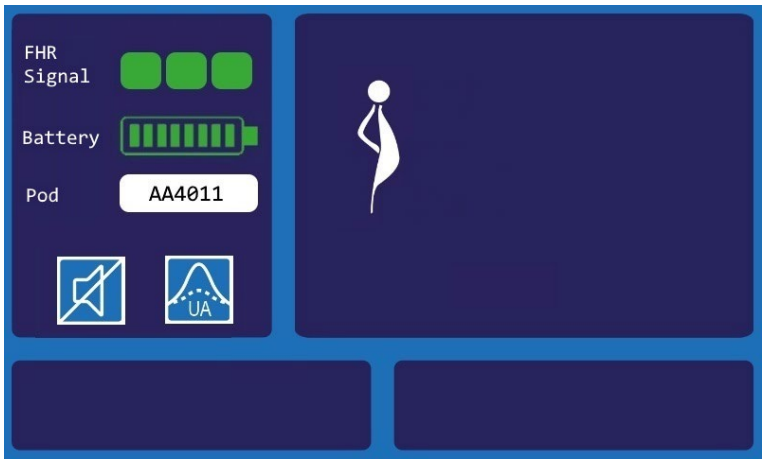
Electrode Check Screen

Once the Pod is attached to the Patch, an 'Electrode Check' screen will appear indicating if the skin preparation at each electrode site has been successful. If there is a skin/electrode problem the screen below will be displayed:

A diagram of the Patch is displayed on the Electrode Check Screen, as shown above, with a description of the symbols shown on each of the electrodes. If an orange circle ○ or red cross ✕ is shown on an electrode corresponding to the electrode site, more skin preparation is required. Follow the steps below to resolve:

1. Press down on center of electrode to ensure good skin contact – then wait 10–20 seconds for gel to absorb. If ○ or ✕ remain proceed to Step 2.
2. Lift problem electrode, wipe gel from skin and repeat exfoliation (see section 7.5) with new piece of prep tape.
3. To avoid over exfoliation, only re-exfoliate the skin once and if ○ or ✕ remain then bypass the electrode check screen by pressing the forward button. Accuracy of the fetal heart rate should not be affected, but fetal heart rate detection may be lower.

When there are 5 green check marks ✓ the monitoring screen shown below will be automatically displayed (MHR Interface display disabled).



Monitoring Screen

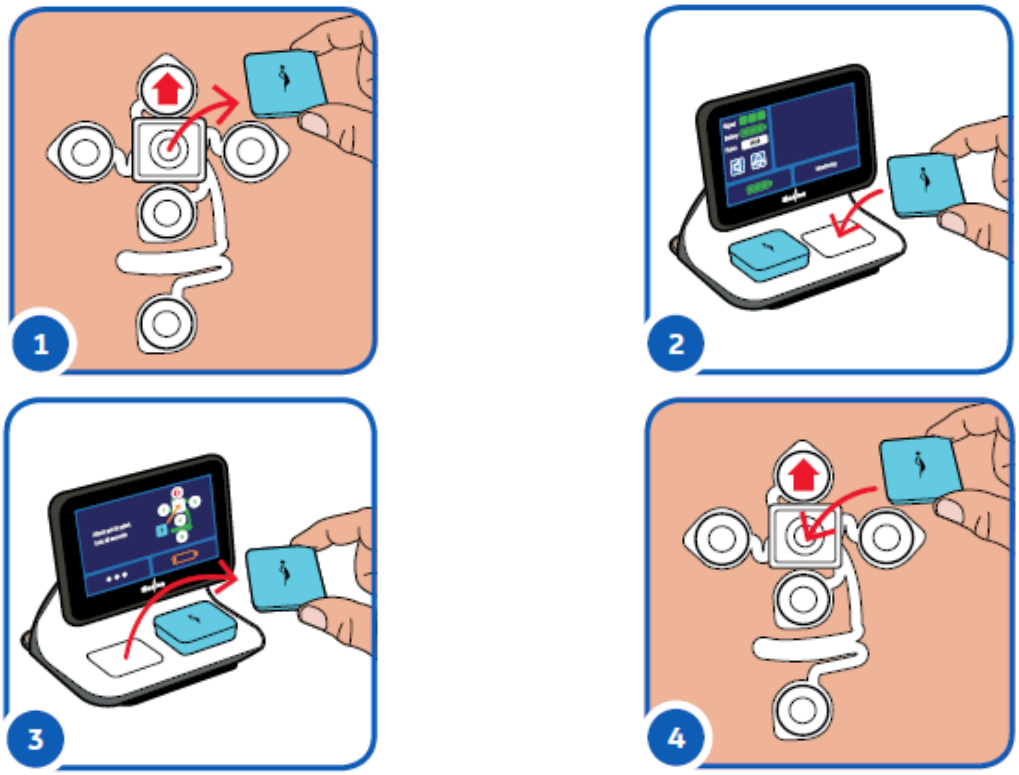
Once the monitoring screen above is displayed, FHR and UA will be immediately seen and heard on the fetal monitor, this is the Novii Mark being printed to indicate the start of a new monitoring session, see section 10.

FHR, MHR and UA monitoring should commence within one to two minutes and be displayed on the fetal monitor. Lights on the Novii Pod will flash slowly together to indicate that MHR is being detected and monitoring has commenced.

All clinical data is displayed on the fetal monitor. The Novii Interface screen helps the user achieve the best signal quality, control the UA sensitivity, view status alerts and if enabled display the MHR.

Caution: **When a Pod is being used for monitoring, the charging bay from where it was taken should not be used if possible**. It is 'locked' and a Pod placed in this charging bay during a monitoring session will not be recognized by the Interface. It will charge, but because it is not recognized by the Interface no battery charge icon, will be displayed, nor will the blue lights on the Pod flash slowly to indicate that the Pod is charging. The charging bay will be 'un-locked' when the monitoring session is ended.

8.2 Ending Monitoring or Swapping Pods



1. Remove Pod from Patch
2. Return Pod to Interface, then wait for battery icon to be displayed on the Start screen above Pod **(Monitoring Ended)**.
3. Once battery icon of returned Pod is displayed, zero the UA, then take fully charged Pod from Interface (if new Pod taken too soon it will not turn on).
4. Place a charged Pod on Patch **(Swapping Pod Complete)**.

Note: If you need to end the setup, remove the Pod from the Patch and return it to the charging bay on the Novii Interface that it came from.

8.3 Patch Removal

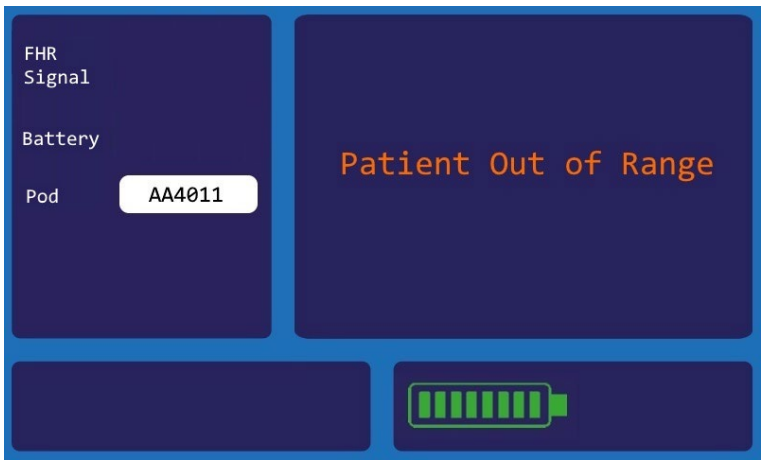
Correct removal will reduce skin irritation: Gently peel electrode back slowly at a low profile (<45°), while supporting the skin

Section 9 - Alert and Help Messages

To help the user the Novii Interface provides a number of help/alert messages or displayed symbols during monitoring. The messages are dynamic, so will disappear when resolved.

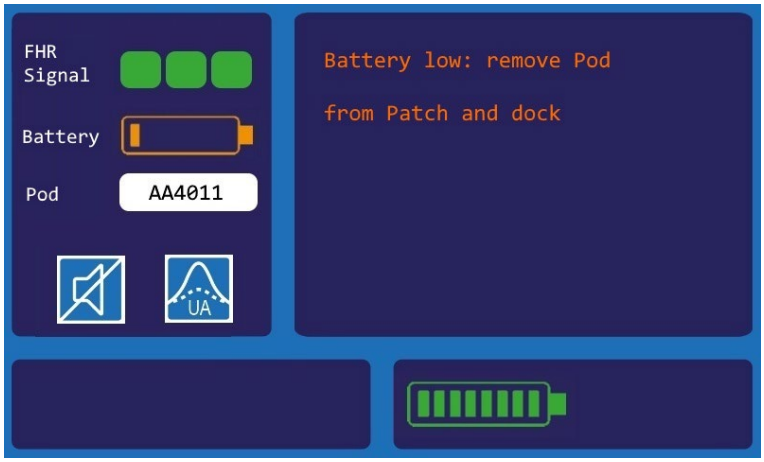
9.1 Alerts/Help during monitoring

9.1.1 Patient out of Bluetooth range



Patient is out of wireless range and the Interface cannot pick up the Bluetooth signal. Message will flash. Note loss of signal and battery information.

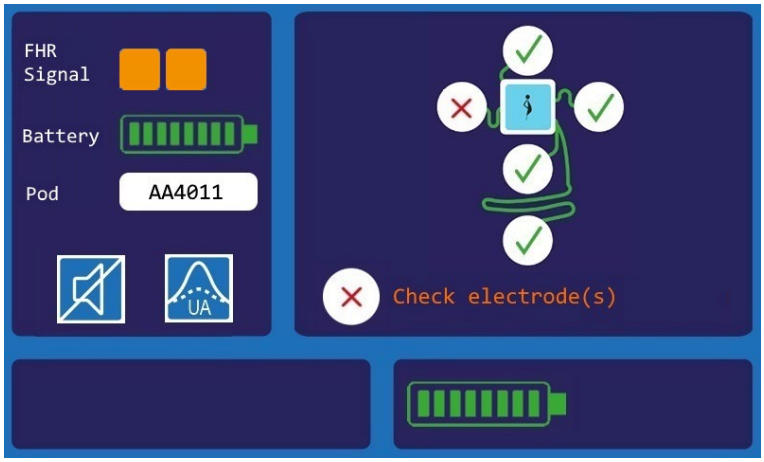
9.1.2 Battery Low



When 60 minutes of battery is remaining, the battery low alert message appears in orange and will flash. If enabled audio alert will sound. Alert message and sound will continue until silenced.

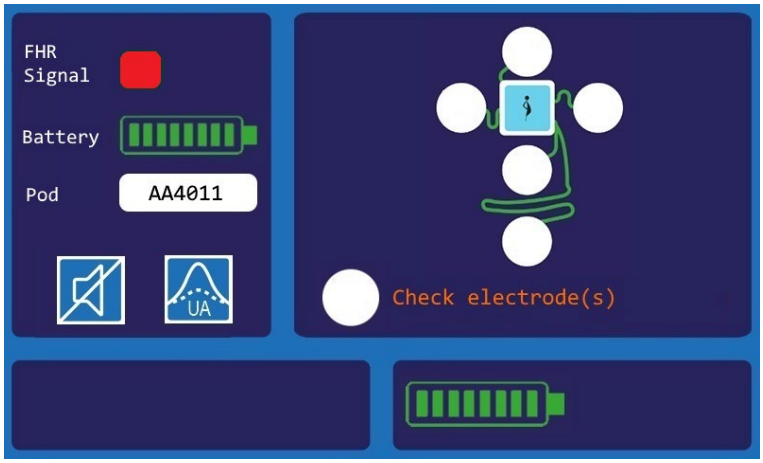
See section 8.2 for swapping Pods

9.1.3 Electrode disconnection - Single



The Novii Interface will create a priority visual alert if an electrode has become disconnected. If only one electrode has become disconnected then the display will indicate the electrode to check. Reattach the highlighted electrode to the skin, if required micropore tape can be used to ensure the electrode is held in place.

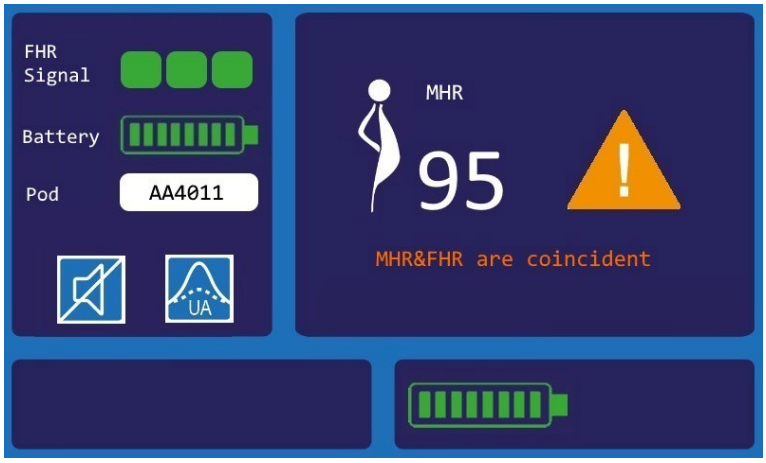
9.1.4 Electrode disconnection - Multiple



If more than one electrode has become disconnected, this display will be shown and **all** electrodes should be checked to ensure a good contact with the skin. Micropore tape can be used to ensure the electrodes are held in place.

9.1.5 MHR/FHR coincidence:

The Novii Interface will create an audio/visual alert if the MHR and FHR are coincident (+/-10BPM for more than 60s). This visual alert is available only when Display MHR on Interface option is enabled.

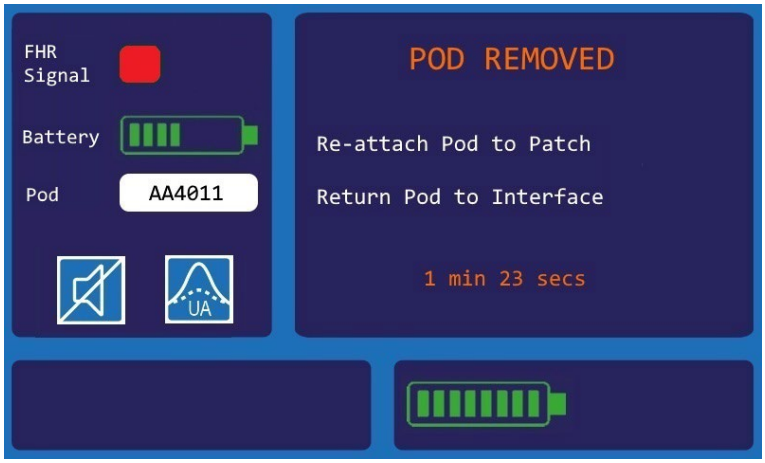


In this example, an audio alert will be heard. The audio alert can be silenced for 60 minutes by touching the 'Sound' icon.

The alert will disappear if the coincidence disappears.

9.1.6 Pod removed from Patch visual alert

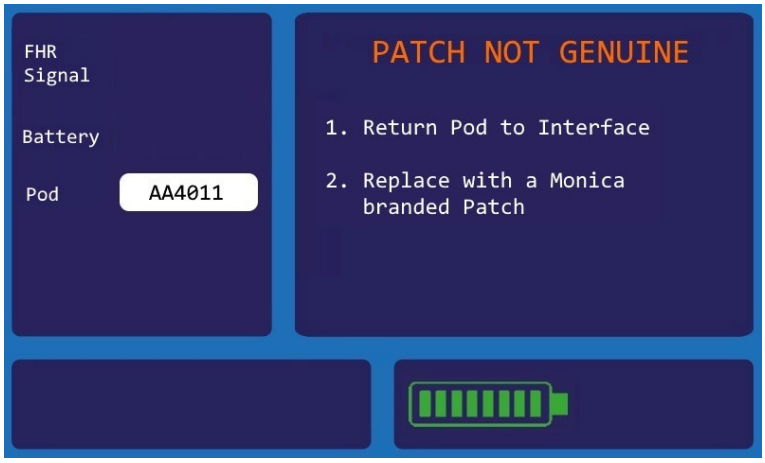
During monitoring if a Pod is removed from Patch. The following 2-minute count-down message will be displayed.



If the Pod has not been re-attached to the Patch or placed in charging bay at the end of the 2 minutes countdown, the monitoring session ends. The Pod switches off and the Interface will return to the Start Screen. The return Pod to charging bay audio/visual alert, Section 9.2.1, will appear after 2 minutes if the Pod is not returned to a charging bay.

9.1.7 A non-Novii Patch is detected during monitoring

During monitoring the Pod will periodically read the security chip and if the Patch is not recognized (non-genuine) the monitoring session will end and the Pod will switch off. The Interface will show the following display with an audio alert for 5 minutes until the Pod is returned to a charging bay on the Interface:



9.1.8 Monitoring Alert priority

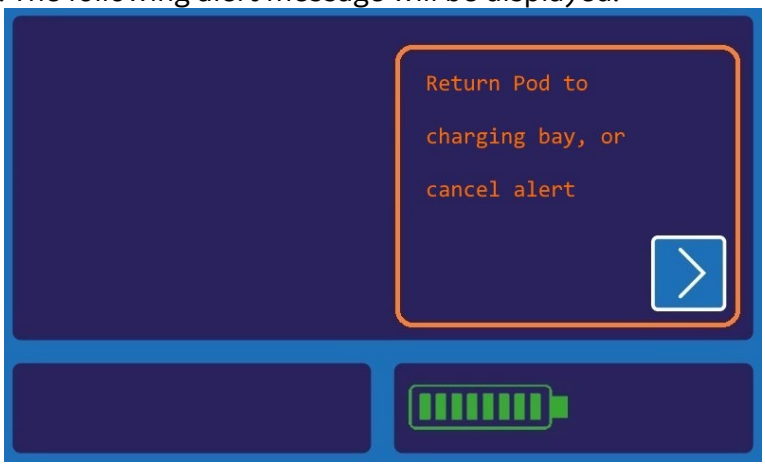
Priority order is:

1. PATIENT OUT OF RANGE
2. CHECK ELECTRODES for a possible disconnection
3. BATTERY LOW
4. MHR/FHR COINCIDENCE (only if MHR is displayed on Interface)
5. Pod Removed

9.2 Interface Alerts/Help – No Monitoring

9.2.1 Return Pod to charging bay visual alert

If a Pod is removed from a charging bay when no monitoring session is in progress and Pod has sufficient charge there will be an audio and visual alert after 2 mins if it has not been placed in a Patch or re-docked. The following alert message will be displayed:



The alert shown above can be cancelled by touching the forward/exit arrow button and it will not be repeated or by returning the Pod to charging bay.

9.2.2 Pod left in Patch without responding to skin/electrode problems

If a monitoring Pod is left on Patch and skin/electrode problems have been detected, but no action taken (bypass or repeat exfoliation). After 10 minutes the 'Return Pod to charging bay' audio/visual alert will appear.

9.2.3 A non-Novii Patch is detected at the start of monitoring visual alert

When the Pod is first connected to the Patch, it will read the security chip embedded in the Patch. If the Patch is not recognized the following message will be displayed:

If back arrow button is pressed, the Pod will turn off, but if the Pod is not placed in a charging bay within 2 mins, the return Pod to charging bay alert triggers (Section 9.2.1)

9.3 Pod Alerts/Help messages

The lower section of the screen shows the charging status of a Novii Pod placed in the right and/or left Novii Interface charging bays.

While the Pod is charging one of the blue lights on the Pod will flash slowly. When the Pod is fully charged it will turn off.

The color of the battery icon indicates if the docked Pod has sufficient charge and is able to start a monitoring session. Green means yes, orange means **no**. If a Pod is removed from the charging bay showing an orange battery icon, the blue lights on the Pod will not turn on. The Pod is off and cannot be used to connect to a Patch. This is because the battery has yet to reach a minimum battery charge level to give at least 4 hours of monitoring.

There are 6 possible status messages/displays for each charging bay, shown by the left icon:

1. Pod has insufficient charge <4 hour – Pod will not switch on if removed.

2. Pod is not recognized e.g. wrong firmware or communication fault. The interface will automatically try to initialize communication again and restart, but if message remains contact your local GE representative to arrange service request.

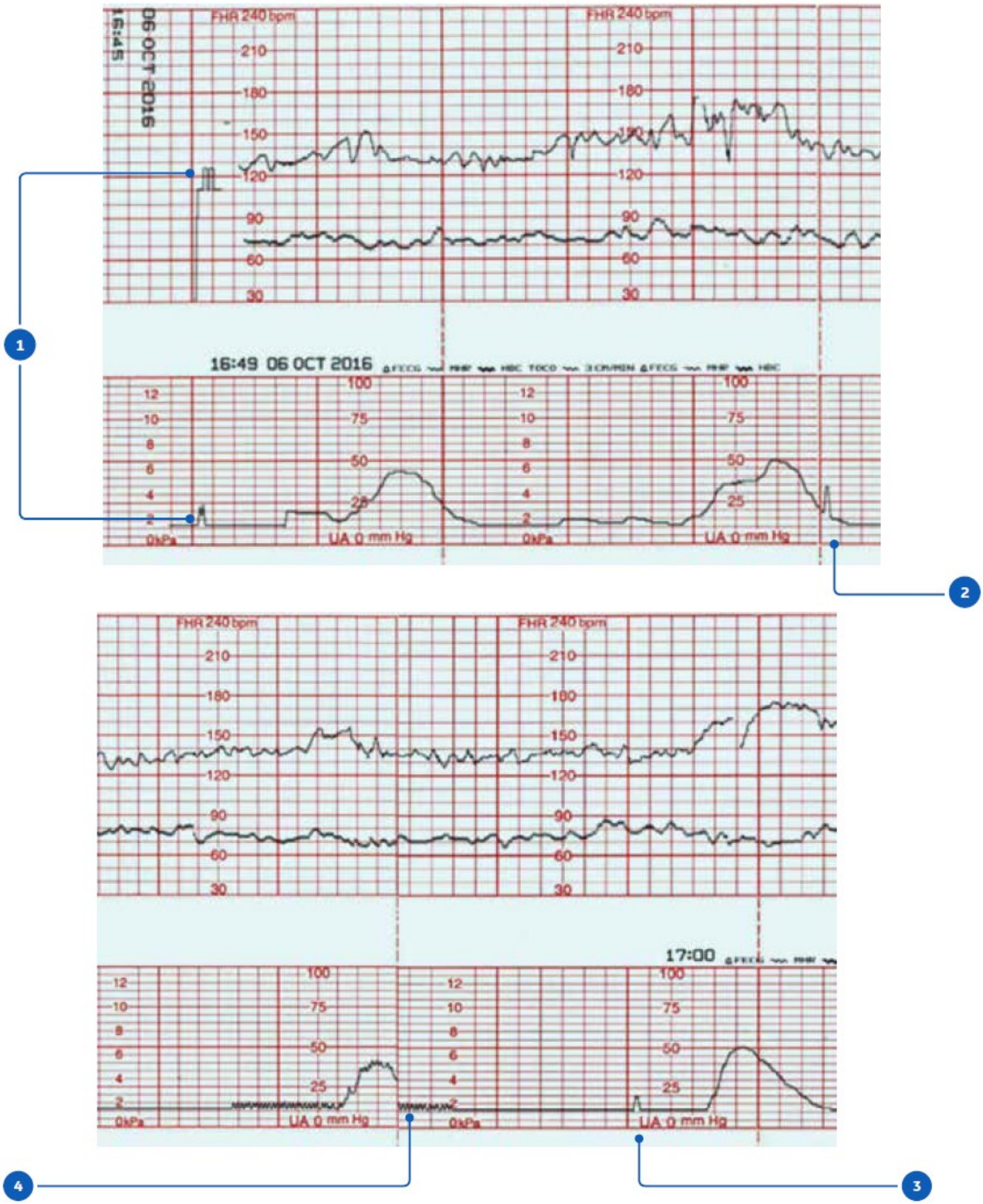
3. Battery fault, contact your local distributor / GE sales representative to arrange service request.

4. Pod is fully charged and can be used to monitor a patient.

5. When a Pod is placed or removed from a charging bay a waiting icon (1, 2, 3 white dots) may appear. This indicates that the Interface has recognized the Pod placement or removal but is waiting for internal checks to be completed.

6. Pod is missing from charging bay

Section 10 - Trace Features



Note: Trace is displayed with print speed at 3cm/minute. Slower speeds will compress appearance of images.

1. Novii Mark (at the start of a new monitoring session).
2. Novii Identifier (every 5 minutes) – larger height indicates high UA Sensitivity
3. Novii Identifier (every 5 minutes) – smaller height indicates low UA Sensitivity
4. Trace is thickened to indicate maternal movement such as ambulation or rocking – caution with UA interpretation as UA artifact may be present.

Novii data is displayed on the Fetal monitor as FECG, MECG and Toco (external UA), the Novii Mark and Identifier enable the user to identify that Novii is or has been used.

10.1 Novii Mark

During the first 10 seconds of a new Novii monitoring episode, a Novii Mark resembling an M will be sent to both the UA and FHR Maternal/Fetal Monitor inputs. This mark will be recorded on the printed trace and electronic record to indicate that Novii monitoring was started.

10.2 Novii Identifier

The Fetal Monitor will print and store on the electronic record, a Novii Identifier (a small identifying spike) on the UA trace every 5 minutes, to indicate that Novii monitoring is in progress.

The height of the Novii Identifier mark is determined by the UA sensitivity setting. Mark height reduces by 50% when Low UA sensitivity is set.

10.3 Maternal Movement Alert using the UA trace

Following a 20 second period of consistent maternal movement (identified by the accelerometer in the Novii Pod), the UA trace printed by the Maternal/Fetal Monitor will be thickened to alert the user that caution needs to be taken when interpreting the trace 20 seconds before the start of the alert and for as long as it is visible on the trace, see example below. Maternal movement can cause UA artifact to be displayed and or compromise the FHR extraction.

Section 11 - Novii Synchronization & Mixed Modality Monitoring

The Novii UA, FHR and MHR traces are all synchronized, but delayed by 10 seconds in relation to real-time events, this relates to a shift on the trace of 5mm at 3cm/min and 1.7mm at 1 cm/min on the trace. This is due to the time it takes to extract, send and confirm the Novii FHR, MHR, UA from the abdominal electrical signals. In normal operation, this will have no impact on the management of the patient or the interpretation of the trace with the following exceptions:

WARNING: GE Healthcare does not recommend or support mixing Novii UA with US/FSE FHR monitoring.

There is a 10-second shift in the Novii UA trace with respect to the US or FSE FHR trace such that late decelerations could appear as early decelerations masking a potential fetal compromise.

Using the US transducer in addition to Novii FHR, MHR and UA to confirm the FHR, for short periods, during gaps or suspected artifact can be used, but the potential for missing a fetal compromise remains, due to US FHR and Novii UA desynchronization.

WARNING: GE Healthcare does not recommend or support mixing Novii FHR/MHR with TOCO/IUPC UA.

If the Novii UA cable is disconnected and the TOCO/IUPC is used (against this recommendation), it is clinically important to understand that the FHR/MHR shift will have changed from 10 to 6 seconds (5 mm to 3 mm at 3cm/min). Early decelerations may appear as 'subtle' late decelerations. This could lead to an unnecessary intervention.

WARNING: Do not use Novii MHR to monitor the patient's response to a test dose during epidural placement.

There is a 10 second MHR shift in reporting the MHR with respect to real time events when the Novii UA Interface is connected to the Maternal/Fetal Monitor (reduced to 6 seconds if the UA Interface cable is not connected).

CAUTION: The 10 second FHR shift should be taken into consideration during prolonged FHR decelerations when resuscitative measures are being used, the impact of any manoeuvre will not be seen for 10 seconds.

CAUTION: The 10-second UA shift should be taken into consideration when coaching patients to push during the second stage. The patient may sense the contraction before it appears on the monitor tracing - the contraction has already been building for 10 seconds.

CAUTION: When the patient is moving and/or the fetus is active caution should be exercised in interpreting the UA trace. If the interpretation of uterine contractile pattern(s) is uncertain, another modality to monitor uterine contractions should be considered and clinical management of the patient adjusted appropriately. The Novii Pod monitors uterine activity by measuring the electrical signals (EMG) generated by the uterine muscle when it contracts, as opposed to the tocodynamometer (TOCO transducer) which monitors uterine activity as measured by the displacement of a plunger or button with respect to a guard ring caused by the tightening of the uterus during a contraction. Small relative changes in the electrode positions used to monitor the uterine EMG resulting from maternal or fetal movement cause electrical signals that can look like uterine activity.

It is not possible to use Novii at the same time as the Mini-Telemetry is connected to the Corometrics 259cx or 174 monitor and powered on, as the front panel inputs will be disabled.

Section 12 - Cleaning

Patch is single used and should be disposed of as hazardous waste

To avoid damage to any parts of the Novii system, clean and disinfect only according to the following instructions. Care MUST be taken to preserve labels on the Novii Pod, Novii Interface and the Maternal/Fetal Monitor cables.

CAUTION: Disconnect Novii Interface from the AC power supply before cleaning.

CAUTION: The Pod gold connection pins need to be kept clean and should be protected at all times; only keep your Pods in the Interface charging bays or clipped to a Patch. Placing it down anywhere else could result in damage to the gold pins.

CAUTION: Do not remove, conceal or deface the labels.

CAUTION: Do NOT use strong oxidants such as bleach.

CAUTION: Do not use bleach solutions that contain sodium hypochlorite, iodine, solutions with a high chlorine content, or any other cleaning solution other than the ones that this manual specifies. Permanent damage can occur if you do not obey.

CAUTION: The water temperature must not exceed 40°C (104°F). Do not use chlorine bleach.

12.1 Cleaning and disinfecting the system

WARNING: Do not put the Interface fully into water or let fluids enter the case. If fluid gets into the Interface, you could get an electric shock.

WARNING: If cleaning solution gets into the Interface, you could get an electrical shock. Disconnect the Interface from the AC power supply before cleaning.

WARNING: ELECTRICAL SHOCK HAZARD Do not clean or service the device while the power cord is connected to an electrical outlet. This can cause an electrical shock. Disconnect the power cord from the electrical outlet before cleaning or service. Connect the device to an electrical outlet only when told to in the cleaning or service procedure.

WARNING: INFECTION HAZARD Do all the cleaning procedure steps fully. Failure to do the steps fully can cause patient or user exposure to contamination or cleaning agents.

WARNING: PATIENT INJURY HAZARD You must do the cleaning and disinfection steps fully as told to in the procedure. If you use a cleaning solution or cleaning procedure that is not approved, you can cause patient infection or damage to the device.

WARNING: PATIENT INJURY HAZARD Inspect the device carefully and do not use it if it is dirty or has visible debris, is damaged, or has missing parts. Before each use, carefully inspect the following accessories to make sure they are clean and not damaged: Pod, Interface, Cables, Connectors

WARNING: Do not autoclave the Novii Interface or Novii Pod or any accessories. Do not gas sterilize.

WARNING: Do not immerse the device or any accessories in liquid and do not expose any connector pin to the cleaning solution. Do not apply oil at any point.

WARNING: Take extra care when cleaning the touch screen display, which is sensitive to rough handling.

12.2 Point-of-use cleaning (cleaning during clinical use)

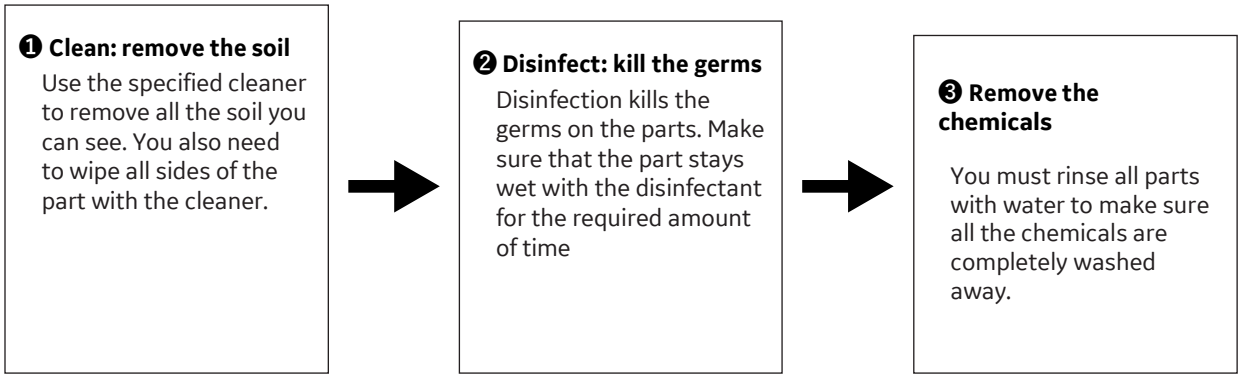
If the device becomes dirty with soil (such as bodily fluids) or other contaminants during clinical use, prompt initial treatment is necessary to remove contamination and not let it dry.

Use a dry lint-free cloth to remove soil or contamination.

12.3 Cleaning and disinfection overview

Your current cleaning process may be different and may not include disinfection or rinsing. See the cleaning process overview that follows to understand why you might need to do more steps or different steps than in your current cleaning process.

Three-step process:



To fully clean, disinfect, and rinse the system, you must do every step.

12.3.1 Dos and Don'ts

- Don't use broken parts.
- Do have separate areas for dirty, clean, and disinfected parts.
- Don't clean near patients.
- Don't spray directly onto the parts.

12.3.2 What you need for cleaning and disinfection

- Separate areas for dirty parts and clean parts. Do not mix parts that have been cleaned, disinfected,and rinsed with parts that are still dirty.
- CaviCide or CaviWipes
- Water to use for rinsing
  *Tap water needs to meet the requirement of utility water as defined in AAMI TIR34
- Gloves
- Disposable lint-free cloths

12.4 Cleaning and disinfection solutions

Solutions in the table that follows are validated for cleaning and disinfection of the device.

Table 1 – Validated solutions

Trade Name / Solution	Concentration limits	Purpose	Disinfectant contact duration
CaviCide™ / CaviWipes™	Isopropanol: 17.2% Ethylene Glycol MonobutylEther (2-Butoxyethanol): 1 to 5% Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride: 0.28% Water: 70 to 80%	Cleaning solution for all parts	NA
		Disinfectant for all parts	3 minutes

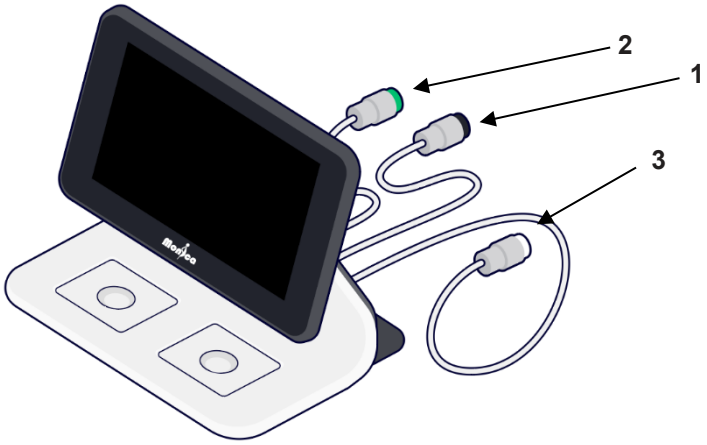
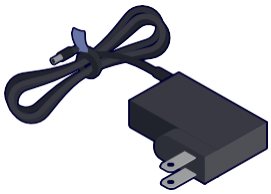
Table 2 – Chemically compatible solutions

Trade Name / Solution	Concentration limits
CaviCide™ / CaviWipes™	Isopropanol: 17.2% Ethylene Glycol Monobutyl Ether (2-Butoxyethanol): 1 to 5% Diisobutylphenoxyethoxyethyl dimethyl benzyl am monium chloride: 0.28% Water: 70 to 80%

12.5 Prepare for cleaning and disinfection

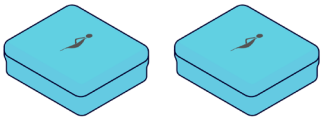
The cleaning and disinfection procedure that follows is specially for the Novii system. This procedure is not for any part that is not a Novii part. Make sure you fully know which parts you should clean. Obey this procedure to clean all those parts and only those parts.

Novii parts to clean and disinfect:

Novii Interface parts		
Novii Interface	**Novii Interface cables**	**Novii power supply**
		

1	Interface FHR cable
2	Interface MHR cable (for connection to Corometrics 259cx)
3	Interface UA cable

Novii Pod 1 or more



12.5.1 Get the system ready to clean

1. Put on new gloves.
2. Unplug the Novii power supply from the power outlet.
3. Unplug the Novii power supply from the connector on the back of the Interface.
4. Remove each Pod from the Interface.
5. Put each Pod on the work surface so its pins point up.
6. If a Pod is clipped to a Patch, remove the Pod from the Patch. Set down the Pod so its pins point up. Throw away the Patch.

12.5.2 Unplug the Novii Interface cables from the Corometrics monitor

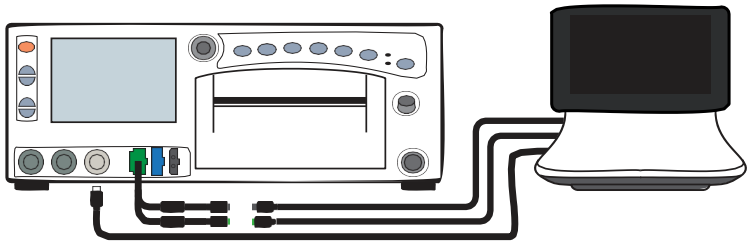
1. Disconnect the Novii UA Interface cable from the white connector on the front panel of the Corometrics monitor.
2. Disconnect the Novii FHR Interface cable from the front of the Corometrics monitor.
   - If the Corometrics monitor that Novii is connected to is a Corometrics 259cx, the Novii FHR Interface cable is connected to the Corometrics Y-adapter. Disconnect the Novii FHR Interface cable from the black connector of the Corometrics Y-adapter.

Figure Black connector on the Corometrics Y-adapter

   - If the Corometrics monitor that Novii is connected to is a Corometrics 174, disconnect the Novii FHR Interface cable from the grey connector on the front panel of the Corometrics 174.
3. If the Corometrics monitor that Novii is connected to is a Corometrics 259cx, disconnect the Novii MHR Interface cable from the green connector on the Corometrics Y-adapter.

Figure Green connector on the Corometrics Y-adapter

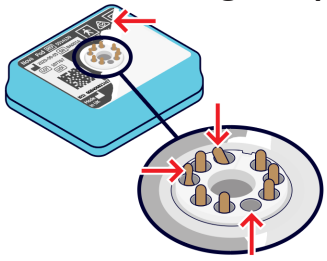
Figure Novii Interface cables disconnected from Corometrics 259cx



12.5.3 Inspect for damage

Before you start to clean, visually inspect all equipment for damage. Inspect every Novii part that you will subsequently clean for damage or wear, such as discoloration, heavy scratches, or cracks. Check the gold pins of each Pod for missing pins, bent pins, or pins that are down too far into the recess. Check for damaged labels. Check for fraying on the cables, bent plug pins.

Figure Pod with label damage and pin damage



If you do see that a device has damage or heavy wear, do not use.

12.6 Cleaning, disinfection, and rinsing

Cleaning

1. Spray CaviCide onto a cloth. NOTE: Do not saturate the cloth to avoid damage to electronics due to liquid ingress.
2. Use a new cloth if it dries out or becomes dirty.
3. Wipe all sides of the Interface, including its display, with the wet cloth. Wipe all sides of each Interface cable with the wet cloth. Use as many cloths as necessary.
4. Make sure the CaviCide gets onto areas that can be hard to reach but avoid plugs and connectors.
5. Make sure the Interface and the Interface cables look clean.
6. Move the Interface and the Interface cables to the disinfection area.
7. Wipe all sides of the power supply with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach but avoid the plug and connector.
8. Make sure the power supply looks clean.
9. Move the power supply to the disinfection area.
10. Wipe all sides of each Pod with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach.
11. Wipe the gold pins on each Pod very lightly.
12. Do not let the CaviCide collect around the Pod pins. If CaviCide does collect around the pins, lightly wipe them with a cloth until the fluid is absorbed.
13. Make sure that each Pod looks clean.
14. Move the Pods to the disinfection area. Put each Pod down so its pins point up.
15. Throw away the cloths that you used to clean the parts.
16. Throw away your gloves.

Disinfection

1. Put on new gloves.
2. Spray CaviCide onto a cloth. NOTE: Do not saturate the cloth to avoid damage to electronics due to liquid ingress. Use a new cloth if it dries out.
3. Wipe all sides of the Interface and the Interface cables with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach. Use as many cloths as necessary.
4. WAIT! Make sure all sides of the Interface and of the Interface cables stay wet for 3 minutes. Watch carefully. The parts must not dry out. Wipe on more CaviCide if any area starts to dry out.
5. Wipe all sides of the power supply with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach but avoid the plug and connector.
6. WAIT! Make sure all sides of the power supply stay wet for 3 minutes. Watch carefully. The part must not dry out. Wipe on more CaviCide if any area starts to dry out.
7. Wipe all sides of each Pod with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach.
8. Wipe the gold pins on each Pod very lightly.
9. Do not let CaviCide collect around the Pod pins. If CaviCide does collect around the pins, lightly wipe them with a cloth until the fluid is absorbed.
10. WAIT! Make sure all sides of each Pod stay wet for 3 minutes. Watch carefully. The parts must not dry out. Wipe on more CaviCide if any area starts to dry out.
11. Throw away the wipes / cloths that you used to disinfect the parts.
12. Wipe all sides of each Pod with a dry cloth.
13. Wipe all sides of the power supply with a dry cloth.

14. Wipe all sides of the Interface and of the Interface cables with a dry cloth.
15. Throw away the cloths that you used to dry the parts.

Remove the chemicals

1. Spray water onto a cloth. NOTE: Do not saturate the cloth to avoid damage to electronics due to liquid ingress.
2. Wipe all sides of each Pod with the wet cloth.
3. Wipe the gold pins on each Pod very lightly.
   Do not let water collect around the Pod pins. If water does collect around the pins, lightly wipe them with a cloth until the fluid is absorbed.
4. Throw away the wipes / cloths that you used to rinse the Pods.
5. Wipe all sides of each Pod with a dry cloth.
6. Wipe the gold pins on each Pod very lightly.
7. When the Interface is fully dry and each Pod is fully dry, put each Pod back onto the Interface.
8. Throw away the wipes / cloths that you used to rinse and dry the parts.
9. Throw away your gloves.

12.7 Assemble the Novii system again for clinical use or storage

1. Put each Pod onto the Interface again.
2. Connect the Novii power supply to the connector on the rear of the Interface.

The Interface can be stored unplugged or plugged into a power outlet.

Tip

If a Pod is in storage, GE recommends to charge the Pod at least 1 time every 3 months to maintain battery performance.

To prevent recontamination during storage, store the device in a separate, clean, dry area. Put a protective cover on the device if necessary.

Section 13 - Accessories & Part Numbers

Part No.	Description
107-PT-001/5697243	Novii Interface
107-PT-003	Novii Pod
5811343	Novii Interface Power Cable
107-PT-004-10	Novii Patch (box of 10)
107-PT-004-50	Novii Patch (box of 50)
100-PT-007	3M red Dot 2236 skin prep tape
5697101	Novii Simulator

13.1 Interface Cables

Input	Description	Part #	Plug Color
FECG	Novii Interface Cable - GE FECG	105-PT-102	
UA	Novii Interface Cable - GE UA	105-PT-106	
MECG	Novii Interface Cable - GE MECG	105-PT-104	

MECG cable is only compatible with the Corometrics 259cx Maternal/Fetal Monitor

When connecting to the GE Corometrics 259cx Maternal/Fetal Monitor it must be equipped with GE Y-adapter cable (part# 1442AA0), shown below:

Section 14 - Patch Specification

General Information	Manufacturer	Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA Tel 1 800 345 2700
	Model	Single Patch 107-PT-004 Box (10 patches) 107-PT-004-10 Box (50 patches) 107-PT-004-50
Input	Electrophysiological signals picked up from the skin surface via the 5 ECG Electrode contact areas integrated into the patch	
Output	Electrical signals collected in a central area for input to the Novii Pod. The Patch is passive.	
Encryption	Microchip containing factory pre-set code (SHA_256 encryption)	
Weight	12g / 0.42 oz.	
Dimensions	190mm x 155mm x 12mm (including clip)	
IP rating	The Patch on its own has no IP rating	
Shelf Life	12 months (from Date of Manufacture)	
Latex & PVC Free	Yes	
Packaging	Individual foil pouches & transportation cards	
Operating and Storage Temperature	+10°C to +30°C (+50°F to +86°F)	

Section 15 - Interface Specification

General Information	Manufacturer	Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA Tel 1 800 345 2700
	Model	107-PT-001/5697243
	Software revision level	Select 'About' in the Set-Up menu of the Interface to display software version, see Section 4.3.6
	Mode of operation	Continuous use
Data I/O	Wireless input Range Output	Bluetooth 100ft / 30m (line of sight) Real-time to Maternal/Fetal Monitor via Interface cables, comprising: • Direct fetal ECG pulse (for FHR) • MECG pulse (for MHR) • Uterine Activity waveform (for UA)
User Interface	Capacitive Touch screen LCD display Alert Buzzer	Resolution 800 x 400 resolution (RGB 65K colors) Viewing Area: 108mm x 65mm. Touch panel durability (tap test): 1 Million Frequency: 3.4kHz ± 0.5kHz
Charging Bays	2x wireless charging bays for Novii Pods (with magnetic location) Charge Time for 2x fully discharged pods – up to 2hrs Uses IrDA to facilitate automatic pairing with the Pod	
Power Supply	Novii reference Manufacturer Input Output Dimensions Weight Energy Efficiency	5811343 XP Power ACM18US05 100V~ to 240V~, 50Hz to 60Hz, 500mA 18W 5V DC / 2500mA 88.0 × 30.0 × 49.5mm 160g /5.4oz (body only) MEPS Class VI (82.5%)

IP rating	IP20
Accessories	Interface Connection Cables for GE Corometrics 259cx and 174 monitors: FHR (105-PT-102); MHR (105-PT-104) UA (105-PT-106) Novii Interface Power Cable – (2111623-001)
Operating Temperature	+10° C to +30° C (+50°F to +86°F)
Storage Temperature	-20° C to +70° C (-4°F to +158°F)
Operating and Storage Humidity	0%RH to 90%RH
Operating and Storage Atmospheric Pressure (kPa)	50kPa to 106kPa (375mmHg to 795.2mmHg)

Section 16 - Pod Specification

General Information		This symbol on your device indicates that you should consult information contained in this book
	Manufacturer	Datex-Ohmeda, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA Tel 1 800 345 2700
	Model	107-PT-003
	Software revision level	Select 'About' in the options of the Interface to display software version (see Section 4.3.6)
	Mode of operation	Real-Time / Continuous use
		TYPE BF EQUIPMENT: Type BF equipment is suitable for intentional external and internal application to the patient, excluding direct cardiac application. Type BF equipment has an F-type applied part.
		<u>Applied Parts:</u> The applied Parts of the Novii Pod are the five electrodes of the Novii Patch that are placed on the patient abdomen. These applied parts connect to the pins at the bottom of the Novii Pod
Data I/O	Wireless output Range	Bluetooth 100ft / 30m (line of sight)
User Interface	LED	
FHR	Range Resolution Accuracy	60-240 beats per minute Resolution: 1/4 BPM produced 4 time per second from a rolling 2s average Bland Altman versus AN24 predicate: 7.1 BPM rms (95% limit of agreement: -13.7 to 14.1 BPM). Bias: 0.194 BPM, see Figure 1 and Figure 2 below
MHR	Range Resolution Accuracy	40-240 beats per minute Resolution: 1/4 BPM Produced 4 time per second from a rolling 2s average Bland Altman versus AN24 predicate: 5.3 BPM rms (95% limit of agreement: -10.4 to 10.5 BPM). Bias: 0.035 BPM See Figure 3 and Figure 4 below
UA	Range Resolution	0-500 microvolts 0-255 levels representing 100% of full scale Produced 4 time per second from a rolling 2s average

	Accuracy	98% percent agreement (95% confidence limit: 96.6%), 86.05% Positive Percent Agreement (95% confidence limit 81.9%)
Power	Battery Battery Life Battery Charging	Rechargeable lithium polymer 3.7V 750mAh 80% capacity after 500 full charge/discharge cycles Up to 11 hours battery life Contactless charging with the Novii Interface
Dimensions	45mm x 39mm x 20mm (including contact pins)	
Weight	40g / 1.4oz	
IP rating	The Novii Pod is rated IP57 only when mated to a Novii Patch. If not mated to a Novii Patch the rating is IPX0	
Accessories	Single Use Novii Patch: 107-PT-004	
Environmental conditions of use	Normal use	+10°C to +30°C (+50°F to +86°F)
	Transport and storage	-20°C to +40°C (-4°F to +104°F)
Type	Type BF Equipment (applied part is the Novii patch, which connects to the pod via the spring contact pins at the bottom of the pod)	

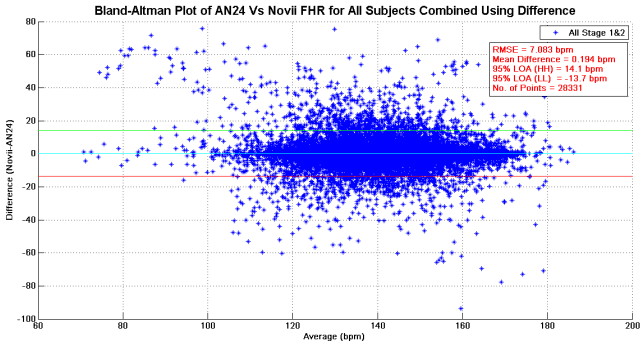


Figure 1: FHR Bland Altman Novii / Predicate Device (difference)

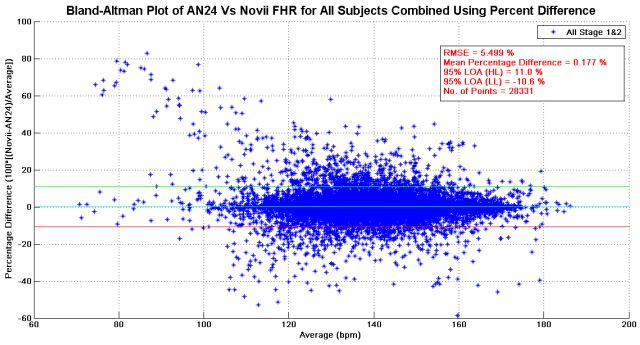


Figure 2: FHR Bland Altman Novii / Predicate device (% difference)

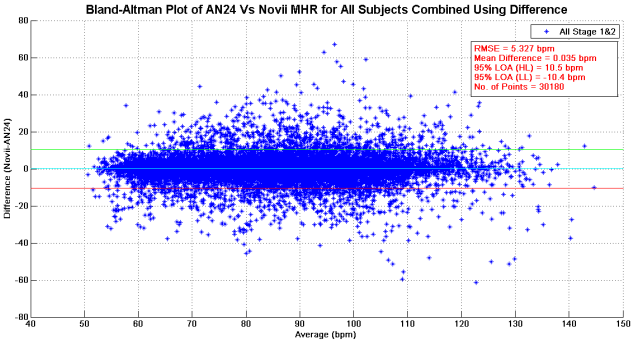


Figure 3: Figure 3: MHR Bland Altman Novii / Predicate device (difference)

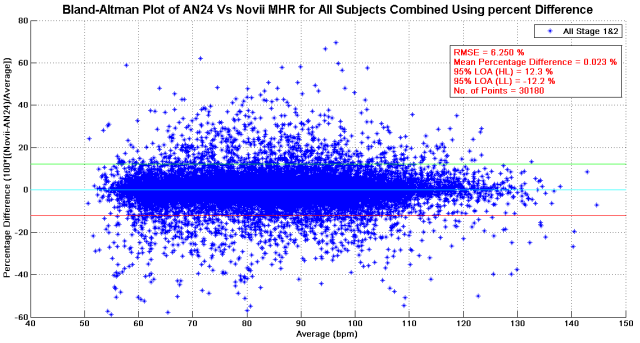


Figure 4: MHR Bland Altman Novii / Predicate device (% difference)

Section 17 - Device Lifecycle

Interface	8 years (display) – calculated
Pod	2 years (Battery Life) – recommended based up on 500+ charging/discharging cycles 12 months (Battery Shelf Life) **Note:** If the Pod is unused or in storage, it is recommended to charge the pods at least once in three months to maintain battery performance.
Patch	12 months shelf life (packed) - tested 48 hours (in use) – recommended

Section 18 - Fault Finding

This section of the manual provides a troubleshooting guide for the most basic Novii operational problems. If the response to a specific question is not found, contact Technical Support.

Inside the United States: 1-800-345-2700, 1-800-437-1171
Outside the United States: Contact your local GE Healthcare representative

18.1 Novii Interface Troubleshooting Table

Possible Causes	Actions and Solutions
Interruption to power supply during monitoring	
Novii power supply cable has been disconnected or switched off, or there is a power failure, the monitoring will not resume once the power is returned.	To continue monitoring, once power is returned remove the Novii Pod from the patch and place in a charging bay. The Interface will return to the start screen and monitoring can be re-started
Should the power to the Maternal/Fetal Monitor disconnect but the power to the Novii Interface remains on	No action: The Novii system is still monitoring and when the Maternal/Fetal Monitor is back on, the recording will continue, but monitoring data during the power loss will not be recoverable
Novii Interface screen is blank (no power).	
The power lead is not plugged into the Novii Interface and/or wall socket, or the power is turned off	Ensure the power lead is plugged into the Novii Interface and wall socket properly, and the power is turned on. The green light on the Power Supply unit should be illuminated. If no green light, replace Power Supply
Power supply cable is damaged.	Visually inspect the cable for any signs of damage. Replace the cable if necessary
Power supply is defective.	Confirm the green light on the power supply unit is on and that the power supply is live. If not, replace the Power Supply.
Wrong power supply used	Novii power supply is labelled with Novii logo, confirm you have the correct power supply.
Novii Interface failure	If above points do not resolve the issue, contact Technical Support for service.
Novii Interface screen displays a frozen image/no response	
Power surge has crashed the display	Disconnect power, wait 30 seconds and reconnect power. If the Novii Interface screen still frozen, with no response, contact Technical Support for service.
Novii Interface does not respond when a Pod is placed in charging bay	
Monitoring session is in Progress	A Pod placed in the empty charging bay during monitoring will not be recognised by the Interface. No action is needed. When the monitoring session is ended by returning the Pod to any empty charging bay, the Pod will be recognised

Faulty Pod	Confirm there is no ongoing monitoring session, the Pod is correctly positioned in the charging bay and the Start Screen is displayed. The blue light on the top of the Pod should be flashing and the battery status should be displayed on the Interface above the Pod. If none of this happens, contact Technical Support for service.
Insufficient battery charge to allow Pod to switch on	Leave Pod in charging bay for 20 mins. Blue Pod light should start to flash and Battery charge status should appear on Interface display above Pod, if not contact Technical Support for service.
Novii Interface does not respond when a Pod is removed from the charging bay	
Monitoring session is in progress	If the Novii Interface is being used to monitor a Patient then the Interface will not respond and the Pod blue lights will switch off when a Pod is removed. This is normal operation. The monitoring session must be ended by removing the Pod from the Patch and returning it to the Interface charging bay.
Battery has insufficient charge	If the battery status display above the removed Pod is orange the Pod will not switch on when removed. Please replace Pod in the charging bay and wait for battery status to turn green.
Faulty Pod	If none of the above apply, replace Novii Pod
Interface is in Standby mode	Placing the Pod back on o the Interface will exit the Standby mode.

18.2 Novii Pod Troubleshooting Table

Possible Causes	Actions and Solutions
Electrode check repeatedly fails during set-up despite following 'Preparing Skin' instructions on Patch pouch.	
User is not performing the skin preparation properly.	Make sure to follow the skin preparation instruction provided in section 7.5
Patch is out of date or electrodes have dried out	Confirm the Patch is in date and the pack has not been opened for a long time allowing the electrolyte on the electrode central foam pad to dry out;
Wrong skin-preparation tape is used.	Confirm the skin-prep exfoliation finger pad (provided with product) or 3M skin-prep tape are used.
Pod has not seated correctly on Patch clip	Check that the Pod is correctly seated in the Patch clip by removing it and then clipping it back on and pressing it firmly down. When the Pod is removed, check the patch connection gold pins on the bottom of the Pod for any evident damage. Replace Pod if necessary.
Dirt/grease/gel/water contaminating Pod/Patch connection	Look for dirt and grease/gel/water in the Patch plastic clip/connector or on the Pod pins. If necessary, clean the inside of the Patch connector and wipe the pins on the back of the Pod using an alcohol wipe and dry thoroughly.

Faulty Pod	Remove Pod and place in charging bay. Take another Pod from the Interface and place in Patch. If electrode check passes replace Pod in charging bay.
Faulty Patch	Remove Patch, wash and dry abdomen and use a new Patch placed over the same location – no further skin-prep is required. If the electrode check fails, replace Novii System

18.3 Maternal/Fetal Monitoring Troubleshooting Table

Possible Causes	Actions and Solutions
FHR/UA or MHR data not being displayed by Maternal/Fetal Monitor	
Maternal/Fetal Monitor is switched off	Confirm that the Maternal/Fetal Monitor is ON and confirm that the Maternal/Fetal Monitor works using the Ultrasound and TOCO transducers.
Cables are not correctly connected	Confirm that the Interface cables are securely plugged into the correct port on the front of the Maternal/Fetal Monitor and the back of the Novii Interface. Novii FHR connects to the FECG port Novii UA connects to the TOCO port Novii MHR connects to the MECG port. From the start screen select the 'Test' button and follow the on-screen instructions. The Novii Interface will send a FHR, MHR and UA signal to the monitor. If none of the test FHR, MHR and UA values are displayed, replace the Interface. If one is missing check the cable(s) for damage. Replace cable(s) if necessary
Cables are damaged	Confirm the cables are not damaged. Replace cables if necessary. From the start screen select the 'Test' button and follow the on-screen instructions. The Novii Interface will send a FHR, MHR and UA signal to the monitor. If none of the test FHR, MHR and UA values are displayed, replace the Interface. If one is missing, check the cable(s) for damage. Replace cable(s) if necessary
FHR/UA or MHR data not being displayed by Maternal/Fetal Monitor	
Pod problems	Make sure the monitoring screen on the Interface is being displayed and the signal quality, x3 green squares, and the Battery Icon below the signal quality is green. If not confirm the status of the two blue lights on the Pod connected to the Patch. If no blue lights are visible, the Pod has switched off. Remove from Patch and place in a charging bay. Is it recognised by the Interface (battery status above Pod will appear)? If not, wait 20minutes, if Pod is still not recognised replace Pod. If the battery status was orange wait for battery to charge. When battery status is green take Pod and place in Patch Clip. If electrode check is good, but the Pod switches off again, replace Pod.

	Was the 'Bypass' button on the Interface electrode check screen used. If yes, remove Pod from Patch and place in charging bay. Wait a few moments for the Pod to be recognised (battery status above Pod will appear). If this does not happen replace the Pod. If it is recognised remove Pod and place in Patch. Ensure that all electrodes pass electrode check.
FHR quality on the Maternal/Fetal Monitor trace is poor in some patients	
Unfortunately, this can happen in some patients especially during stage 2.	Unless it is persistent and occurs on most/all patients it is not a fault. The user should follow the Alert/Help message on the Novii interface. If the FHR is intermittent, the FHR can be confirmed with the Doppler Transducer connected to US 2, but if the problem persists then we would advise removing the Novii Pod/Patch and swapping to another monitoring modality.

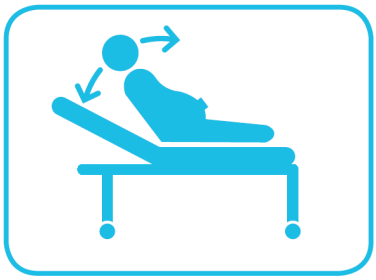
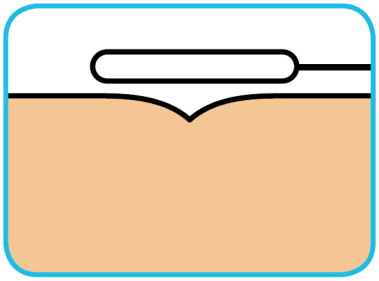
Section 19 - FHR Troubleshooting

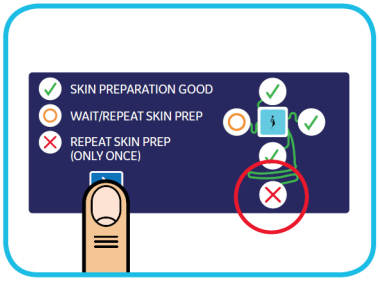
Follow the troubleshooting below when signal quality is poor or bad

While the Novii detects the FHR continuously on many patients, some patients will require troubleshooting to reacquire the FHR signal. A small number of patients will not be able to be monitored successfully with the Novii despite troubleshooting

Inadequate Patch/electrode placement or increased noise (electrical interference) may cause frequent or persistent FHR gapping and/or FHR artifact. Sources of noise may include electrophysiological noise from the patient or fetus and electrical noise from the environment.

Training is important for obtaining the best results with Novii, training videos and further support material is available from www.gehealthcare.com/

Possible Cause/Problem	Action / Solution
 The patient is ambulating - may cause increased muscle noise and/or displaced Patch	• Return patient to bed and/or reduce patient's activity. • Consider using a maternity belt to support pannus during ambulation or upright position. Help/Tip  a) Allow 10-15 minutes of monitoring before starting ambulation. b) The patient should not be encouraged to ambulate unless the FHR trace is consistent and the signal indicator on the Novii Interface shows 3 green squares.
 Patient position/posture -may cause muscle tension/ noise and/or displaced Patch	• Adjust patient's position: head of bed up/down, right/left tilt. • Use a pillow behind back or head to make patient more comfortable, encouraging patient to relax abdominal muscles. • Return patient to a position where Novii worked well. • If patient is high Fowler's or in a curled sitting position for epidural placement, consider placing a rolled towel or baby blanket under the abdomen for support to ensure optimal position of the lowest electrode.  • If patient is on side, support abdomen with a pillow/rolled blanket to support the abdomen so that the Patch remains centered over the uterus.
 Electrode 'detached' or has badcontact with skin - electrode not able to function properly	• Check all electrodes and ensure good skin contact/adhesion. • Re-position Patch or electrode to avoid any skin anomalies. Help/Tip a) The Interface will alert user with a visual message, but only when electrode is fully detached. b) Check electrodes for adhesion after a shower, clinical procedure, ambulation or a position change. c) Electrode(s) should not be placed over a skin lesion, skin fold, or umbilicus. Avoid stretch marks, scars or pronounced linea nigra when possible. d) If necessary use medical tape for adhesion or transparent adhesive dressing to prevent electrode lifting or detachment.



Poor skin prep - dead skin reduces transmission of fECG signal

- Exfoliate skin under 'bad' electrode.

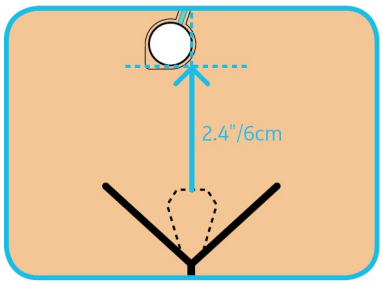
Help/Tip
a) Peel the **X** electrode back, remove excess gel from skin. Wait until skin is dry then exfoliate skin and reapply electrode.
b) May need to use medical tape to hold in place.

- Restart the monitoring session if location of 'bad' electrode not known.

Help/Tip
Remove Pod from Patch, place in charging bay and start new monitoring episode.

- Does a Pod consistently display a X on same electrode?

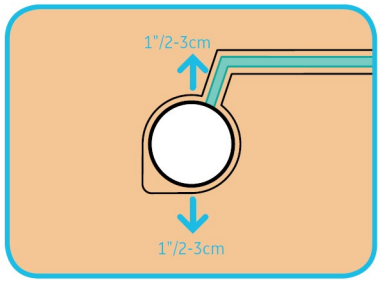
Help/Tip
Check for damaged Pod pins. Replace Pod if needed.



Center of lowest electrode is not 2.4"/6 cm above the symphysis pubis, or in optimal location for individual

- Re-position (lowest electrode on flexible cable) (electrode #5).
- Restart monitoring after any electrode reposition.

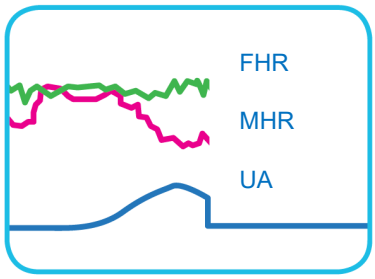
Help/Tip
a) Peel the electrode back, remove excess gel from skin, ensure skin is dry then exfoliate skin and reapply electrode in alternate position.
b) May need to use medical tape to hold in place, once new position provides successful signal.



Pannus covering pubic bone

- Lower electrode may not be optimally placed - some trial and error with positioning may be required
- Remove lowest electrode and place it lower or higher on the abdomen.
- Alternatively place electrode just below the point where the surface curves back on itself ensuring that the electrode is not folded.
- Restart monitoring after any electrode reposition.

Help/Tip
a) Peel the electrode back, remove excess gel from skin, ensure skin is dry then exfoliate skin and reapply electrode in alternate position.
b) May need to use medical tape to hold in place, once new position provides successful signal.



All Novii signals are lost. Blue-tooth communication or cable/power connection problem

- Check Interface for help messages:
- "Patient Out of Range" – Has patient ambulated out of range or submerged Pod under water? Has a mobile phone been placed on or near Pod?
- "Check Electrodes" – Are all electrodes adhered well to patient's skin? Has an electrode been damaged? Is Pod connected securely to Patch, ensuring good Pod pin connection? Try removing and replacing Pod, or swap Pods.
- Has Interface turned off? Check power supply connection.

Help/Tip
a) If Interface has lost power Bluetooth pairing with Pod is lost.
Remove Pod from Patch, place in charging bay and start new monitoring session when power is returned.
b) Interface does not have a battery back-up.

- Is the Interface Start-Screen displayed instead of the Monitoring Screen?

	Help/Tip Pod has switched off – remove Pod from Patch and place in charging bay. Start new monitoring session with another Pod (look for dirt or liquid ingress on the POD connector and/or in Patch clip) • Are all cables and connections secure? Consider returning the Pod to the Interface and completing a Novii Test.
Monitoring stops after a Pod swap	• Current monitoring session must be ended by removing Pod from Patch and docking the Pod. Only then can the other Pod be removed and placed in Patch
None of the above	• Consider 'filling' FHR gaps using the US transducer • Remove Novii and swap back to conventional monitoring modality

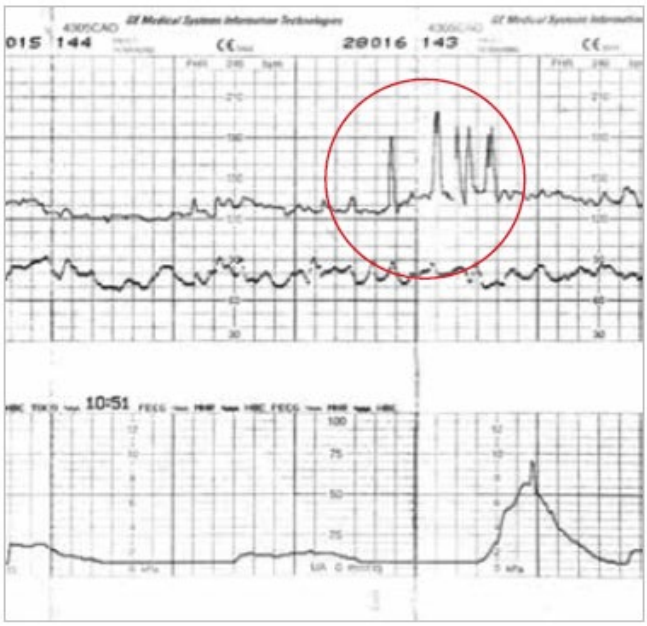
Notes:

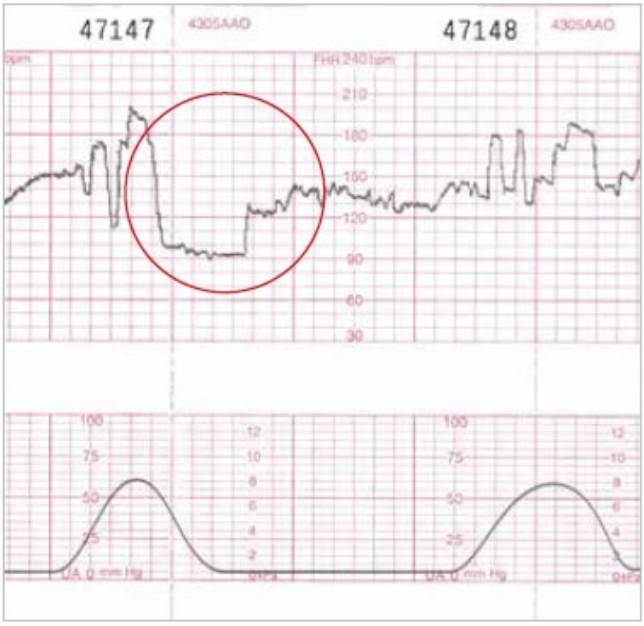
This troubleshooting guide assumes that the patient is supine or semi-supine during Patch placement and Novii set-up

1. Remember that any intervention will take 10 seconds before its impact will be seen on the trace
2. The user is familiar with the placement of Patch and lower mid-line electrode in high BMI patients with a pannus

Section 20 - FHR Artifact

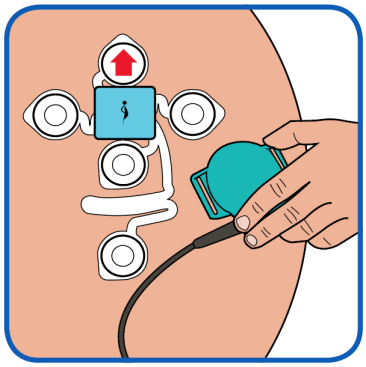
- Due to the challenges of monitoring the fetal heart, all fetal monitors are prone to FHR artifact and signal loss. Most of the time this artifact is easily identifiable from changes in FHR pattern.
- It is important to view the signal quality on the Novii Interface screen.
  Poor or bad signal quality is more likely to result in FHR artifact.
- Use the same troubleshooting advice listed previously to try to increase the fECG signal quality and reduce the noise.
- Use the Ultrasound (US) transducer for FHR confirmation.
- FHR artifact is more likely to be seen during ambulation and position changes when electrophysiological noise increases.
- If FHR artifact is recurrent and unresolvable, a different monitoring mode may be necessary.
- Continuously displaying the Novii MHR on the trace would improve artifact identification, see second example below.





Example of FHR artifact from Novii, recorded at 3cm/min

Reassurance



During loss of the FHR or during suspected FHR artifact, if reassurance is required, plug an US Transducer into the fetal monitor and hold on the patient's abdomen to try to get the FHR from a second source.

The FHR from Novii and US Transducer will be simultaneously printed on the trace, as if you were monitoring Twins. However, the Novii FHR will appear slightly behind the US FHR due to the Novii 10 second delay.

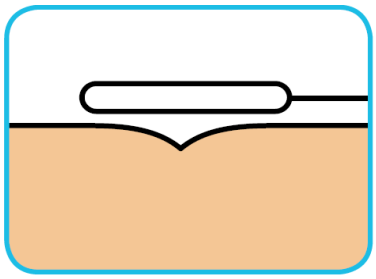
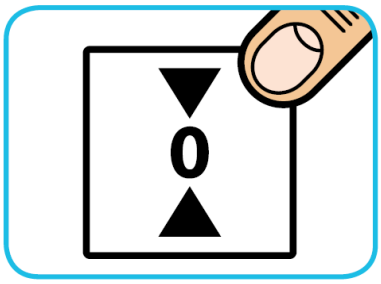
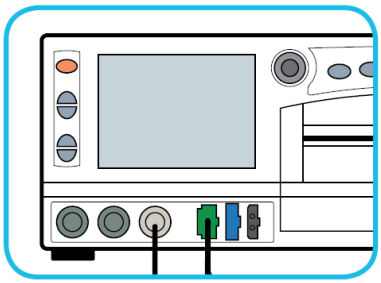
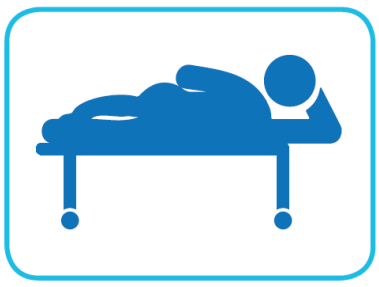
Caution: FHR Offset may be enabled on the fetal monitor.

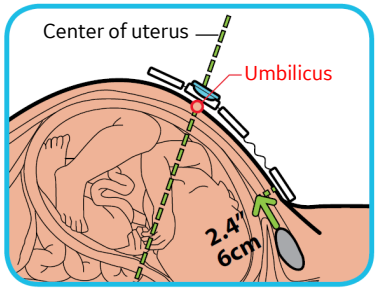
Caution: Novii FHR, Novii MHR and Novii UA are delayed by 10 seconds.

Using a US Transducer to 'fill' in FHR gaps should only be done for short periods. If FHR gaps from Novii continue after trying the trouble shooting suggestions, consider switching from Novii to an alternative monitoring mode.

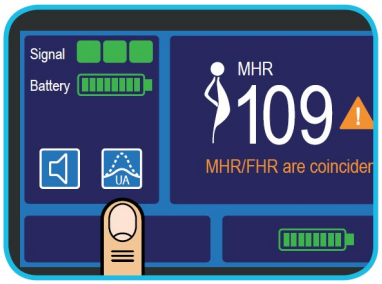
Section 21 - Uterine Activity Troubleshooting

21.1 Low UA

Possible Cause/Problem	Action / Solution
 Electrode(s) not secured well	• Check for electrode disconnection and secure back down. If electrode #3 on patient's left has problem then UA will be lost/flat. OK to use medical tape to hold in place. Help/Tip The Interface will alert user with a visual message, only when electrode is fully detached
 Low UA setting enabled	• Check the Interface UA sensitivity setting and ensure that the High UA setting has been selected.  HIGH
 UA reference problem	• Zero UA before starting Novii monitoring. Do not zero during monitoring. Although UA Reference may be done between contractions, using palpation to confirm, it is best practice to return the Pod to the Interface, and then Zero UA.
 UA cable / connection problem	• Check that UA interface cable between Novii interface and fetal monitor is connected correctly. Wiggle cable connector to ensure the monitor input connector is not loose or defective, run Novii Test (section 5) to confirm.
 Maternal position change	• Was UA trace high, but now low? If so, has patient changed position? Check patch has not moved away from uterus (i.e. high BMI, loose skin). If needed, place pillow under abdomen to support patch back over uterus.

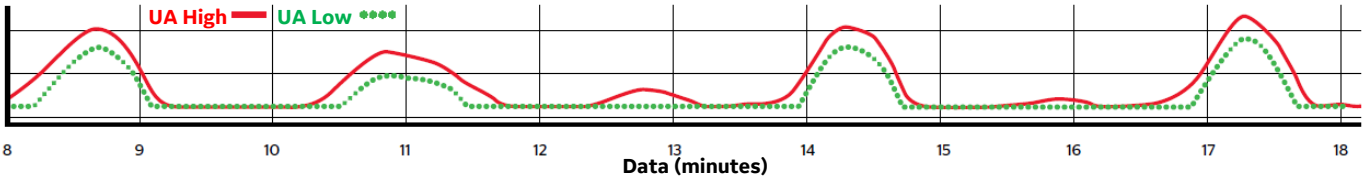
 Patch not optimally placed over uterus	• Confirm Patch is centered on uterus and the center of bottom electrode is 6cm above top rim of pubic bone. Electrode #3 is most important for obtaining good UA, thus poor positioning of this electrode may result in low UA. Reposition Patch if needed.

21.2 High UA (False Positives)

Possible Cause/Problem	Action / Solution
 The patient is ambulating or the fetus is active	• Electrical (EMG) signals from other muscles in the body during patient movement can produce a false contraction on the trace. • Excess movement or pressing on the Patch (electrodes) can produce false UA. • After 20 seconds of patient movement the UA trace will become 'thicker'. Use caution in interpreting a 'thickened' UA trace. See page 13. • Ask patient to return to the bed if ambulation is the cause of false positives. Help/Tip Patient movement may also cause the Patch to shift back and forth across the uterus, causing deflections and the appearance of excessive UA. Use manual palpation to confirm to confirm frequency of contractions.
 The patient is in early (latent) labor or induction	• In early (latent) labor or induction, myometrial activity is disorganized and preparing to produce pressure changing contractions. The electrical signal from this uterine muscle activity may produce small false positive contractions on the Novii UA trace (Verify UA with uterine palpation and maternal perception assessment). • Solution: Select the low UA setting from the Novii Interface to remove these small false positive contractions (Note: Novii UA spike which occurs on trace every 5 minutes will be at 50% height when low UA setting is enabled, see Help/Tip  LOW  HIGH Low UA setting will continue for 60 minutes before defaulting back to high UA setting, which is the default mode. The user can change the mode at any time as indicated.

21.3 UA Sensitivity Modes

Selecting UA Low sensitivity from the Novii display will decrease the UA trace amplitude, suppressing unwanted low amplitude UA, but it will also reduce the contraction duration. There will be no change to the location of the peak. Low amplitude UA is considered to be due to artifact from fetal/maternal movement and unsynchronized myometrial activity.



Low UA Sensitivity is suitable for pre and early induction patients to reduce artifact from maternal/fetal movement and other sources. High UA Sensitivity sets the UA to a suitable level for established labor patients. Sensitivity mode can be changed at any time during the monitoring episode by the user. The default start-up setting is high UA Sensitivity. When Low UA Sensitivity selected the Interface will automatically switch it back to High UA sensitivity after 60 min.

Section 22 - Maintenance

22.1 Maintenance

There are no user serviceable parts inside the Novii POD and the Novii Interface. Please contact your local GE distributor when the Novii System requires servicing.

Equipment should be visually inspected for damage and refer to the Troubleshooting Tables in Section 17, 18 and 20 to resolve common issues. In the event of device failure, please contact technical support:

Inside the United States: 1-800-345-2700, 1-800-437-1171
Outside the United States: Contact your local GE Healthcare representative

WARNING: No Modification of this equipment is allowed.

22.2 Calibration

No calibration is required. Users should use the TEST function to confirm calibration, function and correct connection / setup of the Novii Interface, whenever the Novii Interface is moved and connected to a new Maternal/Fetal Monitor.

22.3 Firmware version for Novii Interface and Pod

Periodically there will be a need to release new versions of the Firmware, please contact your local GE representative to see if you have the latest version.

22.4 Disposal of Product Waste

As you use the Novii system, you will accumulate solid wastes that require proper disposal or recycling. These include patient applied parts (Novii Patch), packaging material and the Novii Pod and Interface equipment.

Novii Patch:

The Novii Patch is a patient applied part intended for single use and should be disposed of properly as medical waste in accordance with regional body controlled guideline.

Packaging material:

Retain original packaging materials for future use in storing or shipping the monitor and accessories. This recommendation includes corrugated shippers and inserts. Whenever possible recycle the packaging.

Novii Pod and Interface:

At the end of its service life, the Novii Interface or Novii Pod, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, please contact GE Healthcare or its representatives.

CAUTION: The rechargeable lithium ion battery in the Novii Pod cannot be replaced and after 500+ charging cycles the ability to retain a charge will start to degrade. Eventually the retained battery charge will make the Novii Pod unusable. It is essential that the Novii Pod and its battery are disposed of safely. Please contact GE Healthcare as listed in Section 22.

The Disposal authority should contact GE Healthcare for instructions to separate the battery from the waste electronics prior to disposal.

Section 23 - Allergic Reaction to Patch

23.1 Overview

When an individual's skin is exposed to ingredients to which they are allergic, any degree of inflammation that occurs is clinically known as *contact dermatitis*. The severity of contact dermatitis can vary from mild irritation and redness, to rash and even to blistering, depending on the sensitivity of the skin.

This inflammatory response is the skin's way of over protecting the rest of the body from the allergen. An *allergen* is the substance that has caused the hypersensitive reaction. Almost any substance can be an allergen for some individual, which is why we can never guarantee against seeing allergic reactions.

It is worth remembering also, that sensitivity of the skin varies from individual to individual and even may vary in the same individual from time to time.

Whilst allergic reactions are unpleasant, it is important to realize that they are an inevitable occurrence as unfortunately, whilst GE Healthcare always takes steps to reduce the risk of allergy, someone at some time will always be sensitive to certain ingredients in the skin contact parts.

23.2 Guidelines

The following are suggestions that have proven in the past to help reduce the occurrence of contact dermatitis in relation to electrodes.

1. Ask the patient if they suffer from any allergies. It is proven that if individuals suffer from *any* allergies, then their risk of developing contact dermatitis increases. But remember, allergy can occur in any individual at any time.
2. If the answer is "yes" then the nurse needs to remain vigilant especially once an epidural is given. If there is any concern, peel back electrode 4 (one just below the clip) and check especially if the monitoring has extended over 12hrs.
3. If a severe allergic reaction has taken place: Review your department's skin prep regime and ensure that the skin preparation instructions are being followed.
    i. If skin abrasion is too aggressive it can compromise the integrity of the skin, leaving the individual at an increased risk of developing contact dermatitis.
    ii. GE Healthcare recommends preparing skin using mild soap and paper towels. This degreases and exfoliates the skin more gently and allows for a less aggressive abrasion
4. Finally, inform patients that unfortunately, a few people *do* react to electrodes, but if they experience any degree of itching or burning, then alert the nurse so that she can check the skin condition by peeling back electrode 4, and if necessary remove the Patch at the earliest opportunity. If individuals are already warned that a reaction *may* occur, then they are far more likely to accept this, and won't be as upset if there appears to be redness when the electrodes are removed.

23.3 Treatment

If contact dermatitis has occurred, initially the area should be thoroughly cleansed to remove any allergen. In most cases, the best treatment is then to do nothing further to the affected area, as contact dermatitis usually resolves spontaneously over time without complications once the allergen has been removed.

Topical corticosteroids may reduce inflammation, but medical advice should be sought when considering any treatment, as overuse of topical corticosteroids can itself bring about problems. In the severest cases, systemic corticosteroids may need to be prescribed by medical personnel, but this is extremely rare.

It is important to realize that allergies in general are on the increase, so if you have found a way to reduce the occurrence in your department, pass on tips to your colleagues and this may help to reduce the number of reactions in the future.

For further information, contact GE Healthcare or contact your local GE representative.

Section 24 - Cleaning, Disinfection and Chemical Removal Guide

Novii cleaning and disinfection process overview

Clean:
Remove the soil

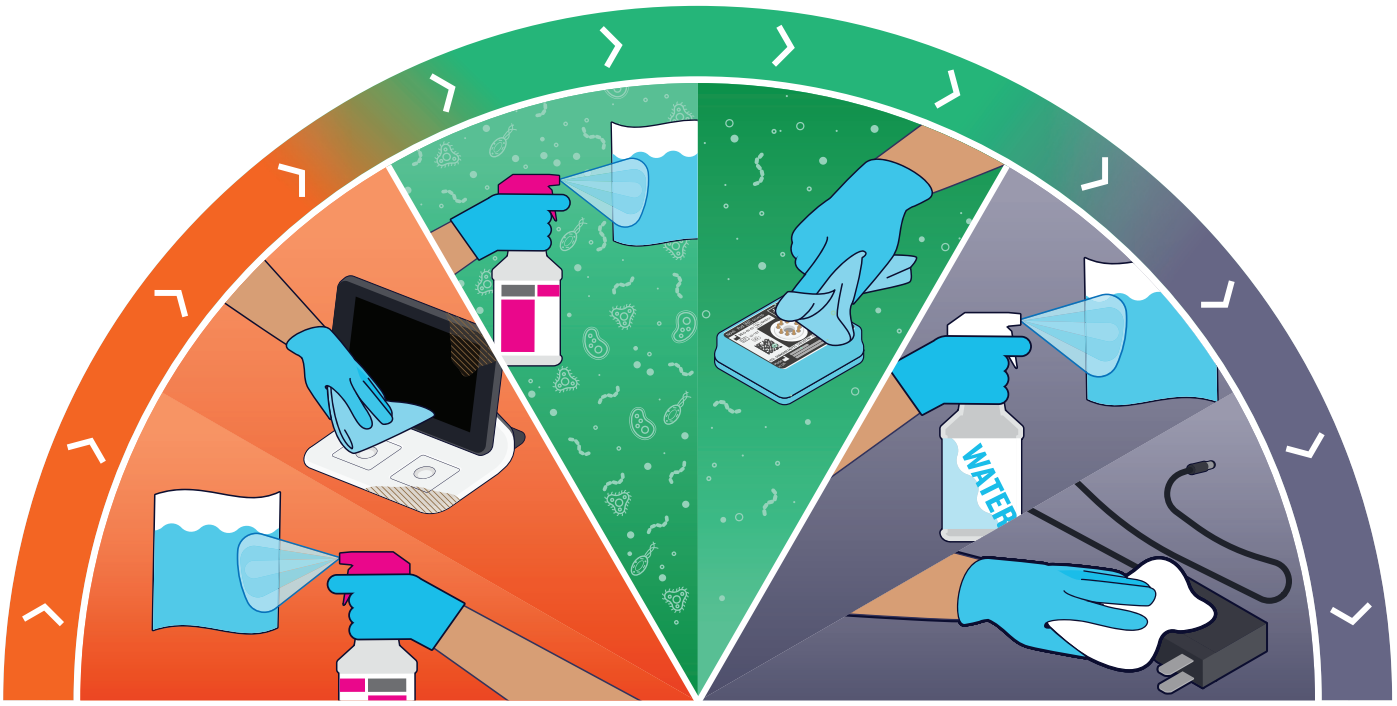
Use the specified cleaner to remove all the soil you can see. You also need to wipe all sides of the part with the cleaner.

Disinfect:
Kill the germs

Disinfection kills the germs on the parts. Make sure that the part stays wet with the disinfectant for the required amount of time.

Remove chemicals

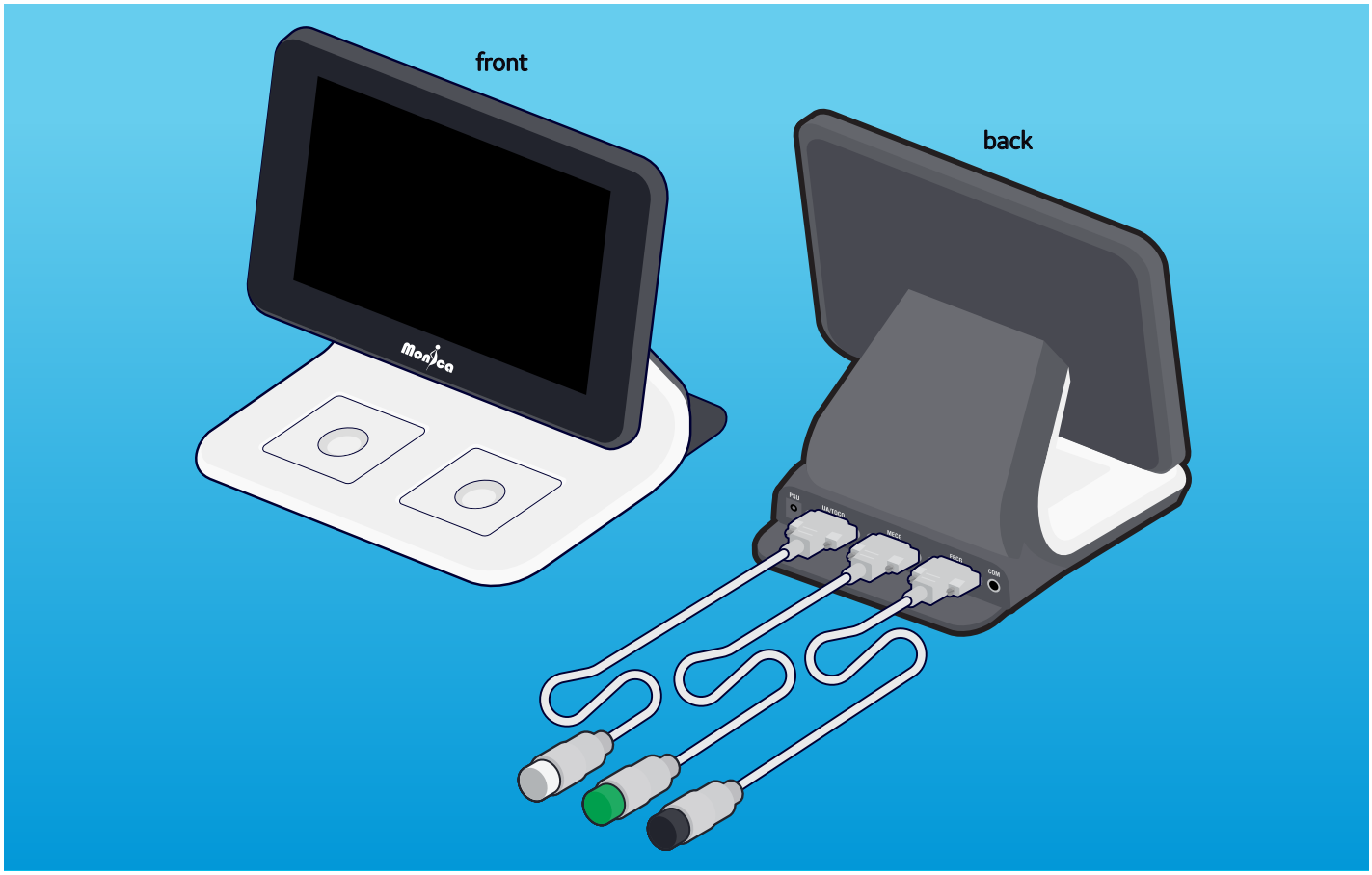
You must rinse all parts with water to make sure all the chemicals are completely washed away.



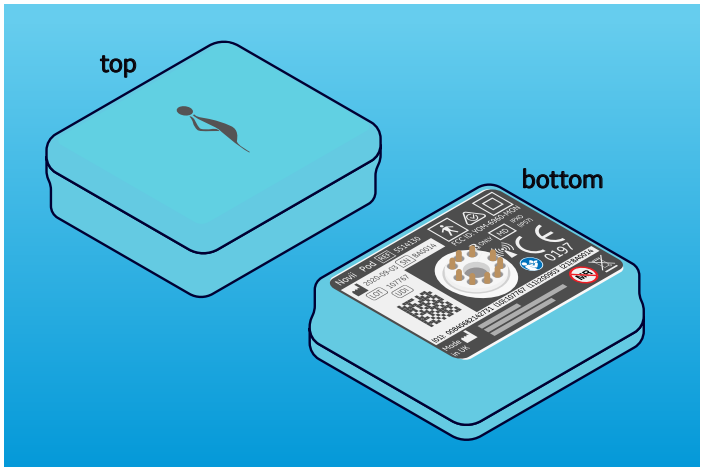
This is a reference guide for cleaning and disinfecting the Novii system and can be used to train the cleaning staff.

Part identification

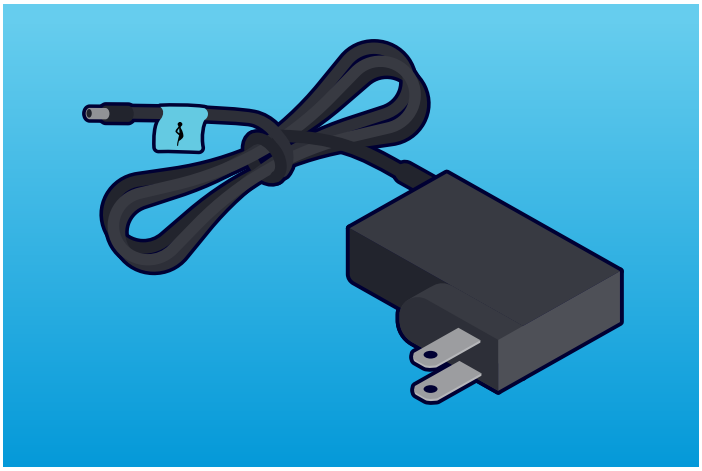
These are the parts of the Novii system that you will clean and disinfect.



- ☐ **Novii Interface**
- ☐ **UA Interface cable**
  white connector
- ☐ **MHR Interface cable**
  (for Novii systems connected to Corometrics 259cx only)
  green connector
- ☐ **FHR Interface cable**
  black connector



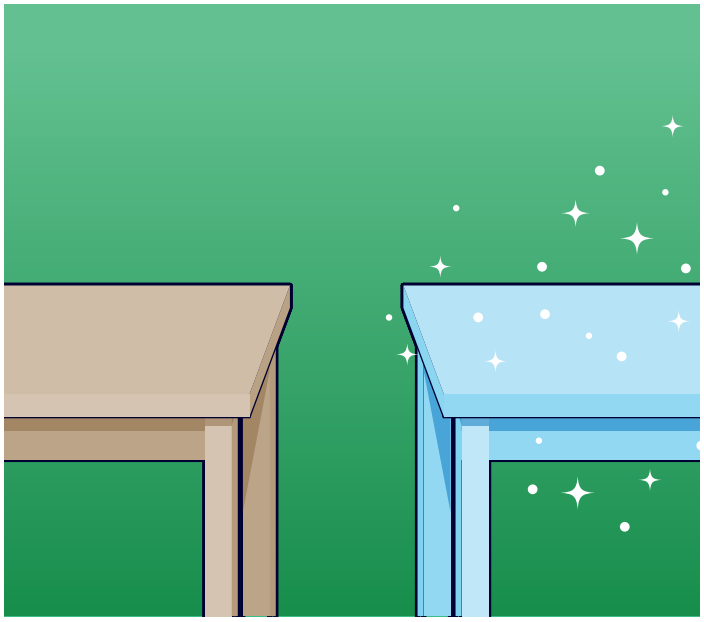
- ☐ **Novii Pod**



- ☐ **Novii Interface power supply**

Dos and don’ts

DON’T
use broken parts.



DO
have separate areas for dirty, clean, and disinfected parts.

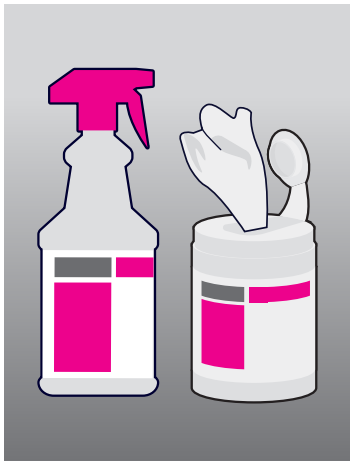
DON’T
clean near patients.

DON’T
spray directly onto the parts.

If you think there is liquid ingress, contact Service

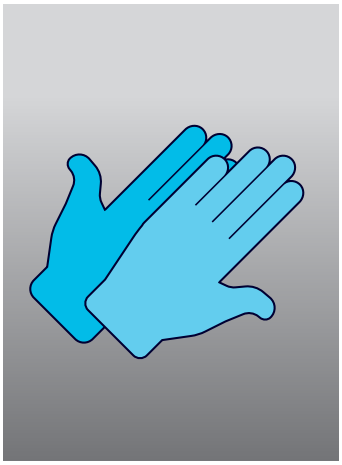
Before you begin

You will need

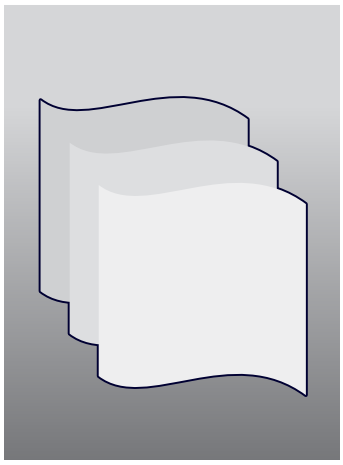


☐ CaviCide or CaviWipes

☐ Water*

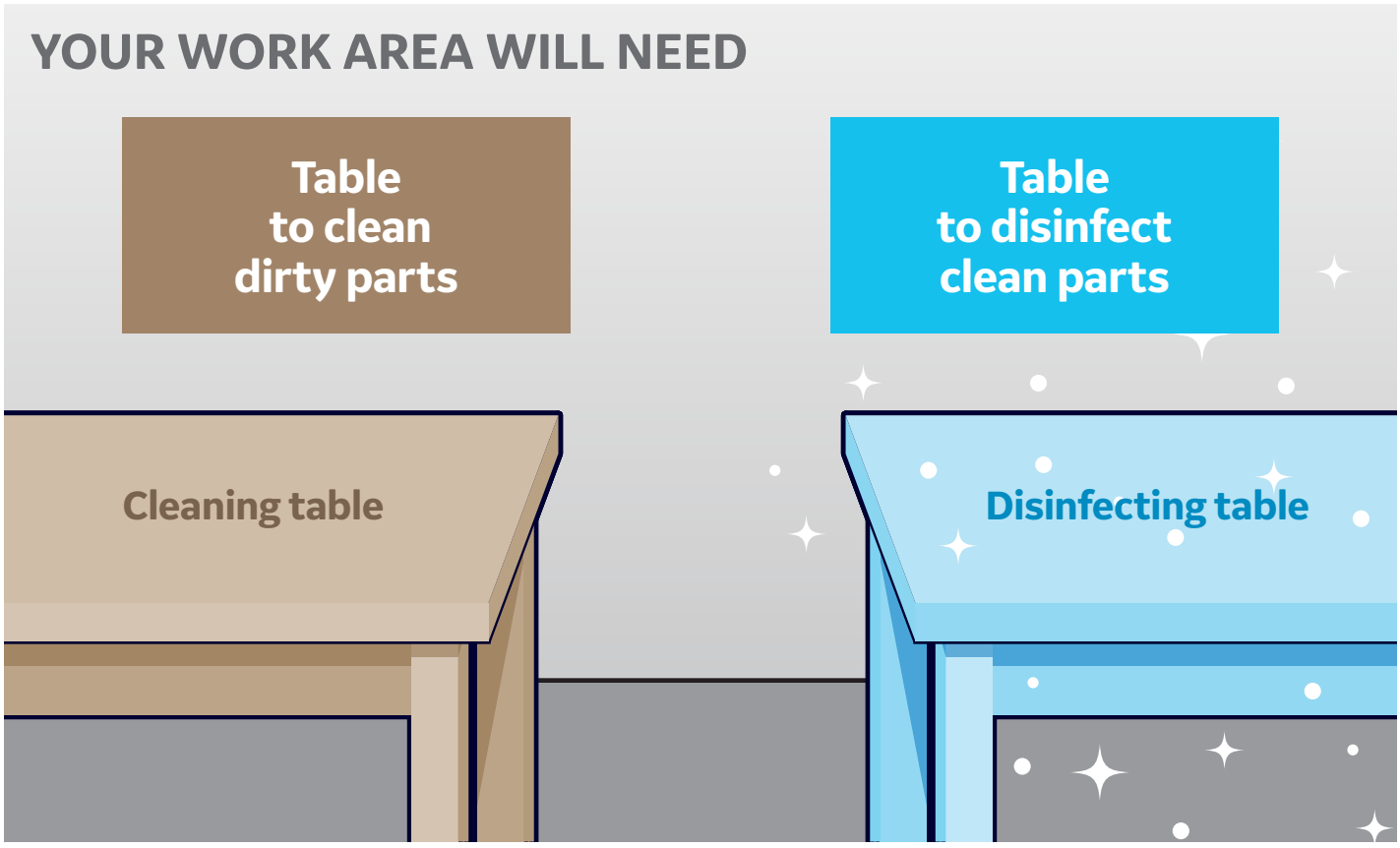


☐ Gloves



☐ Lint-free cloths

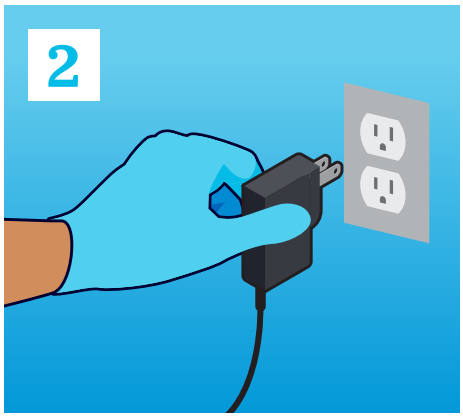
*Tap water needs to meet the requirement of utility water as defined in AAMI TIR34.



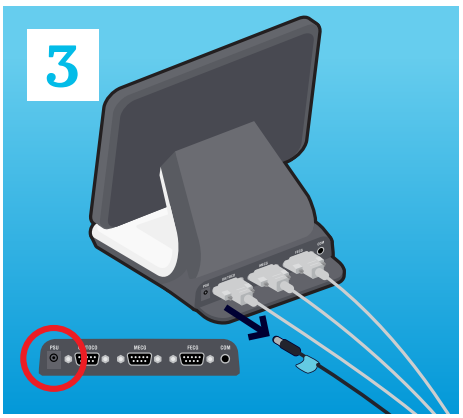
We show tables here, but you can use carts or other suitable areas.

Get the system ready to clean

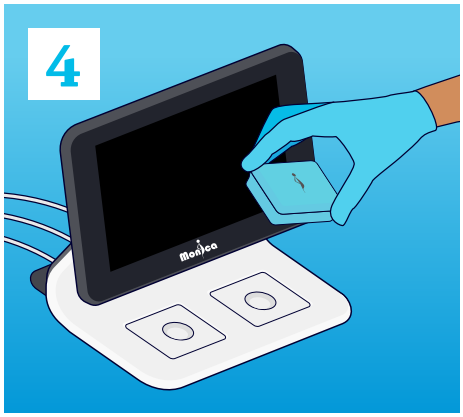
Put on new gloves.



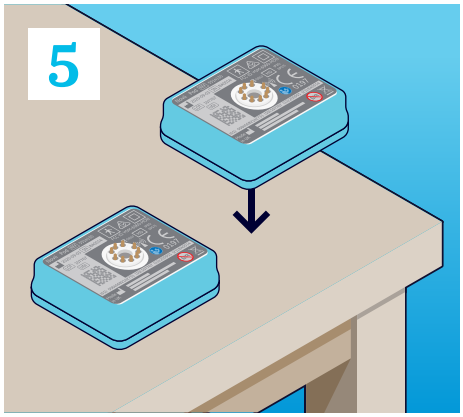
Unplug the Novii power supply from the outlet.



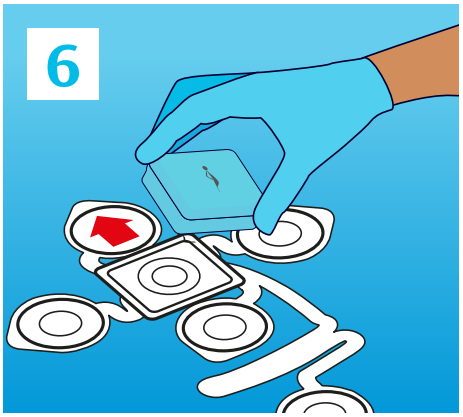
Unplug the Novii power supply from the connector on the back of the Interface.



Remove each Pod from the Interface.

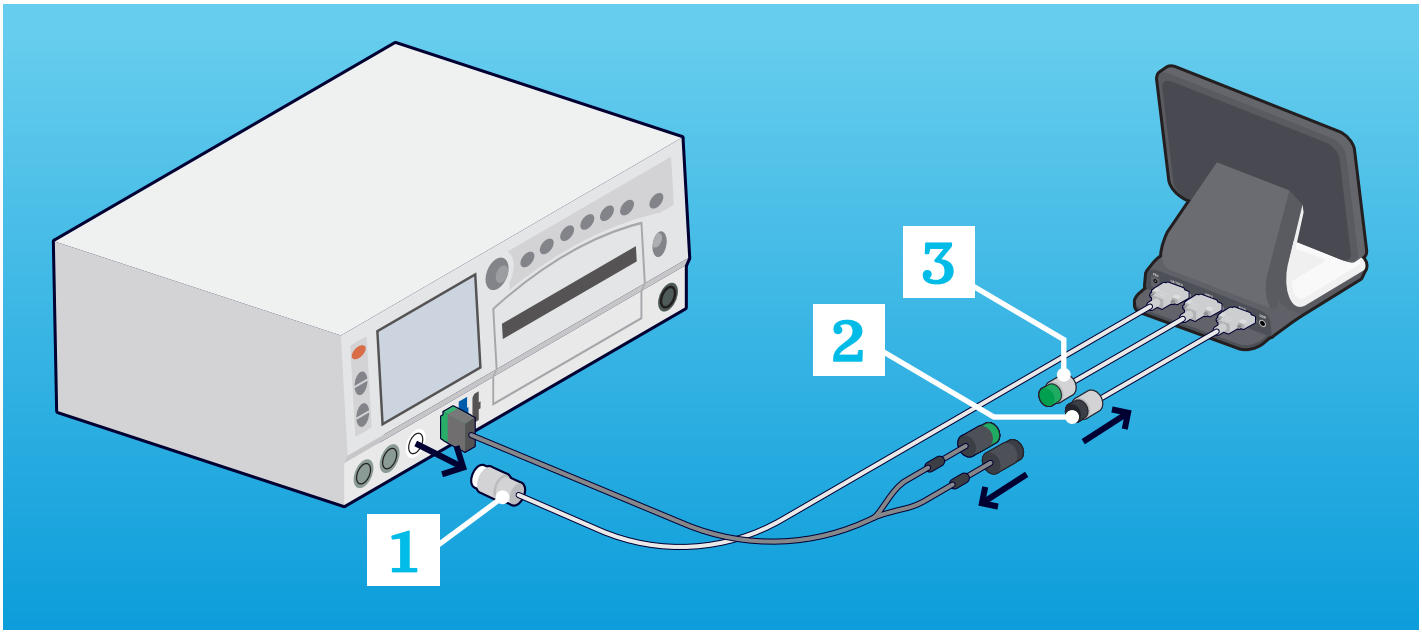


Put each Pod on the work surface so its pins point up.



If a Pod is clipped to a Patch, remove the Pod from the Patch. Set down the Pod so its pins point up. Throw away the Patch.

Unplug the Interface cables from a Corometrics 259cx

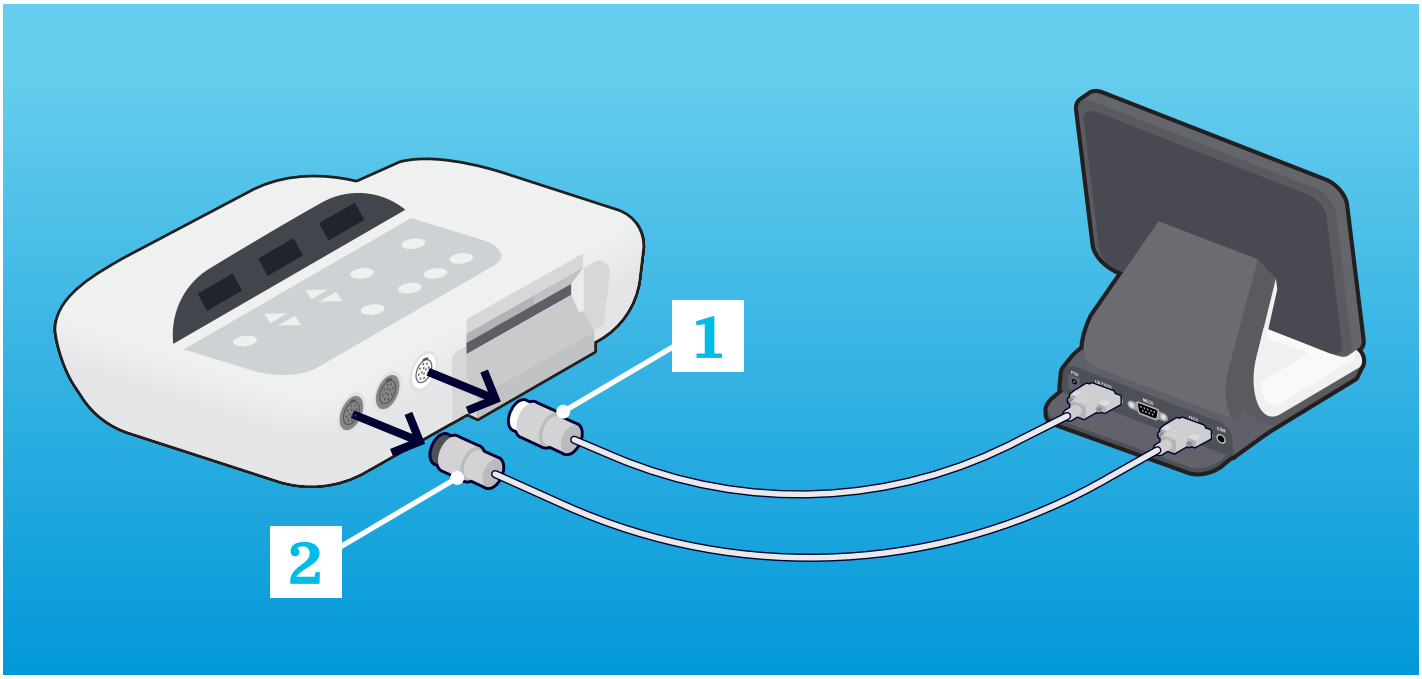


1 Unplug the **Novii UA Interface cable** from the white connector on the front panel of the Corometrics 259cx.

2 Unplug the **Novii FHR Interface cable** from the black connector of the Corometrics Y-adapter.

3 Unplug the **Novii MHR Interface cable** from the green connector of the Corometrics Y-adapter.

Unplug the Interface cables from a Corometrics 174

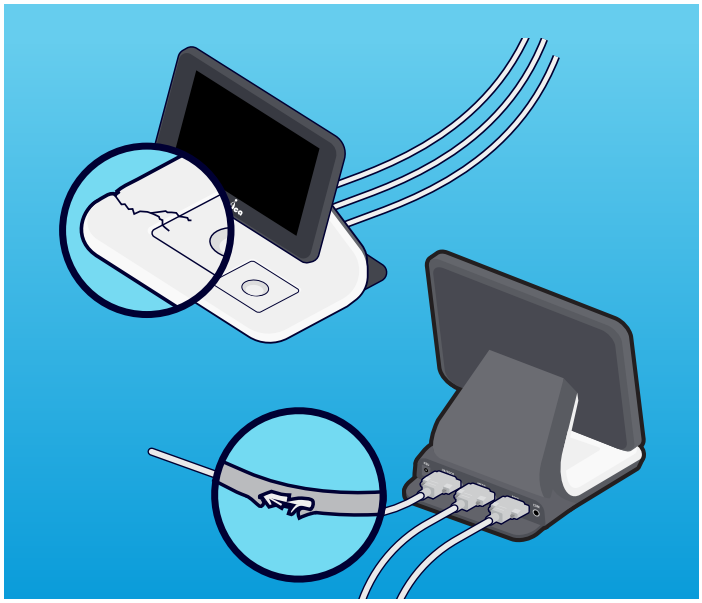


1 Unplug the **Novii UA Interface cable** from the white connector on the front panel of the Corometrics 174.

2 Unplug the **Novii FHR Interface cable** from the black connector on the front panel of the Corometrics 174.

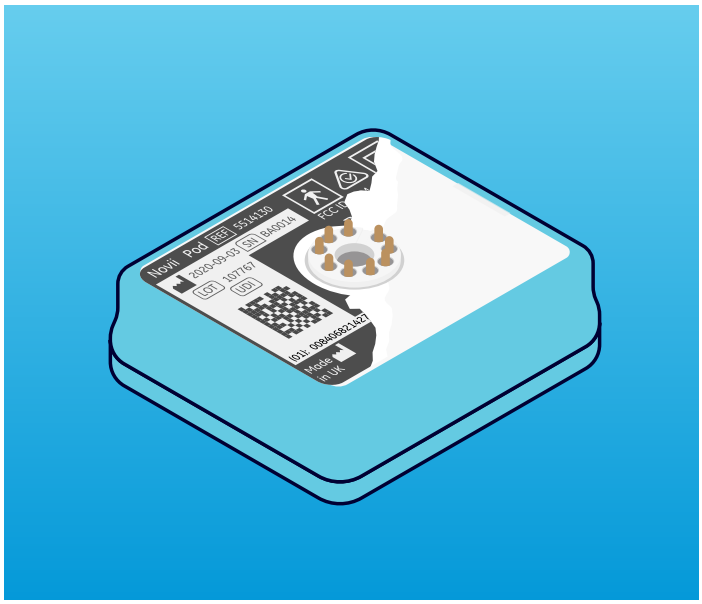
Inspect for damage

Before you start to clean, visually inspect all equipment for damage.

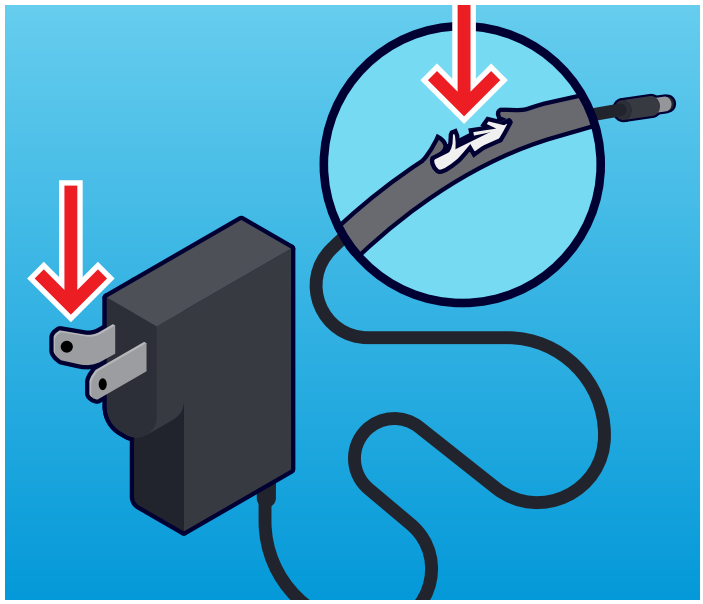


Inspect every Novii part for damage or wear, such as discoloration, heavy scratches, or cracks.

Check the gold pins of each Pod for missing pins, bent pins, or pins that are down too far into the recess.



Check for damaged labels.



Check for fraying on the cables, bent plug pins.

If you do see that a device has damage or heavy wear, do not use it.

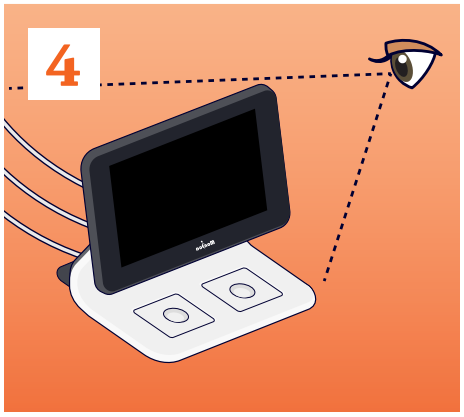
Cleaning and disinfection

Cleaning

Spray CaviCide onto a cloth.
NOTE: Do not saturate the cloth to avoid damage to electronics due to liquid ingress. Use a new cloth if it dries out or becomes dirty.

Wipe all sides of the Interface, including its display, with the wet cloth. Wipe all sides of each Interface cable with the wet cloth. Use as many cloths as necessary.

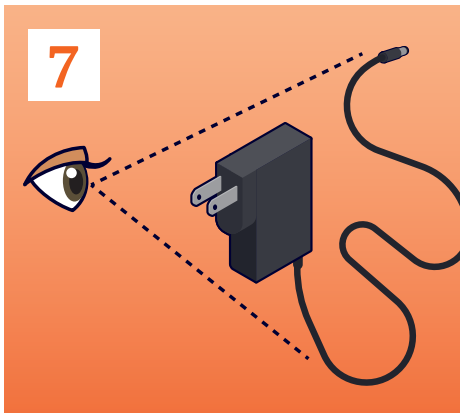
Make sure the CaviCide gets onto areas that can be hard to reach, but avoid plugs and connectors.



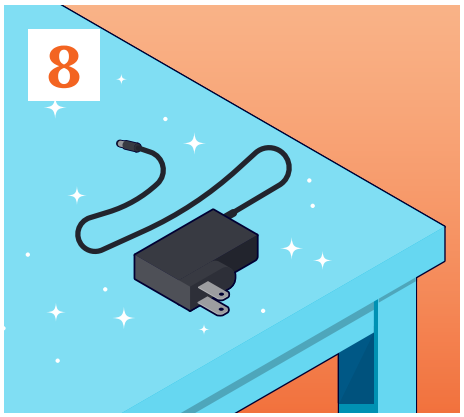
Make sure the Interface and the Interface cables look clean.

Move the Interface and the Interface cables to the disinfection area.

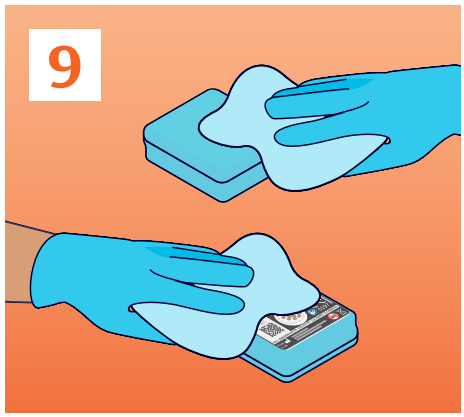
Wipe all sides of the power supply with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach, but avoid the plug and connector.



Make sure the power supply looks clean.



Move the power supply to the disinfection area.

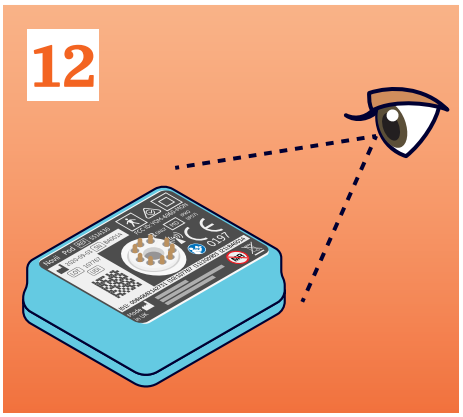


Wipe all sides of each Pod with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach.

Cleaning (continued)

Wipe the gold pins on each Pod very lightly.

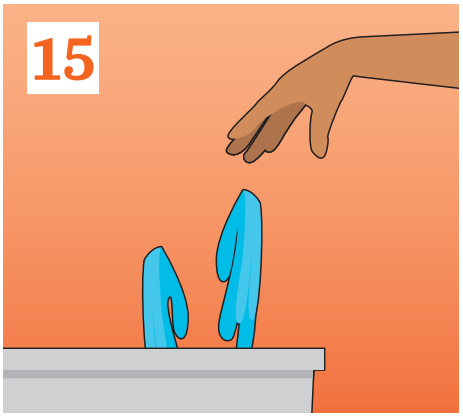
DO NOT let CaviCide collect around the Pod pins. If CaviCide does collect around the pins, lightly wipe them with a cloth until the fluid is absorbed.



Make sure each Pod looks clean.

Move the Pods to the disinfection area. Put each Pod down so its pins point up.

Throw away the cloths that you used to clean the parts.



Throw away your gloves.

Disinfection

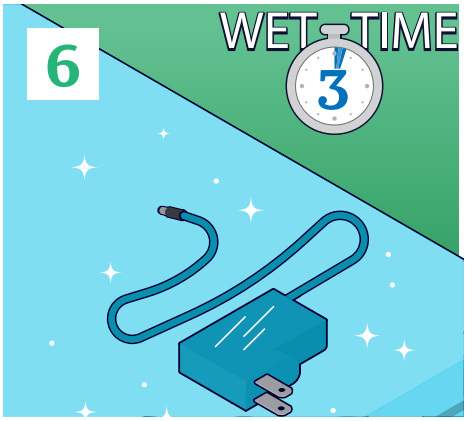
Put on new gloves.

Spray CaviCide onto a cloth.
NOTE: Do not saturate the cloth to avoid damage to electronics due to liquid ingress. Use a new cloth if it dries out.

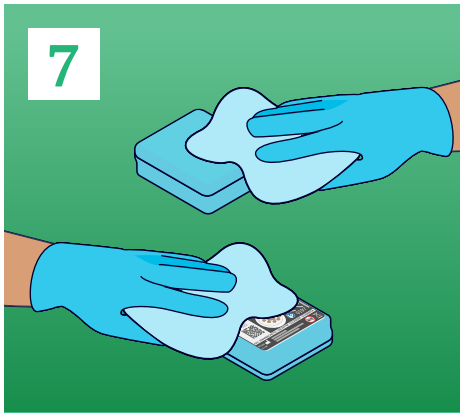
Wipe all sides of the Interface and the Interface cables with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach. Use as many cloths as necessary.

WAIT! Make sure all sides of the Interface and of the Interface cables stay wet for 3 minutes. Watch carefully. The parts must not dry out. Wipe on more CaviCide if any area starts to dry out.

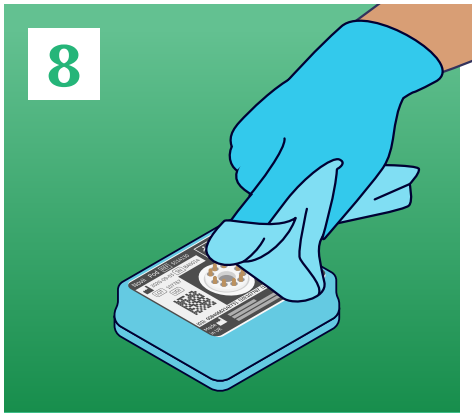
Wipe all sides of the power supply with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach, but avoid the plug and connector.



WAIT! Make sure all sides of the power supply stay wet for 3 minutes. Watch carefully. The part must not dry out. Wipe on more CaviCide if any area starts to dry out.



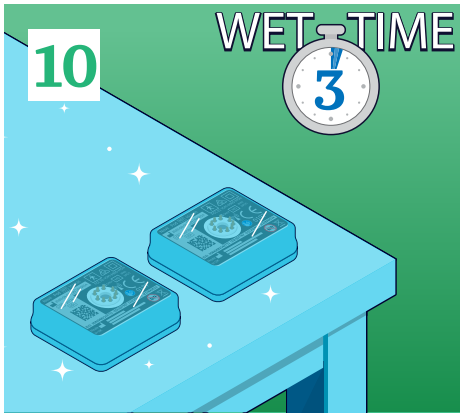
Wipe all sides of each Pod with the wet cloth. Make sure the CaviCide gets onto areas that can be hard to reach.



Wipe the gold pins on each Pod very lightly.

DO NOT let CaviCide collect around the Pod pins. If CaviCide does collect around the pins, lightly wipe them with a cloth until the fluid is absorbed.

Disinfection (continued)



WAIT! Make sure all sides of each Pod stay wet for 3 minutes. Watch carefully. The parts must not dry out. Wipe on more CaviCide if any area starts to dry out.

Throw away the wipes / cloths that you used to disinfect the parts.

Wipe all sides of each Pod with a dry cloth.

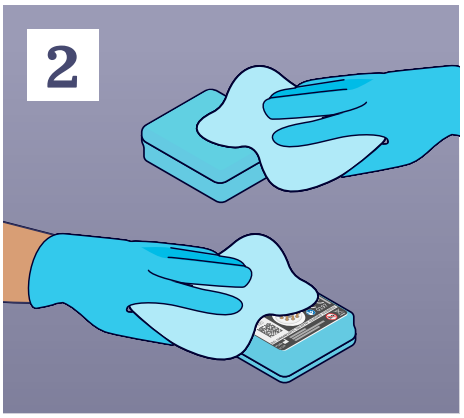
Wipe all sides of the power supply with a dry cloth.

Wipe all sides of the Interface and of the Interface cables with a dry cloth.

Throw away the cloths that you used to dry the parts.

Remove chemicals

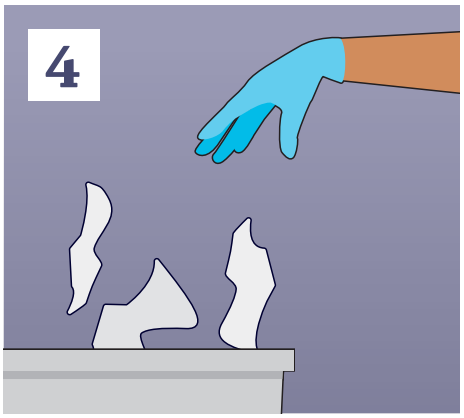
Spray water onto a cloth.
Note: Do not saturate the cloth to avoid damage to electronics due to liquid ingress.



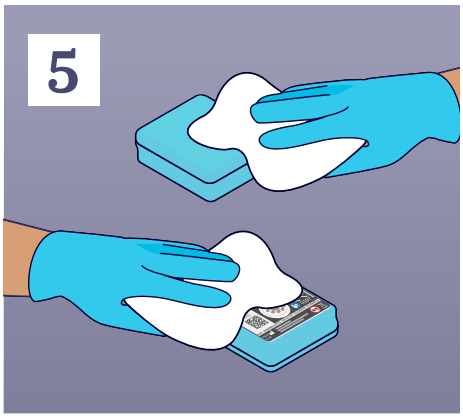
Wipe all sides of each Pod with the wet cloth.

Wipe the gold pins on each Pod very lightly.

DO NOT let water collect around the Pod pins. If water does collect around the pins, lightly wipe them with a cloth until the fluid is absorbed.

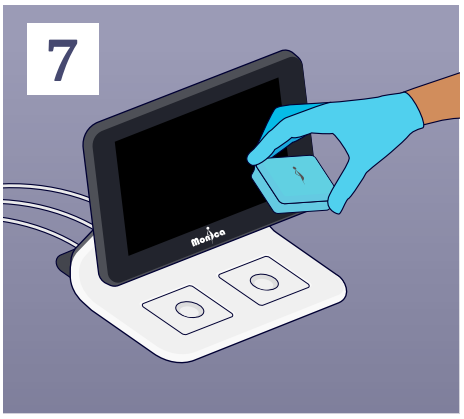


Throw away the wipes / cloths that you used to rinse the Pods.

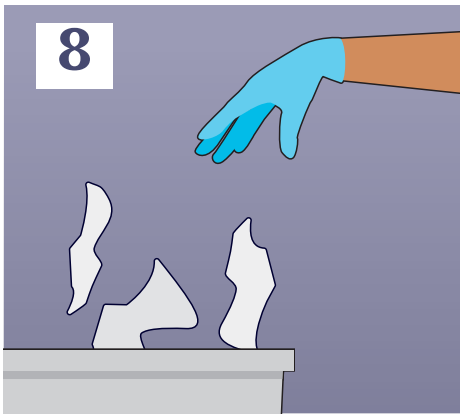


Wipe all sides of each Pod with a **dry cloth**.

Wipe the gold pins on each Pod very lightly.

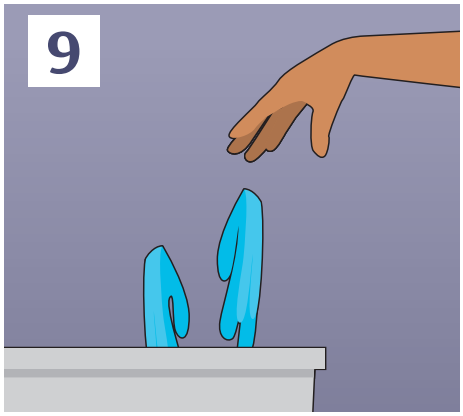


When the Interface is fully dry and each Pod is fully dry, put each Pod back onto the Interface.



Throw away the wipes / cloths that you used to rinse and dry the parts.

Remove chemicals (continued)



Throw away your gloves.

USA

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226 USA
Tel 1 800 345 2700

EC REP

GE Medical Systems SCS
283 Rue de la Minière
78530 BUC, FRANCE

Reporting of Serious Incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To report to GE: Either contact your local service representative or report to:
In-box.complaints@ge.com.

Please provide the following information:

- The catalogue number or the model designation of the product as stated on its identification plate affixed on the product
- The System ID/serial number/lot number of the product
- Date of incident
- Description of incident, including any patient or user impact/injury
- Your contact information (facility, address, contact name, title, and telephone number).

Datex-Ohmeda, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226
USA

Made in UK

CE
0197

Novii Operation and Maintenance Manual
Printed in USA

107-PT-005-EN
Revision H
Language: English

Philips Monitoring System (MUNSON)

Philips Monitoring System (MUNSON)

Introduction

Central Monitoring System

The Philips Patient Information Center is a regulated medical IT system that:

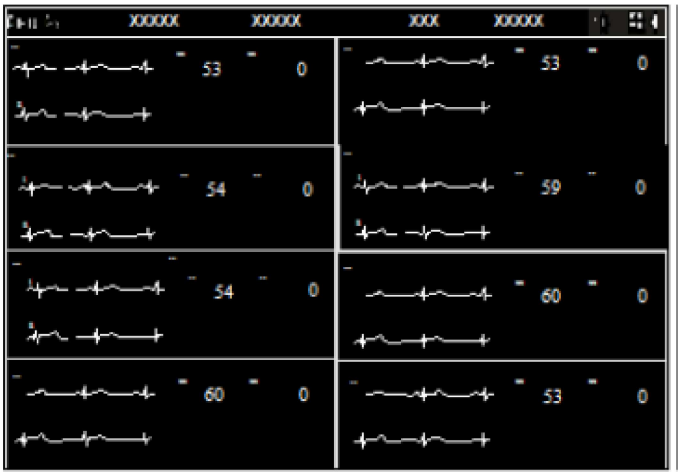
- Provides continuous monitoring of patient vital signs from admission to discharge.
- Consolidates and communicates vital signs data from monitors and third-party devices to caregivers and to the Electronic Medical Record (EMR) for a complete patient record.
- Supports industry standard interfaces to 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.

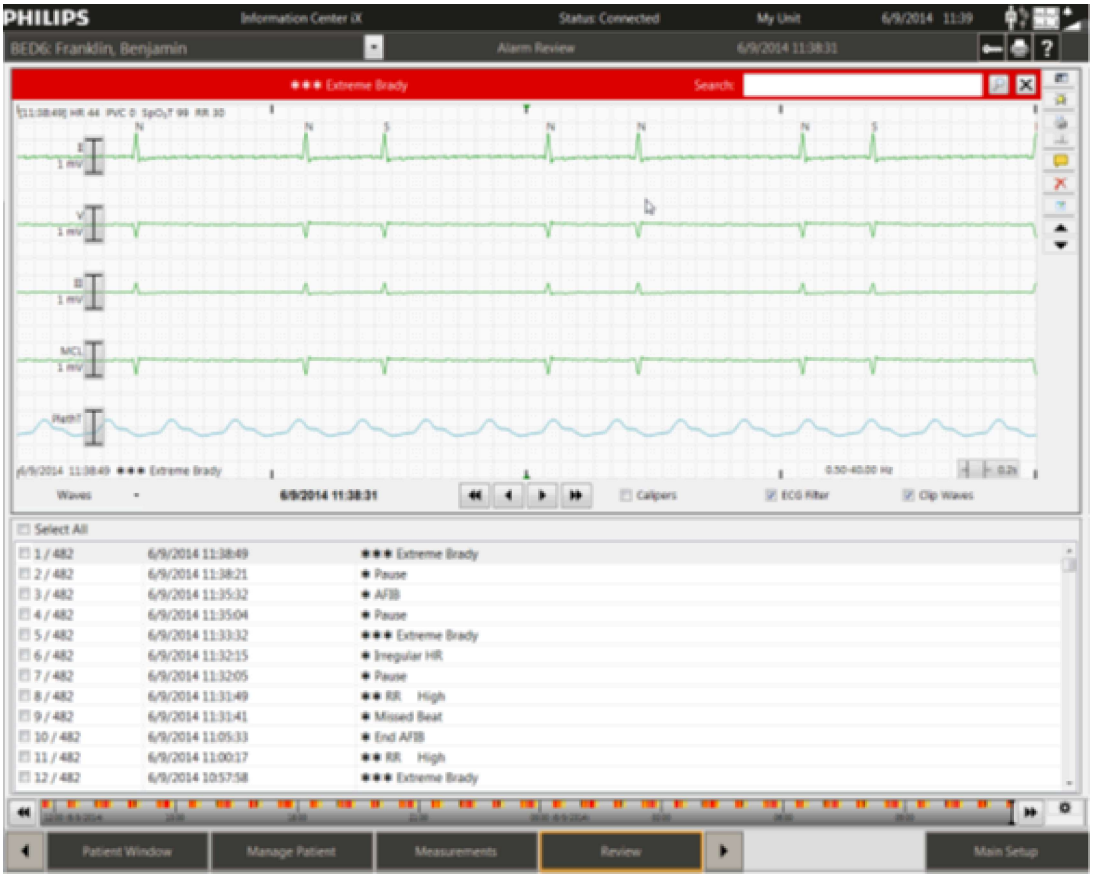
Fast Alarm Review - Select either the Acknowledge key, or the alarm banner in the sector to see alarming waves prior to being available in other applications. Alarm strips can be printed, annotated, or discarded. If you are using secondary notifications, such as with Philips CareEvent, you can manually 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:

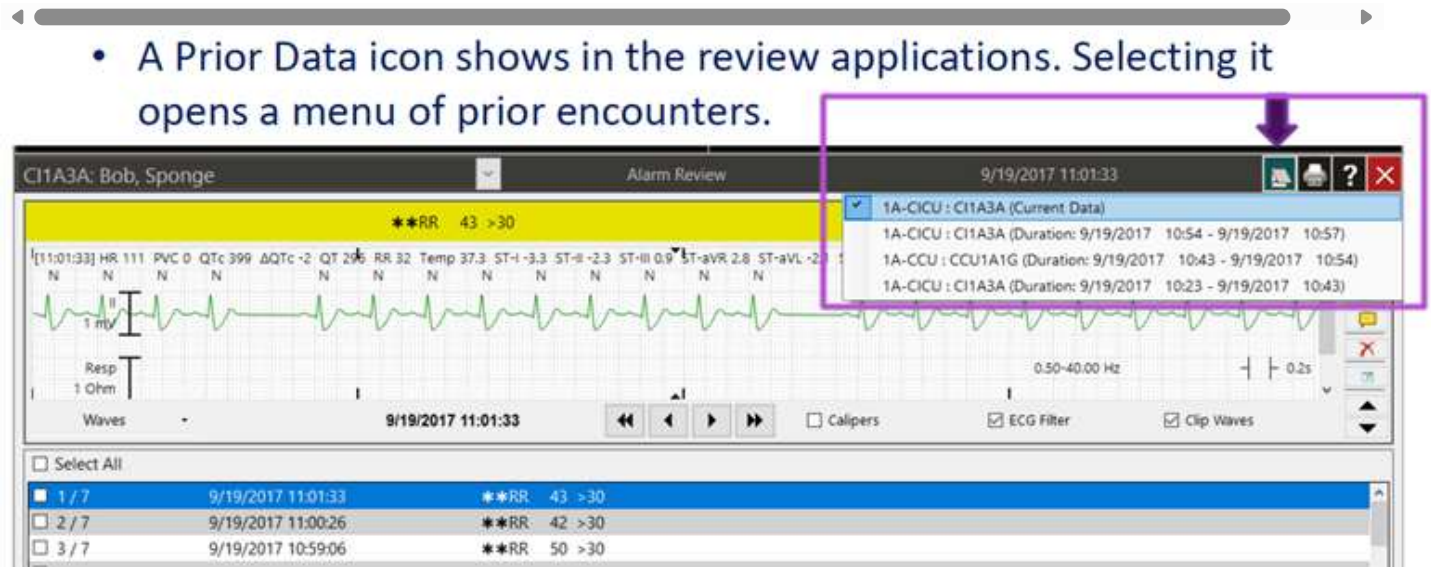
 Do Not Resuscitate. Resuscitation icon. Indicates the patient's current resuscitation status.

 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:

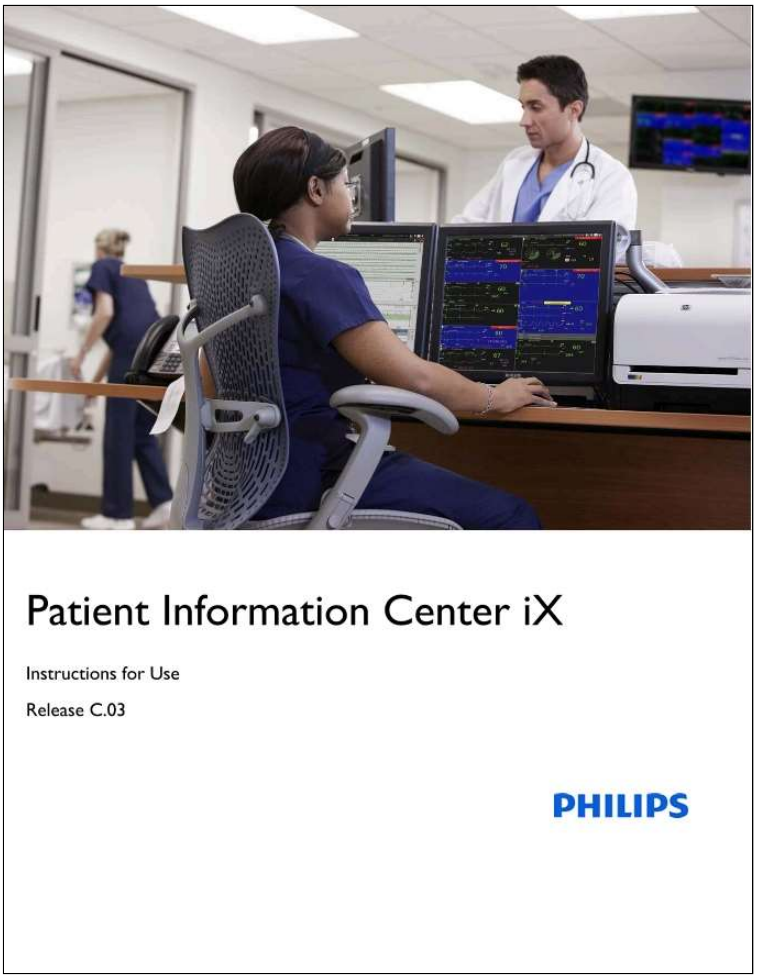
- MX Series QR Codes
- Central Monitoring Station PICiX
  - IFU_-_PIC_iX_Rel_C.03_-_English.pdf- Central station user manual
  - PIICiX Rev C.03 Patient Data Review
- MX40 Telemetry box
  - the MX40 IFU manual link
  - the MX40 quick card reference
- MX400 Large Mounted Monitor
  - IFU MX400-800_IVPM_N0x)Mar2019.pdf User manual
- Invasive pressure Guide
  - Invasive Pressure PDF
- Capnography
  - Capnography Application Guide

Notes

MX Series QR Codes

View image in PDF format.

Philips Monitoring System Manual



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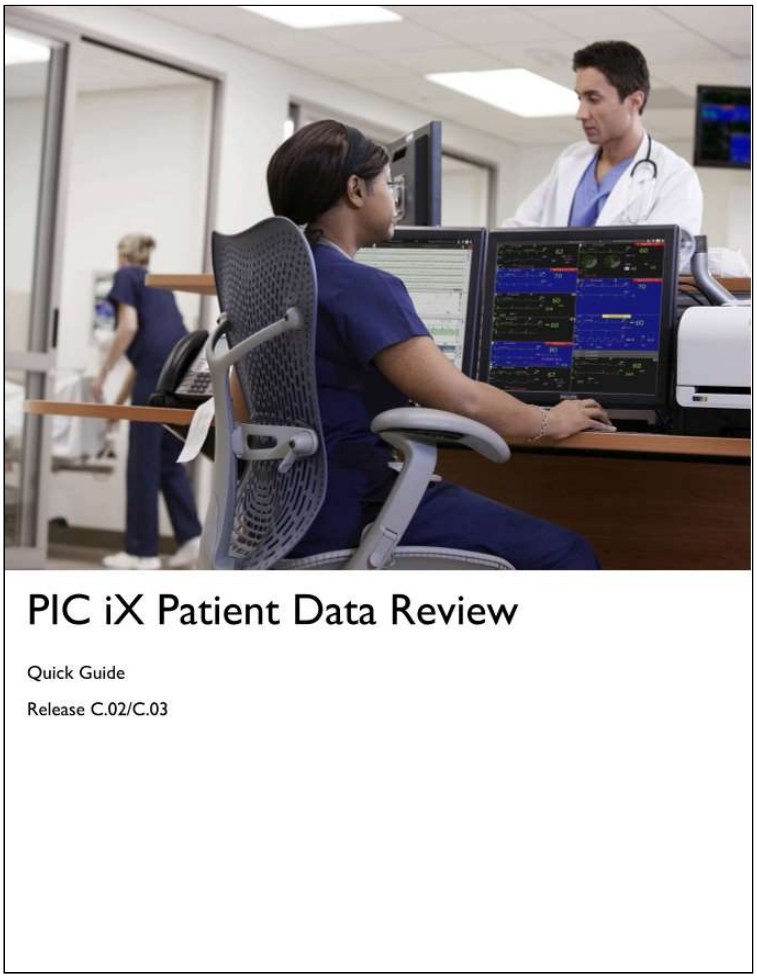


View image in PDF format.

Car Seat Quick Guide

Car Seat Assessment Record (CAR)
Quick Guide

1. Place baby in car seat.
2. Change Screen to **CAR SEAT TEST.**

3. Touch SmartKey – **START CAR.**
4. Select amount of time for Test Duration *(based on hospital protocol)*.

5. Touch **CONFIRM** key.

CAR is now in progress
Monitoring is continued during CAR.

6. If at any time during CAR you need to exit or stop – press the SmartKey **STOP CAR** and **CONFIRM**.

   At any time you can also switch back to your default monitoring screen by touching **Change Screen**, then touch the back arrow at the top of that menu. *CAR will continue to run in the back ground.*

7. When CAR is complete, the countdown timer (to the far right in the CAR Screen) will turn **RED**.

View image in PDF format.

Procedure: Sara Stedy floor lift (MUNSON)
Checklist: Sara Stedy floor lift (MUNSON)
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

Critical Notes

Note: This equipment is not be used on non-weight bearing patients. Patient must demonstrate good trunk control. For use with 1-2 staff members.

Sara Stedy floor lift (MUNSON)

To use the Sara Stedy floor lift for patient transfer according to guidelines. July 17, 2019

Checklist Step	Comments
Y- Meets; N- Does not meet; I- Not Applicable	
Opening and closing the legs:	
__ To open the legs, press down the left pedal. __ To close the legs, press down the right pedal.	

Applying and releasing the brakes on the rear castors:

__ Lock brake.

__ Unlock brake.

Approaching the patient:

__ Pivot the two seat halves up.

__ Open the chassis legs if needed; approach the patient.

__ Position the Sara Stedy so that the patient's feet are placed on the footrest with knees

comfortably against kneepad.

__ Apply both castor brakes.

Transferring the patient from a chair:

__ Have the patient hold the crossbar and use it to stand up.

__ Pivot the two seat halves down.

__ Ask the patient to sit.

__ Release the brakes and proceed with the transfer.

Transferring the patient to a chair:

__ Bring the patient over to the chair and apply the brakes.

__ Ask the patient to stand up.

__ Pivot the two seat halves up.

__ Ask the patient to sit down holding the crossbar.

Guidelines for Oxytocin-Induced Uterine Tachysystole

Purpose: To administer oxytocin as ordered by care provider to achieve an effective labor pattern that produces progressive cervical dilation and adequate contraction pattern, while ensuring fetal and maternal safety.

***Avoid Tachysystole*:** Greater than 5 uterine contractions in 10 minutes averaged over 30 minutes, contractions lasting 2 minutes or more, or contractions of normal duration occurring within one minute of each other.

Guidelines for Oxytocin-Induced Uterine Tachysystole

With Category I FHR (Normal)	***With Category II or III FHR (Indeterminate or Abnormal)***
• Maternal repositioning (either left or right) • IV fluid bolus Lactated Ringer's 500mL, may repeat 500mL bolus x 1 • If uterine activity has not returned to normal after 10 minutes, decrease oxytocin rate by at least half. • If uterine activity has not returned to normal after 10 more minutes, discontinue oxytocin until uterine activity is less than 5 contractions in 10 minutes and update the care provider.	• Decrease or discontinue oxytocin* • Maternal repositioning (either left or right) • IV fluid bolus Lactated Ringer's 500mL, may repeat 500mL bolus x 1 • Consider oxygen at 10L/min via nonrebreather facemask if the first interventions above do not resolve the indeterminate/abnormal FHR pattern. Discontinue as soon as possible. • **If no response, give terbutaline 0.25 mg subcutaneously.** • Notify primary care provider of actions taken and maternal- fetal response.
Resumption of Oxytocin after Resolution of Tachysystole • If oxytocin has been discontinued for less than 30 minutes, the FHR is normal and contraction frequency, intensity and duration are normal, resume oxytocin at no more than half the rate that caused the tachysystole and gradually increase the rate by 1-2 milliunits/minute as appropriate based on practice guidelines and maternal-fetal status. • If the oxytocin is discontinued for more than 30 minutes, resume oxytocin at initial dose ordered.	

**Discontinue oxytocin with a category III FHR tracing. "Clinical judgment is required to determine whether to decrease versus discontinue oxytocin for category II tracing depending on their specific presentation. For example, oxytocin may need to be discontinued in the context of category II tracings with minimal variability and recurrent decelerations, but it may be appropriate to continue oxytocin at a decreased rate in a tracing with moderate variability and intermittent variable decelerations" (Simpson & Creehan, 2014, p.462).*

References

American College of Obstetricians and Gynecologist. (2009). Induction of Labor (Practice Bulletin #107). *Obstetrics & Gynecology, 114* (2), 386-397.

Association of Women's Health, Obstetric and Neonatal Nurses. (2015). *Fetal heart monitoring: Principles and practices* (5th ed.). Washington, DC: Author.

Simpson, K. R. & Creehan, P. A. (2014). *Perinatal nursing*, (4th Ed.). Philadelphia, PA: Wolters Kluwer/ Lippincott Williams & Wilkins.

Please refer to orders for individualized patient care. Patient's orders supersede any information contained within the reference text. Please refer to policy Oxytocin Induction/Augmentation of Labor for further information.

Reviewed 11/18/2019

Refer to orders for individualized patient care. Patient's orders supersede any information contained within the reference text.

Oxytocin Reference Text

Purpose: To achieve an effective labor pattern that produces progressive cervical dilation, while ensuring fetal and maternal safety.

Please refer to policy Oxytocin Induction/Augmentation of Labor for further information.

A. **Electronic surveillance** for 30 minutes prior to initiation of oxytocin shows all the following:
- At least 2 accelerations (15 bpm x 15 sec.), or moderate variability in the past 30 minutes, or the patient has had a biophysical profile in the past 4 hours resulting in a score of 8 or more.
- No late decelerations in the past 30 minutes.
- No more than 2 variable decelerations exceeding 60 seconds, and decreasing more than 60 bpm from baseline in the past 30 minutes (AWHONN, 2012).
  - For a category II FHR tracing, notify care provider to review FHR tracing prior to proceeding with induction or augmentation.

B. **Continuous EFM**: The RN must be able to adequately assess uterine activity and fetal status at all times or oxytocin infusion must be discontinued.

C. **IV:**
1. #18 gauge IV catheter
2. Primary IV: Lactated Ringer's 1000mL; *see care provider's order for rate of infusion*
3. Secondary IV: Oxytocin 30 units in 0.9% NaCl 500mL, premixed solution (or prepared by Pharmacy). Piggyback the oxytocin infusion through an infusion pump at the venipuncture site.
4. **Other IV medications must be given through the primary IV line. The secondary line with oxytocin may not be used to give other medications.**

D. **Oxytocin Administration**

[Adapted from University of Michigan Induction and Augmentation of Labor Clinical Guideline (2022)]

Initial dose: Begin infusion at 2 milliunit/minute.

Dose increase: Increase rate by 2 milliunits/minute every 30 minutes until adequate progress of labor is established.
- Adequate progress of labor is defined as:
  - Contractions resulting in cervical change regardless of frequency/strength OR
  - At least 3 contractions per 10-minute interval, that last 60-90 seconds each and palpate strong to the experienced obstetric care provider or nurse OR
  - The use of an intrauterine pressure catheter, demonstrating a minimum of 200-220 Montevideo Units per 10-minute interval
- Once adequate labor is established, maintain or consider decreasing oxytocin rate to continue labor progress as indicated by:
  - Contractions every 2-3 minutes lasting 40-90 seconds each
  - Contraction intensity moderate to strong by palpation, or in a range amplitude of 40-90 mmHg by intrauterine pressure catheter
  - Resting tone is soft to palpation or ≤ 20 mmHg by intrauterine pressure catheter
  - 200-220 MVU of uterine activity achieved (if calculating)

***Guideline Dose*:** Nursing may increase oxytocin rate as ordered up to a *maximum* of 20 milliunits/minute. If necessary to continue increasing oxytocin beyond 20 milliunits/minute, nursing must notify the primary care provider for an evaluation and written orders. Primary care provider must be immediately available for infusions greater than 20 milliunits/minute.

***Avoid Tachysystole*:** Greater than 5 uterine contractions in 10 minutes averaged over 30 minutes, contractions lasting 2 minutes or more, or contractions of normal duration occurring within one minute of each other.

Guidelines for Oxytocin-Induced Uterine Tachysystole

With Category I FHR (Normal)	*With Category II or III FHR (Indeterminate or Abnormal)*
• Maternal repositioning (either left or right) • IV fluid bolus Lactated Ringer's 500mL, may repeat 500mL bolus x 1 • If uterine activity has not returned to normal after 10 minutes, decrease oxytocin rate by at least half. • If uterine activity has not returned to normal after 10 more minutes, discontinue oxytocin until uterine activity is less than 5 contractions in 10 minutes and update the care provider.	• Decrease or discontinue oxytocin* • Maternal repositioning (either left or right) • IV fluid bolus Lactated Ringer's 500mL , may repeat 500mL bolus X 1 • Consider oxygen at 10L/min via nonrebreather facemask if the first interventions above do not resolve the indeterminate/abnormal FHR pattern. Discontinue as soon as possible. • **If no response, give terbutaline 0.25 mg subcutaneously.** • Notify primary care provider of actions taken and maternal- fetal response.
Resumption of Oxytocin after Resolution of Tachysystole • If oxytocin has been discontinued for less than 30 minutes, the FHR is normal and contraction frequency, intensity and duration are normal, resume oxytocin at no more than half the rate that caused the tachysystole and gradually increase the rate by 2 milliunits/minute as appropriate based on practice guidelines and maternal-fetal status. • If the oxytocin is discontinued for more than 30 minutes, resume oxytocin at initial dose ordered.	
**Discontinue oxytocin with a category III FHR tracing. "Clinical judgment is required to determine whether to decrease versus discontinue oxytocin for category II tracing depending on their specific presentation. For example, oxytocin may need to be discontinued in the context of category II tracings with minimal variability and recurrent decelerations, but it may be appropriate to continue oxytocin at a decreased rate in a tracing with moderate variability and intermittent variable decelerations" (Simpson & Creehan, 2014, p.462).*	

E. The FHR pattern and uterine activity should be evaluated every 15 minutes in the latent and active phase of the first stage of labor and every 5 minutes during the active pushing phase of the second stage of labor. *When evaluating every 15 minutes, the RN will note in the documentation that FHR and uterine activity were reviewed (example, state as an annotation "strip reviewed by nurse").* The FHR pattern and uterine activity pattern should be documented at least every 30 minutes in the first stage of labor if dosage of oxytocin remains unchanged and each time oxytocin dose or rate is increased or decreased. Summary documentation every 30 minutes, during the active pushing phase of the second stage of labor, may be used to document when the nurse remains at the bedside continuously monitoring maternal-fetal status.

1. Maternal vital signs should be evaluated and documented:
   a. Every 60 minutes if dosage of oxytocin remains unchanged
   b. Each time oxytocin dose or rate is increased or decreased
   c. Pulse oximetry or maternal ECG monitor is used with each set of maternal vital signs, and remains on until validation of fetal heart rate is assured

2. Assessment components include:
   a. Uterine activity: Uterine resting tone, contraction frequency, duration, palpated intensity and IUPC reading
   b. FHR pattern: baseline rate, periodic and episodic changes, variability
   c. Maternal vital signs: B/P, pulse, SpO2 (*if used to confirm MHR – see above)*
   d. Other maternal assessments and vital signs per maternity protocol

References

American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2017). *Guidelines for Perinatal Care* (8th ed.). Elk Grove Village, IL: Author.

American College of Obstetricians and Gynecologist. (2009). Induction of Labor (Practice Bulletin #107). *Obstetrics & Gynecology, 114* (2)*,* 386-397.

Association of Women's Health, Obstetric and Neonatal Nurses. (2015). *Fetal heart monitoring: Principles and practices* (5th ed.). Washington, DC: Author.

Association of Women's Health, Obstetric and Neonatal Nurses. (2018). *Templates for protocols and procedures for maternity services* (4th ed.). Washington, DC: Author.

Clark, S. L., Simpson, K. R., Knox, G. E., & Garite, T. J. (2009). Oxytocin: new perspectives on an old drug. *American Journal of Obstetrics & Gynecology, 200*(1), 35e1-35e6.

Institute for Safe Medication Practices. (2019). *High-alert medications in acute care settings*. Retrieved from https://www.ismp.org/recommendations/high-alert-medications-acute-list

Simpson, K. R. & Creehan, P. A. (2014). *Perinatal nursing*, (4th Ed.). Philadelphia, PA: Wolters Kluwer/ Lippincott Williams & Wilkins.

Grobman, W. (2022). Induction of labor with oxytocin. Up-To-Date. Retreived from https://www.uptodate.com/ contents/induction-of-labor-withoxytocin?topicRef=5398&source=related_link#H1773125743

Simpson, K.R. (2020). Cervical ripening and induction and augmentation of labor (5th Ed.). Washington, D.C.: AWHONN

This reference text is attached to order Oxytocin Reference Text

Reviewed and Updated 09/2022

P&T Reviewed and Approved 10/2022

Preeclampsia Early Recognition Tool Guidelines

ASSESS	NORMAL (GREEN)	WORRISOME (YELLOW)	SEVERE (RED)
Awareness	Alert/ oriented	• Agitated/ confused • Drowsy • Difficulty speaking	• Unresponsive
Headache	None	• Mild headache • Nausea, vomiting	• Unrelieved headache
Vision	No changes	• Blurred or impaired	• Temporary blindness
Systolic BP (mm Hg)	100-139	≥155-159	≥160
Diastolic BP (mm Hg)	50-89	90-109	≥110
HR	61-110	110-120	>120
Respiration	11-24	<12 or 25-30	<10 or >30
SOB	Absent	Present	Present
O2 Sat (%)	≥95	<95	<93
Pain: Abdomen or Chest	None	• Nausea, vomiting • Chest pain • Abdominal pain	• Nausea, vomiting • Chest pain • Abdominal pain
Fetal Signs	• Category I • Reactive NST	• Category II • IUGR • Non-reactive NST	• Category III
Urine Output (mL/hr)	≥50	30-49	≤35 in 2 hours
Proteinuria *(level of proteinuria is not an accurate predictor of pregnancy outcome)*	Trace	• ≥+1** • ≥300mg/ 24 hours	• protein (mg/dL)/creatinine (mg/dL) ratio ≥ 0.3
Platelets	>100	50-100	<50
AST/ALT	<70	>70	>70
Creatinine	≤0.8	0.9-1.1	≥1.1
Magnesium Sulfate Toxicity	• DTR +1 • Respirations 16-20	• Depression of patellar reflexes	• Respiration <12

GREEN = NORMAL
Proceed with protocol

YELLOW = WORRISOME
Increase assessment frequency

# Triggers	TO DO
1	☐ Notify provider & charge RN
≥2	☐ Notify provider & charge RN ☐ In-person evaluation ☐ Order labs/tests ☐ Anesthesia consult ☐ Consider magnesium sulfate ☐ Supplemental oxygen

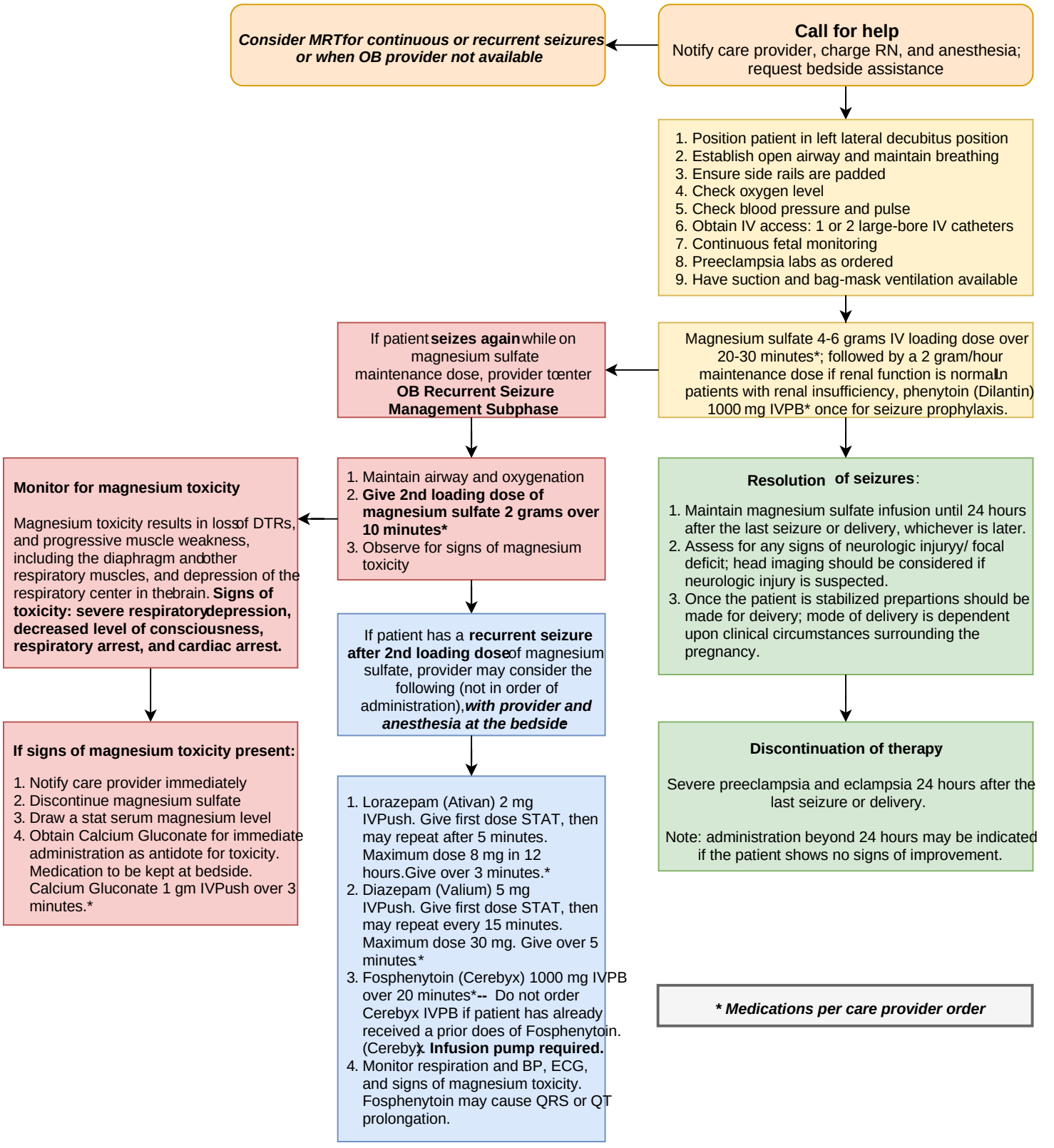
** Provider should be made aware of worsening or new-onset proteinuria

RED = SEVERE

Trigger: 1 of any type listed below	TO DO
1 of any type	☐ Notify provider & charge RN ☐ Anesthesia consult ☐ Immediate evaluation ☐ Transfer to higher acuity level ☐ 1:1 staff ratio with high risk RN
Awareness Headache Visual	☐ Consider neurology consult ☐ CT scan ☐ R/O SAH/ intracranial hemorrhage
BP	☐ Labetalol/Hydralazine/nifedipine within 30 minutes ☐ Magnesium sulfate loading or maintenance infusion
Chest pain	☐ EKG, consider CT angiogram
Respiration SOB O2 Sat	☐ O2 at 10 L per non-rebreather ☐ R/O pulmonary edema ☐ Chest x-ray

This figure was adapted from the Improving Health Care Response to Preeclampsia: A California Quality Improvement Toolkit, funded by the California Department of Public Health, 2014; supported by Title V funds. Approved by MMC OB Section Head, Julia Riddle, D.O., 8/23/2024.

Eclampsia Guidelines Algorithm



Adapted from: California Maternal Quality Care Collaborative.(2013). Eclampsia algorithm. *Preeclampsia Toolkit: Improving Health Care Response to Preeclampsia*. Retrieved from https://www.cmqcc.org/resource/preeclampsia-toolkit-appendix-e-eclampsia-algorithm

Approved by Pharmacy & Therapeutics 04/06/2018, updated 5/31/2023

Magnesium Sulfate Administration

Purpose: To promote the safe use of intravenous magnesium sulfate in the pregnant or postpartum woman.

Magnesium sulfate is a smooth muscle relaxant.

Indications:

- Prevention and treatment of seizures in women with preeclampsia or eclampsia.
- Fetal neuroprotection in patients that are less than 32 weeks gestation and delivery is anticipated within 12 hours.
- Short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal corticosteroids (betamethasone) in pregnant women who are at risk of preterm delivery within 7 days.

Contraindications: Hypocalcemia, Myasthenia gravis, Renal failure

Equipment Needed:

1. Two infusion pumps: One pump for bolus and maintenance infusions and one for primary infusion (Lactated Ringers)
2. Magnesium sulfate bolus dose (loading dose) as ordered (4g or 6g). If a 6g loading dose is ordered, obtain both a 2g and 4g pre-mixed bag from the Pyxis.
3. Magnesium sulfate maintenance infusion (20g/500mL)

Safety Measures:

1. An infusion pump must be used for both the bolus dose and maintenance infusion and infused according to the ordered rate.
2. The bolus dose must be from a separate IV bag which is located in the Pyxis. The bolus dose and maintenance infusion are premixed and must be checked by two nurses prior to administration.
3. IV tubing must be labeled with GREEN magnesium sulfate labels and traced from the patient to the bag with each hand-off or shift change.

Possible Side Effects:

- Maternal flushing
- Lethargy
- Headache
- Muscle weakness
- Malaise/"flu-like" symptoms
- Nausea

Baseline Assessment:

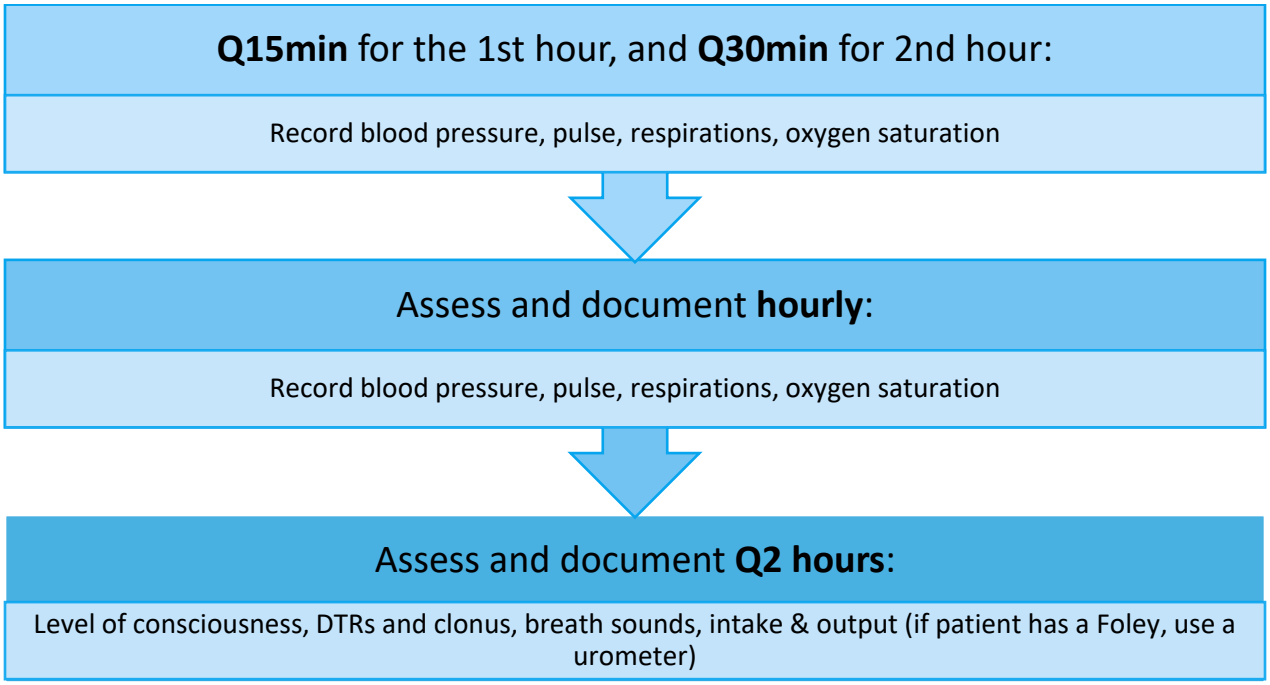
Prior to initiating magnesium sulfate, perform and document a baseline blood pressure, respiratory rate, deep tendon reflexes (DTR's), presence/absence of clonus, level of consciousness, pulse oximeter reading, breath sounds, intake & output, and fetal heart rate.

Adapted from PolicyStat ID 10949261, Magnesium Sulfate Administration. See Policy for references.

Setup:

1. Establish primary IV line (Lactated Ringers) with infusion pump prior to initiating magnesium sulfate.
2. Connect the magnesium sulfate bolus IV tubing to the primary IV at the lowest port on the primary IV tubing. Label your magnesium IV tubing with the GREEN magnesium sulfate stickers.
3. Program the infusion pump for a 4g or 6g bolus, according to the provider's orders. A second RN must verify the correct medication, dose, rate, pump settings and tubing connections prior to administration.
4. RN must remain at bedside during the administration of the bolus dose to monitor for side effects, adverse reactions, and continuously assess fetal status.
5. At the completion of the bolus dose, connect the maintenance magnesium sulfate solution to the same tubing at the lowest port on the primary IV tubing. Program the pump as ordered (typically 2g/hr or 50mL/hr). A second RN must verify the maintenance dose and rate, as well.

Monitoring:



Lab testing:

1. The RN must order per protocol a serum magnesium level 2 hours after the bolus has completed.
2. Serum magnesium level must be ordered q6 hours thereafter. Make sure the order is "Timed/Dated" for q6 hrs after the first serum magnesium level and NOT ordered as "Routine."

When to Notify the Provider:

1. Magnesium sulfate level <4.8mg/dL or >8.4mg/dL
2. Significant change in BP or maternal heart rate
3. Absent deep tendon reflexes

Adapted from PolicyStat ID 10949261, Magnesium Sulfate Administration. See Policy for references.

4. Urine output less than 30mL/hr over 4 hours
5. Respirations less than 12 br/min
6. Shortness of breath or breath sounds suggestive of pulmonary edema
7. Oxygen saturation less than 95%
8. Changes in level of consciousness
9. Visual disturbances

Signs of Magnesium Toxicity:

Loss of DTR's	Decreased level of consiousness	Progressive muscle weakness	Severe respiratory depression	Respiratory or cardiac arrest

If any of these signs are present:

1. Discontinue magnesium sulfate immediately
2. Notify physician immediately and call to bedside
3. Draw a stat serum magnesium level
4. Obtain calcium gluconate for immediate administration (antidote for mag sulfate toxicity)
    - Calcium gluconate 1 gram (10 mL) IVPush over 3 minutes
    - Indication: reversal of respiratory depression. Keep in locked drawer in patient room.

After discontinuation of magnesium sulfate, record blood pressure, pulse, respirations, and oxygen saturation every 4 hours for 24 hours. After 24 hours, record BP, pulse and respirations q8 hours until discharge.

Monitor postpartum patients for signs of uterine atony, such as boggy uterus, elevated fundal height or excessive bleeding.

PRENATAL and INTRAPARTUM INSULIN INFUSION PROTOCOL

TYPE 1 DIABETES MELLITUS

(Not for use in diabetic ketoacidosis)

Blood Glucose (BG) Goal: 90-110 mg/dL

Table #1 Insulin Infusion Initiation with Insulin Bolus

BG* (mg/dL)	Bolus insulin‡ (units)	Initial Insulin Drip (units/hour)	Initial Fluid Type	Initial Fluid Rate (mL/hr)
100 – 140	0	1	D5 LR	125
141 – 180	2	2	D5 LR	125
181 – 220	3	2.5	D5 LR	125
221 – 260	4	3	LR	125
261 – 300	6	3.5	LR	125
> 300	8	4.5	LR	125

*Re-check blood glucose every hour

‡No IV insulin boluses in renal failure (defined as race specific eGFR < 30mL/min)

Table #2 Standard Insulin Infusion Titration (All boluses from the bag)

BG mg/dL	Standard Insulin Infusion (units per hour) - Regular insulin at concentration of 1 unit/mL	Fluid Type
<70	Hold infusion and treat hypoglycemia. If patient can take PO, give 180-240 mLs of juice. Otherwise, give 25 ml of 50% dextrose IV bolus. Re-check, and if necessary, retreat BG every 15 minutes until BG >70 mg/dL, then hourly. When BG≥90mg/dL, restart infusion at 50% of last rate. **Notify provider.**	D5 LR
70 - 89	**Decrease infusion by 50% of last rate.** Re-check BG in 1 hour.	D5 LR
90–110 Target 100 mg/dL	**NO CHANGE** **UNLESS BG REDUCED BY > 20 MG/DL**, then **decrease rate by 50%.** Re-check BG every hour.	D5 LR
111 – 140	**Increase** by **0.5** unit/hour **unless BG reduced by >50 mg/dl**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	D5 LR
141 – 170	**Increase** by **1** unit/hour **unless BG reduced by >50 mg/dl**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	D5 LR
171 – 200	**Increase** by **1.5** units/hour **unless BG reduced by >50 mg/dl**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	D5 LR
201 – 240	**Increase** by **2** units/hour **unless BG reduced by >50 mg/dl**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	LR
241 - 280	**Increase** infusion by **2.5** units/hour **unless BG reduced by >50 mg/dl**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	LR
281 - 320	**Bolus 4 units IV Push**; **increase** infusion by **3** units per hour. Re-check BG in 1 hour. **Notify provider**.	LR
> 320	**Bolus 5 units IV Push**; **increase** infusion by **4** units per hour. Re-check BG in 1 hour. **Notify provider**.	LR

PRENATAL and INTRAPARTUM INSULIN INFUSION PROTOCOL
TYPE 2 and GESTATIONAL DIABETES MELLITUS and STEROID INDUCED HYPERGLYCEMIA
(Not for use in diabetic ketoacidosis)

Blood Glucose (BG) Goal: 90-110 mg/dL

Table #1 Insulin Infusion Initiation with Insulin Bolus

BG* (mg/dL)	Bolus insulin‡ (units)	Initial Insulin Drip (units/hour)	Initial Fluid Type	Initial Fluid Rate (mL/hr)
100 – 140	0	1	D5 LR	125
141 – 180	2	2	D5 LR	125
181 – 220	3	2.5	D5 LR	125
221 – 260	4	3	LR	125
261 – 300	6	3.5	LR	125
> 300	8	4.5	LR	125

*Re-check blood glucose every hour
‡No IV insulin boluses in renal failure (defined as race specific eGFR < 30mL/min)

Table #2 Standard Insulin Infusion Titration (All boluses from the bag)

BG mg/dL	Standard Insulin Infusion (units per hour) - Regular insulin at concentration of 1 unit/mL	Fluid Type
<70	Hold infusion and treat hypoglycemia. If patient can take PO, give 180-240 mL of juice. Otherwise, give 25 ml of 50% dextrose IV bolus. Re-check, and if necessary, retreat BG every 15 minutes until BG >70 mg/dL, then hourly. When BG≥90mg/dL, restart infusion at 50% of last rate. **Notify provider.**	D5 LR
70 - 79	**Hold infusion.** Recheck BG every hour x 2, every 2 hours. When BG ≥90mg/dL restart infusion at 50% of last rate.	D5 LR
80 – 89	**Decrease infusion by 50% of last rate.** Re-check BG in 1 hour.	D5 LR
90–110 Target 100 mg/dL	**NO CHANGE** **UNLESS BG REDUCED BY > 20 MG/DL**, then **decrease rate by 50%.** Re-check BG every hour. When BG between 90 – 110 x 3 consecutive hours, then reduce BG checks to every 2 hours.	D5 LR
111 – 140	**Increase** by **0.5** unit/hour **unless BG reduced by >50 mg/dL**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	D5 LR
141 – 170	**Increase** by **1** unit/hour **unless BG reduced by >50 mg/dL**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	D5 LR
171 – 200	**Increase** by **1.5** units/hour **unless BG reduced by >50 mg/dL**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	D5 LR
201 – 240	**Increase** by **2** units/hour **unless BG reduced by >50 mg/dL**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	LR
241 - 280	**Increase** infusion by **2.5** units/hour **unless BG reduced by >50 mg/dL**, then decrease rate by 1 unit/hour. Re-check BG in 1 hour.	LR
281 - 320	**Bolus 4** units IV Push; **increase** infusion by **3** units per hour. Re-check BG in 1 hour. **Notify provider**.	LR
> 320	**Bolus 5** units IV Push; **increase** infusion by **4** units per hour. Re-check BG in 1 hour. **Notify provider**.	LR

Table #3 Additional Subcutaneous Insulin Lispro Meal and Snack Coverage for Patients not in Active Labor (in addition to insulin infusion if ordered)

Inject insulin lispro <15 mins before or just after patient finishes eating meal

Drip Rate (units/hour)	Ate >50% meal (units)	Ate <50% meal (units)
0 – 0.5	2	0
0.6 – 2	4	2
2.1 – 4	6	3
4.1 – 6	8	4
6.1 – 8	10	5
>8	12	6

Maternal Early Warning Signs (MEWS) Guidelines

Purpose:

To reduce morbidity by implementing an early warning assessment and notification protocol.

Guidelines:

Nurses will identify when a patient's assessment data indicate that a bedside huddle by an OB physician is required or when notification of an OB provider (including Family Medicine Physicians and Certified Nurse Midwives (CNM)) is required.

When a **bedside huddle** is required:

Notify the OB provider, give an SBAR report and request a bedside huddle; if OB provider is a CNM or Family Medicine Physician, also notify the OB backup physician. If the attending OB physician is immediately available, he/she will provide bedside evaluation of the patient within 15 minutes. The laborist will be notified to provide bedside evaluation if the attending physician is not immediately available. Document notification in the electric medical record (EMR).

Repeat assessment of vital signs that meet MEWS criteria will be performed with OB physician at bedside.

Procedure:

A. Perform all assessments in the context of best practice (e.g., B/P measurement: Patients should be seated comfortably with her back supported, upper arm bared, and free of constrictive clothing. The legs should not be crossed. The arm should be supported at the level of the heart, and the cuff should be the correct size. Neither the woman nor nurse should talk during the measurement. Nurses should be alert to variables that can affect blood pressure such as recent exposure to nicotine, or pain during a contraction. Elevated B/P can be repeated immediately in the opposite arm.).

Maternal Early Warning Signs (MEWS) Criteria for Bedside Huddle

Maternal agitation, confusion, or unresponsiveness	
Woman with hypertension reporting a non-remitting headache or shortness of breath	
Heart rate; beats per minute	< 50 or > 120* *exclude during pushing*
Respiratory rate; breaths per minute	< 10 or > 30
Oxygen saturation; %, room air, sea level	< 95
Systolic BP (SBP); mmHg	< 90 **Not applicable when ≤ 30 min post epidural; treat per OB Labor Epidural Analgesia orders.*

B. Notify the OB provider(s) and request a bedside huddle if the patient's assessment data meets MEWS criteria for bedside huddle (see table above). Confirm vital sign assessments within 15 min **before** notifying the OB provider(s); maternal agitation, confusion, unresponsiveness and woman with hypertension reporting non-remitting headache or shortness of breath require **immediate** notification of the OB physician.

Maternal Early Warning Signs (MEWS) Criteria for Provider Notification	
Systolic BP (SBP); mmHg	≥ 160
Diastolic BP (DBP); mmHg	≥ 110
Oliguria; ml/hr for 2 hr	< 35

C. For SBP ≥160 or DBP ≥110, BP measurement should be repeated after 15 minutes. Have patient rest quietly until BP reevaluated. If SBP ≥160 or DBP ≥110 persists, notify the OB provider for Hypertensive Crisis orders.
    a. If all ordered antihypertensive doses (Labetalol 3 steps, Hydralazine 2 steps, or Nifedipine 3 steps) are given and BP remains ≥ 160 SBP or ≥ 110 DBP, notify OB provider(s) and request a bedside huddle.
D. For oliguria (<35ml/hr for 2 hours), notify the OB provider for additional orders.
    a. If no response to ordered treatment after 2 hours, notify OB provider(s) and request a bedside huddle.
E. Notify the Maternity Patient Care Coordinator (PCC) when a patient's assessment data meets MEWS criteria. The PCC will assist with allocation of resources as needed; notification of the OB physician; notification of additional staff such as anesthesia personnel, neonatal resuscitation team, or rapid response team; and determination of level of care.
F. Participate in the multi-disciplinary team (e.g., primary nurse, OB physician, Family Medicine Physician, CNM, PCC, and anesthesia personnel) bedside huddle after differential diagnosis is made by the OB physician. The OB physician will discuss the plan of care such as medications, laboratory tests, frequency of subsequent assessments, criteria for notification, planned interval for re-evaluation, blood and other blood products, and transfer to a high level of care if needed. The OB physician will document the plan in the EMR.
G. Anticipate and prepare for potential orders (e.g., continuous pulse oximetry, indwelling urinary catheter, oxygen by tight facemask, hemorrhage cart to room, or intravenous [IV] supplies if IV access is not present or additional IV access may be needed).
    a. Depending on the clinical evaluation, patient laboratory and diagnostic studies the OB physician may consider include:
        - Pulse oximeter
        - CBC
        - Type and screen or type and cross match if bleeding
        - CMP
        - Magnesium level
        - EKG, particularly in the presence of tachycardia, bradycardia, or chest pain
        - CT angiogram or perfusion scan in patients with acute chest pain
        - CXR if the patient has SOB, particularly if pre-eclamptic
        - Echocardiogram
        - Urine for protein: creatinine ratio
H. If the primary RN and the PCC question any aspect of the patient's care and the issue is not resolved with the attending physician, another appropriate physician (Laborist, Department Chair, Chief Medical Officer, or MFM) and a nurse in the Nursing Chain of Command (Nurse Manager, Nurse Director, or Nursing Supervisor) will be notified according to the Chain of Command: Paging Response Time and Resolving Questions of Care or Safety Policy.

References:

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Approved by OBGYN Department on 8/16/2021

Bakri®

POSTPARTUM BALLOON WITH RAPID INSTILLATION COMPONENTS

Tamponade technique for postpartum hemorrhage

Refer to the Instructions for Use for complete information on product usage and a complete list of precautions, warnings, and contraindications.

1 Confirm before placement.

Confirm that these statements are true:

- The uterus is free of placental fragments.
- The genital tract has no trauma or lacerations.
- The source of the bleeding is not arterial.
- Patient does not present with any contraindications for use of this device.

2 Determine the uterine cavity's volume.

- For transvaginal placement, determine uterine volume by direct examination or ultrasound examination. For transabdominal placement, determine uterine volume by direct examination.
- Place the predetermined volume of sterile fluid in a separate container.
- If you will use the rapid instillation components, note the predetermined volume for rapid instillation.
- The maximum balloon volume is 500 mL.

3 Place the balloon.

Transvaginal placement, postvaginal delivery (Fig. 1)

- Insert the balloon portion of the catheter into the uterus, making certain that the entire balloon is inserted past the cervical canal and internal ostium.

Transabdominal placement, postcesarean delivery (Fig. 2)

- Pass the uninflated balloon, inflation port first, through the cesarean incision and into the uterus and cervix. Remove the stopcock to aid in placement and reattach prior to filling the balloon.
- Have an assistant pull the balloon shaft through the vaginal canal until the base of the balloon contacts the internal cervical ostium.
- Close the incision, being careful not to puncture the uninflated balloon while suturing.

4 Fill the balloon with sterile liquid.

- **Never inflate with air, carbon dioxide, or any other gas.**
- **Do not fill with more than 500 mL. Overinflation may result in the balloon being displaced into the vagina.**
- **Ensure that all product components are intact and that the hysterotomy is securely sutured prior to balloon inflation.**

- Place a Foley catheter in the patient's bladder to collect urine and monitor urine output.
- Use the enclosed syringe or rapid instillation components to fill the balloon to the predetermined volume through the stopcock.
- If desired, apply traction to the balloon's shaft. In order to maintain tension, secure the balloon shaft to the patient's leg or attach to a weight, not to exceed 500 grams. Note: To prevent displacement of the balloon into the vagina, counterpressure can be applied by packing the vaginal canal with iodine- or antibiotic-soaked gauze.
- **Use ultrasound to confirm that the balloon is properly placed.**

5 Flush the lumen and monitor hemostasis.

- Connect the drainage port to a fluid collection bag to monitor hemostasis.
- The balloon drainage port and tubing may be flushed clear of clots with sterile isotonic saline to facilitate monitoring.
- Monitor the patient for signs of increased bleeding and uterine cramping.

6 Remove the balloon.

- **Maximum indwelling time: 24 hours.**
- **The attending clinician determines when the balloon is removed after bleeding is controlled and the patient is stable.**

- Release the tension on the shaft and remove any vaginal packing.
- Aspirate balloon contents until the balloon is completely empty. The fluid may be removed incrementally to allow for periodic observation of the patient. In an emergency, the shaft may be cut to rapidly deflate the balloon.
- Gently retract the balloon and discard it.
- Monitor the patient for signs of bleeding.

COOK® MEDICAL

Illustrations for placing the Bakri balloon (step 3)

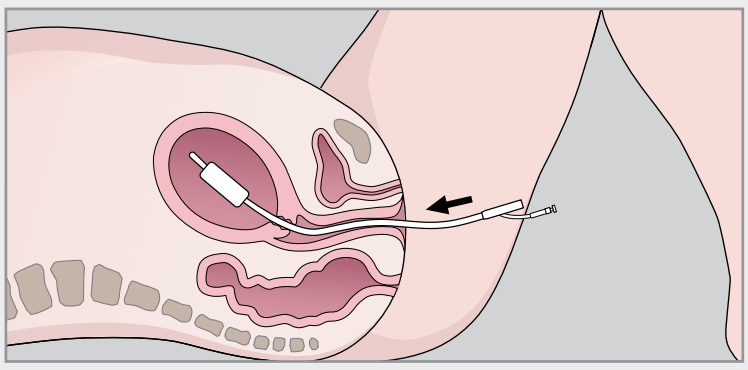


Fig. 1: Transvaginal placement, postvaginal delivery

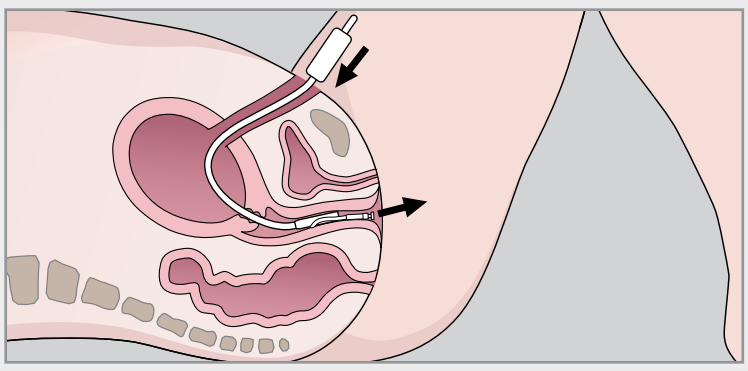


Fig. 2: Transabdominal placement, postcesarean delivery

Proper placement

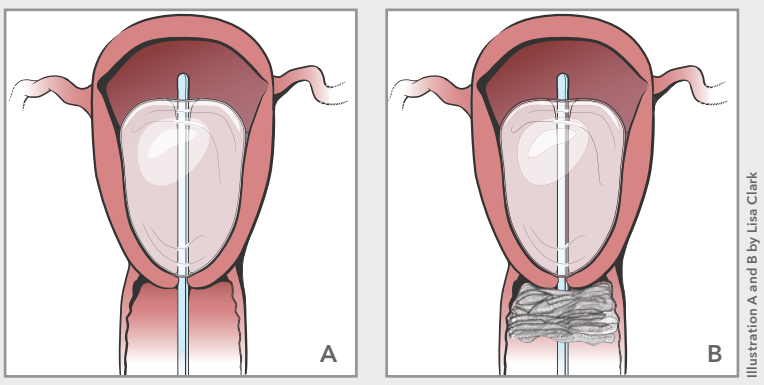


Illustration A and B by Lisa Clark

- Make sure that the entire balloon is inserted past the cervical canal and internal ostium.
- After the balloon is inflated to the predetermined volume, use ultrasound to confirm that it is properly placed.
- If necessary, pack the vagina with iodine- or antibiotic-soaked gauze.
- Do not extend the packing into the uterus.

CONTRAINDICATIONS

- Arterial bleeding requiring surgical exploration or angiographic embolization
- Cases indicating hysterectomy
- Pregnancy
- Cervical cancer
- Purulent infections in the vagina, cervix, or uterus
- Untreated uterine anomaly
- Disseminated intravascular coagulation
- A surgical site that would prohibit the device from effectively controlling bleeding

WARNINGS

- This device is intended as a temporary means of establishing hemostasis in cases indicating conservative management of postpartum uterine bleeding.
- The Bakri Postpartum Balloon is indicated for use in the event of primary postpartum hemorrhage within 24 hours of delivery.
- The device should not be left indwelling for more than 24 hours.
- The balloon should be inflated with a sterile liquid such as sterile water, sterile saline, or lactated Ringer's solution. The balloon should never be inflated with air, carbon dioxide, or any other gas.
- The maximum inflation is 500 mL. Do not overinflate the balloon. Overinflation of the balloon may result in the balloon being displaced into the vagina.
- Patients in whom this device is being used should be closely monitored for signs of worsening bleeding and/or disseminated intravascular coagulation (DIC). In such cases, emergency intervention per hospital protocol should be followed.
- There are no clinical data to support the use of this device in the presence of DIC.
- Patient monitoring is an integral part of managing postpartum hemorrhage. Signs of a deteriorating or unimproving condition should lead to a more aggressive treatment and management of the patient's uterine bleeding.
- The patient's urine output should be monitored while the Bakri Postpartum Balloon is in use.

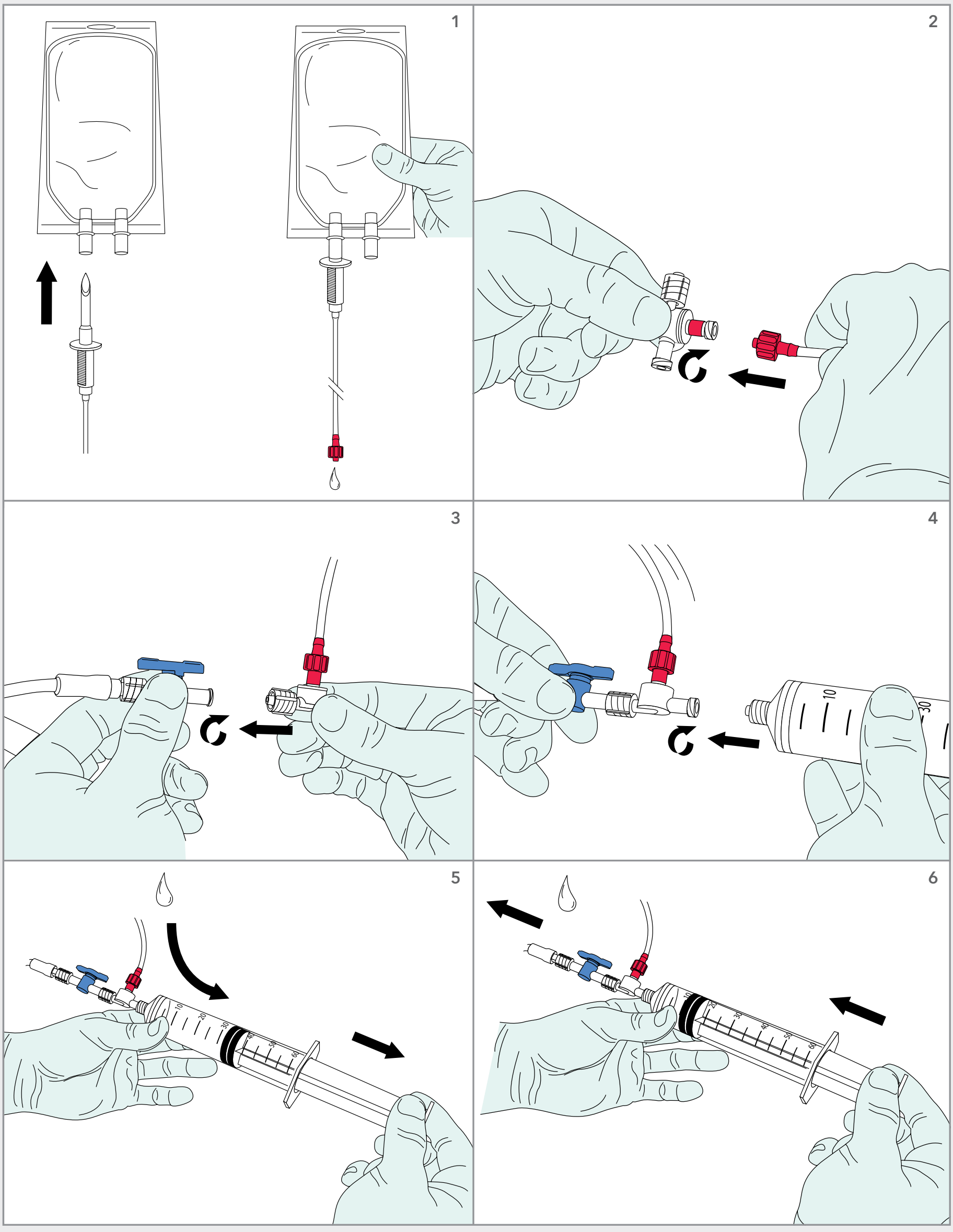
PRECAUTIONS

- Avoid excessive force when inserting the balloon into the uterus.
- This product is intended for use by physicians trained and experienced in obstetrics and gynecological techniques.

Bakri®

POSTPARTUM BALLOON WITH RAPID INSTILLATION COMPONENTS

How to use the rapid instillation components



Cell Saver in OB

- **Scheduling**: If possible, provide notice at least a day before a case is scheduled. To board a case call **1-800-521-9757**. They are also on call for Munson 24/7 for emergencies and can be here in 30 minutes or less most days (contracted time is 1 hour). **Munson's account # is 1464**
- **Procedure**:
    - Prior to the procedure, attending surgeon needs to order a bag of heparinized saline for cell saver as part of his or her requested drugs: It's in the pharmacy system and is 30,000 units to a liter. Nurse can call pharmacy with a VO if need help with ordering it.
    - Once they are in the room, they will bring the machine and all necessary disposables. If the case is boarded in advance, Cell Saver can be included on the resource map. They use a 3L bag of normal saline as a wash, and will bring some with them.
    - **Set up:** machine is generally set up near the head by anesthesia, but they can work with teams to find a place that is generally amenable to everyone working. They only need a power outlet, access to the wall suction, (or a Neptune) and to be close enough for our suction line to reach to/from the field.
    - Before the procedure begins, usually while setting up, they hand off an aspiration line to the **scrub tech** who will keep it on the field until the **surgeon** is ready to begin, at which point they will hand back one end to attach to the cardiotomy reservoir and hep-saline. From this point forward, the line can act as primary suction for the case and everything should proceed as normal.
- **Extra contraindications for Cell Salvage in OB**:
    - Clotting agents
    - Cell-bound antibiotics
    - **Problematic for a surgeon/CST to suction amniotic fluid** to a cell saver reservoir: Theoretically it can cause an amniotic fluid embolism when introducing a product back to the patient, as it does not wash out cleanly.
    - **Presence of meconium is also an issue**, and we stress that this <u>not be suctioned</u> to our machine as well. **Surgeon to irrigate if needed to clear our ammonitic fluid or meconium.** They suggest setting up a backup suction for waste, and utilizing the cell saver suction solely for blood loss. They will bring a leukocyte reduction filter to assist in ensuring that any returned product be as safe as possible in these instances.
    - **Urine** can be a contraindication as it has the potential for bacteremia if a UTI is present, (in which case we'd look to employ one of those leukocyte reduction filters) and procedures in close proximity to, or directly regarding mucous membrane procedures can pose a risk as they sometimes employ the use of vasoconstrictors which do not wash out cleanly and can cause severe hypertension upon readministration, as well as the more simple risk of bacteremia due to the normal resident bacteria present. In this case, they will

discuss the risk/benefit with the attending surgeon and let them make the final call.

- **After the case is finished**, they break down their own kit and clean up their stuff as need be. They usually dispose of all disposables in the red biohazard bags, and have a waste bag that will need to be drained in a waste hopper as well.

Updated 4/20/2023

Procedure: Transfer with an air-assisted transfer device

Checklist: Transfer with an air-assisted transfer 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

Transfer with an air-assisted transfer device

Objective: To transfer a patient using an air-assisted transfer device according to the standard of care.

Checklist Step	Comments
Y- Meets; N- Does not meet; I- Not Applicable	
__ Gather and prepare the necessary equipment and supplies. __ Obtain the assistance of at least two coworkers. __ 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. __ Make sure that the wheels of the bed are locked. __ Raise the bed to waist level before providing care. __ Perform hand hygiene. __ Put on gloves and, as needed, other personal protective equipment.	
Placing the mattress	

__ Have your coworkers stand on the opposite side of the bed or stretcher where the patient is positioned.

__ Roll the mattress lengthwise toward the center from one side.

__ Roll the patient onto the side toward your coworkers.

__ Place the rolled edge of the mattress against the patient with the air entry end of the mattress at the foot end.

__ Roll the patient back toward you.

__ Have your coworkers unroll the mattress.

__ Center the patient on the mattress.

Completing the procedure

__ If necessary, place a fluid-impermeable pad between the patient and the mattress.

__ Attach the safety straps. Make sure that the straps are in loose contact with the patient.

__ Plug in the transfer device air supply unit and make sure that the unit is turned off.

__ Attach the air hose from the transfer device air supply unit to the mattress.

__ Position the transfer surfaces as close together as possible.

__ Adjust the height of the transfer surfaces so that they're even or the receiving surface is slightly lower.

__ Make sure that the wheels on the transfer equipment are locked.

__ Raise the side rail on the far side of the receiving surface.

__ Confirm that nothing will obstruct the path of the mattress and the air hose during the transfer.

__ Verify that all tubing, IV lines, and drains are free to travel with the patient.

__ Make sure that your coworkers are positioned on the opposite side of the patient receiving surface.

__ Inform the patient that you're about to inflate the mattress.

__ Turn on the air supply device and monitor the patient while the mattress inflates.

__ When the mattress is inflated, grasp the handles on the mattress and pull the patient gently toward the receiving surface using a diagonal transfer motion until the patient is centered on the receiving surface.

__ Turn off the transfer device air supply unit and unplug the unit.

__ Return the bed to the lowest position.

__ Remove and discard your gloves and, if worn, other personal protective equipment.

__ Perform hand hygiene.

__ Document the procedure.

EMTALA

COMPLIANCE

FinThrive

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In this course, we will:

- Explain the Emergency Medical Treatment and Labor Act (EMTALA)
- Review the EMTALA process
- Discuss EMTALA violations and penalties
- Understand the importance of EMTALA compliance

FinThrive

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Introduction

EMTALA violation settlements:

- Failure to provide medical screening examinations
- Failure to stabilize
- Inappropriate transfers
- Failure to transfer
- Failure to accept appropriate transfers

In 1987 approximately 31 million Americans did not have health insurance, and emergency departments across the country were refusing to see, or immediately transferring, patients who were unable to pay—a practice known as "patient dumping."

In response, Congress enacted the Emergency Medical Treatment and Labor Act (aka Anti-Dumping Act) to ensure **all patients receive the same emergency medical care, without discrimination and regardless of their ability to pay.**

Despite the Affordable Care Act, EMTALA provisions are still needed today. The National Center for Health Statistics reports that 31.1 million individuals of all ages did not have health insurance in 2021.

In this course, we will review key elements of the EMTALA statute and process.

Let's get started!

What Is EMTALA?

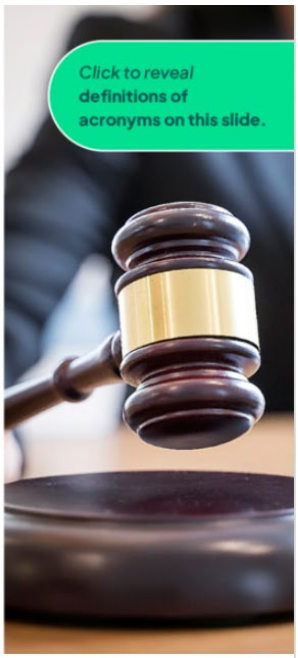
COMPLIANCE

What Is EMTALA?

History

1986	2003	2007
Congress enacts EMTALA as part of COBRA	The revised Final Rule takes effect and CMS establishes the EMTALA TAG taskforce to review regulations, offer application assistance, and solicit input from providers, investigators, state survey agencies, QIOs, and the public	TAG charter expires and some recommendations are implemented while others are left under consideration

Numerous court cases have also changed how EMTALA is applied, and CMS continues to consider revisions and updates to the statute.



What Is EMTALA?

An Obligation

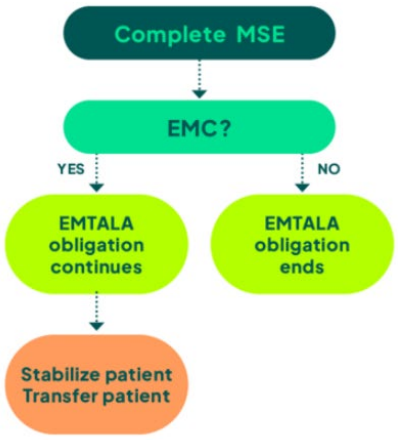
The EMTALA obligation is triggered when an individual requests emergency medical care at a **DED**, or anywhere on the hospital campus, including cancer, children's, long-term care, psychiatric, and rehabilitation hospitals.

Regardless of diagnosis, ability to pay, socioeconomic status, race, religion, disability, or national origin, the hospital is required to provide:

- An appropriate MSE by a physician or QMP
- Stabilizing treatment or an appropriate transfer if an EMC exists

EMTALA obligation ends when:

- A determination is made that no EMC exists.
- The condition ceases to be an EMC.
- The patient has been admitted to inpatient status.
- The patient has been appropriately transferred to another facility.



EMTALA Rule

The term "hospital property" means the main hospital campus (within 250 yards), the parking lot, sidewalks, driveways, and hospital departments, including buildings owned by the hospital. Off-campus facilities (i.e., provider offices) are not included.

Click to reveal **definitions of acronyms on this slide.**

Emergency Medical Condition

The term "emergency medical condition" refers to a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in::

- Placing the health or safety of the patient or unborn child in serious jeopardy
- Serious impairment to bodily functions
- Serious dysfunction of any bodily organ or part

Tip

Under EMTALA, if a minor can request an examination or treatment for an EMC, the hospital is required to determine whether an EMC exists and should not delay awaiting parental consent.

Dedicated Emergency Department

A dedicated emergency department is defined as meeting **one of the following criteria,** regardless of whether the location is on or off the main hospital campus.

DED		
Licensed by the state as an emergency department (ED), including critical access hospitals (CAHs)	Presented to the public as providing care for EMCs on an urgent basis	Provided at least one-third of services as EMC on an urgent basis in the previous calendar year

CLICK HERE TO VIEW A VIDEO ON THE EMTALA COMPLIANCE CHECKLIST.

EMTALA Tip

EMTALA obligation applies to hospital-owned/operated ambulance transports not under emergency medical service (EMS) direction or any ambulances on hospital property.

Q

What defines a DED?

a. Licensed by the state as an emergency room/department

b. Communicated to the public as a place that provides care for EMCs on an urgent basis

c. The preceding calendar year, it provides at least one-third of its visits for treatment of EMCs on an urgent basis

d. All the above

A

What defines a DED?

d. All the above

Rationale:

A dedicated emergency department must either be licensed by the state as an emergency room/department, be communicated to the public as a place that treats EMCs, or at least one-third of its visits provide treatment of EMCs or other urgent care.

EMTALA Process

COMPLIANCE

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EMTALA Process

Medical Screening Exam

An MSE is an ongoing process that begins with triage and continues until a physician or QMP has determined, with reasonable clinical confidence, the presence or absence of an EMC.

An MSE may require:

- Problem-focused medical history
- Comprehensive physical examination
- Checking vital signs at regular intervals
- Any necessary lab testing or radiological imaging

- Once a patient has presented to a DED, the hospital cannot tell the patient to go to the off-site location for the MSE.
- Unless the off-campus site is already a dedicated ED (DED) of the hospital, as defined under EMTALA regulations, EMTALA requirements do not apply.
- Triage alone is not an MSE.

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EMTALA MSE Requirements

- Medical record documentation must reflect continued monitoring according to the patient's needs until it is determined whether or not the patient has an EMC.
- Hospitals and critical access hospitals (CAH) with DEDs are required to conduct an MSE on all individuals who come to the ED, including those suspected of having an infectious disease (e.g., COVID-19). EDs are expected to screen and isolate such patients and contact appropriate health officials for further instruction.
- In some cases, the MSE must be thorough enough to rule out any physical cause. For example, for psychiatric patients or patients who appear intoxicated, an MSE must rule out causes such as trauma, disease, or medication reactions.
- Hospitals must display signs with the EMTALA provision within clear view.

Qualified Medical Personnel

MSEs must be performed by a physician or nonphysician QMP working in consultation with a physician.

Nonphysician QMPs performing MSEs must:

- Act in accordance with state and hospital bylaws
- Perform MSEs as described in their job description
- Be within their scope of practice

Physicians must be on-call to back up QMPs.

Examples of QMPs include:

- Physician assistant (PA)
- Nurse practitioner (NP)
- Certified nurse-midwife (CNM)
- Certified midwife (CM)

EMTALA Rule
Medical specialty consults who provided care for an EMC must also provide outpatient follow-up care for that condition regardless of the patient's ability to pay.

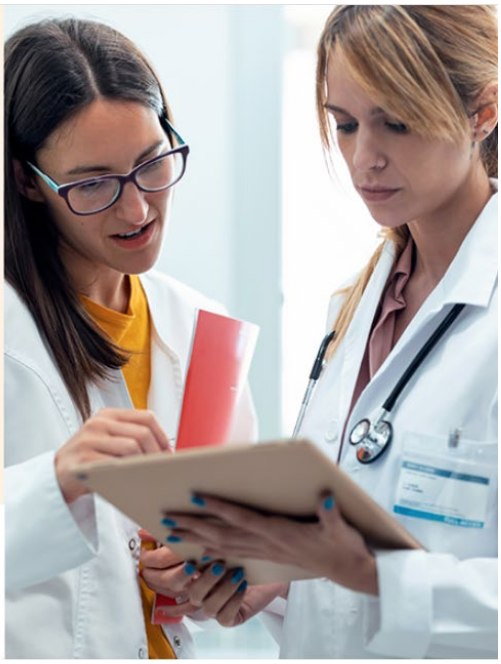
EMTALA Process

On-Call List

Hospitals must maintain an on-call list of medical staff physicians with privileges so that ED staff know which physicians, specialists, and subspecialists (e.g., neurologists), are available.

If an on-call physician fails to respond timely or come to the ED, both the physician and the hospital are in violation of EMTALA. The time the physician is notified and the response (or transfer) time should be documented in the medical record.

The hospital board of directors is accountable to ensure hospital policies meet EMTALA on-call responsibilities, and policies are typically set through staff bylaws or department procedures.



EMTALA Rule
If a hospital offers a specialty service to the public, that service should be available through on-call coverage in the emergency department.

EMTALA Process

EMC - Obstetrics (OB)

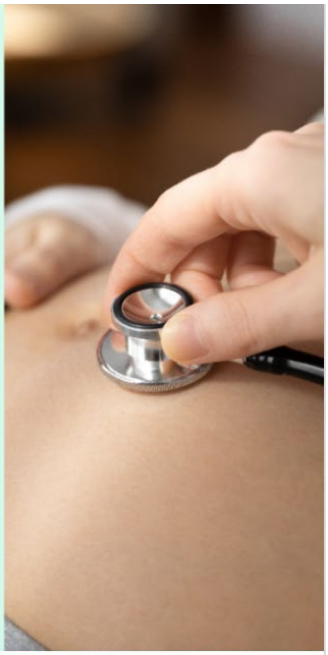
A pregnant patient having contractions has an EMC and is only deemed stable when:

- The infant and placenta are delivered.
- Contractions cease.
- A physician, certified nurse-midwife, or other QMP confirms the patient is in false labor.

Considerations for such transfers include:

- Is the patient likely to deliver before they can be transferred safely to another facility?
- Does transfer pose a threat to the health or safety of the patient or the unborn child?

CMS states a pregnant patient in labor cannot be transferred unless they or their legally allowed representative requests a transfer and a physician or QMP in consultation with a physician certifies the benefits to the patient and/or unborn child outweigh the risk of transfer.



EMTALA Process

Stabilizing Care

The EMTALA legal definition of "stabilized" means:

- No material deterioration of the patient's condition is likely from transfer of the individual from a facility or with respect to a pregnant patient who is in labor, to deliver, including the placenta.
- In other words, appropriate medical care and treatment is provided until the EMC is not at risk for deterioration or loss of life or limb.

EMTALA Rule
Of 230 EMTALA-related settlements between 2002 and 2018, psychiatric emergencies accounted for 19% of OIG civil monetary penalties. Failure to provide an MSE or stabilization were the most common citations. Settlement penalties associated with psychiatric emergencies are nearly triple compared to nonpsychiatric cases.

EMTALA Process

Appropriate Transfer

Under EMTALA, transfer must be medically necessary and the transferring hospital must make every reasonable effort to stabilize patients (including unborn infants) and minimize risk throughout transfer.

Transferring Hospital

- Sends all pertinent medical records to the receiving facility
- Provides QMP and/or transportation equipment, including medically appropriate life support measures during the transfer
- Follows other requirements as the Secretary of HHS may find necessary

Receiving Facility

- Has available space and qualified personnel to treat the patient
- Has agreed to accept the transfer and provide appropriate medical treatment
- Promptly reports (within 72 hours) to CMS or the state survey agency when it suspects it may have received an improperly transferred patient

The receiving hospital may refuse the transfer if they do not have the capacity to provide the necessary care and services.

Transfer of Unstable Patient

The EMTALA appropriate transfer rule states if an individual has an **unstable EMC,** the hospital may not transfer the individual unless:

Patient requests transfer

The hospital may transfer a patient with an unstable EMC if the individual/legal representative requests transfer in **writing,** having been informed of EMTALA rules and transfer risk.

EMC requires specialized care

Hospitals with specialized capabilities or facilities (e.g., burn units, trauma centers, neonatal intensive care units) are **required to accept** an appropriate transfer of a patient needing specialized care as space allows.

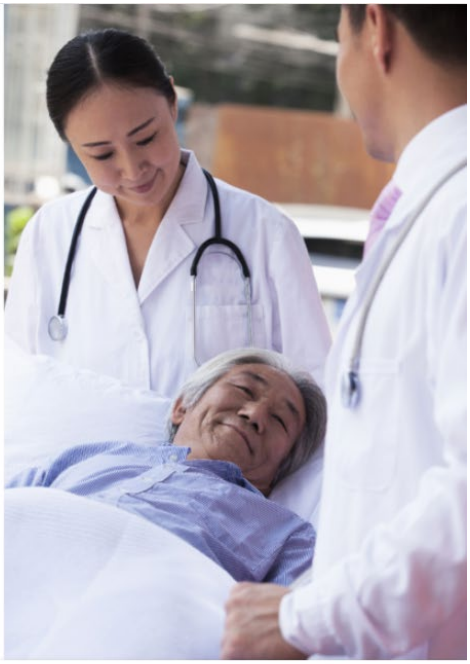
Physician legally certifies transfer

A physician (or QMP with physician cosignature) may certify transfer benefits outweigh risk.

Physician-Certified Transfer

- **Physician certifies transfer benefits outweigh risk.**
  A physician (i.e., a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the state in which they perform such function or activity) has **certified in writing** that, based upon the information available at the time of transfer, the medical benefits **outweigh the increased risk** to the individual, and in the case of labor, the unborn child, from effecting the transfer.

- **Physician cosigns QMP certification for transfer.**
  A QMP signs the certification form in consultation with a physician who is not physically present in the emergency department at the time the patient is transferred. The physician must cosign the certification form.



EMTALA Process

Refusal of Care or Transfer

An individual, or person acting on behalf of the individual, may refuse further medical exam, treatment, or transfer to another medical facility.

In such instances, under EMTALA, the hospital must:

- Inform the individual or their representative of the risks and benefits of the examination, treatment, or transfer
- Take all reasonable steps to secure **written informed consent** from the individual or representative refusing care

EMTALA Tip
Moving a patient between hospital departments (e.g., ED to radiology) or facilities that have the same Medicare provider number is usually not considered an EMTALA transfer. However, hospitals should have written protocols for movement, especially for nonpatients who suffer problems on hospital property.

Matching Exercise

Match the terms with the descriptions.

RESET SUBMIT

MSE	Exam to establish presence of an emergency medical condition
EMC	Condition with qualifying acute, severe symptoms
Triage	Does not fulfill medical screening exam requirement
QMP	Physician, physician assistant, nurse practitioner, etc.

EMTALA Enforcement

COMPLIANCE

Violation and Penalties

A single occurrence of noncompliance with the EMTALA requirements constitutes a violation and is sufficient for an adverse recommendation. CMS reviews all EMTALA complaints. If a complaint appears to be valid, CMS refers the case to the QIO to investigate.

If the EMTALA violation is proven:

1. CMS initiates the process to terminate the hospital's Medicare provider agreement.
2. To avoid termination, the hospital must submit a corrective action plan (e.g., staff education and training) to CMS within 23 days.
3. The hospital and its corrective action plan may be monitored for 90 days to ensure implementation of the policy and procedure changes necessary to comply with EMTALA.

There is a two-year statute of limitations for civil enforcement of any violation.

Penalties

If the OIG/QIO investigation determines an EMTALA violation has occurred, a fine may be imposed.

Fines are:

- Up to $25,000 per violation for hospitals with fewer than 100 beds.
- Up to $104,826 per violation for hospitals with 100 beds or more
- $50,000 per violation for individual physicians, including on-call physicians

These fines are NOT covered by malpractice insurance.

Hospitals may be sued for personal injury in civil court under a "private cause of action."

A receiving facility, having suffered financial loss as a result of another hospital's violation of EMTALA, can bring suit to recover damages.

In very rare instances, hospitals and physicians have been terminated from Medicare because of EMTALA violations.

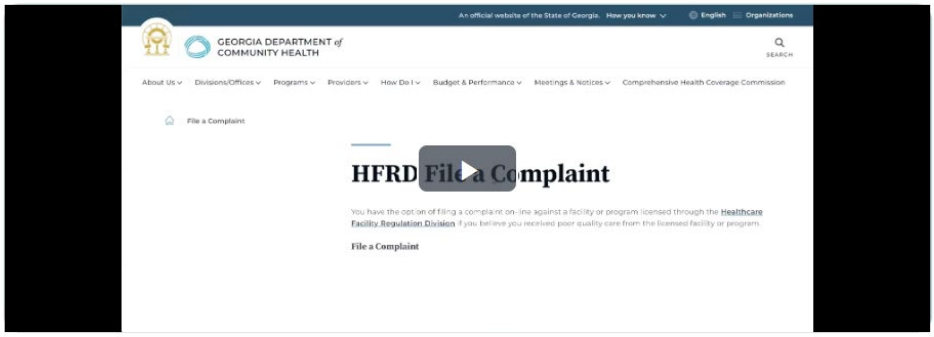
Common Violations

The Supreme Court has ruled no improper financial motive must be proven to find a hospital in violation of EMTALA.

Settlements have been for violations of:

- Failure to screen for an EMC
- Failure to stabilize a patient with an EMC
- Inappropriate transfers of a patient with an EMC
- Failure to transfer a patient with an EMC
- Failure to accept appropriate transfers

Penalties have been up to three times higher for psychiatric and labor- and OB-related citations than for those outside these parameters. (Psychiatric, labor and OB-related patient-dumping complaints account for 36% of all settlements prior to 2019).



Q & A Exercise

Which potential penalty is NOT associated with EMTALA violations?

1. Monetary fines

2. Imprisonment

3. Termination of Medicare provider agreement

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Q & A Exercise

Which potential penalty is NOT associated with EMTALA violations?

2. Imprisonment

FinThrive

EMTALA Exceptions

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Helipad Use

There are a few exceptions in which EMTALA is not triggered or waived.

Two of these involve helipad use:

EMTALA is not applied when a hospital's helipad is used by an ambulance service or other hospital to transfer an individual to a tertiary hospital, as long as an MSE was performed prior to transporting the individual to the helipad.

If as part of the EMS protocol a helicopter evacuation is activated, the hospital with the helipad does not have an EMTALA obligation if they are not the recipient hospital.

However, EMTALA obligation is triggered when:

- An MSE was not performed prior to transporting the patient to the helipad.
- The patient's condition deteriorates while on the helipad, and medical personnel accompanying the individual request another MSE.
- A request is made by EMS personnel, the patient, or a legally responsible person acting on behalf of the patient for examination or treatment of an EMC.

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EMTALA Exceptions

Major Disaster or Public Health Emergency Waiver

When the president has declared a major disaster or emergency **and** the secretary of HHS has declared a public health emergency, the secretary can determine that a waiver of sanctions is necessary for some hospitals in the emergency area or only hospitals in a portion of the emergency area.

EMTALA sanctions may be waived during the national emergency period for:

- An inappropriate transfer
- Direction or relocation of a patient to receive an MSE
  - At an alternative location pursuant to an appropriate state emergency preparedness plan
  - In the case of public health emergency involving a pandemic infectious disease, pursuant to a state pandemic preparedness plan

EMTALA Exceptions

Major Disaster or Public Health Emergency Waiver

To qualify for an EMTALA waiver, a hospital must implement its disaster protocol and notify CMS it has done so. Under a state of emergency, the waiver only waives EMTALA sanctions for 72 hours from the time the hospital implements its disaster protocol.

If a public health emergency involves a pandemic infectious disease, the wavier will be in effect until the termination of the declaration of the public health emergency.

EMTALA Tip
An EMTALA waiver does not apply to actions brought by individuals or hospitals who allege harm due to EMTALA violations, nor does it waive sanctions for individual physician or receiving hospital if they have capacity to treat the patient.

EMTALA Violation Examples

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EMTALA Violation Examples

An elderly man arrived at a university hospital emergency department by ambulance. He was complaining of severe jaw pain following a physical assault. His information was not entered into the ED log. He did not receive an appropriate MSE or stabilizing treatment and died in the waiting room.

The hospital agreed to pay a $50,000 fine.

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EMTALA Violation Examples

A middle-aged man presented to the emergency department. He appeared intoxicated and smelled of alcohol. The man was confused, had slurred speech, and was unsteady on his feet. He was belligerent and had vomit all over himself. He wouldn't give his name, and staff were unable to identify him. The nursing staff determined his vital signs were stable, but did not provide a medical screening exam. Instead they sent him to the homeless shelter in a taxi cab without bringing the case to the attention of the emergency room physician.

The man lost consciousness in the cab and was brought back to the hospital by paramedics, where it was determined he had a depressed skull fracture and a large subdural hematoma. While waiting for neurosurgical consultation and surgery to decompress the intracranial bleed, he went into cardiopulmonary arrest and died.

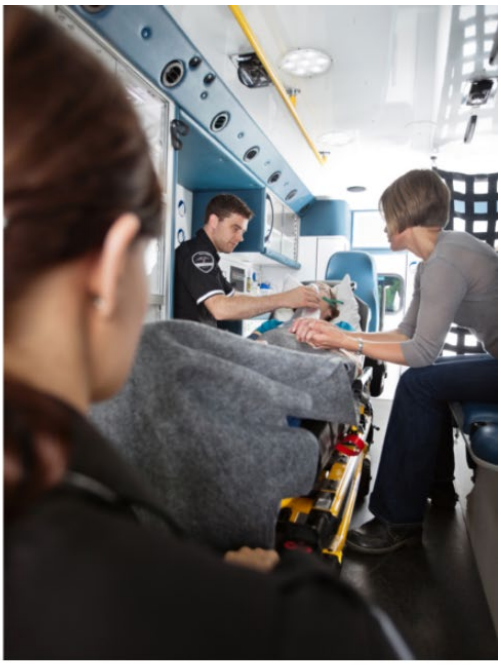
Lab results that became available after his death showed his blood alcohol concentration was 0.07%.

The hospital was found in violation of EMTALA and fined $50,000.

EMTALA Violation Examples

A possible sexual assault victim arrived by ambulance to the emergency department and was sent to another hospital without screening. There was no evidence in the medical record that the receiving hospital was notified or had agreed to accept the patient.

The transferring hospital was fined $25,000.



In Conclusion

COMPLIANCE

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In Conclusion

This course provided an overview of the EMTALA statute and its provisions. We discussed the process involved in MSEs to determine whether or not an EMC is present and appropriate transfers. The course also covered EMTALA violations and penalties.

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Course Completion

Congratulations

You have now finished the course. Please close the window and exit to complete the postcourse quiz.

We hope you enjoyed the course, and we welcome your feedback. Please enjoy the many other courses that we offer.

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MUNSON HEALTHCARE

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Fire Safety in Anesthetizing/ Procedural Areas

Jeannette Reynolds, MSN, BBA, RN, CPAN
Kathy Sahs, BS, CHSP
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Magdalena Stewart, DNP, CNS
Pat Wyers, BSN, RN, CNOR

July 2024

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Goal and Objectives

Goal:

To educate anesthetizing/procedural area staff about the recommended actions for fire prevention and fire response.

Objectives:

After completing this activity, the participant will be able to:

1. Identify the three components of the fire triangle.
2. Identify steps for fire prevention interventions.
3. Describe the staff's role in fire safety.
4. Discuss the steps to extinguish a fire.

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Procedural Fire Facts

According to The Joint Commission (TJC)

- 90-100 surgical fires occur yearly.
- 70% involve use of an electrosurgical device (ESU), also known as a Bovie.
- 15% are related to use of a light source.
- Other contributing factors include:
  - Inadequate orientation, understanding and/or communication of fire risk in procedural areas
  - Insufficient time-out procedures
  - Overconfidence, distraction, or loss of situational awareness
  - Equipment malfunction

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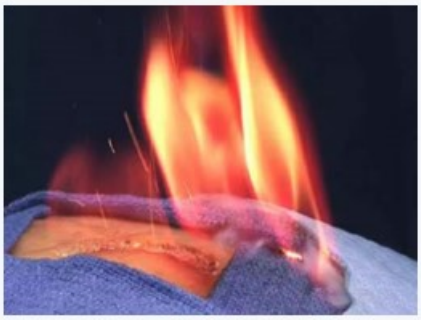
It Happens Here!

In the first quarter of 2022, an MHC OR had two fire/unintentional smoke events from equipment (laser and surgical drill). No patient or staff injury occurred.

Also in April 2022, a fire occurred when a patient applied petroleum jelly to their lips while on high-flow oxygen. The patient sustained first- and second-degree burns.



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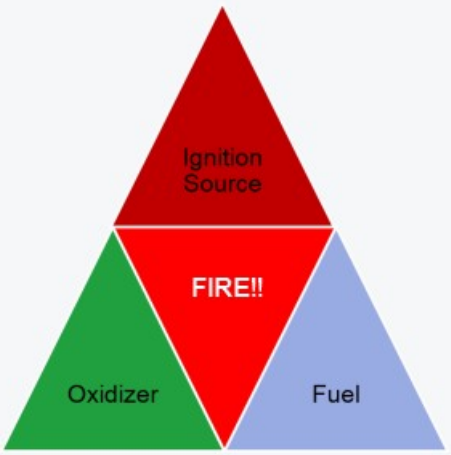
Fire Triangle

There are three elements necessary for a fire:

- Ignition source
- Fuel
- Oxidizer



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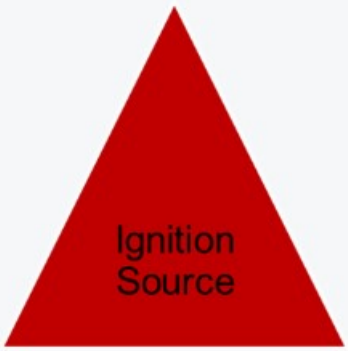
Common Ignition Sources

An ignition source is anything providing enough energy to start a fire:

- ESU/Bovie
- Argon beam coagulator
- Power tools (e.g., drills, burrs)
- Laser
- Fiber Optic light cords
- Defibrillator
- Electrical equipment



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Common Fuels

A fuel is anything that will burn:

- Alcohol-based skin antiseptic agents (preps)
- Drapes
- Gowns
- Endotracheal tubes
- Skin degreasers/tinctures/aerosols
- Body tissues and hair
- Intestinal gases
- Petroleum-based products

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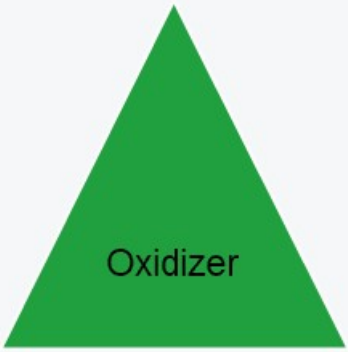
Common Oxidizers

An oxidizer is a gas which supports combustion:

- Oxygen
- Nitrous oxide



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Fire Risk Assessment

Fire risk assessment is a team effort.

As part of the preprocedural briefing process, the proecdural team should initiate a fire risk assessment to assess for the presence of the three elements of the fire triangle (AORN).

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Fire Risk Assessment *(cont.)*

Before each procedure, evaluate the following:

- Are there alcohol-based prep agents or other flammable solutions being used?
- Is the procedure being performed above the xiphoid process?
- Is there open oxygen or nitrous oxide being administered?
- Is an ESU, laser, fiber-optic light cord, defibrillator, drill, or saw being used?
- Are there other possible contributors?

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You must complete the activity.

Controlling Ignition Sources

Click each arrow:

Fiber-Optic Light Source:

- Place the light source in standby mode or turn it off when not in use.
- Inspect light cables before use. Remove from service if broken light bundles are visible.
- Place the scope and light source on a designated heat-resistant surface when not in use.

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Controlling Fuels

Surgical Skin Prep:

- Prevent pooling of skin prep solutions.
- Remove and discard prep-soaked materials, ensuring they are at least 3 feet from an ignition source.
- Skin prep dry time should follow manufacturer instructions for use to allow fumes to dissipate before draping.
- Allow chemicals to dry (e.g., alcohol, collodion, tinctures).
- Use water-soluble gel to cover facial hair.

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Controlling Oxidizers

Considerations for oxygen/flammable gas administration:

- Check the anesthesia circuits for possible leaks prior to the start of the procedure.
- Tent the surgical drapes to allow for free air flow.
- Keep the oxygen percentage as low as possible on non-intubated patients.
- Inform the surgeon when an open oxygen source is being used.
- Turn off oxygen or nitrous for 1 minute prior to use of an ignition source in head, neck, or upper chest procedures.

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Controlling Oxidizers *(cont.)*

Oropharynx Procedures

- Inflate the endotracheal tube cuff with tinted saline.
- Evacuate intended surgical smoke from small or enclosed spaces.
- Pack wet sponges around the back of the patient's throat.
- Document placement and removal of throat sponges.
- If oxygen is being used, suction the patient's oropharynx deeply before using the ignition source.

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See Unintended Smoke or Flames?

Pull the fire alarm!

All team members should be alerted to the presence of a fire or unintended smoke, no matter how small. Alerting other team members decreases the risk of injury to the patient and personnel.

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Fire Pull Station Locations and Responders

- It is the responsibility of each team member to be aware of the locations for fire pulls in his/her areas.
- When a fire pull is activated, the facility response team and the fire department will respond to the alarm.
- Assign a staff member to assist responders with donning disposable coveralls and lead them to the location of the fire.

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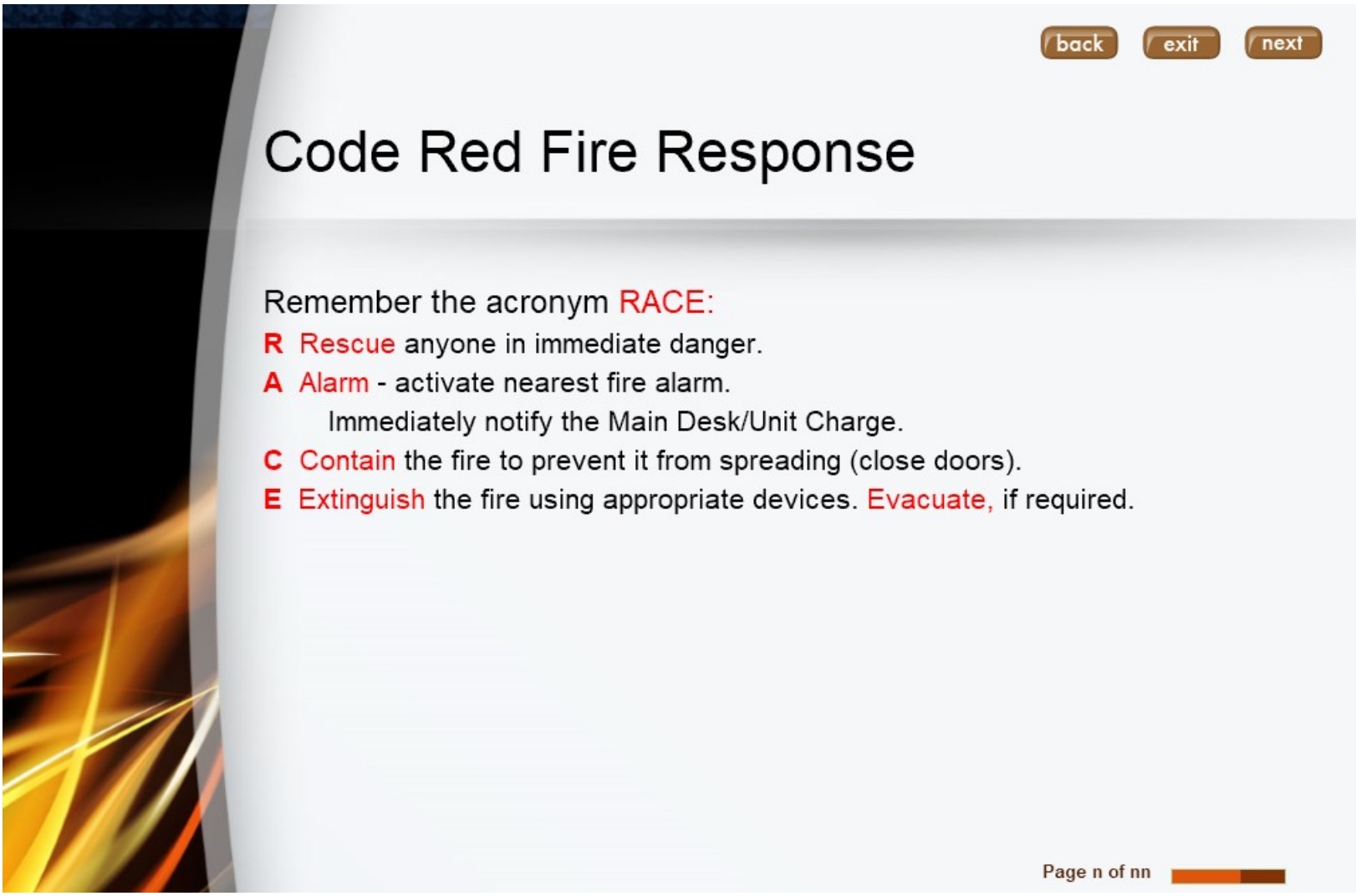
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Code Red Fire Response
Remember the acronym RACE:
R Rescue anyone in immediate danger.
A Alarm - activate nearest fire alarm.
Immediately notify the Main Desk/Unit Charge.
C Contain the fire to prevent it from spreading (close doors).
E Extinguish the fire using appropriate devices. Evacuate, if required.
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Medical Gas Shut-off

Be aware of the medical gas shut-off valve locations in your area. They are typically located outside the procedural suite and labeled.

In the event of a fire, the team should critically evaluate medical gas shut off for that specific area, then communicate medical gases have been emergently shut off in your location.

The decision to further shut off medical gases is made upon mutual consent among Nursing Administration, Respiratory Therapy, Facilities services, and anesthesia providers (if present).

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Extinguish a Fire Using Solution

- Douse the base of the fire with a nonflammable liquid (saline or water) if readily available.
- Impermeable drapes must be removed to effectively extinguish the fire.

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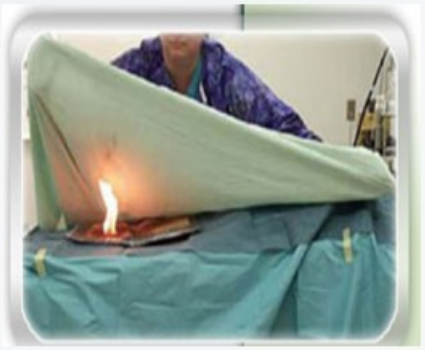
Extinguish a Fire by Smothering

- Keep your body away from fire.
- Hold towel between fire and patient's airway.
- Drop the end of towel closest to the head.
- Drop the other end of towel over the fire.
- Sweep hand over towel from head toward feet. DO NOT PAT the fire! This fans the flames and expands the fire.
- Lift the towel carefully to determine if flames are extinguished.
- Remove drapes or burned material from patient and inspect for injury.



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Extinguish a Fire Using a Fire Extinguisher

Remember the acronym PASS:

P Pull the pin.

A Aim nozzle at the base of the fire.

S Squeeze the handle to release the extinguishing agent.

S Sweep the stream over the base of the fire.

If possible, spray extinguisher away from the patient or other people.

http://www.dol.gov

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Fire Extinguisher Types

Most patient care areas have ABC multipurpose fire extinguishers available for use.

A. Fires involving wood, paper, cloth, and post plastics.
B. Fires involving flammable liquids or grease.
C. Fires involving energized electric equipment.

Some areas (OR, Sterile Processing, and MRI suites) may also have specialty extinguishers such as BC, CO_2, or water mist (non-magnetic) available for use.

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Airway Fire Management

Assist the anesthesia provider to:

1. Stop the medical gas flow.
2. Disconnect the breathing circuit.
3. Pour normal saline or water directly into the airway, if directed.
4. Remove the endotracheal tube, saving any burned segments.
5. Examine the airway.
6. Re-establish airway support.

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After a Fire is Extinguished

1. Inspect the area for a secondary fire on the underlying drapes or towels.
2. Assess the patient for injury.
3. Determine what needs to be done to complete the case (new room, tear down, supplies, instruments, etc.).
4. Complete an incident report using VOICE.
5. Notify nursing administration and the administrator on call.
6. Save all materials from the fire for inspection by facility specialists and the fire department.

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Fire Evacuation

Depending on the severity of the fire, evacuation may be limited to the immediate area followed by partial or total department evacuation.

Unless the patient and staff are in immediate danger, the decision to evacuate and the safest route to go occurs in conjunction with unit/facility leadership.

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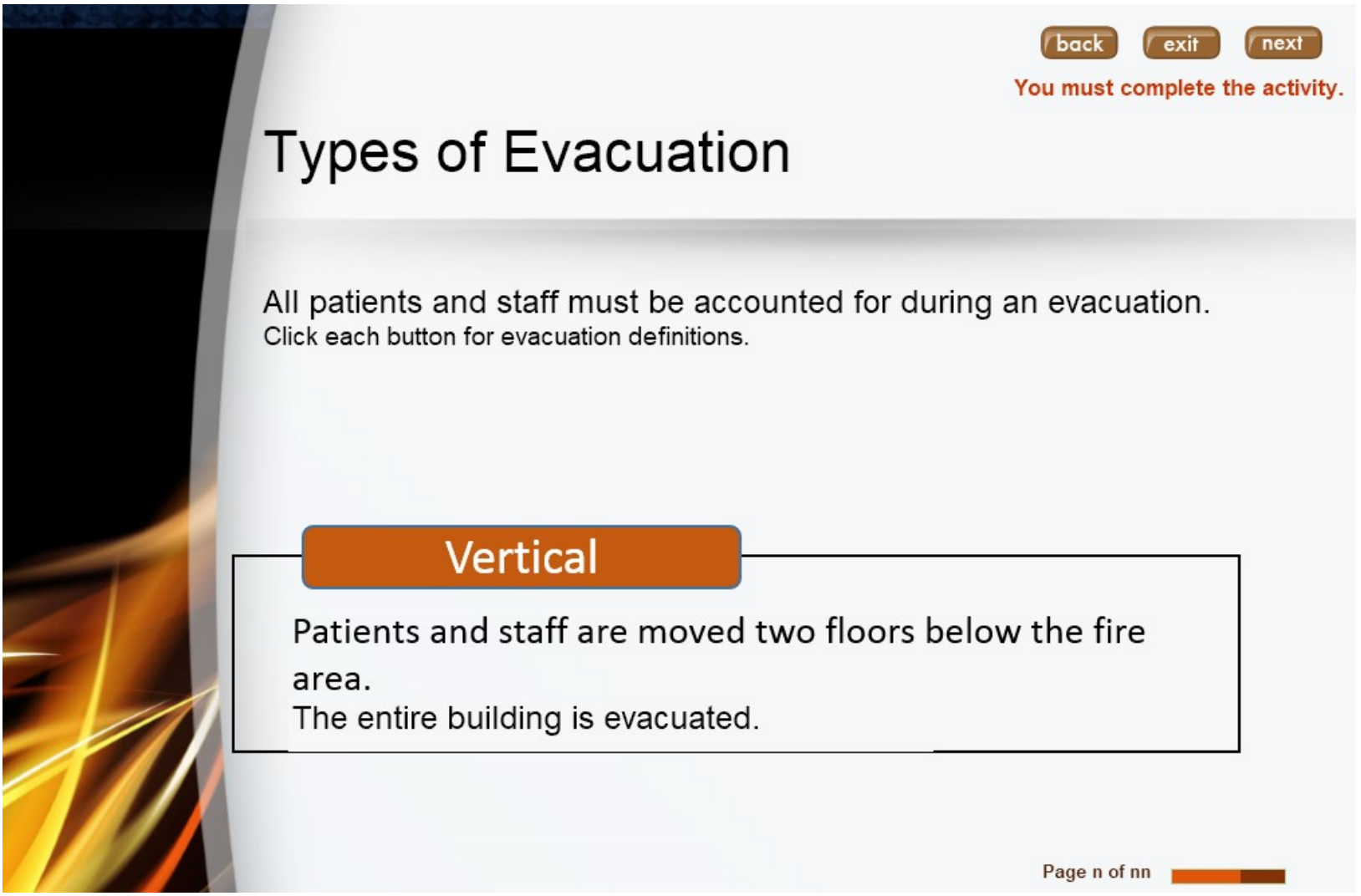
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You must complete the activity.
Types of Evacuation
All patients and staff must be accounted for during an evacuation.
Click each button for evacuation definitions.
Vertical
Patients and staff are moved two floors below the fire area.
The entire building is evacuated.
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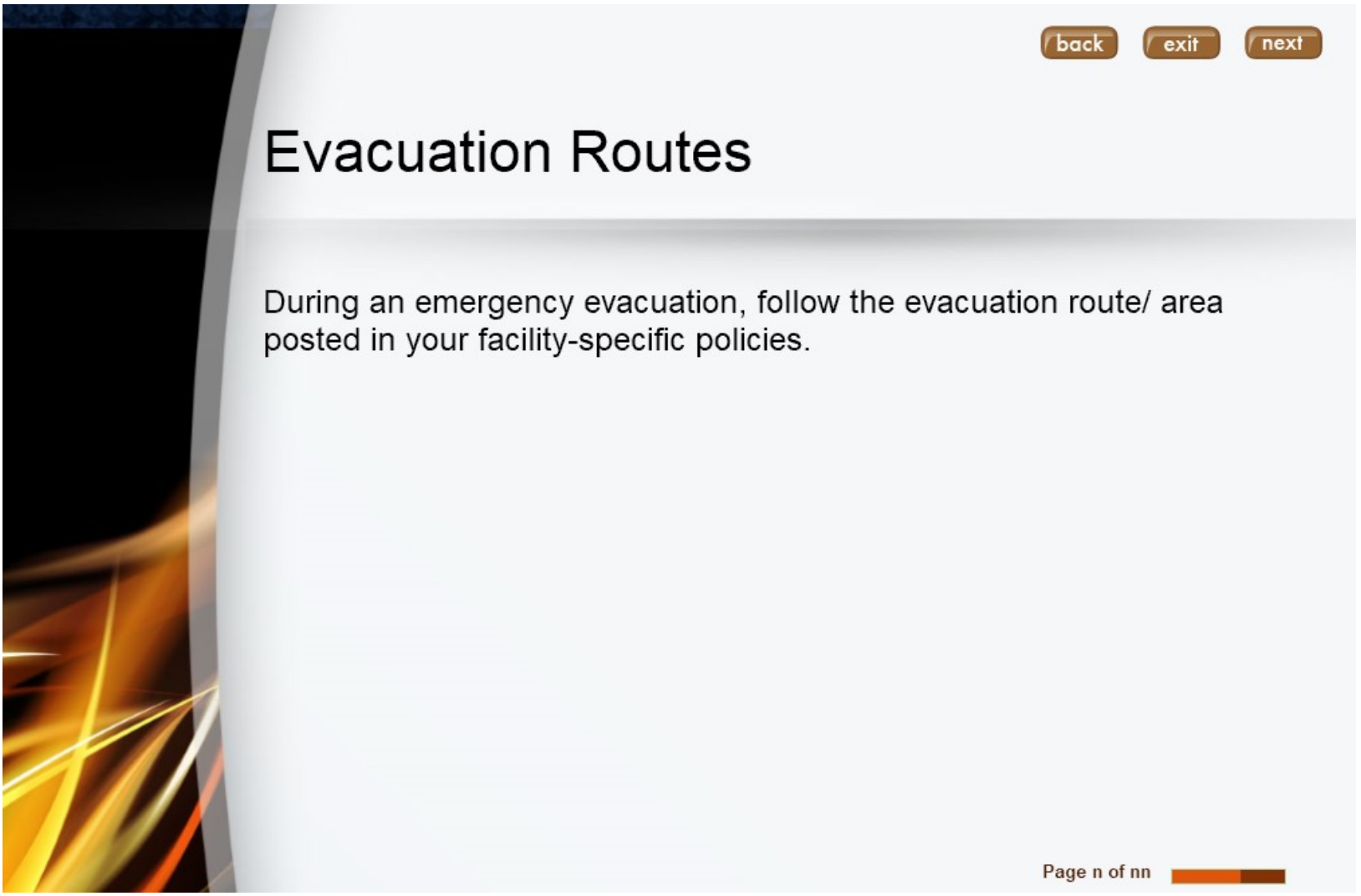
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Evacuation Routes
During an emergency evacuation, follow the evacuation route/ area posted in your facility-specific policies.
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Teamwork

Fire prevention and fire control takes a **critically-thinking team**.
Keep in mind the following:

- Location of the fire alarms, extinguishers, and gas shut-offs.
- Closest evacuation route.
- Cases that are at risk for fires.
- Steps to take to prevent fires.
- Steps to take when there is a fire.
- Who to contact STAT.

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References

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Association of PeriOperative Registered Nurses. (2022). *Fire safety toolkit.* *https://test.aorn.org/guidelines/clinical-resources/tool-kits/fire-safety-tool-kit*

MHC PolicyStat Evacuation Plan

MHC PolicyStat Munson Medical Center Fire Plan

MHC PolicyStat Operating Room Fire Plan

Pfander, Valerie (2017-2022). Fire Safety in the Operating Room. Munson Medical Center

Refer to orders for individualized patient care. Patient's orders supersede any information contained within the guidelines.

Guidelines for Managing Medications for Hypertensive Crisis in Pregnancy

Background: A sustained systolic blood pressure greater than or equal to 160 mmHg OR greater than or equal to 110 mmHg diastolic is treated with antihypertensive medication to protect the patient from cerebral vascular accident.

Goal: To prevent cerebral vascular accident while maintaining placental perfusion. Target blood pressure ≥140/90 but < 160/100. Do not try to lower the blood pressure to "normal;" blood pressure <140/90 can result in decreased fetal perfusion. Treatment with first-line agents should be expeditious and occur **as soon as possible within 30-60 minutes** of confirmed severe hypertension to reduce the risk of maternal stroke.

1. Diagnosis
    a. Systolic blood pressure ≥160 mmHg OR
    b. Diastolic blood pressure ≥ 110 mmHg
        i. Optimal measurement of BP is made with patient comfortably seated and relaxed, legs uncrossed, and the back and arm supported, so that the middle of the cuff on the upper arm is at the level of the right atrium. BP taken in the upper arm with the woman in the left lateral position will falsely lower BP readings because the blood pressure cuff will be above the heart when these readings are made. This approach is discouraged.
        ii. If elevated on initial assessment, the BP measurement should be repeated after 10-15 minutes to attempt to eliminate spuriously elevated BP determinations. Have patient rest quietly until BP reevaluated.
2. Contact care provider and notify charge nurse. **1:1 staff ratio with high risk RN assigned.**
3. Establish IV access; notify care provider promptly if unable to establish IV access
4. First line antihypertensive treatment: Intravenous labetalol or hydralazine. *See care provider orders.*

LABETALOL as primary antihypertensive

ADVISORY: Parenteral labetalol should be avoided in patients with active asthma, cardiac failure or suspected cocaine induced crisis. (*Compatible with magnesium sulfate at the Y site.*)

1. Administer labetalol 20 mg, IVPush, over 2 minutes
2. Reassess blood pressure in 10 minutes
3. If BP threshold is still exceeded, administer labetalol 40mg, IVPush, over 2 minutes
4. Reassess blood pressure in 10 minutes
5. If BP threshold is still exceeded, administer labetalol 80mg, IVPush, over 2 minutes
6. Reassess blood pressure in 10 minutes
7. If all ordered antihypertensive doses are given and BP remains ≥ 160 SBP or ≥ 110 DBP, notify care provider
8. Once target BP achieved, monitor BP q10 min for 1 hour, q 15 min for 2nd hour, q 30 min for 3rd hour, and then every hour for 4 hours

Max cumulative dose not to exceed 220 mg in 24 hours

HYDRALAZINE as primary antihypertensive

ADVISORY: May increase risk of maternal hypotension. (***Not*** *compatible with magnesium sulfate.*)

1. Administer hydralazine 5 mg, IVPush, over 2 minutes
2. Reassess blood pressure in 20 minutes
3. If BP threshold is still exceeded, administer hydralazine 10 mg, IVPush, over 2 minutes
4. Reassess blood pressure in 20 minutes
5. If all ordered antihypertensive doses are given and BP remains ≥ 160 SBP or ≥ 110 DBP, notify care provider
6. Once target BP achieved, monitor BP q10 min for 1 hour, q 15 min for 2nd hour, q 30 min for 3rd hour, and then every hour for 4 hours

Max cumulative dose not to exceed 25 mg in 24 hours

5. Hydralazine and labetalol are two "first line" agents used for hypertension in preeclampsia
    a. Hydralazine is an arteriolar dilator that reduces blood pressure but may cause tachycardia. Possible side effects are headache, risk of delayed maternal hypotension, which can be associated with fetal bradycardia, and rarely, upper abdominal (e.g., "epigastric") pain, which may be confused with worsening preeclampsia.
    b. Labetalol is a combined alpha and beta-blocking agent, which reduces blood pressure by dilating arterioles and decreasing heart rate. Labetalol should be administered intravenously for acute hypertensive emergencies. Asthma, cocaine and amphetamine use (including methamphetamine) are contraindications for labetalol use.
6. Immediate release oral nifedipine also may be considered as a first-line therapy, particularly when IV access is not available. *See care provider orders.*
    a. When nifedipine is used concurrently with magnesium sulfate, monitor maternal vital signs as described in reference to BP, with attention to normal heart rate and blood pressure (*both drugs are calcium antagonists*)
7. For women with severe preeclampsia, the administration of intrapartum-postpartum magnesium sulfate to prevent eclampsia is recommended (ACOG, 2013)

NIFEDIPINE as primary antihypertensive

ADVISORY: Capsules should be administered orally and not punctured or otherwise administered sublingually

1. Administer nifedipine 10 mg oral capsule
2. Reassess blood pressure in 20 minutes
3. If BP threshold is still exceeded, administer nifedipine 20 mg oral capsule
4. Reassess blood pressure in 20 minutes
5. If BP threshold is still exceeded, administer repeat dose of nifedipine 20 mg oral capsule
6. Reassess blood pressure in 20 minutes
7. If all ordered antihypertensive doses are given and BP remains $\geq$ 160 SBP or $\geq$ 110 DBP, notify care provider
8. Once target BP achieved, monitor BP q10 min for 1 hour, q 15 min for 2nd hour, q 30 min for 3rd hour, and then every hour for 4 hours

References

American College of Obstetricians and Gynecologists. (2017). Emergent therapy for acute-onset, severe hypertension during pregnancy and the postpartum period. Committee Opinion No. 692. *Obstetrics & Gynecology (129),* e90–5.

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Reviewed by P&T Committee 08/24/2017