Monica 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.

Monica 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 Monica 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 Monica Healthcare can be used with the device
5. There are no user serviceable parts inside the Monica 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	Electro Static Discharge

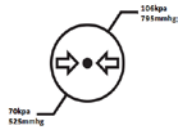
Contents

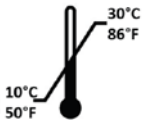
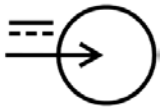
Section 1 - **Symbols and Standards**

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” 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 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).

	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 millimetres. 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 centimetres 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
Rx 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 0843	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 Monica Novii Interface complies with the following standards

Medical Device Standards	Description
IEC 60601-1:2005:A1:2012	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
EN 60601-1:2006:A1:2014 ANSI/AAMI ES 60601-1:2005(R)2012	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance including deviations for US
CAN/CSA-C22.2 No. 60601-1:14	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 60601-1-2:2014 Edition 4.0 EN60601-1-2:2015	Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010/A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62304:2006 (First Edition) + A1:2015 IEC 62304:2015 CSV	Medical device software — Software life-cycle processes Include Danish and Swedish language deviations
IEC 62366:2007 (First Edition) + A1:2014	Medical devices – Application of usability engineering to medical devices
ISO 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5: In Vitro Cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization
ISO 15223-1:2016	Graphical Symbols for use in the labelling of medical devices
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

Wireless Standards	Description
ETSI EN 301 489-17 V3.1.1 : 2017	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 : 2016	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 Monica 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 Monica 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 Monica 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: Monica 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: Monica UA provides information on the frequency and timing of the contraction peak. Interpretation of the Monica 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: **Monica 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: **Monica 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.

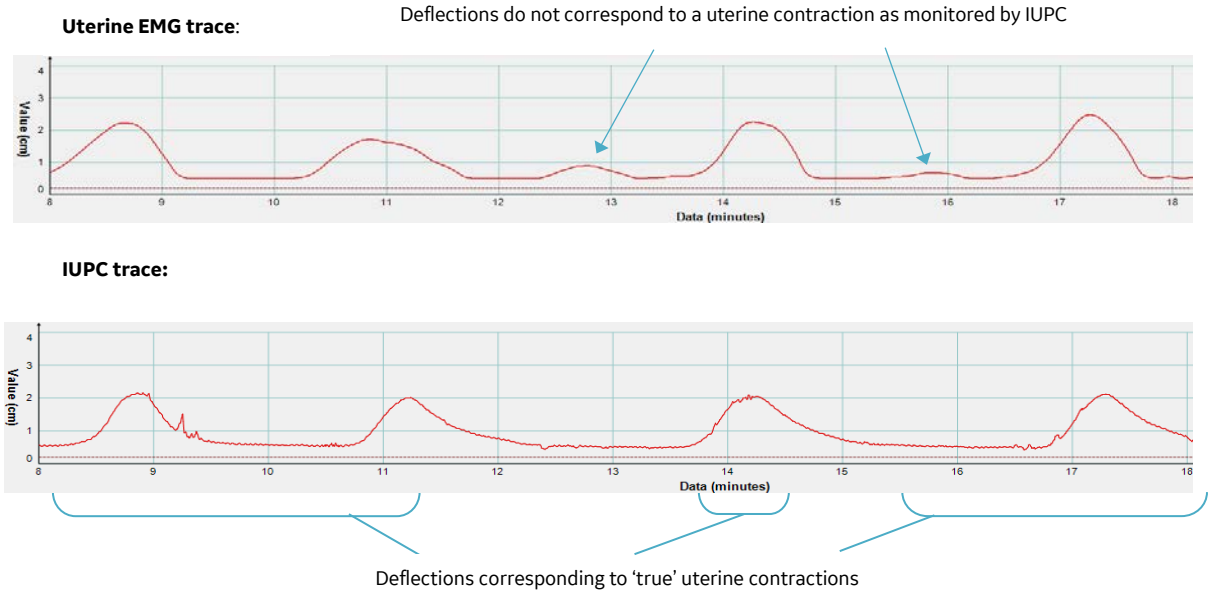
2.3.2 Uterine EMG Activity; Potential Problems with Clinical Interpretation

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: The Monica 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 Monica 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 Monica Novii system yourself.

WARNING: There are no user serviceable parts inside the Monica Novii POD and the Novii Interface. Please contact Monica 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 Novi™ 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 Novi™ 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 Novi™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Novi™ 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			
Novi™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the Novi™ 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 Novi™ 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 IEC 61000-4-3	3 V/m 80 MHz to 6 GHz	3 V/m	

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field 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 Novi™ system is used exceeds the applicable RF compliance level above, the Novi™ 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 Novi™ 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 Novi™ system
Table 6 of EN60601-1-2

The Novi™ system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Novi™ system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Novi™ 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 Monica 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 Monica 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 authenticate 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 and Pin are 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
Bluetooth specification	v2.1 + EDR (Enhanced Data Rate)
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.
Data Encryption / Security	The Bluetooth link between the Novii Pod and Novii Interface is encrypted (128 bit private key link). The Novii Pod and Interface are not discoverable
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 and pin 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.
Communication protocol	Proprietary Back-Channel Communication (transmitted alongside the WPC Message Packets). CRC mechanism for error detection
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 authentication process is carried out using the IrDA wireless protocol to transmit the Pods Bluetooth address and security PIN 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 9600 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 Monica 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

Monica 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
0843

The Novii System bears CE mark CE 0843 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 60601-2

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
- Getting Started / Registration card (Novii Wireless Patch System requires one-time registration before use, see Section 4.1)
- Operations and Maintenance Manual

3.2 General description

The Monica 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 Monica 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.

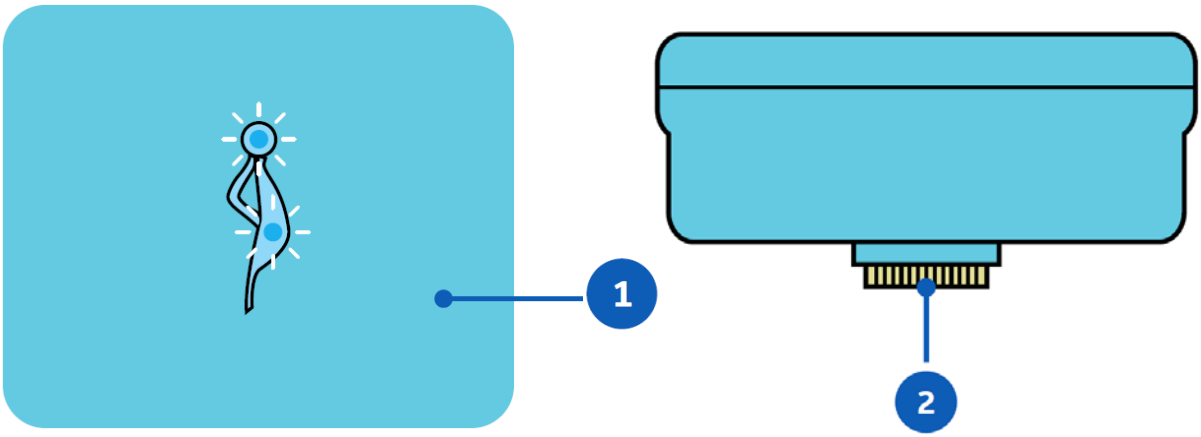
On dispatch, the Interface and all Pods making up one Novii Wireless Patch System are 'locked' i.e. cannot be used until they have been registered, see Section 4.1.

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. 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)

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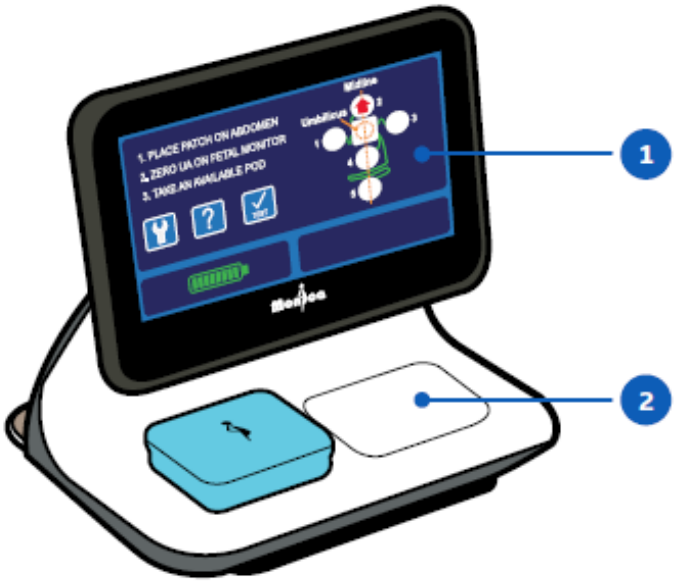
[1] Varies per use depending on Bluetooth range

[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

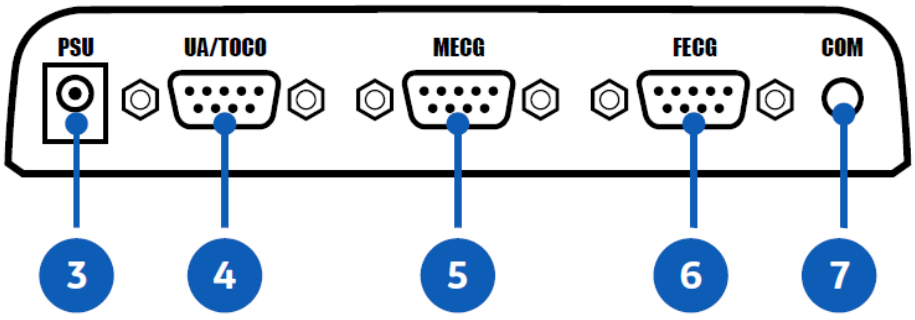
3.4 Novii Interface

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]

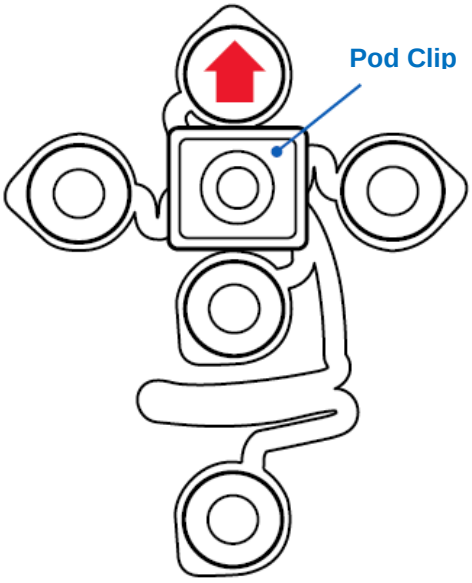


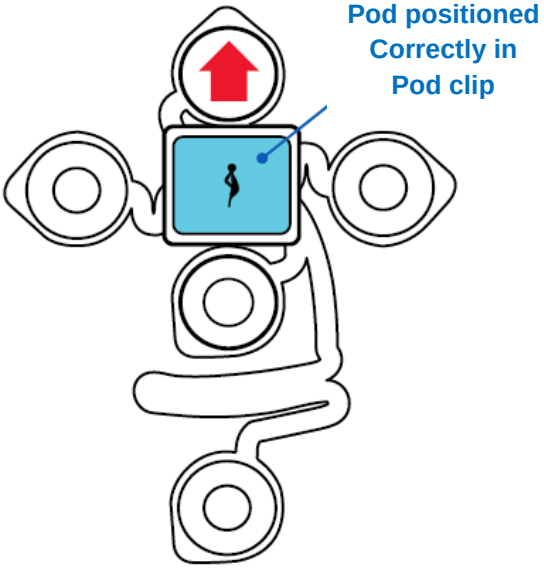
There is no power button on the Novii Interface, removing the power supply will turn the Interface off. If the Interface if switched on and there has been no activity for 10 minutes, the Interface will go into the 'power-save' standby mode, this will allow the Pod(s) to fully charge and then automatically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

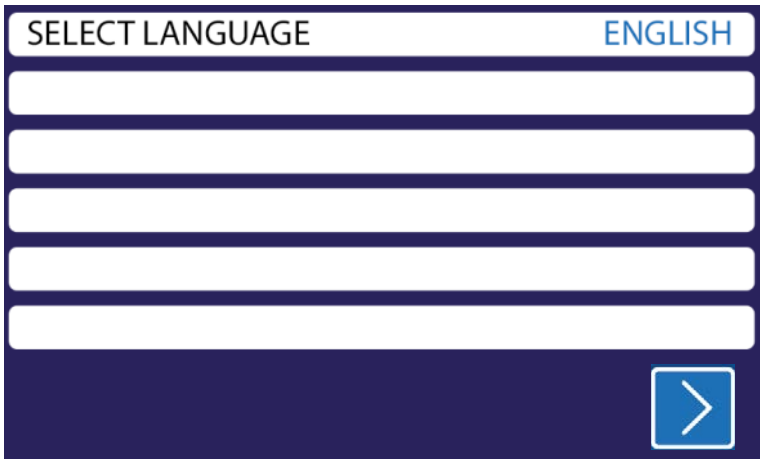
4.1 Device Registration

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

If this is the first time the Interface has been switched on the following language selection screen will appear. Select your language by touching the SELECT LANGUAGE bar, then press the forward arrow key to save and exit.



4.1.3 Device Registration

The Novii Interface and Pods cannot be used until they have been registered with Monica Healthcare Ltd., via an online registration process that issues a registration code for entering into the Interface.

Registration will allow Monica to track your warranty status and to keep you informed of software updates and key device critical information. Any information entered will be treated as confidential and will not be circulated to third parties. Once the device has been registered the Pass Code will be provided.

The Interface and each Pod has to be registered separately, start by register all Interface's first and then use one Interface to register each of the Pod's by placing it in the left charging bay only. The screen below will only be seen when the Interface or a Pod placed in the charging bay has yet to be registered:

To register the Novii Interface and Pods:

1. You will need a computer or notebook PC with Internet access
2. Go to www.monicahealthcare.com/support
3. You will need to Login to your Monica Healthcare account. If you do not have an account with Monica Healthcare you will need to create one by entering your name and email address under the section headed Register. You will then be sent a password to the email address entered which will allow you to Login. Your user name is your email address.
4. Once you Login select 'Register Novii Device' from the menu and follow the on screen instructions.
    a. Enter hospital information (once)
    b. Enter the access code detail on the Interface screen
5. Once you have completed the registration process you will be given a pass code to enter on the Interface display. The back arrow can be used to delete the last number(s)

entered if a mistake has been made. Use the forward arrow  to confirm the correct code and complete the registration.

6. Repeat the process with addition Interfaces / Pods. Go back to the website to enter addition access codes and obtain the relevant pass code ('Register Additional Device' option)

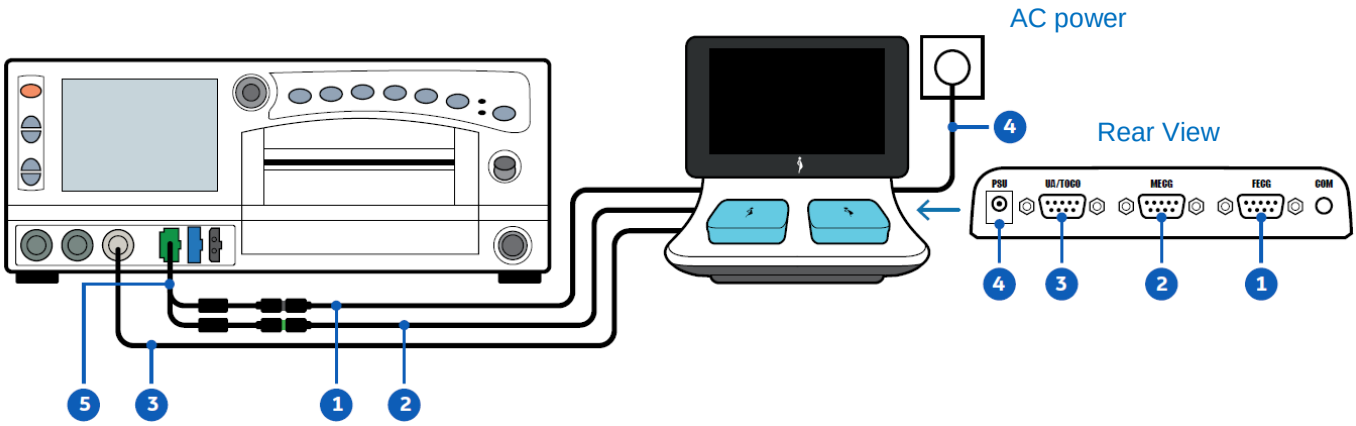
The registration information and pass codes are stored on the website for access later.

CAUTION: To avoid any confusion register one Pod at any time, by placing the Pod in the left charging bay only.

CAUTION: The Novii warranty registration process should only be carried out by a Hospital bio-med engineer or other competent person.

CAUTION: If for any reason the registration process fails the Interface should be disconnected from the power and re-started.

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.

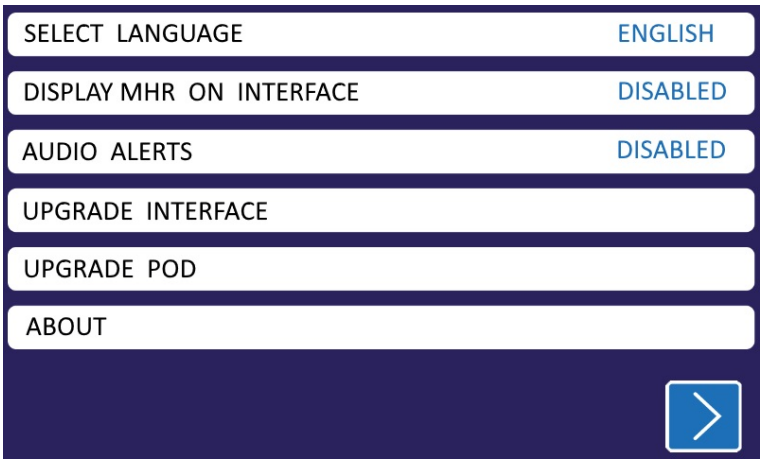
1. Connect the cable of the Novii power supply (107-PT-002) to the power socket on the rear of the Novii Interface (socket labelled PSU), and then connect the power supply to the AC power source.

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 



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 this item 'bar' will provide a list of available languages to choose from.

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 Monica 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 Monica nominated person, see the service manual for instructions.

4.3.6 ABOUT

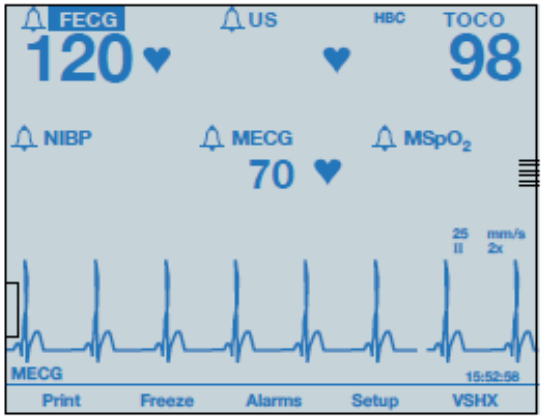
Touching the About item 'bar' will display the Novii Interface firmware version and serial number along with the firmware version and serial number of any Pods docked.

Section 5 - **TEST function**

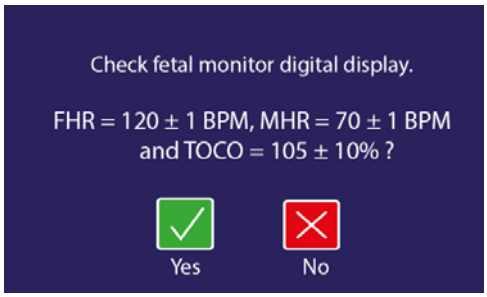
Test Function is used to confirm that the Novii Interface is correctly connected to fetal monitor and that there are no problems with the cables. A signal will be sent to the Maternal/Fetal Monitor to check correct functionality. Monica recommends that whenever the user requires evidence to demonstrate 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



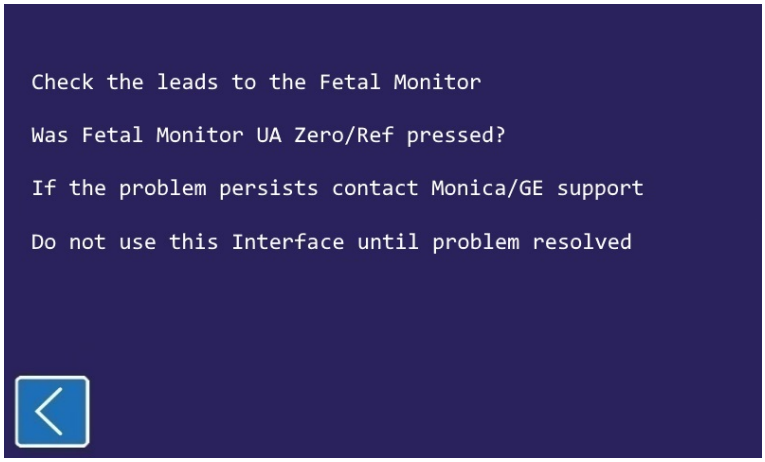
4. Check that all signals are displayed and parameters are in range. Shake Interface cables to test for intermittent breaks in signal and replace cable if needed. If signals are missing, check that connections are secure.

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**

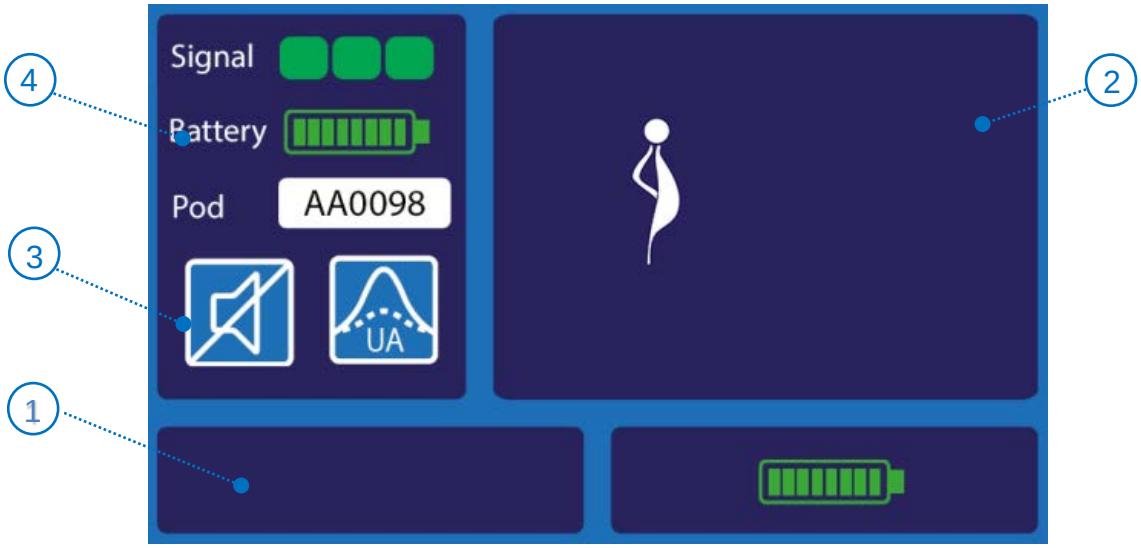
6.1 Introduction

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:

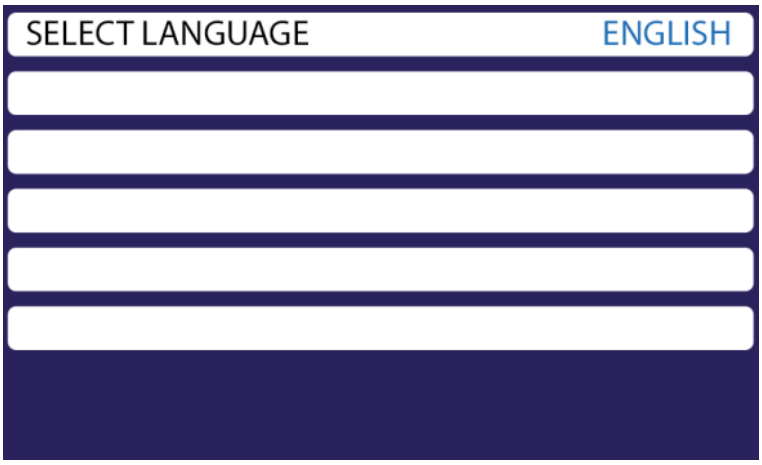


1. Status of the Novii Pod positioned in the charging bay directly below (left or right bay)
2. This area reserved for help/support information, alert messages and Novii MHR display when enabled
3. User controls: SOUND (on/off) and UA SENSITIVITY (high/low) Touching these buttons will toggle between 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 device has not been registered it will ask for the language to be selected. It will then go to the registration screen, please refer to Section 4.1.

If the Novii Interface has been inactive for 10 minutes and there is no monitoring, no Bluetooth connection nor 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.

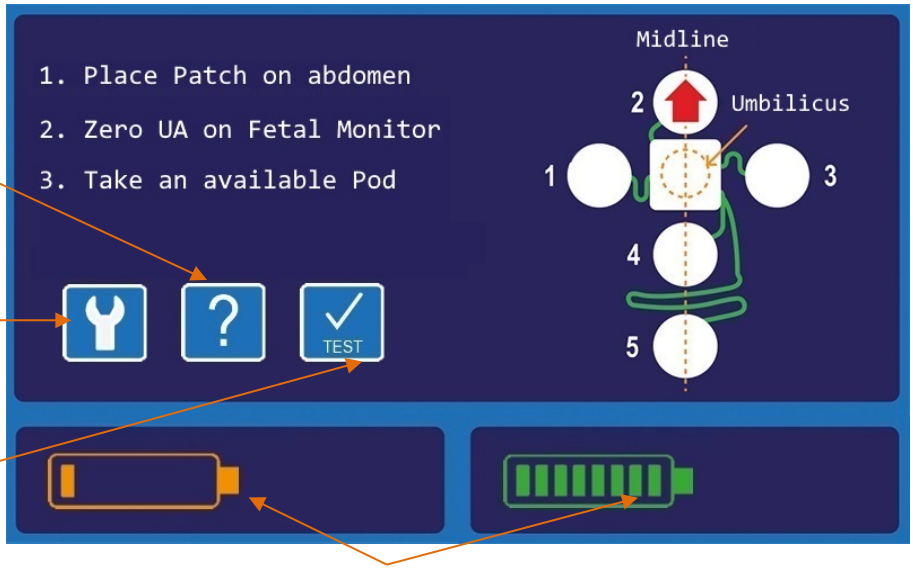
Touching the Standby button  , or removing and redocking a Pod will take the user to the 'start-screen', Section 6.4.

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):



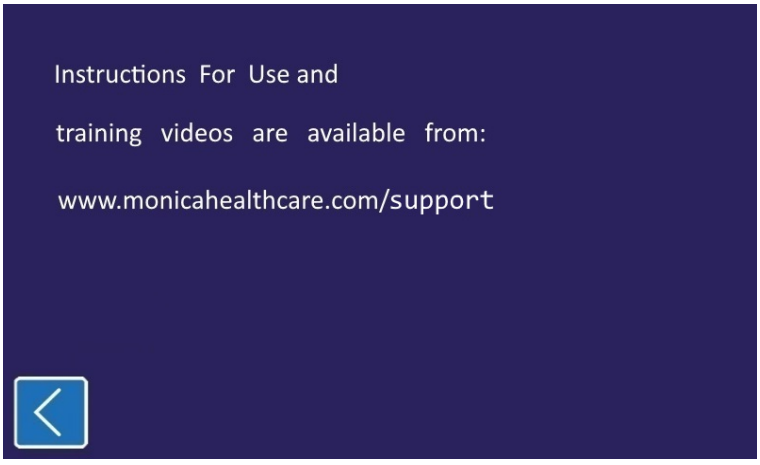
For additional support and help touch the HELP icon

To access the settings touch the SETUP icon, section 4.3

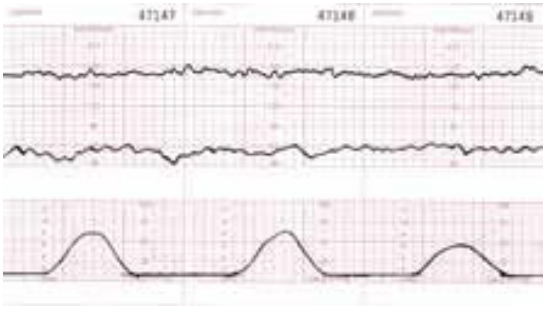
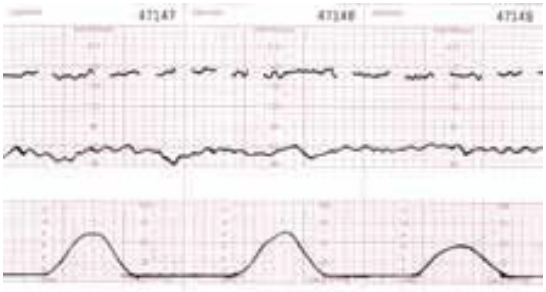
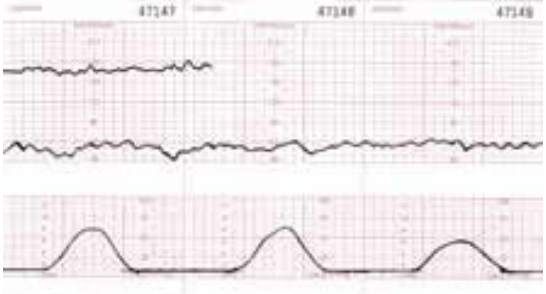
To check the connection to the fetal monitor touch the TEST icon, section 5

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

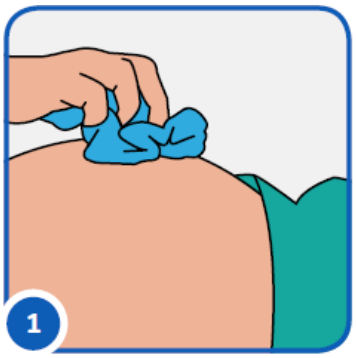
Symbol	Description
	Digital display of the maternal heart rate (MHR). Needs to be enabled in the settings, Section 4.3.2. **Note – MHR is not shown when alert or help messages are being shown**
	When the MHR is shown on the Novii screen. This alert symbol is displayed when the MHR and FHR are within 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
	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.

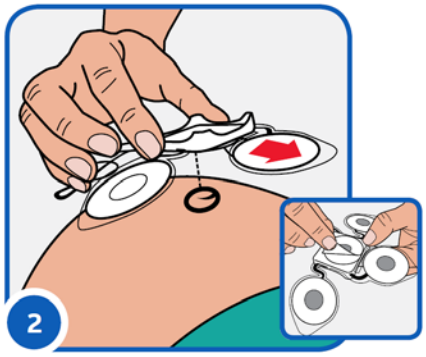


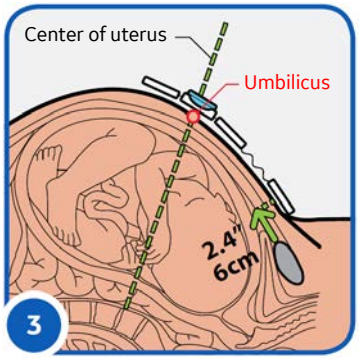
7.2 Before Placing Novii Patch

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.

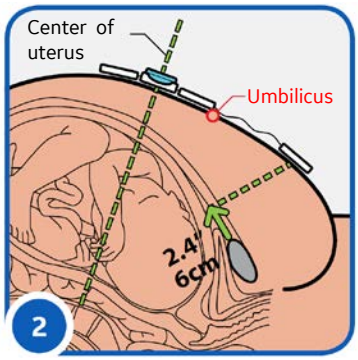
7.4 Patients with Displaced Umbilicus and/or Pannus

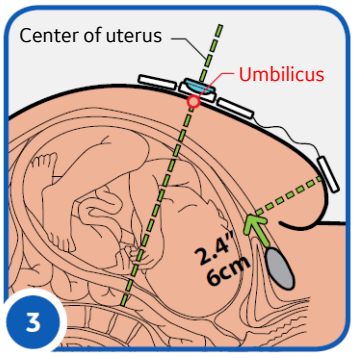
2. Displaced Umbilicus – Where the umbilicus is displaced downwards by more than 3cm from the center of the uterus, with the patient supine or semi supine, you will need to estimate where the center of the uterus is. DO NOT place Pod Clip over the umbilicus.
Find the centre of the uterus and place Pod 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).

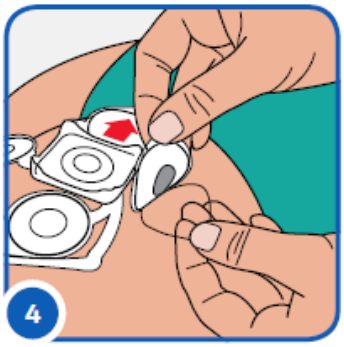
    c. Position Pod clip so that the top edge of electrode #2 is 5" / 12cm below the fundus.

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.

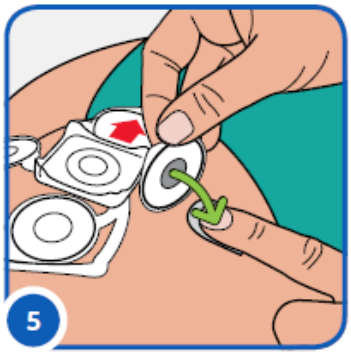




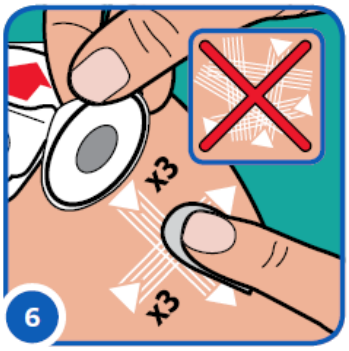
7.5 Applying Electrodes/Skin Preparation



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

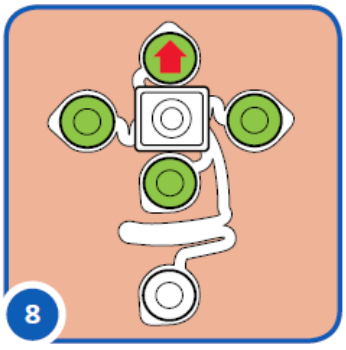


5. Focusing on the area of skin below black foam, use skin prep tape to exfoliate (remove dead skin cells). Use one piece of 1" / 2cm skin prep tape for every 2–3 electrodes.

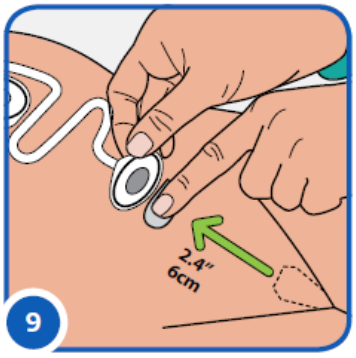


6. Exfoliation technique: using controlled gentle pressure do 3x vertical and 3x horizontal strokes (creating a '+' shape). Keep exfoliation area to a minimum. (Hold skin taught if required).

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.



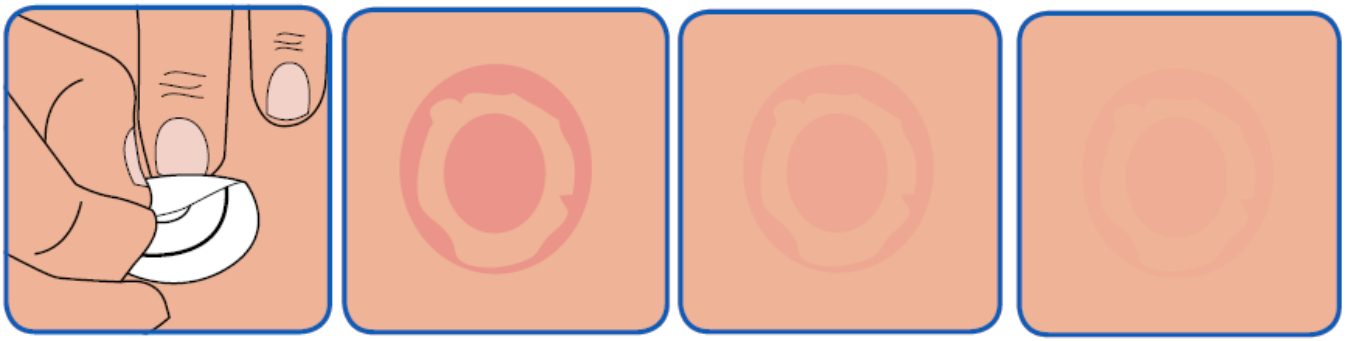
8. Repeat steps 4–7 for the remaining 3 electrodes around the clip.



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.

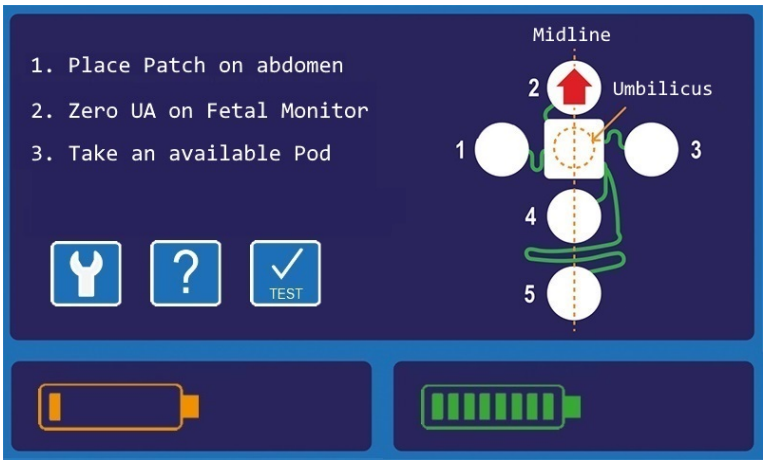
Correct Patch removal will help reduce skin irritation: To remove, gently peel each electrode back slowly at a low profile (<45°), while supporting the skin.

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

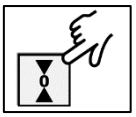


Instruction 1: Place the Patch on the abdomen

See section 7

Instruction 2: Zero UA on Maternal/Fetal Monitor

Press the UA zero reference button on the Fetal Monitor.

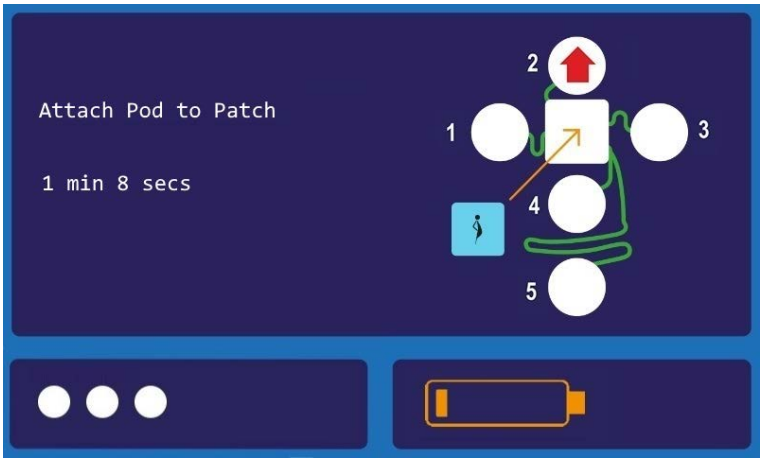


Instruction 3: Select a Charged Pod

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 Monica 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.

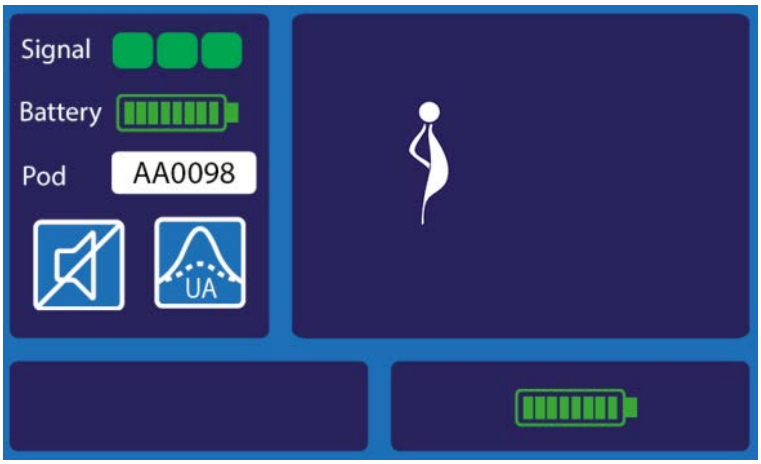
Electrode Check Screen

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 Monica Mark being printed to indicate the start of a new monitoring session, see section 10.

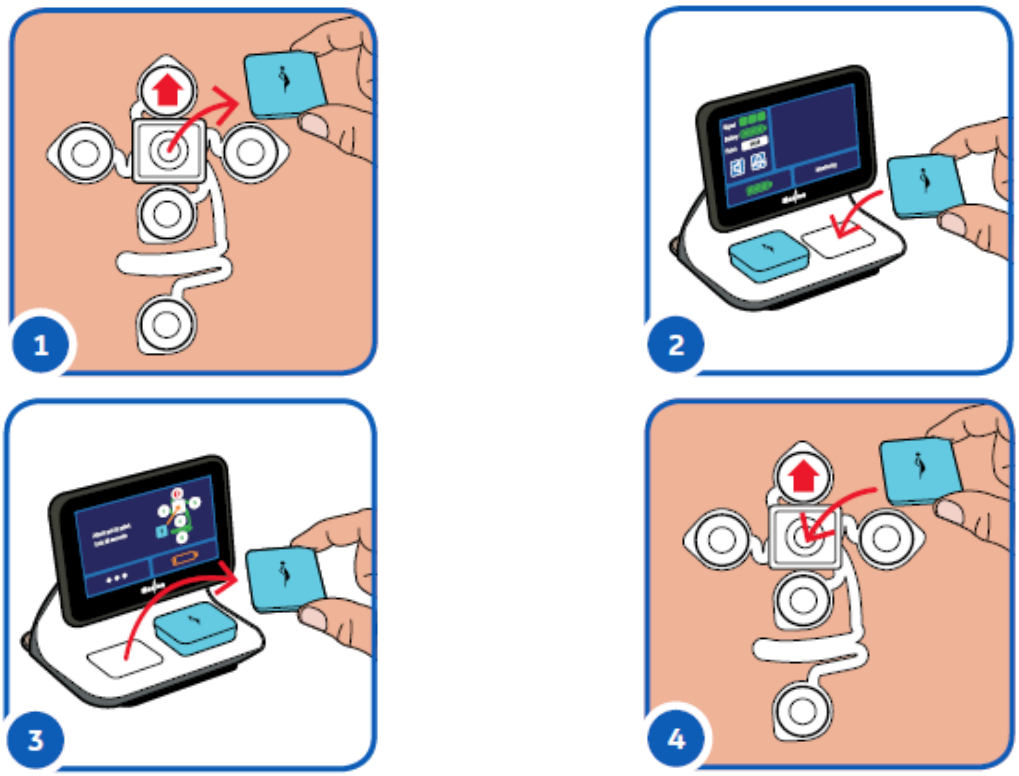
FHR, MHR and UA monitoring should commence within one to two minutes and be displayed on the fetal monitor. Lights on the Novii Pod will flash slowly together to indicate that MHR is being detected and monitoring has commenced.

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

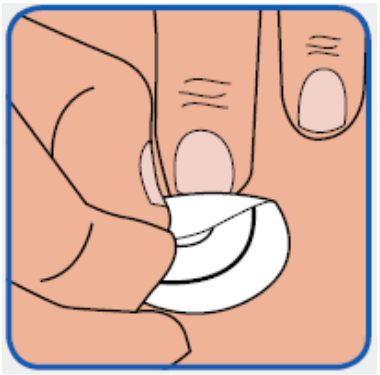


1. Remove Pod from Patch
2. Return Pod to Interface, then wait for battery icon to be displayed on the Start screen above Pod **(Monitoring Ended)**.
3. Once battery icon of returned Pod is displayed, zero the UA, then take fully charged Pod from Interface (if new Pod taken too soon it will not turn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

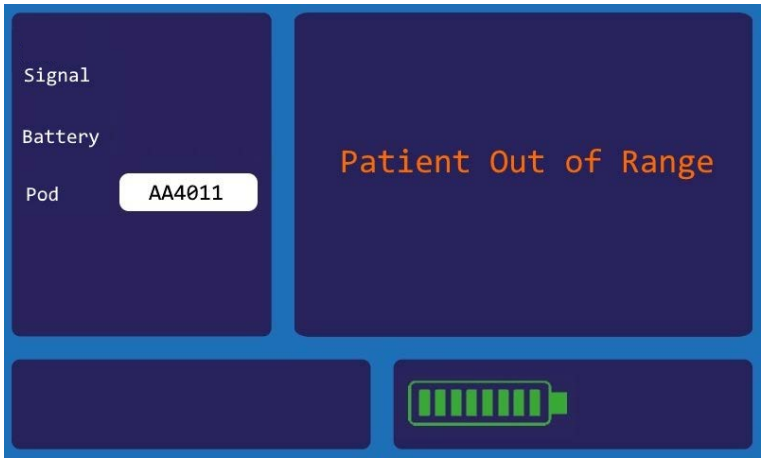


Section 9 - **Alert and Help Messages**

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



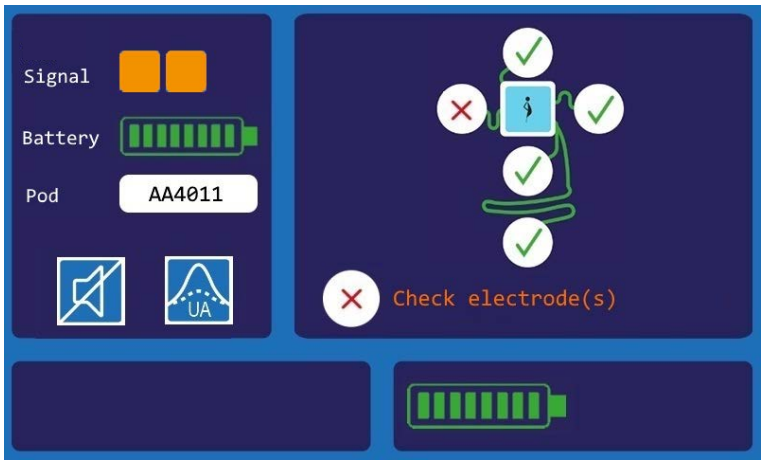
Patient is out of wireless range and the Interface cannot pick up the Bluetooth signal. Message will flash. Note loss of signal and battery information.

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.

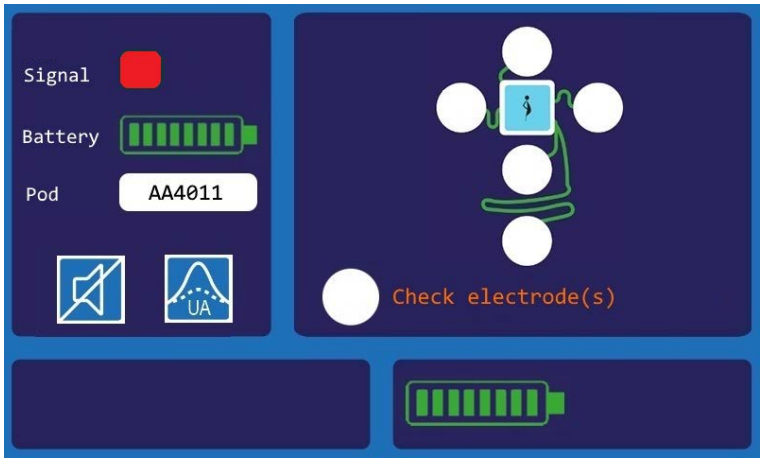
See section 8.2 for swapping Pods

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.

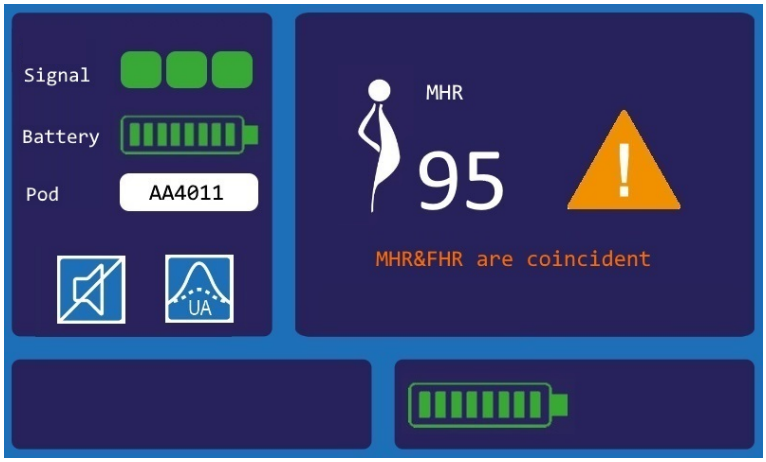
9.1.4 Electrode disconnection - Multiple



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.

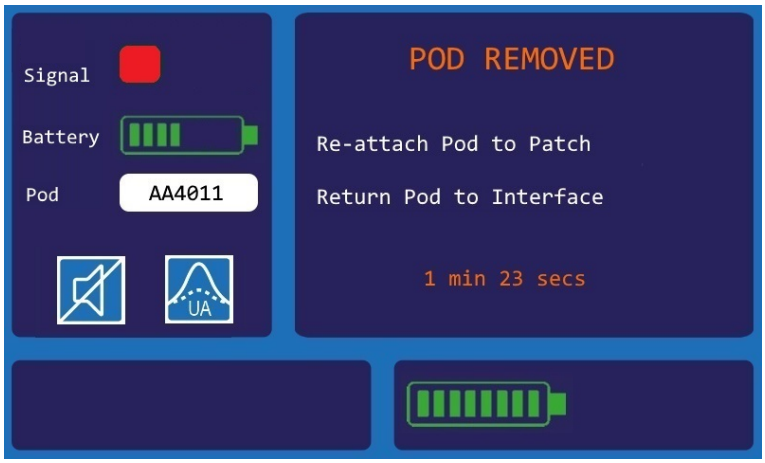


In this example, an audio alert will be heard. The audio alert can be silenced for 60 minutes by touching the 'Sound' icon. 

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-Monica 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

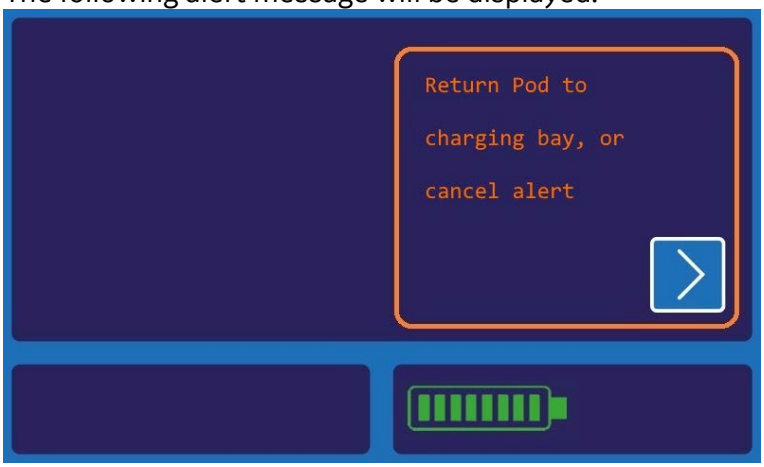
Priority order is:

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-Monica 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.

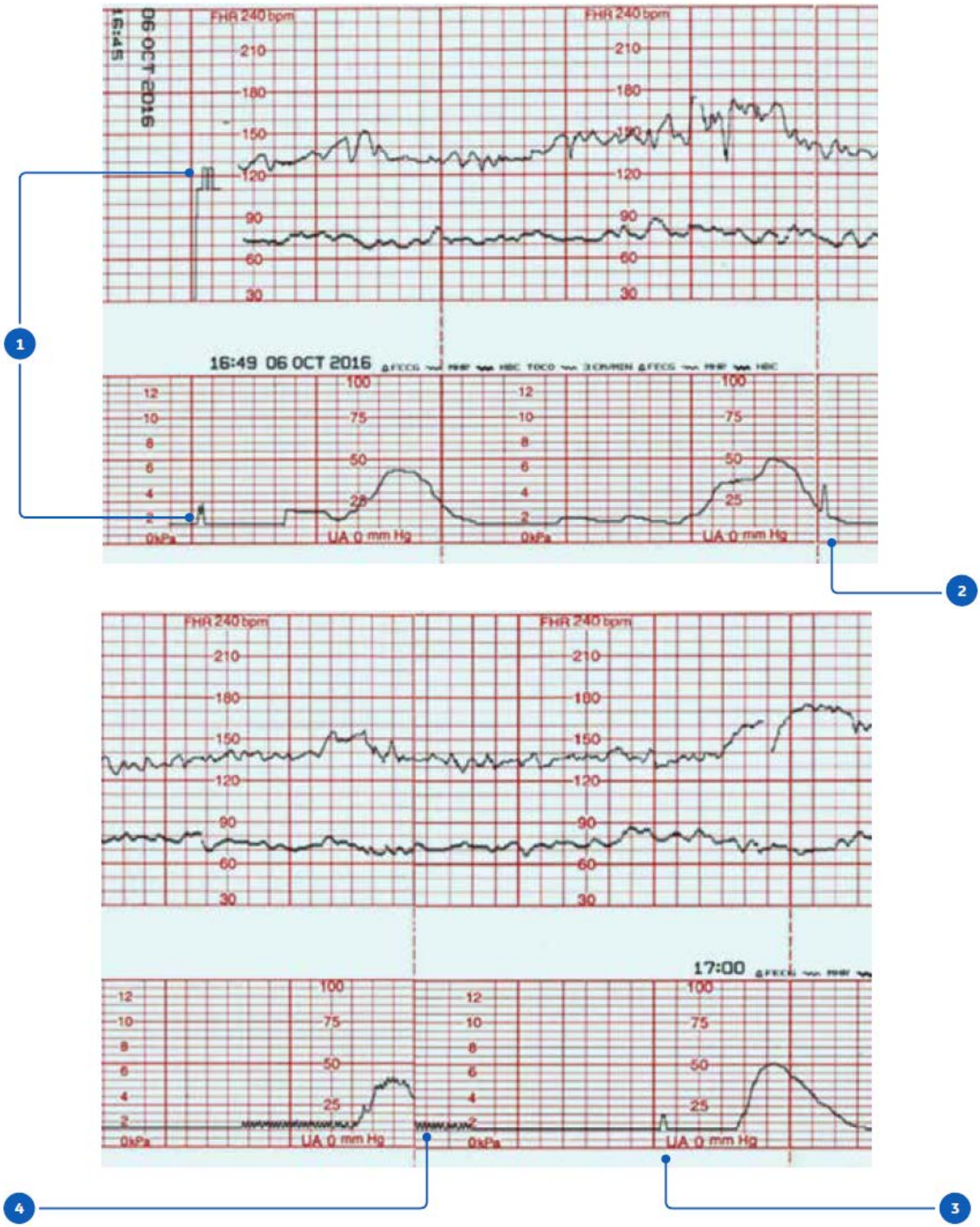
3. Battery fault, contact your local distributor / GE sales representative to arrange service request.

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. Monica Mark (at the start of a new monitoring session).
2. Monica Identifier (every 5 minutes) – larger height indicates high UA Sensitivity
3. Monica 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 Monica Mark and Identifier enable the user to identify that Novii is or has been used.

10.1 Monica Mark

During the first 10 seconds of a new Novii monitoring episode, a Monica 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 Monica Identifier

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

The height of the Monica 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: Monica 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: Monica 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).

To avoid this problem, disconnect the Novii MHR lead from the Maternal/Fetal Monitor and do not use MHR shown on Interface Screen. If the GE Corometrics 259cx Maternal/Fetal Monitor display for MHR has been set to automatic (default) removing the maternal ECG input will default the MHR display to use the SpO2 input for MHR. Replace the Novii MHR lead when epidural placement has been completed.

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

CAUTION: 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.

CAUTION: Do NOT use strong oxidants such as bleach.

CAUTION: Do NOT use bleaches containing sodium hypochlorite or any other cleaning solution other than those recommended here, Table 2, because permanent damage to the Novii Interface, Novii Pod and cables could occur.

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

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

Clean - Wipe the Novii Interface, Novii Pod and Interface cables with a soft non-abrasive cloth or disposable wipe soaked in aqueous detergent/ disinfectant or other solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the Novii Interface, Novii Pod and Interface cables three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the Novii Interface, Novii Pod and cables with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the Novii Interface, Novii Pod, and cables three times with sterile or distilled water to remove cleaning solution residue. Dry the Novii Interface, Novii Pod, connector and cables thoroughly with a sterile soft towel or gauze surgical sponge.

Section 13 - **Accessories & Part Numbers**

Part No.	Description
107-PT-001	Novii Interface
107-PT-003	Novii Pod
107-PT-002-US	Novii Interface Power Cable (US adaptor)
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
100-PT-025	Monica User Manual CD (includes promotional video and other support material)

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	Monica Healthcare Ltd, Unit 8, Octavia House, Interchange 25 Business Park, Sandiacre, Nottingham, NG10 5QG, UK Phone: +44 115 949 6960
	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 Temperature	+10°C to +30°C (+50°F to +86°F)	
Storage Temperature	+10°C to +30°C (+50°F to +86°F)	

Section 15 - **Interface Specification**

General Information	Manufacturer	Monica Healthcare Ltd, Unit 8, Octavia House, Interchange 25 Business Park, Sandiacre, Nottingham, NG10 5QG, UK Phone: +44 115 949 6960
	Model	107-PT-001
	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	Bluetooth V2.1 + EDR Class 1.5
	Protocol	Modified Series 50 protocol.
	Range	100ft / 30m (line of sight)
	Output	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	Resolution 800 x 400 resolution (RGB 65K colors) Viewing Area: 108mm x 65mm. Touch panel durability (tap test): 1 Million
	Alert Buzzer	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	Monica reference	107-PT-002-US
	Manufacturer	Mascot 3326-50
	Input	100V~ to 240V~, 50Hz to 60Hz, 400mA
	Output	18W 5V DC / 3000mA
	Dimensions	103.5 × 46.8 × 38.7mm
	Weight	200g /7.0oz
	Energy Efficiency	82.5% (on full load)

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 – US Adaptor (107-PT-002-US)
Operating Temp	+10° C to +30° C (+50°F to +86°F)
Storage Temp	+10° C to +40° C (+50°F to +104°F)
Relative Humidity	30%RH to 75%RH
Atmospheric Pressure (kPa)	70kPa to 106kPa (52.5mmHg 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	Monica Healthcare, Unit, 8, Interchange 25 Business Park, Nottingham, NG10 5QG, UK, Phone: +44 115 949 6960
	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. This applied parts connect to the pins at the bottom of the Novii Pod
Data I/O	Wireless output Protocol Range	Bluetooth V2.1 + EDR Class 1.5 Modified Series 50 protocol. 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 Accuracy	0-500 microvolts 0-255 levels representing 100% of full scale Produced 4 time per second from a rolling 2s average 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 475 charges cycles Up to 11 hours battery life Contactless charging with the Novii Interface (107-PT-001)	
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 Monica Novii Patch: 107-PT-004		
Environmental conditions of use	Normal use	+10°C to +30°C (+50°F to +86°F)	
	Transport and storage	+10°C to +40°C (+50°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)		

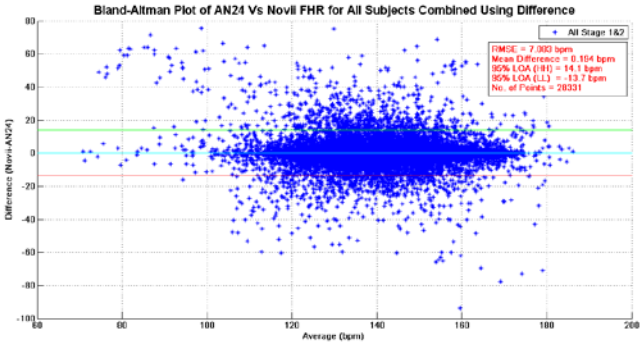


Figure 1: FHR Bland Altman Novii / Predicate device (difference)

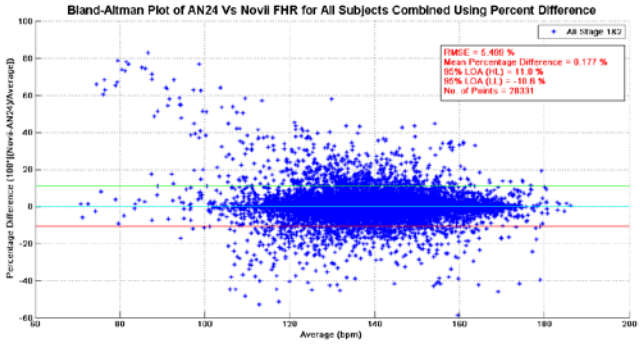


Figure 2: FHR Bland Altman Novii / Predicate device (% difference)

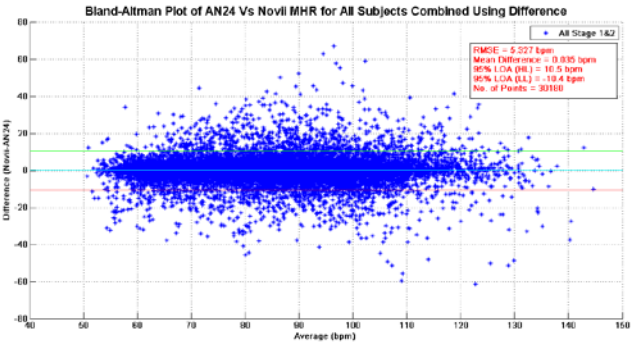


Figure 3: MHR Bland Altman Novii / Predicate device (difference)

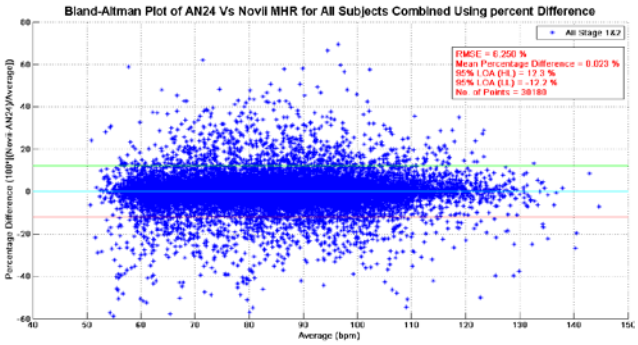


Figure 4: MHR Bland Altman Novii / Predicate device (difference)

Section 17 - **Device Lifecycle**

Interface	8 years (display) – calculated
Pod	2 years (battery life) – recommended
Patch	12 month 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
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 / Monica 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. A Novii simulator (100-PT-200), which has the capability to check the connection of the Pod pins without having to test on a Patch placed on a patient, may be purchased separately from GE Healthcare if required. A display of five green electrode checks on the Novii Interface

	screen when the Pod is placed in the Novii simulator would indicate a 'good' Pod with functional pins. While a display of persistent red X(s) would indicate improper pin connection, so should not be used on a patient until resolved.
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 

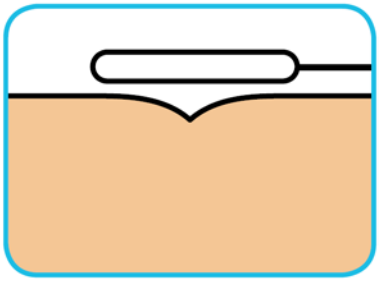
While the Novii detects the FHR continuously on many patients, some patients will require troubleshooting to reacquire the FHR signal. A small number of patients will not be able to be monitored successfully with the Novii despite troubleshooting

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.

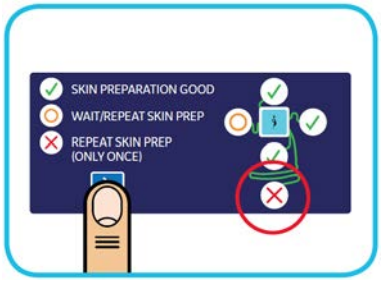
Training is important for obtaining the best results with Novii, training videos and further support material is available from www.monicahealthcare.com/support

<table>
<tr><th>Possible Cause/Problem</th><th>Action / Solution</th></tr>
<tr><td> 
The patient is ambulating - may cause increased muscle noise and/or displaced Patch</td><td>• 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.</td></tr>
<tr><td> 
Patient position/posture -may cause muscle tension/ noise and/or displaced Patch</td><td>• 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.</td></tr>
<tr><td> 
Electrode 'detached' or has badcontact with skin - electrode not able to function properly</td><td>• 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.</td></tr>
</table>

<table>
<tr>
<td> 

Poor skin prep - dead skin reduces transmission of fECG signal</td>
<td>

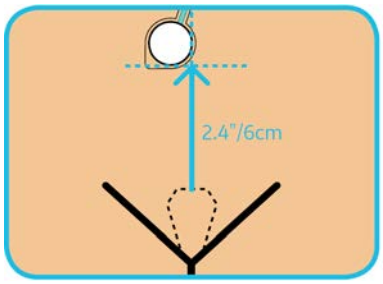
Exfoliate skin under ‘bad’ electrode.

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.

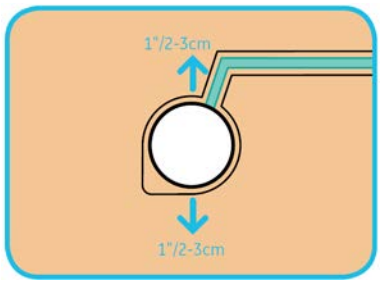
Help/Tip
Remove Pod from Patch, place in charging bay and start new monitoring episode.

Does a Pod consistently display a X on same electrode?

Help/Tip
Check for damaged Pod pins. Replace Pod if needed.
</td>
</tr>
<tr>
<td> 

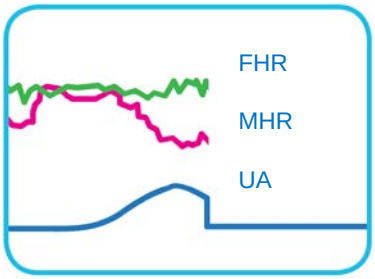
Center of lowest electrode is not 2.4"/6 cm above the symphysis pubis, or in optimal location for individual</td>
<td>

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.
</td>
</tr>
<tr>
<td> 

Pannus covering pubic bone</td>
<td>

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.
</td>
</tr>
<tr>
<td> 

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

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.
</td>
</tr>
</table>

	• 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

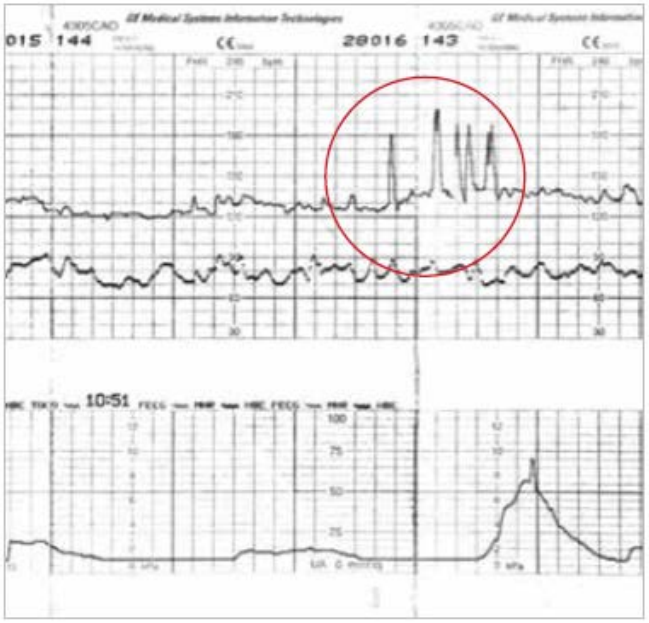
Notes:

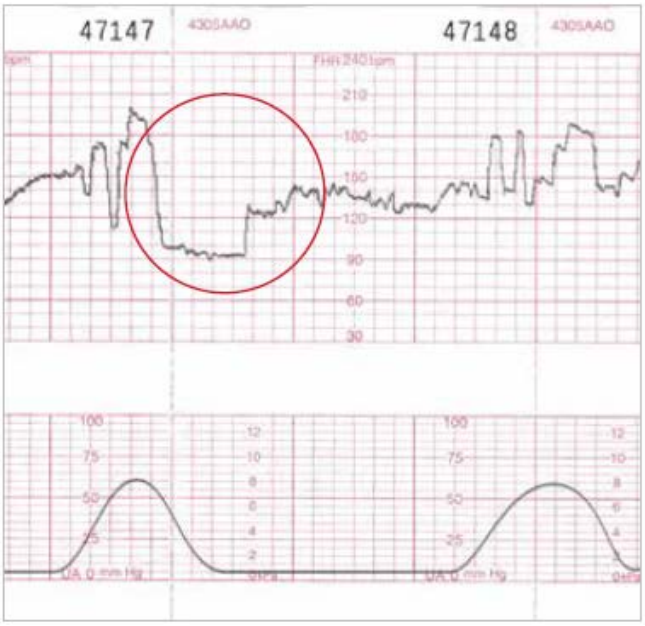
This troubleshooting guide assumes that the patient is supine or semi-supine during Patch placement and Novii set-up

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**

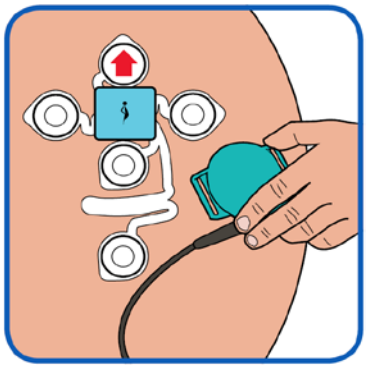
- Due to the challenges of monitoring the fetal heart, all fetal monitors are prone to FHR artifact and signal loss. Most of the time this artifact is easily identifiable from changes in FHR pattern.
- It is important to view the signal quality on the Novii Interface screen.
  Poor or bad signal quality 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.

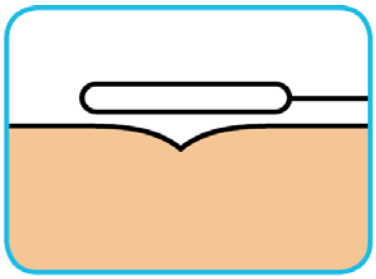
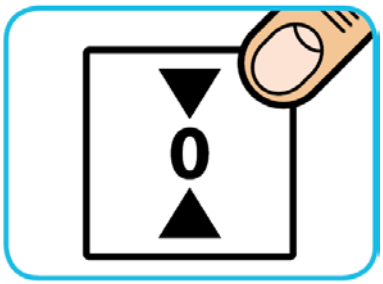
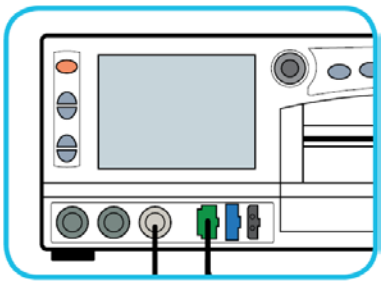
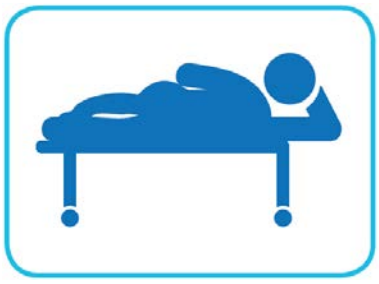
Caution: FHR Offset may be enabled on the fetal monitor.

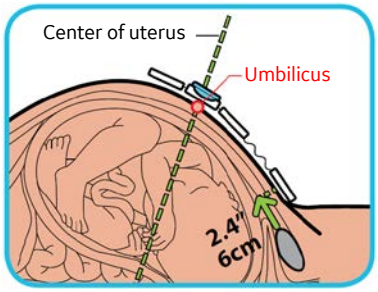
Caution: Novii FHR, Novii MHR and Novii UA are delayed by 10 seconds.

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.

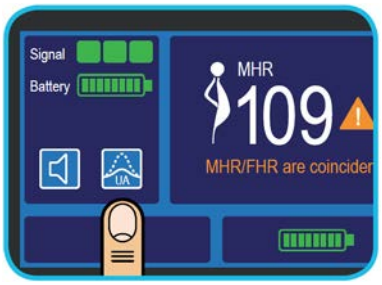
Section 21 - **Uterine Activity Troubleshooting**

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.

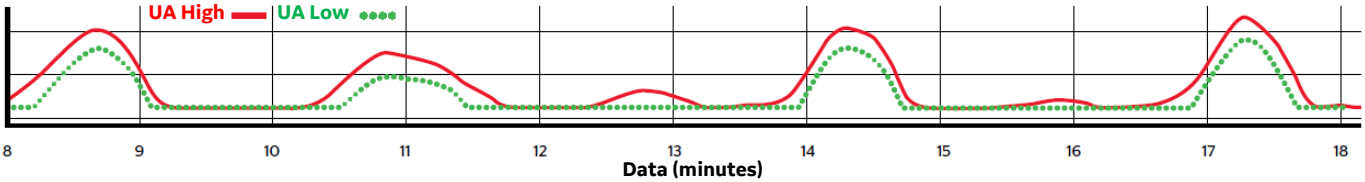
 Patch not optimally placed over uterus	• Confirm Patch is centered on uterus and the center of bottom electrode is 6cm above top rim of pubic bone. Electrode #3 is most important for obtaining good UA, thus poor positioning of this electrode may result in low UA. Reposition Patch if needed.

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 section 10.) 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
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 check the Monica web site (www.monicahealthcare.com/support) or 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 (Monica Novii Patch), packaging material and the Monica Novii Pod and Interface equipment.

Monica Novii Patch:

The Monica 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.

Monica Novii Pod and Interface:

At the end of its service life, the Monica Novii Interface or Monica 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 Monica 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 Monica 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 Monica 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. Monica 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 this may help to reduce the number of reactions in the future.

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

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