



Monica Novii[®] Wireless Patch System

Instructions For Use

107-PT-005-EN rev P

Information contained in this IFU manual corresponds to Novii Interface firmware ver 2.71 and POD firmware ver 2.54.

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This Instruction For Use 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 Instructions For Use

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, 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

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.



On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

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Numbers in brackets () refer to the key number in Figure 1.



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



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Section 1 - Symbols & Standards

This section describes symbols used in this Instructions For Use and the safety precautions that appear as symbols or labels on the Novii Wireless Patch System itself and the standards that it complies with.

1.1 Symbols



Consult Instructions for use



Do Not Use If Package is Damaged



Use by



Batch code



Manufacture date



Manufacturer



ESD - Static sensitive device



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.



Include RF transmitters



Class II Insulation



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.



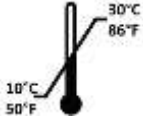
Do not reuse



No Latex used



No PVC used



Temperature limitation



The Novii system is not to be taken into a Magnetic Resonance (MR) environment

FCC ID: YOM-6961-MON

Federal Communication Commission identification number. Complies with United States Radio communication requirements.

1.2 Standards

The Monica Novii Interface complies with the following safety standards

Standard	Description
IEC 60601-1:2005 +A1: 2012 incl. USA deviations	Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007	Medical Electrical Equipment Part 1-2 General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests
EN ISO14971: 2012	Medical Devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
ANSI /AAMI EC12	Disposable ECG electrodes
EN 62133: 2nd Edition 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
EN ISO 10993	Biological evaluation of medical devices
FCC CFR 47: Part 15.107 & 15.109	Title 47--Telecommunication Chapter I – Federal Communications Commission 15 – Radio Frequency devices
EN 60529:1992 +A2:2013	Specification for degrees of protection provided by enclosures (IP code)
EN ISO 15223-1:2012	Graphical Symbols for use in the labelling of medical devices



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, 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.



This symbol is displayed on the Novii Interface, Novii POD packaging and Novii Patch Packaging labels to indicate the Novii system is not to be taken into a Magnetic Resonance (MR) environment.

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: 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 Coro 259 series 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 accidentally 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 since 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 259 Series 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.

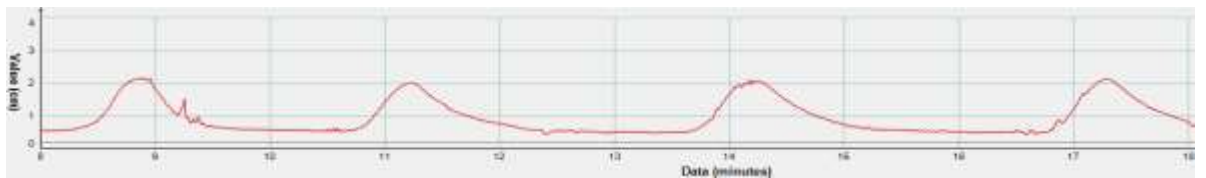
For example, in the following sample Maternal/Fetal Monitor tracing using uterine EMG, there are deflections above the baseline in the tracing that does not correspond to uterine contractions in a the simultaneously monitored IUPC tracing (e.g., deflections identified by arrows). IUPC is considered the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

Uterine EMG trace:

Deflections do not correspond to a uterine contraction as monitored by IUPC



IUPC trace:



Deflections corresponding to ‘true’ 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 259 Series Maternal/Fetal Monitor with the specific interface cable for that monitor, see Section 10.1.

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.

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

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

WARNING: Do not attempt to service the Novii Interface. Only Monica approved and qualified service personnel should attempt any necessary internal 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 Instruction For Use.

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 such as water or

gasoline (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 adequate 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



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 IPX0. 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 only when mated with the Novii Patch. Do not submerge 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, EN60601-1-2:2007, and FFC CRF47 Parts 15.107 & 15.109, Class A limits. However because of proliferation of radio-frequency transmitting equipment and

other sources of electrical noise in the health-care environments, it is possible that high levels of such interference due to proximity or strength of the source may result in the disruption of 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 <u>simultaneous</u> 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 mitigation measures, 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) The Novii system is medical electrical equipment and needs special precautions regarding EMC: it needs to be installed and put into service according to the EMC information provided in this section.

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



WARNING: C) Use of accessories and cables other than those specified in Section 10.1 of this manual may result in increased EMC emissions and/or decreased immunity of the Novii system to other electrical equipment.



The cables listed in Section 10.1 are to be used exclusively with the Monica Novii Interface and Monica IF24. If these cables are used with systems other than the Novii Interface and IF24, it may result in an increase of emissions or decrease in the immunity of that system.

WARNING: D) The Novii Interface connects to a Maternal/Fetal Monitor; hence it will be adjacent to, or stacked on top of, a Maternal/Fetal Monitor. It should be verified that the Novii Interface is correctly calibrated with the Maternal/Fetal Monitor it is connected to and the operation is normal and as expected in the configuration in which it will be used. To confirm correct calibration the TEST function of the Novii Interface should be used. The equipment or system (e.g. the Maternal/Fetal Monitor) should be observed to verify normal operation in the configuration in which it will be used.

WARNING: E) For Electromagnetic Compatibility the Novii Interface has been tested to IEC EN 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: F) 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: G) The Novii Interface may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Guidance and manufacturer's declaration – electromagnetic emissions		
Table 1 of EN60601-1-2		
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
RF emissions CISPR 11	Group 1	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. 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.
RF emissions	CISPR 11 Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity Table 2 of EN60601-1-2			
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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	AC power should meet the standards of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) 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 <i>UT</i> is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity Table 4 of EN60601-1-2			
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: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 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 $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
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: H) 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

The symbol  on the Novii system indicates that it is a Static sensitive device.

The Novii POD pins and the Novii Interface connectors are extremely static sensitive and should be handled using electrostatic discharge 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.
- Always connect the interface cables **first** to the Maternal/Fetal Monitor, and **then** to the Novii Interface.
- If the interface cables are not connected to the Maternal/Fetal Monitor, disconnect the interface cables from the Novii Interface.
- Do not touch any metallic parts of the Novii Interface and the patient at the same time.

WARNING: C) Staff who uses the Novii system should receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.

WARNING: D) The minimum contents of ESD precautionary procedure training should be the explanation of the ESD symbol and the understanding of the principles listed in warning B.

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.



Section 3 - Unpacking

The box should contain (but not limited to) the following items:

- x1 Monica Novii Interface device
- x1 Power Supply for Interface device
- x3 Cables to connect the Novii Interface to your GE Corometrics Fetal Monitor (FECG, TOCO and MECG input cables).
Some package variations exclude the MECG cable
- x2 Monica 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
- x1 3M red Dot 2236 skin prep tape
- x1 Getting Started / Registration card (Novii Wireless Patch System requires one time registration before use, see Section 5.1.2)
- CD containing Instructions For Use and support materials

Check that you can identify all the items in the box .

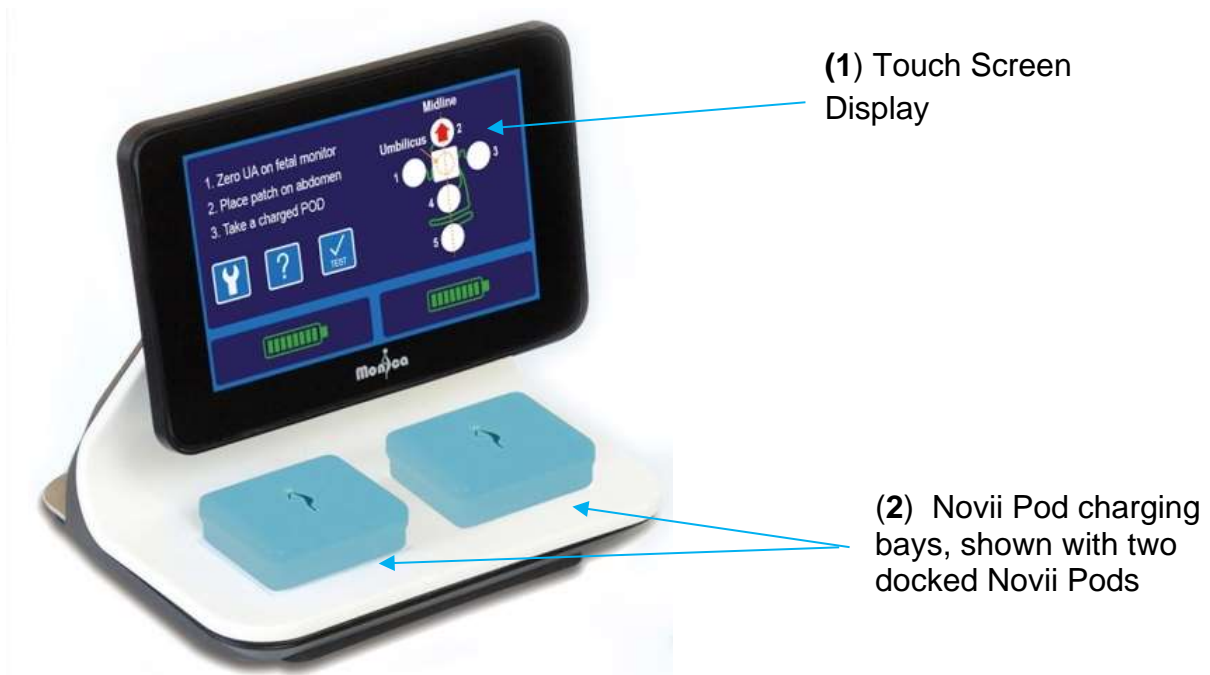


Fig 1a - Monica Novii Interface, front view; showing the start screen, with a POD in each of the two charging bays. Numbers in brackets () in this user manual refer to the key numbers in this figure



(3) Port connectors for the three cables specific to the GE Corometrics 259 monitor, shown connected. The cables connect to the UA/TOCO, MEKG and FEKG ports on the GE Corometric 259 monitor. The DC power input socket is on left of UA/TOCO socket. The serial port to the right of the FEKG socket is only used for maintenance by an employee of Monica Healthcare or by a Monica trained and nominated person

Fig 1b - Monica Novii Interface, rear view, showing the three cables that connect to the GE Corometrics 259 monitor and powers supply cable. Numbers in brackets () in this user manual refer to the key numbers in this figure.

Section 4 - Product Description

4.1 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 259 Series 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 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 6.5.2). 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 DECG (FHR), TOCO (UA) and MCEG 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 5.1.2.

4.2 Data processing

Digital data from the Novii POD is received by the Novii Interface by a Bluetooth wireless connection; fetal heart rate (FHR), uterine contraction (UA) and maternal heart rate (MHR) signals are then converted to analogue signals in real-time by the Novii Interface for transfer to



the Maternal/Fetal Monitor. The Novii POD generates a rolling two second average FHR and MHR updated every ¼ second. The UA resolution is 1 step out of the 255 steps full range i.e. 1/255 and the amplitude is updated every ¼ second from a low pass filtered signal.

4.3 Data viewing

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 5.3.2.

4.4 Data accuracy

The FHR and MHR output to the Maternal/Fetal Monitor is within 1 BPM (Beat Per Minute) of the data received from the Novii POD. The UA resolution is 1 step out of the 255 full range i.e. 1/255.

4.5 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 IPX0 The Novii POD and Patch are rated IPX0 when not connected together and IP57 when connected together
Method of sterilization	Not intended to be sterilized. See Section 9 for cleaning instructions
Suitability for use in an OXYGEN RICH ENVIRONMENT	Not suitable for use in an oxygen rich environment
Mode of Operation	Continuous Operation

4.6 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).

4.6.1 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 power is controllable by software and is typically 4dBm.

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 4.6.2. 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) 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 and Interface	T7V1315
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 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)

4.6.2 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 follow:

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.

4.6.3 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.

4.7 FCC Information (USA)

4.7.1 FCC Rules Compliance

FCC ID

Novii Pod – YOM-6960-MON

Novii Interface – YOM-6961-MON

FCC Rules Compliance

This device complies with Part 15 & Part 18 of the FCC Rules.

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



Section 5 - 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 5.2.
- 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 between patient and the Novii Interface under ideal line of sight situations).



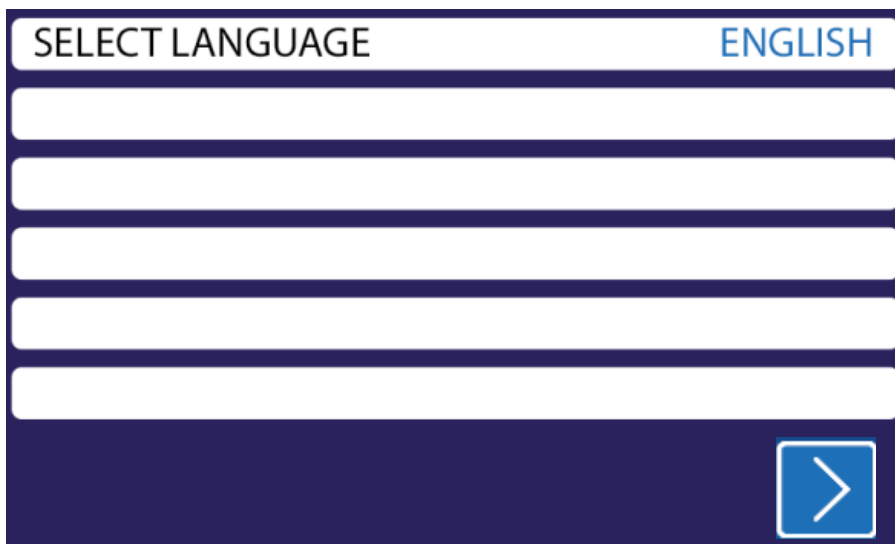
5.1 Initial Screen, Device Registration

5.1.1 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.



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.





5.1.2 Device Registration

The Novii Interface and PODs cannot be used until they have been registered with Monica Healthcare Ltd. The screen below will only be seen when the Interface or a POD placed in the charging bay has yet to be registered:



Warranty will start from the date registered and the data you provide will be used 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 the PODs are effectively locked until the correct pass code is entered via the numeric key pad on the display. The back arrow can be used to delete the last number(s) entered if a mistake has been made. The Interface and each POD has to be registered separately starting with the Interface:

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 screen instructions.

5. Once you have completed the registration process you will be given a pass code to enter on the Interface display.
6. Once the Interface has been unlocked any un-registered POD placed in the Interface charging bay will bring up the Registration display and the process will need to be repeated to unlock the POD(s).



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.

5.2 Cable Connection

1. The Novii Interface will be supplied with specific interface cables and calibrated only for use with GE Corometrics 259 Maternal/Fetal Monitors.

The GE Corometrics 259 Maternal/Fetal Monitor must be equipped with GE Y-adapter cable (part# 1442AA0), shown below



2. Refer to Section 10.1 to confirm that you are using the correct cables for your Corometrics Maternal/Fetal Monitor before beginning the set up.
3. 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 to the FECG (Fetal Scalp Electrode) port on the Fetal Monitor first (using the already connected GE Y adaptor if using the Corometrics 259), then into the port labelled FECG (3) on the rear of the Novii Interface, tighten screw with a screwdriver.
 - b. Connect Novii UA interface cable to the TOCO port on the Fetal Monitor first and then into the port labelled TOCO (3) 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 to the MHR port on the Maternal/Fetal Monitor first (using the already connected GE Y

adaptor if using the Corometrics 259) and then into the port labelled MEEG (3) on the rear of the Novii Interface, tighten screw with a screwdriver.

4. 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.
5. The Power Supply of the Novii Interface is regarded as part of the Medical Electrical Equipment.

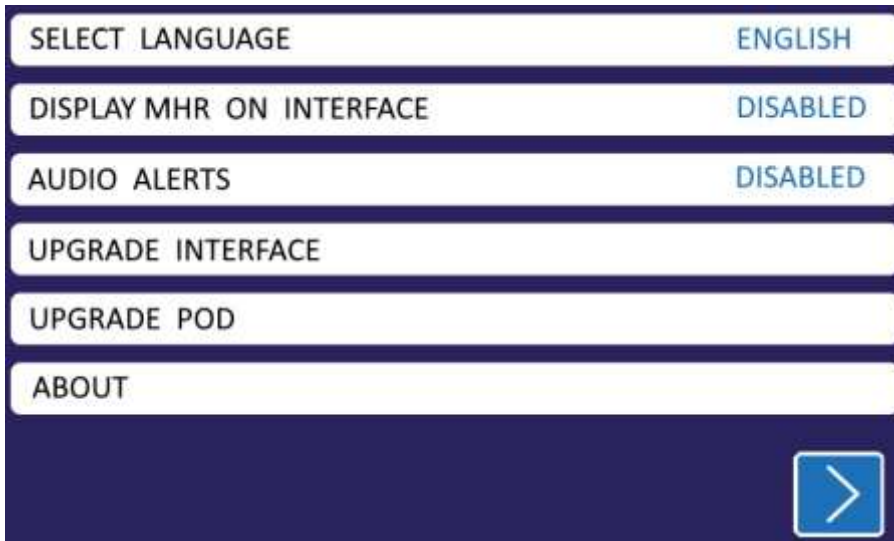


CAUTION: It is important to run the Novii TEST sequence after installation to ensure that the Interface, cables, Y' cable adaptor and Maternal/Fetal Monitor are working correctly, Section 5.8. It is important that during the test the 'Y' cable is moved around to ensure there are no intermittent connection problems. If you see FHR or MHR errors please quarantine the 'Y' cable and advise your GE Healthcare representative,

5.3 Accessing Settings



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



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

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

5.3.1 SELECT LANGUAGE

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



5.3.2 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 5.3.3 below.

5.3.3 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 icon 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

5.3.4 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 and the Monica contact details.

5.3.5 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.

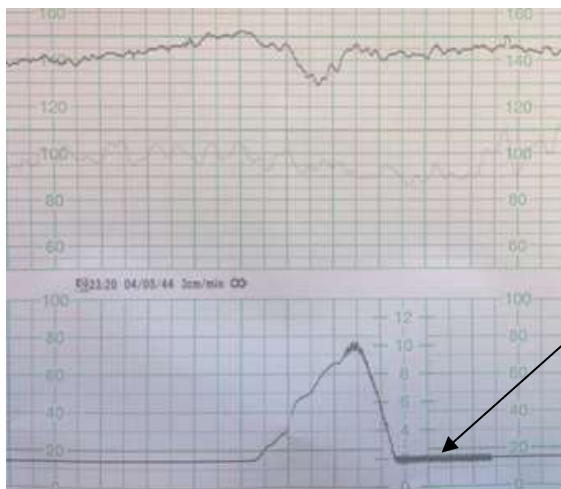
5.3.6 UPGRADE POD

A confirmation screen shows that the Novii POD placed in right or left hand 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.

5.4 Maternal Movement Alert using the UA trace

This feature is always enabled.

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.

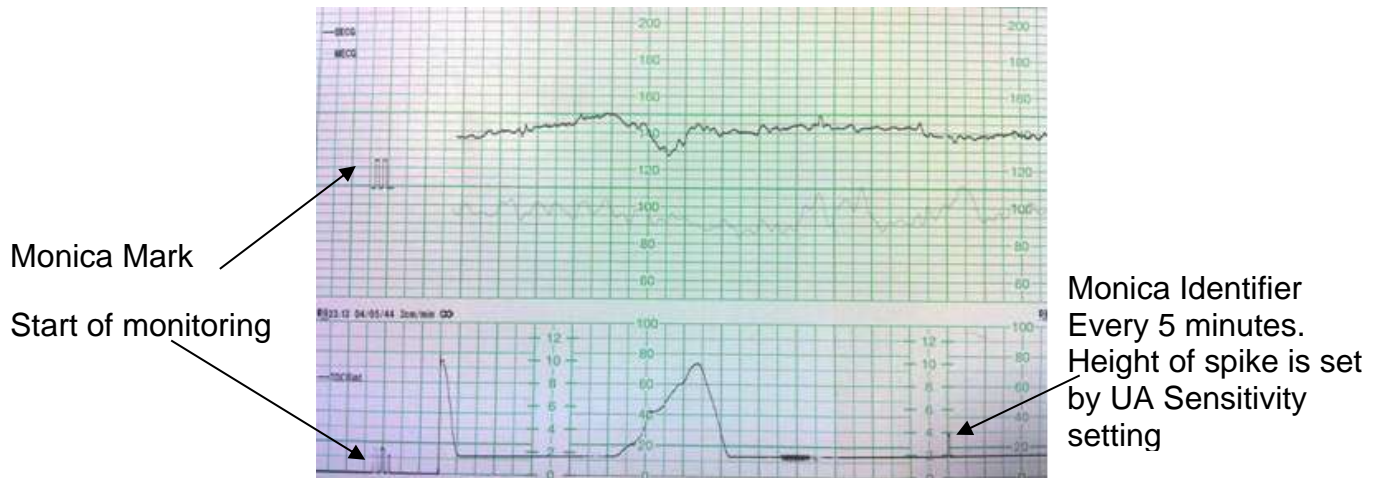


UA Alert –
Trace thickening

5.5 Monica Identifier

This feature is always enabled.

The Maternal/Fetal Monitor will print a Monica Identifier (a small identifying spike) on the UA trace every 5 minutes and, during the first 10 seconds prior to the start 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.



Printing of the Monica Identifier and Mark on the trace ensures during retrospective viewing and viewing of data on a central monitoring system, the user knows that Monica Novii was/is being used. 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.

5.6 Low UA Sensitivity



When selected, it is set to a suitable level for pre and early induction patients to reduce artifact from maternal/fetal movement and other sources. It 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.

5.7 High UA Sensitivity



When selected, it sets the UA to a suitable level for established labor patients. It can be changed at any time during the monitoring episode by the user.

5.8 TEST function



To confirm that the Novii Interface, Maternal/Fetal Monitor, GE Y adaptor and cables work correctly, touch the TEST icon from the Start screen. 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 icon on the Start screen should be used. The GE Y adaptor should always be moved, shaken, to ensure there are no intermittent problems.

After touching the TEST icon the user will be asked to zero the TOCO on the Maternal/Fetal Monitor– see below, and confirm using the forward arrow key.



Once confirmed, a test FHR, MHR and UA signal will be sent from the Novii Interface to the Maternal/Fetal Monitor. The FHR, UA and MHR (if connected) values displayed on the Maternal/Fetal Monitor digital display should match the FHR, MHR and UA numbers displayed on the Novii Interface display:

Check fetal monitor digital display.

FHR = 120 ± 1 BPM, MHR = 70 ± 1 BPM
and TOCO = $105 \pm 10\%$?



Yes



No

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.

The FHR digital display should read 120 ± 1 bpm, the MHR digital display should read 70 ± 1 bpm and the TOCO should read $105 \pm 10\%$ full scale deflection. If the FHR or MHR are not within ± 1 bpm and/or the UA is not $\pm 10\%$ of this expected value please contact your Monica Distributor and do not use this Novii Interface until the problem has been resolved.

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:

Check the leads to the fetal monitor

WAS FETAL MONITOR UA ZERO/REF PRESSED?

If the problem persists contact Monica support


Do not use this Interface until problem resolved



Section 6 - Operating Novii

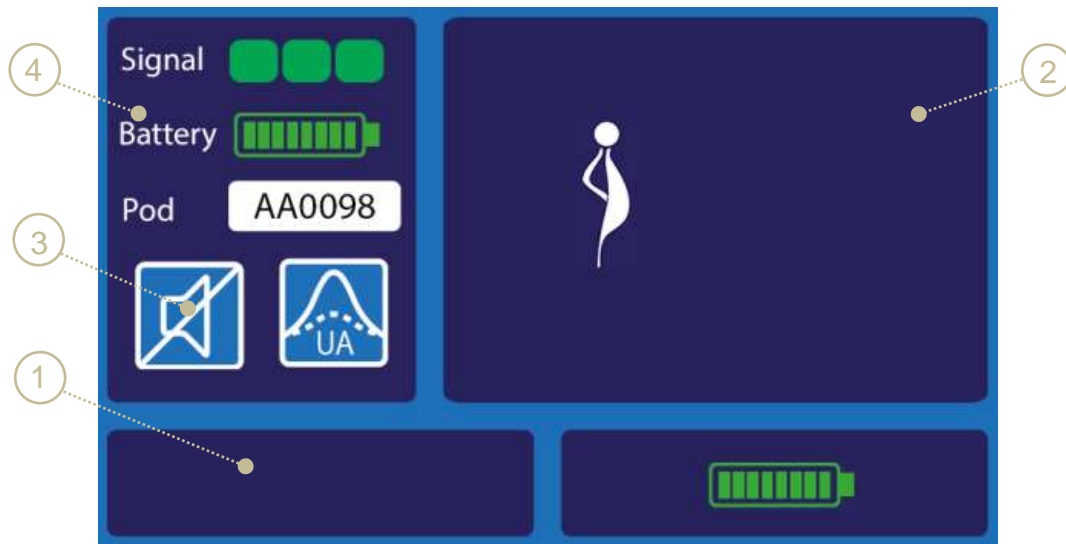
6.1 Introduction

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 AC power source. The Novii Interface follows a number of simple rules and conventions:

Warning and Alerts:	Are always displayed in ORANGE
Touch Icons:	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: Set-Up Icon 
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 Screen Format

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 Novii POD status when placed and removed from right/left Novii Interface charging bays below display.
- ② This area reserved for help/support information, alert messages and Novii MHR display when enabled
- ③ User controls: SETUP, HELP, TEST; (these three are not available during monitoring), SOUND (on/off) and UA SENSITIVITY (high/low); these two are only shown during monitoring. Touching these icons 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 5.1.2.

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:





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

6.4 Start Screen:

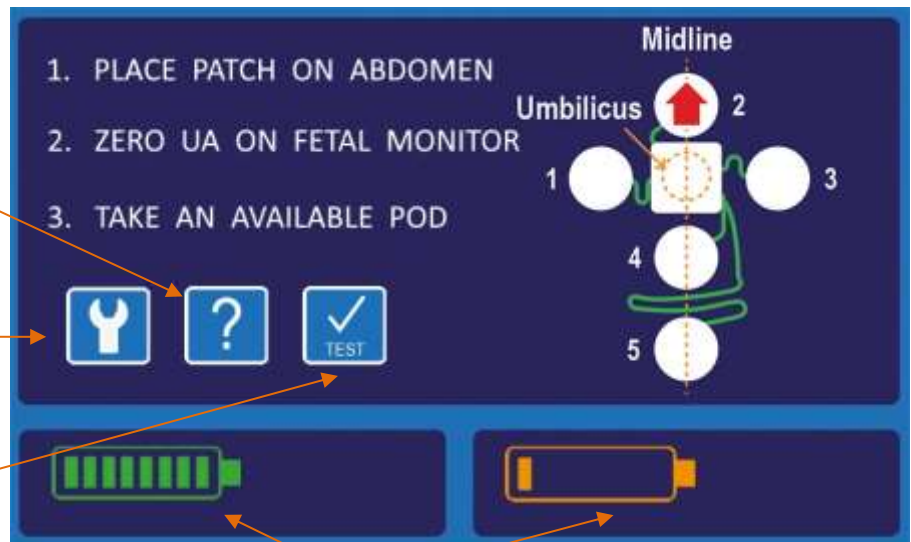
The Start Screen will be displayed if the following conditions are met:

- 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.

To check the connection to the monitor touch the TEST button, Section 5.8



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

6.5 To Start Monitoring

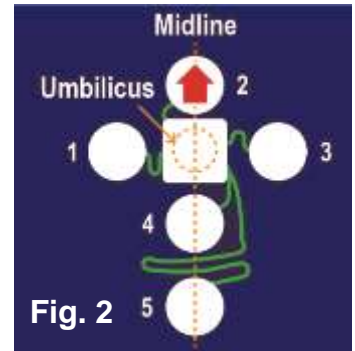
6.5.1 Instruction 1: Place Patch on Abdomen

Place the Novii Patch as described below or refer to the picture instructions on the Patch pouch. The Novii Patch can be left on the patient's skin for up to 48 hours. Do not place the Novii Patch on skin with any lesions.

1. Check the expiry date and confirm the Pouch has not been opened.
2. Wash any cream/oil/gel from abdomen and ensure the area is dry.

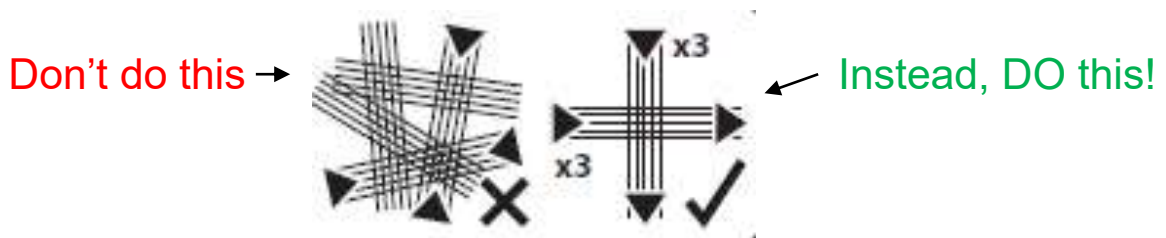
3. Remove the backing from the sticky central area of the Patch under the POD clip.

4. The POD clip should be placed on the midline over the center of the uterus. For most patients the umbilicus is a good anatomical reference. See below for women with a displaced umbilicus. Ensure the Patch is placed correctly as shown in Fig. 2, with the three central electrodes #2, 4 and 5, aligned along the patient's mid-line and the red arrow at top, pointing towards the head, then stick down.



5. Lift up one of the electrodes around the Novii POD clip (electrode #1, 2, 3 or 4); focus on the small area of the skin where the center of the electrode will be placed.

6. Using about 1 1/2cm strip of the 3M skin prep tape to exfoliate the skin in one direction only, with a deliberate but gentle stroke, lifting finger after each stroke; 3 strokes each in 2 perpendicular directions to create an X or cross pattern. The center of the electrode needs to match up with center of the skin prep area.



7. Once done, remove the electrode backing and stick down firmly, trying to avoid pressing the central gel area of electrode

8. Repeat for the remaining 3 electrodes around the clip

9. For the last remaining electrode attached to the long flexible cable, electrode #5, Fig 2:

a. Remove the electrode backing first ready to stick down

b. Prepare the skin (see 6 above) so that the center of the electrode will be positioned on the midline approximately 2.4"/6cm above the rim of the symphysis pubis

c. Stick down precisely over the center of prepared area

10. **In patients with a 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, following one of the following approaches:

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"/10-12cm below the fundus.

The electrode on the flexible cable, electrode #5, Fig. 2, should be placed on top of pannus approximating to the point 2.4"/6cm horizontally from the symphysis pubis looking vertically down. 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.

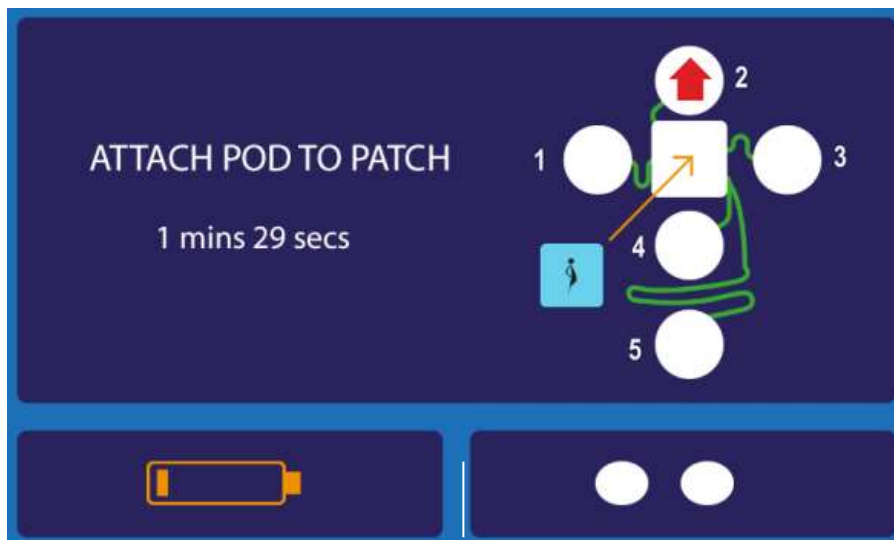



6.5.2 Instruction 1: Zero UA on Maternal/Fetal Monitor

Press the UA zero reference button on the Fetal Monitor.

6.5.3 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.






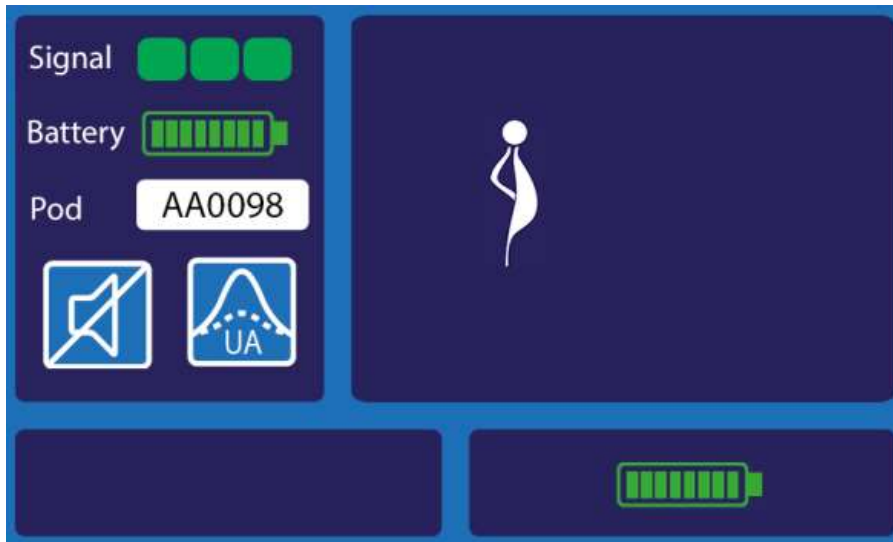
3. The battery charging icon on the Interface will be replaced by a 'busy' icon (1, 2, 3 white dots), indicating that the POD is preparing to commence monitoring. The busy icon will remain until the MHR is detected when it will stop.
4. The POD is attached to the Patch with the Monica symbol  facing up. Magnets in both the Patch **clip and POD ensure correct placement and, no force is required.**

5. 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.
6. If the 2nd POD is removed from the charging bay whilst the 1st POD is monitoring a patient, it will not turn on.
7. 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 shown below will be displayed:



CAUTION: If the POD is removed before the TOCO zero on the Maternal/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 icon on the Maternal/Fetal Monitor.

9. A diagram of the Patch is displayed, as shown above, to the right of the screen with a key to the symbols shown on each of the electrodes to the left. There are three electrode states which are:
 - a. If an orange circle  or red cross  is shown on an electrode corresponding to the electrode site, more skin preparation is required. Lift up the electrode, dry the skin and repeat skin-prep instructions above (Section 6.5.1). Just one orange circle or red cross will prevent the monitoring from starting. Following one re-preparation attempt and green checks not achieved the user can choose to bypass the skin/electrode check by touching the forward arrow icon. Accuracy of the fetal heart rate should not be affected, but fetal heart rate detection may be lower.
 - b. When there are 5 green check marks  the monitoring screen shown below will be automatically displayed (MHR Interface display disabled).





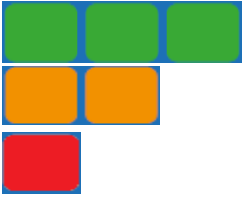
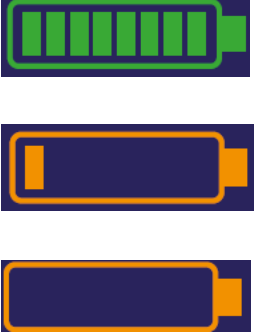

10. If you need to end the setup, or monitoring session, remove the POD from the Patch and return it to the charging bay on the Novii Interface that it came from.
11. The monitoring screen helps the user achieve the best signal quality, control the monitoring mode, view status alerts and if enabled display the MHR. The format of the display is shown above.
12. Once the POD identifies and extracts the MHR both blue lights will flash together every 2 seconds.
13. FHR, MHR and UA monitoring should commence within one minute, once the monitoring screen above is displayed.
14. FHR, MHR and UA data is collected wirelessly from the Novii POD and sent to the Novii Interface and then on to the Maternal/Fetal Monitor via the Novii Interface cables. The Maternal/Fetal Monitor acts as if a FECG scalp cable, MECG cable and a TOCO/IUPC transducer cable are connected and will display and print the FHR, MHR and UA. The user can swap from one or more of the Monica monitoring modalities to another method e.g. Monica UA, simply by removing the Novii UA interface plug and replacing with the TOCO UA transducer plug.











WARNING: This is not supported or recommended because the US FHR and TOCO/IUPC UA are not synchronized with the Novii FHR, MHR and UA, see Section 6.12. It is recommended that a note is made on the trace or patient notes. Please refer to the Maternal/Fetal Monitor manufactures instructions for more details on the display and printing options available.

15. If 'Display MHR on Interface' option is enabled in the settings even if the mECG cable supplied with the Novii Interface is connected to the Maternal/Fetal Monitor, a digital display of MHR will be shown on the Novii Interface.

6.6 Novii Interface Icons and Status Controls/Messages

Symbol	Description
	<p>Digital display of the maternal heart rate (MHR). Needs to be enabled in the settings, Section 5.3.2. Please note – MHR is not shown when alert or help messages are being shown</p>
	<p>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.</p>
	<p>Novii POD fECG signal quality indicator, is indicated by the color and number of squares in the indicator bar.</p> <ul style="list-style-type: none"> • x3 green squares indicates a good mECG/fECG, which should provide good FHR extraction. • x2 orange squares indicates that the FHR extraction may be compromised e.g. maternal movement, poor signal to noise, and the user should be cautious in accepting the FHR trace and seek confirmation. • x1 red square indicates there is no FHR extraction because the abdominal maternal/fetal ECG is poor, the noise levels are high or there is a fault condition preventing FHR extraction.
	<p>Novii Pod battery status, consisting of 8 charge levels.</p> <p>A green battery icon showing all 8 segments indicates the Novii Pod has a battery life of up to 11 hours.</p> <p>A orange battery icon with only one of eight segments showing indicates that the 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 6.7.2.</p> <p>A orange battery icon with no segments indicates an empty POD battery</p>
	<p>Uterine Activity is set high and this is the correct setting for active Labor. Touching the icon will change the mode to low sensitivity as shown below. The default start-up setting is high.</p>

	<p>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 icon will change the mode to high sensitivity as shown above, which is the default start-up setting.</p> <p>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 icon when this happens.</p>
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Symbol	Description
	<p>Sound alerts enabled. Factory default setting is OFF During an audio alert, touching the SOUND ON icon will disable audio.</p>
	<p>All sound alerts disabled except for Battery Low, Return POD to charging bay and Patch not genuine</p>
	<p>Touching this icon will initiate the SET UP options which allows system defaults to be changed and access to other functions. Please refer to Section 5.3.</p>
	<p>Touching this icon will send FHR, MHR and UA reference signal to the Maternal/Fetal Monitor. Please refer Section 5.8.</p>
	<p>Used as a next/exit instruction</p>
	<p>Used as back/cancel instruction</p>
	<p>Help icon: Provides advice where the User Manual can be located</p>

6.7 Novii Interface Monitoring alert/help messages

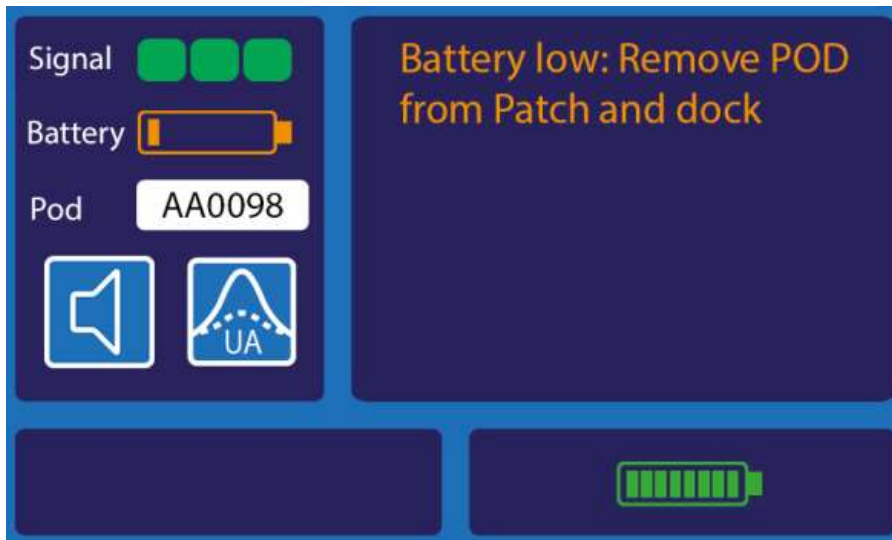
To help the user the Novii Interface provides a number of help/alert messages or displayed symbols during monitoring. The messages are dynamic. These alerts/help messages are shown below.

6.7.1 Patient out of Bluetooth range



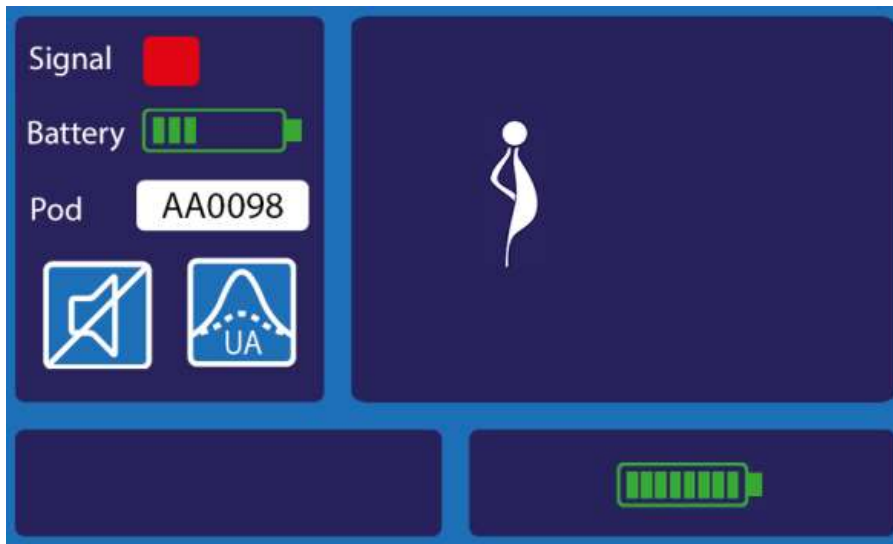
Patient is out of wireless range and the Interface cannot pick up the Bluetooth signal. Message will flash. Note loss of signal and battery information..

6.7.2 Low battery



Low battery: Battery low alert message is in orange and it will flash and audio alert will sound (if sound is off will show on until silenced) when only one segment (around 60 minutes is remaining)

6.7.3 Lost FHR



Unacceptable FHR quality (red):
No message is displayed when fECG signal quality is poor and the FHR **cannot** be extracted. No alert sound.

When using the Monica Novii Interface always use its signal quality indicator and not the quality indicator on the Maternal/Fetal Monitor, If signal quality turns red or orange:

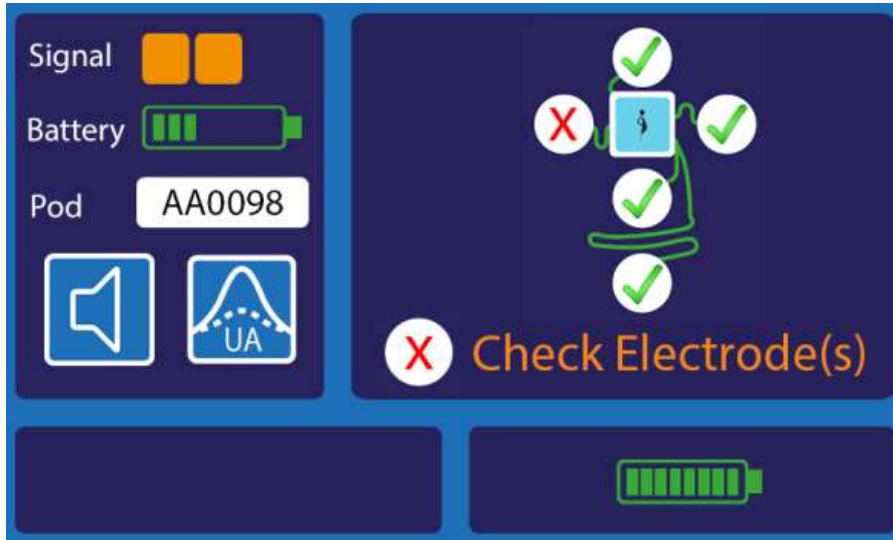
Refer to the FHR Gaps Troubleshooting Table, Section 15, in summary:

- a) Stop the patient ambulating
- b) Make the patient more comfortable so as to relax abdominal muscles to improve the signal to noise e.g. place a pillow to support the patient's back
- c) Change the patient position so as to change the conduction pathway between the fetal heart and abdomen, by moving the fetus in relation to the abdomen e.g. ask patient to lie on her left or right side
- d) If the abdomen is mobile, or patient position has changed use a rolled blanket/towel or pillow to support abdomen so as to keep the Patch centered on the uterus
- e) In a women with a pannus, remove the lower electrode and re-position on the midline 1-2"/3-5cm below the original placement or on the underside of the pannus just below the turn.
- f) You can use the US transducer to provide an FHR during a gap, as long as Novii has not been removed and you understand the impact of the 5mm time shift. The US FHR and TOCO/IUPC UA are not synchronized with the Novii FHR, MHR and UA, see Section 6.12.

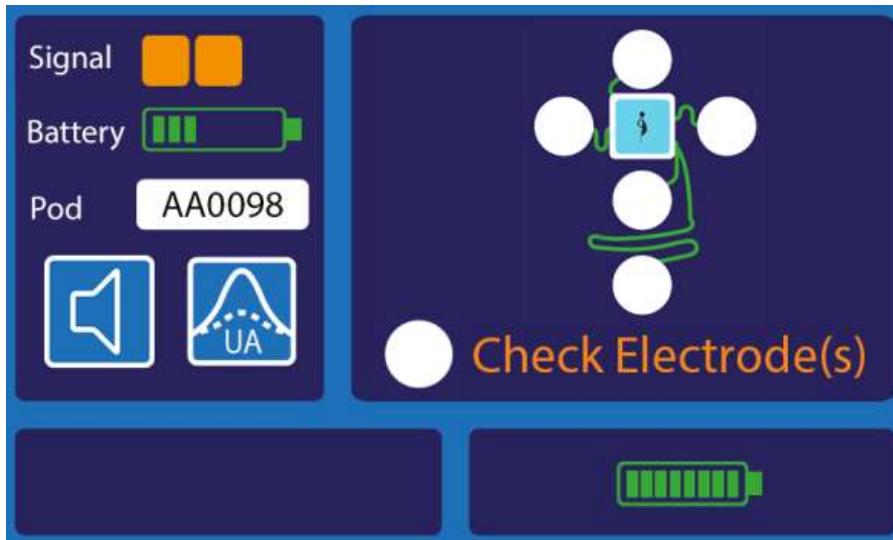
If the situation persists change to another modality e.g. FSE/US FHR or TOCO/IUPC UA and discontinue the use of Novii.

6.7.4 Electrode disconnection:

The Novii Interface will create a priority visual alert if an electrode has become disconnected.



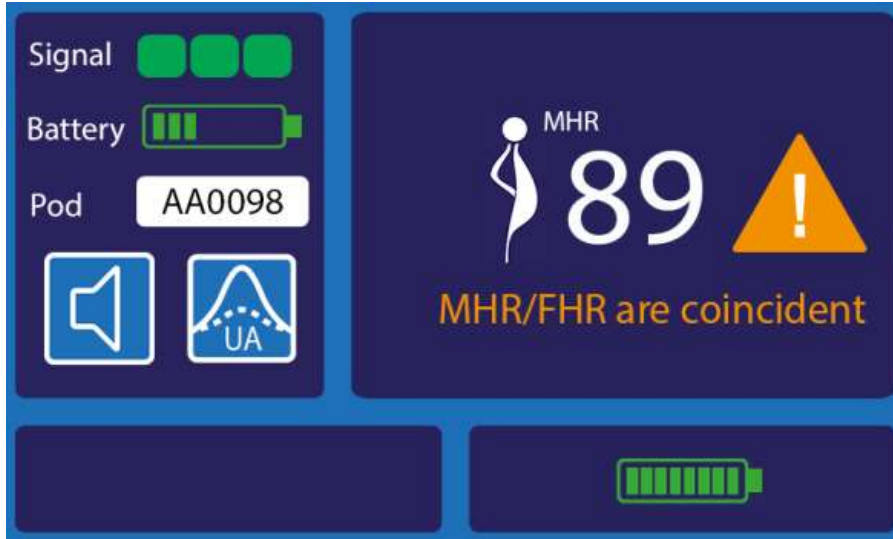
Electrode disconnection: The Novii Interface will create a priority visual alert if an electrode has become disconnected. If only one electrode has become disconnected then the display will indicate the electrode to check. Reattach the highlighted electrode to the skin, if required micropore tape can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



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.

6.7.5 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 will be silenced for 60 minutes by touching the 'SOUND IS ON' icon. The alert will disappear if the coincidence disappears.

6.8 How to continue monitoring when the Low Battery alert is activated

When the battery is low the monitoring session must first be ended before taking a charged POD to connect to the Patch to continue the monitoring session.

To end a monitoring session the POD must be removed from the Patch and placed in an empty charging bay on the Interface.

If possible the POD should be cleaned before it is returned to Interface, preferably as soon as it is removed from Patch

6.9 Placing/Removing PODs from the Novii Interface Charging Wells

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.

When a POD is monitoring a patient 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.

The color of the battery icon indicates if the docked POD has sufficient charge to start a monitoring session. **Green** means yes, **orange** means **no**. If a POD is removed from the charging bay showing an **orange** battery shaped 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 240 mins of monitoring.

There are 6 possible status messages/displays for each charging bay – shown below for left bay:

1. POD in charging bay with low charge <4 hrs i.e. battery icon is orange – POD will not switch on if removed.



2. POD in charging bay is not recognized e.g. wrong firmware or communication fault. The interface will automatically try to initialize communication again, but if message remains contact your local distributor / GE sales representative to arrange service request.



3. POD in charging bay has a battery fault, contact your local distributor / GE sales representative to arrange service request.



4. POD in charging bay is 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



6.10 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 not returned

6.11 Turning Off the Interface

There is no power button on the Novii Interface, removing the power supply will turn the Interface off. Once the PODs are fully charged, the Interface can be turned off. If the Interface is 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.

6.12 Novii FHR, MHR, UA synchronization & mixed modality monitoring

The Novii UA, FHR and MHR traces are all synchronized, but shifted in relation to real-time events by around 5mm (10 seconds) 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 (5mm on the tracing) in the Novii UA trace with respect to the US/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 5 mm to 3 mm (6 seconds). Early decelerations may appear as 'subtle' late decelerations. This could lead to an unnecessary intervention.



WARNING: DO NOT USE THE NOVII MHR TO MONITOR THE PATIENTS 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. If the GE Corometrics 259 Series Maternal/Fetal Monitor display 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.

6.13 The two blue LED lights on the POD

These are used to indicate the status of the POD:

1. Charging: Upper LED (head of pregnant Monica i, flashes slowly when charging and both LEDs will turn off **when fully charged**

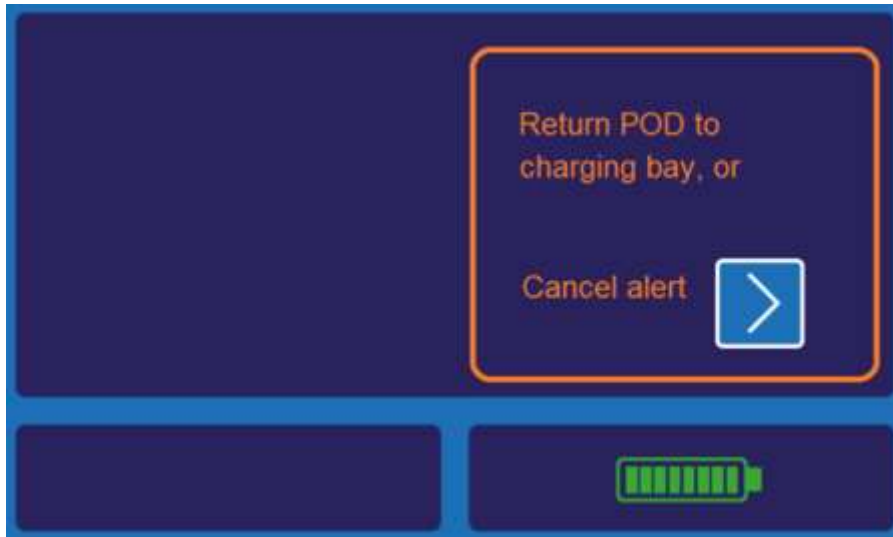


2. POD is 'on/active' when removed from charging bay: if and only if LEDs flash alternately on/off
3. Connected to Patch: Both LEDs are on continuously when connected to patch and waiting for monitoring to start
4. Monitoring/MHR detected: Both LEDs flash slowly together
5. If both LEDs are off when removed from Interface, POD is off and should be returned to Interface for storage and charging.
6. If both LEDs are off when POD is on the Interface, POD is fully charged.

Section 7 - Interface Visual Alerts

7.1 Return POD to charging bay visual alert

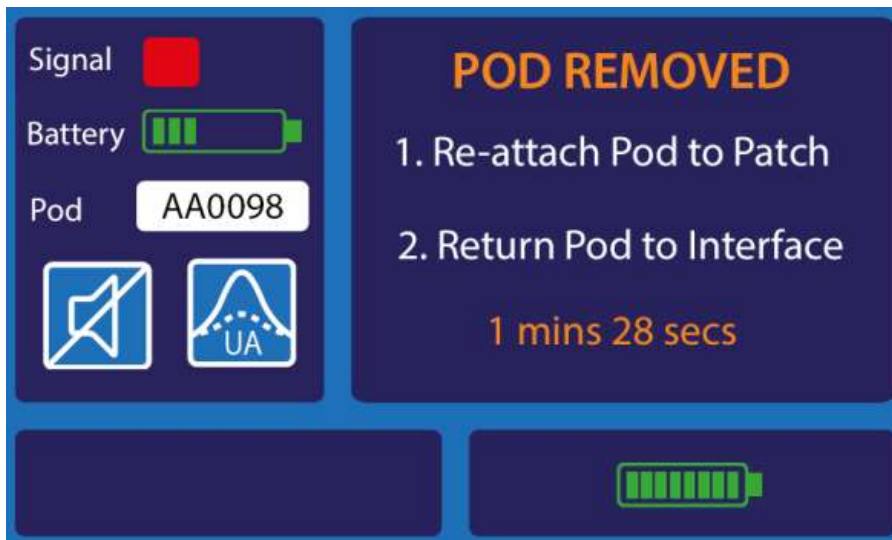
If a POD is removed from a charging bay when no monitoring session is in progress and POD has sufficient charge there will be an audio and visual alert after 2 mins if it has not been placed in a Patch or re-docked. The following alert message will be displayed:



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.

7.2 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.



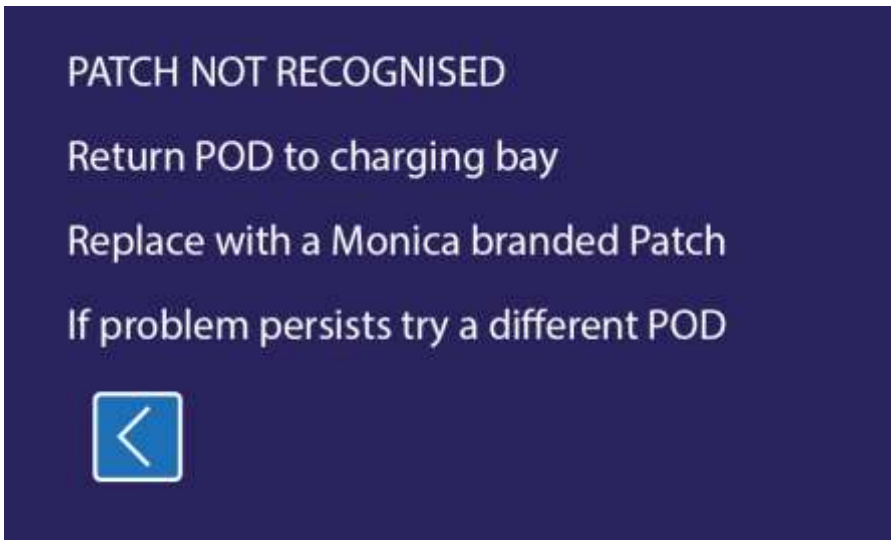
If the POD has not been re-attached to the Patch or placed in charging bay at the end of the 2 minutes countdown, the monitoring session ends. The POD switches off and the Interface will return to the Start Screen. The return POD to charging bay audio/visual alert, Section 7.1, will appear after 2 minutes if the Pod is not returned to a charging bay.

7.3 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, Section 7.1, will appear.

7.4 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 7.1)

7.5 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:

Signal

Battery

Pod **AA0098**

PATCH NOT GENUINE

1. Return Pod to Interface
2. Replace with a Monica branded Patch



Section 8 - Help icon



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



Section 9 - Cleaning

9.1 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 10 - 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)
107-PT-002	Novii Interface Power Cable (UK,EU,AU)
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)


10.1 Interface Cables

Input	Description	Part #	Plug Color
FECG	Monica Interface CTG Cable - GE Corometrics DECG round grey connector	105-PT-102	
UA	Monica Interface CTG Cable - GE Corometrics UA round white connector	105-PT-106	
MECG	Monica Interface CTG Cable - GE Corometrics MECG round green connector (requires GE 'Y' adaptor cable, part # 1442AA0)	105-PT-104	

Section 11 - Patch 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	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	
Dimensions	190mm x 155mm x 12mm (including clip)	
IP rating	IP57 (when attached to patient) only when mated to the Novii Pod, otherwise IPX0	
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	
Storage Temperature	+10°C to +30°C	

Section 12 - Interface 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-001
	Software revision level	Select 'About' in the Set-Up menu of the Interface to display software version, see Section 5.3.4
	Mode of operation	Continuous use
Data I/O	Bluetooth Wireless input	Bluetooth V2.1 + EDR Class 1.5, from Novii Interface.
	Protocol	Modified Series 50 protocol.
	Range	30m (line of sight)
	Output	Real-time to Maternal/Fetal Monitor via Interface cables, comprising: <ul style="list-style-type: none"> • Direct fetal ECG pulse (for FHR) • MECCG 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
	Input	100V~ to 240V~, 50Hz to 60Hz, 400mA
	Output	5V DC / 3000mA
	Dimensions	152 mm x 137 mm x 150 mm
	Weight	688g
IP rating	IPX0	
Accessories	Interface Connection Cables for GE Corometrics 259 Series Maternal/Fetal Monitor: FHR (105-PT-102); MHR (105-PT-104) UA (105-PT-106) Novii Interface Power Cable (107-PT-002-US)	
Operating Temp	+10 deg C to +30 deg C	
Storage Temp	+10 deg C to +30 deg C	

Section 13 - 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 5.3.4)
	Mode of operation	Real-Time / Continuous use
		<p>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.</p> <p><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</p>
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 2 and Figure 3 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 4 and Figure 5 below

UA	Range	0-500 microvolts
	Resolution	0-255 levels representing 100% of full scale Produced 4 time per second from a rolling 2s average
	Accuracy	98% percent agreement (95% confidence limit: 96.6%), 86.05% Positive Percent Agreement (95% confidence limit 81.9%)
Power	Battery	Rechargeable lithium polymer 3.7V 750mAh 80% capacity after 475 charges cycles
	Battery Life	Up to 11 hours battery life
	Battery Charging	Contactless charging with the Novii Interface (107-PT-001)
Dimensions	45mm x 39mm x 20mm (including contact pins)	
Weight	40g	
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
	Transport and storage	+10°C to +30°C
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)	

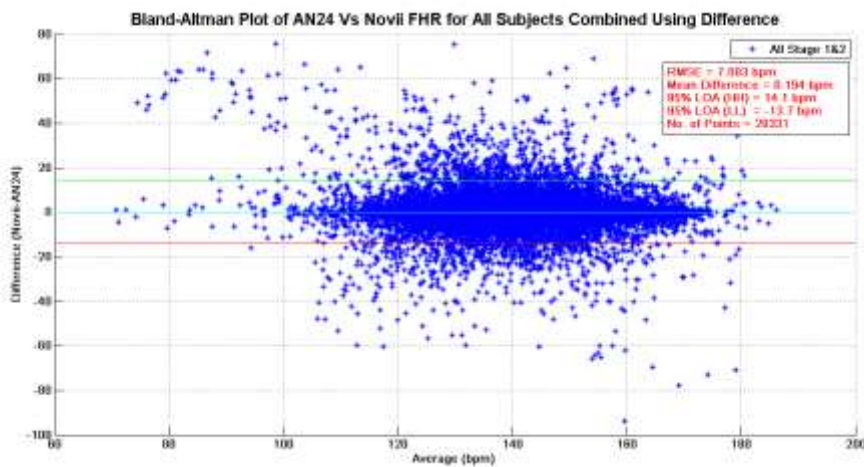


Figure 2: FHR Bland Altman Novii / Predicate device (difference)

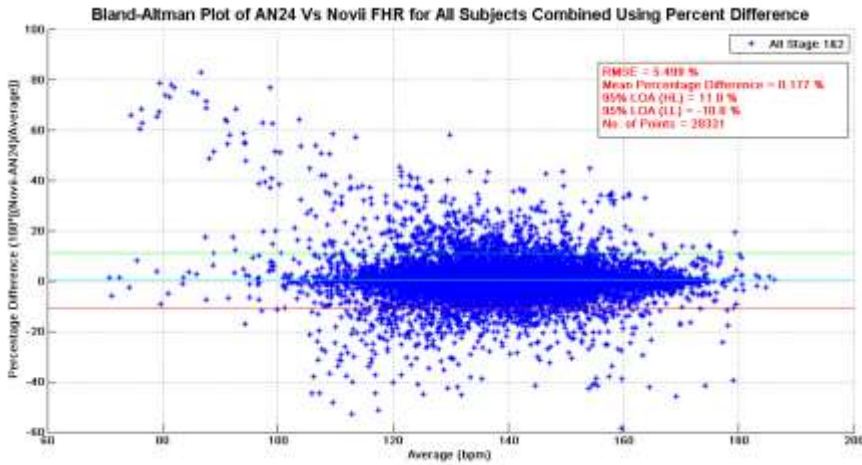


Figure 3: FHR Bland Altman Novii / Predicate device (percent difference)

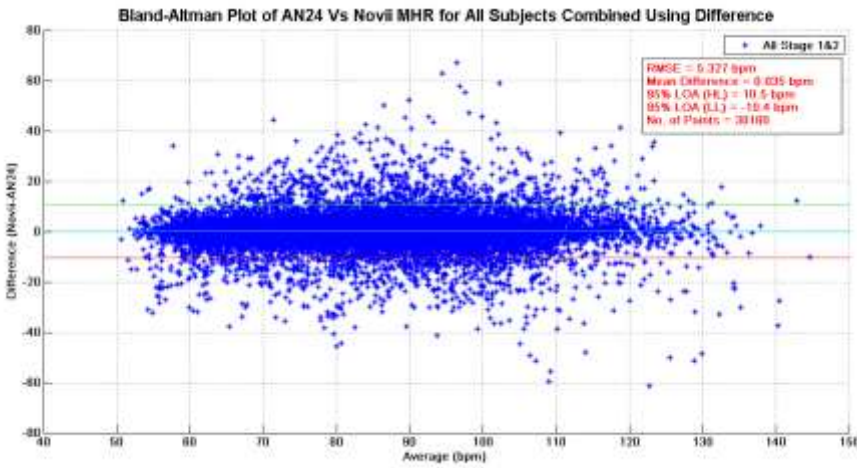


Figure 4: MHR Bland Altman Novii / Predicate device (difference)

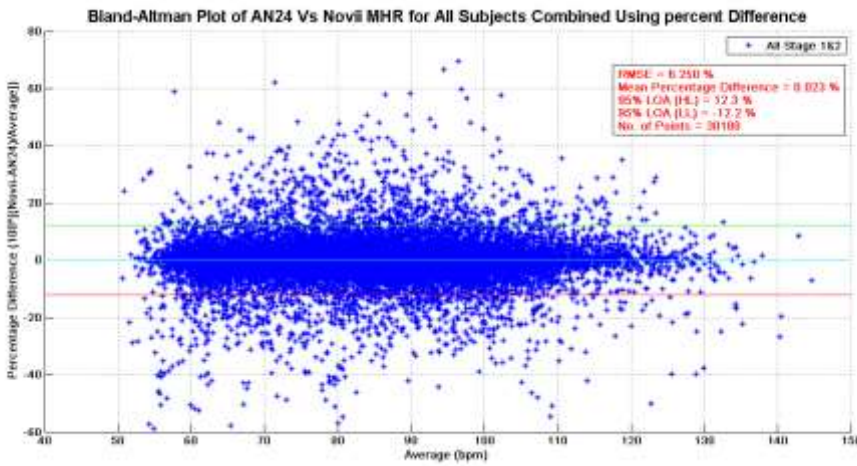


Figure 5: MHR Bland Altman Novii / Predicate device (difference)

Section 14 - Fault Finding

For further support visit www.monicahealthcare.com/support

Novii Interface Troubleshooting Table			
ID	Symptom Description	Possible Causes	Actions and Solutions
S1	Power supply to Novii interface is unplugged or power cut occurs during monitoring	Should the power supply to the Novii interface be disconnected, switched off, or fail due to a power cut, 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
S2	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.
		Novii Interface failure	<i>Confirm that the Novii POD(s) are correctly positioned in charging bays. Check if the POD blue light is flashing or on continuously and make a note of the status of the POD blue lights; if there is no display, replace Novii Interface.</i>
S3	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, replace the Novii Interface.

Novii Interface Troubleshooting Table continued			
ID	Symptom Description	Possible Causes	Actions and Solutions
S4	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, vacated by the monitoring POD, 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 being displayed on the Interface . The blue light on the top of the POD should be flashing or on continuously and the battery status should be displayed on the Interface above the POD. If none of this happens, replace the Novii POD.
		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 replace the Novii POD
S5	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.

Novii POD Troubleshooting Table			
ID	Symptom Description	Possible Causes	Actions and Solutions
S6	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 on patch pouch and in IFU.
		Patch is out of date or electrodes have dried out	<i>Confirm</i> 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 exfoliation finger pad or skin-prep tape is used.	Confirm the skin-prep exfoliation finger pad (provided with product) or 3M skin-prep tape are used.
		POD has not seated correctly on Patch clip	Check that the POD is correctly seated in the Patch clip by removing it and then clipping it back on and pressing it firmly down. When the POD is removed, check the patch connection gold pins on the bottom of the POD for any evident damage. Replace POD if necessary.
		Dirt/grease/gel/water contaminating POD/Patch connection	Look for dirt and grease/gel/water in the Patch plastic clip/connector or on the POD pins. If necessary, clean the inside of the Patch connector and wipe the pins on the back of the POD using an alcohol wipe and dry thoroughly.
		Faulty POD	Remove POD and place in charging bay. Take other POD 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

Maternal/Fetal Monitoring Troubleshooting Table			
ID	Symptom Description	Possible Causes	Actions and Solutions
S8	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 DECG port Novii UA connects to the TOCO port Novii MHR connects to the MECCG 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

Maternal/Fetal Monitoring Troubleshooting Table continued			
ID	Symptom Description	Possible Causes	Actions and Solutions
S8	FHR/UA or MHR data not being displayed by Maternal/Fetal Monitor	POD problems	<p>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.</p>
			<p>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.</p>
S9	FHR quality on the Maternal/Fetal Monitor trace is poor in some patients	Unfortunately this can happen in some patients especially during stage 2.	<p>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.</p>

Section 15 - FHR Gaps Troubleshooting Table

For further support visit www.monicahealthcare.com/support

ID	Possible Cause	Action and Solution ¹
1	During the 'Electrode Check' did you bypass a red X or an orange O on the top or bottom midline electrode? This could result in FHR gapping.	<ul style="list-style-type: none"> Restart the monitoring session to identify which electrode has O or X Peel the electrode back, remove excess gel from skin. Wait until skin is dry then abrade skin and reapply electrode.
2	In patients without a pannus the location of mid-line lower electrode must be vertically above the point 2.4"/6cm horizontally above the symphysis pubis	<ul style="list-style-type: none"> Confirm the placement of the midline lower electrode and re-position
3	Electrode is fully or partially detached from abdomen especially if the gap occurs after a shower, clinical procedure or position change e.g. sitting on chair	<ul style="list-style-type: none"> Confirm that all electrodes are attached to the skin and re-apply if necessary. The Interface should alarm if an electrode comes detached, but partial detachment or lifting e.g. skin folding when bending forward do occur. If necessary use a strip of micropore tape to prevent electrode lifting or detachment.
4	Lost FHR, MHR and UA when patient has left room	<ul style="list-style-type: none"> Check message on Interface and ask patient to return to the room.
5	Lost FHR, MHR and UA when patient is in room	<ul style="list-style-type: none"> Interface switched off or power supply to Interface faulty. Bluetooth pairing with POD is lost. Re-start Interface, remove POD from Patch, dock and start new monitoring episode. Interface does not have a battery back-up
6	Mid-line upper and lower electrodes have been placed over a skin lesion, skin fold, stretch mark, pronounced linea nigra	<ul style="list-style-type: none"> Re-position Patch to avoid the skin problem
7	The mid-line electrode below Patch clip is over the umbilicus, a skin fold or lesion and is not seated correctly	<ul style="list-style-type: none"> Re-position Patch to avoid the skin problem
8	It is important to wait 10-15 minutes after starting Novii before commencing ambulation to allow the electrode gel to penetrate the skin	<ul style="list-style-type: none"> Return patient to bed and review causes 1 and 2 above. The patient should not be encouraged to ambulate unless the FHR trace is good and the signal indicator on the Novii Interface shows 3 green squares
9	The patient is ambulating	<ul style="list-style-type: none"> Return patient to bed; review causes 1, 2 & 3 above

ID	Possible Cause continued	Action and Solution ¹
10	Patient position/posture has changed	<ul style="list-style-type: none"> • If the patient is in bed, the simple use of a pillow behind their back to make them more comfortable/relaxed can improve FHR following • If possible return patient to a position where Novii worked well • If possible turn/encourage patient to lie on left • Review causes 1 and 2 • Has the patient a 'mobile' abdomen or pannus? If yes has the Patch position changed with respect to the uterus? If you suspect this has happened consider supporting the abdomen with a pillow, rolled blanket or support belt to try and re-position the abdomen so the Patch is over the uterus
11	In a high BMI patient with a pannus that has displaced the umbilicus and or covers the symphysis pubis when supine or semi-supine the lower midline electrode is not optimally placed ²	<ul style="list-style-type: none"> • Remove the lower mid-line electrode and place it lower on the abdomen positioned, if possible, to just below the point where the surface curves back on itself ensuring that the electrode is not folded
12	FHR/MHR/UA artefacts and gaps	<ul style="list-style-type: none"> • Check Y connector (replace it), or swap POD (look for dirt or liquid ingress on the POD connector and/or in Patch clip). Place Interface away from potentially interfering devices like bar code reader and Infusion pump.
13	Monitoring stops after a POD swap	<ul style="list-style-type: none"> • 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
14	None of the above	<ul style="list-style-type: none"> • 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 than 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 16 - Allergic Reaction to Patch

16.1 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.

16.2 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.

16.3 Treatment

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

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

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

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



Section 17 - Servicing

Servicing of the Novii Interface must be carried out by Monica Healthcare authorized personnel. Further information is available from your local GE representative or contact Monica Healthcare below:

Company: Monica Healthcare Limited

Address: Unit 8, Interchange 25 Business Park

Bostocks Lane

Nottingham, NG10 5QG, UK

Phone: (+44) 115 949 6960

E-Mail: novii.info@ge.com



WARNING: No Modification of this equipment is allowed.



Section 18 - Maintenance & Fault Reporting

18.1 Maintenance

There is no recommended maintenance schedule other than visual inspection for damage. Please refer to the Troubleshooting Tables, Section 14 and 15 and in the event of device failure, please contact your local GE service representative.

18.2 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.

18.3 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.

18.4 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 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 Section 17 -

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



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