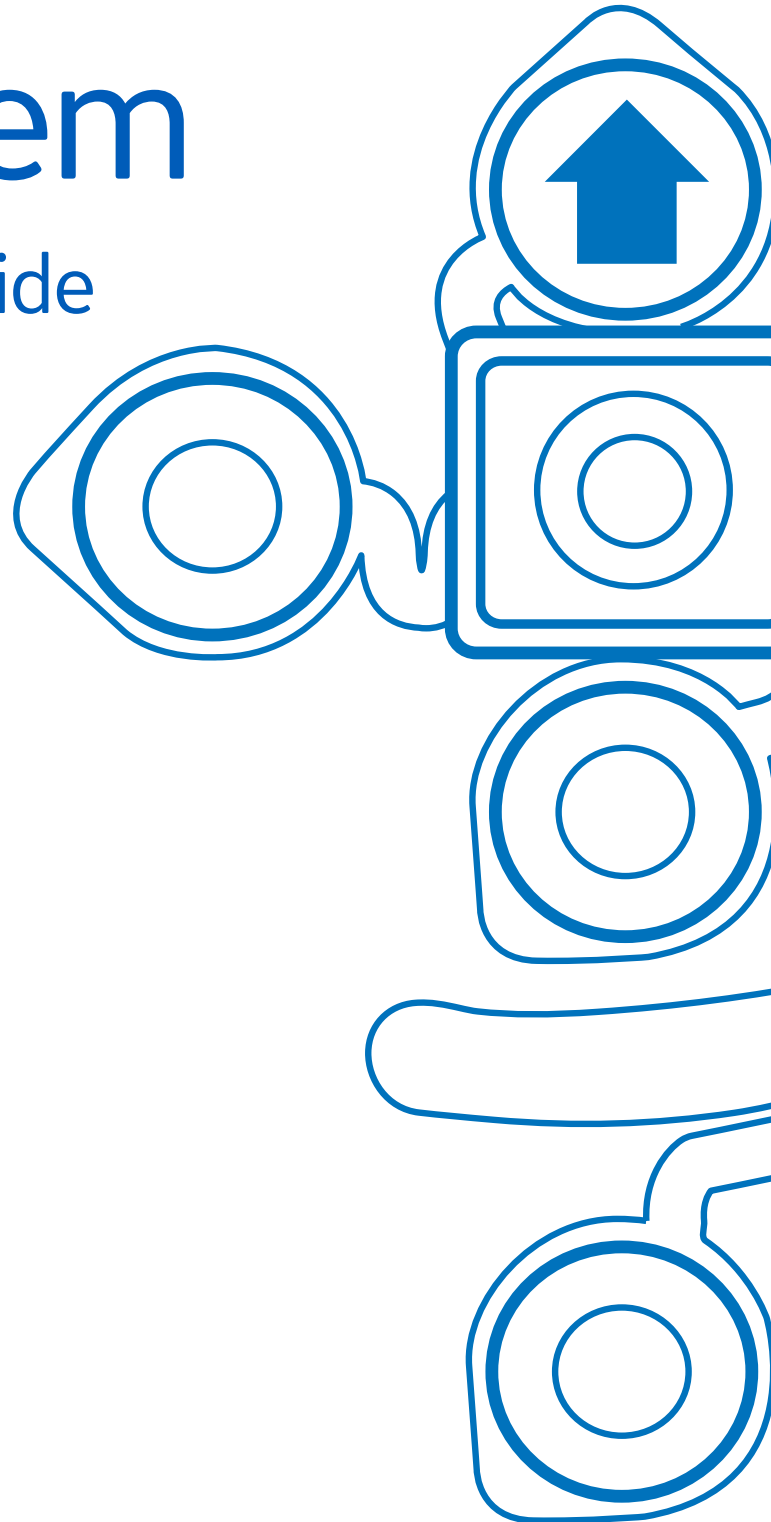




Novii™ Wireless Patch System

Clinical Application Guide





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Introduction

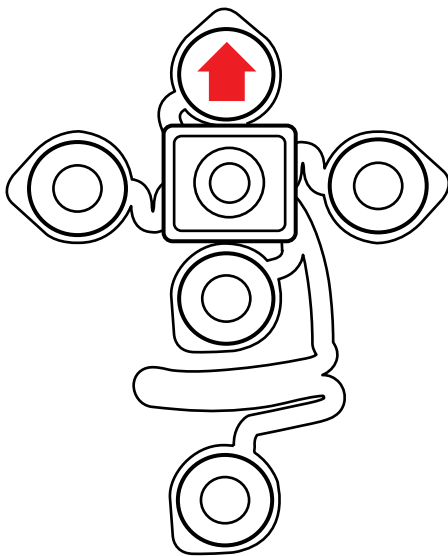
GE Healthcare aims to provide you with the best training available and support you in the clinical use of your Monica Novii Wireless Patch System. This application guide is designed to provide an overview of Novii as well as provide clinical guidelines of how and when to use Novii. This application guide is not a substitute for clinical on-site training offered by GE Healthcare and its representatives. Additional training resources are available at

www.gehealthcare.com/noviitraining

Novii Description

The Monica Novii Pod Fetal-Maternal Monitor is designed as an ambulatory device for the monitoring of a pregnant mother. The monitor enables the abdominal electrophysiological signal to be picked up from three different positions on the maternal abdomen using the 5 electrodes on the Monica Novii Patch. The monitor filters the abdominal signals, converts the abdominal electrophysiological data into a digital format and then processes it in real time to extract the fetal heart rate, maternal heart rate and uterine activity. The result of the processing is transmitted via the Bluetooth connection to the Monica Novii CTG Interface device that is a Monica Approved accessory to the Monica Novii Pod.

Novii Patch



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 CTG Fetal monitor. The Novii Interface enables signals collected by the Novii Pod to be printed and displayed on a CTG Fetal Monitor and sent on to a central network, if connected. The Novii Pod maternal-fetal monitor and its accessories are intended for use by healthcare professionals in a clinical setting

Novii Interface and Pods



Contraindications

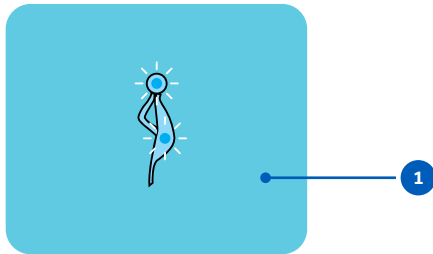
The Novii should not be used with antepartum, preterm (≤ 36 completed weeks) and multiple pregnancies. In addition, the Novii should not be used with equipment that introduces electrical energy in to the body i.e., Transcutaneous Electrical Nerve Stimulation (TENS), cardiac pacemakers, cardiac defibrillators, MRI scanners, CT scanners and diathermy/electro surgery equipment. Recommend only using Novii with monitoring systems that have been certified for compatibility for use with Novii by GE Healthcare.

Expectations

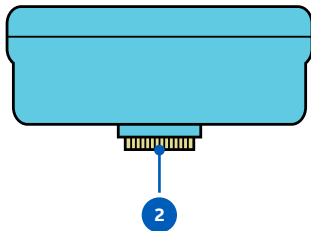
Novii provides advanced monitoring for the majority of laboring women, however like other forms of fetal monitoring, in a small number of women, there may be the need to switch to a different monitoring method if the FHR signal quality is indicated as poor or bad. Novii enables in room ambulation and potentially beyond – up to 100ft/30m. The actual distance of ambulation may vary. Most women are able to walk with good FHR signal quality, while others may find they will need to modify their activity or position to allow Novii to work best for them.

Novii Device Components

Novii Pod



Side view



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

Novii Pod Features

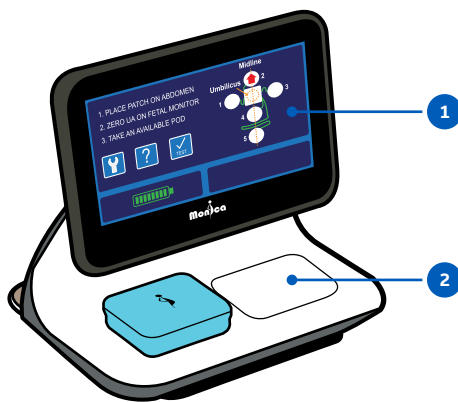
- Up to 11 hours battery life*
- 2 Hour charge time
- Monitors FHR, MHR & UA
- Communicates signals to Novii Interface via Bluetooth
- Bluetooth wireless range 100 ft / 30 m
- Attached by magnets to Novii Interface charging bay or Patch** while in use
- Waterproof only when Pod is attached to Patch

1. Two blue LED lights located on the Novii Pod indicate:

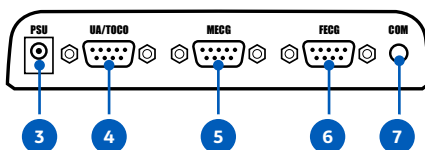
- Charging: Single LED flashes slowly
- Fully Charged: Single LED on constant, then turns off in stand-by mode
- Pod On/Active: Both LEDs flash, alternately
- Connected to Patch: Both LEDs on constant
- Monitoring: Both LEDs flash slowly in unison

2. Connection pins (avoid contact to prevent damage or debris)

Novii Interface



Rear panel view



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

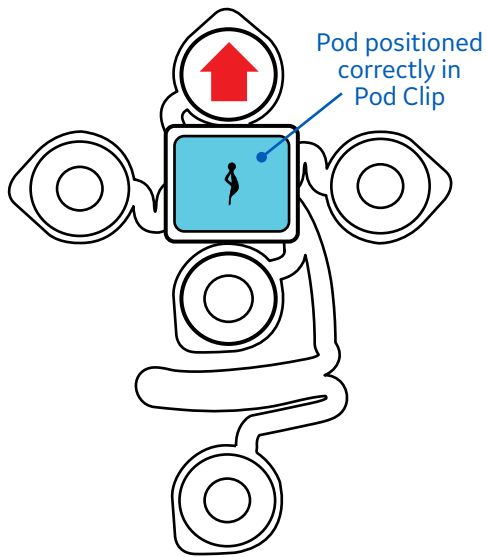
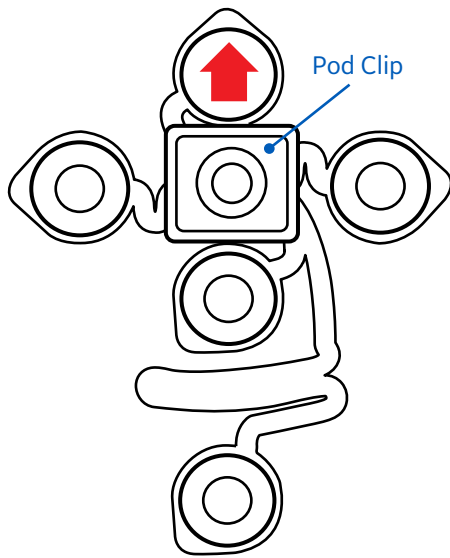
Interface Features

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

*Varies per use depending on Bluetooth range

**Disclaimer: Novii works well in shower with splashing, but Bluetooth signal cannot transmit and all signals will be lost if Pod is submerged under water in a tub.

Novii Patch

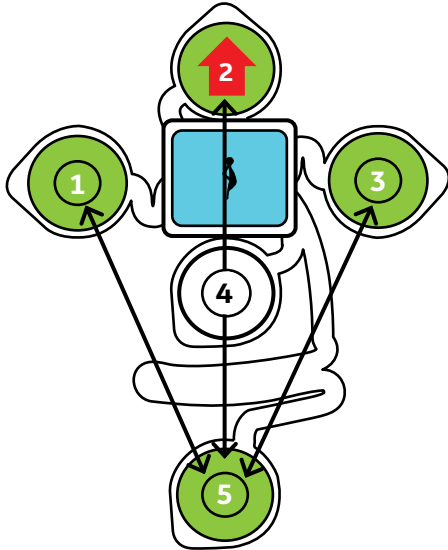


The Novii Patch is an accessory to the Novii Pod and contains the surface electrodes that attach to the maternal abdomen. The Novii Pod connects directly to the Novii Patch via the Pod Clip while in use.

Patch Features

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

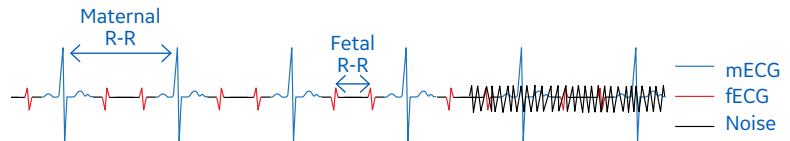
ECG Channels (FHR/MHR)



How Novii Works

Novii electrodes work in pairs to create channels that detect the Fetal ECG, Maternal ECG and electromyography (EMG) signals from the uterine muscle.

- Electrode 4 is the ground electrode and important for reducing electrical noise from the body
- Electrode 5 is most critical for FHR
- Electrode 3 is most critical for UA

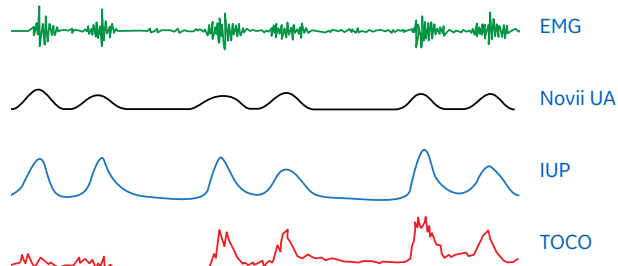
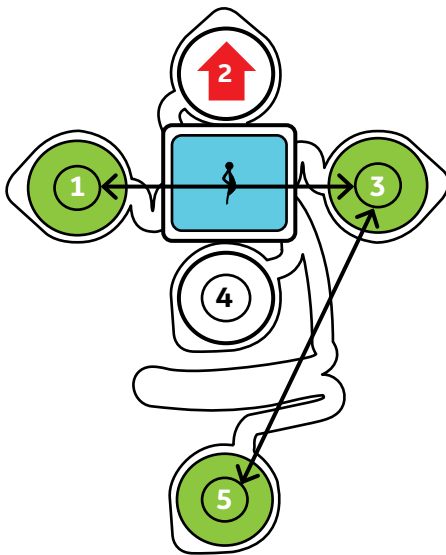


Minimal Confusion – the mECG and fECG are simultaneously monitored and their size and shape make them distinctly different allowing them to be easily separated to avoid confusion.

Accuracy – Novii uses the R-R intervals of the ECG waveform to calculate the FHR and MHR.

Noise – when electrophysiological noise from the body or electrical noise from the environment becomes too big it will hide the very small fECG signal from being detected, and the FHR will be lost. Techniques to minimize electrical noise will improve FHR detection, see FHR Troubleshooting Page 17.

EMG Channels (UA)



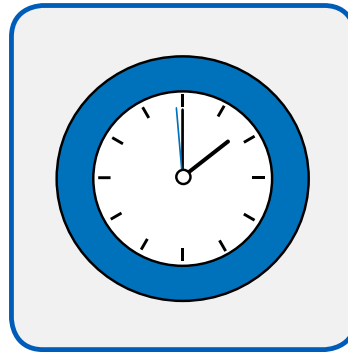
Novii processes the EMG signals from the myometrium and converts them in to the typical bell shaped curve contractions. Novii is able to distinguish between smooth and striated muscle activity, therefore pushing, coughing, vomiting, and fetal kicks will not be reflected on Novii UA.

During labor, Novii accurately and reliably displays contraction frequency and timing of contraction nadir. Novii does not display a measurable contraction strength or resting tone. Contraction duration may differ slightly as compared to TOCO & IUPC. Use uterine palpation to confirm, as per standard practice with other UA monitoring devices.

Applying the Novii Patch

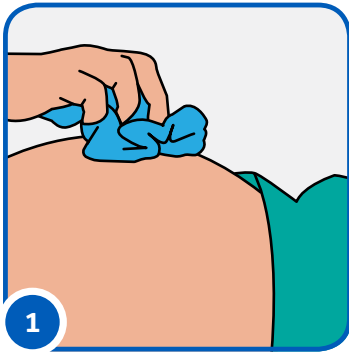


The Novii Patch is Latex Free, however ask if the patient has any other allergies or skin sensitivities that might prevent the Patch from being used.



Place the Novii Patch before connecting Novii Interface to fetal monitor, **to allow gel time to absorb in to the skin.**

Before Placing Novii Patch

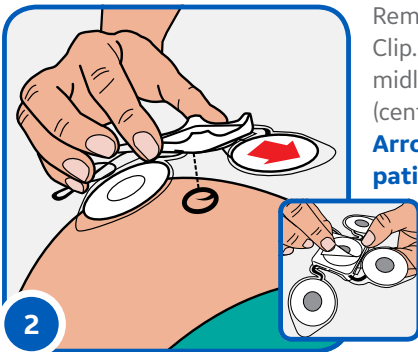


Wash the area where the Patch will be placed with mild soapy water, rinse and ensure the area is dry. Do not use hospital grade anti-microbial soaps which may contribute to adverse skin reactions.

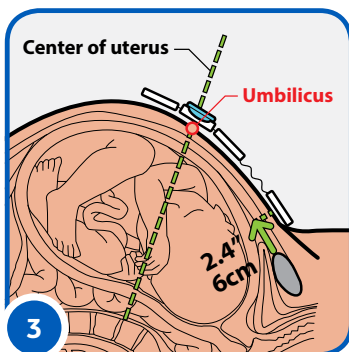


Check Patch expiration date. If Patch is opened but not used, may reseal, date and use within 30 days.

Standard Patch Placement

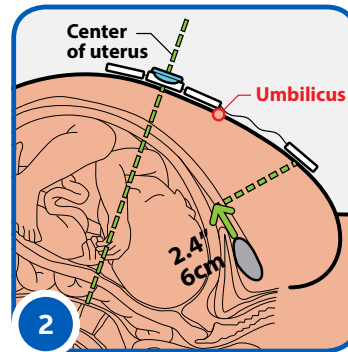


Remove backing from Pod Clip. Place the Pod Clip on the midline over the umbilicus (center of the uterus). **Arrow pointing towards patient's head.**

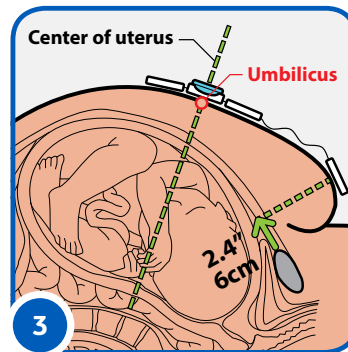


Center of bottom electrode is placed 2.4" / 6cm above (towards the patient's head), the top rim of pubic bone. Typically, this is just above the hairline.

OR Patients with Displaced Umbilicus and/or Pannus

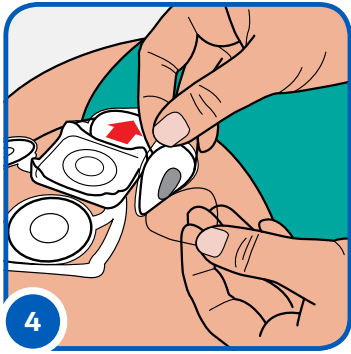


Displaced Umbilicus – **DO NOT** place Pod Clip on umbilicus. Find center of the uterus and place Pod Clip, i.e. midway between fundus and pubic bone. A general guideline is that the top edge of top electrode should be 4"/10cm below the top of the fundus.

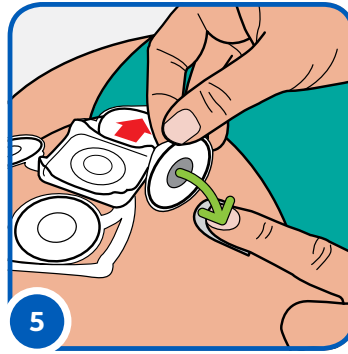


If there is a large Pannus covering the pubic area, place bottom electrode **on top of pannus** approximating to the point 2.4" / 6cm above the estimated pubic bone.

Applying Electrodes/Skin Preparation



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



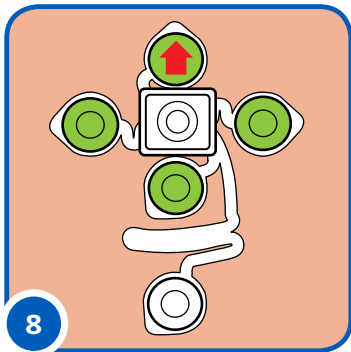
Focusing on the area of skin below black foam, use skin prep tape to exfoliate (remove dead skin cells). Use one piece of 1" / 2cm skin prep tape for every 2-3 electrodes.



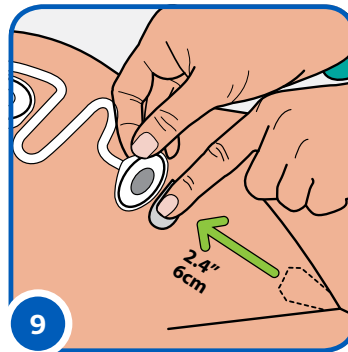
Exfoliation technique: using **controlled gentle pressure** do 3x vertical and 3x horizontal strokes (creating a '+' shape). Keep exfoliation area to a minimum. (Hold skin taut if required).



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



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



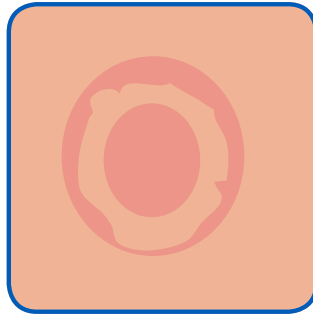
Repeat steps 4-7 for bottom electrode, ensuring center of electrode placement is 2.4" / 6cm above top rim of pubic bone. (See pictures in steps 2 and 3).

Avoiding Skin Redness/Reaction

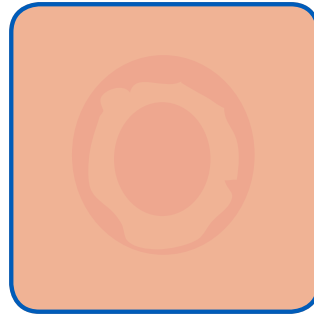
Application of electrodes on patients may result in some skin irritation or redness upon removal, but usually subsides within 24 hours and will leave no permanent marks.



Correct removal will reduce skin irritation: Gently peel electrode back slowly at a low profile (<math><45^\circ</math>), while supporting the skin.



10 minutes after Patch removal



6 hours after Patch removal



24 hours after Patch removal

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

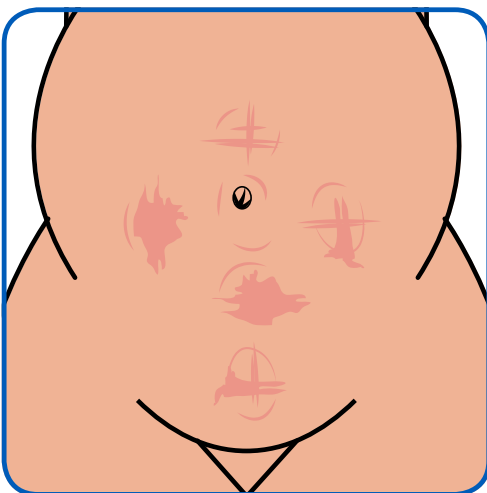
Patient may report a tingling sensation or itching when the Patch is first applied, but this should subside in 15-30 minutes. If this worsens, assess for an allergic reaction by lifting an electrode. The electrode directly below the Patch Clip will have minimal interference with monitoring if lifted. Remove Patch immediately if allergic reaction is noted. Avoid use of isopropyl alcohol or strong soaps on the skin, which dries out the patient's skin and may increase susceptibility to reactions.

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

Do not leave the Patch on for >48 hours.

Redness caused by over preparation


Good skin preparation when first applying the patch will help to avoid skin reactions due to excess exfoliation.



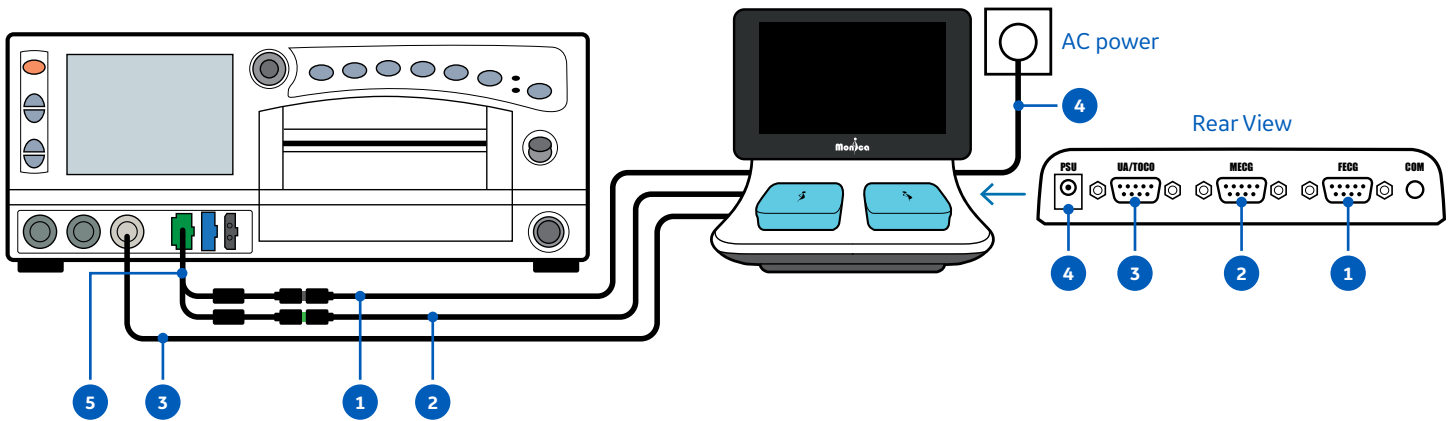
Do:

- Apply controlled gentle pressure during exfoliation
- Keep exfoliated area to a minimum
- Ensure black foam area of electrode is placed accurately over center of exfoliated skin, which avoids having to repeat preparation

Do NOT:

- Apply excess pressure during exfoliation
- Apply too little pressure during exfoliation as it will lead to needing to prepare the skin again
- Prepare the skin more than twice. Use bypass button  if needed (accuracy of the monitoring will be unaffected)

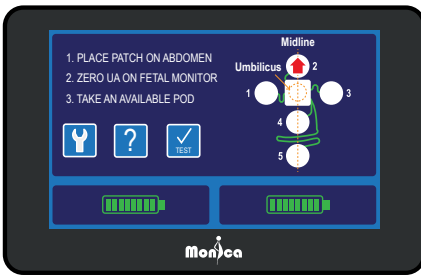
Novii Interface Connection



1. fECG Interface Connection Cable
2. mECG Interface Connection Cable
3. UA Interface Connection Cable
4. Power Supply Cable
5. Y Adapter Cable – needed for GE 259 monitors

Interface Connection Test



Novii Start Screen



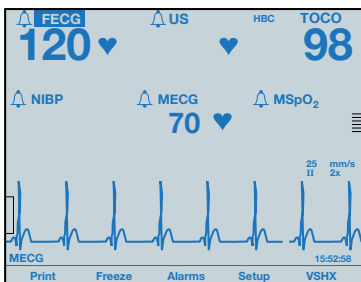
1. On Novii Interface start screen press  TEST

Zero UA Screen



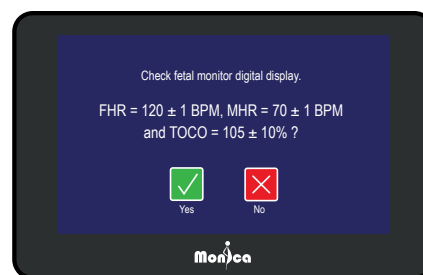
2. Zero UA (press the UA Reference) on Fetal Monitor  until desired baseline reference (10, 15, or 20) is obtained then press 

Fetal Monitor Display



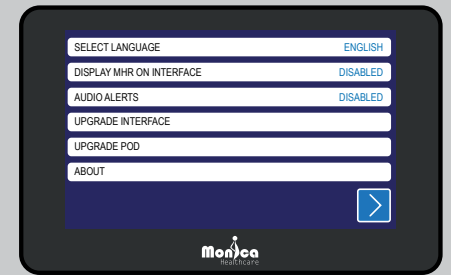
3. FHR, MHR and UA test signals are sent from Novii Interface to Fetal Monitor.

Novii Test Screen



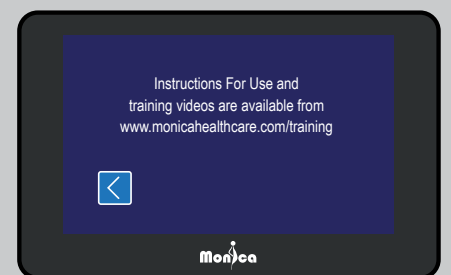
4. Check that all signals are displayed and parameters are in range. Shake Interface cables to test for intermittent breaks in signal and replace cable if needed. If signals are missing, check that connections are secure.

Settings Display Screen



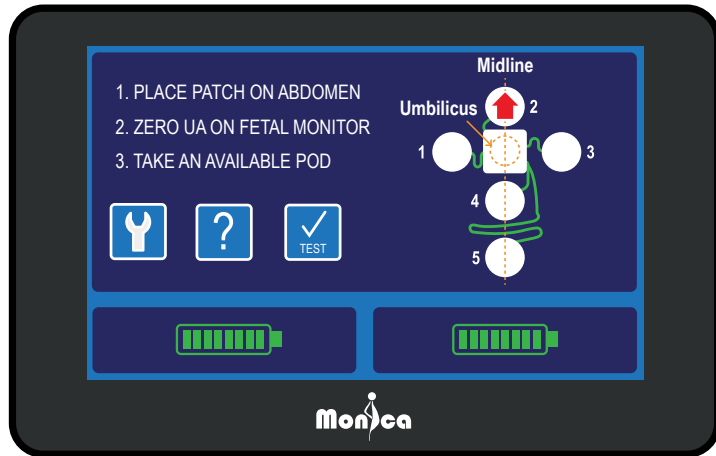
Press Settings icon  to access the settings

Help Display Screen

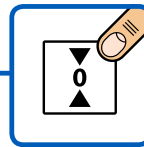
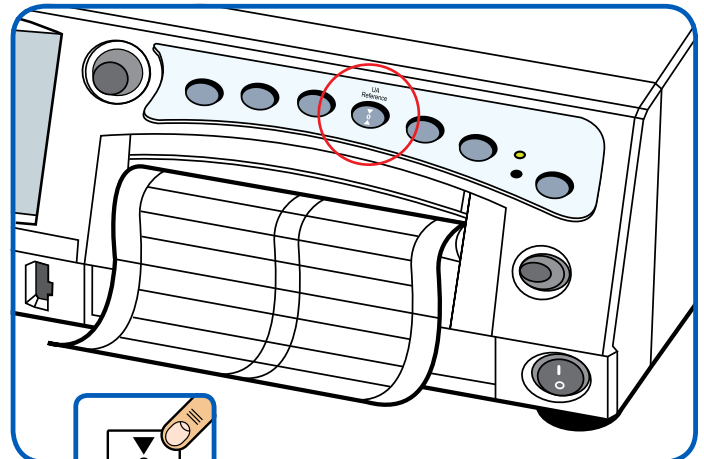


Press Help icon  to access

Interface/Pod Connection



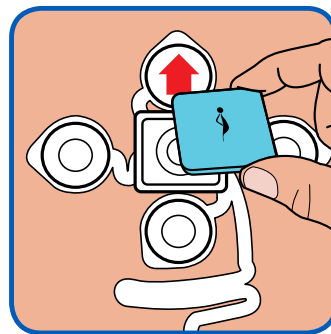
Ensure Novii Patch is placed, Interface is connected to fetal monitor and Novii test is complete. Follow on screen instructions.



Zero UA (press the UA Reference) on Fetal Monitor until desired baseline reference is obtained (10, 15 or 20).



Take a charged Pod. If battery indicator is orange (low) then Pod will not turn on.



Place Pod on Patch Clip. (2 minute count down to place Pod or alarm will sound and Pod will turn off).



Monitoring screen will automatically appear once skin preparation of all 5 electrodes is good. ✓



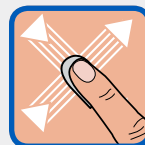
Troubleshooting Skin Preparation



Electrode Check Screen indicates whether the skin preparation has been sufficient – to resolve a **X** or **O** follow steps on right:



Step 1 Press down on center of electrode to ensure good skin contact – then wait 10–20 seconds for gel to absorb. If **X** or **O** remain proceed to Step 2.



Step 2 Lift problem electrode, wipe gel from skin and repeat exfoliation with new piece of prep tape. (See page 9)

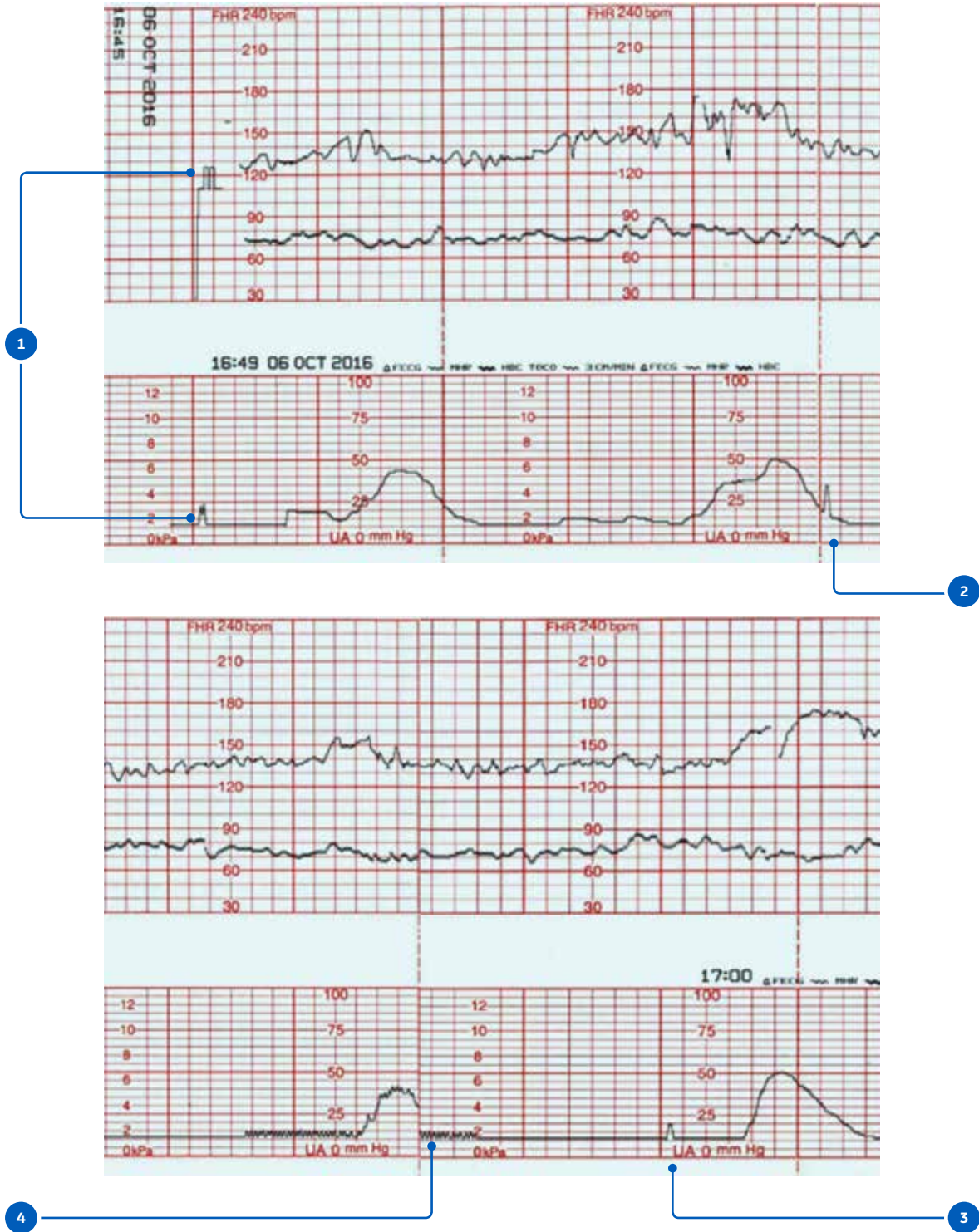


Step 3 Only re-exfoliate the skin once and if **X** or **O** remain then bypass. ➔

Be patient while awaiting signals to acquire and record. Signals may take anywhere from 5 seconds to 2 minutes to be detected and displayed. FHR may take additional time. Use the ultrasound transducer as needed for reassurance while waiting. Attempt to troubleshoot if no FHR or poor signal after approximately 5 minutes. Wait for 10-15 minutes worth of good FHR signal quality before encouraging the patient to ambulate.

Trace Features

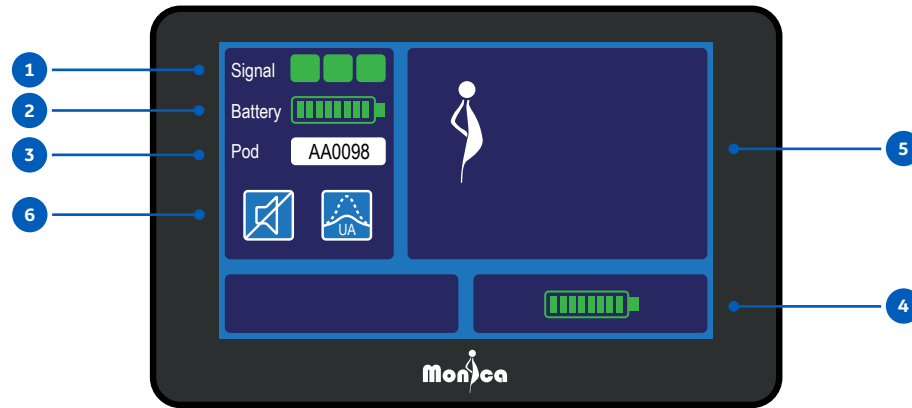
Note: Trace is displayed with print speed at 3cm/minute. Slower speeds will compress appearance of images.



1. Monica Mark (at the start of a new monitoring session).
2. Monica Identifier (every 5 minutes) – larger height indicates high UA Sensitivity (see pg.20).
3. Monica Identifier (every 5 minutes) – smaller height indicates low UA Sensitivity (see pg.20).
4. Trace is thickened to indicate maternal movement such as ambulation or rocking – caution with UA interpretation as UA artifact may be present. (See page 20)

Monitoring Screens

Main Screen



1. FHR signal performance during monitoring – indicates quality of fECG detection.

Note: this is NOT correlated to the Bluetooth signal.



Good Signal Quality – Expect continuous FHR tracing.



Poor Signal Quality – FHR extraction may be compromised, with possible FHR gapping and/or artifact. Be cautious in interpretation and seek confirmation, see FHR Artifact on page 19.



Bad Signal Quality – No fECG can be extracted and FHR gapping or artifact is to be expected. Use ultrasound transducer to obtain/confirm FHR for short durations. Consider troubleshooting if bad signal is frequent or continuous. Increased noise or poor Patch placement may cause poor/bad signal quality. For additional information, see How Novii Works (page 7) and FHR Troubleshooting (page 17).

2. Pod battery status while in use



Battery status of active Pod, consisting of 8 charge levels, lasting 11 hours when full*.



Icon will turn to single orange bar and alert with 60 minutes of charge remaining.

3. Serial number of Pod in use

4. Pod battery status when docked

5. MHR display (option in settings menu) / Alerts / Support Messages

6. User controls



Sound Alerts Enabled

or



Sound Alerts Disabled

(Enabled/disabled in Settings, see pg. 11)



High UA Sensitivity

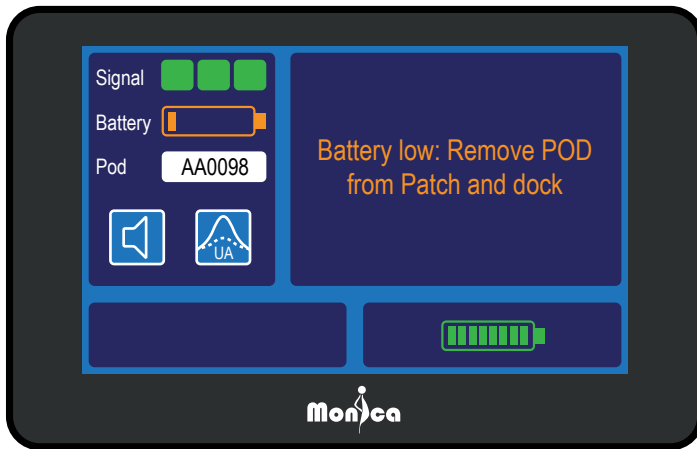
or



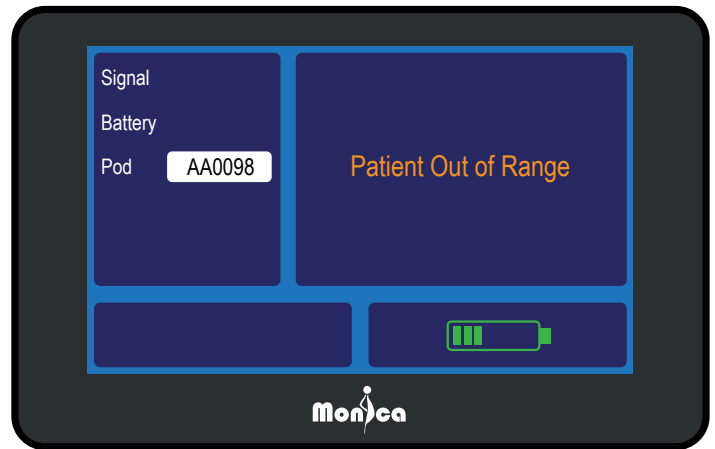
Low UA Sensitivity

(For information, see pg. 20)

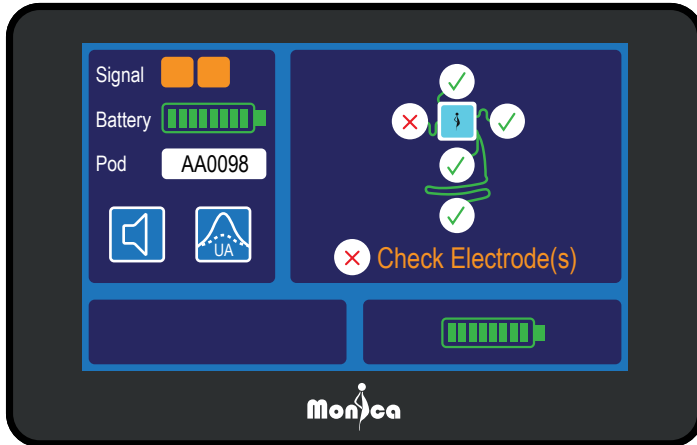
Alerts



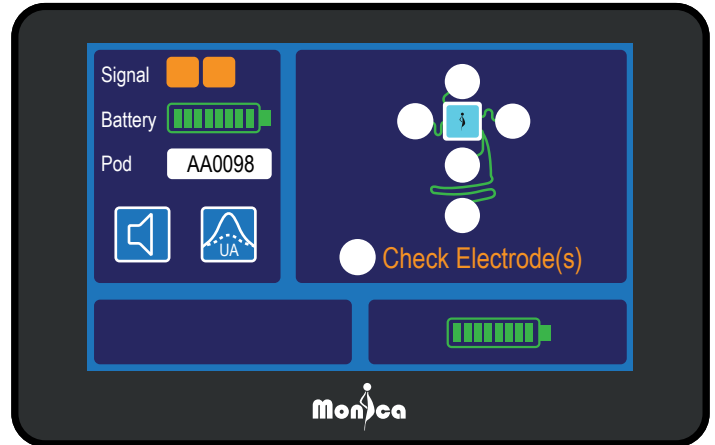
1. Low battery - see instructions for swapping Pods (Page 16).



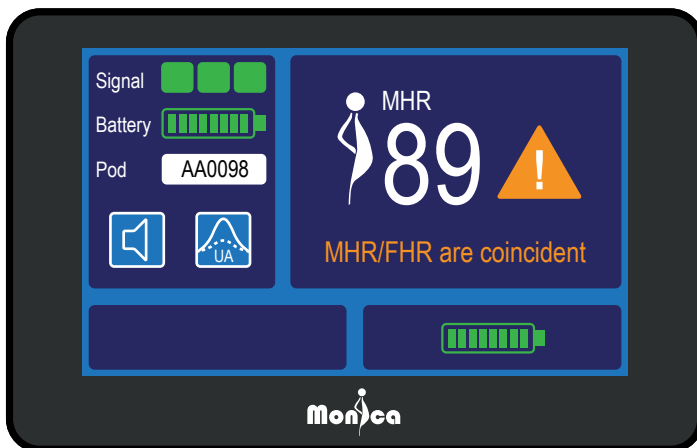
2. Patient out of range – ask patient to return to room, and Novii Pod will automatically reconnect. Will also see this message if patient is in tub with Pod submerged.



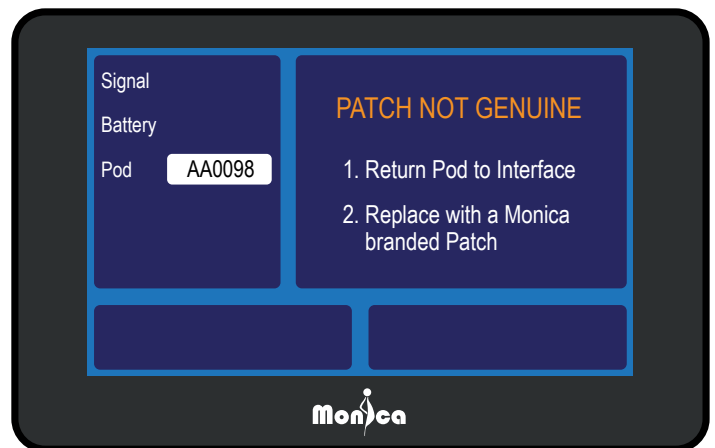
3. Electrode disconnection – reattach the electrode indicated (medical tape can be used to hold in place if needed). If alert continues, ensure Pod has good connection to Patch. Final solution would be to place a new Patch.



4. Multiple electrodes disconnected – check all electrodes to ensure good connection to skin. See #3. If continues, check Pod pins and the Patch connection at center of Pod Clip for damage and dirt, or try a different Pod.

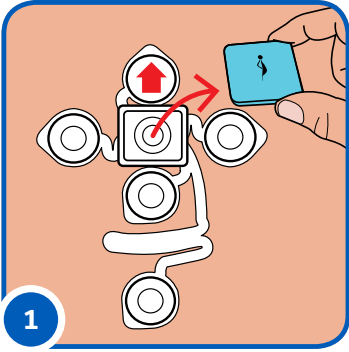


5. MHR and FHR are coincident (± 10 BPM for more than 60 seconds). Only occurs when 'Display MHR on Interface' option is enabled.

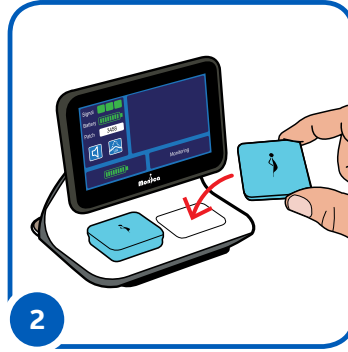


6. Non-genuine Patch used or connection problem. Try restarting the monitoring with a different Pod or use a different Patch.

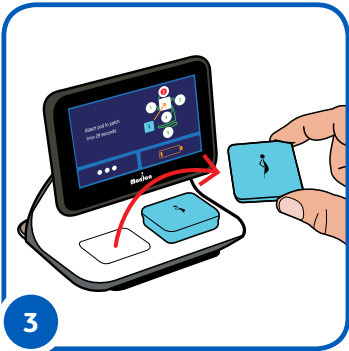
Ending Monitoring/Swapping Pods



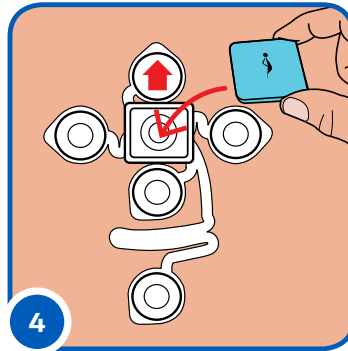
Remove Pod from Patch.



Return Pod to Interface, then wait for battery icon to be displayed above Pod (**Monitoring Ended**).

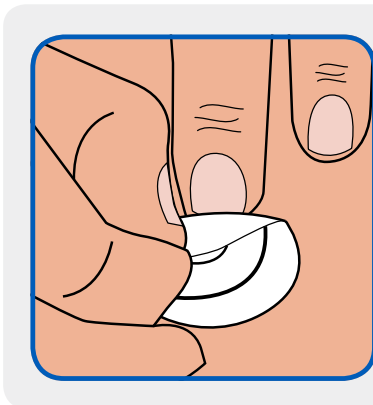


Once battery icon of returned Pod is displayed, zero the UA, then take fully charged Pod from Interface (if new Pod taken too soon it will not turn on).



Place a charged Pod on Patch (**Swapping Pod Complete**).

Patch Removal



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

Patch is single patient use. Dispose of in general waste, or in hazardous waste if soiled with blood or bodily fluids, per hospital protocol.

Interface Troubleshooting

End any active monitoring by returning the Pod to the Interface. Remove the power supply then reconnect it to restart the Interface. Then run the Interface connection test (see page 11), to confirm the correct setup and function of the Interface.

FHR Troubleshooting; when signal quality is poor ■■ or bad ■

- While the Novii detects the FHR continuously on many patients, some patients will require troubleshooting to reacquire the FHR signal.*
- Inadequate Patch/electrode placement or increased noise (electrical interference) may cause frequent or persistent FHR gapping** and/or FHR artifact. Sources of noise may include electrophysiological noise from the patient or fetus and electrical noise from the environment.

POSSIBLE CAUSE/PROBLEM



The patient is ambulating - may cause increased muscle noise and/or displaced Patch

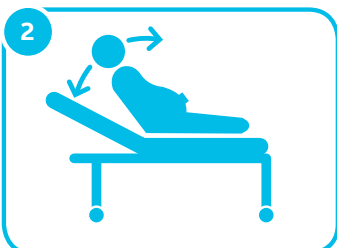
ACTION & SOLUTION

- Return patient to bed and/or reduce patient's activity.
- Consider using a maternity belt to support pannus during ambulation or upright position.

HELP/TIP

- Allow 10-15 minutes of monitoring before starting ambulation.
- The patient should not be encouraged to ambulate unless the FHR trace is consistent and the signal indicator on the Novii Interface shows 3 green squares.

Signal ■■■

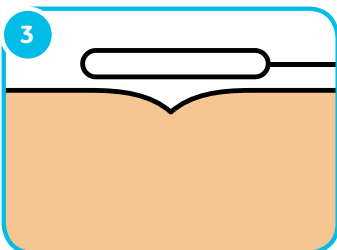


Patient position/posture - may cause muscle tension/noise and/or displaced Patch

- Adjust patient's position: head of bed up/down, right/left tilt.
- Use a pillow behind back or head to make patient more comfortable, encouraging patient to relax abdominal muscles.
- Return patient to a position where Novii worked well.
- If patient is high Fowler's or in a curled sitting position for epidural placement, consider placing a rolled towel or baby blanket under the abdomen for support to ensure optimal position of the lowest electrode.



- If patient is on side, support abdomen with a pillow/rolled blanket to support the abdomen so that the Patch remains centered over the uterus.



Electrode 'detached' or has bad contact with skin - electrode not able to function properly

- Check all electrodes and ensure good skin contact/adhesion.
- Consider re-position Patch or electrode to avoid any skin anomalies. Restart the Novii system for monitoring.

HELP/TIP

- The Interface will alert user with a visual message, but only when electrode is fully detached.
- Check electrodes for adhesion after a shower, clinical procedure, ambulation or a position change.
- Electrode(s) should not be placed over a skin lesion, skin fold, or umbilicus. Avoid stretch marks, scars or pronounced linea nigra when possible.
- If necessary use medical tape or transparent adhesive dressing for added adhesion to prevent electrode lifting or detachment.
- If electrode site is hairy, preventing good contact/adhesion, it may be necessary to clip the hair.

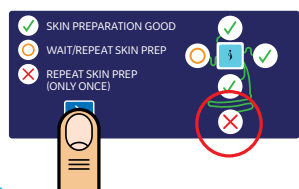
*A small number of patients will not be able to be monitored successfully with the Novii despite troubleshooting.

**During a FHR gap there is silence, and it is therefore advised to explain this to the patient and partners so they are aware and not distressed when there is no audio noise.

POSSIBLE CAUSE/PROBLEM

ACTION & SOLUTION

4



Poor skin prep - dead skin reduces transmission of fECG signal

- Re-exfoliate skin under 'bad' electrode. (See bottom of pg. 12.)
- Restart the monitoring session if location of 'bad' electrode not known.

HELP/TIP

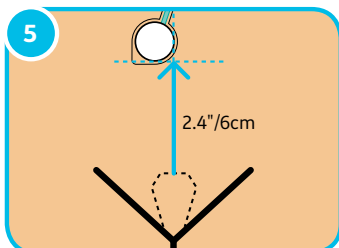
Remove Pod from Patch, place in charging bay and start new monitoring episode.

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

HELP/TIP

Check for damaged Pod pins. Carefully clean Pod pins with 70% isopropyl alcohol, then re-try Pod. Replace Pod if needed.

5



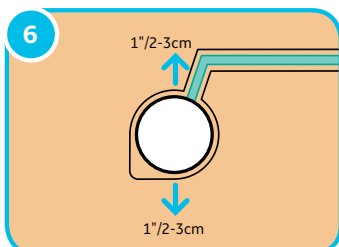
Center of lowest electrode is not 2.4"/6 cm above the symphysis pubis, or in optimal location for individual

- Re-position lowest electrode on flexible cable (electrode #5).

HELP/TIP

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

6



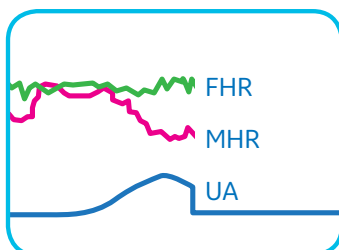
Pannus covering pubic bone; lower electrode placement difficult to estimate

- Some trial and error with positioning of lowest electrode over pannus may be required to achieve optimal fECG signal.
- Remove lowest electrode and place it lower or higher on the abdomen.
- Alternatively place electrode just below the point where the surface curves back on itself ensuring that the electrode is not folded.

HELP/TIP

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

All Novii Signals Lost



All Novii signals are lost. Bluetooth communication or cable/power connection problem

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

HELP/TIP

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

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

HELP/TIP

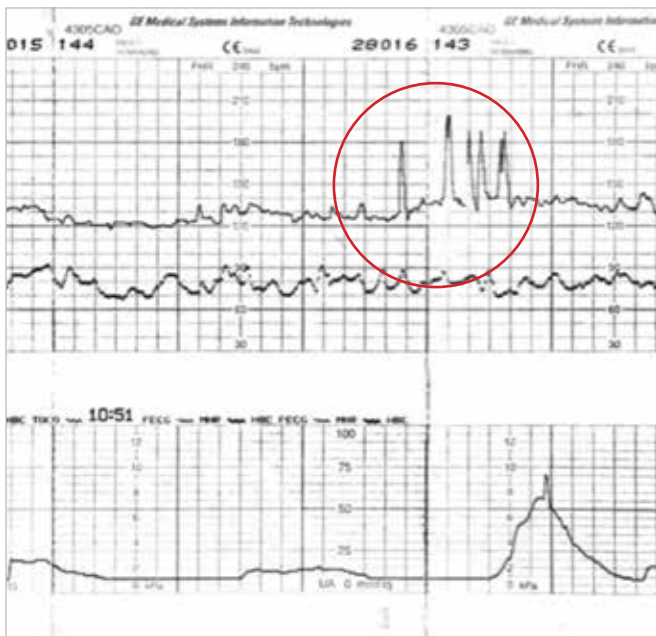
Pod has switched off

– remove Pod from Patch and place in charging bay. Start new monitoring session with other Pod.

- Are all cables and connections secure? Consider returning the Pod to the Interface and completing a Novii Test.

FHR Artifact

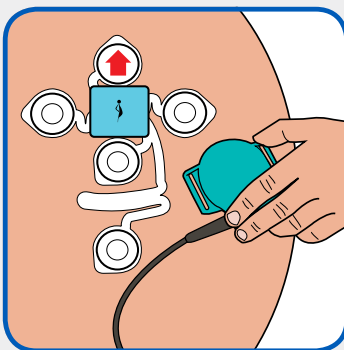
- Due to the challenges of monitoring the fetal heart, all fetal monitors are prone to FHR artifact and signal loss. Most of the time this artifact is easily identifiable from changes in FHR pattern.
- It is important to view the signal quality on the Novii Interface screen. Poor ■ or bad ■ signal quality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



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



Reassurance



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

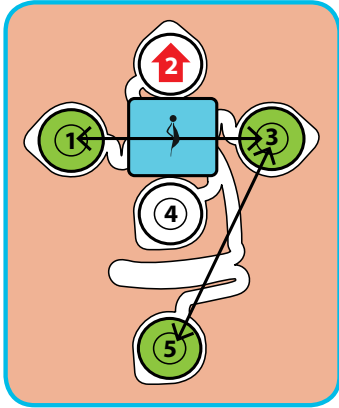
The FHR from Novii and US Transducer will be simultaneously printed on the trace, as if you were monitoring Twins. However, the Novii FHR will appear slightly behind the US FHR due to the Novii 10 second delay.

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

Caution: Novii FHR, Novii MHR and Novii UA are delayed by 10 seconds. See page 22 for Novii timing explanation.

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


UA Troubleshooting

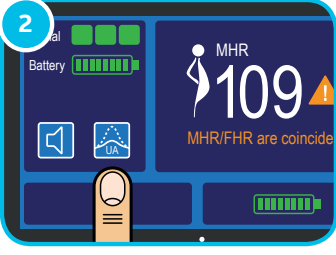




Novii UA – Essential Information

- Novii monitors uterine (EMG) activity on two channels, using 3 electrodes. Electrode #3 is most important for UA monitoring. Quality will be affected if detached or has bad skin prep at start, or if Patch is not optimally positioned over uterus.
- The interpretation of Novii UA is similar to interpretation of a TOCO tracing, so does not provide a measurable contraction strength or measurable uterine baseline tone.
- Novii UA duration may be somewhat different from TOCO/IUPC.
Note: Patient perception, palpation, TOCO, IUPC, and Novii may produce 5 different measurements of duration for the same contraction.
- Novii data is delayed by 10 seconds, so take this into consideration if using Novii UA to coach the patient to push.
- Any assessment of Novii UA should be verified through palpation, as with other monitoring modalities.

High UA (False Positives)

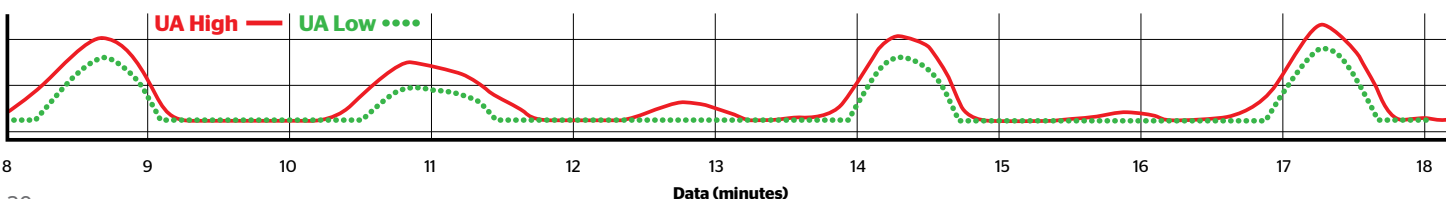
POSSIBLE CAUSE/PROBLEM	ACTION & SOLUTION
<p>1</p>  <p>The patient is ambulating or the fetus is active</p>	<ul style="list-style-type: none"> • Electrical (EMG) signals from other muscles in the body during patient movement can produce a false contraction on the trace. • Excess movement or pressing on the Patch (electrodes) can produce false UA. • After 20 seconds of patient movement the UA trace will become 'thicker'. Use caution in interpreting a 'thickened' UA trace. See page 13. • Ask patient to return to the bed if ambulation is the cause of false positives. <p>HELP/TIP Patient movement may also cause the Patch to shift back and forth across the uterus, causing deflections and the appearance of excessive UA. Palpate to confirm.</p>

<p>2</p>  <p>The patient is in early (latent) labor or induction</p>	<ul style="list-style-type: none"> • In early (latent) labor or induction, myometrial activity is disorganized and preparing to produce pressure changing contractions. The electrical signal from this uterine muscle activity may produce small false positive contractions on the Novii UA trace (Verify UA with uterine palpation and maternal perception assessment). • Solution: Select the low UA setting from the Novii Interface to remove these small false positive contractions (Note: Novii UA spike which occurs on trace every 5 minutes will be at 50% height when low UA setting is enabled. See page 13.) <p>HELP/TIP Low UA setting will continue for 60 minutes before defaulting back to high UA setting, which is the default mode. The user can change the mode at anytime as indicated.</p> <div style="display: flex; justify-content: space-around;">   </div>
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UA Sensitivity Modes

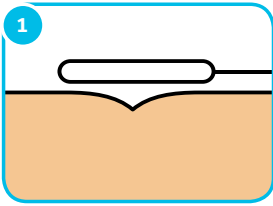
High/Low UA Sensitivity Explained

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



Low UA

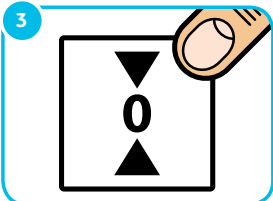
POSSIBLE CAUSE/PROBLEM



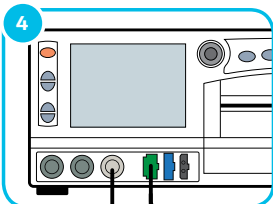
Electrode(s) not secured well



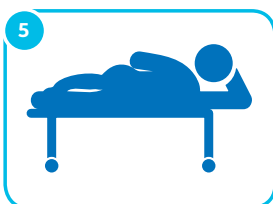
Low UA setting enabled



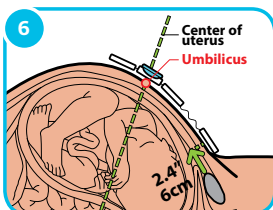
UA Reference problem



UA cable/connection problem



Maternal position change




Patch not optimally placed over uterus

ACTION & SOLUTION

- Check for electrode disconnection and secure back down. If electrode #3 on patient's left has problem then UA will be lost/flat. OK to use medical tape to hold in place.

HELP/TIP

The Interface will alert user with a visual message, only when electrode is fully detached

- Check the Interface UA sensitivity setting and ensure that the High UA setting has been selected.  High

- Zero UA before starting Novii monitoring. Do not zero during monitoring. Although UA Reference may be done between contractions, using palpation to confirm, it is best practice to return the Pod to the Interface, and then Zero UA.

- Check that UA interface cable between Novii interface and fetal monitor is connected correctly. Wiggle cable connector to ensure the monitor input connector is not loose or defective. Run a Novii Test to confirm.

- Was UA amplitude high, but now low? If so, has patient changed position? Check patch has not moved away from uterus (i.e high BMI, loose skin). If needed, place pillow under abdomen to support patch back over uterus.

- Confirm Patch is centered on uterus and the center of bottom electrode is 6cm above top rim of pubic bone. Electrode #3 is most important for obtaining good UA, thus poor positioning of this electrode may result in low UA. Reposition Patch if needed.

Timing

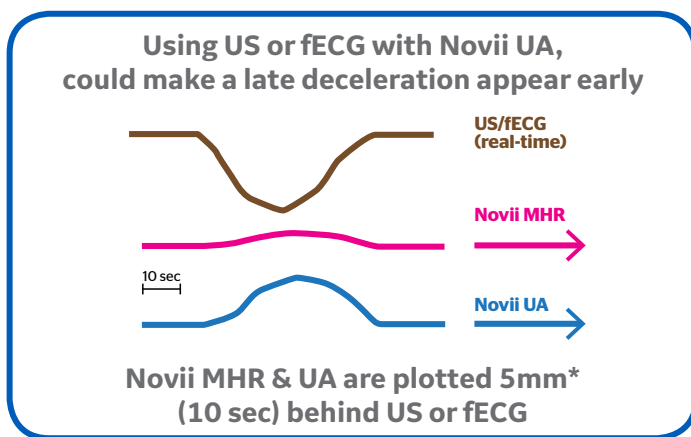
The FHR, MHR and UA signals generated by Novii are all synchronized, but delayed by a maximum of 10 seconds. The delay reduces to 6 seconds if the UA interface cable is unplugged from the fetal monitor. Due to this delay, it is important to consider the following:

- 1. During prolonged FHR decelerations** – use the US transducer simultaneously to obtain a real-time FHR as needed.
- 2. During epidural placement** – if a real-time MHR is needed, disconnect the Novii mECG cable to display the MSpO₂ MHR reading, or change the MHR *source* on the GE Corometrics monitor to MSpO₂. Alternatively, the Corometrics 3 lead mECG set-up may be used instead of Novii mECG.
- 3. Coaching women to push** during contractions may be difficult, due to the contraction beginning to build before Novii displays it 10 seconds later. (Therefore, manual palpation is best to confirm onset of contraction.)
- 4. Mixing monitoring modalities** – not recommended or supported except when using the US transducer to supplement the Novii FHR. See 'Reassurance' section on page 19.

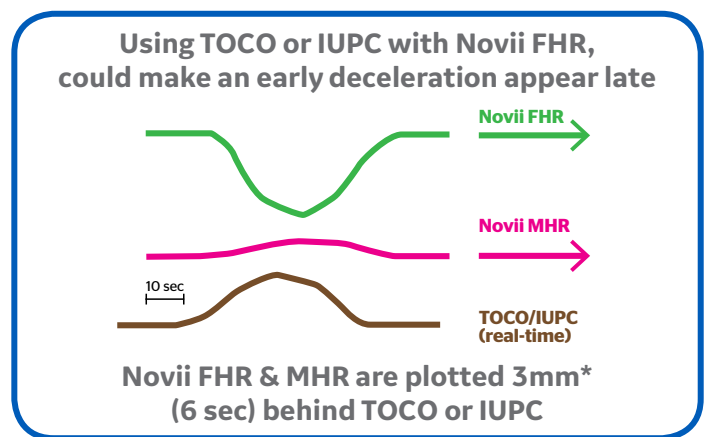
Mixed Modality Monitoring – Do not use

Mixed fetal and UA modality monitoring is not recommended or supported. It is very important to understand what clinical implications could occur if some monitoring modalities are mixed with the Novii, which results from a timing discrepancy of the recorded data. Novii should never be mixed with a TOCO, IUPC, or Scalp fECG as this could lead to misinterpretation of FHR data. US should also not be used continuously with or instead of Novii FHR. Please see the graphs below for clarification of timing discrepancies that could occur with mixing modalities.

Using different sources for the MHR from the Corometrics fetal monitor instead of Novii mECG, which may include mSpO₂ or 3 lead mECG, are acceptable and supported. To use the Corometrics 3 lead mECG, simply disconnect the Novii mECG cable from the Y adapter and connect the 3 lead mECG cable. To use the mSpO₂, change the source of the MHR on the Corometrics monitor to mSpO₂ or simply disconnect the Novii mECG cable.



10 Second Trace Example



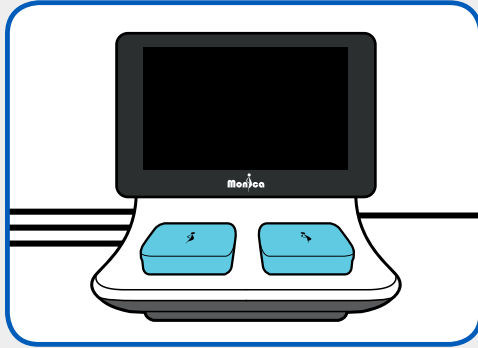
6 Second Trace Example

Mixing modalities may impact on the interpretation of FHR decelerations and for this reason is not recommended by GE Healthcare. The illustrations above highlight the changes caused by mixing modality.

* based on 3 cm per minute paper speed.

Cleaning

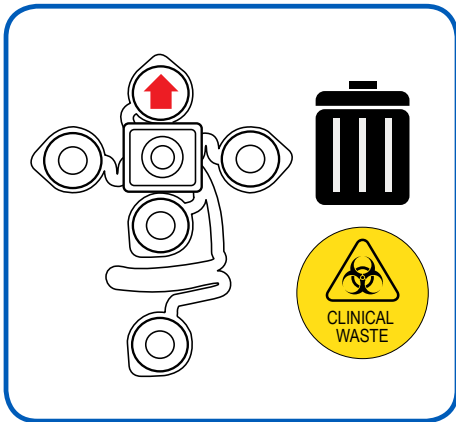
After each patient use, follow your hospital's infection control procedure for surface disinfection. Always follow the cleaning / disinfection solutions manufacturer's instructions for use.



Instructions

1. Unplug from AC power source
2. Use soft cloth to wipe three times with 70% Isopropyl Alcohol
3. If necessary, use a soft bristled brush and disinfection solution to scrub the exterior for 5 minutes
4. Wipe three times with sterile or distilled water to remove disinfection solution

Caution: take care cleaning gold pins on Pod to avoid damage



Do NOT:

- Use bleach (i.e. Sodium Hypochlorite)
- Use strong oxidants (i.e. Hydrogen Peroxide)
- Expose to temperatures above 40°C/104°F (i.e. autoclave)
- Immerse in liquid
- Gas sterilize
- Use aerosol preparations since they may contain organic solvents

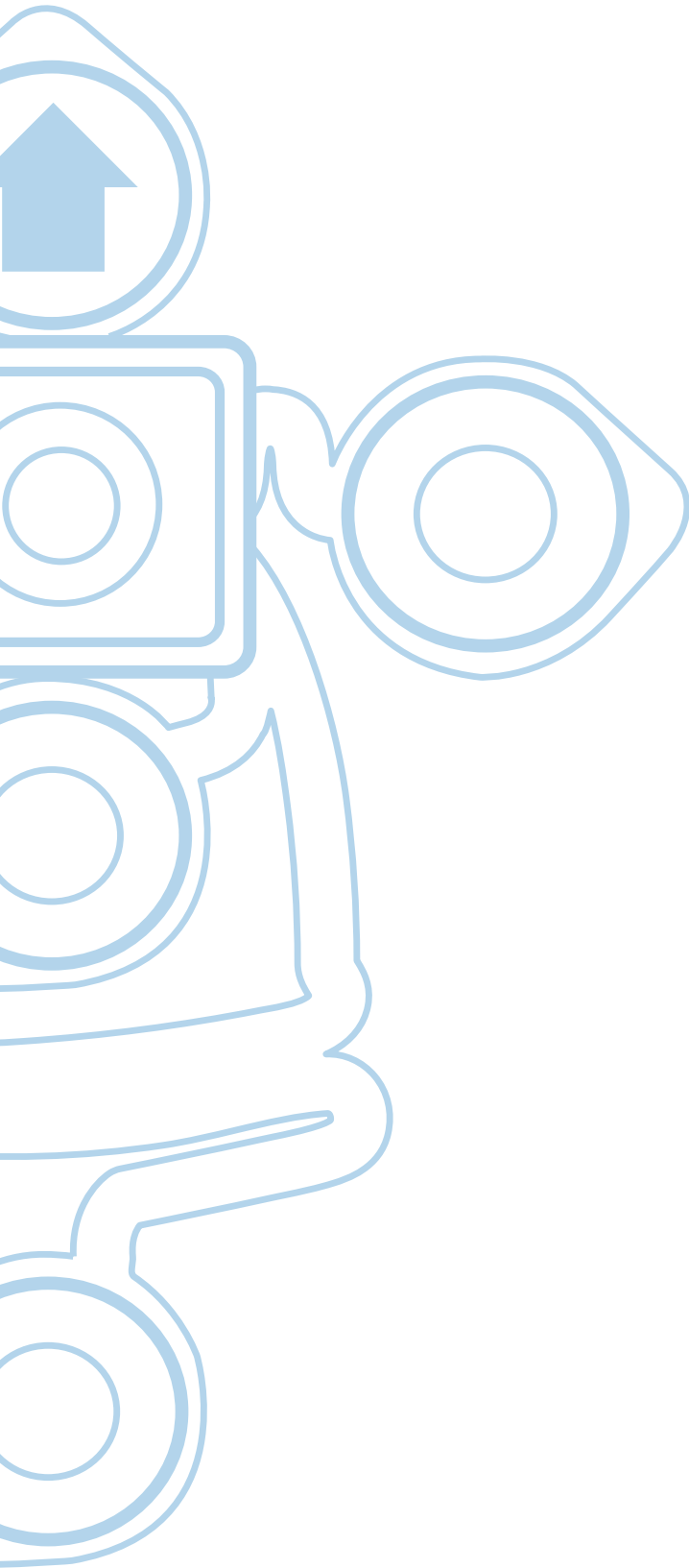
Help/tip:

The Novii Pod pins on the underside of the Pod must be carefully maintained for proper functioning of the Novii and transmission of signals. Inspect the Pod pins regularly for debris or damage, especially if the Pod is dropped. All of the pins should be the same length and feel bouncy when you gently touch them. You may touch the pins for inspection purposes only; otherwise avoid contact. Debris collection around the Pod pins may not allow them to move freely. Follow the cleaning instructions above to clean the Pod pin surfaces carefully after each patient use. Residue or corrosion from using improper cleaning agents could prevent the pins from making good contact with the Novii Patch clip connectors, and lead to permanent damage.

Optional:

A Novii simulator (100-PT-200), which has the capability to check the connection of the Pod pins without having to test on a Patch placed on a patient, may be purchased separately from GE Healthcare if required. A display of five green electrode checks on the Novii Interface screen when the Pod is placed in the Novii simulator would indicate a 'good' Pod with functional pins. While a display of persistent red X(s) would indicate improper pin connection, so should not be used on a patient until resolved.





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