Novii Wireless Patch System

Empowering you and your patients

Novii connects with Corometrics 259cx and 174 maternal/fetal monitors and the data flows seamlessly to your existing surveillance and archival system.

Features

Novii has three constituent parts, the Novii Patch, Novii Pod, and Novii Interface.

Novii Patch

- A single-use, peel-and-stick disposable part, which attaches to the woman's abdomen using comfortable adhesives. The patch incorporates ECG electrode areas which pick up ECG and EMG signals from the skin surface and then transfer them to the Novii Pod

Novii Pod

- A reusable part which magnetically connects to the Novii Patch to pick up the fetal and maternal ECG and EMG signals and then filters, digitises and processes them in real time to extract the FHR, MHR & UA data. The pod transmits this data via Bluetooth to the Novii Interface

Novii Interface

- A reusable part that translates Bluetooth data transmitted by the Novii Pod into the correct signals format for input in to a standard Corometrics fetal-maternal Cardiotocograph (CTG) monitor. The Novii Interface is connected to the CTG monitor via physical cables which attach to the transducer inputs of the CTG monitor. The Novii Interface also has a touch screen for configuration and real-time feedback and has two bays incorporated into its base for charging and pairing of the Novii Pods

Performance Specifications

Novii Wireless Patch System

Components	Novii Interface
	Novii Interface Power Supply
	Novii Interface Cable – GE FECG
	Novii Interface Cable – GE MECG*
	Novii Interface Cable – GE UA
	Novii Pods
	Novii User Manual

Novii Patch

Options	Box (10 patches)
	Box (50 patches)
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	The Patch on its own has no IP rating.
Shelf Life	12 months (from Date of Manufacture)
Latex & PVC Free	Yes
Packaging	Individual foil pouches & transportation cards
Operating Temperature	+10°C to +30°C (+50°F to +86°F)
Storage Temperature	+10°C to +30°C (+50°F to +86°F)

Novii Pod

Operating Mode	Real-Time/ Continuous Use
Bluetooth Wireless	
Output	Bluetooth v2.1 + EDR, Class 1.5, to Novii Interface
Protocol	Modified Series 50
Range	100ft / 30m (line of sight)
User Interface	LED
FHR	
Range	60 -240 BPM
Resolution	¼ BPM, 4 times/ second, rolling 2 sec average
Accuracy	Bland Altman vs AN24 predicate 7.08BPM rms
MHR	
Range	40 -240 BPM
Resolution	¼ BPM, 4 times/ second, rolling 2 sec average
Accuracy	Bland Altman vs AN24 predicate 5.32BPM rms
UA	
Range	0 – 500 microvolts
Resolution	0 – 255 levels representing 100% of full scale, 4 times/ second, rolling 2 second average
Accuracy	97.99% percent agreement (interpretability) 86.05% Positive Percent Agreement (Sensitivity)
Power	
Battery	Rechargeable Lithium Polymer 3.7V, 750mAh 80% capacity after 475 charge cycles
Battery Life	Up to 11 hrs
Battery Charging	Contactless via the Novii Interface x2 fully discharged Pods – up to 2 hours
Weight	40g
Dimensions	45mm x 39mm x 20mm (including contact pins)
IP rating	IP57 only when mated to the Novii Patch, otherwise IPX0
Accessories	Novii Patch
Operating Temperature	+10°C to +30°C (+50°F to +86°F)
Storage Temperature	+10°C to +30°C (+50°F to +86°F)
Type	Type BF Equipment (applied part is the Novii patch, which connects to the pod via the spring contact pins at the bottom of the pod)

*Optional

Novii Interface

Operating Mode	Continuous Use
Data I/O	Bluetooth Wireless
Input	Bluetooth v2.1 + EDR, Class 1.5, from Novii Interface
Protocol	Modified Series 50
Range	100ft / 30m (line of sight)
Output	Real Time to CTG fetal monitor via CTG Interface cables, comprising:
	Direct fetal ECG pulse (for FHR)
	MECG pulse (for MHR)
	Uterine Activity waveform (for UA)
User Interfaces	Capacitive Touch

Screen LCD display

Resolution:	800 x 400 (RGB 65K Colors)
Viewing Area:	108mm x 65mm
Touch Panel Durability:	1 Million (tap test)
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 2 hours
	Facilitate automatic pairing with the Pod
Dimensions	152mm x 137mm x 150mm
Weight	688g
IP rating	IP20
Accessories	CTG Connection Cables for GE Corometrics
Operating Temperature	+10°C to +30°C (+50°F to +86°F)
Storage Temperature	+10°C to +30°C (+50°F to +86°F)
Relative Humidity	30%RH to 75% RH
Atmospheric Pressure (kPa)	70kPA to 106kPa (52.5mmHg to 795.2mmHg)

Power Supply

Input	100 to 240V~, 50Hz to 60Hz, 400mA
Output	18W 5V DC/300mA
USA pin out	Part Number: 107_PT_002_US

Intended 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 term >36 completed weeks, (37.0) in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

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

The Novii Interface is an accessory to the NoviiPod 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.

Imagination at work

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