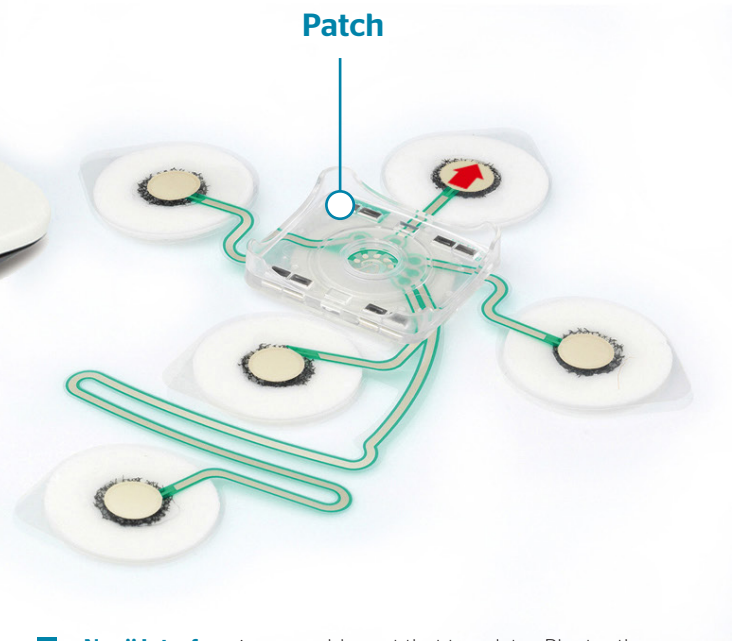


Novii Wireless Patch System



The Monica Novii Wireless Patch System (“Novii”) provides the opportunity to empower you and your patients by enhancing patient comfort & optimizing your workflow. It connects with your Corometrics 174 and 259cx series maternal/fetal monitors and the data flows seamlessly to your existing surveillance and archival system.

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



- **Novii Patch** is a single-use, peel-and-stick disposable part, which attaches to the woman’s abdomen using the comfortable adhesive foam pads. 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** is 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** is a reusable part that translates Bluetooth data transmitted by the Novii Pod into signals of the correct format to input your fetal 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 to allow the user to configure the set-up and has two bays incorporated into its base for charging and pairing of the Novii Pods.

Performance Specifications

Novii Wireless Patch System

System Components*	Novii Interface	107-PT-001
	Novii Interface Power Supply (USA)	107-PT-002-US
	Novii Interface Power Supply (INT)	107-PT-002
	Monica CTG Cables	
	- GE Corometrics DECG round grey connector	105-PT-102
	- GE Corometrics MECG round green connector	105-PT-104
	- GE Corometrics UA round white connector	105-PT-106
	Novii Pods	107-PT-003
	Novii Patch	107-PT-004
	Novii User Manual	107-PT-005
	Novii User Manual (CD)	100-PT-025
	Novii Getting Started Guide	107-PT-006
	Novii FHR Gaps Troubleshooting Guide	107-PT-008
	3M Red Dot 2236 Skin Prep Tape	100-PT-007

Novii Patch

Part Number	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, but converts the electrophysiological signals on the body into electronic signals for the Novii Pod	
Encryption	Microchip containing factory pre-set code (SHA_256 encryption)	
Weight	12g	
Dimensions	190mm x 155mm x 12mm (including clip)	
IP rating	IP57 only when mated to the Novii Pod, otherwise IP20	
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	

**Content and quantity can vary by country*

Novii Pod

Part Number	107-PT-003	
Operating Mode	Real-Time/ Continuous Use	
Bluetooth Wireless	Output Protocol	Bluetooth v2.1 + EDR, Class 1.5, to Novii Interface Modified Series 50
	Range	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 [1]
MHR	Range:	40 -240 BPM
	Resolution:	¼ BPM, 4 times/ second, rolling 2 sec average
	Accuracy:	Bland Altman vs AN24 predicate 5.32BPM rms [2]
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. Charge time for 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 IP20	
Accessories	Novii Patch (107-PT-004)	
Operating Temperature	+10°C to +30°C	
Storage Temperature	+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)	

Novii Interface

Part Number	107-PT-001
Operating Mode	Real-Time/ Continuous Use
Data I/O	Bluetooth Wireless
Input	Bluetooth v2.1 + EDR, Class 1.5, from Novii Interface
Protocol	Modified Series 50
Range	30m (line of sight)
Output	Real Time to fetal monitor via Novii Interface cables, comprising: <ul style="list-style-type: none">• Direct fetal ECG pulse (for FHR)• MEEG 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 uses IrDA to facilitate automatic pairing with the Pod
Power Supply	Input 100 to 240V~, 50Hz to 60Hz, 400mA Output 18 W 5V DC, 2500mA Energy Efficiency VI USA pin out Part Number: 107_PT_002_US EU, UK, AU pin out Part Number: 107_PT_002
Dimensions	152mm x 137mm x 150mm
Weight	688g
IP rating	IP20
Accessories	Interface Connection Cables for GE Corometrics 174 & 259cx Series monitor: FHR (105-PT-102); MHR (105-PT-104) UA (105-PT-106). Power Supply: 107-PT-002_US
Operating Temperature	+10°C to +30°C
Storage Temperature	+10°C to +30°C

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), 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 the Fetal monitor. The Novii Interface enables signals collected by the Novii Pod to be printed and displayed on the 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.

Approvals & Key Certifications

FDA Cleared

CE Marked

IEC 60601-1:2005 +A1: 2012 incl.

Medical Electrical Equipment

USA deviations

Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2015/IEC 60601-1-2:2014 (edition 4)

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 EC12-2000-(R)2015

Disposable ECG electrodes

IEC 62133:2017

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

BS EN 10993

Biological evaluation of medical devices

FCC CFR 47: Part 15 Subpart C & Part 18

FCC CFR 47 Part 15 Subpart C covering the FCC requirements for Intentional Radiators, Part 18 Medical Devices

ANSI-IEC-60529

Specification for degrees of protection provided by enclosures (IP code)

EN 62479:2010

Assessment of the compliance of low power electronic and electrical equipment. (SAR)

EN 61000-3 parts 2 & 3

Limits: Emission limits, Immunity limits

About Monica Healthcare

With over 25 years of research, expert knowledge and collaborations with leading hospitals, Monica Healthcare has developed an advanced electrophysiological technology to produce fetal monitors that are beneficial for midwives, L&D nurses and expectant women.

The patented technology is based on the acquisition of electro-physiological signals that can be passively detected by electrodes positioned on the maternal abdomen. From these signals a number of parameters, fetal heart rate, maternal heart rate, uterine activity and maternal movements can be extracted, in real time, and over an extended period of time.

Monica Healthcare is part of the Maternal Infant Care solutions offered by GE Healthcare. Through GE Healthcare's global network, the Novii Wireless Patch system will help to improve maternal and infant care worldwide.



Part No: 107-TF-100-USrev7
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