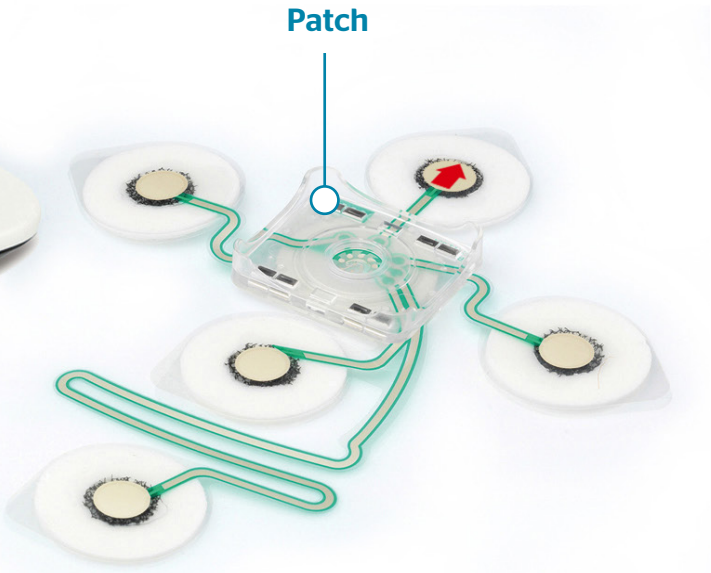
Novii Wireless Patch System

The Monica Novii Wireless Patch System ("Novii") provides the opportunity to enhance your current Labor and Delivery monitoring experience. It connects with your maternal/fetal monitors[1] 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 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** 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 into the correct format input 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 to allow the user to configure it for connection to different CTG models and has two bays incorporated into its base for charging and pairing of the Novii Pods.

[1] Monitors currently supported include the Corometrics* 250 Series.

Performance Specifications

Novii Wireless Patch System			
System Part Number		107-PT-020[2]	
System Package	Novii Interface	107-PT-001	Qty. 1
	Novii Interface Power Supply (USA)	107-PT-002_US	Qty. 1
	Novii GE CTG Interface Cable (FHR-Round)	105-PT-102-Novii	Qty. 1
	Novii GE CTG Interface Cable (MHR)	105-PT-104-Novii	Qty. 1
	Novii GE CTG Interface Cable (UA)	105-PT-106-Novii	Qty. 1
	Novii Pods	107-PT-003	Qty. 3
	Novii Patch	107-PT-004	Qty. 2
	Novii User Manual (CD) including Training Videos and Technical Datasheet	107-PT-005	Qty. 1

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 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	

[2] System part numbers for UK and European varaints are available.

Novii Pod		
Part Number	107-PT-003	
Operating Mode	Real-Time/ Continuous Use	
Bluetooth Wireless	Output	Bluetooth v2.1 + EDR, Class 1.5, to Novii Interface
	Protocol	Modified Series 50
	Range	30m (line of sight)
User Interface	LED	
FHR	Range:	30 -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
Weight	40g	
Dimensions	45mm x 39mm x 18mm (including contact pins)	
IP rating	IP57 only when mated to the Novii Patch, otherwise IPX0	
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 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	
Power Supply	Input	100 to 240V~, 50Hz to 60Hz, 400mA
	Output	5V DC, 3000mA
	USA pin out	Part Number: 107_PT_002_US
	EU pin out	Part Number: 107_PT_002_EU
	UK pin out	Part Number: 107_PT_002_UK
Dimensions	152mm x 137mm x 150mm	
Weight	688g	
IP rating	IPX0	
Accessories	CTG Connection Cables for GE Corometrics: FHR (105-PT-102-Novii); MHR (105-PT-104-Novii) UA (105-PT-106-Novii)	
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). In the USA 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.
Out side of the USA it is indicated for use from 20 weeks through to delivery in singleton pregnancies.

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.

Approvals & Key Certifications

FDA Cleared	
CE Marked	
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)

About Monica Healthcare

Monica Healthcare is developing a series of innovative wearable devices that uses wireless technologies to facilitate globally accessible obstetric services in the home and hospital.

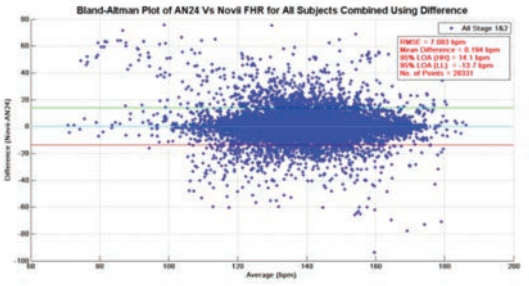
Monica Healthcare Ltd was formed in May 2005 and was the culmination of 15 years of research at the School of Electrical and Electronic Engineering and the School of Human Development at The University of Nottingham, UK.

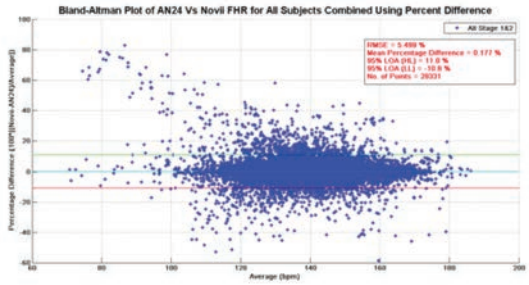
The patented technology is based on the acquisition of electro-physiological signals that can be passively detected by electrodes positioned on the maternal abdomen. From these signals a number of parameters, fetal heart rate, maternal heart rate, uterine activity, maternal movements and parameters describing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

In the USA the Novii Wireless Patch System is sold exclusively for use with the Corometrics* 259cx series fetal/maternal Monitor by GE Healthcare.

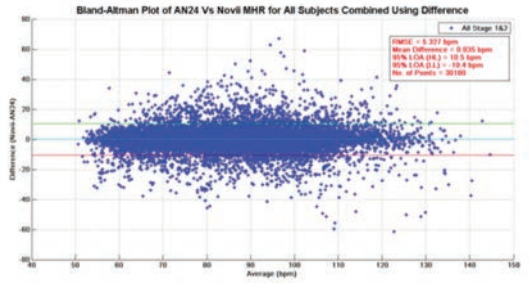
Novii and Monica are trademarks of Monica Healthcare Ltd.

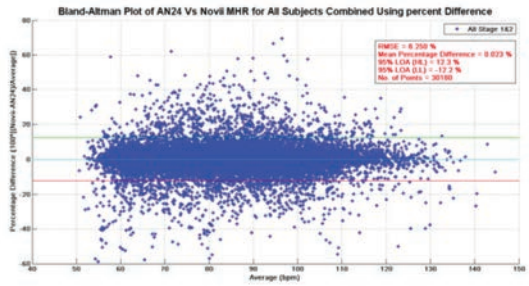
[1] FHR: Bland Altman vs AN24 predicate: 7.08 BPM rms (95% limit of agreement: -13.7 to 4.1 BPM) Bias: 0.194 BPM





[2] MHR: Bland Altman vs AN24 predicate: 5.32 BPM rms (95% limit of agreement: -10.4 to 10.5 BPM) Bias: 0.035 BPM





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