

Novii Wireless Patch System

Improved Maternal
Fetal Monitoring



The Monica Novii Wireless Patch System provides the opportunity to enhance your current monitoring experience.

It connects with your maternal/fetal monitor¹ and the data flows seamlessly to your existing surveillance and archival system.

Enhanced monitoring for difficult to monitor patients

The Monica Novii monitors fetal heart rate, maternal heart rate and uterine activity, all with a single patch. It is an effective solution for monitoring high BMI patients (Ref 1, 2) and minimizes the risk of maternal/fetal heart rate confusion (Ref 3, 4). In addition, the Patch requires no repositioning (Ref 4, 8) and the cable-free system keeps the work environment clear and safe allowing for easier monitoring during some clinical procedures.

Patient satisfaction

The single-patient use Novii Patch is a completely belt-free, wireless solution. It allows for greater freedom of movement during labour and a more comfortable experience for the patient (Ref 7, 8).



“We found Monica to perform excellently in very obese women (35>BMI<60)”

*Prof W Cohen,
University of Arizona College of Medicine, Tucson USA*



Expanding maternal/fetal monitoring

Your Fetal Monitor

The Novii System connects seamlessly with your monitor¹. The **Novii Pod**, a small signal-processing and transmission device, connects effortlessly using magnets to the 'peel and stick' **Novii Patch** shown below. The **Novii Pod** communicates via Bluetooth – **no** cables – **no** belts – **no** transducers– with the **Novii Interface** display device shown on the left, which connects to your fetal monitor transducer inputs.



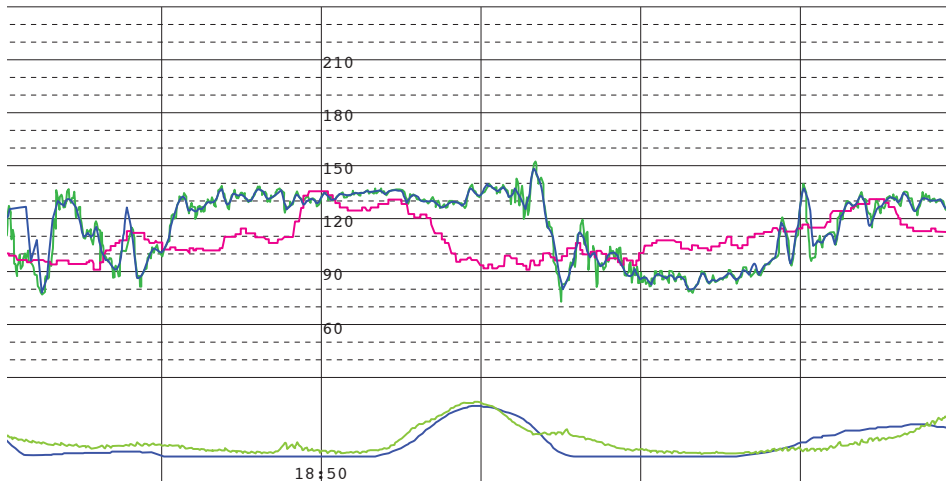
Monitoring High BMI Patients

Picking up consistent, reliable fetal heart rate and uterine activity can be challenging on high BMI patients. Monica Novii monitors the electrical signals on the patient's abdomen. The electrical signals are minimally effected by adipose tissue and therefore, the quality of the monitoring is not compromised by high BMI. Studies, recruiting women up to a BMI of 60, have shown minimal loss in FHR and UA performance as the BMI increases. (Ref 1, Ref 2).

¹ Contact Monica Healthcare or their authorized representative for a full list

Accuracy

Monica Novii uses the abdominal fECG and mECG wave shape to uniquely identify and separate the maternal and fetal heart rates. The fetal QRS complex has a width less than 50% of the maternal QRS. This and other differences between the maternal and fetal ECG allow the Monica Novii to be reasonably certain that the true FHR has been detected (Ref 3, Ref 4). You can be confident that you are monitoring the fetal heart even in the most challenging circumstances shown below. In addition, the uterine EMG is used to extract the UA trace and has been shown in a clinical study to be equivalent to TOCO UA (Ref 5).



— Scalp FHR
— Monica FHR
— SpO2 MHR

— Monica UA
— IUPC UA

This is data from the multi-centre clinical trial (Ref 1) showing the FSE FHR, IUPC UA and SpO2 MHR traces used to manage the patient. Superimposed are the simultaneously monitored Monica UA and FHR. The Monica UA and FHR trace was not seen by the Doctors and Nurses managing the patient.

Risk Mitigation

In a high BMI patient, finding the ideal transducer placement can be difficult. Because the Novii uses electrical signals, it is not impacted by maternal weight. This translates into more reliable tracings (Ref 1, Ref 2). In addition, the Novii's ability to simultaneously monitor and differentiate between the fetal and maternal heart rate can significantly reduce the likelihood of maternal/fetal confusion.

Mobility and Freedom

With **no** cables, belts or transducers and **no** re-positioning, the Novii System allows real freedom and mobility which can help the birthing process (Ref 6). The system's line of sight range of 30m (90 feet) allows the patient to move about the room freely.

With no transducer leads between the patient and the fetal monitor, the working environment around the bed is kept clear and safe. The patient is free to get up without asking for assistance.



Waterproof

The Monica **Novii Patch** and **Pod**, when connected, are rated for total water immersion to 1 meter, so they can be left in place during a bath or shower.

Monitoring continuity cannot be guaranteed when the Novii Pod is totally immersed in water.

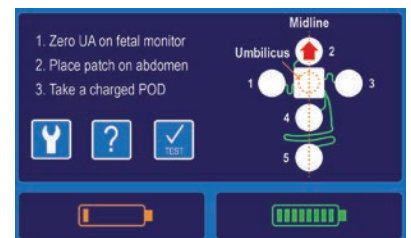
Patient Friendly and Convenient

The Monica Novii is a comfortable alternative to transducers with belts, which can cause irritation for some patients. The patch only needs to be placed once, which means that the patient does not need to be disturbed for repositioning, and since it is cordless, the patient has greater flexibility in the room.

Studies have shown (Ref 7, 8) that patient satisfaction is likely to be higher when monitored on the Novii compared to traditional transducers. It is light, small and causes minimal discomfort.

Workflow Improvements

The Novii's simple, 'peel and stick' design eliminates the need to re-position transducers. The single-patient-use patch minimizes the risk of cross-contamination caused by inadequate cleaning. In addition, the system's 'intelligent' automated set-up provides help and support messages to optimize and simplify operation. To prevent Pods from being lost in operation, they are non-white and the Interface will alert the user if a Pod is not returned to a charging bay after use.



Long Inductions and Labours

The Novii Interface has two inductive charging bays allowing two Pods to be charged at the same time. The Pod battery life is up to 11 hours, with up to 2 hours recharging time. Swapping Pods could not be simpler, just remove and replace, ensuring minimal trace loss and the ability to offer continuity of monitoring over extended periods.



References

High BMI:

Ref 1 – Cohen WR, Hayes-Gill B. Influence of maternal body mass index on accuracy and reliability of external fetal monitoring techniques. *Acta Obstet Gynecol Scand.* 2014 Jun ; 93 (6) : 590-5.

Ref 2 – Graatsma EM, Miller J, Mulder EJ, Harman C, Baschat AA, Visser GH. Maternal body mass index does not affect performance of fetal electrocardiography. *Am J Perinatol.* 2010 Aug ; 27 (7) : 573-7.

MHR/FHR Confusion:

Ref 3 – Cohen WR, Ommani S, Hassan S, Mirza FG, Solomon M, Brown R, Schiffrin BS, Himsworth JM, Hayes-Gill BR. Accuracy and reliability of fetal heart rate monitoring using maternal abdominal surface electrodes. *Acta Obstet Gynecol Scand.* 2012 Nov ; 91 (11) : 1306-13.

Ref 4 – Stampalija T, Signaroldi M, Mastroianni C, Rosti E, Signorelli V, Casati D, Ferrazzi EM. Fetal and maternal heart rate confusion during intra-partum monitoring: comparison of trans-abdominal fetal electrocardiogram and Doppler telemetry. *J Matern Fetal Neonatal Med.* 2012 Aug ; 25 (8) : 1517-20.

Monica UA Compares with IUPC:

Ref 5 – Hayes-Gill B, Hassan S, Mirza FG, Ommani S, Himsworth J, Solomon M, Brown R, Schiffrin BS, Wayne R, Cohen WR. Accuracy and Reliability of Uterine Contraction Identification Using Abdominal Surface Electrodes. *Clinical Medicine Insights: Women's Health* 2012 : 5 65-75.

Mobility and Impact on Stage 1 of Labour:

Ref 6 – Lawrence A, Lewis L, Hofmeyr GJ, Dowswell T, Styles C. Maternal positions and mobility during first stage labour. *Cochrane Database Syst Rev.* 2009 Apr 15 ; (2) : CD003934.

Patient Satisfaction:

Ref 7 – Reinhard J, Hayes-Gill BR, Yi Q, Hatzmann H, Schiermeier S. Comparison of non-invasive fetal electrocardiogram to Doppler cardiotocogram during the 1st stage of labor. *J Perinat Med.* 2010 Mar ; 38 (2) : 179-85.

Ref 8 – Rauf Z, O'Brien E, Stampalija T, Ilioniu FP, Lavender T, Alfirevic Z. Home Labour Induction with Retrieable Prostaglandin Pessary and Continuous Telemetric Trans-Abdominal Fetal ECG Monitoring. *PLoS ONE* 2011 6 (11) : e28129.

In the USA: US law restricts this device to sale by or on the order of a physician for use in a clinical setting.

The Novii device is for use in singleton term intrapartum patients, using surface electrodes on the maternal abdomen in a clinical setting.

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.

Monica Healthcare is working with business partners to distribute and deliver professional solutions meeting the needs of modern obstetric care, risk management and patient satisfaction.

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