

US approval for ground breaking wireless fetal monitor

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A ground breaking wireless fetal monitor developed by Monica Healthcare, a University of Nottingham spin out company, has been cleared for use in America by the US Food and Drug Administration (FDA).

The company has been granted regulatory clearance of their Monica AN24 wireless fetal monitor for use during labour and delivery. This FDA clearance enables Monica technology to be used in the USA during the care of healthy women and single [childbirth](#).

Monica hopes that its technology will lead to improved patient care, raise efficiency, and ultimately reduce the cost of pregnancy care in the hospital. Carl Barratt, CEO of Monica Healthcare, said: “The introduction of Monica AN24 to the US market is a significant milestone for Monica Healthcare, an endorsement of the team here, and represents an exciting opportunity for this advanced technology to positively impact the care of pregnant women during the critical stages

of labor.”

The Monica AN24 uses innovative wireless, non-invasive technology to collect real-time electrical signals from the abdomen of a pregnant mother. The device uses complex algorithms to correctly identify signals related to the fetal heart rate (FHR) and contraction signals on the abdomen of singleton pregnant women using ECG-style electrodes. This method of using electrophysiological signals differs from current external monitoring devices that collect FHR and uterine activity data based on physical changes (e.g. change in reflected sound waves and changes on strain gauge) that may cause problems in data interpretation.

The monitor is simple to use, beltless, requires no wires to connect to the display or printer, and will provide high levels of patient satisfaction. There is also no need for the constant re-positioning of transducers, which is required with the current technology, especially during an epidural when the patient is on her side.

Clinical trials in the US also have demonstrated that the monitor also performs well in obese women. Professor W Cohen from Albert Einstein College of Medicine, New York, said: “We found the Monica AN24 performed excellently in very obese women when compared with available Doppler ultrasound/tocodynamometer techniques.” Obesity in pregnancy is becoming more prevalent and acquiring accurate FHR and uterine activity signals in obese patients using conventional external monitoring is sometimes challenging.

In the hospital, the Monica AN24 will be available exclusively in the USA through Glenveigh Medical.

Provided by University of Nottingham

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