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## **Monica Healthcare gains FDA clearance for groundbreaking wireless fetal monitor**

**Monica Healthcare (based in the UK), has announced that the US Food and Drug Administration (FDA) have granted regulatory clearance of their Monica AN24 wireless fetal monitor for use during Labour and Delivery. This FDA clearance enables Monica technology to be utilised for intrapartum term monitoring for all singleton births in the USA.**

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 and uterine muscle (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 such as discerning FHR vs. MHR data .

The Monica AN24 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 Monica performs well in obese women. Professor W. Cohen from Albert Einstein College of Medicine, New York, stated: "We found the Monica AN24 performed excellently in very obese women (BMI >35) 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.

Carl Barratt, CEO of Monica Healthcare, explained "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 labour." Monica hopes that its technology will lead to improved patient care, raise efficiency, and ultimately reduce the cost of pregnancy care in the hospital

In the hospital, the Monica AN24 will be available exclusively in the USA through Glenveigh Medical. Glenveigh and its sales and distribution partner, Norgenix , will be promoting the device to pregnancy clinicians. It was formally introduced at the 31<sup>st</sup> meeting of the Society of Maternal-Fetal Medicine in San Francisco February 9-11.

For more information on Monica Healthcare, please visit [www.monicahealthcare.com](http://www.monicahealthcare.com) or contact [info@monicahealthcare.com](mailto:info@monicahealthcare.com) In the USA please contact Glenveigh Medical ([www.glenveigh.com](http://www.glenveigh.com)) or Norgenix ([www.norgenixpharma.com](http://www.norgenixpharma.com)).

