

MERIDIAN M110 Monitor

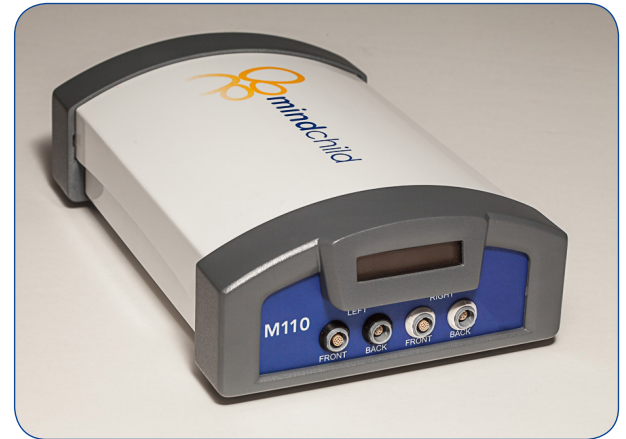
Electrocardiogram (ECG) monitoring has been widely used on adult patients for decades. In adults, signals representing a patient's cardiac activities are collected through a set of skin surface electrodes distributed over the patient's body.

Monitoring of fetal ECG (fECG) in this manner, however, can be difficult due to the co-existence of maternal and fetal signals acquired from a patient, as well as the relatively low fetal signal level relative to the maternal signal and other noise sources.

MindChild has developed the **MERIDIAN M110 Fetal Monitoring System** which is a device that utilizes external electrodes and a proprietary algorithm to discern between fetal and maternal signals allowing for an external, non-invasive device to calculate the fetal heart rate.

FHR Sentinel™

The MERIDIAN M110 monitor overcomes a major safety hazard of traditional monitoring - the inability of Doppler technology to distinguish the maternal heart rate from the fetal heart rate when the mother is tachycardic and the fetal heart rate is similar to the maternal heart rate. By tracking each signal independently, using a dedicated maternal ECG lead, MERIDIAN M110 eliminates the risk of monitoring the mother instead of the fetus.



MERIDIAN M110

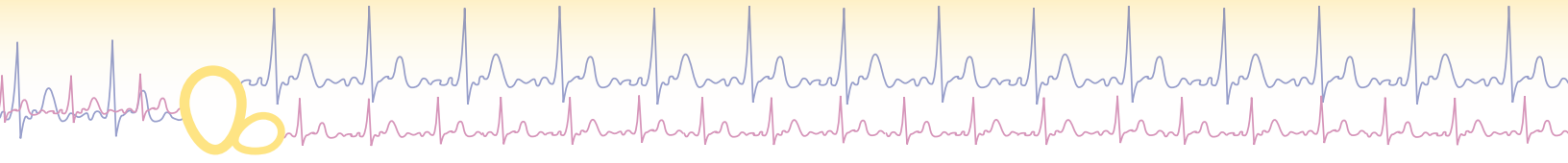
MERIDIAN M110 Gold Standard

At a time when the average BMI of obstetric patients is rising, and clinical excellence demands reliable fetal heart rate and contraction signals from all patients, MERIDIAN M110 is the only fetal monitor on the market that performs as well in obese patients as it does in lean patients. Both the fetal heart rate signal and the contraction signal deteriorate when BMI increases, compromising obstetric safety. MERIDIAN M110 solves this problem with improved technology, raising the safety profile of your unit. MERIDIAN's patented technology is FDA cleared to take the place of not only Doppler and tocometry, but also fetal scalp electrode and the intrauterine pressure catheter. It is no longer necessary to weigh the advantage of invasive monitoring with the risk of infection: MERIDIAN M110 provides gold-standard signal without the risk of invasive monitoring.

Indications for Use

The MERIDIAN M110 Fetal Monitoring System is an intrapartum fetal monitor that externally measures and displays fetal heart rate (FHR), maternal heart rate (MHR), and uterine contractions (UA). The MERIDIAN M110 Fetal Monitoring System acquires and displays the FHR and UA from abdominal surface electrodes that detect the fetal ECG signals, maternal ECG signals, and of uterine muscle contraction signals. Tracings of FHR and UA are displayed onto a primary fetal monitor.

The MERIDIAN M110 Fetal Monitoring System is indicated for use on women who are at ≥ 37 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. The MindChild MERIDIAN is intended for use by health care professionals in a clinical setting.



MERIDIAN Advantages

	Fetal Heart Rate			Uterine Contractions		
	Doppler	FSE	mindchild	TOCO	IUPC	
Consistent, Reliable and Highly Accurate	X	✓	✓	X	✓	» Uninterrupted Monitoring
Non-Invasive	✓	X	✓	✓	X	» Peace of Mind
Dynamic Tracking No Continual Repositioning	X	✓	✓	X	✓	» Best-in-Class Performance
Eliminate Risk of Internal Infection	✓	X	✓	✓	X	» Replaces Existing 4 Sensors
Maternal and Clinician Peace of Mind	X	X	✓	X	X	
Multi-Sensor Capabilities All-in-One Solution	X	X	✓	X	X	

MERIDIAN Clinical Results

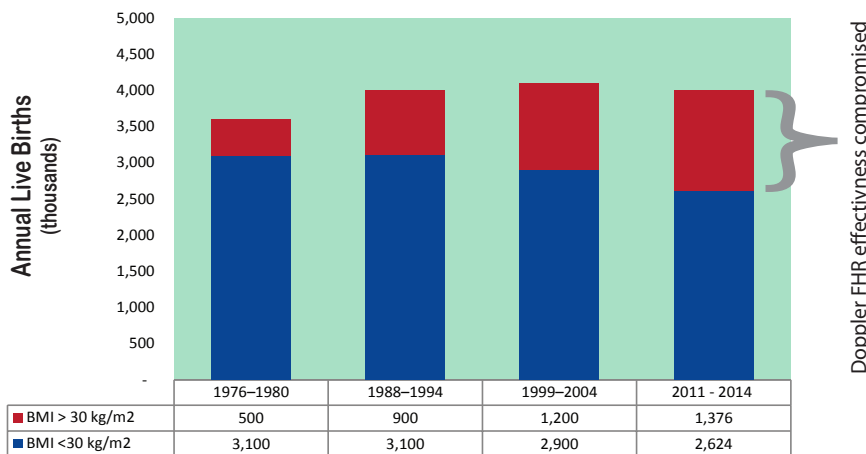
Accuracy (%)	94.3	98.0	98.3
Clinical Parameter	FHR	UA	MHR
Comparator	FSE	IUPC	SPO2

- » BMI = 32.1 (22 - 61)
- » Gestation = 39.1 (37 - 41) weeks
- » Age = 27.4 (18 - 38) years

MERIDIAN M110 Improves Quality of Interaction Between Nurse and Mother

The Meridian M110 eliminates the nursing time required to reposition the fetal monitoring transducer. The MERIDIAN M110 monitor eliminates transducer adjustment by automating sensor selection within the Meridian M110 Disposable Electrode Patch. In fact, workflow analysis suggests that use of MERIDIAN M110 reduces nursing work by 1-2 hours per labor episode. This advantage is particularly pronounced when monitoring obese patients: fetal movement, maternal position, and adipose tissue conspire to make fetal monitoring a full-time job for the covering nurse. MERIDIAN M110 eliminates this hands-on work, freeing nursing staff to focus on more important aspects of patient care.

Increasing Maternal BMI



21 CFR §801.109: "Caution: US Federal Law restricts this device to sale by or on the order of a physician"
 MindChild MERIDIAN is protected by patents in the United States and elsewhere. 7,949,389 - 8,805,485 - 8,892,181

www.mindchild.com



MindChild Medical, Inc.
 1600 Osgood St. Suite #2017
 North Andover, MA 01845
 Phone: 978.566.9880
 Email: sales@mindchild.com