

# Making labor safer for women and their babies

### **MERIDIAN 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 Fetal Heart Rate Monitor 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.

The MERIDIAN Monitor is a hospital or patient room device that consists of a ready roll-up cart with the associated connectors and display that allow for the accurate recording and display of the maternal and fetal heart rates.

21 CFR §801.109: "Caution: US Federal Law restricts this device to sale by or on the order of a physician"

"ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59\_03.pdf Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010 American Family Physician, 1992 Feb;45(2):579-82 http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html Company estimates.



**MERIDIAN M100** 

# About the Fetal Heart Monitoring Market

Over 85% of the 4,000,000 live births occurring in the US during 2011 required fetal monitoring during labor and delivery. Current non-invasive Doppler, employing ultrasound to detect FHR, is subject to loss of fetal heart rate due to maternal/ fetal movement. Fetal Scalp Electrodes (FSE) that connect directly to the fetus during the later stages of labor and delivery are associated with increased risk of maternal/fetal infection. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US, representing an investment of over \$700,000,000. MERIDIAN has been developed to provide uninterruptible fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.





#### **Indications for Use**

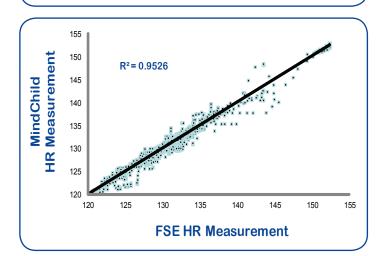
The MindChild Medical MERIDIAN Monitor is an intrapartum fetal monitor that externally or internally measures and displays fetal heart rate (FHR). The MERIDIAN monitor acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). The MERIDIAN may also be used to measure and display fetal heart rate using direct ECG (DECG) with a fetal scalp electrode. The MERIDIAN 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. The MERIDIAN is intended for use by healthcare professionals in a clinical setting.

#### MERIDIAN Advantages

- » Uninterrupted monitoring
- » Peace of Mind
- » Fetal ECG Analysis

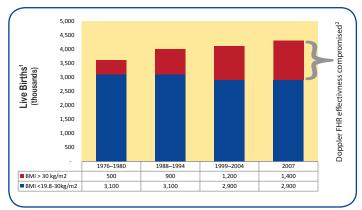
Yes	No No	Yes Yes
No	No	Yes
No	No	Yes
Yes	No	No
<b>(</b>	5	D
	Yes	Yes No

#### MERIDIAN Correlation to DECG



### Increasing Maternal BMI

Distribution of BMI (World Health Organization categories) from 1976 to 2004 Among U.S. Nonpregnant Women 12 to 44 Years of Age



- 1 Derived from Live Births, Deaths, Marriages, and Divorces: 1960 2007 Source: US National Center for Health Statistics, Vital Statistics of the United States, and National Vital Statistics Reports, (NVSR);
- 2 April 2012 fetal monitoring nursing staff survey interview



MindChild MERIDIAN is protected by patents both issued and pending in the United States and elsewhere.

## About MindChild Medical, Inc.

MindChild Medical, Inc., is a privately funded medical device company founded in 2008. MindChild's principal technology platform, the MERIDIAN non-invasive fetal electrocardiograph (fECG) monitor, is designed to report fetal heart rate data equivalent to the gold standard fetal scalp electrode in addition to novel ECG metrics intended to provide obstetricians a deeper understanding of fetal/maternal health and management.

MindChild was co-founded by Adam Wolfberg, MD, previously Assistant Professor, Tufts Medical Center (currently an associate at Boston Maternal-Fetal Medicine), Gari Clifford, PhD, previously Principal Research Scientist at Harvard-MIT Division of Health and Science Technology (currently on the faculty at the University of Oxford in the Department of Engineering Science), James Robertson, President and CEO, and Jay Ward, Executive Vice President, both of E-TROLZ, Inc.

MindChild has exclusively licensed intellectual property from the Massachusetts Institute of Technology, Tufts Medical Center and E-TROLZ, Inc., a Massachusetts technology company that develops and commercializes breakthrough physiologic monitoring platforms for a wide variety of applications.



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