

FOR IMMEDIATE RELEASE – April 10, 2017

MindChild Medical, Inc. Announces Publication of "Evaluation of the fetal QT interval using non-invasive fetal ECG technology" With the MERIDIAN™ Fetal Monitoring System

The MERIDIAN Fetal Monitoring System Enables Non-Invasive Fetal, Maternal Heart Rate and Uterine Contraction Monitoring Using Surface Electrodes

(BusinessWire, North Andover, Massachusetts), MindChild Medical, Inc. today announced publication of "Evaluation of the fetal QT interval using non-invasive fetal ECG technology" in the Journal of Physiological Measurement.¹ The evaluation was conducted by investigators at Technion-IIT, University of Oxford, Tufts Medical Center, Boston Children's Hospital, Seattle Children's Hospital, Brigham and Women's Hospital, MindChild Medical, Emory University and Georgia Institute of Technology. Utilizing MERIDIAN non-invasive fetal electrocardiography (NI-FECG) technology enables accurate extraction of the fetal QT interval. According to senior author, Gari D. Clifford, PhD^{2,3}, "These results provide evidence that non-invasive fetal electrocardiography (NI-FECG) technology enables accurate extraction of the fetal QT interval." Dr. Clifford continued, "Fetal QT interval changes are critical in managing fetal health. The ability to extract high quality fetal QT intervals may have profound diagnostic implications and provide insight to proactive fetal management." Long QT syndrome (LQTS) has been shown to be a major determinant in young sudden death individuals for which an autopsy was performed but had remained inconclusive⁴ and a determinant for as much as 10% of sudden infant death syndrome (SIDS).^{5,6,7}

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 FHR, MHR and UA from abdominal surface electrodes that detect the fetal ECG signals, maternal ECG signals, and 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 MERIDIAN M110 Fetal Monitoring System is intended for use by healthcare professionals in a clinical setting.

Adam Wolfberg, M.D., Chief Medical Officer for MindChild stated, "The ability of extract accurate fetal electrocardiographic information is a tremendous achievement. As this technology enters the labor and delivery clinic, new diagnostic capabilities will undoubtedly emerge, providing insight into fetal

¹ Physiol. Meas. 37 (2016) 1392–1403.

² Gari Clifford, PhD is the Chief Technology Officer of MindChild, Inc.

³ Presently Interim Chair, Associate Professor, Biomedical Informatics (Emory University) and Associate Professor, Biomedical Engineering (Georgia Institute of Technology)

⁴ Mayo Clin Proc. 2012 Jun; 87(6):524-39.

⁵ JAMA. 2001 Nov 14; 286(18):2264-9.

⁶ Circulation. 2007;115(3):361–367.

⁷ Heart Rhythm. 2009;6(2):272–278.

management not currently available.” Dr. Wolfberg continued, “In the coming months and years, MindChild will exploit this technology to improve the safety of obstetrics, and hand a new diagnostic device to obstetricians and pediatric cardiologists.”

Previous Announcements

On January 17, 2017, MindChild Medical, Inc. announced clearance of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M110 Line of Non-Invasive Fetal Heart Rate Monitors.

On December 7, 2015, MindChild Medical, Inc. announced Receipt of Certificate of Registration by BSI Group America Inc., Under the International Organization for Standardization (ISO) 13485:2003.

On November 16, 2015, MindChild Medical, Inc. announced filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M110 Line of Non-Invasive Fetal Heart Rate Monitors.

On April 19, 2015, MindChild Medical, Inc. announced clearance of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M100 Line of Non-Invasive Fetal Heart Rate Monitors.

On November 11, 2014, MindChild Medical, Inc., announced the filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ M100 Line of Non-Invasive Fetal Heart Rate Monitors.

On April 8, 2014, MindChild Medical, Inc., announced the 1,000th successful non-invasive fetal heart monitoring session utilizing the MERIDIAN™ Fetal Heart Monitor.

On May 1, 2013, MindChild Medical, Inc., presented the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 61st Annual Meeting for the American College of Obstetricians and Gynecologists (ACOG) in New Orleans.

On February 13, 2013, MindChild Medical, Inc., presented the MERIDIAN™ Non-Invasive Fetal Heart Rate Monitor at the 33rd Annual Meeting for the Society for Maternal Fetal Medicine (SMFM) in San Francisco, CA.

On June 18, 2012, MindChild announced the appointment Thomas Garite, M.D. to the Clinical Advisory Board for the MERIDIAN Line of Non-Invasive Fetal Heart Rate Monitors.

On June 11, 2012, MindChild announced Results of National Fetal Monitoring Market Survey.

On February 22, 2012, MindChild reported formation of a Clinical Advisory Board for the MERIDIAN™ Line of Non-Invasive Fetal Heart Rate Monitors.

On February 6, 2012, MindChild reported filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the MERIDIAN™ Line of Non-Invasive Fetal Heart Rate Monitors.

About the MERIDIAN Non-Invasive Fetal Heart Rate Monitor

MERIDIAN is a fetal monitor that non-invasively measures and displays fetal heart rate. MERIDIAN acquires and displays the FHR tracing from abdominal surface electrodes that detect the fetal ECG signal (fECG). MERIDIAN is designed for women who are at term (≥ 37 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. MERIDIAN is intended for use by healthcare professionals in a clinical setting.

About the Fetal Heart Monitoring Market

Over 85%⁸ of the 4,000,000⁹ 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 movement¹⁰. 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 infection¹¹. There are an estimated 28,000 fetal monitors spread over 3,400 hospitals in the US¹², representing an investment of over \$700,000,000¹³. MERIDIAN has been developed to provide uninterrupted fECG data while addressing the deficiencies in both Doppler and FSE via innovative non-invasive monitoring technology.

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, Assistant Professor, Tufts Medical Center, Gari Clifford, PhD, previously Principal Research Scientist at Harvard-MIT Division of Health and Science Technology (currently Interim Chair, Associate Professor, Biomedical Informatics (Emory University)), 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. For more information, please visit www.mindchild.com.

Contacts

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⁸ "ACOG Refines Fetal Heart Rate Monitoring Guidelines", 6/22/2009 The American College of Obstetricians and Gynecologists Press Release

⁹ http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_03.pdf

¹⁰ Journal of Midwifery. Vol 18, No, 7: 424-428. July 2010

¹¹ American Family Physician, 1992 Feb;45(2):579-82

¹² <http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html>

¹³ Company estimates.