AirStrip Sense4Baby System Receives FDA Clearance for Patient Self-Administration

*University of Utah to assess integrating home-based Sense4Baby monitoring into health care system while evaluating patient and provider satisfaction, costs and benefits*

SAN ANTONIO – April 1, 2015 – The U.S. Food and Drug Administration has cleared the AirStrip® Sense4Baby™ wireless maternal/fetal monitoring system to be marketed for use in the U.S. by pregnant patients to self-administer non-stress tests (NST).

Sense4Baby already received 510(k) clearance from the FDA for use accompanied by medical professionals. Sense4Baby also received the CE mark from the European Commission in 2013 for self-administration, including the home.

This new clearance is an important step toward integrating out-of-hospital perinatal monitoring data into the AirStrip ONE® interoperable mobility platform and application. AirStrip ONE provides vendor- and data source-agnostic information from multiple data sources and care settings to support coordination among caregivers natively on smartphones, tablets, and personal computers.

AirStrip pioneered mobile monitoring in obstetrics a decade ago with the industry’s first application to make live waveforms accessible via a mobile device. Today, one in six babies born in the U.S. is monitored with AirStrip.

“AirStrip Sense4Baby can supplement care for patients with a prescribed need for NSTs that – with proper training and a care team’s interpretation of data – offers a safe, convenient and cost-effective monitoring method in settings beyond hospital walls,” AirStrip President Matt Patterson, M.D. said. “Sense4Baby is a natural extension of AirStrip ONE, creating a new avenue for seamless mobile monitoring that can connect patients with their care team while encouraging true patient engagement and peace of mind.”

The University of Utah will conduct a research study to test AirStrip Sense4Baby in a local high-risk population. The goal is to assess the feasibility of integrating an at-home NST monitoring program into an established health care system, as well as to evaluate patient and provider satisfaction.

The University of Utah aims to show that mobile connectivity can positively impact prenatal care for both low- and high-risk pregnancies. Currently, NSTs are typically conducted in clinics or hospitals.

“Patients may need to travel for extended periods of time, multiple times per week, in order to receive these tests,” said Erin A.S. Clark, MD, Assistant Professor of Maternal/Fetal Medicine in the Department of Obstetrics and Gynecology. “At-home fetal monitoring may allow patients to save time and money
related to travel for NSTs, and may also increase the capacity and flexibility of health systems to conduct NSTs. The University of Utah strives to provide the very best prenatal care to our patients, with the highest patient satisfaction, at the lowest cost to patients and to the health care system. Strategies that employ mobile connectivity may be a key part of this vision.”

The FDA clearance is the latest in a series of announcements since AirStrip acquired the assets of Sense4Baby, Inc. in 2014. In February, AirStrip announced agreements to launch Sense4Baby in Europe, Africa and Australia/New Zealand. More international expansion announcements are expected soon.

Tweet This: @AirStripmHealth gets FDA clearance to market Sense4Baby fetal monitoring to self-administer non-stress testing http://bit.ly/12a91UT

About AirStrip

AirStrip® (www.airstrip.com) makes transformational and lasting improvements in worldwide healthcare delivery by creating innovative technology for caregivers to collaborate and care for their patients. AirStrip provides a complete, vendor and data source-agnostic, enterprise-wide mobile interoperability platform that advances care collaboration and serves as a catalyst for health system innovation. With deep clinical expertise and strong roots in mobile technology and data integration, AirStrip is empowering leading health systems globally as the industry evolves at a rapid pace. Based in San Antonio, Texas, AirStrip allows health systems to unlock the full potential of their existing technology investments with a mobile interoperability platform that provides access to critical patient data and intelligent insights across the care continuum. AirStrip is backed by investments from Dignity Health, St. Joseph Health, the Gary and Mary West Health Investment Fund, Sequoia Capital, Qualcomm, Inc., Leerink Partners, Hospital Corporation of America (HCA) and the Wellcome Trust. AirStrip’s base of visionary clients includes HCA, Texas Health Resources, Tenet Healthcare, Dignity Health, St. Joseph Health and Ardent Health Services.

Follow AirStrip

• Blog: www.MobileHealthMatters.com

• Twitter: @AirStripmHealth

• LinkedIn: www.linkedin.com/AirStrip

AirStrip Media Contacts

Chris Lato
608.219.7231
chrislato@airstrip.com

Siobhan Nguyen
617.986.5784
Siobhan_Nguyen@lpp.com