Medtronic News

Covidien Announces U.S. Food and Drug Administration 510(k) Clearance for Nellcor™ Portable SpO2 Patient Monitoring System

Monitor is only portable oximeter on the market that is indicated for use in home care settings and is compliant with international standards for devices used in the home health care environment

DUBLIN, Ireland--(BUSINESS WIRE)--Oct. 9, 2014--Covidien plc (NYSE: COV) today announced U.S. Food and Drug Administration 510(k) clearance for the Nellcor™ Portable SpO2 Patient Monitoring System (PM10N). The system is the only commercially available portable oximeter that is equipped with home care and sleep study modes and complies with IEC 60601-1-11 standards for devices used in the home health care environment.

Part of a comprehensive Covidien respiratory function monitoring portfolio, this convenient, handheld patient monitor is simple to use and ideal for fast, accurate, motion-tolerant monitoring of pulse rate and blood oxygenation (SpO2). The Nellcor™ Portable SpO2 Patient Monitoring System's compact design and ability to perform in challenging conditions make it an ideal tool for multiple critical clinical screenings including: Six Minute Walk Test, Critical Congenital Heart Disease Screening and Car Seat Challenge Test.

The lightweight system is user-friendly and features a home care mode that expands the utility of the monitor beyond the hospital to home-use environments. With a simplified user interface, patients can clearly view their vital sign readings, and the settings cannot be easily altered by the patient, so clinicians can feel confident prescribing the home-use of this monitor. The system also features a sleep study mode that enables dimming the LCD display and silencing alarms to prevent disrupting patients' sleep.

"Covidien's new generation of portable monitors is easy to use and brings our proven pulse oximetry technology to patients inside the hospital, in health care facilities, and even in their own homes," said Matt Anderson, vice president & general manager, Patient Monitoring, Covidien. "Because our pulse oximetry technology relies on cardiac signals, it mitigates signal interference, offering caregivers peace of mind. They can count on Covidien to provide accurate patient data, even during difficult conditions. The development of this product exemplifies Covidien's dedication to enhance patient care, both inside and beyond the hospital."

The monitoring system includes a vivid three-inch color LCD screen, as well as connectivity to analytics tools and patient management systems. It is compatible with the entire line of Nellcor™ sensors with OxiMax™ technology and offers a robust monitoring feature set including SpO2, pulse rate, SatSeconds alarm management, pleth waveform, blip bar and tabular trend information. The monitor incorporates Nellcor™ digital signal processing technology to deliver accurate, reliable SpO2 and pulse rate values even during challenging conditions, such as patient motion, noise, signal interference and low perfusion, all of which can interfere with assessing a patient's respiratory status.

The system can be used as a tool for the following critical clinical screenings:

- Six Minute Walk Test – This test evaluates the response of all systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism. The Six Minute Walk Test provides an objective measurement of a patient's exercise capacity.1
- Critical Congenital Heart Disease (CCHD) Screening – Every year, about 4,800 (or 11.6 per 10,000) babies inthe United States alone are born with CCHD. These babies are at significant risk if this condition goes undiagnosed.2 Since 1993, Nellcor™ pulse oximetry technology has been utilized on more than 33,000 newborns spanning five separate clinical studies evaluating the use of pulse oximetry for critical congenital heart disease screening.3-7
- Car Seat Challenge Test – According to the American Academy of Pediatrics guidelines, as part of the discharge process, each preterm infant born less than 37 weeks gestational age should have a period of observation in a car safety seat before hospital discharge to monitor for possible apnea, bradycardia or oxygen desaturation.8-9

More information on the product portfolio is available by visiting Covidien.com/Nellcor.

ABOUT COVIDIEN

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers, Covidien's team of dedicated professionals is privileged to help save and improve lives around the world. With more than 38,000 employees, Covidien operates in 150-plus countries and had 2013 revenue of $10.2 billion. To learn more about our business visit www.covidien.com or connect with us on Twitter.

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Covidien
Rhonda Luniak, 303-406-8743
Vice President
R&MS Communications
rhonda.luniak@covidien.com

or
Coleman Lannum, CFA, 508-452-4343
Vice President
Investor Relations
cole.lannum@covidien.com
or
Lisa Clemence, 508-452-4375
Director
Corporate Communications
lisa.clemence@covidien.com
or
Todd Carpenter, 508-452-4363
Senior Director
Investor Relations
todd.carpenter@covidien.com
