Covidien Announces FDA 510(k) Clearance and CE Mark for Nellcor Bedside Respiratory Patient Monitoring System

Covidien

New system completes enhancement of entire pulse oximetry bedside monitoring portfolio

Covidien (NYSE: COV), a leading global provider of healthcare products and recognized innovator in patient monitoring and respiratory care devices, today announced U.S. Food and Drug Administration 510(k) clearance and European Economic Area (EEA) CE Mark approval for the Covidien Nellcor™ Bedside Respiratory Patient Monitoring system.

This new system provides continuous monitoring of blood oxygenation (SpO2) and pulse rate, along with trend data to help clinicians detect and respond to dangerous respiratory events sooner. The new Nellcor Bedside Respiratory Patient Monitoring system is upgradable onsite to accommodate new parameters and features, including Nellcor Respiration Rate software, thereby reducing service disruptions and costs for hospitals.

“We are pleased to announce clearance to market the Nellcor Bedside Respiratory Patient Monitoring system in the U.S. and the EEA,” said Robert J. White, President, Respiratory and Monitoring Solutions, Covidien. “With this addition, we now offer an updated portfolio of industry-leading bedside monitoring solutions that meet unique care needs in both high- and low-acuity settings, thus enhancing patient safety in hospitals throughout the world.”

The new system features a color touch-screen graphical user interface and provides a variety of wired and wireless connectivity options to meet the various needs found in different hospital settings. It can connect to the Nellcor OxiNet III Remote Respiratory Monitoring system, enabling clinicians to monitor multiple patients from a central monitoring station on the general care floor.

A SatSeconds alarm management feature helps clinicians differentiate between serious and minor events, reducing clinically insignificant desaturation alarms and alarm fatigue. The monitoring system also features a Saturation Pattern Detection alert for automated, real-time detection of patterns of desaturation that indicate repetitive reductions in airflow.

The device meets current and upcoming standards, including compliance with Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and ISO 3rd Edition* standards. The new system will be available in the United States and throughout the EEA in the next few months.

ABOUT COVIDIEN

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2011 revenue of $11.6 billion, Covidien has 43,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Please visit www.covidien.com [1] to learn more about our business.

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