Covidien Nellcor Pulse Oximeters Receive FDA 510(k) Clearance with Labeling for Use in Newborn Screening for Critical Congenital Heart Disease

Covidien

Labeling reconfirms device accuracy during patient motion; Nellcor pulse oximeters are the only oximeters on the market compliant with ISO 80601-2-61

Every year, nearly 7,200 infants are born in the United States with a Critical Congenital Heart Disease (CCHD).1 It is a condition that is often easily detectable and, when discovered, quite treatable.

Far too frequently, however – in nearly one case in three – newborns with CCHD leave the hospital undiagnosed. Generally asymptomatic until it's too late, they go home to face the possibility of long-term disability or sudden death. Each year, 100 to 200 newborns fall victim to CCHD.2

Covidien [1], a leading global provider of healthcare products and recognized innovator in patient monitoring and respiratory care devices, is addressing this situation.

The company's Nellcor pulse oximetry portfolio facilitates quick, noninvasive screenings for CCHD. The products are U.S. Food and Drug Administration (FDA)-510(k) cleared for use on neonates, so physicians can rely on them for accurate CCHD screenings. Now – as part of a broad effort to educate clinicians on the importance of CCHD screenings and encourage hospitals to implement routine CCHD screening for all newborns – Covidien has begun labeling and promoting the use of Nellcor pulse oximetry as a tool to aid healthcare practitioners in CCHD screening.

"CCHD is a life-threatening condition that can be detected and treated earlier through proper screening," said Matthew Anderson, Vice President and General Manager, Respiratory and Monitoring Solutions, Covidien. "Covidien is committed to raising public awareness about this issue and encouraging CCHD screenings. We truly hope our CCHD resources, the educational support we offer clinicians and our pulse oximetry portfolio help make an important difference in the fight against CCHD."

Covidien's CCHD awareness activities ensure clinicians understand how to use pulse oximeters and best generate reliable readings. Covidien offers free CCHD educational resources [2] through its new Professional Affairs and Clinical Education (PACE) Online Platform [3].

Highly Accurate CCHD Screenings

Covidien's new CCHD labeling was introduced as part of the FDA 510(k)-cleared labeling for motion tolerant Nellcor pulse oximeters. In 2011, the U.S. Department of Health and Human Services added CCHD screening to the Federal Recommended Uniform Screening Panel Guidelines. As a follow up to those guidelines, the Consensus Work Group's recommendation specified the use of pulse oximeter devices that are motion tolerant, report functional oxygen saturation, have been validated in low perfusion conditions, and have been cleared by the FDA for use in newborns. The performance of Nellcor pulse oximeters demonstrates that the criteria are fully met and the devices provide accurate readings even during patient movement. This can be particularly important for CCHD screenings in newborns because their tendency to move can prevent accurate readings.

With the FDA's recent clearance of the expanded performance claims, Nellcor pulse oximeters are now the only oximeters on the market certified to be in compliance with ISO 80601-2-61 International Organization for Standardization.

"Our new CCHD labeling reaffirms the longstanding and reliable performance of Nellcor pulse oximeters during patient motion," said Scott Kelley, M.D., Chief Medical Officer, Respiratory and Monitoring Solutions, Covidien. "Clinicians now have added comfort that the same pulse oximeter technology they've trusted for decades continues to enable the highest standards of neonatal care."

Nellcor pulse oximetry technology provides the industry's most accurate readings in neonates (+/-2 percent accuracy), largely because it relies on cardiac-based signals to generate readings closely tied to the patient's physiology. The result is consistent performance during a number of challenging conditions, including patient motion, noise and low perfusion, all of which can impede the assessment of patient respiratory status.

Specific Covidien devices featuring the new CCHD labels include:

- NellcorTM Bedside SpO2 Patient Monitoring System
- NellcorTM Bedside Respiratory Patient Monitoring System
- NellcorTM N-600x Pulse Oximetry Monitoring System

More information about the Nellcor product portfolio is available through the Covidien website [4].

1. According to the Centers for Disease Control and Prevention (CDC)
2. Presentation [5] by W. Robert Morrow, MD, FAAP, Arkansas Children's Hospital, University of Arkansas for Medical Sciences

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