

EarlySense Receives FDA Clearance for Bedside System and Central Display System with Oximetry Integration

The Associated Press

WALTHAM, Mass.--(BUSINESS WIRE)--Oct 17, 2012--EarlySense, the market leader in proactive patient care solutions, announced today that the company has received FDA Clearance for its bedside system and central display system with oximetry integration. This coincides with the Joint Commission's recently issued Sentinel Event Alert (the Alert) on the safe use of opioids in hospitals which recommends implementing better dosing along with oxygenation and ventilation monitoring in post-surgical patients.

The Alert states that opioid analgesics, a painkiller widely used to treat post-surgical patients, may be associated with adverse effects, the most serious effect being respiratory depression, which can potentially lead to death. Similar to the 2011 Anesthesia Patient Safety Foundation's recommendations, the Alert also recommends continuous monitoring, rather than spot checks of oxygenation and ventilation. According to statistics included in the Alert, a typical surgical floor will have on average at least one case of medication related respiratory depression every month.

Avner Halperin, CEO of EarlySense said, "EarlySense is the first in the world to combine contact-free respiratory, cardiac and motion monitoring with oximetry. This means, that for the first time ever, hospitals have the ability to monitor the oxygen saturation of a patient in addition to automatically, continuously and in a contact-free manner, monitor that same patient's vital signs and movement. The oximetry component, meant for post-surgical patients who require a higher level of supervision, seamlessly integrates into the existing EarlySense system, including the central display station. The combination of deliverables provides clinicians with a flexible tool to facilitate individualized care plans for optimal clinical outcomes on the medical surgical floors." The new oximetry feature of the EarlySense System will be introduced at Medica 2012 in Germany in November and officially launched into the market in 2013.

"The Joint Commission's list of recommendations pertaining to the safe use of opioids in hospitals is pointed and well-grounded. Associated adverse effects are extremely serious but are also largely avoidable if the proper precautions are taken and early warning systems are used. Continuous patient monitoring technologies have the potential to make a substantive positive impact in helping medical teams to secure better patient outcomes. The introduction of new technologies that combine contact-free respiratory analysis with oximetry is welcomed news as it is likely to be particularly well-tolerated. We hope that such early warning solutions will eventually become a standard of care on general care floors," said, Dr. David Bates, Chief Quality Officer and Chief of the Division of General Internal Medicine at

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Brigham and Women's Hospital, a Professor of Medicine at Harvard Medical School and the Executive Director of the Center of Patient Safety Research and Practice.

Dalia Argaman, VP of Clinical and Regulatory Affairs said, "In addition to helping hospitals to comply with the Joint Commission's recent sentinel alert recommendations, the EarlySense system is already in use by hospitals across the USA and Europe to help clinical teams to prevent falls and pressure ulcers. This helps them to better comply with the Joint Commission's National Patient Safety Goals #9 and #14. In short: the EarlySense system offers a single integrated patient safety platform that enables hospitals to proactively respond to high priority Joint Commission goals." About EarlySense EarlySense is bringing to market an innovative technology designed to advance proactive patient care and enable clinicians to achieve better patient outcomes. The company's flagship product, the EarlySense system, is an automatic, continuous, contact-free, patient monitoring solution that monitors and documents a patient's vital signs and movement using a sensor that slips under a bed mattress. There are no leads or cuffs to connect to the patient, who has complete freedom of movement and is not burdened by any irritating attachments. The system is designed to monitor non-ICU 'lower risk' patients on medical surgical floors who are usually monitored by on-duty nurses once every four to five hours. The system is currently installed at hospitals and rehabilitation centers in the USA and Europe. It is also commercially available in Canada. EarlySense Inc. is headquartered in Waltham, MA. Investors include: JK&B, Pitango Venture Capital, Etgar Challenge Fund, ProSeed VC Fund (TASE: PRSD), Docor International Management, Noaber, and Bridge Investment Fund, and Peter Soderberg, managing partner of Worthy Ventures Resources, LLC and former president and CEO of Hill-Rom Holdings, Inc. (NYSE: HRC).

For additional information, please visit: www.earlysense.com

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