

EarlySense wins FDA clearance for Ever-ON

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Nurses and doctors simply cannot be in 36 places at once. But a monitoring system recently cleared by FDA might be the next best thing.

The agency has cleared the EverOn Central Display Station (CDS) from EarlySense (Ramat Gan, Israel). The clearance covers the ability of the system to collect real time vital sign information from up to 36 EverOn bedside monitors and display the information on a computer screen at the nurse's station, the company said. This data is also replicated on large LCD displays on the medical surgical floors enabling the clinical teams, as they move from room to room; to continuously observe the condition status of their patients and any corresponding patient safety alerts.

Perhaps the best part about the system is that the data is collected by a contact-free sensor placed under the hospital bed mattress, EarlySense noted, adding that the system has no leads or cuffs and never touches the patient.

"When you look at hospitals today, they are facing a growing challenge of an admitted population that is more and more acutely ill," Avner Halperin, CEO of EarlySense, told *Medical Device Daily*. "On general care floors the patients there on average are clearly getting sicker and sicker due to an aging population, c-omorbidities, etc. and the fact that anyone who is doing even half-well is sent home."

Halperin also noted the increasing pressure hospitals are under from payers and regulatory bodies to be more efficient and also the fact that any errors that are made fall on the hospital's bottom line.

"With today's increased focus on improved quality and patient safety targets coupled with the challenges of shrinking budgets, hospitals are turning to advanced technologies such as EverOn to provide effective alerts on high risk situations," Halperin said.

He added that being able to identify early warning signs of patients who are going down hill helps hospital staff see where the risks are and be able to proactively do something about it. The EverOn CDS has been designed to do just that, he said. According to EarlySense, the CDS is a vital part of its EverOn patient monitoring system. It continuously presents and transmits the respiratory and heart rate data of patients. In addition, it displays bed exit alerts for preselected patients. This information helps to minimize falls, the company noted. Furthermore, the CDS alerts nurses when the system has determined that patients, who are under a pressure ulcer prevention program, need to be turned. This helps nurses to more proactively attend to these patients.

EarlySense also noted that the EverOn system is becoming an integral part of the nurses' workflow as, via the CDS, it sends relevant alerts to their mobile phones, enabling real time notification of any adverse changes in a patient's vital signs.

By making it contact-free, the EverOn system is convenient for both the patient and the nurse and doctor, Halperin said. Existing monitoring technologies have a high number of false alarms, according to Halperin. He told *MDD* that this "cry wolf syndrome" or, to use the technical term for it, "alarm fatigue" can render a monitoring system useless. So EarlySense worked long and hard to make the EverOn system quiet, he said. "It is dramatically better than any other system out there in terms of false alarms," he added.

But what's really interesting about this particular system, according to the Halperin, is how it all works together. "You've got 36 patients on a floor and they all have their own issues and they've got the sensor underneath the mattress" monitoring the patients' heart rates, respiratory rates, movements (if they are moving too much or too little) and "with all of this going on, with this system no matter where the medical professional is on the floor, if something is going on they're going to know about it."

The CDS augments the EverOn contact-free patient supervision system approved in June, the company noted.