Masimo Announces FDA Clearance of Centroid™

Wearable, Wireless Patient Orientation, Activity, and Respiration Sensor Helps Clinicians Monitor Patient Position and Respiration Rate

Masimo announced today that Centroid™, a wearable, wireless patient orientation, activity, and respiration rate sensor, has received FDA clearance. Centroid helps clinicians monitor patient position to avoid preventable pressure ulcers, and can alert clinicians to sudden movements such as fall-like events. In addition, Centroid detects chest movements to continuously provide respiration rate, assisting clinicians with additional data that may inform care decisions.

This press release features multimedia. View the full release here.

Centroid pairs with the Root® Patient Monitoring and Connectivity Platform using Bluetooth® to track a patient's posture, orientation, and activity, providing the ability to monitor patient position and detect changes in position. The data transmitted by Centroid can be displayed in various formats on Root, giving clinicians multiple ways to assess adherence to protocols regarding tissue stress and to tailor care to the specific needs of each patient.

Pressure sores affect nearly 2.5 million patients per year in U.S. hospitals alone, and approximately 60,000 of those patients die as a direct result.1 Centroid is indicated for the orientation monitoring of patients who may be susceptible to pressure ulcers, by tracking patient movement and activity using an accelerometer and gyroscope. Centroid can identify a patient's position and orientation to the nearest degree, with alerts based on the duration in a static position to help clinicians adhere to hospital patient turn protocols. Centroid also features customizable alarm zones to help avoid patient positions that could negatively impact recovery time. Unlike simple time-based rotation protocols, Centroid uses the cumulative time spent in each position, as well as existing sore data, to calculate relative risk, displayed on the Root screen using color-coded markers, helping clinicians identify the potential severity of tissue stress for each position—and ultimately, helping to guide clinical decisions about the most appropriate, least risky positions for each patient.

In addition, because Centroid can identify whether a patient is lying down, standing, sitting upright, walking, or may have fallen, it can notify clinicians of a sudden change in position that might provide early warning of a potential fall, by alerting them when clinician-defined movement thresholds are crossed. Its respiration rate performance, validated against manually scored capnogram respiratory measurements, is accurate to within 3 respirations per minute (rpm) in the range of 8 to 35 rpm.

The Centroid single-patient-use sensor is ergonomically designed for application on the chest using flexible, lightweight material for patient comfort, with a gentle adhesive that supports continuous use during daily activities. Each battery-operated sensor is designed to last four days, minimizing the need for frequent replacement.

Joe Kiani, Founder and CEO of Masimo, said, "We are committed to using our expertise in signal processing and sensor design to develop new ways to provide the highest quality, most relevant data to clinicians in the most intuitive, useful formats, and Centroid, coupled with Root's rich high-resolution display, is a great example of this. We hope that by helping to automate the process of tracking and making decisions about patient position, we can help clinicians reduce the frequency and severity of pressure ulcers, and ultimately improve patient outcomes."

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