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Medtronic receives FDA clearance for Nellcor™ OxySoft™ neonatal-adult SpO2 sensor

- First pulse oximetry sensor with silicone adhesive designed to protect fragile newborn skin while staying adhered longer
- Low profile and brighter LEDs improve accuracy and responsiveness for the most challenging neonatal and adult critical care patients

Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced that the U.S. Food and Drug Administration (FDA) granted 510(k) clearance for the Nellcor™ OxySoft™ SpO_2 sensor. The device is the first pulse oximetry sensor to use a silicone adhesive designed to protect fragile skin and improve repositionability and signal acquisition. This new sensor will help clinicians respond quickly with well-informed decisions for their critical care patients.



“We are committed to developing clinically-meaningful solutions. Listening to the nurses and physicians that we serve, we provide purpose-built technologies that meet the needs of their patients” said Frank Chan, president of the Patient Monitoring business, which is part of the Medical Surgical Portfolio at Medtronic. “Our technologies are always looking out for the most vulnerable patients by providing clinicians with quick, reliable, accurate information to help treat patients most efficiently.

The sensors silicone adhesive and low profile stays in place longer and removes 87 percent fewer skin cells from

fragile skin,[1] keeping up with sudden movements of newborns. Designed to improve workflow, the sensor is easy to peel apart and reposition – withstanding up to 18 repositions. Advanced technology also enhances signal acquisition and time to post in challenging situations such as low perfusion and thicker tissue.

"There are many pressures and critical decisions required of providers delivering care in the NICU. We need devices that provide our caregivers with reliable data that enable them to make time-sensitive decisions without hesitation," said Sam Ajizian, MD and chief medical officer of the Patient Monitoring business at Medtronic. "The Nellcor™ OxySoft™ SpO_2 sensor does just that. We look at every heartbeat to ensure that readings are sensitive and timely, even in the most challenging monitoring conditions."

The new Nellcor™ OxySoft™ SpO_2 sensor will expand the Nellcor™ pulse oximetry portfolio with an everyday sensor made with the most fragile and challenging patients in mind. When combined with Nellcor™ OxiMax™ technology, clinicians can rest assured they are informed with the high-quality data needed to make confident decisions.

For more details and media assets, please visit our media kit.

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[1]internal test report CSR 20210312v1 S20-12, head-to-head testing with MaxN; [2]based on hands-on evaluation; [3]internal head-to-head bench testing using validated equipment against MaxN

The Nellcor™ pulse oximetry monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

https://news.medtronic.com/Nellcor-OxySoft-neonatal-adult-SpO2-sensor