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Medtronic receives FDA clearance for Nellcor™ pulse oximetry system with Nell-EQ™ intelligent processor, a new technology designed to improve reliability across diverse patients and conditions

Medtronic, a global leader in healthcare technology, announced FDA 510(k) clearance of its Nellcor™ pulse oximetry system with Nell-EQ™ intelligent processor. The Nell-EQ™ intelligent processor is a new pulse oximetry processing technology designed to support more consistent and reliable oxygen saturation (SpO₂) and pulse rate monitoring across diverse patient populations, skin tones, and clinical care settings.

This regulatory milestone follows news from earlier this year, when the company announced [positive verification study results](#) for its Nellcor™ pulse oximetry system with Nell-EQ™ intelligent processor. The technology was also [previously granted FDA Safer Technologies Program \(STeP\) designation](#) for medical devices that are reasonably expected to improve the safety of currently available devices.

“With this FDA clearance, our innovative Nell-EQ™ system expands the Medtronic pulse oximetry portfolio with an intelligent processing platform designed to support both clinical confidence and more inclusive care,” said Kate Benedict, president of the Medtronic Acute Care & Monitoring business, which is part of the company’s Medical Surgical Portfolio. “Our Nellcor™ pulse oximetry system with Nell-EQ™ intelligent processor builds on our longstanding commitment to delivering reliable monitoring performance for diverse patient populations across care environments.”

Pulse oximetry plays a critical role in clinical assessment and decision-making. Yet, it is known in the industry that



performance has historically varied depending on clinical conditions, patient physiology, and skin tone, which can impact signal reliability during monitoring. FDA 510(k) clearance of the Nell-EQ™ system comes shortly after the International Organization for Standardization (ISO) published ISO 80601-2-61:2026, at a time when evolving standards and regulatory expectations are placing greater focus on evaluating pulse oximeter performance across diverse patient populations, including defined skin tone groups.

Clinical studies for the Nell-EQ™ system included participants across the full range of skin tones, and the system uses advanced signal processing methods, incorporating patient-specific and sensor-specific signal characteristics to support more consistent and reliable interpretation of optical signals into SpO₂ values. In addition to SpO₂ and pulse rate, the platform supports parameters such as Perfusion Index (PI) and Heart Rate Variability (HRV).

“With our Nellcor™ pulse oximetry system with Nell-EQ™ intelligent processor, Medtronic continues to lead the industry in advancing pulse oximetry technology that helps clinicians deliver confident, equitable care for every patient, in every care setting,” said Dr. Jeb Denny, chief medical officer of the Medtronic Acute Care & Monitoring business. “Our continued leadership reflects a deep commitment to inclusive innovation and equipping clinicians with trusted technology that supports high-quality care for all patients across the continuum of care.”

Nellcor™ pulse oximetry technology with Nell-EQ™ intelligent processor will be available for sale globally in the upcoming months. Medtronic plans to support the rollout with clinician education and training resources.

Evidence shows the company’s Nellcor™ pulse oximeters lead the way in equitable patient monitoring,^{‡1,2} and Medtronic continues to partner and invest in professional education and continued innovation. Educational resources on how pulse oximeters work and tips for getting the most accurate SpO₂ readings from current devices are available through the [Medtronic Academy](#). Medtronic remains committed to delivering better outcomes for all patients through continued innovation and is proud to participate in the STeP program. Learn more about equitable monitoring and the company’s commitment to patient safety at [health equity in pulse oximetry monitoring](#).

Acute Care and Monitoring products should not be used as the sole basis for diagnosis or therapy and are intended only as an adjunct in patient assessment.

Note: Oxygen saturation accuracy can be affected by certain environmental, equipment, and patient physiologic conditions that influence readings of SpO₂.

References

‡ Based on two studies (not funded by Medtronic) not designed for head-to-head comparison of devices. One study enrolled 146 healthy subjects in the 92-96% saturation range and examined paired readings from Nellcor™ N-595 and Masimo Radical 7™* pulse oximeters generated simultaneously. The second study enrolled 319 children with different skin tones undergoing cardiac catheterization and examined paired readings from Nellcor disposable SpO₂ adhesive sensors and Masimo reusable child/adult clip sensors generated simultaneously.

1. Gudelunas MK, Lipnick M, Hendrickson C, et al. Low Perfusion and Missed Diagnosis of Hypoxemia by Pulse Oximetry in Darkly Pigmented Skin: A Prospective Study. *Anesth Analg*. 2024;138(3):552-561.

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2. Starnes JR, Welch W, Henderson CC, Hudson S, Risney S, Nicholson GT, Doyle TP, Janssen DR, Londergan BP, Parra DA, Slaughter JC, Aliyu MH, Graves JA, Soslow JH. Pulse Oximetry and Skin Tone in Children. N. Engl J Med. 2025 Feb 12. doi: 10.1056/NEJMc2414937. Epub ahead of print.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit [medtronic.com](https://www.medtronic.com) and follow Medtronic on [LinkedIn](#).

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