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# Medtronic receives FDA's Safer Technologies Program (STeP) designation for its investigational Nellcor™ pulse oximetry technology

*Regulatory review process to give patients better access to innovation through expedited development, assessment, and review of investigational Nellcor™ technology*

Medtronic, a global leader in healthcare technology, announced today that new Nellcor™ pulse oximetry technology currently in-development has been accepted into the U.S. Food and Drug Administration's (FDA) Safer Technologies Program (STeP). STeP is an FDA program for medical devices that are reasonably expected to improve the safety of currently available devices. The program leverages an interactive process with the FDA to support expedited development, assessment, and review of designated investigational devices. † More details about STeP can be found on the FDA website.

The investigational Nellcor™ technology aims to integrate patient-specific and sensor-specific data into oxygen saturation calculations used in pulse oximetry. Acceptance to the program was based on Eligibility Criterion 2a, which outlines that the device is reasonably expected to improve the benefit-risk profile and reduce the occurrence of serious adverse events.

Pulse oximetry measures blood oxygen levels, one of many important vital signs that helps clinicians provide timely care. Pulse oximeters work by sending light through a patient's finger and measuring its absorption. However, these devices can have blind spots. Melanin, for example, can impact light absorption, potentially leading to unrecognized hypoxemia in patients with darker skin pigmentation. [1,2]

"We appreciate the FDA's designation of Nellcor™ technology currently in-development, which reflects our long-standing commitment to advancing patient safety and clinical confidence in pulse oximetry," said Samir Ibrahim, senior director of regulatory affairs of the Acute Care and Monitoring business, which is part of the Medical Surgical Portfolio at Medtronic.

While recent evidence shows that today's Nellcor™ pulse oximeters lead the way in equitable patient monitoring,[‡1,2] the company continues to partner and invest in professional education and continued innovation. You can find educational resources on how pulse oximeters work and tips for getting the most accurate $SpO_2$ readings from current devices at Medtronic Academy. Medtronic remains committed to delivering better outcomes

for all patients through continued innovation and are proud to participate in the STeP program.

**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 www.Medtronic.com and follow Medtronic on LinkedIn.

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

† STeP designation applies to future product candidates. Nellcor™ technology in the scope of the STeP application is in development. Not approved or cleared by FDA and not available for sale in the U.S. Inclusion in STeP does not guarantee approval, clearance, or granting of future marketing submissions.

‡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. doi:10.1213/ANE.0000000000006755
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.


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https://news.medtronic.com/Medtronic-receives-FDAs-Safer-Technologies-Program-STeP-designation-for-its-investigational-Nellcor-TM-pulse-oximetry-technology