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Medtronic study of investigational Nellcor™ pulse oximetry technology demonstrates positive results across a full range of skin tones

Medtronic, a global leader in healthcare technology, announced verification study results for its investigational Nellcor™ pulse oximetry with Nell-EQ™ intelligent processor at the Society for Technology in Anesthesia (STA) Annual Meeting.

The company successfully completed pivotal clinical studies for its new Nellcor™ pulse oximetry technology. Initial data show that the investigational Nell-EQ™ intelligent processor technology, when paired with a set of market-released sensors representative of the Nellcor™ pulse oximetry sensor line, demonstrated SpO_2 accuracy better than the FDA's draft-recommended[1] threshold. Additionally, pulse rate accuracy was within Nellcor™ technology acceptance limits. These results were observed in a sample inclusive of the full range of skin tones.



Pulse oximetry accuracy has historically varied across skin tones, raising concerns about technology that works for all patients. The investigational Nell-EQ™ intelligent processor technology reflects ongoing efforts of Medtronic to deliver its Nellcor™ technology's consistent SpO_2 and pulse rate accuracy across all skin tones. The company's commitment to getting it right – for every patient – is why Medtronic opened a clinical physiology lab near the Five Points neighborhood of Denver, Colorado. As a result of their extensive community outreach efforts, Medtronic has conducted its clinical studies not only with a diverse array of participants but with greater speed and frequency, leading to faster innovation.

Previously granted FDA Safer Technologies Program (STeP) designation, the company's investigational Nellcor™ pulse oximetry with Nell-EQ™ intelligent processor is currently under 510(k) review, marking an important regulatory milestone in efforts by Medtronic to bring this innovation to market.†

"Today's verification study results demonstrate accuracy across various skin tones, meeting and exceeding both the current U.S. FDA guidance and newer, more-inclusive draft guidance," said Dr. Randall Clark, principal investigator of the Medtronic clinical physiology lab. "Seeing such positive outcomes with the investigational Nellcor™ pulse oximetry technology, paired with Nellcor™ sensors, marks an important step toward advancing medical-grade pulse oximetry that works for every patient."

The verification studies were conducted in consideration of the evolving regulatory guidance[1] and global standards expectations on pulse oximeters for medical purposes, which recommends accuracy testing across the full spectrum of skin tones and maintaining the upper limit of the 95% confidence interval (CI) for SpO_2 accuracy within 3%, regardless of sensor type.

Key findings:

- **Study design:** Three controlled hypoxia studies with 71 participants (ages 20–46) representing diverse skin tones across Monk Skin Tone (MST) cohorts:
  - Light (MST 1–4): 32 participants (45.1%)
  - Medium (MST 5–7): 19 participants (26.8%)
  - Dark (MST 8–10): 20 participants (28.2%)
- **SpO_2 accuracy:** Investigational Nellcor™ pulse oximetry with Nell-EQ™ intelligent processor paired with Nellcor™ sensors demonstrated SpO_2 RMS accuracy ranging from 1.33% (upper 95% CI: 1.48%) to 1.69% (upper 95% CI: 1.93%), outperforming the FDA draft guidance threshold of 3%.
- **Pulse rate accuracy:** RMS accuracy remained within 2 bpm, meeting the Nellcor™ technology acceptance criterion of 3 bpm.

"Medtronic is leading the way for pulse oximetry technology that aims to deliver accuracy and inclusivity for every patient, every time," said Dr. Jeb Denny, chief medical officer of the Medtronic Acute Care & Monitoring business, which is part of the company's Medical Surgical Portfolio. "Our leadership in this space reflects a commitment to advancing standards that represent all patients and empowering clinicians with world-class technology to deliver safe, equitable care for every patient, in every setting."

The findings were presented by Medtronic at STA 2026, with Dr. David MacLeod, anesthesiologist at Duke University Hospital in North Carolina, as the healthcare professional author on the abstract.

Learn more about equitable monitoring and the company's commitment to patient safety at health equity in pulse oximetry monitoring and on Medtronic Academy.

† STeP designation applies to future product candidates. Nellcor™ technology in the scope of the STeP application is 510(k) pending. It is not approved or cleared by the FDA and not available for sale in the U.S. Inclusion in STeP does not guarantee approval, clearance, or granting of future marketing submissions.

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

1. Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations - Draft Guidance for Industry and Food and Drug Administration Staff. 2025.

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 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 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.

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https://news.medtronic.com/Medtronic-study-of-investigational-Nellcor-TM-pulse-oximetry-technology-demonstrates-positive-results-across-a-full-range-of-skin-tones