Medtronic

Technology has a role in driving better, more equitable care

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. Darker skin pigmentation can absorb more light, which could result in overestimated SpO2 readings and delayed intervention. There are nuances in how different pulse oximeters function, calling for a further review of the technology. Therefore, it is important that the medical device industry works to advance pulse oximetry to help ensure safe and effective care for all.

Before the invention of pulse oximetry, clinicians relied on observation, manual pulse, and arterial blood draws to confirm safe management of patients during critical care. Pulse oximetry created a non-invasive method for monitoring a patient's oxygen level and pulse rate. The reassuring beep tones tracking each heartbeat drove pulse oximetry to be widely adopted and the ASA adopted pulse oximetry as an ASA standard in 1986, just a few short years after its introduction to the American market.[1] Today, oxygen saturation is now considered the fifth vital sign across all areas of care.

There are three fundamental principles that allow all pulse oximeters to function. First, pulse oximeters shine red and near-infrared LED light through tissue and then measure the light absorbance that increases periodically when blood volume increases during the arterial pulse. Second, light absorbance varies predictably in the presence of oxygenated and deoxygenated hemoglobin. Third, pulse oximeters translate the electrical and light signals into saturation percentages based on a calibration curve. These principles together allow pulse oximetry devices to measure oxygen saturation using sensor-emitted light.

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.[2-5] This became a major concern during the COVID-19 pandemic when pulse oximetry was used to determine which patients would be treated for respiratory distress. Studies revealed notable treatment disparities,[2,3] prompting a review of this 40-year-old technology through the lens of equity and patient safety.

Not all pulse oximeters work the same way

Medtronic manufactures the Nellcor™ pulse oximetry system[Δ], which was the first widely used pulse oximeter and continues to be used commonly in hospitals across the globe. Nellcor™ OxiMax™ technology takes a unique approach to assessing patient oxygen saturation by using a form of artificial intelligence called a pattern-matching neural network to precisely recognize and track each patient's unique pulse.[6] As a result, when low perfusion or dark skin pigmentation reduce signal strength, the device can couple with high-efficiency LEDs to identify the patient's consistent pulse through poor signal quality.[†] Nellcor™ pulse oximeters with OxiMax™ technology also use a calibration system that is specific to each sensor in order to enable accuracy.[7]

This approach matters as the three fundamentals of pulse oximetry each have a corresponding challenge that can impact their performance.

1. **Low perfusion:** Devices take an oxygen reading when there is an increase in blood volume during the arterial pulse. However, when a patient is poorly perfused, devices can be challenged to confirm the arterial pulse and know when to read oxygen saturation.

2. **Low light levels:** Pulse oximetry sensors detect red and infrared LED light absorbance. However, when tissue is thick or the skin has dark pigmentation, less light penetrates through, making oxygen saturation more difficult to measure.

3. **Low saturation:** Pulse oximeters use calibration curves to help translate the signals into saturation percentages. Careful selection of the right calibration curve matters more so at lower saturation because curves are farther apart.

It is also worth mentioning that some low-cost sensors do not include the higher-grade shielding required to maintain signal quality from the patient sensor to the processor inside the monitor. This component is intended to protect against ambient light and electrical activity common in the acute care setting and help protect signal quality during low signal events such as low perfusion.[†,8]

Recent studies

Gudelunas et al., 2024

An independent prospective study at a leading hypoxia lab evaluated the top-selling medical grade pulse oximeters – from Medtronic[#] and Masimo – for their ability to accurately read blood oxygen in patients with dark skin pigmentation and low perfusion. This study, published in *Anesthesia & Analgesia,* found that the Medtronic Nellcor™ system better identified hypoxemia in patients with dark skin pigmentation and low perfusion.[§,4] Researchers assessed oxygen saturation, skin pigmentation, and perfusion to evaluate device performance across 9,763 readings by comparing pulse oximetry and arterial oxygen saturation results. The cohort included 146 healthy subjects, including 25 with light pigmentation, 78 with medium and 43 with dark. The study found the Medtronic device missed 8% of occult hypoxemic events, while Masimo missed 30%. In addition, the Masimo devices had relatively low concordance between their device readings and arterial blood analysis. In some cases, Masimo pulse oximeters measured 93% oxygen saturation while blood tests put the levels closer to 75%.[§,4]

Starnes et al., 2025

Another independent prospective study published in 2025 in the *New England Journal of Medicine* also evaluated the performance of both Nellcor™ and Masimo pulse oximeters. This single-center cohort study included 320 pediatric patients undergoing cardiac catheterization, including 132 with light pigmentation, 112 with medium, and 75 with dark. Results from this study similarly found that Nellcor™ pulse oximetry performed better than Masimo, with 40% less bias and 23% greater accuracy in the darkest skin category. [◊,5]

Results from these two studies point to notable distinctions in a clinical setting where an artificially high pulse oximeter reading could potentially delay clinical intervention.

Regulatory and academic attention

In January 2025, the FDA published draft guidance on pulse oximeters for medical use.[9] Key changes from previous guidance include:

1. Increasing the required study sample size (previously 10 subjects) and required number of data pairs
2. Ensuring studies leverage two measures for measuring skin pigmentation, the subjective 10-level Monk Skin Tone (MST) Scale, which was the first scale created for representation using a sociological approach, and the objective Individual Typology Angle (ITA) spectrophotometric measurement
3. Defining requirements for ensuring participants are diversely pigmented, with at least 25% of participants falling within each MST group representing light, medium and dark skin tones
4. Adding evaluation criteria for non-disparate performance between MST and ITA groups to address risk of technology bias

Academic researchers are also continuing to evaluate device performance in both laboratory and real-world settings in order to share their findings. The Open Oximetry project is one such initiative that states its objective is "to improve the safety and precision of pulse oximeters in all populations."[10] This project publishes their device testing results on openoximetry.org/oximeters/ and includes evaluation of Nellcor™, Masimo, and dozens of other pulse oximeters.[¶]

The Medtronic commitment

In 2023, Medtronic joined the Global Health Equity Network (GHEN), a World Economic Forum initiative that brings the private and public sectors together to drive change in health equity. As part of the GHEN agenda, Medtronic signed the Zero Health Gaps pledge, committing to help close health gaps.

While recent evidence shows that Medtronic Nellcor™ pulse oximeters lead the way in equitable patient monitoring,[4,5] we believe there is room to do more. Recent industry research found that only 25% of clinicians are aware of equity concerns related to medical devices such as pulse oximeters[11] and Medtronic is working to help close outcome gaps through professional education and partnerships. Our goal is to enable confident use of pulse oximetry in order to protect at-risk patients.

Our research team also opened a Clinical Physiology Lab in Denver, Colorado to investigate device accuracy in diverse patient populations. These studies are incorporating the Monk Skin Tone Scale to make sure pulse oximeters work accurately for all patients. These activities reflect our long-standing commitment to advancing patient safety and clinical confidence in pulse oximetry and reducing disparities in care.

Disclaimers

† Oxygen saturation accuracy can be affected by certain environmental, equipment, and patient physiologic conditions (as discussed in the operator's manual for the monitor) that influence readings of SpO2. Please consult the IFU & manual for full safety information.

‡ Calculations based on a Medtronic analysis of the data in the referenced studies.

§ This study examined paired readings from Nellcor™ pulse oximetry™ N-595# and Masimo™* Radical 7™* pulse oximeters generated simultaneously. This study was not designed for head-to-head comparison of the respective devices. All values were calculated by Medtronic as percent difference and should be interpreted as hypothesis generating only.

◊The observational study (not funded by Medtronic) examined paired readings from Nellcor disposable SpO2 adhesive sensors and Masimo reusable child/adult clip sensors generated simultaneously. This study was not designed for head-to-head comparison of the respective devices. All values were calculated by Medtronic as percent difference and should be interpreted as hypothesis generating only.

¶ Performance data is derived from multiple sources, including studies independently conducted in healthy volunteers as part of the Open Oximetry Project. Data has not been peer-reviewed and may not accurately represent performance in other settings or in real world patient populations. The information displayed shall not be construed as an endorsement by Open Oximetry.

The Nellcor device N595 used in the referenced study is no longer licensed by Health Canada. Although the Nellcor products currently licenced with Health Canada use the same technology.

Δ Licensed as Nellcor Bedside SpO_2 Patient Monitoring System.

References

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For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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