Medtronic

Equitable monitoring

with **Nellcor™ pulse oximetry**

Not all pulse oximeters are equal. Skin pigmentation can affect pulse oximetry readings and consequently lead to disparities in care.[1]
The technology you choose can make a difference.

Response to bias in pulse oximetry

The COVID-19 pandemic brought to light disparities in outcomes for patients with darker skin – which in part has been attributed to biases in pulse oximetry readings.[1] This has spurred a sequence of events to understand the depth and breadth of the issue – with the primary goal to ensure patient safety for all.

2021

FDA Sends Out Alert

FDA sends out Safety Communication on Pulse Oximetry Accuracy and Limitations to alert the market about bias in pulse oximeters.[2]

2022

FDA Panel Provides Regulatory Advice

FDA releases draft for Updated Study Criteria (prospective, large sample size, independent) and funds study out of world renowned hypoxia Lab.[3]

2023

Independent Study: Gudelunas et al

Masimo misses over 30% of hypoxemic events for patients with dark skin tones (3.8x more than Nellcor™ pulse oximetry) and records **10x more data drops**.[†,‡,4]

E-Published 18 Dec 2023.

Our actions to ensure **equitable monitoring**

We increased education on proper application and usage of our pulse oximetry technology while evaluating the performance of our technology.

We participated in the FDA panel and agree on recommendations including:

- increasing the minimum sample size for the darkest skin pigment category
- standardizing the inclusion of skin tone diversity with specified scales, like the Monk Skin Tone scale

While we outperformed the other technology, we are not satisfied with any level of technology bias in our products. **We committed substantial new investments in innovation** to improve our pulse oximetry portfolio and engineer for equity.

†Oxygen saturation accuracy can be affected by certain environmental, equipment, and patient physiologic conditions that influence readings of SpO_2. Please consult the instructions for use and manual for full safety information.
‡The study (not funded by Medtronic) 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. This study was not designed for head-to-head comparison of the respective devices.

FDA Convenes for Stronger Guidelines

FDA suggests **< 3 Arms** recommendation for pulse oximetry.[5]

Arms (Root Mean Square Accuracy) is a statistical measure of accuracy performance expressed as a single number and reflects both measurement bias and precision of readings compared to a reference standard. The lower the Arms value, the more accurate and consistent those readings are.

Independent Study: Fawzy et al

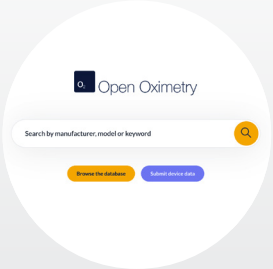
In first prospective, real-world study investigating SpO_2 performance and skin tone bias, study finds **Masimo did not meet the standards** of the 2013 FDA guidance in darkly pigmented patient population (**4.15% Arms**).[6]

Published 1 Aug 2024.

Open Oximetry Website Launches

OpenOximetry.org shares data on commercially available pulse oximeters.[§,7]

Search for data on your pulse oximeter.

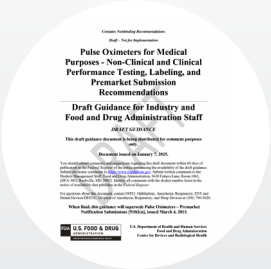


Roots Community Lawsuit

Roots Community Health dismisses Medtronic from its lawsuit against Walgreens, CVS, GE Healthcare, Masimo, and other leading manufacturers and sellers of pulse oximeters to halt further sales of unreliable pulse oximeters.[8]

New FDA Draft Guidance Released

FDA releases long-awaited draft guidance calling for more inclusive and extensive testing, accuracy reporting across skin tones using subjective and objective measures of skin pigmentation, and clearer labelling.[9]



2024

We signed a zero health gaps pledge, organized through the World Economic Forum initiative, pledging that we will continue to understand what the root causes of health inequities are and aim to create a real positive health equity impact.

We opened a clinical physiology lab in Denver, Colorado, and are partnering with the local community to raise awareness of diversity in clinical trials, to ensure greater representation in our studies.

All Nellcor™ pulse oximeters tested passed preliminary verified performance validation for patients across all skin tones. This is the highest level of verification currently available until new FDA guidance is finalized.[§,7]

2025

Because of our proactive efforts in medical education and community partnership, we became the **first and only** manufacturer of FDA-cleared pulse oximeters **dismissed from the Roots Community Pulse Oximetry Lawsuit.**[8]

We are pleased to see this progress,and proud that these **guidelines correspond with our work already underway,** including using the Monk Skin Tone Scale, the more inclusive 10-tone scale cited in the draft guidance, in our clinical research.

§Performs in accordance with 2013 FDA premarket notification submissions guidance and ISO 80601-2-61 (2017). Performance data from healthy volunteers may not accurately represent performance in real world patient populations. The information displayed here shall not be construed as an endorsement by Open Oximetry.

Why updated **study criteria matters**

The 2013 FDA criteria for approving pulse oximetry devices only required testing the device on 2 darkly pigmented participants or 15% of the participant pool, whichever was larger.[10] In draft guidance released in January 2025, new FDA guidelines call for improved study criteria to ensure device accuracy for all patients, including:

- Increasing the minimum sample size overall and for the darkest skin pigment category in particular
- standardizing the inclusion of skin tone diversity with specified scales, like the Monk Skin Tone (MST) scale
- evaluating non-disparate bias performance as a function of standardized skin tone values

The following two studies show how **different the results can be** when more rigorous study criteria is put into practice:

Self-funded study results with limited dark skin participants

In response to disparity findings, Masimo published a self-funded, self-run study[11] concluding that their pulse oximetry technology worked the same for Black and White patients.

Fact check:

- Only 2 participants in darkest skin pigmentation strata (Massey-Martin scale 8-10) where risk for tech bias is greatest
- Retrospective study conducted on healthy volunteers

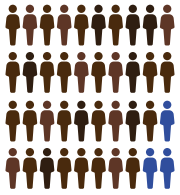
Figure: Adapted from Sharma et al. *J Clin Monit Comput*. 2024;38(2):347-354. doi:10.1007/s10877-023-01113-2.
◊Massey, D. S., & Martin, J. A. (2003). The NIS skin color scale. Office of Population Research, Princeton University.

Independent study results utilizing more inclusive study criteria

The recent prospective study enrolling healthy volunteers evaluated the effects of skin pigmentation and perfusion index on pulse oximeter accuracy.[†,‡] The study concluded that low peripheral perfusion combined with darker skin pigmentation leads to clinically significant high-reading pulse oximeter errors and missed diagnoses of hypoxemia.[4]

Nellcor™ pulse oximetry **vs** **Masimo SET™*** pulse oximetry

Missed hypoxemic events in subjects with dark skin and low perfusion[4]



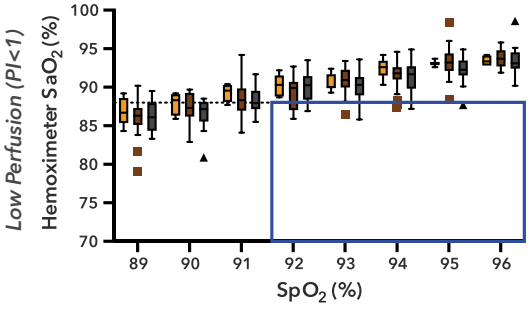
7.9%

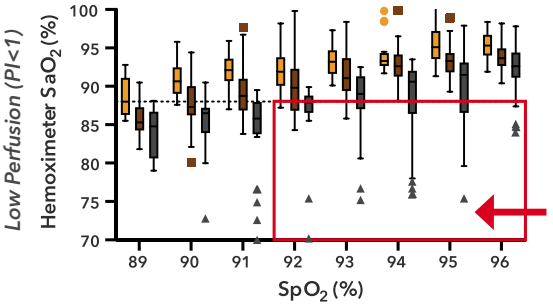
30.2%

Masimo SET™* pulse oximetry missed

3.8x

more hypoxemic events[4]





Multiple clinically significant outliers

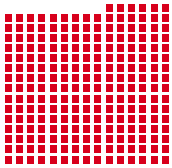
Missed hypoxemia | Light (F1 and F2) | Medium (F3 and F4) | Dark (F5 and F6)

Skin tones F1-F6 as defined in the Fitzpatrick scale

Data dropouts[4]

23

dropouts[4]



231

dropouts[4]

Masimo SET™* pulse oximetry had

10x

more data dropouts[4]

†Oxygen saturation accuracy can be affected by certain environmental, equipment, and patient physiologic conditions that influence readings of SpO_2. Please consult the instructions for use and manual for full safety information.

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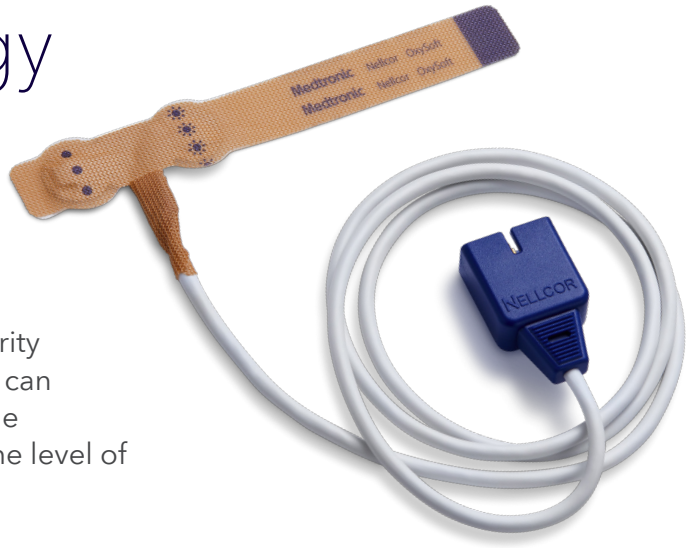
Why is our technology **working better on dark skin?**



Although the root causes of pulse oximetry reading disparity issues are unknown, we do know that inaccurate readings can happen when subtle differences add up. These can include incorrect placement of sensors,[12] patient perfusion, and the level of skin pigmentation.[†,‡,4]

At their core, all pulse oximetry technologies work by reading both the patient's **pulse signal** and **saturation signal**. Without true comparative investigation that concludes why Nellcor™ pulse oximetry performs better than Masimo SET™* pulse oximetry for patients with dark skin,[†,‡,4] we can look at the fundamental difference in how algorithms are designed.

We use each patient's unique **pulse as our foundation**

1 Pulse signal

Nellcor™ pulse oximetry uses an algorithm that **prioritizes the pulse signal**. This means that the sensor first accurately captures each patient heartbeat to qualify the pulse, and then syncs with the saturation signal that is captured through light. This results in moment-to-moment readings that are less susceptible to light variances.[¶]

+

2 Saturation signal

Masimo SET™* pulse oximetry uses signal extraction technology, a saturation-based approach that prioritizes light absorption.[13] Since the saturation signal is captured through light, anything that blocks or interferes with the absorption of light has the potential to cause an inaccurate reading.[14] Although this is still being studied, the difference in algorithm design may help explain why Nellcor™ technology performs better than Masimo SET™* technology for patients with dark skin tones.[†,‡,4]

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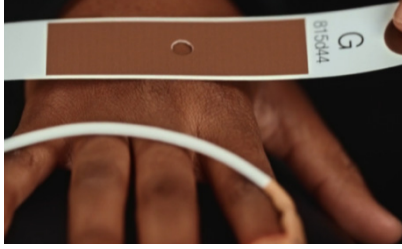
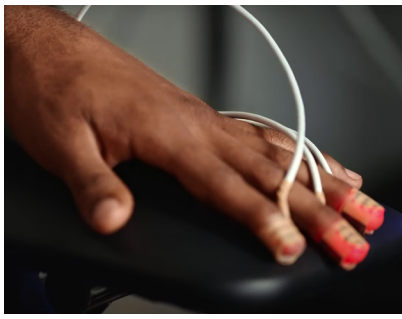
¶As compared to legacy Nellcor™ adhesive sensors.

We are working to **close the technology bias gaps**

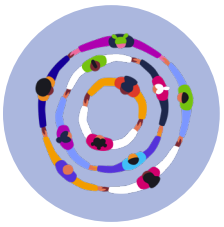
More can be done to advance pulse oximetry technology for all patients.





We are collaborating

with regulators, academics, and clinicians to enhance guidelines to ensure all pulse oximetry technologies meet equity standards.



We are aiming

to include up to 40% enrollees with dark skin in future testing to ensure performance for all patients in our innovations. We are incorporating the Monk Skin Tone (MST) Scale, a more inclusive 10-tone scale designed to represent a broader range of communities.

We are investing

in science and innovation to improve our pulse oximetry portfolio. We opened a clinical physiology lab in Denver's diverse Five Points neighborhood. Through community recruitment, we are able to test devices with a more diverse data set with more speed and frequency.

We are expanding

education on Nellcor™ technology use to enable clinicians to serve all patients. Through a suite of educational materials, online refresher courses, and self-paced learning, we are increasing awareness of technology bias and empowering clinicians with the tools they need to reduce disparities.

"Ensuring every patient gets the best care we can provide — **that's health equity.**"

– **Jason Case**, Vice President, Research & Development, Acute Care & Monitoring

Learn more

about our commitment to solving technology bias in pulse oximetry at **medtronic.com/equityinoximetry**

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.

1. Sjoding MW, Dickson RP, Iwashyna TJ, Gay SE, Valley TS. Racial Bias in Pulse Oximetry Measurement [published correction appears in *N Engl J Med*. 2021 Dec 23;385(26):2496]. *N Engl J Med*. 2020;383(25):2477-2478. doi:10.1056/NEJMc2029240.
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5. *Approach for Improving the Performance Evaluation of Pulse Oximeter Devices Taking Into Consideration Skin Pigmentation, Race and Ethnicity: Discussion Paper and Request for Feedback*. US Food and Drug Administration; November 16, 2023. Accessed February 17, 2025. www.fda.gov/media/173905/download.
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9. *Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.* US Food and Drug Administration; January 6, 2025. Accessed February 17, 2025. www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and.
10. Center for Devices and Radiological Health. *Pulse Oximeters – Premarket Notification Submissions [510(k)s], Guidance for Industry and Food and Drug Administration Staff*. US Food and Drug Administration; March 4, 2013. Docket No. FDA-2007-D-0205. www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug.
11. Sharma V, Barker SJ, Sorci R, Park L, Wilson WC. Racial effects on masimo pulse oximetry: impact of low perfusion index. *J Clin Monit Comput*. 2024;38(2):347-354. doi:10.1007/s10877-023-01113-2.
12. Haynes JM. The ear as an alternative site for a pulse oximeter finger clip sensor. *Respir Care*. 2007;52(6):727-729.
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14. Silverston P, Ferrari M, Quaresima V. Pulse oximetry in primary care: factors affecting accuracy and interpretation. *Br J Gen Pract*. 2022;72(716):132-133. Published 2022 Feb 24. doi:10.3399/bjgp22X718769.

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