

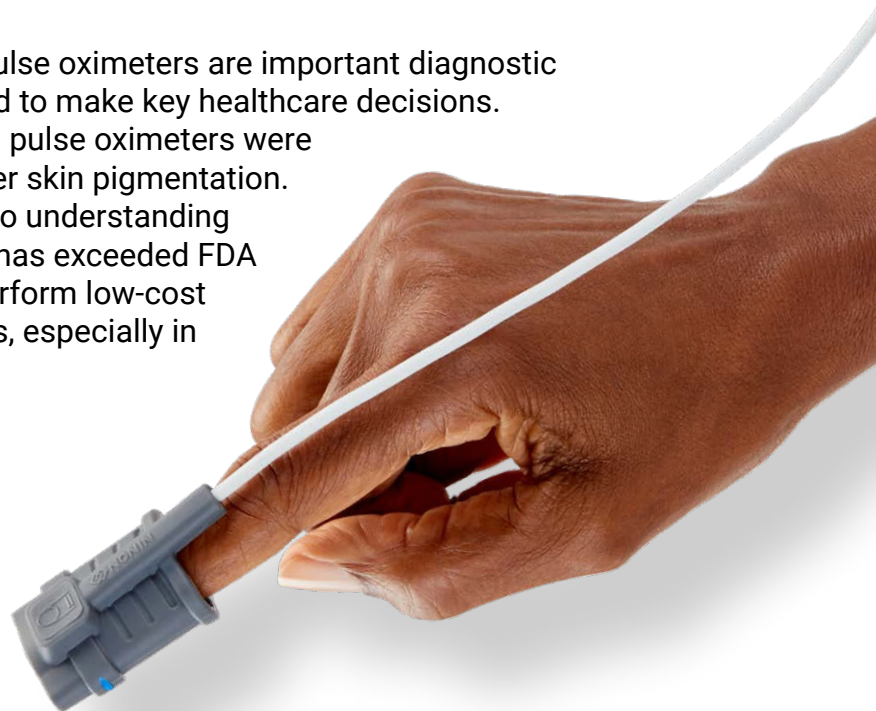


# HEALTHCARE EQUITY IN PULSE OXIMETRY TECHNOLOGY

**Nonin Medical, Inc. believes it is vitally important that all patients in need of pulse oximetry monitoring receive healthcare that is equitable, regardless of differences in skin melanin content.**

*We are fully supportive of the public discussions and the partnership of manufacturers, researchers and the U.S. Food and Drug Administration (FDA) with the goal of addressing disparities in the accuracy of pulse oximeters.*

**Not all pulse oximeters are created equal.** Pulse oximeters are important diagnostic tools when oxygen level readings are required to make key healthcare decisions. During the COVID-19 pandemic, data showed pulse oximeters were missing hypoxic events in patients with darker skin pigmentation. For many patients, oxygen levels are crucial to understanding effective treatment plans. Nonin technology has exceeded FDA requirements,<sup>1</sup> and has been proven to outperform low-cost oximeters and other medical-grade oximeters, especially in patients with darker skin pigmentation.<sup>2, 3, 4</sup>





## Why accuracy is important.

**Accurate pulse oximeter readings provide crucial data for caretakers.** Disparities in accuracy happening today are disproportionately affecting patients of color and can lead to significant health risks. Conditions such as hidden hypoxemia, when low blood oxygen levels are missed, can result in death. The clinical consequences of hidden hypoxemia have been noted by researchers, including significant delay in treatment or undiagnosed eligibility for treatment for COVID-19 in patients of color compared to White patients<sup>5</sup>, and **a mortality rate over 40% higher in Black patients than White patients** in certain intensive care unit settings.<sup>6</sup> While these studies have some limitations, they directionally point to the critical importance of accuracy in pulse oximetry for diverse patients.

**40% higher**  
in Black patients than  
White patients.

**Hidden hypoxemia is disproportionately affecting patients of color, shown to lead to a mortality rate over**

## Nonin's history of equitable engineering.

Since Nonin commercialized the first fingertip pulse oximeter in the global market in 1995, we have prioritized pulse oximetry solutions that take skin pigmentation into consideration. Nonin Medical's breakthrough **PureLight**<sup>®</sup> sensors and **PureSAT**<sup>®</sup> technology are at the heart of our devices. In fact, the study conducted to support our fingertip pulse oximetry devices enrolled and included twice as many dark skin pigmentation subjects than the FDA recommended at the time,<sup>3</sup> and was developed to read accurately, regardless of skin pigmentation, in all clinically important decades of oxygen saturation.<sup>2,3</sup>

## How Nonin is creating change for the better.

Even though Nonin devices have been recognized for their ability to provide accurate measurements in study participants with differences in skin pigmentation,<sup>7</sup> we feel we could still improve. To do this, Nonin undertook three very important steps retrospectively and prospectively to validate our beliefs in the accuracy of our technology:

1. Nonin conducted a subpopulation analysis of our internal clinical study underlying the range of our fingertip devices, taking into consideration skin pigmentation at various decades of oxygen saturation.

## THE REALITY:

**Disparities in accuracy happening today are disproportionately affecting patients of color and can lead to significant health risks.**



- This analysis concluded that Nonin's fingertip devices were within FDA's accuracy ( $Arms < 3$ ) for all decades for all skin pigmentations.<sup>4,8</sup>

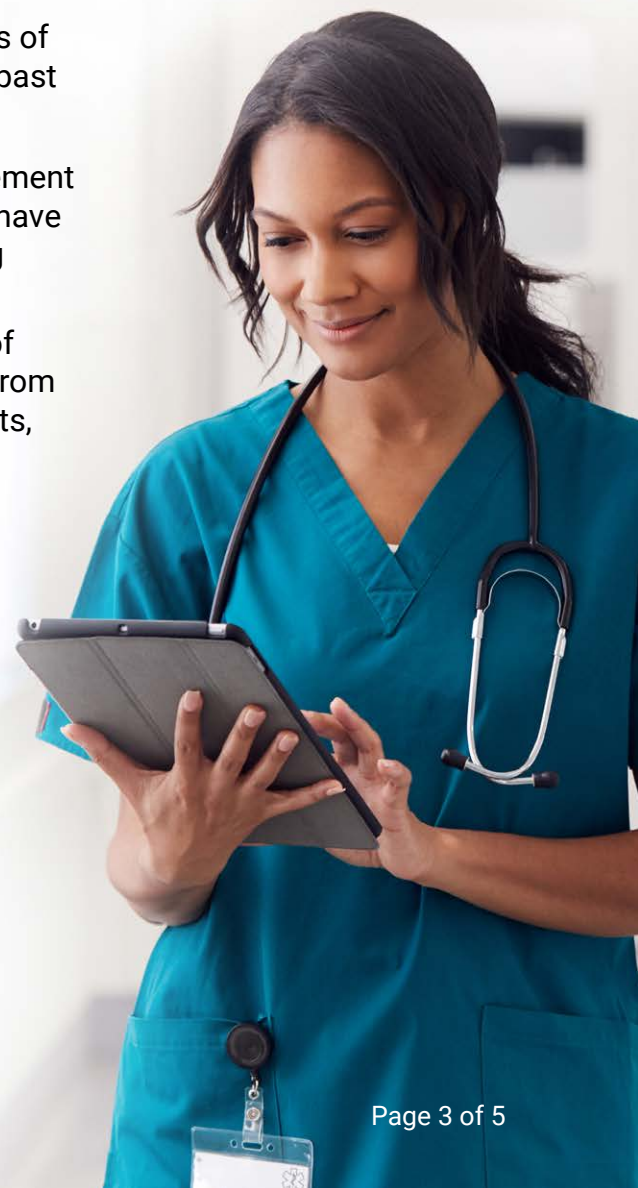
**2.** Nonin obtained an **external, third-party retrospective analysis** of all 21 clinical studies for which skin pigmentation data were reasonably available across all Nonin pulse oximetry platforms. Assuming the appropriateness of pooling the data across all Nonin Medical device types, non-parametric analysis was used to analyze the differences between the median bias for each of three skin pigmentation groups.

- The analysis concluded that there were no statistically significant differences between the median bias of the pulse oximetry measurements of the skin pigmentation groups ( $p > .05$ ) in Nonin's past clinical studies.<sup>1</sup>

**3.** As a part of our commitment to continuous improvement and advancement of the field of pulse oximetry, we have **worked closely with the FDA to develop new testing protocols** for future products.

- These new protocols increase the total number of study subjects, ensure balanced representation from light, medium, and dark skin pigmentation patients, and ensure that skin pigmentation is measured by an objective scale.

More work needs to be done to ensure patient safety. Nonin Medical is a member of the Open Oximetry Project at the University of California at San Francisco and the associated FDA Collaborative Community, both of which are focused on solving the challenges of pulse oximetry accuracy in diverse communities. Nonin Medical is proud to partner with these clinicians, researchers, manufacturers, and regulatory bodies to promote adequate testing and standards to ensure equitable patient care.





## Nonin technology performance – a look at the data.

In addition to the work that Nonin has done internally, the Open Oximetry Project is conducting independent studies to test the performance of pulse oximeters in diverse patients. In its most recent study—conducted by some of the most well-regarded clinicians and researchers in pulse oximetry—the Open Oximetry Project compared the performance of 11 fingertip pulse oximeters, including the Nonin Medical Onyx® Vantage 9590 fingertip pulse oximeter. The data are striking:

- Of 11 fingertip pulse oximeters tested, the Nonin Onyx 9590 **was the only device** that was within current FDA ARMS guidelines for accuracy in all skin pigmentations and in all decades of arterial blood oxygen saturation (70-80, 80-90, and 90-100%).<sup>8</sup>
- In the dangerously low oxygen saturation ranges of 70-80% and 80-90%, the Nonin Onyx 9590 **had the lowest ARMS** of all devices for subjects with dark skin pigmentation.<sup>8</sup>
- The Nonin Onyx 9590 **had the lowest overall ARMS** of all other fingertip pulse oximeters in the study.<sup>8</sup>
- **None** of the low-cost devices met FDA ARMS guidelines in dark skin pigmentations in one or both of the low oxygen saturation ranges (70-80% and 80-90%).<sup>8</sup>

←..... Data comparing the Nonin Medical Onyx Vantage 9590 fingertip oximeter to 10 other devices had striking results.

This study is one of the first to incorporate objective and subjective measurements of skin pigmentation. The study highlights the wide disparity in accuracy of pulse oximeters, especially those which have not been clinically tested and cleared by the FDA.





## *A Note About Health and Wellness Pulse Oximeters*

Devices that are sold as “health and wellness” products are not subject to FDA requirements for accuracy. These devices are currently being sold to consumers, and can have potentially serious implications for patients, especially patients with darker skin pigmentation. It is Nonin Medical’s position that all pulse oximeters used to measure blood oxygen for potential diagnosis and treatment of patients should be subject to FDA clearance, including those in hospitals, clinics, schools, and remote home care settings.

## **Pulse oximetry is a tool to improve the quality of people’s lives.**

At Nonin, we are confident in the performance of our technology. We will continue to leverage each new study and engage stakeholders—especially patients and clinicians—to improve Nonin Medical’s pulse oximetry products and ensure that all patients receive accurate measurements to guide their health care. **All patients across all skin pigmentations deserve the best measurements. This is the mission and vision of our founder, Phil Isaacson—to improve the quality of people’s lives throughout the world by expanding the capabilities of noninvasive measurements.**

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<sup>1</sup> Nonin Medical, Inc. Clinical Data on File.

<sup>2</sup> Bickler P, Feiner J, Severinghaus J. Effects of skin pigmentation on pulse oximeter accuracy at low saturation. *Anesthesiology*. 2005;102(4):715-719. doi:10.1097/00000542-200504000-00004

<sup>3</sup> Nonin Medical, Inc. Clinical Data on File.

<sup>4</sup> Nonin Medical, Inc. Clinical Data on File.

<sup>5</sup> Fawzy A, Wu T, Wang K, et al. Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients With COVID-19. *JAMA Intern Med*. Published online May 31, 2022. doi:10.1001/jamainternmed.2022.1906

<sup>6</sup> Analysis of Discrepancies Between Pulse Oximetry and Arterial Oxygen Saturation Measurements by Race and Ethnicity and Association With Organ Dysfunction and Mortality. Wong AI, Charpignon M, Kim H. et al. *JAMA Netw Open*. 2021 Nov 1;4(11):e2131674. PMID: 34730820. doi:10.1001/jamanetworkopen.2021.31674.

<sup>7</sup> Farkas, J. (December 2020) *PulmCrit*, “Dismantling the systemic racism of pulse oximetry”, <https://emcrit.org/pulmcrit/racism>

<sup>8</sup> Preprint with THE LANCET: “The Performance of 11 Fingertip Pulse Oximeters During Hypoxemia in Healthy Human Subjects with Varied, Quantified Skin Pigment.” [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4578562](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4578562). This study is currently in preprint and under peer review prior to any publication. Saturation: The Effect of Oximeter Probe Type and Gender, *Anesthesiology* December;105(6):S18-S23.

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