

Medtronic

Advancing health equity through partnerships

CDRH Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

February 2, 2024

Sam Ajizian, MD
Chief Medical Officer and VP, Clinical Research and Medical Science
Patient Monitoring and Respiratory Interventions, including
Nellcor™ pulse oximetry

Medtronic supports a collaborative effort to further advance pulse oximetry technology for all patients



We recognize pulse oximeter performance can be affected by skin pigmentation level and other factors



We continue to evaluate and improve the performance of our Nellcor™ technology



We recognize that no one solution or organization can achieve health equity alone; strategic partnerships and community engagement are essential to accelerating clear direction and aligned actions



Combining the power of healthcare technology with strong partnerships, to improve pulse oximeters for all patients



Engage community

Partner with the local community to promote value of diversity in studies through the Medtronic Physiology Lab



Enhance guidelines & standards

Collaborate with regulators, academics, and clinicians



Expand education

Launch several types of education on Nellcor™ technology use and function to enable clinicians to serve all patients



Invest in innovation

Continuing to innovate and invest in our oximetry portfolio and the science of pulse oximetry

Improving performance evaluation of pulse oximeters

Harmonized approach between FDA and ISO¹ is critical

Study population

We agree with FDA's approach to increase the minimum sample size overall and, in particular, for the darkest skin pigment category

Reporting skin pigmentation

We agree with FDA's approach to standardize the inclusion of skin tone diversity with specified scales, like the Monk Skin Tone (MST) scale

- Additionally, based on available data², a tolerance of +/- 1 for the MST scale could be allowed without loss of diversity

Performance evaluation

We agree with FDA's approach to evaluate non-disparate bias performance as a function of standardized skin tone values

- Additionally, considering the novel nature of this method, we request FDA further evaluate the appropriate limits for this parameter prior to establishing a specific threshold requirement

¹ ISO- International Organization for Standardization

² Data collected through UCSF's EquiOx Study and Schumann, Candice, Gbolahan O. Olanubi, Auriel Wright, Ellis Monk Jr, Courtney Heldreth, and Susanna Ricco. "Consensus and Subjectivity of Skin Tone Annotation for ML Fairness." arXiv preprint arXiv:2305.09073 (2023).

A close-up photograph of a person's hand with a pulse oximeter sensor attached to the index finger. The sensor is a small, blue, rectangular device with a white cable extending from it. The hand is being held gently by another hand, suggesting a medical or caregiving context. The background is a soft, out-of-focus white surface, likely a hospital bed or table. The overall lighting is soft and clinical.

Committed to achieving health
equity for all pulse oximetry
patients