

FDA Proposes Updated Recommendations to Help Improve Performance of Pulse Oximeters Across Skin Tones

Pulse oximeters, used to estimate the amount of oxygen in the blood, may be less accurate for Black people.

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[On January 6], the U.S. Food and Drug Administration published [new draft guidance](#) aimed at helping improve the accuracy and performance of [pulse oximeters](#) -- important devices for patient care that are used to estimate the amount of oxygen carried in the blood – across the range of skin pigmentation.

Current scientific evidence suggests there are some accuracy differences in pulse oximeter performance between individuals with lighter and darker skin pigmentation. The FDA [has previously informed](#) patients and health care providers that although pulse oximetry is useful for estimating blood oxygen levels, pulse oximeters have limitations and a risk of inaccuracy under certain circumstances.

To help address these concerns, the FDA has proposed new draft recommendations for manufacturers on how to gather clinical data, among other things, to help improve the clinical study design and validation efforts for pulse oximeters used for medical purposes to evaluate their performance across the range of skin pigmentation. The FDA is committed to working with manufacturers to help ensure the public has access to pulse oximeters that perform accurately across the range of skin pigmentations as soon as possible.

“This draft guidance is aligned with the FDA’s broader commitment to helping facilitate the development of high-quality, safe, and effective medical devices,” said Michelle Tarver, MD, PhD, director of the FDA’s Center for Devices and Radiological Health. “Our draft recommendations are based on the best available science to help address concerns of disparate performance of pulse oximeters based on an individual’s skin pigmentation.”

The updated draft recommendations are aimed at helping generate a more representative study of the intended population for these devices. The FDA believes the implementation of these

recommendations, if finalized, will help improve the accuracy and performance of pulse oximeters used for medical purposes in patients across the range of skin pigmentation.

Some key elements of the FDA's draft recommendations include:

- Gathering clinical data (e.g., controlled desaturation laboratory study or, in certain cases, real-world data) to evaluate device performance accuracy across the range of skin pigmentations;
- Increasing the number of clinical study participants;
- Using both subjective (Monk Skin Tone Scale) and objective (calculation of individual typology angle) methods for more standardized evaluation of study participants' skin tone and accurate assessment of device performance across skin pigmentations; and
- If performance accuracy has been demonstrated in a new premarket submission, including a prominent labeling statement to help users clearly identify that the pulse oximeter has demonstrated that it performs comparably across groups of individuals with diverse skin pigmentation and is intended for medical purposes.

The FDA expects some pulse oximeters that are currently marketed may meet the updated performance criteria without the need for significant hardware or software modifications. In these instances, if a sponsor submits updated labeling to reflect the collection of clinical data that demonstrates comparable performance across skin pigmentations without device modifications, other than changes in labeling, then the FDA generally intends to review the submission expeditiously (within 30 days) to help ensure the public has prompt access to safe and accurate pulse oximeters.

This draft guidance, *Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations*, applies to certain pulse oximeters intended for medical purposes, which are primarily used in hospital settings or doctors' offices. Pulse oximeters for medical purposes are typically used to monitor (i.e., trending or spot checking) oxygen saturation levels of patients to help in clinical decision-making. A small number of pulse oximeters intended for medical purposes are currently available over the counter following clearance by the FDA.

This draft guidance does not apply to pulse oximeters that are sold as general wellness products or sporting/aviation products, which are not reviewed or evaluated by the agency prior to being available to the public. Such products are often sold directly to consumers in stores or online and are intended for estimating oxygen saturation often for purposes of general wellness (i.e., encouraging a general state of health or healthy lifestyle). To date, a large number of pulse oximeters available over the counter or for sporting/aviation are considered general wellness products that have not been evaluated by the FDA for use in clinical decision-making or

determining whether to seek medical intervention.

To help ensure that health care providers and the public can more easily identify which pulse oximeters may be appropriate for their use, the FDA has also proposed creating a publicly available webpage that identifies all FDA-cleared pulse oximeters for medical purposes that demonstrate comparable performance across skin pigmentations and have undergone FDA review of the data used to support the performance labeling statement.

To inform these draft recommendations, the FDA considered numerous data sources, including controlled laboratory desaturation testing, real-world performance of pulse oximeters in both outpatient and hospital settings, as well as feedback from a number of interested parties, including scientists, clinicians and manufacturers, among others.

The agency also held two [advisory committee meetings](#) and issued a [discussion paper](#) to consider the accuracy of pulse oximeters and ways to improve and evaluate their performance, taking into consideration an individual's skin pigmentation. The FDA considered comments received on the discussion paper and advisory committee meetings in developing these draft recommendations.

Additionally, the agency partnered with academic institutions to conduct two FDA-funded prospective clinical studies of pulse oximeter accuracy in [adults](#) and in [pediatric patients](#) (21 years old and younger) with varying skin pigmentation. The studies' methodology helped to inform the agency's proposed approach to appropriately capture and measure skin pigmentation.

The FDA is requesting comments on the draft guidance within 60 days of publication. The agency will then review and consider all comments before finalizing this guidance.

This [news release](#) was published by the Food and Drug Administration on January 6, 2025.