21 CFR 870.2705[13] Infant pulse rate and oxygen saturation monitor for over-the-counter use: An infant pulse rate and oxygen saturation monitor for over-the-counter use is a device that uses photoplethysmography to measure pulse rate and oxygen saturation in infants. The device may contain alarms that alert the caregiver when vital sign(s) go outside preset threshold(s).

21 CFR 870.2710 Ear oximeter: An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

Table 1. Device Types within the Scope of this Guidance.

Product Code	Product Code Name	Regulation Number
DQA	Oximeter	21 CFR 870.2700
NLF	Oximeter, Reprocessed	21 CFR 870.2700
OLK	Pulse Oximeter for Over-the-Counter Use	21 CFR 870.2700
QYU	Infant Pulse Rate and Oxygen Saturation Monitor for Over-The-Counter Use	21 CFR 870.2705
DPZ	Oximeter, Ear	21 CFR 870.2710

Although the product codes listed above are current as of the date of issuance of this guidance, new product codes or classification regulations may be created and could fall within the scope of this guidance. We recommend that you reference the product code database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) or contact OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices if you are uncertain whether this guidance applies to your device and the product code for your device is not already identified in this guidance. Some of the recommendations in this guidance may assist in complying with some of the special controls for infant pulse rate and oxygen saturation monitors for OTC use (product code QYU). For information regarding these special controls, see FDA's website.[14]

This guidance does not address oximeters under product codes OCH (oximeter, infrared, sporting, aviation), or PGJ (oximeter, wellness).[15] In addition, this guidance does not address oximeters under product codes MUD (tissue saturation oximeter), NMD (reprocessed tissue saturation oximeter), QEM (cerebral oximeter), or MMA (fetal pulse oximeter).

[13] This classification regulation includes special controls established in the classification order, available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220091.pdf. The publication of this classification in the Federal Register and codification in the Code of Federal Regulations is currently pending.

[14] See classification order, available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220091.pdf

[15] Oximeters in product codes OCH and PGJ are not reviewed or evaluated by the Agency prior to being available to the public at this time because they are intended for general wellness purposes.

Safety specifications (e.g., electrical, mechanical, environmental)		
Features/design specifications (e.g., alarms, display and indicators, modes)		
Sterility/reprocessing status		
Other relevant characteristics		

C. Labeling[28]

The premarket notification must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels, labeling, and advertisements sufficient to describe the pulse oximeter, its intended use, and the directions for use must be provided in a premarket submission. FDA is including labeling recommendations for manufacturers of pulse oximeters that were previously 510(k)-cleared and all new pulse oximeters within the scope of this guidance.

For Prescription Use: As a prescription device, a pulse oximeter is exempt from the requirement to have adequate directions for use[29] required under section 502(f)(1) of the FD&C Act if the conditions in 21 CFR 801.109 are met. To be so exempt, labeling that furnishes information for use of the prescription device must, among other things, contain "adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended" (21 CFR 801.109(d)). In addition, the label of the device must bear "[t]he symbol statement 'Rx only' or '*℞* only' or the statement 'Caution: Federal law restricts this device to sale by or on the order of a ___', the blank to be filled with the word 'physician,' 'dentist,' 'veterinarian,' or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device" (21 CFR 801.109(b)(1)).

For OTC Use: As an OTC device, under section 502(f) of the FD&C Act and 21 CFR 801.5, the device labeling must include adequate directions for use. The labeling (e.g., package insert) must describe the intended use of the device and include a listing of all conditions, purposes, or uses for which it is recommended, suggested, or commonly used (21 CFR 801.5(a)). The labeling recommendations below are not intended to capture all possible limitations or instructions for all pulse oximeters. Therefore, when developing your labeling, it may be necessary for you to include additional limitations (e.g., contraindications, warnings, precautions, adverse reactions), and other instructions that are appropriate for your device, depending on its specific design,

[28] We note that other labeling recommendations are provided in other sections of this guidance as well (e.g., reprocessing).

[29] Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended (21 CFR 801.5).

features, and performance characteristics, and depending on the results and conclusions drawn from a usability study, if applicable.

Accurate, clear device labeling can help mitigate performance issues associated with pulse oximeters and is important to make users aware of the risks, limitations, and directions for use of pulse oximeters. Moreover, a device shall be deemed misbranded if, among other things: its labeling is false or misleading; its labeling does not contain adequate warnings; or any information required to be in the labeling is not prominently placed with such conspicuousness and in such terms to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see sections 201(n), 502(a), 502(c), and 502(f)(2) of the FD&C Act). As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device. This may include FDA requesting a firm initiate a recall (see 21 CFR 7.45) or taking other actions, including an enforcement action.

This section includes recommended labeling content for pulse oximeters within the scope of this document, as outlined in the following sub-sections: (1) all pulse oximeters (i.e., prescription and OTC); (2) additional labeling specific to prescription pulse oximeters; (3) additional labeling specific to OTC pulse oximeters; and (4) additional labeling specific to pulse oximeters that were previously 510(k)-cleared.

(1) For All Pulse Oximeters

To help manufacturers develop appropriate labeling, FDA recommends that the following labeling content be included for prescription and OTC pulse oximeters within the scope of this guidance. FDA also recommends that you follow the labeling considerations referenced in the currently FDA-recognized version of the consensus standard ISO 80601-2-61 *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*.

a. Package Labeling

Consistent with recommendations shared at the 2024 Panel Meeting,[30] FDA recommends that the package labeling for prescription and OTC pulse oximeters include a prominent statement that the pulse oximeter is intended for medical purposes.[31]

Furthermore, if the manufacturer submits clinical data in a new 510(k) showing non-disparate performance (see Section IV.O), we recommend that you include a prominent statement in the package labeling and package insert, such as "This pulse oximeter has been evaluated to perform

[30] See February 2, 2024: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee Meeting Announcement and materials, https://www.fda.gov/advisory-committees/advisory-committee-calendar/february-2-2024-anesthesiology-and-respiratory-therapy-devices-panel-medical-devices-advisory

[31] To verify whether a specific device has been cleared/granted/approved for marketing authorization by FDA, please refer to FDA databases, such as https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Examples of the types of warnings that should be included, as listed above, are provided in Appendix A.

Precautions

We recommend that manufacturers prominently display appropriate precautions in the instructions for use regarding use of the device on patients, including patients with the following conditions:

- Hypersensitivity to material intended for patient contact; and
- Poor skin integrity at sensor application site(s).

Directions for Use

FDA recommends manufacturers provide clear and simple directions for use to ensure that users understand how to best apply the pulse oximeter sensor for safe and effective device use. FDA recommends providing a complete set of directions for use, including information to address the following:

- Instructions for optimizing measurements of oxygen saturation should take into account optimal placement (e.g., anatomical site and geometry), conditions, and stable SpO_2 values, when present;
- Instructions on how to evaluate/use indicators of signal quality (e.g., percent modulation) and understand the waveform, when present;
- For accurate SpO_2 and pulse rate values, instructions to consider signal inadequacy (e.g., due to low signal intensity, unstable readings);
- Consideration of percent modulation ranges, when available, and methods to improve percent modulation for accurate pulse oximeter performance;
- Instructions for the frequency of inspection of the application site for skin integrity;
- Instructions for the frequency of sensor relocation to a different measurement site; and
- Device service and maintenance information, including cleaning and disinfection instructions for reusable pulse oximeters and accessories.

Examples of directions for use that could be included are provided in Appendix A.

Magnetic Resonance (MR) Safety Information

We recommend you follow the labeling recommendations in FDA's guidance, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment." We also recommend using the standardized terminology and icons as described in the currently recognized version of ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*.

- Evaluate forehead pigmentation of study participants through visual assessment with the Monk Skin Tone (MST) scale[53, 54] – a ten level subjective skin color annotation with a high inter-rater reliability[55] (see Appendix B for printing recommendations) defined in terms of CIELAB[56] color space;
- Evaluate forehead pigmentation of study participants using colorimetry to determine L* and b* values, then calculating the Individual Typology Angle (ITA), which is defined as:[57] $\text{ITA}° = \arctan\left(\frac{L^* - 50}{b^*}\right) * \frac{180}{\pi}$;
- Documenting information related to diversity in race and ethnicity during enrollment as described in Section III of FDA's draft guidance "Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products";[58]
- Allocate enrolled participants into three specific MST groups: 1-4, 5-7, 8-10, while ensuring the following:
  - at least 25% of participants fall within each MST group;
  - at least 50% of the participants in MST group 8-10 have an ITA ≤ -50° at the forehead; and
  - in each MST group, at least 40% of participants are male, and at least 40% of participants are female.

We recommend that you submit the protocol(s) used to assign MST and evaluate ITA in your premarket submission. For additional feedback, we recommend early engagement with the Agency through the Pre-Submission process as described in FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" to discuss your proposed plan for MST assignment and ITA assessment in advance of conducting the study.

Additionally, we recommend measuring ITA values at the surface directly in contact with the sensor emitter. For fingertip sensors, to capture the widest variation in skin pigmentation applicable to sensor placement, we recommend evaluating sensor site ITA values (see yellow

[53] Heldreth CM, Monk EP, Clark AT, Schumann C, Eyee X, Ricco S. Which skin tone measures are the most inclusive? An investigation of skin tone measures for artificial intelligence. ACM Journal on Responsible Computing 1, no. 1 (2024): 1-21.

[54] It is important to note that MST, though validated for capturing race and ethnicity diversity in pigmentations within the US (see *ibid* Heldreth *et al*.), is not a proxy for racial and ethnic diversity.

[55] Schumann C, Olanubi GO, Wright A, Monk Jr. E, Heldreth C, Ricco S. 2024. Consensus and Subjectivity of Skin Tone Annotation for ML Fairness. In Proceedings of the 37th International Conference on Neural Information Processing Systems (NIPS '23). Article 1320: 30319-30348. Curran Associates Inc.

[56] For more information on standard colorimetry methods, refer to pp. 7-8 in the FDA's discussion paper "Approach for Improving the Performance Evaluation of Pulse Oximeter Devices Taking Into Consideration Skin Pigmentation, Race and Ethnicity."

[57] Ly BCK, Dyer EB, Feig JL, Chien AL, Del Bino S. Research Techniques Made Simple: Cutaneous Colorimetry: A Reliable Technique for Objective Skin Color Measurement. J Invest Derm. 2020,140(1):3-12.

[58] When final, this guidance will represent the FDA's current thinking on this topic.

- Modifying the patient population, such as indicating the device for pediatric populations younger than 12 years of age (see Section IV.O(2)). FDA generally considers this to be a significant change or modification to the labeling and/or indications for use. This type of change could significantly affect the safety and effectivenessof the device by changing form, fit and clinical performance.

If your device incorporates existing pulse oximetry technology that is legally marketed for the same intended use, and you have determined your device requires submission of a new 510(k), we recommend you provide the following:

- 510(k) numbers for the submissions where each combination of oximeter, sensor, and cable were cleared for use together;
- Report(s) of all relevant clinical studies (see Section IV.O) that support your current premarket submission and labeling (see Section IV.C);
- Testing that demonstrates that SpO_2 and pulse rate values calculated by the Original Equipment Manufacturer (OEM) system are not corrupted during communication to the host device. We recommend that you conduct the testing using a functional tester (see ISO 80601-2-61 for the definition and appropriate uses of a functional tester) to span the range of saturation and pulse rate values to assure communication between the sensor and the host module.

Appendix A. Example of Labeling for Pulse Oximeters

This appendix provides an example of labeling that contains a representative sampling of the important types of warnings and directions for use that FDA recommends in Section IV.C. of this guidance. This appendix is not intended to encompass an exhaustive list of all warnings and directions for use.

Warnings:

- Only your physician or health care provider can diagnose whether you are experiencing hypoxemia (low blood oxygen levels).
- Seek timely attention if you experience signs and symptoms of low oxygen levels, and do not rely solely on a pulse oximeter to assess your health condition or oxygen level.
- If monitoring at home, pay attention to other signs or symptoms of low oxygen levels, such as:
    - Bluish coloring in the face, lips, or nails;
    - Shortness of breath, difficulty breathing, increase in respiratory rate or a cough that gets worse;
    - Restlessness and discomfort;
    - Chest pain or tightness; and
    - Fast or racing pulse rate.
    - Be aware that some patients with low oxygen levels may not show any or all of these symptoms.
- Do not adjust medications or therapy based on your pulse oximeter readings without first consulting your health care provider since doing so may lead to harm.
- Pulse oximeters are not completely accurate and there is a range of uncertainty around the displayed SpO_2 value. Accuracy of SpO_2 generally decreases with decreasing true blood oxygenation. For example, a pulse oximeter saturation value of 90% may be indicative of an arterial blood oxygenation between 87% to 93% while a pulse oximeter saturation of 80% may be indicative of an arterial blood oxygenation of 75% to 85%. Pulse oximeter readings should only be used as an estimate of arterial blood oxygenation.
- Differences in skin tones may affect the accuracy of oxygen level readings, particularly when oxygen levels are very low. Consult your health care provider if you have questions or concerns about your readings.
- Changes or trends in measurements (e.g., decreasing SpO_2 values from 97% to 90%) may be more meaningful than one single measurement (e.g., SpO_2 of 94%). Accuracy of this pulse oximeter is not typically verified below arterial blood oxygen saturation (SaO_2) levels of 70%.
- Some factors that may affect pulse oximetry accuracy include:
    - Lower blood oxygen saturations;
    - Low blood flow or pulsatility (poor circulation);
    - High ambient light levels;
    - Excessive movement (including shivering);
    - (cold) Skin temperature;

  - Nail polish, artificial nails, or tattoo ink;
  - Presence of intravascular dyes used for medical purposes (e.g., methylene blue);
  - Blood disorders like anemia (e.g., sickle cell disease);
  - Smoking;
  - Radio frequency interference;
  - Pulsations in the veins (these may be caused by valvular heart conditions or vascular access used for hemodialysis); and
  - Presence of abnormal hemoglobin (e.g., methemoglobin, carboxyhemoglobin).
- Continuous wear over the maximum specified time may lead to adverse events (e.g., breakdown of the skin, decreased blood flow to sensor site).
- Continuous wear in certain locations (e.g., hand, foot, ankle) in younger populations (e.g., infants, children) may interfere with normal activity and age-appropriate development, such as turning over, crawling, standing, and walking.
- Alarms and alerts may cause sleep interruptions in those caring for and/or wearing the pulse oximeter.

Directions for Use

- Position the sensor (usually on the finger) below the mid-chest. Positioning the sensor above the level of the heart may reduce accuracy.
- Usually, the ring or middle finger work best for fingertip pulse oximeters.
  - Place the sensor so that the path between each side is straight and without any obstruction (e.g., a ring, tattoo).
- For spot-check use, wait for 30 seconds or more of stable SpO_2 reading.
- If percent modulation is displayed on the pulse oximeter, pay attention whether it is within the value(s) provided to consider whether your estimated oxygen level (SpO_2) is accurate.
- Choose a probe location where the skin is intact, healthy, and does not have any cuts, eczema, infections, swelling or other problems such as poor circulation.
- Remove or reposition the sensor every four hours [or manufacturer's maximum specified time] or if it causes discomfort or skin changes at the site of application.
- In between uses, clean your pulse oximeter using the appropriate materials [per manufacturer's instructions].

Appendix B. Considerations for Printing Monk Skin Tone Color Charts

A scale that is well-defined in a standardized color space, such as CIELAB,[69] should be used to support evaluation of non-disparate performance as described in Section IV.O(1)b of this document. One of the options available is the Monk Skin Tone (MST) scale. FDA recommends evaluating skin tone according to the MST approach, where color charts are based on the following L*a*b* values in Table B1.[70] We recommend that color charts be professionally printed with a calibrated printer on appropriate paper. Color chart accuracy should be verified with a calibrated spectrophotometer.

Table B1: MST Scale as Defined in CIELAB Color Space

MST Level	L*	a*	b*
1	94.2	1.5	5.4
2	92.3	2.1	7.3
3	93.1	0.2	14.2
4	87.6	0.5	17.7
5	77.9	3.5	23.1
6	55.1	7.8	26.7
7	42.5	12.3	20.5
8	30.7	11.7	13.3
9	21.1	2.7	6.0
10	14.6	1.5	3.5

[69] See FDA-recognized consensus standard ISO/CIE 11664-4 *Colorimetry – Part 4: CIE 1976 L*a*b* colour space*.
[70] See https://skintone.google for additional information (last accessed on July 12, 2024).