

Draft Guidance for Industry and FDA Staff

Pulse Oximeters - Premarket Notification Submissions [510(k)s]

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For questions regarding this document, contact Neel Patel at 240-276-3700 or neel.patel@fda.hhs.gov.

When final this document will supersede Non-invasive Pulse Oximeter General Guidance Document, 9/7/1992.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Anesthesia and Respiratory Devices Branch
Division of Anesthesia, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation

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Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to assist industry in preparing a premarket notification submission (510(k)) for a pulse oximeter. The device is intended for non-invasive measurement of the arterial blood oxygen saturation and pulse rate.

The Least Burdensome Approach

This draft guidance document reflects our careful review of what we believe are the relevant issues related to the pulse oximeter device and what we believe would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

A manufacturer who intends to market a device of this generic type should conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87).

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This guidance document identifies the classification regulation and product codes for pulse oximeters (refer to **Section 4. Scope**). In addition, other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in 510(k)s.

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, **Format for Traditional and Abbreviated 510(k)s**,¹ and "**How to Prepare a 510(k) Submission**" on FDA Device Advice at <http://www.fda.gov/cdrh/devadvice/314.html>.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**," <http://www.fda.gov/cdrh/ode/parad510.html>, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to **Section 14. Labeling** for specific information that we recommend you include in labeling.)

¹ <http://www.fda.gov/cdrh/ode/guidance/1567.html>

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Summary report

FDA recommends that the summary report contain:

Description of the device and its intended use

FDA recommends that a device have a description of its performance specifications. When appropriate, include detailed labeled drawings. (Refer to **Section 5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also include an "indications for use" enclosure.²

Description of device design requirements

FDA recommends that you include of a brief description of the device design requirements.

Identification of the risk analysis method

FDA recommends that you identify the risk analysis method(s) used to assess the risk profile for both the general and specific device's design. You should also include the results of this analysis. Please refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.

Discussion of the device characteristics

FDA recommends that you include a discussion of the device characteristics that address the risks identified in this guidance document and any additional risks identified in your risk analysis.

Description of the performance aspects

FDA recommends that you include a brief description of the test method(s) you use or intend to use that address each performance aspect identified in **Sections 7- 13** of this guidance document. When following a suggested test method, citing the method rather than describing it will suffice. When modifying a suggested test method, citing the method will suffice but include adequate information to explain the nature of and reason for the modification. For each test, either (1) briefly present the data resulting from the test in clear and concise form, such as a table, or (2) describe the acceptance criteria that you will apply to your test results.³ (See also 21 CFR 820.30, Subpart C - Design

² Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

³ If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3))

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Controls for the Quality System Regulation.)

Reliance on standards

If any part of the device design or testing relies on a recognized standard, FDA recommends that you submit either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.⁴

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence**

Determinations; Final Guidance for Industry and FDA,

<http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), submission of a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance will suffice. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for a pulse oximeter.

4. Scope

The scope of this document is limited to the class II devices, oximeter, 21 CFR 870.2700, product codes DQA (oximeter) and NLF (reprocessed oximeter) and ear oximeter, 21 CFR

to determine whether marketing of the finished device requires clearance of a new 510(k).

⁴ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

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870.2710, product code DPZ (ear oximeter).

Section 870.2700 – Oximeter

An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

Section 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.

These classification regulations group together all oximeters intended to measure blood oxygen saturation. Sections 870.2700 and 870.2710 include reflectance, transmittance, and fiber optic technologies and are referred to as pulse oximeters, for the purpose of this guidance.

This guidance document pertains to non-invasive pulse oximeters intended to measure arterial blood oxygen saturation (SpO₂) and pulse rate based on the amount of reflected or scattered radiation on various application sites (including finger, ear, foot, hand, forehead, back, and nose). These pulse oximeters may be continuous or spot-checking devices and either stand-alone or multi-parameter modules.

The scope of this guidance does not include other oximeters classified under 21 CFR 870.2700, product code MUD (tissue saturation oximeter), NMD (reprocessed tissue saturation oximeter), and MMA (fetal pulse oximeter).

5. Device Description

We recommend you identify your device by regulation number and product code indicated in **Section 4. Scope** and include the information described below.

Intended Use

We recommend you clarify if the device is intended:

- as a stand-alone device or a multi-parameter module
- for use in spot-checking or continuous monitoring
- for single use
- for out-of-hospital transport
- for home use.

Pulse oximeters intended for continuous monitoring should include high and low SpO₂ and pulse rate alarms.

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Device Design

We recommend you identify and describe:

- scientific principles underlying how the device achieves its intended use, i.e., the theory of operation (e.g., reflectance or transmittance, functional or fractional saturation)
- design features; e.g., functions, alarms
- all patient interface accessories; e.g., patient cable, extender cables, sensors, bandages
- whether the device will be provided sterile
- whether the device is a reprocessed single-use device.

Your description should clearly identify whether your device measures SpO₂ and pulse rate based on reflectance or transmittance technology.

We recommend you include engineering drawings of your device.

We recommend that you compare your device with a legally marketed predicate device (with its 510(k) number, if available) and provide information to show how your device is similar to and different from the predicate. Side by side comparisons, whenever possible, are desirable, for example, using a tabular format as shown below.

Table 1. Comparison of New and Predicate Devices

Description	Your Device	Predicate Device
Intended patient population, such as neonate, infant, pediatric, adult		
Intended application site, such as finger, ear, foot, hand, forehead, back, nose		
Performance Specifications (including use under motion and low perfusion conditions, if applicable)		
Safety Specifications (e.g., electrical, mechanical, environmental)		
Features e.g., alarms, display and indicators, modes.		

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of pulse oximeters addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device. The 510(k) should describe the risk analysis method used and include the results of this

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analysis. If you elect to use an alternative approach to address a particular risk identified in this document or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Table 2. Risks and Mitigation Measures

Identified risk	Recommended mitigation measures
Inadequate device performance	Section 7. Accuracy of Pulse Oximeters Section 8. Device Performance Section 9. Software Information
Electrical and mechanical failure	Section 10. Electrical, Mechanical, and Environmental Safety
Electromagnetic interference	Section 11. Electromagnetic Compatibility
Adverse tissue reactivity	Section 12. Biocompatibility
Cross-contamination and infection	Section 13. Cleaning, Disinfection, and Sterilization
Improper use	Section 14. Labeling

The mitigations we recommend are described in the following sections. For each test described in **Sections 7-13**, we recommend you include:

- detailed description of the test method, including drawings of the test apparatus where appropriate
- description of the actual test conditions
- explicit description of the acceptance criteria for the test
- results of the test
- analysis of the test results
- discussion of any conclusions drawn from the results.

Different Test Methods

If the test method differs from the method described in this document, we recommend you provide an explanation of how the test method is equivalent to the recommended test method.

Device Failure during Testing

If the device fails during a test, we recommend you explain why the failure does not affect the

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safety or effectiveness of the device. If the device was modified after the failed test, we recommend you:

- explicitly identify and completely describe each modification and its intended effect
- provide additional test results to show the modified device passes the previously failed test.

7. Accuracy of Pulse Oximeters

We recommend that you conduct the testing described in Clause 50 of *ISO 9919 (2005): Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use* or equivalent methods.

An oximeter is intended for use as a system - composed of a sensor, any extender or interface cable, and a specific oximeter monitor or module. We recommend you validate each system through appropriate testing, inspection, or analysis.

Grouping Sensors for Testing

It may be appropriate to group certain sensors for testing if they are of similar design or equivalent performance. We consider sensors to be of similar design if they contain identical materials and electro-optical components and have equivalent sensor characteristics (e.g., location of use, intended patient population). If you choose to group sensors for testing based on their similar design, we recommend you indicate that all sensors within each group contain identical materials and electro-optical components. Generally, we believe that clip and adhesive sensors should not be grouped based on similar design because they differ in form, fit, and functional specifications. If you choose to group sensors for testing based on equivalent performance, we recommend you provide valid scientific evidence and statistical analysis to demonstrate that the results of testing are poolable.

Oximeter System Identical to the Original Equipment Manufacturer's Cleared System

If your oximeter system is identical to an Original Equipment Manufacturer's (OEM) system, legally marketed for the same intended use as a system, we recommend you provide:

- the 510(k) numbers for the submissions where each combination of oximeter, sensor, and cable were cleared for use together
- testing that demonstrates that SpO₂ and pulse rate values calculated by the OEM system are not corrupted during communication to your host device (i.e., ensure the calculated and displayed values are identical).

We recommend you conduct the above verification on the bench using a phantom finger and sensor or by simply generating electric signals.

New and Modified Oximeter Systems

A new oximeter system is one that is not currently legally marketed.

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For the purposes of this guidance, we consider a modified oximeter system one that is currently marketed without any modification, but “that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device,” which requires a new 510(k) in accordance with 21 CFR 807.87(g). FDA generally considers any one of the following modifications significant:

- sensor modifications affecting electro-optical, materials components, or construction
- hardware or software modifications to a monitor, module, or accessory.

We recommend you conduct *in vivo* studies to determine the accuracy of SpO₂ (under laboratory and any labeled motion conditions) for new and modified systems. FDA will always consider alternatives to *in vivo* testing when the proposed alternatives are supported by an adequate scientific rationale.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. Generally, FDA believes pulse oximeters addressed by this guidance document are non-significant risk devices, therefore the study is subject to the abbreviated requirements of 21 CFR 812.2(b).⁵ In addition to the requirements of section 21 CFR 812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

7.1 *In vivo* testing for SpO₂ accuracy under laboratory conditions

We recommend you follow Clause 50 and Annex EE.2, *Procedure for invasive laboratory testing on healthy volunteers*, of ISO 9919 or equivalent method to validate the SpO₂ accuracy specifications of your pulse oximeter system by comparing each value from your system and a simultaneous value from co-oximetry of an arterial blood sample. We also recommend you submit a detailed clinical protocol for this testing. Your protocol should show the:

- test apparatus used, including means for arterial catheterization and blood sampling, means for recording SpO₂ values, and means for delivering medical grade oxygen-nitrogen mixtures of varying fractional inspired oxygen (FiO₂) levels
- pulse oximeter system tested
- inclusion and exclusion criteria
- number of subjects
- number or samples taken per subject
- specific conditions of testing, including laboratory conditions, subject motion, low pulse amplitude

⁵ See <http://www.fda.gov/oc/ohrt/irbs/devices.html#risk>

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- type and frequency of motion for testing under motion conditions, if applicable
- criteria and methods for determining stability of reference arterial blood oxygen saturation (SaO₂) at the pulse oximeter sensor site
- desaturation profile, including target saturation plateaus and ranges
- formula used for determination of root mean square difference (Arms) (See Clause 50.101.2.2 of ISO 9919 for recommended formula).

We recommend you conduct the study described in Clause 50 and Annex EE.2 on 10 or more healthy subjects, who range in age, gender, and skin tone. Your study should include a sufficient number of subjects with dark skin pigmentation, e.g., 30%.

Your data should include 200 or more data points (paired observations: pulse oximeter, co-oximeter). These data should be approximately equally spaced over a saturation range of 70 to 100 percent.

If you exclude any data points from your analysis, we recommend you indicate which points you excluded and provide a rationale for each.

We recommend you provide a line listing and a Bland-Altman plot of your data.

The table below outlines the different types of sensors and the worst case Arms between measured values (SpO₂) and reference values (SaO₂) for each (under normal conditions ranging from 70% to 100% SpO₂).

Table 3. Recommended Arms Specification for each Sensor Type

Sensor Type	Arms
Transmittance, wrap and clip	≤ 3.0 %
Ear clip	≤ 3.5 %
Reflectance	≤ 3.5 %

7.2 *In vivo* testing for SpO₂ accuracy for neonates

If your device is intended for use with neonates, we recommend you report performance of neonatal sensors on adult subjects as described in Section 7.1. Adult subjects are acceptable in this case due to the uncertainty of determining the accuracy of sensors intended for use in neonates. We also recommend you provide additional data (See Annex EE.4.1, *Invasive testing on patients*, of ISO 9919), using a statistically valid sample size, collected on neonates to report actual clinical performance.

We recognize neonatal clinical studies are more representative of the intended use than controlled laboratory studies in adults, and there will be inherently greater noise in the

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measurement of neonatal oxygen saturation values. Nonetheless, we recommend you provide data on a sufficient number of neonatal subjects and samples to achieve an appropriate level of precision for measurement of Arms. The Arms level of precision in the neonatal study should demonstrate that the observed Arms is equivalent to the worst case Arms in adults for the specific type of sensor (see Table 3 above).

7.3 *In vivo* testing for SpO₂ accuracy under motion conditions

If your device is intended for use under motion conditions, we recommend you conduct the testing described in Section 7.1 under motion conditions. We recommend you describe the type and frequency of motion selected for testing.

7.4 *In vitro* testing for SpO₂ accuracy under low perfusion conditions

If your device is intended for use under low perfusion conditions, we recommend you perform bench testing to simulate low perfusion conditions. We recommend you verify the SpO₂ accuracy under low perfusion conditions *in vitro* using an optical simulator, set to the minimum signal amplitude defined as low perfusion for the system (e.g., 0.3% modulation).

7.5 *In vitro* testing for Pulse Rate Accuracy under normal conditions

For pulse rate accuracy specification testing, we recommend you provide *in vitro* verification over the specified pulse rate display range. We recommend you test your system on the bench (using an optical simulator) at the lowest pulse amplitude that the oximeter is able to detect.

7.6 *In vitro* testing for Pulse Rate Accuracy under motion conditions

If your device is intended for use under motion conditions, we recommend you perform pulse rate accuracy testing described in Section 7.5 under motion conditions. We recommend you describe the type and frequency of the motion selected for testing.

7.7 *In vitro* testing for Pulse Rate Accuracy under low perfusion conditions

If your device is intended for use under low perfusion conditions, we recommend you perform pulse rate accuracy testing described in Section 7.5 under low perfusion conditions. We recommend you verify the pulse rate accuracy using an optical simulator set to the minimum signal amplitude defined as low perfusion for the system (e.g., 0.3% modulation).

8. Device Performance

We recommend the device undergo performance testing as described in *ISO 9919: Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use* or equivalent method. This should include, but not be limited to testing identified in Sections 8.1 – 8.3 below.

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8.1 Alarms

We recommend you follow ISO 9919, Clause 104 or equivalent method for visual and audible indicators and alarms of the monitor and any remote alarm unit.

8.2 Display values and indicators

We recommend you validate all of the measurement values and indicators that the device incorporates and displays on the monitor (e.g., perfusion index, signal strength, pulse amplitude). We recommend the test procedure include the test method, the objectives of the testing, the equipment used, the tests specifications, the standards to which conformance is demonstrated, the pass/fail criteria, and the summary of the results including an analysis explaining the significance of the results.

8.3 Saturation pulse information signal

If your device includes a variable-pitch auditory information signal to indicate the pulse signal, we recommend the pitch change follow ISO 9919, Clause 103 or equivalent method.

9. Software Information

Please refer to the **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**,⁶ for a discussion of the software documentation that we recommend you provide. FDA generally considers pulse oximeters to be of “Moderate” level of concern for the purposes of software review.

If the device includes off-the-shelf software, we recommend you provide the additional information as recommended in the guidance, **Off-the-Shelf Software Use in Medical Devices**.⁷

10. Electrical, Mechanical, and Environmental Safety

We recommend you follow electrical, mechanical, and environmental safety testing for Type B equipment described in ISO 9919, *IEC 60601-1 (1988): Medical electrical equipment – Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995)*, and *IEC 60601-1-1 Collateral Standard: Safety requirements for medical electrical systems* or equivalent methods. For mechanical and environmental safety testing, this should include, but not be limited to testing identified in **Sections 10.1-10.3** below.

10.1 Mechanical Vibration and Shock Resistance

We recommend you demonstrate your pulse oximeter system continues to operate within specifications, after being subject to the mechanical shocks and vibrations expected in the

⁶ <http://www.fda.gov/cdrh/ode/guidance/337.pdf>

⁷ <http://www.fda.gov/cdrh/ode/guidance/585.html>

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intended environment of use as described in ISO 9919, Clause 21 or equivalent method.

10.2 Fluid Spill Resistance

We recommend you demonstrate your pulse oximeter system continues to operate within specifications after fluids have been dripped on it as described in ISO 9919, Clause 44 or equivalent method.

10.3 Skin Surface Temperature

The device should not present a risk due to excessive surface temperatures of the applied part. Refer to Clause 6.8.2 and Clause 42 of ISO 9919 or equivalent methods.

11. Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is the ability of a device to operate properly in its intended environment of use without introducing excessive electromagnetic disturbances into that environment. EMC testing is described in *IEC 60601-1-2 (2001): Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, including Edition 2 (2001) with Amendment 1 (2004)* and includes both tests for immunity of the device to outside noise and emissions from the device to the outside. We recommend you follow Clause 36 of ISO 9919 and *IEC 60601-1-2 (2001): Medical electrical equipment, Part 1: General Requirements for Safety, 2. Collateral standard: Electromagnetic Compatibility - Requirements and Tests* or equivalent methods

We recommend you include a complete description of the EMC characteristics of the device. We also recommend you include information verifying those characteristics when tested with the third wire ground connected at the plug end of the power cord. Devices intended for home use should be able to safely function without a protective earth ground (See IEC 60601-1, Clause 14.2).

12. Biocompatibility

We recommend that you evaluate the biocompatibility of the patient-contacting materials as described in the FDA guidance on **International Standard Organization (ISO) standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."**⁸ We consider pulse oximeters devices with prolonged contact duration due to the potential for cumulative use. We consider the components that contact the patient to be surface contacting components with skin contact. We recommend testing include:

- irritation or intracutaneous reactivity
- sensitization
- cytotoxicity.

⁸ <http://www.fda.gov/cdrh/g951.html>.

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Materials are identical if they have the identical chemical formulation and identical manufacturing processes. If identical materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing. We also recommend that you provide a list of the patient-contacting materials in your device.

13. Cleaning, Disinfection, and Sterilization

We recommend you provide information on cleaning, disinfection, and sterilization for all pulse oximeters intended for reuse (both single patient and multi-patient).

13.1 Reuse Instructions and Validation

For pulse oximeter systems and accessories intended for reuse, we recommend you evaluate the instructions for cleaning and, as appropriate, disinfection or sterilization.

If the device is intended to be cleaned, high level disinfected, or sterilized by the user for multiple use, we recommend you demonstrate that the device can be cleaned, high level disinfected, or sterilized according to the instructions provided in the device labeling; and that afterwards, the device continues to perform as intended.

In order to demonstrate that the labeled cleaning and disinfection or sterilization methods achieve the desired results, refer to the FDA guidance, **Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities**⁹ for additional recommendations.

13.2 Sterilization Documentation

If the pulse oximeter system or accessories are provided sterile, we recommend you include the documentation described in **Updated 510(k) Sterility Review Guidance K90-1**.¹⁰

14. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Use the following suggestions for assistance in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).¹¹

Intended Use

⁹ <http://www.fda.gov/cdrh/ode/198.pdf>

¹⁰ <http://www.fda.gov/cdrh/ode/guidance/361.pdf>

¹¹ Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

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The intended use should indicate whether the device is intended for spot checking or for continuous monitoring. The intended use should also identify:

- patient populations
- application sites
- use under conditions such as motion and low perfusion, if applicable
- whether the device is intended for single use or reuse
- environments of use.

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, we recommend you provide clear and concise instructions that delineate the technological features of your device and how it is used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

The instructions should also include:

- all applicable safety information, warnings, cautions, and notes
- a description of your pulse oximeter system including the theory of operation (reflectance or transmittance, functional or fractional saturation, etc.), all features, alarms, and accessories
- an identification of whether the system and accessories are provided sterile or non-sterile
- device setup and operation information
- instructions for the frequency of inspection of the application site for skin integrity
- instructions for the frequency of sensor relocation
- device service and maintenance information, including cleaning and disinfection instructions for reusable pulse oximeters and accessories.

Device Specifications

The labeling should include a list of specifications including:

- SpO₂ accuracy specification
- pulse rate accuracy specification
- operating and storage temperature and humidity
- alarm limits and ranges
- default settings.

For devices intended for use with neonates, we recommend the specifications include:

- patient population characteristics of the neonate population tested
- number of subjects

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- number of data samples
- resultant range and accuracy.

The labeling should identify the specific models of pulse oximeters with which the sensors were clinically validated and intended to be used.

We recommend you provide package labeling in your submission. We recommend the package labeling identify whether the device is:

- provided sterile or non-sterile
- intended for single use or reuse.

15. Submissions for Reprocessed Single-Use Sensors

If your device includes a reprocessed single-use sensor, we recommend you provide the following information in addition to the information described in this guidance document.

- electro-optical specifications of the reprocessed sensors
- means to ensure each reprocessed device meets these specifications
- tracking methods used to limit the number of reprocessing cycles

Identification of Components and Uses

We recommend you identify each component that will be replaced when the device or system is reprocessed and each component that will be retained. In particular, we recommend you indicate whether the reprocessor will replace or save the laminate that encloses the optical components. We also recommend you provide a detailed diagram of all the components of the sensors.

Performance Testing

We recommend you describe performance testing conducted to validate the performance of the reprocessed device, including:

- clinical validation of SpO₂ accuracy as described in Section 7 above
- bench testing of pulse rate performance as described in Section 7 above
- high and low temperature and humidity testing in accordance with Clause 10 of IEC 60601-1) or equivalent methods.

We recommend the performance testing for reprocessed sensors is assessed on worst-case basis (i.e., after the maximum number of times the sensor is intended to be reprocessed). In addition, we recommend you simulate use of each sensor after each reprocessing cycle prior to testing recommended above.

We recommend you provide complete reprocessing methods and validation data in accordance with the FDA Guidance, **Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-**

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Use Medical Devices.¹² This should include, but not necessarily be limited to the following information.

Cleaning Methods and Validation Information

We recommend you provide point-of-use cleaning instructions for the healthcare facility (if used) in the device labeling.

We recommend you provide incoming inspection instructions for device-cleaning technicians, including:

- detailed acceptance/rejection criteria to control incoming raw materials for devices that are intended to be reprocessed
- model sorting.

We recommend you provide cleaning instructions used by the device cleaning technicians, including set points and ranges for cleaning methods; e.g., times, temperatures.

We recommend you provide cleaning validation information, including:

- methods that test worst case implementation of set points and ranges described above
- predetermined cleaning endpoints and their scientific rationale
- the adequacy of the proposed cleaning process.

Disinfection and/or Sterilization Validation Information

We recommend you provide comprehensive disinfection and sterilization validation protocols and data, consistent with the intended use, indications, and performance characteristics described in your labeling.

Devices Not Provided Sterile

For devices labeled “non-sterile,” we recommend labeling include a general description of how the packaging materials adequately protect the devices during shipping and handling, including packaging validation protocols and data.

Devices Provided Sterile

For devices labeled “sterile”, we recommend you include the documentation described in **Updated 510(k) Sterility Review Guidance K90-1**.¹³

¹² <http://www.fda.gov/cdrh/ode/guidance/1216.html>

¹³ <http://www.fda.gov/cdrh/ode/guidance/361.pdf>