Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA

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

Anesthesiology and Respiratory Devices Branch
Div. of Anesth., General Hosp, Infect. Contr., & Dental Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket No.00D-1458. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Purpose

This guidance document describes a means by which cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitor devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers submitting premarket notification should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness. It identifies relevant material to include in a 510(k) premarket notification application. This document does not address all FDA requirements regarding premarket notification submissions.

Following the effective date of this final reclassification rule, any firm submitting a 510(k) premarket notification for a cutaneous carbon dioxide (PcCO2) and oxygen (PcO2) monitor device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitor devices identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device, unless exempt from the premarket notification requirements of the Act (refer to 21 CFR 807.85).

This special control guidance document identifies the classification regulations and product codes for the device (refer to Section 4 – **Scope)**. In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with the generic type of device and lead to a timely 510(k) review and clearance. This document supplements other agency documents regarding the specific content requirements of a 510(k) submission. You should also refer to 21 CFR 807.87 and other agency documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, http://www.fda.gov/cdrh/manual/510kprt1.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**[1]," 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 a Class II Special Controls Guidance Document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues**" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

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 special control 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

[1] http://www.fda.gov/cdrh/ode/parad510.html

this guidance 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 you should 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 Class II Special Controls Guidance Document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use.

Summary report

The summary report should contain:

- Description of the device and its intended use. The description should include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. You should also submit an "indications for use" enclosure.[2]

- Description of device design requirements.

- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 5 for the risks to health generally associated with the use of this device that FDA has identified.)

- Discussion of the device characteristics that address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.

- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 6-10 of this Class II Special Controls Guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you should either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the

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

acceptance criteria that you will apply to your test results.[3] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.[4] Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information, see 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), you can submit a traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions as described in Appendix I Suggested Format for Test Reports. Manufacturers considering 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 for cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitor devices.

[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)) 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.

Note: Unless otherwise specified, testing to support either a traditional or Abbreviated 510(k) for a cutaneous carbon dioxide ($PcCO_2$) or oxygen (PcO_2) monitor should be performed under the following conditions:

- Ambient temperature between 15 and 35°C
- Barometric pressure between 68 and 106 kPa
- Ambient humidity should be between 30 and 90%
- For line-powered devices, the line voltage between 110 and 125 V rms

4. Scope

The scope of this document is limited to the following devices:

- Cutaneous Carbon Dioxide ($PcCO_2$) monitor
  (21 CFR 868.2480, Product Code 73 LKD)

- Cutaneous Oxygen (PcO_2) Monitor
  (21 CFR 868.2500, Product Code 73 KLK, for an infant not under gas anesthesia)

- Cutaneous Oxygen (PcO_2) Monitor
  (21 CFR 868.2500, Product Code 73 LPP, for uses other than for infant not under gas anesthesia)

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitor devices 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 also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Improper patient management	Section 6
Electrical shocks/Burns	Section 7
Electromagnetic interference	Section 8

Cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitor devices include parts that are applied to patients and should be considered to have prolonged contact with intact skin. We recommend that you evaluate the biocompatibility of the materials in these parts as described in the International Standard Organization (ISO) standard **ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**. We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).[5] You should select tests appropriate for the duration and level of contact with your device. 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.

From your risk analysis, if you have identified additional risks specific to your device, information should be included in your submission that demonstrates you have properly mitigated these risks. Given that this document recommends the use of multiple standards to mitigate risks, it may be possible to address your risk by the use of this document. If this is the case, you should indicate how the use of this guidance mitigated your risks. Also, existing standards (not mentioned in this document) may exist that can be used to demonstrate you have addressed your risks.

In those cases where this guidance document or an existing standard cannot be used to address a particular risk, additional information should be provided in your premarket notification. This information should include a discussion of the mechanism incorporated (e.g., hardware, software) in the device to mitigate the risks and, if appropriate, test information that demonstrates the risks have been adequately addressed. The following sections outline information that should be provided in your submission to demonstrate risks have been adequately mitigated.

6. Performance of Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors

This section describes performance testing specific to cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitors. You should conduct the performance testing under the environmental conditions stated in Clause 4.3 of *IEC 60601-3-1: Medical electrical equipment—Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment*. You should explicitly state the actual conditions.

You should use the additional standards listed below.

IEC 60601-2-23 (1999): Medical electrical equipment - Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment.

[5] If your device is labeled sterile, we recommend that you follow the guidance for devices intended for contact with intact skin in **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/361.html.

ASTM F 984-86 (Reapproved 1992): Standard Specifications for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide. (See footnote 5.)

International Federation of Clinical Chemistry (IFCC), Scientific Division, Committee on pH, Blood Gases and Electrolytes: Guidelines for Transcutaneous PO2 and PCO_2 measurement.

Since there are slight variation among these standards, the information below will ensure consistency in performance testing for these devices.

6.1 Visual and Audible Indicators and Alarms

Visual and audible indicators and alarms should conform to either:

ASTM F 984 - 86: Standard Specifications for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide[6]
AND
ASTM F 1463-93 (1999): Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care

OR

ASTM F 984 - 86: Standard Specifications for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide
AND
ISO 9703-1 (1992): Anaesthesia and respiratory care alarm signals - Part 1: Visual alarm signals
AND
ISO 9703-2 (1994): Anaesthesia and respiratory care alarm signals - Part 2: Auditory alarm signals

6.2 O_2 and CO_2 Accuracy

The device should indicate the partial pressure of O_2 (cutaneous PO_2) to within 5 mmHg over the range from 0-20.9% O_2, and to within 10 mmHg over the range from 20.9-100% O_2.

The device should indicate the partial pressure of CO_2 (cutaneous PCO_2) to within 5 mmHg over the measurement range specified. The measurement range should be explicitly stated in the submission and in the operator's manual for the device.

[6] ASTM F984 (1986) has been discontinued without replacement. To obtain a copy of this standard, please contact the American Society For Testing And Materials (ASTM), 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

Refer to *ASTM F 984*.

Recommended Test Method

You should test the O_2 and CO_2 accuracy of your device as follows:

- Calibrate the device using the method specified in the operator's manual for the device.
- Test the O_2 accuracy of the device using ±0.03% calibrated gases of 0, 2, 10, and 20.9% O_2, and of a concentration near full-scale of the device.
- Test the CO_2 accuracy of the device using ±0.03% calibrated gases of 0, 3, 5, and 10% CO_2.

6.3 O_2 and CO_2 Drift

The cutaneous PO_2 reading should not drift by more than 5% of the initial reading over the specified calibration interval. You should measure the maximum drift in a one-hour period. The cutaneous PCO_2 reading should not drift by more than 10% of the initial reading over the specified calibration interval. You should measure the maximum drift in a one-hour period. You should state the calibration interval and the maximum drifts measured in the submission and in the operator's manual for the device. See *IEC 60601-3-1(1996-07) Medical electrical equipment - Part 3-1: Essential performance requirements for trancutaneous oxygen and carbon dioxide partial pressure monitoring equipment*.[7]

Recommended Test Method

You should test the O_2 and CO_2 drift of your device using the method of Clause 6.1.1 of *IEC 60601-3-1*.

6.4 Response Time

You should determine the 10-90% response times for step increases and step decreases in the O_2 and CO_2 concentration in test gases. These response times should be explicitly stated in the operator's manual for the device. See *ASTM F 984* and *IEC 60601-3-1*

Please note that the response time only measures the response of the sensing electrode and does not include the time necessary for the area between the sensor and the skin to equilibrate. The area between the sensor and the skin has a conventional configuration that does not unduly add to the ability to respond to physiological changes.

[7] (Now included in IEC 60601-2-23 (1999).)

Recommended Test Method

You should determine the 10-90% response time for cutaneous PO_2 using the test method in Clause 7 of *IEC 60601-3-1* using ±0.03% calibrated gases of 2% and 20.9% O_2.

You should determine the 10-90% response time for cutaneous PCO_2 using the test method in Clause 7 of *IEC 60601-3-1* using ±0.03% calibrated gases of 3% and 10% CO_2.

6.5 Non-linearity and Hysteresis

Hysteresis information is used to determine that the same accuracy levels exist at low and high readings for PO_2 and PCO_2. The device should maintain linearity within ±5 mmHg of the nominal values when tested between 2% and 20.9% O_2, and between 3% and 10% CO_2. You should include this information in the operator's manual. Refer to *IEC 60601-3-1*.

You should justify any non-linearity of the device outside these ranges and explicitly state them in the operator's manual for the device.

Recommended Test Method

You should test the device using the method in Clause 6.2 of *IEC 60601-3-1* using ±0.03% calibrated gases of 2% and 20.9% O_2, and using ±0.03% calibrated gases of 3% and 10% CO_2.

6.6 Effects of Anesthetic Agents

You should determine whether anesthetic agents can cause your device to perform outside its accuracy specification. If so, the operator's manual and the label on the device should identify those anesthetic agents. Please refer to *ASTM F 984* for test methods.

6.7 Sources of Interference

The operator's manual and the label on the device should disclose any interfering gases or vapors known to cause deviation outside the stated accuracy specification. In addition, the operator's manual should disclose expected effects of electrocautery, electrosurgery, defibrillation, X-ray, infrared radiation, conducted transients and RF interference on the device. Please refer to *ASTM F 984 and IEC 60601-3-1.*

6.8 Software Validation Activities

Please refer to the **Guidance for the Content of Premarket Submissions for Software**

Contained in Medical Devices (hereafter, the Software Guidance), http://www.fda.gov/cdrh/ode/software.pdf, for a discussion of the software documentation that you should provide. FDA generally considers cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitors to be of "moderate" level of concern for the purposes of software review.

We encourage you to take advantage of any recognized software standards and provide statements or declarations of conformity as described in FDA guidance, **Use of Standards in Substantial Equivalence Determinations**, http://www.fda.gov/cdrh/ode/guidance/1131.html. Please visit the following website to search for the standards that have been recognized when a medical device contains software, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. We have created a supplemental data sheet for each software standard that we have recognized. The supplemental data sheet includes a table that indicates the documentation that should be included in a submission when a declaration of conformity is provided.

If the device includes off-the-shelf software, you should provide the additional information as recommended in the **Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices**, http://www.fda.gov/cdrh/ode/1252.html.

7. Mechanical and Electrical Safety

The device should meet the electrical and mechanical safety requirements of *IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety* for Type BF equipment and *IEC 60601-1-1 Collateral Standard: Safety requirements for medical electrical systems*. In addition, the device should conform with the additional recommendations in this section (9.1-9.3), which extend or supplement *IEC 60601-1* and *IEC 60601-1-1*. Also, the device should meet the additional safety requirements in *IEC 60601-2-23 (1999-09): Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment, and ASTM F 984-86: Standard Specifications for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide.*

7.1 Set Temperature of the Applied Part

The device should have a control to set the temperature of the applied part, and a numerical indicator of the set temperature. If the control is calibrated, it should be accurate to within 0.5ºC. If an indicator of the actual temperature of the applied part is provided, that indicator should be accurate to within 0.5ºC. The set temperature should not exceed 45ºC, and the actual temperature of the applied part should not exceed the set temperature by more than 0.6ºC for more than 20 seconds in any period of 30 minutes after the settling time of the

device. (The settling time should be explicitly stated in the submission, and in the operator's manual for the device.) In addition, there should be a visible indication when the temperature of the applied part exceeds the set temperature by more than 0.6ºC. Further, the applied part should have an independent temperature limiter that prevents the temperature of the applied part from exceeding 46ºC for more than 20 seconds. See Clause 42.3 of IEC 60601-2-23: Medical electrical equipment, Part 2: Particular requirements for the safety of cutaneous partial pressure monitoring equipment.

If the device is intended to contact the patient for more than four hours, the set temperature should not exceed 44ºC (see Clause 7.1 of Winberley, et al., International Federation of Clinical Chemistry (IFCC) Scientific Division Committee on pH, Blood Gases and Electrolytes: Guidelines for Transcutaneous pO_2 and pCO_2 Measurement. *Ann. Biol. Clin.* 1990, 48:39-43). In this case, the operator's manual for the device should include explicit instructions to change the location of the sensor every four hours to prevent skin burns.

The actual temperature of the applied part should not vary from the set temperature by more than 0.6ºC for more than 20 seconds in any period of 30 minutes. See *IEC 60601-2-23*.

Recommended Test Method

You should test the device using the method of *IEC 60601-2-23*.

7.2 Electrical Power Indicators

The device should have visual electrical power indicators to indicate that the device is energized. You should locate these indicators conspicuously on the device.

7.3 Auxiliary Output

If the device has an auxiliary output (i.e., data port, printer port, etc.), the operator's manual should clearly describe the proper connection of the auxiliary device to the auxiliary output. The device should operate within its specifications during and after application of a short-circuit applied to the auxiliary output.

Recommended Test Method

With the device in the standard operating mode, short-circuit all pins of the auxiliary output together. Verify that the device operates within its specifications during and after application of the short-circuit.

7.4 AC Power Grounding and Polarity

If the power cord for a line-powered device is not polarized, the device should operate

within its specification when the power is connected in either polarity. The device should operate within its specification when operating from a grounded or an ungrounded power source (i.e., with the third-wire ground connected and with it disconnected at the plug end of the power cord).

Recommended Test Method

Power source conductors, patient-contacting circuits and transducer circuits should be adequately insulated to assure protection of the patient and device from overvoltages. Verify that the device operates within its specifications when operating from a grounded and ungrounded power source.

8. 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): General Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests.*

You should include a complete description of the EMC characteristics of the device, and information to verify those characteristics under the following circumstances:

- All devices should be tested with the third wire ground connected at the plug end of the power cord.
- Devices intended for home use should also be tested with the third wire ground disconnected at the plug end of the power cord.

When subjected to immunity tests, the device should operate within its specification during and after exposure to electromagnetic disturbances at the levels specified in this section. The immunity level should be adjusted *upward* by the rms sum of all errors in the measurement of that quantity unless otherwise stated. Patient simulators should be used to provide simulated normal stimulus to sensors during immunity testing.

The device should not, as a result of a specified test condition:

- indicate an equipment alarm;
- exhibit temporary degradation or loss of function or performance that requires operator intervention or system reset; or
- exhibit loss or corruption of stored data.

Any such failure during an immunity test should constitute failure of the test.

The device should meet the EMC requirements of *IEC 60601-1-2* edition 2. The following parts (10.2 - 10.5) specify levels that differ from those in *IEC 60601-1-2*. In addition, the

device should conform with the additional recommendations in part 10.1, 10.6, and 10.7 of this section, which is not part of *IEC 60601-1-2*.

8.1 Magnetic Field Emissions

You should show that the device operates within its specifications without emitting magnetic fields that exceed the Army, 7-cm distance limits given in RE101 of *MIL-STD-461D (1993): Requirements for the Control of Electromagnetic Interference, Emissions and Susceptibility*.

Recommended Test Method

With the device operating normally, measure emitted magnetic field strengths at the Army, 7-cm distance, according to RE101 of *MIL-STD-462D (1993): Measurement of Electromagnetic Interference Characteristics*. You should show that between 30 Hz and 100 kHz, the measured field strengths do not exceed the Army, 7-cm limits in RE101 of *MIL-STD-461D*.

8.2 Power Frequency Magnetic Fields Immunity

The device should operate within its specifications during and after exposure to continuous, 60 Hz continuous magnetic fields having intensities as great as 3 A/m.

Recommended Test Method

You should test the device using the method in *IEC 61000-4-8 (1993): Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 8: Power frequency magnetic field immunity test*, with the exception that a maximum display jitter of 0.6 millimeters is allowed for cathode ray tube displays.

8.3 Conducted Electromagnetic Energy

The device should operate within its specifications during and after exposure of each interconnecting cable, including power cables, to conducted electromagnetic energy at frequencies between 10 kHz and 100 MHz, at the levels specified in CS114, Curve #3 of *MIL-STD-461D*.

Recommended Test Method

You should test the device using the method of CS114 of MIL-STD-462D, with the following modification:

- The carrier should be 80% amplitude-modulated with a 2 Hz sine wave.

The test should show that the device operates within its specifications during and after

exposure to conducted electromagnetic energy at the levels specified in CS114, Curve #3 of *MIL-STD-461D*.

9. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).[10]

Instructions for Use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be 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.

You should follow the labeling recommendations for cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitors and include any information recommended in the standards cited in this Special Controls Guidance Document.

[10] 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.

Appendix I. Suggested Format for Test Reports

If you choose to submit a traditional 510(k) or if you use test methods not given in the standards cited in this guidance, you should submit test reports. These test reports should include the following elements, or a justification for their omission:

- a detailed description of the test method and objective, including drawings of the test apparatus where appropriate;
- a statement of the acceptance criteria for the test and how the criteria were selected;
- a discussion of how the test method simulates the intended environment of use;
- an analysis of the test results; and
- a statement of conclusions drawn from the test.