

Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO₂) and Oxygen (PcO₂) Monitors; Draft Guidance for Industry and FDA

Draft Guidance – Not for Implementation

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Draft released for comment on [release date as stated in FR Notice]**



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

**Anesthesiology and Respiratory Devices Branch
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation**

01D-0577

BDL-1

Preface

Public Comment

For 60 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, 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.

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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 (PcCO₂) and oxygen (PcO₂) 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 attempting to establish that their device is substantially equivalent to a legally marketed cutaneous carbon dioxide (PcCO₂) or oxygen (PcO₂) monitor device 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 submission. All FDA requirements regarding premarket notification submissions are not repeated in this document. This guidance will be issued in conjunction with a Federal Register notice announcing the proposal to reclassify this device type. This guidance is issued for comment purposes only. If a final rule to reclassify this device type is not issued, this guidance document will not be issued as a special control.

FDA has determined that special controls, when combined with the general controls and the specific information discussed in this guidance, are sufficient to provide reasonable assurance of the safety and effectiveness of cutaneous oxygen and carbon dioxide monitors. Thus, a manufacturer who intends to market a device of this generic type should (1) conform with the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification (510(k)) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with the cutaneous carbon dioxide (PcCO₂) and oxygen (PcO₂) monitor devices, and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

Device manufacturers may choose to submit an Abbreviated 510(k) when: (1) a guidance document exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard. FDA believes an Abbreviated 510(k) is the least burdensome means of demonstrating substantial equivalence once a Class II Special Controls Guidance Document has been issued. See also **The New 510(k) Paradigm - Alternate Approaches to**

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Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance, <http://www.fda.gov/cdrh/ode/parad510.html>.

An Abbreviated 510(k) submission should include the required elements identified in 21 CFR 807.87, including a description of the device, the intended use of the device, and the proposed labeling for the device. An Abbreviated 510(k) should also include a summary report. 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). An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including a description of the device, the intended use of the device, and the proposed labeling for the device. An Abbreviated 510(k) should also include a summary report. 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).

The summary report should briefly describe the methods or tests used and the acceptance criteria applied to address the risks identified in this guidance document as well as any additional risks specific to your device. When a suggested test method is followed, a simple reference to the method will be an acceptable description. If there are any deviations from a suggested test method, you should provide more detailed information in the summary report to characterize the particular deviation. The summary report should also either (1) briefly present the data resulting from each test in tabular form **or** (2) describe the acceptance criteria to be applied to the test results. (See also 21 CFR 820.30 Subpart C Design Controls for the Quality System Regulation.)

2. 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)

3. Identification of Risks to Health

FDA has identified five risks to health generally associated with the use of cutaneous carbon dioxide ($PcCO_2$) and oxygen (PcO_2) monitors in the table below. You should also conduct a risk analysis to identify any other risks to health specific to your device. The premarket notification should describe the risk analysis method.

Identified risk	Recommended mitigation measures
Electrical Shock	Section 9
Electromagnetic Interference	Section 10
Toxicity, Tissue Reactivity	Section 11
Burns	Section 12
Inaccurate measurement	Section 12

4. Controls

FDA believes that the controls in the following sections of this guidance, when combined with general controls, will address the identified risks to health associated with the use of the cutaneous carbon dioxide (PcCO₂) and oxygen (PcO₂) monitors. Manufacturers should demonstrate that their device complies with either the specific recommendations of this guidance or with an alternate means to address the above identified risks to health and to provide reasonable assurance of the safety and effectiveness of the device. If you have identified any additional risks, specific to your device, your 510(k) should identify those risks and the verification and/or validation activities required to address these risks.

5. 510(k) Content

An Abbreviated 510(k) that relies on a Class II Special Controls Guidance Document should contain the following:

- a coversheet prominently identifying the submission as an Abbreviated 510(k) and citing the title of the specific Class II Special Controls Guidance Document;
- items required under 21 CFR 807.87, including a description of the device (including detailed, labeled drawings and a complete discussion of the performance specifications), the intended use of the device, and the proposed labeling for the device.
- a summary report that describes how the Class II Special Controls Guidance Document was used to address the risks associated with the particular device type. You should describe the device performance requirements and discuss the hardware and software functions (see sections 6 and 7) provided to address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis. The summary report should also briefly discuss the test method and acceptance criteria for each performance test (see sections 8-13) identified in the Special Controls Guidance document. (If a manufacturer elects to use an alternative approach to address a particular risk, or has identified risks additional to those in the guidance, sufficient detail should be provided to justify the approach or measures taken to address the additional risks.) If any test article does not meet the identified acceptance criteria, you may not market your device. Instead, you must submit a new 510(k) with revised acceptance criteria. The new 510(k) must be cleared by FDA before you market your device.

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- If any part of the device design or testing relies on a recognized standard, the summary report should include:
 - a statement that testing will be conducted and that the product will meet specified acceptance criteria before marketing. For guidance, refer to our guidance **Use of Standards in Substantial Equivalence Determinations** <http://www.fda.gov/cdrh/ode/guidance/1131.html>; or
 - a declaration of conformity to the standard. For guidance, refer to **Guidance on the Recognition and Use of Consensus Standards** <http://www.fda.gov/cdrh/modact/k982.html>. [Note: Testing must be completed before submitting a declaration of conformity to a recognized standard.]
- Indications for Use enclosure.

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that includes all test reports, with supporting data, that address the performance issues presented in Sections 6 - 12. Test reports should include methods, acceptance criteria, data, and conclusions sufficient to satisfy the requirements of 21 CFR 807.87(f) or (g).

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

6. Hardware Verification Activities

You should describe the steps taken to ensure that the hardware in the device meets its specifications. This information should include a concise discussion of the hardware verification process. You should specifically identify those verification activities associated with risks identified during the risk analysis. You should provide complete verification reports including:

- a detailed description of the test method and objective, including drawings of the test apparatus where appropriate;
- an explicit statement of the acceptance criteria for the test and how the criteria are selected;
- a discussion of how the test method simulates the intended environment of use;
- the results of the test;

- an analysis of the test results; and
- an explicit statement of any conclusions drawn from the test.

7. 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 (PcCO₂) and oxygen (PcO₂) 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>.

8. 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
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

9. 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 601-2-23 (1993-09): Medical electrical equipment - Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment*, and *ASTM F 984-86: Standard Specification for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide*.

9.1 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.

9.2 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.

9.3 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.

10. 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 (1993): Medical Electrical Equipment, Part 1: General Requirements for Safety, 2. Collateral Standard: 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 1. 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*.

10.1 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 RE1 01 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*.

10.2 Electrostatic Discharge

You should show that the device operates within its specifications within five seconds of: air discharges of 2, 4 and 8 kV (both positive and negative) applied to insulating surfaces; and contact discharges of 2, 4 and 6 kV (both positive and negative) applied to conductive surfaces, to include any point on the device accessible to the operator or patient. The device should also operate within its specification within five seconds of contact discharges applied to horizontal and vertical conducting planes in the vicinity of the device.

Recommended Test Method

You should test the device using the method in *IEC 61000-4-2 (1999): Electromagnetic Compatibility (EMC)-Part 4-2: Testing and measurement techniques-Electrostatic discharge immunity testing*, with the following addition:

- Internally-powered devices, IEC Class II devices, and devices having circuits isolated from earth ground may be tested in a way that ensures that there is no appreciable charge retention between individual test discharges. Between individual test discharges, the electrical potential of the device may be equalized with that of the ground plane by temporarily attaching a ground strap incorporating two 470 k Ω resistors connected in series. The ground strap should be disconnected and moved at least 1 m away from the device during the application of individual test discharges.

10.3 Radiated Electromagnetic Fields

The device should operate within its specifications during and after exposure to amplitude-modulated electromagnetic fields with radiofrequency (RF) carrier frequencies between 80 MHz and 2.5 GHz and unmodulated field strengths of up to 3 V/m.

Recommended Test Method

You should test the device using the method in *IEC 61000-4-3 (1995): Electromagnetic compatibility (EMC)—Part 4-3: Testing and measurement techniques-Radiated, radio-frequency, electromagnetic field immunity test*.

10.4 Voltage Dips, Short Interruptions and Voltage Variations

The device should operate within its specifications during and after power line dips to:

- less than 1% of nominal line voltage for 0.5 cycles of the power frequency;

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- 40% of nominal line voltage for five cycles of the power frequency; and
- 70% of nominal line voltage for 25 cycles of the power frequency.

In addition, the device should operate within its specifications during and after voltage variations between 75 and 125% of the nominal line voltage.

Recommended Test Method,

You should test the device using the method in *IEC 61000-4-11 (1994): Electromagnetic compatibility (EMC)-Part 4-11: Testing and measurement techniques-Voltage dips, short interruptions and voltage variations immunity tests.*

10.5 Fast Transient Bursts

The device should operate within its specifications during and after transient bursts of 0.5, 1, and 2 kV (positive and negative) applied to AC power leads; and transients bursts of 0.25, 0.5, and 1 kV (positive and negative) capacitively coupled to signal and interconnecting leads at least 3 m in length. The pulse repetition rate should be 5 kHz.

Recommended Test Method

You should test the device using the method in *IEC 61000-4-4 (199.5): Electromagnetic compatibility (EMC)-Part 4-4: Testing and measurement techniques-Electrical fast transient/burst immunity test.* Patient cables should not be tested directly, but should be attached to the device during the testing of power and signal leads.

10.6 Power Frequency Magnetic Fields

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.

10.7 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 CS 114, 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 50% 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.

11. Biocompatibility and Sterility

Cutaneous carbon dioxide (PcCO₂) and oxygen (PcO₂) monitors include a part that is placed on the patient's skin. Manufacturers, should evaluate the biocompatibility and sterility of the materials in the applied part that have direct contact with the patient. These materials should be considered to have skin contact with prolonged contact duration. Please refer to the **Blue Book Memo, General Program memorandum G95-1**, <http://www.fda.gov/cdrh/g951.html> and **510(k) Sterility Review Guidance of 2/12/90 (K90-1)**, <http://www.fda.gov/cdrh/k90-1.html> to address the risks to health for cutaneous oxygen and carbon dioxide monitors. 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.

In addition, you should consider tests to detect chemical components of device materials that may be pyrogenic.

12. Performance Testing of Cutaneous Carbon Dioxide, (PcCO₂) and Oxygen (PcO₂) Monitors

This section describes performance testing specific to cutaneous carbon dioxide (PcCO₂) and oxygen (PcO₂) monitors. You should conduct the performance testing under the environmental conditions stated in Clause 4.3 of IEC 601-3-1: *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 601-Z-23 (1993-09): Medical electrical equipment - Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment.

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

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International Federation of Clinical Chemistry (IFCC), Scientific Division, Committee on pH, Blood Gases and Electrolytes: Guidelines for Transcutaneous PO₂ and PCO₂ measurement.

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

12.1 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 0.5°C. If an indicator of the actual temperature of the applied part is provided, that indicator should be accurate to within 0.5°C. The set temperature should not exceed 45°C, and the actual temperature of the applied part should not exceed the set temperature by more than 0.6°C 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 0.6°C. Further, the applied part should have an independent temperature limiter that prevents the temperature of the applied part from exceeding 46°C for more than 20 seconds. See Clause 42.3 of *IEC 601-2-23: 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 44°C (see Clause 7.1 of Winherley, et al. International Federation of Clinical Chemistry (IFCC) Scientific Division Committee on pH, Blood Gases and Electrolytes: Guidelines for Transcutaneous pO₂ and pCO₂ 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 0.6°C for more than 20 seconds in any period of 30 minutes. See *IEC 601-2-23*.

Recommended Test Method

You should test the device using the method of *IEC 601-2-23*.

12.2 O₂ and CO₂ Accuracy

The device should indicate the partial pressure of O₂ (cutaneous PO₂) to within 5 mmHg over the range from 0-20.9% O₂, and to within 10 mmHg over the range from 20.9-100% O₂.

The device should indicate the partial pressure of CO₂ (cutaneous PCO₂) 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.

Refer to *ASTM F 984*.

Recommended Test Method

You should test the O₂ and CO₂ accuracy of your device as follows:

- Calibrate the device using the method specified in the operator's manual for the device.
- Test the O₂ accuracy of the device using $\pm 0.03\%$ calibrated gases of 0, 2, 10, and 20.9% O₂, and of a concentration near full-scale of the device.
- Test the CO₂ accuracy of the device using $\pm 0.03\%$ calibrated gases of 0, 3, 5, and 10% CO₂.

12.3 O₂ and CO₂ Drift

The cutaneous PO₂ 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 PCO₂ 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 601-3-1 (I 996-07) Medical electrical equipment - Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment*.

Recommended Test Method

You should test the O₂ and CO₂ drift of your device using the method of Clause 6.1.1 of *IEC 601-3-1*.

12.4 Response Time

You should determine the 10-90% response times for step increases and step decreases in the O₂ and CO₂ 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 601-3-1*

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.

Recommended Test Method

You should determine the 10-90% response time for cutaneous PO₂ using the test method in Clause 7 of *IEC 601-3-1* using $\pm 0.03\%$ calibrated gases of 2% and 20.9% O₂.

You should determine the 10-90% response time for cutaneous PCO₂ using the test method in Clause 7 of *IEC 601-3-1* using $\pm 0.03\%$ calibrated gases of 3% and 10% CO₂.

12.5 Non-linearity and Hysteresis

Hysteresis information is used to determine that the same accuracy levels exist at low and high readings for PO₂ and PCO₂. The device should maintain linearity within ± 5 mmHg of the nominal values when tested between 2% and 20.9% O₂, and between 3% and 10% CO₂. You should include this information in the operator's manual. Refer to *IEC 601-3-1*.

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 601-3-1* using $\pm 0.03\%$ calibrated gases of 2% and 20.9% O₂, and using 50.03% calibrated gases of 3% and 10% CO₂.

12.6 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.

12.7 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 601-3-1*.

13. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). All cutaneous carbon dioxide and oxygen monitors are prescription medical devices, and according to 21 CFR 801.109 must bear the following caution statement: “Caution: Federal law restricts this device to sale by or on the order of a physician.”

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. You should also follow the general recommendations for medical device labeling in **Device Labeling Guidance (G91-1)**, <http://www.fda.gov/cdrh/g91-1.html>.