Class II Special Controls Guidance Document: Apnea 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
Division of Anesthesiology General Hospital, Infection Control, and 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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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 apnea monitors 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 classification rule (or a final rule classifying the device if it's a proposal), any firm submitting a 510(k) premarket notification for an apnea monitor 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 surgical suture 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, you should 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 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.

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

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 15 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

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 6-14 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 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.)

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

- 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 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. 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 an apnea monitor.

Note: Unless otherwise specified, testing to support either a traditional or an Abbreviated 510(k) should be performed under the following conditions:

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

4. Scope

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

Apnea Monitors, 21 CFR 868.2377, Product Code FLS, Panel 73

[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.

§ 868.2377 -- Apnea monitor.

(a) *Identification*. An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor also includes indirect methods of apnea detection, such as monitoring of heart rate and other physiological parameters linked to the presence or absence of adequate respiration.

(b) *Classification*. Class II (special controls) "Class II Special Controls Guidance Document: Apnea Monitors; Final Guidance for Industry and FDA."

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of apnea 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
Inadequate alarms	Section 9
Electrical Shock	Section 10
Electromagnetic Interference	Section 11
Inaccurate detection	Section 12, 14
Tissue Reactivity	Section 13

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 a summary of the verification activities, 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 were 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. As discussed in the *Software Guidance*, the "level of concern" is related to the possible consequences of software failure, and may be minor, moderate, or major. The software for apnea monitors is generally considered a "major level of concern." If you believe that the software in your apnea monitor should be consider a minor or moderate level of concern, you should provide a clear scientific justification which discusses the possible consequences of a software failure.

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,** already cited. 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 information sheet for each software standard that we have recognized. The supplemental information sheet includes a table that indicates the documentation that should be included in a submission when you provide a declaration of conformity.

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. Suggestions for Design and/or Features of Apnea Monitors

An apnea monitor should have:

- at least one primary/direct means for detecting apnea;
- at least one secondary/indirect means for detecting apnea, e.g., heart rate;
- a timer to measure the duration of apneic episodes;
- visual and audible alarms to signal an apneic episode;
- visual and audible alarms to signal a secondary/indirect condition due to an apneic episode; and

- a sensor fault alarm for both primary/direct and secondary/indirect means of detecting apnea which activates within 5 seconds of a sensor failure.

The primary/direct detection method should be one of the following types:

- methods for detecting central apnea only;
- methods for detecting both obstructive apnea and central apnea without distinguishing between them; or
- methods for detecting both types of apnea and distinguishing between them.

Examples of methods for detecting central apnea only include: impedance pneumography, inductive plethysmography, and pneumatic abdominal sensors. Methods of detecting both central and obstructive apnea without distinguishing them include: airway thermistors, carbon dioxide sensors, and proximal airway pressure sensors. An example of a method capable of detecting both and distinguishing between them is respiratory inductance plethysmography. Combinations of these methods can be used to monitor both types of apnea and distinguish between them.

The secondary/indirect methods of detecting apnea measure physiologic parameters that change as a result of apnea. For example, apnea may lead to hypoxia, which in turn may lead to bradycardia. Therefore, both pulse oximetry and heart rate monitoring can be used as secondary detection methods.

Strangulation Protection

The apnea monitor should have routing or retention devices, or other designs and/or features to minimize the risk of strangulation of the patient by wires or tubing. This is particularly important when the monitor is used for infants and young children.

Battery Power and Battery Power Backup Suggestions

FDA suggests the following battery power and battery power backup design features for all apnea monitors.

- The apnea monitor should have battery power backup that automatically activates when either line power fails (for AC-powered monitors) or when the primary battery source fails (for DC-powered monitors).

- The apnea monitor should have visible ready signals that indicate that the monitor is energized, and that distinguish between power sources (e.g., between line power and battery power).

- If the apnea monitor has rechargeable batteries, the monitor should have a visible signal that indicates when the batteries are charging.

- Battery power back up should automatically activate within 5 seconds after power

supplied to the monitor (e.g., from line power or the primary battery source) fails.

- Normal operation of the monitor should resume within 5 seconds after line power (for AC-powered monitors) or the primary battery source (for DC-powered monitors) is restored.

- All device settings should be stored after changing from line power to battery backup power and after changing from battery backup power to line power.

- If your monitor is AC-powered, battery power back up should not activate if the line power has failed due to activation of the monitor's overcurrent protection and activation mechanism since this could result in monitor damage, fire, etc.

- Batteries should have sufficient capacity, when fully charged, to supply power for normal operation of the monitor for at least 8 hours.

- You should consider the risk of gas accumulation and ignition and accidental short-circuiting of the battery when designing battery housings or compartments.

- If a safety hazard or malfunction could result from incorrect connection or replacement of a battery, the monitor should be designed to prevent incorrect polarity of connection.

Remote Alarm Unit: Battery Power and Battery Power Backup Suggestions

FDA suggests the following battery power and battery power backup design features for all apnea monitors that include remote alarm units (e.g., apnea monitors intended for home use).

- The remote alarm unit should have battery power backup that automatically activates when either line power fails (for AC-powered alarm units) or when the primary battery source fails (for DC-powered alarm units).

- The remote alarm unit should have visible ready signals that indicate that the remote alarm unit is energized, and that distinguish between power sources (e.g., between line power and battery power).

- If the remote alarm unit has rechargeable batteries, the unit should have a visible signal that indicates when the batteries are charging.

- Battery power backup should automatically activate within 5 seconds after power supplied to the remote alarm unit (e.g., from the monitor, from line power or from the primary battery source) fails.

- Normal operation of the remote alarm unit should resume within 5 seconds after line power (for AC-powered remote alarm units) or the primary battery source (for DC-powered remote alarm units) is restored.

- If the remote alarm unit is AC-powered, battery power back up should not activate if the line power has failed due to activation of the unit's overcurrent protection and activation mechanism since this could result in unit damage, fire, etc.

- Batteries should have sufficient capacity, when fully charged, to supply power for normal operation of the remote alarm unit for at least 8 hours.

- You should consider the risk of gas accumulation and ignition and accidental short-circuiting of the battery when designing battery housings or compartments.

- If a safety hazard or malfunction could result from incorrect connection or replacement of a battery, the monitor should be designed to prevent incorrect polarity of connection.

9. Visible and Audible Indicators and Alarms

The visible and audible indicators and alarms of the monitor and remote alarm unit should conform to either standard or standards shown in the table below, with the modifications listed in sections 9.1 and 9.2.

ASTM F1463-93 (1999): Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	OR	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

9.1 Monitor

Your apnea monitor should include visible and audible alarm signals with the characteristics described below.

Visible alarm signals

- It should not be possible to permanently disable visible alarm signals.

- Visible alarm signals should continue being activated until they are manually reset, even if the condition causing visible alarm signal activation resolves.

- Reset controls should function such that neither continuous activation nor failure of the reset control will permanently disable the visible alarm signal.

- A visible sensor fault alarm signal should be provided for both primary/direct and secondary/indirect means of detecting apnea. The sensor fault alarm signal should activate within 5 seconds of a sensor failure.

- A visible low battery alarm signal should activate at least 15 minutes, but no more than 2 hours, before the battery has insufficient charge remaining for normal operation to occur.

Audible alarm signals

- Audible alarm signals should have a minimum amplitude of 75 dB(A) for monitors intended for home use and a minimum amplitude of 70 dB(A) for monitors intended for hospital use.

- Audible ready signals, if provided to indicate proper operation of the monitor, should be audibly distinct from audible alarm signals and need not exceed 70 dB(A) in amplitude.

- It should not be possible to permanently disable audible alarm signals.

- An audible alarm that is manually silenced should re-alarm within 2 minutes unless the condition causing the alarm has resolved.

- Reset controls should function such that neither continuous activation nor failure of the reset control will permanently disable the audible alarm signal.

- An audible sensor fault alarm signal should be provided for both primary/direct and secondary/indirect means of detecting apnea. The sensor fault alarm signal should activate within 5 seconds of a sensor failure.

- An audible low battery alarm signal should activate at least 15 minutes, but no more than 2 hours, before the battery has insufficient charge remaining for normal operation to occur.

9.2 Remote Alarm Unit

Apnea monitors that are intended for home use should include a remote alarm unit. The remote alarm unit should alarm when an alarm signal of the monitor has been actuated and when the unit is unable to detect the alarm signals from the monitor. Use of the remote alarm unit should not disable the alarm signals of the apnea monitor.

The remote alarm unit should include visible and audible alarm signals with the characteristics described below.

Visible alarm signals

- It should not be possible to permanently disable visible alarm signals.

- Visible alarm signals should continue being activated until they are manually reset, even if the condition causing visible alarm signal activation resolves.

- Reset controls should function such that neither continuous activation nor failure of the reset control will permanently disable the visible alarm signal.

- A visible sensor fault alarm signal should be provided for both primary/direct and secondary/indirect means of detecting apnea. The sensor fault alarm signal should activate within 5 seconds of a sensor failure.

- A visible low battery alarm signal should activate at least 15 minutes, but no more than 2 hours, before the battery has insufficient charge remaining for normal operation to occur.

Audible alarm signals

- Audible alarm signals should have a minimum amplitude of 75 dB(A).

- Audible ready signals, if provided to indicate proper operation of the remote alarm unit, should be audibly distinct from audible alarm signals and need not exceed 70 dB(A) in amplitude.

- It should not be possible to permanently disable audible alarm signals.

- An audible alarm that is manually silenced should re-alarm within 2 minutes unless the condition causing the alarm has resolved.

- Reset controls should function such that neither continuous activation nor failure of the reset control will permanently disable the audible alarm signal.

- An audible sensor fault alarm signal should be provided for both primary/direct and secondary/indirect means of detecting apnea. The sensor fault alarm signal should activate within 5 seconds of a sensor failure.

- An audible low battery alarm signal should activate at least 15 minutes, but no more than 2 hours, before the battery has insufficient charge remaining for normal operation to occur.

- The remote alarm unit should have visual ready signals to indicate that the remote alarm unit is energized and that distinguish between battery power and line power sources.

- Remote alarm units normally powered by the monitor or by line power should resume operating from the monitor or from line power and be fully operational within 5 seconds after monitor or line power is restored.

- Remote alarm units with rechargeable batteries should have a visual signal to indicate when the battery is charging.

10. Electrical and Mechanical 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,* including Amendment 1 (1991) and Amendment 2 (1995) 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 (10.1 – 10.3), which extend or supplement *IEC 60601-1* and *IEC 60601-1-1*.

10.1 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.

10.2 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.

10.3 Connector Protection

The device connectors (including those on wires and tubing) should be designed such that insertion into a receptacle other than one for which they are intended or into a receptacle using an improper orientation is not possible.

Recommended Test Method

The electrode lead wires and patient cables must comply with all applicable sections of 21 CFR 898 Performance Standard for Electrode Lead Wires and Patient Cables.

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.*

Apnea monitors are considered life-supporting equipment and this should be taken into consideration when testing the device to *IEC 60601-1-2 (2001).*

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;
- fail to sound an alarm during a period of apnea; sound spurious alarms; reset alarms, indicators or parameters of the device;
- exhibit other temporary degradation or loss of function or performance that requires operator intervention or system reset; or
- exhibit loss or corruption of stored data.

Any of the above events during an immunity test should constitute failure of the test.

For the purpose of testing according to IEC 60601-1-2 (2001), the essential performance of an apnea monitor should include:

- detection of apnea by a primary/direct means and a secondary/indirect means.
- to provide visual and audible alarm signals upon detection, by both the primary/direct means and the secondary/indirect means for detecting apnea.

The device should meet the EMC requirements of *IEC 60601-1-2 (2001): Medical electrical*

equipment, Part 1: General Requirements for Safety, 2. Collateral standard: Electromagnetic Compatibility - Requirements and Tests, with the following modifications and additions:

11.1 Magnetic Field Emissions

The device should be shown to operate 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.*

11.2 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

The device should be tested 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.*

11.3 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

The device should be tested 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.

12. Performance Testing of Apnea Monitors

12.1 Apnea Duration Setting

For apnea monitors intended for infant and pediatric population, the apnea duration setting should default to 20 seconds.[5] However, you may provide a means to alter this setting. If you provide a means to change the default setting, special tools or procedures should be required to prevent inadvertent or unauthorized adjustments. In addition, the device should provide a visual signal that indicates the apnea duration has been changed from 20 seconds.

Recommended Test Method

You should validate the device to demonstrate the default alarm is 20 seconds.

If you provide a means to change the default setting, you should verify that special tools or procedures are required for setting changes. In addition, you should validate that a visual indicator is present when the apnea duration has been changed from the 20 second default setting.

12.2 Heart Rate Monitor

If the device incorporates a heart rate monitor as a secondary/indirect modality, the device should meet the applicable requirements of ANSI/AAMI EC13 - 1992.

12.3 Self Test

The monitor should include a self-test function that is performed each time the monitor is turned on. In addition to any other tests that may be performed, the self-test should actuate all visual and audible alarms for confirmation by the operator that they are working.

13. Biocompatibility and Sterility

Apnea monitors include parts that are attached to the patient. 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 **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/361.html to address the risks to health for apnea 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.

[5] See Anesthesiology and Respiratory Therapy Devices Panel Transcripts, September 2, 1994 regarding the relevance of this time for infants.

14. Clinical Study

FDA believes that you should perform a clinical study to fully validate the performance characteristics of a new apnea monitor, or an apnea monitor that has been modified in a manner that affects clinical performance. If your apnea monitor has the same intended use as a legally marketed apnea monitor, and has the same hardware and algorithms, your monitor may not require a preclearance clinical study. If you believe that your monitor meets these criteria, you should contact the Agency to discuss the basis for your decision. If no clinical study is performed, your summary report should include a concise scientific justification for our review.

FDA believes clinical evaluation is warranted for apnea monitors meeting the above criteria to ensure that the particular device is as safe and effective as a legally marketed predicate and meets user needs. You should include a clinical study, taking into consideration the issues discussed below. Clinical studies must comply with the applicable sections of 21 CFR Parts 50 and 56. Since the clinical diagnostics results of these devices are not used during the study, the FDA has determined that these devices are non-significant risk, and therefore studies of this device are subject only to the abbreviated requirements of 21 CFR 812.2(b).

Definitions

You should use the following definitions when describing your clinical protocol and reporting the summary results of your clinical study:

Apnea – cessation of respiratory air flow lasting 10 seconds or more.

Central apnea – apnea due to lack of respiratory muscle activity.

Obstructive apnea – apnea due to airways obstruction.

Mixed apnea –both central and obstructive apnea in which respiratory effort is absent for several seconds followed by upper airway occlusion.

Hypoxemia – an oxygen saturation below 90%.

Hypercarbia – a PCO_2 above 48 mmHg.

Infant/child apnea monitor – an apnea monitor intended for use in individuals 3 years of age or younger.

Pediatric/adult monitor – an apnea monitor intended for use individuals over the age of 3 years.

Primary/direct means for detecting apnea – a method that measures a physiologic parameter resulting from either respiratory effort or airflow. For example: impedance pneumography for respiratory effort; carbon dioxide waveforms for airflow.

Secondary/indirect means for detecting apnea – a method that measures a physiologic parameter that changes as a result of apnea, e.g., bradycardia, hypoxemia, or hypercarbia

Clinical diagnostic measures

Statistical methods in evaluation of diagnostic medical devices involve comparison of the diagnostic capability of the test device to an authoritative standard, which is assumed to be correct. In the case of apnea monitors, the authoritative standard is a respiratory tracing scored by a trained analyst. The comparison of the apnea detection capabilities of the monitor with the authoritative standard is illustrated by the clinical diagnostic measures with in the following table:

		AUTHORITATIVE STANDARD (EXPERT SCORED RECORD)	
		Yes	No
DEVICE ALARM	Yes	TP	FP
	No	FN	TN*

These clinical diagnostic measures are defined as follows:

TP – true positive. The subject is truly apneic for 10 seconds or more (as determined by the standard), and the alarm sounds or displays 8-12 seconds from the start of the apneic period. Thus, the alarm occurs within a 2 second window around 10 seconds of apnea.

FN – false negative. The subject is truly apneic for 10 seconds or more, and either there is no alarm, or the alarm occurs outside the 8-12 second window.

FP – false positive. The subject is not apneic, but the alarm sounds or displays.

TN* – this cell of the table usually contains true negatives. However, in the case of prolonged monitoring, true negative is ill-defined, and should not be reported. Since TNs are used in the calculation of specificity, specificity should not be reported either.

You should report all of the above and the following diagnostic measures:

Sensitivity – this equals (TP/(TP+FN))(100%).

PPV – this is the positive predictive value, and equals (TP/(TP+FP))(100%). This number tells the user on average how likely it is that an alarm represents true apnea.

False alarm rate – the number of false alarms per hour of monitoring.

False alarm percentage – the percent of all alarms that were false alarms.

Study Population

The study population should be representative of the population for which the device is intended to be used. In particular, the age group and monitoring environment of subjects should correspond to the desired labeling. The inclusion/exclusion criteria should be defined in your protocol prior to initiating the study.

Some apnea monitors may perform differently in different patient populations. If your monitor is intended for use in more than one patient population, a study in each patient population may be appropriate. You should contact the Agency for additional guidance when planning your study.

Baseline variables

You should collect pertinent baseline variables such as age (post-conceptional age, if applicable), clinical diagnosis, indication for monitoring, monitoring environment (home, hospital, etc.) and all other pertinent baseline variables on a per-patient basis linked to the corresponding monitoring data.

Data Collection

You should collect data from at least three clinical centers, with numbers of subjects distributed approximately equally among them. You should include no more than 6 apneic events per patient in the analysis. Apneas should be recorded and scored. At least one experienced apnea tracing scorer should perform an independent evaluation of the sensor data. The scorer should be masked from the alarm performance of both the device and the predicate. Analysis of this record in comparison with the alarm records from the device should be used to classify all events as TP, FN, and FP as described above. You should analyze your data on a per-patient basis, together with baseline characteristics and total monitoring time. You should record the length of apneic episodes and classify them into two types:

Apneic Episodes

Type 1: between 10 and 20 seconds

Type 2: greater than 20 seconds

You should evaluate the clinical diagnostic measures, sensitivity, PPV, false alarm rate, and false alarm percentage for each apneic episode type separately.

Statistical Hypothesis and Methods

Clinical performance of apnea monitors is generally assessed by comparison with a predicate apnea monitor. A finding of substantial equivalence is typically established by comparing the sensitivity and the positive predictive value of the apnea monitor and a predicate apnea monitor. The predicate device and the parameters of the clinical study should be clearly specified in advance. A non-inferiority study is frequently performed. The non-inferiority margin (i.e., δ_0 should be no more than 5% for sensitivity and 5% for positive predictive value) should be defined.

For example: The null and alternative hypotheses for a non-inferiority study for the evaluation of sensitivity should be as follows:

$$H_0: S_p - S_t = \delta_0$$
$$H_a: S_p - S_t < \delta_0$$

where S_p and S_t are sensitivity for a predicate and a tested apnea monitor.

Given the wide variability of apnea rates in different individuals, accurate prediction of sample size may be difficult. You may therefore wish to undertake a sequential study, after calculating your sample size. If you choose a sequential study, stopping rules need to be specified in advance.

You should clearly state your statistical hypotheses and express them in terms of the appropriate variables, parameters, and decision rules. Your report should contain a detailed study protocol, summary data (in tabular form) for all patients, and summary results of all clinical diagnostic measures discussed above.

15. 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).[6]

Prescription Device

In accordance with 21 CFR 801.109, apnea monitors must bear the following caution statement: "Caution: Federal law restricts this device to sale by or on the order of a physician."

[6] Although final labeling is not required for 510(k) clearance, final labeling must also 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.

Contraindication

If your device only detects central apnea, the first paragraph of both the healthcare practitioner's and the caregiver's operating manuals should contraindicate the use of the device to detect obstructive apnea. For example, "Do not attempt to use this device to detect obstructive sleep apnea. Obstructive sleep apnea cannot be detected by this device."

Warnings and Precautions

All warnings that appear on your apnea monitor should be included in the practitioner's and caregiver's operating manual.

You should provide instructions for use and appropriate warning statements in the manuals to minimize the risk of strangulation by wires and tubing. This is particularly important when this device is in elderly and pediatric populations.

Warning Labels

The following label should be placed on apnea monitors intended for home use.

Warning: Do not connect to an electrical outlet controlled by a wall switch.

Instructions for Use

Both the practitioner's and caregiver's operating manuals should include adequate instructions for the use of the device. When developing the manual and instructions for use for the home caregiver (i.e., parent), please refer to FDA guidance entitled, "Guidance on Medical Device Patient Labeling," http://www.fda.gov/cdrh/ohip/guidance/1128.html. This document contains information for manufacturers developing patient labeling for medical devices and provides guidance to ensure that the labeling is understandable and usable for patients, family members or other lay persons caring for patients.

The caregiver's manual should include a recommendation that the caregiver be trained in cardiopulmonary resuscitation. Also, the manual should contain a discussion of the proper use of remote alarm units.

The operator information should discuss known or recognizable conditions of the environment that may affect the safe and effective use or operation of the monitor.

Clinical Diagnostic Measures

The healthcare practitioner's manual should describe the clinical evaluation performed for the device. This information should summarize the study methods and the analyses performed.

Both the healthcare practitioner's and the caregiver's operating manuals should provide the clinical diagnostic measures, sensitivity, positive predictive value, false alarm rate, and false alarm percentage as defined in section 14. Both manuals should explain the meaning of

these diagnostic measures. For example, for a 90% sensitivity, “This monitor will alarm in 9 out of 10 apneic episodes. It may miss 1 out of 10 apneic episodes.”

If you include any other clinical diagnostic measures in the healthcare practitioner’s and caregiver’s operating manuals, the clinical diagnostic measures should be clearly and concisely described. The Agency will evaluate the use of each such clinical diagnostic measure separately.