DEPARTMENT HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 896

[Docket No. 83N–0193]

RIN 0905–AD83

Performance Standard for the Infant Apnea Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation to establish a mandatory performance standard for infant apnea monitors, which are a subset of breathing frequency monitors also called neonatal apnea monitors. The infant apnea monitor is a system intended for use on infants to detect cessation of breathing. FDA believes that a performance standard is necessary to ensure that infant apnea monitors accurately and reliably detect the absence of effective respiration and provide an alarm in such cases. The objective of this proposed regulation is to establish performance requirements and test methods that will provide reasonable assurance of the safety and effectiveness of the infant apnea monitor.

DATES: Submit written comments by May 22, 1995. FDA is proposing that any final rule that may issue based on this proposal become effective 1 year following its publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James J. McCue, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 10, 1982 (47 FR 39816), FDA issued a final rule under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) classifying the generic type of device, the breathing (ventilatory) frequency monitor (21 CFR 868.2375), into class II (performance standards). In the **Federal Register** of July 8, 1983 (48 FR 31392), FDA initiated a proceeding to establish a performance standard for the breathing frequency monitor, pursuant to section 514(b) of the act (21 U.S.C. 360d(b)) and part 861 (21 CFR part 861). The notice provided interested persons with the opportunity to request a change in the classification of the device. In the **Federal Register** of February 26, 1986 (51 FR 6886), FDA continued the proceeding to establish a performance standard pursuant to section 514(c) of the act (21 U.S.C. 360d(c)) and part 861. The notice invited interested persons to submit an existing standard as a proposed performance standard under section 514 of the act for the device, or to submit an offer to develop such a proposed standard. In that notice, FDA limited the proceeding to those breathing frequency monitors commonly called neonatal apnea monitors, which are intended for use on infants to detect cessation of breathing.

In the **Federal Register** of July 1, 1986 (51 FR 23832), FDA announced that, in accordance with the provisions of section 514(e)(3) of the act and § 861.32, the agency might, upon application (which could be made before the acceptance of the offer), agree to contribute to an accepted offeror's cost for developing a proposed standard if FDA were to determine that its contribution would likely result in a more satisfactory standard than would be developed without such contribution. Subsequently, FDA allocated approximately $250,000 to contribute to the cost for the first year of effort in developing a proposed standard.

In the **Federal Register** of April 22, 1988 (53 FR 13296), FDA advised that a notice of grant award (cooperative agreement) had been issued to the Emergency Care Research Institute (ECRI), 5200 Butler Pike, Plymouth Meeting, PA 19462. The cooperative agreement with ECRI was completed on August 31, 1988. Because certain performance requirements for the infant apnea monitor were not addressed in ECRI's draft document, FDA proceeded to develop a proposed standard itself for the infant apnea monitor, using the information developed during the cooperative agreement with ECRI (21 U.S.C. 380d(f)).

In the **Federal Register** of January 4, 1989 (54 FR 187), FDA announced the availability of its ''First Draft Proposed Standard for the Infant Apnea Monitor—October 1988,'' and requested public comments on the draft standard. In accordance with § 861.30, in the same notice, FDA also announced an open public meeting to discuss the draft standard. The meeting was held on January 25, 1989, in conjunction with the Seventh Annual Conference on Apnea of Infancy held in Rancho Mirage, CA.

In the **Federal Register** of July 25, 1989 (54 FR 30951), FDA announced an open public meeting that was held on September 11 and 12, 1989, at the Crowne Plaza Holiday Inn, Rockville, MD, to discuss current sensor modalities and devices used to measure infant apnea, combinations of sensors used to detect apnea and the pathophysiological result of apnea, and currently used test methods.

In the **Federal Register** of December 6, 1989 (54 FR 50437), FDA announced the availability of its ''Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989'' and again requested public comments on the draft. In the same notice FDA also announced an open public meeting to discuss the draft standard. The meeting was held on January 24, 1990, in conjunction with the Eighth Annual Conference on Apnea of Infancy held in Rancho Mirage, CA.

A summary of the proceedings of the public meetings and all data and information submitted to FDA during these meetings are part of the administrative record of this rulemaking and are available to the public under 21 CFR 20.111 from the Dockets Management Branch (address above).

II. The Proposed Regulation

The second draft proposed standard was based on 22 written comments received in response to the **Federal Register** request for comments on the first draft proposed standard and on the information received at the public meetings. This proposed mandatory standard is based on 22 written comments received in response to the **Federal Register** request for comments on the second draft proposed standard, on information received at the public meeting, and on other information available to FDA.

The proposed standard includes specific requirements for infant apnea monitors in four areas: Patient monitoring, electrical characteristics, mechanical and environmental characteristics, and labeling. FDA has prepared several ancillary documents intended to assist the manufacturer and other interested persons in understanding both the reasons for specific requirements and the recommended means of testing specific devices against the requirements. A document entitled: ''Recommended Test Methods—Infant Apnea Monitor Standard'' (Ref. 1) recommends test methods and groups them in a similar manner to those in the proposed standard. Another document entitled:

''Rationale for Requirements—Infant Apnea Monitor Standard'' (Ref. 3) provides a rationale for each of the requirements contained in the standard and an associated bibliography. In developing the proposed standard, FDA has made extensive use of existing international standards, particularly the International Electrotechnical Commission standards. A section on definitions is intended to provide precise meanings for terms used in the proposed regulation.

The section on patient monitoring includes the requirement that each infant apnea monitor system contain a secondary monitoring modality. The purpose of this requirement is to increase the likelihood that the monitor will detect apneic events. Visual and audible alarms (status indicators) are required, as is the availability of a remote alarm unit for monitors intended for home use. In order to alert the care giver to any malfunction before using the device, a self test requirement is included.

The electrical requirements for infant apnea monitors include requirements for battery backup, operation from an ungrounded power source, and limitation of leakage current. An extensive set of requirements is provided to ensure electromagnetic compatibility of infant apnea monitors, which can be a serious device problem. Given the complexity of certain testing for these devices, FDA has prepared a document entitled: ''Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields—Infant Apnea Monitor Standard'' (Ref. 2), which provides manufacturers some assistance in conducting immunity testing.

The mechanical and environmental requirements mandate tamper proof controls, protection against misconnection of wires and tubing, and the ability to withstand normal shock, vibration, temperature extremes, and fluid spills.

The labeling requirements specify information to be provided by the manufacturer to both operators and health care practitioners, and include specific device labeling requirements.

Recommended test procedures (Ref. 1) are included for each requirement in the standard. These procedures are referee test methods, i.e., they are the methods FDA will use to verify that a specific apnea monitor meets the requirements of the standard. Manufacturers are required, after the effective date of the standard, to meet the requirements of the standard. However, manufacturers may choose to use alternative but equivalent or better test methods for each monitor or, in lieu of individual testing, an analysis for a specific production run of monitors or, in lieu of any specific testing, an analysis which shows that each device meets the requirements of the standard.

The ''Rationale for Requirements—Infant Apnea Monitor Standard'' (Ref. 3) contains a detailed rationale for each requirement in the proposed standard.

Accordingly, the agency is proposing to add new part 896, to the Code of Federal Regulations, to establish a mandatory performance standard for the infant apnea monitor.

Additional guidance for the tests used to determine the immunity of monitors to radiated electromagnetic fields is provided in a separate document (Ref. 2).

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impactstatement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency has concluded that the proposed rule will have a minimal impact on manufacturers of infant apnea monitors. A copy of this analysis is on file in the Dockets Management Branch (address above).

The proposed rule will require that manufacturers comply with performance requirements in four major areas: Patient monitoring, electrical characteristics, mechanical and environmental characteristics, and labeling. This is a set of minimal requirements based on existing technologies. Additionally, the proposed rule will not become effective for 1 year after it is issued in final form. Current manufacturers will have ample time to meet these minimum standards as part of a normal cycle of product improvement and development. Therefore, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities and, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1980

This proposed rule contains information collections which have been reviewed by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and approved under control no. 0910–0073. The title, description, and respondents of the information collections are shown below with the annual recordkeeping burden.

Title: Standard for the Infant Apnea Monitor.

Description: The standard describes basic performance features, and labeling information, for infant apnea monitors which are intended for hospital and/or home use. The monitor shall be a complete system, suitable for its intended purpose of accurately and reliably providing alarms as needed to the caregiver.

Description of Respondents: Manufacturers of apnea monitors. The burden of 360 hours for recordkeeping concerning the design of, and rationale for, the tests used to meet this standard, together with analysis and results of the tests is approved under the OMB information collection 0910–0073. The annual burden for recordkeeping is as follows:

ANNUAL BURDEN FOR RECORDKEEPING

CFR section	Total annual responses	Hours per response	Total hours
896.59	30	12	360

Organizations and individuals desiring to submit comments regarding this burden or any aspects of these information collection requirements including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

VI. Comments

Interested persons may, on or before May 22, 1995, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Center for Devices and Radiological Health (CDRH), ''Recommended Test Methods—Infant Apnea Monitor Standard,'' September 1993.

2. CDRH, ''Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields—Infant Apnea Monitor Standard,'' September 1993.

3. CDRH, ''Rationale for Requirements—Infant Apnea Monitor Standard,'' September 1993.

List of Subjects in 21 CFR Part 896

Administrative practice and procedure, Incorporation by reference, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that new part 896 be added to read as follows:

PART 896—PERFORMANCE STANDARD FOR INFANT APNEA MONITORS

Subpart A—General Provisions

Sec.

Subpart B—Patient Monitoring Requirements

Subpart C—Electrical Performance Requirements

Subpart D—Mechanical and Environmental Performance Requirements

Subpart E—Labeling Requirements

Authority: Secs. 501, 502, 513, 514, 530–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374); secs. 351, 361 of the Public Health Service Act (42 U.S.C. 262, 264).

Subpart A—General Provisions

§ 896.10 Scope.

The standard set forth herein describes basic performance features and labeling requirements that infant apnea monitors, intended for hospital and/or home use, are required to meet. The monitor shall be a complete system, suitable for its intended purpose of accurately and reliably providing alarms as needed to the care giver.

§ 896.11 Applicability.

(a) *General.* The provisions of this standard are applicable to all infant apnea monitors manufactured, imported, or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico after (insert date 1 year after date of publication of the final rule in the **Federal Register**).

(b) *Applicable documents.* Compliance with certain requirements of this section shall be determined by the standards described in the following references, to the extent specified herein, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated, copies of these publications may be purchased from the American National Standards Institute, 11 West 42d St., New York, NY 10036, and may be examined at the Office of Science and Technology, Center for Devices and Radiological Health (HFZ–100), 5600 Fishers Lane, Rockville, MD; or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC:

(1) ''IEC 601–1 (1988): Medical electrical equipment, part 1: General requirements for safety,'' 2d edition.

(2) ''IEC 529 (1989): Classification of degrees of protection provided by enclosures.''

(3) ''IEC 801–1 (1984): Electromagnetic compatibility for industrial process control equipment.''

(4) ''IEC 801–2 (1991): Electrostatic discharge requirements.''

(5) ''IEC 801–3 (1984): Radiated electromagnetic field requirements.''

(6) ''IEC 801–4 (1988): Electrical fast transient/burst requirements.''

(7) ''CISPR 11 (1990): Limits and methods of measurement of radio-interference characteristics of industrial,

scientific, and medical (ISM) equipment.''

(8) ''CISPR 16 (1987): CISPR specification for radio interference measuring apparatus and measurement methods.''

(9) ''ANSI C95.3–1991: Recommended practice for the measurement of potentially hazardous electromagnetic fields—RF and microwave.''

(10) ''IEC 68 (1988): Environmental testing.''

(11) ''ANSI/AAMI EC13–1983: Standard for cardiac monitors, heart-rate meters and alarms.'' Copies of this publication may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, suite 1440, Arlington, VA 22201, and may be examined at the Center for Devices and Radiological Health (HFZ–100), 5600 Fishers Lane, Rockville, MD; or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(12) ''MIL–STD–461C (August 4, 1986): Electromagnetic Emissions and Susceptibility Requirements for the Control of Electromagnetic Interference.'' Copies of this publication may be purchased from the Naval Publishing and Printing Service Office, 700 Robbins Ave., Philadelphia, PA 19111–5094, and may be examined at the Center for Devices and Radiological Health (HFZ–100), 5600 Fishers Lane, Rockville, MD; or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(13) ''MIL–STD–462 (July 31, 1967): Standard for the Measurement of Electromagnetic Interference Characteristics.'' Copies of this publication may be purchased from the Naval Publishing and Printing Service Office, 700 Robbins Ave., Philadelphia, PA 19111–5094.

(c) *Precedence of documents.* All referenced documents shall apply to the extent specified herein. When any requirement of this standard conflicts with a requirement in any of the references specified in paragraph (b) of this section, the following rules of precedence shall apply:

(1) *This standard*. This standard shall have precedence over all applicable subsidiary documents specified in paragraph (b) of this section.

(2) *Referenced documents.* Any referenced document shall have precedence over any applicable subsidiary document referenced therein.

§ 896.12 Definitions.

(a) *Apnea* means cessation of respiratory air flow. The respiratory pause may be central or diaphragmatic (i.e., no respiratory effort), obstructive (usually due to upper airway blockage), or mixed (combination of central and obstructive).

(b) *Artifact* means a signal which may be misinterpreted by the monitor; the three most commonly recognized types of artifacts are cardiogenic, electromagnetic, and motion, as defined in paragraphs (d), (g), and (n) of this section.

(c) *Breath* means an inhalation of a volume of at least 2 milliliters of air per kilogram of body weight.

(d) *Cardiogenic artifact* means an artifact produced by theelectrical and/or mechanical activity of the heart.

(e) *Component* means any material, substance, piece, part, or assembly used during device manufacture that is intended to be included in the finished device.

(f) *Damage* means deformation, loosening, breakage, corrosion, change of fit of any component or part, or any other physical condition resulting in nonconformance of the monitor to the requirements of this standard.

(g) *Electromagnetic artifact* means an artifact produced by extraneous electromagnetic energy.

(h) *Finished device* means a device, or any accessory to a device, which is intended for use, whether or not the device is packaged or labeled for commercial distribution.

(i) *Health care practitioner* means a doctor, nurse, therapist, or other health care provider who is licensed by the State or locality in which he/she practices or is credentialed by a nationally recognized agency.

(j) *Infant apnea monitor* means a complete system intended to alarm upon the cessation of breathing and its consequences that is used on humans less than 3 years of age. The infant apnea monitor includes: Sensors; electrodes; leads; cables; tubing; signal processing systems; alarm systems; power supplies; accessories supplied, recommended, or specified by the manufacturer; complete monitoring systems when the apnea function is supplied as a module; and labeling. The terms ''device'' and ''monitor,'' when used in this standard, also mean infant apnea monitor.

(k) *Inspection* means any examination, visual or auditory, performed without the use of special laboratory instruments or procedures and/or verification of manufacturing and test records.

(l) *Intended* means the same as ''intended uses as specified by the manufacturer.''

(m) *Monitor* means an infant apnea monitor.

(n) *Motion artifact* means an artifact produced by movement of the patient.

(o) *Operator* means the individual who applies the infant apnea monitor to the patient, or who monitors the patient and the functioning of the device. The term ''operator'' includes individuals, such as parents, nurses, therapists, care givers, etc., but does not include business entities, such as hospitals, corporations, partnerships, etc.

(p) *Operator maintenance* means performance by the operator or health care practitioner of those adjustments or procedures specified in the operator or health care practitioner information provided by the manufacturer for the purpose of assuring the continued safe and effective performance of the monitor.

(q) *Patient* means the individual being monitored by the infant apnea monitor.

(r) *Primary monitoring modality* means a method for detecting the cessation of breathing (apnea).

(s) *Secondary monitoring modality* means a method that measures, on a continuous basis, a physiological parameter that responds to the pathophysiological consequences of apnea, such as bradycardia, hypoxemia, or hypercarbia (hypercapnia).

(t) *Service* means performance of the procedures or adjustments described in the manufacturer's service instructions that may affect any aspect of the performance of the infant apnea monitor to which this standard applies.

(u) *Shall* means that a provision is mandatory.

(v) *Should* means that a provision is recommended.

(w) *Status indicator* means a device subsystem that shows, in a timely manner, either the status or condition of a physiological parameter of the patient or a particular characteristic of the device.

Subpart B—Patient Monitoring Requirements

§ 896.20 Primary monitoring modality.

Each monitor shall provide:

(a) A primary monitoring modality which shall incorporate a means for detecting the cessation of breathing or of breathing effort (apnea). The manufacturer shall specify the types of apnea that the primary monitoring modality will detect.

(b) A timer to measure apnea duration, and a system of visual and audible warning status indicators designed to activate (alarm) when the measured apnea duration is greater than the preset time, which shall not exceed 20 seconds. The indicators shall be activated within 1 second after the preset time is exceeded in accordance

with §§ 896.22 and 896.23. Apnea monitors intended for use on both infants and older patients may provide duration settings beyond 20 seconds only if special tools or procedures are required to effect those settings.

(c) A sensor fault alarm for determining when the signal level from the primary sensor is outside the range of values specified for proper operation by the monitor manufacturer. When this condition occurs, audible and visual warning status indicators shall be activated within 5 seconds.

§ 896.21 Secondary monitoring modality.

Each monitor shall provide:

(a) A secondary monitoring modality, which shall incorporate a means for detecting a pathophysiological consequence of apnea that occurs within 60 seconds of the onset of apnea. This modality shall be designed such that values of the critical physiological parameter that are outside the extremes of the monitor's range are not interpreted as being within range. A monitor that includes heart rate monitoring shall meet the requirements of the standard ANSI/AAMI (American National Standards Institute/ Association for the Advancement of Medical Instrumentation) EC13–1983 for pediatric monitors.

(b) A system of visual and audible warning status indicators designed to activate (alarm) when the measured critical physiological parameter goes above or falls below a selected preset limit. The warning indicators shall be activated within 5 seconds after the measured parameter is outside the range of values specified by the preset limit in accordance with §§ 896.22 and 896.23.

(c) A control for presetting secondary modality alarm limits.

(d) A sensor fault alarm for determining when the signal from the sensor for the physiological parameter is outside the range of values specified for proper operation by the monitor manufacturer. When this condition occurs, audible and visual warning status indicators shall be activated within 5 seconds.

§ 896.22 Visual status indicators (alarms).

(a) Visual status indicators shall be of two visually distinct types:

(1) Warning indicators shall indicate the need for immediate attention to the patient.

(2) Ready indicators shall indicate proper operation of the monitor.

(b) Different colors shall be used to distinguish the two types of visual status indicators as follows:

(1) Red for warning indicators; and

(2) Green for ready indicators.

(c) All visual status indicators shall be visible in both a fully illuminated and a darkened room, and shall be located so that they are not obscured from view in the use orientation of the monitor specified by the manufacturer.

(d) Means for disabling any required visual status indicator during operation shall not be provided.

(e) Reset controls for visual status indicators shall function such that neither continuous activation nor failure of the reset control will permanently disable the status indicators.

(f) Warning indicators shall continue being activated until manually reset even if the condition causing indicator activation resolves.

(g) Visual status indicators shall be subject to the labeling requirements specified in § 896.54.

§ 896.23 Audible status indicators (alarms).

(a) All audible status indicators shall be of two audibly distinct types:

(1) Warning indicators shall indicate the need for immediate attention to the patient.

(2) Ready indicators if provided shall indicate proper operation of the monitor.

(b) Different sound characteristics, i.e., pitch, sound level, and time duration, shall be used to distinguish between the types of audible status indicators as follows:

(1) Warning audible indicators shall sound intermittently at 1-second intervals. Sound level shall be at least 85 decibels at 1 meter for home monitors and 70 decibels for hospital monitors.

(2) Ready audible indicators if provided shall have distinctly different sound characteristics than paragraph (b)(1) of this section.

(c) Means for permanently disabling an audible status indicator during operation shall not be provided. Activation of any manual means (reset) for temporarily silencing an audible status indicator shall be accompanied by an automatic realarming of the audible indicator within 2 minutes, and a clear indication of silencing (reset) shall be provided. The audible indicator may automatically reset if the condition causing indicator activation resolves, but any visual status indicator that correlates with a required audible indicator shall continue being activated until manually reset.

(d) Audible status indicator reset controls shall function such that neither continuous activation nor failure of the reset control will permanently disable the status indicators.

§ 896.24 Remote alarm.

(a) Manufacturers of monitors intended for home use shall provide a remote alarm unit for use with the monitor. The remote alarm unit shall include audible warning status indicators that indicate when a warning status indicator at the site of the patient has been activated and when the unit is unable to detect the status indicator signals from the site of the patient as specified in § 896.23.

(b) The use of a remote alarm unit shall not disable the status indicators at the site of the patient.

(c) The remote alarm unit shall have a visual power ready status indicator (pilot light) and an audible power interrupt warning status indicator. If battery operated, the remote alarm unit shall have audible and visual low battery warning status indicators (alarms) that activate when the battery has sufficient charge remaining to supply power to the remote alarm unit for no more than 15 minutes of operation as specified in §§ 896.22 and 896.23.

(d) If line power operated, battery backup shall be provided that automatically activates within 5 seconds after the power fails for any reason. The battery shall have sufficient capacity, when fully charged, to supply power for normal operation for at least 8 hours.

§ 896.25 Self test.

Monitors shall incorporate a self test, for confirmation by the operator, to operate or exercise all visual and audible status indicators each time the monitor is turned on.

Subpart C—Electrical Performance Requirements

§ 896.30 Battery power.

(a) All line-powered monitors intended for use in the home shall have a battery power backup which shall, unless the overcurrent protection specified in § 896.32 has activated, automatically activate when the power fails. The monitor shall operate in compliance with the standard within 5 seconds after the battery backup power has activated.

(b) Monitors intended for use in the home shall have a battery of sufficient capacity, when fully charged, to supply power for normal operation for at least 8 hours.

(c) Monitors intended for use in the home shall have audible and visual battery depletion warning status indicators that activate when the battery has sufficient charge remaining to supply power for monitor operation in accordance with the standard for at least

60 minutes, and which remain activated until the battery is depleted. The monitor shall have a means for silencing the audible battery status indicator.

(d) Housings containing batteries from which gases can escape during charging or discharging shall be ventilated to minimize the risk of accumulation and ignition. Battery compartments shall be designed to prevent the risk of accidentally short-circuiting the battery.

(e) If a safety hazard or monitor malfunction could result from incorrect connection or replacement of a battery, the monitor shall be designed to prevent incorrect polarity of connection.

§ 896.31 Electrical power indicators.

(a) Visual ready status indicators shall be provided to indicate that the monitor is energized. Such indicators shall be located conspicuously on the device and shall distinguish between battery power and line power sources when both sources are provided.

(b) In monitors incorporating a means for battery charging, the charging mode shall be visible to the operator.

§ 896.32 Overcurrent protection.

(a) Overcurrent protection shall be provided for all line powered monitors.

(b) An audible warning status indicator shall be activated if the overcurrent protection device is activated and the monitor cannot be operated; this status indicator (alarm) shall be capable of sounding for at least 15 minutes.

(c) Monitors shall not be fitted with protective devices which may cause disconnection of the monitor from the power line (supply mains) by producing a short circuit which results in operation of an overcurrent protection device.

§ 896.33 Dielectric withstand.

Power source lines, patient contact circuits, and transducer circuits shall be adequately insulated to assure protection of the patient and monitor from overvoltages. The monitor shall meet the requirements of the standard IEC 601–1, Clause 20.

§ 896.34 AC (alternating current) power grounding and polarity.

All monitors intended for home use that operate or recharge batteries from the AC power line shall comply with this standard when operating from an ungrounded power source. If monitor power line connectors are not polarized, the monitor shall operate in compliance with this standard in both polarities of power line connector insertion.

§ 896.35 Leakage current.

Monitors shall meet the requirements of the standard IEC 601–1 for Type BF equipment.

§ 896.36 Electromagnetic compatibility.

All monitors shall meet the electromagnetic compatibility requirements contained herein. Monitors intended for home use shall also meet these requirements when recharging batteries, or operating, from a grounded or an ungrounded AC power source. If monitor power line plugs are not polarized, the monitor shall meet these requirements in both polarities of power line plug insertion.

(a) *Emissions.* The monitor shall operate in compliance with this standard without emitting electromagnetic energy in excess of the levels specified in paragraphs (a)(1) and (a)(2) of this section. The required emission limit shall be that specified by the referenced document, adjusted downward by the root-mean-square sum of all errors in the measurement of that quantity.

(1) *Radiated and conducted electromagnetic energy.* The monitor shall comply with the relevant requirements of CISPR 11 when tested according to the test methods contained therein. These tests shall be conducted using passive patient simulators, which need not simulate normal patient signals. A 1-kilohm resistor shall be used for impedance and electrocardiograph sensors, room air shall be used for CO_2 sensors, a rigid cylinder shall be used for circumference and cross-sectional-area sensors, and an optical filter having optical density between 2 and 4 at both red and infrared wavelengths shall be used for oxygen saturation sensors.

(2) *Magnetic fields.* The monitor shall comply with the relevant requirements of RE01 of the standard MIL–STD–461C, when tested according to RE01 of the standard MIL–STD–462.

(b) *Immunity.* The monitor shall operate in compliance with this standard during and after exposure to electromagnetic interference at the levels specified in paragraphs (b)(1), (b)(2), and (b)(3) of this section. The required immunity level shall be the level stated, adjusted upward by the root-mean-square sum of all errors in the measurement of that quantity, with the exception of the lower steady-state AC voltage limit and the line-voltage sag level, which shall be adjusted downward by the root-mean-square sum of the measurement errors. Unless expressly permitted in paragraphs (b)(1), (b)(2), and (b)(3) of this section, the monitor shall not, as a result of the specified test condition: Detect a false primary or secondary monitoring modality event, indicate a false primary or secondary monitoring modality alarm, indicate an equipment alarm, exhibit temporary degradation or loss of function or performance requiring operator intervention or system reset, or exhibit loss or corruption of stored data. Except as specified in paragraphs (b)(1), (b)(2), and (b)(3) of this section, patient simulators shall be used to provide simulated normal stimulus to primary and secondary sensors during electromagnetic immunity testing.

(1) *Electrostatic discharge.* The monitor shall operate in compliance with this standard within 5 seconds of air discharges of 2, 4, 6, and 8 kilovolt and contact discharges of 2, 4, and 6 kilovolt, both positive and negative, to any point on the monitor accessible to the operator or patient, when tested according to the standard IEC 801–2, with the conditions and modifications specified in paragraphs (b)(1)(i) through (b)(1)(iv) of this section. The monitor shall operate in compliance with this standard within 5 seconds of when contact discharges are applied to horizontal and vertical conducting planes in the vicinity of the monitor, as specified in paragraph (b)(1) of this section, with the exception that detection of a single false primary or secondary monitoring modality event is permitted as a result of each discharge.

(i) The monitor shall be tested according to the test method described in standard IEC 801–2 for tabletop equipment.

(ii) The relative humidity shall not exceed 50 percent during air discharges.

(iii) Air discharges shall be conducted at 2, 4, 6, and 8 kilovolt. Contact discharges shall be conducted at 2, 4, and 6 kilovolt. Discharges of both positive and negative polarity shall be conducted at each voltage.

(iv) In addition to air and contact discharges directly to the monitor, contact discharges shall be made to the horizontal coupling plane under the monitor and to the vertical coupling plane positioned parallel to the faces of the monitor. At least 10 single discharges at each voltage (2, 4, and 6 kilovolt) and polarity shall be applied to each test point.

(2) *Radiated electromagnetic fields.* The monitor shall operate in compliance with this standard during and after exposure to electromagnetic fields at frequencies between 10 megahertz and 1 gigahertz at field strengths of 0.3, 1, and 3 volts per meter, when unmodulated, amplitude modulated 80 percent with a 0.5-hertz

sine wave. Test conditions shall be as follows:

(i) The radiated electric-field (E-field) shall be uniform and linearly polarized in a horizontal plane.

(ii) The test shall be performed with each of the six faces of the monitor facing the antenna. All cables shall be aligned with the horizontal E-field vector over the majority of their length throughout the test. For exposure methods in which the monitor cables cannot be extended fully, if the length of any conducting cable is greater than 1.5 meters, the first 0.75 meters of cable (closest to the monitor) shall be aligned with the horizontal E-field vector and the remaining length shall be bundled in a noninductive, serpentine configuration.

(iii) The test shall be performed with all monitor components and cables positioned at an appropriate distance from any radio frequency (RF)-reflecting object and at a distance from any conducting ground plane that is appropriate for tabletop equipment.

(iv) Patient simulators used during the test shall be either simple passive devices, isolated from earth ground using fiber optic links, or battery operated and shielded. For impedance and electrocardiograph sensors, testing for erroneous breath and heartbeat detection shall be performed using a 1-kilohm resistor as a patient simulator, or a more suitable value defined by the manufacturer for a particular model of apnea monitor. Testing for erroneous breath detection shall also be performed using a battery operated simulator set to produce electrocardiograph signals, but not respiration signals (i.e., set to the apnea mode). Testing for all other fault conditions shall be performed using a battery operated simulator set to produce both respiration signals and electrocardiograph signals.

(v) Connections not normally used during monitor operation that are made to the monitor to assess performance during the test shall be isolated using fiber optic links.

(3) *AC voltage fluctuations, transients, and conducted interference*. The following requirements apply to all monitors that recharge batteries or operate from the AC power line:

(i) *Steady-state voltage*. The monitor shall remain in compliance with this standard, without changing a voltage selection switch, when powered from line voltages between 95 and 132 volts root-mean-square. For monitors intended for home use, the battery power backup shall activate automatically when the line voltage falls below the minimum level necessary for line powered monitor operation, which shall be no greater than 95 volts root-mean-square, and line powered operation shall automatically resume when the line voltage returns to the 95- to 132-volt range.

(ii) *Dropout*. The monitor shall operate in compliance with this standard during and after line voltage dropouts for durations of 10 milliseconds and less.

(iii) *Slow sags and surges*. The monitor shall operate in compliance with this standard during and after line voltage surges to 150 volts root-mean-square and sags to 90 volts root-mean-square, for durations of 500 milliseconds and less.

(iv) *Fast transient bursts*. The monitor shall operate in compliance with this standard during and after bursts of transients of 0.5, 1, and 2 kilovolts applied to AC power leads, and transients of 0.25, 0.5, and 1 kilovolts coupled by way of a capacitive clamp to signal leads, when tested according to IEC 801–4, with the exception that the burst repetition frequency shall not exceed 30 per minute.

(v) *Fast surges*. The monitor shall operate in compliance with this standard during and after exposure to common-mode and differential-mode combination voltage/current transients, both positive and negative, applied to AC power leads.

(A) The test generator used shall have the following specifications:

Open-circuit voltage, differential mode: 0.5 and 1 kilovolts.

Open-circuit voltage, common mode: 0.5, 1, and 2 kilovolts.

Open-circuit voltage risetime: 1.2 microseconds.

Open-circuit voltage falltime: 50 microseconds.

Generator source impedance: 2 kilohm.

Short-circuit current risetime: 8 microseconds.

Short-circuit current falltime: 20 microseconds.

Peak short-circuit current: 1 kilo ampere.

(B) Capacitive coupling shall be used to apply the combination wave to the AC power leads of the monitor under test. Surges shall be applied at the point where the monitor normally would be connected to AC line power.

(C) A decoupling network shall be used to isolate the monitor under test from the AC power network.

(D) A line-to-line test (differential mode) shall be performed using 0.5 and 1-kilovolt surges of both positive and negative polarity applied using a generator source impedance of 2 kilohm and coupling capacitance of 18 micro farads.

(E) A line-to-ground and a both-lines-to-ground test (common mode) shall be performed using 0.5, 1, and 2-kilovolt surges of both positive and negative polarity applied using a generator source impedance of 12 kilohm (10-kilohm resistor in series with test generator) and coupling capacitance of 9 micro farads.

(F) Surges at each amplitude and polarity shall be applied at phase angles of 0, 45, 90, 135, 180, 225, and 270 degrees with respect to the AC line.

(G) Each test shall be repeated 10 times at a rate between 1 and 30 surges per minute.

(vi) *Conducted electromagnetic energy*. The monitor shall operate in compliance with this standard during and after exposure to both differential and common mode conducted electromagnetic energy on the AC power leads at frequencies between 150 kilo Hertz and 80 megahertz at voltages of 0.3, 1, and 3 volts root-mean-square (when unmodulated), amplitude modulated 80 percent with a 0.5 hertz sine wave, added to the power line voltage, when tested according to CS02 of the standard MIL–STD–462, with the modifications and additions specified in paragraphs (b)(3)(vi)(A) through (b)(3)(vi)(E) of this section. If continuous sweep of the test frequency is used, the sweep rate shall not exceed 1×10^{-3} decades per second. If discrete frequency steps are used, the maximum step size is 1 percent of the test frequency, and the minimum dwell time is 10 seconds per step.

(A) The impedance of AC inputs shall be stabilized using line impedance stabilization networks appropriate for the test frequency range.

(B) The power leads under test shall be elevated 5 centimeters above the ground plane.

(C) The interference signal shall be injected at a distance of 5 centimeters from the point at which AC line power enters the monitor. For battery chargers which plug directly into AC outlets, a 10 centimeter length of wire shall be added between the line impedance stabilization networks (LISN's) and the charger. The low-voltage output cable of the charger shall be elevated 5 centimeters above the ground plane.

(D) The differential-mode test shall be conducted as specified in CS02 of the standard MIL–STD–462. The lead between the capacitor and the AC line shall be as short as possible.

(E) The common-mode test shall be conducted as specified in paragraph (b)(3)(vi) of this section, except that two identical capacitors shall be used, one connected from the signal source to the

AC phase lead and one connected from the signal source to AC neutral.

(4) *Magnetic fields.* The monitor shall operate in compliance with this standard during and after exposure to magnetic fields as specified in RS01 and RS02 of the standard MIL–STD–461C. The standard MIL–STD–462 also shall apply with the exception that the pulse repetition frequency for RS02 shall not exceed 30 per minute.

(5) *Quasi-static electric fields.* The monitor shall operate in compliance with this standard during and after exposure to a 0.5 hertz sinusoidal E-field with a peak field strength of 500, 1,000, and 2,000 volts per meter.

§ 896.37 Auxiliary output.

Where an auxiliary output is provided:

(a) The monitor shall meet all the requirements of this standard during and after application of a short circuit applied to the auxiliary output for 1 minute.

(b) The leakage current requirements of § 896.35 shall not be exceeded upon proper connection of an auxiliary device to the auxiliary output. This proper connection shall be described in the operator's manual as specified in § 896.50(b)(2)(iii).

Subpart D—Mechanical and Environmental Performance Requirements

§ 896.40 Controls protection.

The controls of monitors intended for home use shall be protected from inadvertent or unauthorized changes or adjustment. The means of protection shall be such as to preclude their defeat by patients, siblings, or other unauthorized persons.

§ 896.41 Connector protective incompatibility.

(a) Monitor connectors, including those on wires and tubing, shall be designed such that insertion into a receptacle other than the one into which they are intended to be inserted or into a receptacle using an improper orientation is not possible.

(b) Electrical connectors of a monitor (e.g., electrical lead wires) shall include a mechanism to prevent connection of the patient to a power source that may cause a current flow in excess of that specified in § 896.35.

§ 896.42 Mechanical safety.

Each monitor shall:

(a) Not have any exposed sharp edges.

(b) Be mechanically stable in the intended position(s) of use.

(c) Provide protection to the operator and patient from moving parts.

§ 896.43 Mechanical vibration and shock resistance.

The monitor shall remain in compliance with this standard following mechanical shock and vibration as follows:

(a) Shock test specifications shall be as follows:

(1) Peak acceleration: 100 g (1,000 meters per second^2) (g means acceleration of gravity),

(2) Duration: 6 milliseconds, and

(3) Pulse shape: half sine.

(b) Sinusoidal vibration test specifications shall be as follows:

(1) Frequency range: 10 to 500 hertz,

(2) Acceleration amplitude: 1 g (9.8 meters per second^2), and

(3) Duration: 10 sweep cycles in each axis.

(c) Wide band random vibration test specifications shall be as follows:

(1) Frequency range: 20 hertz to 500 hertz, and

(2) Acceleration spectral density: 0.02^2 per hertz, Duration: 9 minutes.

§ 896.44 Fluid spill resistance.

The monitor shall be so constructed that it will continue to operate in compliance with this standard even in the event that fluids are dripped on it. The monitor shall meet the requirements for drip proof equipment as specified in Clause 44.6 of the standards IEC 601–1 and IEC 529.

§ 896.45 Temperature and humidity.

(a) The monitor shall be in compliance with this standard when operating in the environmental temperature range of 5 °C to 40 °C, and in the environmental humidity range of 15 percent to 95 percent, noncondensing.

(b) The monitor shall not be damaged, and shall remain in compliance with this standard, after storage in the environmental temperature range of -40 °C to 70 °C at 95 percent humidity.

§ 896.46 Surface temperature.

The temperature of all surfaces of the monitor with which an operator might come into contact during operation shall not exceed 50 °C in an ambient of 35 °C. The temperature of surfaces with which the patient can come into contact shall not exceed 40 °C in an ambient of 35 °C. Electrochemical transcutaneous sensors are permitted for hospital use only with maximum temperatures up to 44 °C for less than 4 hours (at the same site) if adequate patient protection procedures are clearly described in the labeling.

§ 896.47 Toxic materials.

No toxic material from a monitor shall come in contact with the patient or operator during normal use as specified in § 896.50(b)(1).

§ 896.48 Strangulation.

Provision shall be made in routing, retention devices, or other means to minimize the risk of strangulation of the patient by wires or tubing.

Subpart E—Labeling Requirements

§ 896.49 General.

In addition to the labeling requirements for prescription devices in part 801 of this chapter, each infant apnea monitor shall comply with the labeling requirements of this section. The labeling for each monitor shall prominently state the intended uses and limitations of the device, provide clear instructions, describe potential device malfunctions, and contain adequate operation, maintenance, and service information.

§ 896.50 Operator information.

Manufacturers of infant apnea monitors intended for home use shall provide, with each monitor, an operator instruction manual for laypersons that has been prepared at the fifth-grade reading comprehension level and that includes numerous supporting illustrations. A means of determining the effectiveness of instruction shall also be provided. The manual shall contain:

(a) A statement of the purpose (indications for use) of the monitor and an explanation of how the monitor accomplishes that purpose, including:

(1) A discussion of the types of apnea that the device monitors as well as the parameters monitored by the secondary monitoring modality.

(2) An explanation of how the monitor accomplishes its purpose, including the type of sensors used.

(b) Information pertaining to operating conditions that may affect the efficacy or safety of the monitor, including the following:

(1) Monitor information, including:

(i) An explanation of the function and meaning of each alarm and indicator provided with the monitor,

(ii) A statement that the monitor may not be able to detect all episodes of inadequate breathing,

(iii) Recommended precautions to minimize the risk of strangulation,

(iv) A list of the toxic materials used in the manufacture of the monitor and protective means employed to prevent contact during normal use,

(v) A discussion of the hazards and risks associated with the monitor.

(2) Operator information, including: General operating information, adequate

instructions for monitor setup, check-out, operation, operator maintenance, and service, including:

(i) General operating information, including:

(A) A list of additional reference materials available to the layperson about apnea monitoring and the location where such materials can be obtained,

(B) Reprints of applicable FDA safety alerts,

(C) A statement of when it is advisable to contact the prescribing physician or health care professional,

(D) A recommendation that the operator be trained in cardiopulmonary resuscitation (e.g., Red Cross/American Heart Association Certification),

(ii) Setup shall include unpacking instructions, an accessory checklist, and a visual safety inspection of the monitor, including accessories,

(iii) A check-out of the monitor, including:

(A) A step-by-step procedure for checking proper functioning of all controls, indicators, and alarms,

(B) A troubleshooting guide for use when there are indications of a monitor malfunction during checkout and/or operation,

(iv) Simplified diagrams and illustrations of the fully assembled and ready to operate monitor. Information on device operation shall include:

(A) Each step that must be taken by the operator to achieve the clinical purpose of both the primary and secondary modality, as well as the steps required to prepare the monitor for operation,

(B) Proper connection of auxiliary devices,

(C) Any pre-use cleaning or disinfecting procedures for the monitor, including any accessories,

(D) A description of appropriate warm-up procedures and intervals,

(E) A discussion of the positioning of sensors or electrodes, alternate electrode placement, proper preparation of electrodes and patient for electrode attachment, and identification of loose sensors or electrodes,

(F) Diagrams and illustrations showing proper connection of the patient to the monitor and other equipment, if applicable, including alternate recommended electrode or sensor placement,

(G) Legible reproductions of all required labels and hazard warnings, and graphic representation of all controls, alarms, and indicators provided with the monitor. An explanation of the use of the controls, alarms, and indicators,

(H) A list of error messages from the monitor, if applicable, their meaning, and the corrective steps that can be taken by the operator,

(I) Clear warnings concerning the precautions necessary to avoid possible misoperation or unsafe use of the monitor,

(J) Recommended procedures to be followed in the event of a monitor alarm condition,

(K) A discussion of the proper use of remote alarm units, including recommended placement and the importance of the operator being able to access the patient within 1 minute of alarm activation.

(v) Operational maintenance information, including:

(A) Recommendations for methods and materials for cleaning and disinfecting the monitor,

(B) A schedule of operator initiated maintenance necessary to keep the monitor in compliance with this standard,

(C) Battery care and maintenance procedures, including instructions for recharging or replacement,

(D) A description of periodic visual safety inspections that should be performed by the operator,

(vi) Service information, including:

(A) The frequency of any calibration, repair, or periodic inspections of the monitor necessary to keep it in compliance with this standard,

(B) A list of facilities, and their locations, that may provide these services,

(3) Patient information, including:

(i) A description of any clinical circumstances which might require sensor adjustment or checking for proper operation.

(ii) A description of any circumstances in which there is a possibility of allergenic or chemical reactions and instructions for preventing such reactions, e.g., periodically repositioning electrodes.

(4) Facility information, including a description of what should be expected if electricity to the monitor is lost.

(5) Environmental information, discussing known or recognizable conditions of the infant's environment that may affect the safe and effective use or operation of the monitor, such as lint, dust, sun, light, heat, or humidity, including:

(i) A discussion of the effects and possible sources of electromagnetic interference, e.g., conducted and radiated,

(ii) A discussion of the effects and causes of electrostatic discharge,

(iii) A list of other devices that pose potential electrical problems,

(iv) A description of conditions of the sensors or electrodes, such as loosened electrodes, that can cause environmental effects to be more pronounced,

(v) A description of steps which can be taken by the operator to identify and resolve environmental interference with the safe and effective use of the monitor.

§ 896.51 Health care practitioner information.

Manufacturers of monitors shall provide a health care practitioner instruction manual with each monitor. The manual shall contain all of the information specified in § 896.50 in such detail as is sufficient for the needs of the practitioner, but the information need not be restricted to the fifth-grade reading comprehension level. In addition, the manual shall contain:

(a) A description of equipment required for monitor use and mechanical and/or electrical specifications for electrodes, sensors, leads, cables, tubing, batteries, and accessories with which the monitor will operate in compliance with this standard.

(b) Step-by-step procedures necessary to prepare the monitor for initial and subsequent use. If a manual sensitivity control is provided, instructions as to when to use manual sensitivity and how to adjust the control for optimal breath detection.

(c) Step-by-step procedures recommended for determining whether the monitor is susceptible to the levels of electromagnetic interference occurring at the intended-use site, a recommendation to repeat the testing periodically, and recommended action to be taken if the monitor fails the test. The preferred testing procedure for impedance monitors is as follows:

(1) Set the monitor apnea duration to 20 seconds.

(2) Connect the monitor to a patient simulator with all cables in extended rather than coiled configuration.

(3) Determine that the monitor detects normal respiration and heart beats.

(4) Place the simulator in the apnea mode for 2 minutes.

(5) Determine that the monitor continues to alarm for apnea at full volume beginning at 20 seconds. Alarming at reduced volume, false heart rate alarms, or self-silencing of the apnea alarm prior to the end of the simulated apnea constitute failure of this test.

(d) Precautions and a schedule of maintenance and calibrations necessary to keep the monitor in compliance with this standard.

(e) Complete equipment specifications, including signal processing functions, algorithms, and

averaging times for any monitor function applicable to the operation and use of the device; statements as to whether or not pacemaker pulse rejection and defibrillator protection are included.

(f) For monitors using heart rate as a secondary monitoring modality, a caution statement that low heart rate may not occur during apnea if the patient is receiving drugs or substances which could affect heart rate, e.g., such as theophylline.

(g) A discussion of the importance of evaluating for each patient the response to apnea of candidate secondary monitoring parameters; how this information should be used in the selection of an appropriate secondary monitoring modality and in setting the secondary parameter alarm limits; and the importance of reevaluating the appropriateness of the secondary monitoring parameter and its alarm limit settings as conditions change.

(h) For monitors intended for home use, a discussion of home apnea monitoring that includes:

(1) Instruction and education of the parent and other care givers in the normal operation and hazards of the device and its limitations.

(2) An explanation of the equipment used in home monitoring.

(i) A list of additional reference materials for the health care practitioner about apnea monitoring.

(j) The date of issuance and the date of any revision of the health care practitioner instruction manual provided.

(k) The results of clinical testing for the specific model of apnea monitor and the methods by which these results were obtained.

§ 896.52 Servicing information.

Manufacturers of monitors shall provide to servicing dealers and distributors adequate instructions for service adjustment and service procedures necessary to keep the device in compliance with this standard, including: Theory of operation, block diagrams, software flow charts, schematics, parts lists, and any necessary test procedures.

§ 896.53 Label specifications.

Labels or other equivalent markings required by this section shall be legible, clearly visible during operation, permanently affixed or inscribed on the exterior of the finished device, and shall resist removal or blurring from disinfectants or other normal use of the device.

§ 896.54 Controls, connectors, switches, and indicators.

All controls, switches, connectors, and indicators shall bear clear, concise labels identifying their functions.

§ 896.55 Standard compliance.

The monitor shall bear a label which states that it has been manufactured in compliance with this standard.

§ 896.56 Switched outlet warning.

Each monitor intended for use in the home that can recharge batteries or operate from the AC power line shall bear a label stating: ''DO NOT connect to an electrical outlet controlled by a wall switch''.

§ 896.57 Air mattress warning.

Air mattresses shall be permanently labeled with the warning: ''Inflate only with room air, do NOT use pure oxygen''.

§ 896.58 Monitors intended for hospital use only.

Monitors intended for hospital use only shall be permanently labeled on the front of any module intended to comprise an infant apnea monitor as follows: ''NOT FOR HOME USE''.

§ 896.59 General test methods.

Information concerning the design of, and rationale for, the tests used to meet this standard, together with analyses and results of these tests, shall be available to any person from the manufacturer upon request. In addition, this information shall be maintained in the manufacturer's device master file for a period of 5 years after production of the device has ceased.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0073)

Dated: February 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–4212 Filed 2–17–95; 8:45 am]

BILLING CODE 4160–01–F