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