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