

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 CO₂ 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