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## Safe current limits for electromedical apparatus

Developed by  
**Association for the Advancement of Medical Instrumentation**

Approved 2 December 1993 by  
**American National Standards Institute, Inc.**

### **Abstract:**

This standard provides limits and measuring techniques for risk currents of electromedical apparatus as a function of frequency, the characteristics of the apparatus, and the nature of the intentional contact with the patient.

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## Committee representation

### Association for the Advancement of Medical Instrumentation Electrical Safety Committee

This standard was developed by the AAMI Electrical Safety Committee. Committee approval of the standard does not necessarily imply that all committee members and reviewers voted for its approval.

The AAMI **Electrical Safety Committee** has the following members:

**Cochairs:** Mort Levin  
William Staewen

**Members:** Saul Aronow, CCE, Project HOPE  
Karen Barnes, MS, RN, Harris Methodist Fort Worth, Fort Worth, TX  
Seymour Ben-Zvi, CCE, ScD, SUNY Health Sciences  
Alan Berson, PhD, National Institutes of Health, National Heart, Lung, and Blood Institute  
Steve Daleo, PPG Biomedical  
Dave Daly, Center for Devices and Radiological Health, Food and Drug Administration  
Emanuel Furst, CCE, PhD, PE, Tucson, AZ  
Robert Grass, Grass Instruments  
David Hengl, Mennen Medical  
Haim Klemment, Datascope Corporation  
Martin Kutik, ppd Consulting  
Michael Laks, MD, UCLA School of Medicine, Los Angeles, CA  
Mort Levin, Hewlett-Packard Corporation  
Alan Lipshultz, CCE, Medical Center of Delaware, Newark, DE  
M. T. Merrigan, Underwriters Laboratories  
Robert Mosenkis, CCE, CITECH/ECRI  
Leonard Oberg, Puritan Bennett Corporation  
Bryan Parker, CCE, Montefiore Medical Center  
Philip Przybri, Marquette Electronics  
Monte Raber, Winnipeg, Manitoba  
Frederic Schradt, Travelers Insurance Company  
William Staewen, CCE, Venice, FL  
Peter Suydam, CCE, Florissant, MO

**Alternates:** Harold Arneson, Marquette Electronics  
Don Barth, Hewlett-Packard Corporation  
Ellen Grass, LLD, Grass Instruments  
Vincent Pierdominici, Center for Devices and Radiological Health, Food and Drug Administration

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

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# Safe current limits for electromedical apparatus

## 1 Scope

### 1.1 Inclusions

This standard sets risk current limits and referee test methods for electromedical apparatus intended for use in the patient care vicinity and also sets limits for non-patient-contact electromedical apparatus.

The standard applies to line- and battery-powered apparatus and to apparatus used singly or with properly connected accessory equipment. When more than one electromedical apparatus is powered by a single power cord, the equipment assembly acts like a single apparatus in terms of risk current limit requirements, and shall be considered as such for the purposes of this standard.

The safety and performance criteria defined in this standard are intended for use in design qualification by the device manufacturer.

NOTE—The referee test methods of section 5 are intended to provide means by which conformance with the standard can be established. These tests are not intended for use in verifying the performance of individual devices in routine quality assurance inspections. Also, referee tests allow for the use of alternative methods for design qualification, provided that devices so qualified will also meet the requirements of this standard when tested in accordance with the referee methods.

### 1.2 Exclusions

This standard does not set limits for the composite risk current when several devices are performing different functions for the same patient and are independently connected to the utility power system. This standard does not apply to therapeutic currents.

In addition, this standard does not apply to apparatus designed primarily for nonmedical applications and used in conjunction with electromedical apparatus, but located outside of the patient care vicinity.

NOTE—As indicated above, all devices cannot be readily covered by this standard. Equipment such as video cassette recorders or computing devices are now being used in health care facilities. Such equipment is designed to other standards. If such equipment is not located in the patient care vicinity, such devices are not considered to pose a risk as they are not likely to contact the patient.

## 2 Definitions

For the purposes of this standard, the following definitions apply.

**2.1 accessory:** Device produced or recommended by the manufacturer of an electromedical apparatus, and intended to be electrically connected to that apparatus in order to make the apparatus useful or to improve its efficacy or versatility, and not a modular part of that apparatus.

**2.2 auxiliary apparatus:** Electromedical apparatus used in conjunction with other electromedical apparatus to achieve a common purpose.

NOTE—Auxiliary apparatus includes both interconnected apparatus and noninterconnected apparatus.

**2.3 composite risk current:** Total risk current derived from the risk currents of all the apparatus associated with the patient that can flow through the patient, medical staff, or bystander.

NOTE—This definition is included for reference only. A method of derivation and limits for composite risk current are not covered in this standard.

**2.4 electromedical apparatus:** Instrument, equipment, system, or device that directly or indirectly uses electricity for any medical purpose.

NOTE—Also included are all parts that are connected to such equipment and are required for the normal use of the equipment, including associated patient wiring or cables.

**2.5 enclosure:** Exterior surface of the electromedical apparatus, including all accessible parts, knobs, grips, and shafts.

**2.6 exposed electrically conductive surface:** External metal or otherwise electrically conductive surface that is connected to the internal circuits, mechanisms, or enclosure of an electromedical apparatus.

**2.7 input part:** Part of the electromedical apparatus, other than a patient-applied part, that is intended to receive input signal voltages or currents from other equipment.

**2.8 isolated patient connection:** Connection between the patient and the electromedical apparatus that is isolated from

power ground (earth)<sup>1)</sup>, the utility power system, and other supporting circuitry to such a degree that the risk current flowing through the connection does not exceed the limits given in Table 1—Summary of risk current requirements in rms microamperes ( $\mu\text{A}$ ), provided in section 4.2.

**2.9 modular apparatus:** Electromedical apparatus that includes modules in its construction.

**2.10 module:** Self-contained assembly that performs a function or class of functions in support of the major function of an electromedical apparatus.

NOTE—Modules can generally be removed or replaced without affecting the operation of other assemblies in the apparatus.

**2.11 nonoperational environmental conditions:** Temperature, humidity, altitude, or acceleration limits specified by the manufacturer for storage or shipment.

**2.12 normal condition (NC):** Condition in which all means provided against safety hazards are intact and the device is operating as desired.

**2.13 output part:** Part of the electromedical apparatus, other than a patient-applied part, that is intended to deliver output signal voltages or currents to other equipment.

**2.14 patient-applied part:** Entirety of any part of the equipment that comes intentionally into contact with the patient via a patient connection.

**2.15 patient-applied risk current:** Current flowing from the electromedical apparatus through the patient to power ground (earth) or between patient-applied parts.

**2.16 patient care vicinity:** Space, within a location intended for the examination or treatment of patients, extending 6 feet (ft) (1.8 meters [m]) beyond normal location of the bed, chair, table, treadmill or other device that supports the patient during examination and treatment. The patient care vicinity extends vertically to 7 ft, 6 inches (in) (2.3 m) above the floor.

**2.17 patient connection:** Deliberate connection that can carry current between an electromedical apparatus and a patient. This can be a surface contact (e.g., an ECG electrode), an invasive connection (e.g., an implanted wire or catheter), or an incidental long-term connection (e.g., connective tubing).

NOTE—As used in this standard, "patient connection" is not intended to include adventitious or casual contacts, such as push buttons, bed surfaces, lamps, and hand-held appliances.

**2.18 patient isolation risk current:** Current flowing from the patient to power ground (earth) through a part applied to the patient due to the unintended introduction of a voltage from an external source on the patient.

**2.19 risk current:** Nontherapeutic current that can flow through the patient, medical staff, or bystander as a result of the use of electromedical apparatus.

**2.20 single fault condition (SFC):** Condition in which a single means of protection against a safety hazard in equip-

ment is defective, a component failure could increase the risk current, or a single external abnormal condition exists.

**2.21 sink current:** Current that flows into a device or any part thereof, when an external voltage is applied to it.

**2.22 source current:** Electrical current that flows from any part of an electromedical apparatus to any other part or to power ground (earth), when no external voltages are applied.

**2.23 therapeutic current:** Current that is intentionally applied to the patient for treatment of disease or disorder.

### 3 Classification of electromedical apparatus and measurement conditions

The following sections define specific classes of electromedical apparatus and measurement conditions and detail how these classifications are applied in this standard.

#### 3.1 Classification of electromedical apparatus

For purposes of this standard, four categories of electromedical apparatus have been defined. For each category, risk currents are established. These four categories are listed below:

a) *Electromedical apparatus with isolated patient connection:* Electromedical apparatus intended to be connected to the patient with the patient circuit isolated from power ground (earth), utility power systems, and other circuitry.

b) *Electromedical apparatus with nonisolated patient connection:* Electromedical apparatus intended to be connected to the patient.

c) *Electromedical apparatus likely to contact the patient:* Electromedical apparatus that does not have a patient-applied part, but that is intended for use in the patient care vicinity.

NOTE—See section 2 for definition of patient care vicinity.

d) *Electromedical apparatus with no patient contact:* Electromedical apparatus that is intended for use outside the patient care vicinity and that has no patient connections.

#### 3.2 Classification of measurement conditions

The following sections define normal and fault conditions.

##### 3.2.1 Normal operating conditions

Under normal operating conditions, a device is operating as designed with all means provided for protection against safety hazards intact, connected properly and securely to an approved power source and, if the device includes patient-applied parts, with such parts applied according to the manufacturer's instructions. The following are considered normal operating conditions:

- a) power switch on/power switch off;
- b) power polarity normal/power polarity reversed (cord-connected apparatus only);
- c) patient grounded; patient not grounded.

<sup>1)</sup> The term "power ground" is common in American usage; the term "earth" is common in European usage. Both terms have been used in this document for clarity.

### 3.2.2 Single fault condition

A single failure of a device's protection mechanism against a safety hazard or the failure of a single device component can introduce a hazard condition or lead to the existence of an external hazardous condition. The following are considered to be single fault conditions:

- a) power ground (earth) conductor open;
- b) short circuit of either barrier of double insulation;
- c) failure of a single component that can produce a hazardous current;
- d) (for equipment that is not intended to be grounded) the application of line voltage to an input or output part or to accessible conductive hardware of the enclosure;
- e) (for electromedical apparatus with isolated patient connections) the application of line voltage on a patient-applied part.

## 4 Requirements

### 4.1 Labeling and documentation requirements

#### 4.1.1 Isolated patient connections (labeling)

Patient connections that meet the requirements of this standard for isolated patient connections shall be identified as being isolated at the connector of the apparatus.

NOTE—Labeling of isolated patient connections shall comply with symbol number 3 of table DII, page 329, in the International Electrotechnical Commission (IEC) standard 601-1, second edition (IEC, 1988).

#### 4.1.2 Information manuals

The manufacturer shall supply the user with operating and maintenance instructions specifying how the electromedical apparatus should be operated and maintained to prevent the device's risk current from increasing beyond the limits set by this standard for its particular category (refer to section 3.1). In addition, the manufacturer shall disclose the risk current category for which the apparatus is designed and shall identify the specific limits defined by this standard for that category.

### 4.2 Risk current requirements (general)

Electromedical apparatus shall meet the applicable risk current limits of this standard under normal conditions and under the single fault conditions specified in the test methods of section 5. Table 1 (see next page) summarizes these requirements.

#### 4.2.1 Apparatus interconnection

Electromedical apparatus shall meet the risk current limits of this standard when manufacturer-designated auxiliary apparatus, modular apparatus, or accessories are attached in the quantity and combinations stipulated by the manufacturer. The manufacturer shall supply the user (and shall label the apparatus) with limitations and with directions for the interconnection of modular apparatus, accessories, and auxiliary ap-

paratus, and with directions for the use of convenience receptacles.

### 4.2.2 Cleaning and sterilization

Electromedical apparatus shall meet the risk current limits of this standard after exposure to any disinfection or sterilization process specified by the manufacturer.

### 4.2.3 Environmental conditions

Electromedical apparatus shall meet the risk current limits of this standard after exposure to the nonoperational environmental conditions (e.g., storage, transportation, etc.) and under the worst-case environmental operating conditions specified by the manufacturer.

## 4.3 Enclosure risk current

### 4.3.1 General

Enclosure risk current, when measured with the AAMI standard test load, is that current that flows between power ground (earth) and

- a) exposed chassis conductive surfaces or hardware; or
- b) a 200 cm<sup>2</sup> (centimeters squared) foil in contact with a nonconducting enclosure.

NOTE—A schematic drawing of the AAMI standard test load is given in figure 1.

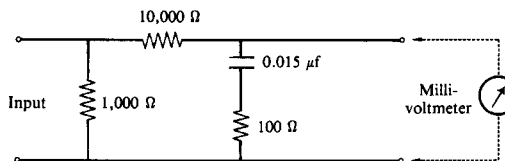


Figure 1—AAMI standard test load

NOTES—

1) The frequency-weighted network compensates for the allowable increase in risk current limits with increasing frequency. For measurement purposes with a voltmeter as shown, the limit remains constant at 1  $\mu\text{A}/\text{mV}$ , independent of frequency. With the meter connected, the entire circuit is called the "risk current tester."

2) Refer to section 5.7.2 for component requirements and tolerances.

### 4.3.2 Risk current limits

Limits for enclosure risk current for all categories of electromedical apparatus, whether battery-powered, cord-connected, or permanently connected, and under both normal and single fault conditions, are shown in table 1.

Table 1—Summary of risk current requirements in rms microamperes (dc to 1 kHz)

Category		Enclosure risk current		Patient-applied risk current (source current)	Patient isolation risk current (sink current)	Earth risk current		
		Cord-connected/battery-powered	Permanent			General cord-connected	Other cord-connected <sup>1)</sup>	Permanent <sup>2)</sup>
Isolated	Normal condition	100 µA	100 µA	10 µA	not applicable	500 µA	2,500 µA	5,000 µA
	Single fault condition	300 µA	5,000 µA	50 µA	50 µA	1,000 µA	5,000 µA	10,000 µA
Non-isolated	Normal condition	100 µA	100 µA	10 µA	not applicable	500 µA	2,500 µA	5,000 µA
	Single fault condition	300 µA	5,000 µA	100 µA	not applicable	1,000 µA	5,000 µA	10,000 µA
Likely to contact patient	Normal condition	100 µA	100 µA	not applicable	not applicable	500 µA	2,500 µA	5,000 µA
	Single fault condition	300 µA	5,000 µA	not applicable	not applicable	1,000 µA	5,000 µA	10,000 µA
No patient contact	Normal condition	100 µA	100 µA	not applicable	not applicable	500 µA	2,500 µA	5,000 µA
	Single fault condition	500 µA	5,000 µA	not applicable	not applicable	1,000 µA	5,000 µA	10,000 µA

<sup>1)</sup> Equipment that has no protectively grounded (earthed) accessible parts and no means for protective grounding (earthing) of other medical equipment and which complies with the applicable requirements for enclosure leakage current and patient leakage current; also mobile x-ray equipment and mobile equipment with mineral insulation.

<sup>2)</sup> Equipment specified to be permanently installed with a protective power ground (earth) that is electrically connected and secured at a specific location so that the connection can only be loosened or moved with the aid of a tool.

#### 4.4 Patient-applied risk current (source current)<sup>2)</sup>

##### 4.4.1 General

Patient-applied risk current, when measured with the AAMI standard test load, is that current that flows between any patient-applied part and

- a) power ground (earth);
- b) exposed chassis conductive surfaces or hardware;
- c) a 200 cm<sup>2</sup> foil in contact with a nonconducting enclosure; or
- d) any other patient-applied parts.

<sup>2)</sup> See section 2 for definitions of "patient-applied risk current" and "source current."



Patient-applied risk current is also that current that flows between all patient connections tied together and (a), (b), (c), and (d) listed above when measured with the AAMI standard test load.

#### 4.4.2 Risk current limits

Limits for patient-applied risk current for all categories of electromedical apparatus, whether battery-powered, cord-connected, or permanently connected, under both normal and single fault conditions, are shown in table 1.

#### NOTES—

1) These limits are not applicable to electromedical apparatus without direct patient-applied connections.

2) The current shall be measured at the patient end of the cable when it is attached to the device. The cable is specified by the manufacturer.

### 4.5 Patient isolation risk current (sink current)<sup>3)</sup>

#### 4.5.1 General

Patient isolation risk current, when measured with the AAMI standard test load, is that current that would flow into a patient-applied part if the patient came into direct contact with a potential of 120 volts (V), 60 hertz (Hz) with respect to power ground (earth).

#### 4.5.2 Risk current limits

Limits for patient isolation risk current for electromedical apparatus with isolated patient-applied part(s), whether cord-connected or permanently connected, are shown in table 1.

NOTE—The current shall be measured at the patient end of the cable when connected to the device.

### 4.6 Earth risk current

#### 4.6.1 General

Earth risk current, when measured with the AAMI standard test load, is that current that flows in the protective earth conductor (ground conductor).

NOTE—Not applicable to double insulated devices using a two-wire power cord.

#### 4.6.2 Risk current limits

Limits for earth risk current for all categories of electromedical apparatus, whether cord-connected or permanently connected, and under both normal and single fault conditions, are shown in table 1.

### 4.7 Risk current limits versus frequency

The risk current limits specified in table 1 are for frequencies from dc to 1 kilohertz (kHz). Above 1 kHz, the limit is increased proportionally to a maximum value 100 times the limit at 1 kHz. Above 100 kHz, the limit is that which is determined for 100 kHz (see figure 2). The use of the AAMI test load automatically compensates for frequency.

<sup>3)</sup> See section 2 for definitions of "patient isolation risk current" and "sink current."

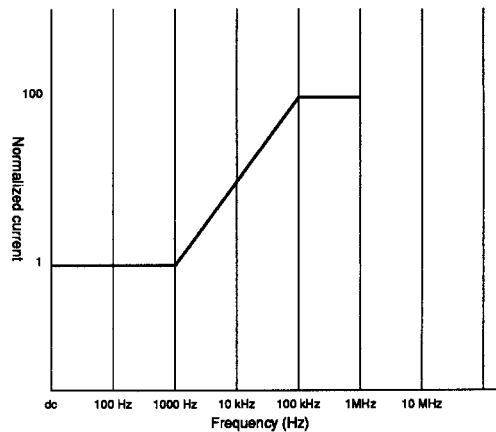


Figure 2—Normalized current limits versus frequency

## 5 Tests

This section contains referee tests and procedures by which compliance with the requirements of section 4 and table 1 can be determined.

**WARNING**—These tests can expose personnel to hazardous electric shock and must be carried out with caution.

### 5.1 Compliance with the labeling requirements

Compliance with the labeling and documentation requirements of section 4.1 shall be verified by inspection.

### 5.2 Compliance with the risk current requirements (general test procedures)

The risk currents of electromedical apparatus shall be measured by the methods described in this section.

#### 5.2.1 Test equipment and power system

##### 5.2.1.1 Measuring instruments

The risk current tester consists of the AAMI standard test load and a millivoltmeter as shown in figure 1. The millivoltmeter shall measure true rms volts; however, it may be calibrated to true rms microamperes ( $\mu\text{A}$ ) by employing a conversion factor of one microampere per millivolt (mV). The millivoltmeter shall have an input impedance of at least 1 megohm and have a bandwidth of dc to at least 1 megahertz (MHz) ( $-3$  decibels). In the band from dc to 100 kilohertz (kHz), the indicated measurement shall not display an error of greater than 5 percent of reading, and shall resolve a signal as small as 1 mV.

Instruments that indicate true rms microamperes and have internal frequency compensation identical to that shown in figure 1 meet the requirements of this section if the measurement indicated does not display an error of greater than 5

percent of reading and resolves a signal as small as 1  $\mu$ A in the band from dc to 100 kHz.

### 5.2.1.2 Power source

**5.2.1.2.1** For line voltage powered equipment, the tests shall be performed on a grounded power system at the rated line voltage plus 10 percent. In the grounded system, the potential between the neutral and grounding conductors at the receptacle selected for the test shall not exceed 3 V.

**5.2.1.2.2** The power ground (earth) terminal used in these tests shall be the grounding terminal of the specific receptacle powering the instrument under test.

**5.2.1.2.3** Battery-powered apparatus shall be tested while powered by the type of battery recommended by the manufacturer and, if applicable, while connected to line power.

### 5.2.2 Test conditions

#### 5.2.2.1 General

First, the apparatus shall be disconnected from all other apparatus except auxiliary apparatus, modular apparatus, or accessories, as defined in the normative definitions (see section 2). A single- or multi-function apparatus in a cabinet or in multiple cabinets with a single power cord connection is tested as a single apparatus. Each individual apparatus shall also be tested independently if described by the manufacturer as a stand-alone apparatus. Tests shall be conducted at the rated line voltage plus 10 percent.

#### 5.2.2.2 Nonconducting enclosure

The risk current shall be measured from an electrically conductive foil the size of the enclosure, but not to exceed 200  $\text{cm}^2$ , in immediate contact with the enclosure. The foil shall be placed at a location—determined by experimentation—such that the current measured to power ground (earth) is a maximum. If exposed chassis hardware is likely to be touched by personnel, then the hardware shall be treated as an exposed electrically conductive surface. Testing of nonconductive exposed surfaces of patient wiring and cables is not required.

#### 5.2.2.3 Controls

During risk current tests, all operator-accessible controls shall be adjusted to yield the largest risk current found by experiment. If the electromedical apparatus normally delivers therapeutic energy to the patient (e.g., a pacemaker), the therapeutic energy shall be zero during the test. Otherwise, the instrument shall be in the active or operable mode; i.e., with output switches closed, with electrodes properly connected to dummy loads, and with final circuit stages properly functioning but without a physiological drive signal.

#### 5.2.2.4 Operation

During the test, the apparatus shall run through a normal cycle and activate all accessories and/or auxiliary apparatus.

### 5.3 Enclosure risk current

#### 5.3.1 Application

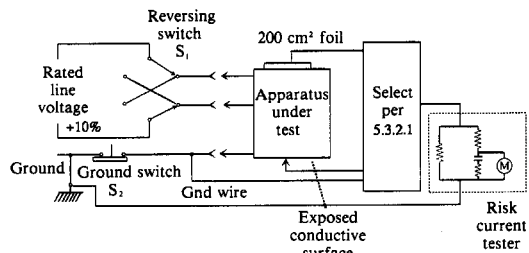
The enclosure risk current tests shall apply to cord-connected, line-powered apparatus, to battery-powered apparatus with

the charger connected, and to permanently connected apparatus.

#### 5.3.2 Cord-connected, normally grounded apparatus

**5.3.2.1** Using the test circuit of figure 3, the enclosure risk current shall be measured:

- between enclosure and power ground (earth);
- between electrically conductive surfaces and power ground (earth);
- between a 200  $\text{cm}^2$  foil in contact with the nonconducting enclosure and power ground (earth).



**Figure 3—Enclosure risk current test circuit (normally grounded)**

**NOTE**—The 200  $\text{cm}^2$  foil line leading from the “select” box to the apparatus under test refers to the connective mode with insulated apparatus. The line with an arrow leading from the “select” box to the apparatus under test refers to connections made with conductive enclosure.

#### 5.3.2.2 Each measurement is performed when:

- the utility electricity supply polarity is normal and when the utility electricity supply polarity is reversed (by reversing  $S_1$ ). These are normal conditions;
- the apparatus power switch is on; the apparatus power switch is off. These are normal conditions;
- the ground switch ( $S_2$ ) is open; the ground switch is closed. The first is a single fault condition; the second is a normal condition;
- each barrier of double insulation is short circuited. These are single fault conditions.

**NOTE**—The test methods for all measurement conditions are not supplied in this standard because they are device- and circuit-specific.

**5.3.2.3** The power on/power off test also applies to apparatus with nonrechargeable batteries.

#### 5.3.3 Cord-connected, normally ungrounded apparatus

**5.3.3.1** Using the test circuit of figure 4 (see next page), the enclosure risk current shall be measured:

- between enclosure and power ground (earth);

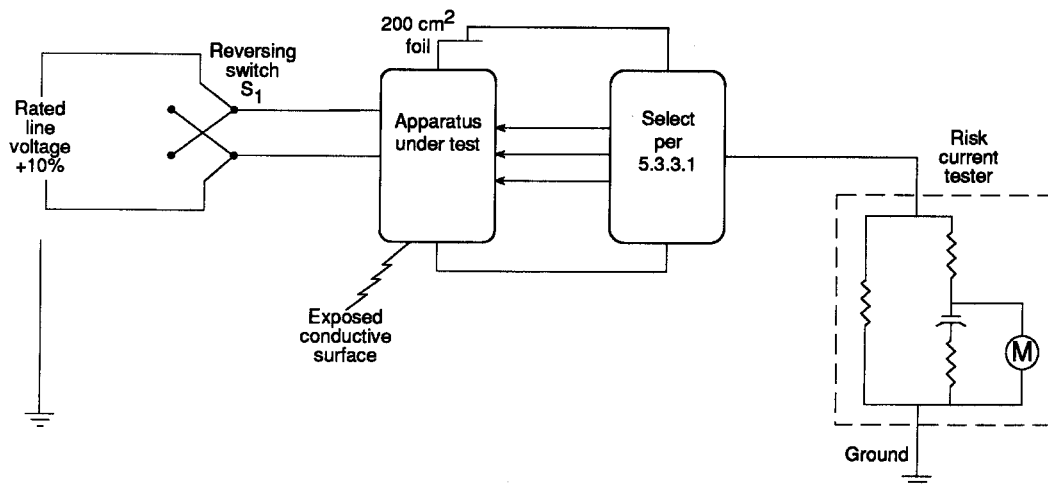


Figure 4—Enclosure risk current test circuit (normally ungrounded)

b) between electrically conductive surfaces and power ground (earth);

c) between a 200 cm<sup>2</sup> foil in contact with the nonconducting enclosure and power ground (earth).

**5.3.3.2** Each measurement is performed when:

a) the utility electricity supply polarity is normal; the utility electricity supply polarity is reversed (by reversing S<sub>1</sub>). These are normal conditions;

b) the apparatus power switch is on; the apparatus power switch is off. These are normal conditions;

c) each barrier of double insulation is short-circuited. These are single fault conditions.

NOTE—The test methods for all measurement conditions are not supplied in this standard because they are device- and circuit-specific.

**5.3.3.3** The power on/power off test also applies to apparatus with nonrechargeable batteries.

**5.3.4** Permanently connected apparatus

Before line-powered apparatus is permanently installed, the enclosure risk current shall be measured according to the procedures described in 5.3.2.

**5.4** Patient-applied risk current (source current)

**5.4.1** Application

The patient-applied risk current tests of this section shall apply to line-powered and battery-powered electromedical apparatus that has a patient connection(s).

**5.4.2** Apparatus with isolated patient connection

**5.4.2.1** Using the test circuit of figure 5 (see next page), the patient-applied risk current (source current) shall be measured between:

a) any patient connection and power ground (earth);

b) any patient connection and any exposed, electrically conductive surface;

c) any patient connection and a 200 cm<sup>2</sup> foil in contact with the nonconducting enclosure;

d) any patient connection and any other patient connection;

e) all patient connections shorted together and power ground (earth);

f) all patient connections shorted together and any exposed, electrically conductive surface;

g) all patient connections shorted together and a 200 cm<sup>2</sup> foil in contact with the nonconducting enclosure;

h) any patient connection and all other patient connections connected together.

NOTE—The test methods for all measurement conditions are not supplied in this standard because they are device- and circuit-specific.

**5.4.2.2** Each measurement is performed when:

a) the utility switch (S<sub>1</sub>) is normal/the utility switch is reversed. These are normal conditions;

b) the apparatus power switch is on/the apparatus power switch is off. These are normal conditions;

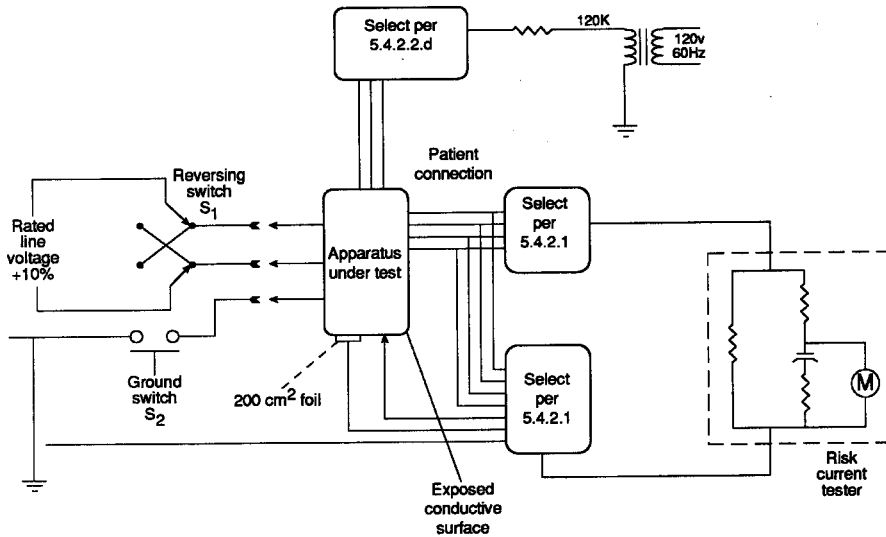


Figure 5—Patient-applied risk current test circuit

NOTE—The 120 K resistance is intended to protect the test operator.

- c) the ground switch ( $S_2$ ) is open/the ground switch is closed. The first is a single fault condition; the second is a normal condition;
- d) line voltage is applied to an input or output part or to accessible conductive hardware of the enclosure, if not grounded under normal conditions. These are single fault conditions;
- e) each barrier of double insulation is short circuited. These are single fault conditions.

#### 5.4.3 Apparatus with nonisolated patient connection

The patient-applied risk current shall be measured by the procedures described in 5.4.2.

#### 5.5 Patient isolation risk current (sink current)

The patient isolation risk current shall be measured in each individual patient connection that is labeled "isolated" when a potential of 120 V rms, 60 Hz, is applied through a series 120 kilohm resistance to the labeled patient connection, as shown in figure 6. The patient isolation risk current is measured with respect to power ground (earth). For solely battery-powered apparatus, the patient isolation risk current is measured with respect to an electrically conductive surface on which the apparatus is positioned, and with an exposed conductive surface or other external electrical connection on the apparatus grounded. This test shall be performed with the apparatus both on and off and properly connected to its electrical supply. The patient cable shall be placed 20 cm away from a grounded surface.

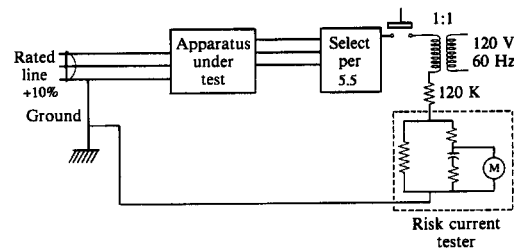


Figure 6—Patient isolation risk current test circuit

NOTE—The 120 K resistance is intended to protect the test operator.

### 5.6 Earth risk current

#### 5.6.1 Application

The earth risk current test shall apply to cord-connected apparatus, to battery-powered apparatus with the charger connected, and to permanently connected apparatus.

#### 5.6.2 Cord-connected, normally grounded apparatus

5.6.2.1 Using the test circuit of figure 7 (see next page), the earth risk current shall be measured in the protective power ground (earth).

5.6.2.2 Measurement shall be performed when:

- a) the utility electrical supply is normal/when the utility electrical supply is reversed (by reversing  $S_1$ ). These are normal conditions;

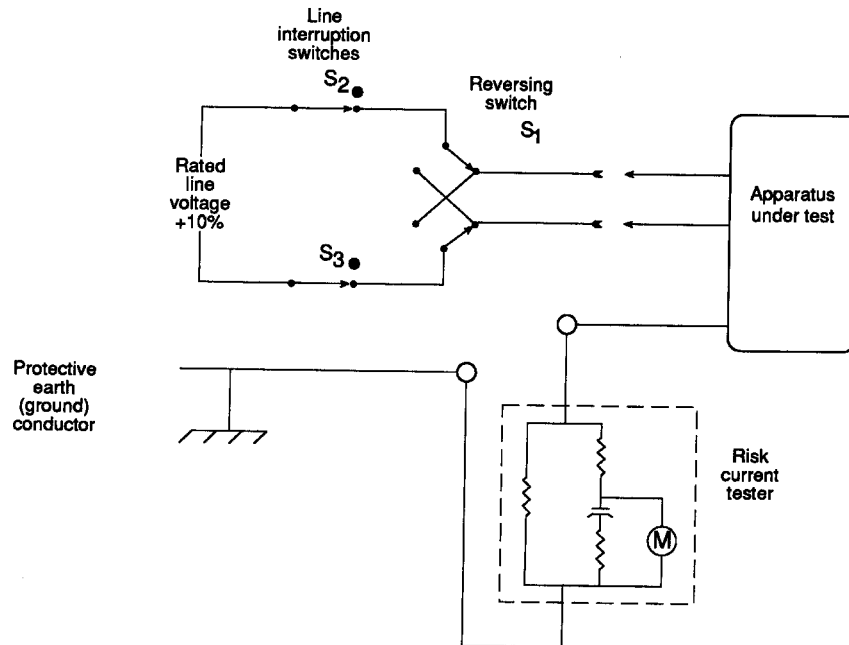


Figure 7—Earth risk current test circuit

- b) the apparatus power switch is on/the apparatus power switch is off. These are normal conditions;
- c) each supply conductor is interrupted, one at a time (opening S<sub>2</sub> and S<sub>3</sub> in turn). This is a single fault condition;
- d) each barrier of double insulation is short-circuited. This is a single fault condition.

**5.6.3 Permanently connected apparatus**

Before the line-powered apparatus is permanently installed, the earth risk current shall be measured according to the procedures described in 5.6.2.

**5.7 Risk current limits versus frequency**

**5.7.1 General**

When multiple risk currents of various frequency and phase relationships are present during a single test, the resultant risk current is related to the voltage across the AAMI standard test load. The risk current of an apparatus shall be the largest current measured during any of the required tests and conditions. The apparatus must meet all applicable limits of table 1.

**5.7.2 AAMI standard test load**

As shown in figure 1, the test load shall be constructed using metal-film resistors with a tolerance of 1 percent or better, and a mica- or plastic-dielectric (extended foil) capacitor with a

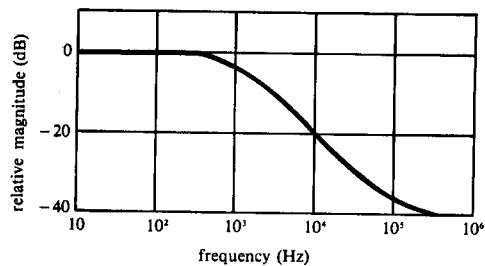


Figure 8—Relative frequency characteristics of millivolt-meter reading in AAMI standard test load of figure 1

tolerance of 5 percent or better. The AAMI standard test load has an impedance frequency characteristic (figure 8) which is the approximate inverse of the curve of figure 2, which shows risk current versus frequency.

**5.7.3 Risk current calculation**

Using the AAMI standard test load of figure 1 and a voltmeter calibrated to indicate rms millivolts, the weighted risk current is read directly from the meter, because:

$$I(\mu\text{A rms}) = \frac{V(\text{mV rms})}{Z(\text{k ohms})}$$

## Annex A (informative)

### Rationale for the development and provisions of this standard

#### A.1 General

The rationale discusses the need for the standard and describes the basic underlying principles, empirical data, assumptions, and sources that support the requirements and test methods adopted in the standard.

#### A.2 Need for the standard

This standard seeks to reduce the risk of inadvertent electric shock from medical devices. In particular, it concerns itself with the risk of injury from the small currents that inevitably flow from or to electromedical apparatus.

The intent of the AAMI Electrical Safety Committee was to develop a general baseline standard. The extent to which the standard should be applied is to be determined by individual institutions, standards groups, and other authorities.

#### A.3 Classification of electromedical apparatus and measurement conditions

Changes from the second edition of the standard (AAMI, 1985) have been made in keeping with changes to the requirements given in section 4.

#### A.4 Rationale for the specific provisions of the standard

##### A.4.1 Labeling and documentation requirements

###### A.4.1.1 Isolated patient connection (labeling)

Fault conditions can contribute to patient risk due to source and sink currents. The greatest risk is with direct cardiac applications; such applications should utilize isolated patient connections. In order to better manage patients requiring direct cardiac connection, the user should be able to readily identify electromedical apparatus with isolated patient connections. Therefore, labels should appear on the electromedical apparatus itself. The standard does not require nonisolated patient connections to carry any special labeling.

###### A.4.1.2 Information manuals

By identifying the risk current classification and risk current limits, the manufacturer is informing the user of the device's intended purpose as that purpose relates to the risk of electric shock. Any special user actions required to ensure that the risk current limits are maintained throughout the life of the equipment should be described in the operating instructions or maintenance manuals.

#### A.4.2 Risk current requirements (general)

The committee felt that grounding should not be the primary approach to limiting the risk of electric shock because it is possible to have a single fault failure in the grounding system. Redundant means of grounding are possible but are controlled by the user and not the manufacturer of the electromedical apparatus. If the grounding is lost or if other safety means fail, the risk current available from the enclosure should not represent a substantial hazard to the patient.

The risk current limits were changed for certain categories as compared to the previous version of this standard (ANSI/AAMI ES1—1985). These changes have been made in order to bring this document into closer harmonization with risk current limits specified in the International Electrotechnical Commission standard, *Medical electrical equipment—Part 1: General requirements for safety* (IEC 601-1, 1988).

In its review of the allowable risk current levels, the committee considered the following:

a) *Likelihood of stimulation of excitable tissue.* The likelihood of stimulation of excitable tissue depends upon:

- 1) the location of the sites at which current enters and leaves the body;
- 2) the area of contact;
- 3) the amount of current flowing;
- 4) the susceptibility to mechanical stimulation;
- 5) the presence of a fault condition;
- 6) the probability of the current having a given value.

Medical devices have been classified into the risk categories described in section 3 because of the different magnitudes of risk associated with these categories.

b) *Survey of published data.* During the several years since the publication of the previous version of this standard (ANSI/AAMI ES1—1985), experience has been gained with respect to the incidence of problems related to risk current and the probability of occurrence of the potential hazard. The available published data on currents causing ventricular fibrillation in humans have also been reexamined. The following have been noted:

- 1) The combination of an open power ground (earth) wire and a person touching both a conductive part of the enclosure and the patient is a low probability event.

2) The combination of an open power ground (earth) wire and a person touching both a conductive part of the chassis and the distal end of an invasive cardiac connection is a low probability event.

3) In one study, Rafferty (1975) found that the smallest current that produced a disturbance in rhythm in humans was 80  $\mu\text{A}$ . In a second study, Watson (1973) found that the smallest current that produced ventricular fibrillation in humans was 15  $\mu\text{A}$ .

4) Mechanically induced ventricular fibrillation has been observed during cardiac catheterization at zero current.

5) The human data obtained by Starmer (1973) and Watson (1973) follow, reasonably well, a normal distribution for currents to 300  $\mu\text{A}$  (see figure A.1, next page). All patients are not equally susceptible to current-induced ventricular fibrillation. According to figure A.1, there is approximately a 1 percent probability of fibrillation at 30  $\mu\text{A}$ .

6) Current perception is a function of contact location, contact pressure, skin condition, moisture, and contact area. Experiments report a wide range of current perception. Daiziel (1968) reports that only approximately 1 percent of the population can perceive 500  $\mu\text{A}$  passing from the fingers of one hand to the fingers of the other hand. Tan and Johnson (1990) report that 300  $\mu\text{A}$  produces a strong sensation for electrodes placed 10 cm apart on the upper arm. Levin (1991) reports that nearly all the population will perceive 500  $\mu\text{A}$  without any reaction for current passing from the finger on one hand to the underside of the wrist on the other hand. Levin further reports that, on the underside of the wrist, the stratum corneum (layer of dead material on the skin surface) is not as thick as that on the forefinger and, therefore, the sensitivity to current perception might be higher. Startle current is that level of perception current that, when first perceived, might result in a nurse or other clinician's involuntary reaction to the sudden sensation of perception current. This uncontrolled reaction is of great concern.

7) Worldwide, since the advent of risk current standards, concern about grounding, and use of better practices in handling catheters and invasive cardiac connections, there have been no reports of incidents involving risk current passing through the patient.

NOTE—A minority of the AAMI Electrical Safety Committee were opposed to increasing risk current limits unless scientific studies supported higher limits.

Also, in order to harmonize with IEC 601-1 and to allow for additional fault conditions as compared to the current standard, the test measurement classifications of "normal condition" (NC) and "single fault condition" (SFC) were introduced.

Measuring risk current under SFC is important because:

- components can fail;
- single faults exist that are not now considered in the standard;
- faults can occur in accessory equipment.

#### A.4.2.1 Apparatus Interconnection

The total risk current associated with a device can be a function of the modules, accessories, and interconnections used with the device. Voltage differences can occur between different parts of a device, particularly if current flows in the grounding circuit. Thus, a remote accessory powered from the device or from a separate source is, for purposes of the standard, considered part of the device.

Auxiliary power outlets may be provided for powering additional devices. The labeling requirements provide some assurance that the user has appropriate guidance about the limitations applying to equipment or accessories connected to an auxiliary power receptacle.

#### A.4.2.2 Cleaning and sterilization

The long-term effects of repeated disinfection or sterilization of a device on risk currents must be considered because of possible degradation of insulating materials.

#### A.4.2.3 Environmental conditions

Temperature, humidity, atmospheric pressure, mechanical shock, and similar environmental constraints can have an effect upon the risk currents. To protect the patient, the risk current limits must also be met in the intended environment.

#### A.4.3 Enclosure risk current

The 100  $\mu\text{A}$  NC values were selected for cord-connected and permanently connected apparatus on theoretical grounds. For a typical ground resistance of 0.2 ohms, 100  $\mu\text{A}$  of enclosure risk current, measured as in figure 3, requires that 500 mA flow in the power ground (earth) wire. This would be a major fault condition.

The 300  $\mu\text{A}$  SFC values for isolated, nonisolated, or likely-to-contact-patient, cord-connected apparatus were selected on the basis of reaction current measurements by Levin and the low probability of risk current reaching the distal end of an invasive heart connection via another person. Levin reported that currents of 300  $\mu\text{A}$  will not produce sensations leading to a "startle" reaction (Levin, 1991).

The 500  $\mu\text{A}$  limit for SFC for cord-connected, no-patient-contact equipment was selected because there is no concern about this current reaching the patient.

The 5,000  $\mu\text{A}$  limit for SFC for permanently connected equipment is basically a power ground (earth) wire current, because the apparatus is, by definition, permanently grounded. This is the current allowed from the enclosure of permanently connected equipment if the power ground (earth) wire were opened. The permanently connected power ground (earth) wire is not expected to open.

#### A.4.4 Patient-applied risk current (source current)

The 10  $\mu\text{A}$  NC limit was selected as the current that may flow directly into the heart continuously. Figure A.1 shows that the probability of inducing ventricular fibrillation is very small if the data on which the chart is based are extrapolated. If only observed values of currents that produced ventricular fibrillation in humans are considered, the probability is approximately zero.

Starmer 60 Hz D = 1.25mm

Watson 50 Hz D = 2.0 mm

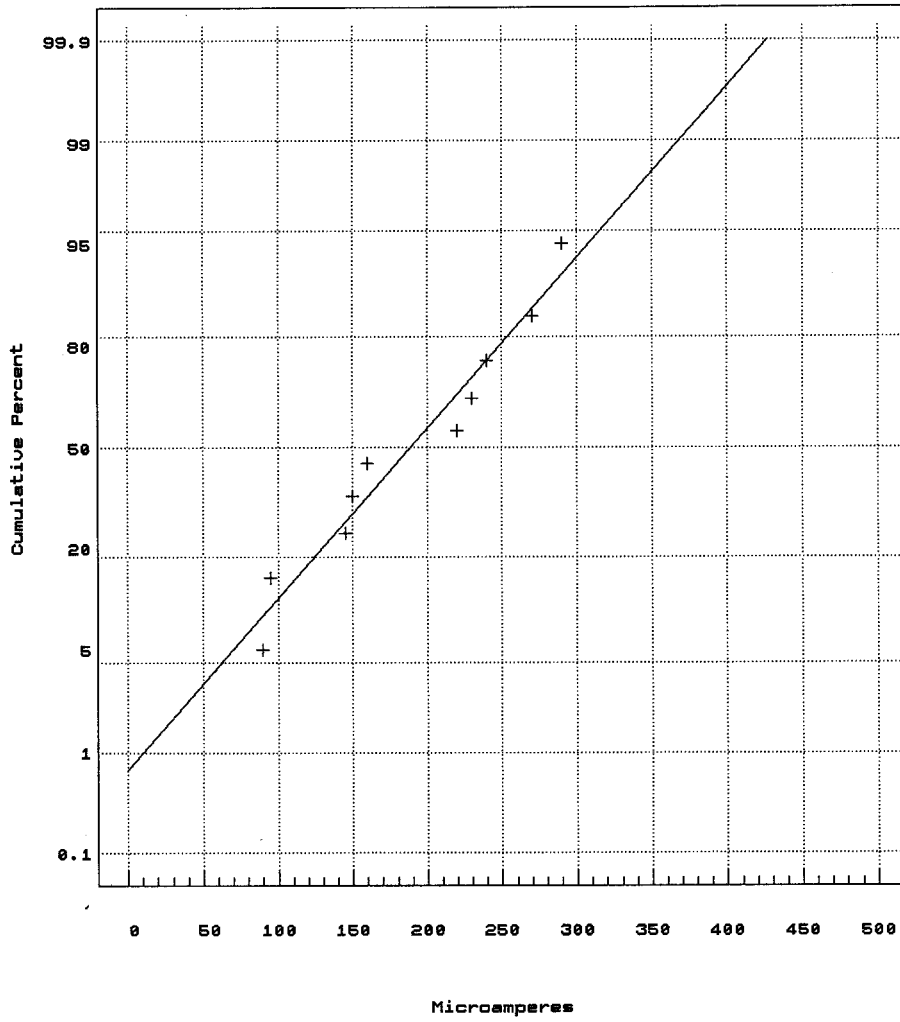


Figure A.1—Normal probability plot



The 50  $\mu\text{A}$  SFC limit for isolated equipment was selected because the probability of causing ventricular fibrillation is low if the data of figure A.1 are extrapolated and is approximately zero if only observed values of currents producing ventricular fibrillation in humans are considered.

The 100  $\mu\text{A}$  SFC limit was selected for nonisolated equipment, because if this current enters and exits the surface of the body, then only a fraction will reach the heart.

#### **A.4.5 Patient Isolation risk current (sink current)**

The 50  $\mu\text{A}$  SFC value for isolated equipment was allowed because of the low probability of line voltage appearing on a patient, and because of the low probability of 50  $\mu\text{A}$  inducing ventricular fibrillation. For line voltage to appear on a patient, a power ground (earth) wire must be open and there must also be a fault in basic insulation. If the data in figure A.1 are extrapolated, then 50  $\mu\text{A}$  has a low probability of inducing ventricular fibrillation. If only recorded human data are considered, the probability of inducing fibrillation at 50  $\mu\text{A}$  is approximately zero.

#### **A.4.6 Earth risk (ground risk) current**

The original standard of 1978 and the revised edition of 1985 did not include earth current as a potential risk current. This was not considered to be an issue as most medical devices of the era utilized conductive enclosures requiring grounding. Thus, earth current was effectively measured as enclosure (chassis) current under the open ground condition.

In the last 25 years, however, the change to nonconductive enclosures negated this equality. The enclosure current is now measured as the capacitive-coupled current to a 200  $\text{cm}^2$  foil in contact with the enclosure. This current bears little resemblance to the earth risk current due to the current-limiting characteristics of the capacitive coupling of the nonconductive enclosure.

The earth risk current does not pose a direct risk to the patient or medical personnel. However, excessive earth risk current,

either by design or internal breakdown, will raise the potential of the device's ground with respect to true power ground (earth) as represented by structural elements, modular wall units, cold water pipes, and other installed piping, or by an adjacent receptacle power ground (earth). Contact with such elements and a second device under test will result in current flow. Thus, the committee felt that leaving the earth risk current unmeasured and unlimited constituted a potential hazard that should be avoided.

The allowable values for earth risk current detailed in this standard are not thought to pose a direct hazard as the current is safely returned to earth. The values selected were chosen to avoid any significant increase in the current flowing through the protective grounding system of the installation and to be consistent with the limits of IEC 601-1 for power ground (earth) and nonconducting enclosures. Further, the 2.5 mA limit in normal mode is within the limit for isolation monitors set by the National Fire Protection Association (NFPA, 1993, section 3.4.3.3), which specifies that isolation monitors should not alarm at 3.75 mA.

#### **A.4.7 Risk current limits versus frequency**

Figure 2 of the standard was derived from strength/frequency data for perceptible and lethal currents (Geddes and Baker, 1971). The flat portion between 100 kHz and 1 MHz does not reflect physiological data obtained with purely sinusoidal currents. Stimulation has been observed with complex waveforms at high frequencies, but little data are available. In the absence of data, it was deemed prudent not to extrapolate beyond 100 kHz.

### **A.5 Tests**

The test procedures documented in section 5 of the standard provide referee test methods for verifying compliance with the requirements of section 4. These referee tests are not necessarily intended for purposes of manufacturing or quality control (although these applications are not precluded), as equivalent measurements may be obtainable by other means.

**Annex B**  
(informative)

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