List of Titles

American National Standard

ANSI/AAMI HF18:2001

Electrosurgical devices

AAMI Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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American National Standard

ANSI/AAMI HF18:2001
(Revision of ANSI/AAMI HF18:1993)

Electrosurgical devices

Developed by
Association for the Advancement of Medical Instrumentation

CORRECTED VERSION

Approved 11 May 2001 by
American National Standards Institute, Inc.

Abstract: This standard establishes minimum safety and performance requirements for electrosurgical systems. An electrosurgical system consists of a high frequency electrical current generator, cables, electrodes, and safety devices for delivering this high frequency electrical energy to the patient to accomplish electrosurgery. The system includes the circuitry and devices needed to control the duration, mode of operation, and intensity of the application. Included within the scope of this standard are electrosurgical devices and the electrosurgical portion of multifunction devices. Examples of devices within the scope of this standard are electrosurgical high frequency generators and directly related accessories, including active electrodes and cables, dispersive electrodes and cables, and footswitches or other operator-controlled mechanisms for activating the generator output.

Keywords: electrosurgical devices, electrosurgical systems, electrosurgery, dispersive electrodes, dispersive cables, electrosurgical high frequency generators

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AAMI Standard

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Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

Printed in the United States of America

ISBN 1–57020–160–9

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Association for the Advancement of Medical Instrumentation

High Frequency Therapeutic Device Committee

This standard was developed by the High Frequency Therapeutic Device Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of this standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI High Frequency Therapeutic Device Committee** had the following members:

Chair:	Jeffrey L. Eggleston
Members:	Kathryn S. Daws-Kopp, U.S. Food and Drug Administration
	Jeffrey L. Eggleston, TYCO Healthcare
	James D. Isaacson, Megadyne Medical Products
	Michael R. Manes, Conmed Corporation
	Samuel G. Netherly, 3M Health Care
	Eric S. Sacks, ECRI
	Kok-Swang Tan, PhD, Health Canada Medical Device Bureau
	David Zieve, TUV Product Service, Inc.
Alternates:	Warren L. Bisbee, Conmed Corporation
	Amelia M. Slaughter, TYCO Healthcare

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.

Foreword

The original edition of this standard was published in 1986 and was developed by the High Frequency Therapeutic Device Committee of the Association for the Advancement of Medical Instrumentation. In developing the provisions of this standard, the committee used the following information as important source material: the contract standard on electrosurgical devices developed by the Emergency Care Research Institute (now ECRI) under the sponsorship of the Bureau of Medical Devices (now the Center for Devices and Radiological Health) of the Food and Drug Administration; the draft standard for electrosurgical devices then under development by the International Electrotechnical Commission; Australian Standards 3200-1978 and 3202-1979; and comments from interested parties.

In 1991, the AAMI High Frequency Therapeutic Device Committee was reactivated to address new electrosurgical issues and to align the standard with the international standards where feasible. In this revision, the committee aligned the document with IEC 601-2-2, *Medical electrical equipment—Part 2: Particular requirements for the safety of high frequency surgical equipment*, wherever possible, and added requirements because of technical improvements and new input from ECRI accident reports.

This latest revision brings this standard up to date with the third edition of IEC 60601-2-2, which became effective in 1998. Many of the redundant requirements have been removed and replaced with references to the IEC 60601-2-2 document. In addition, the format of this standard has been changed to be similar to IEC standards so that the conformance tests are now in the same subclause as the requirements.

The objective of this standard is to provide minimum labeling, performance, and safety requirements to help ensure safe and effective use of electrosurgical devices.

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, and other health care professionals as well as manufacturers and government representatives to develop a standard for those performance levels that could reasonably be achieved at the time of publication.

Suggestions for improving the standard are invited. Comments or suggested revisions should be sent to AAMI, Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard, *Electrosurgical devices* (ANSI/AAMI HF18:2001), but does provide important information about its development and intended use.

Electrosurgical devices

1 Scope

This standard establishes minimum safety and performance requirements for electrosurgical systems. An electrosurgical system consists of a high frequency electrical current generator, cables, electrodes, and safety devices for delivering this high frequency electrical energy to the patient to accomplish electrosurgery. The system includes the circuitry and devices needed to control the duration, mode of operation, and intensity of the application.

Included within the scope of this standard are electrosurgical devices and the electrosurgical portion of multifunction devices. Examples of devices within the scope of this standard are electrosurgical high frequency generators and directly related accessories, including active electrodes and cables, dispersive electrodes and cables, and footswitches or other operator-controlled mechanisms for activating the generator output.

NOTE—When it is necessary to create product standards for specialty devices (e.g., neurological lesion generators, depilation units, endoscopic devices combining a fiber-optic light source or gas insufflator with the electrosurgical generator), then appropriate, applicable requirements for the electrosurgical portion of the unit and its accessories may be necessary.

2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements that are based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Please note that reference to provisions within IEC 60601-2-2 automatically implies reference to the corresponding clauses within IEC 60601-1 and its two amendments, because the IEC 60601-2-2 standard describes only changes or additions to the IEC 60601-1 standard.

2.1 AMERICAN NATIONAL STANDARDS INSTITUTE. ANSI C84.1-1995, *Electric power systems and equipment—Voltage ratings (60 Hz)*. New York: ANSI, 1996. American National Standard.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. ANSI/AAMI ES1:1993, *Safe current limits for electromedical apparatus*. Arlington (Vir.): AAMI, 1993. American National Standard.

2.3 INTERNATIONAL ELECTROTECHNICAL COMMISSION. IEC 60601-1:1988, *Medical electrical equipment—Part 1: General requirements for safety, 2ed*. Geneva: IEC, 1988.

2.4 INTERNATIONAL ELECTROTECHNICAL COMMISSION. IEC 60601-1 Amendment 1:1991*, Medical electrical equipment—Part 1: General requirements for safety.* Geneva: IEC, 1991.

2.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION. IEC 60601-1 Amendment 2:1995*, Medical electrical equipment—Part 1: General requirements for safety.* Geneva: IEC, 1995.

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. IEC 60601-2-2:1998, *Medical electrical equipment—Part 2: Particular requirements for the safety of high frequency surgical equipment, 3ed*. Geneva: IEC, 1998.

2.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION. IEC 60601-2-18:1996, *Medical electrical equipment—Part 2: Particular requirements for the safety of endoscopic equipment, 2ed*. Geneva: IEC, 1996.

3 Terms and definitions

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

3.1 active cable: Conductor between the electrosurgical generator and the active electrode, including any connectors or handle.

3.2 active electrode: Electrode or electrode assembly at which the electrosurgical effect is intended.

3.3 autobipolar operation: Automatic mode of limited bipolar electrosurgical output.

NOTE—The surgeon enables this automatic mode by intentional activation of a control. Once placed in the automatic mode, the electrosurgical device uses a small interrogation current to sense tissue impedance and activates a switch. This switch automatically initiates and/or terminates the electrosurgical output.

3.4 bipolar: Referring to a two-terminal technique in which electrosurgical effect takes place between the paired electrodes of a bipolar instrument placed across the tissue to be treated.

NOTE—A substantial portion of the electrosurgical current is intended to be confined to the tissue between the electrodes.

3.5 bipolar electrode (instrument): Assembly of two active electrodes (e.g., forceps) constructed in a way that, when energized, the high frequency current flows mainly between these electrodes.

3.6 breakdown (dielectric): Failure of insulation under the stress of a voltage, characterized by marked increase in conductivity or disruptive discharge.

3.7 capacitively coupled dispersive electrode: Electrode covered with insulation that serves as a dispersive electrode coupling, not by direct conductive contact with the patient's skin, but by the electrical capacitance between it and the patient.

3.8 coagulation: Sealing of small blood vessels or of body tissue caused by the passage of high frequency current at the active electrode(s).

3.9 common electrical ground: Chassis of the electrosurgical generator or other conductive surface to which a grounding conductor of the input power cord is connected.

3.10 contact quality monitor: Circuit or system in an electrosurgical generator intended to give a warning and to disable the generator whenever the area of contact between the dispersive electrode and patient decreases to the point of potentially causing unsafe temperatures in the patient tissues.

3.11 current: As used in this standard to denote the measured variable, the root-mean-squared (rms) value of current taken over a period encompassing at least several cycles of a periodically recurring waveform, expressed as amperes.

3.12 current density: Quotient of the current flowing through a given area divided by that area, expressed as microamperes per square centimeter.

3.13 cutting: Resection or dissection of body tissue caused by the passage of high frequency or high density current at the active electrode(s).

3.14 damage: Deformation, loosening, breakage, corrosion, or change of fit of any component or part or any physical condition resulting in nonconformance of the electrosurgical device to the provisions of this standard.

3.15 dispersive (neutral) electrode: Electrode of a relatively large area for connection to the body of the patient, intended to provide a return path for the high frequency current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided. It is also known as the patient plate, inactive electrode, indifferent electrode, or return electrode.

3.16 dispersive electrode cable: Conductor between the electrosurgical generator and the dispersive electrode together with any attached connectors.

3.17 dispersive electrode cable monitor: Circuit or device that detects an interruption in dispersive electrode cable continuity between the electrosurgical generator and the dispersive electrode. This is a special form of a patient circuit safety monitor.

3.18 disposable accessory: Electrosurgical accessory (e.g., active electrodes, handles, dispersive electrodes) that is intended to be used only once.

3.19 electrocautery: Searing or destruction of tissue by means of heat delivered to the tissue from an electrical conductor brought to a high temperature by the passage of an electric current through the conductor.

3.20 electrode: Device intended to provide electrical connection (possibly in conjunction with a cable) between a patient and the output terminals of an electrosurgical generator.

3.21 electrosurgery: Intentional passage of high frequency current through tissue to achieve controllable surgical effects such as cutting or coagulation.

NOTE—For the purposes of this standard, *electrocautery* and *medical diathermy* are not considered electrosurgery. Although not entirely appropriate, the term *surgical diathermy* is commonly accepted as synonymous with electrosurgery; for the purposes of this standard, the use of this term is avoided.

3.22 electrosurgical accessory: Device used in conjunction with the electrosurgical generator to accomplish electrosurgery. Such devices include, but are not limited to, footswitches, cables, dispersive electrodes, and active electrodes.

3.23 electrosurgical current: Alternating electrical current of sufficiently high frequency for the performance of electrosurgery without significant neuromuscular stimulation.

3.24 electrosurgical leakage power: Power that results from electrosurgical currents other than those flowing in the intended pathway through the patient and connecting cables and that may be dissipated when these currents are conveyed from accessible parts of the electrosurgical generator, leads, and electrodes by direct or capacitive coupling, or from the patient to ground or other accessible parts, leads, or electrode.

3.25 electrosurgical system: High frequency current generator and its accessories that are intended for use in accomplishing electrosurgery.

3.26 endoscopically used accessory: See definition in IEC 60601-2-18:1996.

3.27 ground referenced: Electrosurgical generator that meets the definition described in IEC 60601-2-2, clause 19.3.101(a).

3.28 inspection: Any visual or aural examination that does not require the use of special laboratory appliances or procedures and that may include verification of manufacturing and test records.

3.29 interrogation current: High frequency therapeutic current used to activate an impedance-sensing switch.

NOTE—The surgeon has direct control of this current, which has minimal surgical effect on the sensed tissue.

3.30 low frequency risk current: Any current, including capacitively coupled currents but excluding electrosurgical currents and electrosurgical leakage currents, that may be conveyed from accessible parts of the electrosurgical generator or accessories to ground or to other accessible parts.

3.31 medical diathermy: Application of a high frequency current, electromagnetic field, or ultrasonic mechanical energy to attain diffuse heating of body tissues, usually at some distance from the energy-coupling electrode or other applicator.

NOTE—In contrast to electrosurgery, tissue temperature rise is limited to a level well below that which would cause tissue destruction. Sometimes also called *therapeutic diathermy*.

3.32 mode (operational): Each of the distinct ways in which the electrosurgical generator can be operated with electrosurgical output (e.g., monopolar cutting, monopolar coagulation, monopolar blended, bipolar coagulation).

3.33 monopolar: Electrosurgical technique in which the electrosurgical effect takes place at a single active electrode only. At the dispersive electrode, no electrosurgical effect is intended or desired.

3.34 monoterminal technique: Technique in which only a single lead comprising the active electrode is used.

NOTE—Capacitive coupling between the patient's body and ground (and thence to the generator) without the use of an intentional dispersive electrode and an associated conductor provides the return pathway for electrosurgical currents.

3.35 nonreactive resistor: Resistor constructed to have such low reactance that, over the range of frequency for which it is claimed to be nonreactive, reactance is a negligible portion of the total impedance, and resistance is essentially equal and constant.

3.36 open circuit peak voltage: For purposes of this standard, the maximum instantaneous output voltage of the electrosurgical waveform under the condition of no intentional load.

3.37 output power: Rate of delivery of electrosurgical energy as determined by the measurement of the rms current in a nonreactive resistor or the rms voltage across the load resistance.

NOTE—Power is calculated by one of the following formulae:

$$P = I^2 \times R,$$
$$P = V^2 / R,$$
or
$$P = V \times I$$

where:

R is the load resistance in ohms,

I is the current in amperes,

V is the voltage in volts, and

P is the power in watts.

3.38 output terminals (electrosurgical): Terminals on the electrosurgical generator to which the cables and electrodes are connected and through which electrosurgical currents pass to accomplish electrosurgery.

3.39 patient circuit safety monitor: Circuit or system in an electrosurgical generator intended to give a warning and to disable the generator output when the occurrence of abnormal conditions could result in excessive electrosurgical currents flowing in other-than-normal pathways.

NOTE—Examples are current monitors capable of detecting electrosurgical currents in other-than-intended pathways.

3.40 rated load: The value of a nonreactive resistor that results in the maximum output power from each operating mode of the electrosurgical generator.

3.41 rated output power: The power in watts produced when the output of an electrosurgical generator is fed into the rated load.

3.42 reusable accessory: Accessory (e.g., an electrode, a cable, a footswitch) that is intended for multiple use.

3.43 suitable packaging unit: Unit of packaging to which a requirement of marking or labeling is logically applicable, or the smallest unit intended for sale by the manufacturer or distributor to the final user.

4 Requirements

4.1 Labeling

In addition to the labeling requirements of applicable federal regulations, labeling for devices within the scope of this standard shall conform to the provisions of this section.

Compliance with all of the labeling requirements of 4.1 can be verified by inspection.

4.1.1 Device markings

Generators must meet the requirements of IEC 60601-2-2, clauses 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, and 6.7.

4.1.2 Generator operator's manual

Manuals must meet the requirements of IEC 60601-1 and IEC 60601-2-2, clauses 6.8.1 and 6.8.2.

4.1.3 Service manual

Generator service manuals must meet the requirements of IEC 60601-1 and IEC 60601-2-2 clauses 6.8.2 and 6.8.3, excluding subclause 6.8.3(d) of IEC 60601-1.

4.1.4 Dispersive electrodes

4.1.4.1 General

Each suitable packaging unit to be stored at the point of use shall be labeled with any restrictions on storage conditions and shall contain complete application instructions for the electrodes, including recommendations for application site selection and preparation; required and recommended application practices; warnings and precautions; and preapplication tests, if required. The date of manufacture of single-use electrodes shall be provided unless an expiration date is given.

Electrodes designed to be used as part of a contact quality monitoring system should be labeled as such.

4.1.4.2 Electrodes intended for use on infants

The unit container labeling of dispersive electrodes intended for use only on infants shall comply with the following additional requirements:

a) The word *infant* shall be part of the name of the device.

b) A prominent statement shall limit the use of the device to patients weighing 11.4 kg (25 pounds) or less.

c) The instructions for use shall include a prominent warning against use of the device for high-powered procedures such as transurethral resection (TUR).

4.1.5 Reusable accessory cables

The labeling accompanying reusable accessory cables shall provide instructions for sterilization (if applicable) and maintenance, including, but not limited to, recommended method of sterilization; recommended means of ensuring that the cable is suitable for use, including a continuity test; and a warning that if a break occurs in the cable wire or the cable becomes otherwise electrically discontinuous, arcing may occur in the patient-return or active circuit and may burn the patient or create a fire. (See also 4.2.5.3.)

4.2 Performance and safety

4.2.1 Mechanical construction

Generators must meet the requirements of IEC 60601-2-2, clauses 20, 21 through 28, and 44.

4.2.2 Electrical construction

Generators must meet the requirements of IEC 60601-2-2, clauses 20, 36, 56, 57, 58, and 59, excluding clause 59.103.

4.2.3 Dispersive electrodes

4.2.3.1 Maximum safe temperature rise

The maximum patient tissue temperature rise shall not exceed 6 °C when the dispersive electrode carries a current of 700 milliamperes (mA) under the test conditions below, unless the device is labeled in accordance with 4.1.4.2. For devices labeled according to 4.1.4.2, the maximum patient tissue temperature rise shall not exceed 6 °C when the dispersive electrode carries a current of 500 mA under the test conditions below.

Compliance with this requirement may be optionally demonstrated by compliance with 4.2.8.2.3 or as follows:

These tests must be conducted on human volunteers or on a suitably structured surrogate medium. The temperature measurement method must have an overall accuracy of better than 0.5 °C and a spatial resolution of at least one sample per square centimeter of the electrode thermal pattern. The thermal pattern must include the area extending 1 cm beyond the geometry of the electrode under test. Spatial correlation from data of two images used to form a delta T determination must be within ± 1.0 cm. The measurement apparatus must scan the entire electrode thermal pattern in less than 15 seconds after cessation of the 700 mA current. The preapplication electrode temperature must be 23 ± 2 °C.

The electrode under test is to carry a current from an electrosurgical generator of 700 mA_{rms} (+10, –0 %) for 60 seconds, unless the device is labeled in accordance with 4.1.4.2, in which case the test current may be 500 mA (+10, –0 %). The test current is to be delivered by an electrosurgical generator set in the pure cut mode and must be attained within 5 seconds of the beginning of the test. The electrode must rest on the skin for 30 minutes before the application of the current. The maximum temperature rise must not exceed 6 °C. These tests must be performed a minimum of four times on each human subject or surrogate medium.

If the tests are conducted on human volunteers, the pool of subjects must consist of at least five males and five females. When human volunteers are used, the tester must include a variety of body types in the sample group rather than concentrate on a single body type (thin, average, or thick layers of subcutaneous body fat). If surrogate media are used, the tester must demonstrate that the media are electrically and thermally similar to human volunteers.

4.2.3.2 Electrode contact impedance

For conductive electrodes, the maximum electrode contact impedance shall not exceed 75 ohms over the frequency range of 200 kHz to 5 MHz when measured as described below. For capacitive electrodes, the minimum capacitance shall be no less than 4 nanofarads (0.004 microfarads) when measured as described below.

Compliance is verified as follows:

The contact impedance is measured by placing the dispersive electrode under test at some convenient site on a human volunteer, in accordance with the manufacturer's instructions. The test must be conducted at a current of 200 mA_{rms} and at frequencies between 200 kHz and 5 MHz. To determine the contact impedance, the rms potential difference between the point of connection of the electrode cable to the dispersive electrode and a reference point located outside of the primary current field is divided by the rms total electrode current.

NOTE—The reference electrode for the potential measurement must be essentially noncurrent carrying (the voltmeter must have an input impedance greater than 2 kilohms at the frequency of measurement).

In the example shown in Figure 1, the electrode under test was placed on the thigh, and the potential reference electrode consisted of an electrocardiogram (ECG) monitoring electrode placed on the calf muscle (out of the primary current field).

The test must be repeated for at least 10 randomly chosen electrodes applied to human volunteers.

Electrode contact impedance may also be measured by placing the dispersive electrode under test on a rigid metal plate larger than the electrode contact area. The test current and frequencies are the same as those specified above. In this case, the rms potential difference to be divided by the rms total electrode current is the difference measured between the point of connection of the electrode cable to the dispersive electrode and a point on the metal plate. This alternative method may be used for all capacitively coupled dispersive electrodes. The value of electrode capacitance, *C*, can be determined from the following formula:

$$C = \frac{I_{rms}}{(2\pi f \times V_{rms})}$$

where:

I is the current in amperes,

f is the frequency of the test current, and

V is the voltage in volts.

Either of the two methods may be used for conductive electrodes, but if in the second method the calculated contact impedance exceeds 50 ohms, then the electrode must be evaluated using the human volunteer test described above.

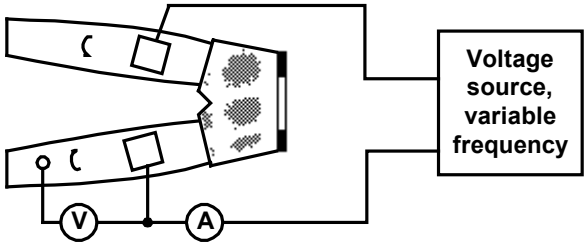


Figure 1—Test setup for measuring electrode contact impedance

4.2.3.3 Electrode adherence

For electrodes that are adhesively attached to the patient, no separation between the electrode adhesive region and underlying skin shall occur (beyond that allowed below) when the electrodes are subjected to the tests below.

NOTE—Electrodes designed to be used as part of a contact quality monitoring system do not have to comply with the requirements in this section.

Compliance is verified as follows:

NOTE—For electrodes intended for use on infants, the following tests may be performed on adult volunteers.

a) *Pull test.* The electrode under test is to be applied to a convenient location on at least 20 human volunteers (at least 10 males and 10 females). At least two electrodes are to be placed on each subject, following the application instructions provided by the manufacturer. These electrodes must be allowed to set for no less than 5 minutes and no more than 10 minutes. For electrodes intended for use on adult patients, each electrode is to be subjected to a force of 10 N directed along each of two orthogonal axes in a plane parallel to the skin surface at the point of cable-electrode connection. At least one of the axes shall consist of the minor dimension of the electrode at that point. For electrodes intended for use on infant patients, each electrode is to be subjected to a force of 5 N, directed as described above. In at least 90 % of the tests, no more than 5 % of the electrode adhesive area shall separate from the skin surface after 10 minutes of applied force on each axis.

b) *Conformability test.* The dispersive electrodes are applied to at least 10 human subjects (at least 5 males and 5 females) at an approximately cylindrical site (e.g., an extremity), the circumference of which is between 1.0 and 1.25 times the total length of the major axis of the electrode, with the major axis of the electrode encircling the site (i.e., parallel to the circumference of the site). No more than 10 % of the adhesive area of the electrode shall separate from the skin surface within 1 hour of the application.

NOTE—The conformability test is not required of electrodes that are not recommended for this kind of application site.

c) *Fluid tolerance test.* The dispersive electrodes are placed on at least 10 human subjects (5 males and 5 females). The appropriate connector is connected to the dispersive electrode if the electrode is intended for use with a reusable cable. One liter of normal saline is poured from a height of 30 cm directly over the dispersive electrode in a period of time not to exceed 15 seconds but not less than 5 seconds. During and for a period of 15 minutes following the completion of this test, no more than 10 % of the adhesive area of the electrode shall separate from the skin surface.

4.2.3.4 Packaging and shelf life

Single-use electrodes shall be manufactured and packaged in such a way that the requirements of 4.2.3.1 through 4.2.3.3 will be met for the specified shelf life or for a minimum of 5 years after the date of manufacture if no shelf life is specified.

Compliance can be verified by conducting the tests of 4.2.3.1 through 4.2.3.3 at the end of the specified shelf life or, if no shelf life is given, after 5 years from the date of manufacture.

4.2.4 Switches

Devices must meet the applicable requirements of IEC 60601-2-2, clauses 46, 56.11, and 56.101.

4.2.5 Cables and accessories

The requirements of 4.2.5.1 and 4.2.5.2 apply to all cables and accessories, except those with a shield that is grounded during normal operation.

4.2.5.1 Dielectric withstand, 60 Hz

The insulation of high frequency cables intended for use with electrosurgical generators shall be capable of withstanding a low frequency test voltage of 3,000 V_{rms} at 60 Hz for 5 minutes after immersion in water for 12 hours immediately prior to the test.

Compliance is verified as follows:

The cable under test—except for portions of the cable within 10 cm of attached accessories or connectors—is immersed in water for at least 12 hours. Then, with an adjustable high voltage source attached between the conductor or conductors and a metal electrode in the water, the voltage is uniformly raised from 0 V to 3,000 V_{rms} at 60 Hz in no less than 10 seconds and no more than 60 seconds, and maintained for 5 minutes unless breakdown occurs first.

4.2.5.2 High frequency leakage current

The high frequency leakage current of monopolar cables and flexible monopolar catheters intended for use with electrosurgical generators shall not exceed 3.6 *dfL* mA, where *d* is the smallest outer dimension of the cable including insulation in millimeters (mm), *f* is the test frequency in megahertz, and *L* is the length of the cable or catheter in centimeters. The corresponding leakage current for bipolar cables, or catheters and dispersive electrode cables, shall not exceed 7.2 *dfL* mA. The applied voltage for these tests shall be 800 V_{p-p} at a test frequency in the range of 0.3 MHz to 1.0 MHz.

Compliance is verified as follows:

With the entire test apparatus shown in Figure 2 placed on an insulated table top (preferably wood), the vessel is filled with normal saline solution so 30 cm of a properly constrained cable will be immersed in the solution.

Starting approximately 30 cm from the proximal end of the cable under test, a 30 cm section of the cable is marked off. The cable is constrained in the saline fixture so that the 30 cm section is parallel to the fixture's central rod and the saline level passes through the 30 cm marks. Any electrode that may be inserted in the device under test should be removed, and the excess cable should be coiled near the base of the saline fixture. The apparatus is connected as shown in Figure 2. Test lead lengths are not to exceed 1 m. For multiconductor cables, all conductors are connected in parallel. The voltage source is adjusted for a sinusoidal signal, and the output is slowly increased from 0 V to 800 V_{p-p} at the manufacturer's specified frequency (not to exceed 1 MHz). The measured leakage current must not exceed the limits above. (See annex B for a suitable test setup.)

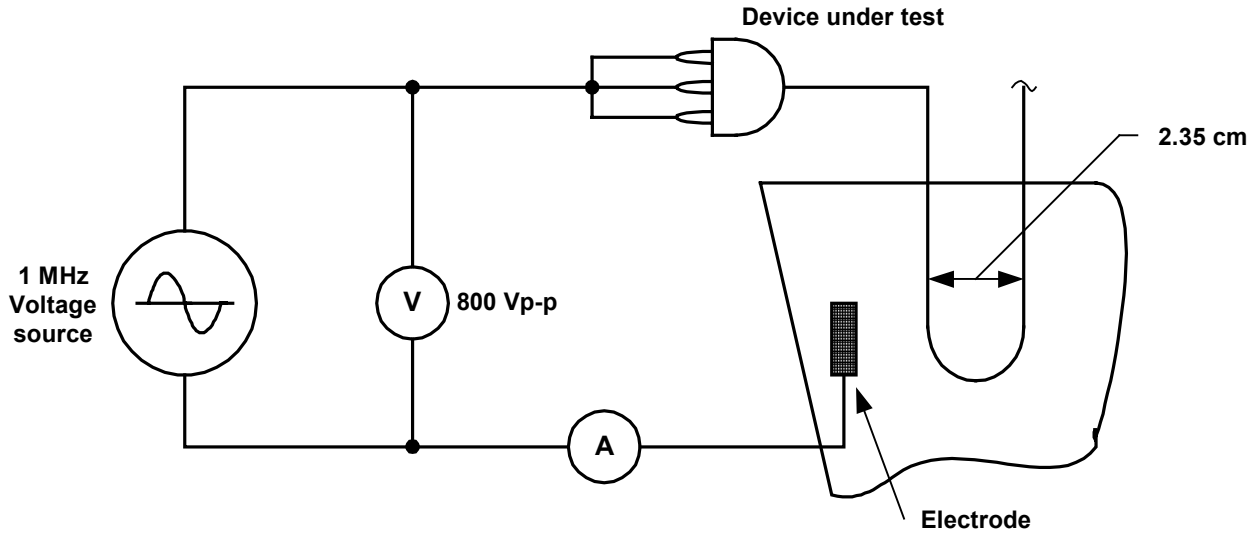


Figure 2—Test setup for measuring high frequency leakage current of cables

4.2.5.3 Sterilization of reusable accessories

Any accessory or cable claimed by the manufacturer to be reusable and sterilizable shall be capable of withstanding 20 sterilization cycles according to the method of sterilization specified by the manufacturer. All sterilized accessories and cables shall meet the requirements of 4.2.5.1, 4.2.5.2, and 4.2.5.4 after 20 manufacturer-specified sterilization cycles. If the manufacturer does not specify a sterilization method, then saturated steam at 134 °C shall be applied for 20 minutes for each sterilization cycle.

Compliance is verified as follows:

All cables and accessories claimed by the manufacturer to be reusable and sterilizable must meet the requirements of 4.2.5.1, 4.2.5.2, and 4.2.5.4 after 20 sterilization cycles conducted according to the manufacturer's recommendations in the instructions for use. If the manufacturer does not specify a sterilization method, then saturated steam at 134 °C is applied for 20 minutes for each sterilization cycle.

4.2.5.4 Dielectric withstand of accessories

The insulated hand-held portions (including active electrode shafts) for endoscopic, laparoscopic, and other types of accessories (excluding cables) of monopolar active accessories, whether or not they are specified for reuse, shall be capable of withstanding, without breakdown or damage, 3,000 V_{rms} at mains frequency (1,500 V_{rms} for gastroenterological accessories) and 1.5 times the maximum specified high frequency voltage rating at the specified frequency.

The insulated hand-held portions (including active electrode shafts) for endoscopic, laparoscopic, and other types of accessories (excluding cables) of bipolar accessories, whether or not they are specified for reuse, shall be capable of withstanding, without breakdown or damage, 1,500 V_{rms} at mains frequency and 1.5 times the maximum specified high frequency voltage rating at the specified frequency.

Compliance is verified as follows:

The following procedure is conducted with the device under test wrapped in conductive material and placed on a metal plate. A high frequency dielectric strength test is then performed using a 1:1.5 (or greater) step-up transformer connected from an electrosurgical generator to the device under test.

The test shall be conducted according to the following procedure:

a) If the device is reusable, it shall be sterilized according to 4.2.5.3.

b) Remove any electrode tip that is designed to be removable.

c) Place a flat, smooth, metal plate or sheet, whose dimensions extend beyond the ends of the accessory by at least 2.5 cm in all directions, on an insulated tabletop (preferably wood).

d) Wrap the device with a damp 0.9 (normal) saline-soaked cloth and position it as close to the center of the metal plate as possible. Material other than 0.9 (normal) saline-soaked cloth can be used as long as it makes effective electrical contact with the entire body of the device without producing edge effects that can occur with aluminum foil. Nonremovable active electrode tips may be insulated to prevent inadvertent arc discharge from the tip to the metal plate or sheet; this added insulation shall have a thickness not greater than 1 mm, nor may it cover more than a 2 mm length of the shaft insulation.

e) For multiconductor cables, connect all conductors in parallel (see Figure C.1).

f) For general monopolar accessories and urological accessories, apply 3,000 V_{rms} at mains frequency between the radio frequency (RF) conductor of the accessory and the metal plate for 60 seconds, unless breakdown occurs sooner. For gastroenterological accessories and bipolar accessories, use 1,500 V_{rms} at mains frequency (see Figure C.2). The trip current for the high potential (high pot) tester should be set at a nominal 1 mA. The voltage ramp-up rate for the high pot tester shall be 500 V per second.

g) Now disconnect the device from the high pot tester. Connect the primary of a 1:1.5 (or greater) step-up transformer to the output terminals of the electrosurgical unit (ESU). Connect the device and the metal plate to the secondary of the transformer. (See annex C for an example of the test setup.)

h) Adjust the generator to produce an output voltage waveform that is 1.5 times the specified high frequency voltage rating (at the specified frequency) of the device. Apply the signal for 30 seconds. If it is necessary to reduce capacitive loading of the generator to achieve the specified test voltage, the insulation may be tested successively in smaller sections until the required area has been tested.

i) After completing this test, the equipment shall show no evidence of dielectric breakdown or other obvious damage. Dielectric breakdown is evident from either the high pot tester tripping, a flash caused by arcing to the 0.9 (normal) saline cloth, or a rapid decrease in the p-p voltage during the test.

j) Immediately after this dielectric strength test, any incorporated finger switch shall be operated 10 times while connected directly to the generator. The output shall become de-energized each time the switch is released.

4.2.5.5 Cable strain relief

Cables and their connections shall be capable of withstanding, without failure, mechanical stress from a steady pull of 40 N and from an impulse of 0.64 joules.

Compliance is verified as follows:

With the electrosurgical accessory or connector held firmly in place, a force gauge is attached to the cable. The pull shall be applied in the most unfavorable direction. The pull is increased uniformly to 40 N over 10 seconds. The pull is maintained for an additional 10 seconds and then released. The cable fails the test if it separates from the connectors or terminations during any phase of the test.

With the electrosurgical accessory or connector held firmly in place, a mass is attached to the cable, positioned near the portion of the accessory that is held firmly in place. The mass is dropped from a height sufficient to produce a 0.64 joule impulse (e.g., a mass of 0.26 kg falling a distance of 25 cm). The mass is dropped from this height three times. The cables are examined for obvious damage and retested for proper functioning of the accessory (e.g., proper operation of the cut and coag switches on a handswitchable active electrode).

4.2.6 Connectors

Devices must meet the requirements of IEC 60601-2-2, clauses 46.106 and 56.3.

In addition, no connector on the electrosurgical generator shall accept any accessory supplied by the manufacturer for that generator unless it is an accessory intended for use with that connector or unless an erroneous connection would not be hazardous.

4.2.7 Indicators and alarms

Devices must meet the requirements of IEC 60601-2-2, clauses 6.3, 6.7, 59.101, and 59.102.

4.2.8 Safety

4.2.8.1 Generators

Generators must meet the requirements of IEC 60601-2-2, clause 59.101.

4.2.8.2 Contact quality monitor

NOTE—This section applies to monopolar mode only.

4.2.8.2.1 Any electrosurgical generator that uses a contact quality monitoring system to evaluate the quality of the contact of the dispersive electrode with the patient will be identified as such.

Compliance can be verified by inspection.

4.2.8.2.2 Activation of the contact quality monitor alarm shall de-energize the output. The condition causing the contact quality monitoring system to alarm must be resolved before the electrosurgical generator can be re-energized as defined in the user manual.

Compliance can be verified as follows:

The generator equipped with the contact quality monitor will be used in the idle (nonactive) mode for evaluation. The return dispersive electrode will be placed on a test subject's thigh and connected to the generator. The return dispersive electrode will be gradually removed from the test subject until the contact quality monitor (CQM) alarm is triggered. The generator will be keyed while it is in the alarm condition to verify that there is no output. The dispersive electrode shall be reapplied to the test subject to verify that the contact quality monitor resets. Two tests per test subject will be performed: removing the electrode in the axis parallel to the split between the two conductors, and then removing the electrode in the axis perpendicular to the split between the two conductors. The test will be performed on at least 5 male and 5 female subjects.

4.2.8.2.3 Where a manufacturer has made specific claim of compatibility between the dispersive electrode and the contact quality monitoring system of the generator, the conditions of subclause 4.2.3.1 shall be met with the split dispersive electrode peeled back to the point of alarm for the contact quality monitoring system of that specific generator.

Compliance can be verified as follows:

A generator equipped with the contact quality monitor for which compatibility is to be demonstrated will be used for evaluation. The return dispersive electrode for which compatibility is to be demonstrated will be placed on the anterior thigh of a human test subject and connected to the generator. The return dispersive electrode will be gradually peeled back from the test subject until the point at which an alarm would sound in actual use under the test conditions as stated in 4.2.3.1. The surface area of the return dispersive electrode remaining in contact with skin of the test subject at the point of alarm will be sufficient to meet the terms of 4.2.3.1. Two tests per test subject will be performed, with one test being done by peeling the dispersive electrode in a direction that is perpendicular with the split between the two conductors and the other test being done by peeling the dispersive electrode in a direction that

is parallel with the split between the two conductors. This test will be performed on at least 5 male and 5 female test subjects.

4.2.8.3 Defibrillator protection

An electrosurgical generator designated as defibrillator proof shall be capable of meeting the tests below.

Compliance can be verified as follows:

(See Figure 3.) With capacitor C1 charged to 2 kV, switch S1 is operated so that a high voltage pulse is developed across R1. The voltage across R1 is applied between the dispersive electrode connection and the conductive enclosure of the device under test, which is connected to common electrical ground. (A device having an insulated enclosure must be placed on a metal surface whose area is at least equal to that of the base of the device under test. The metal plate must be connected to common electrical ground.)

The test is repeated with a pulse of reverse polarity. The device under test must be capable of meeting all other requirements and tests of this standard at the conclusion of the defibrillator protection tests.

NOTE—For electrosurgical units with insulated enclosures, the device must be placed on a metal surface connected to a common electrical ground.

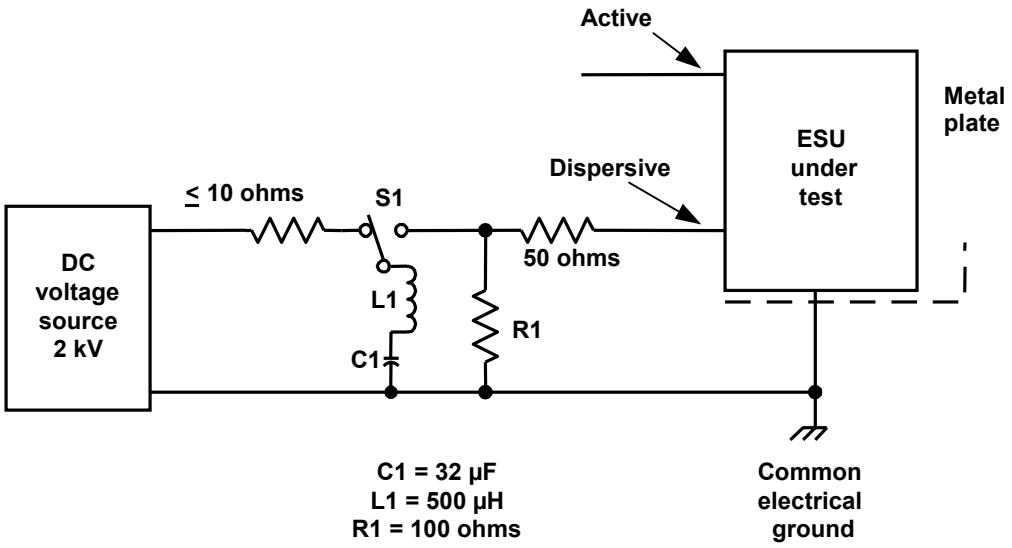


Figure 3—Test setup for assessing defibrillator protection

4.2.9 Low frequency risk current

Generators must meet the requirements of IEC 60601-2-2, clauses 13 through 19.

4.2.10 High frequency leakage current

Generators must meet the requirements of IEC 60601-2-2, subclause 19.3.101.

4.3 Environmental performance

4.3.1 Voltages

The electrosurgical unit shall meet all performance requirements of this standard and conform to the technical specifications supplied by the manufacturer over a voltage range of at least 104 to 127 V_{rms}. Furthermore, the device shall not be damaged by voltages in the range of 95 to 135 V_{rms}.

Compliance is verified as follows:

The equipment is connected to the rated load and operated at the maximum power control setting for a period of 5 seconds, first with an input of 95 V_{rms} applied and then with 135 V_{rms}. At the conclusion of the procedure, the device is checked for damage or failure to conform to the other requirements of this standard.

4.3.2 Output open circuited, short circuited

Generators must meet the requirements of IEC 601-2-2, clause 52.101.

4.3.3 Output control setting accuracy

See 4.4.

4.3.4 Shipping temperatures

Electrosurgical devices and their accessories shall maintain the safety and performance characteristics specified by this standard after exposure while in their normal shipping containers to shipping temperatures between –34 °C (–29 °F) and 65 °C (149 °F).

Compliance is verified as follows:

Starting at room temperature (the ambient temperature at which the device is stored in its normal shipping container), the temperature is lowered to –34 °C (–29 °F). This temperature is maintained for 4 hours. The temperature is then returned to room temperature, and the device is allowed to stabilize. After the device has stabilized, the storage temperature is increased to 65 °C (149 °F) and maintained for 4 hours. The storage temperature is then returned to room temperature, and the device is allowed to stabilize. After 1 hour at the stabilized temperature, the device is tested to show compliance with the relevant portions of 4.2, 4.3, and 4.4 of this standard.

4.3.5 Operating conditions

Unless other limitations are specified by the manufacturer, electrosurgical devices and their accessories, when set up in the normal operating configuration, shall maintain the safety and performance characteristics specified by this standard during operation over the following ranges of environmental conditions, individually or in any combination:

a) a temperature range of 10 °C (50 °F) to 30 °C (86 °F);

b) a range in humidity of 15 % to 80 % (noncondensing).

Compliance is verified as follows:

The manufacturer must determine the worst-case combination of the limits of the conditions stipulated above. The device is set up in its normal operating configuration and subjected to these worst-case conditions for 1 hour. While still operating under these conditions, the generator is tested according to 4.4, and the dispersive electrodes are tested in accordance with 4.2.3.2 and 4.2.3.3.

4.3.6 Mechanical shock

Unpackaged electrosurgical devices and their accessories must meet the requirements of this standard after being subjected to the tests in the relevant sections of IEC 60601-1, clauses 21.5 and 21.6.

4.4 Accuracy of performance specifications

The accuracy of performance specifications for electrosurgical generators shall meet the requirements of IEC 60601-2-2 clauses 50 and 51. In addition, the tolerance for maximum open circuit peak voltages shall be +0, –30 %.

5 Tests

Each subclause of clause 4 includes test methods and procedures by which compliance of the device with the requirements of clause 4 can be verified. It is not intended or required that each referee test (or its equivalent) be conducted on all devices during the manufacturing process. Although these referee tests (or their equivalents) may be suitable for design qualification, they are not necessarily intended or suitable for quality assurance purposes.

All measurements and tests, unless indicated otherwise, shall be made at the following standard ambient conditions:

- Temperature: 23 °C ± 4 °C (73 °F ± 7 °F)
- Relative humidity: No greater than 80 %
- Voltage: Nominal supply voltage ± 2 %
- Line frequency: 60 ± 2 Hz

5.1 Accuracy of instruments and test apparatus

The accuracy of instruments used to measure the test conditions and of the equipment used in performing the tests shall be verified within 12 months before the tests. All instruments and test equipment shall:

a) be appropriate for measuring the test parameter;

b) have an accuracy of at least one-third of the tolerance for the variable to be measured;

c) conform to laboratory standards whose calibration, where possible, is traceable to the primary standards at the National Institute of Standards and Technology (NIST).

Specifications for test equipment. The resistance of nonreactive resistors shall be within ± 2 % of the stated value. The reactance at frequencies under measurement shall not exceed 15 % of the resistance. Radio frequency ammeters shall be rms indicating with a time constant not to exceed 1 second and a tolerance not to exceed 5 % of full scale. Humidity indicators shall have a tolerance not to exceed 5 % of full scale.

5.2 General procedures for the tests

Where applicable, these procedures shall be followed:

a) When the requirements call for tests in all modes and the electrosurgical generator has variable control of the degree of blended electrosurgical currents, tests in the blended mode shall be performed by setting the blended control to yield the maximum output power.

b) Load resistances shall be nonreactive resistors meeting the requirements stated above.

c) Sufficient time shall elapse between activations to allow the generator to stabilize so that data is not affected by previous activations.

d) Electrosurgical current is to be recorded from 3 to 4 seconds following activation.

e) Required connections to a common electrical ground shall be made to a point or terminal on the electrosurgical generator chassis or enclosure in direct electrical continuity with or as close as practical to the place where a grounding connector in the power cord would be connected to the chassis.

f) All high frequency electrical tests shall be performed on an insulating surface at least 20 cm from all conducting planes, unless noted otherwise.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This annex explains the need for the standard and the rationale for each of its provisions.

In October 1976, the Emergency Care Research Institute (ECRI) submitted to the Food and Drug Administration (FDA) the "Proposed Standard for Performance and Safety of Electrosurgical Devices," which had been developed under contract with the FDA's Bureau of Medical Devices (now the Center for Devices and Radiological Health). This standard was the result of a 12-month study undertaken by ECRI to determine those device characteristics that should and could be addressed by a standard to increase the safety of electrosurgical units and to help ensure the reliability of their performance. The final report of this study was issued in March 1977 and is available from the National Technical Information Service (order No. PB 265 893, NTIS, 5285 Port Royal Road, Springfield, VA 22261). The study report and proposed standard contain recommended labeling, safety, and performance criteria for electrosurgical devices and an extensive bibliography of medical literature references.

In 1979, using the ECRI report as a point of departure, the Association for the Advancement of Medical Instrumentation (AAMI) began to develop, at the FDA's request, a voluntary consensus standard for electrosurgical devices. This work was undertaken by the AAMI High Frequency Therapeutic Device Committee, with the objective of producing an American National Standard.

The provisions of the first edition of this standard were based largely on the findings of the ECRI study, but relevant standards then under development by the International Electrotechnical Commission (IEC) were also taken into consideration.

In June 1991, the AAMI High Frequency Therapeutic Device Committee was reactivated to address new electrosurgical safety issues and to revise the standard to align it, where feasible, with international standards. The committee aligned with IEC 601 wherever possible and added additional requirements in response to technological improvements and information contained in ECRI accident reports.

In June 1994, the AAMI High Frequency Therapeutic Device Committee began a review of the standard and ultimately decided on a major alignment with the newly released IEC 60601-2-2 (3ed.) standard.

In revising this standard, the AAMI High Frequency Therapeutic Device Committee strived to make the document more comprehensive in its scope, incorporating new technologies and related safety issues.

A.2 Need for the standard

Electrosurgical procedures are changing at a very rapid pace. The development of new accessories and procedures has increased the types of operations that can be performed with electrosurgery, benefiting the medical world. Accompanying the new devices are new risks.

This standard is intended to align with IEC standards for electrosurgical devices and to ensure uniform measurement, testing, and evaluation of "new" technologies. A standard means of evaluation of all types of electrosurgical systems will reduce risks overall.

A.3 Definitions

For the purposes of this standard, the definitions given in section 3 apply. This section has been reformatted to more closely resemble the corresponding section of IEC 60601-2-2 (3ed.).

A.4 Rationale for the specific provisions of this standard

A.4.1 Labeling requirements

A.4.1.1 Device markings

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.1.2 Generator operator's manual

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.1.3 Service manual

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.1.4 Dispersive electrodes

The requirements of 4.1.4 are intended to ensure that adequate information for the safe and effective use of dispersive electrodes will be available to the clinician. See also A.4.2.3.1 and A.4.2.3.2.

A.4.1.5 Reusable accessory cables

Reusable cables can deteriorate after multiple uses and resterilizations. It is important that the user have information on proper sterilization techniques to prolong the useful life of the cable and ensure its continued safe performance. Electrical discontinuities in the cable—which can cause arcing in the patient-return or active circuit and, hence, patient burns or a fire hazard—may not be apparent during visual inspection; therefore, the user should be advised of functional tests that can be performed to verify the safety of the cable.

A.4.2 Performance and safety

A.4.2.1 Mechanical construction

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.2 Electrical construction

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.3 Dispersive electrodes

A.4.2.3.1 Maximum safe temperature rise

The purpose of the dispersive electrode in monopolar electrosurgical procedures is to reliably conduct the required surgical current with minimal rise in skin temperature. A safe and effective dispersive electrode must accomplish this purpose while minimizing the portion of the total surgical current in return pathways other than the dispersive electrode. Measurements with heated metallic blocks (Moritz and Henriques, 1947) and with small circular electrodes carrying electrosurgical current (Pearce, et al., 1983) show that the maximum safe skin temperature for short-term and long-term exposure is 45 °C. Normal resting skin temperature varies between about 29 °C and 33 °C, depending on room temperature and humidity. Electrodes that create temperature increases approaching 12 °C cannot be considered safe. However, 6 °C represents a conservative safety factor of two and a maximum allowable temperature rise for an acceptable dispersive electrode. No acceptable electrode should exceed the 6 °C temperature rise when subjected to the required current and duration test.

Human volunteer subjects are the reference standard. To date, no adequate surrogate medium has been either suggested or used that has all of the properties of human tissue for the purpose of determining electrode performance. If a surrogate medium is used, the tester must demonstrate the equivalence of the test medium to human tissue.

Because electrosurgical burns may be confined to very small areas, the qualification measurement must have an adequate spatial sampling frequency to ensure that unacceptable electrodes will always be detected. The requirement for one sample per square centimeter is a minimum. Current technology provides for many more samples per square centimeter. However, because noise in the thermal detector can cause individual pixels to appear superheated, a statistical averaging technique should be used to determine the temperature rise within any single square centimeter area. The initial temperature of electrodes applied to human skin must be the same in all tests so that all results will be comparable.

Cutting and coagulating currents are normally delivered in repetitive short bursts of varying amplitude and duration. Maximum currents and duration of activation depend on the individual technique used and on the type of surgical procedure. The test of 4.2.3.1 is intended to simulate the worst-case single activation, with a considerable safety factor. Two sources of information were used to estimate the likely current and duration maxima.

A 1973 article in *Health Devices* presented data in terms of the average currents, voltages, impedances, and minute duty cycles over all procedures studied (ECRI, 1973). The unpublished data of Milligan and associates was presented in terms of the maximum, minimum, and average currents and durations for each procedure studied; this data can be used to estimate population variations. In both studies, it was found that the highest currents and longest durations were found in transurethral resection procedures.

For TUR procedures, the ECRI study showed an average current of 680 mA (for cutting) and 480 mA (for coagulation) with minute duty cycles of 15 % (average) and 45 % (maximum). Milligan and associates studied a smaller sample, 25 TUR procedures, under 13 surgeons using five electrosurgical units at eight hospitals; the reported data for all TUR procedures are summarized in Table A.1 (averages and standard deviations are calculated over the 25 cases). This data provides useful estimates of the means and variance in measured currents and durations.

Table A.1—Summary of measured currents and durations for transurethral resection procedures

	Average	Standard deviation
Length of surgery (hours)	0.86	0.49
Number of activations (per hour)	225	105
Cutting current		
Maximum current during procedure (mA)	407	297
Average current during procedure (mA)	297	200
Maximum duration (seconds)	3.8	2.3
Average duration (seconds)	2.1	0.7
Coagulating current		
Maximum current (mA)	339	130
Average current (mA)	258	88
Maximum duration (seconds)	5.7	7.6
Average duration (seconds)	2.0	0.7

The total energy dissipated at the dispersive electrode is given by the formula:

$$E = I^2 Rt$$

where:

E is energy dissipated (joules),

I is root-mean-squared (rms) electrode current (amperes),

t is the duration of current flow (seconds), and

R is the real part of the impedance at the electrode site (ohms).

The impedance, *R*, is not generally definable, because its value depends on the electrode design and the anatomical structure of the tissue to which it is applied. A “heating factor” (HF) may be defined to describe the “stress” placed on a dispersive electrode: $HF = I^2 t$ (A^2 seconds). This heating factor has the significance of energy dissipated per ohm of impedance.

Dispersive electrodes should be able to handle heating factors representative of surgical procedures. A current of 700 mA applied for 60 seconds yields a heating factor of 30 A^2 seconds. This value is far in excess of the maximum likely current and duration for a TUR procedure. The maximum likely value can be found by multiplying the largest likely current—0.68 A from ECRI (1973) data (average) plus one standard deviation (i.e., 0.2 A from the Milligan data)—squared by the maximum likely duration—5.0 seconds (average) plus one standard deviation (i.e., 7.6 seconds from the Milligan data)—to get a heating factor of 8.7. Thus, 30 A^2 seconds is a conservative test criterion.

A similarly conservative test criterion can be derived for dispersive electrodes designed for use on infants. Because TUR procedures are not performed on infants, a reasonable approach is to use the current and duration data available for general surgical procedures. This data, reported by Pearce, et al. (1981), is given in Table A.2.

Table A.2—Summary of measured currents and durations for general surgical procedures

	Average	Standard deviation
Length of surgery (hours)	1.56	0.84
Number of activations (per hour)	63	84
Cutting current		
Maximum current during procedure (mA)	340	101
Average current during procedure (mA)	281	147
Maximum duration (seconds)	7.6	11
Average duration (seconds)	2.2	1.8
Coagulating current		
Maximum current (mA)	267	157
Average current (mA)	198	114
Maximum duration (seconds)	11	7.5
Average duration (seconds)	6.5	5.2

Using the data for general surgery and multiplying the square of the maximum likely current plus one standard deviation by the maximum likely duration plus one standard deviation yields a value of 4.7 for the heating factor. Thus, a value of 15 A^2 seconds is a conservative test criterion and is readily obtained using a current of 500 mA applied for 60 seconds.

At one time, this standard included a long-term test and the short-term test described above. The long-term test was deleted because the short-term test was found to be consistently more severe; the long-term test, therefore, did not provide any additional useful information about device performance.

A.4.2.3.2 Electrode contact impedance

The contact impedance must be low enough that the dispersive electrode represents the preferred current pathway. In the case of ground-referenced electrosurgical generators, this will minimize the possibility of alternate return current paths other than the dispersive electrode. A value of 75 ohms is judged an acceptable maximum contact impedance for the *conductive* electrodes. Because the impedance of *capacitive* electrodes varies as the inverse of the frequency, it is appropriate to describe their impedance characteristics in terms of capacitance. A value of 4 nanofarads was specified as the minimum acceptable capacitance because it is consistent with the characteristics of the majority of capacitive electrodes that have been commercially available for many years and found to be clinically acceptable.

The test current of 200 mA represents the low limit of average currents from the two studies cited above. Tissue-electrode impedance generally increases as the electrode current decreases, making the lower limit preferable. The frequency range of 200 kHz to 5 MHz is believed to encompass the range over which existing generators develop significant energy levels.

A.4.2.3.3 Electrode adherence

After application, dispersive electrodes should remain in place when subjected to stresses that may occur during customary use as a result of the site chosen for placement, inadvertent pulling, or accidental contact with preparatory solutions or physiologic fluids. 4.2.3.3(a) specifies different pull forces for electrodes intended for use on adults versus those intended for use on infants because the latter devices are designed to accommodate the fragile skin of infants and, thus, cannot be expected to adhere as firmly as electrodes intended for adults.

A.4.2.3.4 Packaging and shelf life

Devices should be safe and effective for their specified shelf life. Inventories held by the user are likely to be depleted within 5 years.

A.4.2.4 Switches

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.5 Cables and accessories

A.4.2.5.1 Dielectric withstand, 60 Hz

This requirement is intended to ensure adequate dielectric strength to reduce electrical breakdown or excessive leakage that would produce burns in the patient.

A.4.2.5.2 High frequency leakage current

Several premises underlie the original leakage current requirement and the latest revisions:

a) Insulation leakage current densities must be kept below the recognized burn threshold of 100 mA/cm^2 for 10 seconds.

b) The cable designs in general use at this writing are acceptable, because virtually no injuries have been attributed to these designs.

c) A laboratory equipment-based test yields repeatable results.

d) Although many manufacturers are moving toward lower frequencies in electrosurgical units, some higher frequency models are on the market, necessitating compensation for frequency in the calculation of the acceptable limit.

e) Catheters whose insulation touches patient surfaces have similar risks of burns as extension wires and are, therefore, included in this revision of the standard.

The limits were developed in conjunction with the test apparatus of annex B. The 1 MHz maximum operating frequency and the 800 $V_{p\text{-}p}$ applied voltage constitute a reasonable margin between the test limits and the performance of present-day cables, while maintaining a considerable margin between the test limits and that which would produce current densities of 100 mA/cm^2. The 1 MHz maximum test frequency is normalized to represent a reasonable median frequency and maintains constant limits with previous editions of this standard. The 800 $V_{p\text{-}p}$ level was selected as a value that represents a reasonable electrosurgical operating level (160 watts into 500 ohms).

All of the selected values in combination (N = 3.16, f = 1.0 MHz, V = 800 $V_{p\text{-}p}$) permit an equivalent current density of 11.46 mA/cm^2, which is nearly an order of magnitude below the recognized burn threshold of 100 mA/cm^2 for 10 seconds. Therefore, while it may be argued that the levels of one or more of the factors may be higher under extreme clinical conditions, the safety margin built into the requirements is judged to be sufficient.

The cables of dispersive electrodes are allowed twice the leakage of active cables, because the voltage levels developed between the conductors of such cables and the patient's skin are generally much lower than those of active cables. Bipolar accessories are allowed twice the leakage of monopolar cables because the voltage of use is generally much lower than monopolar.

A.4.2.5.3 Sterilization of reusable accessories

This requirement is intended to ensure that repeated sterilizations will not degrade the electrical and mechanical properties of cables and electrodes.

A.4.2.5.4 Dielectric withstand of accessories

These requirements are designed to minimize the shock and burn hazard to the operator and the patient. The mains frequency test is compatible with IEC requirements, whereas the high frequency test subjects the device to a combination of high voltage and high frequency that more nearly simulates clinical conditions. Bipolar devices are subjected to lower levels corresponding to clinical conditions.

A.4.2.5.5 Cable strain relief

Cables and their connections or connectors usually undergo stresses in a clinical setting. These stresses can result either from a steady pull or from someone tripping over the cable. The requirement minimizes the possibility of an accessory failing to operate properly or creating a burn under typical conditions of use.

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.6 Connectors

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

Some combinations of accessories and output jacks can be hazardous (e.g., connection of a bipolar forceps to a monopolar output connector). The requirement of 4.2.6 precludes such hazardous configurations within a single manufacturer's product line.

A.4.2.7 Indicators and alarms

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.8 Safety

A.4.2.8.1 Generators

In 1999, reference was made to the appropriate section of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.8.2 Contact quality monitor

The tests for contact quality monitoring systems were included to identify critical points in systems that are already being marketed or that are in development. The intent was not to increase pad size or system complexity but, rather, to define what parameters the systems on the market have and what values of those parameters promote safety.

A.4.2.8.2.3 By definition, the function of a contact quality monitor is to quantitatively measure the contact between the dispersive electrode and the patient. For any generator with a CQM system, this means that the manufacturer has designed a system that specifically relates in a fixed, numerical fashion the measurement of one or more variables with a certain amount of dispersive electrode contact and has defined a critical level or levels for those variables at which an alarm should sound. The language of the previous revision of this standard was written with an assumption that all CQM systems could accurately be tested in the standby mode, and this assumption is no longer valid. The language of this clause makes this distinction irrelevant and requires that the testing be performed at the alarm point that would occur under the conditions of 4.2.3.1. In this way, the testing required will be directly linked to the actual design of that particular CQM system as it was intended to perform in actual use, without the need to specify either a mode of use or variables that are specific to a single brand of generator. In addition, this language should be broadly applicable to any new CQM system designs which may be developed in the future.

A.4.2.8.3 Defibrillator protection

Any device for which defibrillator protection is claimed must pass the designated test, which is consistent with the test specified by the IEC.

A.4.2.9 Low frequency risk current

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.2.10 High frequency leakage current

Rationale for the requirements of this section may be found in appendix AA of IEC 60601-2-2 (3ed.).

A.4.3 Environmental performance

Electrosurgical devices may be exposed to extremes of temperature, humidity, and atmospheric pressure during shipment and storage. Because this kind of exposure is often unavoidable, the device should be designed and manufactured to maintain its accuracy under adverse environmental conditions. No electromedical device, however, is totally invulnerable to all conceivable environmental extremes. This standard attempts to provide assurance of device performance over defined ranges of temperature, humidity, and input voltages and frequencies. In addition,

the device is required to withstand defined shock conditions without degradation of performance. These requirements were chosen to encompass the conditions that the device could reasonably be expected to tolerate.

A.4.3.1 Voltages

The environmental conditions specified are similar to those expected under worst-case operating conditions. The device must perform at voltages deviating from the device's nominal rated voltage. The voltage range specified (104 V to 127 V_{rms}) is derived from ANSI C84.1, *Electric power systems and equipment—Voltage ratings (60 Hz)* (normative reference 2.1). ECRI conducted a study in which line voltages were recorded continuously to determine typical variability in line voltages. In more than 10,000 recording hours, voltages of less than 108 V were observed less than 1 % of the time (17 hours); no voltages greater than 129 volts were observed (ECRI, 1979). Although power crises could create very unusual line voltages, the committee felt that a required voltage range of 104 V to 127 V_{rms} was consistent with the ECRI data and would present a rigorous challenge to electrosurgical devices. Including normative reference 2.1 by reference was considered to be the best way to ensure that the line voltage requirements of the AAMI electrosurgical standard would be appropriately updated over time.

A.4.3.2 Output open circuited/output short circuited

Short periods of open circuit operation during equipment use are common. Short circuited output is possible but not common. Thus, for reliable and effective performance, electrosurgical devices are required by this standard to be capable of withstanding at least the specified conditions, which are consistent with IEC standards.

A.4.3.4 Storage and shipping temperatures

Based on substantial documentation, ECRI's final report (ECRI, 1979) proposed that all mobile and portable medical devices be capable of withstanding storage and shipping temperatures in the range of –34 °C (–29 °F) to 65 °C (149 °F). This range was adopted by the AAMI committee.

In 1999, the committee decided to modify the requirement to apply to shipping only and to remove the requirement for extended (or unlimited) storage at the listed temperatures.

A.4.3.5 Operating conditions

The range of operating conditions recommended in this standard was chosen to reflect the environmental conditions likely to be encountered in practice. The recommendations of ECRI (1979) were followed to the extent practicable.

A.4.3.6 Mechanical shock

This requirement was developed to help ensure that electrosurgical devices can withstand a reasonable level of mechanical abuse during use. Because electrosurgical devices are fragile, the user is, to a great extent, responsible for handling the device properly; however, the committee did judge that the device should be capable of withstanding at least a moderate drop test.

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

A.4.4 Accuracy of performance specifications

In 1999, reference was made to the appropriate sections of the IEC standard to eliminate redundancy that existed in the past and to maximize harmonization. Please consult the IEC standard for additional rationale.

Annex B
(informative)

An example of a test setup for measuring the high frequency leakage current of cables

B.1 Introduction

This annex defines a specific test apparatus suitable for use in performing the tests of 4.2.5.2 of the standard.

B.2 Equipment list

Refer to Figures B.1–B.4.

a) Signal generator. Any laboratory-quality generator with a 50-ohm output impedance that is capable of generating the prescribed waveform.

b) 50-ohm coax.

c) 50-ohm terminator.

d) Power amplifier. Transformer T1 may require redesign to accommodate other amplifiers. General amplifier requirements for the circuit shown in Figure B.1 are as follows:

   1) frequency range: 300 kHz to 3 MHz (minimum);

   2) output power: approximately 175 watts into 50 ohms;

   3) load: reactive.

e) Transformer T1.

f) Oscilloscope. Any scope capable of making the differential voltage measurement. (Float the scope chassis off ground.)

g) RF milliammeter. Any 4-1/2 inch thermocouple-type RF milliammeter or equivalent may be used.

h) 0.9 (normal) saline fixture. Fixture designs other than the one shown will yield equivalent results provided that 30 cm of cable are immersed, the diameter of the capstan is maintained, and the cable under test is kept parallel to the conductive rod.

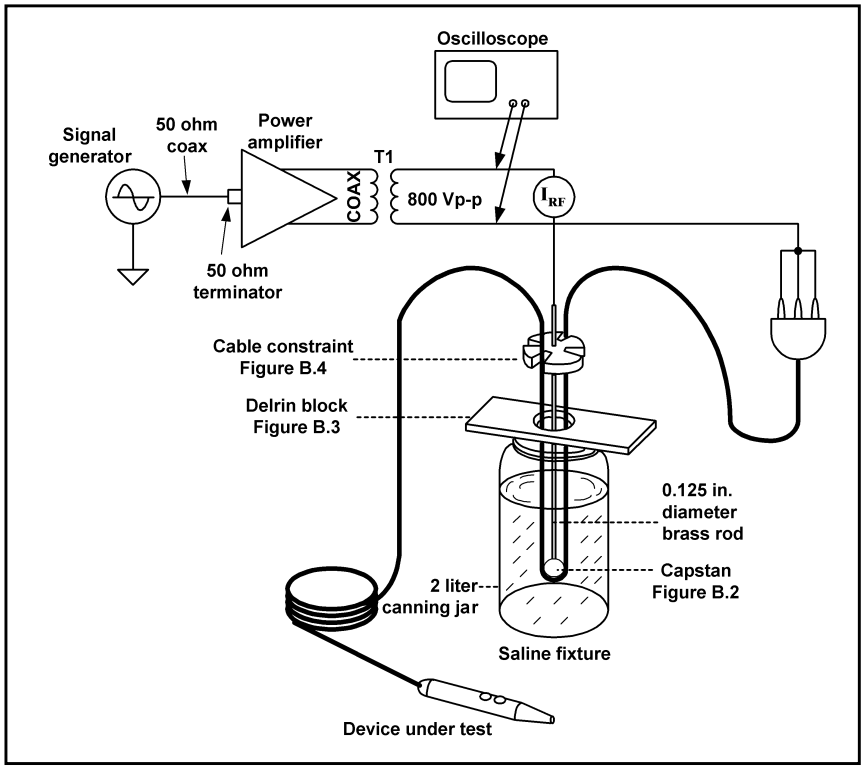


Figure B.1—Test setup for measuring high frequency leakage current of cables

NOTE—No ground connection is to be made between the scope and the test circuit. Other voltage measurement techniques may be used if their accuracy under these conditions can be verified and the applied voltage and leakage current are unaffected by reverse connection of the voltage monitoring leads. Because the power amplifier is a very-high-gain device, care must be taken in the placement of leads connected to the amplifier's input and output to avoid oscillations.

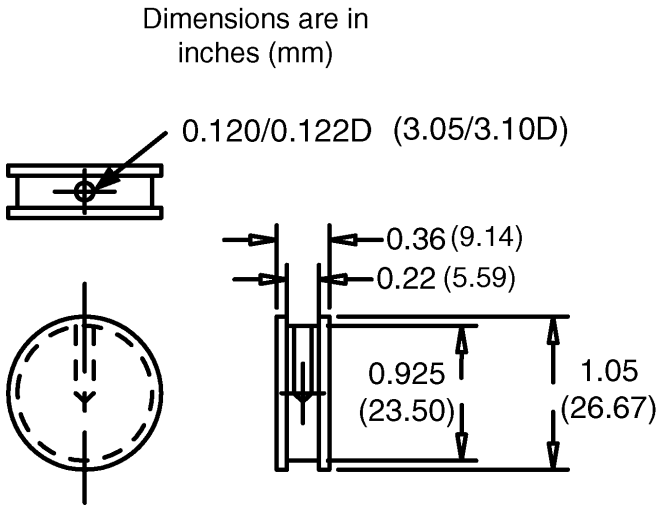
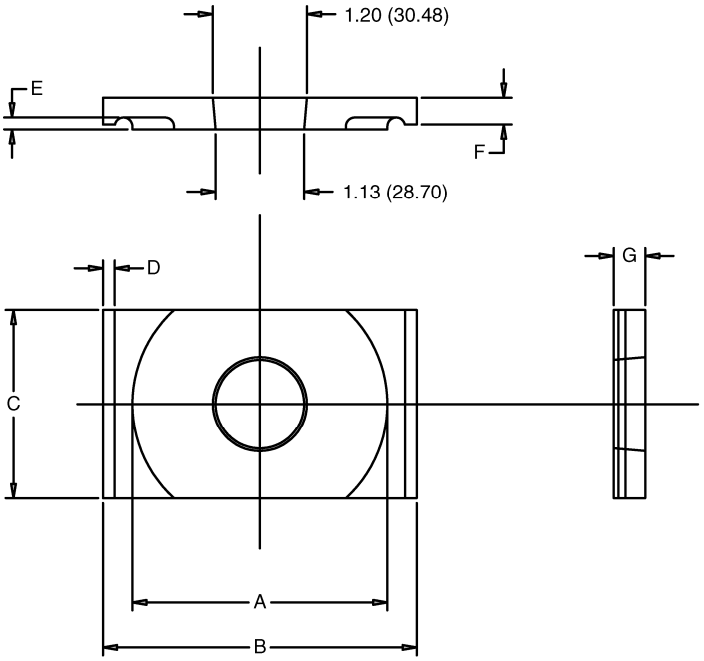


Figure B.2—Capstan, saline fixture; Material: Delrin or equivalent

NOTE—The only critical dimensions are the 0.925 and 0.120/0.122 diameters.



FOR 2 LITER JAR

DIMENSION DESIGNATOR	NOMINAL DIM. FOR 2 LITER JAR
A	3.25 (82.55)
B	4.0 (101.6)
C	2.4 (61)
D	0.15 (3.81)
E	0.15 (3.81)
F	0.34 (8.64)
G	0.40 (10.16)

Dimensions are in inches (mm)

Figure B.3—Delrin block, saline fixture; Material: Delrin or equivalent

NOTE—The only critical dimensions are those of the tapered hole. They must be compatible with the tapered cable restraint. Dimensions A through G are not critical. They must be compatible with the saline vessel used. Dimensions for a 2-liter canning jar are shown in the table.

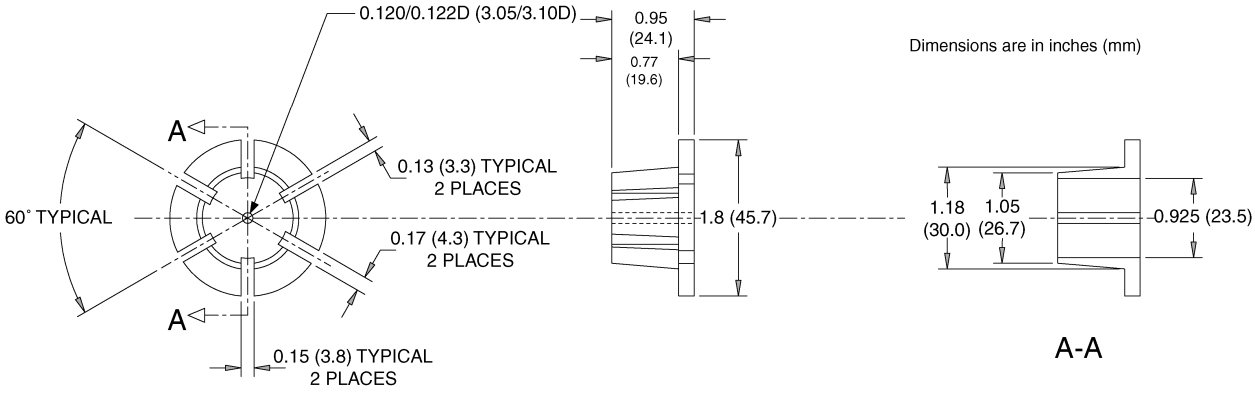


Figure B.4—Cable constraint, saline fixture; Material: Delrin or equivalent

NOTE—The most significant dimensions are the 0.925 diameter of the notch bottoms, and the center hole diameter. Other dimensions may be modified considerably, provided that compatibility with the Delrin block is maintained.

Annex C
(informative)

An example of a dielectric withstand test for accessory cables

C.1 Introduction

This annex defines a test apparatus suitable for use in performing the tests required by 4.2.5.4.

C.2 Equipment list

The following equipment is needed:

a) standard electrosurgical unit;

b) 0.9 (normal) saline-soaked cloth;

c) high voltage probe;

d) transformer T1 (1:1.5 or greater IEC test transformer);

e) oscilloscope;

f) high pot tester.

C.3 Test setup

The test setup is shown in Figures C.1 and C.2.

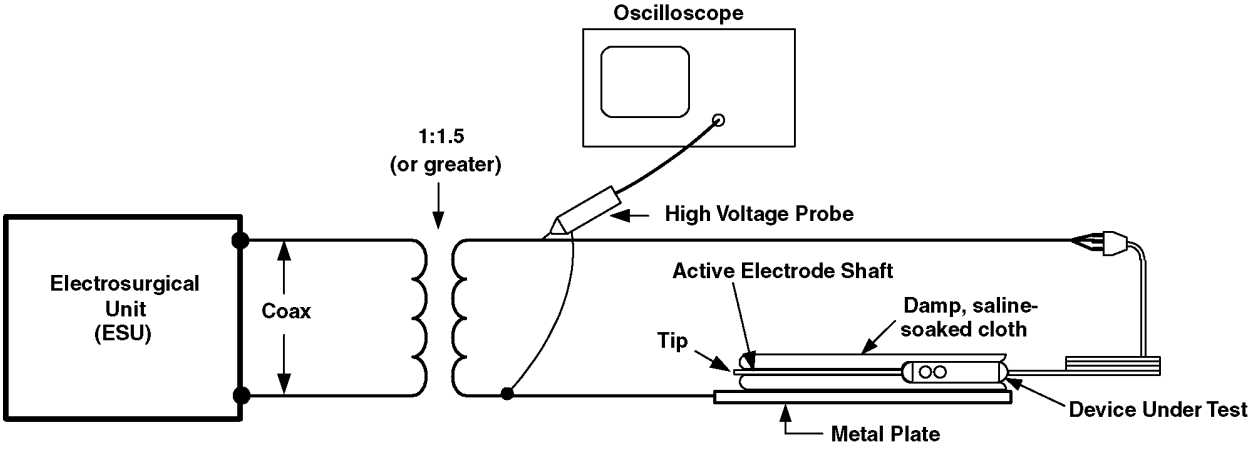


Figure C.1—H.F. dielectric withstand test setup

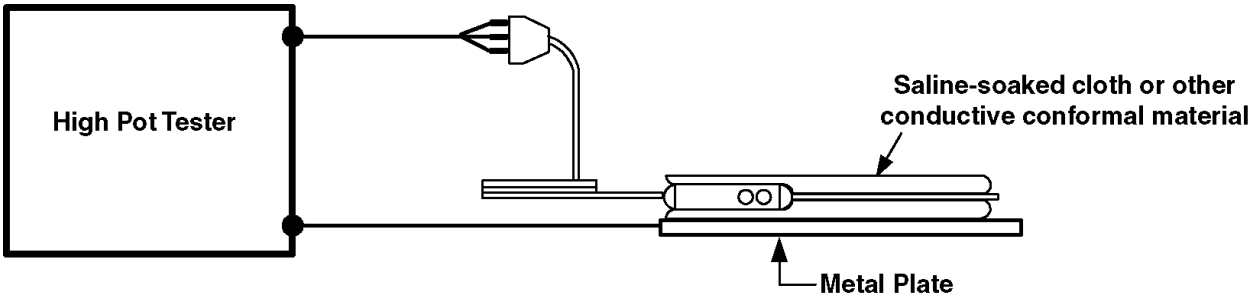


Figure C.2—Mains frequency dielectric withstand test setup

Annex D
(informative)

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