

American National Standard

ANSI/AAMI HF18:2001

Electrosurgical devices

AAMI

Association for the
Advancement of Medical
Instrumentation



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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.

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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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Electrosurgical devices

Developed by
Association for the Advancement of Medical Instrumentation

CORRECTED VERSION

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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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Committee representation

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:

<i>Chair:</i>	Jeffrey L. Eggleston
<i>Members:</i>	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
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	David Zieve, TUV Product Service, Inc.
<i>Alternates:</i>	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.