NORME INTERNATIONALE

INTERNATIONAL STANDARD

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Quatrième édition
Fourth edition
2006-07

Appareils électromédicaux –

Partie 2-2: Exigences particulières pour la sécurité des appareils d'électrochirurgie à courant haute fréquence

Medical electrical equipment –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

FOREWORD

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International Standard IEC 60601-2-2 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition of IEC 60601-2-2 cancels and replaces the third edition published in 1998, of which it constitutes a technical revision.

Significant revisions in this fourth edition refer mainly to the following:

– revision of requirements and compliance testing for HF SURGICAL ACCESSORIES to make them independent of specific HF surgical generators;
– revision and expansion of Cause 2 definitions;
– addition of thermal, electrical and adhesive requirements testing for NEUTRAL ELECTRODES;

– revision of dielectric strength requirements for HF SURGICAL ACCESSORIES;

– accommodation of HF surgical generators that don't require continuous operation of the SWITCH SENSOR;

– addition of Annex BB to provide EMD information about HF SURGICAL EQUIPMENT.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/548/FDIS	62D/560/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This Particular Standard amends and supplements IEC 60601-1:1998 (second edition) *Medical Electrical Equipment – Part 1: General requirements for safety*, modified by Amendment 1 and Amendment 2, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.[1)]

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;

– *test specifications, headings of subclauses and headings of items: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

1) A third edition of IEC 60601-1 was published in 2005, incorporating significant structural modifications. Future editions of this Part 2-2 will be based on the latest edition of Part 1 and any amendments.

INTRODUCTION

This fourth edition represents an extensive revision of the previous edition. It is being released as a new edition to improve readability and usage. It was felt that the breadth of the technical changes, and the improved safety that they will provide, were too important to wait for the harmonization effort with the new edition of the General Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of HIGH FREQUENCY SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES used in medical practice, as defined in 2.1.110 and hereinafter referred to as HF SURGICAL EQUIPMENT.

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this Particular Standard. These exemptions are indicated in the relevant requirements.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of HF SURGICAL EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety,*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests*
Amendment 1 (2004)

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*
Amendment 1 (1999)

For brevity, IEC 60601-1 is referred to, in this Particular Standard, either as the “General Standard” or as the “General Requirement(s)”, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-1-4 as the Collateral Standard(s).

The term "this Standard" covers the Particular Standard used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk *. These rationales can be found in an informative Annex AA. Annex AA should be used in determining the relevance of the requirements addressed but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standards applies without modification. Where it is intended that any part of the General Standard or Collateral Standards, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard, replacing or modifying requirements of the General Standard or Collateral Standards, takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

2.1.101
ACTIVE ACCESSORY
HF SURGICAL ACCESSORY intended for manipulation by the OPERATOR to produce surgical effects at the intended site on the PATIENT, generally comprising an ACTIVE HANDLE, active cord, ACTIVE CONNECTOR and ACTIVE ELECTRODE

2.1.102
ACTIVE CONNECTOR
part of an ACTIVE ACCESSORY intended for connection to an ACTIVE OUTPUT TERMINAL, which may include additional terminals for connection of a FINGERSWITCH to a SWITCH SENSOR

2.1.103
ACTIVE ELECTRODE
part of an ACTIVE ACCESSORY extending from the ACTIVE HANDLE to the surgical site

2.1.104
ACTIVE HANDLE
part of an ACTIVE ACCESSORY intended to be held by the OPERATOR

***2.1.105**
ASSOCIATED EQUIPMENT
EQUIPMENT other than HF SURGICAL EQUIPMENT that may be electrically connected to the PATIENT CIRCUIT and not intended for independent use

2.1.106
BIPOLAR ELECTRODE
assembly of two or more ACTIVE ELECTRODES on the same support, so constructed that, when energized, the HF current flows mainly between these two electrodes

2.1.107
CONTACT QUALITY MONITOR
CQM
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to a MONITORING NE providing an alarm in the event that NE contact with the PATIENT becomes insufficient

NOTE A CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE.

2.1.108
ENDOSCOPICALLY USED ACCESSORY
an accessory, which may be the APPLIED PART of MEDICAL ELECTRICAL EQUIPMENT that is not ENDOSCOPIC EQUIPMENT, introduced into a patient through the same orifice in the PATIENT as the ENDOSCOPE

[IEC 60601-2-18, definition 2.1.102]

2.1.109
FINGERSWITCH
device generally included with an ACTIVE ACCESSORY which, when manipulated by the OPERATOR, enables HF output to be produced and, when released disables HF output

NOTE Requirements for similar switches intended to perform functions other than activation of HF output are under consideration.

2.1.110
HF SURGICAL ACCESSORY
ACCESSORY intended to conduct, supplement or monitor HF energy applied to the PATIENT from HF SURGICAL EQUIPMENT

NOTE HF SURGICAL ACCESSORIES include HF surgical application electrodes, including cords and connectors for attachment to HF SURGICAL EQUIPMENT, as well as other ASSOCIATED EQUIPMENT intended for connection to the HF surgical PATIENT CIRCUIT.

2.1.111
MONITORING NE
NEUTRAL ELECTRODE (NE) intended for use with a CONTACT QUALITY MONITOR

NOTE A CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE.

2.1.112
NE CONTINUITY MONITOR
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an NE, except MONITORING NE, providing an alarm in the event of electrical discontinuity in the NE cable or its connections

NOTE An NE CONTINUITY MONITOR is intended for use only with NEs other than MONITORING NEs.

2.1.113
NEUTRAL ELECTRODE
NE
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

NOTE The NEUTRAL ELECTRODE is also known as plate, plate electrode, passive, return or dispersive electrode.

2.1.114
SWITCH SENSOR
part of HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT which controls activation of HF output in response to operation of a connected FINGERSWITCH or footswitch

***2.2.101**
HF SURGICAL EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT including its associated ACCESSORIES intended for the performance of surgical operations, such as the CUTTING or COAGULATION of biological tissue by means of HIGH FREQUENCY (HF) currents

2.3.101
ACTIVE ELECTRODE INSULATION
electrical insulation material affixed to part of an ACTIVE ELECTRODE intended to prevent unintended injury to the OPERATOR or adjacent PATIENT tissue

***2.4.101**
MAXIMUM OUTPUT VOLTAGE
for each available HF SURGICAL MODE, the magnitude of the maximum possible peak HF output voltage appearing between PATIENT CIRCUIT connections

2.4.102
RATED ACCESSORY VOLTAGE
MAXIMUM OUTPUT VOLTAGE which may be applied to a MONOPOLAR HF SURGICAL ACCESSORY with respect to an NE connected to the PATIENT. For a BIPOLAR HF SURGICAL ACCESSORY, the MAXIMUM OUTPUT VOLTAGE which may be applied to pairs of opposite polarity

2.7.101
ACTIVE OUTPUT TERMINAL
part of HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an ACTIVE ACCESSORY and for delivery of HF current thereto

***2.12.101**
BIPOLAR
method of applying HF output current to a PATIENT via multiple-pole ACTIVE ELECTRODES

***2.12.102**
COAGULATION
use of HF current to elevate the temperature of tissue, e.g. to reduce or terminate undesired bleeding

NOTE COAGULATION may take the form of contact or non-contact COAGULATION.

***2.12.103**
CUTTING
resection or dissection of body tissue caused by the passage of HIGH FREQUENCY current of high current density at the ACTIVE ELECTRODE(S)

***2.12.104**
EARTH REFERENCED PATIENT CIRCUIT
PATIENT CIRCUIT which includes components, such as capacitors, installed to provide a low-impedance path to earth for HF currents

***2.12.105**
FULGURATION
form of COAGULATION using long (0,5 mm or more) electrical sparks to heat tissue surfaces superficially, with no intentional mechanical contact between the ACTIVE ELECTRODE and the tissue

2.12.106
HF ISOLATED PATIENT CIRCUIT
PATIENT CIRCUIT where there are no components installed to provide a low-impedance path to earth for HF currents

***2.12.107**
HF SURGICAL MODE
any of a number of OPERATOR selectable HF output characteristics intended to provide a specific indicated surgical effect at a connected ACTIVE ACCESSORY, such as CUTTING, COAGULATION and the like

NOTE Each available HF SURGICAL MODE may be provided with an OPERATOR adjustable output control to set the desired intensity or speed of the surgical effect.

***2.12.108**
HIGH FREQUENCY
HF
frequencies greater than 200 kHz

***2.12.109**
MONOPOLAR
method of applying HF output current to a PATIENT via an ACTIVE ELECTRODE and returning via a separately-connected NE or via the PATIENT'S body capacitance to earth

2.12.110
RATED LOAD
value of non-reactive load resistance connected to simulate the PATIENT that results in the maximum HF output power from each HF SURGICAL MODE of the HF SURGICAL EQUIPMENT

2.12.111
RATED OUTPUT POWER
for each HF SURGICAL MODE set at its maximum output setting, the power in watts produced when all ACTIVE OUTPUT TERMINALS which can be activated simultaneously are connected to a RATED LOAD

***2.12.112**
CREST FACTOR
dimensionless value equal to the peak output voltage divided by the r.m.s. voltage as measured at the output of HF SURGICAL EQUIPMENT in an open circuit condition

NOTE Specific information on the correct way to make the measurements needed to calculate this value may be found in Annex AA.

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Additional SINGLE FAULT CONDITIONS:

aa) failure in the NE CONTINUITY MONITOR or CONTACT QUALITY MONITOR which might cause a SAFETY HAZARD (see 59.101);

bb) a defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see 56.11);

cc) any defect which results in the unwanted energization of the PATIENT CIRCUIT (see 59.102);

dd) any defect which results in a significant increase in output power relative to the output setting (see 51.5).

4 General requirements for tests

This clause of the General Standard applies except as follows:

*4.7 Supply and test voltage, type of current, nature of supply, frequency

Add the following:

i) Particular care shall be taken to ensure accuracy and safety during measurement of HF output. See Annex AA for guidance.

5 Classification

This clause of the General Standard applies except as follows:

*5.2 According to the degree of protection against electric shock:

Amendment:

Delete TYPE B APPLIED PART.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

l) *Classification*

Addition:

The relevant symbols required for marking DEFIBRILLATION-PROOF APPLIED PARTS shall be attached to the front panel, but are not required on the APPLIED PARTS.

Connections on the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT for the connection of NE leads shall be marked with the following symbols:

IEC 1192/06

Figure 101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT

IEC 1193/06

Figure 102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT

NOTE These two symbols have been submitted to SC 3 for approval within IEC 60417.

* p) *Output*

This item of the General Standard does not apply.

*6.3 Marking of controls and instruments

Additional item:

aa) The output control shall have a scale and/or associated indicator showing the relative units of HIGH FREQUENCY output. The indication shall not be marked in watts unless the indicated power is delivered with an accuracy of ± 20 % over the total load resistance range specified in 6.8.3.
The numeral "0" shall not be used unless no HF power in excess of 10 mW is delivered from an ACTIVE or BIPOLAR ELECTRODE in this position.

NOTE The compliance test is the application of Clause 50.

*6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition:

Where certain functions are indicated by lights, these indicator lights shall have the following colours:

green: power supply switched on;

red: fault condition, for example in the PATIENT CIRCUIT;

yellow: CUTTING mode activated;

blue: COAGULATION mode activated.

Blue and yellow lights shall not be used simultaneously for 'blend' modes.

b) Colours of unilluminated push-buttons

Addition:

The colour shall be similar with the colour coding of that pushbutton of FINGERSWITCH or of that footswitch-pedal which is activated at this time.

NOTE Blended outputs are regarded as a CUTTING mode.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Additional items:

*aa) For HF SURGICAL EQUIPMENT, information concerning the selection and use of HF SURGICAL ACCESSORIES in order to avoid incompatibility and unsafe operation. (see also 56.103).

Advice for the OPERATOR to avoid HF output settings where MAXIMUM OUTPUT VOLTAGE, according to 6.8.2 ee), may exceed RATED ACCESSORY VOLTAGE.

Advice concerning selection of a MONITORING NE with respect to compatibility with the OPERATOR's available CONTACT QUALITY MONITOR.

*bb) Notes on the application of HF SURGICAL EQUIPMENT. These notes shall draw the attention of the OPERATOR to certain precautions which are necessary in order to reduce the risk of accidental burns. In particular, advice, when appropriate, shall be given on the following:

* 1) The entire area of the NEUTRAL ELECTRODE should be reliably attached to the PATIENT'S body and as close to the operating field as possible (see Notes 1 and 2).

* 2) The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.

* 3) Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze (see Notes 1 and 2).

* 4) When HF SURGICAL EQUIPMENT and physiological monitoring EQUIPMENT are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.

* 5) The cables to the surgical electrodes should be positioned in such a way that contact with the PATIENT or other leads is avoided.

Temporarily unused ACTIVE ELECTRODES should be stored in a location that is isolated from the PATIENT.

* 6) For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of BIPOLAR techniques may be desirable in order to avoid unwanted tissue damage.

7) The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a SAFETY HAZARD at low power settings. For example, with argon beam COAGULATION, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.

*8) Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power (see Notes 1 and 2).

9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.

10) For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.

11) For HF SURGICAL EQUIPMENT with an operating mode as described in 46.103 b), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use.

NOTE 1 This requirement does not apply for HF SURGICAL EQUIPMENT only incorporating BIPOLAR output.

NOTE 2 This requirement does not apply for HF SURGICAL EQUIPMENT intended for use without a NEUTRAL ELECTRODE.

cc) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic EQUIPMENT.

dd) Advice for the OPERATOR regularly to inspect the ACCESSORIES. In particular, electrode cables and ENDOSCOPICALLY USED ACCESSORIES should be checked for possible damage.

*ee) For ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES, including separately supplied parts thereof, the RATED ACCESSORY VOLTAGE.

*ff) For HF SURGICAL EQUIPMENT, the MAXIMUM OUTPUT VOLTAGE for each HF SURGICAL MODE and instruction regarding the RATED ACCESSORY VOLTAGE as follows:

i) For situations where the MAXIMUM OUTPUT VOLTAGE (U_{max}) is less than or equal to 1 600 V, provide instruction that ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES should be selected that have a RATED ACCESSORY VOLTAGE equal to or greater than the MAXIMUM OUTPUT VOLTAGE.

ii) For situations where the MAXIMUM OUTPUT VOLTAGE (U_{max}) is greater than 1 600 V, calculate the variable y using the formula:

$$y = \frac{U_{max} - 400\,[\text{Volts}]}{600\,[\text{Volts}]}$$

Take the smaller of variable y or the number 6. If the result is less than or equal to the CREST FACTOR for that HF SURGICAL MODE, then provide instruction that ASSOCIATED EQUIPMENT and ACTIVE accessories should be selected that have a RATED ACCESSORY VOLTAGE equal to or greater than the MAXIMUM OUTPUT VOLTAGE.

iii) For situations where the MAXIMUM OUTPUT VOLTAGE (U_{max}) is greater than 1 600 V, and the CREST FACTOR is less than the variable y calculated above, a warning shall be provided that any ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES used with such mode or setting must be rated to withstand the combination of actual voltage and CREST FACTOR.

Where the MAXIMUM OUTPUT VOLTAGE varies with the output setting, that information shall be presented diagrammatically as a function of output setting.

NOTE The establishment of HF dielectric strength classes in order to make it easier for the user to judge the suitability of accessories versus output settings is under consideration.

*gg) A warning that failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.

*hh) A statement of compatibility with specific MONITORING NE.

A warning that, unless a compatible MONITORING NE is used with a CONTACT QUALITY MONITOR, loss of safe contact between the NE and the patient will not result in an auditory alarm.

NOTE 1 This requirement does not apply for HF SURGICAL EQUIPMENT only incorporating BIPOLAR output.

NOTE 2 This requirement does not apply for HF SURGICAL EQUIPMENT intended for use without a NEUTRAL ELECTRODE.

ii) On end use packaging for NEUTRAL ELECTRODES:

- If marked for SINGLE use, an expiration date.
- Precautions necessary to prevent burns at the NE site, e.g. limitation of output setting and/or activation duration.
- If intended for use only on small PATIENTS, a marking in kg indicating the maximum PATIENT weight for which it is intended to be used. See 59.104.5

jj) On instructions for use for MONITORING NEUTRAL ELECTRODES:

- For MONITORING NEs, a statement of compatibility with specific CONTACT QUALITY MONITOR(s).

*kk) HF SURGICAL EQUIPMENT or HF SURGICAL ACCESSORIES intended for use where the applied patient current is expected to exceed 500 mA for over 2 min at applied duty cycles greater than 50 % shall be accompanied by instructions, warnings and cautions for the proper use of NEUTRAL ELECTRODES.

***6.8.3 Technical description**

Additional items:

**aa*) Power output data – MONOPOLAR output (for all HF SURGICAL MODES available, any variable "blend" control being set to the maximum position)

1. Diagrams showing the power output at full and half output control settings minimally over the range of load resistance 100 Ω to 2 000 Ω, but extended as necessary to include the RATED LOAD.

2. Diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above.

*bb) Power output data – BIPOLAR output (for all HF SURGICAL MODES as defined in item aa))

1. Diagrams showing the power output at full and half output control settings minimally over the range of load resistance 10 Ω to 1 000 Ω, but extended as necessary to include the RATED LOAD.

2. Diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above.

cc) Voltage output data – MONOPOLAR and BIPOLAR output (for all HF SURGICAL MODES available)

Maximum voltage data required by 6.8.2 ee).

*dd) Designation of the APPLIED PART(S) according to 19.3.101 of this Particular Standard.

Where HF SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE, this shall be stated. Where HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT is designed to have a single, fixed output setting, then reference to "half output control settings" shall be ignored.

7 Power input

This clause of the General Standard applies except as follows:

7.1

Amendment:

The operational settings shall be such that HF SURGICAL EQUIPMENT delivers the RATED OUTPUT POWER on all outputs which may be activated simultaneously.

HF SURGICAL EQUIPMENT shall be operated as specified in the test of 50.1.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

14 Requirements related to classification

This clause of the General Standard applies except as follows:

14.6 TYPES B, BF and CF APPLIED PARTS

Replacement:

The APPLIED PARTS of HF SURGICAL EQUIPMENT shall be TYPE BF or CF APPLIED PARTS.

17 Separation

This clause of the General Standard applies except as follows:

*17 h) Defibrillator protection

Amendment:

PATIENT CIRCUITS of HF SURGICAL EQUIPMENT shall be considered as APPLIED PARTS in the context of this subclause.

Compliance is checked by the common-mode test only, as described in item h) of 17 and in Figure 50 of the General Standard using a test voltage of 2 kV instead of 5 kV.

After this test, HF SURGICAL EQUIPMENT shall be capable of meeting all the requirements and tests of this Particular Standard and of performing its intended function as described in the ACCOMPANYING DOCUMENTS.

18 Protective earthing, functional earthing and potential equalization

This clause of the General Standard applies except as follows:

Additional item:

**aa)* Generally, a PROTECTIVE EARTH CONDUCTOR shall not carry functional current. However, in HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W and intended for use without a NEUTRAL ELECTRODE, the PROTECTIVE EARTH CONDUCTOR of the mains cord may be used as a return path for the functional HIGH FREQUENCY current.

*19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

19.1 General requirements

Item b)

Addition:

– With the HF output inoperative, but in such a way that the low-frequency LEAKAGE CURRENTS are not affected.

**Item g)*

Amendment:

These investigations shall be carried out with the HF SURGICAL EQUIPMENT switched on but with PATIENT CIRCUITS not activated.

19.2 SINGLE FAULT CONDITIONS

Item a)

Addition:

– the simulation of a defect in the output switching circuit resulting in an increase of PATIENT LEAKAGE CURRENT (see 56.11).

*19.3 Allowable values

Item a) and Table IV

Amendment:

PATIENT AUXILIARY CURRENTS associated with CONTACT QUALITY MONITORS shall not exceed the allowable values for TYPE BF.

Item b)

Amendment:

The 10 mA limit for LEAKAGE CURRENT does not apply to HF LEAKAGE CURRENTS tested from ACTIVE and NEUTRAL ELECTRODES with PATIENT CIRCUITS activated (see 19.3.101).

Additional subclause:

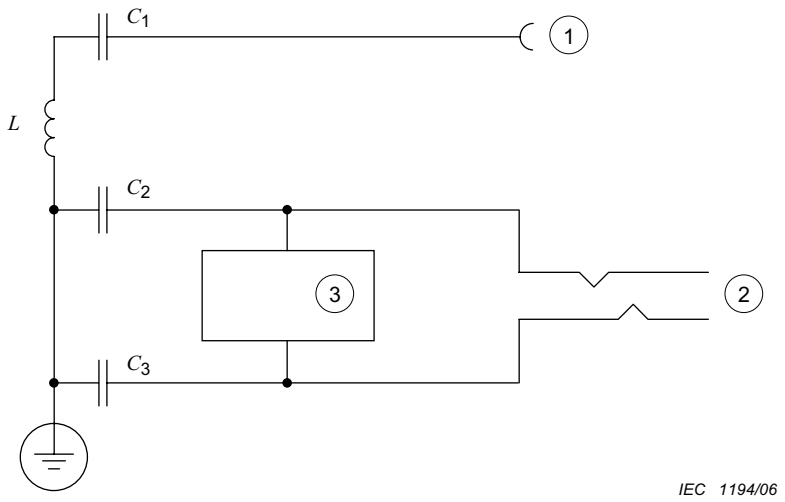
19.3.101 Thermal effects of HF LEAKAGE CURRENTS

In order to prevent unintended thermal burns, HF LEAKAGE CURRENTS tested from ACTIVE and NEUTRAL ELECTRODES with PATIENT CIRCUITS activated shall, depending on their design, comply with the following requirements.

*a) *HIGH FREQUENCY LEAKAGE CURRENTS*

1) *NEUTRAL ELECTRODE referenced to earth*

The PATIENT CIRCUIT is isolated from earth but the NEUTRAL ELECTRODE is referenced to earth at HIGH FREQUENCIES (see Figure 103) by components (for example a capacitor) satisfying the requirements of a TYPE BF APPLIED PART. When tested as described below, the HF LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE through a non-inductive 200 Ω resistor to earth shall not exceed 150 mA.



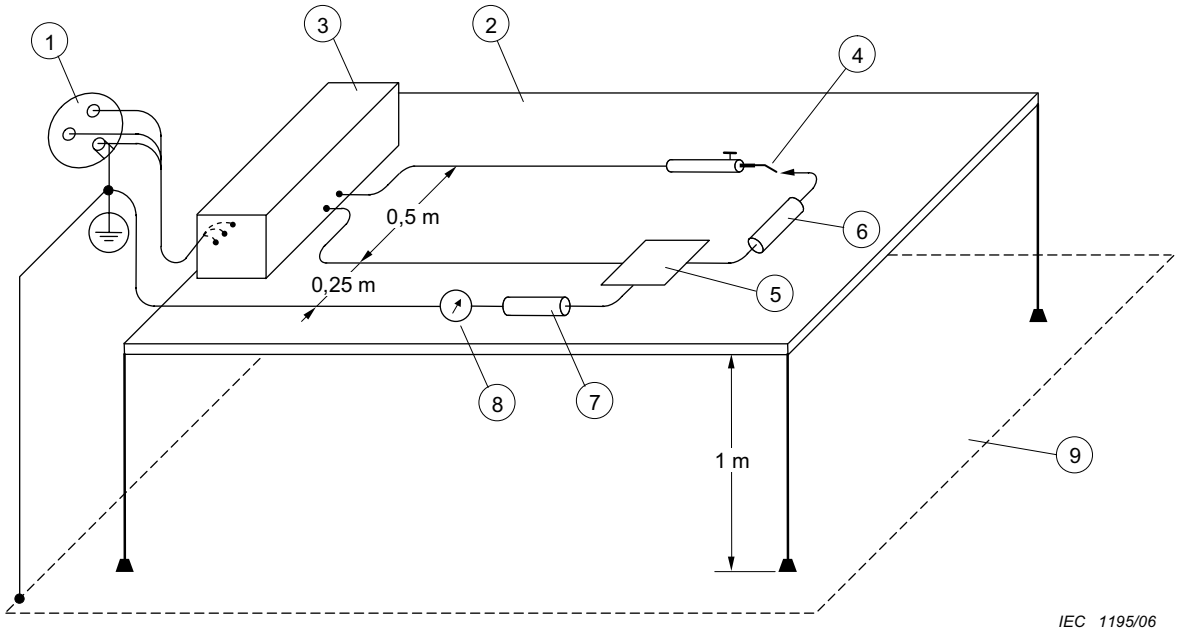
Key

1 Connector for ACTIVE ELECTRODE
2 Connector for NEUTRAL ELECTRODE
3 Monitor
C_1 not to exceed 0,005 µF
C_2 = C_3 not to exceed 0,025 µF
X_{C2} and X_{C3} at operating frequency each not to exceed 20 Ω
Z_L at 50 Hz not to exceed 1 Ω

Figure 103 – Example of PATIENT CIRCUIT with NEUTRAL ELECTRODE referenced to earth at operating frequencies (see 19.3.101 a) 1) and 59.105)

Compliance is checked by the following tests.

Test 1 – The test is performed on each single output of the HF SURGICAL EQUIPMENT in turn with the electrode cables and electrodes as shown in Figure 104. The cables are spaced 0,5 m apart on an insulating surface 1 m above an earthed conductive plane.



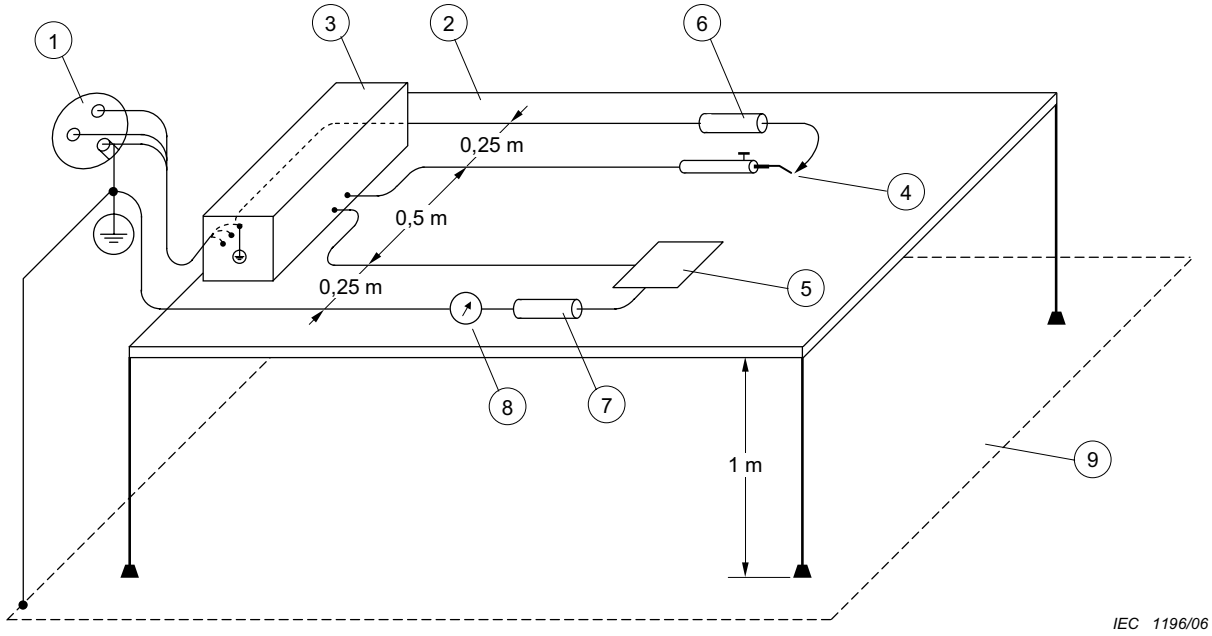
Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
4 ACTIVE ELECTRODE
5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
6 Load resistance, 200 Ω
7 Measuring resistance, 200 Ω
8 HF current meter
9 Earthed conductive plane

Figure 104 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load between electrodes (see test 1 of 19.3.101 a) 1))

The output is loaded with 200 Ω and the HF SURGICAL EQUIPMENT is operated at maximum output setting in each operating mode. The HF LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE through a non-inductive resistor of 200 Ω to earth is measured.

Test 2 – The HF SURGICAL EQUIPMENT is set up as for test 1, but the 200 Ω load resistor is connected between the ACTIVE ELECTRODE and the PROTECTIVE EARTH TERMINAL of the HF SURGICAL EQUIPMENT as shown in Figure 105. The HF LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE is measured.



Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
4 ACTIVE ELECTRODE
5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
6 Load resistance, 200 Ω
7 Measuring resistance, 200 Ω
8 HF current meter
9 Earthed conductive plane

Figure 105 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load from ACTIVE ELECTRODE to earth (see test 2 of 19.3.101 a) 1))

2) NEUTRAL ELECTRODE isolated from earth at HIGH FREQUENCY

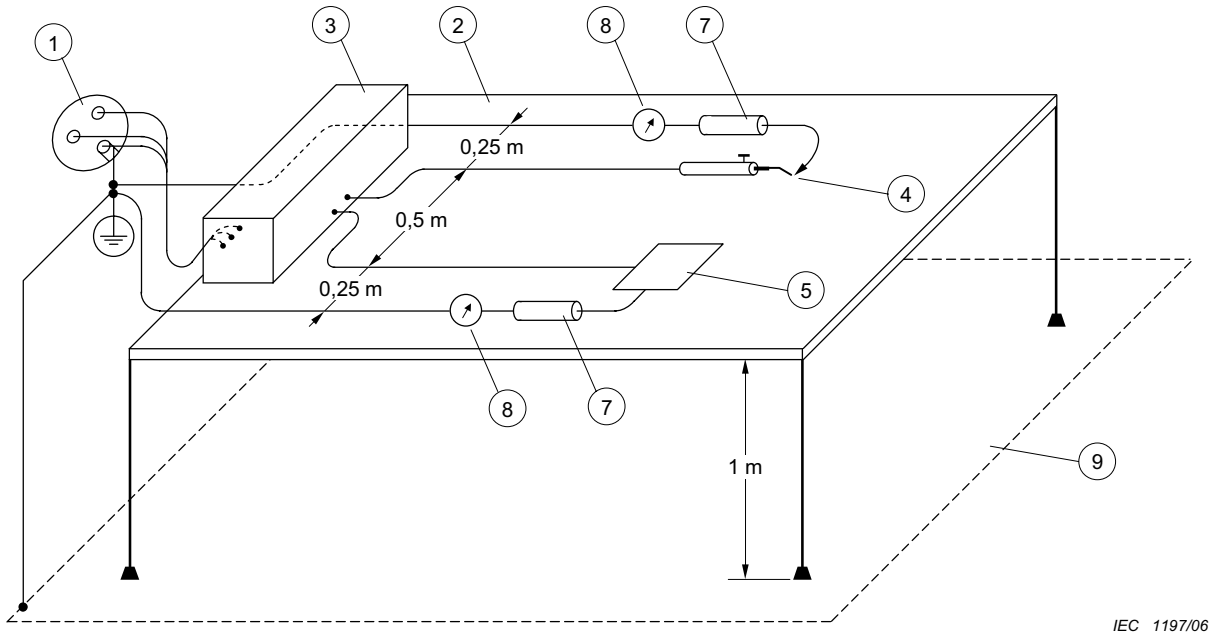
The PATIENT CIRCUIT is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as described for test 1 of 19.3.101 a) 1), the output being unloaded and loaded at the RATED LOAD*.*

Any metal ENCLOSURES of CLASS II HF SURGICAL EQUIPMENT and INTERNALLY POWERED HF SURGICAL EQUIPMENT shall be connected to earth. HF SURGICAL EQUIPMENT having an insulating ENCLOSURE shall be positioned on earthed metal having an area at least equal to that of the base of the HF SURGICAL EQUIPMENT, during this test (see Figure 106). The HF LEAKAGE CURRENT is measured from each electrode in turn while the HF SURGICAL EQUIPMENT is operated at maximum output setting in each HF SURGICAL MODE.

NOTE The above requirements do not apply for HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W and intended for use without a NEUTRAL ELECTRODE.



Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
4 ACTIVE ELECTRODE
5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
7 Measuring resistance, 200 Ω
8 HF current meter
9 Earthed conductive plane

Figure 106 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE isolated from earth at HIGH FREQUENCY (see 19.3.101 a) 2))

*3) *BIPOLAR application*

Any PATIENT CIRCUIT specifically designed for BIPOLAR application shall be isolated from earth and from other APPLIED PARTS at both high and low frequencies.

The HF LEAKAGE CURRENT flowing from either pole of the BIPOLAR output to earth and to the NEUTRAL ELECTRODE via a 200 Ω non-inductive resistor in each line shall not exceed the value which produces a power in a 200 Ω non-inductive resistor equal to 1 % of the maximum BIPOLAR RATED OUTPUT POWER, with all output controls set to maximum.

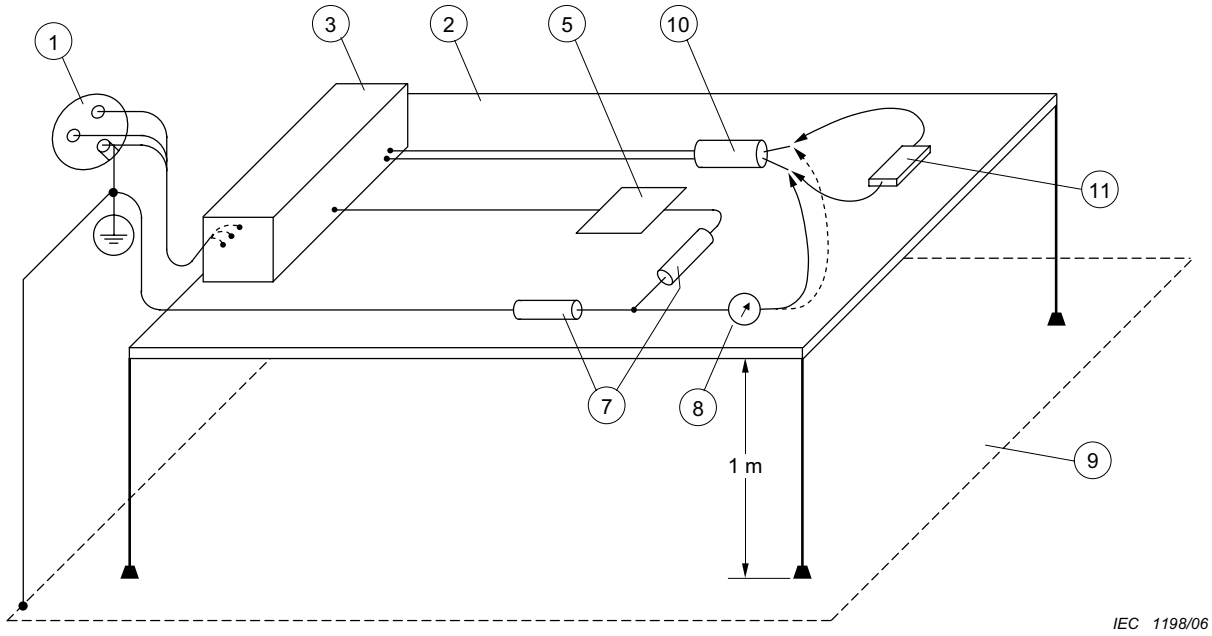
Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as shown in Figure 107. The test is conducted using one side of the BIPOLAR output and using BIPOLAR and (if applicable) NEUTRAL ELECTRODE leads supplied or recommended by the manufacturer. The test is conducted with the output first being unloaded and then repeated with the output loaded at the RATED LOAD. The squared current value multiplied by 200 Ω shall not exceed the requirement above. The test is then repeated for the other side of the BIPOLAR output.

Any metal ENCLOSURES of CLASS II HF SURGICAL EQUIPMENT and INTERNALLY POWERED HF SURGICAL EQUIPMENT shall be connected to earth. HF SURGICAL EQUIPMENT having an insulating ENCLOSURE shall be positioned on earthed metal having an area at least equal to that of the base of the HF SURGICAL EQUIPMENT.

During all measurements of HF LEAKAGE CURRENTS, the POWER SUPPLY CORD of the HF SURGICAL EQUIPMENT shall be folded up to form a bundle having a length not exceeding 40 cm.

NOTE The above requirements 1), 2) and 3) apply to HF SURGICAL EQUIPMENT with both TYPE BF and TYPE CF APPLIED PARTS. Requirements for HF ENCLOSURE LEAKAGE CURRENTS are under consideration.



Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
7 Measuring resistance, 200 Ω
8 HF current meter
9 Earthed conductive plane
10 Activated BIPOLAR ELECTRODE
11 Load resistance as required with HF power measuring device

Figure 107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ELECTRODE (see 19.3.101 a) 3))

*b) *HIGH FREQUENCY LEAKAGE CURRENTS measured directly at the HF SURGICAL EQUIPMENT terminals*

The preceding item a) may alternatively be fulfilled with a limit of 100 mA for *1)* and *2)* and with unchanged limits corresponding to 1 % of the BIPOLAR RATED OUTPUT POWER into 200 Ω and not to exceed 100 mA for 3) when the HF LEAKAGE CURRENT is measured directly at the HF SURGICAL EQUIPMENT terminals.

Compliance is checked by measurement similar to the tests described in 19.3.101 a), but without the electrode cables, and using leads as short as practicable for connecting the load resistor, the measuring resistor and the current measuring instrument to the HF SURGICAL EQUIPMENT terminals.

c) *Cross-coupling between different HF PATIENT CIRCUITS*

1) A non-activated MONOPOLAR PATIENT CIRCUIT shall produce no more than 150 mA HIGH FREQUENCY current into a 200 Ω load to earth and, in turn, to the NEUTRAL ELECTRODE.

2) A non-activated BIPOLAR PATIENT CIRCUIT shall produce no more than 50 mA into a 200 Ω load connected across the two terminals or – with short circuited terminals – into a 200 Ω load to earth and into a 200 Ω load to the NEUTRAL ELECTRODE (both currents added, see Figure 107) .

This is when any other PATIENT CIRCUIT is activated at its highest output settings and at all available operation modes.

Compliance is checked by measurements using the test arrangements specified in 19.3.101 b) and the HF SURGICAL EQUIPMENT is set up as shown in Figure 105 (for MONOPOLAR) or Figure 107 (for BIPOLAR PATIENT CIRCUITS).

*20 Dielectric strength

This clause of the General Standard applies except as follows:

Amendment:

The requirements and tests for HF SURGICAL ACCESORIES are given in 59.103 and 59.104 .

The requirements and tests for ENDOSCOPICALLY USED ACCESSORIES are given in IEC 60601-2-18.

*20.2 Requirements for EQUIPMENT with an APPLIED PART

For HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT, separation B-e need not be tested (see also 57.10). When investigating insulation other than separation B-e, tests may be conducted at a standard atmospheric pressure greater than 960 hPa to fix the insulating properties of the atmosphere.

20.3 Values of test voltages

Table V, NOTE 2: Replacement:

For the test voltage on APPLIED PARTS, the reference voltage (*U*) shall be determined by measuring the peak HF voltage, calculating the r.m.s. value of a mains frequency sinusoidal waveform having the same peak voltage and using this calculated value as the reference voltage (*U*) in Table V. However, the reference voltage (*U*) shall be minimally 250 V.

*20.4 *Tests*

Additional item:

aa) *If, during the testing of separation B-a, a breakdown or flashover occurs through the atmosphere at the AIR CLEARANCE specified in 57.10, an insulating barrier may be placed to prevent this breakdown so that the protective insulation can be tested.*

If, during the testing of separation B-a, a breakdown or flashover occurs at the CREEPAGE DISTANCE specified in 57.10, then the test shall be carried out on such components which insulate separation B-a, such as transformers, relays, optocouplers or CREEPAGE DISTANCES on printed circuit boards.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

36 Electromagnetic compatibility

In accordance with Amendment 2 of the General Standard, the Collateral Standard IEC 60601-1-2 applies, except as follows:

36.201 EMISSIONS

*36.201.1 PROTECTION OF RADIO SERVICES

Add the following text:

HF SURGICAL EQUIPMENT shall comply with the requirements of 36.201, when it is switched on but the HF output is not energized and with all the electrode cables attached to the HF SURGICAL EQUIPMENT. Under these test conditions, the HF SURGICAL EQUIPMENT shall comply with the CISPR 11 Group 1 limits.

36.202 IMMUNITY

36.202.1 General

j) Compliance criteria

Addition at end of j)

The following shall be considered an acceptable DEGRADATION of performance:

– The interruption of HF power output or reset into standby mode when clearly indicated on the operation panel of HF SURGICAL EQUIPMENT.
– A change in the delivered output power as allowed in 50.2

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply except as follows:

39 Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

This clause of the General Standard applies except as follows:

39.3 Prevention of electrostatic charges

Additional subclause:

39.3.101 Footswitches

The electrically conductive path from footswitches to a conductive floor shall have a resistance of no more than 10 MΩ.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

*42 Excessive temperatures

This clause of the General Standard applies except as follows:

Compliance test for 42.1 to 42.3:

3) *Duty cycle*

Replacement:

HF SURGICAL EQUIPMENT, set up to deliver its RATED OUTPUT POWER into a resistive load using the electrode cable, is operated for 1 h with a DUTY CYCLE as specified by the manufacturer but with operating times of at least 10 s alternating with a resting time of not more than 30 s (see 6.1 m) of the General Standard).

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

This clause of the General Standard applies except as follows:

*44.3 Spillage

Replacement:

The ENCLOSURE of the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT shall be constructed so that liquid spillage in NORMAL USE does not wet electrical insulation or other components which, when wetted, are likely to affect adversely the safety of the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT.

Compliance is checked by the following test.

A quantity of one litre of water is poured steadily onto the middle of the top surface of the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT over a period of 15 s. HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT intended to be built into a wall or cabinet is tested mounted as recommended, the water being poured onto the wall above the control panel. After this treatment, the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT shall withstand the dielectric strength test specified in Clause 20, and inspection shall show that water which may have entered the ENCLOSURE cannot adversely affect the safety of the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT. In particular, there shall be no trace of water on the insulation for which CREEPAGE DISTANCES are specified in 57.10 of the General Standard.

44.6 Ingress of liquids

Addition:

*aa) The electrical switching parts of footswitches for HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT intended for use in operating rooms shall be protected against the effects of ingress of liquids that might cause inadvertent energization of the APPLIED PART.

Compliance is checked by the following test.

The footswitch shall be completely immersed in 0,9 % saline to a depth of 150 mm for a period of 30 min. While immersed it shall be connected to a SWITCH SENSOR corresponding to its NORMAL USE and actuated 50 times. The SWITCH SENSOR shall register deactivation upon each release.

NOTE Revisions of the immersion test to replace inspection with functional and dielectric strength testing are under consideration. No current IEC 60529 tests are deemed appropriate for the expected surgical theatre environment.

*bb) The electrical parts of FINGERSWITCHES shall be protected against the effects of ingress of liquids that might cause inadvertent energization of the APPLIED PART (see also 59.103.2).

Compliance is checked by the following test.

The a.c. impedance of each of the switching terminals of the ACTIVE CONNECTOR shall be measured using a frequency of at least 1 kHz and a voltage of less than 12 V. The ACTIVE ELECTRODE handle is supported horizontally at least 50 mm above any surface with the switch activating parts uppermost. One litre of 0,9 % saline solution is poured steadily from above over the ACTIVE ELECTRODE handle over a period of 15 s so as to wet the entire length of the ACTIVE ELECTRODE handle. The liquid is allowed to drain away freely. The a.c. impedance of the switching terminals shall remain greater than 2 000 Ω.

Immediately after, each FINGERSWITCH is operated and released 10 times. The a.c. impedance of the switching terminals shall exceed 2 000 Ω within 0,5 s after each release.

*44.7 Cleaning, sterilization and disinfection

Addition:

Unless marked for single use only, ACTIVE ACCESSORIES and all detachable parts thereof, except ACTIVE CONNECTORS detachable from cords without use of tools, shall comply with the requirements of this Particular Standard after being tested according to this subclause of the General Standard.

46 Human errors

This clause of the General Standard applies except as follows:

Additional subclauses:

***46.101** Where a double footswitch assembly is used to select CUTTING and COAGULATION output modes, the arrangement shall be such that, when viewed by the OPERATOR, the left pedal activates CUTTING and the right pedal activates COAGULATION.

Compliance is checked by inspection.

***46.102** In an ACTIVE HANDLE which incorporates separate FINGERSWITCHES for selectively activating CUTTING and COAGULATION HF SURGICAL MODES, that which activates CUTTING shall be nearer to the ACTIVE ELECTRODE than is the other.

Compliance is checked by inspection.

***46.103** It shall not be possible to energise simultaneously more than one ACTIVE OUTPUT TERMINAL, unless

a) each ACTIVE OUTPUT TERMINAL has independent sets of controls for selection of HF SURGICAL MODE, HF output setting and SWITCH SENSORS, or

b) two MONOPOLAR ACTIVE OUTPUT TERMINALS have independent SWITCH SENSORS and share a common FULGURATION output.

During simultaneous activation the audible tone shall be different from the tone produced during single output activation. See also 59.102. Under no circumstances shall any PATIENT CIRCUIT become energized by more than is defined in 19.3.101 *c)*, unless the output for that PATIENT CIRCUIT is activated by the OPERATOR.

Compliance is checked by inspection and functional check.

***46.104**

a) ACTIVE OUTPUT TERMINALS on HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT shall differ in configuration sufficiently such that MONOPOLAR ACTIVE ACCESSORIES, NEUTRAL ELECTRODES and BIPOLAR ACTIVE ACCESSORIES cannot be improperly connected. See Annex AA

b) ACTIVE CONNECTORS having more than one pin shall have fixed pin spacing. “Flying leads” are prohibited.

c) ACTIVE CONNECTORS having no more than a single pin need not be investigated.

Compliance is checked by inspection.

***46.105** Where more than one HF SURGICAL MODE can be energized by a single SWITCH SENSOR, an indication shall be provided to show which HF SURGICAL MODE is selected before an output is energized.

Compliance is checked by inspection and functional test.

***46.106** Operating controls, output terminals, indicator lights (see 6.7 a)), pedals (see 46.101) and pushbuttons of FINGERSWITCHES (see 46.102) associated with a particular HF SURGICAL MODE shall be identified by the following colour coding:

yellow for CUTTING;

blue for COAGULATION.

Compliance is checked by inspection.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

50.1 Marking of controls and instruments

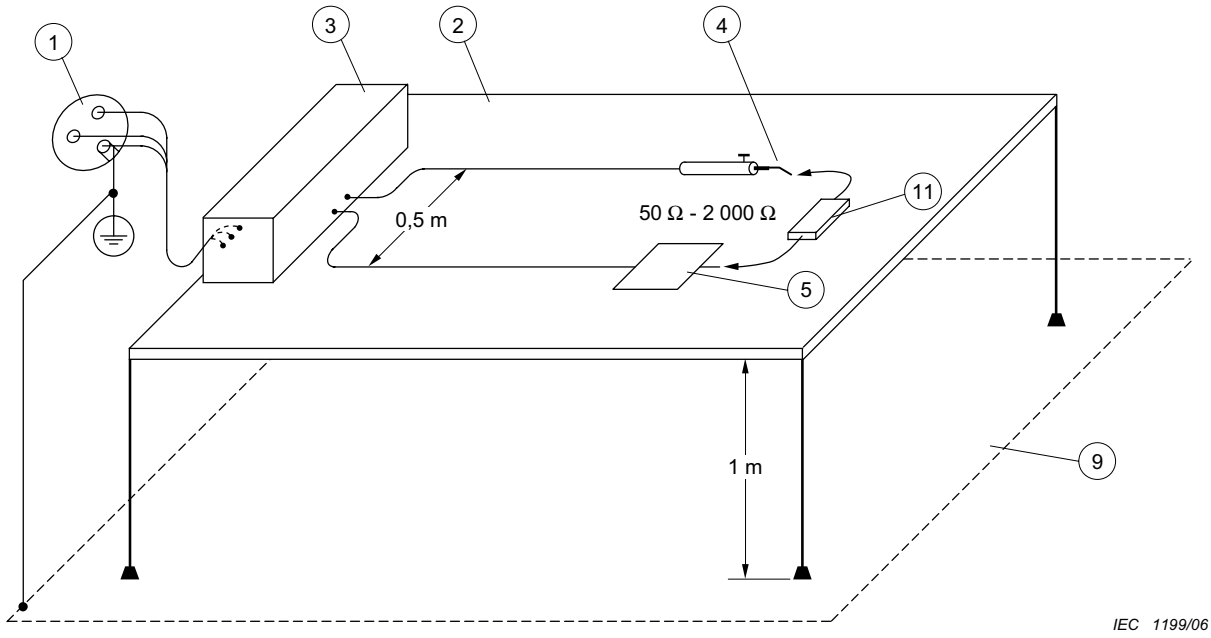
Replacement:

***50.1.101** Except as provided for in 6.8.2 bb) item 7, for each MONOPOLAR HF SURGICAL MODE, HF SURGICAL EQUIPMENT shall incorporate means (an output control) to enable the output power to be reduced to not more than 5 % of the RATED OUTPUT POWER or 10 W, whichever is smaller (see also 6.3). For particular values of load resistance, the output power shall not increase with the decrease of the output control setting (see 6.8.3 aa) and Figure 108).

Compliance is checked by the following test:

The output power as a function of the output control setting is measured at a minimum of five particular values of the load resistance, including 100 Ω, 200 Ω, 500 Ω, 1 000 Ω, 2 000 Ω and at the RATED LOAD. ACTIVE ACCESSORIES *and* NEUTRAL ELECTRODES *supplied with* HF SURGICAL EQUIPMENT *or 3 m lengths of insulated conductors shall be used for connection of the load resistors.*

NOTE If necessary for activation, FINGERSWITCH operation may be simulated by use of an insulated jumper no longer than 100 mm.



Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
4 ACTIVE ELECTRODE
5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
9 Earthed conductive plane
11 Load resistance as required with HF power measuring device

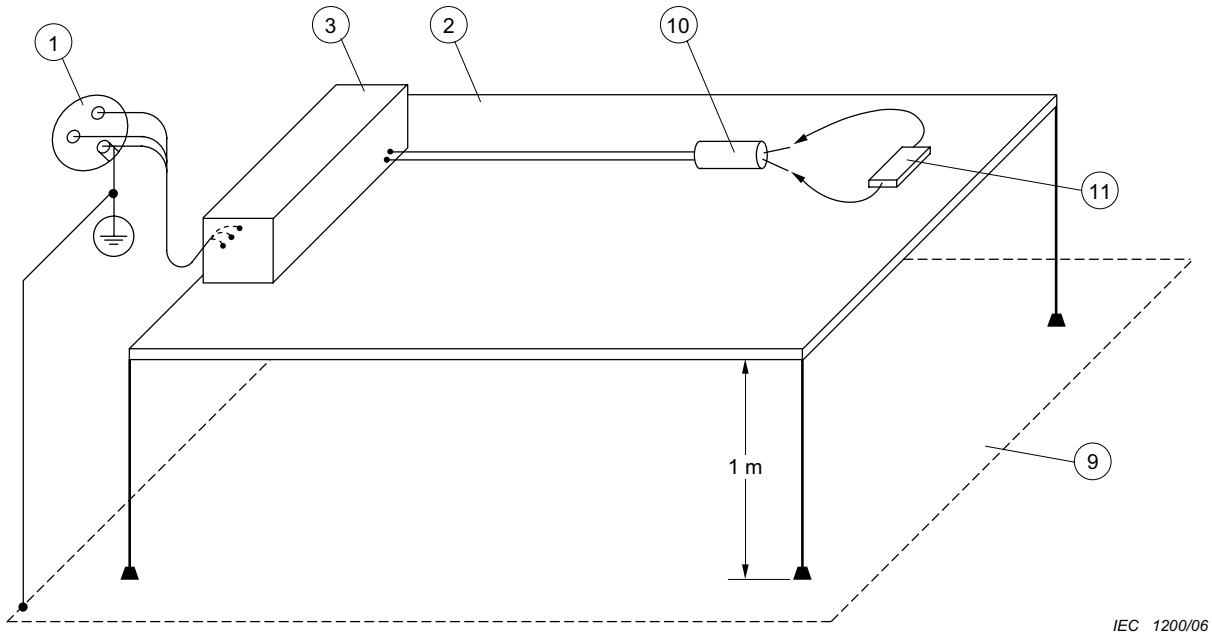
Figure 108 – Measurement of RATED OUTPUT POWER – MONOPOLAR output (see 50.1 a))

50.1.102 Except as provided for in 6.8.2 bb) item 7, for each BIPOLAR HF SURGICAL MODE, HF SURGICAL EQUIPMENT shall incorporate means (an output control) to enable the output power to be reduced to not more than 5 % of the RATED OUTPUT POWER or 10 W, whichever is smaller (see 6.3). For particular values of the load resistance, the output power shall not increase with the decrease of the output control setting (see 6.8.3 bb) and Figure 109).

Compliance is checked by the following test

The output power as a function of the output control setting is measured at a minimum of five particular values of the load resistance, including 10 Ω, 50 Ω, 200 Ω, 500 Ω, 1 000 Ω and at the RATED LOAD. The BIPOLAR cord supplied with the HF SURGICAL EQUIPMENT *or a 3 m length of two conductor insulated cord* RATED *600 V or greater shall be used for the connection of the load resistors.*

NOTE If necessary for activation, FINGERSWITCH operation may be simulated by use of an insulated jumper no longer than 100 mm.



Key

1 SUPPLY MAINS
2 Table, made of insulating material
3 HF SURGICAL EQUIPMENT
9 Earthed conductive plane
10 Activated BIPOLAR ELECTRODE
11 Load resistance as required with HF power measuring device

Figure 109 – Measurement of RATED OUTPUT POWER – BIPOLAR output (see 50.1 b))

***50.1.103** For each HF SURGICAL MODE available in HF SURGICAL EQUIPMENT, the MAXIMUM OUTPUT VOLTAGE applied to the ACTIVE OUTPUT TERMINALS shall not exceed that specified in 6.8.2 ee).

Compliance is checked by oscilloscopic observation. See also 4.7 h). Measurements shall be taken at the output setting and load condition which yields the highest peak output voltage for each HF SURGICAL MODE.

50.2 Accuracy of controls and instruments

For output powers in excess of 10 % of the RATED OUTPUT POWER, the actual power as a function of the load resistance and output control setting shall not deviate from that shown in the diagrams specified in 6.8.3 aa) and 6.8.3 bb) by more than ± 20 %.

Compliance is checked by performing the test of 50.1 but using appropriate values of load resistance.

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

***51.2 Indication of parameters relevant to safety**

Replacement:

The total output power in any HF SURGICAL MODE, including simultaneous activation of independent outputs if available, shall not exceed 400 W averaged over any period of 1 s when each of the outputs is terminated at the RATED LOAD.

Compliance is checked by measurement.

***51.5 Incorrect output**

Additional requirement:

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER greater than 50 W and all BIPOLAR HF surgical generators shall be provided with an alarm and/or interlock system to indicate and/or prevent a significant increase in the output power relative to the output setting.

The maximum allowed output power under SINGLE FAULT CONDITIONS shall be calculated separately for each PATIENT CIRCUIT and operation mode.

The maximum allowed output power in SINGLE FAULT CONDITIONS is defined as follows:

Table 1 – Maximum output powers in single fault conditions

Setting (range in % of RATED OUTPUT POWER)	**Maximum allowed output power in single fault conditions (but not more than 400 W)**
less than 10	20 % of RATED OUTPUT POWER
10 to 25	setting x 2
greater than 25 and up to 80	setting + 25 % of RATED OUTPUT POWER
greater than 80 and up to 100	setting + 30 % of RATED OUTPUT POWER

Compliance is checked by examination of the technical documentation and testing by simulation of appropriate SINGLE FAULT CONDITIONS.

Additional subclauses:

51.101 When HF SURGICAL EQUIPMENT is switched off and on again or when the mains supply is interrupted and re-established

– the output power for a given setting of the output control shall not increase by more than 20 %,

– the previously selected HF SURGICAL MODE shall not be changed except to a stand-by mode in which no output is produced.

Compliance is checked by measurement of the power, averaged over a period of 1 s, and observation of the operating mode

a) with repeated operation of the mains switch of the HF SURGICAL EQUIPMENT;

b) with interruption and re-establishment of the mains supply, the switch in the HF SURGICAL EQUIPMENT being left in the "ON" position.

***51.102** For HF SURGICAL EQUIPMENT providing simultaneous activation of more than one PATIENT CIRCUIT (see 46.103), the PATIENT CIRCUITS shall not deliver an output power that exceeds the range of deviation defined in 50.2 by more than 20 % when they are simultaneously activated under any available combination of HF SURGICAL MODES.

Any single activated PATIENT CIRCUIT shall comply with 50.2.

Compliance is checked by the following tests (see Figure 110).

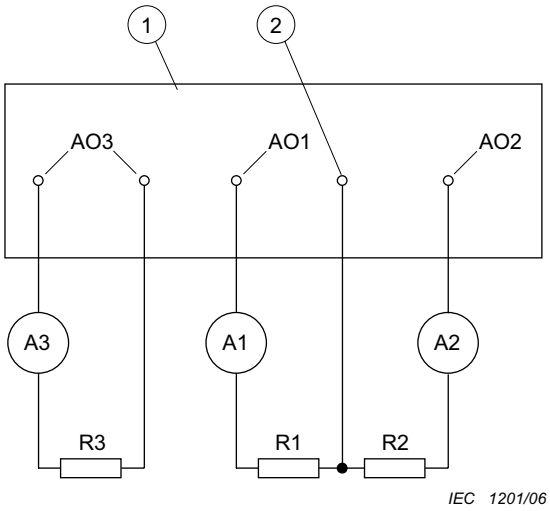
For HF SURGICAL EQUIPMENT as defined in 46.103 a):

The output under test is activated at 20 % of its RATED OUTPUT POWER and the HF current reading of this output noted. Any other output is then activated at maximum power and the current of the output under test shall not increase by more than 10 %.

For HF SURGICAL EQUIPMENT as defined in 46.103 b):

The output under test is activated at 50 % and at 100 % output settings and the current values noted. These values shall not increase by more than 10 % when the other output is activated additionally.

These tests are repeated with all possible combinations of outputs which may be activated together at any one time.



Key

①	HF SURGICAL EQUIPMENT
②	Connector for NEUTRAL ELECTRODE
R1	RATED LOAD for that active output
R2	RATED LOAD for that active output
R3	RATED LOAD for that active output
AO1	MONOPOLAR active output
AO2	MONOPOLAR active output
AO3	BIPOLAR active output

Figure 110 – Method of testing feedback from one active output to another in simultaneous activation (see 51.102)

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply except as follows:

52 Abnormal operation and fault conditions

This clause of the General Standard applies except as follows:

Additional subclause:

*52.101 Protection against the effects of short-circuiting of the electrodes

HF SURGICAL EQUIPMENT shall be capable of withstanding, without damage, the effects of short-circuiting or open-circuiting the output when energized at maximum output setting.

Compliance is checked by the following test.

Connect the conductors described in 50.1, items a) and b) to the PATIENT CIRCUIT connections and, for each HF SURGICAL MODE, set the output control to the maximum position. The output is then switched on, and the remote ends of the activated pair of conductors are short-circuited for a period of 5 s and then open-circuited for a period of 15 s. The output is then switched off for a period of 1 min. The above cycle is repeated for a total of 10 times.

After this test the HF SURGICAL EQUIPMENT shall comply with all the requirements of this Particular Standard.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.3 Connections – General

*Item c)

Amendment:

This requirement shall not apply to the ACTIVE CONNECTORS.

Any NEUTRAL ELECTRODE connector shall be constructed in such a manner that no CONDUCTIVE CONNECTION of that connector which is remote from the PATIENT can contact LIVE conductive parts of FIXED MAINS SOCKET-OUTLETS or MAINS CONNECTORS.

If able to be plugged into a FIXED MAINS SOCKET-OUTLET or MAINS CONNECTOR, the said part shall be protected from making contact with parts at mains voltage by insulating means providing a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of 1 500 V.

Compliance is checked by inspection and by applying the dielectric strength test to the conductive connection of that part of the connector identified above.

*56.11 Cord-connected hand-held and foot-operated control devices

a) *Limitation of operation voltages*

Amendment:

This item of the General standard shall not apply. See 56.101.1

d) *Entry of liquids*

Amendment:

This item of the General standard shall not apply. See 44.6.

e) *Connection cords*

Amendment:

This item of the General standard shall not apply to the anchorages of cords of ACTIVE ACCESSORIES. See 56.102 for applicable requirements.

Addition:

Any control intended to energise the PATIENT CIRCUIT shall require continuous activation by the OPERATOR except as provided for in 56.101.2.

*56.101 SWITCH SENSORS

*56.101.1 General

Except where provided for in 56.101.2, HF SURGICAL EQUIPMENT and applicable ASSOCIATED EQUIPMENT shall be provided with a SWITCH SENSOR requiring continuous activation in order to energise the ACTIVE OUTPUT TERMINALS.

The SWITCH SENSOR shall be supplied from a power source isolated from the MAINS PART and from earth, and having a voltage not exceeding 12 V, if a CONDUCTIVE CONNECTION to the APPLIED PART exists, and not exceeding 24 V a. c. or 34 V d. c. in other cases.

NOTE This requirement applies to voltages appearing within SWITCH SENSORS. Common-mode HF voltages should be disregarded.

Under SINGLE FAULT CONDITION the SWITCH SENSOR shall not cause low-frequency PATIENT LEAKAGE CURRENT(S) exceeding the allowable limits (see 19.3 a)).

Compliance is checked by inspection, functional check, and by measurement of voltage and leakage current(s).

Where the SWITCH SENSOR is provided with input terminals intended for connection to external electrical switch contacts, it shall not be possible to activate any output of the HF SURGICAL EQUIPMENT when the input terminals are bridged by a resistance equal to or greater than 1 000 Ω.

Compliance is checked by a functional test.

Each SWITCH SENSOR shall activate only its intended single ACTIVE OUTPUT TERMINAL and shall control no more than one HF SURGICAL MODE.

NOTE For the purpose of this requirement the two arms of a rocker style switch are considered to be two individual switches.

56.101.2 Non-continuous activation

Non continuous activation mode of the SWITCH SENSOR is accepted only if

a) the output of the HF SURGICAL EQUIPMENT is automatically stopped in accordance with the specific application of the EQUIPMENT.

b) a visible indicator is provided to indicate to the OPERATOR that the HF SURGICAL EQUIPMENT is set to such a specific application mode, and

c) a possibility for manual output deactivation is provided.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS *and functional test.*

56.101.3 Impedance sensing activation

A SWITCH SENSOR which is intended to activate HF output in response to the impedance appearing between BIPOLAR ACTIVE OUTPUT TERMINALS is accepted only for BIPOLAR COAGULATION.

Where such an impedance-sensing SWITCH SENSOR is provided as an alternative or in addition to a contact-closure sensing SWITCH SENSOR, then

a) it shall not be possible under any conditions for HF output to be energized solely as a result of interruption and restoration of the mains supply, and

b) impedance-sensing activation shall be enabled only in response to a specific OPERATOR selection, and

c) that selection shall be visibly indicated to the OPERATOR.

Impedance sensing SWITCH SENSORS shall not be permitted for MONOPOLAR output activation. The requirements of this subclause do not apply to SWITCH SENSORS which are capable only of automatically terminating HF output according to the purpose of specific application modes (see 56.101.2 a).

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS and functional test.

56.101.4 Footswitches

Footswitches shall comply with the following requirement (see also 44.6 and 46.101).

The force required to actuate the switch shall be not less than 10 N, applied over an area of 625 mm^2 anywhere on the operating surface of the footswitch.

Compliance is checked by measurement of the actuating force.

56.102 Anchorages of cords of ACTIVE ACCESSORIES

Anchorages of cords of ACTIVE ACCESSORIES shall be designed to minimise the risk to PATIENTS and OPERATORS arising from damage to conductors or insulation caused by cable flexure or excessive tension.

Compliance shall be checked by inspection and by the following test:

The anchorages on ACTIVE HANDLES *and* ACTIVE CONNECTORS *are tested one at a time.*

The ACTIVE HANDLE *or* ACTIVE CONNECTOR *under test is fixed in an apparatus similar to that shown in Figure 111, so that when the oscillating member of the apparatus is at the middle of its travel, the axis of the cord, where it leaves the part under test is vertical and passes through the axis of oscillation. The cord is passed through an aperture 300 mm from the axis of oscillation and a weight equal to the cord and connector of the* ACTIVE ACCESSORY *is affixed to the cable below this aperture for the purpose of applying tension to the cord. The maximum diameter of the hole should not be more than 2 times of the diameter of the cord.*

Where an anchorage of the ACTIVE HANDLE *or* ACTIVE CONNECTOR *under test is fitted with two or more cords, these shall be tested together, with the total weight affixed to the anchorage being the sum of the weights required to be applied to each cord individually.*

The oscillating member is rotated through an angle of 90 º (45 º on each side of the vertical).

The number of cycles applied to cable anchorages of ACTIVE HANDLES *shall be 10 000 (200 for* ACTIVE ACCESSORIES *marked for single use only) at the rate of approximately 30 cycles per minute. The number of cycles applied to anchorages of cables of* ACTIVE CONNECTORS *shall be 5 000 (100 for* ACTIVE ACCESSORIES *marked for single use only) at the rate of approximately 30 cycles per minute.*

After the test, the cord shall not have worked loose nor shall it show any damage. For multi-conductor cables there shall be no short circuits between individual conductors. The tensioning weight shall be increased to 1 kg and individual conductors checked for continuity using a d.c., current not in excess of 1 A.

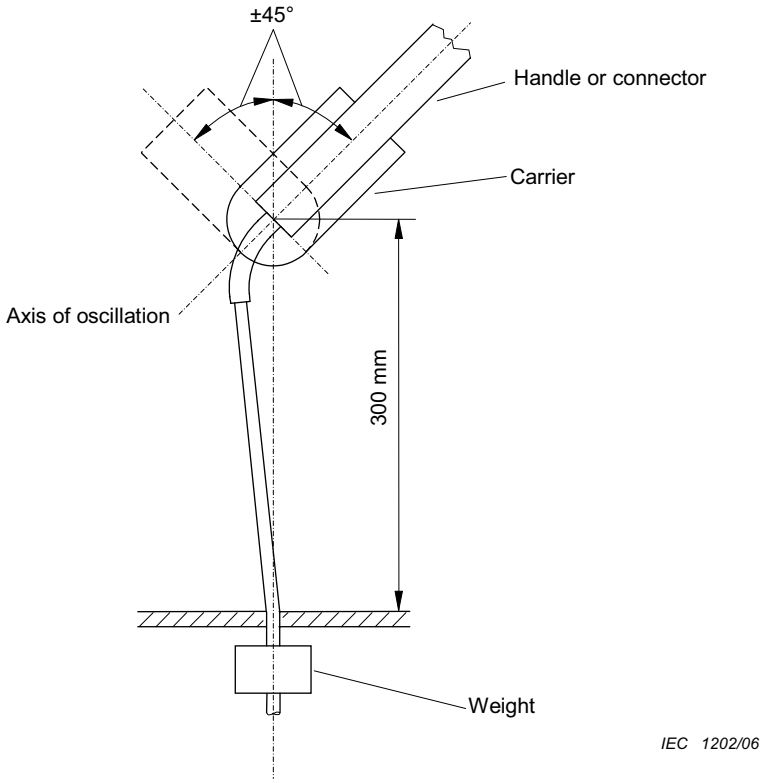


Figure 111 – Test apparatus for anchorages of cords of ACTIVE ACCESSORY (see 56.102)

*56.103 Active accessories with detachable ACTIVE ELECTRODES

56.103.1 Compatibility with third party ACTIVE ELECTRODES

a) The manufacturer of an ACTIVE ACCESSORY with a detachable ACTIVE ELECTRODE shall provide upon request the dimensions and associated tolerances for the mating part of any ACTIVE ELECTRODE which is intended to be attached to the ACTIVE ACCESSORY.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

b) The manufacturer of an ACTIVE ACCESSORY with a detachable ACTIVE ELECTRODE shall specify in the ACCOMPANYING DOCUMENTS the ACTIVE ELECTRODES with which it is intended to be compatible.

Compliance is checked by demonstrating conformance with all relevant requirements of this Particular Standard.

56.103.2 Retention of detachable ACTIVE ELECTRODES

The manufacturer of a detachable ACTIVE ELECTRODE shall specify in its ACCOMPANYING DOCUMENTS the ACTIVE ACCESSORIES with which it is intended to be used.

a) The detachable ACTIVE ELECTRODE shall fit securely into the specified ACTIVE ACCESSORIES.

Compliance shall be checked by inspection and by the following test:

The detachable ACTIVE ELECTRODE is inserted ten times into a specified ACTIVE ACCESSORY. Afterwards, the ACTIVE ELECTRODE shall not detach when subjected to a pull equivalent to ten times the weight of the ACTIVE ELECTRODE up to a maximum of 10 N for one minute along the axis of insertion.

b) When a detachable ACTIVE ELECTRODE is inserted into a specified ACTIVE ACCESSORY, the combination shall conform to all other applicable requirements of this Particular Standard.

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

*a) Values

Amendment:

For HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES, separation B-d and B-e need not be tested.

The CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the APPLIED PARTS and the ENCLOSURE including SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS and between different PATIENT CIRCUITS shall be at least 3 mm/kV or 4 mm, whichever is the greater. The reference voltage shall be the maximum peak voltage.

This requirement does not apply for components when the adequacy of ratings can be demonstrated, for example by component manufacturers ratings or by the dielectric strength test of Clause 20.

59 Construction and layout

This clause of the General Standard applies except as follows:

Additional subclauses:

*59.101 NEUTRAL ELECTRODE monitoring circuit

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER of more than 50 W shall be provided with an NE CONTINUITY MONITOR and/or a CONTACT QUALITY MONITOR arranged so as to de-energise the output and to give an audible alarm when a failure of the NEUTRAL ELECTRODE circuit or its connections occurs. The audible alarm shall meet the sound level requirements of 59.102 and shall not be externally adjustable.

The monitoring circuit shall be supplied from a power source isolated from the MAINS PART and from earth and having a voltage not exceeding 12 V. The limitation of monitoring current for a CONTACT QUALITY MONITOR is defined in 19.3.

An additional visible warning consisting of a red indicator light should be provided (see 6.7a)).

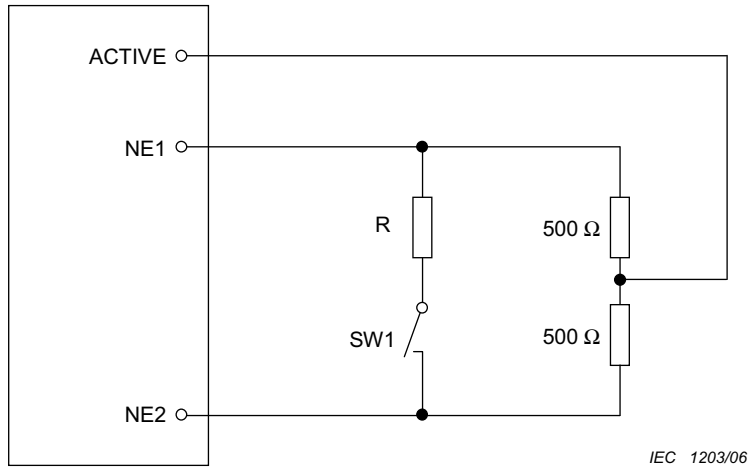
Compliance of an NE CONTINUITY MONITOR is checked by operating the HF SURGICAL EQUIPMENT at maximum output control setting in each operating mode into the circuit shown in Figure 112. The switch is closed and opened five times and the HF output shall be disabled and the alarm shall sound at each opening of the switch.

Compliance of a CONTACT QUALITY MONITOR *is checked by switching on the mains of the HF* SURGICAL EQUIPMENT *and setting its controls for* MONOPOLAR *operation, except that it shall not be activated. Then a compatible* MONITORING NE*, selected according to the advice per 6.8.2 gg), is connected to the* NE *connections of the* CONTACT QUALITY MONITOR.

The NE *is then placed, according to marked instructions for use, with full contact on a human subject or a suitable surrogate surface, and the* CONTACT QUALITY MONITOR *is set up according to instructions for use. The* HF SURGICAL EQUIPMENT *is then activated in a* MONOPOLAR HF SURGICAL MODE*. No alarm shall sound and* HF *output shall be present. With the* HF SURGICAL EQUIPMENT *now activated, the contact area between the* NE *and the human subject or a suitable surrogate surface is gradually reduced until a* NE *alarm occurs. The remaining contact area (alarm area),* A_a *shall be recorded for subsequent thermal rise testing per 59.104.5), and no* HF *output shall be produced when activation is attempted.*

This test shall be repeated along both axes using at least three samples of each compatible MONITORING NE*.*

NOTE Care should be taken so, under NORMAL CONDITION, the monitoring circuit does not introduce any interfering voltage (for example at mains frequency or its harmonics) at the NEUTRAL ELECTRODE which can adversely affect the operation of any PATIENT monitoring EQUIPMENT.



For single plates : R = 0 Ω

For split plates : R as specified by the manufacturer so as just to keep the EQUIPMENT active with SW1 closed.

NOTE NEUTRAL ELECTRODES which are split into more than two parts should be tested accordingly.

Figure 112 – Circuit suitable for testing compliance to 59.101

59.102 Output indicator

HF SURGICAL EQUIPMENT shall be provided with a device which gives an audible signal when any output circuit is energized by the operation of a SWITCH SENSOR or as a result of a SINGLE FAULT CONDITION. The sound output shall have its major energy content in the band of frequencies between 100 Hz and 3 000 Hz. The sound source shall be capable of producing a sound level of at least 65 dBA at a distance of 1 m from the HF SURGICAL EQUIPMENT according to the one direction specified by the manufacturer. An accessible sound level control may be provided, but shall not reduce the sound level below 40 dBA. For simultaneous activation see also 46.103.

In order that the OPERATOR may distinguish between the audible alarm called for in 59.101 and the signal specified above, either the former shall be pulsed or two different frequencies shall be employed.

Compliance is checked by functional check and measurement of the sound level.

*59.103 ACTIVE ACCESSORY insulation

ACTIVE ACCESSORIES and cords of ACTIVE ACCESSORIES shall be sufficiently insulated to mitigate unintended thermal burn risk to the PATIENT and OPERATOR under conditions of normal use.

Compliance is checked as follows:

Test samples, other than those marked for SINGLE USE*, shall have undergone the sterilization test of 44.7.*

The insulated parts of all ACTIVE ACCESSORIES, other than ACTIVE HANDLES and ACTIVE CONNECTORS, shall be preconditioned by immersion in 0,9 % saline for at least 12 h, but no longer than 24 h. Operative conductors which may have been exposed in preparation for testing, as well as the insulation of the cords of ACTIVE ACCESSORIES within 100 mm of the ends, shall be protected from contact with saline. Upon completion of this preconditioning, excess saline shall be removed from surfaces and cavities by shaking and/or wiping with a dry cloth.

Immediately following saline preconditioning, applicable electrical testing shall be conducted in the following order:

– *HF leakage (59.103.5)*
– *HF dielectric strength (59.103.6)*
– *Mains frequency dielectric strength (59.103.7)*

59.103.1 Not used.

59.103.2 Not used.

59.103.3 Not used.

59.103.4 Not used.

Additional subclauses:

***59.103.5** The insulation applied to cords for ACTIVE ACCESSORIES intended for MONOPOLAR application shall limit HF leakage current $I_{leakage}$ passing through the external surface of the insulation to less than

$$I_{leakage} = 9{,}0 \times 10^{-7} \times d \times L \times f_{test} \times U_{peak} \text{ [mA]}$$

where

d = smallest outer dimension of the insulation in mm,

f_{test} = HF test voltage frequency in kHz,

L = length of sample insulation through which HF leakage current passes, in mm, and

U_{peak} = peak HF test voltage.

The corresponding limit for cords intended for BIPOLAR application is

$$I_{leakage} = 1{,}8 \times 10^{-6} \times d \times L \times f_{test} \times U_{peak} \text{ [mA]}$$

Compliance is checked as follows:

The full length of the sample insulation except that within 10 mm of exposed conductors, but no more than 300 mm of length, shall be immersed in a 0,9 % saline bath or wrapped in a saline-soaked porous cloth. All operative inner conductors shall be connected together to one pole of an HF *voltage source having an approximately sinusoidal waveform and a frequency* f_{test} *of 300 to 1 000 kHz. The opposite pole of the* HF *voltage source is connected to a conductive electrode immersed in the saline bath or to foil wrapped around the midsection of the saline-soaked cloth.* HF *leakage current* $I_{leakage}$ *is monitored by means of a suitable instrument connected in series with the* HF *voltage source output. The HF test voltage* U_{peak} *is monitored between the* HF *voltage source output poles.*

The HF test voltage U_{peak} is advanced until the peak voltage equals the lesser of RATED ACCESSORY VOLTAGE or 400 V_{peak}. The measured HF leakage current $I_{leakage}$ shall not exceed the specified limit.

***59.103.6 HF dielectric strength**

The insulation applied to ACTIVE ACCESSORIES shall be capable of withstanding HF voltage of 120 % of the RATED ACCESSORY VOLTAGE .

Compliance is checked as follows:

The tests shall be performed at a test voltage related to the RATED ACCESSORY VOLTAGE specified by the manufacturer of the HF SURGICAL ACCESSORY in the instructions for use (see 6.8.2 ee), as detailed in the following test methods. For the cords of ACTIVE ACCESSORIES and ACTIVE ELECTRODES, a portion of the insulation which has been preconditioned in saline is wound max. five turns of bare conductive wire having a diameter of 0,4 mm ± 10 % at a pitch of at least 3 mm without deforming the surface of the sample. If necessary to prevent inadvertent arc discharge, the creepage distance between this wire and operative conductive parts of ACTIVE ELECTRODES may be increased to 10 mm by application of insulation. Such added insulation shall have a thickness no greater than 1 mm and shall cover no more than 2 mm of ACTIVE ELECTRODE INSULATION. One pole of the HF test voltage source shall be connected to the bare conductive test wire, and the opposite pole shall be connected simultaneously to all operative conductors in the sample being tested.

ACTIVE ELECTRODE handles, together with any detachable cords and detachable ACTIVE ELECTRODES which are specified as compatible, shall be wrapped in a porous cloth soaked in 0,9 % saline. This cloth shall cover the entire exterior surface of the handle and extend at least 150 mm on to the surface of the cord and 5 mm on to the ACTIVE ELECTRODE INSULATION. If necessary, the creepage distance between the cloth and exposed operative conductive parts of the ACTIVE ELECTRODE may be insulated as described above. The midsection of the saline-soaked cloth is wrapped with metal foil and connected to one pole of the HF test voltage source. All operative inner conductors in the samples being tested, including the operative tip(s) of the ACTIVE ELECTRODE, shall be connected simultaneously to the opposite pole.

The peak HF test voltage is monitored between the HF voltage source output poles. The output of the HF test voltage source is then increased until the peak voltage equals 120 % of the peak voltage according to the RATED ACCESSORY VOLTAGE and maintained for 30 s in such a manner that it stresses the insulation of the test sample. No breakdown of the insulation material shall occur and the same insulation shall subsequently be tested at mains frequency according to 59.103.7.

NOTE Blue corona is normal and is not considered a breakdown of insulation.

Those parts of the test samples which are not insulated in normal use shall be adequately protected against contact with the saline solution during preconditioning, and this protection shall be left in place during the tests.

Tests:

Apply an approximately sinusoidal voltage at a frequency of 400 kHz ± 100 kHz with a continuous waveform, or alternatively with a modulated waveform (modulation frequency higher than 10 kHz) with the peak test voltage equal to 120 % of the peak voltage according to the RATED ACCESSORY VOLTAGE specified by the manufacturer of the HF SURGICAL ACCESSORY and with a test CREST FACTOR (cf_{test}) which is defined as follows:

For RATED ACCESSORY VOLTAGES less than or equal 1 600 V:

$$cf_{test} \leq 2$$

For RATED ACCESSORY VOLTAGES greater 1 600 V and less than or equal to 4 000 V:

$$cf_{test} = \frac{U_{acc} - 400\,[Volts]}{600\,[Volts]} \pm 10\ \%$$

where U_{acc} = RATED ACCESSORY VOLTAGE in Volts

For RATED ACCESSORY VOLTAGES greater 4 000 V:

$$cf_{test} = 6 \pm 10\ \%$$

ACTIVE ACCESSORIES intended to be used with HF SURGICAL MODES or output settings requiring specific approval shall withstand 120 % of the peak output voltage of such HF SURGICAL MODE or output setting. They shall be tested under the same conditions as described above but with the actual CREST FACTOR of such HF SURGICAL MODE or output setting. (see 6.8.2 ff) iii))

***59.103.7 Mains frequency dielectric strength**

The insulation applied to an ACTIVE ACCESSORY, including those portions of insulation having been tested at HF according to 59.103.6, shall withstand a d.c. or mains frequency peak voltage of 1 000 V greater than the RATED ACCESSORY VOLTAGE specified by the manufacturer of the HF SURGICAL ACCESSORY.

Compliance is tested as follows:

The test voltage source shall produce a d.c. or mains frequency signal. The test duration shall be 30 s for ACTIVE HANDLES and ACTIVE CONNECTORS. The test duration for the cords of ACTIVE ACCESSORIES shall be 5 min. Although corona discharge may occur, no breakdown of the insulation or flashover shall occur. Immediately after this dielectric strength test, any incorporated FINGERSWITCH shall be operated 10 times. An ohmmeter shall be used to test if the switching mechanism operates as intended to ensure that, when connected to HF SURGICAL EQUIPMENT, the HF output will be de-energized when the FINGERSWITCH is released.

The insulated parts of ACTIVE CONNECTORS more than 10 mm creepage distance from exposed operative conductors shall be wrapped with a porous cloth soaked in 0,9 % saline. The midsection of the cloth is then wrapped with metal foil. The test voltage is applied between the foil and all of the operative ACTIVE CONNECTORS contacts.

The entire length of the insulation of cords of ACTIVE ACCESSORIES, including that portion previously tested at HF according to 59.103.6, but exclusive of the sections within 100 mm of the ends, shall be immersed in a bath of 0,9 % saline. The test voltage is applied between a conductive electrode immersed in the saline bath and all of the conductors in the cord simultaneously.

ACTIVE HANDLES complete with detachable electrodes are prepared for testing and connected to the test voltage source using the same techniques as described in 59.103.6. The saline-soaked cloth and foil applied for that test may be left in place for this test provided care is taken to ensure that the cloth remains thoroughly wetted.

59.104 NEUTRAL ELECTRODE

***59.104.1** Except for any PATIENT CIRCUIT intended only for connection to a BIPOLAR ELECTRODE, HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER in excess of 50 W shall be provided with a NEUTRAL ELECTRODE.

Compliance is checked by inspection.

***59.104.2** The NEUTRAL ELECTRODE shall be reliably connected to the cable. Except for a MONITORING NE, any current used for monitoring the electrical continuity of the electrode cable and its connections shall pass through a section of the electrode.

Compliance is checked by the following test.

An electrical continuity test is conducted using a current of at least 1 A but not more than 5 A from a d.c. or mains frequency current source with a no-load voltage not exceeding 6 V. The electrical continuity shall be 1 Ω or less.

***59.104.3** Any contacts of the electrical connector of an NE cord for attachment to a detachable NE shall be designed so that their conductive parts cannot come into contact with the body of the PATIENT in the event of inadvertent disconnection.

Compliance is checked by the following test.

The NE *cord is detached from the* NE *and, using the standard test finger shown in Figure 7 of the General Standard, it is verified that contact with conductive parts of the cable connector is not possible.*

***59.104.4** The insulation of NE cords shall be adequate to prevent a burn injury to the PATIENT and the OPERATOR.

Compliance is checked by application of the following tests in the order shown:

– *HF leakage test according to 59.103.5 with a test voltage of 400* V_{peak} *. HF LEAKAGE CURRENT* $I_{leakage}$ *shall not exceed*

$1{,}80 \times 10^{-6} \times d \times L \times f_{test} \times U_{peak}$ *[mA]*

– *HF dielectric strength test according to 59.103.6 with an HF test voltage of 500* V_{peak}*. No breakdown of the insulation shall occur.*

– *Mains frequency dielectric strength test according to 59.103.7 with a test voltage of 2 100* V_{peak}*. No breakdown of the insulation shall occur.*

***59.104.5** An NE shall not subject a PATIENT to a risk of thermal injury at the NE application site under conditions of NORMAL USE and when applied in accordance with instructions for use.

Compliance is checked by the following test.

For an NE with the PATIENT *weight range marked as follows, the maximum temperature rise of any 1 cm square area under or within 1 cm of the NE contact site on a PATIENT shall not exceed 6* °*C immediately after a 60 s application of the specified test current,* I_{test}*.*

Table 2 – Test currents by weight range

PATIENT weight range	I_{test} mA
<5 kg	350
5 kg to 15 kg	500
> 15 kg or unspecified	700

For all MONITORING NE the contact area shall be A_a *the alarm area, as evaluated in the compliance test for 59.101.*

For all other NE the contact area shall be the area of the NE when applied according to the instructions for use.

For NEs intended for use on small patients, these tests may be performed on adult subjects. The test surface to which the NE *under test is applied shall be the skin of human subjects, or electrically and thermally equivalent surrogate media or test devices. These tests shall be repeated using a minimum of four different samples of the* NE *under test on each human subject or surrogate media. Where a surrogate medium or test device is used, at least 10 different samples of the* NE *shall be tested.*

The NE *and test surface temperatures of surrogate media or test devices shall be (23 ± 2) °C, and a reference temperature scan of the test surface shall be recorded immediately prior to application of the* NE *to the test surface. The* NE *shall be applied to the test surface in accordance with supplied instructions for use, except that contact area shall be A_a. The* NE *shall rest on the test surface for 30 min in a stable temperature environment before the application of the test current. If a thermally equivalent surrogate medium or test device is used the test may commence once thermal equilibrium is achieved.*

The test current, I_{test}, applied to the electrode under test shall have an approximately sinusoidal HF waveform, and must be attained within 5 s of the beginning of the test and maintained between 100 % and 110 % of I_{test} for (60 ± 1) s.

A second temperature scan of the test surface shall be completed within 15 s following cessation of the test current. Upon comparison with the reference scan, the temperature rise of any 1 cm square area shall not exceed 6 °C.

The temperature scanning apparatus shall have an accuracy of better than 0,5 °C and a spatial resolution of at least one sample per square cm over the entire NE *contact area plus the area extending 1 cm beyond the edge of that area. Spatial correlation between the reference and second temperature scans shall be within ± 1,0 cm.*

Where human subjects are employed, they shall comprise a pool of at least five males and five females having a variety of skin tissue morphologies, i.e. thin, average and thick layers of subcutaneous body fat.

Any surrogate medium or test device shall bear documented evidence that it is expected to yield temperature rise results no smaller than those from this test protocol as applied to at least 20 human subjects.

***59.104.6** The impedance of the electrical contact between the surface of the NE application site and the NE cord connection shall be low enough to prevent a risk of PATIENT burn due to ohmic heating during passage of HF surgical current.

For conductive NE, contact impedance shall not exceed 50 Ω, and for capacitive NEs, contact capacitance shall be no less than 4 nF over the frequency range of 200 kHz to 5 MHz

NOTE For purposes of this Particular Standard, unless otherwise specified by the manufacturer, a conductive NE presents a contact impedance with a phase angle of less than 45° at 200 kHz, and a capacitive NE a 200 kHz phase angle of 45° or greater.

Compliance is checked by the following test using at least 10 random samples of the NE *under test.*

The NE *under test is placed in full and firm contact on a 20 cm x 30 cm flat metallic plate. A true r.m.s. responding a.c. voltmeter having an input impedance greater than 2 kΩ and accuracy of better than 5 % over the 200 kHz – 5 000 kHz range is connected between the plate and the NE cord conductors in order to measure voltage U_{test}. An essentially sinusoidal test current, I_{test}, of approximately 200 mA. and frequency f_{test} the range of 200 kHz – 5 000 kHz is passed between the* NE *cord and the plate and monitored by use of a suitable true r.m.s. a.c. ammeter.*

U_{test} and I_{test} are recorded at f = 200 kHz, 500 kHz, 1 000 kHz, 2 000 kHz and 5 000 kHz. For each f_{test}, contact impedance Z_c is computed as:

$$Z_c = \frac{U_{test}}{I_{test}}$$

and contact capacitance C_c is computed as:

$$C_c[nF] = \frac{I_{test} \times 10^6}{2\pi \times f_{test} \times U_{test}}$$

where

I_{test} is the r.m.s. HF test current in A

U_{test} is the r.m.s. HF test voltage in V

f_{test} is the HF test voltage frequency in kHz

***59.104.7** For NEs, except MONITORING NEs and NEs marked for use with patients weighing less than 15 kg , if the instructions for use indicate that the NE is adhesively attached to the PATIENT, the peel strength of the adhesive shall be adequate to ensure a safe degree of contact under expected conditions of use.

Compliance is checked by the following tests.

For NEs intended for use on small patients, these tests may be performed on adult subjects. Surrogate test surfaces that are shown to be equivalent to human subjects may be used.

a) Pull test

At least two samples of the NE under test are applied to convenient locations on at least 10 male and 10 female human subjects, according to instructions for use. After application, NEs allowed to set undisturbed for 5 min to 10 min. For NEs intended for use on adult patients, the attached NE cord is subjected for 10 min to a 10 N force directed along each of two orthogonal axes in a plane parallel to the skin surface at the NE cord connection point. At least one of the axes shall consist of the minor dimension of the NE at that point. No more than 5 % of the NE adhesive area shall separate from the skin surface in at least 90 % of the tests.

b) Conformability test

NEs under test are applied to at least 5 male and 5 female human subjects on approximately cylindrical sites (e.g., extremities) having circumferences from 1,0 to 1,25 times the length of the major axis of the NE, with the major axis of the NE encircling the site. No more than 10 % of the adhesive area of the NE shall have separated from the skin surface at 1 h after application.

NOTE The conformability test is not required where this kind of application site is counter indicated in the instructions for use.

c) Fluid tolerance test

The NEs are placed on at least 5 male and 5 female human subjects. The appropriate connector is connected to the NE if the NE is intended for use with a reusable cable. One litre of 0,9 % saline is poured for 5 s to 15 s from a height of 300 mm directly over the NE. No more than 10 % of the adhesive area of the NE shall have separated from the skin surface within 15 min after the saline is poured.

***59.104.8** NEs marked for single use shall comply with the requirements of 59.104.5 through 59.104.7 on the expiration date specified in 6.1 v). Test samples may be produced by actual storage of the NEs according to their instructions for use, or by accelerated aging of the NEs through a cycle which has been shown to be at least as severe as equivalent recommended storage condition aging.

Compliance shall be verified by testing devices within 30 days of the expiration date or the date when accelerated aging is completed..

***59.104.9** Requirements for NEs for high current and/or prolonged activation are under consideration.

NOTE See also 6.8.2 kk).

*59.105 Neuromuscular stimulation

In order to minimize the possibility of neuromuscular stimulation, a capacitance shall be incorporated into the PATIENT CIRCUIT so that it is effectively in series with the ACTIVE ELECTRODE or one conductor of a BIPOLAR ELECTRODE. This capacitance shall not exceed 5 000 pF for MONOPOLAR PATIENT CIRCUITS and 50 nF for BIPOLAR PATIENT CIRCUITS. The d.c. resistance between ACTIVE and NEUTRAL ELECTRODE terminals, or between the terminals of a BIPOLAR output circuit, shall not be less than 2 MΩ. For an example, see capacitor C_1 in Figure 103.

Compliance is checked by inspection of the circuit arrangement and by measurement of the d.c. resistance between the output terminals.

The appendices of the General Standard apply except as follows:

Appendix L

References – Publications mentioned in this standard

Appendix L of the General Standard applies except as follows:

Addition:

IEC Standards

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-2-2:1998, *Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment*

IEC 60601-2-4:2005, *Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators*

IEC 60601-2-18:1996, *Medical electrical equipment – Part 2-18: Particular requirement for the safety of endoscopic equipment*
Amendment 1 (2000)

IEC 60601-2-34:2000, *Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*

IEC 61000-4-3:2006*, Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency electromagnetic field immunity test*

IEC 61000-4-6:2003*, Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*
Amendment 1 (2004)

CISPR 11:2003, *Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement*

CISPR 16-2-1:2003*, Specification for radio disturbance and immunity measuring apparatus and methods – Part 2-1: Methods of measurement of disturbances and immunity – Conducted disturbance measurements*

Other Standards

ANSI/AAMI HF18:2001, *Electrosurgical devices*

Annex AA
(informative)

Guidance and rationale for particular clauses and subclauses

This annex provides a concise rationale for the important requirements of this Particular Standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA.1.1

The scope does not include EQUIPMENT for cautery, i.e. for medical treatment with electrically heated metal rods or wire loops. This edition provides, to the extent feasible, separate requirements and tests for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES, independent of manufacture. ASSOCIATED EQUIPMENT is included in the definition of ACCESSORIES.

AA.2.1.105

Examples of ASSOCIATED EQUIPMENT are argon beam adaptors, accessory leakage monitors, NEUTRAL ELECTRODE contact monitors, and the like. Independent use means the devices are not used unless it is in conjunction with HF SURGICAL EQUIPMENT.

AA.2.2.101

To the extent possible, this edition sets requirements for HF SURGICAL ACCESSORIES independently from HF SURGICAL EQUIPMENT, regardless of manufacture. This provides for safe and effective use of any conforming HF SURGICAL ACCESSORY with any conforming HF SURGICAL EQUIPMENT, according to common clinical practice. In general, footswitches supplied by the HF SURGICAL EQUIPMENT manufacturer remain connected for the entire service life and thus may be treated as part of that EQUIPMENT. See Figure AA.101 below for examples of these various parts of an HF surgical system.

AA.2.4.101

This parameter is intended for comparison by the OPERATOR to RATED ACCESSORY VOLTAGE to ensure SAFETY.

AA.2.12.101

This term is intended to apply equally to EQUIPMENT and ACCESSORIES and thus is distinct from, and could possibly supplant, that of the existing subclause 2.1.106 (BIPOLAR ELECTRODE).

AA.2.12.102

Clinical application and HF SURGICAL MODES marked on HF SURGICAL EQUIPMENT have expanded beyond the primitive pair from two decades past. It is appropriate that the modern lexicon has a recognized source. Thus the new definitions in this Clause 2.

AA.2.12.103

It is generally believed that HF surgical CUTTING involves microscopic cellular ablation resulting from short electrical sparks being struck between the ACTIVE ELECTRODE and the tissue.

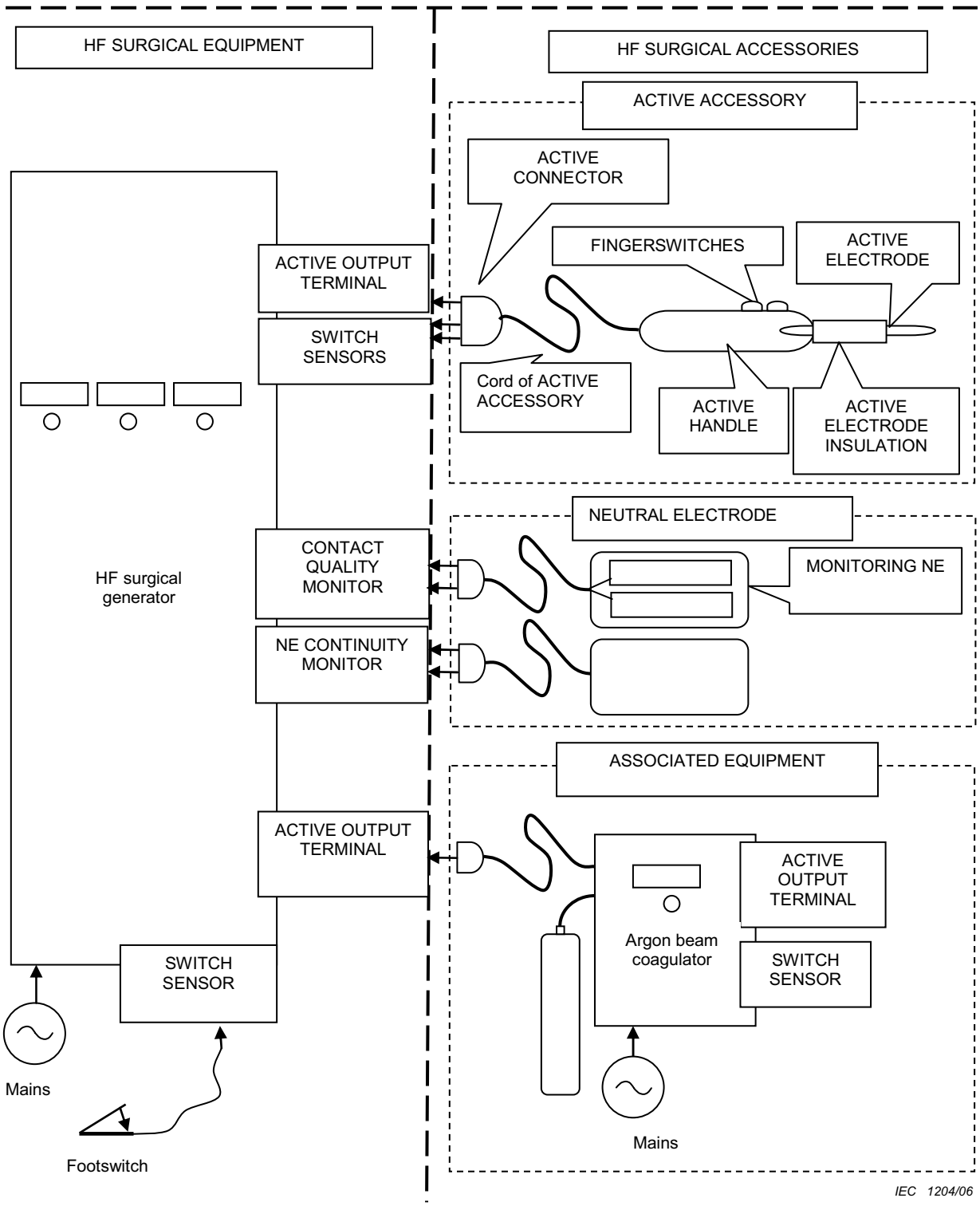


Figure AA.101 – Example of various parts of an HF surgical system (see AA.2.2.101)

AA.2.12.104

For purposes of this Particular Standard, the impedance of this path, at the lowest HF operating frequency, is 10 Ω or less. See Figure 107.

AA.2.12.105

FULGURATION generally requires HF peak output voltages of at least 2 kV in order ignite and sustain the long sparks. This mode is also known as spray or non-contact COAGULATION and may be enhanced by incorporation of a stream of inert gas such as Argon.

AA.2.12.107

The term HF SURGICAL MODE should be clearly distinct from “mode of operation” as used in 5.6 and 6.1 m) in reference to operational duty cycle.

AA.2.12.108

Frequencies above 0,2 MHz should be used in order to avoid the unwanted stimulation of nerves and muscles which would result from the use of low frequency current. Normally, frequencies above 5 MHz are not used in order to minimize the problems associated with HIGH FREQUENCY leakage currents. However, higher frequencies may be used in the case of BIPOLAR techniques. It is generally recognized that 10 mA is the lower threshold of thermal effects on tissue.

AA.2.12.109

This definition is intended to apply equally to EQUIPMENT and ACCESSORIES and thus is distinct from that of the existing subclause 2.1.103 (ACTIVE ELECTRODE).

AA.2.12.112

The measurement of CREST FACTOR is mathematically simple but difficult to carry out in a reliable manner. The r.m.s. voltage is particularly difficult to measure. The definition states that the measurements should be made in an open circuit condition. This means that the normal loads seen on the output of HF SURGICAL EQUIPMENT are not present. The load presented by the high voltage probe used to measure these voltages (10 MΩ to 100 MΩ typical) is considered to be essentially an open circuit. The following is a suggested method for these measurements that has shown a reasonable accuracy.

The measurements should be made from the output to the NE for MONOPOLAR outputs and across the two output poles for BIPOLAR outputs using a 1 000x or 100x high voltage probe connected to a high quality Digital Storage Oscilloscope (DSO) with automatic measurement capabilities.

First the exact period of the signal is then measured. For continuous sinusoidal waveforms (cf = 1,4) that is the reciprocal of the fundamental frequency of the waveform. For non continuous waveforms, the time period of the bursts is measured. For example, a COAGULATION waveform may have a fundamental frequency of 400 kHz with a burst repetition rate of 20 kHz. It is the precise measurement of the 20 kHz burst repetition rate that is needed. Once this time period is measured, the time base of the DSO should be modified to make the entire screen hold between 5 and 10 exact periods. For example, if the burst repetition rate is exactly 20 kHz, the period will be 50 µs. By setting the time base of the DSO to 50 µs per division, you should get exactly 10 waveform bursts on the screen.

The waveform is then captured and stored. Measure and record the MAXIMUM OUTPUT VOLTAGE (the absolute value of the largest peak). The r.m.s. voltage is then calculated. The most reliable method is to set the DSO to calculate the r.m.s. of the entire screen. Since the time base was adjusted to capture an exact multiple of waveforms, the calculation of r.m.s. voltage should be accurate.

An alternate way of measuring the r.m.s. voltage would be to connect the output of the high voltage probe into a thermal sensing true r.m.s. voltmeter that is RATED for the CREST FACTOR of the waveform you are measuring.

The CREST FACTOR can now be calculated.

AA.4.7 i)

Instruments used to measure HF currents, including HF voltmeter/current sensor combinations, should register true r.m.s. with a total verified accuracy of 5 % of reading or better from 10 KHz to at least 5 times the FUNDAMENTAL FREQUENCY of the HF SURGICAL MODE being tested. HF output instruments should register to specified accuracy within 3 s of application of the measured variable. Transient readings of less than 1 s duration may be ignored.

Resistors used for HF testing:

- should be RATED at no less than 50 % of the expected power dissipation expected for a given test, and
- should present a resistive component of impedance within 3 % of the specified value and no more than 8,5 degrees of impedance phase from 10 KHz to 5 times the fundamental frequency for the HF SURGICAL MODE being tested.

Instruments used for measuring HF voltages should be RATED a no less than 150 % of the expected peak voltage and should have verified accuracy of 5 % of reading or better from 10 KHz to 5 times the fundamental frequency of the signal being measured.

For each HF SURGICAL MODE, the term “fundamental frequency” means the frequency of the highest amplitude spectral line of the measured HF output voltage when operated at maximum power setting into an open circuit.

A primary objective of the revision of this particular standard is to isolate HF ACCESSORY requirements and tests from any specific HF SURGICAL EQUIPMENT. Further, this standard should clearly specify instrumentation for required tests to ensure repeatability of results, particularly for test agencies which may not be conversant with accepted HF test methods. Due to the brevity of power application and the greater availability of lower-power resistors which satisfy the low reactance requirement, resistors RATED as low as 50 % of expected power are suitable, but no lower.

AA.5.2

Type B APPLIED PART is deleted, as the APPLIED PART has to be isolated from earth at mains frequency (see Clause 19).

AA.6.1 p)

Knowledge by the OPERATOR of these parameters, which were previously required markings, does not enhance SAFETY.

AA.6.3

As the power delivered to the load depends on the load resistance, a graduation in relative units is considered to be adequate. However, if an output indication displays the actual power output in watts, it must do so over the total range of load resistance, otherwise the power delivered to the PATIENT may differ from that indicated and hence be a SAFETY HAZARD. If the numeral "0" were displayed, the OPERATOR would expect zero output at this position of the control.

AA.6.7

The standardization of the colours of indicator lights is regarded as a safety feature. The specified colours and their meanings are in line with the General Standard.

For many years the yellow indicator light has been used to signify that the CUTTING mode is selected or in use on HF SURGICAL EQUIPMENT. During surgery, a "blend" mode is used mainly for CUTTING with varying amounts of COAGULATION added. As the main function of "blend" is to cut, it is considered that a yellow light is most appropriate when "blend" is in use.

AA.6.8.2 aa)

Some OPERATORS believe incorrectly that CQM is intrinsic to either the CONTACT QUALITY MONITOR or MONITORING NE alone. It is important that all OPERATORS understand all of the physical requirements necessary to achieve CQM functionality.

AA.6.8.2 bb)

The advice concerning avoidance of unwanted burns is based on experience. In particular:

1) Minimising the distance between the operating field and the NEUTRAL ELECTRODE reduces the load resistance and, for a given power at the site of the ACTIVE ELECTRODE, the power output required from HF SURGICAL EQUIPMENT and also the HF voltage across the PATIENT. Hence the hazard of unwanted burns is reduced.

2) Small area contacts with objects having a low impedance to earth at HIGH FREQUENCIES may result in high current densities and hence unwanted burns.

3) There may be some HF voltage difference between these parts of the PATIENT's body which may cause an unwanted current to flow.

4) The current flowing to the leads of the monitoring EQUIPMENT may cause burns at the site of the monitoring electrodes.

5) The capacitance between the electrode cable and the PATIENT may result in some local high current densities.

6) Especially where bony structures and joints having a relatively high resistance are involved, a BIPOLAR technique can avoid unwanted tissue damage.

8) In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power.

Not all advice is necessary, if only a BIPOLAR output or a RATED OUTPUT POWER not exceeding 50 W without NEUTRAL ELECTRODE is available.

11) Certain devices or accessories may present a SAFETY HAZARD at low power settings. For example, with argon beam COAGULATION, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.

AA.6.8.2 ee) and ff)

This information should enable the OPERATOR to judge the suitability of an HF SURGICAL EQUIPMENT or its output setting for a particular ACCESSORY with regard to its isolation quality.

IEC 60601-2-18 contains requirements prescribing that manufacturers of ENDOSCOPICALLY USED ACCESSORIES shall specify them as suitable for a certain maximum allowed HF peak output voltage which shall be defined in the ACCOMPANYING DOCUMENTS for such ACCESSORIES.

However Amendment 1 (2000) of IEC 60601-2-18 requires a "RATED recurring peak voltage" together with the "mode(s) of intended use". It was felt that this information on one hand is insufficient as the modes of intended use like "spray COAGULATION" are not clearly technically defined and may vary much between different brands and models of HF SURGICAL EQUIPMENT. On the other hand it was considered as impracticable to give such rather complex information to the user of the equipment.

Therefore it was considered as more practicable to provide the user only with a RATED ACCESSORY VOLTAGE and a MAXIMUM OUTPUT VOLTAGE for any output setting in order to enable the user to judge whether any HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT can be safely used with any certain output setting of the generator.

At HIGH FREQUENCY the stability of insulation is affected by dielectric heating so the relationship between the MAXIMUM OUTPUT VOLTAGE and the CREST FACTOR is important.

Further it was considered that with all currently known brands and models of generators in modes and settings producing higher output voltages, the CREST FACTOR is always increased along with the voltage. Therefore a general relation between output voltage and CREST FACTOR was developed as shown in Figure AA.102.

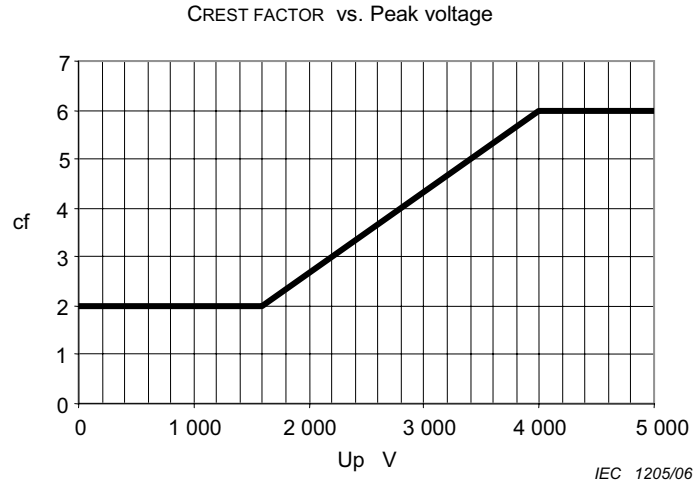


Figure AA.102 – CREST FACTOR vs peak voltage

A safe situation exists whenever a RATED ACCESSORY VOLTAGE is matched to an output voltage of an HF SURGICAL EQUIPMENT having a CREST FACTOR which falls on or above the line in the diagram. The RATED ACCESSORY VOLTAGE must not be less than the MAXIMUM OUTPUT VOLTAGE, since the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT must fulfil the requirements of 59.103.6, which takes into account the CREST FACTOR.

Provision is made for the case in which a generator at a certain setting has a MAXIMUM OUTPUT VOLTAGE with a corresponding CREST FACTOR which falls below the line. In this case, to ensure safety, the RATED ACCESSORY VOLTAGE must be high enough to ensure that there is no insulation breakdown of the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT when used with that particular HF SURGICAL EQUIPMENT in that particular HF SURGICAL MODE at that particular output setting. This precaution is necessary in order to take into account the dielectric heating produced by lower CREST FACTOR waveforms. The safe value of RATED ACCESSORY VOLTAGE must be found by testing the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT with the HF SURGICAL EQUIPMENT.

AA.6.8.2 gg)

The OPERATOR must know which MONITORING NEs are safe and functional with the CQM. Many OPERATORs mistakenly believe that with the advent of CQM, intraoperative surveillance of NE contact is no longer necessary.

AA.6.8.2 hh)

The conductive and adhesive properties of a disposable NE typically decay over time. Infant NEs are subject to less demanding thermal requirements and must be used with greater care. The OPERATOR must know which CQM(s) are operative with a given NE. A statement of compatibility may take different forms as long as it can be understood by the USER (e.g. an impedance based CQM system where the alarm sounds based on the following conditions ...., a CQM system found in the following list of equipment ..., a CQM system from the following manufacturers ..., as well as other forms).

AA.6.8.2 kk)

For systems of HF SURGICAL DEVICES used under these conditions, there is an increased concern for NEUTRAL ELECTRODE burns.

AA.6.8.3

Some specialized HF SURGICAL EQUIPMENT do not provide OPERATOR adjustable output settings.

AA.6.8.3 aa), bb)

These diagrams should enable the OPERATOR to judge the suitability of an HF SURGICAL EQUIPMENT for a particular purpose. If the HF SURGICAL EQUIPMENT has discreet blend selections (e.g. blend 1, blend 2, etc) then a diagram would be created for each discreet mode. If the HF SURGICAL EQUIPMENT has a variable blend control where the setting may be continuously adjusted, then the control should be set to the blend setting that provides the greatest hemostasis.

AA.6.8.3 dd)

It should be made clear to the OPERATOR whether the APPLIED PART is completely floating or referenced to earth at HIGH FREQUENCY.

AA.17 h)

Measurements show that a 5 kV defibrillation pulse in the usual clinical situation will result in no more than 1 kV at the neutral and ACTIVE ELECTRODES. A 2 kV test pulse provides a safety margin. The inductance value (Figure 50 of the General Standard) results in a test pulse having a faster than normal rise time. This is required in order to provide increased stress on the insulation for test purposes.

AA.18 aa)

For low powered MONOPOLAR HF SURGICAL EQUIPMENT used without a NEUTRAL ELECTRODE this is common practice; it is considered not to create any safety problem.

AA.19

The requirements for LEAKAGE CURRENT specified in the General Standard are intended to provide protection against the risk of electric shock.

In this Particular Standard some requirements for HF LEAKAGE CURRENT are also given in order to reduce the risk of unwanted burns.

AA.19.1 g)

This subclause is concerned with LEAKAGE CURRENTS which lead to electric shock, not with therapeutic currents such as are produced by HF SURGICAL EQUIPMENT. Appropriate tests for HF LEAKAGE CURRENT for HF SURGICAL EQUIPMENT with multiple patient circuits are given in 19.3.101, item c), cross-coupling between different HF PATIENT CIRCUITS.

AA.19.3 a)

Monitoring currents which flow exclusively between the parts of a split NEUTRAL ELECTRODE are considered not to need limitation according to TYPE CF APPLIED PARTS, independent of the degree of protection against electric shock (TYPE BF or CF APPLIED PARTS), because these currents can be expected never to flow across the heart.

AA.19.3.101 a)

HF SURGICAL EQUIPMENT designed for use without a NEUTRAL ELECTRODE had to be exempted since, in such HF SURGICAL EQUIPMENT, a differentiation between functional and HF LEAKAGE CURRENT is impossible. Therefore, the measurement of functional and HF LEAKAGE CURRENT is meaningless.

As distinct from the LEAKAGE CURRENT measurements of the General Standard, a measuring resistance of 200 Ω is specified here to simulate the load impedances prevailing in actual situations so as to give the maximum leakage power. The values specified result in a power of 4,5 W, which is considered to be a reasonable limit.

Test 2 of the earth referenced case is specified to verify that the impedance to earth at HIGH FREQUENCY is sufficiently low.

An earthed conductive plane under the insulating table and bundling the power supply cord rather than coiling it, improve the reproducibility of the measurement considerably.

AA.19.3.101 a) 3)

Experience in testing BIPOLAR HF SURGICAL EQUIPMENT has shown that these limits are reasonable and the test realistic.

AA.19.3.101 b)

A test of the isolation of HF SURGICAL EQUIPMENT at HIGH FREQUENCY is easily achieved by placing load resistances and measuring devices directly on the output terminals. In this case a limit of 100 mA is specified because the contribution from the leads is not included. However, in order to ensure that all complex impedances resulting from leads and ACCESSORIES (for example ACTIVE ELECTRODES with fingerswitches) are considered, the test in 19.3.101 a) is also included.

AA.20

Clause 59 has been restructured to accommodate separate requirements and tests for HF SURGICAL ACCESSORIES.

AA.20.2

The introduction to Clause 20 states that "Only insulation with a safety function need be subject to testing“. The requirement of an F-TYPE APPLIED PART in HF SURGICAL EQUIPMENT is to prevent dangerous voltage which appears on the PATIENT because of some other external fault from causing excessive PATIENT LEAKAGE CURRENT to earth via the HF SURGICAL EQUIPMENT. These rare and transient requirements are adequately covered by the BASIC INSULATION tests of B-d using the reference voltages specified in 20.3. There is no evidence

that existing HF SURGICAL EQUIPMENT, which has been tested to the B-d requirements, has proved unsatisfactory or unsafe. In the unlikely event that HF breakdown between an APPLIED PART and the ENCLOSURE should occur, a SAFETY HAZARD to the PATIENT will not result.

The insulating properties of air change with the atmospheric pressure. Some tests are difficult to complete due to the breakdown of air before the solid insulation is tested. Subclause 20.4 allows for the use of an additional insulating barrier to stop air breakdown during a solid insulation dielectric test. The allowance of a minimum atmospheric pressure gives greater flexibility to those conducting the test, and greater repeatability of tests performed at different testing locations. Without the allowance, testing locations at high altitudes would be testing to a more difficult level than stated in the subclause.

AA.20.4

The purpose of this subclause is to test the safety of solid insulation in a component or device. The test stresses the protective insulation with a voltage that is much greater than is normally seen for that component or device. The use of an insulating barrier is allowed when the breakdown of CREEPAGE DISTANCES or AIR CLEARANCES prevents the protective insulation from being fully tested. Subclause 57.10 specifies the CREEPAGE DISTANCES and AIR CLEARANCES necessary to prevent the breakdown of air or between uninsulated conductors along the surface of an insulator.

AA.36.201.1

HF surgery is a very long established modality with known interference inherent during activation. Since the clinical benefits of HF SURGICAL EQUIPMENT outweigh the risks of interference and since HF SURGICAL EQUIPMENT is normally operated for short periods only, this type of EQUIPMENT is exempt from the requirements of 36.201.1 when it is activated.

HF SURGICAL EQUIPMENT performs its CUTTING and COAGULATION functions through the use of radio frequency energy, and HF EMISSION frequently much above the CISPR 11 limits is present. The power levels and harmonic content of the output of the HF SURGICAL EQUIPMENT are necessary to enable the HF SURGICAL EQUIPMENT to carry out its clinical function effectively.

The EMISSIONS strongly depend on the arrangement and length of the active and neutral cords, on the operating mode (sparking or not) and on many other application conditions. Furthermore, many diagnostic, monitoring, anaesthetic and infusion EQUIPMENT have APPLIED PARTS or PATIENT CIRCUITS which are directly connected to the PATIENT.

For such EQUIPMENT, particular test arrangements simulating direct connection to the PATIENT CIRCUITS of a HF SURGICAL EQUIPMENT are necessary for testing EMC IMMUNITY (see 36.202.7 and Figures 108 and 109 of IEC 60601-2-34). This was considered the best way to assure electromagnetic compatibility between HF SURGICAL EQUIPMENT and some other medical devices used in its vicinity.

For a standardized source of electromagnetic interference to be used for such tests, the following conditions have been determined in IEC 60601-2-34.

"The HF SURGICAL EQUIPMENT shall comply with IEC 60601-2-2, shall have a minimum cut mode of 300 W, a minimum COAGULATION mode of 100 W and a working frequency of 400 kHz ± 50 kHz."

However, during stand-by operation, the HF SURGICAL EQUIPMENT may be energized for long periods and compliance with the EMC requirements is considered necessary.

During the immunity tests of IEC 61000-4-3 and IEC 61000-4-6, the manufacturer will need to specify how compliance to the standard is checked. This includes precautions needed to ensure the duty cycle of the generator is not exceeded as well as how perturbations in the output power are detected.

Additional information on the electromagnetic EMISSIONS created by HF SURGICAL EQUIPMENT may be found in Annex BB

AA.42

The operating conditions specified here are deemed to be the most severe conditions likely to occur in practical use.

AA.44.3

The test quantity of one litre represents a liquid filled bottle (for example an infusion solution), the presence of which in an operating room is considered to be likely.

AA.44.6 aa)

A footswitch may be exposed to a considerable amount of water or other liquids during certain operations, and also when it is cleaned (for example by total immersion); consequently watertightness is required.

AA.44.6 bb)

A certain degree of water protection has to be required for fingerswitches to prevent inadvertent activation of an output by the ingress of conductive fluids. This test is independent of specific HF SURGICAL EQUIPMENT. An a.c. impedance measurement of 1 kHz avoids measurement errors due to polarization effects in saline which may bridge the switching contacts, and a SELV voltage is consistent with 56.101.1. The impedance limit was chosen as twice the maximum threshold stipulated by 56.101.1.

AA.44.7

Applicable to all ACCESSORY specific requirements added by this revision, and replaces the existing FINGERSWITCH sterilization requirement in 59.103.2. The specified parts are expected to enter the sterile surgical field during use and thus will be re-sterilised after each use. There are no requirements or tests which can rationally be excepted from this requirement.

ACTIVE ACCESSORIES marked for single use are presumed to be unsuitable for re-sterilisation and thus are exempted from this requirement.

AA.46.101 and 46.102

The standardization of the position of activating controls is required to reduce human errors. Controls for functions other than CUTTING and COAGULATION activation may also appear on the ACTIVE HANDLE.

AA.46.103

In clinical use, the problems of co-ordination of the simultaneous use of more than one ACTIVE OUTPUT TERMINAL are considered to create unacceptable HAZARDS if only one output switch and set of controls are incorporated.

AA.46.104

Adds BIPOLAR ACTIVE ACCESSORIES to the list and specifically places the burden for avoidance of incorrect connections on the EQUIPMENT. Flying leads do not adequately discourage improper connections. Misconnection of a single pin ACCESSORY presents no conceivable HAZARD.

Examples of BIPOLAR ACTIVE CONNECTOR configurations which conform to this requirement are under consideration.

AA.46.105

The pre-indication of the output and/or function (for example CUTTING or COAGULATION) is an essential safety feature where they are energized by the same output switch.

AA.46.106

The same colour coding as specified for indicator lights should be used in other places to avoid confusion.

AA.50.1.101

In the load resistance range normally prevailing in practical use, lowering the output setting should never result in an increase in output power

AA.50.1.103

The maximum peak output voltage may appear at output settings other than maximum and with applied loads other than open circuit.

AA.51.2

The hazard of burns increases with power. The maximum power specified is considered to be adequate for the most demanding procedures.

In the case of more than one MONOPOLAR circuit the total output power has to be limited to 400 W in order to keep the current density on the side of the NEUTRAL ELECTRODE to a safe level.

AA.51.5

Although not required for MONOPOLAR HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W, compliance with this subclause is recommended. This requirement is intended to apply to all HF SURGICAL EQUIPMENT having BIPOLAR output, not just BIPOLAR only.

AA.51.102

Independent outputs must deliver their intended output power to prevent a hazard. This is especially true when one output is set at a level substantially lower than another, but both can be activated simultaneously.

Where multiple outputs share the power of a single mode (e.g. simultaneous COAGULATION), a hazard could exist if a single output delivers more power than the intended power or if the sum total of the power delivered in all of the simultaneously activated outputs exceeds the intended power.

AA.52.101

Some ACCESSORIES, for example resectoscopes or BIPOLAR ELECTRODES, may short-circuit the output in normal use and the output circuit is frequently energized while open circuited. It is considered practical to design HF SURGICAL EQUIPMENT which will not be damaged by repeated short circuiting and by the open circuiting of the output for short periods of time. The revised text is intended to eliminate a question of which BIPOLAR output terminal is the NEUTRAL ELECTRODE and whether this requirement applies to BIPOLAR outputs.

AA.56.3c)

This subclause of the General Standard is designed to prevent a connection between the PATIENT and either ground or a hazardous voltage. This subclause assumes that a connection may occur at any time, and that the contact with the PATIENT is either continuous or unsupervised.

The situation with electrosurgical APPLIED PARTS is quite different, because this kind of EQUIPMENT is intended to be used only under the control of a doctor or trained medical staff. Possible hazardous situations, which may occur by insertion of connectors of NEUTRAL ELECTRODES into mains connectors, such as mains outlets or sockets of detachable power supply cords, are covered by this subclause of the Particular Standard.

Unlike electrocardiographic monitoring electrodes which can be expected to be applied by OPERATORS untrained in electrical hazards, HF SURGICAL EQUIPMENT and ACCESSORIES are accessible only to OPERATORS highly qualified and trained in restricted access locations.

ACTIVE and BIPOLAR ELECTRODES are applied only under the direct control of a surgeon who may be expected to interrupt contact with the PATIENT at the slightest sign of an unexpected PATIENT's response.

AA.56.11

The output switch is required to be of a momentary type in order to prevent unintentional energization of the output. The requirement for isolated extra-low voltage takes into account the severe environmental conditions under which these footswitches, fingerswitches and their cables are used. The requirement against the effects of entry of liquids is already defined in 44.6 of this Particular Standard.

AA.56.101

This subclause assumes the EQUIPMENT is turned on.

AA.56.101.1

It is considered that using one FINGERSWITCH for selecting a multiple function, for example CUTTING or COAGULATION, could result in confusion and a potential hazard if a surgeon unfamiliar with the system were to use it. One example of this is light pressure on the switch may give COAGULATION, heavier pressure may give CUTTING.

AA.56.103

The requirements of 56.103 (derived from IEC 60601-2-4) are specified because ACTIVE ACCESSORIES and their cables are subject to considerable stress in use and typical failure modes can present a hazard to staff and/or PATIENTS. Once a cable fatigues in use, it is common that it will overheat and either ignite itself or ignite nearby materials, endangering staff and patients. These requirements will establish a reference level for durability of such cables.

The requirements of 56.103.1 and 56.103.2 relate to the compatibility of detachable parts of ACTIVE ACCESSORIES. This issue becomes important for third party accessories and can cause operational difficulties in clinical practice, leading to delayed or interrupted procedures.

Many ACTIVE HANDLES provide for the use of any of a variety of specialized, OPERATOR selected, detachable ACTIVE ELECTRODES. There is no standardization of electrode interface amongst the ACTIVE HANDLES of different manufacture. It is known that, although it may appear to the OPERATOR that an ACTIVE ELECTRODE from one manufacturer may fit the ACTIVE HANDLE from another, PATIENT injuries have resulted from incompatibilities such as:

- inadequate SEPARATION between the conductive parts of the ACTIVE HANDLE – ACTIVE ELECTRODE interface and PATIENT tissue;
- arcing across a gap between the intended electrical mating parts, resulting in melting and/or ignition of insulation;
- inadequate mechanical retention force, resulting in the ACTIVE ELECTRODE, which may have become quite hot, falling into a PATIENT body cavity.

AA.57.10a)

These reduced requirements are considered to be adequate to the fact that the "voltages stressing the insulation..." (see 20.2 B-e in the General Standard) are of HIGH FREQUENCY and therefore the SAFETY HAZARD, when this insulation fails, is much lower than at low frequencies, for which B-e distances initially have been defined.

AA.59.101

Undetected interruption of the NEUTRAL ELECTRODE cable in HF SURGICAL EQUIPMENT or insufficient electrical contact between the NEUTRAL ELECTRODE and the PATIENT may lead to severe burns. Therefore, as a minimum requirement, monitoring of a failure of the NEUTRAL ELECTRODE circuit or its connections is required for such HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER in excess of 50 W.

The revised subclause title is intended to distinguish over the various other monitor circuits which may be present in HF SURGICAL EQUIPMENT, such as output power fault detection, and the like.

A CONTACT QUALITY MONITOR should be shown to function effectively when used with any MONITORING NE listed as compatible. When combined with new requirements for NE thermal performance, the risk of NE site burns is effectively mitigated. Because of the technical variations and proprietary nature of existing CQM schemes, imposition of a fully ACCESSORY independent requirement is judged infeasible.

Full contact means that the NE has been applied according to the instructions for use such that conductive portion within the NE is as close to the human subject (or suitable surrogate surface) as possible without any voids or spaces.

The following literature is recommended as a guide in evaluating suitable surrogate surfaces:

NESSLER N., REISCHER W., SALCHNER M. *Measurement Science Review,* Volume 3, Section 2, 2003.

NESSLER N., *Current Density distribution in Human skin under the Grounding electrode of Electrosurgery*, BEMS 17th Annual Meeting, Boston, MA., 1995.

NESSLER N., HUTER H., WANG L. Sicherheitstester für HF-Chirurgie-Neutralelektroden. *Biomedizinische Technik,* 1993, Vol. 38, p 5-9.

NESSLER N., REISCHER W., SALCHNER M. *Electronic Skin – Test Device For Electrosurgical Electrodes.* 12th IMEKO TC4 International Symposium, Zagreb 2002.

AA.59.103

HF SURGICAL EQUIPMENT is capable of producing high voltages which will appear on the insulated conductive parts of HF SURGICAL ACCESSORIES. The insulation on these accessories must withstand this voltage stress and limit the HF leakage current density appearing on exposed surfaces in order to mitigate the risk of unintended burns to the PATIENT and the OPERATOR. This insulation is subjected to considerable stress in practical use, and therefore the requirements contain a safety margin. The insulation applied to any part of an ACTIVE ACCESSORY must maintain adequate dielectric strength after extended exposure to conductive fluids and, except for accessories intended for single use, repeated sterilization.

NOTE This subclause has been completely redrafted to cover only dielectric strength of the various parts ACTIVE ACCESSORY insulation, independent from any particular HF SURGICAL EQUIPMENT. Accordingly, former subclauses 59.103.1 through 59.103.4 are shown as “Not used”, and the revised requirements and tests for ACTIVE ACCESSORY INSULATION now appear as 59.103.5 through 59.103.7. The revised requirements and compliance tests have drawn upon the current editions of ANSI/AAMI HF-18 and IEC 60601-2-18 with a goal of harmonisation.

Requirements for NEs are now compiled under 59.104.

AA.59.103.5

The HF leakage requirements are based on ANSI/AAMI HF18:2000, subclause 4.2.5.2. The rationale for these requirements is excerpted below. In order to use common SI units, the text and formulas for both the normative language and the rationale have been changed from the original.

The 1 000 kHz maximum operating frequency and the RATED ACCESSORY 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.

All of the selected values in combination 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 s. 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 NEUTRAL ELECTRODES are allowed twice the leakage of the cables of ACTIVE ACCESSORIES because the voltage levels developed between the conductors of such cables and the patient's skin are generally much lower. BIPOLAR accessories are allowed twice the leakage of MONOPOLAR cables because the voltage of use is generally much lower than with the MONOPOLAR mode.

The following allowances have been incorporated in this Particular Standard to permit use of ordinary HF SURGICAL EQUIPMENT to generate test voltages:

The allowable test voltage range for MONOPOLAR ACCESSORIES should exceed the Paschen minimum of about 280 V_{peak} in order to permit corona development, but need not exceed the typical CUT output voltage of about 1 000 V_{peak}. Nor should the peak test voltage exceed the RATED ACCESSORY VOLTAGE.

These allowances are accommodated in harmonisation with ANSI/AAMI HF18 by adjusting the HF leakage current conformance limit as follows:

$$I_{\text{leakage}} = 9{,}0 \times 10^{-7} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

For BIPOLAR cords and NE cords, the HF leakage current is doubled:

$$I_{\text{leakage}} = 1{,}8 \times 10^{-6} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

The risk of HF leakage current passing through ACTIVE ELECTRODE INSULATION and the insulation of NE cords is deemed at least as serious as that of cords of ACTIVE ACCESSORIES, and therefore those parts are included in these requirements.

NOTE Alternative requirements and compliance tests based on capacitance measurements alone are under consideration pending empirical proof of equivalence by MT17 experts.

Alternate HF leakage test (under consideration):

The equivalent capacitance of the ANSI/AAMI HF18 HF leakage test path is derived as follows:

Given

$$I_{\text{leakage}}[\text{A}] = \frac{U_{\text{test}}[\text{V}]}{X_{\text{leakage}}[\Omega]}$$

and

$$X_{\text{leakage}}\,[\Omega] = \frac{1}{(2\pi \times f_{\text{test}}\,[\text{Hz}] \times C[\text{F}])}$$

then

$$I_{\text{leakage}}\,[\text{mA}] \times 10^{-3} = U_{\text{test}}\,[\text{V}] \times f_{\text{test}}\,[\text{kHz}] \times 10^{3} \times 2\pi \times C[\text{pF}] \times 10^{-12}$$

thus

$$C[\text{pF}] = \frac{I_{\text{leakage}}\,[\text{mA}] \times 10^{6}}{[2\pi \times U_{\text{test}}\,[\text{V}] \times f_{\text{test}}\,[\text{kHz}]]} \quad \text{Equation AA.1}$$

The r.m.s. value of a sinusoidal test voltage is evaluated as:

$$V = \frac{V_{\text{p–p}}}{2\sqrt{2}} = 0{,}3536 \times V_{\text{p–p}}$$

The constants used for the HF leakage test are:

U_{test} = 800;
$V_{\text{p-p}}$ = 282,8 [V];
f_{test} = 1 000 [kHz];
I_{leakage} = 3,6d x L [mA].

The limiting capacitance according to Equation AA.1 is thus:

C = 2,026d x L [pF]

for all but BIPOLAR ACTIVE ACCESSORIES and NE cords. These are tested at 400 V_{pp}, which yields

C = 4,052d x L [pF].

For purposes of this standard, these results are rounded down to 2d x L and 4d x L [pF] respectively.

AA.59.103.6

As the dielectric stress is at HIGH FREQUENCY in practice, additional testing at HIGH FREQUENCY is required. A saline test electrode reasonably simulates the wet PATIENT and OPERATOR tissue in or near the surgical site. The use of a thin wire wrapped over insulation has been shown to induce corona discharge damage which can be detected by the subsequent mains frequency dielectric strength test.

These requirements and tests harmonize to the extent possible with IEC 60601-2-18.

AA.59.103.7

It is known that HF test voltages greater than 120 % of that available from HF SURGICAL EQUIPMENT are difficult to achieve. Step-up transformers tend to distort the HF waveform, and the capacitance of the dielectric being tested can load the HF test voltage source. In order to stress insulation with an acceptably high margin, a d.c. or mains frequency test is required. This test follows the HF dielectric strength test in order to detect any corona-induced weaknesses.

Elevated temperatures produced by dielectric stress can alter the internal structure of HF ACTIVE ACCESSORIES. Any incorporated FINGERSWITCH should function reliably and not activate its output inadvertently following the all of the dielectric strength tests.

NOTE The metal foil used in the compliance test should be highly conductive.

AA.59.104.1

For low-powered HF SURGICAL EQUIPMENT, for example for dental use, experience has shown that an arrangement where the neutral end of the output circuit is connected to earth is satisfactory. The return of the HF current from the PATIENT is accomplished capacitively, for example to the earthed metal frame of the dental chair. Consequently this HF SURGICAL EQUIPMENT is exempted from the requirement for a NEUTRAL ELECTRODE.

AA.59.104.2

The electrical connection of the NE CORD to the part of an NE, except for a MONITORING NE, which is in contact with the PATIENT should be formed such that the NE CONTINUITY MONITOR is capable of detecting any interruption of that connection. MONITORING NEs are exempted, since such an interruption is expected to appear as a loss of contact area with the patient.

The test method of 18 f) is suitable for detecting connections which may fuse open during normal use, however that use is not expected to exceed 1 A.

AA.59.104.3

In the case of detachment of the NE cord from the NE, it should not be possible for monitoring current from an NE CONTINUITY MONITOR or a CONTACT QUALITY MONITOR to pass through the PATIENT, thus producing a false indication of proper NE attachment.

AA.59.104.4

Although the voltage difference between the NE application site on the PATIENT and the NE cord conductors may be small, a significant voltage gradient may develop along the PATIENT's body proximal to the surgical site, especially during application of high HF surgical current. Thus, there is a risk of a burn should the NE cord come in contact with a more proximal part of the PATIENT. Application of the HF leakage current requirements of 59.103.5 mitigates this risk. Since lower voltages are expected to be present, the higher leakage current limit is deemed appropriate.

Dielectric breakdown of NE cord insulation presents a similar risk to both the PATIENT and the OPERATOR, and thus the HF and mains frequency dielectric strength requirements are deemed necessary. The test voltage magnitudes are unchanged from the prior editions of this Particular Standard.

The cables of DISPERSIVE ELECTRODES are allowed twice the leakage of the cables of ACTIVE ACCESSORIES, because the voltage levels developed between the conductors of such cables and the patient's skin are generally much lower.

AA.59.104.5

The following literature is recommended as a guide in evaluating suitable surrogate surfaces:

NESSLER N., REISCHER W., SALCHNER M. *Measurement Science Review,* Volume 3, Section 2, 2003.

NESSLER N., *Current Density distribution in Human skin under the Grounding electrode of Electrosurgery*, BEMS 17th Annual Meeting, Boston, MA., 1995.

NESSLER N., HUTER H., WANG L. Sicherheitstester für HF-Chirurgie-Neutralelektroden. *Biomedizinische Technik,* 1993, Vol. 38, p 5-9.

NESSLER N., REISCHER W., SALCHNER M. *Electronic Skin – Test Device For Electrosurgical Electrodes.* 12th IMEKO TC4 International Symposium, Zagreb 2002.

This requirement was adopted from ANSI/AAMI HF18:2000, subclause 4.2.3.1. The rationale for that requirement is also adopted, with minor lexical and subclause reference changes for this Particular Standard, as follows:

The purpose of the NEUTRAL ELECTRODE (NE) in MONOPOLAR electrosurgical procedures is to reliably conduct the required HF surgical current with minimal rise in skin temperature.

Measurements with heated metallic blocks (Moritz & Henriques, 1947) and with small circular electrodes carrying HF surgical 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. Therefore, NEs that create temperature increases approaching 12 °C cannot be considered safe. Six degrees Centigrade represents a conservative safety factor of two and a maximum allowable temperature rise for an acceptable NE. No acceptable NE should exceed a 6 °C temperature rise when subjected to the required current and duration test.

It is recognized that the use of human subjects for qualifying NEs to the requirements of this Particular Standard may be troublesome or prohibited in many laboratories. However, the specified conformance test is based upon a large volume of empirical data from human tests, using 10 µm infrared imaging instruments, collected and validated by numerous manufacturers and test houses since 1980. Although the use of media and apparatus which yield equivalent results is permitted, documentation of that equivalency must be in place. Therefore, the worst case electrical and thermal properties of NE application sites on a variety of human subjects are the reference standards against which the accuracy of surrogate media and other alternative temperature rise test apparatus are qualified.

Because NE site burns may be confined to very small areas, the qualification measurement must have an adequate spatial sampling frequency to ensure that unacceptable NEs will always be detected. The requirement for one sample per square centimetre is a minimum. Current technology provides for many more samples per square centimetre. 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 centimetre area. The initial temperature of NEs applied to human skin must be the same in all tests so that all results will be comparable.

At the end of the 60 s application of HF current, the NE is removed from the test surface prior to measuring the final temperature.

HF surgical 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 conformance test current 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:

1. 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).
2. The unpublished data of Milligan and associates were presented in terms of the maximum, minimum, and average currents and durations for each procedure studied.

These 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 (TUR) procedures. For TUR procedures, the ECRI study showed an average CUTTING current of 680 mA and 480 mA for COAGULATION, with duty cycles of 15 % average and 45 % maximum. Milligan studied a smaller sample of 25 TUR procedures performed by 13 surgeons using five electrosurgical units at eight hospitals.

The reported data for all TUR procedures are summarized in Table AA.1. Means and standard deviations σ are calculated over the 25 cases. These data provide useful estimates of the means and variance in measured currents and durations.

Table AA.1 – Summary of measured current and durations for 25 TUR procedures

	Mean	**Standard deviation**
Length of surgery (hours)	0,86	0,49
Number of activations (per hour)	225	105
CUTTING Current		
Maximum current (mA)	407	297
Average current (mA)	297	200
Maximum duration (s)	3,8	2,3
Average duration (s)	2,1	0,7
COAGULATION current		
Maximum current (mA)	339	130
Average current (mA)	258	88
Maximum duration (s)	5,7	7,6
Average duration (s)	2,0	0,7

The total energy dissipated at the NE application site is given by:

$$E = (I_{\text{rms}})^2 \times R \times t$$

where

E is energy dissipated [joules];

I is the NE current [amperes];

t is the duration of current flow [seconds];

R is the real part of the impedance at the NE site [Ω].

The impedance, R, is not generally definable, since its value depends on the NE design and the anatomical structure of the tissue to which it is applied. A "heating factor" Θ may be defined to describe the "stress" placed on an NE as:

$\Theta = I^2 t$ (A^2s).

This heating factor has the significance of energy dissipated per Ω of impedance. NEs should be able to handle Θ values representative of surgical procedures. A current of 700 mA applied for 60 s yields Θ = 30 A^2s. This value is far in excess of the maximum likely current and duration for a TUR procedure. The maximum likely Θ value can be found by multiplying the square of the largest likely current, i.e. 0,68 A from ECRI (1973) data (average) plus one standard deviation, i.e., 0,2 A from the Milligan data by the maximum likely duration, i.e., 5,0 s (average) plus one standard deviation, i.e., 7,6 s from the Milligan data, to get

Θ = 8,7 A^2s

Thus, 30 A^2s is a conservative test criterion.

A similarly conservative test criterion can be derived for NEs marked for "INFANT" use. Since TUR procedures are not performed on infants, a reasonable approach is to use the current and duration data available for general surgical procedures. These data, reported by Pearce (1981), are given in Table AA.2:

Table AA.2 – Summary of measured currents and durations for general surgical procedures

	Mean	**Standard deviation**
Length of surgery (hours)	1,56	0,84
Number of activations (per hour)	63	84
CUTTING current		
Maximum current (mA)	340	101
Average current (mA)	281	147
Maximum duration (s)	7,6	11
Average duration (s)	2,2	1,8
COAGULATION current		
Maximum current (mA)	267	157
Average current (mA)	198	114
Maximum duration (s)	11	7,5
Average duration (s)	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

$$\Theta = 4{,}7A^2s$$

Thus,

$$\Theta = 15\ A^2s$$

is a conservative test criterion and is readily obtained using a current of 500 mA applied for 60 s.

The safety margins inherent in these Θ values are intended to maintain a reasonable margin of safety even in the event of unintended partial loss of contact area between the NE and the PATIENT's skin. Where NEs other than MONITORING NEs are used, advice to the OPERATOR according to 6.8.2 gg) is relied upon prevent a hazardous loss of contact area. However, where CONTACT QUALITY MONITORS and MONITORING NEs are in use, the OPERATOR expects to be relieved of the burden of NE contact surveillance, relying fully upon the CONTACT QUALITY MONITOR to alert the OPERATOR to area loss before it becomes hazardous. Therefore, MONITORING NEs are tested with the same area loss which will cause the CONTACT QUALITY MONITOR to sound an alarm.

References:

EMERGENCY CARE RESEARCH INSTITUTE. Clinical studies. *Health Devices*, 1973, vol. 2, nos. 8-9, p. 194-195.

EMERGENCY CARE RESEARCH INSTITUTE. *Draft Environmental Requirements and Test Methods for Non-Implantable Medical Devices* (Contract No. FDA-74-230). Plymouth Meeting, PA: ECRI, July 1978.

EMERGENCY CARE RESEARCH INSTITUTE. *Development of Environmental Test Methods for Non-Implantable Medical Devices, Final Report* (Contract No. 223-77-5035). Plymouth Meeting, PA: ECRI, April 1979.

MORITZ, AR, HENRIQUES, FC. Studies in thermal injury: II. The relative importance of time and surface temperature in the causation of cutaneous burns. *Amer J Path*, 1947, vol. 23, no. 5, p. 695-720.

PEARCE, JA, FOSTER, KS, MULLIKIN, JC, GEDDES, LA. *Investigations and Studies on Electrosurgery*

(HHS publication FDA 84-4186). Rockville, MD: U.S. Food and Drug Administration, 1981.

PEARCE, JA, GEDDES, LA, VAN VLEET, JF, FOSTER, K, ALLEN, J. Skin burns from electrosurgical current. *Med Instrum*, 1983, vol. 17, no. 3, p. 225-231.

AA.59.104.6

This requirement was adopted from ANSI/AAMI HF18:2000, subclause 4.2.3.2. The 200 kHz phase angle criterion for distinguishing conductive and capacitive NEs was developed, lacking a clear published definition, *a priori* or otherwise.

The rationale from ANSI/AAMI HF18:2000, subclause A.4.2.3.2 is also adopted, with minor lexical and subclause reference changes for this Particular Standard, as follows:

The contact impedance must be low enough that the NEUTRAL ELECTRODE (NE) represents the preferred current pathway. In the case of HF SURGICAL EQUIPMENT having an EARTH REFERENCED PATIENT CIRCUIT, this will minimize the possibility of alternate return current paths other than via the NE. A value of 75 Ω is judged an acceptable maximum contact impedance for conductive NEs when measured according to ANSI/AAMI HF-81:2000 using human subjects. However, that standard imposes a 50 Ω limit when a metal plate is used in lieu of a human subject; this reduction compensates for the impedance contribution of the deeper subcutaneous tissue which becomes part of the measured NE contact impedance.

Since the impedance of capacitive NEs varies as the inverse of the frequency, it is appropriate to describe their impedance characteristics in terms of capacitance. A value of 4 nF was specified as the minimum acceptable capacitance because it is consistent with the characteristics of the majority of capacitive NEs which 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-NE impedance generally increases as the current decreases, making the lower limit preferable. The frequency range of 200 kHz to 5 MHz is believed to encompass the range over which MONOPOLAR HF SURGICAL EQUIPMENT develops significant energy levels.

The dimensions of the test plate represent the estimated area of contact between a small surgical PATIENT and the surface of an operating table cushion.

Capacitive NEs are permitted a higher impedance because they do not dissipate heat.

AA.59.104.7

This requirement was adopted from ANSI/AAMI HF18:2000, subclause 4.2.3.3.

After application, NEs except MONITORING NEs 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. Smaller pull forces are specified for NEs intended for use on fragile infant skin, because they cannot be expected to adhere as firmly as NEs intended for adults.

MONITORING NEs are exempt from this requirement because contact area loss due to adhesive failure is expected to cause a CONTACT QUALITY MONITOR alarm, thus preventing a hazard to the PATIENT.

AA.59.104.8

The adhesives and conductive gels used on single use NEs may deteriorate over time, even when stored according to the instructions for use. Therefore, it is necessary to determine that these devices conform after storage until the marked expiration date.

AA.59.104.9

Newly developed HF surgical procedures, such as rollerball ablation of the prostate and endometrium, are known to use HF currents well in excess of the 700 mA test current of 59.104.5. PATIENTS have suffered thermal injuries during these procedures even where conforming NEs have been in 100 % contact.

AA.59.105

Due to the rectifying effect of arcs between the ACTIVE ELECTRODE and tissue, d.c. and low frequency components may cause neuromuscular stimulation. This undesirable stimulation is effectively eliminated by the use of an appropriate value of series capacitance and shunt resistance.

Annex BB
(informative)

Electromagnetic disturbances created by HF SURGICAL EQUIPMENT

BB.1 Scope and object

Medical devices used in surgery are exposed to many sources and types of EMISSIONS which may result in an ELECTROMAGNETIC DISTURBANCE (EMD). The most prevalent source is from the HF SURGICAL EQUIPMENT that is used to cut and coagulate tissue. Although there are standards for many types of EMD, there is little information available regarding the EMISSIONS created by HF SURGICAL EQUIPMENT.

The purpose of this annex is to provide medical device manufacturers with information about the specific types and levels of EMMISIONS generated by HF SURGICAL EQUIPMENT. It also includes tests which manufacturers may wish to use in determining if their designs are resistant to these type of EMMISSIONS.

BB.2 Terms and definitions

For the purpose of this Annex the definitions of terms appearing in small capitals are those from this particular standard and the standards listed in 1.3.

NOTE Definitions for ELECTROMAGNETIC DISTURBANCE and EMISSIONS may be found in IEC 60601-1-2.

BB.2.1
E-field
electric field induced by the flow of current from the HF SURGICAL EQUIPMENT

BB.2.2
H-field
magnetic field induced by the flow of current from the HF SURGICAL EQUIPMENT

BB.3 Technical information

BB.3.1 General information about HF SURGICAL EQUIPMENT

During surgery, HF energy may be used for CUTTING tissue or provide hemostasis (COAGULATION). This energy is generated by the HF SURGICAL EQUIPMENT and delivered to the surgical site using various sterile ACCESSORIES. The fundamental frequency of the HF energy is typically between 200 kHz and 1 MHz. These frequencies are high enough that human tissue cannot respond to them, and thus no nerve or muscle stimulation occurs. All of the surgical effect is due to the current density of the HF energy.

The HF energy may be delivered to the surgical site in one of two ways. The first method is called MONOPOLAR or unipolar. This means that the surgical effect occurs at a single pole which is under the surgeon's control. The energy is generated in the HF SURGICAL EQUIPMENT, is carried through a cord to an ACCESSORY held by the surgeon, through the patient, is collected by a large surface area patient return electrode (NEUTRAL ELECTRODE) and is carried

back to the HF SURGICAL EQUIPMENT. It is the current density at the tip of the ACCESSORY ACTIVE ELECTRODE(s) that causes the localized surgical effect. After entering the patient's body, the current disperses, limiting the area of the surgical effect. The large surface area of the patient return electrode (NEUTRAL ELECTRODE) is designed to keep the current density low to prevent heating or other tissue effects. The patient return electrode is the second pole in the circuit. The most common MONOPOLAR ACCESSORY is the HF surgical pencil, so named because it resembles a thick pencil held by the surgeon.

The second method of energy delivery is called BIPOLAR. The surgical ACCESSORY being used by the surgeon has two electrodes, each with a small surface area. The HF energy passes from the HF surgical unit, to one electrode, through the tissue, to the other electrode and back to the HF surgical unit. The area of the electrodes and the tissue between them is small and so the current density is high. Thus, the surgical effect occurs only in the tissue grasped between the electrodes. A patient return electrode is not required. The most common BIPOLAR ACCESSORY is HF surgical forceps.

Most HF SURGICAL EQUIPMENT allows the user to control the output power as a means of controlling the depth and speed of the surgical effect. The output voltage and current may vary depending on the power setting and the load presented to the HF SURGICAL EQUIPMENT.

The surgical effect of CUTTING is generally achieved using a sine wave with a voltage between 200 V and 1 200 V. The current density at the tip of the electrode causes heating of the contents of cells immediately adjacent to the electrode. The cell contents turn to steam and the cell wall ruptures. The electrode moves through this steam layer and very small arcs pass from the electrode tip to the tissue. A pure sine wave cuts with little or no hemostasis. If the sine wave is interrupted, various levels of hemostasis may be achieved in addition to the CUTTING action. The lower the duty cycle the greater the hemostasis. However, lowering the duty cycle also requires that the rms voltage be increased to achieve the same output power. Power levels used in the cut mode range between 10 W and 300 W.

The surgical effect of COAGULATION may be achieved using several different methods. A pure sine wave which is below 200 V will not cut tissue but will desiccate and coagulate tissue. This waveform does not produce arcs. It is used for contact COAGULATION in both the MONOPOLAR and BIPOLAR modes. When the surgeon needs to coagulate bleeding tissue without touching it, a high voltage interrupted sinusoid waveform is generally used. This waveform may use a voltage between 1 200 V and 4 600 V. Power levels used for the MONOPOLAR COAGULATION mode range from 10 W to 120 W. Power levels for the BIPOLAR COAGULATION mode range from 1 W to 100 W.

The worst case EMMISSIONS created by HF SURGICAL EQUIPMENT occur during activation of the COAGULATION mode at the maximum power setting while arcing to tissue or metal.

BB.3.2 Types of emmissions created by HF SURGICAL EQUIPMENT

BB.3.2.1 Radiated

During surgery, the therapeutic current flows from the HF surgical unit through the ACCESSORY cable, through the patient, through an ACCESSORY cable again, and back to the unit. This circuit may take on different forms, sizes and arrangements. The current flowing creates both a radiated E-FIELD and an H-FIELD. These fields may couple to the ACCESSORY, or POWER SUPPLY CORD used by other EQUIPMENT. The worst case scenario for E-FIELD coupling is to have the HF SURGICAL ACCESSORY cables in close proximity and parallel with other ACCESSORY cables. E-FIELD coupling is also made worse during clinical situations where arcs occur.

The worst case scenario for H-FIELD coupling is to have the HF surgical circuit spread out in a large circle and other ACCESSORY cables attached to the patient who is within that circle. E-FIELD coupling typically generates worst case EMMISSIONS that are higher in frequency (tens to hundreds of megahertz) than H-FIELD coupling (tens to hundreds of kilohertz).

BB.3.2.2 Conducted through the mains POWER SUPPLY CORD

Electromagnetic noise conducted through the mains POWER SUPPLY CORD increases during activation of the HF SURGICAL EQUIPMENT through a combination of internal coupling to the HF output and high voltage power supplies that are only active during HF output generation.

BB.3.2.3 Conducted through the patient

The therapeutic current that is applied to the patient to achieve CUTTING and COAGULATION impresses a voltage on the patient that may be coupled into other EQUIPMENT. This coupling may be direct or capacitive. Direct coupling occurs into the inputs of devices that are measuring patient voltages (e.g. ECG, EEG, EMG, evoked potential monitors). Capacitive coupling occurs when EQUIPMENT cables or sensors are in close contact with the patient (e.g. pulse oximeter probes, invasive blood pressure transducers, temperature probes, camera systems). A combination of these methods is possible. The value of the voltage impressed on the patient is highly dependant on the HF SURGICAL MODE used. BIPOLAR modes utilize peak-to-peak voltages ranging from tens to a few hundred of volts and generate little or no sparking. CUTTING modes utilize peak to peak voltages from several hundred to a few thousand volts and generate very small sparks. COAGULATION modes utilize peak to peak voltages from a few thousand up to fourteen thousand volts with large sparks frequently being desired. Generally only a fraction of the HF voltage is coupled into other EQUIPMENT but for devices that measure in the millivolt or microvolt range, that can be a problem.

BB.3.3 Measurement techniques

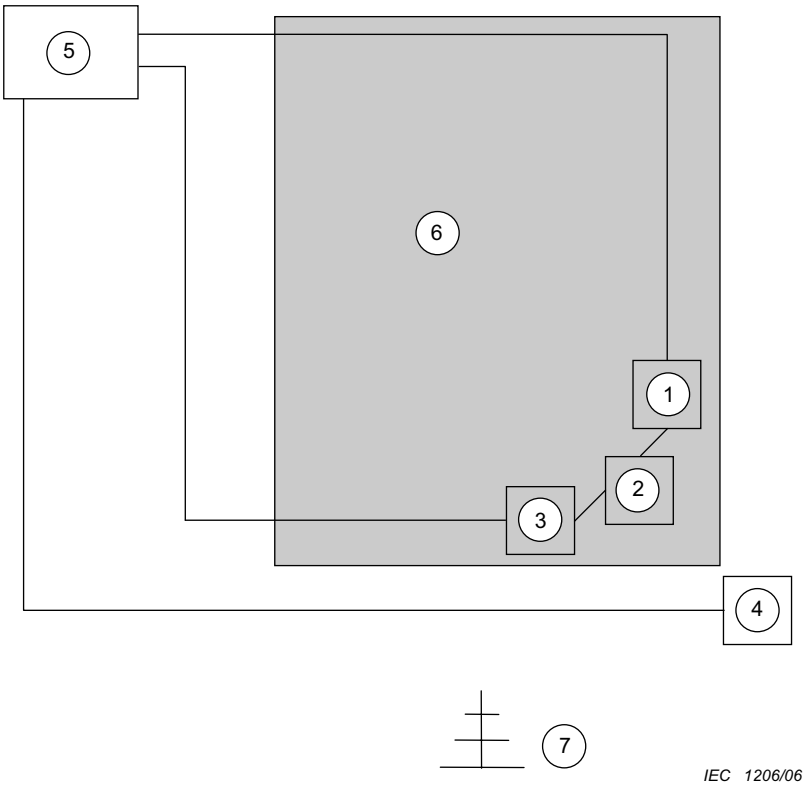
For the purpose of this annex, the measurements were taken using techniques intended to create the worst case values that may be experienced by MEDICAL ELECTRICAL EQUIPMENT during surgery.

The measurements reported below were taken multiple times using all of the output modes available and using the maximum output powers the units were capable of. Four different clinical situations were simulated. These situations were: open circuit activation, activation at the RATED LOAD of the HF SURGICAL EQUIPMENT (the load which produces the maximum output power), sparking to metal, and sparking to a saline-soaked sponge to simulate sparking to tissue.

All of these measurements were repeated multiple times using HF SURGICAL EQUIPMENT from a variety of manufacturers. The resulting data were used to create the worst case values of BB 3.4.4.

BB.3.3.1 E-FIELD measurements

A non-conductive table 1 m above a ground plane was used to support the ACCESSORY cables from the HF SURGICAL EQUIPMENT under test. The set up is illustrated in Figure BB.1. The measurements were recorded as peak or quasi-peak values that occur between 30 MHz and 1 GHz.



Key

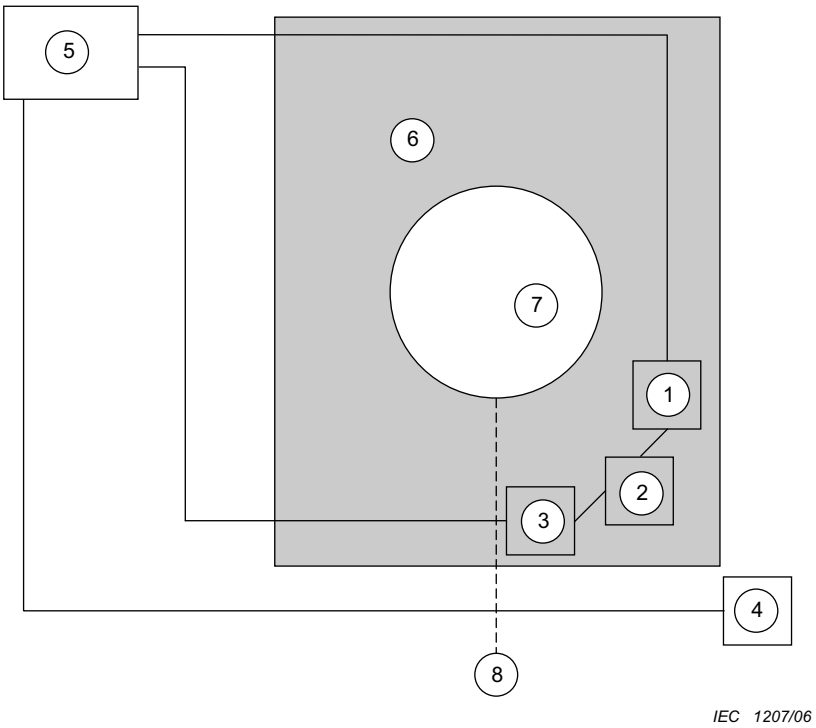
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna – 10 m distance, vertical polarity

Figure BB.1 – E-FIELD EMISSIONS test setup

BB.3.3.2 H-FIELD measurements

A non-conductive table 1 m above a ground plane was used to support the ACCESSORY cables from the HF SURGICAL EQUIPMENT unit under test. The set up is illustrated in Figure BB 2.

The measurements were recorded as peak or quasi-peak values that occur between 10 kHz and 30 MHz.



Key

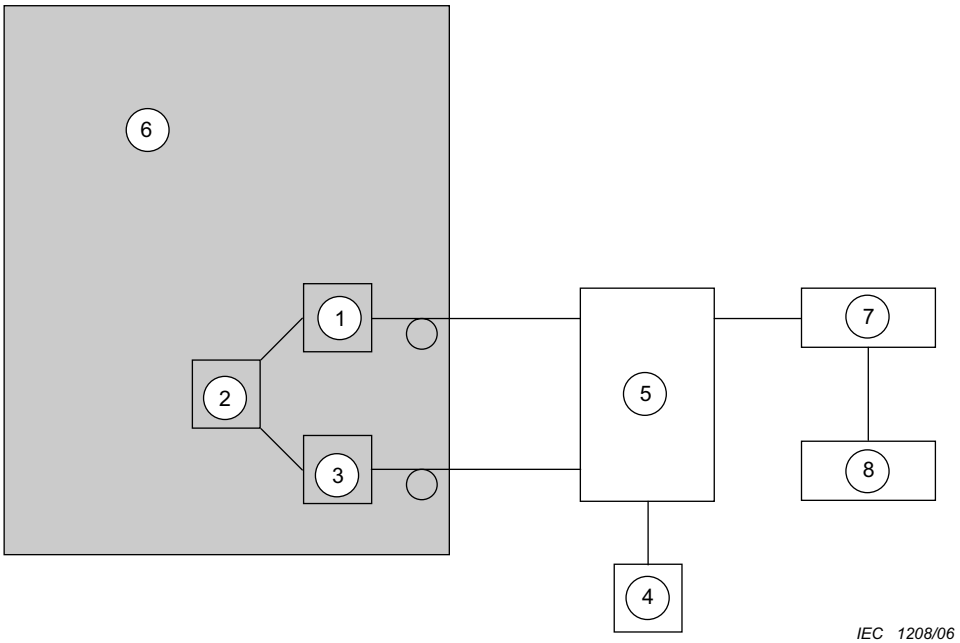
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna
8 Cable to measurement equipment

Figure BB.2 – H-FIELD EMMISSIONS test setup

BB.3.3.3 Mains conducted measurements

A non-conductive table 1 m above a ground plane was used to support the ACCESSORY cables from the HF SURGICAL EQUIPMENT under test. The set up is illustrated in Figure BB.3.

The measurements were recorded as peak or quasi-peak values that occur between 150 kHz and 30 MHz.



Key

1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Test equipment
8 Analyzer

Figure BB.3 – Conducted EMMISSIONS test setup

BB.3.4 Data summary

BB.3.4.1 E-field emmissions

The greatest values were typically below 50 MHz, with lower energy at higher frequencies. Arcing increases the energy at all frequencies, with arcing to metal being the worst case clinical situation.

BB.3.4.2 H-field emmissions

The greatest values were typically at the fundamental frequency of the HF SURGICAL EQUIPMENT, with additional peaks at multiples of the fundamental frequency. Arcing increases the energy at all frequencies, with arcing to metal being the worst case clinical situation.

BB.3.4.3 Mains conducted EMMISSIONS

The greatest values were typically at the fundamental frequency of the HF SURGICAL EQUIPMENT with additional peaks at multiples of the fundamental frequency. Arcing increases the energy at all frequencies, with arcing to metal being the worst case clinical situation.

BB.3.4.4 Maximum emmission levels of HF SURGICAL EQUIPMENT

The greatest level of EMMISSIONS was generated by spark gap units. This type of HF SURGICAL EQUIPMENT is no longer sold but still found in many hospitals. This type of unit creates the worst case EMD environment due to a very high output voltage and the use of a spark gap to create COAGULATION waveforms. The use of a spark gap tends to generate much higher levels of EMMISSIONS at higher frequencies. The worst case EMMISSION values are shown in Table BB.1 and Table BB.2.

Table BB.1 – Worst case emmissions of spark gap type HF SURGICAL EQUIPMENT

Emmission type	No arcing	Arcing to saline	Arcing to metal
E-FIELD	92 dBµV/m (40 mV/m)	80 dBµV/m (10 mV/m)	95 dBµV/m (56 mV/m)
H-FIELD	96,47dBµA (67 mA)	99,47 dBµA (94 mA)	96,47 dBµA (67 mA)
Mains conducted	117 dBµV (708 mV)	Not measured	Not measured

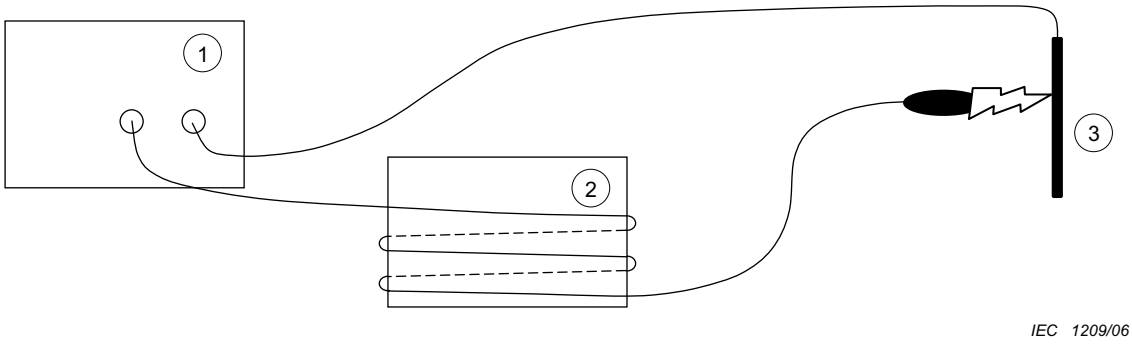
Table BB.2 – Worst case emmissions of non spark gap HF SURGICAL EQUIPMENT

Emmission type	No arcing	Arcing to saline	Arcing to metal
E-FIELD	78 dBµV/m (8mV/m)	77 dBµV/m (7 mV/m)	83 dBµV/m (14 mV/m)
H-FIELD	61,47 dBµA/m (1,1 mA/m)	63,47 dBµA/m (1,5 mA/m)	62,47 dBµA/m (1,3 mA/m)
Mains conducted	97 dBµV (71 mV)	Not measured	100 dBµV (100 mV)

BB.4 Suggested tests

The following information describes some ad hoc tests that have been used by EQUIPMENT manufacturers to determine if their products can withstand the EMMISSIONS produced by HF SURGICAL EQUIPMENT. These tests are meant to serve as guides only and may be modified based on how the EQUIPMENT is situated with respect to the HF SURGICAL EQUIPMENT. The tests below were designed to simulate the two types of equipment being situated in close proximity (both the enclosures and the cables). Just as in IEC 60601-1-2, the EQUIPMENT manufacturer should define what the acceptable response to this test should be prior to conducting it.

BB.4.1 Set up the EQUIPMENT that is to be tested. Wrap the cord of a MONOPOLAR HF SURGICAL ACCESSORY around the EQUIPMENT so that at least two full loops of the cord are present as shown in Figure BB.4



Key
1 HF SURGICAL EQUIPMENT
2 Unit under test
3 Metal plate

Figure BB.4 – Unit ad hoc test

Attach one end of a cord to the NEUTRAL ELECTRODE connector of the HF SURGICAL EQUIPMENT and the other end to a metal plate. Using the MONOPOLAR HF SURGICAL ACCESSORY, activate the HF SURGICAL EQUIPMENT in each possible output mode and arc the ACCESSORY to the metal plate. For each mode, adjust the HF SURGICAL EQUIPMENT to the setting which will create the highest peak output voltage.

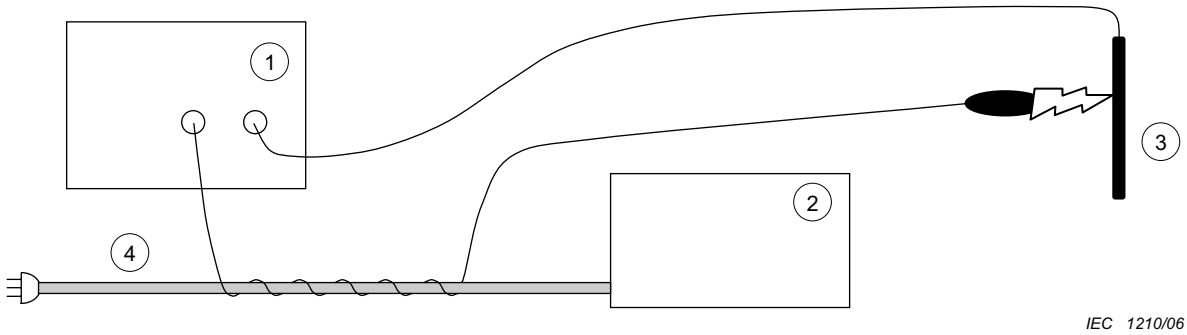
This test generates high E-FIELDS and high H-FIELDS with the greatest possible spread of frequencies.

BB.4.2 Repeat the test of BB.4.1 with the MONOPOLAR HF SURGICAL ACCESSORY short circuited to (touching) the metal plate. The HF SURGICAL EQUIPMENT should be adjusted to obtain the maximum output power for each output mode.

This test generates the highest output currents and thus the greatest H-FIELDS. It also creates high E-FIELDS at the fundamental output frequency.

BB.4.3 Repeat the tests of BB 4.1 and BB 4.2 with the cord of the MONOPOLAR HF SURGICAL ACCESSORY wrapped around the mains power cord of the unit under test as shown in Figure BB.5.

This test simulates the noise that can be coupled into the EQUIPMENT through the mains power cord.

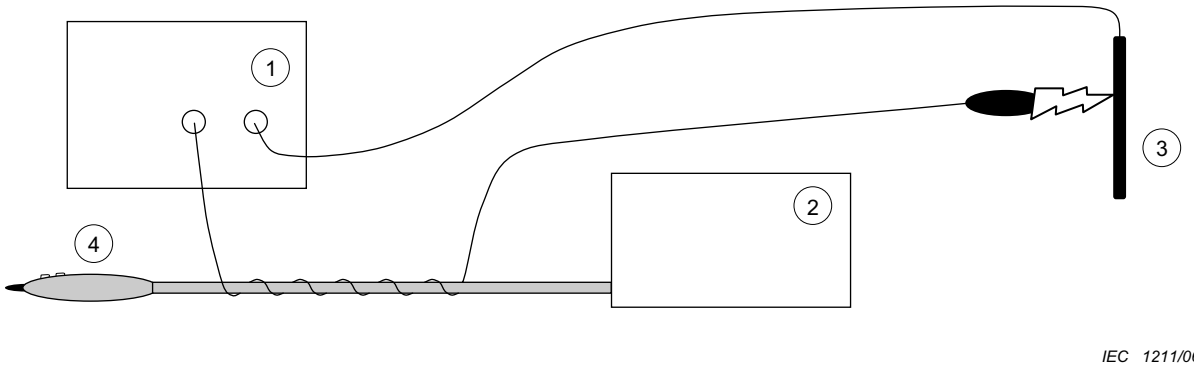


Key

1 HF SURGICAL EQUIPMENT
2 Unit under test
3 Metal plate
4 Mains power cord of unit under test

Figure BB.5 – Power cord ad hoc test

BB.4.4 If the EQUIPMENT has cords that enter the sterile field, coupling can also occur between those cords and the MONOPOLAR HF SURGICAL ACCESSORY cord. To test for this possibility, repeat the tests of BB 4.1 and BB 4.2 with the cord of the MONOPOLAR HF SURGICAL ACCESSORY wrapped around the ACCESSORY cord of the unit under test as shown in Figure BB.6.



Key

1 HF SURGICAL EQUIPMENT
2 Unit under test
3 Metal plate
4 MONOPOLAR HF SURGICAL ACCESSORY of unit under test

Figure BB.6 – ACCESSORY cord ad hoc test

BB.4.5 Tests to determine the impact of EMMISSIONS that are conducted through the patient may vary widely based on how well coupled the EQUIPMENT is to the patient. The reader is urged to consult the particular standard(s) for their type of equipment for additional information. Many of these particular standards have already included this type of test.

INDEX OF DEFINED TERMS

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