भारतीय मानक **IS 13450 (Part 2/Sec 2) : 2024**

Indian Standard

चिकित्सीय विद्युत उपकरण

भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष अपेक्षाएँ

अनुभाग 2 उच्च आवृत्ति शल्य चिकित्सा उपकरण और उच्च आवृत्ति शल्य चिकित्सा सहायक उपकरण

(IEC 60601-2-2 : 2023, संशोधित)

(पहला पुनरीक्षण)

Medical Electrical Equipment

Part 2 Particular Requirements for Basic Safety and Essential Performance

Section 2 High frequency Surgical Equipment and High Frequency Surgical Accessories

(IEC 60601-2-2 : 2023, MOD)

(First Revision)

ICS 11.040.30

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NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 2) (First Revision) which is modified adoption of IEC 60601-2-2 : 2023 'Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical, Diagnostic Imaging and Radiotherapy Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was originally published in 1974 and revised in 1991 as IS 7583 : 1991 'Medical electrical equipment — High frequency surgical equipment — Specification (First Revision) based on IEC 601-2- 2 : 1982 'Medical electrical equipment — Part 2: Particular requirements for the basic safety of high frequency surgical equipment'. This was superseded by IS 13450 (Part 2/Sec 2) : 2019 which was identical with IEC 60601-2-2 : 2017. This revision has been undertaken to align it with the latest consolidated version IEC 60601-2-2 : 2023 i.e. IEC 60601-2-2 : 2017 + AMD 1 : 2023 (Edition 6.1).

The text of IEC standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standard also exists. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1 : 2005 + AMD 1 : 2012 + AMD 2 : 2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2023 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (IEC 60601-1 : 2020, MOD) (*third revision*)	Modified
IEC 60601-1-2 : 2014 + AMD 1 : 2020 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility disturbances — Requirements and tests	IS 13450 (Part 1/Sec 2) : 2023 Medical electrical equipmen : Part 1 General requirements for basic safety and essential performance, Section 2 Electromagnetic compatibility disturbances — Requirements and tests (IEC 60601-1-2 : 2020, MOD) (s*econd revision*)	Modified
IEC 60601-1-8 : 2006 + AMD 1 : 2012 + AMD 2 : 2020 Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IS 13450 (Part 1/Sec 8) : 2023 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 8 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8 : 2020, MOD) (*first revision*)	Modified

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of HIGH FREQUENCY SURGICAL EQUIPMENT.

This particular standard amends and supplements IEC 60601-1:2005 and Amendment 1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this document.

INTRODUCTION to Amendment 1

The 6th Edition of IEC 60601-2-2 was published in 2017. This amendment is intended to align the standard to IEC 60601-1:2005/AMD2:2020. Additionally, this amendment is intended to address several issues reported from the national committees, including but not limited to:

- requirement for including the length of an accessory in the instructions for use;
- clarification of test setup for HF LEAKAGE CURRENTS;
- considering modes with high DUTY CYCLES above 45 % in the risk management;
- including text of the interpretation sheet 62D/1703/INF regarding the HIGH CURRENT MODE to Annex AA.

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

SECTION 2 HIGH FREQUENCY SURGICAL EQUIPMENT AND HIGH FREQUENCY SURGICAL ACCESSORIES

(IEC 60601-2-2 : 2023, MOD)

(First Revision)

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES as defined in 201.3.224 and 201.3.223.

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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES as defined in 201.3.224 and 201.3.223.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 and IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

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[1] The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 88.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

Addition:

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
CISPR 11:2015/AMD1:2016
CISPR 11:2015/AMD2:2019

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

Replace NOTE 1 with the following:

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the RMS values of an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

Addition:

201.3.201
ACTIVE ACCESSORY
HF SURGICAL ACCESSORY intended for manipulation by the OPERATOR to produce an effect by electrical conduction adjacent to the ACTIVE ELECTRODE at the intended site on the PATIENT, generally comprising an ACTIVE HANDLE, the cord of an ACTIVE ACCESSORY, ACTIVE CONNECTOR and ACTIVE ELECTRODE

201.3.202
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

201.3.203
ACTIVE ELECTRODE
part of an ACTIVE ACCESSORY extending from the ACTIVE HANDLE to the surgical site and intended to pass HF current into body tissue

201.3.204
ACTIVE ELECTRODE INSULATION
electrical insulation material affixed to part of an ACTIVE ELECTRODE intended to prevent unintended injury to PATIENT tissue or the OPERATOR

201.3.205
ACTIVE HANDLE
part of an ACTIVE ACCESSORY intended to be held by the OPERATOR

201.3.206
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

Note 1 to entry: An ACTIVE CONNECTOR is that which plugs into an ACTIVE OUTPUT TERMINAL.

Note 2 to entry: See Figure AA.1.

201.3.207
***ASSOCIATED EQUIPMENT**
MEDICAL ELECTRICAL EQUIPMENT other than HF SURGICAL EQUIPMENT that may be electrically connected to the PATIENT circuit

201.3.208
***BIPOLAR**
method of applying HF current to a PATIENT between two or more ACTIVE ELECTRODES without the need for a separately connected NEUTRAL ELECTRODE (or the need to use the PATIENT'S body capacitance to earth) in which an effect is intended in tissue near one or more ACTIVE ELECTRODES

Note 1 to entry: The BIPOLAR method includes devices energizing pairs of ACTIVE ELECTRODES as well as devices energizing groups of ACTIVE ELECTRODES where the HF current source and return may have different numbers of electrodes.

Note 2 to entry: See Figure AA.1 and Figure AA.3.

201.3.209
BIPOLAR ACCESSORY
ACTIVE ACCESSORY comprising two or more ACTIVE ELECTRODES on the same support, so constructed that, when energized, the HF current flows mainly amongst these electrodes

201.3.210
COAGULATION
use of HF current to induce a thermal effect, e.g. to control or prevent bleeding, induce tissue destruction, or induce tissue shrinkage

Note 1 to entry: COAGULATION may take the form of contact or non-contact COAGULATION.

Note 2 to entry: FULGURATION, desiccation, spray, forced, swift, soft and argon beam (plasma) COAGULATION are all names of COAGULATION types.

201.3.211
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 NEUTRAL ELECTRODE (NE) contact with the PATIENT becomes insufficient

Note 1 to entry: CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE.

201.3.212
CONTINUITY MONITOR
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an NE providing an alarm in the event of electrical discontinuity in the NE cable or its connections

201.3.213
***CREST FACTOR**
dimensionless value equal to the peak output voltage divided by the RMS voltage as measured at the output of HF SURGICAL EQUIPMENT in an open circuit condition

Note 1 to entry: Specific information on the correct way to make the measurements needed to calculate this value may be found in Annex AA.

201.3.214
***CUTTING**
division of body tissue caused by the passage of HIGH FREQUENCY current of high current density at the ACTIVE ELECTRODE (S)

201.3.215
***EARTH REFERENCED PATIENT CIRCUIT**
PATIENT circuit which includes components, such as capacitors, installed to provide a low-impedance path to earth for HF currents

201.3.216
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 1 to entry: Requirements for similar switches intended to perform functions other than activation of HF output are under consideration.

201.3.217
***FULGURATION**
the use of HF current to produce an effect on a tissue surface by electrical sparks from an ACTIVE ELECTRODE that is not in physical contact with the tissue

201.3.218
***HEATING FACTOR**
a value equal to $I^2 \times t$ where I is the MONOPOLAR current in amperes and t is the duration of the current flow in s

Note 1 to entry: The HEATING FACTOR is expressed as A^2s (amperes squared seconds).

Note 2 to entry: See subclause 201.15.101.5 in Annex AA for additional information.

201.3.219
***HIGH CURRENT MODE**
MONOPOLAR output mode whose INTENDED USE (MAXIMUM OUTPUT CURRENT and maximum DUTY CYCLE) results in a HEATING FACTOR of greater than 30 A^2s in any 60 s period

201.3.220
***HIGH FREQUENCY**
HF
frequencies less than 5 MHz and generally greater than 200 kHz

Note 1 to entry: HIGH FREQUENCY (HF) and radio frequency (RF) are considered as equivalent in the context of this document as long as the frequency is within the range defined in this definition.

201.3.221
HF ISOLATED PATIENT CIRCUIT
HF PATIENT CIRCUIT where there are no components installed to provide a low-impedance path to earth for HF currents

201.3.222
HF PATIENT CIRCUIT
any electrical circuit which contains one or more PATIENT CONNECTIONS including all conductive parts of the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT circuits through which HF current is intended to flow between the ME EQUIPMENT and the PATIENT in NORMAL CONDITION or SINGLE FAULT CONDITION

201.3.223
HF SURGICAL ACCESSORY
ACCESSORY intended to conduct, supplement or monitor HF energy applied to the PATIENT from HF SURGICAL EQUIPMENT

Note 1 to entry: HF SURGICAL ACCESSORIES include ACTIVE ACCESSORIES, including cords and connectors for attachment to HF SURGICAL EQUIPMENT, NEUTRAL ELECTRODES, as well as other ASSOCIATED EQUIPMENT intended for connection to the HF surgical PATIENT circuit. See Figure AA.1.

Note 2 to entry: Not all accessories used with HF surgical equipment are HF surgical accessories.

201.3.224

HF SURGICAL EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT which generates HIGH FREQUENCY currents intended for the performance of surgical tasks, such as the CUTTING or COAGULATION of biological tissue by means of these HIGH FREQUENCY currents

Note 1 to entry: HF SURGICAL EQUIPMENT is also variously known as surgical diathermy, electrosurgical equipment, electrosurgical generator, RF generator or HF generator.

Note 2 to entry: A footswitch is an example of an associated ACCESSORY that is part of HF SURGICAL EQUIPMENT. See Figure AA.1.

201.3.225

***HF SURGICAL MODE**

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

Note 1 to entry: Each available HF SURGICAL MODE may be provided with an OPERATOR-adjustable output control to set the desired intensity or speed of the effect.

201.3.226

***MAXIMUM OUTPUT CURRENT**

for each available HF SURGICAL MODE, the magnitude of the maximum possible HF output current during INTENDED USE

201.3.227

***MAXIMUM OUTPUT VOLTAGE**

for each available HF SURGICAL MODE, the magnitude of the maximum possible peak HF output voltage appearing between PATIENT circuit connections

201.3.228

***MONITORING NE**

NE intended for use with a CONTACT QUALITY MONITOR

Note 1 to entry: A MONITORING NEUTRAL ELECTRODE is also known as a split plate, dual plate, dual foil electrode or CQM electrode.

201.3.229

***MONOPOLAR**

method of applying HF output current to a PATIENT via an ACTIVE ELECTRODE and returning via a separate PATIENT-connected NEUTRAL ELECTRODE (or via the PATIENT'S body capacitance to earth) in which an effect is intended only in tissue at or near the ACTIVE ELECTRODE

Note 1 to entry: See Figures AA.1 and AA.2.

201.3.230

NEUTRAL ELECTRODE

NE

electrode intended to provide an electrical return path for the MONOPOLAR application of HIGH FREQUENCY current with such a low current density in the PATIENT'S tissue that effects such as excessive rise in temperature or unwanted burns are avoided

Note 1 to entry: The NEUTRAL ELECTRODE is also known as plate, plate electrode, electrosurgical pad, passive, return or dispersive electrode.

Note 2 to entry: To keep the current density low enough to prevent unwanted heating, the NEUTRAL ELECTRODE needs to have a large enough area.

Note 3 to entry: A NEUTRAL ELECTRODE is usually in contact with the PATIENT at a location that is separate from the MONOPOLAR ACTIVE ELECTRODE.

Note 4 to entry: See Figures AA.1 and AA.2.

201.3.231.1
RATED ACCESSORY VOLTAGE
<MONOPOLAR HF SURGICAL ACCESSORY> maximum peak HF output voltage which may be applied with respect to an NE connected to the PATIENT

201.3.231.2
RATED ACCESSORY VOLTAGE
<BIPOLAR HF SURGICAL ACCESSORY> maximum peak HF output voltage which may be applied to pairs of opposite polarity

201.3.232
RATED LOAD
value of non-reactive load resistance which, when connected results in the maximum HF output power from each HF SURGICAL MODE of the HF SURGICAL EQUIPMENT

201.3.233
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 their respective RATED LOADS

201.3.234
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

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

Additional subclauses:

201.4.1.101 * Additional conditions for application

The compliance of HF SURGICAL EQUIPMENT to this document and the compliance of HF SURGICAL ACCESSORIES to this document shall be independent of each other, except where specifically required by conformance tests or by the MANUFACTURER.

201.4.2.3.101 * Evaluating RISK

MANUFACTURERS shall include, within their RISK ANALYSIS, the potential for their HF SURGICAL EQUIPMENT and/or HF SURGICAL ACCESSORIES to be used in HIGH CURRENT MODE and the impact this would have on the heating under the NEUTRAL ELECTRODE (for example, see 201.7.9.2.2.101 f)).

Additionally, the impact on the heating under the NEUTRAL ELECTRODE shall be considered within RISK ANALYSIS for any mode with a duty cycle above 45 % according to its intended use even if the HEATING FACTOR is below 30 A^2s in any 60 s interval.

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

The requirements listed in the third hyphen of 201.8.4.101 and in 201.12.4.101 shall be considered ESSENTIAL PERFORMANCE requirements.

NOTE 101 Please refer to Annex AA.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Additional subclause:

201.4.7.101 Specific SINGLE FAULT CONDITIONS

The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests in this document:

a) failure in the CONTINUITY MONITOR or CONTACT QUALITY MONITOR which might cause a unacceptable RISK (see 201.8.4.101);

b) a defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see 201.8.10.4.101.1);

c) any defect which results in the unwanted energization of the PATIENT circuit (see 201.12.4.2.101);

d) any defect which results in a significant increase in output power relative to the output setting (see 201.12.4.4.101).

201.4.11 Power input

Replacement of first dash in compliance tests:

– The HF SURGICAL EQUIPMENT shall be operated in the manner (combination of operating setting, load, etc.) which creates the greatest steady state input current. Input current is measured and compared with the markings and the contents of the technical description.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 * Other conditions

Addition:

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.8.2 Other power sources

Amendment:

Subclause 7.2.8.2 of the general standard does not apply to ACTIVE OUTPUT TERMINALS or NE terminals.

201.7.2.10 APPLIED PARTS

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 symbols given in Figures 201.101 and 201.102 as follows:

Figure 201.101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT

Figure 201.102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT

Additional subclause:

201.7.2.10.101 * HF SURGICAL ACCESSORIES

HF SURGICAL ACCESSORIES (excluding HF ASSOCIATED EQUIPMENT) shall not be required to display the TYPE BF or TYPE CF mark on the ACCESSORY itself, the ACCOMPANYING DOCUMENTS, or on the packaging unless the RISK MANAGEMENT FILE identifies an unacceptable RISK associated with this exclusion.

201.7.4.2 * Control devices

Addition:

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 201.7.9.3.1.

The numeral "0" shall not be used unless no HF power in excess of 10 mW is delivered from an ACTIVE ELECTRODE or BIPOLAR ACCESSORY in this position.

NOTE The compliance test is the application of subclause 201.12.1.102.

201.7.8.1 * Colours of indicator lights

Replace Table 2 in the general standard with the following Table 201.101:

Table 201.101 – Colours of indicator lights and their meaning for HF SURGICAL EQUIPMENT

Name	On when	Indicator light[a]	Alarm indicator light	Accompanied by sound	Operator requirement
Warning [b]	Hazardous situation	Red, flashing or not	-	- [c]	Immediate response by the operator is required, for example, a fault in the patient circuit
CUTTING mode	CUTTING activation	Yellow, flashing or not	-	Yes [d]	-
COAGULATION mode	COAGULATION activation	Blue, flashing or not	-	Yes [d]	-
Ready for use	ME EQUIPMENT is ready for use	Green	-	-	-
Other	Situations other than that of red, yellow, blue or green	Any colour other than red, yellow, blue or green	-	-	-

[a] These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS.

[b] Such warnings and cautions are frequently accompanied by a SAFETY SIGN.

[c] Sound may be utilized, but IEC 60601-1-8 requires that it be perceived as different than auditory ALARM SIGNALS.

[d] As defined in 201.12.4.2.101.

201.7.8.2 * Colours of controls

Addition:

Where operating controls, output terminals, indicator lights, pedals (see 201.12.2) and pushbuttons of FINGERSWITCHES (see 201.12.2) are associated with a particular HF SURGICAL MODE, they shall be identified by a consistent, unique colour not in conflict with Table 201.101.

Compliance is checked by inspection.

201.7.9.2.2 Warning and safety notices

Additional subclause:

201.7.9.2.2.101 Additional information in instructions for use

a) * 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 a suitably prepared and appropriate area of the PATIENT's body as defined by the MANUFACTURER.

   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.).

   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.

   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 PATIENT leads 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 an unacceptable RISK 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.

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 and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.

10) For PATIENTS with electrically conductive implants, a possible HAZARD exists due to concentration or re-direction of HF currents. In case of doubt, qualified advice should be obtained.

11) For HF SURGICAL EQUIPMENT with an operating mode as described in 201.12.2 c) 2), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use.

b) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic equipment. For PATIENTS with cardiac pacemakers or other active implants, a possible HAZARD exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, qualified advice should be obtained.

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

1) 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.

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

$$y = \frac{U_{max} - 400\ [V]}{600\ [V]}$$

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.

3) 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 shall 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.

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

e) * 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. (See 201.15.101).

f) Where the temperature under the NEUTRAL ELECTRODE, during intended or foreseen use, may exceed the limits listed in 11.1.2.2 of the general standard or 201.15.101.5 of this document, instructions, warnings and cautions for proper use of the NEUTRAL ELECTRODE shall be provided.

g) * A warning addressing the RISKS resulting from neuromuscular stimulation which can occur especially with modes which produce electrical arcs between the ACTIVE ELECTRODE and tissue.

h) * For HF SURGICAL EQUIPMENT that can be energized without continuous activation of a SWITCH SENSOR as per subclause 201.8.10.4.101.2, warnings or cautions regarding the RISKS.

i) * For HF SURGICAL EQUIPMENT, the maximum permissible length of the ACCESSORY and its cord for each connector type.

NOTE 3 See Annex AA for additional information.

201.7.9.2.14 * ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall include:

a) Information concerning the selection and use of HF SURGICAL ACCESSORIES in order to avoid incompatibility and unsafe operation (see also 201.15.4.1.101 and 201.15.4.1.102).

b) Advice for the OPERATOR to avoid HF output settings where MAXIMUM OUTPUT VOLTAGE may exceed RATED ACCESSORY VOLTAGE.

c) Advice concerning the compatibility between a MONITORING NE and a CONTACT QUALITY MONITOR.

d) Advice for the OPERATOR regularly to inspect the ACCESSORIES. In particular, electrode cables and HF ENERGIZED ENDOTHERAPY DEVICES (see IEC 60601-2-18) should be checked (e.g. under magnification) for possible damage.

e) * For ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES, including separately supplied parts thereof, the RATED ACCESSORY VOLTAGE together with a warning to use only with HF SURGICAL MODE output settings resulting in a peak output voltage not greater than the RATED ACCESSORY VOLTAGE.

f) * On end use packaging for NEUTRAL ELECTRODES:

- If marked for single use, an expiration date.
- Information necessary to prevent burns at the NE site, e.g. limitation of output setting, PATIENT preparation 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 201.15.101.5

g) * On instructions for use for MONITORING NEUTRAL ELECTRODES:

- A statement of compatibility with specific CONTACT QUALITY MONITOR (s).

h) HF SURGICAL ACCESSORIES where the temperature under the NE, during intended or foreseen use, may result in the temperature exceeding the limits listed in subclause 11.1.2.2 of the general standard or subclause 201.15.101.5 of this document shall be accompanied by instructions, warnings and cautions for the proper use of NEUTRAL ELECTRODES.

i) On instructions for use for HF SURGICAL ACCESSORIES intended for use only with specific HF SURGICAL EQUIPMENT or HF waveforms or voltages, a detailed statement to that effect.

j) * For ACTIVE ELECTRODES and ACTIVE HANDLES, information to assess the following HAZARDOUS SITUATIONS:

- visibly exposed metal of the ACTIVE ELECTRODE shaft where it connects with the ACTIVE HANDLE
- poor electrical connection between the ACTIVE HANDLE and the ACTIVE ELECTRODE shaft
- poor fit between the ACTIVE HANDLE and the ACTIVE ELECTRODE shaft

k) * the length of the HF SURGICAL ACCESSORY.

NOTE 101 See Annex AA for additional information.

201.7.9.2.15 Environmental protection

Addition:

The instructions for use shall provide advice to the OPERATOR regarding the advisability of the use of smoke-plume extraction.

201.7.9.3 Technical description

201.7.9.3.1 * General

Addition:

- power output data – MONOPOLAR output (for all HF SURGICAL MODES available, any variable “blend” control being set to the maximum position) including:
  - 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;
  - diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above;
- power output data – BIPOLAR output (for all HF SURGICAL MODES as defined above) including:
  - 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;
  - diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above;
- voltage output data – MONOPOLAR and BIPOLAR output (for all HF SURGICAL MODES available). MAXIMUM OUTPUT VOLTAGE data required by 201.7.9.2.2.101 c);

– 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;
– the MAXIMUM OUTPUT CURRENT for each HF SURGICAL MODE;
– the maximum HEATING FACTOR generated in any 60 second period when the HF SURGICAL EQUIPMENT is used in any HIGH CURRENT MODE.

NOTE 101 The manufacturer can describe the specific behaviour of the HF SURGICAL EQUIPMENT, e.g. short circuit protection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy

Additional subclauses:

201.8.4.101 * NEUTRAL ELECTRODE monitoring circuit

HF SURGICAL EQUIPMENT having an NE connection point shall be provided with one or more of the following:

– a CONTINUITY MONITOR;
– a CONTACT QUALITY MONITOR;
– an alternate means to ensure that no unacceptable temperature rise (see 201.15.101.5) occurs under the NE. Any alternate means shall be considered ESSENTIAL PERFORMANCE.

These may be deactivated in situations when the HF SURGICAL EQUIPMENT is used without NE as described in 201.8.6.1.

These shall be arranged so as to de-energize the MONOPOLAR output and to give an audible alarm when a failure of the NEUTRAL ELECTRODE circuit, its connections, or the alternate means occurs. The audible alarm shall meet the sound level requirements of 201.12.4.2.101 and shall not be externally adjustable. For the use of non-MONITORING NEs, the CONTACT QUALITY MONITOR may be deactivated. That selection shall be visibly indicated to the OPERATOR. In this case, the requirement for either a continuity monitor or an alternate means to ensure that no unacceptable temperature rise occurs under the NE shall still apply.

NOTE 1 In this subclause the use of the conjunction “or” is inclusive and can mean either the first choice, the second choice, or both.

NOTE 2 This audible alarm and visible indicator light are not intended to meet the definition of an ALARM SIGNAL in IEC 60601-1-8. See also Clause 208 of this document.

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 201.8.7.3.

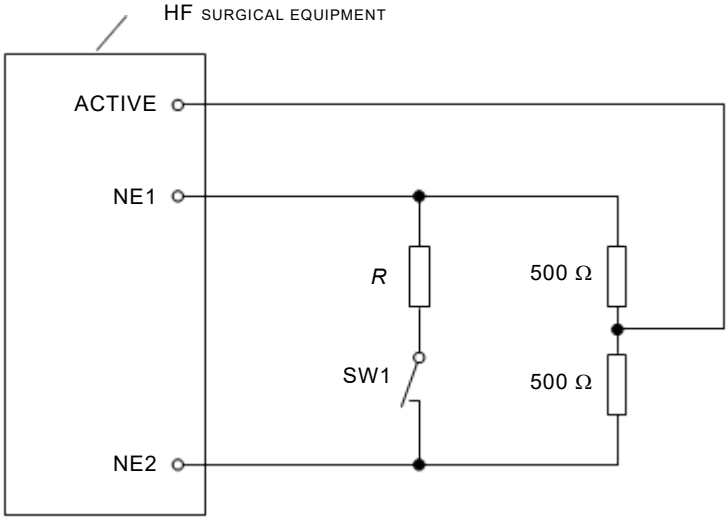
An additional visible warning consisting of a red indicator light shall be provided (see 201.7.8.1).

Compliance of a 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 201.103. 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 201.7.9.2.2.101 e), 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 subclause 201.15.101.5, 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.

Compliance of an alternate means to ensure that no unacceptable temperature rise occurs under the NE is checked by review of the MANUFACTURER'S documentation and RISK MANAGEMENT FILE.



For single plates: $R = 0\ \Omega$

For split plates: *R* as specified by the MANUFACTURER so as juts to keep the equipment active with SW1 closed

IEC

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

Figure 201.103 – Circuit suitable for testing compliance to 201.8.4.101

201.8.4.102 * 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 ACCESSORY. This capacitance shall not exceed 5 nF for MONOPOLAR PATIENT circuits and 50 nF for BIPOLAR PATIENT circuits. The DC resistance between ACTIVE and NEUTRAL ELECTRODE terminals, or between the terminals of a BIPOLAR output circuit, shall not be less than 2 MΩ.

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

201.8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Amendment:

For HF SURGICAL EQUIPMENT, the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the HF APPLIED PARTS and the ENCLOSURE including SIGNAL INPUT/OUTPUT PARTS, between the HF PATIENT CIRCUITS and the intermediate circuit and between different HF 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. These separations need not be subjected to the dielectric strength test of 201.8.8.3. HF PATIENT CIRCUITS of HF SURGICAL EQUIPMENT shall be considered as APPLIED PARTS in the context of this subclause. These CREEPAGE DISTANCES and AIR CLEARANCES are intended to represent two MEANS OF PROTECTION.

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 201.8.8.3.

This requirement does not apply to HF SURGICAL ACCESSORIES. The requirements and tests for HF SURGICAL ACCESSORIES are found in 201.8.8.3 and 201.15.101.4.

201.8.5.2.3 * PATIENT leads or PATIENT cables

Amendment:

This requirement shall not apply to the ACTIVE CONNECTORS or to any NE connectors except as detailed below.

For NEUTRAL ELECTRODE cables, the connector which is remote from the PATIENT shall be constructed so that the connections cannot contact conductive live 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.

201.8.5.5 * DEFIBRILLATION-PROOF APPLIED PARTS

Amendment:

HF 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 8.5.5.1 and Figure 9 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 document and of performing its intended function as described in the ACCOMPANYING DOCUMENTS.

201.8.6.1 * Applicability of requirements

Addition:

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.

201.8.7.1 * General requirements

Item b)

Addition:

– with the HF not energized, but in such a way that the low-frequency LEAKAGE CURRENTS are not affected.

Amendment:

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

NOTE Temporary internal modifications to the HF SURGICAL EQUIPMENT can be used (e.g. bridging of relay contacts) to ensure the correct measurement of low-frequency LEAKAGE CURRENTS.

201.8.7.3 * Allowable values

Item b)

Addition:

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

Item e)

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 201.8.7.3.101).

Additional subclause:

201.8.7.3.101 Thermal effects of HF LEAKAGE CURRENTS

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

*a) HIGH FREQUENCY LEAKAGE CURRENTS

For all measurements of HF LEAKAGE CURRENTS, any metal ENCLOSURES of CLASS II HF SURGICAL EQUIPMENT and INTERNALLY POWERED HF SURGICAL EQUIPMENT shall be connected to earth. During these tests, HF SURGICAL EQUIPMENT having an insulating ENCLOSURE shall be positioned on earthed metal having an area at least equal to the base of the HF SURGICAL EQUIPMENT, during these tests.

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.

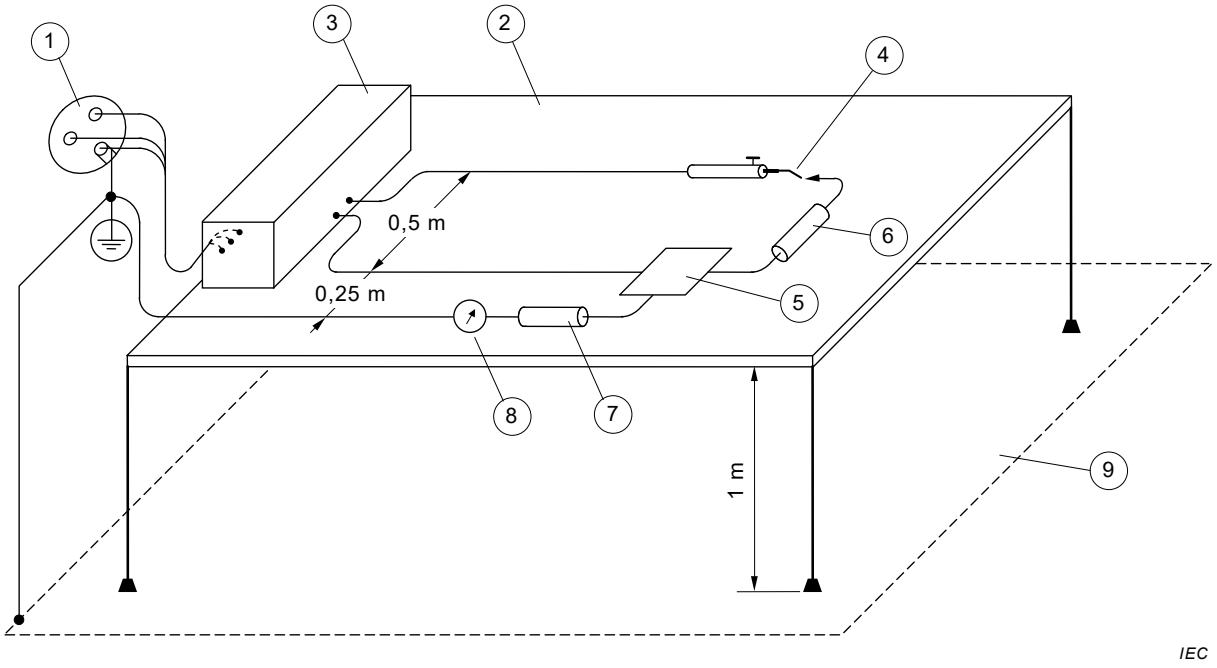
1) For MONOPOLAR EARTH REFERENCED PATIENT CIRCUITS

   The PATIENT circuit is isolated from earth but the NEUTRAL ELECTRODE is referenced to earth at HIGH FREQUENCIES 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.

   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 201.104. The cables are spaced 0,5 m apart on an insulating surface 1 m above an earthed conductive plane.

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.

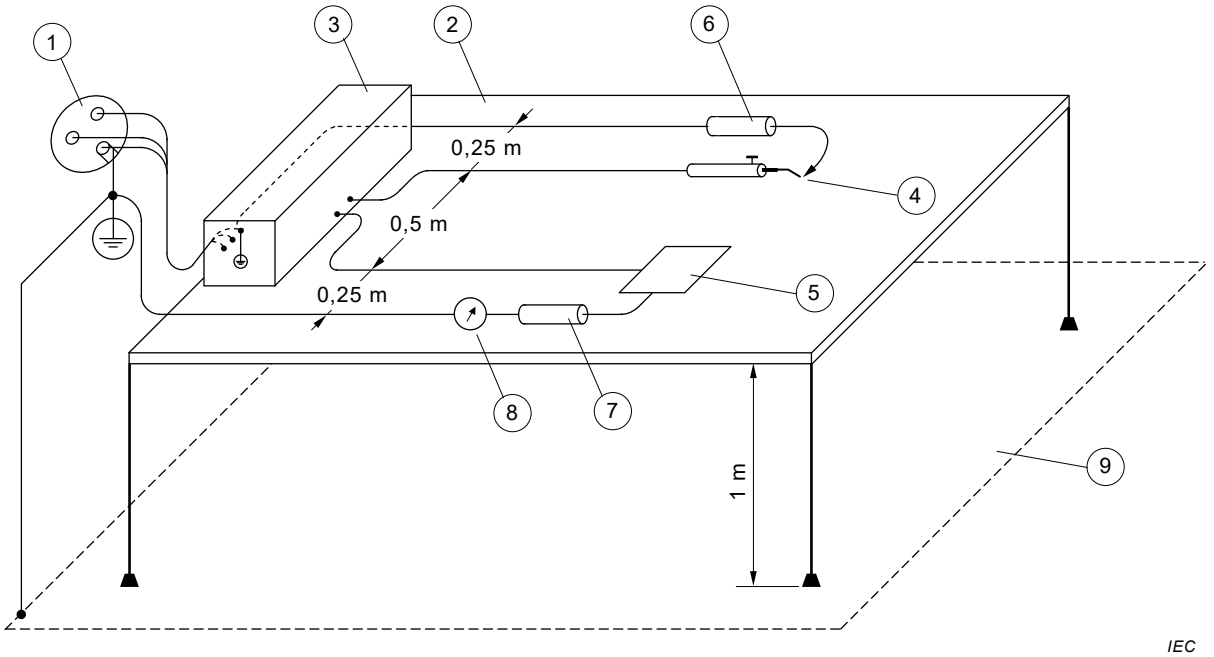


Key

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 201.104 – Measurement of HF LEAKAGE CURRENT for EARTH REFERENCED PATIENT CIRCUITS and load between electrodes

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 201.105. 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 201.105 – Measurement of HF LEAKAGE CURRENT for EARTH REFERENCED PATIENT CIRCUITS and a load resistance from ACTIVE ELECTRODE to earth

2) For MONOPOLAR HF ISOLATED PATIENT CIRCUITS

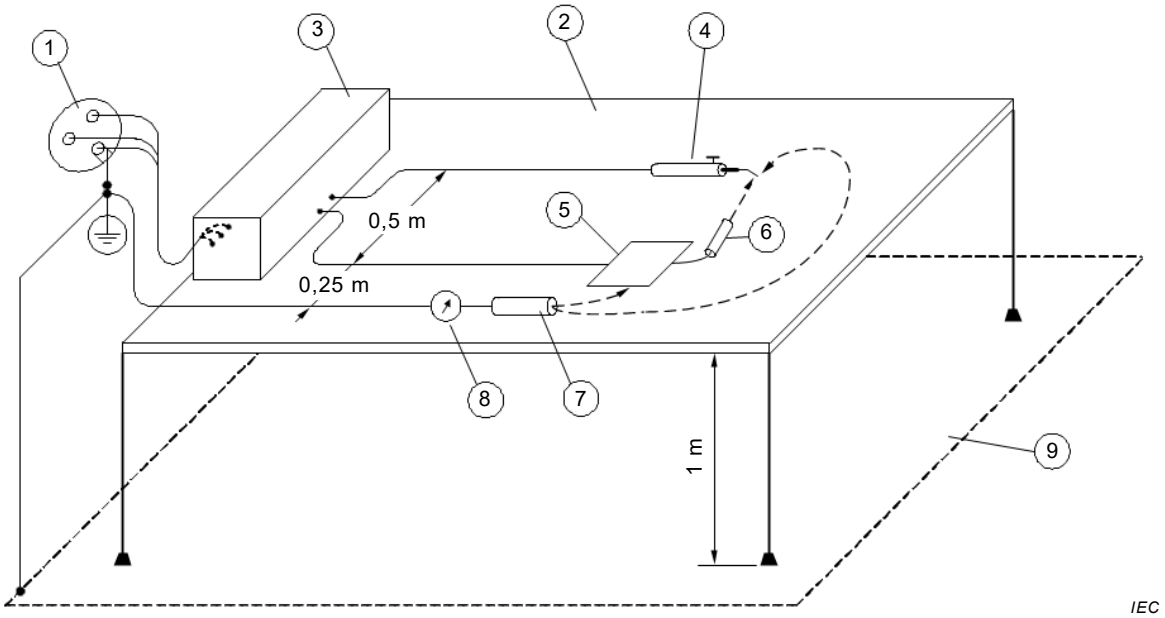
The PATIENT circuit is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing, in turn, from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106. Each electrode is tested with the output first being unloaded and then repeated with the output loaded at the RATED LOAD.

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.

NOTE1 The above requirements 1) and 2) 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
6	RATED LOAD
7	Measuring resistance, 200 Ω
8	HF current meter
9	Earthed conductive plane

Figure 201.106 – Measurement of HF LEAKAGE CURRENT for HF ISOLATED PATIENT CIRCUITS

*3) For BIPOLAR HF PATIENT CIRCUITS

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

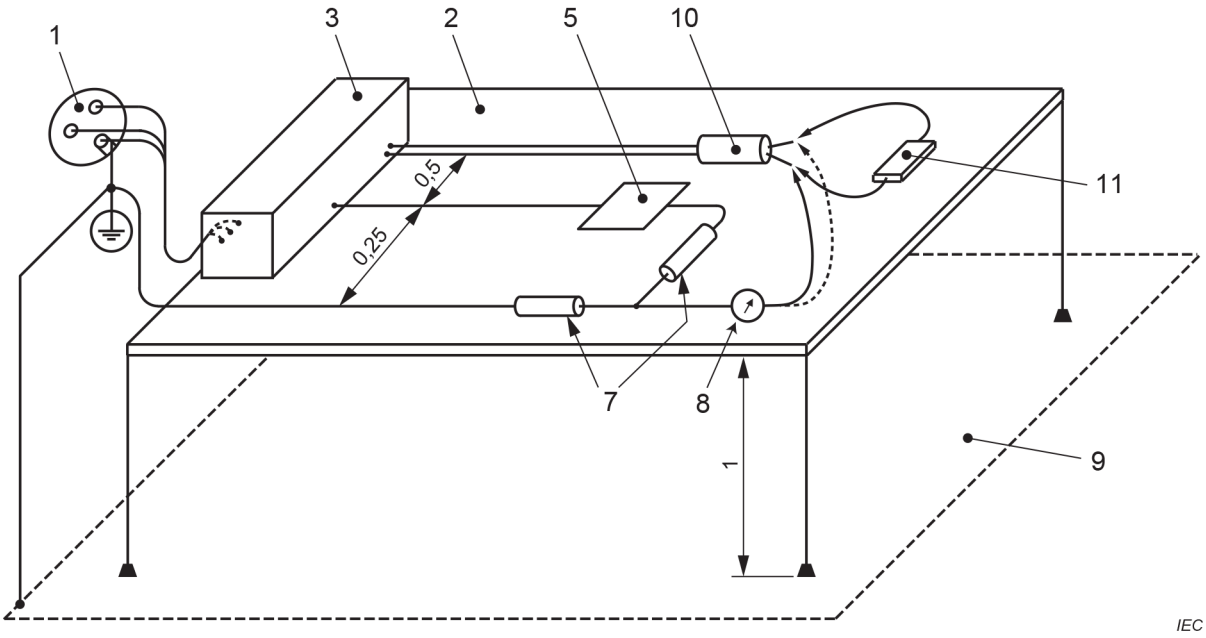
The HF LEAKAGE CURRENT flowing from either pole of the BIPOLAR output to earth and to the NEUTRAL ELECTRODE via a 200 Ω non-inductive resistor in each line shall not exceed the value which produces a power in a 200 Ω non-inductive resistor equal to 1 % of the maximum BIPOLAR RATED OUTPUT POWER, with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

Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.107. 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 or with the highest load resistance that produces an HF output 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.

NOTE 2 The above requirements 1), 2) and 3) apply to HF SURGICAL EQUIPMENT with both TYPE BF and TYPE CF APPLIED PARTS.

Dimensions in meters



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 ACCESSORY
11	Load resistance as required with HF power measuring device

Figure 201.107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ACCESSORY

*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 201.8.7.3.101 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

When any other PATIENT circuit is activated at its highest output settings and at all available operation modes, then:

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 201.107).

Compliance is checked by measurements using the test arrangements specified in subclause 201.8.7.3.101 b) and the HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106 (for MONOPOLAR) or Figure 201.107 (for BIPOLAR PATIENT circuits).

201.8.8.2 Distance through solid insulation or use of thin sheet material

Amendment:

The requirements 8.8.2 a) and 8.8.2 b) of the general standard do not apply to HF SURGICAL ACCESSORIES.

201.8.8.3 Dielectric strength

Amendment:

These requirements do not apply to HF SURGICAL ACCESSORIES. The requirements and tests for HF SURGICAL ACCESSORIES are given in 201.8.8.3.101 and 201.15.101.4.

Additional test conditions:

aa) If, during dielectric strength testing of solid insulation forming MEANS OF PATIENT PROTECTION, a breakdown or flashover occurs through the atmosphere at the AIR CLEARANCE specified in 8.9 of the general standard and 201.8.5.1.2 of this document, an insulating barrier may be placed to prevent this breakdown so that the protective insulation can be tested.

bb) If, during dielectric strength testing of solid insulation forming MEANS OF PATIENT PROTECTION, a breakdown or flashover occurs at the CREEPAGE DISTANCE specified in 8.9 of the general standard and 201.8.5.1.2 of this document, then the test shall be carried out on the components which provide MEANS OF PATIENT PROTECTION, such as transformers, relays, optocouplers or CREEPAGE DISTANCES on printed circuit boards.

Additional subclauses:

201.8.8.3.101 * 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 cleaning, disinfection and sterilization methods using the number of cycles as specified in the instructions for use. See 7.9.2.12 in the general standard.

The insulated parts of all ACTIVE ACCESSORIES, other than ACTIVE HANDLES and ACTIVE CONNECTORS, shall be preconditioned by immersion in 0,9 % saline for 12 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 (201.8.8.3.102);*
- *HF dielectric strength (201.8.8.3.103);*
- *mains frequency dielectric strength (201.8.8.3.104).*

201.8.8.3.102 * ACTIVE ACCESSORY HF leakage

a) Measured HF LEAKAGE CURRENT

The insulation applied to ACTIVE ACCESSORIES, including ACTIVE ELECTRODE INSULATION and ACTIVE HANDLES, but excluding ACTIVE CONNECTORS, shall limit HF LEAKAGE CURRENT passing through the external surface of the insulation to less than $I_{leakage}$.

The limit for ACTIVE ACCESSORIES intended for MONOPOLAR application is:

$$I_{leakage}[\text{mA}] = 2{,}0 \times 10^{-5} \times d \times L \times f_{test} \times U_{peak}$$

where

d is the smallest outer dimension of the insulation in mm,

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

L is the length of sample insulation through which HF LEAKAGE CURRENT passes, in cm, and

U_{peak} is the peak HF test voltage.

The corresponding limit for ACTIVE ACCESSORIES intended for BIPOLAR application is

$$I_{leakage}[\text{mA}] = 4{,}0 \times 10^{-5} \times d \times L \times f_{test} \times U_{peak}$$

Compliance is checked as follows:

The full length of the sample insulation except that within 1 cm of exposed conductors, but no more than 30 cm of length, shall be immersed in a 0,9 % saline bath or wrapped in a saline-soaked porous cloth during the entire course of the test. 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 kHz to 1 MHz. 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.

NOTE In this paragraph, '*d*' is the outer diameter of an insulation with a circular cross section. It is noted that the current formula can only be used for ACTIVE ACCESSORIES with circular cross section. For an ACTIVE ACCESSORY with a non-circular cross section, a value '*d*' is calculated from the circumference '*c*' of the original shape. In this case, the value *d* corresponds to the circumference divided by π.

$d = c / \pi$

b) Measured HF leakage capacitance

The preceding item a) may alternatively be fulfilled by limiting measured HF leakage capacitance for ACTIVE ACCESSORIES intended for MONOPOLAR application to no more than

$$C_{leakage}[\text{pF}] = 4{,}4 \times d \times L$$

and for ACTIVE ACCESSORIES intended for BIPOLAR application to no more than

$$C_{leakage}[\text{pF}] = 8{,}8 \times d \times L$$

where

d is the smallest outer dimension of the insulation, in mm, and

L is the length of sample insulation immersed in saline bath, in cm.

The measured HF leakage capacitance shall not exceed the specified relevant limit.

Compliance is checked as follows:

The full length of the sample insulation except that within 1 cm of exposed conductors, but no more than 30 cm of length, shall be immersed in a 0,9 % saline bath or wrapped in a saline-soaked porous cloth during the entire course of the test. All operative inner conductors shall be connected together to one measuring terminal of a capacitance-measuring instrument having a sensing frequency of 100 kHz to 1 MHz. The opposite measuring terminal of the capacitance measuring instrument is connected to a conductive electrode immersed in the saline bath or to foil wrapped around the mid-section of the saline soaked cloth. HF leakage capacitance is the capacitance indicated by the capacitance measuring instrument when operated according the instrument MANUFACTURER's recommended practices.

201.8.8.3.103 * ACTIVE ACCESSORY 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 201.7.9.2.14 e)), as detailed in the following test methods. For ACTIVE ELECTRODES and the cords of ACTIVE ACCESSORIES, a portion of the insulation which has been preconditioned in saline is wound with a maximum of 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 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 201.8.8.3.104.

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.

Test conditions:

Apply an approximately sinusoidal voltage at a frequency of 400 kHz ± 100 kHz with a continuous waveform, or alternately 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:

$$cf_{test} = \frac{U_{acc} - 400\,[V]}{600\,[V]} \quad \text{(with a tolerance of } \pm 10\ \%\text{)}$$

where

U_{acc} is the rated accessory voltage in V.

For RATED ACCESSORY VOLTAGES greater 4 000 V:

$$cf_{test} = 6 \text{ (with a tolerance of } \pm 10\ \%\text{)}$$

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 201.7.9.2.2.101 c) 3)).

In situations where the test conditions present a capacitive load that prevents maintaining the characteristics of the HF test voltage, testing of the ACTIVE HANDLES may be conducted in sufficiently small sections of the insulation, in sequence, until the entire exterior surface of the handle (including at least 150 mm onto the surface of the cord and 5 mm onto the ACTIVE ELECTRODE INSULATION) has been tested.

201.8.8.3.104 * ACTIVE ACCESSORY mains frequency dielectric strength

The insulation applied to an ACTIVE ACCESSORY, including those portions of insulation having been tested at HF according to 201.8.8.3.103, shall withstand a DC 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 DC or mains frequency signal. The test duration shall be 30 s for ACTIVE HANDLES, ACTIVE ELECTRODES 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, or other suitable means, shall be used to test whether 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 CONNECTOR contacts.

The entire length of the insulation of cords of ACTIVE ACCESSORIES, including that portion previously tested at HF according to 201.8.8.3.103, 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 201.8.8.3.103. 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.

201.8.9.1.5 ME EQUIPMENT RATED for high altitudes

Amendment:

This requirement does not apply for the separation between HF PATIENT CIRCUITS and the ENCLOSURE including SIGNAL INPUT/OUTPUT PARTS and between different HF PATIENT CIRCUITS.

For HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT, requirements for separation between HF PATIENT CIRCUITS and the ENCLOSURE including SIGNAL INPUT/OUTPUT PARTS, between HF PATIENT CIRCUITS and the intermediate circuit and between different HF PATIENT CIRCUITS are specified by 201.8.5.1.2.

201.8.10.4 Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

201.8.10.4.1 Limitation of operating voltages

Subclause 8.10.4.1 of the general standard does not apply. See 201.8.10.4.101.

201.8.10.4.2 * Connection cords

Replacement:

Anchorages of cords of ACTIVE ACCESSORIES shall be designed to minimize 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 201.108, 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 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 ° (45 ° 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 DC, current not in excess of 1 A.

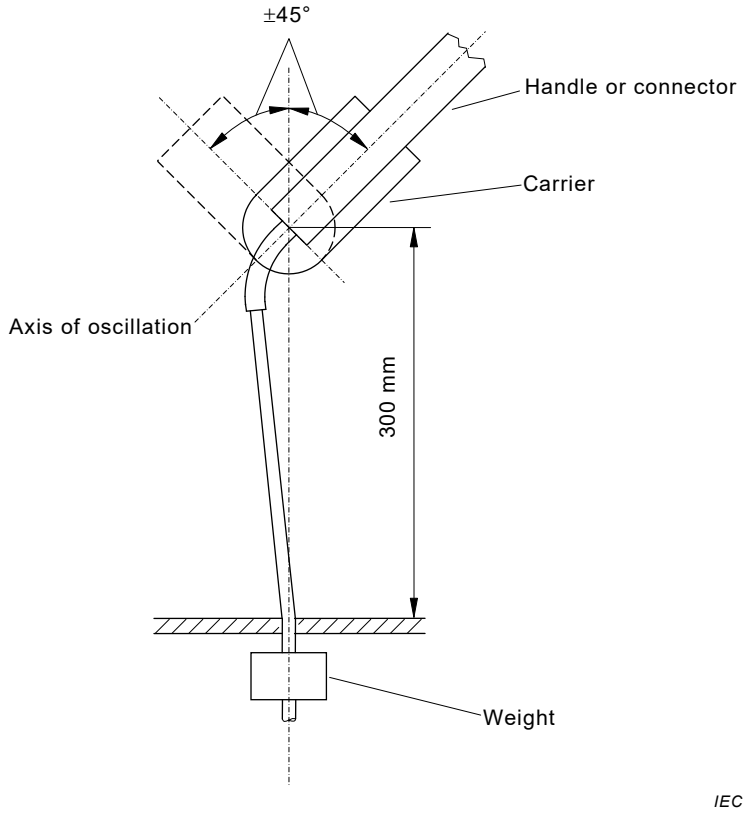


Figure 201.108 – Test apparatus for anchorages of cords of ACTIVE ACCESSORY

Additional subclauses:

201.8.10.4.101 * SWITCH SENSORS

201.8.10.4.101.1 General

Except where provided for in subclause 201.8.10.4.101.2, HF SURGICAL EQUIPMENT and applicable ASSOCIATED EQUIPMENT shall be provided with a SWITCH SENSOR requiring continuous activation in order to energize the ACTIVE OUTPUT TERMINALS.

The SWITCH SENSOR for cord-connected ACTIVE ACCESSORIES shall be supplied from a power source isolated from the MAINS PART and from earth, having a voltage not exceeding 12 V, if a

CONDUCTIVE CONNECTION to the APPLIED PART exists, and not exceeding 24 V AC or 34 V DC in other cases.

NOTE 1 This requirement applies to voltages appearing within SWITCH SENSORS. Common-mode HF voltages are disregarded.

Under SINGLE FAULT CONDITION the SWITCH SENSOR shall not cause low-frequency PATIENT LEAKAGE CURRENT (S) exceeding the allowable limits (see 201.8.7.3).

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 at any one time.

NOTE 2 For the purpose of this requirement the two arms of a rocker style switch are considered to be two individual switches.

201.8.10.4.101.2 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 means of manual output deactivation is provided.

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

201.8.10.4.101.3 Impedance sensing activation

A SWITCH SENSOR which is intended to activate HF output in response to the impedance appearing between ACTIVE OUTPUT TERMINALS is acceptable 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 SUPPLY MAINS, 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 HF 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 201.8.10.4.101.2 a)).

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

201.8.10.4.101.4 Footswitches

Footswitches shall comply with the following requirement (see also 201.11.6.5 and 201.12.2).

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.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.1 * Maximum temperature during NORMAL USE

Addition:

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.

201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

Addition:

ACTIVE ELECTRODES are considered to be APPLIED PARTS intended to supply heat to a PATIENT as part of their intended clinical effect (CUTTING and COAGULATION). Disclosure of temperatures and clinical effects is not required.

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Addition:

NEUTRAL ELECTRODES are considered to be APPLIED PARTS not intended to supply heat to a PATIENT (see 201.12.4.101 and 201.15.101.5)

201.11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

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 201.8.8.3, 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 8.9.1 of the general standard.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

a) * 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.

b) * 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 201.8.8.3.103).

Compliance is checked by the following test.

The AC 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 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 HANDLE over a period of 15 s so as to wet the entire length of the ACTIVE HANDLE. The liquid is allowed to drain away freely. The AC impedance of the switching terminals shall remain greater than 2 000 Ω.

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

201.11.6.7 * Sterilization of ME EQUIPMENT and ME SYSTEMS

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.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

When HF SURGICAL EQUIPMENT is switched off and on again or when the SUPPLY MAINS is interrupted and re-established

- the output power for a given setting of the output control shall not increase by more than 20 %, and
- the 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 SUPPLY MAINS, the switch in the HF SURGICAL EQUIPMENT being left in the "ON" position.*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 Accuracy of output control setting

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 201.7.9.3.1 by more than ± 20 %.

Compliance is checked by performing the test of 201.12.1.102 but using appropriate values of load resistance.

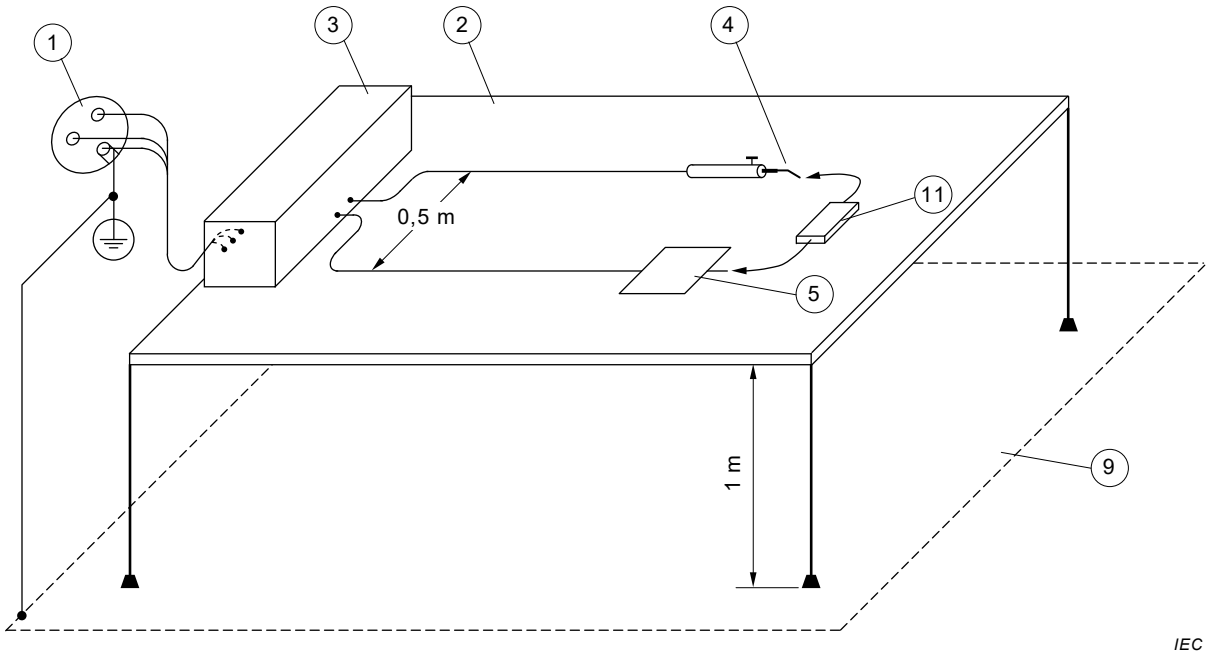
201.12.1.102 Monotonicity of output control setting

The output power shall not increase with the decrease of the output control setting (see 201.7.9.3.1, Figure 201.109 and Figure 201.110).

Compliance is checked by the following test:

a) ** MONOPOLAR outputs*

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.



Key

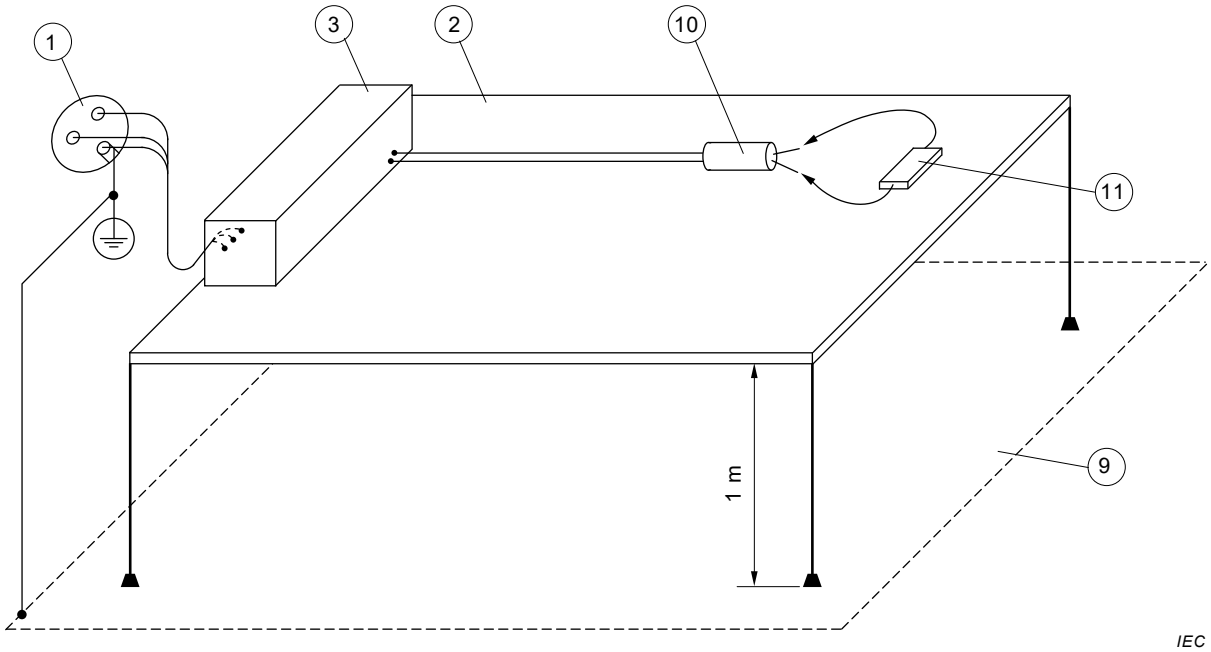
1	SUPPLY MAINS
2	Table, made of insulating material
3	HF SURGICAL EQUIPMENT
4	ACTIVE ELECTRODE
5	NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
9	Earthed conductive plane
11	Load resistance as required with HF power measuring device

Figure 201.109 – Measurement of output power – MONOPOLAR output

*b) * BIPOLAR outputs*

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.

MANUFACTURERS shall provide specific instructions on how to set up these measurements on alternate forms of BIPOLAR ACCESSORIES.



Key

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

Figure 201.110 – Measurement of output power – BIPOLAR output

201.12.1.103 * Accuracy of MAXIMUM OUTPUT VOLTAGE

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 201.7.9.3.1.

Compliance is checked by use of an oscilloscope. See also 201.5.4 aa). Measurements shall be taken at the output setting and load condition which yields the highest peak output voltage for each HF SURGICAL MODE.

201.12.2 Usability of ME EQUIPMENT

Addition:

a) 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.

b) * 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.

c) It shall not be possible to energize simultaneously more than one ACTIVE OUTPUT TERMINAL, unless:

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

or

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

Compliance is checked by inspection and functional check.

d) * During simultaneous activation the audible tone shall be different from the tone produced during single output activation. See also 201.12.4.2.101. Under no circumstances shall any PATIENT circuit become energized by more than is defined in 201.8.7.3.101 c), unless the output for that PATIENT circuit is activated by the OPERATOR.

Compliance is checked by inspection and functional check.

e) * 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.

NOTE See Annex AA.

Compliance is checked by inspection.

f) * ACTIVE CONNECTORS having more than one pin shall have permanently FIXED pin spacing. “Flying leads” are prohibited.

Compliance is checked by inspection.

g) * 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.

201.12.4 Protection against hazardous output

Additional subclause:

201.12.4.101 * Use of HIGH CURRENT MODE

HF SURGICAL EQUIPMENT shall provide a means such that in HIGH CURRENT MODE, NEUTRAL ELECTRODE(S) shall be used which have sufficient current carrying capacity so as to ensure no unacceptable temperature rise. In doing so, the requirements of 201.15.101 shall be specifically analyzed in the RISK MANAGEMENT FILE for the HIGH CURRENT MODE conditions. This requirement shall be considered an ESSENTIAL PERFORMANCE requirement.

Compliance is checked by inspection of the MANUFACTURER’S documentation and RISK MANAGEMENT FILE.

201.12.4.2 * Indication relevant to safety

Addition:

If the total output power in any HF SURGICAL MODE, including simultaneous activation of independent outputs if available, exceeds 400 W averaged over any period of 1 s when each of the outputs is terminated at the RATED LOAD, then special consideration of potential HAZARDS shall be addressed in the RISK MANAGEMENT FILE, especially with regard to NEUTRAL ELECTRODES.

Compliance is checked by measurement.

Additional subclause:

201.12.4.2.101 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 kHz. 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 201.12.2 d).

In order that the OPERATOR may distinguish between the audible alarm called for in 201.8.4.101 and the signal specified above, either the former shall be pulsed or two different frequencies shall be employed.

NOTE This audible signal is not intended to meet the definition of ALARM SIGNAL in IEC 60601-1-8. See also Clause 208 of this document.

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

201.12.4.3 Accidental selection of excessive output values

Additional subclause:

201.12.4.3.101 Output reduction means

Except as provided for in 201.7.9.2.2.101 a) item 7, and 201.7.9.3.1. – 5th dash, for each HF SURGICAL MODE, HF SURGICAL EQUIPMENT shall incorporate means 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 201.12.1.102).

Compliance is checked by measurement of output power and inspection.

201.12.4.4 Incorrect output

Additional subclauses:

201.12.4.4.101 * Maximum allowed output power in SINGLE FAULT CONDITIONS

MONOPOLAR HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER greater than 50 W and all BIPOLAR outputs of HF EQUIPMENT 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 according to Table 201.102:

Table 201.102 – Maximum output powers in SINGLE FAULT CONDITIONS

Setting (range in % of RATED OUTPUT POWER)	Maximum allowed output power in SINGLE FAULT CONDITIONS
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.

201.12.4.4.102 * Output power during simultaneous activation

For HF SURGICAL EQUIPMENT providing simultaneous activation of more than one PATIENT circuit (see 201.12.2), the PATIENT circuits shall not deliver an output power that exceeds the range of deviation defined in 201.12.1.101 by more than 20 % when they are simultaneously activated under any available combination of HF SURGICAL MODES.

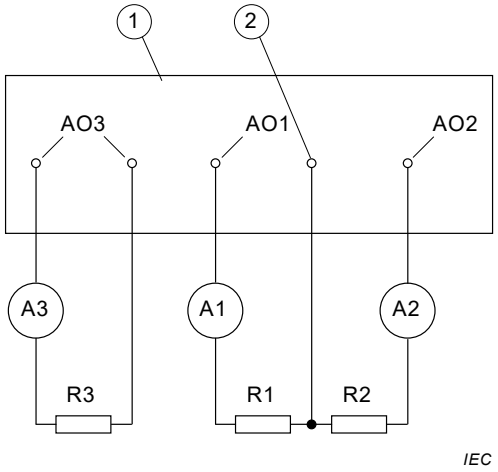
Any single activated PATIENT circuit shall comply with 201.12.1.101.

Compliance is checked by the following tests (see Figure 201.111).

For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 1): 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 201.12.2 c) 2): 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 201.111 – Method of testing feedback from one active output to another in simultaneous activation

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.2.13 Overload

Additional subclause:

201.13.2.13.101 * 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 201.12.1.102, 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.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4.1 Construction of connectors

Additional subclauses:

201.15.4.1.101 * Compatibility with third party ACTIVE ELECTRODES

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.

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.

201.15.4.1.102 * 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.

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.

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.

Additional subclauses:

201.15.101 * NEUTRAL ELECTRODES

201.15.101.1 General requirements for NEUTRAL ELECTRODES

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

Compliance is checked by inspection.

201.15.101.2 * NE cord attachment

The NEUTRAL ELECTRODE shall be reliably connected to the cord. Except for a MONITORING NE, any current used for monitoring the electrical continuity of the electrode cord 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 DC or mains frequency current source with a no-load voltage not exceeding 6 V. The resistance shall be 1 Ω or less.

201.15.101.3 * NE cord connector

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 6 of the general standard, it is verified that contact with conductive parts of the cable connector is not possible.

201.15.101.4 * NE cord insulation

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 201.8.8.3.102 a) with a test voltage [U_{peak}] of 400 V_{peak}. HF LEAKAGE CURRENT shall not exceed*

$$I_{leakage}\ [mA] = 4{,}0 \times 10^{-5} \times d \times L \times f_{test} \times U_{peak}$$

or alternatively the HF leakage capacitance test according to 201.8.8.3.102 b). The HF leakage capacitance shall not exceed

$$C_{leakage}\ [pF] = 8{,}8 \times d \times L$$

where

d is the smallest outer dimension of the insulation, in mm, and

L is the length of sample insulation immersed in saline bath, in cm;

– *HF dielectric strength test according to 201.8.8.3.103 with an HF test voltage of 500* V_{peak}. *No breakdown of the insulation shall occur;*

– *mains frequency dielectric strength test according to 201.8.8.3.104 with a test voltage of 2 100* V_{peak}. *No breakdown of the insulation shall occur.*

201.15.101.5 * NE thermal performance

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 for conventional NEUTRAL ELECTRODES is checked by the following test.

NOTE A conventional NEUTRAL ELECTRODE is one that is not suitable for use with a HIGH CURRENT MODE.

For an NE with the PATIENT weight range marked as follows, the maximum temperature rise of any 1 cm square area under and extending 1 cm beyond 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 201.103 – 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 subclause 201.8.4.101.*

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 live 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. Each of these at least 10 different samples shall be tested with the alarm area A_a *from another human subject. For each human subject the test shall be performed with the individual alarm area* A_a, *as evaluated in the compliance test for subclause 201.8.4.101. The alarm area* A_a *can also be determined by means of a test device if such test device has a CQM simulation circuit.*

The NE and test surface temperatures of surrogate media or test devices shall be 23 $\pm$ *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 shall be attained within 5 s of the beginning of the test and maintained between 100 % and 110 % of I_{test} for 60 s ± 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.

201.15.101.6 * NE contact impedance

The impedance of the electrical contact between the surface of the NE application site and the NE cord connection, within 5 cm of its connection to the NE conductive surface, 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 document, 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 flat metallic plate. A true RMS responding AC voltmeter having an accuracy of better than 5 % over the 200 kHz to 5 MHz range is connected between the plate and the NE cord conductors, within 5 cm of their attachment to the conductive surface of the NE, in order to measure voltage U_{test}. An essentially sinusoidal test current, I_{test}, of approximately 200 mA and frequency f_{test} in the range of 200 kHz to 5 MHz is passed between the NE cord and the plate and monitored by use of a suitable true RMS AC ammeter.

U_{test} and I_{test} are recorded at f = 200 kHz, 500 kHz, 1 MHz, 2 MHz and 5 MHz. 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:

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

where

I_{test} *is the RMS HF test current in A;*

U_{test} *is the RMS HF test voltage in V;*

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

201.15.101.7 * NE adhesion

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 are allowed to remain 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. 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.

201.15.101.8 * NE shelf life

NEs marked for single use shall comply with the requirements of 201.15.101.5 through 201.15.101.7 on the expiration date specified by the NE MANUFACTURER. 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.

201.15.101.9 * Adult NEUTRAL ELECTRODES for conventional procedures

Conductive NEs intended for use on adult PATIENTS, and therefore approved for a PATIENT weight of more than 15 kg shall be MONITORING NES. This requirement shall not apply to NEs used with a HIGH CURRENT MODE.

NOTE 1 For purposes of this document, unless otherwise specified by the MANUFACTURER, a conductive NE presents a contact impedance with a phase angle of less than 45º at 200 kHz, and a capacitive NE a 200 kHz phase angle of 45º or greater.

NOTE 2 Conventional procedures are those which do not use a HIGH CURRENT MODE

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply except as follows:

202.2 Normative references

Replace 5th reference “IEC 60601-2-2:2009” by “IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023”

202.3 Terms and definitions

In paragraph 1, replace “IEC 60601-2-2:2009” by “IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023”

202.5.2.2.4 Requirements applicable to ME EQUIPMENT that includes RF transmitters

Addition:

The output of HF SURGICAL EQUIPMENT shall not be considered an RF transmitter.

202.5.2.2.6 Requirements applicable to ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT

Addition:

NOTE See Annex BB for additional information on assessing compatibility.

202.7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS

202.7.1.2 Operating modes

Addition:

a) HF SURGICAL EQUIPMENT shall not be tested for radiated or conducted RF EMISSIONS when the HF output is energized.

b) HF SURGICAL EQUIPMENT shall comply with the requirements of CISPR 11 group 1, when it is switched on and in an idle state with the HF output not energized. The MANUFACTURER

shall declare whether the HF SURGICAL EQUIPMENT is Class A or Class B according to its INTENDED USE.

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 General

Addition:

For HF SURGICAL EQUIPMENT, the following degradations shall be considered acceptable because they do not result in unacceptable RISK:

– 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 HF output power as allowed in 201.12.1.101

Compliance shall be considered to be met if the requirements of IEC 60601-1-2 are met with the above changes.

202.101 Index of defined terms

Replace all occurrences of “IEC 60601-2-2:2009” with “IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023”

Replace 201.3.218 with 201.3.220.

Replace 201.3.221 with 201.3.223.

Replace 201.3.222 with 201.3.224.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply except as follows:

Amendment:

The audible alarm and the red indicator warning light described in 201.8.4.101 shall not be considered an ALARM SIGNAL as defined in this collateral standard.

The audible signal described in 201.12.4.2.101 shall not be considered an ALARM SIGNAL as defined in this collateral standard.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

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.

NOTE Testing of these devices for compliance or operation when the HF is turned on can cause test equipment to operate outside of its normal operation due to the HF electric field exposure. Suitable precautions and checks of the test instrumentation are taken into account. This situation can also occur with the medical support instrumentation near the device.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

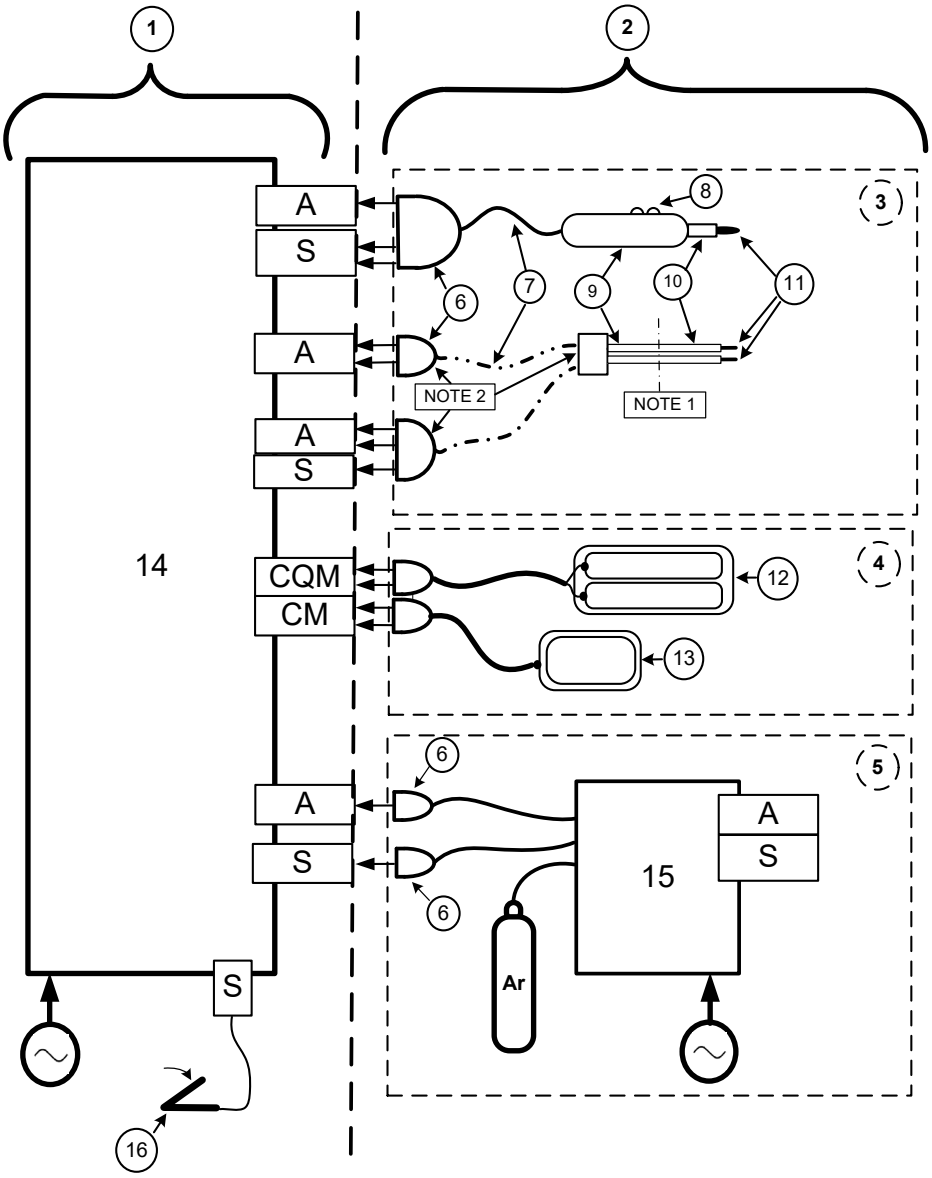
The scope does not include equipment for cautery, i.e. for medical treatment with electrically heated metal rods or wire loops. This edition provides, to the extent feasible, separate requirements and tests for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES, independent of manufacture. ASSOCIATED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

Definition 201.3.207– ASSOCIATED EQUIPMENT

Examples of ASSOCIATED EQUIPMENT are argon beam adaptors, ACCESSORY leakage monitors, NEUTRAL ELECTRODE contact monitors, and the like. See Figure AA.1.

Definition 201.3.208 – BIPOLAR

This term is intended to apply equally to equipment and ACCESSORIES and thus is distinct from, and could possibly supplant, that of subclause 201.3.209 (BIPOLAR ACCESSORY).



NOTE 1 The MANUFACTURER determines the location of boundary line between ACTIVE HANDLE and ACTIVE INSULATION.

NOTE 2 BIPOLAR ACCESSORIES may or may not include switching as part of the ACTIVE ACCESSORY.

NOTE 3 ACCESSORIES and NEUTRAL ELECTRODES are not shown to scale.

Key

1 HF SURGICAL EQUIPMENT
2 HF SURGICAL ACCESSORIES
3 ACTIVE ACCESSORIES
4 NEUTRAL ELECTRODES
5 ASSOCIATED EQUIPMENT
6 ACTIVE CONNECTOR
7 cord of ACTIVE ACCESSORY
8 FINGERSWITCHES
9 ACTIVE HANDLE
10 ACTIVE ELECTRODE INSULATION
11 ACTIVE ELECTRODE

12 MONITORING NEUTRAL ELECTRODE

13 non-MONITORING NEUTRAL ELECTRODE

14 HF surgical generator

15 argon beam coagulator

16 footswitch

A ACTIVE OUTPUT TERMINAL

S SWITCH SENSOR

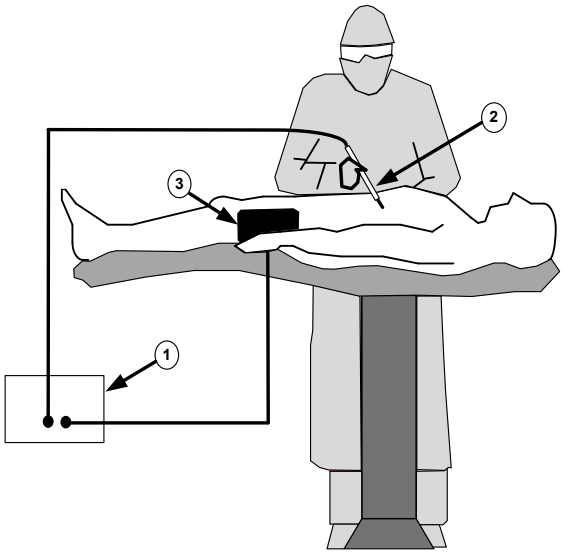
CQM CONTACT QUALITY MONITOR

CM NE CONTINUITY MONITOR

Ar Argon gas source

SUPPLY MAINS

Figure AA.1 – Examples of various parts of an HF surgical ME SYSTEM



IEC

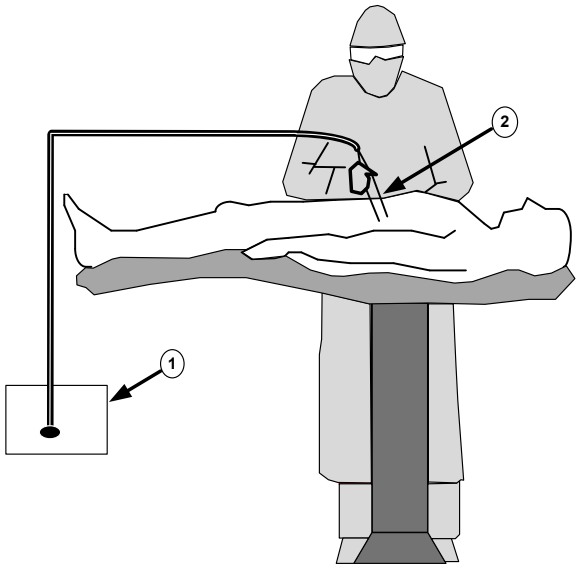
Key

1 HF SURGICAL EQUIPMENT (generator)

2 ACTIVE ACCESSORY

3 NEUTRAL ELECTRODE

Figure AA.2 – Example of MONOPOLAR method of HF surgery using a NEUTRAL ELECTRODE



Key

1 HF SURGICAL EQUIPMENT (generator)

2 BIPOLAR ACCESSORY

Figure AA.3 – Example of BIPOLAR method of HF surgery

Definition 201.3.213 – CREST FACTOR

The measurement of CREST FACTOR is mathematically simple but difficult to carry out in a reliable manner. The RMS 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) this 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 RMS voltage is then calculated. The most reliable method is to set the DSO to calculate the RMS. of the entire screen. Since the time base was adjusted to capture an exact multiple of waveforms, the calculation of RMS voltage should be accurate.

An alternate way of measuring the RMS voltage would be to connect the output of the high voltage probe into a thermal sensing true RMS voltmeter that is RATED for the CREST FACTOR of the waveform being measured.

The CREST FACTOR can now be calculated.

Definition 201.3.214 – CUTTING

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.

Definition 201.3.215 – EARTH REFERENCED PATIENT CIRCUIT

For purposes of this particular standard, the impedance of this path, at the lowest HF operating frequency, is 10 Ω or less. See Figure AA.5.

Definition 201.3.217 – FULGURATION

FULGURATION generally requires HF peak output voltages of at least 2 kV in order to 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.

Definition 201.3.218 – HEATING FACTOR

This value is a way to describe the thermal stress placed on a NE based on the energy delivered during a finite period of time.

NOTE See subclause 201.15.101.5 in this annex for additional information.

Definition 201.3.219 – HIGH CURRENT MODE

This mode describes situations where the NE thermal stress is greater than the value present in the validation test of subclause 201.15.101.5.

The definition of HIGH CURRENT MODE is being misinterpreted with the effect that conventional HF SURGICAL EQUIPMENT used for many years with compatible, conventional NEUTRAL ELECTRODES without incidents are now erroneously declared as HIGH CURRENT MODE devices. This is not the intention of the document.

Users of the document should understand that

1) The load resistances specified in 201.7.9.3 and 201.12.1 do not define the INTENDED USE. The INTENDED USE is defined by the MANUFACTURER according to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44.
2) The MAXIMUM OUTPUT CURRENT is the RMS current at the lowest relevant impedance determined by the MANUFACTURER ignoring transients of less than 1 s when the device is operated according to the instructions for use.
3) The document requires that the MANUFACTURER performs a RISK ANALYSIS to review situations and reasonably foreseeable misuse that could result in current levels higher than the MAXIMUM OUTPUT CURRENT.

The HEATING FACTOR is calculated according to 201.3.218. The HEATING FACTOR is used to determine if a generator contains a HIGH CURRENT MODE or not according to 201.3.219.

Definition 201.3.220 – HIGH FREQUENCY

Frequencies above 200 kHz should be used for MONOPOLAR applications in order to avoid the unwanted stimulation of nerves and muscles which would result from the use of low frequency current. Lower frequencies may be used for BIPOLAR techniques if the RISK ANALYSIS shows the possibility of neuromuscular stimulation has been mitigated to an acceptable level.

Normally, frequencies above 5 MHz are not used in order to minimize the problems associated with HIGH FREQUENCY LEAKAGE CURRENTS. It is generally recognized that 10 mA is the lower threshold of thermal effects on tissue.

Definition 201.3.225 – HF SURGICAL MODE

The term HF SURGICAL MODE should be clearly distinct from "mode of operation" as used in subclauses 6.6 and 7.2.11 of the general standard in reference to operational DUTY CYCLE.

Definition 201.3.226 – MAXIMUM OUTPUT CURRENT

This information is required by MANUFACTURERS in order to design a NE suitable for use with the HIGH CURRENT MODE. This value is used to calculate a maximum HEATING FACTOR to which the NE(S) will be exposed.

Definition 201.3.227 – MAXIMUM OUTPUT VOLTAGE

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

Definition 201.3.228 – MONITORING NE

A CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE. A MONITORING NE is also known as a split or divided plate since the conductive area is split into two or more parts.

Definition 201.3.229 – MONOPOLAR

This definition is intended to apply equally to equipment and ACCESSORIES and thus is distinct from that of the previous subclause 201.3.203 (ACTIVE ELECTRODE).

Subclause 201.4.1.101 – Additional conditions for application

The market for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES has developed into one where a customer has multiple suppliers to choose from when purchasing HF SURGICAL ACCESSORIES. Since it is not always possible for a MANUFACTURER to know what HF SURGICAL ACCESSORIES will be attached to their equipment, this document attempts to separate all the requirements for HF SURGICAL EQUIPMENT from those for HF SURGICAL ACCESSORIES. With this separation, and the known marketplace variety, it is illogical to require HF SURGICAL EQUIPMENT MANUFACTURERS to prove conformance of their equipment with all possible HF SURGICAL ACCESSORIES. For the same reason it is illogical to require MANUFACTURERS of HF SURGICAL ACCESSORIES to prove conformance of their ACCESSORIES with all possible HF SURGICAL EQUIPMENT.

There are situations where a MANUFACTURER may produce dedicated combinations of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES to ensure INTENDED PURPOSE.

Subclause 201.4.2.3.101 – Evaluating RISK

In MONOPOLAR surgery, the three elements that are used as a system are the HF SURGICAL ACCESSORY, the HF generator and the NEUTRAL ELECTRODE. MANUFACTURERS of any one or more of these elements need to consider the possible use of their products during high current situations. These situations might include, but are not limited to: tissue lesioning, tissue ablation, tissue vaporization, and procedures where conductive fluid is introduced into the surgical site for distension or to conduct the HF current. In high current situations, there is a RISK that heating under a NEUTRAL ELECTRODE may be high enough to cause HARM to the PATIENT.

The requirements for conventional NEUTRAL ELECTRODES are based on data with a maximum duty cycle of 45 % (see rationale for 201.15.101.5). For modes that are used with higher duty cycles according to their intended use, this is addressed in risk management.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

With the exception of the subclauses listed in 201.4.3 it is believed that all of the clauses deal with BASIC SAFETY as defined in the general standard. The requirement for NEs used in conjunction with a HIGH CURRENT MODE are considered ESSENTIAL PERFORMANCE because there is insufficient technical information publically available to create pass/fail criteria and the potential for a PATIENT burn is an unacceptable RISK. On the other hand, the pass/fail criteria for conventional NEs are based on ample technical information to adequately prevent an unacceptable RISK and thus are not deemed ESSENTIAL REQUIREMENTS. MANUFACTURERS have the ability to identify other functions of HF SURGICAL EQUIPMENT which are considered ESSENTIAL PERFORMANCE in accordance with their RISK MANAGEMENT process.

Subclause 201.5.4 – Other conditions

Instruments used to measure HF currents, including HF voltmeter/current sensor combinations, should register true RMS 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 HF currents or HF power of less than 1 s duration may be ignored.

Resistors used for HF testing should be RATED at no less than 50 % of the 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.

This revision of this particular standard continues the objective stated in the 4th Edition (AA 2.2.101) and the 5th Edition (Subclause 201.5.4) to separate HF ACCESSORY requirements and tests from any specific HF SURGICAL EQUIPMENT. Further, this document 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, but no lower, are suitable.

Subclause 201.7.2.10.101 – HF SURGICAL ACCESSORIES

In most instances the HF SURGICAL ACCESSORY, which includes the APPLIED PART, does not provide the TYPE BF or TYPE CF PATIENT protection. This is built into the HF SURGICAL EQUIPMENT.

Subclause 201.7.4.2 – Control devices

This subclause applies only if there is an output control. An output control is not required by this document.

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 shall do so over the total range of load resistance, otherwise the power delivered to the PATIENT may differ from that indicated and hence create an unacceptable RISK. If the numeral "0" is displayed, the OPERATOR will expect zero output at this position of the control.

Subclause 201.7.8.1 – Colours of indicator lights

The standardization of the colours of indicator lights is regarded as a safety feature.

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.

Subclause 201.7.8.2 – Colours of controls

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

Subclause 201.7.9.2.2.101 a)

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

1) In past editions of this document, this subclause included advice to place the NEUTRAL ELECTRODE as close to the operating field as possible. In general, 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. However, if the direct path between the ACTIVE ELECTRODE and the NEUTRAL ELECTRODE includes small cross sectional areas of tissue, the current density could cause undesired heating and tissue damage. Therefore the OPERATOR should rely on the instructions for use provided by the MANUFACTURER of the NEUTRAL ELECTRODE for specific placement instructions.
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) In certain cases, BIPOLAR technique can avoid unwanted tissue damage, especially where bony structures having a relatively high resistance or parts of the body having a relatively small cross section are involved
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.

Subclause 201.7.9.2.2.101 c)

Past editions of IEC 60601-2-18 contained requirements prescribing that MANUFACTURERS of HF energized devices provide information regarding the maximum allowed peak HF voltage as well as modes of intended use. It is felt that this information on the one hand is insufficient, as the modes of intended use such as "spray COAGULATION" are not clearly technically defined

and may vary considerably between different brands and models of HF SURGICAL EQUIPMENT. On the other hand, it was considered impracticable to give such rather complex information to the user of the equipment.

Therefore it was considered 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.4.

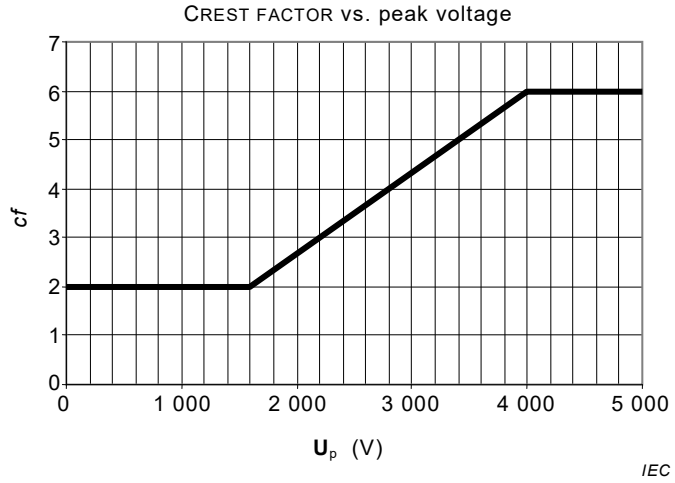


Figure AA.4 – CREST FACTOR vs. peak voltage

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 shall not be less than the MAXIMUM OUTPUT VOLTAGE, since the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT shall fulfil the requirements of 201.8.8.3.103 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 shall 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 shall be found by testing the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT with the HF SURGICAL EQUIPMENT.

Subclause 201.7.9.2.2.101 e)

The OPERATOR shall 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.

Subclause 201.7.9.2.2.101 g)

Although the required measures in 201.8.4.102 are intended to reduce neuromuscular stimulation significantly, it cannot be completely eliminated especially when electrical arcs are produced. Therefore a warning is necessary to make the user aware that in sensitive structures neuromuscular stimulation can still occur leading to secondary RISKS like injury caused by muscle contractions. See also the rationale for 201.8.4.102.

Subclause 201.7.9.2.2.101 h)

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

Subclause 201.7.9.2.2.101 i)

It is understood that general purpose HF SURGICAL EQUIPMENT is utilized with a variety of ACTIVE ACCESSORIES not necessarily provided by the MANUFACTURER of the ME EQUIPMENT. For this reason, information regarding the maximum permissible length of ACCESSORIES to be used with the HF SURGICAL EQUIPMENT is provided to assist the OPERATOR in the selection of compatible HF SURGICAL ACCESSORIES (see 201.7.9.2.14).

The maximum permissible length of the ACCESSORY and its cord takes into consideration:

1) the configuration of the ME that was noted when performing ELECTROMAGNETIC EMISSIONS and IMMUNITY testing, specifically the type and length of PATIENT-COUPLED cables, as both the ELECTROMAGNETIC EMISSIONS and IMMUNITY of the ME are influenced by the length of ACCESSORIES and their cords;
2) the maximum length of the ACCESSORY and its cord that allows compliance with 201.8.7.3.101.

The MANUFACTURER should not presume conformity to EMC and HF LEAKAGE CURRENT requirements with ACCESSORIES and cord lengths that greatly differ from the configuration selected to produce maximum ELECTROMAGNETIC EMISSIONS, minimum IMMUNITY, and acceptable HF LEAKAGE CURRENTS when performing compliance testing.

Subclause 201.7.9.2.14 – ACCESSORIES, supplementary equipment, used material

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.

Subclause 201.7.9.2.14 e)

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.

Subclause 201.7.9.2.14 f)

The OPERATOR shall know which CQM(s) are operative with a given NE.

Subclause 201.7.9.2.14 g)

A statement of compatibility may take different forms as long as it can be understood by the OPERATOR (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).

Subclause 201.7.9.2.14 j)

This information is needed so the OPERATOR can ensure disconnection during use is not possible and that there are no exposed conductive surfaces at the connection point.

Subclause 201.7.9.2.14 k)

HF SURGICAL ACCESSORIES act as antennas from an EMC point of view, so the user needs the length to ensure length compatibility between the HF SURGICAL EQUIPMENT and the accessory.

Subclause 201.7.9.3.1 – General

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

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 haemostasis.

Subclause 201.8.4.101 – NEUTRAL ELECTRODE monitoring circuit

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, and for those having a MONOPOLAR RATED OUTPUT POWER of less than or equal to 50 W that are provided with a connection point for a NE.

The revised subclause title is intended to distinguish between 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 impractical.

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

Fulfilment of these requirements using an alternate means has been added to accommodate technologies that are other than a CONTINUITY MONITOR or a CONTACT QUALITY MONITOR.

The references [1] to [5][2] in the bibliography are recommended as a guide in evaluating suitable surrogate surfaces.

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2 Figures in square brackets refer to the Bibliography.

Subclause 201.8.4.102 – Neuromuscular stimulation

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

Subclause 201.8.5.1.2 – MEANS OF PATIENT PROTECTION (MOPP)

These reduced requirements are considered to be adequate because the "voltages stressing the insulation..." are of HIGH FREQUENCY and therefore, if insulation fails between the HF PATIENT CIRCUITS and the ENCLOSURE, the RISK is much lower than at lower frequencies. HF PATIENT CIRCUITS of HF SURGICAL EQUIPMENT are parts that have to be treated as APPLIED PARTS in the context of this subclause.

In this case the term intermediate circuit would be the SECONDARY CIRCUIT as defined in 3.110 and shown in Figure J.5 of the general standard.

Subclause 201.8.5.2.3 – PATIENT leads or PATIENT CABLES

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

The situation with HF SURGICAL ACCESSORIES 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 ACCESSORIES and BIPOLAR ACCESSORIES 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 response from a PATIENT.

Subclause 201.8.5.5 – DEFIBRILLATION-PROOF APPLIED PARTS

The common mode test represents the situation that can occur with the use of a defibrillator in combination with HF SURGICAL ACCESSORIES and HF APPLIED PARTS. Measurements show that a 5 kV defibrillation pulse in the usual clinical situation will result in no more than 1 kV at the NEUTRAL ELECTRODE and ACTIVE ELECTRODES. A 2 kV test pulse provides a safety margin. The inductance value (Figure 9 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.

Subclause 201.8.6.1 – Applicability of requirements

For low powered MONOPOLAR HF SURGICAL EQUIPMENT used without a NEUTRAL ELECTRODE using the PROTECTIVE EARTH CONDUCTOR of the mains cord as a return path for the functional HIGH FREQUENCY current is common practice; it is considered not to create any safety problem.

Subclause 201.8.7.1 – General requirements

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.

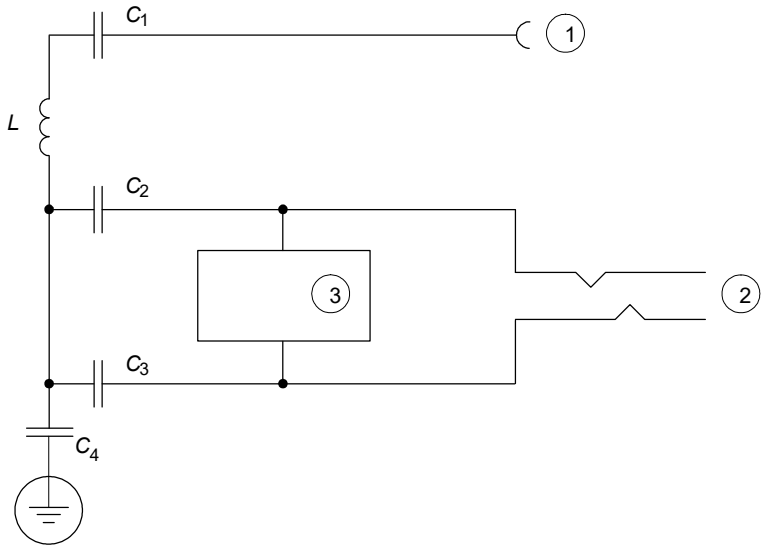
This subclause of the general standard is concerned with LEAKAGE CURRENTS which lead to electric shock, not with therapeutic currents such as are produced by HF SURGICAL EQUIPMENT. Appropriate tests for HF LEAKAGE CURRENT for HF SURGICAL EQUIPMENT with multiple PATIENT circuits are given in 201.8.7.3.101 c) cross-coupling between different HF PATIENT CIRCUITS.

Subclause 201.8.7.3 – Allowable values

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 TYPE CF APPLIED PARTS), because these currents can be expected never to flow across the heart.

Subclause 201.8.7.3.101 a) – Thermal effects of HF LEAKAGE CURRENTS

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.



Key

1 Connector for ACTIVE ELECTRODE

2 Connector for NEUTRAL ELECTRODE

3 Monitor

C_1 not to exceed 5 nF

$C_2 = C_3$ not to exceed 25 nF

X_{C2} and X_{C3} at operating frequency each not to exceed 20 Ω

Z_L at 50 Hz not to exceed 1 Ω

NOTE C_4 may or may not exist depending on the design of the ME.

Figure AA.5 – Example of PATIENT circuit with NEUTRAL ELECTRODE referenced to earth at operating frequencies

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.

Subclause 201.8.7.3.101 a) 3)

Experience in testing BIPOLAR HF SURGICAL EQUIPMENT has shown that these limits are reasonable and the test realistic. The RISK MANAGEMENT FILE may be reviewed for adequate explanation of alternate means of measurement and/or RISK mitigation.

Subclause 201.8.7.3.101 b) – HIGH FREQUENCY LEAKAGE CURRENTS measured directly at the HF SURGICAL EQUIPMENT terminals

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 201.8.7.3.101 a) is also included.

Subclause 201.8.8.3.101 – ACTIVE ACCESSORY insulation

HF SURGICAL EQUIPMENT is capable of producing high voltages which will appear on the conductive parts of HF SURGICAL ACCESSORIES. The insulation on these ACCESSORIES shall 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 shall maintain adequate dielectric strength after extended exposure to conductive fluids and, except for ACCESSORIES intended for single use, repeated sterilization.

NOTE This subclause was completely redrafted in the 5th Edition of this document to cover only dielectric strength of the various parts of ACTIVE ACCESSORY insulation, independent from any particular HF SURGICAL EQUIPMENT. The revised requirements and compliance tests have drawn upon the current editions of ANSI/AAMI HF18 and IEC 60601-2-18 with a goal of harmonization.

Requirements for NEs are now compiled under 201.15.101.

Subclause 201.8.8.3.102 – ACTIVE ACCESSORY HF leakage

The HF leakage requirements are based on ANSI/AAMI HF18:2001, 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 MHz 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 25 mA/cm^2, which is a quarter of 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.

In previous editions of this particular standard, the foregoing rationale was drawn from the 1st Ed of ANSI/AAMI HF18-1986 and cited "…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.." At that time, endoscopic HF surgery was largely unknown in general practice, so this limitation did not impose a technical hurdle. Recently developed small joint arthroscopic ACTIVE ELECTRODES require much thinner insulation and an evaluation of this corresponding reduction of the admittedly generous safety margin to ¼ of the burn threshold, or 25 mA/cm^2. Note further that, since power density varies as the square of current density, this change also corresponds to a 16x, versus 100x, margin in power density. See bibliography reference [12] for derivation of the 100 mA/cm^2 for 10 s skin burn threshold. Well perfused tissue may be expected to require greater current density for the equivalent temperature rise due to more effective heat removal by blood flow.

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 harmonization with ANSI/AAMI HF18, with the amended current density limit of 25 mA/cm^2, by adjusting the HF LEAKAGE CURRENT conformance limit as follows:

$$I_{\text{leakage}}\,[\text{mA}] = 2{,}0 \times 10^{-5} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

For BIPOLAR cords and NE cords, the HF LEAKAGE CURRENT is doubled:

$$I_{\text{leakage}}\,[\text{mA}] = 4{,}0 \times 10^{-5} \times d \times L \times f_{\text{test}} \times U_{\text{peak}}$$

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.

Alternate HF LEAKAGE test:

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

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

The RMS value of a sinusoidal test voltage is evaluated as:

$$V = \frac{V_{\text{p-p}}}{2\sqrt{2}} = 0{,}353\,6 \times V_{\text{p-p}}$$

The constants used for the HF leakage test are:

$V_{p\text{-}p}$ = 800 [V];

U_{test} = 282,8 [V];

f_{test} = 1 000 [kHz];

$I_{leakage}$ = 7,85 $d \times L$ [mA].

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

$$C \text{ [pF]} = 4{,}42 \times d \text{ [mm]} \times L \text{ [cm]}$$

for all but BIPOLAR ACTIVE ACCESSORIES and NE cords. These are allowed twice the LEAKAGE CURRENT which yields:

$$C \text{ [pF]} = 8{,}84 \times d \text{ [mm]} \times L \text{ [cm]}.$$

For purposes of this document, these results are rounded down to 4,4 × d × L and 8,8 × d × L [in pF] respectively.

The technical equivalence of the foregoing alternate capacitance-based test method to the precedent HF LEAKAGE CURRENT method has been validated by Keller [6] and König [7]. This calculation was based on the original HF18 current density limit of 11,46 mA/cm^2, however, application of the revised 25 mA/cm^2 limit allows for an approximate doubling of the limiting capacitance.

Subclause 201.8.8.3.103 – ACTIVE ACCESSORY HF dielectric strength

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. Each test was independently selected to exert worst case stress on the insulation being challenged. The measurement of V_{peak} and the CREST FACTOR should occur simultaneously with the test of the ACCESSORY to ensure that their values do not change due to loading by the ACCESSORY. During these tests, measuring the CREST FACTOR in a loaded state is acceptable.

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

NOTE The gaps between ACTIVE HANDLE and ACTIVE ELECTRODE or detachable cord connector have to be protected against entering saline passing out of the cloth. Therefore the cloth has to be dripped off thoroughly. In case of a breakdown caused by saline in these gaps anyway, the test is repeated with a piece of thin, conductive metal foil wrapped around over the juncture, which prevents the entering of saline into the gaps. Additional requirements for the protection against the effects of ingress of liquids are defined in 201.11.6.5.

Subclause 201.8.8.3.104 – ACTIVE ACCESSORY mains frequency dielectric strength

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 DC 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 all of the dielectric strength tests.

NOTE 1 The metal foil used in the compliance test is highly conductive.

NOTE 2 The gaps between ACTIVE HANDLE and ACTIVE ELECTRODE or detachable cord connector have to be protected against entering saline passing out of the cloth. Therefore the cloth has to be dripped off thoroughly. In case of a breakdown caused by saline in these gaps anyway, the test is repeated with a piece of thin, conductive metal foil wrapped around over the juncture, which prevents the entering of saline into the gaps. Additional requirements for the protection against the effects of ingress of liquids are defined in 201.11.6.5.

Subclause 201.8.10.4.2 – Connection cords

The requirements of these two subclauses (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.

Subclause 201.8.10.4.101 – SWITCH SENSORS

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 subclause 201.11.6.5 of this particular standard.

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 unacceptable example of this is light pressure on the switch may give COAGULATION, heavier pressure may give CUTTING.

This subclause assumes the equipment is turned on.

Subclause 201.11.1.1 – Maximum temperature during NORMAL USE

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

Subclause 201.11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

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

Subclause 201.11.6.5 a)

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 water tightness is required.

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 operating room environment.

Subclause 201.11.6.5 b)

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 AC impedance measurement of 1 kHz avoids measurement errors due to polarization effects in saline which may bridge the switching contacts, and the voltage is consistent with subclause 201.8.10.4.101. The impedance limit was chosen as twice the maximum threshold stipulated by 201.8.10.4.101.

Subclause 201.11.6.7 – Sterilization of ME EQUIPMENT and ME SYSTEMS

Applicable to all ACCESSORY specific requirements. 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 unsuitable for re-sterilisation and thus are exempted from this requirement.

Subclause 201.12.1.102 a) – MONOPOLAR outputs

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

Subclause 201.12.1.102 b) BIPOLAR outputs

The RISK MANAGEMENT FILE may be reviewed for adequate explanation of alternate means of measurement.

Subclause 201.12.1.103 – Accuracy of MAXIMUM OUTPUT VOLTAGE

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

Subclause 201.12.2 b)

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.

Subclause 201.12.2 d)

Within this subclause, the term simultaneous activation refers to either situation described in 201.12.2 c).

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.

Subclause 201.12.2 e)

This subclause provides some requirements for avoidance of incorrect connections on the MANUFACTURERS of HF SURGICAL EQUIPMENT.

Subclause 201.12.2 f)

This subclause specifically places the majority of the burden for avoidance of incorrect connections on the MANUFACTURERS of HF SURGICAL ACCESSORIES. "Flying leads" used as ACTIVE CONNECTORS are prohibited because of the RISKS arising from, for example, the misconnection of a BIPOLAR ACCESSORY to a MONOPOLAR output resulting in excessive HF CURRENT being applied to a PATIENT. Misconnection of a single pin ACCESSORY presents no conceivable HAZARD.

Subclause 201.12.2 g)

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.

Subclause 201.12.4.101 – Use of HIGH CURRENT MODE

New clinical procedures require the use of higher currents and longer activation times than have been used in the past. This combination can result in thermal stresses that are greater than the design characteristics of traditional NEs (those validated using subclause 201.15.101.5).

MANUFACTURERS that produce ME with a HIGH CURRENT MODE are now required to ensure that their NE solution (whether provided or recommended) can safely handle the expected thermal stress for their output.

Subclause 201.12.4.2 – Indication relevant to safety

Within this subclause, the term simultaneous activation refers to the situation described in 201.12.2 c) 1).

Subclause 201.12.4.4.101 – Maximum allowed output power in SINGLE FAULT CONDITIONS

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 BIPOLAR outputs of HF SURGICAL EQUIPMENT.

Subclause 201.12.4.4.102 – Output power during simultaneous activation

Independent outputs shall 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.

Subclause 201.13.2.13.101 – Protection against the effects of short-circuiting of the electrodes

Some ACCESSORIES, for example resectoscopes or BIPOLAR ACCESSORIES, 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.

Subclause 201.15.4.1.101 and 201.15.4.1.102

The requirements of these subclauses 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.

Subclause 201.15.101 – NEUTRAL ELECTRODES

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 referenced 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.

Subclause 201.15.101.2 – NE cord attachment

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 is suitable for detecting connections which may fuse open during NORMAL USE, however that use is not expected to exceed 1 A.

Subclause 201.15.101.3 – NE cord connector

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.

Subclause 201.15.101.4 – NE cord insulation

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 201.8.8.3.102 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 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.

The alternative measured HF leakage capacitance test method may prove simpler to implement than the precedent HF LEAKAGE CURRENT method. See subclause 201.8.8.3.102 for rationale.

Subclause 201.15.101.5 – NE thermal performance

The references [1] to [5] in the bibliography are recommended as a guide in evaluating suitable surrogate surfaces.

This requirement was adopted from ANSI/AAMI HF18:2001, 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 [11]) and with small circular electrodes carrying HF surgical current (Pearce et al., 1983 [13]) show that the maximum safe skin temperature for short-term and long-term exposure is 45 °C. Furthermore, reference to CENELEC Guide 29 [16], Table A1, and interpolating between 48 °C and 43 °C for 8 h or more, gives a maximum allowed surface temperature of 45 °C for 100 min. 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 shall 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 shall 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 shall 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:

- a 1973 article in Health Devices presented data in terms of the average currents, voltages, impedances, and minute DUTY CYCLES over all procedures studied (ECRI, 1973);
- the unpublished data of Milligan and associates 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.

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

	Mean	Standard deviation
Length of surgery (h)	0,86	0,49
Number of activations (/h)	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 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.

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 in joules (J);

I is the NE current in amperes (A);

t is the duration of current flow in seconds (s);

R is the real part of the impedance at the NE site in ohms (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:

$$\Theta = I^2 \times t \ (\text{A}^2\text{s}).$$

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) [8] 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

$$\Theta = 9{,}8 \ \text{A}^2\text{s}$$

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 the following Table AA.2:

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

	Mean	Standard deviation
Length of surgery (h)	1,56	0,84
Number of activations (/h)	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

$$\Theta = 3{,}6\ A^2s$$

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 201.7.9.2.2.101 d) is relied upon to 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 are found in the bibliography items [8] through [13].

The test currents by weight range in Table 201.103 were derived as follows. NEUTRAL ELECTRODES for adults, when tested with the 700 mA current based on the HF18 standard, result in a HEATING FACTOR of 30 A^2s.

NEUTRAL ELECTRODES for children (PATIENT weight 5 kg to 15 kg) have active contact areas that are approximately one half of adult sized NEUTRAL ELECTRODES. When tested with the 500

mA current based on the HF18 standard, results in a HEATING FACTOR of 15 A^2s, which is one half of the maximum allowed adult value.

NEUTRAL ELECTRODES for newborns (PATIENT weight less than 5 kg) have active contact areas that are approximately one half as those for children and thus using a HEATING FACTOR that is one half of that used for children was chosen. This results in a HEATING FACTOR of 7,5 A^2s which implies the test current of 350 mA. Although there is no statistical data to prove the selection of this test current, surgical power settings for these small PATIENTs are always very low so it is felt the 350 mA test current for 60 s results in a reasonable safety margin.

Subclause 201.15.101.6 – NE contact impedance

This requirement was adopted from ANSI/AAMI HF18:2001, 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 HF18:2001, 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 shall be low enough that the NEUTRAL ELECTRODE 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 HF18:2001 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.

It is known that the largely inductive reactance of the NE cord can be significantly larger than the impedance of the contact between the conductive portion of the NE and the PATIENT'S skin and that it can vary significantly depending on its physical layout during INTENDED USE.

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 metallic test plate should be at least as large as the NEUTRAL ELECTRODE.

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

Subclause 201.15.101.7 – NE adhesion

This requirement was adopted from ANSI/AAMI HF18:2001, 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. 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.

Subclause 201.15.101.8 – NE shelf life

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.

Subclause 201.15.101.9 – Adult NEUTRAL ELECTRODES for conventional procedures

During the use of a compatible MONITORING NE in combination with a CONTACT QUALITY MONITOR, the loss of safe contact area between the NE and the PATIENT can be detected. This detection of a safe contact area between the NE and the PATIENT is not possible with the use of a non-MONITORING NE.

For this reason, the RISK of burns at the NE site is significantly reduced with the use of a MONITORING NE in combination with a CONTACT QUALITY MONITOR.

The experience, evaluation and analysis of problem cases in recent years has shown this clearly and has resulted in this requirement.

Since the introduction of CONTACT QUALITY MONITORS, the rate of NE burns has been significantly reduced. Today the vast majority of HF SURGICAL EQUIPMENT for general purpose use is equipped with a CQM-system. However the benefit of CQM-systems is often offset by the use of non-MONITORING NEs which are still available and often preferred due to lower market prices. Therefore it is felt that by adding this requirement the situation will be improved significantly as this will affect the vast majority of electrosurgical procedures.

On the other side it was taken into account that, for special applications (small PATIENTS, high current procedures), exemptions are still needed, as well as for capacitive NEs which are currently not available in CQM monitoring versions.

NEUTRAL ELECTRODES that meet the requirements of 201.15.101 and its subclauses were designed to be used in conventional surgical procedures with HF currents and activation times as described in the Subclause 201.15.101.5 section of this annex. These NEUTRAL ELECTRODES were never designed or intended to be used with HIGH CURRENT MODES which is the reason the additional language “for conventional procedures” was added.

Clause 202 – ELECTROMAGNETIC DISTURBANCES – Requirements and tests

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 EMISSIONS requirements of IEC 60601-1-2:2014, 7.1.2 when the HF output is energized.

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 may be necessary for testing electromagnetic IMMUNITY. However, during stand-by operation, for long periods the HF SURGICAL EQUIPMENT may not be energized and compliance with the EMC requirements is considered necessary.

During the immunity tests, 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.

HF SURGICAL EQUIPMENT is evaluated regarding EMC utilizing ACTIVE ACCESSORIES that represent the least favourable configuration according to IEC 60601-1-2. This configuration is considered when determining the maximum permissible length of accessories (see 201.7.9.2.2.101 i)). The relevant length is for example the fully extended length between the ACTIVE CONNECTOR and the distal end of the ACTIVE ELECTRODE.

The MANUFACTURER may choose not to re-evaluate EMC, if previously completed EMC testing can be shown to be applicable by objective evidence for the configuration.

HF SURGICAL ACCESSORIES, including ASSOCIATED EQUIPMENT, that include active electronic circuits should be evaluated for EMC.

Ensuring compatibility between HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES is an OPERATOR responsibility.

Annex BB
(informative)

ELECTROMAGNETIC DISTURBANCES created by HF SURGICAL EQUIPMENT

BB.1 Overview

Medical devices used in surgery are exposed to many sources of 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 ELECTROMAGNETIC DISTURBANCE 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 ELECTROMAGNETIC DISTURBANCE.

BB.2 Terms and definitions

For the purposes of this annex, the definitions of terms appearing in small capitals are those from this particular standard and the standards listed in clause 1.3 of the general standard, plus the following terms and definitions.

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

BB.2.1
E-FIELD
electric field present in the far field as induced by the magnetic field from 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 to provide haemostasis (COAGULATION). This energy is generated by the HF SURGICAL EQUIPMENT and delivered to the surgical site using various sterile ACCESSORIES. The 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 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 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 NEUTRAL 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 HF SURGICAL MODE, 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 haemostasis. If the sine wave is interrupted, various levels of haemostasis may be achieved in addition to the CUTTING action. The greater the CREST FACTOR the greater the haemostasis. However, increasing the CREST FACTOR also requires that the peak 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 sinusoidal 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 EMISSIONS 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 EMISSIONS 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 EMISSIONS 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 dependent 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.

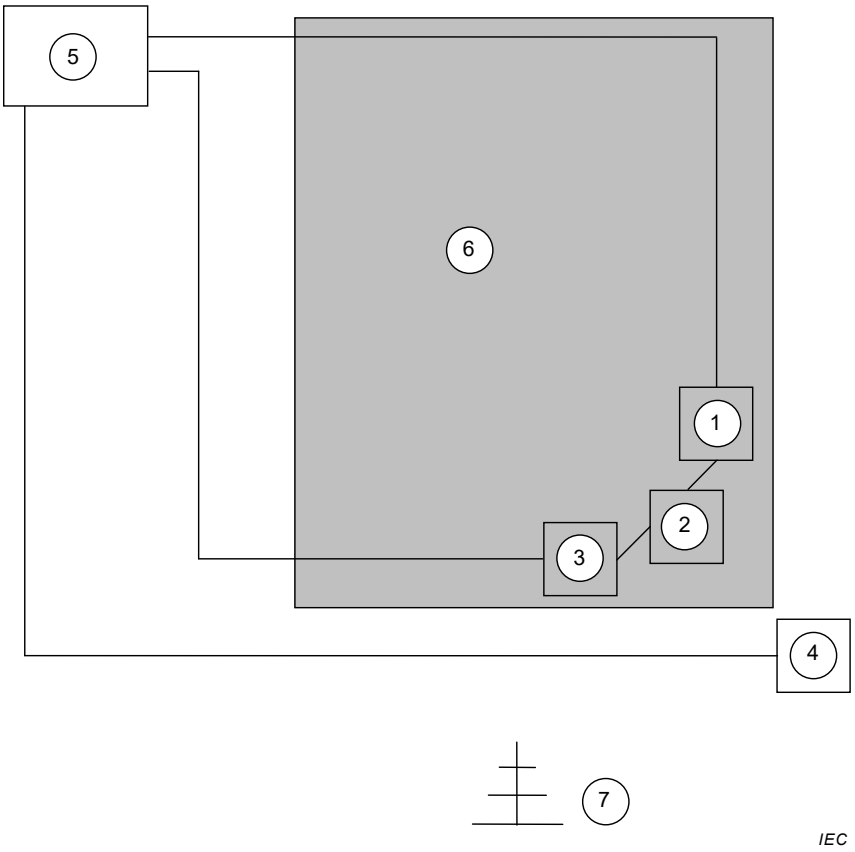
BB.3.3 Measurement techniques

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 measurement techniques found in CISPR 11 were used. The setup 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

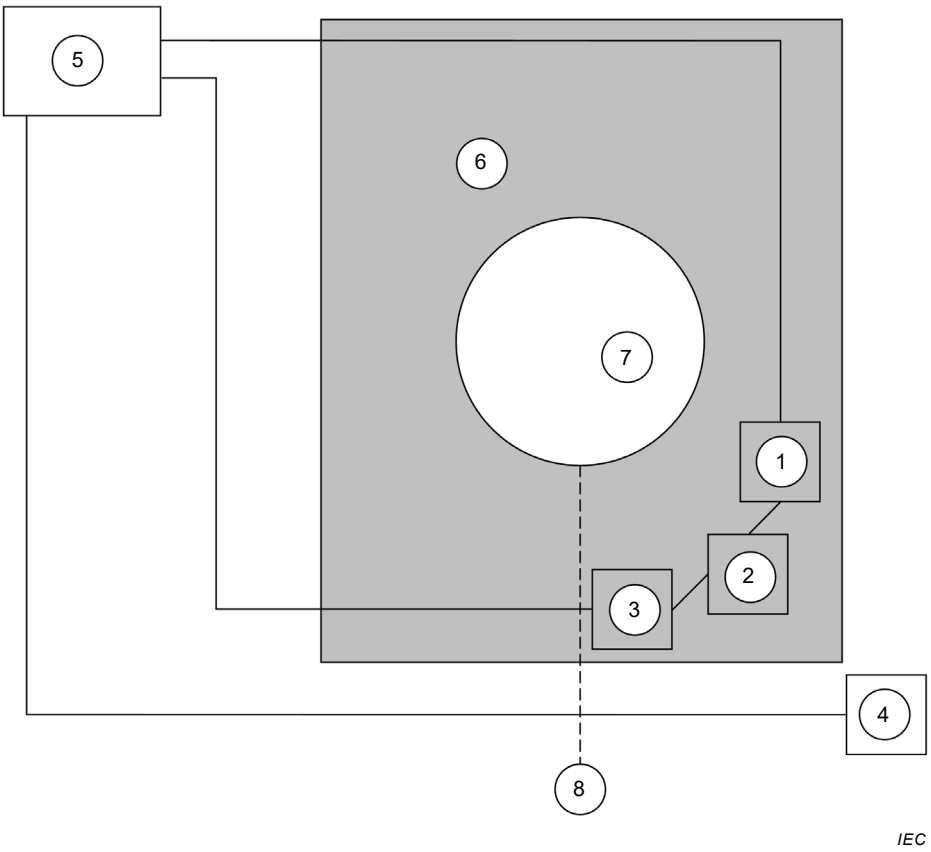
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna – 10 m distance, vertical polarity

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 setup 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

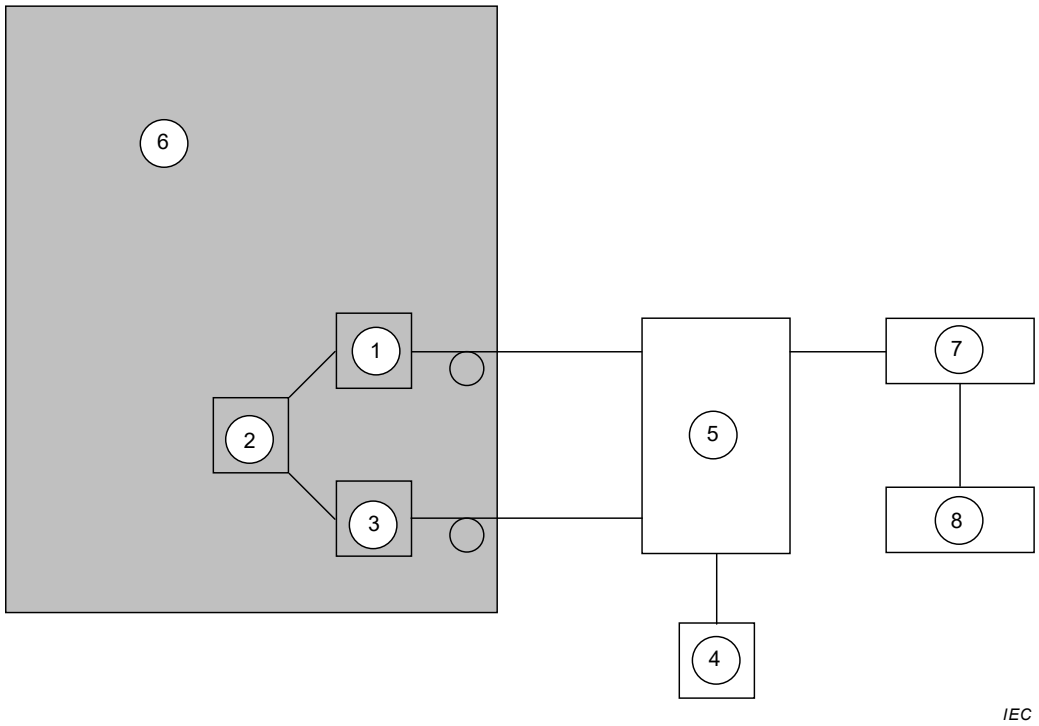
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna
8 Cable to measurement equipment

Figure BB.2 – H-FIELD EMISSIONS 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 setup 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 EMISSIONS test setup

BB.3.4 Data summary

BB.3.4.1 E-FIELD EMISSIONS

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 EMISSIONS

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 EMISSIONS

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 EMISSION levels of HF SURGICAL EQUIPMENT

The greatest level of EMISSIONS 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 EMISSIONS at higher frequencies. The worst case EMISSION values are shown in Table BB.1 and Table BB.2. The E-FIELD measurements were from a distance of 10 m.

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

EMISSION 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/m (67 mA/m)	99,47 dBμA/m (94 mA/m)	96,47 dBμA/m (67 mA/m)
Mains conducted	117 dBμV (708 mV)	Not measured	Not measured

Table BB.2 – Worst case EMISSIONS of non-spark gap (modern) HF SURGICAL EQUIPMENT

EMISSION 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)

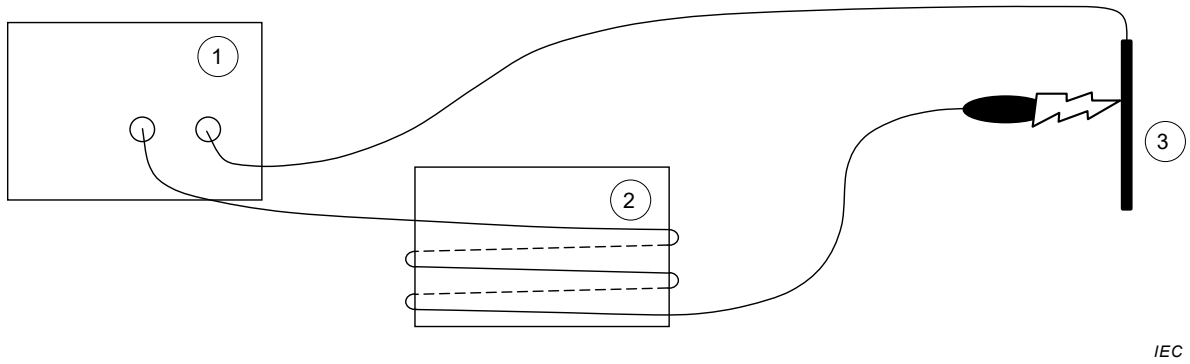
BB.4 Suggested tests

BB.4.1

The following information describes some ad hoc tests that have been used by equipment MANUFACTURERS to determine if their products can withstand the EMISSIONS 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.4.2

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.4.3

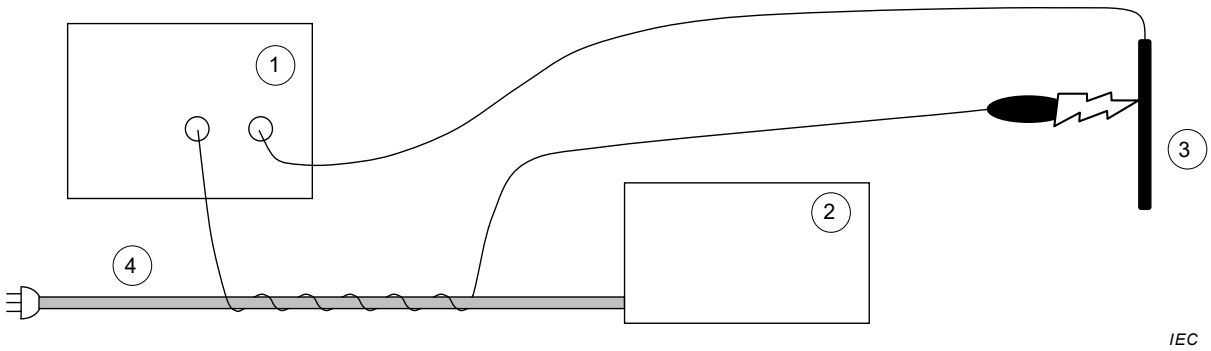
Repeat the test of BB.4.2 with the MONOPOLAR HF SURGICAL ACCESSORY short circuited to (touching) the metal plate. The HF SURGICAL EQUIPMENT should be adjusted to obtain the maximum output power for each output mode.

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.4.4

Repeat the tests of BB.4.2 and BB.4.3 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.



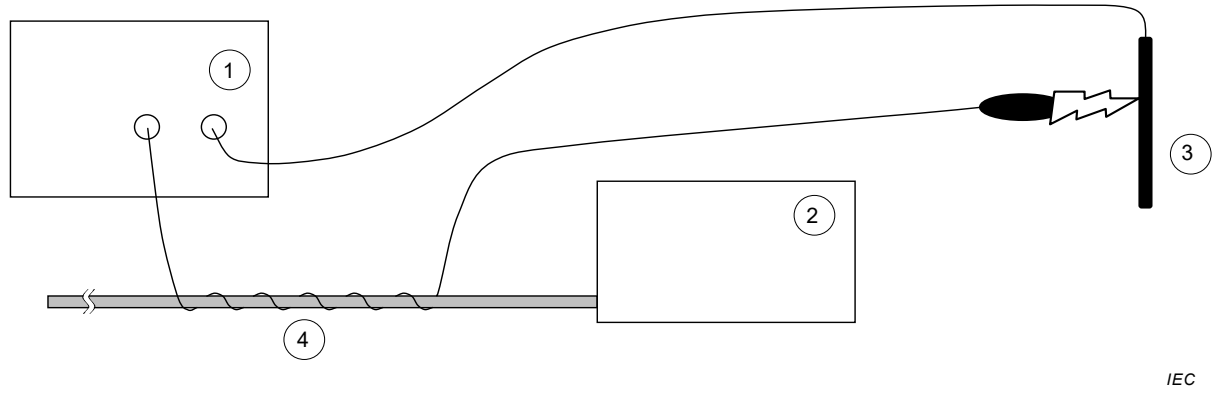
Key

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.4.5

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.4.2 and BB.4.3 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 ACCESSORY cord of unit under test

Figure BB.6 – ACCESSORY cord ad hoc test

BB.4.6

Tests to determine the impact of EMISSIONS 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.

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Index of defined terms used in this particular standard

NATIONAL ANNEX CC
(*National Foreword*)

CC-1 BIS CERTIFICATION MARKING

CC-1.1 The product may also be marked with the Standard Mark.

CC-1.1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act,* 2016 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

(*Continued from second cover*)

The Committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that these are acceptable for use in conjunction with this standard:

International Standard	*Title*
CISPR 11 : 2015 + AMD 1 : 2016 + AMD 2 : 2019	Industrial, scientific and medical equipment — Radio frequency disturbance characteristics — Limits and methods of measurement

This standard is a modified adoption as the Indian standards cross-referred (Column 2) in the first table above are not identical to the referred (Column 1) International Standards.

Only the English language text of the International Standard has been retained while adopting it in this Indian Standard, and as such the page numbers given here are not the same as in the IEC standard.

The standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex CC.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values *(second revision)*'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

This Indian Standard has been developed from Doc No.: MHD 15 (22664).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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