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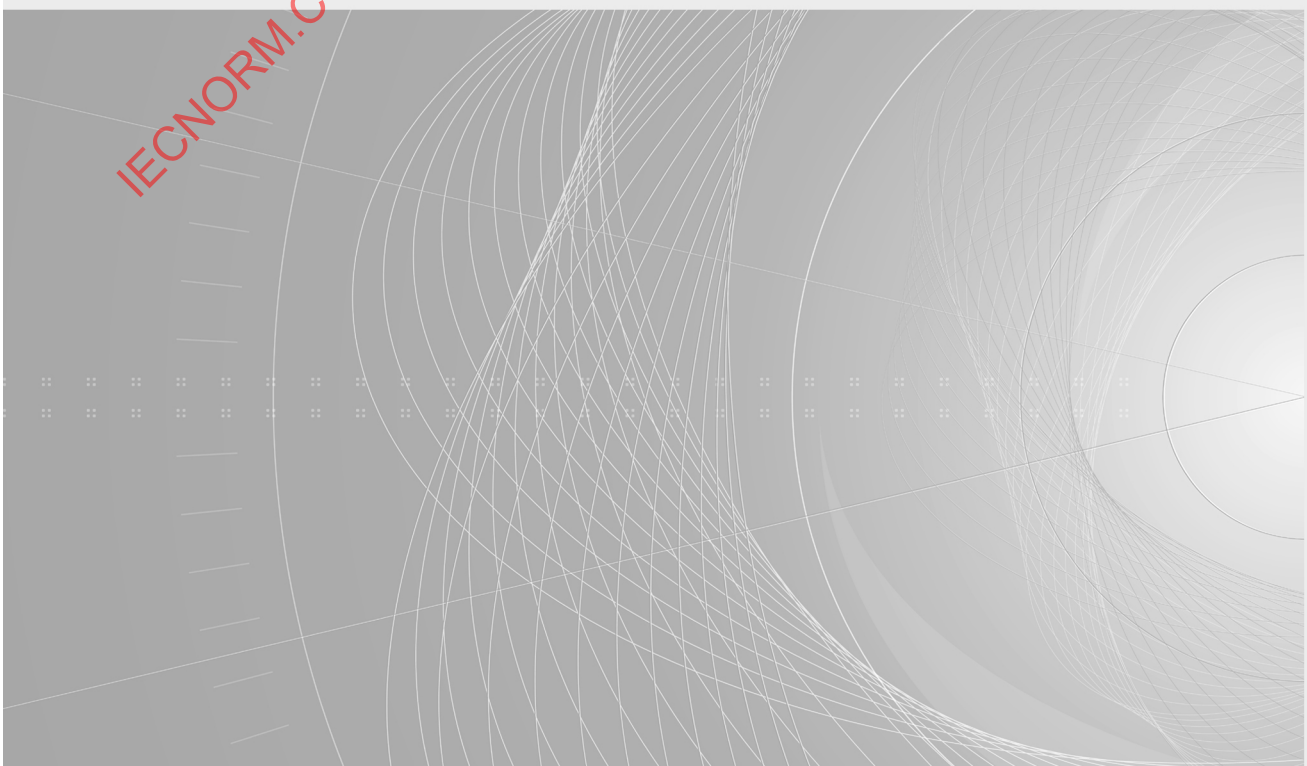
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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



IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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

This sixth edition cancels and replaces the fifth edition published in 2009. This edition constitutes a technical revision. This edition includes the following significant technical changes with respect to the previous edition:

– refinement and additions to the defined terms;
– additional separation of the requirements for HF surgical equipment and HF surgical accessories;
– a new requirement for adult neutral electrodes to be contact quality monitoring neutral electrodes;
– new requirements for devices that have or use a high current mode.

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

FDIS	Report on voting
62D/1427/FDIS	62D/1442/RVD

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

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

In this standard, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type;*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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

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

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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.

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

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 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11[2] 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/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

[2] ~~IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* (in preparation).~~

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 87.

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

Replacement:

IEC 60601-1-2:~~2007~~ 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~ disturbances – Requirements and tests*

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*

Addition:

CISPR 11:~~2003~~ 2015, *Industrial, scientific and medical equipment – Radio-frequency ~~equipment – Electromagnetic~~ disturbance characteristics – Limits and methods of measurement*

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

IEC 61000-4-6:~~2003~~ 2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1~~:2005~~ and the following apply~~, except as follows:~~

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 ~~surgical~~ 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 ~~adjacent~~ 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 ~~and not intended for independent use~~

201.3.208
***BIPOLAR**
method of applying HF ~~output~~ current to a PATIENT ~~via multiple pole~~ 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 ~~ELECTRODE~~ ACCESSORY
~~assembly of~~ 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 ~~elevate the temperature of tissue, e.g. to reduce or terminate undesired bleeding~~ 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 ~~, except MONITORING 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**
~~resection or dissection~~ 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**
~~form of COAGULATION using long (0,5 mm or more) electrical sparks to heat tissue surfaces superficially, with no intentional mechanical contact between the ACTIVE ELECTRODE and the tissue~~ 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

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 ~~HF surgical application electrodes~~ 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 ~~including associated ACCESSORIES~~ which generates HIGH FREQUENCY currents intended for the performance of surgical ~~operations~~ 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 ~~indicated surgical~~ 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 ~~surgical~~ 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~~ly~~ 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 ~~of a relatively large area for connection to the body of the PATIENT,~~ intended to provide an electrical return path for the MONOPOLAR application of HIGH FREQUENCY current with such a low current density in the ~~body~~ PATIENT'S tissue that ~~physical~~ 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 ~~MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS~~

~~*Addition:*~~

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

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

~~*Addition:*~~

Additional ~~SINGLE FAULT CONDITIONS~~ 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

~~*Amendment:*~~

Replacement of first dash in compliance tests:

– The HF SURGICAL EQUIPMENT shall be operated in the output mode and using the load which creates the greatest steady state input current. Input current is measured and compared with 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 ~~ELECTRODE~~ 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

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required, for example, a fault in the PATIENT circuit
Yellow	CUTTING mode
Blue	COAGULATION mode
Green	Ready for use
Any other colour	Meaning other than that of red, yellow, blue or green

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 ~~cardiac pacemakers or other active implants, a possible HAZARD exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged~~ electrically conductive implants, a possible HAZARD exists due to concentration or re-direction of HF currents. In case of doubt, ~~approved~~ 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 instruction 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 ~~must~~ 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 ~~and/~~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 ~~and/~~or activation duration.

– If intended for use only on small PATIENTS, a marking in kg indicating the maximum PATIENT weight for which it is intended to be used. See 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

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.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

~~**201.8.3 Classification of APPLIED PARTS**~~

~~*Addition:*~~

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

201.8.4 Limitation of voltage, current or energy

Additional subclauses:

201.8.4.101 * NEUTRAL ELECTRODE monitoring circuit

HF SURGICAL EQUIPMENT having a ~~RATED OUTPUT POWER of more than 50 W~~ NE connection point shall be provided with one or more of the following:

– a CONTINUITY MONITOR ~~and/or~~ ;

– 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.

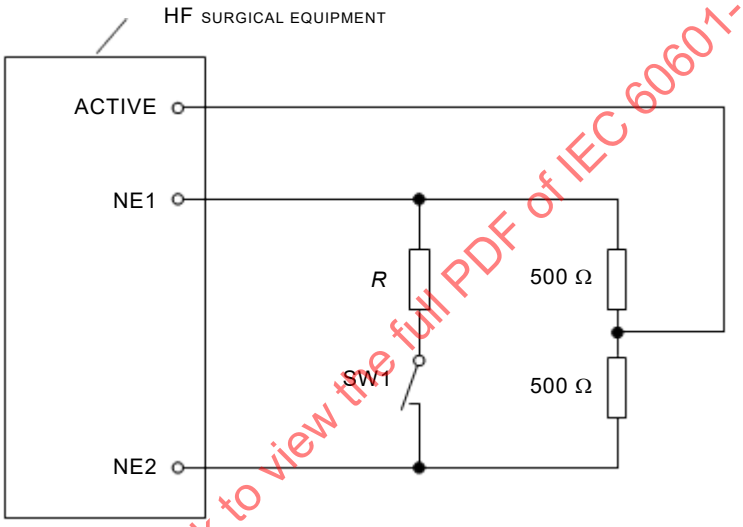
The monitoring circuit shall be supplied from a power source isolated from the MAINS PART and from earth and having a voltage not exceeding 12 V. The limitation of monitoring current for a CONTACT QUALITY MONITOR is defined in 201.8.7.3.

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.



~~NOTE~~ 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 ~~ELECTRODE~~ 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 ~~and HF SURGICAL ACCESSORIES~~, the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the HF APPLIED PARTS and the ENCLOSURE including SIGNAL INPUT/OUTPUT PARTS, between the HF ~~APPLIED PARTS~~ 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.

~~NOTE~~ 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.

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.

~~NOTE Independent requirements and conformance tests for HF SURGICAL EQUIPMENT and ACCESSORIES are under consideration.~~

*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.

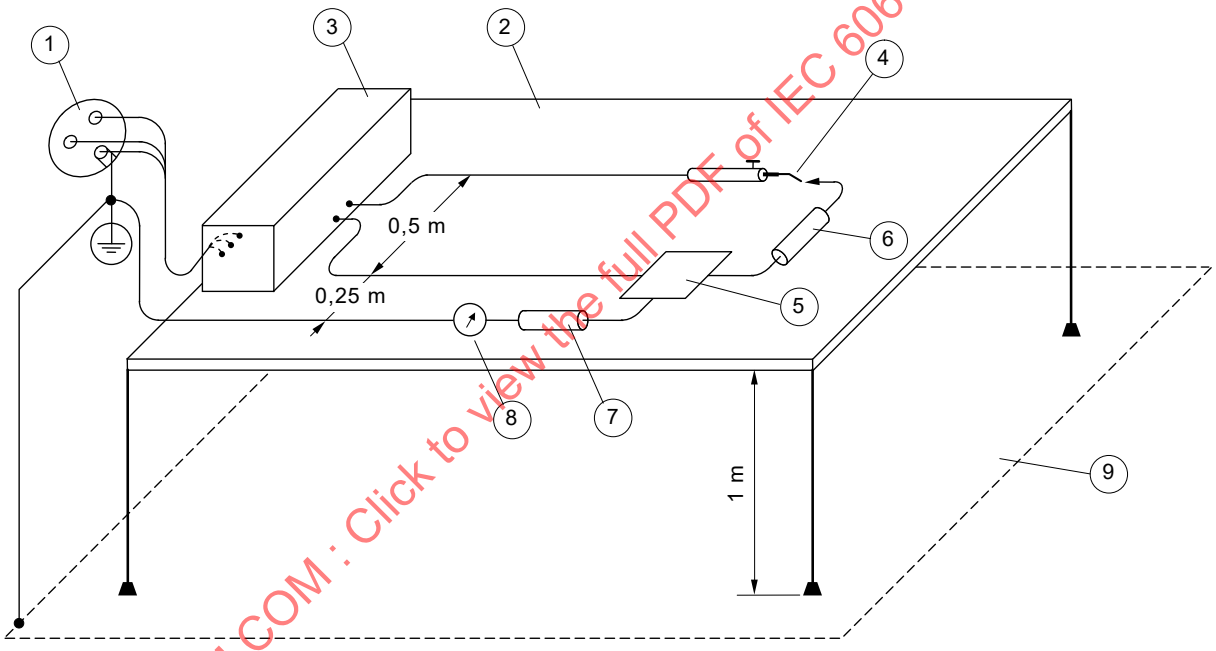
1) ~~NEUTRAL ELECTRODE referenced to earth~~ For MONOPOLAR EARTH REFERENCED PATIENT CIRCUITS

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.

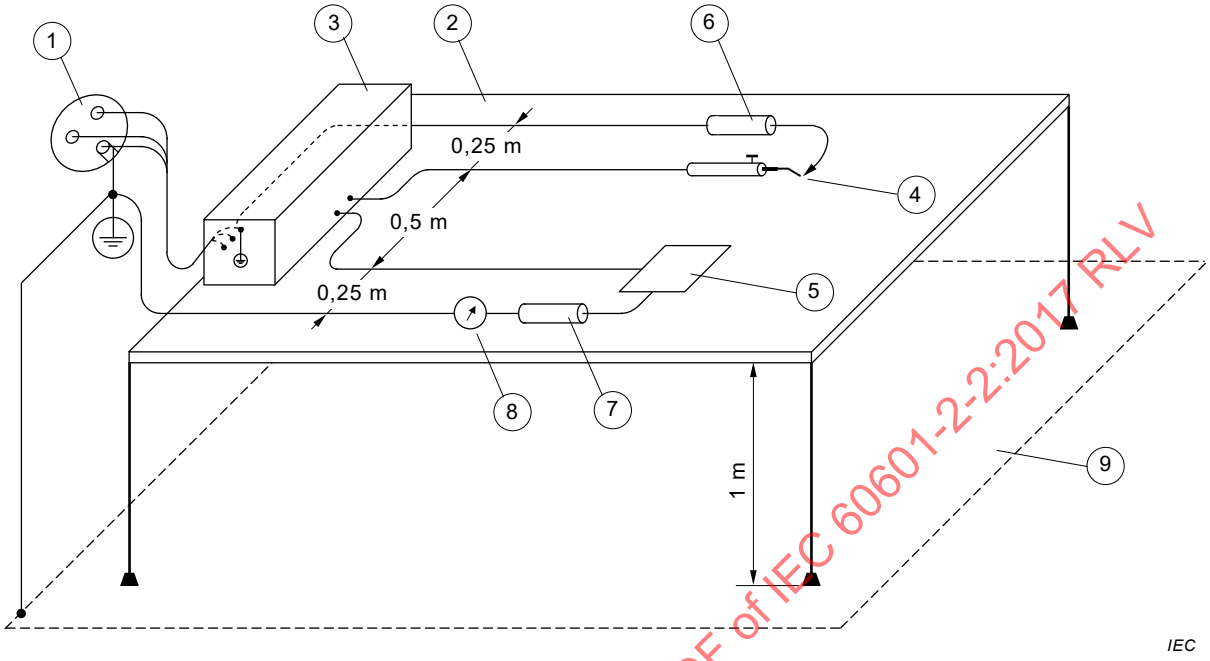


Key

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 ~~with NEUTRAL ELECTRODE referenced to earth~~ 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 ~~with NEUTRAL ELECTRODE referenced to earth~~ for EARTH REFERENCED PATIENT CIRCUITS and a load resistance from ACTIVE ELECTRODE to earth

2) ~~NEUTRAL ELECTRODE ISOLATED from earth at HIGH FREQUENCY~~ For MONOPOLAR HF ISOLATED PATIENT CIRCUITS

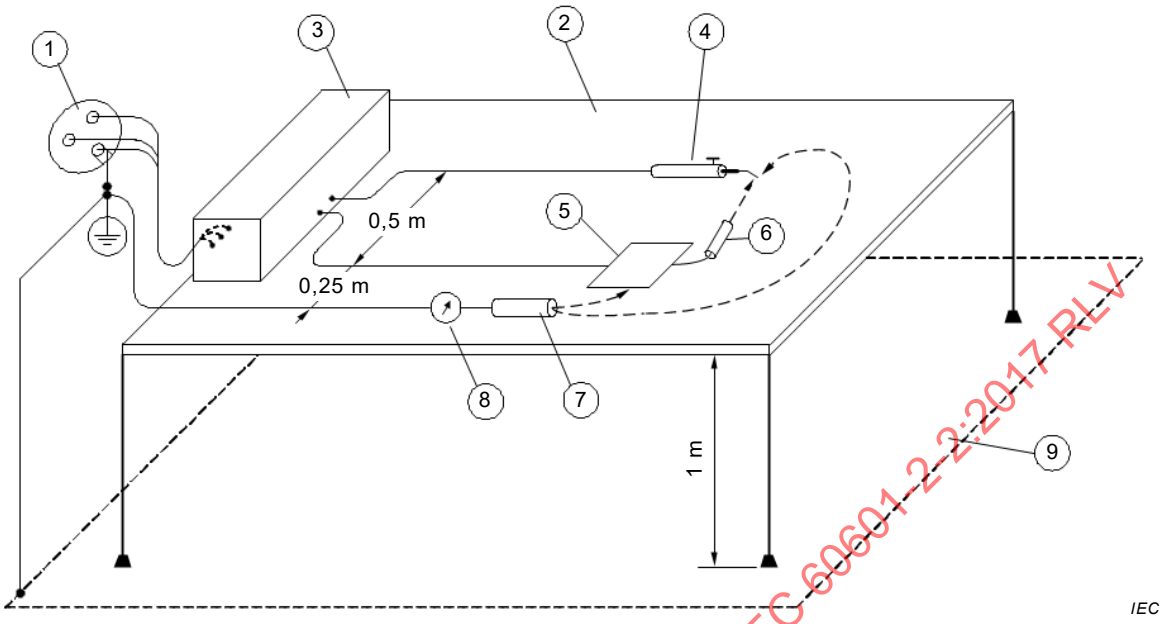
The PATIENT circuit is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing, in turn, from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106, the output being unloaded and loaded at the RATED LOAD.

~~*Any metal ENCLOSURES of CLASS II HF SURGICAL EQUIPMENT and INTERNALLY POWERED HF SURGICAL EQUIPMENT shall be connected to earth. HF SURGICAL EQUIPMENT having an insulating ENCLOSURE shall be positioned on earthed metal having an area at least equal to that of the base of the HF SURGICAL EQUIPMENT, during this test.*~~ *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 ~~with NEUTRAL ELECTRODE isolated from earth at high frequency~~ for HF ISOLATED PATIENT CIRCUITS

*3) For BIPOLAR ~~application~~ 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.

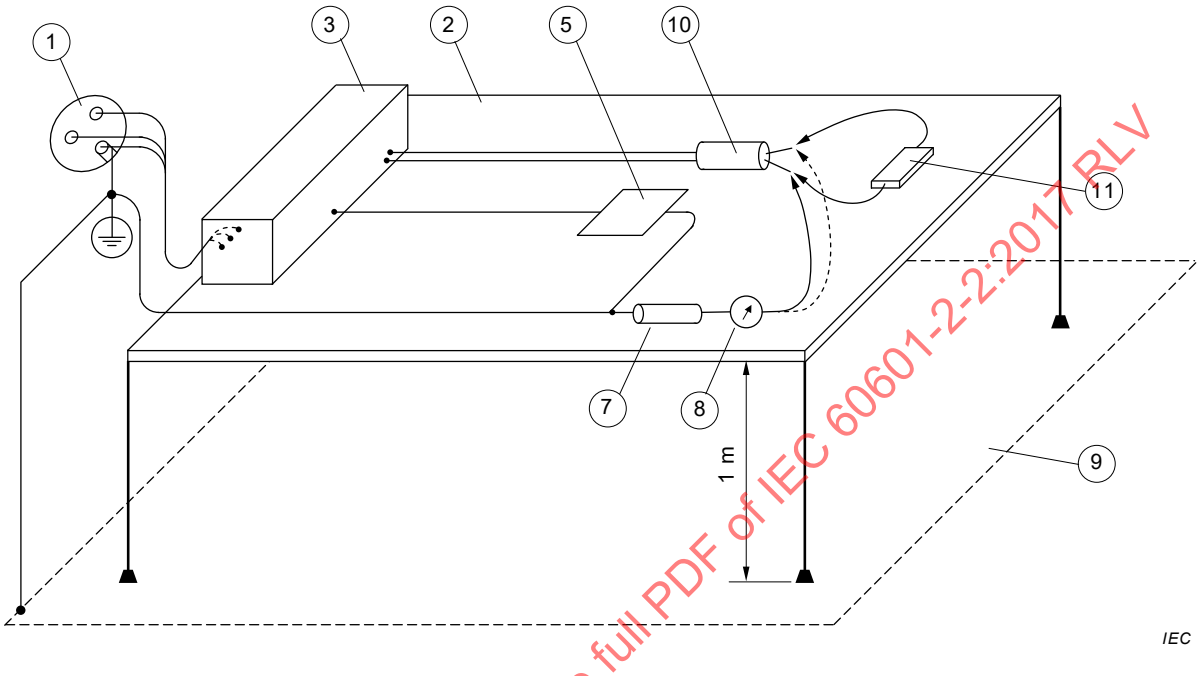
Compliance is checked by the following test.

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 and then repeated with the output loaded at the RATED LOAD. The squared current value multiplied by 200 Ω shall not exceed the requirement above. The test is then repeated for the other side of the BIPOLAR output.

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

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

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



Key

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

Figure 201.107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ~~ELECTRODE~~ 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 ~~cords for ACTIVE ACCESSORIES intended for MONOPOLAR application~~ ACTIVE ACCESSORIES, including ACTIVE ELECTRODE INSULATION 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:

$$I_{leakage}[\text{mA}] = 9{,}0 \times 10^{-6} \times d \times L \times f_{test} \times U_{peak}$$

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

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 ~~cords~~ ACTIVE ACCESSORIES intended for BIPOLAR application is

$$I_{leakage}[\text{mA}] = 1{,}8 \times 10^{-5} \times d \times L \times f_{test} \times U_{peak}$$

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

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.

b) Measured HF leakage capacitance

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

~~$C_{\text{leakage}}[\text{pF}] = 2 \times d \times L$~~

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

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

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

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

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.

~~NOTE HF leakage limits and tests for all parts of ACTIVE ACCESSORIES are under consideration.~~

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:

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

where

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

For RATED ACCESSORY VOLTAGES greater 4 000 V:

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

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

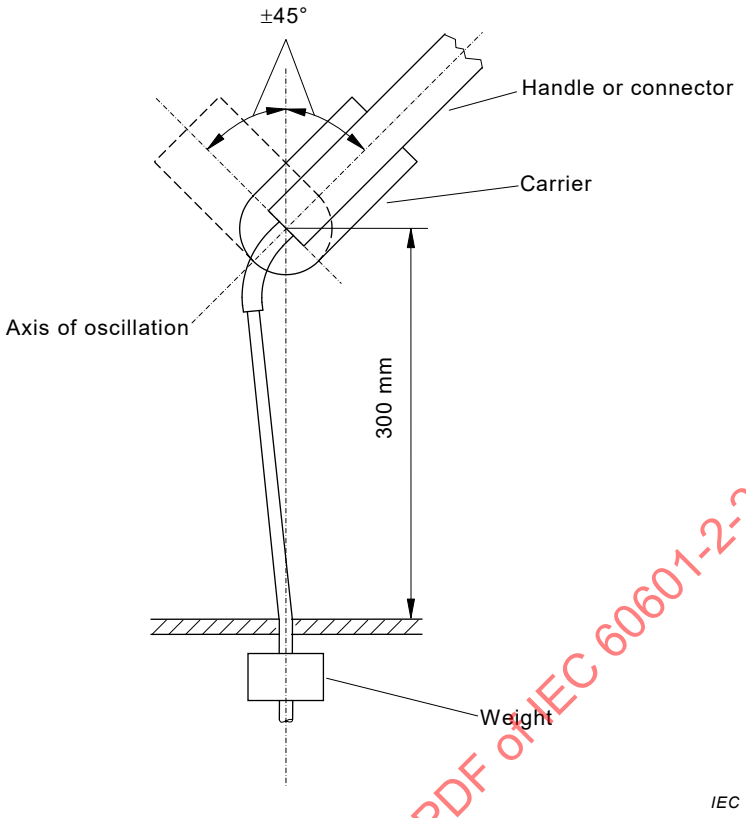


Figure 201.108 – Test apparatus for anchorages of cords of ACTIVE ACCESSORY

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 ~~should be~~ 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 ~~BIPOLAR~~ 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:

~~Duty cycle:~~ 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.

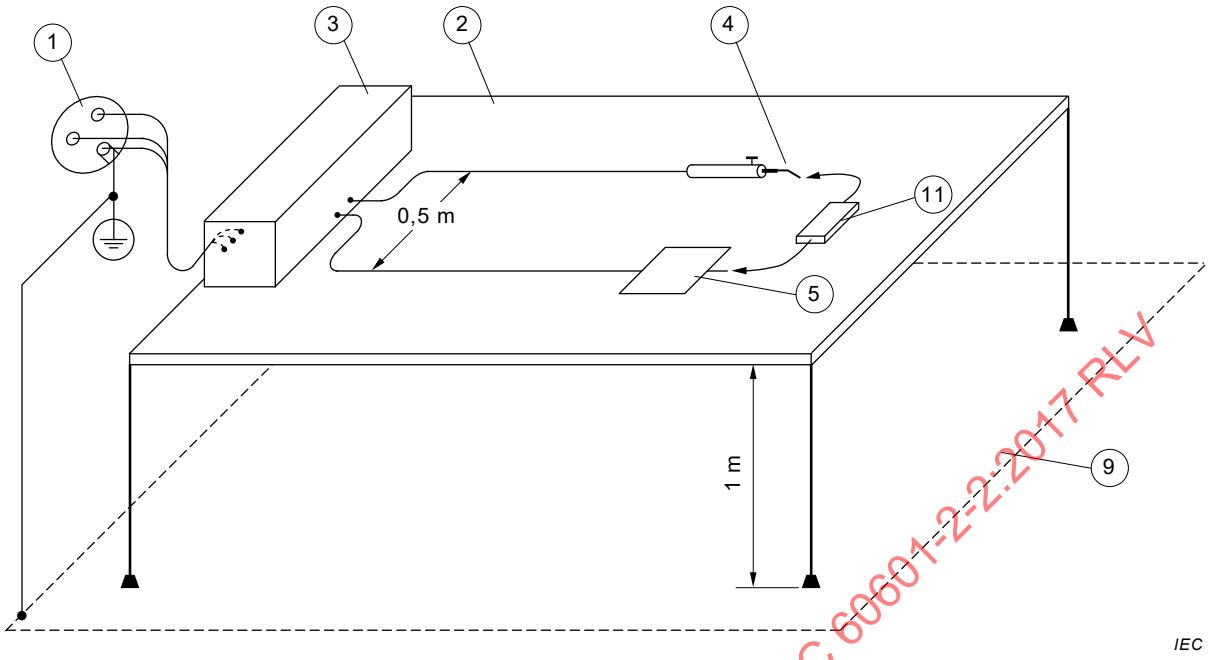
201.12.1.102 Monotonicity of output control setting

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 of 3 m lengths of insulated conductors shall be used for connection of the load resistors.



Key

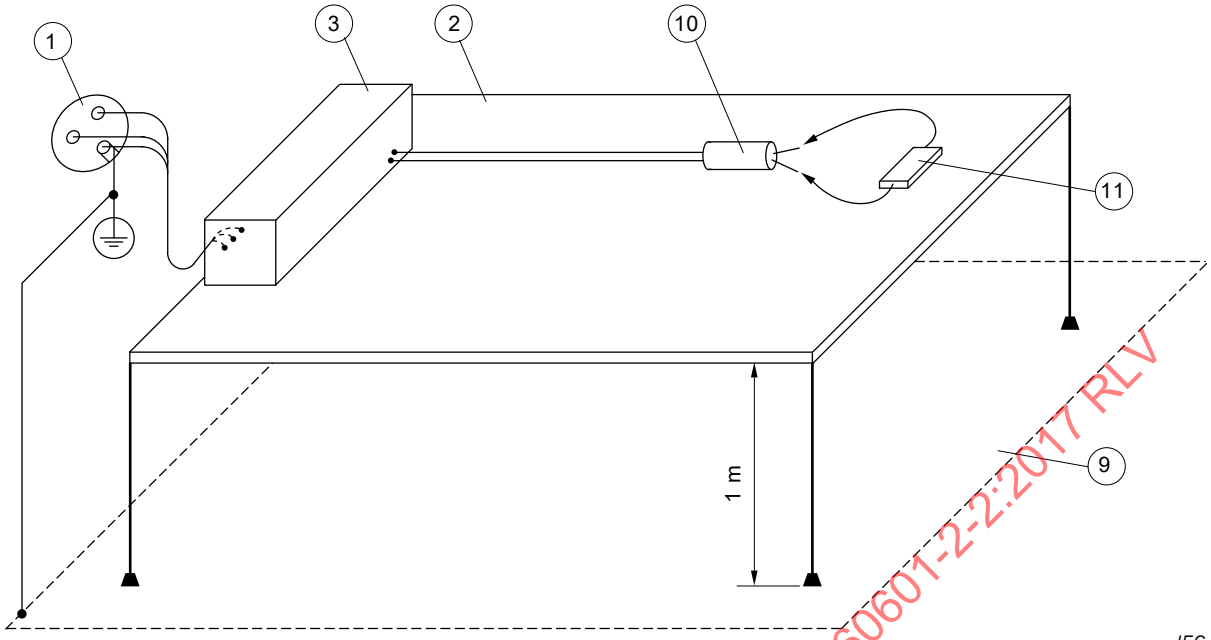
1	SUPPLY MAINS
2	Table, made of insulating material
3	HF SURGICAL EQUIPMENT
4	ACTIVE ELECTRODE
5	NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
9	Earthed conductive plane
11	Load resistance as required with HF power measuring device

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 ~~ELECTRODES~~ ACCESSORIES.



Key

1	SUPPLY MAINS
2	Table, made of insulating material
3	HF SURGICAL EQUIPMENT
9	Earthed conductive plane
10	Activated BIPOLAR ~~ELECTRODE~~ 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 ~~of parameters~~ 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, 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.

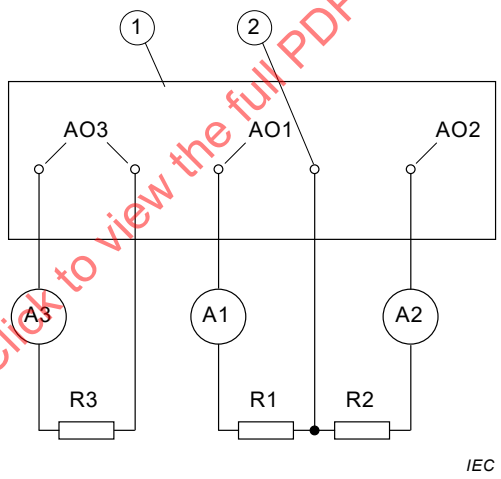
Compliance is checked by the following tests (see Figure 201.111).

For HF SURGICAL EQUIPMENT as defined in 201.12.2 c):

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 %.

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 ~~ELECTRODE~~ 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~~, no conductive parts on PATIENT~~

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*

$$I_{leakage}\ [mA] = \sout{1,8}\ 4,0 \times 10^{-5} \times d \times L \times f_{test} \times U_{peak}$$

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

$$C_{leakage}\ [pF] = 4\ 8{,}8 \times d \times L$$

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 ± 2 °C, and a reference temperature scan of the test surface shall be recorded immediately prior to application of the NE to the test surface. The NE shall be applied to the test surface in accordance with supplied instructions for use, except that contact area shall be A_a. The NE shall rest on the test surface for 30 min in a stable temperature environment before the

application of the test current. If a thermally equivalent surrogate medium or test device is used the test may commence once thermal equilibrium is achieved.

The test current, I_{test}, applied to the electrode under test shall have an approximately sinusoidal HF waveform, and ~~must~~ 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 input impedance greater than 2 kΩ and~~ 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 ~~compatibility~~ DISTURBANCES – Requirements and tests

IEC 60601-1-2:~~2007~~ 2014 applies except as follows:

202.2 Normative references

Replace 5th reference “IEC 60601-2-2:2009” by “IEC 60601-2-2:2016”

202.3 Terms and definitions

In paragraph 1, replace “IEC 60601-2-2:2009” by “IEC 60601-2-2:2016”

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.

~~**202.6.1 EMISSIONS**~~

~~**202.6.1.1.1 Requirements**~~

~~*Addition:*~~

~~aa) These requirements and tests do not apply to HF SURGICAL EQUIPMENT when the HF output is energized.~~

~~bb) 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.~~

~~**202.6.2 IMMUNITY**~~

~~**202.6.2.1.10 Compliance criteria**~~

~~Addition:~~

~~The following shall be DEGRADATION of performance that does not affect ESSENTIAL PERFORMANCE or BASIC SAFETY:~~

~~– the interruption of HF power output or reset into standby mode when clearly indicated on the operation panel of HF SURGICAL EQUIPMENT;~~

~~– a change in the delivered output power as allowed in 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.*~~

202.7 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 60601-2-2:2016”

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 applies 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 ~~may~~ 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 ~~should be~~ are taken into account. This situation ~~may~~ 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

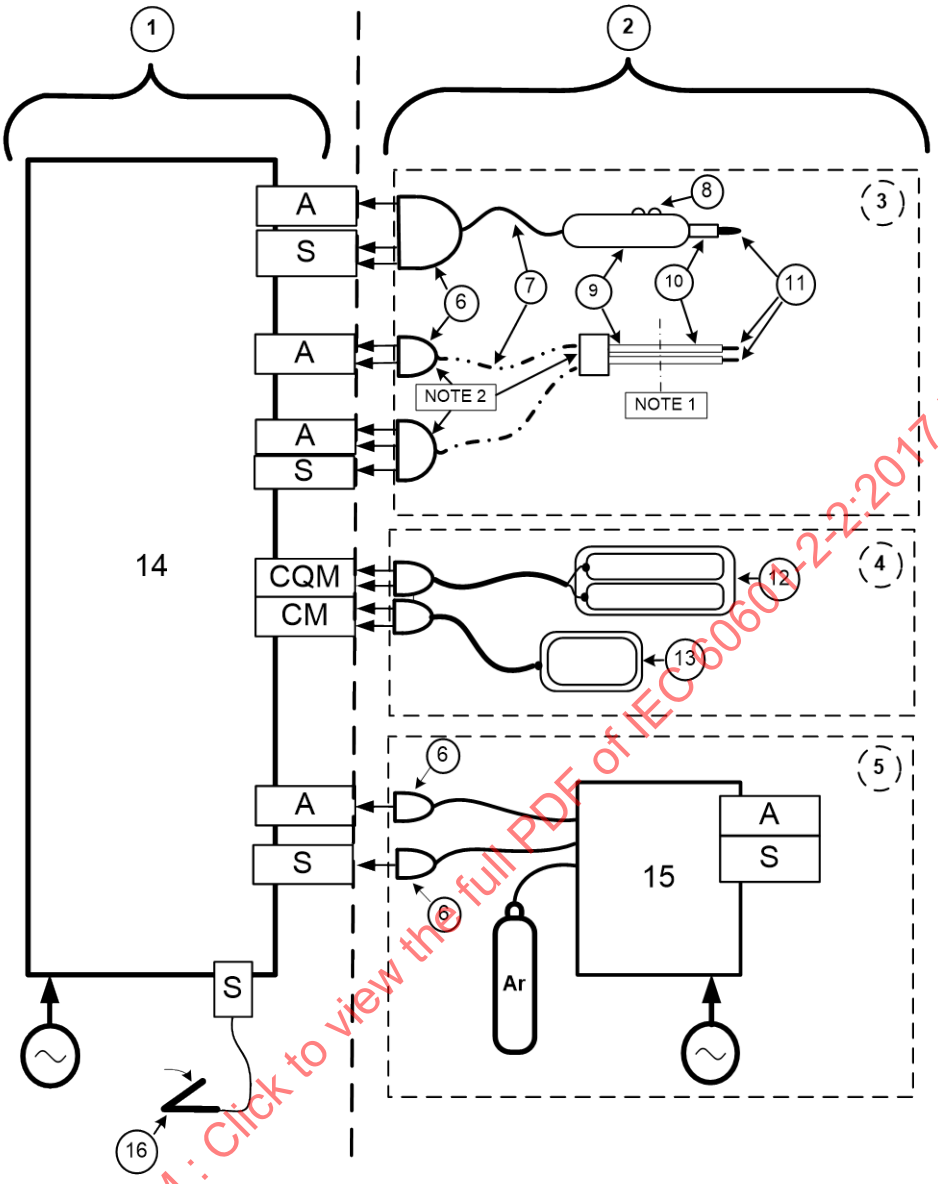
The scope does not include equipment for cautery, i.e. for medical treatment with electrically heated metal rods or wire loops. This edition provides, to the extent feasible, separate requirements and tests for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES, independent of manufacture. ASSOCIATED 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. ~~The text "not intended for independent use" means the devices are used only in conjunction with HF SURGICAL EQUIPMENT.~~ 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 ~~ELECTRODE~~ ACCESSORY).



IEC

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.

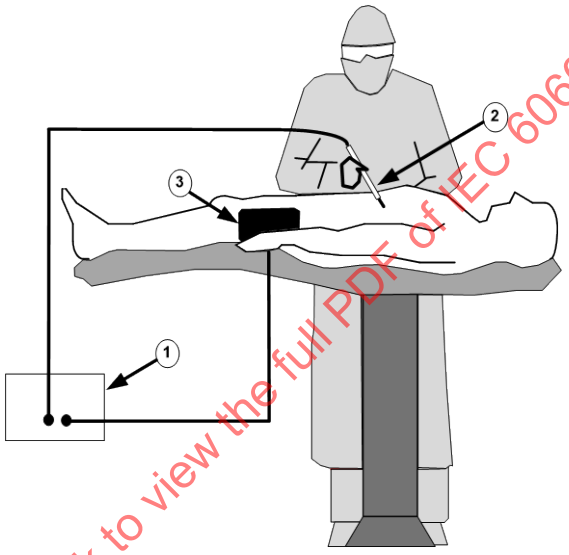
Key

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

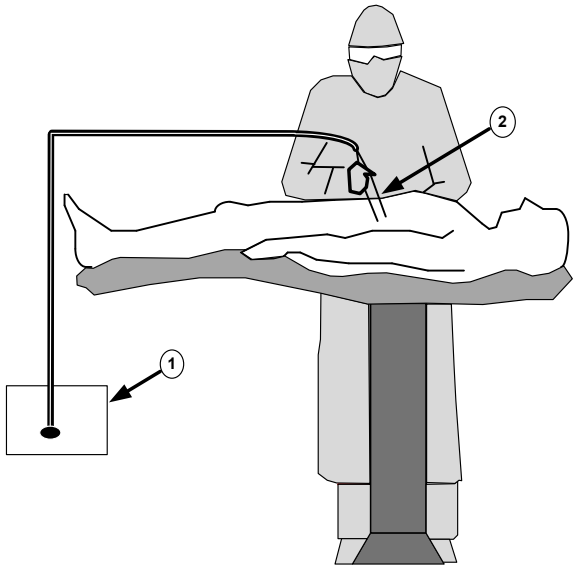


IEC

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.

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. ~~However, higher frequencies may be used in the case of BIPOLAR techniques.~~ It is generally recognized that 10 mA is the lower threshold of thermal effects on tissue.

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 ~~existing~~ 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 ~~MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS~~

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 ~~non-traditional,~~ 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.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

~~After a careful consideration of the clauses within this standard, it was decided that they all~~ 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 ~~expected~~ power dissipation expected for a given test, and should present a resistive component of impedance within 3 % of the specified value and no more than 8,5 degrees of impedance phase from 10 kHz to 5 times the fundamental frequency for the HF SURGICAL MODE being tested.

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

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

~~A primary objective of the revision of this particular standard is to isolate~~ 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 ~~must~~ 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)

~~IEC 60601-2-18:1996 contains requirements prescribing that MANUFACTURERS of HF energized endotherapy devices shall specify them as suitable for a certain maximum allowed HF peak output voltage which shall be defined in the ACCOMPANYING DOCUMENTS for such ACCESSORIES.~~

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. ~~However IEC 60601-2-18-A1 (2000) requires a "RATED recurring peak voltage" together with the "mode(s) of intended use". The experts of Maintenance Team 17~~ 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.

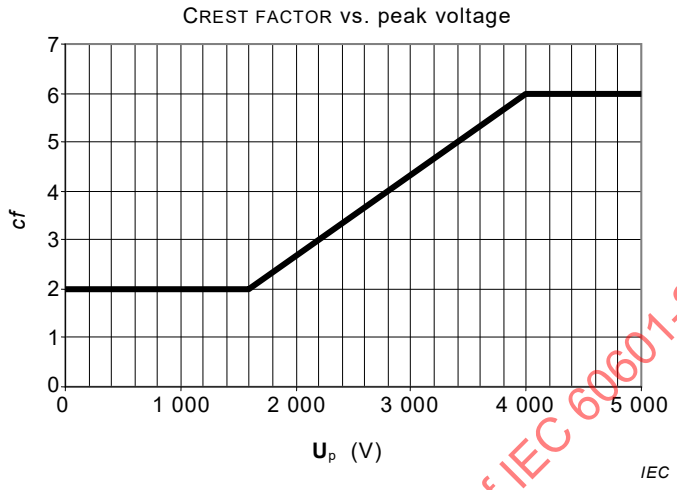


Figure AA.4 – CREST FACTOR vs. peak voltage

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 ~~must~~ shall not be less than the MAXIMUM OUTPUT VOLTAGE, since the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT ~~must~~ 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 ~~must~~ 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 ~~must~~ 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 ~~must~~ 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 ~~must~~ 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 201.7.9.3.1 – 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 ~~over~~ 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][3] in the bibliography are recommended as a guide in evaluating suitable surrogate surfaces.

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 ~~APPLIED PARTS~~ 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.

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3 Figures in square brackets refer to the Bibliography.

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 ~~ELECTRODES~~ 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.

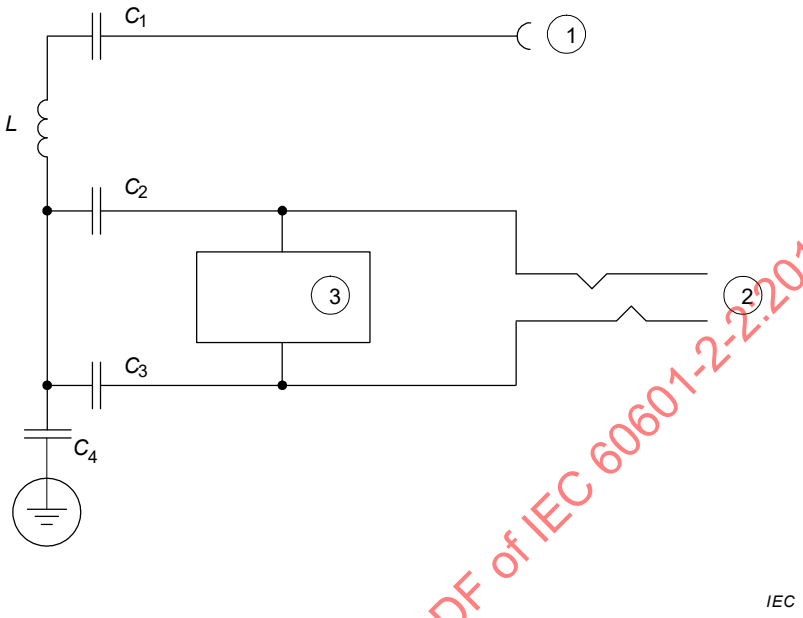
This subclause of the general standard is concerned with LEAKAGE CURRENTS which lead to electric shock, not with therapeutic currents such as are produced by HF SURGICAL EQUIPMENT. Appropriate tests for HF LEAKAGE CURRENT for HF SURGICAL EQUIPMENT with multiple PATIENT circuits are given in 201.8.7.3.101 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 ~~2~~ 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 ~~insulated~~ conductive parts of HF SURGICAL ACCESSORIES. The insulation on these ACCESSORIES ~~must~~ 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 ~~must~~ shall maintain adequate dielectric strength after extended exposure to conductive fluids and, except for ACCESSORIES intended for single use, repeated sterilization.

NOTE This subclause has been completely redrafted to cover only dielectric strength of the various parts 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 ~~11,46~~ 25 mA/cm^2, which is ~~nearly an order of magnitude below~~ 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:

~~$$I_{leakage}\,[mA] = 9{,}0 \times 10^{-6} \times d \times L \times f_{test} \times U_{peak}$$~~

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

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

~~$$I_{leakage}\,[mA] = 1{,}8 \times 10^{-5} \times d \times L \times f_{test} \times U_{peak}$$~~

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

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

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

and

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

then

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

thus

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

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

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

The constants used for the HF leakage test are:

$V_{\mathrm{p\text{-}p}}$ = 800 [V];
U_{test} = 282,8 [V];
f_{test} = 1 000 [kHz];
I_{leakage} = ~~3,6~~ 7,85 $d \times L$ [mA].

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

C [pF] = ~~2,026~~ 4,42 × d [mm] × L [cm]

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

C [pF] = ~~4,052~~ 8,84 × d [mm] × L [cm].

For purposes of this document, these results are rounded down to ~~2 × d × L and 4 × d × L~~ 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 ~~should be~~ 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) ~~– Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS~~

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) ~~Monotonicity of output control setting –~~ 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) ~~and f)~~

~~Specifically places the burden for avoidance of incorrect connections on the equipment. Flying leads do not adequately discourage improper connections. Misconnection of a single pin ACCESSORY presents no conceivable HAZARD.~~

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

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 ~~of parameters~~ relevant to safety

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

Subclause 201.12.4.3.101 – Output reduction means

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

Subclause 201.12.4.4.101 – 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 ~~must~~ 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 ~~ELECTRODES~~ 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~~, no conductive parts on PATIENT~~

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 ~~must~~ 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 ~~must~~ 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 ~~must~~ 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:

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

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:

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

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

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

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

A similarly conservative test criterion can be derived for NEs marked for "INFANT" use. Since TUR procedures are not performed on infants, a reasonable approach is to use the current and duration data available for general surgical procedures. These data, reported by Pearce (1981), are given in 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 ~~must~~ 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 ~~it is activated~~ 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 ~~are~~ may be necessary for testing electromagnetic IMMUNITY ~~(see 202.6.2.101 and Figures 201.109, 201.110 and 201.111 of IEC 60601-2-34[4)]). This was considered the best way to assure electromagnetic compatibility between HF SURGICAL EQUIPMENT and some other medical devices used in its vicinity.~~ 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.

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

~~"The HF SURGICAL EQUIPMENT shall comply with IEC 60601-2-2, shall have a minimum cut mode of 300 W, a minimum COAGULATION mode of 100 W and a working frequency of 450 kHz ± 100 kHz."~~

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

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

~~4) Third edition, in preparation: IEC 60601-2-34, *Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*~~

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 ~~lower the duty cycle~~ greater the CREST FACTOR the greater the haemostasis. However, ~~lowering the duty cycle~~ 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.

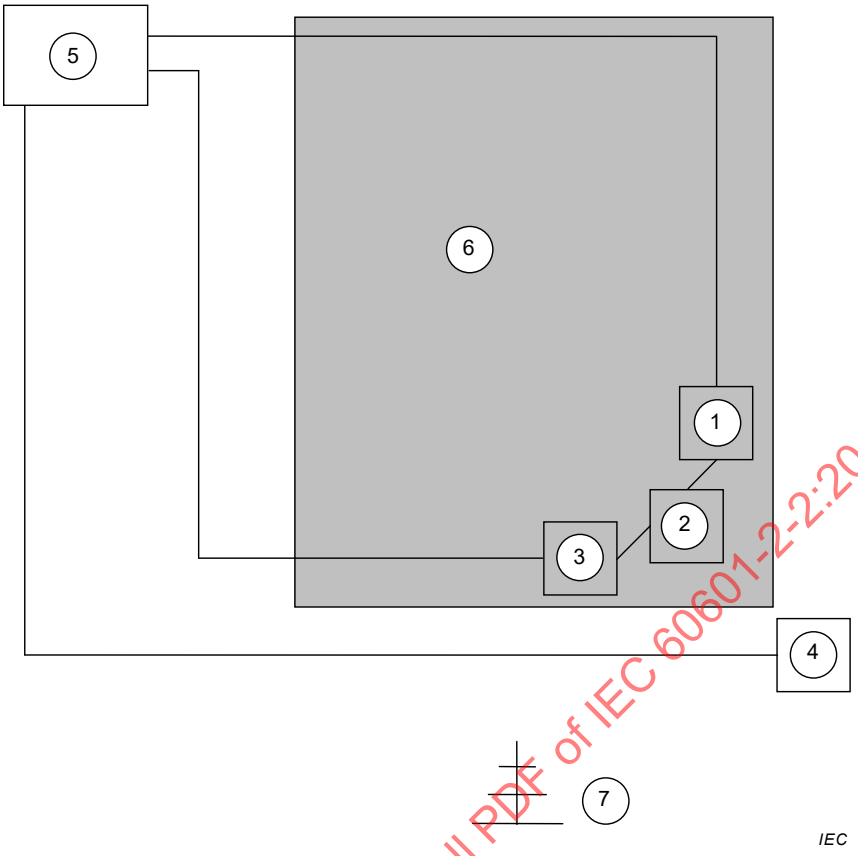
BB.3.3 Measurement techniques

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

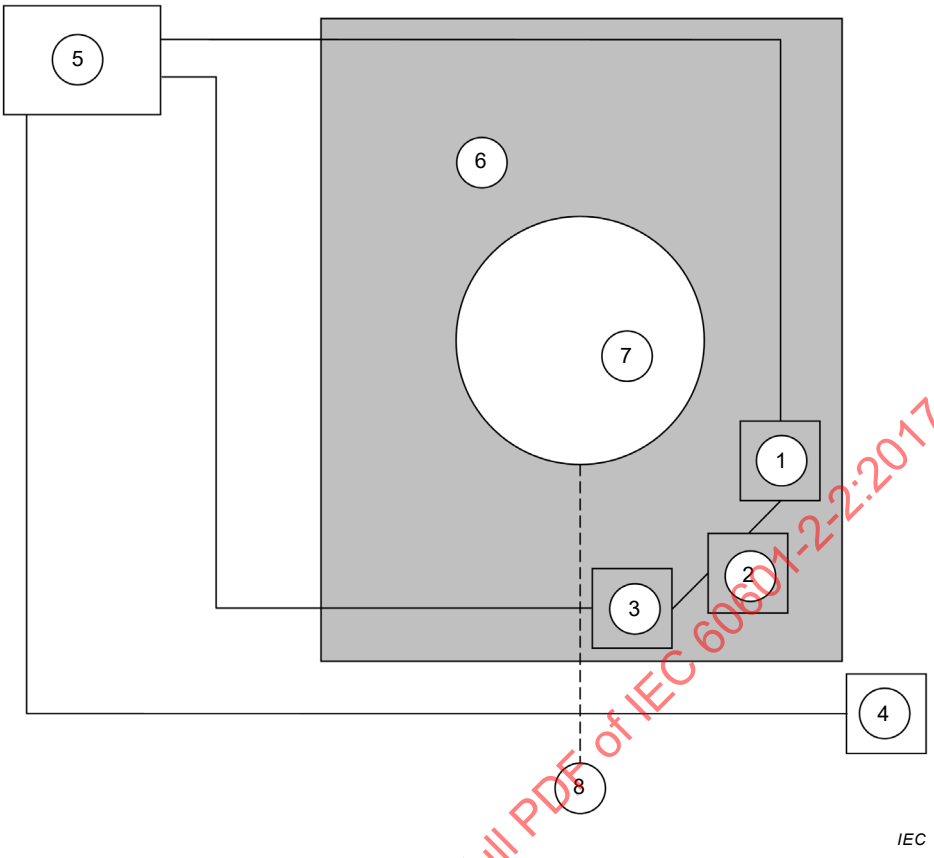
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna – 10 m distance, vertical polarity

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

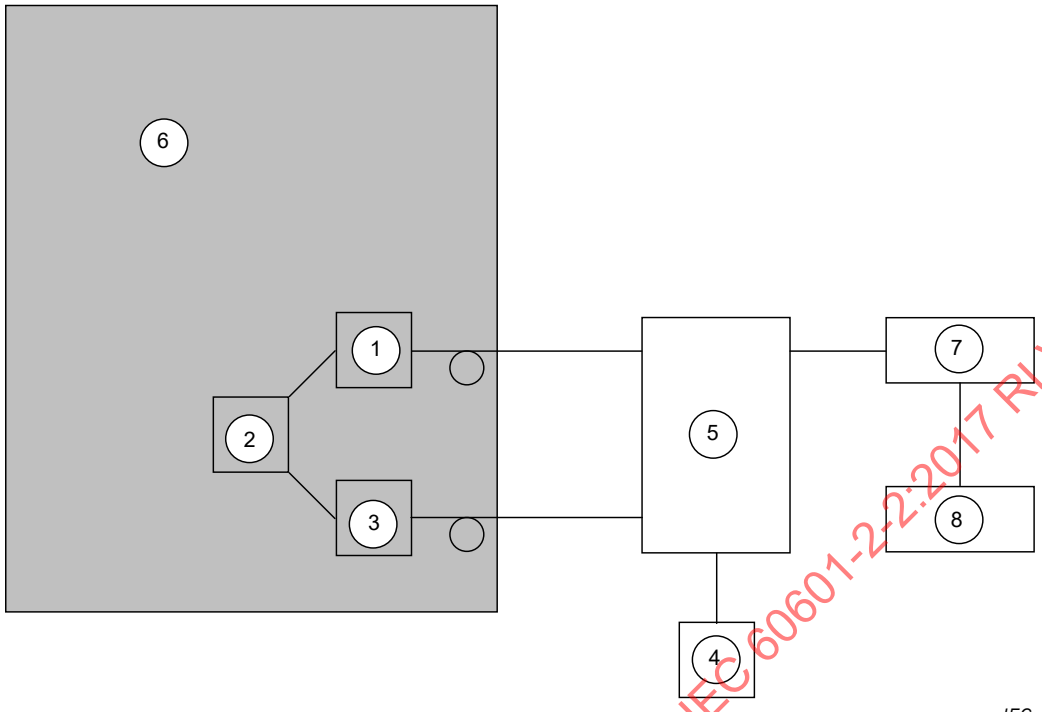
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna
8 Cable to measurement equipment

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)

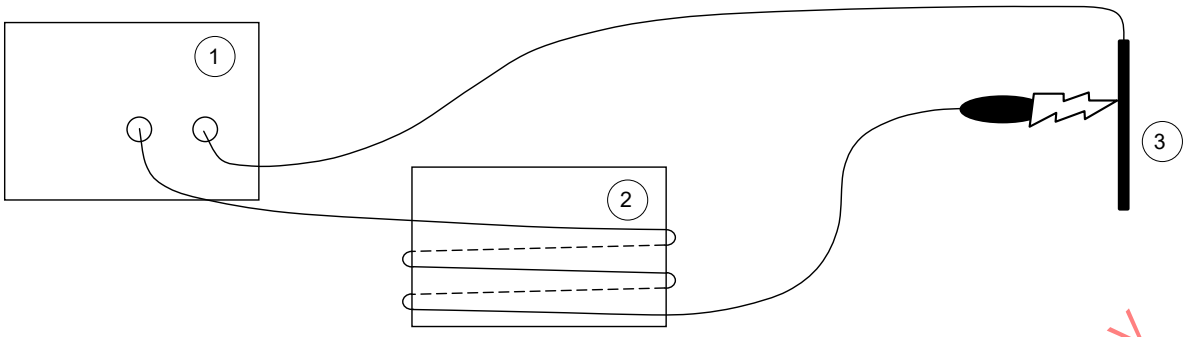
BB.4 Suggested tests

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

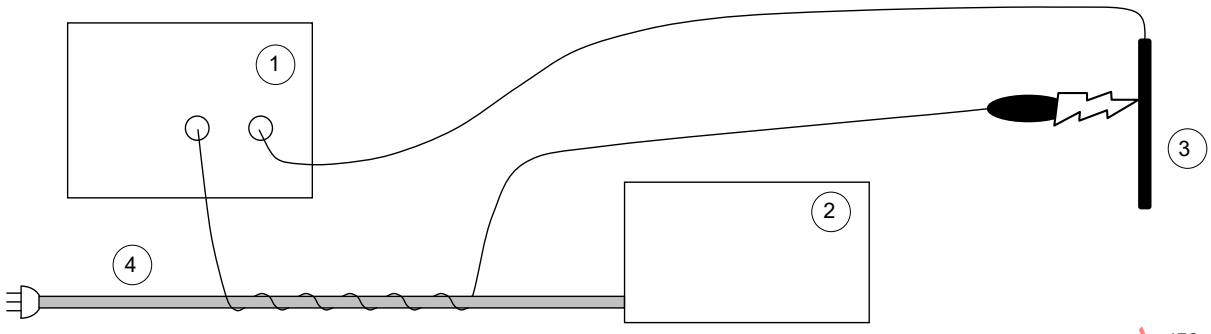
Repeat the test of BB.4.2 with the MONOPOLAR HF SURGICAL ACCESSORY short circuited to (touching) the metal plate. The HF SURGICAL EQUIPMENT should be adjusted to obtain the maximum output power for each output mode.

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.



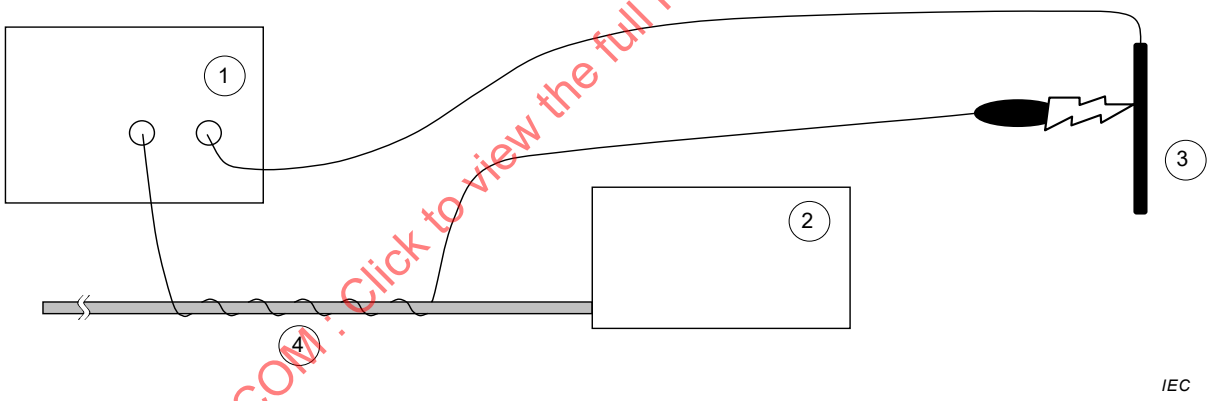
Key

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

IEC 60601-2-2

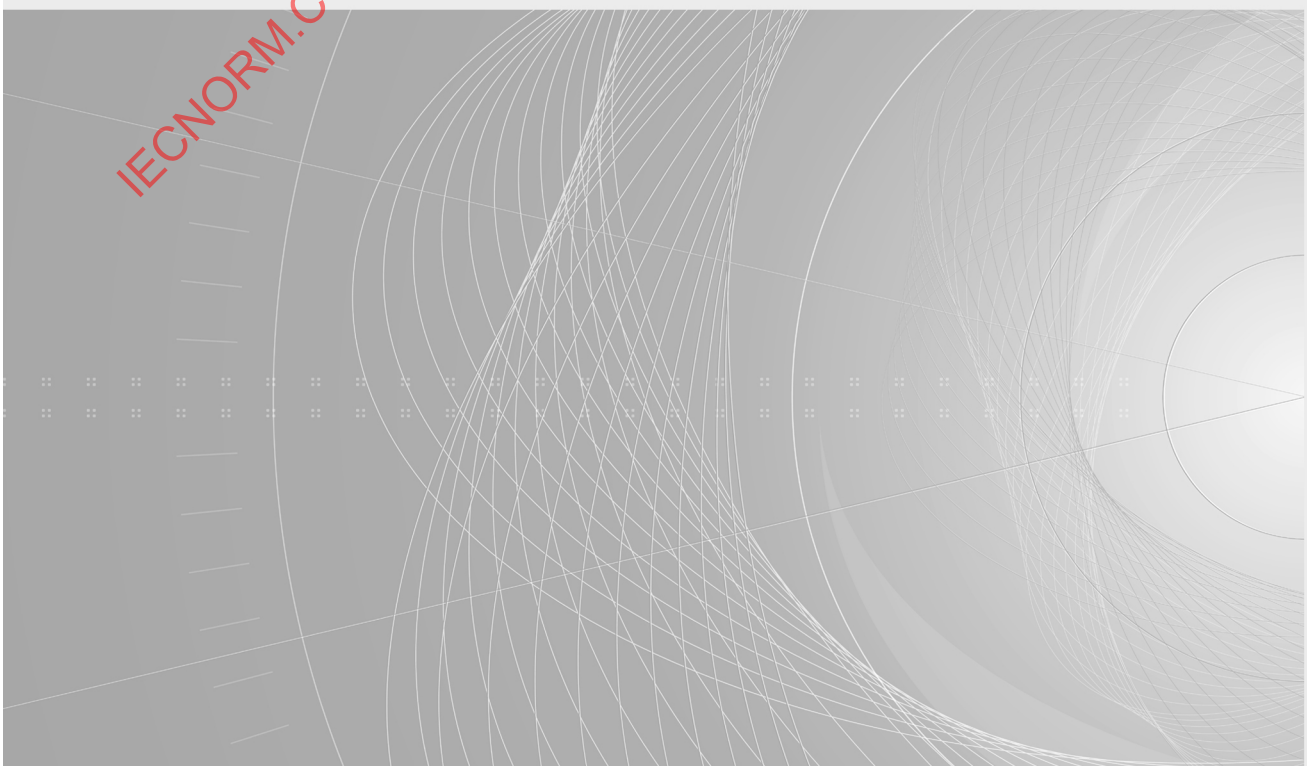
Edition 6.0 2017-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence



IEC 60601-2-2:2017-03(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-2 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This sixth edition cancels and replaces the fifth edition published in 2009. This edition constitutes a technical revision. This edition includes the following significant technical changes with respect to the previous edition:

– refinement and additions to the defined terms;
– additional separation of the requirements for HF surgical equipment and HF surgical accessories;
– a new requirement for adult neutral electrodes to be contact quality monitoring neutral electrodes;
– new requirements for devices that have or use a high current mode.

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

FDIS	Report on voting
62D/1427/FDIS	62D/1442/RVD

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

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

In this standard, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type;*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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

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

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.

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

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 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11 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 ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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

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 87.

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 60601-1-8:2006, *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*

Addition:

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

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

IEC 61000-4-6:2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

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

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)).

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 output mode and using the load which creates the greatest steady state input current. Input current is measured and compared with 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

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required, for example, a fault in the PATIENT circuit
Yellow	CUTTING mode
Blue	COAGULATION mode
Green	Ready for use
Any other colour	Meaning other than that of red, yellow, blue or green

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 instruction 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

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.

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.

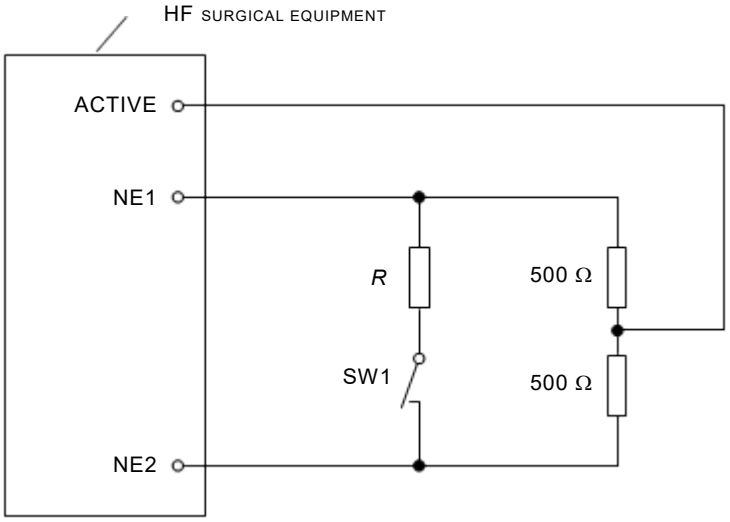
The monitoring circuit shall be supplied from a power source isolated from the MAINS PART and from earth and having a voltage not exceeding 12 V. The limitation of monitoring current for a CONTACT QUALITY MONITOR is defined in 201.8.7.3.

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.



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.

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.

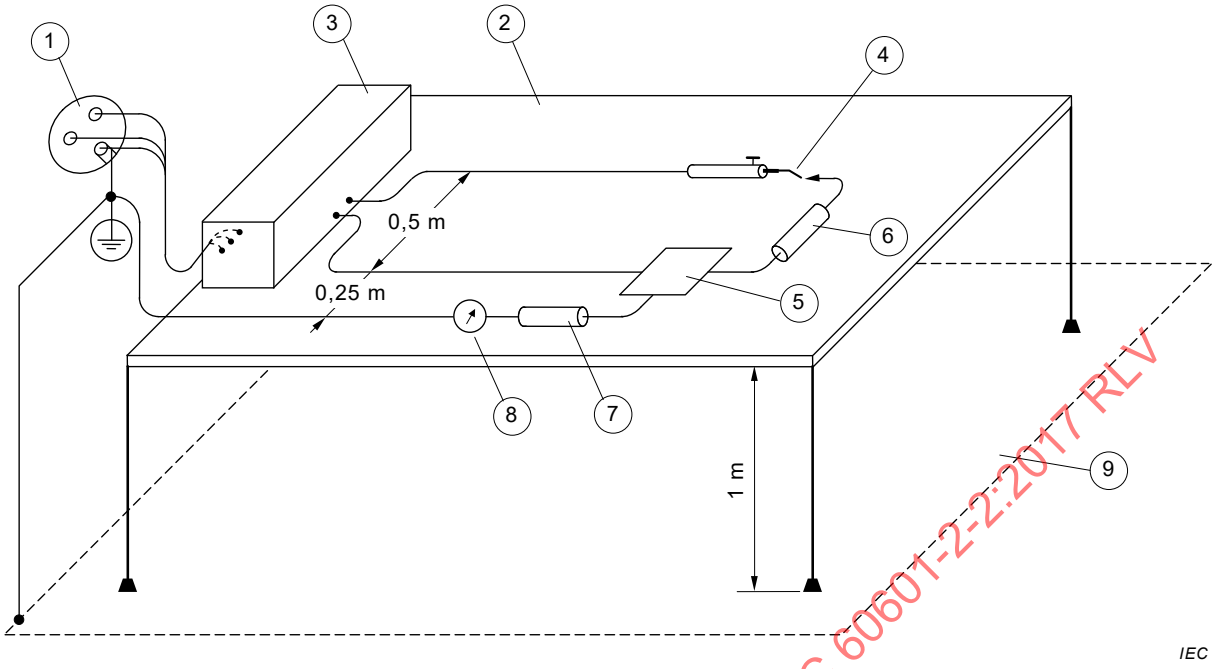
1) For MONOPOLAR EARTH REFERENCED PATIENT CIRCUITS

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.

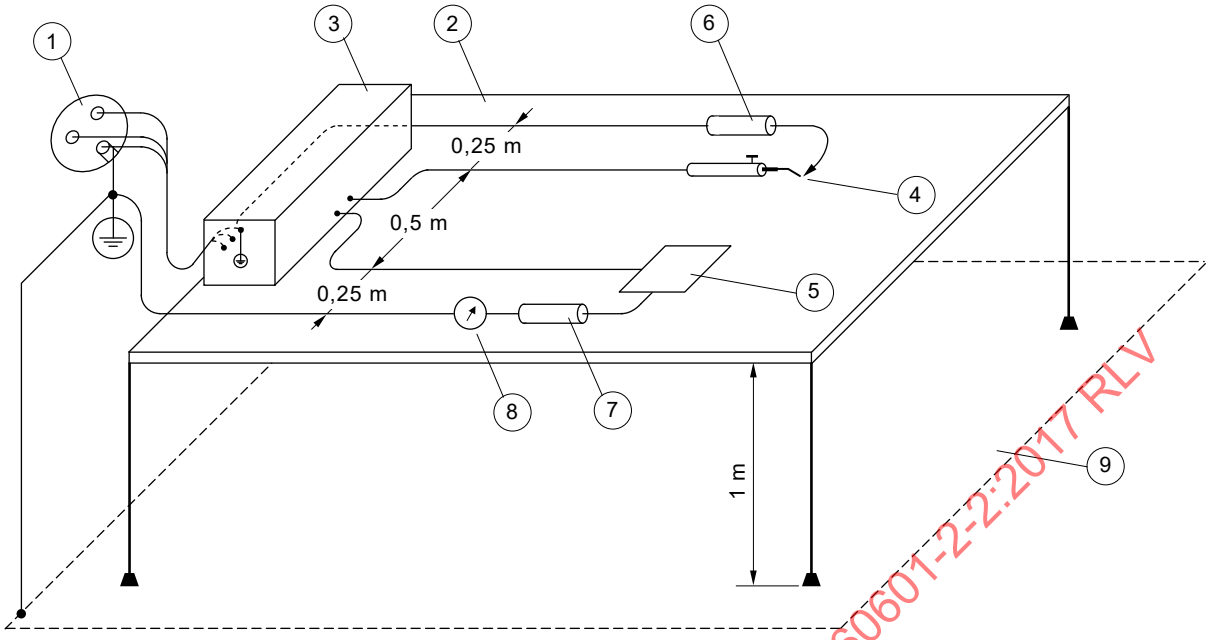


Key

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

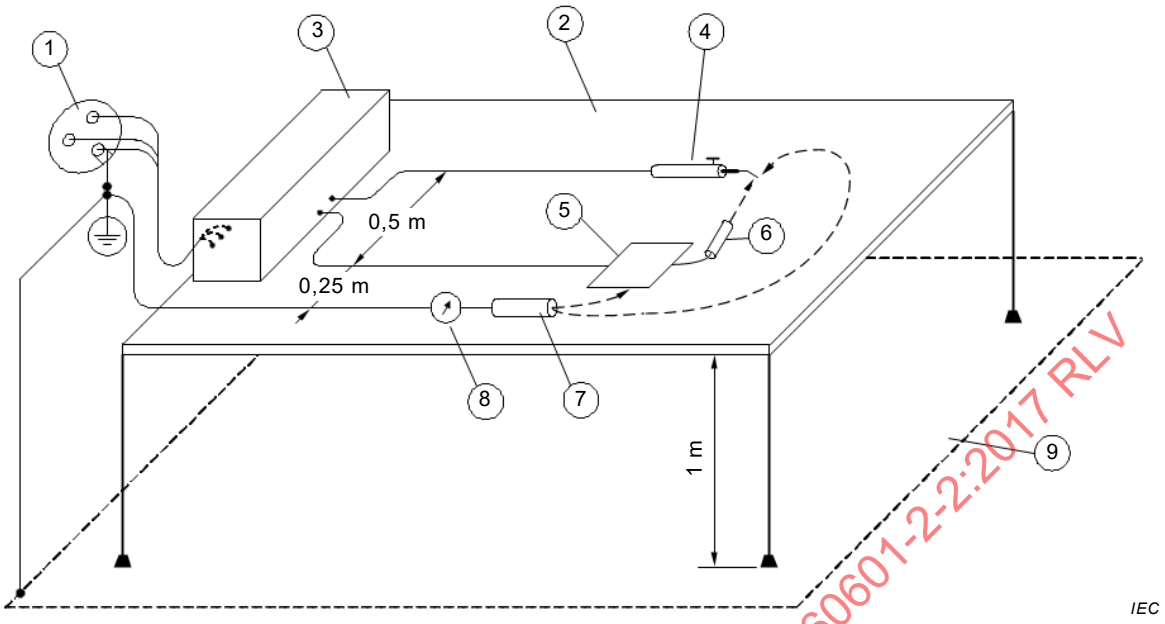
The PATIENT circuit is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing, in turn, from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106, the output being unloaded and 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

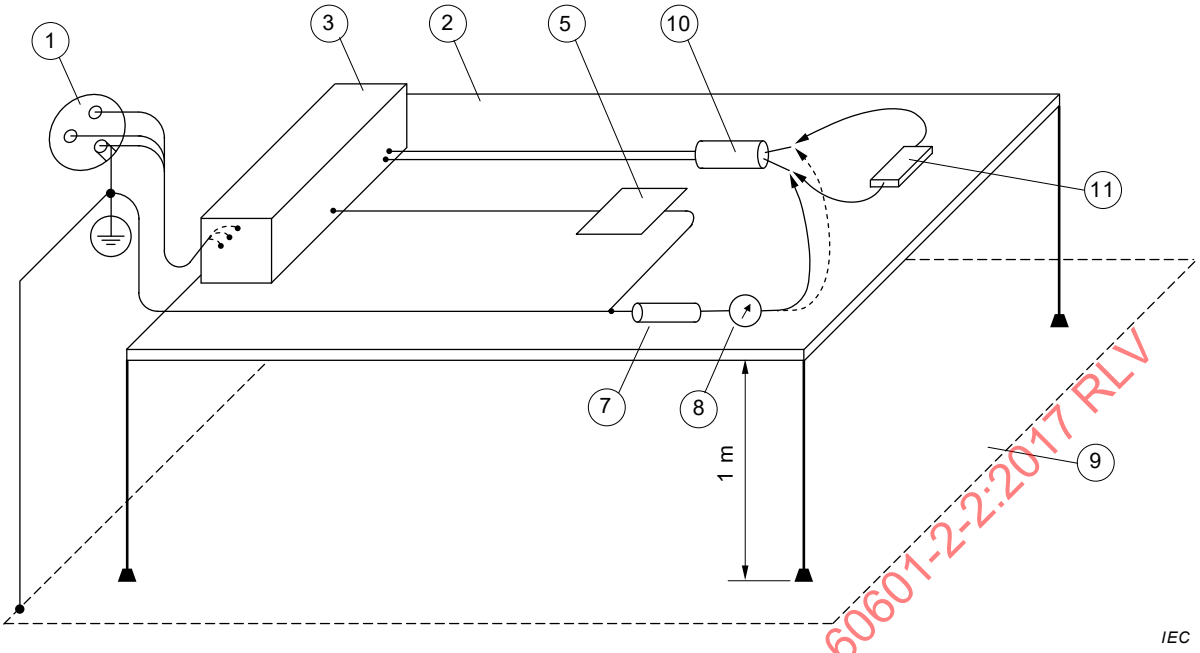
Any PATIENT circuit specifically designed for BIPOLAR application shall be isolated from earth and from other APPLIED PARTS at both high and low frequencies.

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 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.



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 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.

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:

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

where

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

For RATED ACCESSORY VOLTAGES greater 4 000 V:

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

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

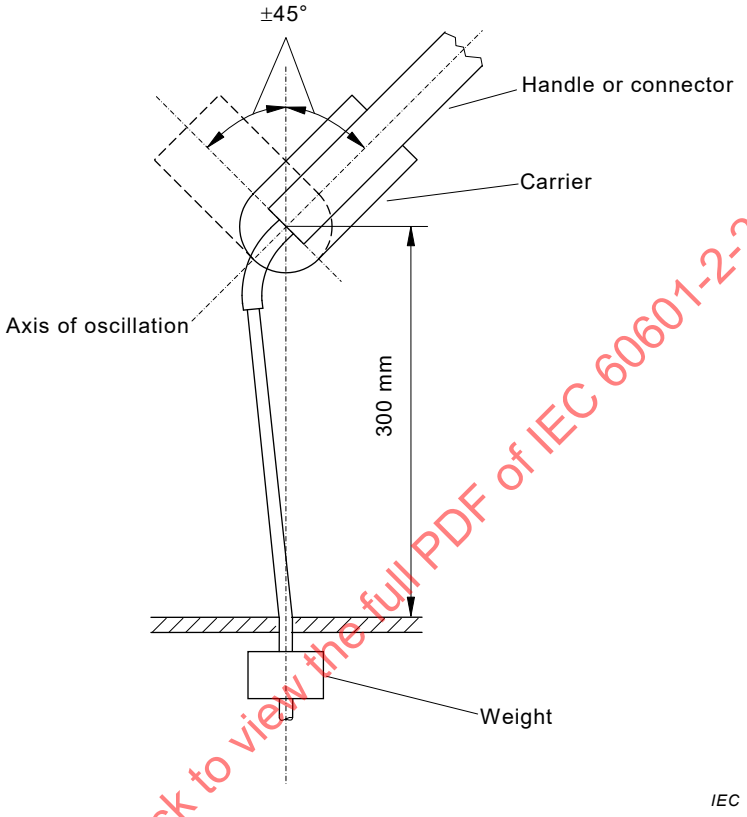


Figure 201.108 – Test apparatus for anchorages of cords of ACTIVE ACCESSORY

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.

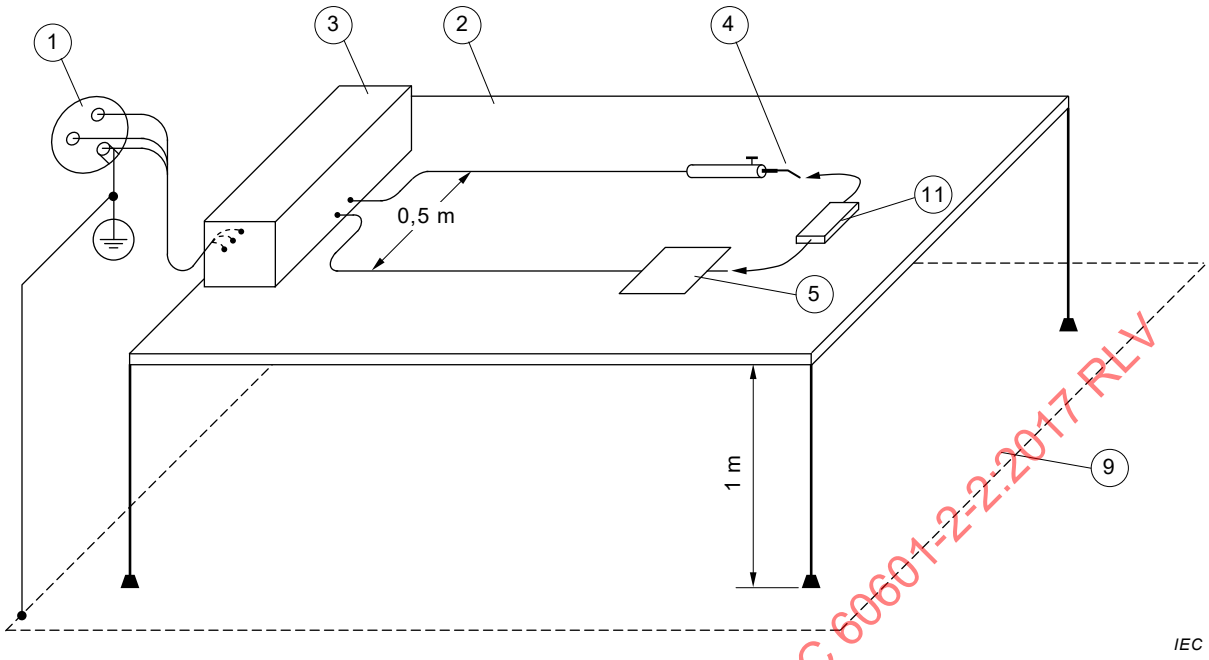
201.12.1.102 Monotonicity of output control setting

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

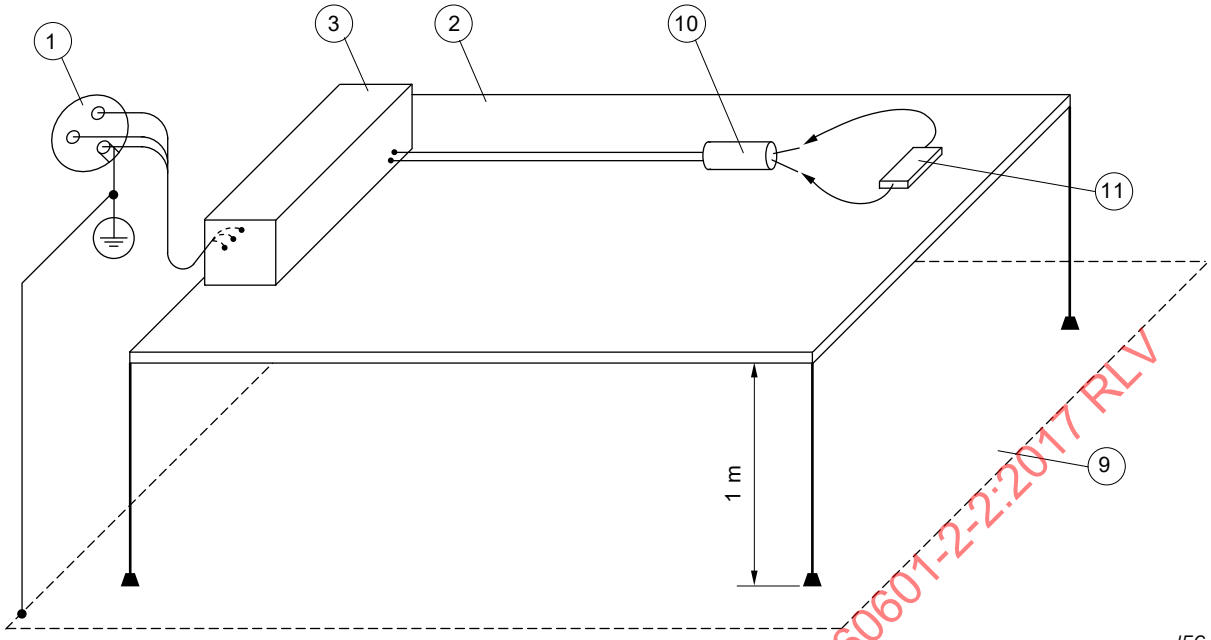
1	SUPPLY MAINS
2	Table, made of insulating material
3	HF SURGICAL EQUIPMENT
4	ACTIVE ELECTRODE
5	NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
9	Earthed conductive plane
11	Load resistance as required with HF power measuring device

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, 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.

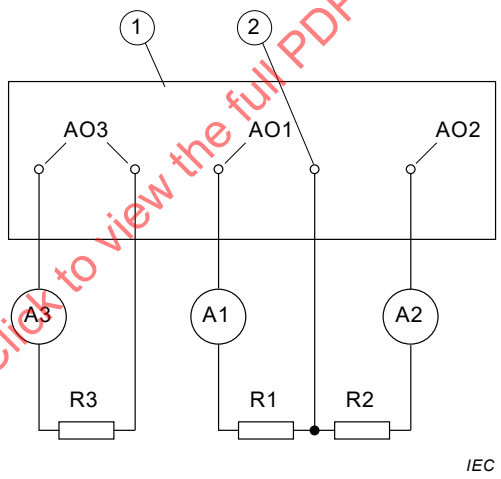
Compliance is checked by the following tests (see Figure 201.111).

For HF SURGICAL EQUIPMENT as defined in 201.12.2 c):

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 %.

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 ± 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 applies except as follows:

202.2 Normative references

Replace 5th reference “IEC 60601-2-2:2009” by “IEC 60601-2-2:2016”

202.3 Terms and definitions

In paragraph 1, replace “IEC 60601-2-2:2009” by “IEC 60601-2-2:2016”

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 60601-2-2:2016”

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 applies 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

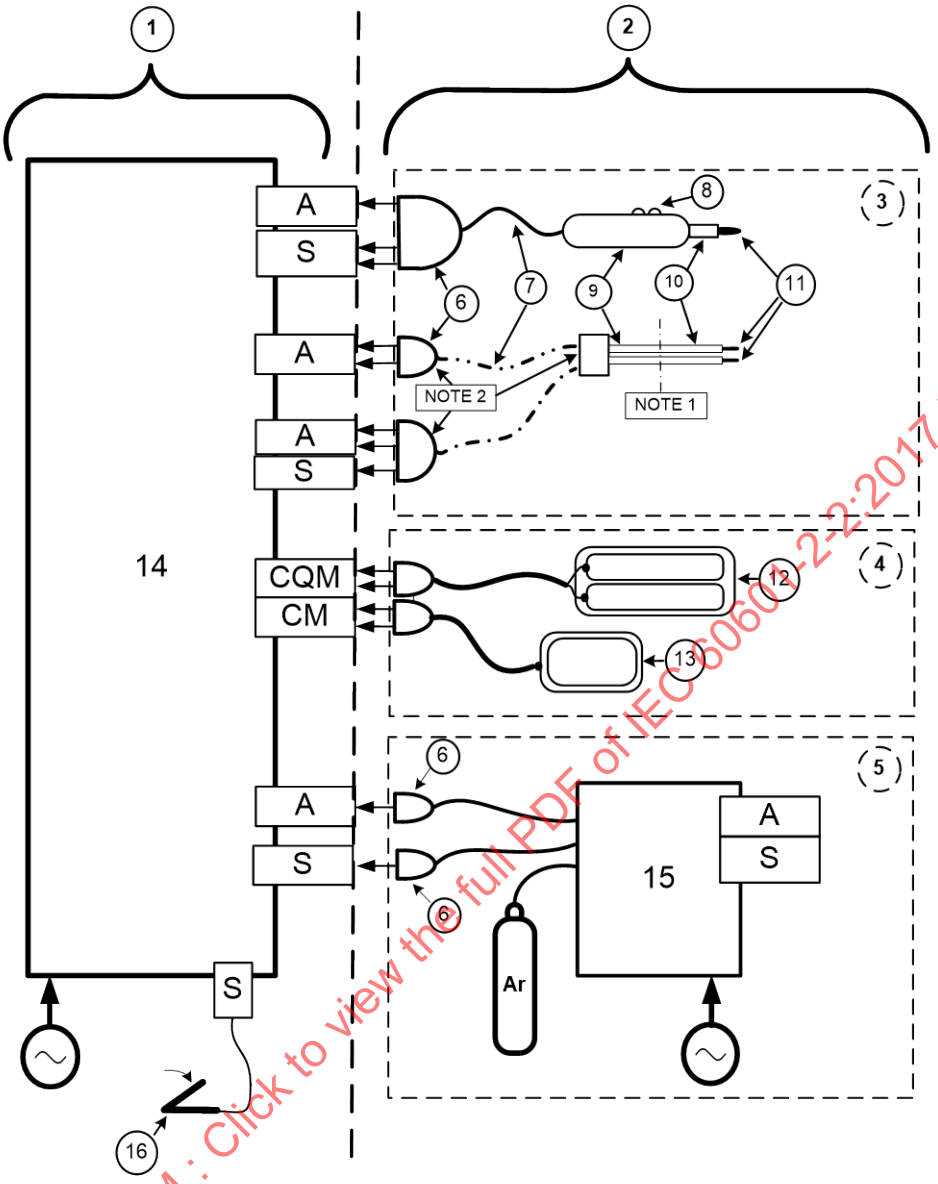
The scope does not include equipment for cautery, i.e. for medical treatment with electrically heated metal rods or wire loops. This edition provides, to the extent feasible, separate requirements and tests for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES, independent of manufacture. ASSOCIATED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

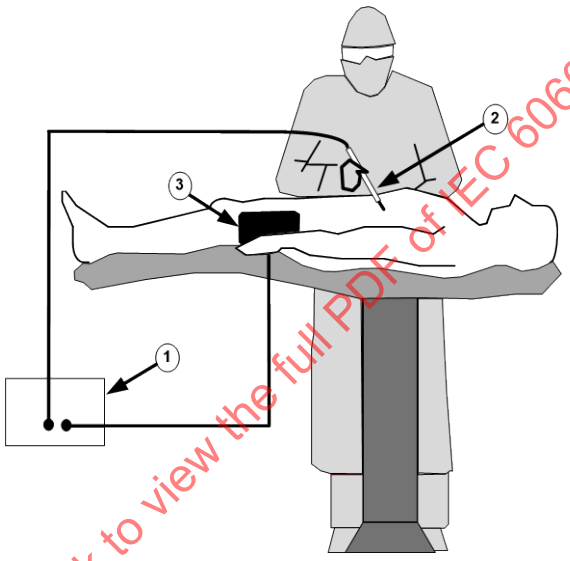
Key

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

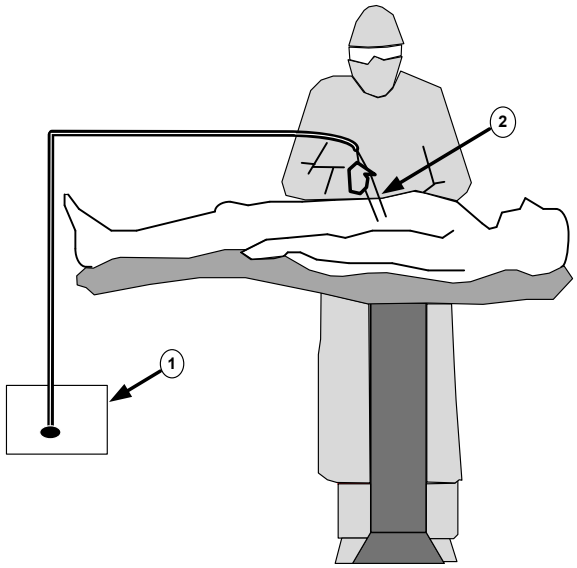


IEC

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.

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.

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.

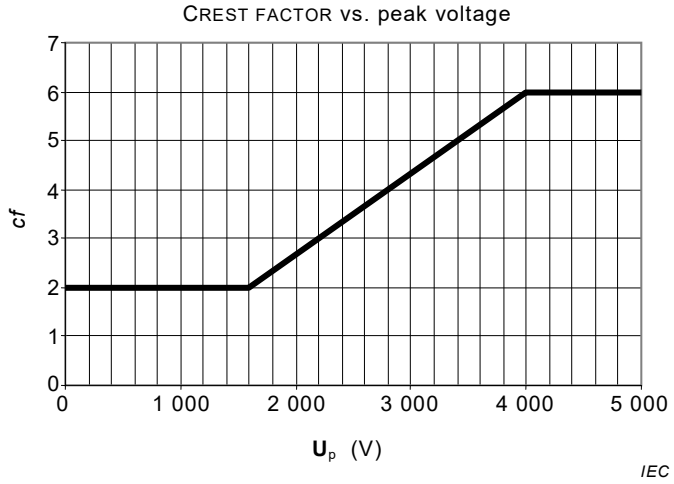


Figure AA.4 – CREST FACTOR vs. peak voltage

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 201.7.9.3.1 – 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.

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.

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2 Figures in square brackets refer to the Bibliography.

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.

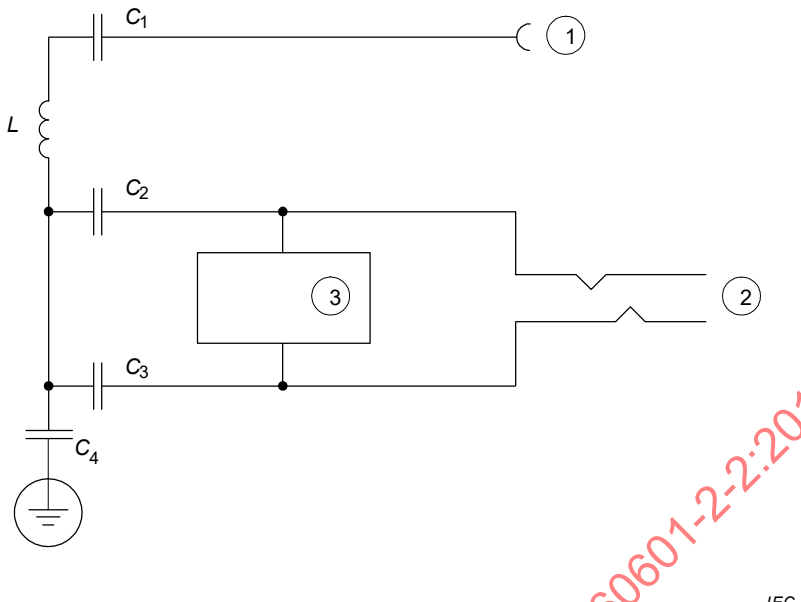
This subclause of the general standard is concerned with LEAKAGE CURRENTS which lead to electric shock, not with therapeutic currents such as are produced by HF SURGICAL EQUIPMENT. Appropriate tests for HF LEAKAGE CURRENT for HF SURGICAL EQUIPMENT with multiple PATIENT circuits are given in 201.8.7.3.101 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 has been completely redrafted 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:

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

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

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

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

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

and

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

then

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

thus

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

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

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

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 201.12.4.3.101 – Output reduction means

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

Subclause 201.12.4.4.101 – 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:

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

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:

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

This HEATING FACTOR has the significance of energy dissipated per Ω of impedance. NEs should be able to handle Θ values representative of surgical procedures. A current of 700 mA applied for 60 s yields Θ = 30 A^2s. This value is far in excess of the maximum likely current and duration for a TUR procedure. The maximum likely Θ value can be found by multiplying

the square of the largest likely current, i.e. 0,68 A from ECRI (1973) [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

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

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

A similarly conservative test criterion can be derived for NEs marked for “INFANT” use. Since TUR procedures are not performed on infants, a reasonable approach is to use the current and duration data available for general surgical procedures. These data, reported by Pearce (1981), are given in 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 of IEC 61000-4-3 and IEC 61000-4-6, the MANUFACTURER will need to specify how compliance to the standard is checked. This includes precautions needed to ensure the DUTY CYCLE of the generator is not exceeded as well as how perturbations in the output power are detected.

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

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.

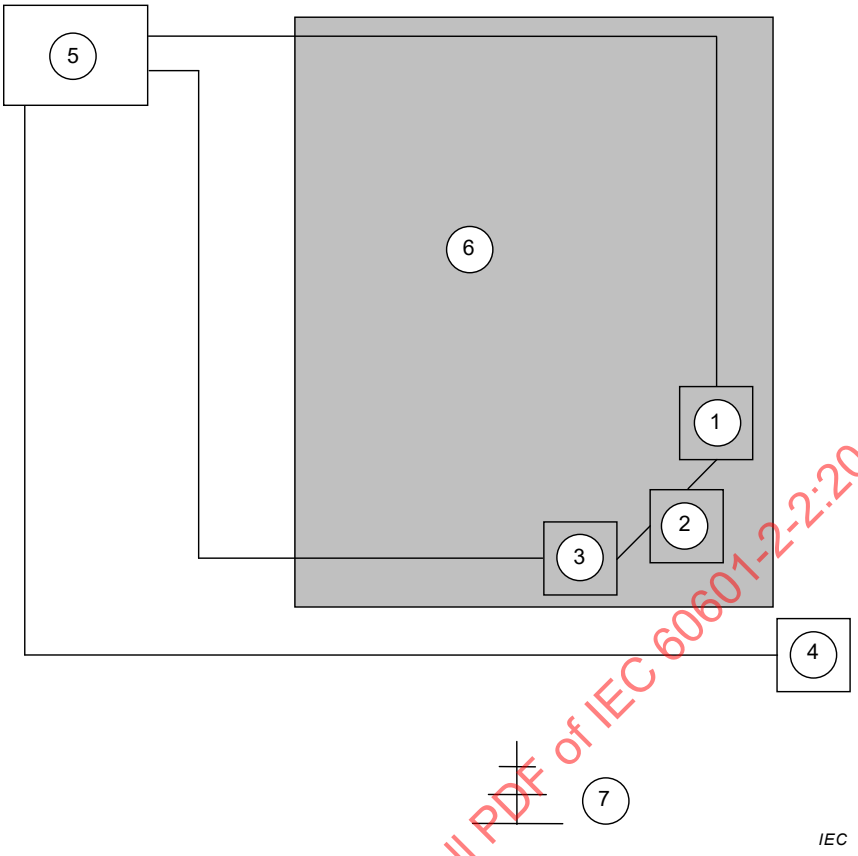
BB.3.3 Measurement techniques

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

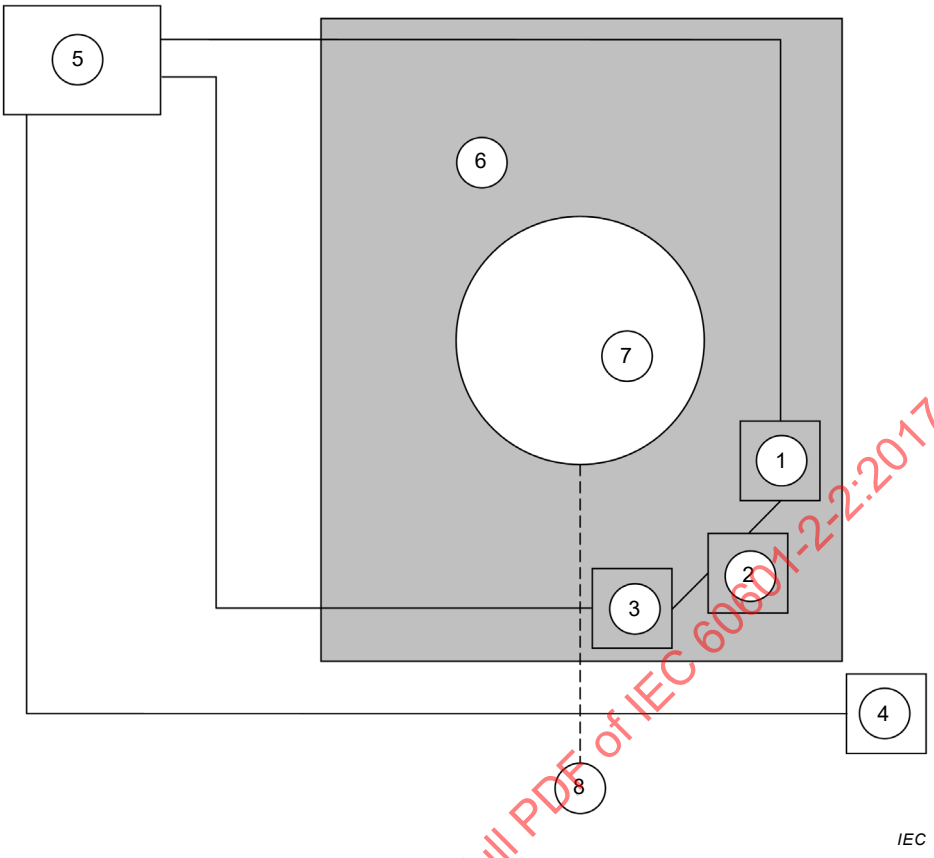
1 ACTIVE ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna – 10 m distance, vertical polarity

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

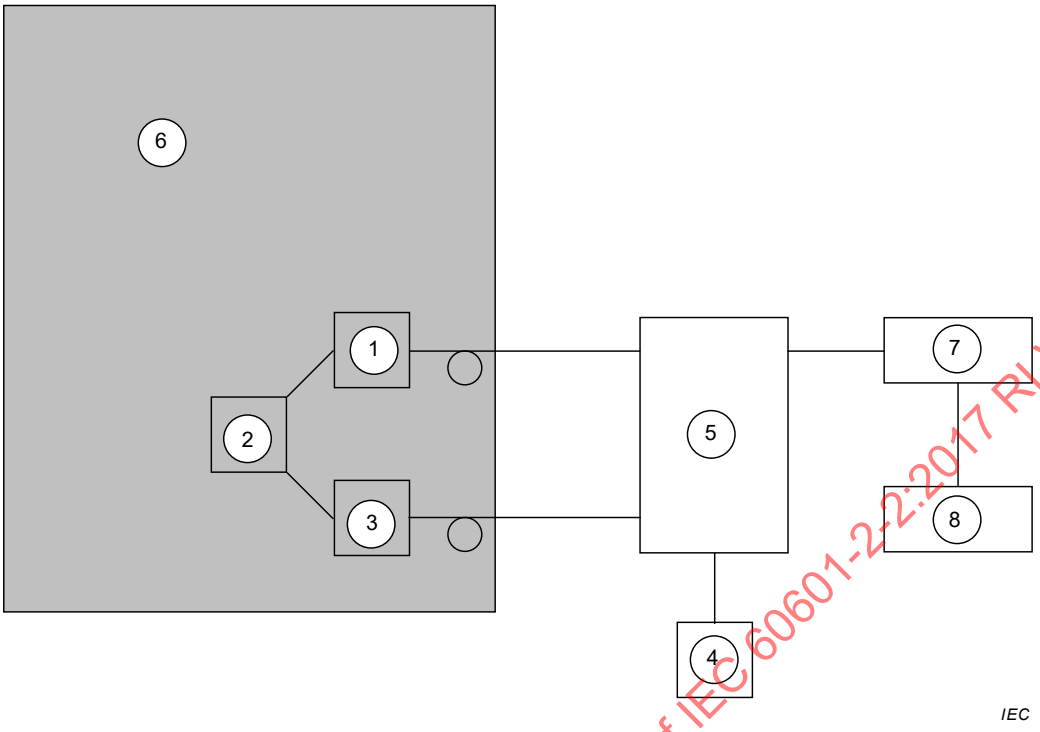
1 ACCESSORY
2 Load
3 NE or saline soaked sponge
4 Footswitch
5 HF SURGICAL EQUIPMENT
6 Non-conductive table
7 Antenna
8 Cable to measurement equipment

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)

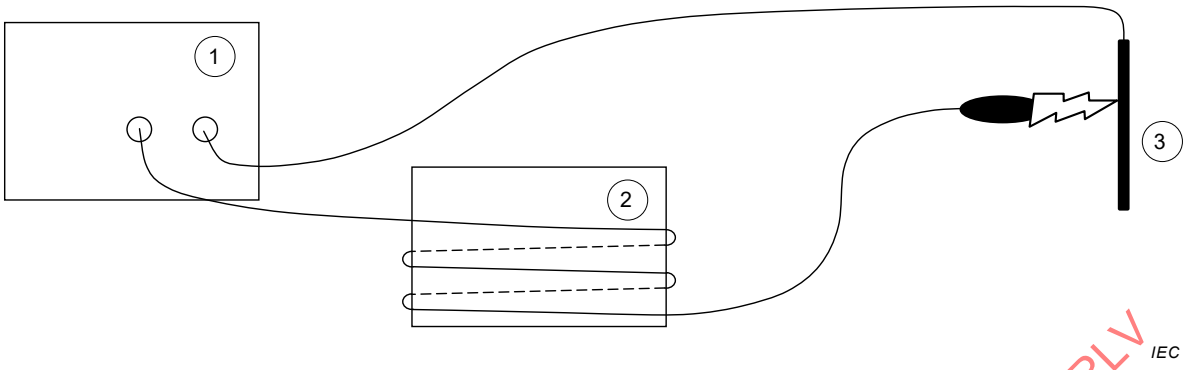
BB.4 Suggested tests

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

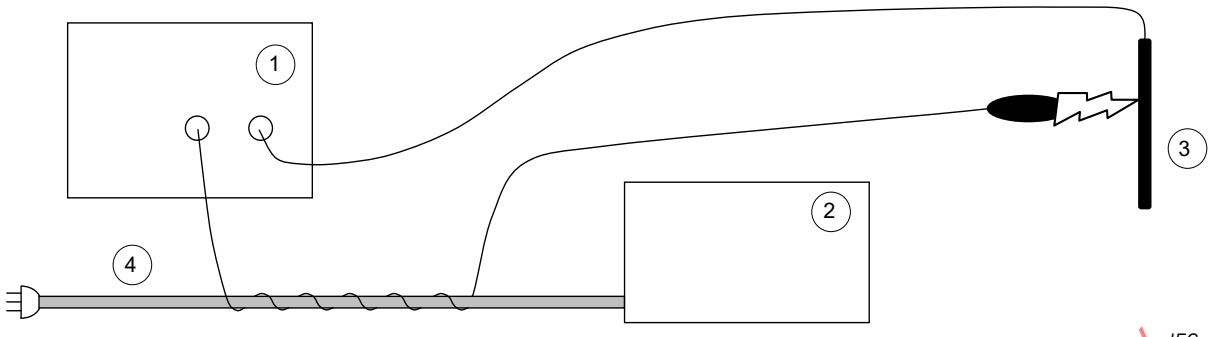
Repeat the test of BB.4.2 with the MONOPOLAR HF SURGICAL ACCESSORY short circuited to (touching) the metal plate. The HF SURGICAL EQUIPMENT should be adjusted to obtain the maximum output power for each output mode.

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.



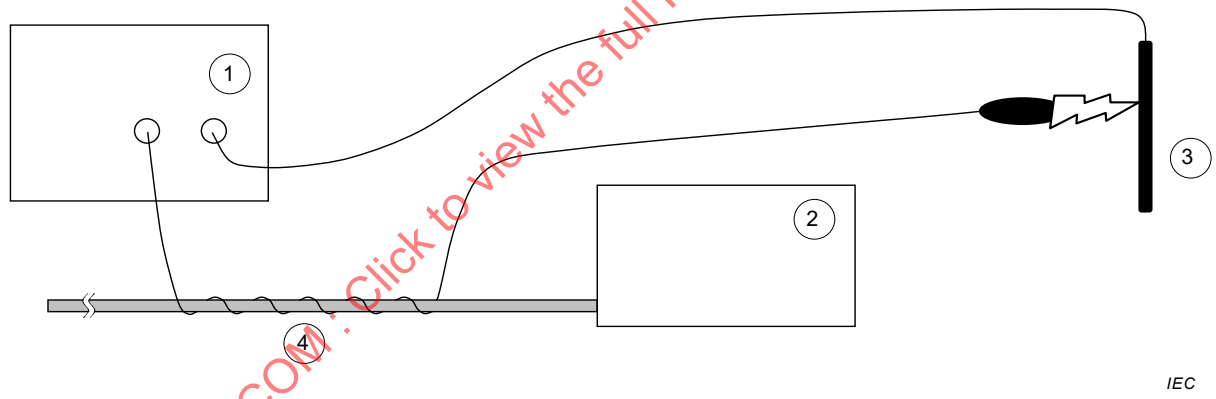
Key

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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[18] IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

Index of defined terms used in this particular standard

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

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9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme internationale IEC 60601-2-2 a été établie par le sous-comité 62D: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette sixième édition annule et remplace la cinquième édition parue en 2009. Cette édition constitue une révision technique. Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

– des précisions et des ajouts aux termes définis;

– une séparation supplémentaire des exigences relatives aux appareils d'électrochirurgie à courant haute fréquence (HF) et aux accessoires d'électrochirurgie à courant haute fréquence (HF);
– une nouvelle exigence concernant les électrodes neutres adultes devant servir d'électrodes neutres de surveillance de la qualité du contact;
– de nouvelles exigences relatives aux appareils ayant ou utilisant un mode de courant élevé.

Le texte de cette norme particulière est issu des documents suivants:

FDIS	Rapport de vote
62D/1427/FDIS	62D/1442/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette norme particulière.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;
– *modalités d'essais*: *caractères italiques;*
– indications de nature informative figurant hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure de la présente norme, le terme

– «article» désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
– «paragraphe» désigne une subdivision numérotée d'un article (par exemple 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans la présente norme, les références à des articles sont précédées du mot «Article» suivi du numéro de l'article concerné. Dans la présente norme, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans la présente norme, la conjonction «ou» est utilisée avec la valeur d'un «ou inclusif». Ainsi, un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins de la présente norme:

– «devoir» mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme;
– «il convient» signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité à la présente norme;
– «pouvoir» mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un titre d'alinéa ou de tableau, il indique l'existence d'un guide ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

INTRODUCTION

Les exigences minimales de sécurité spécifiées dans la présente norme particulière sont établies comme assurant un degré pratique de sécurité dans le fonctionnement des appareils d'électrochirurgie à courant HAUTE FREQUENCE.

La présente norme particulière modifie et complète l'IEC 60601-1:2005 et son Amendement 1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*, appelée «norme générale» dans la suite du texte (voir 201.1.4).

Les exigences sont suivies de spécifications relatives aux essais correspondants.

Une section «Guide particulier et justifications» comprenant, le cas échéant, des notes explicatives concernant les exigences les plus importantes, figure en Annexe AA.

Les articles ou paragraphes comportant des notes explicatives en Annexe AA sont marqués d'un astérisque (*).

Il est estimé que la connaissance des raisons qui ont conduit à énoncer ces exigences facilitera non seulement l'application correcte de la norme, mais accélèrera en temps utile toute révision rendue nécessaire par suite de modifications dans la pratique clinique ou d'évolutions technologiques. Cependant, cette annexe ne fait pas partie intégrante des exigences du présent document.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS D'ELECTROCHIRURGIE HF et des ACCESSOIRES D'ELECTROCHIRURGIE HF définis en 201.3.224 et 201.3.223.

Les APPAREILS D'ELECTROCHIRURGIE HF dont la PUISSANCE DE SORTIE ASSIGNEE est inférieure ou égale à 50 W (destinés, par exemple, à la micro COAGULATION, à l'ophtalmologie ou à l'usage dentaire) sont exemptés de certaines exigences de la présente norme particulière. Ces exemptions sont indiquées dans les exigences correspondantes.

201.1.2 Objet

Remplacement:

La présente norme particulière a pour objet d'établir des exigences particulières relatives à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS D'ELECTROCHIRURGIE HF et des ACCESSOIRES D'ELECTROCHIRURGIE HF tels qu'ils sont définis en 201.3.224 et 201.3.223.

201.1.3 Normes collatérales

Addition:

La présente norme particulière se réfère aux normes collatérales applicables spécifiées à l'Article 2 de la norme générale et en 201.2 de la présente norme particulière.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-8:2006 s'appliquent telles que modifiées respectivement par l'Article 202 et l'Article 208. L'IEC 60601-1-3, l'IEC 60601-1-10 et l'IEC 60601-1-11 ne sont pas applicables. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles qu'elles sont publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction

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[1] La norme générale est l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*.

de ce qui est approprié à l'APPAREIL EM particulier considéré. De plus, ces normes particulières peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, l'IEC 60601-1 est désignée dans la présente norme particulière par le terme «norme générale». Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe «201» (par exemple, 201.1 dans la présente norme aborde le contenu de l'Article 1 de la norme générale) ou de la norme collatérale applicable avec le préfixe «20x», où x est (sont) le(s) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont spécifiées par l'utilisation des termes suivants:

«*Remplacement*» signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

«*Addition*» signifie que le texte de la présente norme particulière est complémentaire aux exigences de la norme générale ou de la norme collatérale applicable.

«*Amendement*» signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière.

Les paragraphes, figures ou tableaux qui viennent s'ajouter à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, comme les définitions dans la norme générale sont numérotées de 3.1 à 3.147, les définitions complémentaires dans la présente norme sont numérotées à partir de 201.3.201. Les annexes complémentaires sont référencées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes, les figures ou tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où «x» est le numéro de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression «le présent document» est utilisée pour faire référence à la norme générale, à toute norme collatérale applicable et à la présente norme particulière, prises comme un tout.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification. Lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la bibliographie commençant à la page 183.

L'Article 2 de la norme générale s'applique avec les exceptions suivantes:

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

IEC 60601-1-8:2006, *Appareils électromédicaux – Partie 1-8: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux*

Addition:

CISPR 11:2015, *Appareils industriels, scientifiques et médicaux – Caractéristiques de perturbations radioélectriques – Limites et méthodes de mesure*

IEC 61000-4-3:2006, *Compatibilité électromagnétique (CEM) – Partie 4-3, Techniques d'essai et de mesure – Essai d'immunité aux champs électromagnétiques rayonnés aux fréquences radioélectriques*

IEC 61000-4-6:2013, *Compatibilité électromagnétique (CEM) – Partie 4-6: Techniques d'essai et de mesure – Immunité aux perturbations conduites, induites par les champs radioélectriques*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC 60601-1 ainsi que les suivants, s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

Remplacer la NOTE 1 par la suivante:

NOTE 1 Les termes «tension» et «courant» utilisés dans le présent document désignent, sauf indication contraire, des valeurs efficaces des tensions ou courants alternatifs, continus ou complexes moyennés sur 1 s.

Addition:

201.3.201
ACCESSOIRE ACTIF
ACCESSOIRE D'ELECTROCHIRURGIE HF destiné à être manipulé par l'OPERATEUR pour produire un effet par conduction électrique à côté de l'ELECTRODE ACTIVE au niveau du site prévu sur le PATIENT, comprenant généralement un PORTE-ELECTRODES ACTIVES, un CABLE ACTIF, un CONNECTEUR ACTIF et une ELECTRODE ACTIVE

201.3.202
CONNECTEUR ACTIF
partie d'un ACCESSOIRE ACTIF destinée au raccordement à une BORNE DE SORTIE ACTIVE qui peut comporter des bornes supplémentaires pour la connexion d'un INTERRUPTEUR MANUEL à un CAPTEUR A INTERRUPTEUR

201.3.203
ELECTRODE ACTIVE
partie d'un ACCESSOIRE ACTIF qui va du PORTE-ELECTRODES ACTIVES au site chirurgical et qui est destinée à faire passer du courant HF dans du tissu biologique

201.3.204
ISOLATION DE L'ELECTRODE ACTIVE
matériel d'isolation électrique FIXE à une partie d'une ELECTRODE ACTIVE destiné à prévenir d'éventuelles blessures au tissu du PATIENT ou à l'OPERATEUR

201.3.205
PORTE-ELECTRODES ACTIVES
partie d'un ACCESSOIRE ACTIF destinée à être tenue par l'OPERATEUR

201.3.206
BORNE DE SORTIE ACTIVE
partie d'un APPAREIL D'ELECTROCHIRURGIE HF ou de l'APPAREIL ASSOCIE destinée à être connectée à un ACCESSOIRE ACTIF et à lui fournir du courant HF

Note 1 à l'article: Un CONNECTEUR ACTIF est un connecteur qui se branche dans une BORNE DE SORTIE ACTIVE.

Note 2 à l'article: Voir la Figure AA.1.

201.3.207
***APPAREIL ASSOCIE**
APPAREIL ELECTROMEDICAL autre que les APPAREILS D'ELECTROCHIRURGIE HF qui peut être électriquement raccordé au circuit PATIENT

201.3.208
***BIPOLAIRE**
méthode d'application d'un courant HF à un PATIENT entre deux ELECTRODES ACTIVES ou plus sans recourir à une ELECTRODE NEUTRE raccordée séparément (ou recourir à l'utilisation de la capacité par rapport à la terre du corps du PATIENT) qui implique un effet dans le tissu biologique se trouvant près d'une ou plusieurs ELECTRODES ACTIVES

Note 1 à l'article: La méthode BIPOLAIRE comprend des appareils qui alimentent des paires d'ELECTRODES ACTIVES ainsi que des appareils qui alimentent des groupes d'ELECTRODES ACTIVES lorsque la source et le retour de courant HF peuvent avoir un nombre différent d'électrodes.

Note 2 à l'article: Voir la Figure AA.1 et la Figure AA.3.

201.3.209
ACCESSOIRE BIPOLAIRE
ACCESSOIRE ACTIF comprenant deux ou plus de deux ELECTRODES ACTIVES placées sur le même support et fabriquées de telle sorte que, lorsqu'elles sont mises sous tension, le courant HF passe principalement entre elles

201.3.210
COAGULATION
utilisation d'un courant HF afin d'induire un effet thermique, par exemple pour contrôler ou empêcher les saignements, induire une destruction de tissu biologique ou induire une réduction de tissu biologique

Note 1 à l'article: La COAGULATION peut prendre la forme d'une COAGULATION par contact ou sans contact.

Note 2 à l'article: La FULGURATION, la dessiccation, la COAGULATION par étincelage, la COAGULATION forcée, la COAGULATION «swift», la COAGULATION «soft» et la COAGULATION au faisceau argon (plasma) sont tous des types de COAGULATION.

201.3.211
DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT
CQM
circuit dans un APPAREIL D'ELECTROCHIRURGIE HF ou un APPAREIL ASSOCIE destiné à être raccordé à une ELECTRODE NEUTRE DE SURVEILLANCE et qui déclenche une alarme si le contact de l'ELECTRODE NEUTRE avec le PATIENT devient insuffisant

Note 1 à l'article: Un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT n'est fonctionnel que lorsqu'il est utilisé avec une ELECTRODE NEUTRE DE SURVEILLANCE.

Note 2 à l'article: L'abréviation «CQM» est dérivée du terme anglais développé correspondant «contact quality monitor».

201.3.212
DISPOSITIF DE SURVEILLANCE DE CONTINUITE
circuit d'un APPAREIL D'ELECTROCHIRURGIE HF ou d'un APPAREIL ASSOCIE destiné à être raccordé à une ELECTRODE NEUTRE et générant une alarme en cas de discontinuité électrique dans le câble de l'ELECTRODE NEUTRE ou ses connexions

201.3.213
***FACTEUR DE CRETE**
valeur adimensionnelle égale à la tension de crête de sortie divisée par la tension efficace, telle que mesurée à la sortie de l'APPAREIL D'ELECTROCHIRURGIE HF en circuit ouvert

Note 1 à l'article: L'Annexe AA donne des informations spécifiques concernant la manière correcte d'effectuer les mesurages nécessaires au calcul de cette valeur.

201.3.214
***INCISION**
division des tissus biologiques due au passage d'un COURANT A HAUTE FREQUENCE de forte densité dans la (les) ELECTRODES ACTIVES

201.3.215
***CIRCUIT PATIENT REFERENCE A LA TERRE**
circuit PATIENT qui comprend des composants, tels que des condensateurs, destinés à fournir aux courants HF un chemin à faible impédance vers la terre

201.3.216
INTERRUPTEUR MANUEL
dispositif généralement compris avec un ACCESSOIRE ACTIF et qui, lorsqu'il est manipulé par l'OPERATEUR, permet de générer la sortie HF et, lorsqu'il est libéré, désactive la sortie HF

Note 1 à l'article: Les exigences applicables à des interrupteurs similaires destinés à des fonctions autres que l'activation de la sortie HF sont actuellement à l'étude.

201.3.217
***FULGURATION**
utilisation de courant HF afin de produire un effet sur une surface de tissu par le biais d'étincelles électriques produites par une ELECTRODE ACTIVE qui n'est pas en contact physique avec le tissu

201.3.218
***FACTEUR D'ECHAUFFEMENT**
valeur égale à $I^2 \times t$ où I est le courant MONOPOLAIRE en ampères et t est la durée du flux de courant en s

Note 1 à l'article: Le FACTEUR D'ECHAUFFEMENT est exprimé en A^2s (ampères carrés secondes).

Note 2 à l'article: Pour de plus amples informations, voir 201.15.101.5 à l'Annexe AA.

201.3.219
***MODE DE COURANT ELEVE**
mode de sortie MONOPOLAIRE dont l'UTILISATION PREVUE (COURANT MAXIMAL DE SORTIE et CYCLE D'UTILISATION maximal) donne lieu à un FACTEUR D'ECHAUFFEMENT supérieur à 30 A^2s au cours d'une période quelconque de 60 s

201.3.220
***HAUTE FREQUENCE**
HF
fréquences inférieures à 5 MHz et généralement supérieures à 200 kHz

201.3.221
CIRCUIT PATIENT ISOLE HF
CIRCUIT PATIENT HF ne comportant aucun composant destiné à fournir aux courants HF un chemin de faible impédance vers la terre

201.3.222
CIRCUIT PATIENT HF
tout circuit électrique contenant une ou plusieurs CONNEXIONS PATIENT, y compris toutes les parties conductrices des circuits de l'APPAREIL D'ELECTROCHIRURGIE HF et de l'APPAREIL ASSOCIE par lesquels le courant HF est destiné à passer entre l'APPAREIL EM et le PATIENT en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT

201.3.223
ACCESSOIRE D'ELECTROCHIRURGIE HF
ACCESSOIRE destiné à conduire, compléter ou surveiller l'énergie HF appliquée au PATIENT par l'APPAREIL D'ELECTROCHIRURGIE HF

Note 1 à l'article: Les ACCESSOIRES D'ELECTROCHIRURGIE HF comprennent les ACCESSOIRES ACTIFS, y compris les câbles et les connecteurs de raccordement aux APPAREILS D'ELECTROCHIRURGIE HF et aux ELECTRODES NEUTRES ainsi que les autres APPAREILS ASSOCIES destinés à être connectés au circuit PATIENT d'électrochirurgie HF. Voir la Figure AA.1.

Note 2 à l'article: Les ACCESSOIRES utilisés avec des APPAREILS D'ELECTROCHIRURGIE HF ne sont pas tous des ACCESSOIRES D'ELECTROCHIRURGIE HF.

201.3.224
APPAREIL D'ELECTROCHIRURGIE HF
APPAREIL ELECTROMEDICAL qui génère des courants à HAUTE FREQUENCE destiné à des tâches chirurgicales, telles que l'INCISION ou la COAGULATION de tissus biologiques, au moyen de ces courants à HAUTE FREQUENCE

Note 1 à l'article: Les APPAREILS D'ELECTROCHIRURGIE HF sont également appelés appareils de diathermie électrique, appareils d'électrochirurgie, générateurs électrochirurgicaux, générateurs RF ou générateurs HF.

Note 2 à l'article: Une pédale est un exemple d'ACCESSOIRE associé qui fait partie de l'APPAREIL D'ELECTROCHIRURGIE HF. Voir la Figure AA.1.

201.3.225
***MODE ELECTROCHIRURGICAL HF**
une des caractéristiques de sortie HF sélectionnable par l'OPERATEUR et destinée à fournir un effet spécifique au niveau d'un ACCESSOIRE ACTIF connecté, tel qu'une INCISION, une COAGULATION et des actions similaires

Note 1 à l'article: Chaque MODE ELECTROCHIRURGICAL HF disponible peut être fourni par une commande de sortie réglable par l'OPERATEUR pour obtenir l'intensité ou la vitesse souhaitée de l'effet.

201.3.226
***COURANT MAXIMAL DE SORTIE**
pour chaque MODE ELECTROCHIRURGICAL HF disponible, l'amplitude du COURANT MAXIMAL DE SORTIE HF possible pendant l'UTILISATION PREVUE

201.3.227
***TENSION MAXIMALE DE SORTIE**
pour chaque MODE ELECTROCHIRURGICAL HF disponible, l'amplitude de la TENSION MAXIMALE DE SORTIE HF de crête possible apparaissant entre les connexions du circuit PATIENT

201.3.228
***ELECTRODE NEUTRE DE SURVEILLANCE**
ELECTRODE NEUTRE destinée à être utilisée avec un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT

Note 1 à l'article: Les ELECTRODES NEUTRES DE SURVEILLANCE sont également appelées plaques double zone, doubles plaques, électrodes à double feuille ou électrodes du DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT.

201.3.229
***MONOPOLAIRE**
méthode d'application d'un courant de sortie HF à un PATIENT par l'intermédiaire d'une ELECTRODE ACTIVE et de retour dudit courant par une ELECTRODE NEUTRE connectée séparément (ou par la capacité du corps du PATIENT par rapport à la terre) dans laquelle un effet est prévu uniquement dans le tissu au niveau ou à proximité de l'ELECTRODE ACTIVE

Note 1 à l'article: Voir les Figures AA.1 et AA.2.

201.3.230
ELECTRODE NEUTRE
NE
électrode destinée à fournir un chemin de retour électrique pour l'application MONOPOLAIRE de courant à HAUTE FREQUENCE d'une densité suffisamment faible dans le tissu du PATIENT pour éviter certains effets tels qu'un échauffement excessif ou des brûlures indésirables

Note 1 à l'article: L'ELECTRODE NEUTRE est également appelée plaque, électrode plaque, tampon électrochirurgical, électrode passive, électrode de référence ou électrode de dispersion.

Note 2 à l'article: Pour maintenir une densité de courant suffisamment faible pour empêcher les échauffements indésirables, la surface de l'ELECTRODE NEUTRE doit être suffisamment grande.

Note 3 à l'article: Une ELECTRODE NEUTRE est généralement en contact avec le PATIENT à un emplacement séparé de l'ELECTRODE ACTIVE MONOPOLAIRE.

Note 4 à l'article: Voir les Figures AA.1 et AA.2.

Note 5 à l'article: L'abréviation «NE» est dérivée du terme anglais développé correspondant «neutral electrode».

201.3.231.1
TENSION ASSIGNEE D'ACCESSOIRE
<ACCESSOIRE D'ELECTROCHIRURGIE HF MONOPOLAIRE> tension de sortie HF maximale de crête qui peut être appliquée par rapport à une ELECTRODE NEUTRE raccordée au PATIENT

201.3.231.2
TENSION ASSIGNEE D'ACCESSOIRE
<ACCESSOIRE D'ELECTROCHIRURGIE HF BIPOLAIRE> tension de sortie HF maximale de crête qui peut être appliquée dans des paires de polarités opposées

201.3.232
CHARGE ASSIGNEE
valeur de la résistance de charge non réactive qui, une fois raccordée, donne lieu à la puissance de sortie HF maximale de chaque MODE ELECTROCHIRURGICAL HF de l'APPAREIL D'ELECTROCHIRURGIE HF

201.3.233
PUISSANCE DE SORTIE ASSIGNEE
pour chaque MODE ELECTROCHIRURGICAL HF réglé à la valeur de sortie maximale, puissance en watts produite lorsque toutes les BORNES DE SORTIE ACTIVES qui peuvent être activées simultanément sont raccordées à leurs CHARGES ASSIGNEES respectives

201.3.234
CAPTEUR A INTERRUPTEUR
partie d'un APPAREIL D'ELECTROCHIRURGIE HF ou de l'APPAREIL ASSOCIE qui commande l'activation de la sortie HF en réponse à l'actionnement d'un INTERRUPTEUR MANUEL ou d'une pédale connecté(e)

201.4 Exigences générales

L'Article 4 de la norme générale s'applique avec les exceptions suivantes:

Paragraphes complémentaires:

201.4.1.101 * Conditions supplémentaires d'application

La conformité des APPAREILS D'ELECTROCHIRURGIE HF au présent document et la conformité des ACCESSOIRES D'ELECTROCHIRURGIE HF au présent document doivent être indépendantes l'une de l'autre sauf lorsqu'elles sont spécifiquement exigées par les essais de conformité ou par le FABRICANT.

201.4.2.3.101 * Évaluation du RISQUE

Les FABRICANTS doivent inclure, dans leur ANALYSE DU RISQUE, la probabilité pour leurs APPAREILS D'ELECTROCHIRURGIE HF et/ou ACCESSOIRES D'ELECTROCHIRURGIE HF d'être utilisés en MODE DE COURANT ELEVE et l'impact que cela présenterait sur l'échauffement sous l'ELECTRODE NEUTRE (par exemple, voir 201.7.9.2.2.101 f)).

201.4.3 * PERFORMANCE ESSENTIELLE

Addition:

Les exigences énumérées au troisième tiret de 201.8.4.101 et en 201.12.4.101 doivent être définies comme des exigences de PERFORMANCES ESSENTIELLES.

NOTE 101 Se reporter à l'Annexe AA.

201.4.7 CONDITION DE PREMIER DEFAUT pour APPAREILS EM

Paragraphe complémentaire:

201.4.7.101 Conditions spécifiques de premier défaut

Dans le présent document, les conditions de premier défaut suivantes font l'objet d'exigences et d'essais spécifiques:

a) défaillance du DISPOSITIF DE SURVEILLANCE DE CONTINUITE ou du DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT qui pourrait donner lieu à un RISQUE inacceptable (voir 201.8.4.101);

b) un défaut du circuit de commutation des sorties donnant lieu à un COURANT DE FUITE basse fréquence du PATIENT excessif (voir 201.8.10.4.101.1);

c) tout défaut qui donne lieu à une mise sous tension involontaire du circuit PATIENT (voir 201.12.4.2.101);

d) tout défaut qui donne lieu à une augmentation significative de la puissance de sortie par rapport au réglage correspondant (voir 201.12.4.4.101).

201.4.11 Puissance absorbée

Remplacement du premier tiret dans les essais de conformité:

– Les APPAREILS D'ELECTROCHIRURGIE HF doivent être utilisés en mode de sortie et avec la charge qui génère le courant d'entrée le plus élevé en régime établi. Le courant d'entrée est mesuré et comparé aux marquages et au contenu de la description technique.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique avec les exceptions suivantes:

201.5.4 * Autres conditions

Addition:

aa) Une attention toute particulière doit être accordée à l'exactitude et à la sécurité pendant le mesurage de la sortie HF. Voir l'Annexe AA qui constitue un guide à cet effet.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique avec les exceptions suivantes:

201.7.2.8.2 Autres sources de puissance

Amendement:

Le paragraphe 7.2.8.2 de la norme générale ne s'applique pas aux BORNES DE SORTIE ACTIVES ou aux bornes des ELECTRODES NEUTRES.

201.7.2.10 PARTIES APPLIQUEES

Addition:

Les symboles correspondants exigés pour le marquage des PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION doivent être apposés sur le panneau avant, mais ne sont pas exigés sur les PARTIES APPLIQUEES.

Les connexions à l'APPAREIL D'ELECTROCHIRURGIE HF et à l'APPAREIL ASSOCIE pour le raccordement des conducteurs des ELECTRODES NEUTRES doivent être marquées des symboles donnés en Figures 201.101 et 201.102 comme suit:

Figure 201.101 – Symbole utilisé avec un CIRCUIT PATIENT REFERENCE A LA TERRE

Figure 201.102 – Symbole utilisé avec un CIRCUIT PATIENT ISOLE HF

Paragraphe complémentaire:

201.7.2.10.101 * ACCESSOIRES D'ELECTROCHIRURGIE HF

L'affichage du marquage TYPE BF ou TYPE CF sur les ACCESSOIRES D'ELECTROCHIRURGIE HF (à l'exception des APPAREILS HF ASSOCIES) ne doit pas être exigé sur les ACCESSOIRES eux-mêmes, sur les DOCUMENTS D'ACCOMPAGNEMENT ou sur l'emballage, sauf lorsqu'un DOSSIER DE GESTION DES RISQUES identifie un RISQUE inacceptable associé à cette exclusion.

201.7.4.2 * Dispositifs de commande

Addition:

La commande de la puissance de sortie doit comporter une échelle et/ou un indicateur associé, marqués en unités relatives de puissance de sortie HAUTE FREQUENCE. L'indication ne doit pas être marquée en watts à moins que la puissance indiquée ne soit délivrée avec une exactitude de ± 20 % de la plage totale des résistances de charge spécifiée en 201.7.9.3.1.

Le chiffre «0» ne doit pas être utilisé, sauf si, pour la position correspondante, aucune puissance de sortie HF de plus de 10 mW n'est délivrée d'une ELECTRODE ACTIVE ou d'un ACCESSOIRE BIPOLAIRE.

NOTE L'essai de conformité est l'application de 201.12.1.102.

201.7.8.1 * Couleurs des voyants lumineux

Remplacer le Tableau 2 de la norme générale par le Tableau 201.101 suivant:

Tableau 201.101 – Couleurs des voyants lumineux et leur signification pour les APPAREILS D'ELECTROCHIRURGIE HF

Couleur	Signification
Rouge	Avertissement – réponse immédiate de l'OPERATEUR exigée, par exemple, défaut dans le circuit PATIENT
Jaune	mode d'INCISION
Bleu	mode de COAGULATION
Vert	Prêt à l'emploi
Toute autre couleur	Signification autre que rouge, jaune, bleu ou vert

201.7.8.2 * Couleurs des organes de commande

Addition:

Les commandes de manœuvre, les bornes de sortie, les voyants lumineux, les pédales (voir 201.12.2) et les boutons-poussoirs d'INTERRUPTEURS MANUELS (voir 201.12.2) associés à un MODE ELECTROCHIRURGICAL HF particulier doivent être identifiés par une couleur conforme unique qui n'est pas contraire à celle donnée dans le Tableau 201.101.

La conformité est vérifiée par examen.

201.7.9.2.2 Avertissement et consignes de sécurité

Paragraphe complémentaire:

201.7.9.2.2.101 Informations complémentaires dans les instructions d'utilisation

a) * Consignes pour l'application des APPAREILS D'ELECTROCHIRURGIE HF. Ces consignes doivent attirer l'attention de l'OPERATEUR sur certaines précautions indispensables pour diminuer le RISQUE de brûlures accidentelles. Le cas échéant, des recommandations doivent notamment porter sur les points ci-après:

1) Il convient de relier toute la surface de l'ELECTRODE NEUTRE de façon fiable à une partie du corps du PATIENT correctement préparée et appropriée définie par le FABRICANT.

2) Il convient que le PATIENT ne soit pas en contact avec des parties métalliques mises à la terre ou présentant par rapport à la terre une capacité appréciable (par exemple supports de table d'opération, etc.).

3) Il convient d'éviter le contact peau contre peau (par exemple entre les bras et le corps du PATIENT), par exemple, par l'interposition de gaze sèche.

4) Si des APPAREILS D'ELECTROCHIRURGIE HF et des appareils de surveillance physiologique sont utilisés simultanément sur le même PATIENT, il convient de placer les électrodes de surveillance aussi loin que possible des électrodes d'électrochirurgie. Les électrodes aiguilles de surveillance ne sont pas recommandées.

   Dans tous les cas, les systèmes de surveillance comportant des dispositifs de limitation des courants HAUTE FREQUENCE sont recommandés.

5) Il convient de placer les conducteurs PATIENTs de façon à éviter le contact avec le PATIENT ou avec d'autres conducteurs.

   Il convient de placer les ELECTRODES ACTIVES non utilisées temporairement dans un emplacement isolé du PATIENT.

6) Au cours d'opérations chirurgicales où le courant HF pourrait circuler à travers des parties du corps de section relativement faible, l'utilisation de techniques BIPOLAIRES peut être souhaitable pour éviter d'endommager des tissus de manière indésirable.

7) Il convient que la puissance de sortie sélectionnée soit la plus faible possible pour le BUT RECHERCHE. Certains appareils ou ACCESSOIRES peuvent présenter un RISQUE inacceptable à de faibles réglages de la puissance. Par exemple, pour la COAGULATION au faisceau argon, il y a augmentation du RISQUE d'embolie gazeuse s'il n'y a pas suffisamment de puissance HF pour produire rapidement une escarre imperméable sur le tissu cible.

8) Une puissance de sortie apparemment faible ou une défaillance de l'APPAREIL D'ELECTROCHIRURGIE HF aux réglages de fonctionnement normaux peut indiquer une application défectueuse de l'ELECTRODE NEUTRE ou un mauvais contact dans ses connexions. Dans ce cas, il convient de vérifier la mise en place de l'ELECTRODE NEUTRE et de ses connexions avant de sélectionner une puissance de sortie plus élevée.

9) Il convient d'éviter toute utilisation d'anesthésiques inflammables ou de gaz oxydants tels que l'oxyde nitreux (N_2O) et l'oxygène lors d'une opération chirurgicale sur le thorax ou la tête, à moins que ces agents ne soient évacués par aspiration.

   Il convient dans toute la mesure du possible d'utiliser des agents non inflammables pour le nettoyage et la désinfection.

   Il convient de laisser évaporer les agents inflammables utilisés pour le nettoyage ou la désinfection, ou comme solvants de produits adhésifs, avant application de la chirurgie HF. Il y a RISQUE d'accumulation de solutions inflammables sous le PATIENT ou dans les dépressions ou cavités de son corps telles que le nombril ou le vagin. Il convient d'éliminer tout fluide accumulé dans ces zones avant utilisation de l'APPAREIL D'ELECTROCHIRURGIE HF. Il convient de prêter une attention toute particulière au DANGER présenté par l'inflammation des gaz endogènes. Certains

matériaux, comme le coton ou la gaze, peuvent, lorsqu'ils sont saturés d'oxygène, être inflammables par les étincelles produites en UTILISATION NORMALE des APPAREILS D'ELECTROCHIRURGIE HF.

10) Pour les PATIENTS avec des implants électriquement conducteurs, la concentration ou la redirection de courants HF peut engendrer un DANGER. En cas de doute, il convient d'avoir recours à des conseils avisés.

11) Pour les APPAREILS D'ELECTROCHIRURGIE HF disposant d'un mode de fonctionnement comme décrit en 201.12.2 c) 2), un avertissement est exigé concernant le fait que la puissance de sortie de toute ELECTRODE ACTIVE peut changer en cours d'utilisation.

b) Un avertissement précisant que l'interférence produite par le fonctionnement d'un APPAREIL D'ELECTROCHIRURGIE HF peut avoir une influence néfaste sur le fonctionnement d'autres appareils électroniques. Pour les PATIENTS avec des stimulateurs cardiaques ou d'autres implants actifs, les interférences qui peuvent exister avec l'action de l'implant peuvent engendrer un DANGER ou peuvent endommager l'implant actif. En cas de doute, il convient de faire appel à des conseils compétents.

c) * Pour les APPAREILS D'ELECTROCHIRURGIE HF, la TENSION MAXIMALE DE SORTIE pour chaque MODE ELECTROCHIRURGICAL HF ainsi que les instructions relatives à la TENSION ASSIGNEE D'ACCESSOIRE comme indiqué ci-après:

1) Lorsque la TENSION MAXIMALE DE SORTIE (U_{max}) est inférieure ou égale à 1 600 V, fournir des instructions indiquant qu'il convient de sélectionner l'APPAREIL ASSOCIE et les ACCESSOIRES ACTIFS ayant une TENSION ASSIGNEE D'ACCESSOIRE supérieure ou égale à la TENSION MAXIMALE DE SORTIE.

2) Lorsque la TENSION MAXIMALE DE SORTIE (U_{max}) est supérieure à 1 600 V, calculer la variable *y* en utilisant la formule suivante:

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

Utiliser le chiffre 6 ou la valeur de la variable *y*, selon que l'une ou l'autre de ces valeurs est la plus faible. Si le résultat est inférieur ou égal au FACTEUR DE CRETE pour le MODE ELECTROCHIRURGICAL HF concerné, fournir alors des instructions indiquant qu'il convient de sélectionner l'APPAREIL ASSOCIE et les ACCESSOIRES ACTIFS ayant une TENSION ASSIGNEE D'ACCESSOIRE supérieure ou égale à la TENSION MAXIMALE DE SORTIE.

3) Lorsque la TENSION MAXIMALE DE SORTIE (U_{max}) est supérieure à 1 600 V, et le FACTEUR DE CRETE est inférieur à la variable *y* calculée ci-dessus, un avertissement doit être prévu indiquant que tout APPAREIL ASSOCIE et tous les ACCESSOIRES ACTIFS utilisés avec un tel mode ou réglage doivent avoir les caractéristiques assignées pour résister à la combinaison de la tension réelle et du FACTEUR DE CRETE.

Lorsque la TENSION MAXIMALE DE SORTIE varie en fonction du réglage de la sortie, ces informations doivent être présentées sous forme de diagramme en fonction du réglage de la sortie.

d) Un avertissement précisant que la défaillance de l'APPAREIL D'ELECTROCHIRURGIE HF peut entraîner une augmentation involontaire de la puissance de sortie.

e) * Une déclaration de compatibilité avec des ELECTRODES NEUTRES DE SURVEILLANCE spécifiques.

Un avertissement selon lequel, à moins d'utiliser une ELECTRODE NEUTRE DE SURVEILLANCE compatible avec un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT, il n'y aura pas d'alarme sonore en cas de perte du contact de sécurité entre l'ELECTRODE NEUTRE et le PATIENT.

NOTE 1 Cette exigence ne s'applique pas aux APPAREILS D'ELECTROCHIRURGIE HF ne comportant qu'une sortie BIPOLAIRE.

NOTE 2 Cette exigence ne s'applique pas aux APPAREILS D'ELECTROCHIRURGIE HF destinés à être utilisés sans ELECTRODE NEUTRE. (Voir 201.15.101).

f) Lorsque la température sous l'ELECTRODE NEUTRE, au cours d'une UTILISATION NORMALE ou prévue, peut donner lieu à une température dépassant les limites énumérées en 11.1.2.2 de la norme générale ou en 201.15.101.5 du présent document, des instructions,

avertissements et mises en garde en vue de l'utilisation appropriée de l'ELECTRODE NEUTRE doivent être fournis.

g) * Un avertissement abordant les RISQUES résultant de la stimulation neuromusculaire pouvant avoir lieu en particulier avec des modes produisant des arcs électriques entre l'ELECTRODE ACTIVE et le tissu.

h) * Pour les APPAREILS D'ELECTROCHIRURGIE HF pouvant être mis sous tension sans activation continue d'un CAPTEUR A INTERRUPTEUR selon 201.8.10.4.101.2, des avertissements ou des mises en garde relatifs aux RISQUES.

i) * Pour les APPAREILS D'ELECTROCHIRURGIE HF, la longueur maximale admissible de l'ACCESSOIRE et de son câble pour chaque type de connecteur.

NOTE 3 Pour de plus amples informations, voir l'Annexe AA.

201.7.9.2.14 * ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Addition:

Les instructions d'utilisation doivent comporter:

a) Des informations relatives à la sélection et à l'utilisation des ACCESSOIRES D'ELECTROCHIRURGIE HF afin d'éviter les incompatibilités et tout fonctionnement dangereux (voir également 201.15.4.1.101 et 201.15.4.1.102).

b) Des conseils destinés à l'OPERATEUR afin d'éviter des réglages de sortie HF lorsque la TENSION MAXIMALE DE SORTIE peut dépasser la TENSION ASSIGNEE D'ACCESSOIRE.

c) Des conseils portant sur la compatibilité entre une ELECTRODE NEUTRE DE SURVEILLANCE et un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT.

d) Une consigne conseillant à l'OPERATEUR de vérifier régulièrement les ACCESSOIRES. Il convient plus particulièrement de vérifier (par exemple sous grossissement) les câbles d'électrodes et les APPAREILS D'ENDOTHERAPIE SOUS TENSION HF (voir l'IEC 60601-2-18) pour détecter tout endommagement potentiel.

e) * Pour l'APPAREIL ASSOCIE et les ACCESSOIRES ACTIFS, y compris lorsque leurs pièces sont fournies séparément, la TENSION ASSIGNEE D'ACCESSOIRE ainsi qu'un avertissement indiquant d'utiliser uniquement avec les réglages de sortie du MODE ELECTROCHIRURGICAL HF fournissant une tension de sortie de crête inférieure ou égale à la TENSION ASSIGNEE D'ACCESSOIRE.

f) * Sur l'emballage jetable des ELECTRODES NEUTRES:

- Si un marquage indique qu'elles sont à usage unique, une date d'expiration.
- Les informations nécessaires pour éviter les brûlures au niveau du site de l'ELECTRODE NEUTRE, par exemple limitation du réglage de la puissance de sortie, préparation du PATIENT ou durée d'activation.
- Si leur usage est destiné uniquement à de jeunes PATIENTS, un marquage en kg indiquant le poids maximal du PATIENT auquel il est destiné. Voir 201.15.101.5.

g) * Sur les instructions relatives à l'utilisation des ELECTRODES NEUTRES DE SURVEILLANCE:

- Une déclaration de comptabilité avec un (des) DISPOSITIF(S) DE SURVEILLANCE DE LA QUALITE DU CONTACT spécifique(s).

h) Les ACCESSOIRES D'ELECTROCHIRURGIE HF dont la température sous l'ELECTRODE NEUTRE, au cours d'une UTILISATION NORMALE ou prévue, peut donner lieu à une température dépassant les limites énumérées en 11.1.2.2 de la norme générale ou en 201.15.101.5 du présent document, doivent être accompagnés d'instructions, d'avertissements et mises en garde en vue de l'utilisation appropriée des ELECTRODES NEUTRES.

i) Dans les instructions d'utilisation des ACCESSOIRES D'ELECTROCHIRURGIE HF destinés à être utilisés uniquement avec un APPAREIL D'ELECTROCHIRURGIE HF spécifique ou des formes d'onde ou tensions HF, une déclaration détaillée à cet effet.

j) * Pour les ELECTRODES ACTIVES et les PORTE-ELECTRODES ACTIVES, des informations permettant d'évaluer les SITUATIONS DANGEREUSES suivantes:

- métal visiblement exposé de l'arbre de l'ELECTRODE ACTIVE à l'endroit de sa connexion au PORTE-ELECTRODES ACTIVES;
- mauvaise connexion électrique entre le PORTE-ELECTRODES ACTIVES et l'arbre de l'ELECTRODE ACTIVE;
- mauvaise compatibilité entre le PORTE-ELECTRODES ACTIVES et l'arbre de l'ELECTRODE ACTIVE.

NOTE 101 Pour de plus amples informations, voir l'Annexe AA.

201.7.9.2.15 Protection de l'environnement

Addition:

L'instruction d'utilisation doit fournir des recommandations à l'OPERATEUR concernant l'opportunité d'utiliser un dispositif d'extraction des panaches de fumée.

201.7.9.3 Description technique

201.7.9.3.1 * Généralités

Addition:

- données concernant la puissance de sortie – sortie MONOPOLAIRE (pour tous les MODES ELECTROCHIRURGICAUX HF disponibles, toute commande «mixte» réglable étant placée en position maximale), y compris:
  - des schémas représentant la puissance de sortie aux réglages maximaux et mi-puissance de la commande de sortie au minimum dans la plage de résistance de charge comprise entre 100 Ω et 2 000 Ω, mais étendue si nécessaire pour inclure la CHARGE ASSIGNEE;
  - des schémas représentant la puissance de sortie par rapport au réglage de la commande de sortie pour une résistance de charge spécifiée située dans la plage définie ci-dessus;
- données concernant la puissance de sortie – sortie BIPOLAIRE (pour tous les MODES ELECTROCHIRURGICAUX HF définis ci-dessus), y compris:
  - des schémas représentant la puissance de sortie aux réglages maximaux et mi-puissance de la commande de sortie au minimum dans la plage de résistance de charge comprise entre 10 Ω et 1 000 Ω, mais étendue si nécessaire pour inclure la CHARGE ASSIGNEE;
  - des schémas représentant la puissance de sortie par rapport au réglage de la commande de sortie pour une résistance de charge spécifiée située dans la plage définie ci-dessus;
- données concernant la tension de sortie – sortie MONOPOLAIRE et BIPOLAIRE (pour tous les MODES ELECTROCHIRURGICAUX HF disponibles). Données concernant la TENSION MAXIMALE DE SORTIE exigées par 201.7.9.2.2.101 c);
- lorsque l'APPAREIL D'ELECTROCHIRURGIE HF est spécifié pour être utilisé sans ELECTRODE NEUTRE, cela doit être indiqué;
- lorsque l'APPAREIL D'ELECTROCHIRURGIE HF ou l'APPAREIL ASSOCIE est conçu pour avoir un seul réglage FIXE de la puissance de sortie, la référence aux «réglages mi-puissance de la commande de sortie» doit alors être ignorée;
- le COURANT MAXIMAL DE SORTIE pour chaque MODE ELECTROCHIRURGICAL HF;
- le FACTEUR D'ECHAUFFEMENT maximal généré au cours d'une période quelconque de 60 s lorsque l'APPAREIL D'ELECTROCHIRURGIE HF est utilisé en MODE DE COURANT ELEVE quel qu'il soit.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de la norme générale s'applique avec les exceptions suivantes:

201.8.4 Limitation de la tension, du courant ou de l'énergie

Paragraphes complémentaires:

201.8.4.101 * Circuit de surveillance de l'ELECTRODE NEUTRE

Un APPAREIL D'ELECTROCHIRURGIE HF ayant un point de raccordement d'ELECTRODE NEUTRE doit être équipé d'un ou de plusieurs des éléments suivants:

– un DISPOSITIF DE SURVEILLANCE DE CONTINUITE;

– un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT;

– un moyen alternatif d'assurer qu'aucun échauffement inacceptable (voir 201.15.101.5) ne se produit sous l'ELECTRODE NEUTRE. Tout moyen alternatif doit être pris en compte pour les PERFORMANCES ESSENTIELLES.

Ces éléments peuvent être désactivés lorsque l'APPAREIL D'ELECTROCHIRURGIE HF est utilisé sans ELECTRODE NEUTRE comme décrit en 201.8.6.1.

Ces éléments doivent être disposés de manière à mettre hors tension la sortie MONOPOLAIRE et à émettre une alarme sonore en cas de défaillance du circuit de l'ELECTRODE NEUTRE, de ses connexions ou du moyen alternatif. L'alarme sonore doit satisfaire aux exigences relatives au niveau sonore de 201.12.4.2.101 et ne doit pas être ajustable de l'extérieur.

Pour l'utilisation d'ELECTRODES NEUTRES non destinées à la SURVEILLANCE, le DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT peut être désactivé. Cette sélection doit être visible à l'OPERATEUR. Dans ce cas, l'exigence quant à la présence d'un DISPOSITIF DE SURVEILLANCE DE CONTINUITE ou d'un moyen alternatif pour s'assurer qu'aucun échauffement inacceptable ne se produit sous l'ELECTRODE NEUTRE doit encore s'appliquer.

NOTE 1 Dans le présent paragraphe, l'utilisation de la conjonction «ou» est inclusive et peut signifier soit le premier choix, soit le deuxième, ou bien les deux.

NOTE 2 Cette alarme sonore et le voyant lumineux visible ne sont pas destinés à satisfaire à la définition d'un SIGNAL D'ALARME de l'IEC 60601-1-8. Voir également l'Article 208 du présent document.

Le circuit de surveillance doit être alimenté à partir d'une source isolée de la PARTIE RELIEE AU RESEAU et de la terre, et dont la tension ne dépasse pas 12 V. La limite du courant de surveillance pour un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT est définie en 201.8.7.3.

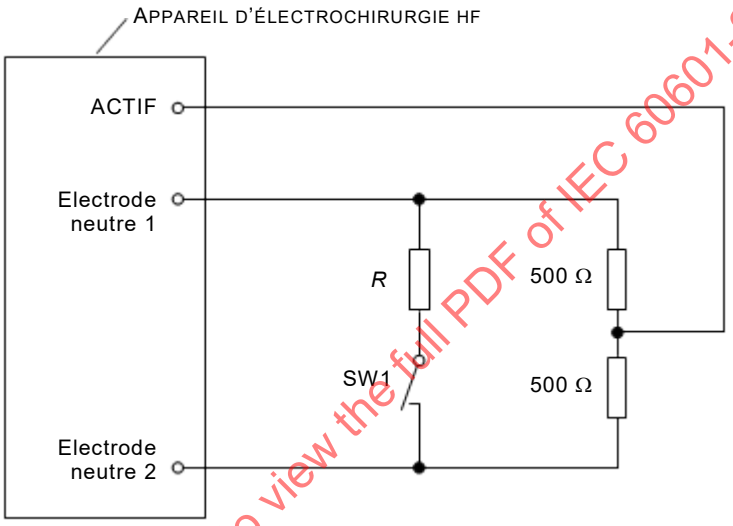
Un avertissement visible supplémentaire consistant en un voyant lumineux rouge doit être prévu (voir 201.7.8.1).

La conformité d'un DISPOSITIF DE SURVEILLANCE DE CONTINUITE est vérifiée en faisant fonctionner l'APPAREIL D'ELECTROCHIRURGIE HF au réglage maximal de la commande de la puissance de sortie dans chaque mode de fonctionnement dans le circuit représenté à la Figure 201.103. L'interrupteur est fermé et ouvert cinq fois et la puissance de sortie HF doit être interrompue et l'alarme doit retentir à chaque ouverture de l'interrupteur.

La conformité d'un DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT est vérifiée en mettant sous tension le réseau de l'APPAREIL D'ELECTROCHIRURGIE HF et en réglant ses commandes pour un fonctionnement MONOPOLAIRE, sauf qu'il ne doit pas être activé. Ensuite, une ELECTRODE NEUTRE DE SURVEILLANCE compatible, sélectionnée conformément au conseil énoncé en 201.7.9.2.2.101 e), est raccordée aux connexions de L'ELECTRODE NEUTRE du DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT. L'ELECTRODE NEUTRE est ensuite placée, conformément aux instructions d'utilisation indiquées, en assurant un contact total sur

un sujet humain ou sur une surface de substitution appropriée, et le DISPOSITIF DE SURVEILLANCE DE LA QUALITE DU CONTACT est configuré conformément aux instructions d'utilisation. L'APPAREIL D'ELECTROCHIRURGIE HF est ensuite activé en MODE ELECTROCHIRURGICAL HF MONOPOLAIRE. Aucune alarme ne doit retentir et la puissance de sortie HF doit être présente. L'APPAREIL D'ELECTROCHIRURGIE HF étant à présent activé, la surface de contact entre l'ELECTRODE NEUTRE et le sujet humain ou une surface de substitution appropriée est réduite progressivement jusqu'à ce qu'une alarme d'ELECTRODE NEUTRE retentisse. La surface de contact restante (surface d'alarme), A_a, doit être enregistrée pour les essais d'échauffement ultérieurs conformément à 201.15.101.5 et aucune puissance de sortie HF ne doit être produite lorsqu'il y a tentative d'activation. Cet essai doit être répété le long des deux axes en utilisant au moins trois échantillons de chaque ELECTRODE NEUTRE DE SURVEILLANCE compatible.

La conformité d'un moyen alternatif pour assurer qu'aucun échauffement inacceptable ne se produit sous l'ELECTRODE NEUTRE est vérifiée par examen de la documentation fournie par le FABRICANT et du DOSSIER DE GESTION DES RISQUES.



Pour les plaques uniques: $R = 0\ \Omega$

Pour les plaques double zone: *R* selon les spécifications du FABRICANT uniquement pour maintenir l'appareil actif lorsque l'interrupteur SW1 est fermé

IEC

Il convient que les ELECTRODES NEUTRES qui sont divisées en plus de deux parties soient soumises aux essais en conséquence.

Figure 201.103 – Circuit adapté aux essais de conformité selon 201.8.4.101

201.8.4.102 * Stimulation neuromusculaire

Afin de réduire le plus possible la possibilité de stimulation neuromusculaire, une capacité doit être incorporée dans le circuit PATIENT de façon à être effectivement connectée en série avec l'ELECTRODE ACTIVE ou l'un des conducteurs d'un ACCESSOIRE BIPOLAIRE. Cette capacité ne doit pas dépasser 5 nF pour les circuits PATIENTS MONOPOLAIRES et 50 nF pour les circuits PATIENTS BIPOLAIRES. La résistance en courant continu entre les bornes de l'ELECTRODE ACTIVE et de l'ELECTRODE NEUTRE, ou entre les bornes d'un circuit de sortie BIPOLAIRE, ne doit pas être inférieure à 2 MΩ.

La conformité est vérifiée par examen de la disposition des circuits et par mesurage en courant continu de la résistance entre les bornes de sortie.

201.8.5.1.2 * MOYEN DE PROTECTION DU PATIENT

Amendement:

Pour les APPAREILS D'ELECTROCHIRURGIE HF, les LIGNES DE FUITE et les DISTANCES DANS L'AIR de l'isolation entre les PARTIES APPLIQUEES HF et l'ENVELOPPE, y compris les ENTREES/SORTIES DE SIGNAL, entre les CIRCUITS PATIENTS HF et le circuit intermédiaire et entre les différents CIRCUITS PATIENTS HF doivent être d'au moins 3 mm/kV ou 4 mm, en fonction de la valeur la plus élevée. La tension de référence doit être la tension de crête maximale. Il n'est pas nécessaire de soumettre la séparation diélectrique à l'essai de tension de tenue de 201.8.8.3. Les CIRCUITS PATIENTS HF des APPAREILS D'ELECTROCHIRURGIE HF doivent être considérés comme des PARTIES APPLIQUEES dans le contexte du présent paragraphe. Les LIGNES DE FUITE et les DISTANCES DANS L'AIR de l'isolation sont destinées à représenter deux MOYENS DE PROTECTION.

La présente exigence ne s'applique pas aux composants lorsque l'adaptation des caractéristiques assignées peut être démontrée, par exemple par les caractéristiques assignées des FABRICANTS de composants ou par l'essai de tension de tenue de 201.8.8.3.

La présente exigence ne s'applique pas aux ACCESSOIRES D'ELECTROCHIRURGIE HF. Les exigences et essais relatifs aux ACCESSOIRES D'ELECTROCHIRURGIE HF sont fournis en 201.8.8.3 et 201.15.101.4.

201.8.5.2.3 * Conducteurs PATIENTS ou câbles PATIENTS

Amendement:

La présente exigence ne doit pas s'appliquer aux CONNECTEURS ACTIFS ni à aucun connecteur de l'ELECTRODE NEUTRE, avec les exceptions détaillées ci-dessous.

Pour les câbles de l'ELECTRODE NEUTRE, le connecteur qui est éloigné du PATIENT doit être construit de sorte que les liaisons ne puissent pas être en contact avec des parties sous tension conductrices des socles FIXES de prise de courant réseau ou des PRISES RESEAU.

S'il est possible d'introduire ladite partie dans un socle FIXE de prise de courant réseau ou dans une PRISE RESEAU, ladite partie doit être protégée contre l'établissement d'un contact avec les parties à la tension réseau par des moyens d'isolation fournissant une LIGNE DE FUITE d'au moins 1,0 mm et une tension de tenue de 1 500 V.

La conformité est vérifiée par examen et en appliquant l'essai de tension de tenue à la liaison conductrice de la partie du connecteur identifiée ci-dessus.

201.8.5.5 * PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION

Amendement:

Les CIRCUITS PATIENTS HF des APPAREILS D'ELECTROCHIRURGIE HF doivent être considérés comme des PARTIES APPLIQUEES dans le contexte du présent paragraphe.

La conformité est vérifiée par l'essai en mode commun uniquement, comme décrit en 8.5.5.1 et à la Figure 9 de la norme générale en utilisant une tension d'essai de 2 kV au lieu de 5 kV.

Après cet essai, l'APPAREIL D'ELECTROCHIRURGIE HF doit pouvoir satisfaire à toutes les exigences et tous les essais du présent document et réaliser les fonctions prévues décrites dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.8.6.1 * Applicabilité des exigences

Addition:

De manière générale, un CONDUCTEUR DE TERRE DE PROTECTION ne doit pas être parcouru par un courant fonctionnel. Toutefois, dans un APPAREIL D'ELECTROCHIRURGIE HF ayant une PUISSANCE DE SORTIE ASSIGNEE ne dépassant pas 50 W et destiné à être utilisé sans ELECTRODE NEUTRE, le CONDUCTEUR DE TERRE DE PROTECTION du câble de raccordement réseau peut être utilisé comme chemin de retour du courant HAUTE FREQUENCE fonctionnel.

201.8.7.1 * Exigences générales

Point b)

Addition:

– avec une sortie HF hors tension mais de telle sorte que les COURANTS DE FUITE basse fréquence ne soient pas affectés.

Amendement:

Ces investigations doivent être effectuées en mettant l'APPAREIL D'ELECTROCHIRURGIE HF sous tension mais avec les circuits PATIENTs non activés.

201.8.7.3 * Valeurs admissibles

Point b)

Addition:

Les COURANTS AUXILIAIRES PATIENTS associés aux DISPOSITIFS DE SURVEILLANCE DE LA QUALITE DU CONTACT ne doivent pas dépasser les valeurs admissibles pour les PARTIES APPLIQUEES DE TYPE BF.

Point e)

Amendement:

La limite de 10 mA pour le COURANT DE FUITE ne s'applique pas aux COURANTS DE FUITE HF soumis aux essais à partir d'ELECTRODES ACTIVES et NEUTRES avec des circuits PATIENTS activés (voir 201.8.7.3.101).

Paragraphe complémentaire:

201.8.7.3.101 Effets thermiques des COURANTS DE FUITE HF

Afin d'éviter des brûlures thermiques involontaires, les COURANTS DE FUITE HF soumis aux essais à partir d'ELECTRODES ACTIVES et NEUTRES avec des CIRCUITS PATIENTS HF activés doivent, en fonction de leur conception, satisfaire aux exigences suivantes.

*a) COURANTS DE FUITE A COURANT HAUTE FREQUENCE

Pour tous les mesurages des COURANTS DE FUITE HF, toutes les ENVELOPPES métalliques des APPAREILS D'ELECTROCHIRURGIE HF DE CLASSE II et des APPAREILS D'ELECTROCHIRURGIE HF ALIMENTES DE MANIERE INTERNE doivent être reliées à la terre. Au cours de ces essais, les APPAREILS D'ELECTROCHIRURGIE HF équipés d'une ENVELOPPE isolante doivent être positionnés sur le métal mis à la terre ayant une surface au moins égale à la base des APPAREILS D'ELECTROCHIRURGIE HF.

Au cours de tous les mesurages des COURANTS DE FUITE HF, le CABLE D'ALIMENTATION des APPAREILS D'ELECTROCHIRURGIE HF doit être replié pour former un faisceau d'une longueur inférieure à 40 cm.

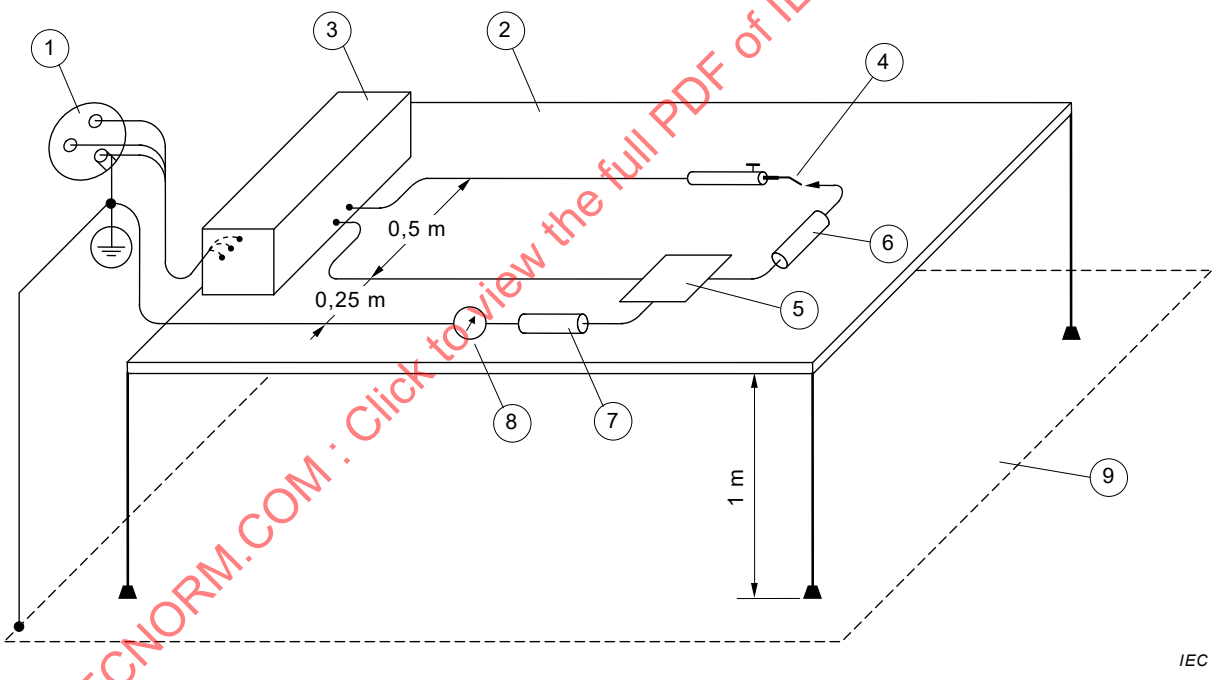
1) Pour les CIRCUITS PATIENTS MONOPOLAIRES REFERENCES A LA TERRE

Le circuit PATIENT est isolé de la terre, mais l'ELECTRODE NEUTRE est référencée à la terre pour les COURANTS A HAUTE FREQUENCE par des composants (par exemple un condensateur) satisfaisant aux exigences d'une PARTIE APPLIQUEE DE TYPE BF. Lorsqu'il est mesuré conformément aux essais décrits ci-dessous, le COURANT DE FUITE HF s'écoulant de l'ELECTRODE NEUTRE vers la terre par une résistance non inductive de 200 Ω ne doit pas dépasser 150 mA.

La conformité est vérifiée par les essais suivants.

Essai 1 – L'essai est effectué à tour de rôle sur chacune des sorties de l'APPAREIL D'ELECTROCHIRURGIE HF avec les câbles d'électrodes et les électrodes disposés selon la Figure 201.104. Les câbles, espacés de 0,5 m, sont placés sur une surface isolante à 1 m au-dessus d'un plan conducteur relié à la terre.

Une charge de 200 Ω est utilisée pour la sortie et l'APPAREIL D'ELECTROCHIRURGIE HF fonctionne à sa puissance de sortie maximale pour chaque mode de fonctionnement. Le COURANT DE FUITE HF s'écoulant de l'ELECTRODE NEUTRE vers la terre à travers une résistance non inductive de 200 Ω est mesuré.

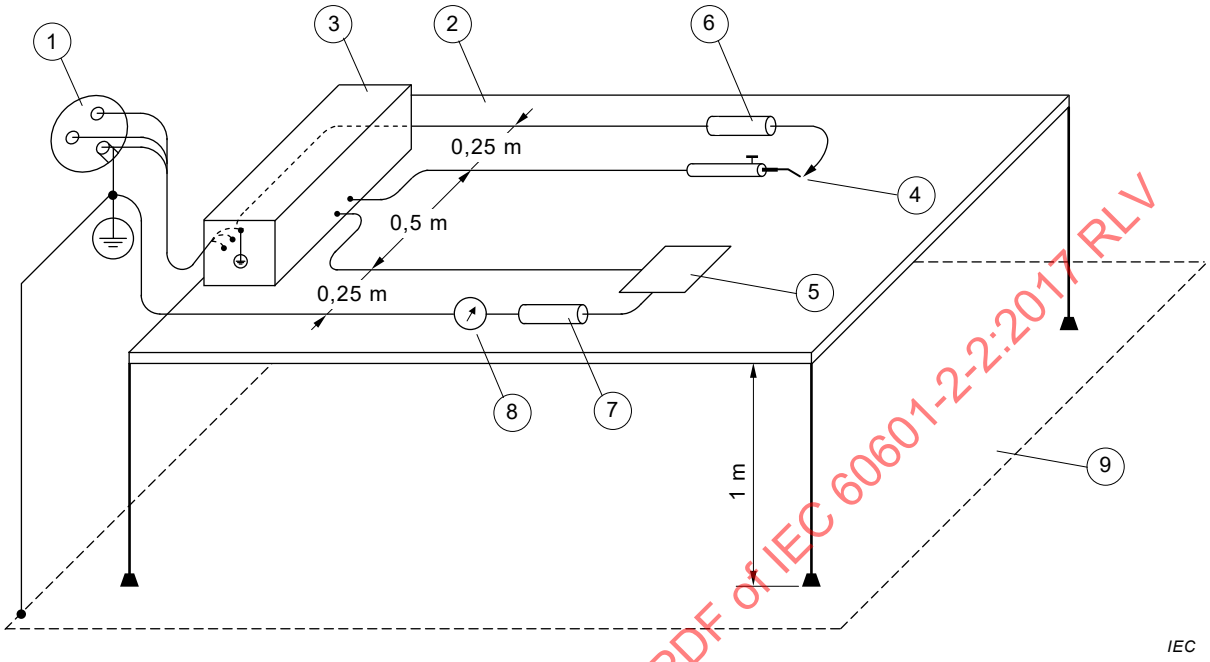


Légende

1	ALIMENTATION RESEAU
2	Table en matériau isolant
3	APPAREIL D'ELECTROCHIRURGIE HF
4	ELECTRODE ACTIVE
5	ELECTRODE NEUTRE, en métal ou en contact avec une feuille métallique de mêmes dimensions
6	Résistance de charge de 200 Ω
7	Résistance de mesure de 200 Ω
8	Ampèremètre courant HF
9	Plan conducteur relié à la terre

Figure 201.104 – Mesurage du COURANT DE FUITE HF pour les CIRCUITS PATIENTS REFERENCES A LA TERRE et résistance de charge entre électrodes

Essai 2 – L'APPAREIL D'ELECTROCHIRURGIE HF est installé comme pour l'essai 1, la résistance de charge de 200 Ω étant toutefois placée entre l'ELECTRODE ACTIVE et la BORNE DE TERRE DE PROTECTION de L'APPAREIL D'ELECTROCHIRURGIE HF, comme représenté à la Figure 201.105. Le COURANT DE FUITE HF s'écoulant de l'ELECTRODE NEUTRE est mesuré.



Légende

1 ALIMENTATION RESEAU
2 Table en matériau isolant
3 APPAREIL D'ELECTROCHIRURGIE HF
4 ELECTRODE ACTIVE
5 ELECTRODE NEUTRE, en métal ou en contact avec une feuille métallique de mêmes dimensions
6 Résistance de charge de 200 Ω
7 Résistance de mesure de 200 Ω
8 Ampèremètre courant HF
9 Plan conducteur relié à la terre

Figure 201.105 – Mesurage du COURANT DE FUITE HF pour les CIRCUITS PATIENTS REFERENCES A LA TERRE et résistance de charge entre l'ELECTRODE ACTIVE et la terre

2) Pour les CIRCUITS PATIENTS ISOLES HF MONOPOLAIRES

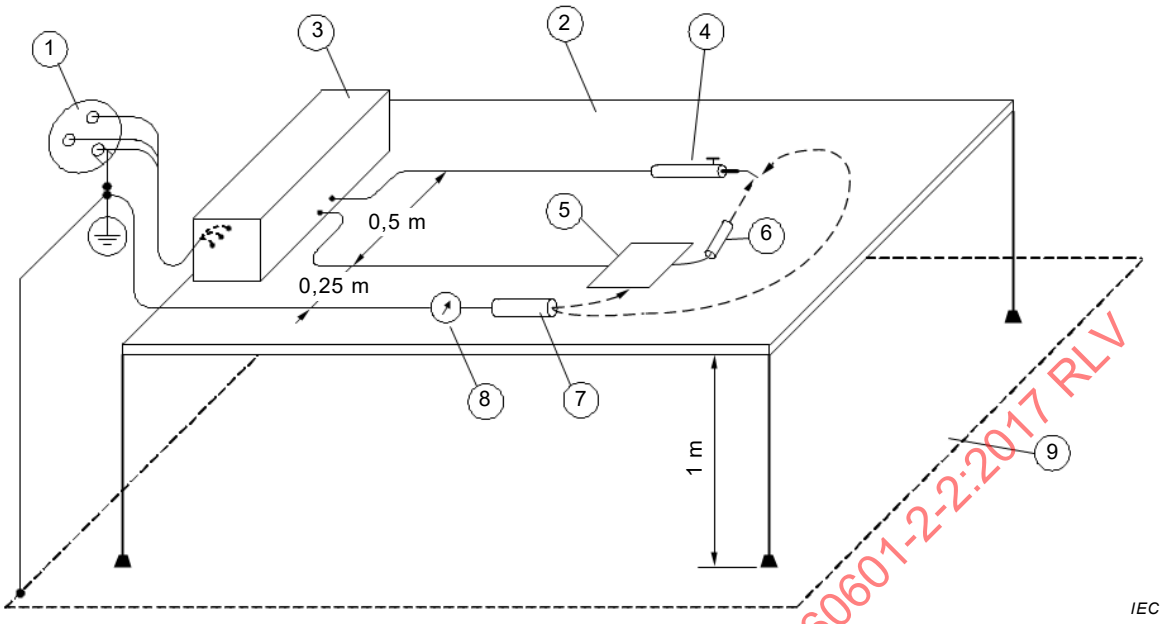
Le circuit PATIENT est isolé de la terre pour les courants HAUTE FREQUENCE et basse fréquence, et l'isolation doit être telle que le COURANT DE FUITE HF s'écoulant successivement de chaque électrode vers la terre à travers une résistance non inductive de 200 Ω ne dépasse pas 150 mA lorsqu'il est mesuré selon l'essai décrit ci-dessous.

La conformité est vérifiée par l'essai suivant.

L'APPAREIL D'ELECTROCHIRURGIE HF est installé comme cela est représenté à la Figure 201.106, la sortie étant déchargée et chargée à la CHARGE ASSIGNEE.

Pour chaque MODE ELECTROCHIRURGICAL HF, le COURANT DE FUITE HF s'écoulant de chaque électrode est mesuré tour à tour tandis que l'APPAREIL D'ELECTROCHIRURGIE HF fonctionne à sa puissance de sortie maximale.

NOTE 1 Les exigences 1) et 2) ci-dessus ne s'appliquent pas aux APPAREILS D'ELECTROCHIRURGIE HF ayant une PUISSANCE DE SORTIE ASSIGNEE ne dépassant pas 50 W et destinés à être utilisés sans ELECTRODE NEUTRE.



Légende

1	ALIMENTATION RESEAU
2	Table en matériau isolant
3	APPAREIL D'ELECTROCHIRURGIE HF
4	ELECTRODE ACTIVE
5	ELECTRODE NEUTRE, en métal ou en contact avec une feuille métallique de mêmes dimensions
6	CHARGE ASSIGNEE
7	Résistance de mesure de 200 Ω
8	Ampèremètre courant HF
9	Plan conducteur relié à la terre

Figure 201.106 – Mesurage du COURANT DE FUITE HF pour les CIRCUITS PATIENTS ISOLES HF

*3) Pour les CIRCUITS PATIENTS HF BIPOLAIRES

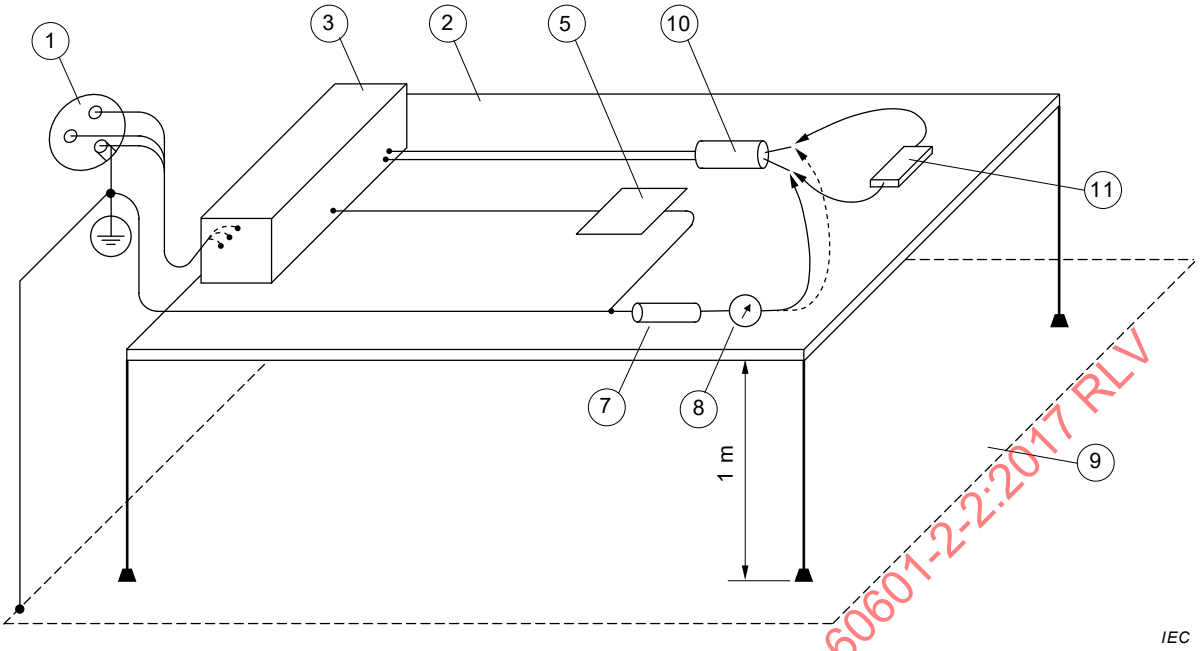
Tout circuit PATIENT conçu spécifiquement pour une application BIPOLAIRE doit être isolé de la terre et des autres PARTIES APPLIQUEES pour les hautes et basses fréquences.

Le COURANT DE FUITE HF s'écoulant de chaque pôle de la sortie BIPOLAIRE vers la terre et vers l'ELECTRODE NEUTRE à travers une résistance non inductive de 200 Ω dans chaque ligne ne doit pas excéder la valeur produisant dans la résistance non inductive de 200 Ω une puissance égale à 1 % de la PUISSANCE DE SORTIE ASSIGNEE BIPOLAIRE maximale, toutes les commandes de sortie étant réglées au maximum.

La conformité est vérifiée par l'essai suivant.

L'APPAREIL D'ELECTROCHIRURGIE HF est mis en place comme indiqué à la Figure 201.107. L'essai est réalisé en utilisant un côté de la sortie BIPOLAIRE et en utilisant un conducteur BIPOLAIRE et (le cas échéant) les conducteurs de l'ELECTRODE NEUTRE fournis ou recommandés par le FABRICANT. L'essai est réalisé avec la sortie tout d'abord déchargée, puis est répété avec la sortie chargée à la CHARGE ASSIGNEE. La valeur du courant au carré multipliée par 200 Ω ne doit pas dépasser l'exigence ci-dessus. L'essai est ensuite répété pour l'autre côté de la sortie BIPOLAIRE.

NOTE 2 Les exigences 1), 2) et 3) ci-dessus s'appliquent aux APPAREILS D'ELECTROCHIRURGIE HF avec des PARTIES APPLIQUEES DE TYPE BF et de TYPE CF.



Légende

1	ALIMENTATION RESEAU
2	Table en matériau isolant
3	APPAREIL D'ELECTROCHIRURGIE HF
5	ELECTRODE NEUTRE, en métal ou en contact avec une feuille métallique de mêmes dimensions
7	Résistance de mesure de 200 Ω
8	Ampèremètre courant HF
9	Plan conducteur relié à la terre
10	ACCESSOIRE BIPOLAIRE activé
11	Résistance de charge exigée avec le dispositif de mesure de la puissance HF

Figure 201.107 – Mesurage du COURANT DE FUITE HF d'un ACCESSOIRE BIPOLAIRE

*b) COURANTS DE FUITE A HAUTE FREQUENCE mesurés directement sur les bornes de l'APPAREIL D'ELECTROCHIRURGIE HF

En variante, les exigences du point a) précédent peuvent être satisfaites avec une limite de 100 mA pour 1) et 2) et avec des limites inchangées correspondant à 1 % de la PUISSANCE DE SORTIE ASSIGNEE BIPOLAIRE sur 200 Ω et ne dépassant pas 100 mA pour 3) lorsque le COURANT DE FUITE HF est mesuré directement aux bornes de l'APPAREIL D'ELECTROCHIRURGIE HF.

La conformité est vérifiée en effectuant des mesurages similaires à ceux décrits dans les essais de 201.8.7.3.101 a), mais sans les câbles des électrodes, et en utilisant des conducteurs aussi courts que possible pour la connexion de la résistance de charge, de la résistance de mesure et de l'instrument de mesure du courant, aux bornes de l'APPAREIL D'ELECTROCHIRURGIE HF.

c) Couplage mutuel entre différents CIRCUITS PATIENTS HF

Lorsque tout autre circuit PATIENT est activé aux réglages de la puissance de sortie les plus élevés et à tous les modes de fonctionnement disponibles, alors:

1) Un circuit PATIENT MONOPOLAIRE non activé ne doit pas produire un courant A HAUTE FREQUENCE supérieur à 150 mA sur une charge de 200 Ω à la terre puis à L'ELECTRODE NEUTRE.

2) Un circuit PATIENT BIPOLAIRE non activé ne doit pas produire plus de 50 mA sur une charge de 200 Ω connectée aux deux bornes ou – avec des bornes court-circuitées – sur une charge de 200 Ω à la terre et sur une charge de 200 Ω à l'ELECTRODE NEUTRE (les deux courants ajoutés, voir la Figure 201.107).

La conformité est vérifiée en effectuant des mesurages en utilisant les montages d'essai spécifiés en 201.8.7.3.101 b), et l'APPAREIL D'ELECTROCHIRURGIE HF est mis en place comme représenté à la Figure 201.106 (pour les circuits PATIENTS MONOPOLAIRES) ou à la Figure 201.107 (pour les circuits PATIENTS BIPOLAIRES).

201.8.8.2 Distance à travers une isolation solide ou utilisation d'une feuille mince comme matériau d'isolation

Amendement:

Les exigences de 8.8.2 a) et 8.8.2 b) de la norme générale ne s'appliquent pas aux ACCESSOIRES D'ELECTROCHIRURGIE HF.

201.8.8.3 Tension de tenue

Amendement:

Ces exigences ne s'appliquent pas aux ACCESSOIRES D'ELECTROCHIRURGIE HF. Les exigences et les essais relatifs aux ACCESSOIRES D'ELECTROCHIRURGIE HF sont donnés en 201.8.8.3.101 et en 201.15.101.4.

Conditions d'essai supplémentaires:

aa) Si, au cours de l'essai de tension de tenue d'une isolation solide constituant un MOYEN DE PROTECTION DU PATIENT, un claquage ou un contournement se produit à travers l'atmosphère à la DISTANCE DANS L'AIR spécifiée en 8.9 de la norme générale et en 201.8.5.1.2 du présent document, une barrière isolante peut être placée afin d'éviter ce claquage de telle sorte que l'isolation de protection puisse être soumise aux essais.

bb) Si, au cours de l'essai de tension de tenue d'une isolation solide constituant un MOYEN DE PROTECTION DU PATIENT, un claquage ou un contournement se produit à la LIGNE DE FUITE spécifiée en 8.9 de la norme générale et en 201.8.5.1.2 du présent document, l'essai doit alors être réalisé sur des composants fournissant un MOYEN DE PROTECTION DU PATIENT, tels que des transformateurs, des relais, des optocoupleurs ou des LIGNES DE FUITE sur les cartes de circuits imprimés.

Paragraphes complémentaires:

201.8.8.3.101 * Isolation des ACCESSOIRES ACTIFS

Les ACCESSOIRES ACTIFS et câbles d'ACCESSOIRES ACTIFS doivent avoir une isolation suffisante pour réduire tout RISQUE de brûlure thermique involontaire du PATIENT et de l'OPERATEUR dans des conditions d'UTILISATION NORMALE.

La conformité est vérifiée de la façon suivante:

Les échantillons d'essai autres que ceux dont le marquage indique qu'ils sont à usage unique doivent avoir subi des méthodes de nettoyage, de désinfection et de stérilisation appliquant un nombre de cycles tel que spécifié dans les instructions d'utilisation. Voir 7.9.2.12 de la norme générale.

Les parties isolées de tous les ACCESSOIRES ACTIFS autres que les PORTE-ELECTRODES ACTIVES et les CONNECTEURS ACTIFS doivent être préconditionnées par immersion dans une solution saline à 0,9 % pendant une durée de 12 h. Les conducteurs opérationnels qui ont pu être exposés pendant la préparation de l'essai, ainsi que l'isolation des câbles d'ACCESSOIRES ACTIFS à 100 mm des extrémités, doivent être protégés de tout contact avec la solution saline. Une fois le préconditionnement terminé, tout excès de solution saline doit être retiré des surfaces et des cavités en secouant les ACCESSOIRES et/ou en les essuyant au moyen d'un morceau de tissu sec.

Immédiatement après le préconditionnement dans une solution saline, les essais électriques applicables doivent être réalisés dans l'ordre suivant:

- *COURANT DE FUITE HF (201.8.8.3.102);*
- *tension de tenue HF (201.8.8.3.103);*
- *tension de tenue à la fréquence réseau (201.8.8.3.104).*

201.8.8.3.102 * Fuite HF des ACCESSOIRES ACTIFS

a) COURANT DE FUITE HF mesuré

L'isolation appliquée aux ACCESSOIRES ACTIFS, y compris l'ISOLATION DE L'ELECTRODE ACTIVE et à l'exception des CONNECTEURS ACTIFS, doivent limiter le COURANT DE FUITE HF traversant la surface externe de l'isolant à une valeur inférieure à I_{fuite}

La limite des ACCESSOIRES ACTIFS destinés à une application MONOPOLAIRE est:

$$I_{\text{fuite}}[\text{mA}] = 2{,}0 \times 10^{-5} \times d \times L \times f_{\text{essai}} \times U_{\text{crête}}$$

où

d est la dimension extérieure la plus faible de l'isolant, en mm,

f_{essai} est la fréquence de la tension d'essai HF, en kHz,

L est la longueur de l'isolation de l'échantillon traversée par le COURANT DE FUITE HF, en cm, et

$U_{\text{crête}}$ est la tension de crête HF d'essai.

La limite correspondante pour des ACCESSOIRES ACTIFS destinés à une application BIPOLAIRE est

$$I_{\text{fuite}}[\text{mA}] = 4{,}0 \times 10^{-5} \times d \times L \times f_{\text{essai}} \times U_{\text{crête}}$$

La conformité est vérifiée de la façon suivante:

Toute la longueur de l'isolation de l'échantillon, à l'exception d'une distance de 1 cm à l'extrémité des conducteurs exposés, mais sur une longueur de 30 cm au maximum, doit être, pendant toute la durée de l'essai, immergée dans une solution saline à 0,9 % ou enveloppée dans un tissu poreux trempé dans une solution saline. Tous les conducteurs fonctionnels internes doivent être connectés ensemble à un pôle d'une source de tension HF ayant une forme d'onde approximativement sinusoïdale et une fréquence f_{essai} comprise entre 300 kHz et 1 MHz. Le pôle opposé de la source de tension HF est relié à une électrode conductrice immergée dans la solution saline ou à une feuille enroulée sur la mi-section du tissu imbibé de solution saline. Le COURANT DE FUITE HF I_{fuite} est surveillé au moyen d'un instrument approprié branché en série sur la sortie de la source de tension HF. La tension d'essai HF $U_{\text{crête}}$ est surveillée entre les pôles de sortie de la source de tension HF.

La tension d'essai HF $U_{\text{crête}}$ est augmentée jusqu'à ce que la tension de crête soit égale à la valeur la plus faible de la TENSION ASSIGNEE D'ACCESSOIRE ou 400 $V_{\text{crête}}$. Le COURANT DE FUITE HF I_{fuite} mesuré ne doit pas dépasser la limite spécifiée.

b) Capacité du COURANT DE FUITE HF mesuré

En variante, les exigences du point a) précédent peuvent être satisfaites en limitant la capacité du COURANT DE FUITE HF mesuré pour des ACCESSOIRES ACTIFS destinés à une application MONOPOLAIRE à une valeur inférieure à

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

et pour des ACCESSOIRES ACTIFS destinés à une application BIPOLAIRE à une valeur inférieure ou égale à

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

où

d est la dimension extérieure la plus faible de l'isolant, en mm, et

L est la longueur de l'isolation de l'échantillon immergée dans une solution saline, en cm.

La capacité du COURANT DE FUITE HF mesuré ne doit pas dépasser la limite spécifiée applicable.

La conformité est vérifiée de la façon suivante:

Toute la longueur de l'isolation de l'échantillon, à l'exception d'une distance de 1 cm à l'extrémité des conducteurs exposés, mais sur une longueur de 30 cm au maximum, doit être, pendant toute la durée de l'essai, immergée dans une solution saline à 0,9 % ou enveloppée dans un tissu poreux trempé dans une solution saline. Tous les conducteurs fonctionnels internes doivent être connectés ensemble à une borne de mesure d'un instrument de mesure de la capacité comportant une fréquence de détection comprise entre 100 kHz et 1 MHz. La borne de mesure opposée de l'instrument de mesure de la capacité est raccordée à une électrode conductrice immergée dans la solution saline ou à une feuille enroulée à mi-section du tissu imbibé de solution saline. La capacité de fuite HF est la capacité indiquée par l'instrument de mesure de la capacité lorsqu'il est mis en fonctionnement conformément aux pratiques recommandées par le FABRICANT de l'instrument.

201.8.8.3.103 * Tension de tenue HF des ACCESSOIRES ACTIFS

L'isolation appliquée aux ACCESSOIRES ACTIFS doit pouvoir résister à une tension HF de 120 % de la TENSION ASSIGNEE D'ACCESSOIRE.

La conformité est vérifiée de la façon suivante:

Les essais doivent être conduits à une tension d'essai liée à la TENSION ASSIGNEE D'ACCESSOIRE spécifiée par le FABRICANT de l'ACCESSOIRE D'ELECTROCHIRURGIE HF dans les instructions d'utilisation (voir 201.7.9.2.14 e)), comme décrit de manière détaillée dans les méthodes d'essai suivantes. Pour les ELECTRODES ACTIVES et les câbles d'ACCESSOIRES ACTIFS, cinq tours maximum de fils conducteur nu, d'un diamètre de 0,4 mm ± 10 %, sont enroulés sur une partie de l'isolation qui a été préconditionnée dans la solution saline, à un pas d'au moins 3 mm sans déformer la surface de l'échantillon. Si nécessaire, pour éviter une décharge en arc par inadvertance, la LIGNE DE FUITE entre ce fil conducteur et les parties fonctionnelles conductrices des ELECTRODES ACTIVES peut être portée à 10 mm par application de l'isolation. Ce supplément d'isolation doit avoir une épaisseur maximale de 1 mm et ne doit pas couvrir plus de 2 mm de l'ISOLATION DE L'ELECTRODE ACTIVE. Un pôle de la source de tension d'essai HF doit être relié au fil conducteur nu utilisé pour l'essai et le pôle opposé doit être connecté simultanément à tous les conducteurs fonctionnels de l'échantillon soumis à l'essai.

Les PORTE-ELECTRODES ACTIVES, ainsi que tout câble non FIXE à demeure et les ELECTRODES ACTIVES amovibles qui sont spécifiés comme étant compatibles doivent être enveloppés dans un tissu poreux trempé dans une solution saline à 0,9 %. Ce tissu doit couvrir l'ensemble de la surface extérieure des porte-électrodes et s'étendre sur au moins 150 mm sur la surface du câble et 5 mm sur l'ISOLATION DE L'ELECTRODE ACTIVE. Si nécessaire, la LIGNE DE FUITE entre le tissu et les parties fonctionnelles conductrices exposées de l'ELECTRODE ACTIVE peut être isolée comme décrit ci-dessus. Une feuille métallique est utilisée pour envelopper à mi-section le tissu imbibé de solution saline; la mi-section est raccordée à un pôle de la source de tension d'essai HF. Tous les conducteurs fonctionnels internes des échantillons soumis à

l'essai, y compris la(les) extrémité(s) fonctionnelle(s) de l'ELECTRODE ACTIVE, doivent être connectés simultanément au pôle opposé.

La tension d'essai HF de crête est surveillée entre les pôles de sortie de la source de tension HF. La puissance de sortie de la source de tension d'essai HF est ensuite augmentée jusqu'à ce que la tension de crête soit égale à 120 % de la tension de crête selon la TENSION ASSIGNEE D'ACCESSOIRE. La puissance de sortie est maintenue pendant 30 s de sorte que l'isolation de l'échantillon d'essai est soumise à une contrainte. Aucun claquage du matériau isolant ne doit avoir lieu et la même isolation doit ensuite être soumise à l'essai, à la fréquence réseau, conformément à 201.8.8.3.104.

NOTE Un effet couronne de couleur bleue est normal et n'est pas considéré comme un claquage de l'isolation.

Les parties des échantillons d'essai qui ne sont pas isolées en UTILISATION NORMALE doivent être protégées de manière adéquate contre tout contact avec la solution saline lors du préconditionnement et cette protection doit rester en place pendant les essais.

Conditions d'essai:

Appliquer une tension approximativement sinusoïdale à une fréquence de 400 kHz ± 100 kHz de forme d'onde continue ou, en variante, de forme d'onde modulée (fréquence de modulation supérieure à 10 kHz), la tension d'essai de crête étant égale à 120 % de la tension de crête, conformément à la TENSION ASSIGNEE D'ACCESSOIRE spécifiée par le FABRICANT de l'ACCESSOIRE D'ELECTROCHIRURGIE HF et avec un FACTEUR DE CRETE de l'essai (cf_{essai}) comme défini ci-après:

Pour les TENSIONS ASSIGNEES D'ACCESSOIRE inférieures ou égales à 1 600 V:

$$cf_{essai} \leq 2$$

Pour les TENSIONS ASSIGNEES D'ACCESSOIRE supérieures à 1 600 V et inférieures ou égales à 4 000 V:

$$cf_{essai} = \frac{U_{acc} - 400\,[V]}{600\,[V]} \quad \text{(avec une tolérance de ± 10 %)}$$

où

U_{acc} est la tension assignée d'accessoire, en V.

Pour les TENSIONS ASSIGNEES D'ACCESSOIRE supérieures à 4 000 V:

$$cf_{essai} = 6 \quad \text{(avec une tolérance de ± 10 %)}$$

Les ACCESSOIRES ACTIFS destinés à être utilisés avec des MODES ELECTROCHIRURGICAUX HF ou des réglages de la puissance de sortie exigeant une approbation spécifique doivent résister à 120 % de la tension de crête de sortie d'un tel MODE ELECTROCHIRURGICAL HF ou réglage de la puissance de sortie. Ils doivent être soumis à l'essai dans les mêmes conditions que celles décrites ci-dessus, mais avec le FACTEUR DE CRETE réel d'un tel MODE ELECTROCHIRURGICAL HF ou réglage de la puissance de sortie (voir 201.7.9.2.2.101 c) 3)).

Lorsque les conditions d'essai présentent une charge capacitive empêchant le maintien des caractéristiques de la tension d'essai HF, des essais peuvent être réalisés sur les PORTE-ELECTRODES ACTIVES dans des sections suffisamment petites de l'isolation, en séquence, jusqu'à ce que la totalité de la surface extérieure du PORTE-ELECTRODES ACTIVES (dont 150 mm sur la surface du câble et 5 mm sur l'ISOLATION DE L'ELECTRODE ACTIVE au minimum) ait été vérifiée.

201.8.8.3.104 * Tension de tenue à la fréquence réseau des ACCESSOIRES ACTIFS

L'isolation appliquée à un ACCESSOIRE ACTIF, y compris les parties de l'isolation qui ont été soumises aux essais HF conformément à 201.8.8.3.103, doivent supporter une tension de crête en courant continu ou à la fréquence du réseau de 1 000 V supérieure à la TENSION ASSIGNEE D'ACCESSOIRE, comme spécifié par le FABRICANT de l'ACCESSOIRE D'ELECTROCHIRURGIE HF.

La conformité est vérifiée comme suit:

La source de tension d'essai doit générer un signal en courant continu ou à la fréquence réseau. La durée de l'essai doit être de 30 s pour les PORTE-ELECTRODES ACTIVES, LES ELECTRODES ACTIVES et les CONNECTEURS ACTIFS. La durée de l'essai pour les câbles des ACCESSOIRES ACTIFS doit être de 5 min. Bien qu'une décharge en couronne puisse se produire, aucun claquage de l'isolation ou aucun contournement ne doit se produire. Immédiatement après cet essai de tension de tenue, tout INTERRUPTEUR MANUEL incorporé doit être mis 10 fois en fonctionnement. Un ohmmètre, ou tout autre moyen approprié, doit être utilisé pour l'essai visant à vérifier si le mécanisme de commutation fonctionne comme prévu en s'assurant que, lorsqu'il est connecté à un APPAREIL D'ELECTROCHIRURGIE HF, la sortie HF est mise hors tension lorsque l'INTERRUPTEUR MANUEL est libéré.

Les parties isolées des CONNECTEURS ACTIFS dont la LIGNE DE FUITE est à plus de 10 mm des conducteurs fonctionnels exposés doivent être enveloppées d'un tissu poreux imbibé de solution saline à 0,9 %. Le tissu est ensuite enveloppé à mi-section d'une feuille métallique. La tension d'essai est appliquée entre la feuille métallique et l'ensemble des contacts des CONNECTEURS ACTIFS fonctionnels.

Toute la longueur de l'isolation des câbles d'ACCESSOIRES ACTIFS, y compris la partie précédemment soumise à l'essai HF conformément à 201.8.8.3.103, mais à l'exclusion des sections qui se trouvent à 100 mm des extrémités, doit être immergée dans une solution saline à 0,9 %. La tension d'essai est appliquée entre l'électrode conductrice immergée dans la solution saline et tous les conducteurs du câble simultanément.

Les PORTE-ELECTRODES ACTIVES équipés de leurs électrodes amovibles sont préparés pour l'essai et raccordés à la source de tension d'essai en utilisant les mêmes techniques que celles décrites en 201.8.8.3.103. Le tissu imbibé de solution saline et la feuille métallique appliquée pour cet essai peuvent être laissés en place à condition de s'assurer que le tissu reste bien humide.

201.8.9.1.5 APPAREILS EM de CARACTERISTIQUES ASSIGNEES pour altitudes élevées

Amendement:

Cette exigence ne s'applique pas à la séparation entre les CIRCUITS PATIENTS HF et l'ENVELOPPE, y compris les ENTREES DE SIGNAL et les SORTIES DE SIGNAL, et entre les différents CIRCUITS PATIENTS HF.

Pour les APPAREILS D'ELECTROCHIRURGIE HF et les APPAREILS ASSOCIES, les exigences relatives à la séparation entre les CIRCUITS PATIENTS HF et l'ENVELOPPE, y compris les ENTREES DE SIGNAL et les SORTIES DE SIGNAL, entre les CIRCUITS PATIENTS HF et le circuit intermédiaire et entre les différents CIRCUITS PATIENTS HF, sont spécifiées en 201.8.5.1.2.

201.8.10.4 Dispositifs de commande TENUS A LA MAIN et pédales de commande

201.8.10.4.1 Limitation des tensions de fonctionnement

Le paragraphe 8.10.4.1 de la norme générale ne s'applique pas. Voir 201.8.10.4.101.

201.8.10.4.2 * Câbles de raccordement

Remplacement:

Les dispositifs d'arrêt de traction d'ACCESSOIRES ACTIFS doivent être conçus de manière à réduire le plus possible tout RISQUE pour les PATIENTS et les OPERATEURS résultant de conducteurs ou d'isolation endommagés du fait d'une flexion ou d'une tension excessive des câbles.

La conformité doit être vérifiée par examen et par l'essai suivant:

Les dispositifs d'arrêt de traction sur des PORTE-ELECTRODES ACTIVES et des CONNECTEURS ACTIFS sont soumis à l'essai un à la fois.

Le PORTE-ELECTRODES ACTIVES ou le CONNECTEUR ACTIF soumis à l'essai est FIXE sur un appareil similaire à celui représenté à la Figure 201.108, de sorte que lorsque l'élément oscillant de l'appareil est au milieu de sa course, l'axe du câble, au point où il sort de la partie soumise à l'essai, est vertical et passe par l'axe d'oscillation. Le câble est inséré par une ouverture de 300 mm à partir de l'axe d'oscillation et un poids égal à celui du câble et du connecteur de l'ACCESSOIRE ACTIF est FIXE au câble sous cette ouverture afin d'appliquer une tension au câble. Il convient que le diamètre maximal du trou n'excède pas le double du diamètre du câble.

Lorsqu'un dispositif d'arrêt de traction du PORTE-ELECTRODES ACTIVES ou du CONNECTEUR ACTIF soumis à l'essai est équipé de deux câbles ou plus, ils doivent être soumis aux essais ensemble, le poids total FIXE au dispositif d'arrêt de traction étant la somme des poids dont il est exigé qu'ils soient individuellement appliqués à chaque câble.

L'élément oscillant subit une rotation d'un angle de 90° (45° de chaque côté de l'axe vertical).

Le nombre de cycles appliqués aux dispositifs d'arrêt de traction des PORTE-ELECTRODES ACTIVES doit être de 10 000 (200 pour les ACCESSOIRES ACTIFS à usage unique) à un taux d'environ 30 cycles par minute. Le nombre de cycles appliqués aux dispositifs d'arrêt de traction des CONNECTEURS ACTIFS doit être de 5 000 (100 pour les ACCESSOIRES ACTIFS à usage unique) à un taux d'environ 30 cycles par minute.

Après l'essai, le câble ne doit pas s'être détendu et ne doit pas présenter d'éventuels dommages. Pour les câbles multiconducteurs, il ne doit pas y avoir de court-circuit entre les conducteurs individuels. Le poids de traction doit être augmenté jusqu'à 1 kg et il est vérifié, au moyen d'un courant continu, que la continuité des conducteurs individuels ne dépasse pas 1 A.

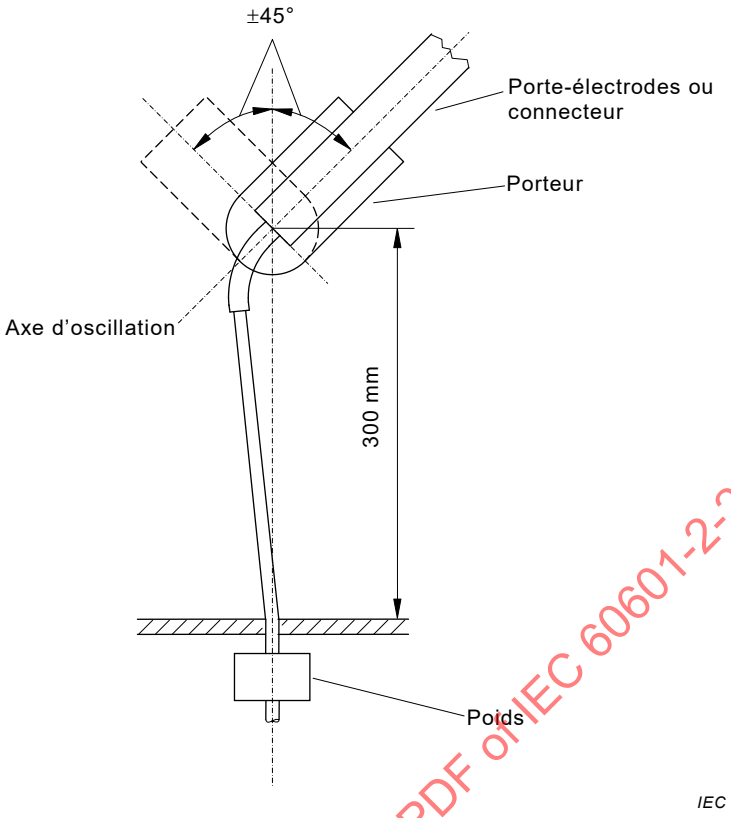


Figure 201.108 – Montage d'essai pour dispositifs d'arrêt de traction d'ACCESSOIRE ACTIF

Paragraphes complémentaires:

201.8.10.4.101 * CAPTEURS A INTERRUPTEUR

201.8.10.4.101.1 Généralités

Sauf disposition différente de 201.8.10.4.101.2, l'APPAREIL D'ELECTROCHIRURGIE HF et l'APPAREIL ASSOCIE applicable doivent être équipés d'un CAPTEUR A INTERRUPTEUR exigeant une activation continue pour alimenter les BORNES DE SORTIES ACTIVES.

Le CAPTEUR A INTERRUPTEUR pour les ACCESSOIRES ACTIFS raccordés par câble doit être alimenté à partir d'une source isolée de la PARTIE RELIEE AU RESEAU et de la terre, d'une tension ne dépassant pas 12 V s'il existe une LIAISON CONDUCTRICE avec la PARTIE APPLIQUEE, et ne dépassant pas 24 V en courant alternatif ou 34 V en courant continu dans les autres cas.

NOTE 1 Cette exigence s'applique aux tensions apparaissant dans les CAPTEURS A INTERRUPTEUR. Les tensions HF en mode commun ne sont pas prises en compte.

En CONDITION DE PREMIER DEFAUT, le CAPTEUR A INTERRUPTEUR ne doit pas donner lieu à un (des) COURANT(S) DE FUITE PATIENT basse fréquence supérieur(s) aux limites admissibles (voir 201.8.7.3).

La conformité est vérifiée par examen, vérification fonctionnelle et mesurage de la tension et du(des) COURANT(S) DE FUITE.

Lorsque le CAPTEUR A INTERRUPTEUR est équipé de bornes d'entrée pour le raccordement à des contacts de commutation électrique externe, il ne doit pas être possible d'activer les sorties de l'APPAREIL D'ELECTROCHIRURGIE HF lorsque les bornes d'entrée sont reliées par une résistance supérieure ou égale à 1 000 Ω.

La conformité est vérifiée par un essai fonctionnel.

Chaque CAPTEUR A INTERRUPTEUR doit uniquement activer son unique BORNE DE SORTIE ACTIVE prévue et ne doit pas commander plus d'un MODE ELECTROCHIRURGICAL HF à tout moment.

NOTE 2 Pour les besoins de la présente exigence, les deux bras d'un interrupteur à touche basculante sont considérés comme étant deux interrupteurs individuels.

201.8.10.4.101.2 Activation non continue

Un mode d'activation non continue du CAPTEUR A INTERRUPTEUR est uniquement accepté si

a) la sortie de l'APPAREIL D'ELECTROCHIRURGIE HF s'arrête automatiquement conformément à l'application spécifique de l'appareil;

b) un indicateur visible est prévu pour indiquer à l'OPERATEUR que l'APPAREIL D'ELECTROCHIRURGIE HF est réglé sur ledit mode d'application spécifique, et

c) il est prévu un moyen de désactivation manuelle des sorties.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT et essai fonctionnel.

201.8.10.4.101.3 Activation de variation d'impédance

Un CAPTEUR A INTERRUPTEUR destiné à activer une sortie HF en réponse à une impédance apparaissant entre des BORNES DE SORTIES ACTIVES n'est acceptable que pour la COAGULATION BIPOLAIRE.

Lorsqu'un tel CAPTEUR A INTERRUPTEUR à variation d'impédance est prévu comme solution de remplacement ou comme supplément à un CAPTEUR A INTERRUPTEUR de détection de la fermeture des contacts, alors

a) il ne doit pas être possible, quelles que soient les conditions, d'alimenter la sortie HF uniquement par suite d'une interruption et d'un rétablissement de l'ALIMENTATION RESEAU, et

b) l'activation à variation d'impédance ne doit être validée qu'en réponse à une sélection spécifique de l'OPERATEUR, et

c) cette sélection doit être indiquée de manière visible pour l'OPERATEUR.

Les CAPTEURS A INTERRUPTEUR à variation d'impédance ne doivent pas être autorisés pour l'activation de sorties HF MONOPOLAIRES. Les exigences du présent paragraphe ne s'appliquent pas aux CAPTEURS A INTERRUPTEUR qui sont uniquement capables de connecter automatiquement une sortie HF conformément à l'objectif prévu de modes d'application spécifiques (voir 201.8.10.4.101.2 a)).

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT et essai fonctionnel.

201.8.10.4.101.4 Pédales

Les pédales doivent être conformes à l'exigence suivante (voir également 201.11.6.5 et 201.12.2).

La force exigée pour actionner la pédale doit être supérieure ou égale à 10 N, appliquée sur une surface de 625 mm^2 en tout point de la surface de fonctionnement de la pédale.

La conformité est vérifiée par mesurage de l'effort de commande.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

L'Article 9 de la norme générale s'applique.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 de la norme générale s'applique.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de la norme générale s'applique avec les exceptions suivantes:

201.11.1.1 * Température maximale en UTILISATION NORMALE

Addition:

L'APPAREIL D'ELECTROCHIRURGIE HF, réglé pour fournir sa PUISSANCE DE SORTIE ASSIGNEE sur une charge résistive en utilisant les câbles d'électrodes, est mis en fonctionnement pendant 1 h au CYCLE D'UTILISATION spécifié par le FABRICANT, mais avec des temps de fonctionnement d'au moins 10 s alternant avec un temps de repos ne dépassant pas 30 s.

201.11.1.2.1 PARTIES APPLIQUEES destinées à fournir de la chaleur à un PATIENT

Addition:

Les ELECTRODES ACTIVES sont considérées comme des PARTIES APPLIQUEES destinées à fournir de la chaleur à un PATIENT dans le cadre de leur effet clinique prévu (INCISION et COAGULATION). L'indication des températures et des effets cliniques n'est pas exigée.

201.11.1.2.2 PARTIES APPLIQUEES non destinées à fournir de la chaleur à un PATIENT

Addition:

Les ELECTRODES NEUTRES sont considérées comme des PARTIES APPLIQUEES non destinées à fournir de la chaleur à un PATIENT (voir 201.12.4.101 et 201.15.101.5).

201.11.6.3 * Renversement sur des APPAREILS EM et des SYSTEMES EM

Remplacement:

L'ENVELOPPE de l'APPAREIL D'ELECTROCHIRURGIE HF et des APPAREILS ASSOCIES doit être construite de façon que du liquide renversé en UTILISATION NORMALE ne mouille pas les isolations électriques ou autres composants susceptibles, lorsqu'ils sont humides, de compromettre la sécurité de l'APPAREIL D'ELECTROCHIRURGIE HF et des APPAREILS ASSOCIES.

La conformité est vérifiée par l'essai suivant.

Un litre d'eau est versé de façon continue au centre de la surface supérieure de l'APPAREIL D'ELECTROCHIRURGIE HF et des APPAREILS ASSOCIES pendant 15 s. Les APPAREILS D'ELECTROCHIRURGIE HF et les APPAREILS ASSOCIES destinés à être encastrés dans une cloison ou une armoire sont soumis aux essais, montés comme recommandé, en versant l'eau sur la cloison au-dessus du tableau de commande. Après ce traitement, l'APPAREIL D'ELECTROCHIRURGIE HF et les APPAREILS ASSOCIES doivent satisfaire à l'essai de tension de tenue spécifié en 201.8.8.3, et il doit être vérifié par examen que l'eau qui a pu pénétrer dans

l'ENVELOPPE ne peut pas compromettre la sécurité de l'APPAREIL D'ELECTROCHIRURGIE HF et des APPAREILS ASSOCIES. En particulier, il ne doit pas y avoir de trace d'eau sur les isolants dont les LIGNES DE FUITE sont spécifiées en 8.9.1 de la norme générale.

201.11.6.5 Pénétration d'eau ou de corps solides dans les APPAREILS EM et les SYSTEMES EM

Addition:

a) * Les pièces de commutation électrique des pédales d'APPAREILS D'ELECTROCHIRURGIE HF et d'APPAREILS ASSOCIES destinés à être utilisés en salles d'opération doivent être protégées contre les effets de la pénétration des liquides susceptibles d'entraîner une mise sous tension intempestive de la PARTIE APPLIQUEE.

La conformité est vérifiée par l'essai suivant.

La pédale doit être complètement immergée sous 150 mm d'eau salée à 0,9 % pendant 30 min. Pendant cette période d'immersion, elle doit être reliée à un CAPTEUR A INTERRUPTEUR correspondant à celui auquel elle est reliée en UTILISATION NORMALE et actionnée 50 fois. Le CAPTEUR A INTERRUPTEUR doit enregistrer une désactivation à chaque libération de la pédale.

b) * Les parties électriques d'INTERRUPTEURS MANUELS doivent être protégées contre les effets de la pénétration des liquides susceptible d'entraîner une mise sous tension intempestive de la PARTIE APPLIQUEE (voir également 201.8.8.3.103*)*.

La conformité est vérifiée par l'essai suivant.

L'impédance en courant alternatif de chacune des bornes de commutation du CONNECTEUR ACTIF doit être mesurée à une fréquence d'au moins 1 kHz et à une tension inférieure à 12 V. Le PORTE-ELECTRODES ACTIVES est maintenu horizontalement, à 50 mm au moins au-dessus d'une surface quelconque, les parties actives de l'interrupteur se trouvant dans la position la plus élevée. Un litre de solution saline à 0,9 % est versé de façon continue sur le dessus du PORTE-ELECTRODES ACTIVES pendant 15 s de façon à ce qu'il soit mouillé sur toute sa longueur. Il est admis que le liquide s'écoule librement. L'impédance en courant alternatif des bornes de commutation doit rester supérieure à 2 000 Ω.

Immédiatement après, chaque INTERRUPTEUR MANUEL est actionné et libéré 10 fois. L'impédance en courant alternatif des bornes de commutation doit dépasser 2 000 Ω dans les 0,5 s suivant chaque libération.

201.11.6.7 * Stérilisation des APPAREILS EM et des SYSTEMES EM

Addition:

Sauf s'ils sont marqués comme étant destinés à un usage unique, les ACCESSOIRES ACTIFS ainsi que toutes les pièces amovibles correspondantes, à l'exception des CONNECTEURS ACTIFS qui peuvent être séparés des câbles sans l'utilisation d'OUTILS, doivent répondre aux exigences de la présente norme particulière après avoir été soumis aux essais conformément au présent paragraphe de la norme générale.

201.11.8 Coupure de l'alimentation / du RESEAU D'ALIMENTATION vers l'APPAREIL EM

Addition:

Lors de la remise sous tension d'un APPAREIL D'ELECTROCHIRURGIE HF, consécutive à une mise hors tension, ou lors de coupures et de rétablissements de l'ALIMENTATION RESEAU

- la puissance de sortie, pour un réglage donné de la commande correspondante, ne doit pas augmenter de plus de 20 %, et
- le MODE ELECTROCHIRURGICAL HF ne doit pas être modifié, sauf s'il s'agit d'un passage en état de veille sans aucune sortie.

La conformité est vérifiée par mesurage de la puissance moyenne sur 1 s et observation du mode de fonctionnement

a) *lors de manœuvres répétées de l'interrupteur réseau de l'APPAREIL D'ELECTROCHIRURGIE HF;*

b) *lors de coupures et de rétablissements de l'ALIMENTATION RESEAU, l'interrupteur de l'APPAREIL D'ELECTROCHIRURGIE HF étant laissé sur la position «MARCHE».*

201.12 Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

L'Article 12 de la norme générale s'applique avec les exceptions suivantes:

201.12.1 Précision des commandes et des instruments

Paragraphes complémentaires:

201.12.1.101 Exactitude du réglage de la commande de puissance de sortie

Pour les puissances de sortie supérieures à 10 % de la PUISSANCE DE SORTIE ASSIGNEE, la puissance effective, en fonction de la résistance de charge et du réglage de la commande de la puissance de sortie, ne doit pas s'écarter de plus de ± 20 % de celle indiquée sur les schémas spécifiés en 201.7.9.3.1.

La conformité est vérifiée en effectuant l'essai de 201.12.1.102 mais en utilisant les valeurs appropriées de la résistance de charge.

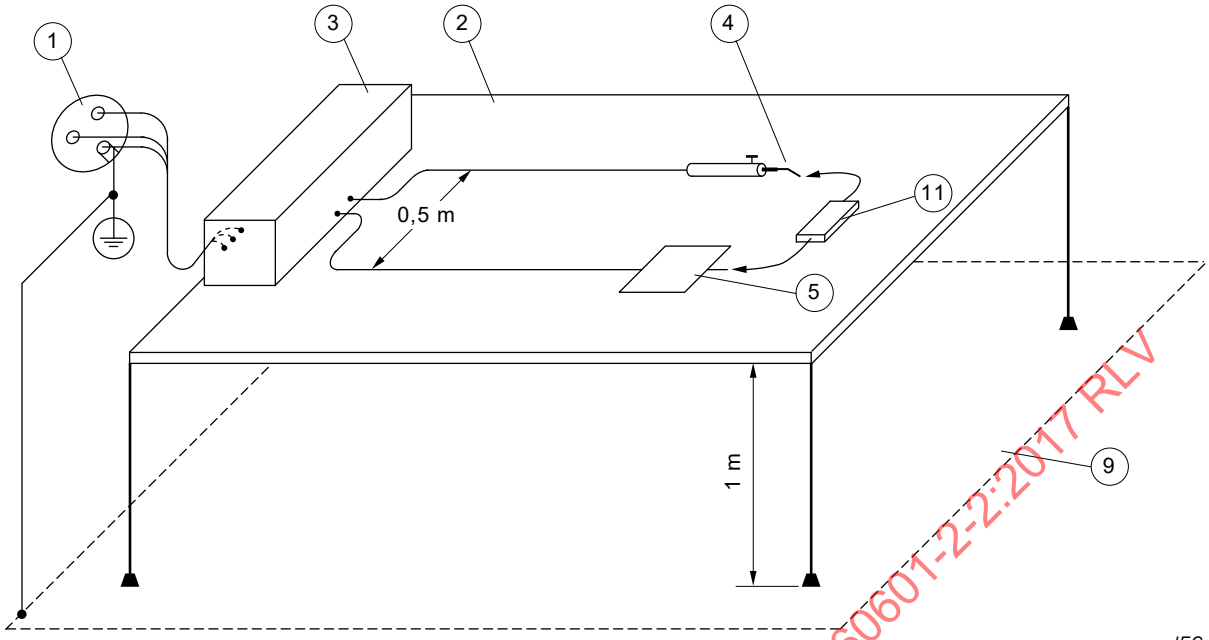
201.12.1.102 Monotonicité du réglage de la commande de puissance de sortie

La puissance de sortie ne doit pas augmenter avec la diminution du réglage de la commande de la puissance de sortie (voir 201.7.9.3.1, la Figure 201.109 et la Figure 201.110).

La conformité est vérifiée par l'essai suivant:

a) ** Sorties MONOPOLAIRES*

La puissance de sortie en fonction du réglage de la commande de la puissance de sortie est mesurée à au moins cinq valeurs particulières de la résistance de charge, à savoir 100 Ω, 200 Ω, 500 Ω, 1 000 Ω, 2 000 Ω, et à la CHARGE ASSIGNEE. Des ACCESSOIRES ACTIFS et des ELECTRODES NEUTRES fournis avec l'APPAREIL D'ELECTROCHIRURGIE HF ou des longueurs de conducteurs isolés de 3 m doivent être utilisé(e)s pour la connexion des résistances de charge.



Légende

1 ALIMENTATION RESEAU
2 Table en matériau isolant
3 APPAREIL D'ELECTROCHIRURGIE HF
4 ELECTRODE ACTIVE
5 ELECTRODE NEUTRE, en métal ou en contact avec une feuille métallique de mêmes dimensions
9 Plan conducteur relié à la terre
11 Résistance de charge exigée avec le dispositif de mesure de la puissance HF

Figure 201.109 – Mesurage de la puissance de sortie – sortie MONOPOLAIRE

b) * *Sorties BIPOLAIRES*

La puissance de sortie en fonction du réglage de la commande de la puissance de sortie est mesurée à au moins cinq valeurs particulières de la résistance de charge, à savoir 10 Ω, 50 Ω, 200 Ω, 500 Ω, 1 000 Ω, et à la CHARGE ASSIGNEE. Le câble BIPOLAIRE fourni avec l'APPAREIL D'ELECTROCHIRURGIE HF ou une longueur de 3 m de câble isolé à deux conducteurs d'une TENSION ASSIGNEE de 600 V ou plus doit être utilisé(e) pour la connexion des résistances de charge.

Les FABRICANTS doivent fournir des instructions spécifiques sur la façon de mettre en place ces mesurages sur des formes alternatives d'ACCESSOIRES BIPOLAIRES.