

Medical electrical equipment —

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

The European Standard EN 60601-2-2:2007 has the status of a
British Standard

ICS 11.040.30

National foreword

This British Standard was published by BSI. It is the UK implementation of EN 60601-2-2:2007. It is identical with IEC 60601-2-2:2006. It supersedes BS EN 60601-2-2:2001 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**Medical electrical equipment -
Part 2-2: Particular requirements for the safety
of high frequency surgical equipment
(IEC 60601-2-2:2006)**

Appareils électromédicaux -
Partie 2-2: Exigences particulières
pour la sécurité des appareils
d'électrochirurgie à courant
haute fréquence
(CEI 60601-2-2:2006)

Medizinische elektrische Geräte -
Teil 2-2: Besondere Festlegungen
für die Sicherheit
von Hochfrequenz-Chirurgiegeräten
(IEC 60601-2-2:2006)

This European Standard was approved by CENELEC on 2006-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/548/FDIS, future edition 4 of IEC 60601-2-2, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-2 on 2006-10-01.

This European Standard supersedes EN 60601-2-2:2000.

Significant revisions in EN 60601-2-2:2007 refer mainly to the following:

- revision of requirements and compliance testing for HF SURGICAL ACCESSORIES to make them independent of specific HF surgical generators;
- revision and expansion of Clause 2 definitions;
- addition of thermal, electrical and adhesive requirements testing for NEUTRAL ELECTRODES;
- revision of dielectric strength requirements for HF SURGICAL ACCESSORIES;
- accommodation of HF surgical generators that don't require continuous operation of the SWITCH SENSOR;
- addition of Annex BB to provide EMD information about HF SURGICAL EQUIPMENT.

This Particular Standard amends and supplements EN 60601-1:1990, *Medical Electrical Equipment – Part 1: General requirements for safety*, and its amendments, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2007-10-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2009-10-01

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications and headings of items: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC (MDD). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-2:2006 was approved by CENELEC as a European Standard without any modification.

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INTRODUCTION

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

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

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

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

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

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

1.2 Object

Replacement:

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

1.3 Particular Standards

Addition:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

2.1.101

ACTIVE ACCESSORY

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

2.1.102**ACTIVE CONNECTOR**

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

2.1.103**ACTIVE ELECTRODE**

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

2.1.104**ACTIVE HANDLE**

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

2.1.105*ASSOCIATED EQUIPMENT**

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

2.1.106**BIPOLAR ELECTRODE**

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

2.1.107**CONTACT QUALITY MONITOR****CQM**

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

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

2.1.108**ENDOSCOPICALLY USED ACCESSORY**

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

[IEC 60601-2-18, definition 2.1.102]

2.1.109**FINGERSWITCH**

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

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

2.1.110**HF SURGICAL ACCESSORY**

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

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

2.1.111

MONITORING NE

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

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

2.1.112

NE CONTINUITY MONITOR

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

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

2.1.113

NEUTRAL ELECTRODE

NE

electrode of a relatively large area for connection to the body of the PATIENT, intended to provide a return path for the HIGH FREQUENCY current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided

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

2.1.114

SWITCH SENSOR

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

*2.2.101

HF SURGICAL EQUIPMENT

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

2.3.101

ACTIVE ELECTRODE INSULATION

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

*2.4.101

MAXIMUM OUTPUT VOLTAGE

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

2.4.102

RATED ACCESSORY VOLTAGE

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

2.7.101

ACTIVE OUTPUT TERMINAL

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

*2.12.101

BIPOLAR

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

2.12.102*COAGULATION**

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

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

2.12.103*CUTTING**

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

2.12.104*EARTH REFERENCED PATIENT CIRCUIT**

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

2.12.105*FULGURATION**

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

2.12.106**HF ISOLATED PATIENT CIRCUIT**

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

2.12.107*HF SURGICAL MODE**

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

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

2.12.108*HIGH FREQUENCY****HF**

frequencies greater than 200 kHz

2.12.109*MONOPOLAR**

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

2.12.110**RATED LOAD**

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

2.12.111**RATED OUTPUT POWER**

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

***2.12.112**

CREST FACTOR

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

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

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Additional SINGLE FAULT CONDITIONS:

- aa) failure in the NE CONTINUITY MONITOR or CONTACT QUALITY MONITOR which might cause a SAFETY HAZARD (see 59.101);
- bb) a defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see 56.11);
- cc) any defect which results in the unwanted energization of the PATIENT CIRCUIT (see 59.102);
- dd) any defect which results in a significant increase in output power relative to the output setting (see 51.5).

4 General requirements for tests

This clause of the General Standard applies except as follows:

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

Add the following:

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

5 Classification

This clause of the General Standard applies except as follows:

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

Amendment:

Delete TYPE B APPLIED PART.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

l) Classification

Addition:

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

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



IEC 1192/06

Figure 101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT



IEC 1193/06

Figure 102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT

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

* p) Output

This item of the General Standard does not apply.

*6.3 Marking of controls and instruments

Additional item:

- aa) The output control shall have a scale and/or associated indicator showing the relative units of HIGH FREQUENCY output. The indication shall not be marked in watts unless the indicated power is delivered with an accuracy of $\pm 20\%$ over the total load resistance range specified in 6.8.3.

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

NOTE The compliance test is the application of Clause 50.

*6.7 Indicator lights and push-buttons

a) Colours of indicator lights

Addition:

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

green: power supply switched on;

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

yellow: CUTTING mode activated;
blue: COAGULATION mode activated.

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

b) Colours of unilluminated push-buttons

Addition:

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

NOTE Blended outputs are regarded as a CUTTING mode.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Additional items:

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

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

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

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

- * 1) The entire area of the NEUTRAL ELECTRODE should be reliably attached to the PATIENT's body and as close to the operating field as possible (see Notes 1 and 2).
- * 2) The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.
- * 3) Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze (see Notes 1 and 2).
- * 4) When HF SURGICAL EQUIPMENT and physiological monitoring EQUIPMENT are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

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

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

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

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

- 7) The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a SAFETY HAZARD at low power settings. For example, with argon beam COAGULATION, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.
- *8) Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power (see Notes 1 and 2).
- 9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

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

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

- 10) For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.
- 11) For HF SURGICAL EQUIPMENT with an operating mode as described in 46.103 b), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use.

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

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

- cc) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic EQUIPMENT.
- dd) Advice for the OPERATOR regularly to inspect the ACCESSORIES. In particular, electrode cables and ENDOSCOPICALLY USED ACCESSORIES should be checked for possible damage.
- *ee) For ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES, including separately supplied parts thereof, the RATED ACCESSORY VOLTAGE.
- *ff) For HF SURGICAL EQUIPMENT, the MAXIMUM OUTPUT VOLTAGE for each HF SURGICAL MODE and instruction regarding the RATED ACCESSORY VOLTAGE as follows:
 - i) For situations where the MAXIMUM OUTPUT VOLTAGE ($U_{\max}$) is less than or equal to 1 600 V, provide instruction that ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES should be selected that have a RATED ACCESSORY VOLTAGE equal to or greater than the MAXIMUM OUTPUT VOLTAGE.

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

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

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

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

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

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

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

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

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

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

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

- ii) On end use packaging for NEUTRAL ELECTRODES:

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

- jj) On instructions for use for MONITORING NEUTRAL ELECTRODES:

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

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

*6.8.3 Technical description

Additional items:

- *aa) Power output data – MONOPOLAR output (for all HF SURGICAL MODES available, any variable “blend” control being set to the maximum position)
 - 1. Diagrams showing the power output at full and half output control settings minimally over the range of load resistance 100 Ω to 2 000 Ω , but extended as necessary to include the RATED LOAD.
 - 2. Diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above.
- *bb) Power output data – BIPOLAR output (for all HF SURGICAL MODES as defined in item aa))
 - 1. Diagrams showing the power output at full and half output control settings minimally over the range of load resistance 10 Ω to 1 000 Ω , but extended as necessary to include the RATED LOAD.
 - 2. Diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above.
- cc) Voltage output data – MONOPOLAR and BIPOLAR output (for all HF SURGICAL MODES available)

Maximum voltage data required by 6.8.2 ee).
- *dd) Designation of the APPLIED PART(S) according to 19.3.101 of this Particular Standard.

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

7 Power input

This clause of the General Standard applies except as follows:

7.1

Amendment:

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

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

SECTION TWO – ENVIRONMENTAL CONDITIONS

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

SECTION THREE – PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS

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

14 Requirements related to classification

This clause of the General Standard applies except as follows:

14.6 TYPES B, BF and CF APPLIED PARTS

Replacement:

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

17 Separation

This clause of the General Standard applies except as follows:

***17 h) Defibrillator protection**

Amendment:

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

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

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

18 Protective earthing, functional earthing and potential equalization

This clause of the General Standard applies except as follows:

Additional item:

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

***19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**

This clause of the General Standard applies except as follows:

19.1 General requirements

Item b)

Addition:

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

**Item g)*

Amendment:

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

19.2 SINGLE FAULT CONDITIONS

Item a)

Addition:

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

*19.3 Allowable values

Item a) and Table IV

Amendment:

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

Item b)

Amendment:

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

Additional subclause:

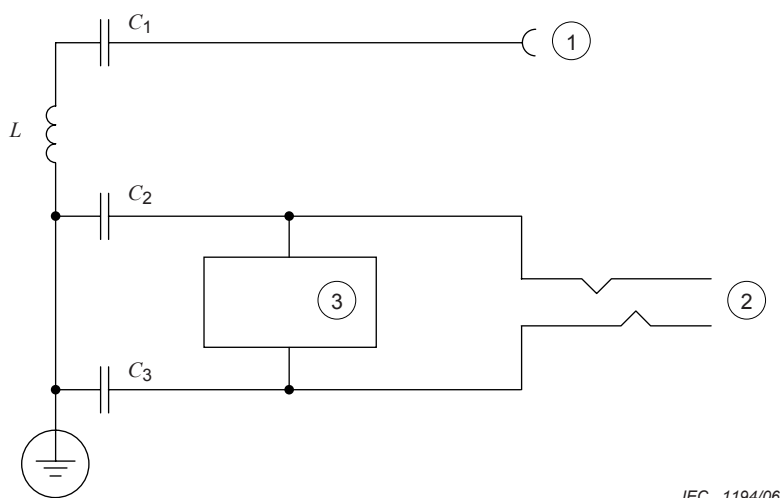
19.3.101 Thermal effects of HF LEAKAGE CURRENTS

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

*a) HIGH FREQUENCY LEAKAGE CURRENTS

1) NEUTRAL ELECTRODE referenced to earth

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



Key

- ① Connector for ACTIVE ELECTRODE
- ② Connector for NEUTRAL ELECTRODE
- ③ Monitor

C_1 not to exceed $0,005 \mu\text{F}$

$C_2 = C_3$ not to exceed $0,025 \mu\text{F}$

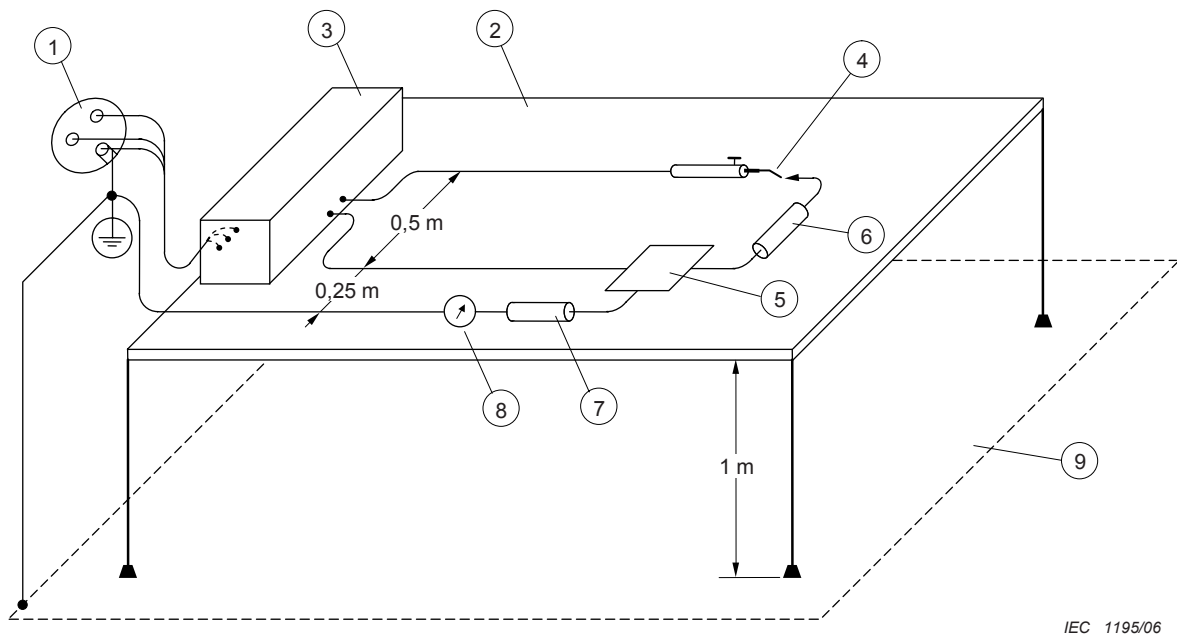
X_{C2} and X_{C3} at operating frequency each not to exceed 20Ω

Z_L at 50 Hz not to exceed 1Ω

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

Compliance is checked by the following tests.

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



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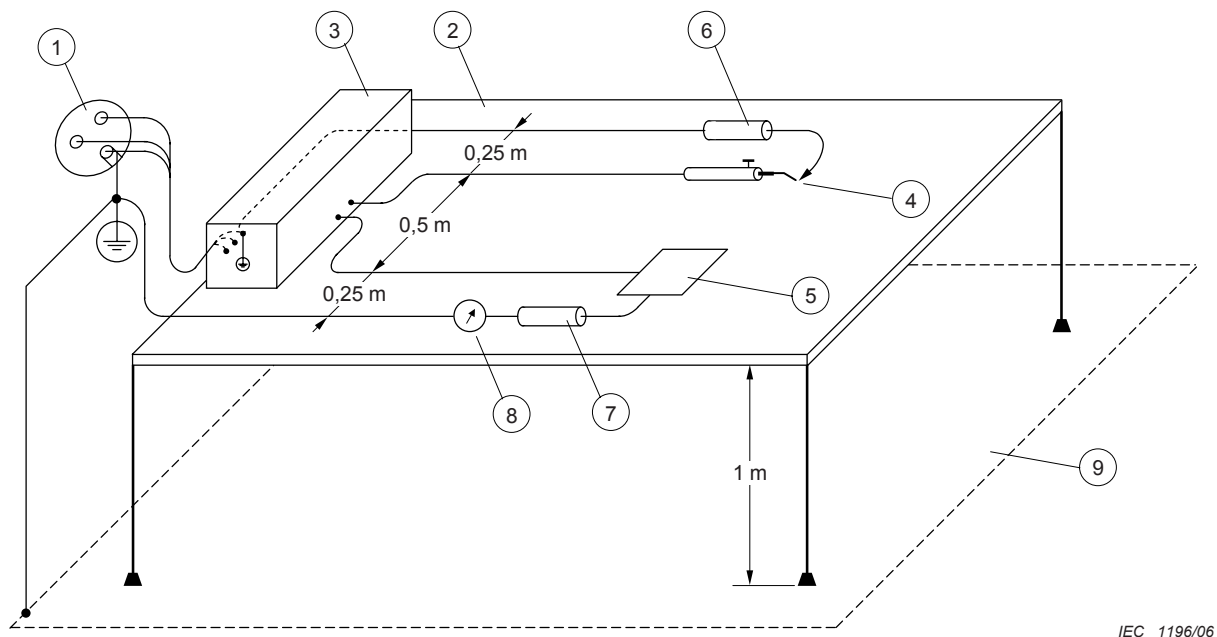
Key

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

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

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

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



IEC 1196/06

Key

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

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

2) NEUTRAL ELECTRODE isolated from earth at HIGH FREQUENCY

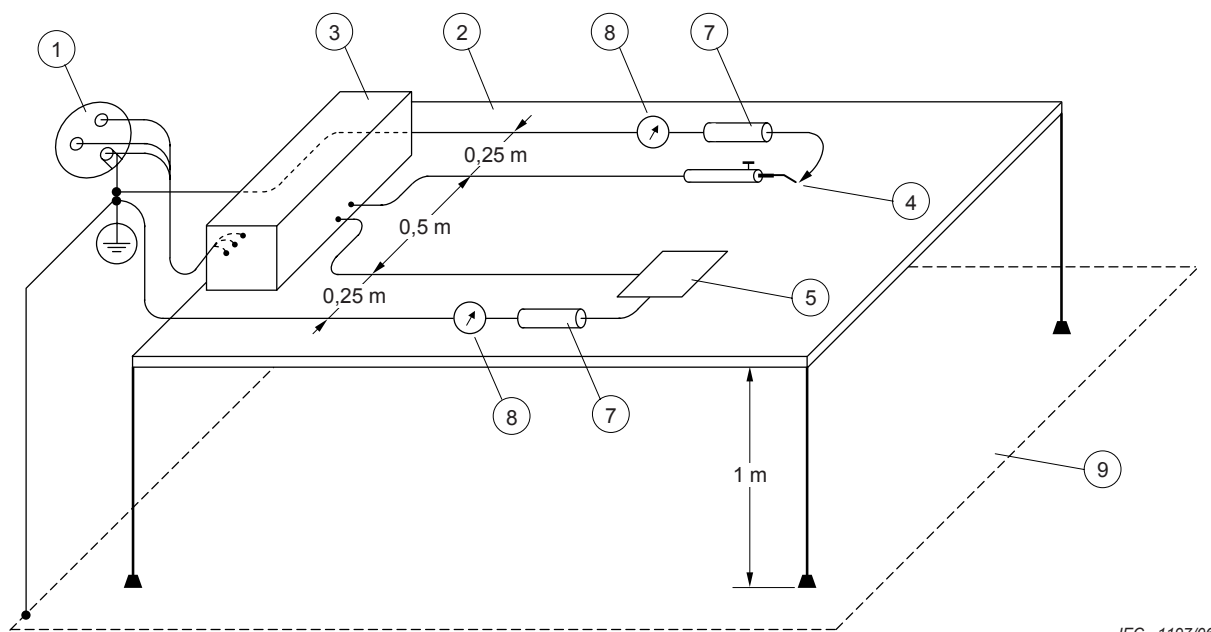
The PATIENT CIRCUIT is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Compliance is checked by the following test.

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

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

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



IEC 1197/06

Key

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

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

***3) BIPOLAR application**

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

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

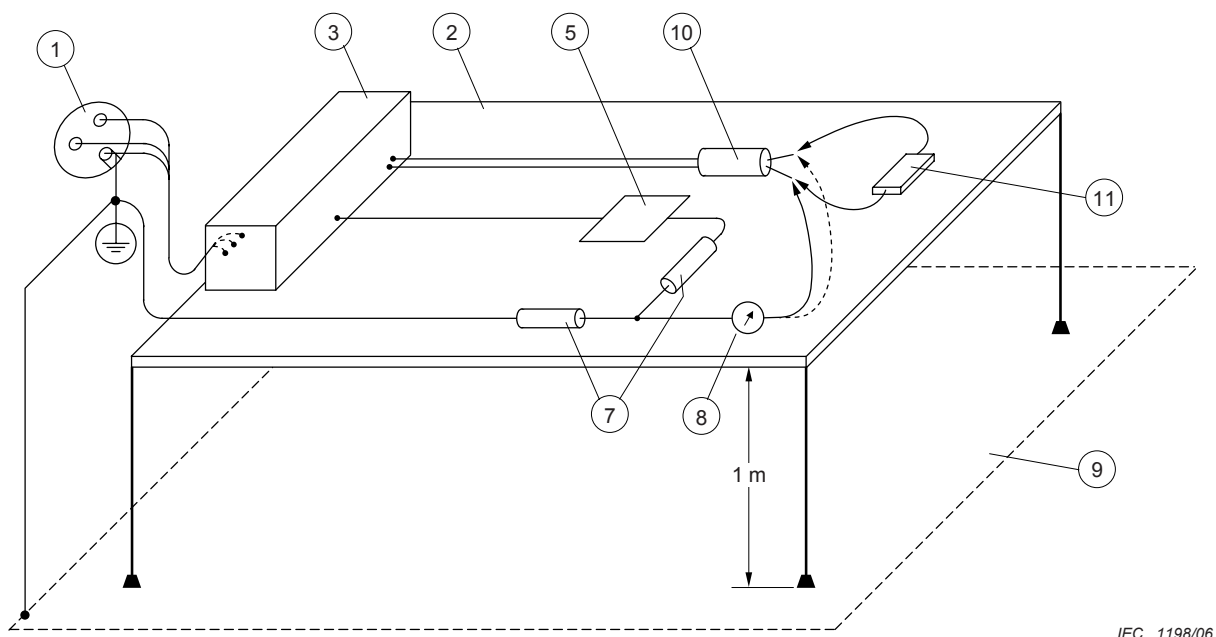
Compliance is checked by the following test.

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

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

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

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



IEC 1198/06

Key

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

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

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

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

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

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

- 1) A non-activated MONOPOLAR PATIENT CIRCUIT shall produce no more than 150 mA HIGH FREQUENCY current into a 200 Ω load to earth and, in turn, to the NEUTRAL ELECTRODE.
- 2) A non-activated BIPOLAR PATIENT CIRCUIT shall produce no more than 50 mA into a 200 Ω load connected across the two terminals or – with short circuited terminals – into a 200 Ω load to earth and into a 200 Ω load to the NEUTRAL ELECTRODE (both currents added, see Figure 107) .

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

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

***20 Dielectric strength**

This clause of the General Standard applies except as follows:

Amendment:

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

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

***20.2 Requirements for EQUIPMENT with an APPLIED PART**

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

20.3 Values of test voltages

Table V, NOTE 2: Replacement:

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

***20.4 Tests**

Additional item:

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

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

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

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

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

36 Electromagnetic compatibility

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

36.201 EMISSIONS

***36.201.1 PROTECTION OF RADIO SERVICES**

Add the following text:

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

36.202 IMMUNITY

36.202.1 General

j) Compliance criteria

Addition at end of j)

The following shall be considered an acceptable DEGRADATION of performance:

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

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

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