INTERNATIONAL STANDARD

IEC 60601-2-2

Third edition
1998-09

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-2:
Règles particulières de sécurité pour appareils d'électrochirurgie à courant haute fréquence

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For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition of IEC 60601-2-2 cancels and replaces the second edition published in 1991, and constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/291/FDIS	62D/297/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.

Annex AA is for information only.

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: in italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

INTRODUCTION

The revisions for this third edition of the Particular Standard refer mainly to the following:

– Split NEUTRAL ELECTRODES are dealt with in more detail.

– Limitation of incorrect output power in SINGLE FAULT CONDITION.

– The requirements for AP EQUIPMENT are revised.

– White indicator lamps on coloured backgrounds for CUTTING and COAGULATION mode are no longer allowed.

– Limitation of monitoring current to 100 µA for HF SURGICAL EQUIPMENT with BF or CF APPLIED PARTS.

– Revised requirements for CREEPAGE DISTANCE and AIR CLEARANCE of APPLIED PARTS.

– Simultaneous activation of more than one PATIENT CIRCUIT is dealt with in more detail and a compliance test method is now defined.

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 used in medical practice, as defined in 2.1.101 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 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1: Collateral Standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2: Collateral Standard: Electromagnetic compatibility – Requirements and tests*

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

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 to 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 of 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:

Additional definitions:

***2.1.101**
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 (h.f.) currents.

2.1.102
ACTIVE ELECTRODE
Electrode intended to produce certain physical effects required in electrosurgery, for example CUTTING and COAGULATION.

2.1.103
BIPOLAR ELECTRODE
Assembly of two ACTIVE ELECTRODES on the same support, so constructed that, when energized, the h.f. current flows mainly between these two electrodes.

2.1.104
NEUTRAL ELECTRODE
Electrode of a relatively large area for connection to the body of the PATIENT, intended to provide a return path for the high frequency current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided.

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

2.1.105
ENDOSCOPICALLY USED ACCESSORY
See definition in IEC 60601-2-18:1996.

NOTE – The reader is referred to IEC 60601-2-18 to ensure that a consistent definition is used.

2.12.101
RATED OUTPUT POWER
The power in watts produced when the h.f. output is fed into the RATED LOAD.

2.12.102
CUTTING
Resection or dissection of body tissue caused by the passage of high frequency current of high current density at the ACTIVE ELECTRODE(S).

2.12.103
COAGULATION
Sealing of small blood vessels or of body tissue caused by the passage of high frequency current at the ACTIVE ELECTRODE(S).

2.12.104
RATED LOAD
The value of non-reactive load resistance that results in the maximum h.f. output power from each operating mode of the HF SURGICAL EQUIPMENT.

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Additional SINGLE FAULT CONDITIONS:

aa) failure in the NEUTRAL ELECTRODE monitoring circuit which would result in 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:

4.6 Other conditions

Additional item:

aa) *Where reference is made in test specifications to electrode cables and/or electrodes, those supplied or recommended by the manufacturer shall be used.*

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*

Additions:

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 for the NEUTRAL ELECTRODE leads shall be marked with the following symbols.

for PATIENT CIRCUITS according to 19.3.101 a) 1)

for PATIENT CIRCUITS according to 19.3.101 a) 2)

*p) *Output*

Replacement:

– RATED OUTPUT POWER, in watts, and RATED LOAD, in ohms, for each operating mode.
– Operating frequency or frequencies (RATED VALUE of the fundamental frequency or frequencies), in megahertz or kilohertz.

***6.3 Marking of controls and instruments**

Additional item:

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

The numeral "0" shall not be used unless no h.f. 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. The colour shall be similar to the colour coding of the pushbutton of the fingerswitch or of the footswitch-pedal which is activated at the same time.

NOTE – Blended outputs are regarded as a CUTTING mode.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Additional items:

*aa) Information concerning the use of suitable cables, ACCESSORIES, ACTIVE and NEUTRAL ELECTRODES, including values for the highest allowed h.f. peak voltage, in order to avoid incompatibility and unsafe operation.

Advice for the OPERATOR to ensure that connected ACCESSORIES are rated for at least the maximum peak output voltage of the HF SURGICAL EQUIPMENT set at the intended output control setting in the intended operating mode, with reference to the diagrams required by 6.8.2 ee).

*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 so that they are isolated from the PATIENT.

*6) For surgical procedures where the h.f. 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 coagulation.

7) The output power selected should be as low as possible for the intended purpose.

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

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

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

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of h.f. 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 to HF SURGICAL EQUIPMENT only incorporating bipolar output.

NOTE 2 – This requirement does not apply to 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 USER regularly to inspect the ACCESSORIES. In particular, electrode cables and ENDOSCOPICALLY USED ACCESSORIES should be checked for possible damage to the insulation.

*ee) Information shall include diagrams showing the maximum possible peak output voltage of the HF SURGICAL EQUIPMENT versus the output control setting for all operating modes available.

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

*6.8.3 Technical description

Additional items:

*aa) *Power output data – monopolar output (for all operating 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 operating 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 operating modes available)*

Diagrams showing the maximum possible peak output voltage versus the output control setting.

*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.

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:

*17h) *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 clause 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 h.f. 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:

Currents intended to monitor the integrity of contact between a split NEUTRAL ELECTRODE and the PATIENT shall meet the requirements for TYPE BF APPLIED PART AUXILIARY CURRENT.

Item b)

Amendment:

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

Additional subclause:

19.3.101 Thermal effects of h.f. LEAKAGE CURRENTS

In order to prevent unintended thermal burns, h.f. 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 107) by components (for example a capacitor) satisfying the requirements of a TYPE BF APPLIED PART. When tested as described below, the h.f. 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 101. 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 h.f. 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 102. The h.f. LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE is measured.

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 h.f. 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 19.3.101a) 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 103). The h.f. LEAKAGE CURRENT is measured from each electrode in turn while the HF SURGICAL EQUIPMENT is operated at maximum output setting in each operating 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.

*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 h.f. 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 (these two values are added if a NEUTRAL ELECTRODE is present on the HF SURGICAL EQUIPMENT) 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 104. 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 h.f. 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 h.f. ENCLOSURE LEAKAGE CURRENTS are under consideration.

*b) *High frequency LEAKAGE CURRENTS measured directly at the HF SURGICAL EQUIPMENT terminals*

The preceding item a) shall 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 exceeding 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 h.f. 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 104).

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 subclause 19.3.101 b) and the HF SURGICAL EQUIPMENT is set up as shown in figure 102 (for monopolar) or figure 104 (for bipolar PATIENT CIRCUITS).

20 Dielectric strength

This clause of the General Standard applies except as follows:

Amendment:

The requirements and tests for h.f. electrodes, electrode cables, connectors and handles are given in 59.103.4.

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, 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 or 720 mm Hg 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 h.f. 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 subclause 57.10, 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

***36.201.1.6 HF SURGICAL EQUIPMENT**

Replacement:

HF SURGICAL EQUIPMENT shall comply with the requirements of 36.201, when it is switched on but the output switch (see 56.11) is not activated and with all the electrode cables attached to the HF SURGICAL EQUIPMENT.

NOTE – Frequencies which are reserved for international emergency communications (for example 500 kHz ± 5 kHz) should not be used for the fundamental frequency in HF SURGICAL EQUIPMENT.

36.202 IMMUNITY

Compliance test:

Addition:

In the context of the compliance test, failures which do not create a SAFETY HAZARD and which shall be accepted during the tests are

- *interruption of the h.f. power output,*
- *switching-off of the HF SURGICAL EQUIPMENT,*
- *reset into stand-by mode,*

provided that after the interference has ceased, NORMAL CONDITION is restored, either spontaneously or after power to the HF SURGICAL EQUIPMENT is switched off and on again.

Unacceptable failures creating a SAFETY HAZARD, which shall not occur during the tests, are

– *unintended energization of any PATIENT CIRCUIT,*
– *unintended increase of output power by more than the defined power in 51.5,*
– *unintended changes of operating mode or power setting during stand-by or activation,*
– *permanent failure of any visible or audible indicator.*

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

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

39 Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

This clause of the General Standard applies except as follows:

39.3 Prevention of electrostatic charges

Additional subclause:

39.3.101 Footswitches

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

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

*42 Excessive temperatures

This clause of the General Standard applies except as follows:

42.3

3) *DUTY CYCLE*

Replacement:

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

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

This clause of the General Standard applies except as follows:

***44.3 Spillage**

Replacement:

The ENCLOSURE of the HF SURGICAL EQUIPMENT 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.

Compliance is checked by the following test.

A quantity of 1 l of water is poured steadily onto the middle of the top surface of the HF SURGICAL EQUIPMENT over a period of 15 s. HF SURGICAL 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 shall withstand the dielectric strength test specified in clause 20, and inspection shall show that water which may have entered the ENCLOSURE cannot adversely affect the safety of the HF SURGICAL EQUIPMENT. In particular, there shall be no trace of water on the insulation for which CREEPAGE DISTANCES are specified in 57.10 of the General Standard.

***44.6 Ingress of liquids**

Addition:

aa) The electrical switching parts of footswitches for HF SURGICAL EQUIPMENT intended for use in operating rooms shall comply with the following test.

The footswitch shall be completely immersed in water to a depth of 150 mm for a period of 30 min. While immersed, it shall be connected in a circuit corresponding to its NORMAL USE and actuated 50 times. After completion of this test the switch shall be inspected. There shall be no evidence of entry of water and the switch shall pass the dielectric strength test specified in clause 20.

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

Compliance is checked by the following test.

The ACTIVE ELECTRODE handle is supported horizontally at least 50 mm above any surface with the switch actuating parts uppermost, connected to the HF SURGICAL EQUIPMENT which is switched on and ready for operation. One litre of 0,9 % saline solution is poured steadily from above over the ACTIVE ELECTRODE handle over a period of 15 s so as to wet the entire length of the ACTIVE ELECTRODE handle. The liquid is allowed to drain away freely. No output of the HF SURGICAL EQUIPMENT shall become energized.

Immediately after, the switch is operated 10 times. The output shall become energized and de-energized at each operation of the switch.

46 Human errors

This clause of the General Standard applies except as follows:

Additional subclauses:

***46.101** Where a double footswitch assembly is used to select CUTTING and COAGULATION output modes, the arrangement shall be such that, when viewed by the OPERATOR, the "CUT" pedal is at the left and the "COAGULATE" pedal at the right-hand side.

Compliance is checked by inspection.

***46.102** Where the ACTIVE ELECTRODE handle incorporates two fingerswitches, the switch nearer to the electrode shall activate the CUTTING mode. The switch further from the electrode shall activate the COAGULATION mode.

Compliance is checked by inspection.

***46.103** It shall not be possible to energize simultaneously more than one PATIENT CIRCUIT unless

a) each PATIENT CIRCUIT has independent sets of controls (e.g. for output power and operation mode) and of switching (handswitch or footswitch), or

b) two monopolar PATIENT CIRCUITS have an independent set of switching (handswitch or footswitch) and share the output of one non-contact COAGULATION mode, such as spray- or fulguration-mode.

NOTE – For HF SURGICAL EQUIPMENT with such an operating mode, a warning, in the instructions for use, that the output from either ACTIVE ELECTRODE may change during use is required under 6.8.2 bb) 11).

Under no circumstances shall any PATIENT CIRCUIT become energized by more than is defined in 19.3.101 c), unless the output switch (handswitch or footswitch) for that PATIENT CIRCUIT is activated by the OPERATOR.

Compliance is checked by inspection and functional check.

***46.104** Connectors for ACTIVE and NEUTRAL ELECTRODES shall not be interchangeable.

Compliance is checked by inspection.

***46.105** Where more than one function can be energized by one output switch, an indication shall be provided to show which function is selected before an output is energized.

Compliance is checked by inspection and functional test.

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

yellow for CUTTING;

blue for COAGULATION.

Compliance is checked by inspection.

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

50 Accuracy of operating data

This clause of the General Standard applies except as follows:

50.1 Marking of controls and instruments

Replacement:

***50.1a)** Monopolar HF SURGICAL EQUIPMENT shall incorporate means (an output control) to enable the output power to be reduced to not more than 5 % of the RATED OUTPUT POWER or 10 W, whichever is smaller (see also 6.3). For particular values of load resistance, the output power shall not increase with the decrease of the output control setting (see 6.8.3 aa) and figure 105).

Compliance is checked by the following test:

The output power as a function of the output control setting is measured at a minimum of five particular values of the load resistance, including 100 Ω, 200 Ω, 500 Ω, 1 000 Ω, 2 000 Ω and at the RATED LOAD. The electrode cables shall be used for connection of the load resistors.

50.1 b) Bipolar HF SURGICAL EQUIPMENT shall incorporate means (an output control) to enable the output power to be reduced to not more than 5 % of the RATED OUTPUT POWER or 10 W, whichever is smaller (see 6.3). For particular values of the load resistance, the output power shall not increase with the decrease of the output control setting (see 6.8.3 bb) and figure 106).

Compliance is checked by the following test:

The output power as a function of the output control setting is measured at a minimum of five particular values of the load resistance, including 10 Ω, 50 Ω, 200 Ω, 500 Ω, 1 000 Ω and at the RATED LOAD. The BIPOLAR ELECTRODE cable supplied or recommended by the manufacturer shall be used for the connection of the load resistors.

50.2 Accuracy of controls and instruments

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

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

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

*51.2 Indication of parameters relevant to safety

Replacement:

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

Compliance is checked by measurement.

*51.5 Incorrect output

Additional requirement:

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

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

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

Setting (range in % of RATED OUTPUT POWER)	**Maximum allowed output power in SINGLE FAULT CONDITIONS (but not more than 400 W)**
Less than 10	20 % of RATED OUTPUT POWER
10 to 25	Setting × 2
Greater than 25 and up to 80	Setting +25 % of RATED OUTPUT POWER
Greater than 80 and up to 100	Setting +30 % of RATED OUTPUT POWER

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

Additional subclauses:

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

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

– the mode of operation shall not be changed except to a stand-by mode in which no output is produced.

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

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

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

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

Any single activated PATIENT CIRCUIT shall comply with 50.2.

Compliance is checked by the following tests (see figure 109).

For HF SURGICAL EQUIPMENT as defined in 46.103 a):

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

For HF SURGICAL EQUIPMENT as defined in 46.103 b):

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

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

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS;
ENVIRONMENTAL TESTS

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

52 Abnormal operation and fault conditions

This clause of the General Standard applies except as follows:

Additional subclause:

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

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

Compliance is checked by the following test.

The electrode cables and electrodes are connected to the HF SURGICAL EQUIPMENT and the output control set to the maximum position. The output is then switched on, and the ACTIVE and NEUTRAL ELECTRODES 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 10 times.

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

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

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

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.3 Connections – General

**Item c)*

Amendment:

This requirement shall not apply to the connectors of ACTIVE ELECTRODES.

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

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

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.

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

Addition:

In addition to the mains switch, an output switch (finger- or footswitch) requiring continuous activation shall be provided to energize the PATIENT CIRCUIT. Impedance sensing systems designed to activate HF SURGICAL EQUIPMENT outputs shall not be permitted for monopolar outputs.

Impedance sensing switching is accepted for bipolar COAGULATION mode only if

a) the impedance sensing mode selection is optional to the foot- or hand-operated mode, and

b) the HF SURGICAL EQUIPMENT automatically switches back to foot- or hand-operated mode after the mains power supply has been interrupted and restored, and

c) a visible indication is provided on the front panel of the HF SURGICAL EQUIPMENT to indicate to the OPERATOR that the HF SURGICAL EQUIPMENT is set to automatic sensing mode.

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

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

Compliance is checked by inspection, functional check, and by measurement of voltage and LEAKAGE CURRENT(S).

Item d) Entry of liquids

Amendment:

This item of the General Standard shall not apply.

Additional items:

aa) Where the output switch employs contacts for its operation, it shall not be possible to activate any output of the HF SURGICAL EQUIPMENT when the contacts are bridged by a resistance of 1 000 Ω.

Compliance is checked by a functional test.

*bb) Each output switch (finger- or footswitch) shall activate only its intended single PATIENT CIRCUIT and shall control one single mode only, for example CUTTING or COAGULATION.

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

Additional subclause:

***56.101 Cord-connected footswitches**

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

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

Compliance is checked by measurement of the actuating force.

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

***a) *Values*

Amendment:

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

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

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

59 Construction and layout

This clause of the General Standard applies except as follows:

Additional subclauses:

***59.101 Monitoring circuit**

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

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

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

Requirements concerning a protective connection to an endoscope are under consideration.

Compliance is checked by operating the HF SURGICAL EQUIPMENT at maximum output control setting in each operating mode into the circuit shown in figure 108. The switch is closed and opened five times and the h.f. output shall be disabled and the alarm shall sound at each opening of the switch.

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

59.102 Output indicator

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

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

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

59.103 HF electrodes, electrode cables, connectors and handles

***59.103.1** The insulation of ACTIVE ELECTRODE cables, whether or not they are specified for re-use, shall be capable of withstanding a mains-frequency voltage of 3 000 V r.m.s. and an h.f. voltage of 1,5 times the maximum open-circuit h.f. voltage of the HF SURGICAL EQUIPMENT.

Compliance is checked by the following tests.

Test 1 – Mains frequency: Approximately 20 cm of the cable to be tested is formed into a loop by joining the suitable bared conductors at each end. The cable is lowered into water, the conductivity of which has been increased by the addition of a small amount of salt, until a total length of 10 cm of insulated cable has been immersed. The cable shall remain in the water for at least 24 h following which the test voltage shall be applied for 5 min between the conductor or conductors and the water.

Test 2 – High frequency: A test sample of the cable is prepared and immersed as in test 1. A quantity of transformer oil is then added, just sufficient to produce a visible continuous film on the water surface (this technique reduces the curvature of the meniscus). An h.f. voltage, produced by the HF SURGICAL EQUIPMENT via a step-up h.f. transformer which produces a voltage 1,5 times higher, is applied between the cable conductor and a bare conductor in the water, while the HF SURGICAL EQUIPMENT is operated in each operating mode in turn at the maximum setting of the corresponding control for 30 s.

During these tests no breakdown or flashover shall occur.

***59.103.2** The handle of any ACTIVE ELECTRODE and any insulated bipolar forceps together with their cables shall fulfil the requirements of 44.7 of the General Standard regarding sterilization, and shall subsequently withstand a dielectric strength test with 1,5 times the maximum possible peak h.f. voltage of the corresponding HF SURGICAL EQUIPMENT output circuit.

Any incorporated fingerswitch shall function normally after the sterilization procedure.

ACCESSORIES marked as being intended for single use are exempted from these requirements regarding sterilization.

Compliance is checked by application of the sterilization test of 44.7 of the General Standard.

Subsequently a high frequency voltage produced as in test 2 of 59.103.1 is applied for 30 s between the current-carrying parts and metal foil wrapped around the insulating parts up to a distance of 10 mm from bare current-carrying parts.

Immediately after this dielectric strength test, any incorporated fingerswitch shall be operated 10 times while connected to the HF SURGICAL EQUIPMENT. The output shall become energized and de-energized at each operation of the switch.

***59.103.3** Any connector provided for attachment of the neutral electrode to its cable shall be designed so that conductive parts of the electrode holder cannot come into contact with the body of the patient in the event of inadvertent disconnection.

Compliance is checked by the following test.

Any cable to the NEUTRAL ELECTRODE connector is disconnected from the electrode and, using the standard test finger shown in figure 7 of the General Standard, it is verified that contact with conductive parts of the cable connector is not possible.

59.103.4 The insulation of the NEUTRAL ELECTRODE cables, whether or not they are specified for re-use, shall be capable of withstanding a mains-frequency voltage of 1 500 V r.m.s. and an unmodulated h.f. peak voltage of 500 V.

59.104 NEUTRAL ELECTRODE

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

Compliance is checked by inspection.

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

Compliance is checked by inspection and by testing the electrical continuity using the test specified in item f) of clause 18 of the General Standard.

*59.105 Neuromuscular stimulation

In order to minimize the possibility of neuromuscular stimulation, a capacitance shall be incorporated into the PATIENT CIRCUIT so that it is effectively in series with the ACTIVE ELECTRODE or one conductor of a BIPOLAR ELECTRODE. This capacitance shall not exceed 5 000 pF for monopolar PATIENT CIRCUITS and 50 nF for bipolar PATIENT CIRCUITS. The d.c. resistance between ACTIVE and NEUTRAL ELECTRODE terminals, or between the terminals of a bipolar output circuit, shall not be less than 2 MΩ. For an example, see capacitor C_1 in figure 107.

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

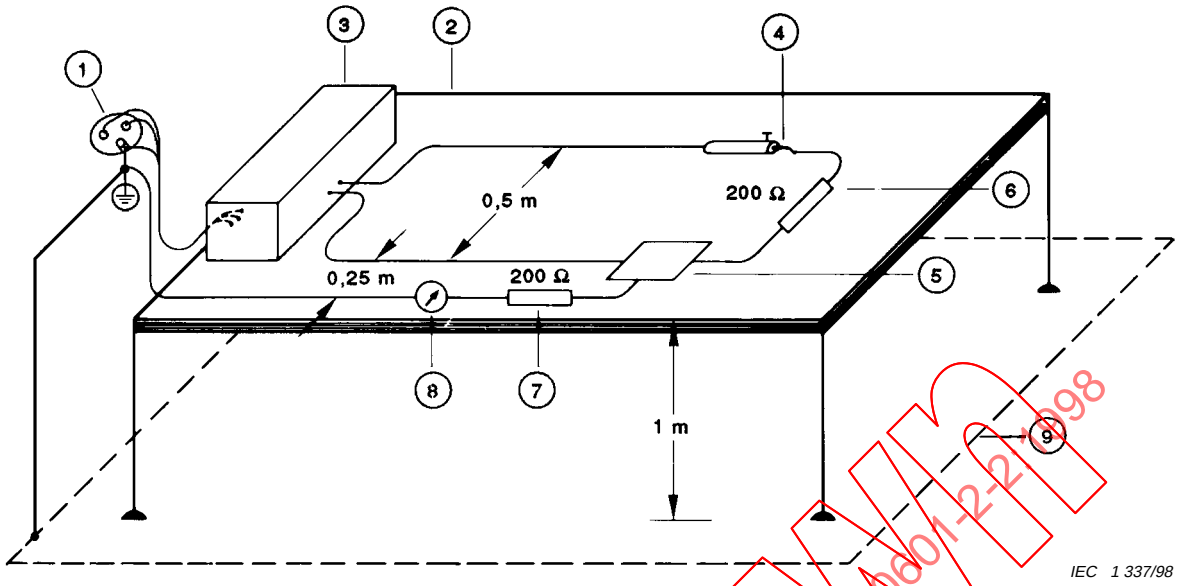


Figure 101 – Measurement of h.f. LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth, and load between electrodes (see test 1 of 19.3.101 a) 1))

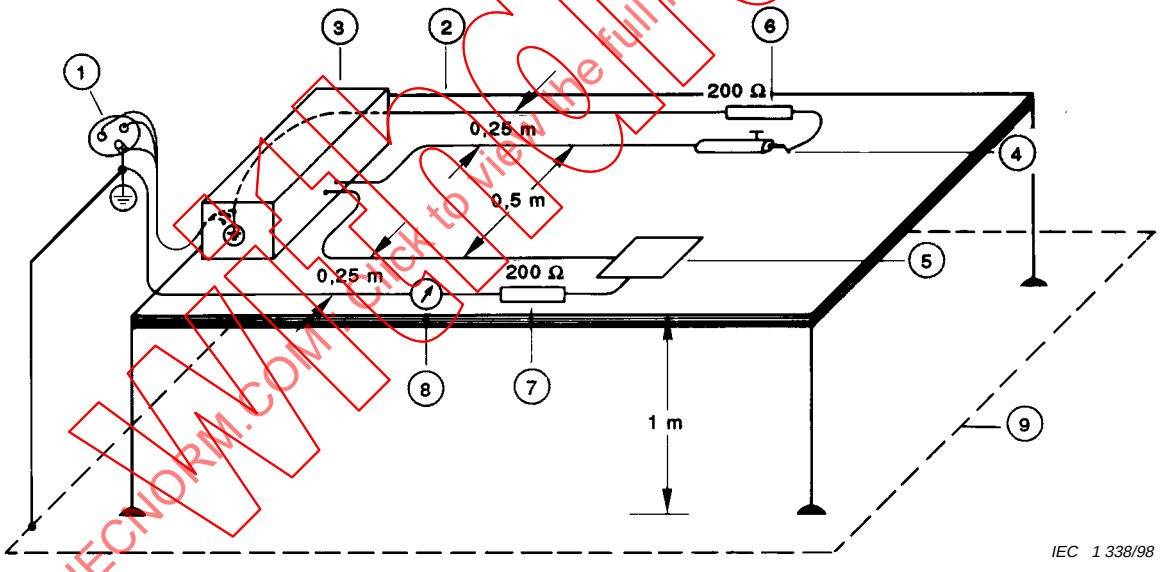


Figure 102 – Measurement of h.f. LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load from ACTIVE ELECTRODE to earth (see test 2 of 19.3.101 a) 1))

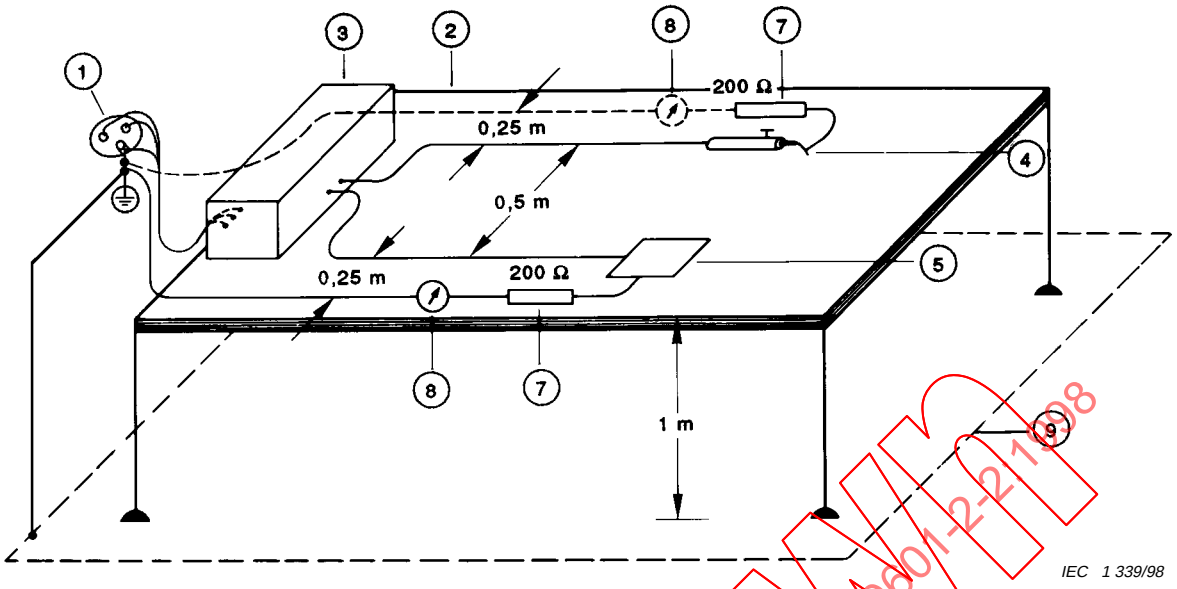


Figure 103 – Measurement of h.f. LEAKAGE CURRENT with NEUTRAL ELECTRODE isolated from earth at high frequency (see 19.3.101 a) 2))

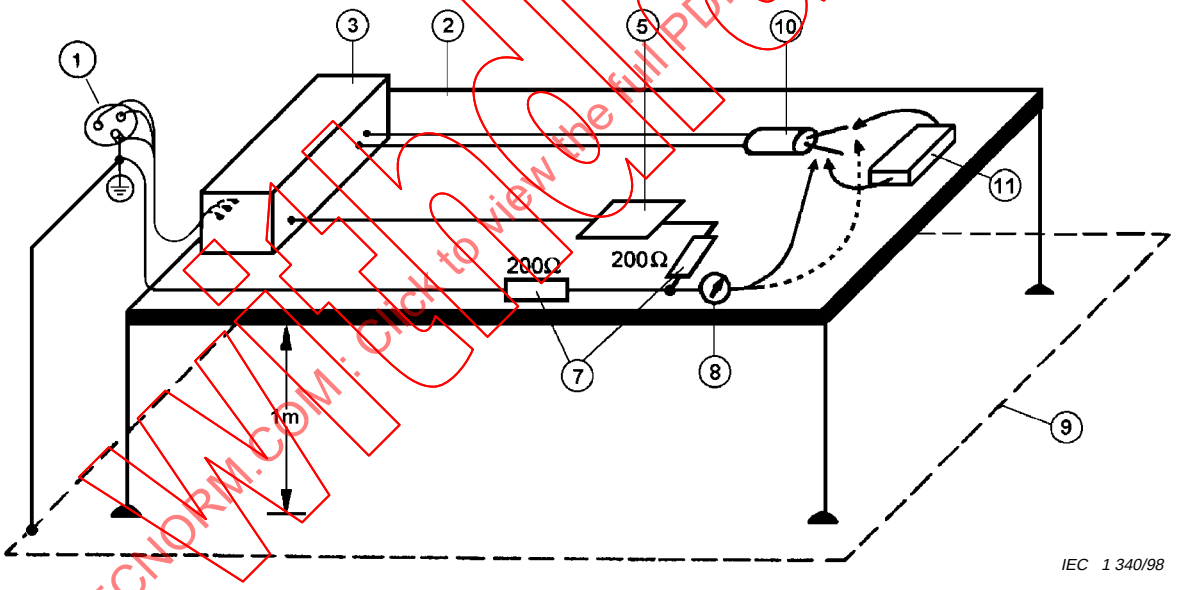


Figure 104 – Measurement of h.f. LEAKAGE CURRENT from a BIPOLAR ELECTRODE (see 19.3.101 a) 3))

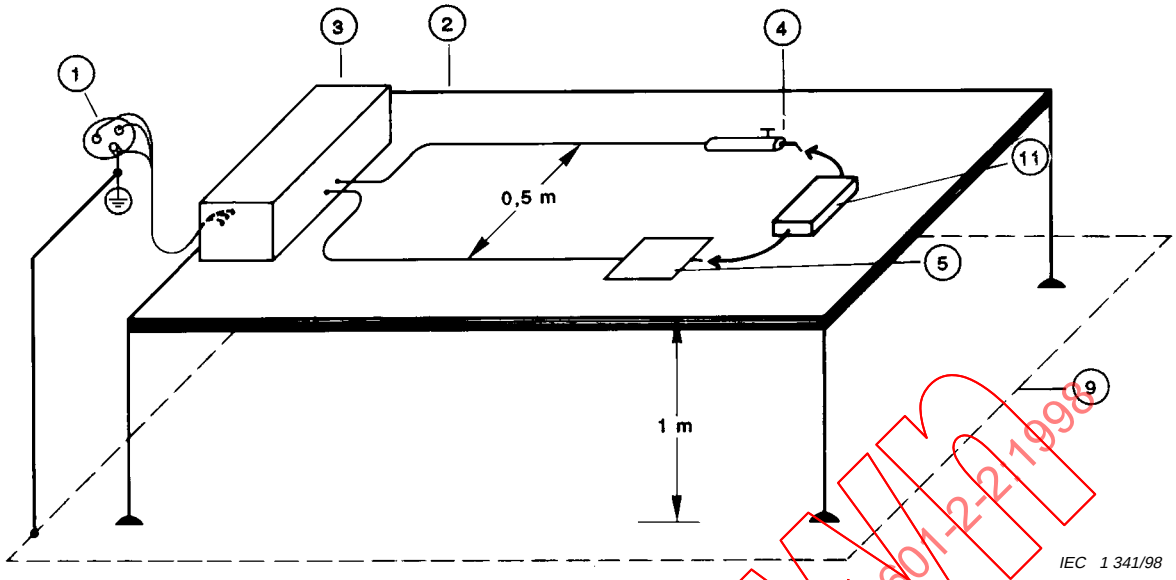


Figure 105 – Measurement of OUTPUT POWER – Monopolar output (see 50)

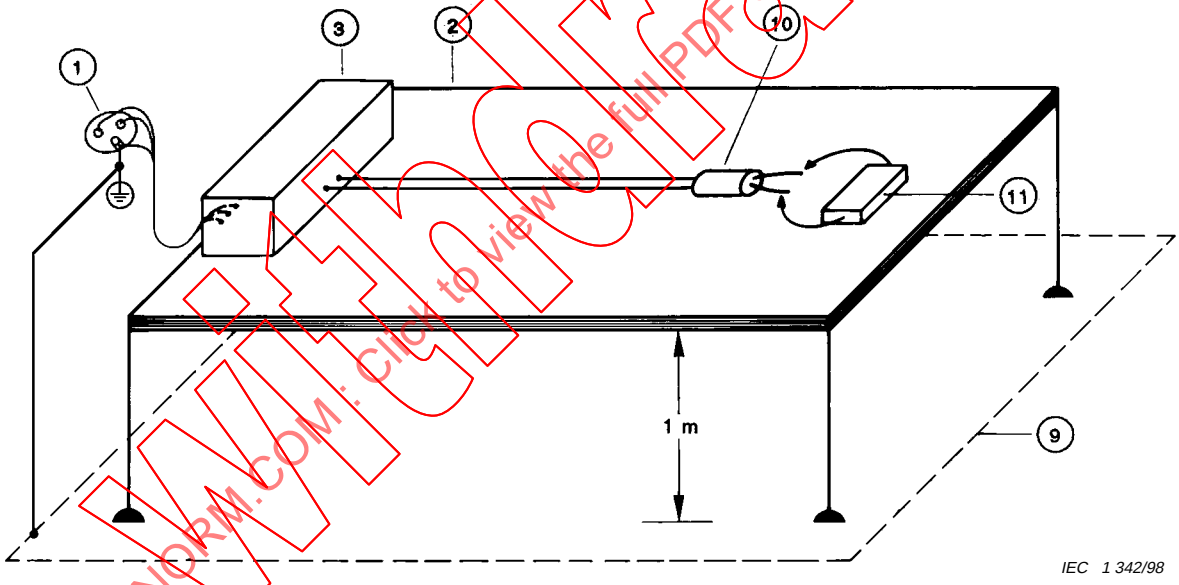
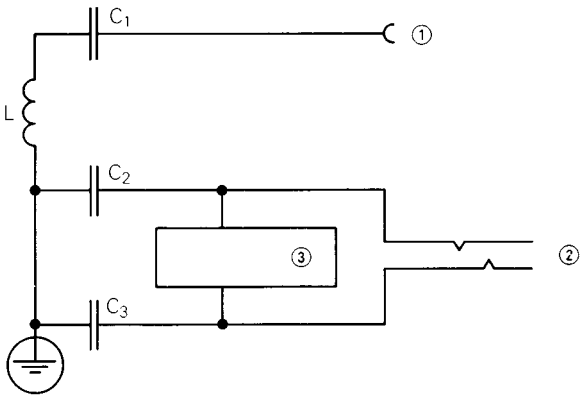


Figure 106 – Measurement of OUTPUT POWER – Bipolar output (see 50)

Legend for figures 101 to 106

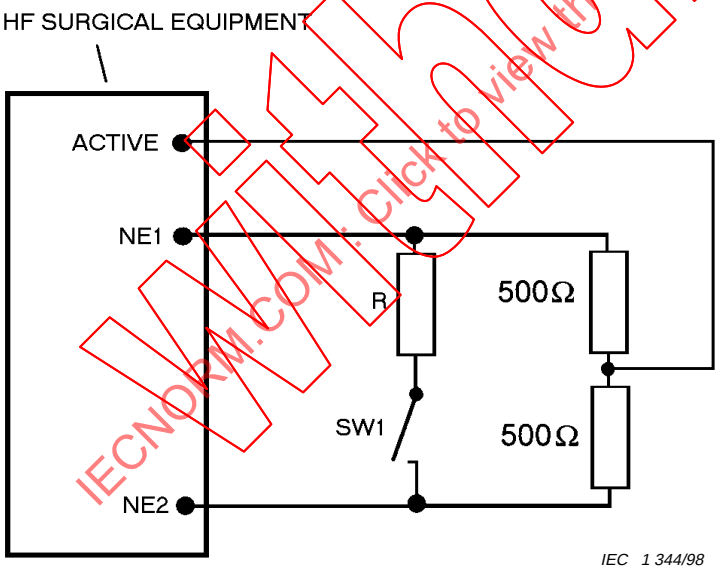
① SUPPLY MAINS
② Table, made of insulating material
③ HF SURGICAL EQUIPMENT
④ ACTIVE ELECTRODE
⑤ NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size
⑥ Load resistance, 200 Ω
⑦ Measuring resistance, 200 Ω
⑧ HF current meter
⑨ Earthed conductive plane
⑩ Activated BIPOLAR ELECTRODE
⑪ Load resistance as required, with h.f. power measuring device



IEC 1 343/98

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

Figure 107 – Example of PATIENT CIRCUIT with NEUTRAL ELECTRODE referenced to earth at operating frequencies (see 19.3.101 a) 1) and 59.105)



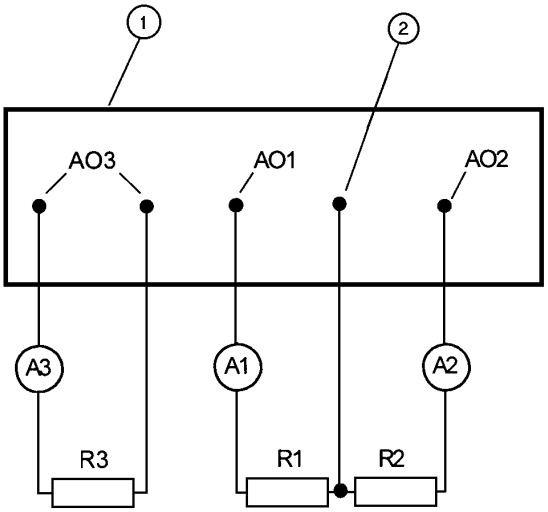
IEC 1 344/98

For single plates: R = 0 Ω

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

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

Figure 108 – Circuit suitable for testing compliance with 59.101



① HF SURGICAL EQUIPMENT
② Connector for NEUTRAL ELECTRODE

R1 – R3: RATED LOAD for that active output
AO1 – AO2: monopolar active outputs
AO3: bipolar active output

IEC 1 345/98

Figure 109 – Method of testing feedback from one active output to another in simultaneous activation (see 46.103 and 51.102)

The appendices of the General Standard apply except as follows:

Appendix L

References – Publications mentioned in this standard

Appendix L of the General Standard applies except as follows:

IEC Standards

Addition:

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-2-2:1991, *Medical electrical equipment – Part 2: Particular requirements for safety of high frequency surgical equipment*

IEC 60601-2-18:1996, *Medical electrical equipment – Part 2: Particular requirements for the safety of endoscopic equipment*

IEC 60601-2-34:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of direct blood pressure monitoring equipment*

CISPR 11:1997, *Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement*

Annex AA
(informative)

Guidance and rationale for particular clauses and subclauses

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

1.1 The scope does not include EQUIPMENT for cautery, i.e. for medical treatment with electrically heated metal rods or wire loops.

2.1.101 Frequencies above 0,3 MHz should be used in order to avoid the unwanted stimulation of nerves and muscles which would result from the use of low frequency current. Normally, frequencies above 5 MHz are not used in order to minimize the problems associated with high frequency LEAKAGE CURRENTS. However, higher frequencies may be used in the case of bipolar techniques.

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

6.1 p) The markings are necessary to assess the suitability of a particular HF SURGICAL EQUIPMENT for an intended purpose. HF SURGICAL EQUIPMENT having more than one PATIENT CIRCUIT may have more than one value of RATED OUTPUT POWER.

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

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

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

6.8.2 aa) Information concerning the use of suitable cables, ACCESSORIES, ACTIVE and NEUTRAL ELECTRODES, including values for the highest allowed h.f. peak voltage, in order to avoid incompatibility and unsafe operation, is considered essential.

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

1) Minimizing 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 h.f. voltage across the PATIENT. Hence the hazard of unwanted burns is reduced.

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

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

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

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

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

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

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

6.8.2 ee) These diagrams should enable the OPERATOR to judge the suitability of an HF SURGICAL EQUIPMENT or its output setting for a particular ACCESSORY with regard to its isolation quality. IEC 60601-2-18 contains requirements prescribing that manufacturers of ENDOSCOPICALLY USED ACCESSORIES shall specify them as suitable for a certain maximum allowed h.f. peak output voltage which shall be defined in the ACCOMPANYING DOCUMENTS for such ACCESSORIES.

6.8.3 aa), bb) These diagrams should enable the OPERATOR to judge the suitability of an HF SURGICAL EQUIPMENT for a particular purpose.

6.8.3 dd) It should be made clear to the OPERATOR whether the APPLIED PART is completely floating or referenced to earth at high frequency.

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