

BS EN 60601-2-2:2009+A11:2011



BSI Standards Publication

Medical electrical equipment

Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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National foreword

This British Standard is the UK implementation of EN 60601-2-2:2009+A11:2011. It is identical to IEC 60601-2-2:2009. It supersedes BS EN 60601-2-2:2009, which will be withdrawn on 1 October 2014.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this subcommittee 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.

© The British Standards Institution 2012.
Published by BSI Standards Limited 2012.

ISBN 978 0 580 77240 5

ICS 11.040.30

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2009.

Amendments/corrigenda issued since publication

Date	Text affected
31 March 2012	Implementation of CENELEC amendment A11:2011: Annex ZZ replaced

English version

**Medical electrical equipment -
Part 2-2: Particular requirements
for the basic safety and essential performance
of high frequency surgical equipment
and high frequency surgical accessories
(IEC 60601-2-2:2009)**

Appareils électromédicaux -
Partie 2-2: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils d'électrochirurgie
à courant haute fréquence
et des accessoires d'électrochirurgie
à courant haute fréquence
(CEI 60601-2-2:2009)

Medizinische elektrische Geräte -
Teil 2-2: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Hochfrequenz-Chirurgiegeräten
und HF-chirurgischem Zubehör
(IEC 60601-2-2:2009)

This European Standard was approved by CENELEC on 2009-04-01. 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: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62D/726/FDIS, future edition 5 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 2009-04-01.

This European Standard supersedes EN 60601-2-2:2007.

Revisions in EN 60601-2-2:2009 include new language for preconditioning accessories prior to insulation testing, refining the requirements for electromagnetic compatibility testing and correcting some of the equations used in deriving the thermal test for NEUTRAL ELECTRODES.

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) 2010-01-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2012-04-01

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 MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-2:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-2-18 + A1 NOTE Harmonized as EN 60601-2-18:1996 + A1:2000 (not modified).

Foreword to amendment A11

This document (EN 60601-2-2:2009/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2012-10-01
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2014-10-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
Replace the references to IEC 60601-1-2 and IEC 60601-1-8 by:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
Addition:				
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3 + IS1	2006 2009
IEC 61000-4-6	2003	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6 ¹⁾ + corr. August + IS1	2007 2007 2009
CISPR 11 (mod)	2003	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement	EN 55011 ²⁾	2007

¹⁾ EN 61000-4-6:2007 includes A1:2004 + A2:2006 to IEC 61000-4-6:2003. It is superseded by EN 61000-4-6:2009, which is based on IEC 61000-4-6:2008.

²⁾ EN 55011:2007 includes A1:2004 (mod) to CISPR 11:2003 (mod).

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

- Essential Requirement 6a
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of high frequency surgical equipment.

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

The requirements are followed by specifications for the relevant tests.

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

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

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HF SURGICAL EQUIPMENT as defined in 201.3.222.

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HF SURGICAL EQUIPMENT as defined in 201.3.222.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-2 and IEC 60601-1-8 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11²⁾ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

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

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 79.

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

Replacement:

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

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

Addition:

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

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

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

201.3 Terms and definitions

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

Replace NOTE 1 with the following:

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

Addition:

201.3.201

ACTIVE ACCESSORY

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

201.3.202

ACTIVE CONNECTOR

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

201.3.203

ACTIVE ELECTRODE

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

201.3.204

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

201.3.205

ACTIVE HANDLE

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

201.3.206

ACTIVE OUTPUT TERMINAL

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

201.3.207

***ASSOCIATED EQUIPMENT**

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

201.3.208

***BIPOLAR**

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

201.3.209

BIPOLAR ELECTRODE

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

201.3.210

COAGULATION

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

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

201.3.211

CONTACT QUALITY MONITOR

CQM

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

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

201.3.212

CONTINUITY MONITOR

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

201.3.213

***CREST FACTOR**

dimensionless value equal to the peak output voltage divided by the 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.

201.3.214

***CUTTING**

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

201.3.215

***EARTH REFERENCED PATIENT CIRCUIT**

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

201.3.216

FINGERSWITCH

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

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

201.3.217

***FULGURATION**

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

201.3.218

***HIGH FREQUENCY**

HF

frequencies generally greater than 200 kHz

201.3.219

HF ISOLATED PATIENT CIRCUIT

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

201.3.220

HF PATIENT CIRCUIT

any electrical circuit which contains one or more PATIENT CONNECTIONS

201.3.221

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.

201.3.222

HF SURGICAL EQUIPMENT

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

NOTE HF SURGICAL EQUIPMENT is also known as surgical diathermy or electrosurgical equipment.

201.3.223

***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.

201.3.224

***MAXIMUM OUTPUT VOLTAGE**

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

201.3.225

***MONITORING NE**

NE intended for use with a CONTACT QUALITY MONITOR

201.3.226

*MONOPOLAR

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

201.3.227

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.

201.3.228

RATED ACCESSORY VOLTAGE

maximum peak HF 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 peak HF output voltage which may be applied to pairs of opposite polarity

201.3.229

RATED LOAD

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

201.3.230

RATED OUTPUT POWER

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

201.3.231

SWITCH SENSOR

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

201.4 General requirements

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

201.4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Addition:

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

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

NOTE 101 Please refer to Annex AA.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

Additional SINGLE FAULT CONDITIONS:

- aa) failure in the CONTINUITY MONITOR or CONTACT QUALITY MONITOR which might cause a unacceptable RISK (see 201.8.4.101);
- bb) a defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see 201.8.10.4.101.1);
- cc) any defect which results in the unwanted energization of the PATIENT circuit (see 201.12.4.2.101);
- dd) any defect which results in a significant increase in output power relative to the output setting (see 201.12.4.4.101).

201.4.11 Power input

Amendment:

The HF SURGICAL EQUIPMENT shall be operated in the output mode and using the load which creates the greatest steady state current.

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.4 * Other conditions

Addition:

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.8.2 Other power sources

Amendment:

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

201.7.2.10 APPLIED PARTS

Addition:

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

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



IEC 1192/06

Figure 201.101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT



IEC 1193/06

Figure 201.102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT

201.7.4.2 * Control devices

Addition:

The output control shall have a scale and/or associated indicator showing the relative units of HIGH FREQUENCY output. The indication shall not be marked in watts unless the indicated power is delivered with an accuracy of $\pm 20\%$ over the total load resistance range specified in 201.7.9.3.1.

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

NOTE The compliance test is the application of subclause 201.12.1.102.

201.7.8.1 * Colours of indicator lights

Replace Table 2 in the general standard with the following:

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

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

201.7.8.2 * Colours of controls

Addition:

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

Compliance is checked by inspection.

201.7.9.2.2 Warning and safety notices

Additional subclause:

201.7.9.2.2.101 * Additional information in instructions for use

- a) Notes on the application of HF SURGICAL EQUIPMENT. These notes shall draw the attention of the OPERATOR to certain precautions which are necessary in order to reduce the risk of accidental burns. In particular, advice, when appropriate, shall be given on the following:
 - 1) * The entire area of the NEUTRAL ELECTRODE should be reliably attached to a suitably prepared and appropriate area of the PATIENT'S body as defined by the MANUFACTURER.

- 2) * The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).
 - 3) * Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.
 - 4) * When HF SURGICAL EQUIPMENT and physiological monitoring equipment are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.
 - 5) * The PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided.

Temporarily unused ACTIVE ELECTRODES should be stored in a location that is isolated from the PATIENT.
 - 6) * For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of BIPOLAR techniques may be desirable in order to avoid unwanted tissue damage.
 - 7) The output power selected should be as low as possible for the intended purpose. Certain devices or ACCESSORIES may present an unacceptable RISK at low power settings. For example, with argon beam COAGULATION, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.
 - 8) * Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power.
 - 9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (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 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 201.12.2 b), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use.
- b) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic equipment.
- c) * For HF SURGICAL EQUIPMENT, the MAXIMUM OUTPUT VOLTAGE for each HF SURGICAL MODE and instruction regarding the RATED ACCESSORY VOLTAGE as follows:

- 1) For situations where the MAXIMUM OUTPUT VOLTAGE ($U_{\max}$) is less than or equal to 1 600 V, provide instruction that ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES should be selected that have a RATED ACCESSORY VOLTAGE equal to or greater than the MAXIMUM OUTPUT VOLTAGE.
- 2) For situations where the MAXIMUM OUTPUT VOLTAGE ($U_{\max}$) is greater than 1 600 V, calculate the variable y using the formula:

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

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.

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

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

- d) A warning that failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.
- e) * A statement of compatibility with specific MONITORING NE.

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

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

NOTE 2 This requirement does not apply for HF SURGICAL EQUIPMENT intended for use without a NEUTRAL ELECTRODE. (See 201.15.101).

- f) Where the temperature under the NEUTRAL ELECTRODE, during intended or foreseen use, may exceed the limits listed in subclause 11.1.2.2 of the general standard or 201.15.101.5 of this standard, instructions, warnings and cautions for proper use of the NEUTRAL ELECTRODE shall be provided.
- g) * A warning addressing the risks resulting from neuromuscular stimulation which can occur especially with modes which produce electrical arcs between the ACTIVE ELECTRODE and tissue.
- h) * For HF SURGICAL EQUIPMENT that can be energized without continuous activation of a SWITCH SENSOR as per subclause 201.8.10.4.101.2, warnings and/or cautions regarding the risks.

201.7.9.2.14 * Accessories, supplementary equipment, used material

Addition:

The instructions for use shall include:

- a) Information concerning the selection and use of HF SURGICAL ACCESSORIES in order to avoid incompatibility and unsafe operation (see also 201.15.4.1.101 and 201.15.4.1.102).
- b) Advice for the OPERATOR to avoid HF output settings where MAXIMUM OUTPUT VOLTAGE may exceed RATED ACCESSORY VOLTAGE.
- c) Advice concerning the compatibility between a MONITORING NE and a CONTACT QUALITY MONITOR.
- d) Advice for the OPERATOR regularly to inspect the ACCESSORIES. In particular, electrode cables and HF ENERGIZED ENDOTHERAPY DEVICES (see IEC 60601-2-18) should be checked (e.g. under magnification) for possible damage.

- e) * For ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES, including separately supplied parts thereof, the RATED ACCESSORY VOLTAGE .
- f) * On end use packaging for NEUTRAL ELECTRODES:
 - If marked for single use, an expiration date.
 - Information necessary to prevent burns at the NE site, e.g. limitation of output setting, PATIENT preparation and/or activation duration.
 - If intended for use only on small PATIENTS, a marking in kg indicating the maximum PATIENT weight for which it is intended to be used. See 201.15.101.5
- g) * On instructions for use for MONITORING NEUTRAL ELECTRODES:
 - A statement of compatibility with specific CONTACT QUALITY MONITOR(s).
- h) HF SURGICAL ACCESSORIES where the temperature under the NE, during intended or foreseen use, may result in the temperature exceeding the limits listed in subclause 11.1.2.2 of the general standard or subclause 201.15.101.5 of this standard shall be accompanied by instructions, warnings and cautions for the proper use of NEUTRAL ELECTRODES.
- i) On instructions for use for HF SURGICAL ACCESSORIES intended for use only with specific HF SURGICAL EQUIPMENT or HF waveforms or voltages, a detailed statement to that effect.

201.7.9.2.15 Environmental protection

Addition:

- Provide advice to the OPERATOR regarding the advisability of the use of smoke-plume extraction.

201.7.9.3 Technical description

201.7.9.3.1 * General

Addition:

- power output data – MONOPOLAR output (for all HF SURGICAL MODES available, any variable “blend” control being set to the maximum position) including:
 - diagrams showing the power output at full and half output control settings minimally over the range of load resistance 100 Ω to 2 000 Ω , but extended as necessary to include the RATED LOAD;
 - diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above;
- power output data – BIPOLAR output (for all HF SURGICAL MODES as defined above) including:
 - diagrams showing the power output at full and half output control settings minimally over the range of load resistance 10 Ω to 1 000 Ω , but extended as necessary to include the RATED LOAD;
 - diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above;
- voltage output data – MONOPOLAR and BIPOLAR output (for all HF SURGICAL MODES available). Maximum voltage data required by 201.7.9.2.2.101 c);
- where HF SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE, this shall be stated;
- where HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT is designed to have a single, fixed output setting, then reference to “half output control settings” shall be ignored.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.3 Classification of APPLIED PARTS

Addition:

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

Additional subclause:

201.8.4.101 * NEUTRAL ELECTRODE monitoring circuit

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER of more than 50 W shall be provided with a CONTINUITY MONITOR and/or a CONTACT QUALITY MONITOR 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 201.12.4.2.101 and shall not be externally adjustable.

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

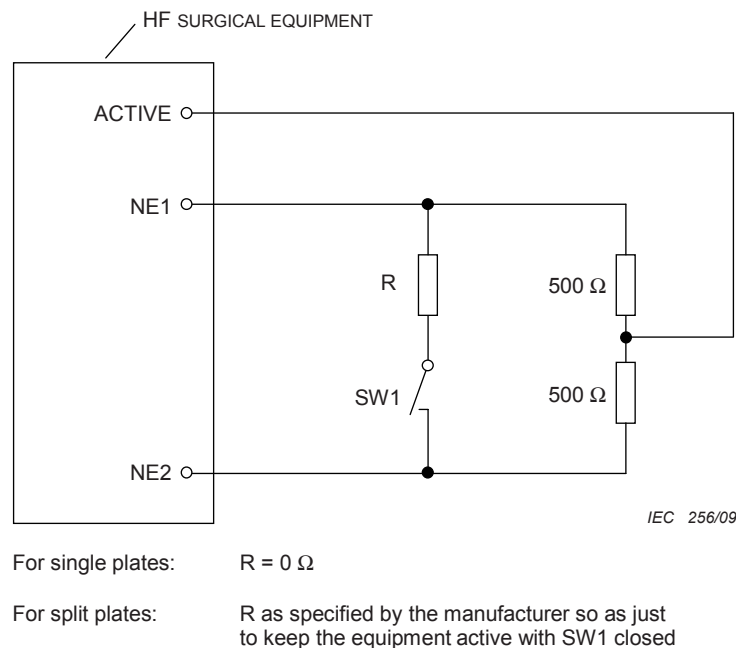
The monitoring circuit shall be supplied from a power source isolated from the MAINS PART and from earth and having a voltage not exceeding 12 V. The limitation of monitoring current for a CONTACT QUALITY MONITOR is defined in 201.8.7.3.

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

Compliance of a CONTINUITY MONITOR is checked by operating the HF SURGICAL EQUIPMENT at maximum output control setting in each operating mode into the circuit shown in Figure 201.103. The switch is closed and opened five times and the HF output shall be disabled and the alarm shall sound at each opening of the switch.

Compliance of a CONTACT QUALITY MONITOR is checked by switching on the mains of the HF SURGICAL EQUIPMENT and setting its controls for MONOPOLAR operation, except that it shall not be activated. Then a compatible MONITORING NE, selected according to the advice per 201.7.9.2.2.101 e), is connected to the NE connections of the CONTACT QUALITY MONITOR. The NE is then placed, according to marked instructions for use, with full contact on a human subject or a suitable surrogate surface, and the CONTACT QUALITY MONITOR is set up according to instructions for use. The HF SURGICAL EQUIPMENT is then activated in a MONOPOLAR HF SURGICAL MODE. No alarm shall sound and HF output shall be present. With the HF SURGICAL EQUIPMENT now activated, the contact area between the NE and the human subject or a suitable surrogate surface is gradually reduced until a NE alarm occurs. The remaining contact area (alarm area), A_a shall be recorded for subsequent thermal rise testing per subclause 201.15.101.5, and no HF output shall be produced when activation is attempted.

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



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

Figure 201.103 – Circuit suitable for testing compliance to 201.8.4.101

201.8.4.102 * Neuromuscular stimulation

In order to minimize the possibility of neuromuscular stimulation, a capacitance shall be incorporated into the PATIENT circuit so that it is effectively in series with the ACTIVE ELECTRODE or one conductor of a BIPOLAR ELECTRODE. This capacitance shall not exceed 5 nF 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.

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

201.8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Amendment:

For HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES, separation between the HF APPLIED PARTS and the ENCLOSURE including SIGNAL INPUT PARTS and SIGNAL OUTPUT PARTS and between different HF PATIENT CIRCUITS need not be subjected to the dielectric strength test of 201.8.8.3.

The CREEPAGE DISTANCES and AIR CLEARANCES of insulation of such separation shall be at least 3 mm/kV or 4 mm, whichever is the greater. The reference voltage shall be the maximum peak voltage.

This requirement does not apply for components when the adequacy of ratings can be demonstrated, for example by component manufacturers' ratings or by the dielectric strength test of 201.8.8.3.

201.8.5.2.3 * PATIENT leads

Amendment:

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

For NEUTRAL ELECTRODE cables, the connector which is remote from the PATIENT shall be constructed so that the connections can not contact conductive live parts of FIXED mains socket outlets or MAINS CONNECTORS.

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

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

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

Amendment:

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 subclause 8.5.5.1 and Figure 9 of the general standard using a test voltage of 2 kV instead of 5 kV.

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

201.8.6.1 * Applicability of requirements

Addition:

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

201.8.7.1 * General requirements

Item b)

Addition:

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

Amendment:

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

201.8.7.3 * Allowable values

Item b)

Addition:

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

Item e)

Amendment:

The 10 mA limit for LEAKAGE CURRENT does not apply to HF LEAKAGE CURRENTS tested from ACTIVE and NEUTRAL ELECTRODES with PATIENT circuits activated (see 201.8.7.3.101).

Additional subclause:

201.8.7.3.101 Thermal effects of HF LEAKAGE CURRENTS

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

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

***a) HIGH FREQUENCY LEAKAGE CURRENTS**

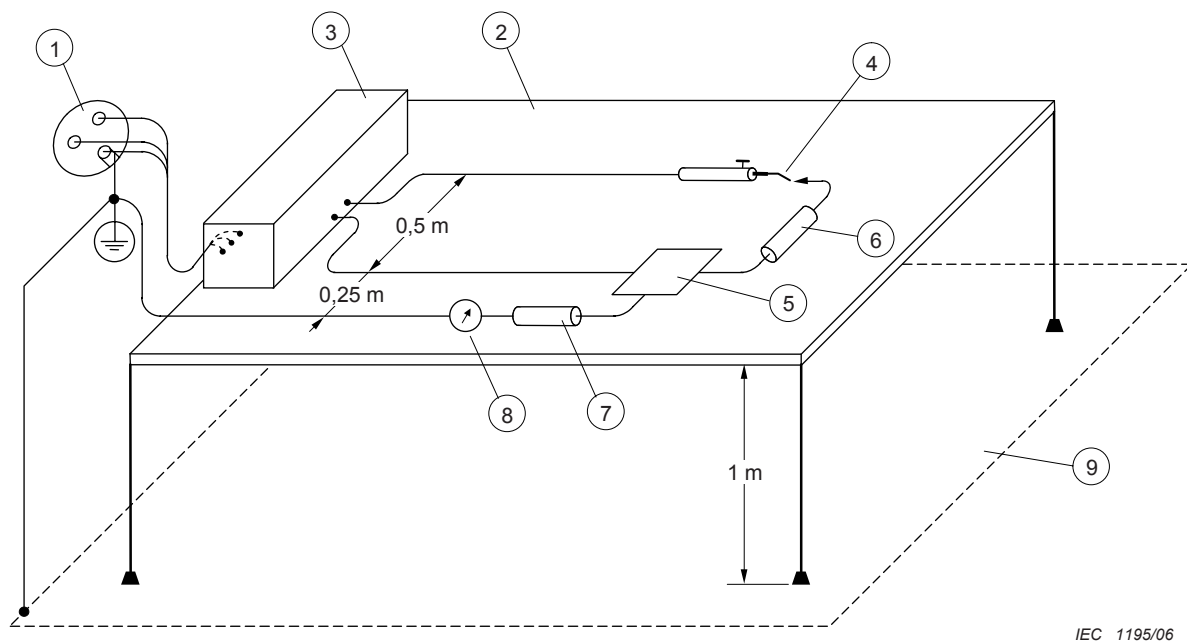
1) NEUTRAL ELECTRODE referenced to earth

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

Compliance is checked by the following tests.

Test 1 – The test is performed on each single output of the HF SURGICAL EQUIPMENT in turn with the electrode cables and electrodes as shown in Figure 201.104. The cables are spaced 0,5 m apart on an insulating surface 1 m above an earthed conductive plane.

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



IEC 1195/06

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 201.104 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load between electrodes

Test 2 – The HF SURGICAL EQUIPMENT is set up as for test 1, but the 200 Ω load resistor is connected between the ACTIVE ELECTRODE and the PROTECTIVE EARTH TERMINAL of the HF SURGICAL EQUIPMENT as shown in Figure 201.105. The HF LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE is measured.