



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

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-2:2018+A1:2024. It is identical to IEC 60601-2-2:2017, incorporating amendment 1:2023. It supersedes BS EN IEC 60601-2-2:2018, which will be withdrawn on 31 July 2027.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

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

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

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Amendments/corrigenda issued since publication

Date	Text affected
30 September 2024	Implementation of IEC amendment 1:2023 with CENELEC endorsement A1:2024

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 60601-2-2:2017)

Appareils électromédicaux - Partie 2-2: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils d'électrochirurgie à courant haute
fréquence et des accessoires d'électrochirurgie à courant
haute fréquence
(IEC 60601-2-2:2017)

Medizinische elektrische Geräte - Teil 2-2: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Hochfrequenz-
Chirurgiegeräten
(IEC 60601-2-2:2017)

This European Standard was approved by CENELEC on 2017-05-05. 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 CEN-CENELEC Management Centre or to any CENELEC member.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1427/FDIS, future edition 6 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 approved by CENELEC as EN IEC 60601-2-2:2018.

The following dates are fixed:

- latest date by which the document has to be (dop) 2018-11-18
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2021-05-18
standards conflicting with the
document have to be withdrawn

This document supersedes EN 60601-2-2:2009.

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Endorsement notice

The text of the International Standard IEC 60602-2-2:2017 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60529	NOTE	Harmonized as EN 60529.
IEC 60601-2-4:2010	NOTE	Harmonized as EN 60601-2-4:2011.
IEC 60601-2-18:2009	NOTE	Harmonized as EN 60601-2-18:2015.

European foreword to Amendment 1

The text of document 62D/2010/FDIS, future edition 6 of IEC 60601-2-2/AMD1, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-2:2018/A1:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2025-05-01 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-07-31 document have to be withdrawn

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Endorsement notice

The text of the International Standard IEC 60601-2-2:2017/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1-3	NOTE	Approved as EN 60601-1-3
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-1-11	NOTE	Approved as EN 60601-1-11
IEC 60601-1-2	NOTE	Approved as EN 60601-1-2

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

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>
Replacement in Annex ZA of EN 60601-1:2006:				
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
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
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
+ A2	2020		+ A2	2021

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
Addition to Annex ZA of EN 60601-1:2006:				
CISPR 11	2015	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2016
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	2006
IEC 61000-4-6	2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	2014

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories**

FOREWORD

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

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

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

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

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

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

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

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

The requirements are followed by specifications for the relevant tests.

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

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

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

INTRODUCTION to Amendment 1

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

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: 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 part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES as defined in 201.3.224 and 201.3.223.

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

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

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

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

Replacement:

A1 IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020 **A1**

A1 IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems* IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020 **A1**

Addition:

A1 CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
CISPR 11:2015/AMD1:2016
CISPR 11:2015/AMD2:2019 **A1**

201.3 Terms and definitions

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

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

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

Replace NOTE 1 with the following:

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

Addition:

201.3.201

ACTIVE ACCESSORY

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

201.3.202

ACTIVE CONNECTOR

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

201.3.203

ACTIVE ELECTRODE

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

201.3.204

ACTIVE ELECTRODE INSULATION

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

201.3.205

ACTIVE HANDLE

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

201.3.206**ACTIVE OUTPUT TERMINAL**

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

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

Note 2 to entry: See Figure AA.1.

201.3.207***ASSOCIATED EQUIPMENT**

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

201.3.208***BIPOLAR**

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

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

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

201.3.209**BIPOLEAR ACCESSORY**

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

201.3.210**COAGULATION**

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

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

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

201.3.211**CONTACT QUALITY MONITOR****CQM**

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

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

201.3.212**CONTINUITY MONITOR**

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

201.3.213***CREST FACTOR**

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

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

201.3.214

*CUTTING

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

201.3.215

*EARTH REFERENCED PATIENT CIRCUIT

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

201.3.216

FINGERSWITCH

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

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

201.3.217

*FULGURATION

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

201.3.218

*HEATING FACTOR

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

Note 1 to entry: The HEATING FACTOR is expressed as A²s (amperes squared seconds).

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

201.3.219

*HIGH CURRENT MODE

MONOPOLAR output mode whose INTENDED USE (MAXIMUM OUTPUT CURRENT and maximum DUTY CYCLE) results in a HEATING FACTOR of greater than 30 A²s in any 60 s period

201.3.220

*HIGH FREQUENCY

HF

frequencies less than 5 MHz and generally greater than 200 kHz

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

201.3.221

HF ISOLATED PATIENT CIRCUIT

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

201.3.222

HF PATIENT CIRCUIT

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

201.3.223

HF SURGICAL ACCESSORY

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

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

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

201.3.224

HF SURGICAL EQUIPMENT

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

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

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

201.3.225

*HF SURGICAL MODE

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

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

201.3.226

*MAXIMUM OUTPUT CURRENT

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

201.3.227

*MAXIMUM OUTPUT VOLTAGE

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

201.3.228

*MONITORING NE

NE intended for use with a CONTACT QUALITY MONITOR

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

201.3.229

*MONOPOLAR

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

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

201.3.230

NEUTRAL ELECTRODE

NE

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

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

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

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

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

201.3.231.1

RATED ACCESSORY VOLTAGE

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

201.3.231.2

RATED ACCESSORY VOLTAGE

<BIPOLEAR HF SURGICAL ACCESSORY> maximum peak HF output voltage which may be applied to pairs of opposite polarity

201.3.232

RATED LOAD

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

201.3.233

RATED OUTPUT POWER

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

201.3.234

SWITCH SENSOR

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

201.4 General requirements

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

Additional subclauses:

201.4.1.101 * Additional conditions for application

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

201.4.2.3.101 * Evaluating RISK

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

[A₁] Additionally, the impact on the heating under the NEUTRAL ELECTRODE shall be considered within RISK ANALYSIS for any mode with a duty cycle above 45 % according to its intended use even if the HEATING FACTOR is below 30 A²s in any 60 s interval. **[A₁]**

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

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

NOTE 101 Please refer to Annex AA.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Additional subclause:

201.4.7.101 Specific SINGLE FAULT CONDITIONS

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

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

201.4.11 Power input

A1 *Replacement of first dash in compliance tests:*

- The HF SURGICAL EQUIPMENT shall be operated in the manner (combination of operating setting, load, etc.) which creates the greatest steady state input current. Input current is measured and compared with the markings and the contents of the technical description. **A1**

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.4 * Other conditions

Addition:

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.8.2 Other power sources

Amendment:

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

201.7.2.10 APPLIED PARTS

Addition:

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

Connections on the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT for the connection of NE leads shall be marked with the symbols given in Figures 201.101 and 201.102 as follows:

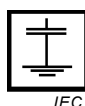


Figure 201.101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT



Figure 201.102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT

Additional subclause:

201.7.2.10.101 * HF SURGICAL ACCESSORIES

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

201.7.4.2 * Control devices

Addition:

The output control shall have a scale and/or associated indicator showing the relative units of HIGH FREQUENCY output. The indication shall not be marked in watts unless the indicated power is delivered with an accuracy of $\pm 20\%$ 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 ACCESSORY in this position.

NOTE The compliance test is the application of subclause 201.12.1.102.

201.7.8.1 * Colours of indicator lights

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

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

Name	On when	Indicator light ^a	Alarm indicator light	Accompanied by sound	Operator requirement
Warning ^b	Hazardous situation	Red, flashing or not	-	- ^c	Immediate response by the operator is required, for example, a fault in the patient circuit
CUTTING mode	CUTTING activation	Yellow, flashing or not	-	Yes ^d	-
COAGULATION mode	COAGULATION activation	Blue, flashing or not	-	Yes ^d	-
Ready for use	ME EQUIPMENT is ready for use	Green	-	-	-
Other	Situations other than that of red, yellow, blue or green	Any colour other than red, yellow, blue or green	-	-	-
^a These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS. ^b Such warnings and cautions are frequently accompanied by a SAFETY SIGN. ^c Sound may be utilized, but IEC 60601-1-8 requires that it be perceived as different than auditory ALARM SIGNALS. ^d As defined in 201.12.4.2.101.					

201.7.8.2 * Colours of controls

Addition:

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

Compliance is checked by inspection.

201.7.9.2.2 Warning and safety notices

Additional subclause:

201.7.9.2.2.101 Additional information in instructions for use

- a) * Notes on the application of HF SURGICAL EQUIPMENT. These notes shall draw the attention of the OPERATOR to certain precautions which are necessary in order to reduce the RISK of accidental burns. In particular, advice, when appropriate, shall be given on the following:
- 1) The entire area of the NEUTRAL ELECTRODE should be reliably attached to a suitably prepared and appropriate area of the PATIENT's body as defined by the MANUFACTURER.
 - 2) The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).
 - 3) Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.
 - 4) When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as

far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

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

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

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

- 6) For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of BIPOLAR techniques may be desirable in order to avoid unwanted tissue damage.
- 7) The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present an unacceptable RISK at low power settings. For example, with argon beam COAGULATION, the risk of gas embolism rises if there is insufficient HF power to produce a rapid, impermeable eschar on the target tissue.
- 8) Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power.
- 9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (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 electrically conductive implants, a possible HAZARD exists due to concentration or re-direction of HF currents. In case of doubt, qualified advice should be obtained.
 - 11) For HF SURGICAL EQUIPMENT with an operating mode as described in 201.12.2 c) 2), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use.
- b) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic equipment. For PATIENTS with cardiac pacemakers or other active implants, a possible HAZARD exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, qualified advice should be obtained.
 - c) * For HF SURGICAL EQUIPMENT, the MAXIMUM OUTPUT VOLTAGE for each HF SURGICAL MODE and **A1** instructions **A1** 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:

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

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

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

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

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

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

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

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

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

NOTE 3 See Annex AA for additional information.

201.7.9.2.14 * ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall include:

- a) Information concerning the selection and use of HF SURGICAL ACCESSORIES in order to avoid incompatibility and unsafe operation (see also 201.15.4.1.101 and 201.15.4.1.102).
- b) Advice for the OPERATOR to avoid HF output settings where MAXIMUM OUTPUT VOLTAGE may exceed RATED ACCESSORY VOLTAGE.
- c) Advice concerning the compatibility between a MONITORING NE and a CONTACT QUALITY MONITOR.
- d) Advice for the OPERATOR regularly to inspect the ACCESSORIES. In particular, electrode cables and HF ENERGIZED ENDOTHERAPY DEVICES (see IEC 60601-2-18) should be checked (e.g. under magnification) for possible damage.
- e) * For ASSOCIATED EQUIPMENT and ACTIVE ACCESSORIES, including separately supplied parts thereof, the RATED ACCESSORY VOLTAGE together with a warning to use only with HF SURGICAL MODE output settings resulting in a peak output voltage not greater than the RATED ACCESSORY VOLTAGE.

- f) * On end use packaging for NEUTRAL ELECTRODES:
 - If marked for single use, an expiration date.
 - Information necessary to prevent burns at the NE site, e.g. limitation of output setting, PATIENT preparation or activation duration.
 - If intended for use only on small PATIENTS, a marking in kg indicating the maximum PATIENT weight for which it is intended to be used. See 201.15.101.5
- g) * On instructions for use for MONITORING NEUTRAL ELECTRODES:
 - A statement of compatibility with specific CONTACT QUALITY MONITOR (s).
- h) HF SURGICAL ACCESSORIES where the temperature under the NE, during intended or foreseen use, may result in the temperature exceeding the limits listed in subclause 11.1.2.2 of the general standard or subclause 201.15.101.5 of this document shall be accompanied by instructions, warnings and cautions for the proper use of NEUTRAL ELECTRODES.
- i) On instructions for use for HF SURGICAL ACCESSORIES intended for use only with specific HF SURGICAL EQUIPMENT or HF waveforms or voltages, a detailed statement to that effect.
- j) * For ACTIVE ELECTRODES and ACTIVE HANDLES, information to assess the following HAZARDOUS SITUATIONS:
 - visibly exposed metal of the ACTIVE ELECTRODE shaft where it connects with the ACTIVE HANDLE
 - poor electrical connection between the ACTIVE HANDLE and the ACTIVE ELECTRODE shaft
 - poor fit between the ACTIVE HANDLE and the ACTIVE ELECTRODE shaft
-  k) * the length of the HF SURGICAL ACCESSORY. 

NOTE 101 See Annex AA for additional information.

201.7.9.2.15 Environmental protection

Addition:

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

201.7.9.3 Technical description

201.7.9.3.1 * General

Addition:

- power output data – MONOPOLAR output (for all HF SURGICAL MODES available, any variable “blend” control being set to the maximum position) including:
 - diagrams showing the power output at full and half output control settings minimally over the range of load resistance 100 Ω to 2 000 Ω , but extended as necessary to include the RATED LOAD;
 - diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above;
- power output data – BIPOLAR output (for all HF SURGICAL MODES as defined above) including:
 - diagrams showing the power output at full and half output control settings minimally over the range of load resistance 10 Ω to 1 000 Ω , but extended as necessary to include the RATED LOAD;
 - diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above;
- voltage output data – MONOPOLAR and BIPOLAR output (for all HF SURGICAL MODES available). MAXIMUM OUTPUT VOLTAGE data required by 201.7.9.2.2.101.

- where HF SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE, this shall be stated;
- where HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT is designed to have a single, FIXED output setting, then reference to “half output control settings” shall be ignored;
- the MAXIMUM OUTPUT CURRENT for each HF SURGICAL MODE;
- the maximum HEATING FACTOR generated in any 60 second period when the HF SURGICAL EQUIPMENT is used in any HIGH CURRENT MODE.

NOTE 101 The manufacturer can describe the specific behaviour of the HF SURGICAL EQUIPMENT, e.g. short circuit protection. **NOTE 102**

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.4 Limitation of voltage, current or energy

Additional subclauses:

201.8.4.101 * NEUTRAL ELECTRODE monitoring circuit

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

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

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

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

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

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

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

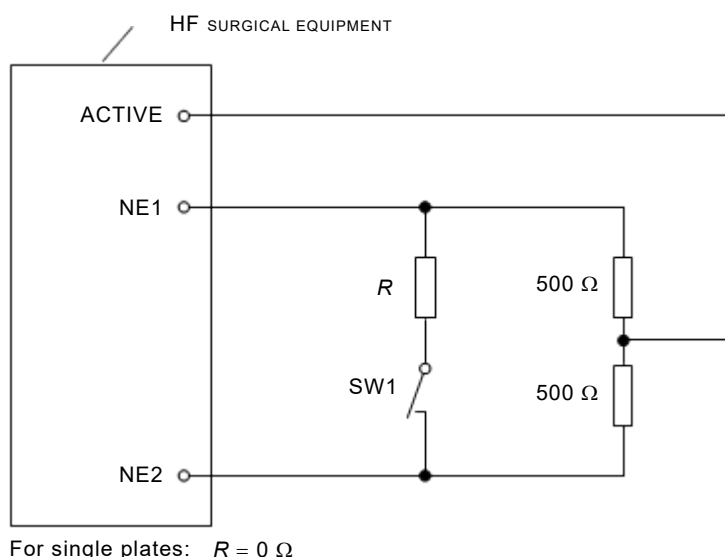
An additional visible warning consisting of a red indicator light shall be provided (see 201.7.8.1).

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

Compliance of a CONTACT QUALITY MONITOR is checked by switching on the mains of the HF SURGICAL EQUIPMENT and setting its controls for MONOPOLAR operation, except that it shall not

be activated. Then a compatible MONITORING NE, selected according to the advice per 201.7.9.2.2.101 e), is connected to the NE connections of the CONTACT QUALITY MONITOR. The NE is then placed, according to marked instructions for use, with full contact on a human subject or a suitable surrogate surface, and the CONTACT QUALITY MONITOR is set up according to instructions for use. The HF SURGICAL EQUIPMENT is then activated in a MONOPOLAR HF SURGICAL MODE. No alarm shall sound and HF output shall be present. With the HF SURGICAL EQUIPMENT now activated, the contact area between the NE and the human subject or a suitable surrogate surface is gradually reduced until a NE alarm occurs. The remaining contact area (alarm area), A_a shall be recorded for subsequent thermal rise testing per subclause 201.15.101.5, and no HF output shall be produced when activation is attempted. This test shall be repeated along both axes using at least three samples of each compatible MONITORING NE.

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



IEC

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

Figure 201.103 – Circuit suitable for testing compliance to 201.8.4.101

201.8.4.102 * Neuromuscular stimulation

In order to minimize the possibility of neuromuscular stimulation, a capacitance shall be incorporated into the PATIENT circuit so that it is effectively in series with the ACTIVE ELECTRODE or one conductor of a BIPOLAR ACCESSORY. This capacitance shall not exceed 5 nF for MONOPOLAR PATIENT circuits and 50 nF for BIPOLAR PATIENT circuits. The DC resistance between ACTIVE and NEUTRAL ELECTRODE terminals, or between the terminals of a BIPOLAR output circuit, shall not be less than 2 M Ω .

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

201.8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Amendment:

For HF SURGICAL EQUIPMENT, the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the HF APPLIED PARTS and the ENCLOSURE including SIGNAL INPUT/OUTPUT PARTS, between the HF PATIENT CIRCUITS and the intermediate circuit and between different HF PATIENT CIRCUITS shall be at least 3 mm/kV or 4 mm, whichever is the greater. The reference voltage shall be the maximum peak voltage. These separations need not be subjected to the dielectric strength test of 201.8.8.3. HF PATIENT CIRCUITS of HF SURGICAL EQUIPMENT shall be considered as APPLIED PARTS in the context of this subclause. These CREEPAGE DISTANCES and AIR CLEARANCES are intended to represent two MEANS OF PROTECTION.

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

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

201.8.5.2.3 * PATIENT leads or PATIENT cables

Amendment:

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

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

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

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

201.8.5.5 * DEFIBRILLATION-PROOF APPLIED PARTS

Amendment:

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

Compliance is checked by the common-mode test only, as described in 8.5.5.1 and Figure 9 of the general standard using a test voltage of 2 kV instead of 5 kV.

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

201.8.6.1 * Applicability of requirements

Addition:

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

201.8.7.1 * General requirements

Item b)

Addition:

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

Amendment:

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

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

201.8.7.3 * Allowable values

Item b)

Addition:

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

Item e)

Amendment:

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

Additional subclause:

201.8.7.3.101 Thermal effects of HF LEAKAGE CURRENTS

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

*a) HIGH FREQUENCY LEAKAGE CURRENTS

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

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

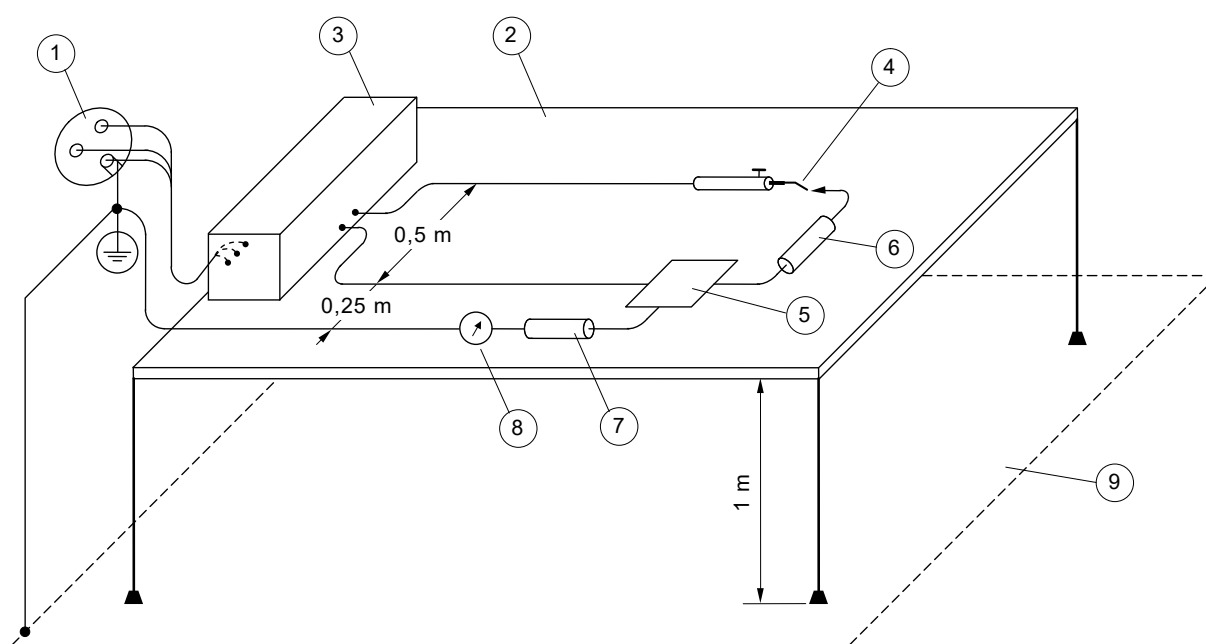
1) For MONOPOLAR EARTH REFERENCED PATIENT CIRCUITS

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

Compliance is checked by the following tests.

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

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



IEC

Key

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

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

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