

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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

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



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## 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 fifth edition cancels and replaces the fourth edition published in 2006. This edition constitutes a technical revision. Revisions in this edition 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 text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/726/FDIS	62D/755/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 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.

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 particular standard will remain unchanged until the maintenance result date indicated on the IEC web site 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

The contents of the corrigendum of February 2014 have been included in this copy.

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Withdrawn



## 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.

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Withstand

## MEDICAL ELECTRICAL EQUIPMENT –

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

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> 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 60601-1-11<sup>2)</sup> 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

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

<sup>2)</sup> 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:*