

# 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 –** [IEC 60601-2-2:2017](#)  
**Partie 2-2: Exigences particulières pour la sécurité de base et les performances**  
**essentielle des appareils d'électrochirurgie à courant haute fréquence et des**  
**accessoires d'électrochirurgie à courant haute fréquence**



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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

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**IEC 60601-2-2 edition 6.1 contains the sixth edition (2017-03) [documents 62D/1427/FDIS and 62D/1442/RVD] and its amendment 1 (2023-02) [documents 62D/2010/FDIS and 62D/2021/RVD].**

**In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.**



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 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.

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 the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific publication. At this date, the publication will be

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[IEC 60601-2-2:2017](https://standards.iteh.ai/catalog/standards/sist/529df6b9-7a8c-45d0-8e3f-2a045b3bbb59/iec-60601-2-2-2017)

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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 60601-1:2005 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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

### INTRODUCTION to Amendment 1

The 6<sup>th</sup> 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 standard<sup>1</sup> 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

<sup>1</sup> 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 89.

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

### *Replacement:*

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

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

*Addition:*

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

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

~~IEC 61000-4-6:2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*~~

### 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**

##### **BIPOLAR 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.