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Edition 6.1 2023-02
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Corrected version
2025-11

colour inside

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

IEC 60601-2-2:2017-03+AMD1:2023-02 CSV(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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IEC 60601-2-2

Edition 6.0 2017-03
Amendment 1 2023-02

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

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this interpretation sheet is based on the following documents:

DISH	Report on voting
62D/2255/DISH	62D/2274/RVDISH

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

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Interpretation of 201.3.223, 201.3.224, 201.4.1.101, 201.7.9.2.2.101 i), 201.7.9.2.14 k), 202.7.1.2 and the rationales to 201.4.1.101, 201.7.9.2.2.101 i), 201.7.9.2.14 k), Clause 202 of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023.

This interpretation sheet is intended to clarify the requirements for EMC testing and compatibility.

Definition 201.3.223 HF SURGICAL ACCESSORY

The requirements in this definition of IEC 60601-2-2:2017 are clarified by the following.

The IEC 60601-2-2:2017 defined term HF SURGICAL EQUIPMENT does not modify the IEC 60601-1 definition of medical electrical equipment.

ICS 11.040.30

IEC 60601-2-2:2017-03/AMD1:2023-02/ISH1:2025-11(en-fr)

Definition 201.3.224 HF SURGICAL EQUIPMENT

The requirements in this definition of IEC 60601-2-2:2017 are clarified by the following.

HF SURGICAL ACCESSORIES are not HF SURGICAL EQUIPMENT. This standard defines HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORY uniquely.

Subclause 201.4.1.101 * Additional conditions for application

The requirements in this subclause of IEC 60601-2-2:2017 are clarified by the following.

It does not exempt HF SURGICAL EQUIPMENT from the requirements of IEC 60601-1-2.

It does not exempt HF SURGICAL ACCESSORIES from the requirements of IEC 60601-1-2.

Subclause 201.7.9.2.2.101 Additional information in instructions for use

The requirements in this subclause of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 are clarified by the following.

i) This subclause only requires the manufacturer to provide the length.

Subclause 201.7.9.2.14 *ACCESSORIES, supplementary equipment, used material

The requirements in this subclause of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 are clarified by the following.

k) This subclause only requires the manufacturer to provide the length.

Subclause 202.7.1.2 Operating modes

The requirements in this subclause of IEC 60601-2-2:2017 are clarified by the following.

Subclause 202.7.1.2 does not exempt HF SURGICAL ACCESSORIES from the requirements of IEC 60601-1-2, particularly the configuration requirements of subclause 4.3.1.

While HF SURGICAL EQUIPMENT actually meets the definition of CISPR 11 Group 2 equipment, subclause 202.7.1.2 specifies (as does CISPR 11) that when switched on and in idle state, HF SURGICAL EQUIPMENT should meet the limits of CISPR 11 Group 1. For this reason, the accompanying documents should state the limits with which the HF SURGICAL EQUIPMENT complies, but should also state that it is CISPR 11 Group 2 equipment.

Annex AA
(informative)

Particular guidance and rationale

AA.2 Rationale for particular clauses and subclauses

Subclause 201.4.1.101 Additional conditions for application

The rationale to this subclause of IEC 60601-2-2:2017 is clarified by the following.

It does not exempt HF SURGICAL EQUIPMENT from the requirements of IEC 60601-1-2.

It does not exempt HF SURGICAL ACCESSORIES from the requirements of IEC 60601-1-2.

Subclause 201.7.9.2.2.101 i) Additional information in instructions for use

The rationale to this subclause of IEC 60601-2-2:2017 is clarified by the following.

i) The last paragraph points out that the whole configuration is relevant for EMC results. Configuration is to be understood according to the description in IEC 60601-1-2:2014, 4.3.1. Not only the length, but also the type of HF SURGICAL ACCESSORIES is relevant. Type includes, but is not limited to, the materials and construction, electrical components, electrical circuits, and impedance.

Subclause 201.7.9.2.14 *ACCESSORIES, supplementary equipment, used material

The rationale to this subclause of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 is clarified by the following.

k) This informative content does not communicate that EMC is the only consideration with respect to compatibility between HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES.

It does not imply that the maximum length is the worst-case length condition with regard to EM EMISSIONS or IMMUNITY.

It does not imply that the HF SURGICAL ACCESSORY length is the only condition for determination of electromagnetic compatibility between the HF SURGICAL EQUIPMENT and the HF SURGICAL ACCESSORY.

Clause 202 – ELECTROMAGNETIC DISTURBANCES – Requirements and tests

The rationale to this clause of IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023 is clarified by the following.

– Paragraph 6 points out that the maximum permissible length of HF SURGICAL ACCESSORY is derived from the least favorable configuration according to the description in IEC 60601-1-2:2014, 4.3.1. Other parameters could also affect the EM EMISSIONS and IMMUNITY of the ME SYSTEM.

– Paragraph 6 is not intended to imply that the maximum permissible length is considered the least favorable configuration according to IEC 60601-1-2:2014, 4.3.1.

– Paragraph 7 is not intended to imply that no EMC assessment is necessary.

– Paragraph 9 points out that the OPERATOR has the responsibility to ensure that the length of HF SURGICAL ACCESSORY is not violating the maximum permissible length specified by the manufacturer of the HF SURGICAL EQUIPMENT. 201.7.9.2.2.101 i) and 201.7.9.2.14 k) provide the requirements for MANUFACTURERS to include information so that the OPERATOR can manage the combination of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES.

– Paragraph 9 is intended to clarify that the OPERATOR'S responsibility is to ensure a compatible combination of HF SURGICAL ACCESSORIES and HF SURGICAL EQUIPMENT is used that is in line with EMC compliance requirements. This is intended to be basic information provided by the MANUFACTURERS for making such combinations. The provision of information, along with EMC compliance, is the responsibility of each MANUFACTURER of HF SURGICAL ACCESSORIES and HF SURGICAL EQUIPMENT.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-2-2 edition 6.1 contains the sixth edition (2017-03) [documents 62D/1427/FDIS and 62D/1442/RVD], its amendment 1 (2023-02) [documents 62D/2010/FDIS and 62D/2021/RVD] and the Interpretation sheet 1 of the amendment 1 (2025-11).

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 in the data related to the specific publication. At this date, the publication will be

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 standard[1] 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

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[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 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*~~

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[15] ANSI/AAMI HF18:2001, *Electrosurgical Devices*

[16] CENELEC Guide 29:2007, *Temperatures of hot surfaces likely to be touched*

[17] IEC 60601-2-4:2010, *Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators*

[18] IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

[19] IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

[20] IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

[21] 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*

[22] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*