IEC 60601-2-2

Edition 6.0 2023-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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(en-fr)

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

IEC 60601-2-2

Edition 6.0 2023-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.30

ISBN 978-2-8322-6466-9

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

AMENDMENT 1

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to IEC 60601-2-2:2017 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 Amendment is based on the following documents:

Draft	Report on voting
62D/2010/FDIS	62D/2021/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

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

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

_____

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.

201.1 Scope, object and related standards

Replace, in footnote 1 to the first sentence, "IEC 60601-1:2005/AMD1:2012" *with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

201.1.3 Collateral standards

Replace the existing second paragraph with the following:

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.

201.2 Normative references

Replace the existing reference to IEC 60601-1-2:2014 with the following:

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

Replace the existing reference to IEC 60601-1-8:2006 with the following:

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

Delete the existing references to IEC 61000-4-3:2006 and IEC 6100-4-6:2013.

Replace the existing reference to CISPR 11:2015 with the following:

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

201.3.220
*** HIGH FREQUENCY**

Add, after the existing definition, the following new note:

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.

201.4.2.3.101 * Evaluating risk

Add, at the end of the existing subclause, the following new text:

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 A^2s in any 60 s interval.

201.4.11 Power input

Replace the text of this paragraph with the following:

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.

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

Replace the existing table with the following new table:

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.

201.7.9.2.2.101 Additional information in instructions for use

*Replace, in the first sentence of item c), "*instruction*" with "*instructions*".*

201.7.9.2.14 * ACCESSORIES, supplementary equipment, used material

Add, before NOTE 101, the following new item:

k) * the length of the HF SURGICAL ACCESSORY.

201.7.9.3.1 * General

Add, at the end of the existing subclause, the following new note:

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

201.8.7.1 * General requirements

Add, after the last sentence, the following new note:

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.

201.8.7.3.101 Thermal effects of HF LEAKAGE CURRENT

Replace, under item 2) for MONOPOLAR HF ISOLATED PATIENT CIRCUITS*, the sentence beginning with "The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106,…" with the following:*

The HF SURGICAL EQUIPMENT is set up as shown in Figure 201.106. Each electrode is tested with the output first being unloaded and then repeated with the output loaded at the RATED LOAD.

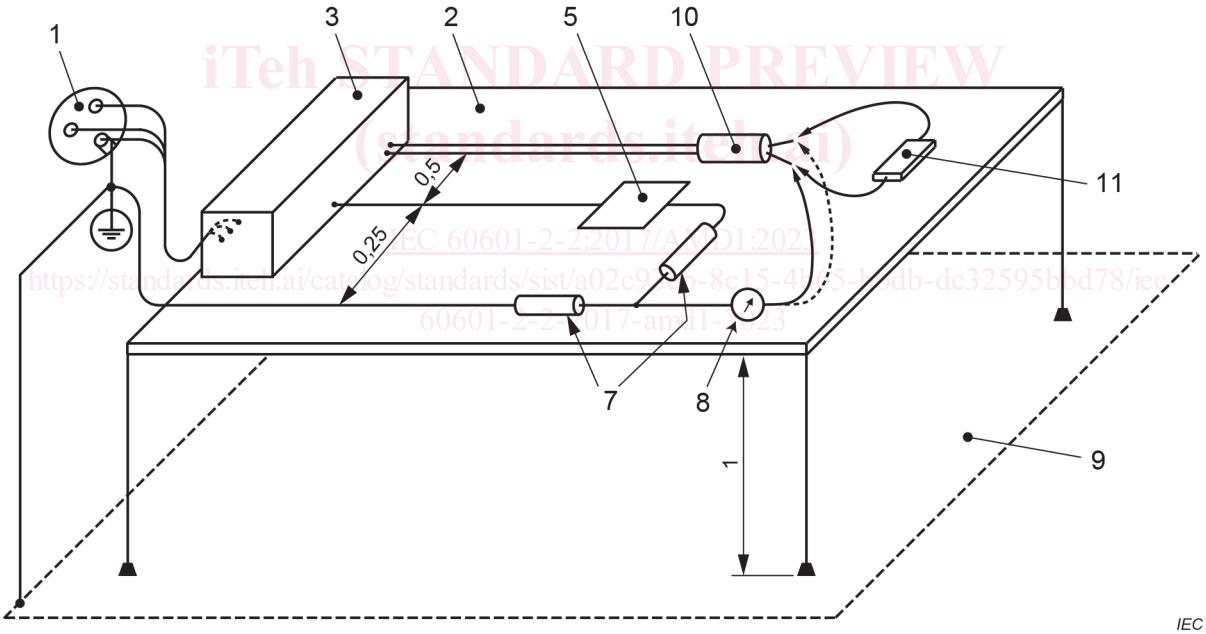
Replace, in item 3), the sentence beginning with "The test is conducted with the output…" in the fourth paragraph with the following:

The test is conducted with the output first being unloaded or with the highest load resistance that produces an HF output and then repeated with the output loaded at the RATED LOAD.

Figure 201.107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ACCESSORY

Replace the existing figure with the following new figure:

Dimensions in meters



Key

1 SUPPLY MAINS

2 Table, made of insulating material

3 HF SURGICAL EQUIPMENT

5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size

7 Measuring resistance, 200 Ω

8 HF current meter

9 Earthed conductive plane

10 Activated BIPOLAR ACCESSORY

11 Load resistance as required with HF power measuring device

Figure 201.107 – Measurement of HF LEAKAGE CURRENT from a BIPOLAR ACCESSORY

201.8.8.3.102 * ACTIVE ACCESSORY HF leakage

*Replace the existing sentence starting with "*The insulation applied to ACTIVE ACCESSORIES…" *with "*The insulation applied to ACTIVE ACCESSORIES, including ACTIVE ELECTRODE INSULATION and ACTIVE HANDLES, but excluding ACTIVE CONNECTORS, shall limit HF LEAKAGE CURRENT passing through the external surface of the insulation to less than $I_{leakage}$."

Add, at the end of item a), the following new note:

NOTE In this paragraph, '*d*' is the outer diameter of an insulation with a circular cross section. It is noted that the current formula can only be used for ACTIVE ACCESSORIES with circular cross section. For an ACTIVE ACCESSORY with a non-circular cross section, a value '*d*' is calculated from the circumference '*c*' of the original shape. In this case, the value *d* corresponds to the circumference divided by π.

$d = c / \pi$

201.12.4.3.101 * Output reduction means

Delete the existing asterisk in the subclause title.

Replace the first sentence of this subclause with the following:

Except as provided for in 201.7.9.2.2.101 a) item 7, and 201.7.9.3.1. – 5th dash, for each HF SURGICAL MODE, HF SURGICAL EQUIPMENT shall incorporate means to enable the output power to be reduced to not more than 5 % of the RATED OUTPUT POWER or 10 W, whichever is smaller (see also 201.12.1.102).

201.12.4.4.102 * Output power during simultaneous activation

Delete the existing introductory sentence in the compliance statement: "For HF SURGICAL EQUIPMENT as defined in 201.12.2 c)".

Add, before the sentence starting with "The output under test is activated at 20 %", *the following new sentence* "For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 1):".

Add, before the sentence starting with "The output under test is activated at 50 %", *the following new sentence* "For HF SURGICAL EQUIPMENT as defined in 201.12.2 c) 2):".

202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests

Replace "IEC 60601-1-2:2014 applies" *with* "IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply".

202.2 Normative references

Replace the existing reference to "IEC 60601-2-2:2016" *with* "IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023".

202.3 Terms and definitions

Replace the existing reference to "IEC 60601-2-2:2016" *with* "IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023".

202.101 Index of defined terms

Replace the existing reference to "IEC 60601-2-2:2016" *with* "IEC 60601-2-2:2017 and IEC 60601-2-2:2017/AMD1:2023".

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Replace "IEC 60601-1-8:2006 applies" *with* "IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply".

Definition 201.3.219 – HIGH CURRENT MODE

Add, after the existing text, the following new text:

The definition of HIGH CURRENT MODE is being misinterpreted with the effect that conventional HF SURGICAL EQUIPMENT used for many years with compatible, conventional NEUTRAL ELECTRODES without incidents are now erroneously declared as HIGH CURRENT MODE devices. This is not the intention of the document.

Users of the document should understand that

1) The load resistances specified in 201.7.9.3 and 201.12.1 do not define the INTENDED USE. The INTENDED USE is defined by the MANUFACTURER according to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44.
2) The MAXIMUM OUTPUT CURRENT is the RMS current at the lowest relevant impedance determined by the MANUFACTURER ignoring transients of less than 1 s when the device is operated according to the instructions for use.
3) The document requires that the MANUFACTURER performs a RISK ANALYSIS to review situations and reasonably foreseeable misuse that could result in current levels higher than the MAXIMUM OUTPUT CURRENT.

The HEATING FACTOR is calculated according to 201.3.218. The HEATING FACTOR is used to determine if a generator contains a HIGH CURRENT MODE or not according to 201.3.219.

Subclause 201.4.2.3.101 – Evaluating RISK

Add, after the existing text, the following new text:

The requirements for conventional NEUTRAL ELECTRODES are based on data with a maximum duty cycle of 45 % (see rationale for 201.15.101.5). For modes that are used with higher duty cycles according to their intended use, this is addressed in risk management.

Subclause 201.7.9.2.14 – ACCESSORIES, supplementary equipment, used material

Add, after the existing text of Subclause 201.7.9.2.14 j), the following new item:

Subclause 201.7.9.2.14 k)

HF SURGICAL ACCESSORIES act as antennas from an EMC point of view, so the user needs the length to ensure length compatibility between the HF SURGICAL EQUIPMENT and the accessory.

Subclause 201.8.8.3.101 – ACTIVE ACCESSORY insulation

Replace the first sentence of the existing note with the following:

This subclause was completely redrafted in the 5th Edition of this document to cover only dielectric strength of the various parts of ACTIVE ACCESSORY insulation, independent from any particular HF SURGICAL EQUIPMENT.

Subclause 201.12.4.3.101 – Output reduction means

Delete the existing title and text.

Clause 202 – ELECTROMAGNETIC DISTURBANCES – Requirements and tests

Replace, in the fourth existing paragraph, the first sentence with "During the immunity tests, the MANUFACTURER will need to specify how compliance to the standard is checked."

Add, at the end of the existing subclause, the following new text:

HF SURGICAL EQUIPMENT is evaluated regarding EMC utilizing ACTIVE ACCESSORIES that represent the least favourable configuration according to IEC 60601-1-2. This configuration is considered when determining the maximum permissible length of accessories (see 201.7.9.2.2.101 i)). The relevant length is for example the fully extended length between the ACTIVE CONNECTOR and the distal end of the ACTIVE ELECTRODE.

The MANUFACTURER may choose not to re-evaluate EMC, if previously completed EMC testing can be shown to be applicable by objective evidence for the configuration.

HF SURGICAL ACCESSORIES, including ASSOCIATED EQUIPMENT, that include active electronic circuits should be evaluated for EMC.

Ensuring compatibility between HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES is an OPERATOR responsibility.

Bibliography

Add the following new references [19] to [22] as follows:

[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*

_____