

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1 AMENDEMENT 1

**Medical electrical equipment –
Part 2-77: Particular requirements for the basic safety and essential performance
of robotically assisted surgical equipment**

**Appareils électromédicaux –
Partie 2-77: Exigences particulières pour la sécurité de base et les performances
essentiels des appareils chirurgicaux robotiquement assistés**





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment

AMENDMENT 1

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Amendment 1 to IEC 80601-2-77:2019 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO technical committee 299: Robotics.

The text of this Amendment is based on the following documents:

| | |
|---------------|------------------|
| Draft | Report on voting |
| 62D/2070/FDIS | 62D/2102/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/.

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- withdrawn, or
- revised.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1881/RR.

201.1 Scope, object and related standards

Replace the text of the existing footnote with the following:

- 3 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*.

201.1.3 * Collateral standards

Replace the text of the existing second paragraph with the following:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply as modified in Clauses 202 and 206 respectively.

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 [8], IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 [9], and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [10] do not apply.

201.1.4 Particular standards

Replace in the existing third paragraph, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" with "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

201.2 Normative references

Replace the existing text with the following:

NOTE Informative references are listed in the Bibliography.

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 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-1:2015/AMD1:2020

Addition:

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

201.3 Terms and definitions

Replace the existing text of the first paragraph with the following new text:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the following apply.

201.3.202

Replace the existing term, definition and source with the following new term, definition and source:

*** CAPACITIVELY COUPLED HF CURRENT**

unavoidable HIGH FREQUENCY current flowing due to capacitive coupling from the APPLIED PART of HF SURGICAL EQUIPMENT to another part of the RASE or RASS

[SOURCE: IEC 60601-2-18:2009, 201.3.201, modified – Replacement of " from an ENERGIZED ENDOTHERAPY DEVICE that is the APPLIED PART of HF SURGICAL EQUIPMENT to the ENDOSCOPE" by "from the APPLIED PART of HF SURGICAL EQUIPMENT to another part of the RASE or RASS".]

201.7.8.1 Colours of indicator lights

Replace the entire subclause, including Table 201.102, with the following:

201.7.8.1 * Colours of indicator lights

Add row 2 and 3 of Table 201.102 above the note of Table 2, and add note ^e, ^f and ^g of Table 201.102 to the note of Table 2:

Table 201.102 – Colours and meanings of indicator lights for RASE and RASS

| Name | On when | Indicator light ^a | Alarm indicator light | Accompanied by sound | OPERATOR requirement |
|---|------------------------|--------------------------------------|-----------------------|----------------------|----------------------|
| Cutting mode ^e | Cutting activation | Yellow, flashing or not ^f | – | Yes ^g | – |
| Coagulation mode ^e | Coagulation activation | Blue, flashing or not ^f | – | Yes ^g | – |
| <p>^a These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS.</p> <p>^e Applicable when RASE and RASS incorporate HF SURGICAL EQUIPMENT.</p> <p>^f Yellow and blue indicator lights can also be used to indicate additional modes if multiple functions share the same control device, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.</p> <p>^g As defined in 201.12.4.2.101 of IEC 60601-2-2:2017.</p> | | | | | |

Addition at the end of subclause 201.7.8.1:

In addition to Table 2, red, yellow, and blue indicator colours may be used as the following, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.

- Red for situations where immediate response by the OPERATOR is required,
- Yellow for situations where prompt response by the OPERATOR is required,
- Blue for any situations other than those for red or yellow colours as indicated above.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and test

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

206 * USABILITY

Replace “IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013” with “IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020”.

206.4.2 USABILITY ENGINEERING PROCESS for ME EQUIPMENT

Replace, in the first and second paragraphs, “IEC 62366-1:2015” with “IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020” (2 occurrences).

206.5 Replacement of requirements given in IEC 62366

Replace, in the existing note, “Clause 5 of IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013” with “Clause 5 of IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020”.

AA.2 Rationale for particular clauses and subclauses

Add the following new subclause:

Subclause 201.7.8.1 – Colours of indicator lights

Subclause 201.7.8.1 was amended to be in line with the IEC 60601-1:2005/AMD2:2020, subclause 7.8.1 and IEC 60601-2-2:2017/AMD:2023 for activating cutting and coagulation modes of HF SURGICAL EQUIPMENT. The amended text and table do not change the allowable use of colours of indicator light as previously indicated in IEC 80601-2-77:2019.

Figure 201.AA.105 – Example of RISK ASSESSMENT related to structural component

Replace in the existing note, “IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012” with “IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020”.

Subclause 201.17 – ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Replace, in the existing subclause the reference “IEC 60601-1-2:2014” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020” (3 occurrences).

EE.2 Electromagnetic (EM) Phenomena aspects in RASE applications

Replace the reference “IEC 60601-1-2:2014” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020”.

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<https://standards.iteh.ai/catalog/standards/sist/e60ef771-f054-4fb7-bd29-f3328767472d/iec-80601-2-77-2019-amd-1-2023>

Bibliography

Replace the existing references [8], [9] and [10] with the following new references:

- [8] IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021
- [9] IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*
IEC 60601-1-9:2007/AMD1:2013
IEC 60601-1-9:2007/AMD2:2020
- [10] IEC 60601-1-11:2015, *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*
IEC 60601-1-11:2015/AMD1:2020

Replace, in the existing footnote 4 to reference [23], reference “IEC 60601-1-2:2014” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020”.

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Index of defined terms used in this particular standard

Replace the existing entries as follows:

| | |
|--------------------------------------|--|
| AIR CLEARANCE | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, 3.5 |
| HARM..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.38 |
| HAZARD..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.39 |
| HAZARDOUS SITUATION | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD1:2020, 3.40 |
| INTENDED USE, INTENDED PURPOSE | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44 |
| MANUFACTURER..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.55 |
| OBJECTIVE EVIDENCE | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.72 |
| PROCEDURE | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.88 |
| PROCESS | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.89 |
| RESIDUAL RISK..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.100 |
| RISK | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.102 |
| RISK ANALYSIS | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.103 |
| RISK ASSESSMENT..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.104 |
| RISK CONTROL | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.105 |
| RISK MANAGEMENT..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.107 |
| RISK MANAGEMENT FILE | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.108 |
| USABILITY..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.136 |
| USABILITY ENGINEERING | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.137 |
| USABILITY ENGINEERING FILE..... | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.147 |
