FINAL
DRAFT

AMENDMENT

ISO 80601-2-77:2019 FDAM 1

ISO/TC **299**

Secretariat: **SIS**

Voting begins on:
2023-08-18

Voting terminates on:
2023-10-13

Medical electrical equipment —

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

AMENDMENT 1

Appareils électromédicaux —

Partie 2-77: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux robotiquement assistés

AMENDEMENT 1

Member bodies are requested to consult relevant national interests in IEC/TC 62 before casting their ballot to the e-Balloting application.

Reference number
ISO 80601-2-77:2019/FDAM 1:2023(E)

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Published in Switzerland

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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/XX/FDIS	62D/XX/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- withdrawn, or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 60601-9:2007/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]	–

[a] These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS.

[e] Applicable when RASE and RASS incorporate HF SURGICAL EQUIPMENT.

[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.

[g] As defined in 201.12.4.2.101 of IEC 60601-2-2:2017.

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*".*

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*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).