IEC 80601-2-78

Edition 1.0 2024-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

Appareils électromédicaux –
Partie 2-78: Exigences particulières pour la sécurité de base et les performances essentielles des robots médicaux dédiés à la rééducation, l'évaluation, la compensation ou l'atténuation

IEC 80601-2-78:2019-07/AMD1:2024-03(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

AMENDMENT 1

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Amendment 1 to IEC 80601-2-78:2019 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC Technical Committee 62: Medical equipment, software, and systems, and ISO Technical Committee 299: Robotics.

This publication is published as a double logo standard.

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

Draft	Report on voting
62D/2085A/FDIS	62D/2109/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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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/1882/RR.

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201.1 Scope, object and related standards

Replace the text of the existing footnote 1 with the following new text:

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*.

201.1.3 Collateral standards

Replace the existing second paragraph with the following new paragraph:

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, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 206, 208, 210 and 211 respectively. IEC 60601-1-3 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

Replace the existing third paragraph with the following:

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

201.2 Normative references

Replace the existing text with the following new text:

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 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

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

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

IEC 60601-1-10:2007, *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*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

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

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

ISO 22523:2006, *External limb prostheses and external orthoses – Requirements and test methods*

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/AMD1:2020 apply.

201.4.2.3.102 * RISK MANAGEMENT and SITUATION AWARENESS

*Replace the existing first sentence of the third paragraph with "*IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, 5.5 requires HAZARD-RELATED USE SCENARIOS to be evaluated using a SUMMATIVE EVALUATION including SITUATION AWARENESS*".*

201.7.2.4 ACCESSORIES

Replace, in the existing first paragraph, "6.2 of ISO 14971:2007" *with* " 7.1 of ISO 14971:2019".

201.15.3.101 Toppling for WALKING RACA ROBOT

Add, after the existing Note 2, the following new note:

NOTE 3 Toppling testing can be found in the IEC 60068-2-31:2008, 5.1.3.3.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and test

Replace the existing text with the following new text:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply except as follows:

206 USABILITY

Replace the existing text with the following new text:

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

206.5 * Replacement of requirements given in IEC 62366-1

Replace the existing text with the following new text:

Replacement:

In addition to the requirements of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, the following shall apply.

The instructions for use shall include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY. The same information shall also be included in the technical description, if this is provided as a separate document.

NOTE An important purpose of this description is to help the OPERATOR to develop adequate SITUATION AWARENESS of the ME EQUIPMENT.

The instructions for use shall contain a summary of the application specification.

Add to 3.21 of IEC 62366-1:2015:

Note 101 to entry: USE ERRORS can occur to due to loss or lack of OPERATOR SITUATION AWARENESS.

Add, to the second paragraph of 5.2 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, after the first sentence:

This identification shall include consideration of reasonably foreseeable loss or lack of OPERATOR SITUATION AWARENESS as a source of USE ERROR.

Add to 5.2 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020:

NOTE 101 USE ERRORS can occur in different ways and with different probabilities of occurrence due to the level or condition of OPERATOR SITUATION AWARENESS.

Add, after NOTE 2 of 5.3 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020:

NOTE 101 Application of the concept of SITUATION AWARENESS could make the identification of HAZARDS or HAZARDOUS SITUATIONS more thorough.

Add, after NOTE 1 of 5.7.1 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020:

NOTE 101 Examples of methods to evaluate adequate SITUATION AWARENESS can be found in Annex BB of this document.

208 * General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

Replace the existing text with the following new text:

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply, except as follows:

210 * Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

Replace the existing text with the following new text:

IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply, except as follows:

Addition:

NOTE Additional information can be found in Annex AA, Clause 210.

211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

Replace the existing text with the following new text:

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply, except as follows:

Annex AA (informative) — Particular guidance and rationale

Subclause 202.4.3 – General test conditions

Replace the existing last sentence of the first paragraph with the following new sentence:

However, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 does not explicitly exclude EMC testing under SINGLE FAULT CONDITION.

Subclause 206.5 – Replacement of requirements given in IEC 62366-1

Replace the existing text with the following new text:

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 refer to IEC 62366:2007 and IEC 62366:2007/AMD1:2014 which do not align well with SITUATION AWARENESS, in comparison to IEC 62366-1:2015. Clause 5 of IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 was updated to reflect this change in reference to the newer version of the standard. In addition, the original text of Clause 5 of IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 referred to an OPERATOR'S mental model. The original text was modified to align with the concept of SITUATION AWARENESS.

Although designing for USABILITY implicitly requires dealing with SITUATION AWARENESS, as outlined in Clause BB.1, SITUATION AWARENESS has been dealt with poorly in many other industries, often with catastrophic results. The intent of the addition to Clause 5 of IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 is to explicitly require the MANUFACTURER to address SITUATION AWARENESS through the USABILITY ENGINEERING PROCESS. For example, 5.2 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020 requires the MANUFACTURER to identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS but does not explicitly mention that USE ERRORS can occur due to loss of SITUATION AWARENESS. 9.3 of IEC TR 62366-2:2016, in

reference to FUNCTION ANALYSIS, provides the only explicit reference to SITUATION AWARENESS in either IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020 or IEC TR 62366-2:2016.

Annex BB provides additional information on SITUATION AWARENESS, including how to design for adequate SITUATION AWARENESS and how to assess it.

Clause 208 – General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

Replace the existing text with the following new text:

When a RACA ROBOTs is provided with an ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, the MANUFACTURER should place particular emphasis on SITUATION AWARENESS in order to determine the OPERATOR'S ability to be aware of the HAZARDOUS SITUATION causing the ALARM CONDITION and the appropriate response required to avoid an unacceptable RISK.

Clause 210 – Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

Replace the existing first sentence with the following new sentence:

The collateral standard IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 uses the term "mental model" in numerous places, for example, Annex A of IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020.

Annex BB (informative) — **Guidance and examples of SITUATION AWARENESS**

BB.2 Brief background on SITUATION AWARENESS

Replace the existing three paragraphs following the Figure BB.1 with the following new paragraphs:

The relationship between SITUATION AWARENESS and existing processes can be seen in Figure BB.2, which was modified from Figure A.5 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020. There are three changes to the figure (see the red text boxes) that demonstrate two common scenarios in which SITUATION AWARENESS impacts these existing processes.

- The first scenario relates to HAZARDS or HAZARDOUS SITUATIONS identified initially as part of the USER INTERFACE specification (IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, 5.2). The link between USABILITY and RISK now includes a specific consideration for SITUATION AWARENESS (201.4.2.3.102) as well as a NOTE (ISO 14971:2019, 7.1 and 7.2), both in red text boxes in Figure BB.2, to remind the MANUFACTURER that RISK CONTROLS should be designed for SITUATION AWARENESS.
- The second scenario relates to RISK CONTROLS identified and implemented to address HAZARDS and HAZARDOUS SITUATIONS identified as part of the RISK MANAGEMENT process (ISO 14971:2019, 7.1 and 7.2) after the initial use specification and identification of user interface characteristics related to safety (IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, 5.1 and 5.2). As per the new note (see the red text box in Figure BB.2)

for ISO 14971:2019, 7.3, the MANUFACTURER needs to be aware that if these new RISK CONTROLS require SITUATION AWARENESS, then the MANUFACTURER needs to loop back to USABILITY ENGINEERING again to ensure that the OPERATOR will have adequate SITUATION AWARENESS for the RISK CONTROL to be effective.

Figure BB.2 – Relationship between SITUATION AWARENESS, the RISK MANAGEMENT PROCESS (ISO 14971:2007) and the USABILITY ENGINEERING PROCESS (IEC 62366-1:2015)

Replace the existing figure, text and title with the following: