SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-78:2026

01-julij-2026

Medicinska električna oprema - 2-78. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih robotov za rehabilitacijo, ocenjevanje, nadomestitev funkcij ali lajšanje simptomov

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

Medizinische elektrische Geräte - Teil 2-78: Besondere Festlegungen an die Sicherheit, einschließlich der wesentlichen Leistungsmerkmale von medizinischen Robotern zur Rehabilitation, Beurteilung, Kompensation oder Linderung

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

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-78:2026**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

oSIST prEN IEC 80601-2-78:2026 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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62D/2304/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-78 ED2**	
DATE OF CIRCULATION: **2026-06-05**	CLOSING DATE FOR VOTING: **2026-08-28**
SUPERSEDES DOCUMENTS: **62D/2278/CD, 62D/2290A/CC**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

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Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

PROPOSED STABILITY DATE: 2030

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NOTE FROM TC/SC OFFICERS:

All comments in 62D/2290A/CC with resolutions stating “will be adopted by the central office for the CDV” have been incorporated into this Committee Draft for Vote.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

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International standard IEC 80601-2-78 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems 62: Medical equipment, software, and systems, and ISO Technical Committee 299: Robotics.

This publication is published as a double logo standard.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type;*

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147 – informative material appearing outside of tables, such as notes, examples and references in smaller type.
148 Normative text of tables is also in a smaller type;

149 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS
150 NOTED: SMALL CAPITALS.

151 In referring to the structure of this document, the term

152 – "clause" means one of the seventeen numbered divisions within the table of contents,
153 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

154 – "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
155 subclauses of Clause 7).

156 References to clauses within this document are preceded by the term "Clause" followed by the
157 clause number. References to subclauses within this particular standard are by number only.

158 In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any
159 combination of the conditions is true.

160 The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC
161 Directives, Part 2. For the purposes of this document, the auxiliary verb:

162 – "shall" means that compliance with a requirement or a test is mandatory for compliance with
163 this document;

164 – "should" means that compliance with a requirement or a test is recommended but is not
165 mandatory for compliance with this document;

166 – "may" is used to describe a permissible way to achieve compliance with a requirement or
167 test.

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168 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title
169 indicates that there is guidance or rationale related to that item in Annex AA.

170 A list of all parts of the IEC 80601 and IEC 60601 International Standard, published under the
171 general title *Medical electrical equipment,* can be found on the IEC website.

172

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The committee has decided that the contents of this document and its amendment 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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION

During the September 21, 2023, meeting of IEC SC62D Plenary in Seoul, Republic of Korea, the subcommittee discussed the need to proceed with a new edition of IEC 80601-2-78. The need for a new edition was to include/modify the standard based on the latest medical robots for rehabilitation, assessment, compensation or alleviation (RACA).

A resolution was taken to proceed towards the 2nd edition of the IEC 80601-2-78.
The review report for the new edition can be found in the IEC 62D/2158/RR document.
This 2nd edition of the IEC 80601-2-78 supersedes the IEC 80601-2-78 edition 1.1 standard.

In this second edition, compared to the first edition, the following significant points were added or modified:

- revised the scope to clarify which product falls in the scope of this standard
- revised definitions, including RACA ROBOT, for clarity
- added new requirements for battery management systems of secondary batteries
- revised requirements for support systems for clarity
- added new requirements for use of Head Mounted Displays (HMD) or other extended reality (XR) devices with RACA ROBOTS

The following flowchart provides guidance on whether an ME EQUIPMENT or ME SYSTEM is a RACA ROBOT.

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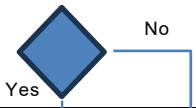
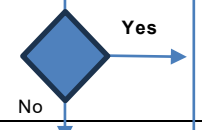
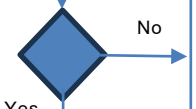
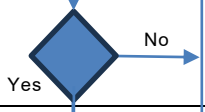
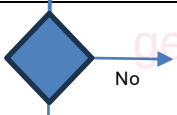
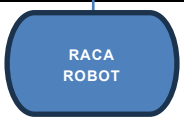
No	Decision	Description	Further Information
1		Is the device a ME EQUIPMENT or ME SYSTEM?	Refer to definition: 1. IEC 60601-1[1] Clause 3.63 ME EQUIPMENT 2. IEC 60601-1 Clause 3.64 ME SYSTEM
2		Is the ME EQUIPMENT or ME SYSTEM a • external limb prosthetic devices • electric wheelchairs • diagnostic imaging equipment • personal care robots	The listed devices are addressed in following standards: • ISO 22523 • ISO 7176 (all parts) • e.g. MRI, IEC 60601-2-33 • ISO 13482
3		Is the INTENDED USE of ME EQUIPMENT or / ME SYSTEM related to REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION?	Refer to definition: 1. IEC 80601-2-78[2]Clause 201.3.202 ALLEVIATION "Treatment to ease symptoms due to an IMPAIRMENT of a PATIENT" 2. IEC 80601-2-78 Clause 201.3.203 ASSESSMENT "Procedure to quantify or to aid in the qualification of the level of IMPAIRMENT of a PATIENT" 3. IEC 80601-2-78 Clause 201.3.205 COMPENSATION "Mitigation of IMPAIRMENT of a PATIENT through support of body structures or through support or replacement of body functions" 4. IEC 80601-2-78 Clause 201.3.211 * REHABILITATION "Treatment to improve MOVEMENT FUNCTIONS related to an IMPAIRMENT of a PATIENT"
4		Does the ME EQUIPMENT or / ME SYSTEM have an ACTUATED APPLIED PART?	Refer to definition: IEC 80601-2-78 Clause 201.3.201 ACTUATED APPLIED PART "Intended to provide actively controlled physical interactions with the PATIENT»
5		Is the ACTUATED APPLIED PART intended to physically interact with a PATIENT, related to PATIENT MOVEMENT FUNCTIONS, to perform a clinical function?	Refer to definition: 1. IEC 80601-2-78 Clause 201.3.209 MOVEMENT FUNCTIONS "Function consisting of one or more of sensory, neuromusculoskeletal or movement-related body functions that comprise PATIENT motor control"
6		Does the ME EQUIPMENT or ME SYSTEM have a LEVEL OF AUTONOMY greater than zero?	Refer to definition: 1. IEC 80601-2-78 Clause 201.3.214EVEL OF AUTONOMY extent to which functions or tasks under NORMAL USE are performed without OPERATOR intervention"
7		The ME EQUIPMENT or / ME SYSTEM is a RACA ROBOT	
8		**The device is <u>not</u> a** RACA ROBOT	

The defined terms can be found in:

1 IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

2 IEC 80601-2-78 Medical electrical equipment – Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

or may also be listed in Electropedia; https://www.electropedia.org

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

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 80601 applies to the general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of medical robots that physically interact with a PATIENT with an IMPAIRMENT to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the PATIENT'S MOVEMENT FUNCTIONS, as intended by the MANUFACTURER.

Note: A MOVEMENT FUNCTION is a function consisting of one or more of sensory, neuromusculoskeletal or movement-related body functions that comprise PATIENT motor control.

A RACA ROBOT is defined in this standard as a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS) with a LEVEL OF AUTONOMY greater than zero, comprising an ACTUATED APPLIED PART, intended by its MANUFACTURER to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION

Note 1: a LEVEL OF AUTONOMY of zero is defined as having no AUTONOMY in any of its functions

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RACA ROBOTS covered by this particular standard include but are not limited to:

- Exoskeletons or robotic orthoses for upper and lower limbs for ASSESSMENT, REHABILITATION, ALLEVIATION or COMPENSATION
- Robotic end-effectors for upper / lower extremities for ASSESSMENT or REHABILITATION
- Active balance control equipment for ASSESSMENT or REHABILITATION
- Overhead robotic body weight support systems
- Robotic walkers
- Robots intended to alleviate hemiplegic shoulder/ joint pain or spasticity through movement
- Continuous Passive Motion devices with a LEVEL OF AUTONOMY

Note 2: Annex AA lists examples of RACA ROBOT.

Note 3: This particular standard is primarily focused on human beings but, may also be used for animal PATIENTS. The RISK MANAGEMENT PROCESS may be necessary to address specific BASIC SAFETY and ESSENTIAL PERFORMANCE for animal PATIENTS.

This particular standard does not apply to:

- Devices that support activities of daily living (including active assisted living), but do not directly address PATIENT MOVEMENT FUNCTIONS, such as:
  - electric wheelchairs (use ISO 7176 (all parts)),
  - personal care / service robots (use ISO 13482: 2014), e.g. feeding robots, robotic hoists, robotic bed
- Devices with a LEVEL OF AUTONOMY of zero
  - E.g. Continuous Passive Motion devices with no AUTONOMY
- the following devices which are covered by other standards:
  - external limb prosthetic devices (use ISO 22523: 2006),
  - diagnostic imaging equipment (e.g. MRI, use IEC 60601-2-33: 2022),

[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*.

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- stationary training equipment (ISO 20957 series) e.g. treadmills

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL ROBOTS that physically interact with a PATIENT with an IMPAIRMENT, to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the PATIENT'S MOVEMENT FUNCTIONS.

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, 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.

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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 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 60601-1:2005 and 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.

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 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.

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"*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

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NOTE Informative references are listed in the Bibliography.

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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
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