SLOVENSKI STANDARD
SIST EN IEC 80601-2-78:2020

01-julij-2020

Medicinska električna oprema - 2-78. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih robotov za rehabilitacijo, ocenjevanje, nadomestitev funkcij ali lajšanje simptomov (IEC 80601-2-78:2019)

Medical Electrical Equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation (IEC 80601-2-78:2019)

Medizinische elektrische Geräte - Teil 2-78: Besondere Festlegungen an die Sicherheit, einschließlich der wesentlichen Leistungsmerkmale von medizinischen Robotern zur Rehabilitation, Beurteilung, Kompensation oder Linderung (IEC 80601-2-78:2019)

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)

Ta slovenski standard je istoveten z: **EN IEC 80601-2-78:2020**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN IEC 80601-2-78:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-78

April 2020

ICS 11.040.01

English Version

Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation (IEC 80601-2-78:2019)

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This European Standard was approved by CENELEC on 2019-08-13. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1676/FDIS, future edition 1 of IEC 80601-2-78, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-78:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 80601-2-78:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 13482:2014	NOTE	Harmonized as EN ISO 13482:2014 (not modified)
ISO 9999:2016	NOTE	Harmonized as EN ISO 9999:2016 (not modified)
ISO 10535:2006	NOTE	Harmonized as EN ISO 10535:2006 (not modified)
IEC 60601-2-33	NOTE	Harmonized as EN 60601-2-33
ISO 10218-1:2011	NOTE	Harmonized as EN ISO 10218-1:2011 (not modified)
IEC 60601-1-9:2007	NOTE	Harmonized as EN 60601-1-9:2008 (not modified)
IEC 61924-2:2012	NOTE	Harmonized as EN 61924-2:2013 (not modified)
ISO 11064-7:2006	NOTE	Harmonized as EN ISO 11064-7:2006 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN 60601-1:2006 is applicable, except as follows:

Publication	Year	Title	EN/HD	Year
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	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
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		-
ISO 14971	2007	Medical devices_- Application of risk-management to medical devices		-
Addition:				
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	EN 60601-1-10	2008
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		-

Publication	Year	Title	EN/HD	Year
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
			+AC	2015
ISO 22523		External limb prostheses and external orthoses – Requirements and test methods	EN ISO 22523	2006

IEC 80601-2-78

Edition 1.0 2019-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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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

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.

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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 IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-78 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, and ISO Technical Committee 299: Robotics.

This publication is published as a double logo standard.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1676/FDIS	62D/1688/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

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;*

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

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

In referring to the structure of this document, the term

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

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

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

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

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

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

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

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

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

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://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.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This part of IEC 80601 International Standard was written at a time when technical evolution of MEDICAL ROBOTS was in rapid progress and the scientific foundation of safe use was still being expanded.

This document is the result of work that began in ISO/TC 184/SC 2/WG 7 in October 2006 on personal care ROBOTS, to address an emerging type of MEDICAL ROBOT that was used outside of an industrial environment. That group was working on a new standard, ISO 13482, which was published as an International Standard (IS) in 2014. While initially focused on non-medical applications, WG 7 recognized that work was needed on medical devices utilizing robotic technology. In October 2009, ISO/TC 184/SC 2 established a WG 7, *Study Group (SG) on Medical care robots*, comprised of experts from Canada, France, Germany, Japan, Korea, Romania, Switzerland, UK and USA.

The work of ISO/TC 184/SC 2/WG 7 SG cumulated in a proposal to form a Joint Working Group (JWG 9) with IEC/TC 62/SC 62A focusing on MEDICAL ELECTRICAL EQUIPMENT using robotic technology. This JWG began developing a technical report (IEC TR 60601-4-1) dealing with degree of autonomy. While developing this document, a particular standard was deemed required for REHABILITATION type ROBOTS. This led to the creation of a Joint Working Group 36 (MEDICAL ROBOTS for REHABILITATION) in April, 2015 within IEC/TC 62/SC 62D to develop particular requirements of SAFETY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for REHABILITATION type ROBOTS. ISO/TC 184/SC 2 has since been promoted to ISO/TC 299, and JWG 9 has merged with JWG35 and 36 to form JWG 5 (MEDICAL ROBOT Safety) on the ISO side. This proposal was approved from both IEC and ISO and work began.

The minimum safety requirements specified in this particular standard are presented to provide for an acceptable degree of BASIC SAFETY and ESSENTIAL PERFORMANCE 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 .

The requirements are followed by particular specifications for the relevant tests.

MEDICAL ELECTRICAL EQUIPMENT –

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.

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.

This particular standard does not apply to

- external limb prosthetic devices (use ISO 22523),
- electric wheelchairs (use ISO 7176 (all parts)),
- diagnostic imaging equipment (e.g. MRI, use IEC 60601-2-33), and
- personal care ROBOTS (use ISO 13482).

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.

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1 The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

IEC 60601-1-2:2014, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013, and IEC 60601-1-11:2015 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

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 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.

"*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

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 60601-1-6:2010, *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 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for 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

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

Addition:

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 60601-1-11:2015, *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 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

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

201.3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An Index of defined terms is found beginning on page 74.

Amendment: