

**ELEKTRILISED MEDITSIINISEADMED.
OSA 2-78: ERINÕUDED TAASTUSRAVIKS, HINDAMISEKS,
KOMPENSEERIMISEKS VÕI LEEVENDAMISEKS ETTE
NÄHTUD MEDITSIINILISTE ROBOTITE ESMASELE
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE**

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 + IEC 80601-2-78:2019/AMD1:2024)

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN IEC 80601-2-78:2020+A1:2024 sisaldab Euroopa standardi EN IEC 80601-2-78:2020 ja selle muudatuse A1:2024 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 80601-2-78:2020+A1:2024 consists of the English text of the European standard EN IEC 80601-2-78:2020 and its amendment A1:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.04.2020, muudatused A1 20.09.2024.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 03.04.2020, for A1 20.09.2024.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega $\boxed{A1}$ $\langle A1 \rangle$. Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags $\boxed{A1}$ $\langle A1 \rangle$. The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.040.01

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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 + IEC 80601-2-78:2019/AMD1:2024)

Appareils électromédicaux - Partie 2-78: Exigences
particulières pour la sécurité de base et les performances
essentielle des robots médicaux dédiés à la rééducation,
l'évaluation, la compensation ou l'atténuation
(IEC 80601-2-78:2019 + IEC 80601-2-78:2019/AMD1:2024)

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 + IEC 80601-2-78:2019/AMD1:2024)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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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:

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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)

A1 Amendment A1 European foreword

The text of document 62D/2085/FDIS, future edition 1 of IEC 80601-2-78/AMD1, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-78:2020/A1:2024.

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IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (not modified)

A1

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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
essentielle des robots médicaux dédiés à la rééducation, l'évaluation, la
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INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Medical electrical equipment –
Part 2-78: Particular requirements for basic safety and essential performance of
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**Appareils électromédicaux –
Partie 2-78: Exigences particulières pour la sécurité de base et les performances
essentielle des robots médicaux dédiés à la rééducation, l'évaluation, la
compensation ou l'atténuation**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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.

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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.

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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/.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.



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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.

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A1 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. **A1**

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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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ 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.

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*. 

^{A1} 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. ^{A1}

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.

^{A1} 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. ^{A1}

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

A1 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* **A1**