



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN IEC 80601-2-78:2020+A1:2024. It is identical to IEC 80601-2-78:2019, incorporating amendment 1:2024. It supersedes BS EN IEC 80601-2-78:2020, which will be withdrawn on 31 July 2027.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Amendments/corrigenda issued since publication

Date	Text affected
30 September 2024	Implementation of IEC amendment 1:2024 with CENELEC endorsement A1:2024

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)**

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

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.

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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)

European foreword to Amendment 1

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.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2025-05-01 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-07-31 document have to be withdrawn

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.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 80601-2-78:2019/AMD1:2024 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 standard indicated:

IEC 60601-1-9:2007	NOTE	Approved as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Approved as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (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:

<u>Publication</u> <u>Replacement</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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
+ A1	2020		+ A1	2021
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
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021
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	EN 60601-1-8	2007
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
+ A2	2020		+ A2	2021
ISO 14971	2019		EN ISO 14971	2019
-	-		+ A11	2021

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>addition:</i>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ 1	2012		+ 1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ 2	2020		+ 2	2021
-	-		+ AC	2022
-	-		+ A13	2024
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
+ 1	2013		+ 1	2015
+ 2	2020		+ 2	2021
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	EN 60601-1-11	2015
+ 1	2020		+ 1	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
-	-		+ AC	2016
+ 1	2020		+ 1	2020
ISO 22523	2006		EN ISO 22523	2006

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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

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.
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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. **Documents**



Document Sharing Hub

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.

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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.

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.

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 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. **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

 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

A1 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. **A1**

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 76.

Amendment:

201.3.63

*** MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT**

Addition:

Note 1 to entry: See Figure AA.1.

201.3.65

MOBILE

Addition:

Note 1 to entry: MOBILE also includes equipment intended to support the movement of a PATIENT from one location to another.

201.3.144

*** BODY-WORN**

Replacement:

PORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

Addition:

201.3.201

***ACTUATED APPLIED PART**

subcategory of APPLIED PART that is intended to provide actively controlled physical interactions with the PATIENT that are related to the PATIENT'S MOVEMENT FUNCTIONS, to perform a CLINICAL FUNCTION of a RACA ROBOT

Note 1 to entry: "Actively controlled" as used above is intended to mean controlled by the RACA ROBOT, including shared control with the PATIENT or OPERATOR.

Note 2 to entry: Actively controlled physical interactions include position control, force control, impedance control, admittance control, or any other controls that regulate the interaction between a RACA ROBOT and the PATIENT.

Note 3 to entry: Each ACTUATED APPLIED PART is part of an actuation system according to 9.8.1 of the general standard.

201.3.202

ALLEVIATION

treatment to ease symptoms due to an IMPAIRMENT of a PATIENT

Note 1 to entry: An example of ALLEVIATION is physical therapy performed by a RACA ROBOT to reduce pain or other secondary effects of an IMPAIRMENT.

201.3.203

* ASSESSMENT

procedure to quantify or to aid in the qualification of the level of IMPAIRMENT of a PATIENT.

Note 1 to entry: The term "ASSESSMENT" should not be confused with the term "RISK ASSESSMENT"

Note 2 to entry: ASSESSMENT in this definition focuses on the level of IMPAIRMENT of body functions and structures and not of activity limitations or participation restrictions ([1]², Chapter 4).

Note 3 to entry: ASSESSMENT can be distinguished from both measurement and diagnosis. Measurement typically refers to the physiological parameter being measured (e.g. PATIENT hand position by a RACA ROBOT) and is typically related to, or is the direct output of a transducer. Those measurements are then used to quantify an IMPAIRMENT (e.g., proprioception, planning of a movement, etc). Because IMPAIRMENTS are not the same as the underlying pathology, but are the manifestations of an underlying pathology, an ASSESSMENT that quantifies the IMPAIRMENT can then be used by a clinician to support a diagnosis that identifies the pathology, or to monitor the progression of a pathology or recovery from an injury. See Annex AA for an example.

201.3.204

CLINICAL FUNCTION

clinically significant operation that the ME EQUIPMENT or ME SYSTEM is intended to perform, as specified by the MANUFACTURER

Note 1 to entry: CLINICAL FUNCTION is generally a subset of the INTENDED USE of the ME EQUIPMENT or ME SYSTEM and is related to the PATIENT.

Note 2 to entry: In the context of this document, a clinically significant operation refers to:

- support of the diagnosis of a PATIENT with an IMPAIRMENT,
- treatment, mitigation, or monitoring of an IMPAIRMENT of a PATIENT.

[SOURCE: IEC TR 60601-4-1:2017, 3.6, modified – In the definition, the words "medical operation" have been replaced by "clinically significant operation", and Note 2 to entry has been added.]

201.3.205

COMPENSATION

mitigation of IMPAIRMENT of a PATIENT through support of body structures or through support or replacement of body functions

Note 1 to entry: COMPENSATION could be provided by, for example, externally powered orthoses. COMPENSATION does not include the improvement of MOVEMENT FUNCTIONS related to an IMPAIRMENT, which is defined as REHABILITATION.

201.3.206

EMERGENCY STOP

manually initiated interruption of operation intended to stop the RACA ROBOT to prevent HARM

Note 1 to entry: EMERGENCY STOP is meant as a last resort when no other means to reduce RISK are available.

Note 2 to entry: EMERGENCY STOP does not allow an automatic restart, in contrast to a PROTECTIVE STOP.

Note 3 to entry: The activation of an EMERGENCY STOP does not necessarily shut down all the power in a RACA ROBOT. Refer to 9.2.4 of the general standard for further clarification.

201.3.207

* IMPAIRMENT

problem in body function or structure, such as significant deviation or loss

Note 1 to entry: "Problems" here is used to refer to a (negative) deviation from generally accepted population normality levels in the biomedical status of the body and its functions. Notification of the constituents of IMPAIRMENT is undertaken primarily by those qualified to judge functioning according to the generally accepted normality levels. An IMPAIRMENT usually follows a disease or accident, but also includes birth defects.

² Numbers in square brackets refer to the Bibliography.

Note 2 to entry: This document only concerns ME EQUIPMENT or ME SYSTEM, meaning that it addresses IMPAIRMENT of a PATIENT and not normal age-related IMPAIRMENTS.

[SOURCE: ISO 9999:2016, 2.11, modified – The term is here in singular instead of plural. The notes to entry have been added.]

201.3.208

MEDICAL ROBOT

ROBOT intended to be used as ME EQUIPMENT or ME SYSTEM

[SOURCE: IEC TR 60601-4-1:2017, 3.20]

201.3.209

MOVEMENT FUNCTION

function consisting of one or more of sensory, neuromusculoskeletal or movement-related body functions that comprise PATIENT motor control

Note 1 to entry: "Sensory", "neuromusculoskeletal" and "movement-related" come from the body functions classification presented in [1].

Note 2 to entry: A RACA ROBOT does not need to address all of these aspects.

201.3.210

*** PROTECTIVE STOP**

interruption of operation automatically initiated by the RACA ROBOT, that allows a cessation of motion for BASIC SAFETY and ESSENTIAL PERFORMANCE purposes, which could allow the PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)/PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) to facilitate a restart

Note 1 to entry: See also ISO 8373:2012, 5.17.

Note 2 to entry: A PROTECTIVE STOP is defined in contrast to an EMERGENCY STOP or a normal stop; clarification is provided in Table 201.102.

Note 3 to entry: "Automatically initiated" means that the RACA ROBOT is detecting a potentially HAZARDOUS SITUATION and as a result of this detection the RACA ROBOT then initiates a stopping procedure

Note 4 to entry: The defined term is related to FALLBACK MODE defined in IEC 60601-1-10:2007, 3.11.

Note 5 to entry: Even during the cessation of motion, the actuators are not necessarily deactivated. In certain conditions, the actuators may hold the PATIENT or PATIENT'S limbs in a stable position.

201.3.211

*** REHABILITATION**

treatment to improve MOVEMENT FUNCTIONS related to an IMPAIRMENT of a PATIENT

EXAMPLE Relearning of motor control of the upper or lower extremities, restoration of muscle strength and endurance.

Note 1 to entry: REHABILITATION can be carried out in situations where a PATIENT has an IMPAIRMENT due to an accident or disease or congenital conditions (e.g. cerebral palsy) or can be used to slow down the expected loss of body functions due to neurodegenerative diseases (e.g. Parkinson's, multiple sclerosis).

Note 2 to entry: This definition differs from the World Health Organization (WHO) definition and covers only a subset of that definition, in order to agree with the scope of this document.

201.3.212

REHABILITATION, ASSESSMENT, COMPENSATION AND ALLEVIATION ROBOT

RACA ROBOT

MEDICAL ROBOT intended by its MANUFACTURER to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION comprising an ACTUATED APPLIED PART

201.3.213

*ROBOT

programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended tasks

201.3.214

* SITUATION AWARENESS

OPERATOR'S perception, comprehension and projection of a RACA ROBOT's behaviour in its environment

Note 1 to entry: SITUATION AWARENESS allows the OPERATOR of the RACA ROBOT to react appropriately and timely to the RACA ROBOT's behaviour both under NORMAL USE and in the case of a SINGLE FAULT CONDITION.

Note 2 to entry: SITUATION AWARENESS has a direct link to USABILITY ENGINEERING PROCESS. However, IEC 62366-1:2015 relates to SITUATION AWARENESS through the use of the concepts of "perception" and "cognition". Annex AA provides additional information.

201.3.215

* WALKING

MOBILE equipment that, once installed and placed into service, is intended to move from one location to another, by making reciprocating motion having intermittent contact with the travel surface and the RACA ROBOT

EXAMPLE A powered exoskeleton for the lower limbs is an example of a WALKING RACA ROBOT that is intended by the MANUFACTURER to ambulate the PATIENT.

Note 1 to entry: WALKING is a new subcategory of TRANSPORTABLE ME EQUIPMENT and ME SYSTEM as shown in Figure AA.1.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.2.3 Evaluating RISK

Additional subclauses before 4.2.3.1:

201.4.2.3.101 General

In performing a RISK MANAGEMENT PROCESS, the degree of autonomy of the RACA ROBOT shall be taken into consideration.

NOTE 1 IEC TR 60601-4-1 provides considerations on the effects that the degree of autonomy could have on the RISK MANAGEMENT PROCESS. For example, RACA ROBOTS could accomplish a task fully autonomously with less RISK than an OPERATOR performing the same intended task, or vice versa.

NOTE 2 Degree of autonomy has the potential for increasing performance, adding functionality or improving USABILITY of RACA ROBOTS. However, a higher degree of autonomy can increase the complexity of the system and thus can increase the number and complexity of HAZARDOUS SITUATIONS. It is important the MANUFACTURER takes this complexity into account in its RISK MANAGEMENT PROCESS. As one or more PESS provide the autonomy, these PESS deserve specific scrutiny.

NOTE 3 The role of the OPERATOR can differ depending on their tasks and interactions with the RACA ROBOT. The SITUATION AWARENESS of the OPERATOR can become more important for RACA ROBOTS with a higher degree of autonomy.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.4.2.3.102 * RISK MANAGEMENT and SITUATION AWARENESS

The MANUFACTURER shall identify the HAZARDS or HAZARDOUS SITUATIONS that could occur following a loss of SITUATION AWARENESS in the RISK MANAGEMENT PROCESS, when an OPERATOR is needed to supervise a task of, or interact with, a RACA ROBOT to reduce RISK to an

acceptable level. The MANUFACTURER shall include the necessary information in the ACCOMPANYING DOCUMENTS.

Compliance shall be checked by inspection of the RISK MANAGEMENT FILE and, where applicable, of the ACCOMPANYING DOCUMENTS.

A1 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. **A1** Because of the subjective nature of evaluating SITUATION AWARENESS, it can be considered sufficient to perform a FORMATIVE EVALUATION of this HAZARD-RELATED USE SCENARIO instead.

NOTE Additional guidance can be found in Annex BB.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

Table 201.101 lists potential sources of unacceptable RISK identified to characterize the ESSENTIAL PERFORMANCE of RACA ROBOTS and the subclauses in which the requirements are found.

Table 201.101 – List of potential ESSENTIAL PERFORMANCES

Potential ESSENTIAL PERFORMANCE	Subclause
Movement or force/torque of the RACA ROBOT	201.12.101
ASSESSMENT measurement	201.12.102

201.4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

NOTE 101 Especially in the situation of SINGLE FAULT CONDITION, SITUATION AWARENESS can be very important to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE, particularly in cases where the OPERATOR takes over the responsibility of the RACA ROBOT for specific tasks. For example, to address the perception of the OPERATOR, two means of warning can be used (e.g. lighting and sound) in order to ensure that an ME EQUIPMENT is SINGLE FAULT SAFE.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.9.1 APPLIED PARTS

Additional subclause:

201.5.9.1.101 ACTUATED APPLIED PARTS

ACTUATED APPLIED PARTS are identified by inspection and referenced in the ACCOMPANYING DOCUMENTS.

201.5.9.2.1 Test finger

Addition:

The tests as described in the general standard are additionally performed with the small finger probe shown in Figure 1 of IEC 60601-1-11:2015 for RACA ROBOTS, where applicable.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.4 ACCESSORIES

Replacement:

If misidentification of ACCESSORIES results in an unacceptable RISK, the MANUFACTURER shall follow **A1** 7.1 of ISO 14971:2019 **A1** and the stated priorities for RISK CONTROL.

ACCESSORIES shall be marked as has been identified in the RISK MANAGEMENT PROCESS, but at least with

- the name or trademark of their MANUFACTURER,
- a MODEL OR TYPE REFERENCE,
- a serial number or lot or batch identifier, if applicable, and
- the date of manufacture or use-by date, if applicable.

NOTE 1 See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

NOTE 2 The serial number, lot or batch identifier, and the date of manufacture can be provided in a human readable code or through automatic identification technology, such as barcodes or radio-frequency identification.

Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.

201.7.9.2.5 ME EQUIPMENT description

Addition to the list of the first paragraph:

- a sufficient description of functions that have a degree of autonomy (including start-up PROCEDURE, restart PROCEDURE, shutdown PROCEDURE and maintenance), as needed for OPERATORS to develop adequate SITUATION AWARENESS.

201.7.9.2.9 Operating instructions

Addition at the end of the first paragraph:

This shall also include information determined by the RISK MANAGEMENT PROCESS related to SITUATION AWARENESS (described in 201.4.2.3.102).

201.7.9.3.1 General

Addition to the bullet list of the first paragraph:

- a description of functions that have a degree of autonomy which could create a HAZARDOUS SITUATION, for e.g. SERVICE PERSONNEL.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 Classification of APPLIED PARTS

Addition:

NOTE 101 ACTUATED APPLIED PARTS are classified in the same way as APPLIED PARTS, as either type CF, BF or B.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.1 MECHANICAL HAZARDS of ME EQUIPMENT

Table 19 – MECHANICAL HAZARDS covered by this clause

Addition:

Misalignment HAZARD	201.9.101
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201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.1 General

Addition:

A RACA ROBOT, especially if it is BODY-WORN or WALKING, can move in its environment and contact objects in the environment, such as walls, different walking surfaces, chairs or tables, while performing its INTENDED USE. If applicable, the MANUFACTURER shall consider these aspects in the RISK MANAGEMENT process. If applicable, information for safety shall be given to reduce RISKS.

NOTE 101 ISO 13482:2014, 5.10.8, can be helpful for the MANUFACTURER to consider RISK CONTROL measures (ISO 13482 describes RISK CONTROL as RISK reduction) related to collision with objects in the environment (ISO 13482 uses the term "safety-related obstacles").

To fulfil their INTENDED USE, RACA ROBOTS move one or more PATIENT body parts, therefore different stopping procedures (see Table 201.102), including automatic stopping procedures, should be considered in the RISK MANAGEMENT PROCESS.

Table 201.102 – Overview of different stopping procedures

Function	EMERGENCY STOP	PROTECTIVE STOP	Normal stop
Situation	Emergency	Abnormal condition	Intended operation
Initiation	Manual	Automatic	Manual or automatic
Requirements	Shall meet 201.9.2.4	Shall meet 201.9.2.101	Design specific
Restart	Manual	Manual or automatic	Not applicable
Use frequency	Infrequent	Often to infrequent	Always
Intended effect	Immediately stop HAZARDOUS SITUATION	Risk controlled to acceptable level	Suspension of operation

201.9.2.2.1 General

Addition:

For those RACA ROBOTS that contact objects in their environment, in order to fulfil their INTENDED USE, the space between the RACA ROBOT and its environment may not be feasible to

be considered a TRAPPING ZONE. This situation shall be assessed in the RISK MANAGEMENT PROCESS.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 * Unintended movement

Replacement and additional subclauses:

201.9.2.3.1.101 Unintended movement related to controls

Controls shall be positioned, recessed, or protected by other means so that they cannot be accidentally actuated, unless the USABILITY ENGINEERING PROCESS concludes otherwise for the intended PATIENT (e.g. PATIENT with special needs) or activation does not result in an unacceptable RISK.

NOTE Controls are understood as USER INTERFACES on the control devices actuated by the OPERATOR, such as switches, joysticks, touch panels (including smart devices), dials, or knobs.

Compliance is checked by inspection of ME EQUIPMENT, and, if the control is part of the PRIMARY OPERATING FUNCTIONS, by inspection of the USABILITY ENGINEERING FILE.

201.9.2.3.1.102 * Unintended movement related to shared control between the PATIENT, OPERATOR or RACA ROBOT

The MANUFACTURER shall identify unintended or unexpected movement or force/torque related to shared control between the PATIENT, OPERATOR or RACA ROBOT and address them in the RISK MANAGEMENT PROCESS. In case of unacceptable RISK, additional RISK CONTROL shall be implemented.

If the movement of the RACA ROBOT is controlled according to physiological signals (e.g. EMG, ECG, or EEG signals) related to MOVEMENT FUNCTIONS of the PATIENT, this shall be considered in the RISK MANAGEMENT PROCESS. If it is implemented through a PESS, Clause 14 of the general standard applies.

NOTE Unintended movements related to shared control are likely to occur during normal operation of RACA ROBOTS, as the movement of a RACA ROBOT is typically a result of PATIENT ability, OPERATOR intentions, PATIENT movement intentions, and the control system of the RACA ROBOT. Unintended movement can be unexpected by the OPERATOR or other persons in the environment.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.9.2.3.1.103 Unintended movement related to unexpected release of energy

The MANUFACTURER shall address unintended movement related to unexpected release of energy in the RISK MANAGEMENT PROCESS; in case of unacceptable RISK, additional RISK CONTROL shall be implemented.

NOTE Examples of energy sources are loaded springs, pressurized vessels (hydraulic or pneumatic), counterweights, flywheels. Stored electrical energy, when discharged, can through an actuator lead to unintended movement.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

201.9.2.3.1.104 Unintended movement related to start-up, restart or normal stop

Unintended movement of RACA ROBOTS may occur during or immediately upon start-up, restart or normal stop procedure.

The MANUFACTURER shall address such unintended movement in the RISK MANAGEMENT PROCESS. In case of unacceptable RISK, additional RISK CONTROL shall be implemented.

NOTE An example of unintended movement related to start-up or restart is sudden and fast movements caused by internal software states left from previous operation

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

201.9.2.3.1.105 Unintended movement related to PROTECTIVE STOP

Unintended movement may occur as an effect of a PROTECTIVE STOP. The MANUFACTURER shall address such unintended movement in the RISK MANAGEMENT PROCESS. In case of unacceptable RISK, additional RISK CONTROL shall be implemented.

NOTE An example of unintended movement related to a PROTECTIVE STOP is movements in an unexpected manner due to gravity or inertia after sudden loss of power or support.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

201.9.2.3.2 Overtravel end stops

Addition:

When the PATIENT contributes power to the movement, row 4 of Table 33 of the general standard applies.

If the RACA ROBOT has different control modes, the worst-case test scenario shall be considered.

Additional subclause:

201.9.2.3.101 Movement beyond pre-set limits for individual PATIENT movement

During RISK ANALYSIS, the MANUFACTURER shall consider HAZARDS related to movement beyond pre-set limits for individual PATIENT movement.

NOTE 1 To reduce RISK to an acceptable level, the MANUFACTURER can consider the following RISK CONTROL measures:

- limit the movement of the RACA ROBOT not to go beyond the pre-set motion limits (e.g position, angle, speed, acceleration, deceleration and jerks);
- limit the output force or torques not to go beyond pre-set force or torque limits.

These RISK CONTROL measures can be implemented by mechanical and/or electrical means or through a PESS and be configurable by the OPERATOR.

Compliance is checked by inspection of the RISK MANAGEMENT FILE, and the following:

- *functional testing where the RISK CONTROL measure limits the output force or torque; or*
- *tests specified in 201.9.2.3.2, where the RISK CONTROL measure limits the movement.*

Specific limits to the movement of a RACA ROBOT can be required to be pre-set by the OPERATOR for each training session or each PATIENT, taking into account the abilities, limitations and progress of each PATIENT'S MOVEMENT FUNCTIONS.

NOTE 2 When movement beyond pre-set limits leads to unacceptable RISK, to be SINGLE FAULT SAFE, the implementations of these RISK CONTROL measures can either fulfil the requirements of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS of all relevant components or consist of two independent control chains.

201.9.2.4 Emergency stopping devices

Addition:

If the RACA ROBOT is intended to be used with limited or no supervision and it is the PATIENT that may need to activate the EMERGENCY STOP, then the PATIENT is the OPERATOR.

emergency stopping device. Based on the RISK MANAGEMENT PROCESS, the MANUFACTURER shall provide adequate information in the ACCOMPANYING DOCUMENTS. This information shall include requirements regarding PATIENT capability to operate the EMERGENCY STOP and sufficient PATIENT training instructions to ensure adequate SITUATION AWARENESS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.9.2.5 Release of PATIENT

Addition to the list of the first paragraph:

- when a RACA ROBOT stops PATIENT movement, this may lead to a HAZARDOUS SITUATION for the PATIENT. For example, if a release of the PATIENT is not possible within a limited time period, this may lead to a HAZARDOUS SITUATION. Therefore, in certain cases, it may be required that the RACA ROBOT or its parts can be moved manually in a powered-down state to release the PATIENT.

During the RISK MANAGEMENT PROCESS, additional special attention shall be given to the following factors:

- limited ability of the PATIENT due to IMPAIRMENT or unconsciousness;
- limited or no availability of the OPERATOR;
- SITUATION AWARENESS;
- the PATIENT can be the OPERATOR;
- the RACA ROBOT may be operable in a HOME HEALTHCARE ENVIRONMENT (refer to IEC 60601-1-11). In this case, a LAY person may not be able or available to release the PATIENT from the RACA ROBOT;
- more than one OPERATOR may be required to release the PATIENT from the RACA ROBOT.

Additional subclause:

201.9.2.101 PROTECTIVE STOP functions

Where it is considered necessary to have one or more PROTECTIVE STOP functions, they shall comply with all the following requirements:

- reduce RISK to an acceptable level;
- be initiated automatically by PEMS/PESS;
- if applicable, comply with Clause 14 of the general standard (PEMS).

The restart shall be initiated manually by the OPERATOR unless automatic restart by PEMS/PESS does not lead to unacceptable RISK.

The PROTECTIVE STOP can require drive power to be maintained, in order to reduce RISK to an acceptable level.

Compliance is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE and by functional tests.

201.9.3 MECHANICAL HAZARDS associated with surfaces, corners and edges

Addition:

NOTE Rough surfaces, sharp corners and edges can also occur in textile parts and flexible components, such as cuffs, belts or straps.