IEC 80601-2-78

Edition 1.1 2024-03
CONSOLIDATED VERSION

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

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

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications, symboles graphiques et le glossaire. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

IEC 80601-2-78

Edition 1.1 2024-03
CONSOLIDATED VERSION

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8522-0

CONTENTS

FOREWORD 4
INTRODUCTION 7
INTRODUCTION to Amendment 1 7
201.1 Scope, object and related standards 8
201.2 Normative references 10
201.3 Terms and definitions 11
201.4 General requirements 14
201.5 General requirements for testing of ME EQUIPMENT 15
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 16
201.7 ME EQUIPMENT identification, marking and documents 16
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 17
201.10 Protection against unwanted and excessive radiation HAZARDS 22
201.11 Protection against excessive temperatures and other HAZARDS 22
201.12 Accuracy of controls and instruments and protection against hazardous outputs 22
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 23
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 23
201.15 Construction of ME EQUIPMENT 24
201.16 ME SYSTEMS 25
201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS 25
202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests 25
206 USABILITY 26
208 * General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS 26
210 * Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS 27
211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT 27
Annexes 29
Annex A (informative) General guidance and rationale 29
Annex AA (informative) Particular guidance and rationale 30
Annex BB (informative) Guidance and examples of SITUATION AWARENESS 59
Bibliography 74
Index of defined terms used in this particular standard 77

Figure AA.1 – Relationship of the terms used to describe equipment, accessories or equipment parts 31
Figure AA.2 – Endsley's model of SITUATION AWARENESS (based on [10], drawn by Dr. Peter Lankton, May 2007) 35
Figure AA.3 – Model of user-medical device interaction 36
Figure AA.4 – RACA ROBOT shared control system block diagram: control by PATIENT and RACA ROBOT 40

Figure AA.5 – RACA ROBOT shared control system block diagram: control by PATIENT, OPERATOR and RACA ROBOT 41
Figure AA.6 – RACA ROBOT shared control system block diagram: control by PATIENT and RACA ROBOT, and control modulation by OPERATOR 42
Figure AA.7 – WALKING RACA ROBOT using motion-related biosignal input....43
Figure AA.8 – System block diagram of a WALKING RACA ROBOT using a motion-related biosignal as input....43
Figure AA.9 – RACA ROBOT that is an arm exoskeleton for REHABILITATION that applies a PATIENT-cooperative shared control strategy 44
Figure AA.10 – System block diagram of an arm exoskeleton for REHABILITATION that applies a PATIENT-cooperative shared control strategy 45
Figure AA.11 – Cane-type RACA ROBOT for REHABILITATION of walking....46
Figure AA.12 – System block diagram of a cane-type RACA ROBOT 46
Figure AA.13 – Example of ROBOT arm type RACA ROBOT for lower extremities 47
Figure AA.14 – Example of ROBOT arm type RACA ROBOT for upper extremities....48
Figure AA.15 – Example of exoskeleton type RACA ROBOT for upper extremities....49
Figure AA.16 – Example of exoskeleton type RACA ROBOT for knee joint....51
Figure AA.17 – Example of soft artificial muscle-type RACA ROBOT for knee joint 52
Figure AA.18 – Example of exoskeleton-type WALKING RACA ROBOT 53
Figure AA.19 – Example of RACA ROBOT for balance control 54
Figure AA.20 – Example of a body-weight support-type RACA ROBOT with gait following function....56
Figure BB.1 – All the proximate causes of loss of SITUATION AWARENESS [19] 60
Figure BB.2 – Relationship between SITUATION AWARENESS, the RISK MANAGEMENT PROCESS (ISO 14971:~~2007~~2019) and the USABILITY ENGINEERING PROCESS (IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020) 63
Figure BB.3 – Relationship between GDTA and RISK MANAGEMENT and USABILITY ENGINEERING PROCESSES....66
Figure BB.4 – WALKING exoskeleton RACA ROBOT 72

Table 201.101 – List of potential ESSENTIAL PERFORMANCES....15
Table 19 – MECHANICAL HAZARDS covered by this clause....17
Table 201.102 – Overview of different stopping procedures 17
Table 28 – Mechanical strength test applicability 24
Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE 27
Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE 28
Table AA.1 – Correlation mapping between Figure AA.2 and Figure AA.3....37
Table BB.1 – Example of using GDTA in BB.5.2 68
Table BB.2 – Example of using GDTA in BB.5.3 69
Table BB.3 – Example of using GDTA in BB.5.4 71
Table BB.4 – Example of using GDTA in BB.5.5 73

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.
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.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
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) IEC and ISO draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC and ISO take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC and ISO had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch and www.iso.org/patents. IEC and ISO shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-78 edition 1.1 contains the first edition (2019-07) [documents 62D/1676/FDIS and 62D/1688/RVD] and its amendment 1 (2024-03) [documents 62D/2085A/FDIS and 62D/2109/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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.

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 and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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.

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 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.

---

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*.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 206, 208, 210 and 211 respectively. IEC 60601-1-3 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

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

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*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:~~2007~~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

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.

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 77.

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.