

American National Standard

ANSI/AAMI/ IEC 80601-2- 78:2020

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

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

Approved 08 May 2020 by
AAMI

Approved 03 August 2020 by
American National Standards Institute

Abstract: 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.

Keywords: rehabilitation, assessment, compensation, alleviation, ME equipment, ME system

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
WWW.aami.org

© 2020 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-276-0793.

Printed in the United States of America

ISBN 978-1-57020-773-0

Contents

Page

Committee representation	iv
Background of ANSI/AAMI adoption of IEC 80601-2-78:2019	v
Foreword	vi
Introduction	ix
201.1 Scope, object and related standards	1
201.2 Normative references.....	2
201.3 Terms and definitions.....	3
201.4 General requirements	6
201.5 General requirements for testing of ME EQUIPMENT	7
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	8
201.7 ME EQUIPMENT identification, marking and documents	8
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	9
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	9
201.10 Protection against unwanted and excessive radiation HAZARDS	14
201.11 Protection against excessive temperatures and other HAZARDS	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	14
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	15
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	15
201.15 Construction of ME EQUIPMENT	15
201.16 ME SYSTEMS.....	16
201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	17
202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests	17
206 USABILITY	17
208* General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS	18
210* Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS.....	18
211* Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT	18
Annex AA (informative) General guidance and rationale	21
Annex BB (informative) Particular guidance and rationale	22
Annex CC (informative) Guidance and examples of situation awareness.....	49
Bibliography	61
Index of defined terms used in this particular standard.....	63

Committee representation

Association for the Advancement of Medical Instrumentation

Robotics Committee

The adoption of IEC 80601-2-78 as an American National Standard was initiated by the AAMI Robotics Committee. AAMI RB provides input to the U.S. Technical Advisory Group (TAG) to IEC/SC 62D which is the responsible group for providing the U.S. input to the relevant group in IEC. U.S. representatives from AAMI Robotics Committee and the TAG played an active part in developing the IEC document.

At the time this document was published, the **AAMI Robotics Committee** has the following members:

Cochair: Michael Yramategui

Members: Je Hi An, FDA/CDRH
Gregory Chase, TUV Rheinland of North America Inc
Thomas Claiborne, Neocis Inc
Pamela Gwynn, UL LLC
Colin Murphy, Medtronic Inc Campus
Adam Shames, Core Human Factors Inc
Angad Singh, Mirus LLC
William Stearns, Intertek
Stephen Still, Stryker Instruments Division
James Treharn, St Peters Community Hospital
Harry Weber, Johnson & Johnson
Michael Yramategui, Intuitive Surgical Inc
Adam Zoss, Ekso Bionics
Joel Zuhars, THINK Surgical

Alternates: Sheldon Davis, FDA/CDRH
David Deaven, GE Healthcare
Tsun-Ren Jeng, Industrial Technology Research Institute/Center for Measurement Standards
Elizabeth Casey, Intertek
Hamilton Gonzalez, Johnson & Johnson
Adam Stewart, Stryker Instruments Division
Paul Evers, UL LLC

NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 80601-2-78:2019

As indicated in the foreword to the main body of this document (page vi), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by IEC SC62D to specify the minimum safety requirements for medical robots that interact with a patient who has an impairment to support or perform a number of tasks related to the patient's movement functions.

U.S. participation in IEC/SC 62D is organized through the U.S. Technical Advisory Group, U.S. TAG to IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of robotically assisted surgical equipment. Upon review of IEC 80601-2-78, the U.S. TAG to IEC/SC 62D and the AAMI Robotics Committee decided to adopt it verbatim, as a first edition of ANSI/AAMI/IEC 80601-2-78:2020.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the recommended practice. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

"May" is used to indicate that a course of action is permissible within the limits of the standard. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color);
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.);
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15).

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE Beginning with the IEC foreword on page vi, this American National Standard is identical to IEC 80601-2-78:2019.

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

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

This publication is published as a double logo standard.

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

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

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

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

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type*;
- informative material appearing outside of tables, such as notes, examples and references in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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

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

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

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

Introduction

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

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

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

The minimum safety requirements specified in this particular standard are presented to provide for an acceptable degree of BASIC SAFETY and ESSENTIAL PERFORMANCE for MEDICAL ROBOTS that physically interact with a PATIENT with an IMPAIRMENT, to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the PATIENT'S MOVEMENT FUNCTIONS .

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

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

201.1 Scope, object and related standards

Clause 1 of the general 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:

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

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional Annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-8:2006/AMD1:2012

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

Addition:

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-10:2007/AMD1:2013

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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

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

201.3 Terms and definitions

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

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

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

NOTE An Index of defined terms is found beginning on page 63.

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.

2 Numbers in square brackets refer to the Bibliography.

[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.

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.

IEC 62366-1:2015, 5.5 requires HAZARD-RELATED USE SCENARIOS to be evaluated using a SUMMATIVE EVALUATION. 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 6.2 of ISO 14971:2007 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
---------------------	-----------

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 of the 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.