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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/2278/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: IEC 80601-2-78 ED2	
DATE OF CIRCULATION: 2025-11-21	CLOSING DATE FOR COMMENTS: 2026-01-30
SUPERSEDES DOCUMENTS: 62D/2158/RR	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Safety	

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Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

NOTE FROM TC/SC OFFICERS:

Please note that changes are highlighted in red.

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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

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International standard IEC 80601-2-78 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems; 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;*

- 147 – informative material appearing outside of tables, such as notes, examples and references in smaller type.
148 Normative text of tables is also in a smaller type;
- 149 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS
150 NOTED: SMALL CAPITALS.

151 In referring to the structure of this document, the term

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

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

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

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

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

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

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

172

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.

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INTRODUCTION

During the September 21, 2023, meeting of IEC SC62D Plenary in Seoul, Republic of Korea, the subcommittee discussed the need to proceed with a new edition of IEC 80601-2-78. The need for a new edition was to include/modify the standard based on the latest medical robots for rehabilitation, assessment, compensation or alleviation (RACA).

A resolution was taken to proceed towards the 2nd edition of the IEC 80601-2-78. The review report for the new edition can be found in the IEC 62D/2158/RR document. This 2nd edition of the IEC 80601-2-78 supersedes the IEC 80601-2-78 edition 1.1 standard.

In this second edition, compared to the first edition, the following significant points were added or modified:

- revised the scope to clarify which product falls in the scope of this standard
- revised definitions, including RACA ROBOT, for clarity
- added new requirements for battery management systems of secondary batteries
- revised requirements for support systems for clarity
- added new requirements for use of Head Mounted Displays (HMD) or other extended reality (XR) devices with RACA ROBOTS

The following flowchart provides guidance on whether an ME EQUIPMENT or ME SYSTEM is a RACA ROBOT.

N°	Decision	Description	Further Information
1		Is the device a ME EQUIPMENT or / ME SYSTEM	Refer to definition: 1. IEC 60601-1 ¹ Clause 3.63 ME EQUIPMENT 2. IEC 60601-1 Clause 3.64 ME SYSTEM
2		Is the ME EQUIPMENT or / ME SYSTEM a • external limb prosthetic devices • electric wheelchairs • diagnostic imaging equipment • personal care robots	The listed devices are addressed in following standards: • ISO 22523 • ISO 7176 (all parts) • e.g. MRI, IEC 60601-2-33 • ISO 13482
3		Is the INTENDED USE of ME EQUIPMENT or / ME SYSTEM related to REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION?	Refer to definition: 1. IEC 80601-2-78 ² Clause 201.3.202 ALLEVIATION "Treatment to ease symptoms due to an IMPAIRMENT of a PATIENT" 2. IEC 80601-2-78 Clause 201.3.203 ASSESSMENT "Procedure to quantify or to aid in the qualification of the level of IMPAIRMENT of a PATIENT" 3. IEC 80601-2-78 Clause 201.3.205 COMPENSATION "Mitigation of IMPAIRMENT of a PATIENT through support of body structures or through support or replacement of body functions" 4. IEC 80601-2-78 Clause 201.3.211 * REHABILITATION "Treatment to improve MOVEMENT FUNCTIONS related to an IMPAIRMENT of a PATIENT"
4		Does the ME EQUIPMENT or / ME SYSTEM have an ACTUATED APPLIED PART?	Refer to definition: IEC 80601-2-78 Clause 201.3.201 ACTUATED APPLIED PART "Intended to provide actively controlled physical interactions with the PATIENT"
5		Is the ACTUATED APPLIED PART intended to physically interact with a PATIENT, related to their MOVEMENT FUNCTIONS, to perform a clinical function?	Refer to definition: 1. IEC 80601-2-78 Clause 201.3.209 MOVEMENT FUNCTIONS "Function consisting of one or more of sensory, neuromusculoskeletal or movement-related body functions that comprise PATIENT motor control"
6		Does the MEDICAL ELECTRICAL EQUIPMENT or / MEDICAL ELECTRICAL SYSTEM perform any functions or tasks with AUTONOMY?	Refer to definition: 1. IEC 80601-2-78 Clause 201.3.X autonomy "ability to perform functions or tasks under NORMAL USE without OPERATOR intervention"
7		The ME EQUIPMENT or / ME SYSTEM is a RACA ROBOT	
8		The device is <u>not</u> a RACA ROBOT	

The defined terms can be found in:

- 1 IEC 60601-1 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- 2 IEC 80601-2-78 - Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

- 3 IEC TR 60601-4-1 - Medical electrical equipment- Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a level of autonomy.

or may also be listed in Electropedia.

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.

Note: A MOVEMENT FUNCTION is a function consisting of one or more of sensory, neuromusculoskeletal or movement-related body functions that comprise PATIENT motor control.

A RACA ROBOT is a PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS) with a LEVEL OF AUTONOMY greater than zero, comprising an ACTUATED APPLIED PART, intended by its MANUFACTURER to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION

RACA ROBOTS covered by this particular standard include but are not limited to:

- Exoskeletons or robotic orthoses for upper and lower limbs for ASSESSMENT, REHABILITATION, ALLEVIATION or COMPENSATION
- Robotic end-effectors for upper / lower extremities for ASSESSMENT or REHABILITATION
- Balance control equipment for ASSESSMENT or REHABILITATION
- Overhead robotic body weight support systems
- Robotic walkers
- Robots intended to alleviate hemiplegic shoulder/ joint pain or spasticity through movement
- Continuous Passive Motion devices with a LEVEL OF AUTONOMY

Note 1: Annex AA lists a couple of RACA ROBOT examples.

Note 2: This particular standard is primarily focused on human beings. It is recognized that this standard may be used for animal PATIENTS. As such the use of the RISK MANAGEMENT PROCESS may be necessary to address BASIC SAFETY and ESSENTIAL PERFORMANCE for animal PATIENTS.

This particular standard does not apply to

- Devices that address activities of daily living (including active assisted living) but do not directly address PATIENT MOVEMENT FUNCTIONS (e.g. of fingers, arms, legs) are excluded, such as
 - electric wheelchairs (use ISO 7176 (all parts)),
 - personal care / service ROBOTS (use ISO 13482; 2014), e.g. feeding robots, robotic hoists, robotic bed
- Devices without a LEVEL OF AUTONOMY
 - E.g. Continuous Passive Motion devices without a LEVEL OF AUTONOMY
- Devices which are covered by other standards:
 - external limb prosthetic devices (use ISO 22523; 2006-10),
 - diagnostic imaging equipment (e.g. MRI, use IEC 60601-2-33; 2022),

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.*

- stationary training equipment (ISO 20957 series) e.g. treadmills

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.

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.

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 14971:2019, *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 76.

Amendment:

201.3.63

*** MEDICAL ELECTRICAL EQUIPMENT**

ME EQUIPMENT

Addition:

Note to entry: See Figure AA.1.

201.3.65

MOBILE

Addition:

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

201.3.144

Replacement:*

RACA BODY-WORN

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

Note to entry: RACA BODY-WORN is a subcategory of PORTABLE ME EQUIPMENT and ME SYSTEM, replacing BODY-WORN, as shown in Figure AA.1

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 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**COMPENSATION**

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

Note 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.

201.3.205**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.

² Numbers in square brackets refer to the Bibliography.

201.3.206*** 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.]

201.3.207*** MOVEMENT FUNCTION**

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

Note to entry: "Sensory", "neuromusculoskeletal" and "movement-related" come from the body functions classification presented in [1] [6] For example: Gait pattern functions are considered a MOVEMENT FUNCTION, whereas walking is considered an activity. [6]

201.3.208*** 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.

201.3.209*** 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.

201.3.210*** REHABILITATION, ASSESSMENT, COMPENSATION AND ALLEVIATION ROBOT RACA ROBOT**

PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS) with a LEVEL OF AUTONOMY greater than zero, comprising an ACTUATED APPLIED PART, intended by its MANUFACTURER to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION

Note 1 to entry: a LEVEL OF AUTONOMY zero is understood as having no AUTONOMY

201.3.211*** 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.

201.3.212*** WALKING**

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

201.3.213**AUTONOMY**

ability to perform functions or tasks under NORMAL USE without OPERATOR intervention

Note to entry: a PATIENT can be an OPERATOR

201.3.214**LEVEL OF AUTONOMY**

extent to which functions or tasks under NORMAL USE are performed without OPERATOR intervention

Note to entry: a PATIENT can be an OPERATOR

201.3.215**BATTERY**

assembly of one or more BATTERY CELLS ready for use as a source of electrical energy characterized by its voltage, size, terminal arrangement, capacity and rate capability [IEC 62368-1:2023, definition 3.3.17.1, modified]

NOTE to entry: A BATTERY pack is considered to be a BATTERY.

201.3.216*** BATTERY CELL**

basic manufactured unit providing a source of electrical energy by direct conversion of chemical energy, that consists of electrodes, separators, electrolyte, container and terminals [IEC 62368-1:2023, definition 3.3.17.2, modified]

201.3.217**COIN OR BUTTON CELL BATTERY**

small BATTERY, composed of a single BATTERY CELL having a maximum diameter of 32 mm and a diameter greater than its height [IEC 62368-1:2023, definition 3.3.17.3, modified]

201.3.218**HIGHEST SPECIFIED CHARGING TEMPERATURE**

highest surface temperature on the BATTERY CELLS within the BATTERY specified by the MANUFACTURER during the charging of the SECONDARY BATTERY [IEC 62368-1:2023, definition 3.3.17.4, modified]

539 NOTE to entry: It is assumed that the MANUFACTURER is responsible to specify the safety-sensitive temperatures,
 540 voltages or currents of the BATTERY, such as the HIGHEST SPECIFIED CHARGING TEMPERATURE, based on the
 541 specification provided by the BATTERY supplier.

542 **201.3.219**

543 **LOWEST SPECIFIED CHARGING TEMPERATURE**

544 lowest surface temperature on the BATTERY CELLS within the BATTERY specified by the
 545 MANUFACTURER during the charging of the SECONDARY BATTERY [IEC 62368-1:2023, definition
 546 3.3.17.4, modified]

547 NOTE to entry: It is assumed that the MANUFACTURER is responsible to specify the safety-sensitive temperatures,
 548 voltages or currents of the BATTERY, such as the LOWEST SPECIFIED CHARGING TEMPERATURE, based on the
 549 specification provided by the BATTERY supplier.

550 **201.3.220**

551 **MAXIMUM SPECIFIED CHARGING CURRENT**

552 highest charging current specified by the MANUFACTURER during the charging of the SECONDARY
 553 BATTERY [IEC 62368-1:2023, definition 3.3.17.6]

554 **201.3.221**

555 **MAXIMUM SPECIFIED CHARGING VOLTAGE**

556 highest charging voltage specified by the MANUFACTURER during the charging of the SECONDARY
 557 BATTERY [IEC 62368-1:2023, definition 3.3.17.7]

558 **201.3.222**

559 **PRIMARY BATTERY**

560 BATTERY which is not designed to be electrically recharged [Adapted from definition of primary
 561 cell in IEV 482-01-02]

562 **201.3.223**

563 **SECONDARY BATTERY**

564 BATTERY which is designed to be electrically recharged [Adapted from definition of secondary
 565 cell in IEV 482-01-03]

566 NOTE to entry: The recharge is accomplished by way of a reversible chemical reaction.

567 **201.3.224**

568 **SECONDARY LITHIUM BATTERY**

569 SECONDARY BATTERY that incorporates one or more secondary lithium BATTERY CELLS [IEC
 570 62368-1:2023, definition 3.3.17.8, modified]

571 NOTE to entry: Examples of a SECONDARY LITHIUM BATTERY include a rechargeable lithium-ion BATTERY, a
 572 rechargeable lithium-polymer BATTERY and a rechargeable lithium metal or alloy BATTERY.

573

574 **201.4 General requirements**

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

576 **201.4.2.3 Evaluating RISK**

577 *Additional subclauses before 4.2.3.1:*

578 **201.4.2.3.101 General**

579 In performing a RISK MANAGEMENT PROCESS, the LEVEL OF AUTONOMY of the RACA ROBOT shall be
 580 taken into consideration.

NOTE 1: IEC TR 60601-4-1 provides considerations on the effects that the **LEVEL 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: LEVEL OF AUTONOMY has the potential for increasing performance, adding functionality or improving USABILITY of RACA ROBOTS. However, a higher LEVEL 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 **LEVEL 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 is checked by inspection of the RISK MANAGEMENT FILE and, where applicable, of the ACCOMPANYING DOCUMENTS.

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. 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.

201.4.2.3.103 RISK MANAGEMENT related to head mounted displays (HMDs) or other extended reality (XR) devices

When incorporating Head Mounted Displays (HMDs) or other Extended Reality (XR) devices as part of a RACA ROBOT, the MANUFACTURER shall identify associated HAZARDS through the RISK MANAGEMENT PROCESS and the USABILITY ENGINEERING PROCESS. The MANUFACTURER shall include the necessary information in the ACCOMPANYING DOCUMENTS.

NOTE 1: XR includes Augmented Reality (AR), Virtual Reality (VR) and Mixed Reality (MR).

NOTE 2: HAZARDS related to the use of XR devices, may include, but are not limited to:

- Sensitivity to motion/cyber sickness for the person wearing the XR device
 - Lack of attention to the environment by the person wearing the XR device
 - Lack of SITUATION AWARENESS due to lack of information on PATIENT, RACA ROBOT or environment, through limited visual or auditory input available to the OPERATOR
 - After-effects (disorientation, vergence accommodation conflicts) for the person wearing the XR device
 - APPLIED PART aspects, such as leakage currents, biocompatibility for the PATIENT
 - Contact temperature (thermal energy) for the person wearing the XR device
 - Exposure of eyes to thermal energy for the person wearing the XR device
 - Inadequate refresh rate, brightness, resolution, luminance for the person wearing the XR device
 - Inability of the PATIENT to remove the device from their head
 - Biomechanical stress caused by weight, modified center of mass, or compression for the person wearing the XR device
- HAZARDS should be considered in the context of:
- the USE SPECIFICATION,
 - the intended PATIENT population, and
 - PATIENT limitations.

Source: UL 8400 Virtual Reality, Augmented Reality and Mixed Reality Technology Equipment 2025

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the USABILITY ENGINEERING FILE and, where applicable, of the ACCOMPANYING DOCUMENTS.

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 7.1 of ISO 14971:2019 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.

201.7.3.3 BATTERIES

Addition:

See Annex CC.8.2 for additional requirements applicable to SECONDARY BATTERIES.

201.7.9.2.5 ME EQUIPMENT description

Addition to the list of the first paragraph:

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

Replacement of the 3rd dash

- the significant physical and performance characteristics of the RACA ROBOT, including the ACTUATED APPLIED PART

Note: examples of performance characteristics of the ACTUATED APPLIED PART may include

- Range or accuracy of any of the following:
 - Position/pose or range-of-motion
 - Movement force or torque
 - Attachment contact pressure
 - Speed
 - Acceleration
 - Battery life

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 **LEVEL 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 other APPLIED PARTS, as either type CF, BF or B including DEFIBRILLATION-PROOF

Note 102: If a RACA ROBOT has other APPLIED PARTS that deliver or sense electrical signals (ECG, EEG; EMG; FES; EOG or others) then corresponding standards such as IEC 60601-2-40; IEC 60601-2-10 or IEC 80601-2-26 are applicable. If the RACA ROBOT can be considered as a PHYSIOLOGICAL CLOSED LOOP CONTROLLER, IEC 60601-1-10 is applicable.

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 RACA 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

747 **201.9.2.2.1 General**748 *Addition:*

749 For those RACA ROBOTS that contact objects in their environment, in order to fulfil their INTENDED
 750 USE, the space between the RACA ROBOT and its environment may not be feasible to be
 751 considered a TRAPPING ZONE. This situation shall be assessed in the RISK MANAGEMENT PROCESS.

752 **201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts**753 **201.9.2.3.1 * Unintended movement**754 *Delete and replace with:*755 **201.9.2.3.1.101 Unintended movement related to controls**

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

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

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

764 **201.9.2.3.1.102 * Unintended movement related to shared control between the PATIENT,**
 765 **OPERATOR or RACA ROBOT**

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

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

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

778 *Compliance is checked by inspection of the RISK MANAGEMENT FILE.*

779 **201.9.2.3.1.103 Unintended movement related to unexpected release of energy**

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

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

786 *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

In the RISK MANAGEMENT PROCESS, 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.

In case this applies, the ACCOMPANYING DOCUMENTATION shall indicate the need to pre-set movement limits for the individual PATIENT and provide instructions on how to adapt movement limits for the individual PATIENT.

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.

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.

201.9.4.2.1 Instability in transport position

Addition:

For WALKING RACA ROBOT, transport position shall be understood as including possible additional means, e.g. a transport rack, required for transport of the WALKING RACA ROBOT.

NOTE: For a WALKING RACA ROBOT, the meaning of transport in this subclause is relocating it within its environment during NORMAL USE, without PATIENT, e.g. in between treatments. WALKING RACA ROBOTS are intended by the MANUFACTURER to be used in their INTENDED USE for walking in an environment, worn by the PATIENT, which is not considered transport.

201.9.4.3.1 Instability in transport position

Addition:

For WALKING RACA ROBOT, transport position shall be understood as including possible additional means, e.g. a transport rack, required for transport of the WALKING RACA ROBOT.

201.9.8 * MECHANICAL HAZARDS associated with support systems**201.9.8.1 General**

Replacement of the first dash:

- The construction of the support, suspension, or actuation system shall be designed based upon 201.9.8.2 and the TOTAL LOAD of each support, suspension or actuation system.

Addition to the last dash:

where the MANUFACTURER has not specified a qualified installer (see 7.9.2.6), the following information shall be provided by the MANUFACTURER in the ACCOMPANYING DOCUMENTATION:

- requirements for the installation location, regarding its construction, materials or properties, as relevant to safe operation
- installation procedure to be followed
- inspection or test procedures that confirm proper installation of the system, and documentation requirements of compliance
- requirement for RESPONSIBLE ORGANIZATION to retain such documentation.

Addition to the list of the first paragraph:

- For RACA ROBOTS performing repetitive movements of their ACTUATED APPLIED PARTS, if the RISK ASSESSMENT indicated UNACCEPTABLE RISK due to premature failure during the EXPECTED SERVICE LIFE, then the RISK CONTROL MEASURES implemented shall be validated by adequate fatigue or durability testing.

NOTE: See 201.9.8 in Annex AA for examples indicating support systems, suspension systems or actuation systems in RACA ROBOTS. These examples provide the MANUFACTURERS of RACA ROBOTS clarification of what types of support systems, suspension systems or actuation systems exist and how to identify their TOTAL LOADS.

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

Addition:

RACA ROBOT support systems may include support, suspension and actuation systems, and the ACTUATED APPLIED PARTS of a RACA ROBOT which are per definition part of an actuation system. The RACA ROBOT itself may also be a support system (e.g., see Example 6: exoskeleton type RACA ROBOT for lower extremities for walking in Annex AA 201.9.8). A RACA ROBOT can contain multiple different support, suspension, or actuation systems which can each have a different

920 TOTAL LOAD. The MANUFACTURER shall identify and assess each of them during the RISK
921 MANAGEMENT PROCESS.

922 NOTE 101: See 201.9.8 of Annex AA for further explanations about support systems, suspension systems or
923 actuation systems.

924 If failure of a support system would lead to unacceptable RISK then the structural strength of
925 support systems shall comply with the TENSILE SAFETY FACTOR of Table 21 of the general
926 standard. The MANUFACTURER shall identify the respective TOTAL LOADS for each part of each
927 support system, suspension system or actuation system.

928 NOTE 102: The selection of Case A or Case B of Table 21 of the general standard depends not only on identification
929 of TOTAL LOAD but also on knowledge of material TENSILE STRENGTH. See the footnotes of Table 21 of the general
930 standard. Case A assumes TOTAL LOAD and the material TENSILE STRENGTH are known accurately. If knowledge of
931 either of them is uncertain, Case B of Table 21 applies.

932 NOTE 103: A typical HAZARD for the supported or suspended PATIENT is the loss of their balance and falling down
933 immediately after a mechanical failure of the support or suspension systems.

934 NOTE 104: A support or suspension system can be a means to maintain position or posture of a PATIENT, against
935 gravity.

936 NOTE 105: TYPE TESTING using an appropriate human body test apparatus can be performed to support the RISK
937 MANAGEMENT PROCESS (for an example of human body mass distribution, refer to Figure A.19 of the general standard).

938 **201.9.8.2 TENSILE SAFETY FACTOR**

939 *Addition after the first paragraph:*

940 NOTE 101: For RACA ROBOTS, support systems include support, suspension and actuation systems, and the
941 ACTUATED APPLIED PARTS of a RACA ROBOT are by definition part of an actuation system.

942 NOTE 102: In providing for structural strength requirements, the selection of Case A or Case B of Table 21 of the
943 general standard depends not only on identification of TOTAL LOAD but also on knowledge of material TENSILE
944 STRENGTH. See the footnotes of Table 21 of the general standard. Case A assumes that both TOTAL LOAD and the
945 material TENSILE STRENGTH are known accurately. If knowledge of either of them is uncertain, Case B of Table 21
946 applies.

947 NOTE 103: Alternative methods to demonstrate structural integrity throughout EXPECTED SERVICE LIFE can include
948 fatigue testing or use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

949 *Replacement of the last two paragraphs, excluding the notes, after Table 21:*

950 Compliance with 201.9.8.1 and 201.9.8.2 is checked by inspection of the ME EQUIPMENT and the
951 RISK MANAGEMENT FILE, and when necessary by tests in conjunction with the following
952 requirements:

- 953 – the construction of the support, suspension or actuation system;
- 954 – the specifications and description of the materials used;
- 955 – the processing specifications for these materials;
- 956 – the supporting calculations / specifications for TOTAL LOADS as per Annex AA; and
- 957 – where necessary, by test(s) to demonstrate that the MANUFACTURER's specified limits are
958 maintained.

959 A test load equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR is gradually
960 applied to the support assembly under test. The support assembly under test shall be in
961 equilibrium after 1 min, or in case of failure, this shall not result in an unacceptable RISK.

962 **201.9.8.3.1 General**

963 *Addition:*

964 NOTE 1: 9.8.3 of the general standard only applies to support or suspension systems that support the full body
965 mass of a PATIENT or OPERATOR. Examples and the rationale are given in 9.8.3.3 of Annex A of the general standard.

NOTE 2: If a RACA ROBOT is intended to be used with a hoist or lifting device, ISO 10535 can provide additional guidance concerning HAZARDS not addressed in IEC 60601 (all parts).

NOTE 3: 201.9.8 of Annex AA provides examples of the application of 201.9.8 to different types of RACA ROBOTS.

Additional subclause:

201.9.101 MECHANICAL HAZARDS associated with misalignment

HAZARDS associated with misalignment between PATIENT and ACTUATED APPLIED PART shall be addressed in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

Where dynamic forces can be exerted on RACA ROBOT parts intended to move/actuate, support or suspend a PATIENT or OPERATOR in NORMAL USE, the RACA ROBOT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Note: Such dynamic forces may occur due to

- sitting down,
- standing up,
- activities related to PATIENT treatment, including pre- and post-treatment set-up,
- interaction of the ACTUATED APPLIED PART with the PATIENT,
- movement of the RACA ROBOT in NORMAL USE.

Compliance is checked by the applicable following test(s):

A) For seating surfaces, the test from clause 9.8.3.3 of the general standard applies

B) For all other RACA ROBOT dynamic loading conditions (e.g. interaction with harness/tether points, cuffs/orthoses, handholds, grab bars, footplates), the following test applies:

- *Set the RACA ROBOT to the least favourable adjustment for each loading condition (e.g. maximum person size/height, tightest strap, lowest support percentage, highest speed mode).*
- *Identify the direction of normal loading on the part of the RACA ROBOT under test, as in NORMAL USE.*
- *Because the test is performed as a drop of a test-mass in the vertical direction, orient the part of the RACA ROBOT under test, so that its normal loading direction is aligned with the test load free-fall direction. Where it is not practical orienting the entire RACA ROBOT, it is permitted to use a subassembly of the RACA ROBOT.*
- *Identify a drop test height representing the worst-case loading force*
- *Prepare a test-mass that is equal to the SAFE WORKING LOAD.*
 - *Example: a flexible bag, such as a sand-bag*
- *The test-mass is dropped from the identified height onto:*
 - *the part of the RACA ROBOT under test, or*
 - *a surface suspended with a non-elastic connection from the part of the RACA ROBOT under test.*

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

Support parts that break loose from the me equipment, or exhibit any permanent distortion, cracking or other evidence of break-down constitute a failure.

1021 **201.10 Protection against unwanted and excessive radiation HAZARDS**

1022 Clause 10 of the general standard applies.

1023 **201.11 Protection against excessive temperatures and other HAZARDS**

1024 Clause 11 of the general standard applies.

1025 **201.12 Accuracy of controls and instruments and protection against hazardous**
1026 **outputs**

1027 Clause 12 of the general standard applies, except as follows.

1028 *Additional subclauses:*

1029 **201.12.101 Movement or force/torque of RACA ROBOT**

1030 The MANUFACTURER, through the RISK MANAGEMENT PROCESS, shall identify foreseeable HAZARDS
1031 related to loss or degradation of movements or force/torque of the ACTUATED APPLIED PARTS of
1032 the RACA ROBOT. If the movement or force/torque is a clinical function, then the MANUFACTURER
1033 shall define performance limits considering both NORMAL CONDITION and SINGLE FAULT CONDITION.
1034 If characteristics of movement or force/torque outside of the performance limits lead to an
1035 unacceptable RISK, then movement or force/torque is an ESSENTIAL PERFORMANCE. In this case,
1036 the MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK to an acceptable
1037 level.

1038 NOTE: Characteristics of movement or force/torque can depend on many different factors, such as: spatial
1039 coordination, timing, speed, stability, range, pressure, fitting/misalignment, installation and other relevant factors.

1040 *Compliance is checked by inspection of the design documents/performance limits, the*
1041 *ACCOMPANYING DOCUMENTS, the RISK MANAGEMENT FILE and by functional tests as necessary.*

1042 The MANUFACTURER, through the RISK MANAGEMENT PROCESS, shall take into consideration
1043 foreseeable HAZARDS related to interaction forces between ACTUATED APPLIED PARTS and the
1044 patient; this includes for example skin damage, pressure points, integrity of bone, muscle and
1045 tendons tissues.

1046 The RISK MANAGEMENT PROCESS shall take into consideration the various medical conditions of
1047 the PATIENT.

1048 Note: medical conditions, such as osteoporosis, spinal cord lesions, Alzheimers disease, muscle atrophy, sarcopenia,
1049 among others, could lead to lack of sensation, increased sensitivity, lack of awareness of excessive forces, that
1050 influence possible impact of forces and movement.

1051 Based on the RISK MANAGEMENT PROCESS, the MANUFACTURER shall provide adequate information
1052 in the ACCOMPANYING DOCUMENTS.

1053 **201.12.102 ASSESSMENT measurement**

1054 The MANUFACTURER, through the RISK MANAGEMENT PROCESS, shall identify foreseeable HAZARDS
1055 related to loss or degradation of the ASSESSMENT measurement by the RACA ROBOT. If the
1056 ASSESSMENT measurement is a clinical function, then the MANUFACTURER shall define
1057 performance limits considering both NORMAL CONDITION and SINGLE FAULT CONDITION. If loss or
1058 degradation of the ASSESSMENT measurement leads to an unacceptable RISK, then the
1059 ASSESSMENT measurement is an ESSENTIAL PERFORMANCE. In this case, the MANUFACTURER shall
1060 implement RISK CONTROL measures to reduce the RISK to an acceptable level.