# IEC 80601-2-78

Edition 1.1 2024-03
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

colour inside

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

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



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

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8522-0

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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# MEDICAL ELECTRICAL EQUIPMENT –

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

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

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

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

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

This publication is published as a double logo standard.

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

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

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

- reconfirmed,
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# INTRODUCTION

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

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

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

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

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

## INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1882/RR.

# MEDICAL ELECTRICAL EQUIPMENT –

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

## 201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

### 201.1.1 Scope

*Replacement:*

This part of IEC 80601 applies to the general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ROBOTS that physically interact with a PATIENT with an IMPAIRMENT to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the PATIENT'S MOVEMENT FUNCTIONS, as intended by the MANUFACTURER.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to

- external limb prosthetic devices (use ISO 22523),
- electric wheelchairs (use ISO 7176 (all parts)),
- diagnostic imaging equipment (e.g. MRI, use IEC 60601-2-33), and
- personal care ROBOTS (use ISO 13482).

### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL ROBOTS that physically interact with a PATIENT with an IMPAIRMENT, to support or perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION related to the PATIENT'S MOVEMENT FUNCTIONS.

### 201.1.3 Collateral standards

*Addition:*

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

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1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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

### 201.1.4 Particular standards

*Replacement:*

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

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

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

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

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

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

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

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

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

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

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

standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

## 201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

*Replacement:*

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

ISO 14971:~~2007~~2019, *Medical devices – Application of risk management to medical devices*

*Addition:*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

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

IEC 60601-1-11:2015/AMD1:2020

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-1:2015/AMD1:2020

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

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD1:2020 apply.

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

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

NOTE An Index of defined terms is found beginning on page 77.

*Amendment:*

**201.3.63**
*** MEDICAL ELECTRICAL EQUIPMENT**
**ME EQUIPMENT**

*Addition:*

Note 1 to entry: See Figure AA.1.

**201.3.65**
**MOBILE**

*Addition:*

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

**201.3.144**
*** BODY-WORN**

*Replacement:*

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

*Addition:*

**201.3.201**
***ACTUATED APPLIED PART**
subcategory of APPLIED PART that is intended to provide actively controlled physical interactions with the PATIENT that are related to the PATIENT's MOVEMENT FUNCTIONS, to perform a CLINICAL FUNCTION of a RACA ROBOT

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

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

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

**201.3.202**
**ALLEVIATION**
treatment to ease symptoms due to an IMPAIRMENT of a PATIENT

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

**201.3.203**
*** ASSESSMENT**
procedure to quantify or to aid in the qualification of the level of IMPAIRMENT of a PATIENT.

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

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

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

**201.3.204**
**CLINICAL FUNCTION**
clinically significant operation that the ME EQUIPMENT or ME SYSTEM is intended to perform, as specified by the MANUFACTURER

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

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

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

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

**201.3.205**
**COMPENSATION**
mitigation of IMPAIRMENT of a PATIENT through support of body structures or through support or replacement of body functions

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

**201.3.206**
**EMERGENCY STOP**
manually initiated interruption of operation intended to stop the RACA ROBOT to prevent HARM

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

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

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

**201.3.207**
*** IMPAIRMENT**
problem in body function or structure, such as significant deviation or loss

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

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[2] Numbers in square brackets refer to the Bibliography.

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

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

### 201.3.208
**MEDICAL ROBOT**
ROBOT intended to be used as ME EQUIPMENT or ME SYSTEM

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

### 201.3.209
**MOVEMENT FUNCTION**
function consisting of one or more of sensory, neuromusculoskeletal or movement-related body functions that comprise PATIENT motor control

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

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

### 201.3.210
*** PROTECTIVE STOP**
interruption of operation automatically initiated by the RACA ROBOT, that allows a cessation of motion for BASIC SAFETY and ESSENTIAL PERFORMANCE purposes, which could allow the PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)/PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) to facilitate a restart

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

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

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

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

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

### 201.3.211
*** REHABILITATION**
treatment to improve MOVEMENT FUNCTIONS related to an IMPAIRMENT of a PATIENT

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

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

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

### 201.3.212
**REHABILITATION, ASSESSMENT, COMPENSATION AND ALLEVIATION ROBOT**
**RACA ROBOT**
MEDICAL ROBOT intended by its MANUFACTURER to perform REHABILITATION, ASSESSMENT, COMPENSATION or ALLEVIATION comprising an ACTUATED APPLIED PART

**201.3.213**
***ROBOT**
programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended tasks

**201.3.214**
*** SITUATION AWARENESS**
OPERATOR'S perception, comprehension and projection of a RACA ROBOT's behaviour in its environment

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

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

**201.3.215**
*** WALKING**
MOBILE equipment that, once installed and placed into service, is intended to move from one location to another, by making reciprocating motion having intermittent contact with the travel surface and the RACA ROBOT

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

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

## 201.4 General requirements

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

### 201.4.2.3 Evaluating RISK

*Additional subclauses before 4.2.3.1:*

#### 201.4.2.3.101 General

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

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

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

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

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

#### 201.4.2.3.102 * RISK MANAGEMENT and SITUATION AWARENESS

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

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

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

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.

#### 201.4.3 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~~ 7.1 of ISO 14971:~~2007~~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.

### 201.7.9.2.5 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 inthe 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.*

#### 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.

### 201.9.8 * 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 list of the first paragraph:*

– For RACA ROBOTs sperforming 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 TOTAL LOAD. The MANUFACTURER shall identify and assess each of them during the RISK MANAGEMENT PROCESS.

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

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

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

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

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

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

#### 201.9.8.2 TENSILE SAFETY FACTOR

*Addition after the first paragraph:*

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

NOTE 102 In providing for structural strength requirements, the selection of Case A or Case B of Table 21 of the general standard depends not only on identification of TOTAL LOAD but also on knowledge of material TENSILE STRENGTH. See the footnotes of Table 21 of the general standard. Case A assumes that both TOTAL LOAD and the

material TENSILE STRENGTH are known accurately. If knowledge of either of them is uncertain, Case B of Table 21 applies.

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

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

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

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

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

#### 201.9.8.3.1 General

*Addition:*

NOTE 1 9.8.3 of the general standard only applies to support or suspension systems that support the full body 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.*

### 201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

### 201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

### 201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

*Additional subclauses:*

#### 201.12.101 Movement or force/torque of RACA ROBOT

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

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

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

#### 201.12.102 ASSESSMENT measurement

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

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

### 201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

#### 201.13.2 SINGLE FAULT CONDITIONS

*Additional subclause:*

#### 201.13.2.101 Failure of parts that might result in a loss of SITUATION AWARENESS

The requirements related to parts which may result in loss of SITUATION AWARENESS are found in 201.4.2.3.102.

NOTE 1 Typically, these parts can impact the perception and/or comprehension of the OPERATOR and would influence their SITUATION AWARENESS. For example, the parts associated with audio/visual/tactile feedback provided to the OPERATOR.

NOTE 2 Not in every case of temporary loss of SITUATION AWARENESS is there a direct relation between the failed part and BASIC SAFETY and ESSENTIAL PERFORMANCE. For example, if a monitor that displays information on the status of the RACA ROBOT fails, the OPERATOR will be able to easily detect this missing information visually and react appropriately to the situation.

### 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

## 201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

### 201.15.1 Arrangements of controls and indicators of ME EQUIPMENT

*Addition:*

NOTE USABILITY of controls and indicators can have significant impact on SITUATION AWARENESS.

### 201.15.3.1 * General

**Table 28 – Mechanical strength test applicability**

*Addition:*

| ME EQUIPMENT type | Test |
|---|---|
| WALKING | Push (15.3.2) |
| | Impact (15.3.3) |
| | Drop (201.15.3.4.101) |
| | Moulding stress relief (15.3.6) |
| | Toppling (201.15.3.101) |

### 201.15.3.4 Drop test

*Additional subclauses:*

#### 201.15.3.4.101 WALKING RACA ROBOT

WALKING RACA ROBOT, ACCESSORIES and parts, shall withstand the stress caused by free fall onto a hard surface, from the heights indicated in Table 29 of the general standard.

*Compliance is checked by the following tests.*

*The sample to be tested is lifted, without any load, above a 50mm ±5 mm thick hardwood board (for example, > 600 kg/m$^3$), that lies flat on a concrete floor or a similar rigid base, to a height as specified in Table 29 of the general standard. The sample is dropped 3 times from each orientation in which it can be placed during unloaded transport situation of NORMAL USE, with all fixable parts fastened according to instructions for use. After the test, any damage that results in an unacceptable RISK constitutes a failure.*

### 201.15.3.101 Toppling for WALKING RACA ROBOT

Toppling in NORMAL USE of a WALKING RACA ROBOT shall not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

*Compliance is checked by inspection of the RISK MANAGEMENT FILE and functional tests if necessary.*

NOTE 1 Toppling means losing balance and falling over from any NORMAL USE position. An example of toppling would be a WALKING RACA ROBOT standing in NORMAL USE position, then being tilted until it reaches a position of instability, and then falls over freely from this position on to the ground.

NOTE 2 One way to address this is to implement RISK CONTROL measures to prevent the WALKING RACA ROBOT from toppling during NORMAL USE.

NOTE 3 Toppling testing can be found in the IEC 60068-2-31:2008, 5.1.3.3.

#### 201.15.4.3 Batteries

*Additional subclause before 15.4.3.1 of the general standard:*

#### 201.15.4.3.101 General

In addition to the requirements of 15.4.3 of the general standard, non-lithium batteries shall comply with an applicable IEC or ISO component standard for the actual battery technology according to the principles in 4.8 and Figure 5 of the general standard. HAZARDS associated with battery technologies not covered by any applicable IEC or ISO component standard shall be addressed according to 4.2.3.2 of the general standard.

*Compliance shall be checked by inspection of the battery design documentation or by performance of the tests identified in the applicable IEC or ISO component standards and, where applicable, by inspection of the RISK MANAGEMENT FILE.*

#### 201.15.4.5 Pre-set controls

*Addition:*

NOTE 1 This subclause refers to RISKS associated with manually adjustable hardware pre-set controls which are not completely addressed by other clauses of the general standard (e.g. Clause 12).

NOTE 2 The RISKS associated with software pre-sets are addressed by other parts of the general standard (e.g. Clause 12 or 14).

*Additional subclause*:

#### 201.15.4.101 Cordless HAND-HELD and foot-operated control devices

The requirements of 15.4.7 of the general standard apply for cordless HAND-HELD and foot-operated devices.

### 201.16 ME SYSTEMS

Clause 16 of the general standard applies.

### 201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies, except as follows:

*Addition:*

NOTE Clause 202 provides more information.

## 202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 ~~applies~~ apply, except as follows:

#### 202.4.3 *General test conditions

#### 202.4.3.1 Configurations

*Addition:*

The MANUFACTURER shall consider the SINGLE FAULT CONDITION and address it in the RISK MANAGEMENT FILE. However, for EMC testing, the SINGLE FAULT CONDITION requirements of the general standard do not apply.

## 206 USABILITY

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 ~~applies~~ apply, except as follows:

### 206.4.2 * USABILITY ENGINEERING PROCESS for ME EQUIPMENT

*Replacement, in the first paragraph, of "IEC 62366:2007+A1:—[3]", including the corresponding note, by "IEC 62366-1:2015".*

*Replacement, in the second paragraph, of "IEC 62366" by "IEC 62366-1".*

### 206.5 * Replacement of requirements given in IEC 62366-1

*Replacement:*

In addition to the requirements of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, the following shall apply.

The instructions for use shall include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY. The same information shall also be included in the technical description, if this is provided as a separate document.

NOTE An important purpose of this description is to help the OPERATOR to develop adequate SITUATION AWARENESS of the ME EQUIPMENT.

The instructions for use shall contain a summary of the application specification.

*Add to 3.21 of IEC 62366-1:2015:*

Note 101 to entry: USE ERRORS can occur to due to loss or lack of OPERATOR SITUATION AWARENESS.

*Add, to the second paragraph of 5.2 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, after the first sentence:*

This identification shall include consideration of reasonably foreseeable loss or lack of OPERATOR SITUATION AWARENESS as a source of USE ERROR.

*Add to 5.2 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020:*

NOTE 101 USE ERRORS can occur in different ways and with different probabilities of occurrence due to the level or condition of OPERATOR SITUATION AWARENESS.

*Add, after NOTE 2 of 5.3 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020:*

NOTE 101 Application of the concept of SITUATION AWARENESS could make the identification of HAZARDS or HAZARDOUS SITUATIONS more thorough.

*Add, after NOTE 1 of 5.7.1 of IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020:*

NOTE 101 Examples of methods to evaluate adequate SITUATION AWARENESS can be found in Annex BB of this document.

## 208 * General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 ~~applies~~ apply, except as follows:

*Addition:*

NOTE Additional information can be found in Annex AA, Clause 208.

## 210 * Process requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:20 ~~applies~~ apply, except as follows:

*Addition:*

NOTE Additional information can be found in Annex AA, Clause 210.

## 211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 ~~applies~~ apply except as follows:

### 211.7.4 Instructions for use

*Additional subclause:*

#### 211.7.4.101 Additional requirement for RACA ROBOTS

The ACCOMPANYING DOCUMENTS shall explain the effects of degree of autonomy of the PEMS in terms that are understandable by the LAY OPERATOR.

NOTE The understanding of the autonomous behavior of the RACA ROBOTS by the LAY OPERATOR is key to the OPERATOR'S SITUATION AWARENESS and USABILITY ENGINEERING.

*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the USABILITY ENGINEERING FILE.*

### 211.10.1.1 General requirements for mechanical strength

**Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE**

*Addition:*

| ME EQUIPMENT usage and type | Test from the general standard or this standard | Test from IEC 60601-1-11 |
|---|---|---|
| Non-TRANSIT-OPERABLE and WALKING | Push (15.3.2) | |
| | Impact (15.3.3) | |
| | Drop (201.15.3.4.101) | |
| | | Shock (10.1.3 a) ) |
| | | Vibration (10.1.3 c) ) |
| | Moulding stress relief (15.3.6) | |
| | Toppling (201.15.3.101) | |