

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

**Part 2-77: Particular requirements for the basic safety and essential performance
of robotically assisted surgical equipment**

Appareils électromédicaux –

**Partie 2-77: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils chirurgicaux robotiquement assistés**



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

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

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IEC 80601-2-77

Edition 1.1 2023-11
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

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performance of robotically assisted surgical equipment**

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Partie 2-77: Exigences particulières pour la sécurité de base et les
performances essentielles des appareils chirurgicaux robotiquement assistés**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01, 11.040.30

ISBN 978-2-8322-7891-8

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VERSION REDLINE



Medical electrical equipment –

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Appareils électromédicaux –

Partie 2-77: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux robotiquement assistés

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT

FOREWORD

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

IEC 80601-2-77 edition 1.1 contains the first edition (2019-07) [documents 62D/1675/FDIS and 62D/1689/RVD] and its amendment 1 (2023-11) [documents 62D/2070/FDIS and 62D/2102/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 80601-2-77 has been prepared by 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 nineteen 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 60601 and IEC 80601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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

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

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

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

INTRODUCTION

This part of IEC 80601 is written at a time when technical evolution of medical robots is in rapid progress and the scientific foundation of safe use is 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 environment¹. That group was working on a new standard, ISO 13482[1]², which was published as an International Standard (IS) in 2014. While initially focused on non-medical applications, WG 7 recognized that work was likely to be 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 60601-4-1:2017[2]) dealing with degree of autonomy. While developing this document, a particular standard was proposed for robotic equipment used in surgical applications. This led to the creation of a Joint Working Group 35 in April 2015 within IEC/TC 62/SC 62D to develop particular requirements of safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS that utilize robotic technology. The work would include medical robots for SURGERY. This proposal was approved, resulting in the formation of Joint Working Group (JWG 35).

During IEC/TC 62/SC 62D discussion, there was a strong opinion that some types of MEDICAL ELECTRICAL EQUIPMENT could be a medical robot, but not all MEDICAL ELECTRICAL EQUIPMENT were medical robots. According to this opinion, JWG 35 discussed and agreed that the majority of existing MEDICAL ELECTRICAL EQUIPMENT, including those used for surgical PROCEDURES, were not considered medical robots, so it would be better to capture this type of ME EQUIPMENT through a different definition – ROBOTICALLY ASSISTED SURGICAL EQUIPMENT (RASE).

JWG 9 defined medical robots as ME EQUIPMENT with a degree of autonomy (IEC TR 60601-4-1:2017). JWG 35 found that some RASE have zero autonomy. Therefore, by definition, RASE could not be equivalent to a medical robot. Regulatory agencies objected to employ the term robot as defined in IEC TR 60601-4-1 and felt that it implied that the RASE were performing the surgical PROCEDURE rather than the surgeon. The consensus in JWG 35 was that the RASE only assists the surgeon. The surgeon maintains some level of control or supervision of the RASE.

The minimum safety requirements specified in this particular standard for ROBOTICALLY ASSISTED SURGICAL EQUIPMENT are presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

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

¹ ISO TC 184/SC 2 was reorganized as ISO TC 299 in 2016.

² Numbers in square brackets refer to the Bibliography.

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/1881/RR.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT

201.1 Scope, object and related standards

Clause 1 of the general standard³ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT (RASE) and ROBOTICALLY ASSISTED SURGICAL SYSTEMS (RASS), hereafter referred to as ME EQUIPMENT and ME SYSTEMS together with their INTERACTION CONDITIONS and INTERFACE CONDITIONS. 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.

If RASE or RASS, or its ACCESSORIES fall within scope of another particular standard, then the particular standard applies in addition to this standard.

EXAMPLES IEC 60601-2-2[3] for HF SURGICAL EQUIPMENT; IEC 60601-2-18[4] for ENDOSCOPIC EQUIPMENT; IEC 60601-2-22[5] for laser equipment; IEC 60601-2-37[6] for ultrasound equipment; IEC 60601-2-46[7] for operating tables, etc.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ROBOTICALLY ASSISTED SURGICAL EQUIPMENT and ROBOTICALLY ASSISTED SURGICAL SYSTEMS.

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 apply as modified in Clauses 202 and 206 respectively.

³ 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 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 [8], IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 [9], and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [10] do not apply.

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

IEC 62366-1:2015/AMD1:2020

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

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/AMD2:2020 and the following 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 53.

Addition:

201.3.201

BODY ORIFICE

natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheostomy

[SOURCE: GHTF/SG1/N77:2012[11]]

201.3.202

*** CAPACITIVELY COUPLED HF CURRENT**

unavoidable HIGH FREQUENCY current flowing due to capacitive coupling from the APPLIED PART of HF SURGICAL EQUIPMENT to ~~an~~ another part of the RASE or RASS

[SOURCE: IEC 60601-2-18:2009, 201.3.201, modified – Replacement of " from an ENERGIZED ENDOTHERAPY DEVICE that is the APPLIED PART of HF SURGICAL EQUIPMENT to the ENDOSCOPE" by "from the APPLIED PART of HF SURGICAL EQUIPMENT to ~~an~~ another part of the RASE or RASS ".]

201.3.203

ENDOSCOPIC EQUIPMENT

energized endoscope together with its supply unit(s), as required for its INTENDED USE

[SOURCE: IEC 60601-2-18:2009, 201.3.204]

201.3.204

HIGH FREQUENCY

HF

frequencies less than 5 MHz and generally greater than 200 kHz

[SOURCE: IEC 60601-2-2:2017, 201.3.220]

201.3.205

HF SURGICAL ACCESSORY

ACCESSORY intended to conduct, supplement or monitor HF energy applied to the PATIENT from HF SURGICAL EQUIPMENT

[SOURCE: IEC 60601-2-2:2017, 201.3.223, modified – The notes have been deleted.]

201.3.206

HF SURGICAL EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT which generates HIGH FREQUENCY currents intended for the performance of surgical tasks, such as the cutting or coagulation of biological tissue by means of these HIGH FREQUENCY currents

[SOURCE: IEC 60601-2-2:2017, 201.3.224, modified – The notes have been deleted.]

201.3.207

*** INTERACTION CONDITIONS**

conditions that shall be fulfilled to achieve BASIC SAFETY when RASE or RASS is used simultaneously with multiple ROBOTIC SURGICAL INSTRUMENTS or with an APPLIED PARTS of other ME EQUIPMENT, at least one APPLIED PART of which uses energy for providing its INTENDED USE, e.g. HF current, ultrasound, or laser

201.3.208

*** INTERFACE CONDITIONS**

conditions that shall be fulfilled to achieve BASIC SAFETY for any FUNCTIONAL CONNECTION between RASE or RASS and other ME EQUIPMENT or non-ME EQUIPMENT in the ROBOTIC SURGERY CONFIGURATION

[SOURCE: IEC 60601-2-18:2009, 201.3.211, modified – Replacement of "endoscopic EQUIPMENT" by "RASE or RASS", and of "configuration for ENDOSCOPIC EQUIPMENT" by "ROBOTIC SURGERY CONFIGURATION".]

201.3.209

INVASIVE DEVICE

device, which, in whole or in part, penetrates inside the body, either through a BODY ORIFICE or through the surface of the body

[SOURCE: GHTF/SG1/N77:2012[11]]

201.3.210

*** MECHANICAL INTERFACE**

mounting surface on RASE or RASS that allows for attachment of detachable ACCESSORIES, components, or parts that are mechanically manipulated by the RASE or RASS

Note 1 to entry: A MECHANICAL INTERFACE can be used to attach items that are sterile.

Note 2 to entry: A MECHANICAL INTERFACE can provide insulation and other functions (e.g., sterile boundary) to achieve BASIC SAFETY.

Note 3 to entry: RASE or RASS can have zero, one, or more MECHANICAL INTERFACE per each ROBOTIC SURGICAL INSTRUMENT.

201.3.211

MOUNTED PART

any part of RASE or RASS, including ACCESSORIES intended to be mounted to an operating table or on another supporting structure which is not part of the RASE or RASS

201.3.212

RASE PROTECTIVE STOP

type of interruption of operation that allows a cessation of motion as a RISK CONTROL measure and which retains the ability of PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) to facilitate resumption of the operation of the RASE or RASS

Note 1 to entry: A RASE PROTECTIVE STOP can be manually initiated, or automatically initiated by means of PEMS.

Note 2 to entry: A RASE PROTECTIVE STOP can be coordinated with deactivation of energy of ROBOTIC SURGICAL INSTRUMENT and ACCESSORIES if required as a RISK CONTROL measure.

Note 3 to entry: Annex CC tabulates differences between emergency stop and RASE PROTECTIVE STOP.

201.3.213

*** ROBOTICALLY ASSISTED SURGICAL EQUIPMENT**

RASE

MEDICAL ELECTRICAL EQUIPMENT that incorporates PEMS actuated mechanism intended to facilitate the placement or manipulation of ROBOTIC SURGICAL INSTRUMENT(s)

Note 1 to entry: "Placement" includes INTENDED PURPOSE of positioning, maintaining, or holding of a ROBOTIC SURGICAL INSTRUMENT.

Note 2 to entry: RASE can be referred to as surgical robots, robotically assisted surgical devices, computer-assisted surgical systems, surgical manipulators, etc.

Note 3 to entry: A ROBOTIC SURGICAL INSTRUMENT is considered to be a part of the RASE or RASS in this document.

Note 4 to entry: This note applies to the French language only.

201.3.214

ROBOTICALLY ASSISTED SURGICAL SYSTEM

RASS

MEDICAL ELECTRICAL SYSTEM that incorporates PEMS actuated mechanism intended to facilitate the placement or manipulation of ROBOTIC SURGICAL INSTRUMENT(s)

Note 1 to entry: This note applies to the French language only.

201.3.215

*** ROBOTIC SURGERY CONFIGURATION**

combination of RASE or RASS by means of INTERACTION CONDITIONS and INTERFACE CONDITIONS with one or more of the following:

- ACCESSORIES;
- other RASE or RASS;
- other ME EQUIPMENT;
- non-ME EQUIPMENT; or

– ME SYSTEM

201.3.216

* ROBOTIC SURGICAL INSTRUMENT

INVASIVE DEVICE with APPLIED PART, intended to be manipulated by the RASE or RASS to perform tasks in SURGERY

Note 1 to entry: Tasks include visualization.

Note 2 to entry: A ROBOTIC SURGICAL INSTRUMENT can be detachable by means of a MECHANICAL INTERFACE. See definition of MECHANICAL INTERFACE (201.3.206) and Annex AA about the attachment of ROBOTIC SURGICAL INSTRUMENT to RASE.

Note 3 to entry: A ROBOTIC SURGICAL INSTRUMENT can be an ACCESSORY of RASE or RASS.

201.3.217

SURGERY

PROCEDURE involving the incision, excision, manipulation or suturing of tissue which usually requires regional or general anaesthesia or profound sedation to control pain

[SOURCE: WHO/IER/PSP/2008.07[12], modified – The words "conducted in the operating room" have been deleted.]

201.4 General requirements

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

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Additional subclause:

201.4.1.101 * ROBOTIC SURGICAL INSTRUMENTS and other ME EQUIPMENT

Where requirements for ROBOTIC SURGICAL INSTRUMENTS and other ME EQUIPMENT given in other applicable particular standards conflict with the requirements for INTERACTION CONDITIONS of this particular standard, the requirements of this particular standard shall take precedence.

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – List of ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
To ensure there is no unacceptable RISK if information essential to perform SURGERY is degraded.	201.13.1.101 Information essential to perform SURGERY
To ensure there is no unacceptable RISK if motion control of the ROBOTIC SURGICAL INSTRUMENT has performance degradation.	201.13.1.102 Motion control of the ROBOTIC SURGICAL INSTRUMENT

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Addition:

NOTE Additional information is provided in Annex AA.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

When applying 4.7, the INTERACTION CONDITIONS and INTERFACE CONDITIONS shall be taken into account.

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.4 Other conditions

Addition to a):

Before carrying out tests, RASE shall be prepared for operation as specified by the MANUFACTURER.

201.5.7 Humidity preconditioning treatment

Addition:

Single-use equipment drapes are not subject to humidity preconditioning treatment.

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:

201.7.2.2 Identification

Additional subclauses:

201.7.2.2.101 Marking of maximum PATIENT mass and SAFE WORKING LOAD

If an operating table is a part of RASE, it shall be marked with the corresponding maximum PATIENT mass and SAFE WORKING LOAD (for symbol, see Figure 201.101).

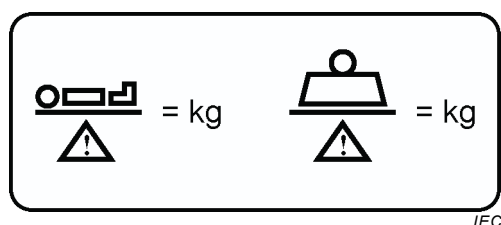


Figure 201.101 – Graphic symbol for maximum PATIENT mass and SAFE WORKING LOAD

201.7.2.2.102 Marking of the mass of MOUNTED PART

If RASE has one or more MOUNTED PARTS, each MOUNTED PART shall be marked with its maximum mass unless the HAZARD related to the mass would not lead to an unacceptable RISK

(for example, when the mass is negligible) or the marking is not practicable (for symbol, see Figure 201.102).

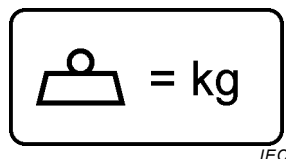


Figure 201.102 – Graphic symbol for mass of MOUNTED PART

Mass of the MOUNTED PART should include the maximum mass of the attached instruments and ACCESSORIES.

201.7.2.9 * IP classification

Addition:

If marking an IP classification is required for a RASE, and if a protective cover, for example, an equipment drape, is required to meet the classification, the IP symbol marking shall be applied to the protective cover.

ROBOTIC SURGICAL INSTRUMENTS supplied with specific instructions detailing allowable reprocessing methods and parameters are excluded from this requirement. No symbol is required to identify the reprocessing PROCEDURE by this particular standard. See also 7.9.2.12 of the general standard.

201.7.2.10 APPLIED PARTS

Addition:

If marking of an APPLIED PART is not practicable and the APPLIED PART is single-use, the required marking shall be on the individual packaging, or on the equipment adjacent to the connector for the APPLIED PART.

Compliance is checked by inspection.

Additional subclause:

201.7.2.101 Alternative marking

Information which is accessible by the OPERATOR on an output device (e.g. display) of ME EQUIPMENT is considered equivalent to marking on the equipment for requirements of 7.2 of the general standard, as long as the marking is visible at the time the information is required.

Compliance is checked by inspection.

201.7.4.2 Control devices

Addition:

Alternative or no markings of control devices (for example, multi-function buttons) is acceptable if the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.

NOTE Visual cues such as colour, tactile, location, shape can be used in lieu of markings.

Compliance is checked by inspecting the USABILITY ENGINEERING FILE.

201.7.8.1 * Colours of indicator lights

~~Replacement of Table 2 by the following Table 201.102, and replacement of references to Table 2 to Table 201.102:~~

~~Table 201.102 – Colours of indicator lights and their meaning for ME EQUIPMENT~~

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	— Caution – prompt response by the OPERATOR is required; — Cutting mode of HF SURGICAL EQUIPMENT if applicable; or — Additional modes if multiple functions share the same control device, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.
Blue	— Coagulation mode of HF SURGICAL EQUIPMENT if applicable; or; — Additional modes if multiple functions share the same control device, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK; — Any meaning other than red or yellow colour if the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.
Green	Ready for use
Any other colour	Any meaning other than red, yellow, blue or green colour

Add row 2 and 3 of Table 201.102 above the note of Table 2, and add note ^e, ^f and ^g of Table 201.102 to the note of Table 2:

Table 201.102 – Colours and meanings of indicator lights for RASE and RASS

Name	ON WHEN	Indicator light ^a	Alarm indicator light	Accompanied by sound	OPERATOR requirement
Cutting mode ^e	Cutting activation	Yellow, flashing or not ^f	–	Yes ^g	–
Coagulation mode ^e	Coagulation activation	Blue, flashing or not ^f	–	Yes ^g	–
^a These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS. ^e Applicable when RASE and RASS incorporate HF SURGICAL EQUIPMENT. ^f Yellow and blue indicator lights can also be used to indicate additional modes if multiple functions share the same control device, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK. ^g As defined in 201.12.4.2.101 of IEC 60601-2-2:2017.					

Addition at the end of subclause 201.7.8.1:

In addition to Table 2, red, yellow, and blue indicator colours may be used as the following, provided the USABILITY ENGINEERING PROCESS demonstrates that this does not result in unacceptable RISK.

- Red for situations where immediate response by the OPERATOR is required,
- Yellow for situations where prompt response by the OPERATOR is required,
- Blue for any situations other than those for red or yellow colours as indicated above

201.7.9.2.2 Warning and safety notices

Addition:

In addition to requirements in other particular standards that can be relevant, the following warning and safety notices shall be provided as applicable:

Warnings regarding INTERACTION CONDITIONS:

- a) warning that, if the ROBOTIC SURGERY CONFIGURATION requires TYPE CF APPLIED PARTS, the APPLIED PARTS of other ME EQUIPMENT used within the ROBOTIC SURGERY CONFIGURATION shall be TYPE CF APPLIED PARTS;
- b) warning that, if the ROBOTIC SURGERY CONFIGURATION requires TYPE BF APPLIED PARTS, the APPLIED PARTS of other ME EQUIPMENT used within the ROBOTIC SURGERY CONFIGURATION shall be F-TYPE APPLIED PARTS;
- c) warning that, when other ME EQUIPMENT are used with ROBOTIC SURGICAL INSTRUMENTS, PATIENT LEAKAGE CURRENTS can be additive;
- d) warning that, when RASE or RASS is used with laser equipment, advice concerning their safe use shall be given, including avoidance of potential injury, for example, wearing suitable personal protective equipment, or by inserting a suitable filter for the ROBOTIC SURGICAL INSTRUMENTS;
- e) warning that, before each use, the compatibility of RASE or RASS with any ROBOTIC SURGICAL INSTRUMENTS and other APPLIED PARTS including those of other ME EQUIPMENT shall be checked according to any criteria for safe use defined in the instructions for use;
- f) warning that, before each use, the outer surface of the portions of any ROBOTIC SURGICAL INSTRUMENTS which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which can cause HARM;

Warnings regarding MECHANICAL INTERFACE:

- g) warning that, ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT that are not specified or allowed by the MANUFACTURER shall not be connected to the MECHANICAL INTERFACES and other interface of the RASE (see also 16.2 of the general standard);

Safety notices regarding INTERFACE CONDITIONS:

- h) advice on the avoidance of RISKS caused by the use of RASE together with ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT within a ROBOTIC SURGERY CONFIGURATION (see also 15.4.1 and 16.2 of the general standard).

Compliance is checked by inspection of the instructions for use.

Additional subclause:

201.7.9.2.101 Release of PATIENT

The instructions for use shall contain the information necessary for the OPERATOR to remove any invasive parts of the RASE from the PATIENT quickly and safely (see also 201.9.2.5).

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:

MANUFACTURER shall consider INTERACTION CONDITIONS in the classification of APPLIED PARTS (for example, HF ROBOTIC SURGICAL INSTRUMENT rating).

NOTE For non-endoscopic RASE applications, see 201.11.101.

201.8.5.1.1 General

Addition:

NOTE 101 ACCESSORIES such as equipment drapes can provide a MEANS OF PROTECTION, when appropriate property testing can be defined, which can include, mechanical, thermal resistance, moisture resistance, any fire resistance. Electrical property testing is well defined in 8.7, 8.8 and 8.9, (including 8.8.2 for thin materials, when applicable).

201.8.5.2 Separation of PATIENT CONNECTIONS

Additional subclause:

201.8.5.2.101 * F-Type insulation

Compliance with separation requirements of F-TYPE APPLIED PARTS shall be maintained during NORMAL USE and reasonably foreseeable misuse (e.g. collision during SURGERY).

Compliance is checked by inspection of the ME EQUIPMENT, and the USABILITY ENGINEERING FILE or the RISK MANAGEMENT FILE.

201.8.6.3 Protective earthing of moving parts

Replacement:

For any PROTECTIVE EARTH CONNECTION used on a moving part, the MANUFACTURER shall demonstrate that the connection will remain reliable during the EXPECTED SERVICE LIFE of the RASE.

Compliance is checked by inspection of the RASE and, if necessary, inspection of the RISK MANAGEMENT FILE.

These PROTECTIVE EARTH CONNECTIONS shall be tested to 8.6.4 of the general standard.

Testing should consider the dynamic effect of movement on the PROTECTIVE EARTH CONNECTIONS.

201.8.9.1.1 * General

Addition:

CREEPAGE DISTANCES and AIR CLEARANCES may be reduced in the ROBOTIC SURGICAL INSTRUMENT to allow the construction of small dimension parts if adequate safety is demonstrated by the RISK MANAGEMENT PROCESS, in which case the requirements of 8.5.1.3 of the general standard for two MEANS OF OPERATOR PROTECTION, pollution degree 1, shall be met.

NOTE Refer to Annex J of IEC 60601-2-18:2009 [4] for an example of energized endoscope and HF SURGICAL EQUIPMENT used with ME EQUIPMENT.

201.9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.9.2.2.4.4 * Other RISK CONTROL measures

Replacement, in the first paragraph, of the first dashed item:

- moving parts that start to move while they are in the reach of persons shall not lead to an unacceptable RISK;

Replacement, in the second paragraph, of the introduction sentence to the list:

Other RISK CONTROL measures (e.g. electro-mechanical, PEMS) shall be designed and incorporated into the control system so that:

Replacement, in the second paragraph, of the second dashed item:

- if the RISK CONTROL measure is defeated in a SINGLE FAULT CONDITION, a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4 of the general standard) or RASE PROTECTIVE STOP(s) (see 201.3.212), or the RASE shall otherwise be SINGLE FAULT SAFE (see 4.7 of the general standard).

201.9.2.2.5 * Continuous activation

Replacement of items a) to c) (inclusive):

- a) the movement is in the field of view of one or more OPERATORS;

Compliance is checked by inspection.

- b) movement of the RASE or its parts is possible only by the continuous activation of the control by the OPERATOR, and additional OPERATOR has the access to the deactivation of the movement, as long as the response of the OPERATOR(s) to deactivate the device can be relied on to prevent HARM;

NOTE Manually operated movements are also considered to comply with this subclause, as long as mass and velocity allow adequate control of positioning without causing an unacceptable RISK.

Compliance is checked by inspection.

- c) the continuous activation system is defeated in a SINGLE FAULT CONDITION, then a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4 of the general standard) or RASE PROTECTIVE STOP(s) (see 201.9.2.101), or the RASE shall otherwise be SINGLE FAULT SAFE (see 4.7 of the general standard).

Compliance is checked by the following as necessary:

- inspection of the RASE;
- examination of the construction and circuits;
- conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.

201.9.2.2.6 * Speed of movement(s)

Addition:

The MANUFACTURER shall consider speed of movement with respect to all RASE movement both within and outside the PATIENT. The MANUFACTURER may apply different limits.

NOTE 1 See Annex BB for an example of method to estimate the stopping performance and the minimum distances.

NOTE 2 The MANUFACTURER can specify the coordinate frame within which to measure velocity. For example, if the PATIENT can move, the RASE can stop relative to the PATIENT.

201.9.2.3.2 * Overtravel end stops

Addition before the first paragraph:

Where a mechanical end stop is not the RISK CONTROL measure, 9.2.3.2 does not apply. In this case, the MANUFACTURER assures that the other stopping means shall not lead to an unacceptable RISK under SINGLE FAULT CONDITIONS.

201.9.2.4 Emergency stopping devices

Addition:

NOTE 101 Refer to Annex CC.

201.9.2.5 * Release of PATIENT

Replacement of the first two sentences of the first paragraph:

Means shall be provided to permit the release of the PATIENT quickly and safely in the event of

- breakdown of the RASE,
- failure of the power supply (see 11.8 of the general standard),
- activation of a RISK CONTROL measure,
- emergency stopping, or
- decision of the OPERATOR.

Special attention shall be given to the following.

Addition to the list of the first paragraph:

- Release of the PATIENT shall include removing the ROBOTIC SURGICAL INSTRUMENT of the RASE as necessary from the PATIENT.

Additional subclause:

201.9.2.101 * RASE PROTECTIVE STOP functions

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

- The RASE PROTECTIVE STOP shall reduce RISK to an acceptable level.
- The resumption of the RASE shall be initiated manually by the OPERATOR unless automatic resumption by PEMS does not lead to unacceptable RISK.
- The RASE PROTECTIVE STOP shall comply with Clause 14 (PEMS), if applicable.

NOTE The RASE PROTECTIVE STOP can allow power to be maintained, in order to reduce RISK to an acceptable level.

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

201.9.3 MECHANICAL HAZARD associated with surfaces, corners and edges

Addition after the second paragraph:

Damage to ACCESSORIES, for example cables, suction tubes, or equipment drapes, shall be considered.

201.9.4.2.4.3 * Movement over a threshold

Addition:

For RASE incorporating MOBILE ENDOSCOPIC EQUIPMENT, the general standard may be applied instead of IEC 60601-2-18:2009.

201.9.8.1 * General

Replacement of the first dash:

- The construction of the support, suspension or actuation system shall be designed based upon Table 21 of the general standard and the TOTAL LOAD, unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the RASE.

NOTE An example of an alternative method is given in Annex DD.

Additional subclause:

201.9.101 Person collision with RASE

The RISK associated with a person colliding with the RASE shall be considered as part of the RISK MANAGEMENT PROCESS, when the ROBOTIC SURGICAL INSTRUMENT is in or in proximity to the PATIENT.

NOTE 1 This HAZARDOUS SITUATION can lead to the following events, for example, but not limited to

- overbalance that exceeds the design limit related to 9.4.2,
- deformation of the structure that can degrade the motion control of the RASE, or
- unintended movement of the ROBOTIC SURGICAL INSTRUMENT.

NOTE 2 Person means OPERATOR, PATIENT and other persons near the RASE in NORMAL USE.

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

201.9.102 RASE collision with itself and other objects

The RISK associated with a RASE colliding either with itself or with other objects during NORMAL USE and reasonably foreseeable misuse, shall be considered as part of the RISK MANAGEMENT PROCESS. Foreseeable collisions shall not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

NOTE This HAZARDOUS SITUATION can lead to the following events, for example, but not limited to

- damage to equipment,
- loss of calibration,
- inability to recover from a collision, or
- unintended or uncontrolled movement of the ROBOTIC SURGICAL INSTRUMENT.

Compliance is checked by the inspection of the RISK MANAGEMENT FILE and where necessary, functional test.

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, except as follows:

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

The tests are done based on worst-case NORMAL USE conditions, as per the MANUFACTURER'S design specification. If applicable, the tests are performed with the protective covers such as equipment drapes applied to the RASE.

NOTE The design specification can include, but is not limited to, the RASE covered with the protective covers for its designated maximum duration of surgical PROCEDURE, from pre-SURGERY to post-SURGERY, and operating at the highest ambient temperature specified by the MANUFACTURER.

201.11.6.1 * General

Addition after the first paragraph:

The applicable fluid protection tests (leakage, spillage, overflow and ingress) are done based on worst-case NORMAL USE conditions. As applicable, fluid protection testing is performed with or without protective covers such as equipment drapes applied to the RASE. The tests methods can be the same or different depending on use scenarios. For example, different spill or ingress test methods, including the use of protective covers, can be appropriate.

NOTE There can be a period when the protective covers are not present; yet spillage might occur, such as pre-operative or post-operative activities.

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

Addition:

Inspection of the RISK MANAGEMENT FILE shall include compliance with the ESSENTIAL PERFORMANCE as applicable.

NOTE 1 RASE can include structures and functions that cannot be verified by visual inspection only.

NOTE 2 Additional sterilization ISO standards can be considered (for example, ISO 17664:2017[13]).

Additional subclauses:

201.11.101 INTERACTION CONDITIONS

201.11.101.1 General

The following requirements in this subclause do not apply to ROBOTIC SURGERY CONFIGURATION with ENDOSCOPIC EQUIPMENT.

NOTE 201.11.101 in IEC 60601-2-18:2009 is applicable in case of the ROBOTIC SURGERY CONFIGURATION with ENDOSCOPIC EQUIPMENT.

201.11.101.2 Thermal and other HAZARDS from INTERACTION CONDITIONS with lasers

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall address the possibility of thermal and other RISKS to the PATIENT or OPERATOR from the use of laser equipment with RASE, including:

- a) thermal damage (including ignition) to the RASE from reflected laser energy;
- b) potential eye damage from reflected laser energy.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

201.11.101.3 * Thermal and other HAZARDS from INTERACTION CONDITIONS with HF SURGICAL EQUIPMENT

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall address the possibility of thermal and other RISKS to the PATIENT or OPERATOR from the use of HF SURGICAL EQUIPMENT with RASE, including:

- a) thermal damage to the RASE caused by electrical discharge or CAPACITIVELY COUPLED HF CURRENT;
- b) isolation of conductive parts being accessible to contact from the thermal effects of CAPACITIVELY COUPLED HF CURRENT.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

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

201.13.1.4 Specific MECHANICAL HAZARDS

Additional subclauses:

201.13.1.4.101 Additional MECHANICAL HAZARDS

The RISK MANAGEMENT PROCESS shall include an analysis of SINGLE FAULT CONDITIONS for potential MECHANICAL HAZARDS to the PATIENT and PATIENT ENVIRONMENT, including

- person colliding with RASE (see 201.9.101),
- RASE colliding with itself and other objects (see 201.9.102).

201.13.1.101 * Information essential to perform SURGERY

The possibility of degradation of the information essential to perform SURGERY shall be addressed in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.13.1.102 * Motion control of the ROBOTIC SURGICAL INSTRUMENT

The possibility of performance degradation of the motion control of the ROBOTIC SURGICAL INSTRUMENT shall be addressed in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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:

201.15.3.1 General

Addition:

Subclauses 15.3.1 to 15.3.7 (inclusive) of the general standard do not apply to ROBOTIC SURGICAL INSTRUMENTS. The RISK associated with the mechanical strength of ROBOTIC SURGICAL INSTRUMENTS shall be considered as part of the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.15.4 ME EQUIPMENT components and general assembly

Additional subclause:

201.15.4.101 Fixing, prevention of maladjustment of MECHANICAL INTERFACE

- a) MECHANICAL INTERFACE shall be so secured that they cannot be pulled off or work loose unintentionally during NORMAL USE.
- b) Incorrect connection of the MECHANICAL INTERFACE shall be prevented if it can result in an unacceptable RISK.

Compliance is checked by the RISK MANAGEMENT FILE.

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:

For EM DISTURBANCE testing, the SINGLE FAULT CONDITION requirements of the general standard do not apply.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests

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

202.8.1 General

Addition:

If applicable, the IMMUNITY test may alternatively be designed as follows.

- A single representative worst-case configuration of the operation of the RASE may be used during IMMUNITY testing.

NOTE 101 Selected combination of ESSENTIAL PERFORMANCE can be tested concurrently, if possible.

Additional subclauses:

202.8.101 IMMUNITY pass/fail criteria

When considering BASIC SAFETY, RISK CONTROLS addressing release of PATIENT shall be maintained.

202.8.102 IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS

RASE intended for use within 2 m of active HF SURGICAL EQUIPMENT or to have a connection to a PATIENT undergoing treatment with HF SURGICAL EQUIPMENT shall be evaluated for IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS, and tested as applicable.

NOTE Testing methods can vary by the particular configuration of the RASE. See Annex EE for an example of a testing method.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

206 * USABILITY

IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 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 and IEC 62366-1:2015/AMD1:2020".

Replacement, in the second paragraph, of "IEC 62366" by "IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020".

206.5 Replacement of requirements given in IEC 62366

Replacement:

NOTE Clause 5 of IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 was to replace Clause 6 of IEC 62366:2007 and IEC 62366:2007/AMD1:2014, which does not exist in IEC 62366-1:2015.

Annexes

The annexes of the general standard apply, except as follows:

Annex D (informative)

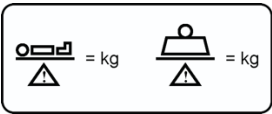
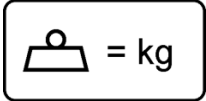
Symbols on marking

Annex D of the general standard applies except as follows:

Addition:

Additional symbols for marking RASE are listed in Table 201.D.101.

Table 201.D.101 – Symbols for marking RASE or its parts

No.	Symbol	Reference	Title
101		IEC 60601-2-52:2009[14], Figure 201.105	Maximum PATIENT weight and SAFE WORKING LOAD
102		N/A	Mass of MOUNTED PART

Annex AA (informative)

Particular guidance and rationale

AA.1 General guidance

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of RASE. RASE is an emerging field with a wide range of applications that have been investigated. Although RASE have a wide range of configurations with different INTENDED USES, different mechanical structures and different means of control, there are certain common aspects in those ME EQUIPMENT, including the following.

- RASE uses robotic technology to accurately place and manipulate ROBOTIC SURGICAL INSTRUMENTS.
- RASE is typically not used by itself in SURGERY. It can be integrated with other ME EQUIPMENT, such as ENDOSCOPIC EQUIPMENT, HF SURGICAL EQUIPMENT and ACCESSORIES. Also, other ME EQUIPMENT is likely connected to the PATIENT as well.

The requirements in this document are based on the above understanding, and the ROBOTIC SURGERY CONFIGURATION, INTERACTION CONDITIONS and INTERFACE CONDITIONS are introduced to maintain the safety under such combinations of use.

The ESSENTIAL PERFORMANCE and the BASIC SAFETY of RASE are largely dependent on those of the ROBOTIC SURGICAL INSTRUMENTS, and many of them are already covered by other particular standards of IEC 60601 series. Therefore, this particular standard mostly focuses on the safety of the robotic part – it does not directly cover the ESSENTIAL PERFORMANCE and the BASIC SAFETY of ROBOTIC SURGICAL INSTRUMENTS with other dedicated particular standards, but it complements other particular standards, for example IEC 60601-2-2 and IEC 60601-2-18. Therefore, it can be used in conjunction with other particular standards when applicable.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.3 – Collateral standards

Since environmental impact of RASE or RASS is covered by local legislation sufficiently and it is not directly related to the scope of ESSENTIAL PERFORMANCE and BASIC SAFETY of RASE or RASS, it was decided to not apply IEC 60601-1-9 and handle the subject outside of this document.

Definition 201.3.202 – CAPACITIVELY COUPLED HF CURRENT

The design of the RASE, e.g. narrow dimensions, can result in it being electrically capacitively coupled to an APPLIED PART of HF SURGICAL EQUIPMENT with which they are used. Some of this HIGH FREQUENCY current will be coupled from the HF SURGICAL EQUIPMENT to parts of the RASE or RASS, and can flow from the equipment via the PATIENT and/or OPERATOR back to the HF SURGICAL EQUIPMENT.

Definition 201.3.207 – INTERACTION CONDITIONS

This new term has been derived from the term "interconnection conditions" in IEC 60601-2-18 to include the non-endoscopic applications.

There can be HAZARDS from the interaction between ROBOTIC SURGICAL INSTRUMENTS, or between a ROBOTIC SURGICAL INSTRUMENT and an APPLIED PART of other ME EQUIPMENT. In IEC 60601-2-18 the relevant HAZARDS are associated with "interconnection conditions", which relies on the term "energized endotherapy device" to describe the source of energy HAZARDS. The energy term "energized endotherapy device" is incorporated into the definition of INTERACTION CONDITION.

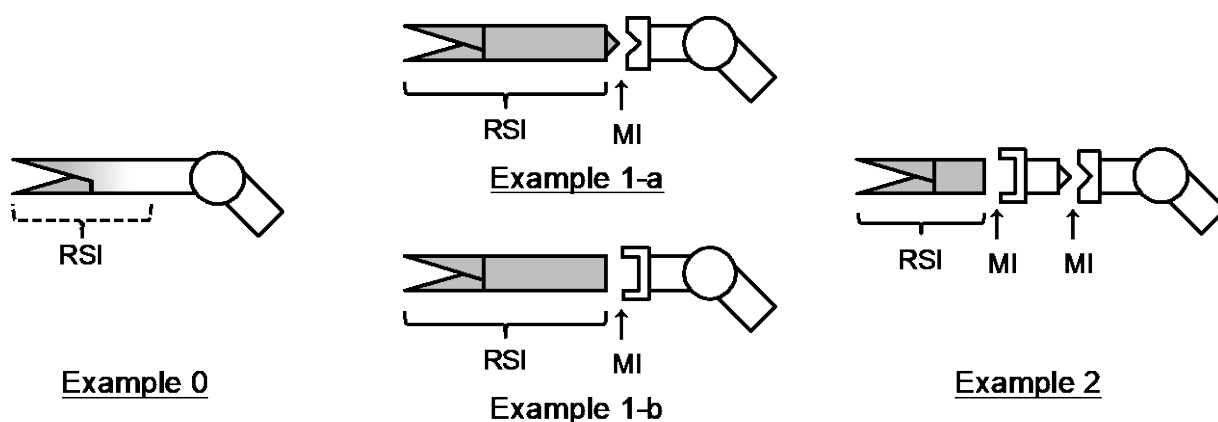
Definition 201.3.208 – INTERFACE CONDITIONS

INTERFACE CONDITIONS are introduced from IEC 60601-2-18:2009 to allow a RASE or RASS and other ME EQUIPMENT or non-ME EQUIPMENT used in a ROBOTIC SURGERY CONFIGURATION with a FUNCTIONAL CONNECTION.

Similarly, when a RASE or RASS and an ENDOSCOPIC EQUIPMENT have a FUNCTIONAL CONNECTION, they have common INTERFACE CONDITIONS. See also the Annex AA.2, definition 201.3.215 for the definition of ROBOTIC SURGERY CONFIGURATION.

Definition 201.3.210 – MECHANICAL INTERFACE

MECHANICAL INTERFACE in ISO 8373:2012[15] is an attachment interface of an end effector to a robot. In the case of RASE, attachments of the ROBOTIC SURGICAL INSTRUMENT to the RASE by means of a MECHANICAL INTERFACE can be generalized as illustrated in Figure 201.AA.101. The MECHANICAL INTERFACE can also provide a sterile boundary between the ROBOTIC SURGICAL INSTRUMENT and the rest of the RASE. For example, in Example 2 below, the MECHANICAL INTERFACE between ROBOTIC SURGICAL INSTRUMENT and/or MECHANICAL INTERFACE on the RASE can be part of a sterile boundary.



IEC

Key

MI MECHANICAL INTERFACE
RSI ROBOTIC SURGICAL INSTRUMENT

Figure 201.AA.101 – Examples of MECHANICAL INTERFACE attachments

Example 0: No MECHANICAL INTERFACE. An example is a small RASE without detachable border between the ROBOTIC SURGICAL INSTRUMENT and the rest of the RASE.

Example 1: One MECHANICAL INTERFACE. Many RASE employ this structure. A ROBOTIC SURGICAL INSTRUMENT can be of two cases:

- **Example 1-a:** ROBOTIC SURGICAL INSTRUMENT with a specifically designed MECHANICAL INTERFACE; or
- **Example 1-b:** ROBOTIC SURGICAL INSTRUMENT, without a specifically designed MECHANICAL INTERFACE at the ROBOTIC SURGICAL INSTRUMENT side.

Example of 1-a can be a forceps of RASE, examples 1-b can be a milling drill of bone milling RASE and a catheter of catheter guiding RASE.

Example 2: Two or more MECHANICAL INTERFACE. An example of this is to use a manual equipment as the ROBOTIC SURGICAL INSTRUMENT, e.g., an endoscope. The endoscope is attached to the endoscope holder, which is the first MECHANICAL INTERFACE. The endoscope holder is detachable from the rest of RASE by means of another MECHANICAL INTERFACE.

Definition 201.3.213 – ROBOTICALLY ASSISTED SURGICAL EQUIPMENT, RASE

There is a wide range of ME EQUIPMENT for surgical assistance that use robotic technologies. For an exhaustive list, see [1]. They are often referred to as "surgical robots", "robotic surgical devices", or "robotically assisted surgical devices"[17], etc. Since they are quite broad in terms of their variety of configurations and INTENDED USES, this document first tried to illustrate the common characteristics that are typical of this type of ME EQUIPMENT.

The original proposed title of this document was "Medical robots for SURGERY" but generally speaking, the word "robot" in plain language is used quite vaguely and there is no universally accepted definition. ISO 8373:2012, 2.6, defines a robot as "an actuated mechanism programmable in two or more axis with a degree of autonomy, moving within its environment, to perform intended tasks". Joint Working Group 35 found that it would be better to define this type of ME EQUIPMENT in another way without using the defined term robot for the following reasons.

- There is considerable difference in interpretation of the meaning of "degree of autonomy", which is currently defined as a taxonomy and is not readily quantifiable.
- Hence "degree of autonomy" is not suitable as a part of a key definition in a standard.
- The majority of ME EQUIPMENT on the market is not considered autonomous, and using a definition based on the degree of autonomy provides less clarity and is unnecessary for describing the ME EQUIPMENT covered by this document.

From these reasons, this document builds a new definition of these ME EQUIPMENT without using the words of "medical robot for SURGERY" or "surgical robot".

This term RASE is derived from the term used in certain jurisdictions with minor modification, to replace the word "device" with "equipment" to be consistent with the series of this document. "Assisted" implies the OPERATOR controls the RASE, under direct control or supervision.

Definition 201.3.215 – ROBOTIC SURGERY CONFIGURATION

The ROBOTIC SURGERY CONFIGURATION can include other ME EQUIPMENT and ME SYSTEMS. Figures 201.AA.102 and 201.AA.103 illustrate two examples of ROBOTIC SURGERY CONFIGURATIONS. These figures are examples only, and are not intended to reflect any specific configuration necessary for compliance with this document.

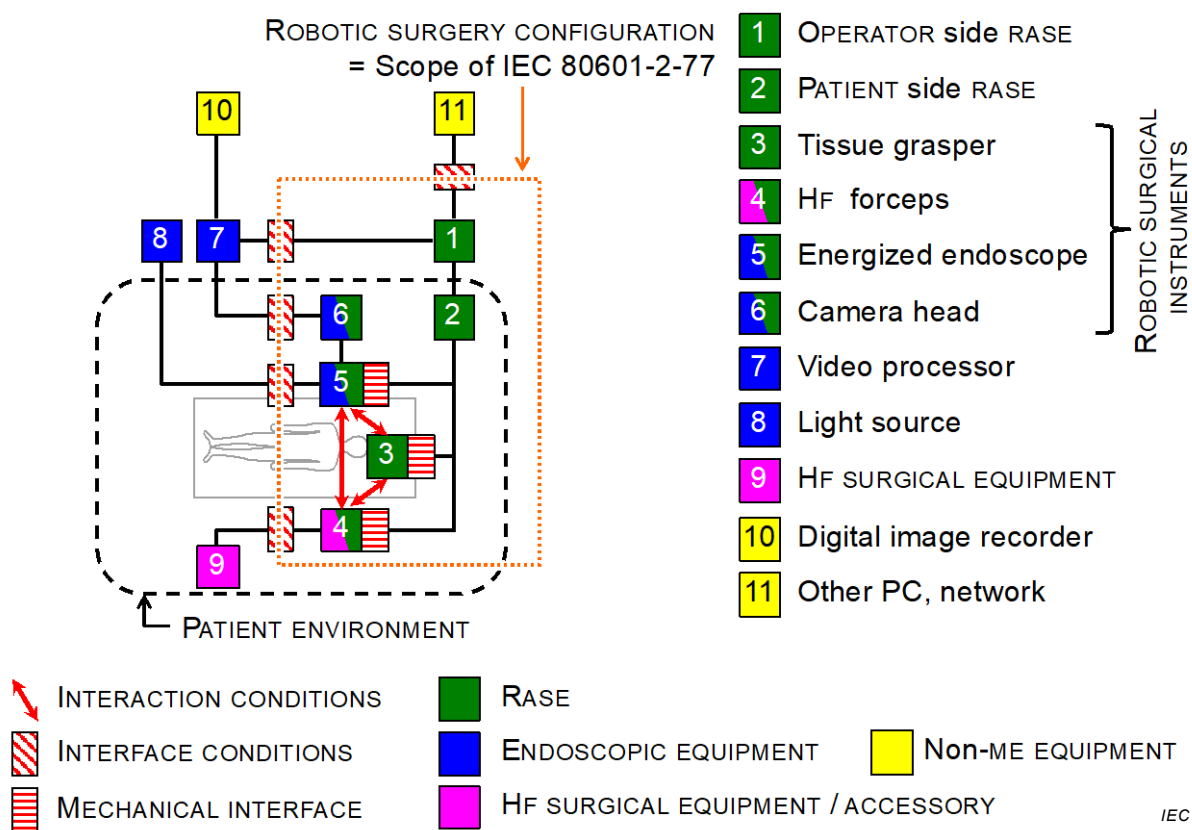


**Figure 201.AA.102 – Example 1 of ROBOTIC SURGERY CONFIGURATION:
a case of laparoscopic RASS**

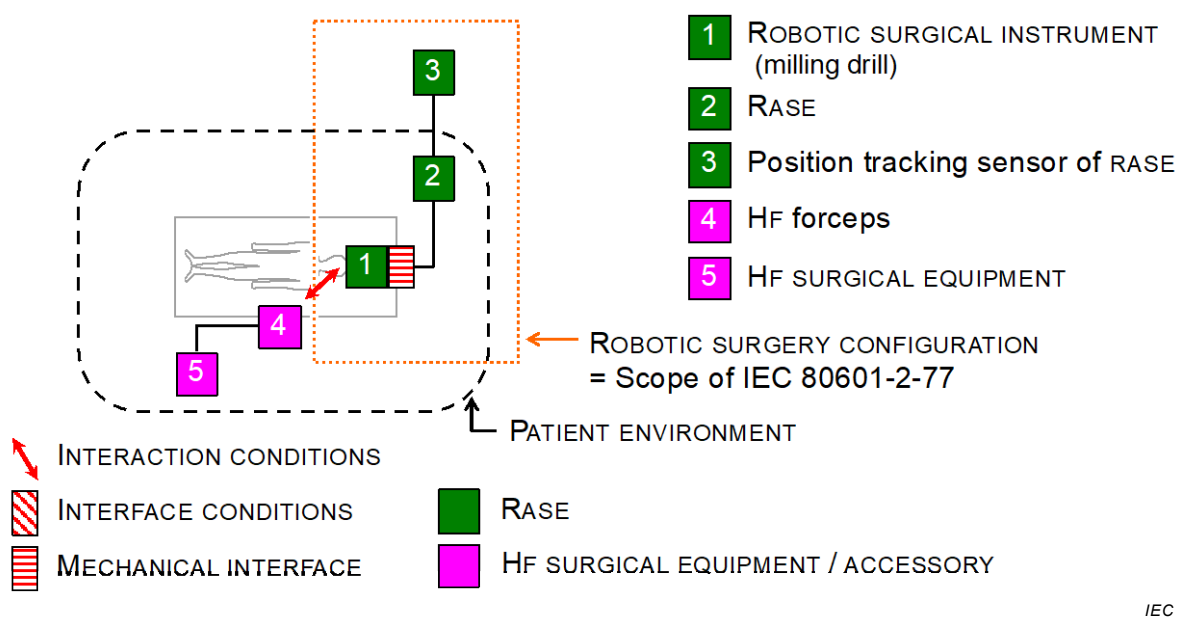


**Figure 201.AA.103 – Example 2 of ROBOTIC SURGERY CONFIGURATION:
a case of bone milling RASE**

NOTE The operating table is not shown in Figures 201.AA.102 and 201.AA.103 as part of the ROBOTIC SURGERY CONFIGURATION in these examples, however, it depends on the INTENDED USE.

Definition 201.3.216 – ROBOTIC SURGICAL INSTRUMENT

It was considered not practical to define ROBOTIC SURGICAL INSTRUMENT by explicitly listing the INTENDED PURPOSES, actions, or names of instruments that fit in this definition. By analysing [16] we observed that

- interpretation of the terms "interventional" and "surgical" by qualified medical practitioner (general surgeon, orthopedist, etc.) is discipline-dependent, and differs by medical practices, even when the actual TASKS are alike, and
- surgical devices and equipment used in and maneuvered by RASE applications are invasive or non-invasive.

Therefore, this document defines ROBOTIC SURGICAL INSTRUMENT based on public documents[11][12]. The definition limits the scope of ROBOTIC SURGICAL INSTRUMENT to INVASIVE DEVICES. The inclusion of non-INVASIVE DEVICES and equipment (i.e., removing "INVASIVE DEVICE with" from the definition) will make the coverage of ROBOTIC SURGICAL INSTRUMENT unnecessarily and unacceptably wide.

The following examples do not agree with the definition of ROBOTIC SURGICAL INSTRUMENT and are therefore out of scope of this document:

- high-intensity ultrasound equipment for tumour ablation maneuvered by a robotic arm;
- pointing guidance maneuvered by robotic arm, without APPLIED PART.

These ME EQUIPMENT have non-invasive equipment and device, the former with the APPLIED PART, the latter without it (in NORMAL USE). However, this document can be a useful guidance for similar ME EQUIPMENT.

ROBOTIC SURGICAL INSTRUMENT roughly corresponds to the end effector in robotics terminology. However, in the case of RASE, the definition of "end effector" found in ISO 8373:2012 (3.11) does not agree in a strict sense that the definition of "end effector" assumes there is an "attachment" to the MECHANICAL INTERFACE, whilst ROBOTIC SURGICAL INSTRUMENT of RASE can have no MECHANICAL INTERFACE nor attachment.

Subclause 201.4.1.101 – ROBOTIC SURGICAL INSTRUMENTS and other ME EQUIPMENT

There can be a similar subclause in other particular standards, such as 201.4.1.101 of IEC 60601-2-18:2009. When there is a conflict between this and other applicable particular standards, if the ME EQUIPMENT is a RASE, this particular standard takes precedence. See 201.11.101.1 for the ROBOTIC SURGERY CONFIGURATION with an ENDOSCOPIC EQUIPMENT.

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

After careful consideration of the clauses within this document, the following ESSENTIAL PERFORMANCE items are identified as common in many RASE. Figure 201.AA.104 illustrates these items.

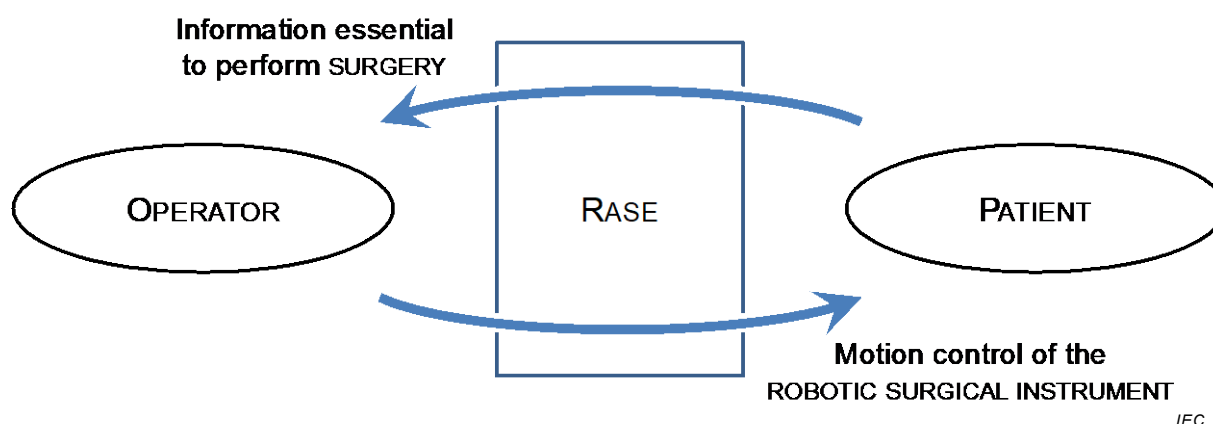


Figure 201.AA.104 – Typical ESSENTIAL PERFORMANCE items of RASE

Information essential to perform SURGERY:

Information can be any data provided by the RASE or other equipment of the RASS that is used to make clinical decisions or to influence clinical actions or results. It can be

- visual, for example, video or other image based data,
- computational, for example, virtual boundary imposed by RASE, position tracking information for instruments, or
- tactile, for example, haptic feedback from RASE.

Some RASE utilize imaging technology to facilitate the movement and placement of the ROBOTIC SURGICAL INSTRUMENTS. This can be in the form of the OPERATOR viewing live or pre-operative images to guide placement of the ROBOTIC SURGICAL INSTRUMENTS. It can also include image recognition algorithms and augmented reality to provide additional information to the OPERATOR. Other RASE utilize other information such as the position-tracking information. The effects of degradation of information essential to perform SURGERY should be considered in formulating the requirements essential for each type of RASE. See examples of such degradation in the rationale of 201.13.1.101.

Motion control of the ROBOTIC SURGICAL INSTRUMENT:

Motion control is considered as the spatio-temporal control of positioning and manipulation, which is a combination of the control and the movement. The motion control of the ROBOTIC SURGICAL INSTRUMENT of RASE can

- constrain range of movement of the ROBOTIC SURGICAL INSTRUMENT, for example, virtual boundary,
- alter the speed and distance ratios of the OPERATOR'S input to RASE output of movement of the ROBOTIC SURGICAL INSTRUMENT, for example, tremor attenuation,
- include some automated functions of the ROBOTIC SURGICAL INSTRUMENT, for example, automated instrument alignment, or torque attenuation of the cutting TOOL,
- orient and hold the position of a ROBOTIC SURGICAL INSTRUMENT relative to PATIENT anatomy and compensate for PATIENT movement, or
- directly cause the movement of the ROBOTIC SURGICAL INSTRUMENT without the OPERATOR'S input.

Motion control of the ROBOTIC SURGICAL INSTRUMENT is essential to RASE in performing its intended function, and ESSENTIAL PERFORMANCE around motion control should be established for each RASE. Specific ESSENTIAL PERFORMANCE requirements will depend on the INTENDED USE of the RASE.

The examples for this ESSENTIAL PERFORMANCE include, but not limited to

- the fidelity of the positioning and speed of ROBOTIC SURGICAL INSTRUMENTS to those of the OPERATOR input, or
- the pose accuracy of the ROBOTIC SURGICAL INSTRUMENT according to the computed path.

Existing RASE can have only a few of these as their ESSENTIAL PERFORMANCE. The MANUFACTURER can also consider any ESSENTIAL PERFORMANCE specified by other specific particular standards that have been addressed.

Subclause 201.4.6 – ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

The RISK ASSESSMENT should consider

- PATIENTS undergoing SURGERY with RASE or RASS are typically anaesthetized, or otherwise unable to perceive or respond to negative stimulus, and
- RASE contact between equipment parts when ROBOTIC SURGICAL INSTRUMENTS are attached and manipulated in accordance with NORMAL USE and reasonably foreseeable misuse (e.g. collision).

Subclause 201.7.2.9 – IP classification

The intent is to have the higher IP classification marking on the ACCESSORIES that impart such IP classification marking to the RASE. The non-covered RASE can itself be marked with a lower classification or no IP marking.

ROBOTIC SURGICAL INSTRUMENTS supplied with specific instructions detailing allowable reprocessing methods and parameters are excluded from the requirement to be marked with an IP classification because this additional information is likely to confuse OPERATORS, and the IP marking will not inform the OPERATOR of the necessary details to allow safe and effective reprocessing. An alternative marking (for example, by a symbol), replacing the IP symbol could not be standardized by this particular standard because of the different reprocessing PROCEDURES. See also 7.9.2.12 of the general standard.

Subclause 201.7.8.1 – Colours of indicator lights

Subclause 201.7.8.1 was amended to be in line with the IEC 60601-1:2005/AMD2:2020, subclause 7.8.1 and IEC 60601-2-2:2017/AMD:2023 for activating cutting and coagulation modes of HF SURGICAL EQUIPMENT. The amended text and table do not change the allowable use of colours of indicator light as previously indicated in IEC 80601-2-77:2019.

Subclause 201.8.5.2.101 – F-Type insulation

An example of F-TYPE APPLIED PART separation requirements are for a RASE intended to position a ROBOTIC SURGICAL INSTRUMENT that incorporates an endoscope with a light source and camera; and/or HF SURGICAL ACCESSORIES or instruments. The IEC 60601-2-18:2009, 201.8.3 c), for ENDOSCOPIC EQUIPMENT requires their respective APPLIED PARTS to have an F-TYPE APPLIED PART insulation to all other equipment parts.

Subclause 201.8.5.2.101 requires that for any F-TYPE APPLIED PART ROBOTIC SURGICAL INSTRUMENT, the F-TYPE APPLIED PART insulation requirements be maintained during the SURGERY, which includes all NORMAL USE and reasonably foreseeable misuse positions that might occur during the SURGERY. See also 201.4.6 and 201.11.1.101.3.

Generally PATIENT support surfaces with TYPE B APPLIED PART are considered to provide acceptable RISK, even for SURGERIES where all surgical instruments are F-TYPE APPLIED PARTS, based on a long history of clinical experience supporting this judgement. In other cases, the MANUFACTURER'S RISK MANAGEMENT PROCESS can identify the need for RISK CONTROLS to address the use of PATIENT support surface with TYPE B APPLIED PART.

Subclause 201.8.9.1.1 – General

Because of the constructional requirements of ROBOTIC SURGICAL INSTRUMENTS necessary to meet the appropriate clinical requirements, it might be difficult or impossible for the APPLIED PARTS of ROBOTIC SURGICAL INSTRUMENTS to meet the requirements of 8.9 of the general standard. Because ROBOTIC SURGICAL INSTRUMENTS are cleaned and sterilized before use, sealed units and any live circuits within the ROBOTIC SURGICAL INSTRUMENTS are always on the secondary side, it is considered that an adequate level of safety for these parts will be provided by two MEANS OF OPERATOR PROTECTION, pollution degree 1. Regarding the pollution degree, refer to Annex E of IEC 61010-1:2010 [18].

Subclause 201.9 – Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

HAZARDOUS SITUATIONS associated to MECHANICAL HAZARDS of RASE can be similar to those of other robot applications, such as industrial robots. However, there is one significant difference in the way to understand and prioritize the HAZARDOUS SITUATIONS of ME EQUIPMENT: use the motto: "PATIENT safety first". The following are examples of HAZARDOUS SITUATIONS associated with MECHANICAL HAZARDS of RASE, originally in Table A.1 of ISO 10218-1:2011[19], which have been modified to be valid for RASE applications:

- movements (normal or unexpected by one or more OPERATORS) of any part of the RASE;
- actuation (normal or unexpected by one or more OPERATORS) of any part of the APPLIED PART;
- movements (normal or unexpected by one or more OPERATORS) of any independent axis of the APPLIED PART;
- mechanical failure of the APPLIED PART (separation) including the HAZARDS associated with ejection of foreign bodies into the PATIENT;
- unexpected movement of the APPLIED PART when the RASE is not configured for a surgical intervention;
- materials ejected by the APPLIED PART;
- unintended release of the APPLIED PART;
- movement or rotation of sharp TOOL surfaces of the APPLIED PART;
- movement of actuator parts;
- rotation of the ROBOTIC SURGICAL INSTRUMENT;
- rotational motion of any of the actuator axes of the RASE;
- entanglement of OPERATOR loose clothing;
- trapping between the RASE and any other FIXED item in the operating room;
- trapping between the APPLIED PART and any FIXED item in the operating room;
- unintended release of potential energy from stored sources within the RASE.

NOTE HAZARDOUS SITUATIONS are not limited to the above.

Subclause 201.9.2.2.4.4 – Other RISK CONTROL measures

The requirement has been changed to take into account subsystems of the PEMS (either hardware or software) that provide RISK CONTROL measures related to moving parts. An example is SINGLE FAULT SAFE PESS (PROGRAMMABLE ELECTRICAL SUBSYSTEMS), developed with a special PROCESS and running in a special hardware environment that can stop the movement due to direct access to the brakes of the RASE.

Subclause 201.9.2.2.5 – Continuous activation

The requirement has been changed to take into account that not only surgeons are in the range of motion of the RASE but also other operating room staff. Therefore, all OPERATORS with awareness of the situation can be responsible for continuous activation or for actively stopping the motion.

Subclause 201.9.2.2.6 – Speed of movement(s)

The requirement has been changed to take into account that the RASE has a moving part inside and outside the PATIENT body which could result in different HAZARDS due to speed of movements. See Annex BB.

Subclause 201.9.2.3.2 – Overtravel end stops

The requirement has been changed to take into account that it is not obligatory that a RASE has mechanical end stops. Other means to prevent overtravel past limits are possible, for example electro-mechanical end stops.

Subclause 201.9.2.5 – Release of PATIENT

The title of the subclause is retained from the general standard, and for RASE this includes removal of instruments and ACCESSORIES from the PATIENT.

The requirement has been changed to take into account that the OPERATOR can decide to release the PATIENT due to medical reasons, for example, in an emergency situation where the SURGERY has to be transformed from a robotic to a manual SURGERY.

Subclause 201.9.2.101 – RASE PROTECTIVE STOP functions

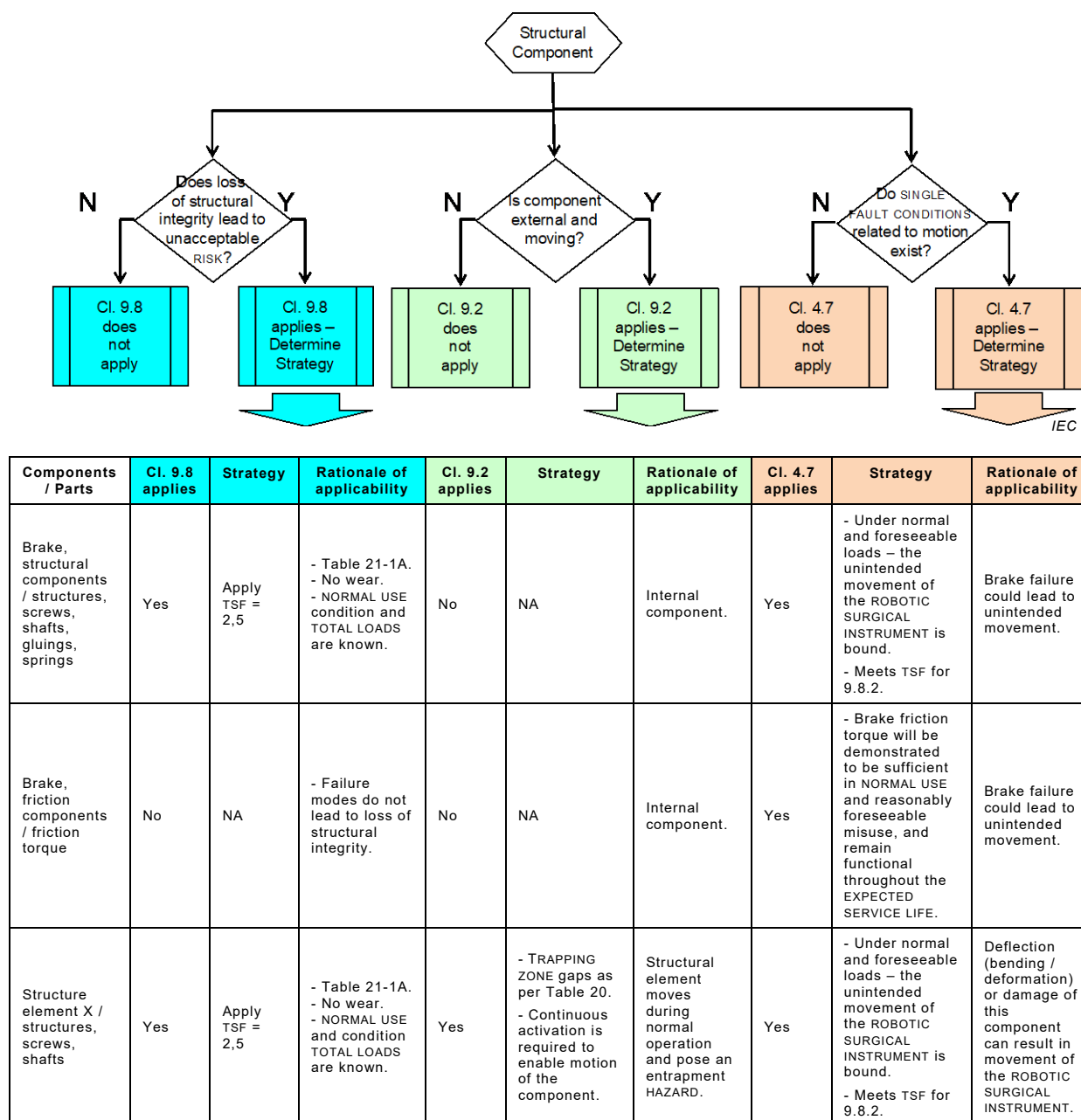
Name of RASE PROTECTIVE STOP is intentionally distinguished from "protective stop" of other standards to avoid confusion. See Annex CC for RASE PROTECTIVE STOP and other stopping functions of RASE. Identification of functional tests to assess protective measure for applicable SINGLE FAULT CONDITIONS should be included in the RISK MANAGEMENT FILE.

Subclause 201.9.4.2.4.3 – Movement over a threshold

When IEC 60601-2-18:2009 was published, IEC 60601-1:2005 required a 20 mm threshold, at manual speed of 0,4 m/s. IEC 60601-2-18 modified to require 15 mm threshold at 0,3 m/s. When Amendment 1 to the general standard was published in 2012 the threshold was lowered to 10 mm with 2 mm radius edge, at manual speed of 0,8 m/s. The amended general and IEC 60601-2-18:2009 particular standard are both considered as verifying acceptable RISK for carts associated with endoscopic systems.

Subclause 201.9.8.1 – General

Subclause 9.8 of the general standard is about the BASIC SAFETY of the structural component so that it does not cause catastrophic damage such as collapsing. However, a RASE arm can be both a support system and a functional component. The flowchart in Figure 201.AA.105 is an example to help classification of these matters.



Key

TSF TENSILE SAFETY FACTOR

NOTE References in this figure are taken from IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Figure 201.AA.105 – Example of RISK ASSESSMENT related to structural component

Subclause 201.11.6.1 – General

Protective covers such as equipment drapes can be a suitable candidate for RISK CONTROL for fluid protection based on their properties as a sterile boundary, which includes requirements to resist transmission of pathogens, and sufficient mechanical resistance to tears and punctures during the installation of the protective covers.

Subclause 201.11.101.3 – Thermal and other HAZARDS from INTERACTION CONDITIONS with HF SURGICAL EQUIPMENT

Thermal effects can result from the interaction between APPLIED PARTS in a ROBOTIC SURGERY CONFIGURATION without ENDOSCOPIC EQUIPMENT by virtue of the current density of CAPACITIVELY COUPLED HF CURRENT. The MANUFACTURER'S RISK MANAGEMENT PROCESS should be used to identify such RISKS under both normal and SINGLE FAULT CONDITIONS, so that appropriate RISK CONTROL measures can be taken during the design PROCESS, and/or relevant safety warnings can be provided in the instructions for use.

Exposed conductive parts of RASE that can be in proximity with the APPLIED PARTS of HF SURGICAL EQUIPMENT might need to be isolated to protect the PATIENT or OPERATORS from the thermal effects of CAPACITIVELY COUPLED HF CURRENT. The isolation can be achieved by different measures, e.g. by separation of components or by an insulation.

It can be determined through RISK MANAGEMENT that it is not possible to conduct a CAPACITIVELY COUPLED HF CURRENT from an accessible surface of the RASE in normal and SINGLE FAULT CONDITIONS. In other cases, it might be necessary to measure the CAPACITIVELY COUPLED HF CURRENT from each exposed conductive part.

The test method described and illustrated in IEC 60601-2-18:2009, 201.11.101.2 c)2) can be adapted to measure CAPACITIVELY COUPLED HF CURRENT. When conducting the test, the HF APPLIED PART (item 6 in Figure 201.102 of IEC 60601-2-18:2009) should be installed as intended in the ROBOTIC SURGERY CONFIGURATION in a fashion representing worst-case NORMAL USE during SURGERY. While HF APPLIED PART is energized, the CAPACITIVELY COUPLED HF CURRENT can be measured from accessible surfaces of RASE (corresponding to item 7 in Figure 201.102 of IEC 60601-2-18:2009) through a 200 Ω non-inductive resistor to the HF reference. For non-conductive accessible surfaces, the measurement can be made from a metal foil in intimate contact with non-conductive surface with surface area of 10 cm by 10 cm, or otherwise representing 50 % of largest reasonably foreseeable contact area.

A maximum HF current of 50 mA flowing from such exposed conductive parts is considered by IEC 60601-2-18:2009 to provide sufficient protection, which assumes a contact surface area of the skin area around the surgeon's eye in contact with the eye piece of an endoscope (i.e. approximately 10 cm by 10 cm). The MANUFACTURER'S RISK MANAGEMENT PROCESS can identify a more appropriate limit.

Subclause 201.13.1.101 – Information essential to perform SURGERY

The examples of such information include, but are not limited to,

- endoscopic images provided to the OPERATOR of the RASE,
- position tracking information (data) to register the RASE coordinate system to PATIENT location, or
- 3D bone models used to guide the surgical PROCEDURE.

The examples of degradation of the information include, but are not limited to,

- endoscopic image is not a live image or unacceptably delayed,
- position tracking information is interrupted by occluding the tracking markers from the tracking camera,
- position tracking information is corrupted by movement of the PATIENT tracking markers, or
- 3D bone models do not accurately represent the PATIENT anatomy due to excessive noise in the CT images or warping of MR images, causing degraded registration accuracy.

Subclause 201.13.1.102 – Motion control of the ROBOTIC SURGICAL INSTRUMENT

The examples of performance degradation of the motion control of the ROBOTIC SURGICAL INSTRUMENT include, but are not limited to,

- delay of the positioning and speed of ROBOTIC SURGICAL INSTRUMENTS to that of the OPERATOR input, or
- deviation of the pose of ROBOTIC SURGICAL INSTRUMENTS from the computed path, surface, or static position.

MANUFACTURER may consider using other standards such as ASTM F2554-10[20].

NOTE ASTM F2554-10 does not specify normative testing methods to test the accuracy, repeatability, etc., and can be not applicable to some RASE.

Subclause 201.16 – ME SYSTEMS

MECHANICAL HAZARDS and HAZARDOUS SITUATIONS can occur in ME SYSTEMS that include RASE. Clause 9 of the general standard and 201.9 shall be applied to ME SYSTEMS.

Planning software and surgical navigation equipment can be part of ME SYSTEMS that include RASE.

Subclause 201.17 – ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

This is the equivalent requirement to 4.2 of IEC 60601-1-2:2007[23]. It is known that testing SINGLE FAULT CONDITIONS of RASE during the EM DISTURBANCE testing is not reasonably achievable. However, the IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 does not explicitly exclude testing under SINGLE FAULT CONDITIONS.

Certain SINGLE FAULT CONDITIONS would have a significant adverse effect on EM DISTURBANCE performance of a ME EQUIPMENT or ME SYSTEM. Some EM DISTURBANCE techniques redirect disturbances to earth or dissipate them in circuit components. If the PROTECTIVE EARTH CONDUCTOR is interrupted or failure of a component in a filter is simulated during EM DISTURBANCE testing, it could be very difficult to meet the EM DISTURBANCE requirements of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020. Therefore, EM DISTURBANCE testing is specified to be performed under NORMAL CONDITIONS and not SINGLE FAULT CONDITIONS.

The IMMUNITY TEST LEVELS in IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are considered to be representative of the use environment.

It is possible that a SINGLE FAULT CONDITION could occur in combination with an expected EM DISTURBANCE or there could be a SINGLE FAULT CONDITION in a means for protection against EM DISTURBANCES that could result in a HAZARD. These HAZARDS should be considered in the RISK MANAGEMENT PROCESS.

Clause 206 – UsABILITY

When applying UsABILITY ENGINEERING PROCESS to RASE applications, MANUFACTURERS can consider that the user profile should take into account experience of each surgeon for the RASE's INTENDED USE. For example IEC 62366-1:2015 defines the user profile under 3.29 to include special characteristics, such as occupational skills, job requirements and working conditions. For RASE or RASS, this can include defining the clinical experience of the user in terms of the approximate total number of surgical PROCEDURES performed over the user's career, including the surgeries performed with and without RASE as well as the cumulative experience working in SURGERY. The user's experience can also include listing of specific RASE or RASS. Users of RASE or RASS can include qualified personnel who need to interact with the device during a surgical PROCEDURE.

Annex BB (informative)

Equations for the calculation of the overall system stopping performance and minimum distances

BB.1 General

In order to fulfil the requirement of 9.2.2.6 of the general standard, the MANUFACTURER can estimate the overall stopping performance and the stopping distance of the RASE.

Annex BB provides an example of a method to estimate these using simple equations. It is not limited to this method. It is based on the method described in ISO 13855[21].

BB.2 Overall system stopping performance

The overall system stopping performance comprises at least two time phases. The two time phases are linked by Equation (BB.1):

$$T = t_1 + t_2 \quad (\text{BB.1})$$

where

T is the overall system stopping performance time;

t_1 is the maximum time between the occurrence of the actuation of the safeguard output signal achieving the OFF state;

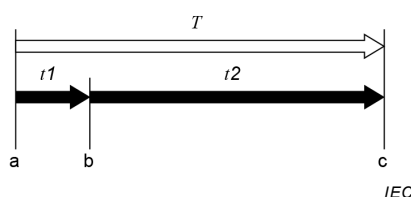
t_2 is the stopping time.

t_1 includes, as applicable, the maximum latency time between the occurrence of the event and the time when PEMS actually detected it. The PEMS latency time could vary depending on the time sequence of the HAZARDOUS SITUATION that generated an interrupt request, or if the system polls input data, or PROCESSES input data to determine that a HAZARDOUS SITUATION that requires a RASE PROTECTIVE STOP exists.

t_2 is the maximum time required to terminate the HAZARDOUS SITUATION of the RASE, after the output signal from the safeguard achieves the OFF state. The response time of the control system of the RASE will be included in t_2 .

t_1 and t_2 are influenced by various factors, for example temperature, actuation time of stopping devices, and ageing of components.

t_1 and t_2 are illustrated in Figure 201.BB.101. t_1 and t_2 are functions of the safeguard and the RASE, respectively, and are determined by design and evaluated by measurement. The evaluation of these two values will include the uncertainties resulting from the measurements, calculations and/or construction.



Key

- a Actuation of safeguard
- b Operation of safeguard (OFF signal generated)
- c termination of HAZARDOUS SITUATION (safe condition)

Figure 201.BB.101 – Relationship between t_1 and t_2

The overall system stopping performance time, T , is an essential characteristic for the location of the protective device. Any deviation of the stopping time of the machine, t_2 , will be taken into account during the estimation of T . Where the stopping time can deteriorate during the lifetime of the RASE, technical or organizational measures should be taken to ensure the correct overall system stopping performance. These measures can be, for example,

- braking performance control devices, and
- checks, the nature and the frequency of which should be defined in the user's manual.

NOTE There can be additional aspects to take into account, for example, cases where inadequate stopping performance prevents the application of annex (e.g. it is not possible to stop the RASE during a certain cycle phase or the stopping performance cannot be predicted).

Measurements of stopping performance of a system require careful consideration in order to obtain accurate and relevant time values.

BB.3 Stopping distance

The stopping distance of the RASE related to a HAZARDOUS SITUATION can be calculated by using Equation (BB.2).

$$S = (K \times T) \pm A \quad (\text{BB.2})$$

where

S is the distance, in millimetres (mm);

K is the velocity, based on the MANUFACTURER'S specification in the worst-case, in millimetres per second (mm/s);

T is the overall system stopping performance time, in seconds (s);

A is the tolerance of the stopping distance, based on the MANUFACTURER'S specification or measurement, in millimetres (mm).

NOTE 1 A can be calculated from measurement of the statistically meaningful sample size.

NOTE 2 Worst-case velocity alone can be insufficient to fully characterize safe stopping distance. Other factors such as mass and acceleration of the moving part and braking power of motors could need to be considered.

Annex CC (informative)

Stopping functions of the RASE

CC.1 General

Annex CC is to provide a guidance of stopping functions of the RASE.

It is recognized that the stopping of a RASE can require maintaining control rather than simple manual intervention to activate an emergency motion stop, or an emergency power off.

CC.2 Introduction of RASE PROTECTIVE STOP

There are times when the RASE itself through either hardware or PEMS will recognize that a stop or pause in motion should occur. This concept of a RASE PROTECTIVE STOP is introduced to the RASE. In this RASE PROTECTIVE STOP mode, the safe action is to leave power enabled, so that the PEMS can continue to be in control of the stop motion, and to watch if an error condition still exists, or if it has cleared movement can be resumed.

For example, for a camera-based tracking system for a RASE, if a person stands between the tracking markers attached to the PATIENT and the camera, position data is lost, and the RASE knows to stop motion due to the loss of position data. If the person standing between the PATIENT and the tracking camera moves out of the way, the OPERATOR can activate a resume function to continue the PROCEDURE from where it was interrupted.

RASE PROTECTIVE STOP was introduced in 201.9.2.101. Initiation into this stopping mode could be automatic as described previously, but it could also be manual. For example, if an OPERATOR needs to enter a stop mode in order to prevent a collision, a manual pause could be pressed and the operation could resume when the OPERATOR is ready to initiate restart. During this stop, all position data and power can be maintained in the hardware and/or PEMS to facilitate expedient continuation of the surgical PROCEDURE after restart is initiated.

This mode is different from a normal stop, which would be a planned stop in the normal PROCESS flow of the surgical PROCEDURE.

The RASE PROTECTIVE STOP function can be integral to a normal stop, according to the design specification. Table 201.CC.101 shows the differences of three typical stopping functions.

Table 201.CC.101 – Different stopping functions

Function	Emergency stop	RASE PROTECTIVE STOP	Normal stop
Situation	Emergency	Abnormal condition	Intended operation
Initiation	Manual	Automatic or manual	Automatic or manual
Requirements	Shall meet 201.9.2.4	Shall meet 201.9.2.101	Design-specific
Requirement to restart	Manual	Automatic or manual	Not applicable
Use frequency	Infrequent	Often to infrequent	Always
Intended effect	Immediately stop HAZARDOUS SITUATION	RISK CONTROL to acceptable level	Suspension of operation

CC.3 Stopping RASE

The RASE should be designed to ensure that it comes to a safe stop without causing any HAZARDOUS SITUATIONS such as rollovers, runaways, or drops of RASE's parts and loads in case of an intended braking at any speed.

Annex DD (informative)

Alternative method to demonstrate structural integrity throughout the EXPECTED SERVICE LIFE of the RASE

Subclause 201.9.8 requires that the construction of the support, suspension or actuation system shall be designed based upon Table 21 of the general standard and the TOTAL LOAD. Alternatively, it accepts an alternative method that demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the RASE. Annex DD provides an example of an alternative method. It is not limited to this method.

A series of life testing can be used to demonstrate structural integrity throughout the EXPECTED SERVICE LIFE of the RASE. Generally, a series of life tests should continue for the RASE'S actual service life; however, it is acceptable applying accelerated testing techniques such as highly accelerated life test (HALT) and component testing with a load equivalent to actual condition.

Table 201.DD.101 indicates a typical set of design and test items which can be appropriate to the RASE, but other items can be included. Design and test items should be identified as a result of RISK MANAGEMENT.

Table 201.DD.101 – Alternative to safety factors: life testing

Component	Failure condition	Design and test methods to demonstrate sufficient strength of component
Motors	Motor temperature rise, resulting in failure of a built-in component	RASE should be operated under the worst-case NORMAL USE condition. The test should continue until the motor(s) temperature stabilizes. The measured temperature should be less than specification values for all built-in components, plastics and chemicals.
	Failure of motor rotation due to: 1) wear of rotation-supporting hardware, 2) loss or degradation of electrical connectivity, or 3) a breakdown of the rotation position sensor	RASE should be operated under the worst-case NORMAL USE condition. The test should continue for a duration equivalent to the EXPECTED SERVICE LIFE. After testing the motor(s) should be fully functional. Parameters to ensure full functionality of the motor(s) should be identified in the RISK MANAGEMENT FILE. After testing all values of identified parameters should be measured and be within the acceptable range. The acceptable range of each parameter should be identified in the RISK MANAGEMENT FILE.
	Motor brake functionality failure	RASE should be operated under the worst-case NORMAL USE condition. The test should continue for a duration equivalent to the EXPECTED SERVICE LIFE. After testing the motor brake(s) should be fully functional. Parameters to ensure full functionality of the motor brake(s) should be identified in the RISK MANAGEMENT FILE. After testing all values of identified parameters should be measured and be within the acceptable range. The acceptable range of each parameter should be identified in the RISK MANAGEMENT FILE.
Gears	Chips / wears on gear teeth, resulting in gear backlash	Calculations should show that the gear teeth will withstand mechanical stress under the worst-case NORMAL USE condition.
		RASE should be operated under the worst-case NORMAL USE condition. The test should continue for a duration equivalent to the EXPECTED SERVICE LIFE. After testing the gears should be fully functional. Parameters to ensure full functionality of the gears should be identified in the RISK MANAGEMENT FILE. After testing all values of identified parameters should be measured and be within the acceptable range. The acceptable range of each parameter should be identified in the RISK MANAGEMENT FILE.

Component	Failure condition	Design and test methods to demonstrate sufficient strength of component
Bearings	Degradation or breakdown of bearings	Calculations should show that the bearing(s) will withstand mechanical stress under the worst-case NORMAL USE condition.
		RASE should be operated under the worst-case NORMAL USE condition. The test should continue for a duration equivalent to the EXPECTED SERVICE LIFE. After testing the bearing(s) should be fully functional. Parameters to ensure full functionality of the bearing(s) should be identified in the RISK MANAGEMENT FILE. After testing all values of identified parameters should be measured and be within the acceptable range. The acceptable range of each parameter should be identified in the RISK MANAGEMENT FILE.
Metal bushings	Degradation or breakdown of metal bushings	Calculations should show that the metal bushing(s) will withstand mechanical stress under the worst-case NORMAL USE condition.
		RASE should be operated under the worst-case NORMAL USE condition. The test should continue for a duration equivalent to the EXPECTED SERVICE LIFE. After testing the metal bushing(s) should be fully functional. Parameters to ensure full functionality of the metal bushing(s) should be identified in the RISK MANAGEMENT FILE. After testing all values of identified parameters should be measured and be within the acceptable range. The acceptable range of each parameter should be identified in the RISK MANAGEMENT FILE.
Frames	Deformation or breakdown - in use	Using finite element analysis (FEA), calculations should identify the weakest portion of each frame component while simulating the worst-case NORMAL USE condition. The yield point or 0,2 % proof stress of material strength of each frame component should be more than the calculated stress with adequate safety factors.
	Deformation or breakdown - interference with external objects	RASE should be operated under the worst-case NORMAL USE condition. The actual stress that appeared on the identified portion per FEA should be equal to or less than the calculated value.
Screws	Loosening of screw	RASE should be operated with the highest operational speed parameter, and collide with an object. Application and condition of this test should be based on the result of the RISK MANAGEMENT FILE. The direction of RASE motion and the location of the hitting portion of the RASE at the time of collision should be the one(s) giving highest stress to the weakest portion calculated per FEA. If single testing cannot give the highest stress to all of identified weakest portion, multiple modes of collision should be considered so that each identified weakest portion can be tested. Collision test should be performed at least 1 time per each collision mode. Collision detection or avoidance function, if SINGLE FAULT SAFE, can be relied on during testing. If collision detection or avoidance function can be defeated in SINGLE FAULT CONDITION, testing is conducted under the SINGLE FAULT CONDITION. After each collision test, BASIC SAFETY and ESSENTIAL PERFORMANCE of the RASE should be maintained. Alternatively, testing can be done at the conclusion of all collision tests if desired by the MANUFACTURER. APPLIED PARTS intended to lose their function after collision can be replaced with a new part after each collision prior to reconfirming the BASIC SAFETY and ESSENTIAL PERFORMANCE. (see 5.6 of the general standard). ^{a b}
	Slipping of fastened component -interference with external objects	As a result of collision testing above, there should be no slipping of components fastened by screw(s).