



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN 80601-2-77:2021+A1:2023. It is identical to IEC 80601-2-77:2019, incorporating amendment 1:2023. It supersedes BS EN IEC 80601-2-77:2021, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Amendments/corrigenda issued since publication

Date	Text affected
31 October 2021	This corrigendum renumbers BS IEC 80601-2-77:2019 as BS EN IEC 80601-2-77:2021
31 December 2023	Implementation of IEC amendment 1:2023 with CENELEC endorsement A1:2023

English Version

**Medical electrical equipment - Part 2-77: Particular requirements
for the basic safety and essential performance of robotically
assisted surgical equipment
(IEC 80601-2-77:2019)**

Appareils électromédicaux - Partie 2-77: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils chirurgicaux robotiquement
assistés
(IEC 80601-2-77:2019)

Medizinische elektrische Geräte - Teil 2-77: Besondere
Festlegungen an die Sicherheit, einschließlich der
wesentlichen Leistungsmerkmale von durch Roboter
unterstützte Chirurgiegeräte
(IEC 80601-2-77:2019)

This European Standard was approved by CENELEC on 2020-01-08. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1675/FDIS, future edition 1 of IEC 80601-2-77, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-77:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2022-04-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-10-01

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Endorsement notice

The text of the International Standard IEC 80601-2-77:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 13482:2014 NOTE Harmonized as EN ISO 13482:2014 (not modified)
IEC 60601-2-2:2017 NOTE Harmonized as EN IEC 60601-2-2:2018 (not modified)
IEC 60601-2-18:2009 NOTE Harmonized as EN 60601-2-18:2015 (not modified)
IEC 60601-2-22:2007 NOTE Harmonized as EN 60601-2-22:2013 (not modified)
IEC 60601-2-37:2007 NOTE Harmonized as EN 60601-2-37:2008 (not modified)
IEC 60601-2-46:2016 NOTE Harmonized as EN IEC 60601-2-46:2019 (not modified)
IEC 60601-1-3:2008 NOTE Harmonized as EN 60601-1-3:2008 (not modified)
IEC 60601-1-9:2007 NOTE Harmonized as EN 60601-1-9:2008 (not modified)
IEC 60601-1-11:2015 NOTE Harmonized as EN 60601-1-11:2015 (not modified)
ISO 17664:2017 NOTE Harmonized as EN ISO 17664:2017 (not modified)
ISO 10218-1:2011 NOTE Harmonized as EN ISO 10218-1:2011 (not modified)
ISO 13855:2010 NOTE Harmonized as EN ISO 13855:2010 (not modified)
ISO 10993 series NOTE Harmonized as EN ISO 10993 series
IEC 60601-1-2:2007 NOTE Harmonized as EN 60601-1-2:2007 (modified)

European foreword to amendment A1

The text of document 62D/2070/FDIS, future IEC 80601-2-77/AMD1, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-77:2021/A1:2023.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2024-09-20
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2026-12-20

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN IEC 80601-2-77:2021 applies with the following changes:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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Replace the following references:

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	EN 60601-1-2	2015
+ 1	2020		+ 1	2021
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ 1	2013		+ 1	2015
+ 2	2020		+ 2	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ 1	2020		+ 1	2020

Add the following references:

IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar. 2010	
+ 1	2012		+ A1	2013
-	-		+ A12	2014
+ 2	2020		+ A2	2021

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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

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

A1 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. **A1**

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.

^{A1} 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. ^{A1}

^{A1} 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*. ^{A1}

^{A1} 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. ^{A1}

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, ^{A1} IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ^{A1} 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

A1 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 **A1**

201.3 Terms and definitions

A1 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. **A1**

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

A1 * CAPACITIVELY COUPLED HF CURRENT

unavoidable HIGH FREQUENCY current flowing due to capacitive coupling from the APPLIED PART of HF SURGICAL EQUIPMENT to another part of the RASE or RASS **A1**

A1 [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 another part of the RASE or RASS ".] **A1**

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.