IEC 80601-2-77

Edition 1.0 2019-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

IEC 80601-2-77:2019-07(en-fr)

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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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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.

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

FDIS	Report on voting
62D/1675/FDIS	62D/1689/RVD

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

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

In this document, the following print types are used:

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

In referring to the structure of this document, the term

– "clause" means one of the 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 will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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- withdrawn,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

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

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

INTRODUCTION

This part of IEC 80601 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 environment[1]. 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.

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

2 Numbers in square brackets refer to the Bibliography.

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 standard[3] 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 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply as modified in Clauses 202 and 206 respectively. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013[8], IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013[9], and IEC 60601-1-11:2015[10] do not apply.

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

201.1.4 Particular standards

Replacement:

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

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

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

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 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 60601-1-6:2010, *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 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

Addition:

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, and IEC 60601-1:2005/AMD1:2012 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 51.

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: