SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-77:2026

01-julij-2026

Medicinska električna oprema - 2-77. del: Posebne zahteve za osnovno varnost in bistvene lastnosti robotsko podprte kirurške opreme

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

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

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

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-77:2026**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

oSIST prEN IEC 80601-2-77:2026 **en**

62D/2299/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-77 ED2**	
DATE OF CIRCULATION: **2026-06-05**	CLOSING DATE FOR VOTING: **2026-08-28**
SUPERSEDES DOCUMENTS: **62D/2277/CD, 62D/2289A/CC**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

CONTENTS

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.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 80601-2-77 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, 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 to Edition 1

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.

---

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 Edition 2

During the September 21, 2023, meeting of IEC SC 62D Plenary in Seoul, Republic of Korea, the subcommittee discussed the need to proceed with a new edition of IEC 80601-2-77. The need for a new edition was to include/modify the standard based on the latest ROBOTICALLY ASSISTED SURGICAL EQUIPMENT (RASE).

A resolution was taken to proceed towards the 2nd edition of the IEC 80601-2-77.

The review report for the new edition can be found in the IEC document 62D/2157/RR.

This 2nd edition of the IEC 80601-2-77 supersedes the IEC 80601-2-77 edition 1.1 standard. Major changes in this edition are;

– Extend the scope of this document by extending the definition of ROBOTIC SURGICAL INSTRUMENT,
– Clarify the definition of SURGERY in the Annex AA,
– Add guidance on image-guided RASE in the Annex FF.

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.

Note: ME EQUIPMENT can be used with RASS for intraoperative surgical planning and visualization.

ME EQUIPMENT and ME SYSTEMS intended to be used for radiotherapy, nuclear medicine and radiation dosimetry (example: IEC 60601-2-68[8]) are excluded from the scope of this document.

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 [9], IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 [10], and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 [11] 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 3.154, 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 62.

Addition:

201.3.201
*** CAPACITIVELY COUPLED HF LEAKAGE CURRENT**
unavoidable HF LEAKAGE CURRENT flowing due to capacitive coupling from the APPLIED PART of HF SURGICAL EQUIPMENT to 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 another part of the RASE or RASS", insertion of “leakage”.]

201.3.202
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]

201.3.203
HIGH FREQUENCY
HF
frequencies less than 5 MHz and generally greater than 200 kHz

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

201.3.204
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.]

201.3.205
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.]

201.3.206
*** 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

201.3.207
*** 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".]

201.3.208
*** 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.

201.3.209
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

201.3.210
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.

201.3.211
*** 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.

201.3.212
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.

201.3.213
*** 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

201.3.214
*** ROBOTIC SURGICAL INSTRUMENT**
device intended by the MANUFACTURER 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 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.