# SLOVENSKI STANDARD
# SIST EN IEC 80601-2-77:2021

**01-december-2021**

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**Medicinska električna oprema - 2-77. del: Posebne zahteve za osnovno varnost in bistvene lastnosti robotsko podprte kirurške opreme (IEC 80601-2-77:2019)**

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)

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)



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)



**Ta slovenski standard je istoveten z:** **EN IEC 80601-2-77:2021**

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**ICS:**

| | | |
|---|---|---|
| 11.040.30 | Operacijski instrumenti in materiali | Surgical instruments and materials |

**SIST EN IEC 80601-2-77:2021** **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN IEC 80601-2-77

October 2021

ICS 11.040.01, 11.040.30

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.



Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.



This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.



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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

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

## 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) |

# 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.

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| *Addition* | | | | |
| IEC 60601-1 | 2005 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | EN 60601-1 | 2006 |
| - | - | | + corrigendum Mar. | 2010 |
| + A1 | 2012 | | + A1 | 2013 |
| - | - | | + A12 | 2014 |
| *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 | EN 60601-1-2 | 2015 |
| 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 |
| + A1 | 2013 | | + A1 | 2015 |
| IEC 62366-1 | 2015 | Medical devices - Part 1: Application of usability engineering to medical devices | EN 62366-1 | 2015 |
| - | - | | + AC | 2015 |

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 ASSISTES

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.01; 11.040.30

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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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.
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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: