EESTI STANDARD EVS-EN IEC 80601-2-77:2021+A1:2023

Sisaldab värvilisi lehekülgi
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ELEKTRILISED MEDITSIINISEADMED. OSA 2-77: ERINÕUDED ROBOTISEERITUD KIRURGILISTE SEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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 + IEC 80601-2-77:2019/AMD1:2023)

EVS EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 80601-2-77:2021 +A1:2023 sisaldab Euroopa standardi EN IEC 80601-2-77:2021 ja selle muudatuse A1:2023 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 80601-2-77:2021+A1:2023 consists of the English text of the European standard EN IEC 80601-2-77:2021 and its amendment A1:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.10.2021, muudatus A1 22.12.2023.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 01.10.2021, for A1 22.12.2023.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1] <A1>. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A1] <A1>. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.01, 11.040.30

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NORME EUROPÉENNE

EUROPÄISCHE NORM

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October 2021, December 2023

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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 + IEC 80601-2-77:2019/AMD1:2023)

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 + IEC 80601-2-77:2019/AMD1:2023)

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 + IEC 80601-2-77:2019/AMD1:2023)

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Europäisches Komitee für Elektrotechnische Normung

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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
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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)

A1 Amendment A1 European foreword

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.

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The text of the International Standard IEC 80601-2-77:2019/AMD1:2023 was approved by CENELEC as a European Standard without any modification. A1

IEC 80601-2-77

Edition 1.1 2023-11
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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+AMD1:2023-11 CSV(en-fr)

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

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

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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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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

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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

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- replaced by a revised edition, or
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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.

A1 Amendment A1 FOREWORD

Amendment 1 to IEC 80601-2-77:2019 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.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/2070/FDIS	62D/2102/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

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A1

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.

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

2 Numbers in square brackets refer to the Bibliography.

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1881/RR.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general 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.

〖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.

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3 〖A1〗 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〉

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 56.

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