ICS 11.040.01, 11.040.30 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2024

STN	**Zdravotnícke elektrické zariadenia Časť 2-77: Osobitné požiadavky na základnú bezpečnosť a základné výkony roboticky podporovaných chirurgických zariadení Zmena A1**	**STN EN IEC 80601-2-77/A1** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/24

STN EN IEC 80601-2-77 z januára 2022 sa bez tejto zmeny A1 môže používať do 20. 12. 2026.

Obsahuje: EN IEC 80601-2-77:2021/A1:2023, IEC 80601-2-77:2019/Amd 1:2023

138435

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-77:2021/A1

December 2023

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/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/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/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 80601-2-77:2021; it was approved by CENELEC on 2023-12-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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

Ref. No. EN IEC 80601-2-77:2021/A1:2023 E

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.

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

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/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

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.cencenelec.eu.

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

Publication	Year	Title	EN/HD	Year
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
+ A1	2020		+ A1	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
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ A1	2020		+ A1	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
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021

IEC 80601-2-77

Edition 1.0 2023-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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(en-fr)

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IEC 80601-2-77

Edition 1.0 2023-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

AMENDMENT 1

FOREWORD

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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/.

The committee has decided that the contents of this document 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, or
- revised.

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 or ISO 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 committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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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.

201.1 Scope, object and related standards

Replace the text of the existing footnote with the following:

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*.