SLOVENSKI STANDARD

SIST EN IEC 60601-2-76:2019/oprA1:2022

01-julij-2022

Medicinska električna oprema - 2-76. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za hemostazijo z nizkoenergijskim ioniziranim plinom - Dopolnilo A1

Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

Medizinische elektrische Geräte - Teil 2-76: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten zur Koagulation mittels ionisierten Gasen

Appareils électromédicaux - Partie 2-76: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d’hémostase à gaz ionisé à faible pouvoir calorifique

Ta slovenski standard je istoveten z: EN IEC 60601-2-76:2019/prA1:2022

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN IEC 60601-2-76:2019/oprA1:2022 **en**

62D/1952/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-76/AMD1 ED1**	
DATE OF CIRCULATION: **2022-05-20**	CLOSING DATE FOR VOTING: **2022-08-12**
SUPERSEDES DOCUMENTS: **62D/1811A/RR**	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ 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.

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

IEC 60601-2-76 ED1 is being amended to be in alignment with the IEC 60601-1 series amendment projects. Refer to 62D/1792/DC and 62D/1808/INF documents for the project maintenance decision.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment

AMENDMENT 1

FOREWORD

This Amendment has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Draft	Report on voting
62D/****/NP	62D/****/RV

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.

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.

A bilingual version of this publication may be issued at a later date.

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.

The National Committees are requested to note that for this document the stability date is 20xx.

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

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 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 29 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 may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D1808/INF. The review report for this amendment is 62D/1811/RR

201.1 Scope, object and related standards

Replace the text in footnote 1 with:

The general standard is IEC 60601-1:2005 and 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.

201.1.4 Particular standards

Replace the existing text of the 3rd paragraph with the following:

For brevity, IEC 60601-1:2005 and 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.

201.2 Normative references

Replace the existing reference with the following:

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

Replace the existing first paragraph with:

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.

Replacement of existing NOTE 1 by the following with:

NOTE1 Where the terms “voltage” and “current” are used in this document, they mean the RMS values of a voltage or current unless stated otherwise. When a direct voltage and current is measured, the voltage or current is averaged over 1 s with a sampling rate of at least 10^4 sample/s. When an alternating or composite voltage or current is measured, it is averaged over 20 periods with an obtained number of samples of at least 10^4.

Example: When a frequency of measuring current is 100 kHz, a sampling rate of 5×10^7 sample/s shall be used. 20 periods × 1 / (100×10^3) s × 5×10^7 sample/s = 1×10^4 samples.