SLOVENSKI STANDARD
SIST EN IEC 80601-2-59:2019/oprA1:2021

01-november-2021

Dopolnilo A1 - Medicinska električna oprema - 2-59. del: Posebne zahteve za osnovno varnost in bistvene lastnosti presejalnih termografov za spremljanje človekove temperature pri mrzlici

Amendment 1 - Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

Medizinische elektrische Geräte - Teil 2-59: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Wärmebildkameras für Reihenuntersuchungen von Menschen auf Fieber

Appareils électromédicaux - Partie 2-59: Exigences particulières pour la sécurité de base et les performances essentielles des imageurs thermiques pour le dépistage des humains fébriles

Ta slovenski standard je istoveten z: **EN IEC 80601-2-59:2019/prA1:2021**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN IEC 80601-2-59:2019/oprA1:2021 **en**

62D/1892/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-59/AMD1 ED2**	
DATE OF CIRCULATION: **2021-09-10**	CLOSING DATE FOR VOTING: **2021-12-03**
SUPERSEDES DOCUMENTS: **62D/1888/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

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 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

IEC 80601-2-59:2017 ED2 is being amended to align to the Amendment projects of the IEC 60601 -1 series. Refer to IEC 62D/1808/INF and 62D/1828/AC for more information.

FOREWORD

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

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

Draft	Report on voting
62D/XXXX/FDIS	62D/XXXX/RVD

Full information on the voting for its approval 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.

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.

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.

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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 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/1888/RR.

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Replace the text in footnote 2 with:

"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*".

201.1.3 Collateral standards

In the second paragraph, replace the first sentence with:

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.

201.1.4 Particular standards

In the third paragraph, replace the first sentence with:

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

In the eighth paragraph, replace "3.147" with "3.154".

201.2 Normative references

Replace the first four entries with:

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 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

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