SLOVENSKI STANDARD
SIST EN IEC 80601-2-60:2020/oprA1:2025

01-maj-2025

Medicinska električna oprema - 2-60. del: Posebne zahteve za osnovno varnost in bistvene lastnosti zobozdravstvene opreme - Dopolnilo A1

Amendment 1 - Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

Medizinische elektrische Geräte - Teil 2-60: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Dental-Geräten

Appareils électromédicaux - Partie 2-60: Exigences particulères pour la sécurité de base et les performances essentielles des équipements dentaires

Ta slovenski standard je istoveten z: **EN IEC 80601-2-60:2020/prA1:2025**

ICS:

11.060.20	Zobotehnična oprema	Dental equipment

SIST EN IEC 80601-2-60:2020/oprA1:2025 **en**

62D/2209/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 80601-2-60/AMD1 ED2	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2025-03-21	**2025-06-13**
SUPERSEDES DOCUMENTS:	
62D/2150/CD, 62D/2206/CC	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT:	SECRETARY:
United States of America	Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED:	
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.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

AMENDMENT 1

FOREWORD

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International standard IEC 80601-2-60 has been prepared by a Joint Working Group of subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and subcommittee 6: Dental equipment, of ISO technical committee 106: Dentistry.

This document amends IEC 80601-2-60:2019.

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

Draft	Report on voting
62D/XX/XXXX	62D/XX/XXX

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 publication is published as a double logo standard.

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 seventeen 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 series, 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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

AMENDMENT 1

201.1.4 Particular standards

Replace the third paragraph with the following:

For brevity, IEC 60601-1:2005, 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

Delete normative reference:

IEC 60825-1:2014, Safety of laser products – Part 1: Equipment classification and requirements

IEC 60601-2-22:2007, Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-22:2007/AMD1:2012

Change the existing dated references with the following:

ISO 7494-1:2018*, Dentistry — Stationary dental units and dental patient chairs — Part 1: General requirements*

In Clause 201.2 normative References, change the following dated references

IEC 60601-2-2:2017/AMD1:2023, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60664-1:2020, Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests

IEC 61810-1:2015/AMD1:2019, *Electromechanical elementary relays – Part 1: General and safety requirements*

ISO 1942, *Dentistry – Vocabulary*