SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-57:2022

01-september-2022

Medicinska električna oprema - 2-57. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme z nelaserskim svetlobnim virom, namenjene za terapevtsko, diagnostično, nadzorovalno in kozmetično/estetsko uporabo

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Medizinische elektrische Geräte - Teil 2-57: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten mit Nicht-Laser-Lichtquellen für die Anwendung in der Therapie, Diagnose, Überwachung und für kosmetische/ästhetische Zwecke

Appareils électromédicaux - Partie 2-57: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à source de lumière non-laser prévus pour des utilisations thérapeutiques, de diagnostic, de surveillance et de cosmétique/esthétique

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-57:2022**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
11.040.60	Terapevtska oprema	Therapy equipment

oSIST prEN IEC 60601-2-57:2022 **en**

76/706/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-57 ED2	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-06-24	**2022-09-16**
SUPERSEDES DOCUMENTS:	
76/696/CD, 76/703/CC	

IEC TC 76 : OPTICAL RADIATION SAFETY AND LASER EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Mr William Ertle
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62A	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 **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.	☐ 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:

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

PROPOSED STABILITY DATE: 2026

NOTE FROM TC/SC OFFICERS:

History

v17: 27-Feb-2022; the initial document is the WORD file, which was submitted as a CD, 76/696/CD, closing date 2022-02-18. Comments have been received from the NCs and from SC62D. A total of 60 comments (AU1, GB 4, IR 8, JP 15, SC62D 32) were collated and numbered, file name 220419_CC_76_696_CD_NC including SC62D comments_observed.docx. The observations have been included in comment bubbles, leaving the text body including the line numbering almost unaltered.

v18: Edits were done, technical changes remain marked. LC's comments, received March 19th 2022, were implemented in this v18. Draft to be distributed among WG4 for further input, due April 30, 2022.

v19: Markings were cleaned; comment bubbles were removed. Comments from WG4 experts have been observed and included as marked.

v19.1: Clause 201.10.102 Output uniformity, was reconsidered, Refer to Comments GB3, GB4. WG4 comments were considered.

v20: v19.1 cleaned.

v20.1: Comments from YL 220425, as observed by the convenor, implemented, marked.

v21: v20.1 cleaned. Approved by the voting majority of the experts of WG4, V21 is now submitted as a CDV. It is intended that the NC comments to be received will be observed during the WG4 meeting along with the TC76 meeting planned to take place in September 19-23, 2022, in Sydney. To inform the NCs about the past of this draft, its history is retained in the CDV.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT

Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

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International Standard IEC 60601-2-57 has been prepared by IEC technical committee TC 76: Optical radiation safety and laser equipment

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

FDIS	Report on voting

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “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 publication will remain unchanged until the stability date1 indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

1 The National Committees are requested to note that for this publication the stability date is [....]

INTRODUCTION

This particular standard amends and supplements IEC 60601-1:2005+AMD1:2012+AMD2:2020 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*.

This edition of the standard constitutes a major review of the previous edition and covers the recent development of LS EQUIPMENT. It now includes the Risk Group 1C (RG-1C). LS EQUIPMENT of RG-1C incorporates technical means which inhibit emission into free space when the APPLICATOR is not in GOOD CONTACT with the target tissue.

It now excludes LS EQUIPMENT of RG-1 and RG-2 as these are assumed to represent no hazard. RG-1C is only included if the incorporated light source is of RG-3.

This edition of the standard clarifies its relation to the concept of Risk Groups (RGs), as introduced in IEC 62471-1. The information about classification and rules for the determination of Risk Groups is now linked to IEC 62471-1.

Although this particular standard was applicable to LS EQUIPMENT containing UV sources, more emphasis was given to UV applications of the equipment than in the previous edition.

This edition of the standard now excludes LS EQUIPMENT which is intended to be used on animals.

The requirements of this particular standard should be taken as the minimum to comply with, in order to achieve a reasonable level of safety and reliability during operation and application of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

An asterisk (*) notes clauses for which there is rationale comment in annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of this particular standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

MEDICAL ELECTRICAL EQUIPMENT

Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

201.1 Scope, object and related standards

Clause 1 of the general standard[2)] applies, except as follows:

201.1.1 *Scope

Replacement:

This particular Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment incorporating one or more sources of OPTICAL RADIATION in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and intended to create photobiological effects in humans for therapeutic, diagnostic, monitoring, or cosmetic/aesthetic applications; hereafter referred to as light source equipment (LS EQUIPMENT).

This particular standard applies to LS EQUIPMENT of Risk Group 1C (but only if the embedded source of OPTICAL RADIATION is of RG-3), and of Risk Group 3.

Note: Classification rules for Risk Groups, see 201.6.1.102

This particular standard does not apply to equipment for sun tanning such as sunlamp products, for ophthalmic instruments, for lighting purposes in medical/cosmetic environments, for photography/video, for equipment which produces visual or non-visual effects such as circadian entrainment, or for infant phototherapy and infant radiant warmers. This particular standard does not apply to sterilisation equipment.

This particular standard does not apply to home-use appliances. It does not apply to home light therapy equipment, such as equipment which is intended to be used in the HOME HEALTHCARE ENVIRONMENT and is typically used by a LAY OPERATOR.

Note: Home-use appliances are covered by IEC 60335-2-113:2016. Appliances for skin exposure to OPTICAL RADIATION, such as sunlamp products are covered by IEC 60335-2-27. Home light therapy equipment providing light therapy by means of eye-mediated photobiological effects, which can be visual or non-visual, and skin-mediated photobiological effects, possible applications including pain relief, psoriasis treatment, and treatment of winter depression (SAD), is covered by IEC 60601-2-83:2019. See Bibliography.

Note: Safety requirements in this particular standard are intended to address only HAZARDS to the eye and superficial tissues including skin or mucosa. As OPTICAL RADIATION does not penetrate more than a few mm in tissue, HAZARDS to underlying tissues are not considered.

201.1.2 Object

Replacement:

The objects of this particular standard are:

– to establish the risk from OPTICAL RADIATION, specify basic safety and essential performance requirements for LS EQUIPMENT;

– to specify requirements for the MANUFACTURER to supply information and establish procedures so that proper precautions can be adopted;

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2) The general standard is IEC 60601-1:2005, including Amendment 1:2012 and Amendment 2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

– to provide warning to individuals of risks associated with accessible OPTICAL RADIATION from LS EQUIPMENT through signs, labels and instructions;

– to reduce the possibility of adverse effects and injuries by minimizing unnecessary accessible OPTICAL RADIATION; to provide means of improved control of the HAZARDS related to OPTICAL RADIATION through engineering controls;

– to specify requirements for protection against other HAZARDS resulting from the operation and use of LS EQUIPMENT.

201.1.3 Collateral standards

Addition:

This particular standard refers to the applicable collateral standards that are listed in Clause 2 of the general standard.

All collateral standards apply, except IEC 60601-1-11 which does not apply.

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, IEC 60601-1 is 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 particular standard 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 3.139, additional definitions in this particular standard 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 standard" 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

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60947-3, Low voltage switchgear and controlgear – Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units

IEC 62471-1:xxxx, Photobiological safety of lamps and lamp systems - Part 1: General requirements and Risk Group determination [currently under development]

ISO 3864-2, Graphical symbols – Safety colours and safety signs – Part 2: Design principles for product safety labels

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and the following apply.

Addition:

201.3.201
APPLICATOR
A mechanical or optical means of transferring OPTICAL RADIATION from the source to the human tissue

201.3.202
CONTINUOUS OPERATION
operation with a continuous OPTICAL RADIATION output for a duration equal to or greater than 0,25 s for wavelengths in the range 400 to 700 nm and 10 s for all other wavelengths

[SOURCE: IEC 60601-1, 3.18, modified]

201.3.203
EMERGENCY STOP
device intended to stop the LS EQUIPMENT OUTPUT immediately in case of emergency

201.3.204
EMISSION APERTURE
opening or window through which the OPTICAL RADIATION is emitted

201.3.205
EXPOSURE DURATION
duration of a PULSE, or series, or train of PULSES or of continuous emission of OPTICAL RADIATION incident upon the human body during operation, maintenance or servicing of LS EQUIPMENT

Note to entry: For a single PULSE, this is the duration between the half-peak power point of the leading edge and the corresponding point on the trailing edge. For a train of PULSES (or subsections of a train of PULSES), this is the