IEC 60601-2-57

Edition 2.0 2023-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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, cosmetic and aesthetic use

Appareils électromédicaux – Partie 2-57: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à source de lumière non laser destinés à des usages thérapeutiques, de diagnostic, de surveillance, cosmétiques et esthétiques

IEC 60601-2-57:2023-07(en-fr)

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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, cosmetic and aesthetic use

FOREWORD

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

This second edition cancels and replaces the first edition published in 2011. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) This edition 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.

b) 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.

c) It clarifies its relation to the concept of Risk Groups (RGs), as introduced in IEC 62471.

d) Although the previous edition was applicable to LS EQUIPMENT containing UV sources, more emphasis is given to UV applications of the equipment in this edition.

e) This edition excludes LS EQUIPMENT which is intended to be used on animals.

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

Draft	Report on voting
76/734/FDIS	76/737/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 International Standard 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.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, in this document 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 document 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 2:2021. 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 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.

IMPORTANT – The "colour inside" logo on the cover page of this document 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

This document amends and supplements 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*.

The requirements of this document 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 or 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 document 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, cosmetic and aesthetic use

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 *Scope

Replacement:

This part of IEC 60601-2 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, and cosmetic or aesthetic applications; hereafter referred to as light source equipment (LS EQUIPMENT).

This document applies to LS EQUIPMENT of RISK GROUP 1C if the incorporated source of OPTICAL RADIATION is of RG-3, and of Risk Group 3.

NOTE 1 For classification rules for Risk Groups, see 201.6.1.102.

This document does not apply to equipment for sun tanning such as sunlamp products, for ophthalmic instruments, for lighting purposes in medical or 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 document does not apply to sterilization equipment.

This document 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 2 Home-use appliances are covered by IEC 60335-2-113:2016 [1][1]. Appliances for skin exposure to OPTICAL RADIATION, such as sunlamp products, are covered by IEC 60335-2-27 [2]. 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), are also covered by IEC 60601-2-83:2019 [3].

NOTE 3 Safety requirements in this document 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 millimetres in tissue, HAZARDS to underlying tissues are not considered.

[1] Numbers in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

The objects of this document 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;

– 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 document refers to the applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

All collateral standards apply, except IEC 60601-1-11.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601 1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.139, additional definitions in this document 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 final digit(s) of the collateral standard document number, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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, *Photobiological safety of lamps and lamp systems*

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

201.3 Terms and definitions

Clause 3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Replacement:

201.3.18
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 nm to 700 nm and 10 s for all other wavelengths

201.3.73
OPERATOR
person handling the LS EQUIPMENT

Note 1 to entry: In general, the OPERATOR controls the delivery of optical radiation. The OPERATOR can appoint one or more other persons who assist with the selection and/or setting of the parameters. The more general term "user" is interpreted in its generic meaning. The meaning of "user" may include the definition of "OPERATOR".

201.3.76
PATIENT
person undergoing the treatment or diagnostic procedure

Addition:

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

201.3.202
EMERGENCY STOP
device intended to stop the LS EQUIPMENT OUTPUT immediately in case of emergency

201.3.203
EMISSION APERTURE
opening or window through which the OPTICAL RADIATION is emitted

201.3.204
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 1 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 duration between the first half-peak power point of the leading PULSE and the last half-peak power point of the last PULSE.

Note 2 to entry: EXPOSURE DURATION is measured in seconds (s).

201.3.205
GOOD CONTACT
state that is established when the APPLICATOR of the LS EQUIPMENT which is classified RG-1C is positioned at the target tissue so as to effectively prevent HAZARDOUS eye exposure to STRAY OPTICAL RADIATION

201.3.206
LS EQUIPMENT
ME EQUIPMENT which incorporates one or more sources of OPTICAL RADIATION in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and which is intended to create photobiological effects for therapeutic, diagnostic, monitoring, and cosmetic or aesthetic applications

201.3.207
LS EQUIPMENT OUTPUT
radiant power, radiant energy, irradiance or radiant exposure emitted by and as relevant to the LS EQUIPMENT

201.3.208
OCULAR EXPOSURE LIMIT
maximum level of exposure to the eye that is not expected to result in adverse biological effects

Note 1 to entry: OCULAR EXPOSURE LIMITS can be found in ICNIRP Guidelines:
https://www.icnirp.org/cms/upload/publications/ICNIRPVisible_Infrared2013.pdf [4]
https://www.icnirp.org/cms/upload/publications/ICNIRPUV2004.pdf [5].

201.3.209
OCULAR HAZARD DISTANCE
OHD
shortest distance from an EMISSION APERTURE at which the projected radiant exposure or irradiance for a given EXPOSURE DURATION equals the applicable OCULAR EXPOSURE LIMIT

Note 1 to entry: OCULAR HAZARD DISTANCE is measured in metres (m).

201.3.210
OPTICAL RADIATION
electromagnetic radiation with wavelengths between 100 nm and 1 mm

201.3.211
PULSE
PULSED
emission with the duration shorter than 0,25 s in the range 400 nm to 700 nm and shorter than 10 s at all other wavelengths

201.3.212
PULSE DURATION
time increment measured between the half-peak (50 %) power points at the leading and trailing edges of a PULSE

Note 1 to entry: PULSE DURATION is measured in seconds (s).

201.3.213
PULSE INTERVAL
time between the end of one PULSE and the onset of the following PULSE, measured at the 50 % trailing and leading edges, respectively

Note 1 to entry: PULSE INTERVAL is measured in seconds (s).

201.3.214
PULSE TRAIN
series of PULSES where the total on time of the PULSES in any series of PULSES in any single exposure sequence does not exceed 0,25 s for wavelengths in the range 400 nm to 700 nm and does not exceed 10 s for all other wavelengths

201.3.215
READY
condition in which the LS EQUIPMENT is capable of emitting OPTICAL RADIATION and emission takes place when the control switch is activated

201.3.216
READY INDICATOR
visible or audible signal that indicates when LS EQUIPMENT is in the READY condition

Note 1 to entry: The purpose of the READY INDICATOR is to make all persons present in the vicinity aware of the need to take precautions against HAZARDOUS OPTICAL RADIATION.

201.3.217
RISK GROUP 1C
RG-1C
classification of LS EQUIPMENT that contains a source of up to Risk Group 3, that is used in contact with the skin, and that has engineering controls which contain the optical radiation so that any leakage does not exceed RG-1 in any of the hazard spectral regions, when assessed at 0,5 m from the APPLICATOR

201.3.218
SET VALUE
intended LS EQUIPMENT OUTPUT incident on the TREATMENT AREA, as set by the OPERATOR

201.3.219
STAND-BY
condition in which the power supply (SUPPLY MAINS or battery) is connected, and the SUPPLY MAINS switch activated, and the LS EQUIPMENT is not capable of emitting the OPTICAL RADIATION even if the control switch is activated

201.3.220
STRAY OPTICAL RADIATION
OPTICAL RADIATION that is unintentionally emitted from the EMISSION APERTURE or from the target tissue, including scattered, reflected and leakage radiation

201.3.221
TREATMENT AREA
extent of the field over which the OPTICAL RADIATION is intended to produce a therapeutic response

Note 1 to entry: For LS EQUIPMENT where OPTICAL RADIATION exposure is carried out in contact with the surface to be treated, this is equivalent to the device aperture.

201.3.222
ULTRAVIOLET
UV
OPTICAL RADIATION having wavelengths between 100 nm and 400 nm

Note 1 to entry: For ULTRAVIOLET (UV) radiation, the range between 100 nm and 400 nm is commonly subdivided into: UV-A, from 315 nm to 400 nm; UV-B, from 280 nm to 315 nm; and UV-C, from 100 nm to 280 nm. These designations for the UV are not precise limits, particularly for photobiological effects. In some fields of photobiology the wavelength bands are taken from 200 nm to 290 nm, from 290 nm to 320 nm, and from 320 nm to 400 nm. Sometimes these are (incorrectly) called by the names UV-A, UV-B and UV-C, respectively.

201.3.223
VISIBLE
VIS
OPTICAL RADIATION having wavelengths between 380 nm and 780 nm

Note 1 to entry: There are no precise limits for the spectral range of VISIBLE radiation since they depend on the amount of radiant power reaching the retina and the responsivity of the observer, The lower limit is generally taken between 360 and 400 nm and the upper limit between 760 and 830 nm.

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

The requirements for manufacturers are summarized in Annex BB.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.6.1 General

Addition:

201.6.1.101 Classification responsibilities

The LS EQUIPMENT shall be classified by the manufacturer according to the classification rules as defined in IEC 62471, if the Risk Group is not 1C.

201.6.1.102 Classification rules

LS EQUIPMENT is different from lamps used in general lighting, as the radiation is used for treatment or diagnosis purposes on humans rather than general exposure purposes such as general lighting, illumination or disinfection. To be able to attribute a Risk Group to LS EQUIPMENT, its handpieces, APPLICATORS or its incorporated freely emitting sources shall be considered as "lamps" as covered by IEC 62471.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Addition:

201.7.2.101 Labels and marking of LS EQUIPMENT

201.7.2.101.1 Specification of labels and marking

The MANUFACTURER of LS EQUIPMENT shall provide risk group marking. The label shall include the designated risk group and wording according to Table 201.104.

Wording that conveys an equivalent meaning is acceptable.