IEC 60601-2-57

Edition 1.0 2011-01

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 and cosmetic/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 prévus pour des utilisations thérapeutiques, de diagnostic, de surveillance et de cosmétique/esthétique

IEC 60601-2-57:2011

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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
76/438/FDIS	76/441/RVD

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 date 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.

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

This particular standard amends and supplements IEC 60601-1:2005 (third edition): *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*.

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[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International 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 non-visual photobiological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications; hereafter referred to as light source equipment (LS EQUIPMENT).

This particular standard does not apply to equipment for sun tanning, for ophthalmic instruments or for infant phototherapy.

NOTE Safety requirements in this particular standard are intended to address only HAZARDS to the eye and skin; hazards to internal tissues are not included in its scope.

LS EQUIPMENT may consist of a single or multiple sources of OPTICAL RADIATION, with or without power supply, or may be incorporated into a complex system that includes optical, electrical or mechanical systems or sources of other radiation.

NOTE Annexes AA to EE have been included for purposes of general guidance and to illustrate many typical cases. However, the annexes should not be regarded as definitive or exhaustive.

201.1.2 Object

Replacement:

The objects of this particular standard are:

– to establish optical radiation safety, 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 HAZARDS associated with accessible OPTICAL RADIATION from LS EQUIPMENT through signs, labels and instructions;

– to reduce the possibility of injury by minimizing unnecessary accessible OPTICAL RADIATION; to provide means of improved control of the HAZARDS related to OPTICAL RADIATION through protective features and to assist safe use of LS EQUIPMENT;

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

– to protect persons against other HAZARDS resulting from the operation and use of LS EQUIPMENT.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in Clause 201.2 of this particular standard.

All published collateral standards in the IEC 60601 series apply as published.

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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 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 on page 33.

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, *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

NOTE An index of defined terms used in this document is found beginning on page 34.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, 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 to 700 nm and 10 s for all other wavelengths

Addition:

201.3.201
ANGLE OF ACCEPTANCE
γ
plane angle within which a detector responds to OPTICAL RADIATION

NOTE 1 THE ANGLE OF ACCEPTANCE may be controlled by apertures or optical elements.

NOTE 2 The ANGLE OF ACCEPTANCE is sometimes referred to as the field-of-view.

SI Unit: radian (rad)

201.3.202
ANGULAR SUBTENSE
α
visual angle subtended by the source or apparent source at the eye of an observer or at the point of measurement

NOTE In this particular standard subtended angles are denoted by the full included angle, not the half angle.

SI Unit: radian (rad)

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
EMISSION LIMIT
maximum accessible emission permitted for a particular risk group

201.3.206
EXPOSURE LIMIT
maximum level of exposure of the eye or skin that is not expected to result in adverse biological effects

NOTE EXPOSURE LIMITS are shown in Table BB.1

201.3.207
EXPOSURE TIME
PULSE DURATION (for a single pulse), duration of a pulse train or of a continuous emission of optical radiation incident upon the human or animal body during operation, maintenance or servicing of LS EQUIPMENT

SI Unit: second (s)

201.3.208
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 non-visual photo-biological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications

201.3.209
LS EQUIPMENT OUTPUT
either radiant power or radiant energy emitted by the LS EQUIPMENT

201.3.210
OCULAR HAZARD DISTANCE (OHD)
distance from an EMISSION APERTURE within which the projected radiant exposure or irradiance for a given EXPOSURE TIME equals the applicable EXPOSURE LIMIT value for the eye

SI Unit: m

201.3.211
OPTICAL RADIATION
electromagnetic radiation with wavelengths between 100 nm and 1 mm

201.3.212
PULSE/PULSED
accessible emission with the duration shorter than 0,25 s in the range 400 nm to 700 nm and shorter than 10 s at other wavelengths

201.3.213
PULSE DURATION
time increment measured between the half peak (50 %) power points at the leading and trailing edges of a PULSE

SI Unit: second (s)

201.3.214
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

SI Unit: second (s)

201.3.215
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

201.3.216
READY
ready condition: the LS EQUIPMENT is capable of emitting OPTICAL RADIATION when the control switch is activated

201.3.217
READY INDICATOR
visible or audible signal that indicates when LS EQUIPMENT is in the ready condition; 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

201.3.218
SET VALUE
intended LS EQUIPMENT output incident on the treatment area, as set by the OPERATOR

201.3.219
SHORT WAVELENGTH BOUNDARY
wavelength at the 50 % point of the emission spectrum at its short wavelength edge

SI Unit: nm

201.3.220
SKIN HAZARD DISTANCE
distance from an EMISSION APERTURE within which the projected radiant exposure or irradiance for a given EXPOSURE TIME equals the applicable EXPOSURE LIMIT value for the skin

201.3.221
STAND-BY
stand-by condition: the power supply (SUPPLY MAINS or battery) is connected and the SUPPLY MAINS switch activated; the LS EQUIPMENT is not capable of emitting the OPTICAL RADIATION even if the control switch is activated

201.3.222
USER
person, who controls the delivery of the LS EQUIPMENT OUTPUT to the treatment area

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.1 General

Addition:

201.6.1.101 *Classification responsibilities

The MANUFACTURER shall provide the classification of LS EQUIPMENT.

The LS EQUIPMENT shall be classified on the basis of the emission of the accessible OPTICAL RADIATION over the full range of capability during operation at any time after manufacture and under every reasonably foreseeable single fault condition.

NOTE Classification of LS EQUIPMENT provides the basis for the range of control measures which the USER should take in order to minimize risk of excessive exposure to OPTICAL RADIATION.

201.6.1.102 *Classification rules

The classification is used to indicate the potential risk of adverse health effects.

For the purpose of classification rules, the following ranking of the risk groups, in order of increasing risk at a distance of 200 mm from the EMISSION APERTURE, shall be used. Assessment shall be made by the method specified in IEC 62471:

– Exempt Group – no photo-biological HAZARD;
– Risk Group 1 – low risk group; the risk is limited by normal behavioural limitations on exposure;
– Risk Group 2 – moderate risk group; the risk is limited by the aversion response to very bright light sources. However, such reflex responses do not occur universally;
– Risk Group 3 – high risk group; LS EQUIPMENT that may pose a risk even for momentary or brief exposure.

NOTE Risk Groups are described in IEC 62471.

201.6.1.102.1 Classification of continuous operation LS EQUIPMENT

a) Exempt Risk Group

CONTINUOUS OPERATION LS EQUIPMENT shall be assigned to the Exempt Risk Group if its accessible emission does not exceed the EMISSION LIMITS in any of the HAZARD spectral regions of Table 201.101 when assessed for the time criteria of Table 201.102 and the ANGLE OF ACCEPTANCE γ specified in Table 201.103.

b) Risk Group 1

CONTINUOUS OPERATION LS EQUIPMENT shall be assigned to Risk Group 1 if its accessible emission exceeds one or more EMISSION LIMITS for the Exempt Group as defined in Table 201.101 and does not exceed EMISSION LIMITS of Risk Group 1 in any of the HAZARD