

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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
essentiels des appareils à source de lumière non-laser prévus pour des
utilisations thérapeutiques, de diagnostic, de surveillance et de
cosmétique/esthétique**



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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

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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.

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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.

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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

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ 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 photo-biological 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;

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.