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Standards

Irish Standard
I.S. EN 60601-2-57:2011

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
(IEC 60601-2-57:2011 (EQV))

I.S. EN 60601-2-57:2011

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English version

**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
(IEC 60601-2-57:2011)**

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
(CEI 60601-2-57:2011)

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
(IEC 60601-2-57:2011)

This European Standard was approved by CENELEC on 2011-03-07. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 76/438/FDIS, future edition 1 of IEC 60601-2-57, prepared by IEC TC 76, Optical radiation safety and laser equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-57 on 2011-03-07.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2011-12-07
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2014-03-07

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-57:2011 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Addition:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60947-3	-	Low-voltage switchgear and controlgear - Part 3: Switches, disconnectors, switch- disconnectors and fuse-combination units	EN 60947-3	-
IEC 62471 (mod)	-	Photobiological safety of lamps and lamp systems	EN 62471	-
ISO 3864-2	-	Graphical symbols - Safety colours and safety - signs - Part 2: Design principles for product safety labels		-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EU Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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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.
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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 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*.

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