IEC 60601-2-83

Edition 1.1 2022-12
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

Appareils électromédicaux –
Partie 2-83: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de luminothérapie à domicile



IEC 60601-2-83:2019-05+AMD1:2022-12 CSV(en-fr)



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

FOREWORD

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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-2-83 edition 1.1 contains the first edition (2019-05) [documents 62D/1682/FDIS and 62D/1687/RVD] and its amendment 1 (2022-12) [documents 62D/1931/CDV and 62D/1962/RVC].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 60601-2-83 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD 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 particular standard 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. 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 the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under 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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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 part of IEC 60601 has been prepared to provide safety requirements for HOME LIGHT THERAPY EQUIPMENT, based on IEC 60601-1 and its collateral standards. This equipment is intended to be used in the HOME HEALTHCARE ENVIRONMENT and is typically used by a LAY OPERATOR, who is familiar with this environment and the specific characteristics of lamps. Some requirements of IEC 60601-1-11 are amended to better suit this type of ME EQUIPMENT and the environment in which it is used.

HOME LIGHT THERAPY EQUIPMENT provides light therapy by means of eye-mediated photobiological effects (which can be visual or non-visual) and skin-mediated photobiological effects (non-visual only). Possible applications include pain relief, psoriasis treatment, and treatment of winter depression (seasonal affective disorder, SAD).

This document is developed because IEC 60601-2-57 [2][1] only covers light source equipment providing light therapy by means of non-visual photobiological effects, which excludes an important group of light source equipment creating visual photobiological effects. Further, IEC 60601-2-57 focuses on radiation aspects and related markings but hardly provides any product-specific safety requirements. IEC 60335-2-113 [1] provides such specific requirements for household appliances with light sources for cosmetic and beauty care, but does not apply to equipment with medical purposes. IEC 60601-2-83 addresses all safety requirements for HOME LIGHT THERAPY EQUIPMENT and has taken over relevant requirements from [1] and [2].

~~This document is the first edition of IEC 60601-2-83. It is aligned with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, and IEC 60601-1-11:2015.~~

This document is aligned with:

– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020;
– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020;
– IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020; and
– IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020.

INTRODUCTION to Amendment 1

The first edition of IEC 60601-2-83 was published in May 2019. Since the publication of IEC 60601-2-83:2019, the IEC Subcommittee (SC) 62A has published amendments to the general and collateral standards, thus requiring amendments to the particular standards for alignment as discussed at the IEC SC 62D meeting in Shanghai, China, in October 2019.

Because this is an amendment to IEC 60601-2-83:2019, the style in force at the time of publication of IEC 60601-2-83 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2021 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified

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

the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This part of IEC 60601 is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HOME LIGHT THERAPY EQUIPMENT, intended for use in the HOME HEALTHCARE ENVIRONMENT. HOME LIGHT THERAPY EQUIPMENT is typically used by a LAY OPERATOR.

The scope of this document includes all light sources except laser.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of HOME LIGHT THERAPY 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 Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, and IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 206 and 211, respectively. IEC 60601-1-3, IEC 60601-1-8, IEC 60601-1-10 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 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

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2 The general standard is 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*.

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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are 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 document 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 from 3.1 through 3.147, 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 number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" 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:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

ISO 15223-1:~~2016~~2021, *Medical devices – Symbols to be used with ~~medical device labels, labelling and~~ information to be supplied by the manufacturer – Part 1: General requirements*

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

ISO 3864-1:2011, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs and safety markings*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-11 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 34.

Addition:

201.3.201
*** ANGLE OF ACCEPTANCE**

γ
plane angle within which a detector responds to OPTICAL RADIATION

Note 1 to entry: The ANGLE OF ACCEPTANCE can be controlled by apertures or optical elements.

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

[SOURCE: IEC 60601-2-57:2011, 201.3.201, modified – Unit deleted.]

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 1 to entry: In this particular standard ANGULAR SUBTENSE is denoted by the full included angle, not the half angle.

[SOURCE: IEC 60601-2-57:2011, 201.3.202, modified – Unit deleted.]

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

[SOURCE: IEC 60601-2-57:2011, 201.3.204]

201.3.204
EMISSION LIMIT
maximum accessible emission permitted for a particular RISK group

[SOURCE: IEC 60601-2-57:2011, 201.3.205]

201.3.205
EXPOSURE LIMIT
maximum level of exposure of the eye or skin that is not expected to result in adverse biological effects

[SOURCE: IEC 60601-2-57:2011, 201.3.206, modified – Note deleted.]

201.3.206
EXPOSURE TIME
time period during which the human body is exposed to OPTICAL RADIATION emitted from the HOME LIGHT THERAPY EQUIPMENT

201.3.207
*** HOME LIGHT THERAPY EQUIPMENT**
ME EQUIPMENT which incorporates one or more sources of OPTICAL RADIATION in the wavelength range between 200 nm and 3 000 nm, with the exception of laser radiation, which is intended to create photobiological effects for therapeutic or diagnostic applications, and which is intended to be used in the HOME HEALTHCARE ENVIRONMENT

201.3.208
INTENSE PULSED LIGHT
periodically emitted non-coherent OPTICAL RADIATION in the wavelength range between 500 nm and 1 200 nm intended to create thermal effects in the skin

Note 1 to entry: Periodic emission does not relate to high-frequency pulsed emission of OPTICAL RADIATION but to periods with emission alternating with periods without emission, which are typically in the order of one to several seconds.

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

[SOURCE: IEC 60601-2-57:2011, 201.3.210, modified – Abbreviated term "OHD" deleted, word "shortest" inserted, word "within" replaced by "at", and unit deleted.]

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

[SOURCE: IEC 60601-2-57:2011, 201.3.211]

201.3.211
SKIN HAZARD DISTANCE
shortest distance from an EMISSION APERTURE at which the projected radiant exposure or irradiance for a given EXPOSURE TIME equals the applicable EXPOSURE LIMIT value for the skin

[SOURCE: IEC 60601-2-57:2011, 201.3.220, modified – Word "shortest" inserted and word "within" replaced by "at".]

201.3.212
STRAY OPTICAL RADIATION
OPTICAL RADIATION that is unintentionally emitted from the EMISSION APERTURE or from the target tissue, including scattered, reflected, and leakage radiation

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

For the purposes of this document, HOME LIGHT THERAPY EQUIPMENT is considered to have no ESSENTIAL PERFORMANCE.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.2 ACCESSIBLE PARTS

201.5.9.2.1 * Test finger

Addition, after the first paragraph, of the following sentence:

The test shall be performed with the lamp(s) mounted.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

Additional subclause:

201.6.101 *Protection against OPTICAL RADIATION

HOME LIGHT THERAPY EQUIPMENT shall be classified on the basis of the emitted OPTICAL RADIATION, including STRAY OPTICAL RADIATION, over the full range of its capability in NORMAL CONDITION and SINGLE FAULT CONDITION.