ELEKTRILISED MEDITSIINISEADMED. OSA 2-83: ERINÕUDED KODUSE VALGUSRAVISEADME ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment (IEC 60601-2-83:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60601-2-83:2020 +A11:2021 sisaldab Euroopa standardi EN IEC 60601-2-83:2020 ja selle muudatuste A11:2021 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60601-2-83 :2020+A11:2021 consists of the English text of the European standard EN IEC 60601-2-83:2020 and its amendment A11:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.04.2020, muudatus A11 02.04.2021.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 03.04.2020 for A11 02.04.2021.
Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A11] [A11]. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags [A11] [A11]. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-83 + A11

April 2020, April 2021

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English Version

Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment (IEC 60601-2-83:2019)

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)

Medizinische elektrische Geräte - Teil 2-83: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Heim-Lichttherapiegeräten (IEC 60601-2-83:2019)

This European Standard was approved by CENELEC on 2020-01-01. Amendment A11 was approved by CENELEC on 2020-11-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendment the status of a national standard without any alteration.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1682/FDIS, future edition 1 of IEC 60601-2-83, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-83:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 60601-2-83:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335-2-113	NOTE	Harmonized as FprEN 60335-2-113 to be published
IEC 60601-2-57:2011	NOTE	Harmonized as EN 60601-2-57:2011 (not modified)
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
IEC 60601-1-12	NOTE	Harmonized as EN 60601-1-12

A11 Amendment A11 European foreword

This document (EN IEC 60601-2-83:2020/A11:2021) has been prepared by CLC/TC 62 "*Electrical equipment in medical practice*".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2021-10-02
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For the relationship with EU Directive(s) see informative Annexes ZZA and ZZB, which are an integral part of this document. /A11

IEC 60601-2-83

Edition 1.0 2019-05

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(en-fr)

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IEC 60601-2-83

Edition 1.0 2019-05

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

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

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

FDIS	Report on voting
62D/1682/FDIS	62D/1687/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

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 this document will remain unchanged until the stability date indicated on the IEC website under "http://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.

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.

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

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, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-11:2015 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:

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2 The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 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 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

ISO 15223-1:2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – 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 60601-1-11:2015, *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 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 39.

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