

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 sisaldab Euroopa standardi EN IEC 60601-2-83:2020 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60601-2-83:2020 consists of the English text of the European standard EN IEC 60601-2-83:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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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)

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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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

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

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

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN 60601-1:2006 is applicable, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replace</i>				
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	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	EN ISO 15223-1	2016
			+prA1	
<i>Addition</i>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+A12	2014
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011
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 (mod)	2006	Photobiological safety of lamps and lamp systems	EN 62471	2008

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 3864-1	2011	Graphical symbols - Safety colours and-safety signs - Part 1: Design principles for safety signs and safety markings		-

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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
201.1 Scope, object and related standards	6
201.2 Normative references.....	7
201.3 Terms and definitions.....	8
201.4 General requirements	10
201.5 General requirements for testing ME EQUIPMENT	10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	10
201.7 ME EQUIPMENT identification, marking and documents	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	15
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	15
201.10 Protection against unwanted and excessive radiation HAZARDS	15
201.11 Protection against excessive temperatures and other HAZARDS	17
201.12 Accuracy of controls and instruments and protection against hazardous outputs	18
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	18
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	18
201.15 Construction of ME EQUIPMENT	18
201.16 ME SYSTEMS	18
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	18
202 Electromagnetic disturbances – Requirements and tests	18
206 Usability	19
211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT.....	19
Annexes	20
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	21
Annex D (informative) Symbols on marking.....	24
Annex AA (informative) Particular guidance and rationale	25
Annex BB (informative) Protective eyewear for HOME LIGHT THERAPY EQUIPMENT	28
Bibliography.....	29
Index of defined terms used in this particular standard.....	30
Table 201.101 – EMISSION LIMITS for risk groups of HOME LIGHT THERAPY EQUIPMENT	11
Table 201.102 – Time criteria for risk groups of HOME LIGHT THERAPY EQUIPMENT	12
Table 201.103 – Applicable ANGLE OF ACCEPTANCE for the assessment of emitted OPTICAL RADIATION from HOME LIGHT THERAPY EQUIPMENT.....	12
Table 201.C.101 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	21
Table 201.C.102 –Safety signs per HAZARD and per risk group.....	22
Table 201.C.103 – ACCOMPANYING DOCUMENTS, instructions for use	22
Table 201.C.104 –Caution statements per HAZARD and per risk group.....	23
Table 201.D.1 – General symbols	24
Table 201.D.2 – Safety signs	24

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 standard² 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:

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

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*.