IEC 60601-2-83

Edition 1.0 2022-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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MEDICAL ELECTRICAL EQUIPMENT –

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

AMENDMENT 1

FOREWORD

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Amendment 1 to IEC 60601-2-83:2019 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/1931/CDV	62D/1962/RVC

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

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- 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- withdrawn,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 or ISO 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 mandatory implementation nationally not earlier than 3 years from the date of publication.

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 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.

INTRODUCTION

Replace the existing last paragraph with:

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.

201.1 Scope, object and related standards

Replace the existing footnote 2 with:

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*.

201.1.3 Collateral standards

Replace the first sentence of the second paragraph with:

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.

201.1.4 Particular standards

Replace the first sentence of the third paragraph with:

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.

201.2 Normative references

Replace the existing references to IEC 60601-1-2, IEC 60601-1-6 and ISO 15223-1 with the following new references:

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 15223-1:2021, *Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*

Replace the existing references to IEC 60601-1 and IEC 60601-1-11 with the following new references:

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

201.7.2.3 Consult ACCOMPANYING DOCUMENTS

Replace, in the existing first paragraph, "safety sign" *in two places with* "SAFETY SIGN".

Replace, in the existing NOTE, "safety signs" *with* "SAFETY SIGNS".

201.7.2.13 Physiological effects (safety signs and warning statements)

Replace, in the title, "safety signs" *with* "SAFETY SIGNS".

Replace the reference to “ISO 15223-1:2016” *with* “ISO 15223-1:2021”.

201.7.2.13.101 * Markings and symbols for HOME LIGHT THERAPY EQUIPMENT

Replace, in the existing first paragraph, "safety sign" *in two places with* "SAFETY SIGN".

Replace the existing second paragraph with:

HOME LIGHT THERAPY EQUIPMENT for which the emitted OPTICAL RADIATION exceeds the EMISSION LIMIT for the Exempt Group for the actinic UV HAZARD and/or the near UV HAZARD, shall be marked with SAFETY SIGN 101 or SAFETY SIGN 102 of Table 201.D.2.

Replace the existing third paragraph with:

HOME LIGHT THERAPY EQUIPMENT for which the emitted OPTICAL RADIATION exceeds the EMISSION LIMIT for the Exempt Group for the retinal thermal HAZARD and/or the corneal/lens IR HAZARD, shall be marked with SAFETY SIGN 101 or SAFETY SIGN 103 of Table 201.D.2.

Replace, in the existing fourth paragraph, "safety sign" *with* "SAFETY SIGN".

Replace, in the existing NOTE, "safety signs" *with* "SAFETY SIGNS".

201.10.104 Skin detection feedback

Replace, in the existing first and second paragraphs and in the existing NOTE, "signal" *with* "INFORMATION SIGNAL" *(3 occurrences).*

201.10.105 Means to assess the skin pigmentation level

Add, after the existing first paragraph, the following note:

NOTE 1 HOME LIGHT THERAPY EQUIPMENT emitting INTENSE PULSED LIGHT can also emit a part of its spectral output at wavelengths above 1 200 nm. The absorption of that part of the OPTICAL RADIATION by the skin becomes independent of the skin pigmentation level and is included in the EXPOSURE LIMIT for the thermal HAZARD for the skin.

Replace the existing second paragraph with:

The assessment of the skin pigmentation level shall be at or adjacent to the area of skin irradiation. There shall be continuous full skin contact between the moment of assessment of the skin pigmentation level and the emission of OPTICAL RADIATION.

NOTE 2 The purpose of these requirements is to prevent irradiation of skin with a different pigmentation level than the skin that was assessed.

A colour chart may be used additionally to advise the user on adjustment of the output of OPTICAL RADIATION.

201.10.106 Protection measures

Replace, in the existing second paragraph, "safety sign" *in two places with* "SAFETY SIGN".

202 Electromagnetic disturbances – Requirements and tests

Replace the existing first paragraph with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

206 Usability

Replace the existing first paragraph with:

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

Replace the existing first paragraph with:

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply, except as follows:

211.8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT

Replace the existing second paragraph with:

The ENCLOSURE of HOME LIGHT THERAPY EQUIPMENT that is not BODY-WORN, shall either:

a) maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP21; or

b) be marked with SAFETY SIGN ISO 7010-W001:2011-05 (see IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Table D.2, SAFETY SIGN 2) as well as with

   1) the text "KEEP DRY" or

   2) symbol 5.3.4 of ISO 15223-1:2021 (see Table 201.D.1, symbol 102).

Add, after the existing second paragraph, the following new paragraph:

If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the HOME LIGHT THERAPY EQUIPMENT shall be tested while inside the carrying case.

Annex C – Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Replace, in the second and third sentences of the existing first paragraph, "safety signs" *with* "SAFETY SIGNS".

Add, after the existing first paragraph, the following note:

NOTE The requirements in 201.7.2.13.101 allow the use of SAFETY SIGN 101 of Table 201.D.2 as alternative for SAFETY SIGN 102 or SAFETY SIGN 103 of Table 201.D.2.

Table 201.C.102 – Safety signs per HAZARD and per risk group

Replace, in the table title and in the column heading, "Safety signs" *with* "SAFETY SIGNS".

Annex D – Symbols on marking

Table 201.D.1 – General symbols

Replace, for symbols 101 and 102, the reference to "ISO 15223-1:2016" *with* "ISO 15223-1:2021".

Table 201.D.2 – Safety signs

Replace, in the table title, "Safety signs" *with* "SAFETY SIGNS".

Replace, in the column heading, "Safety sign" *with* "SAFETY SIGN".

Annex AA – Particular guidance and rationale

AA.2 Rationale for particular clauses and subclauses

Subclause 201.6.101 – Protection against OPTICAL RADIATION

Replace, in the existing second paragraph, "safety signs" *with* "SAFETY SIGNS".

Subclause 201.7.2.13.101 – Markings and symbols for HOME LIGHT THERAPY EQUIPMENT

Subclause 201.7.9.2.2.101 – Additional warnings and safety notices

Subclause 201.7.9.2.17 – ME EQUIPMENT emitting radiation

Replace, in the existing first paragraph, "safety signs" *with* "SAFETY SIGNS".

Index of defined terms used in this particular standard

Update the references for the following defined terms:

HAZARD ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.40
MANUFACTURER ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.55
PRIMARY OPERATING FUNCTION ..... IEC 60601-1:2005/AMD2:2020, 3.146
RISK ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.102

Add the following new defined terms:

INFORMATION SIGNAL ..... IEC 60601-1:2005/AMD2:2020, 3.150
SAFETY SIGN ..... IEC 60601-1:2005/AMD2:2020, 3.154

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

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

AMENDEMENT 1

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. A cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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L'Amendement 1 à l'IEC 60601-2-83:2019 a été établi par le sous-comité 62D: Équipements, logiciels et systèmes médicaux particuliers, du comité études 62 de l'IEC: Equipement médical, logiciels et systèmes médicaux.

Le texte de cet Amendement est issu des documents suivants:

Projet	Rapport de vote
62D/1931/CDV	62D/1962/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.