# SLOVENSKI STANDARD
# SIST EN IEC 60601-2-83:2020/oprA1:2022

**01-april-2022**

---

**Medicinska električna oprema - 2-83. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za svetlobno terapijo na domu - Dopolnilo A1**

Amendment 1 - Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

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

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



**Ta slovenski standard je istoveten z:** **EN IEC 60601-2-83:2020/prA1:2022**



---

**ICS:**

| | | |
|---|---|---|
| 11.040.60 | Terapevtska oprema | Therapy equipment |

| | |
|---|---|
| **SIST EN IEC 60601-2-83:2020/oprA1:2022** | **en** |

# 62D/1931/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

| | |
|---|---|
| PROJECT NUMBER: **IEC 60601-2-83/AMD1 ED1** | |
| DATE OF CIRCULATION: **2022-01-28** | CLOSING DATE FOR VOTING: **2022-04-22** |
| SUPERSEDES DOCUMENTS: **62D/1857/CD, 62D/1927/CC** | |

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

| | |
|---|---|
| SECRETARIAT: United States of America | SECRETARY: Ms Ladan Bulookbashi |
| OF INTEREST TO THE FOLLOWING COMMITTEES: | PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary. |

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING ☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

**Attention IEC-CENELEC parallel voting**

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.



This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

**Amendment 1 - Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment**

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

This document is circulated as the Committee Draft for Vote (CDV). This standard is amended in order to align with the published IEC 60601-1 series Amendment projects.

# FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

| Draft | Report on voting |
|---|---|
| 62D/xxxx/FDIS | 62D/xxxx/RVD |

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

The committee has decided that the contents of this amendment and the base publication 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 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

*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, IEC 60601-1-6 and IEC 60601-1-11 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 standards 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 medical device labels, labelling and information to be supplied – 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* "safety sign" *in two places in the existing first paragraph with* "SAFETY SIGN".

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

### 201.7.2.13 Physiological effects (safety signs and warning statements)

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

### 201.7.2.13.101 * Markings and symbols for HOME LIGHT THERAPY EQUIPMENT

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

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



### 201.10.104 Skin detection feedback

*Replace* "signal" *in the existing first and second paragraphs and in the existing NOTE with* "INFORMATION SIGNAL".

### 201.10.105 Means to assess the skin pigmentation level

*After the existing first paragraph, add the following note:*

NOTE 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:*

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

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

## 202 Electromagnetic disturbances – Requirements and tests

*Replace the exisiting first paragraph with:*

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

## 206 Usability

*Replace the exisiting 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 exisiting 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, 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).



*After the existing second paragraph, add 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* “safety signs” *in the second and third sentences of the existing first paragraph with* “SAFETY SIGNS”.

*After the existing first paragraph, add 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* “Safety signs” *in the table title and in the column heading with* “SAFETY SIGNS”.