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

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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

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IEC 60601-2-83:2019-05(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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

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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;

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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.

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

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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.

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201.1.2 Object

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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

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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*.

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.

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"*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.

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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.

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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

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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.

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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 30.

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

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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

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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:

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201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

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201.5.9.2 ACCESSIBLE PARTS

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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.

HOME LIGHT THERAPY EQUIPMENT shall be assessed by the method specified in IEC 62471 at a distance of 200 mm from the EMISSION APERTURE or from the apparent source.

If the HOME LIGHT THERAPY EQUIPMENT incorporates a skin detection device as specified in 201.10.103, the EMISSION LIMITS listed in Table 201.101 for actinic UV and near UV HAZARDS shall apply with the skin detection device disabled, and the EMISSION LIMITS for blue light, retinal thermal and corneal/lens IR HAZARDS shall apply with the skin detection device enabled. Otherwise, the EMISSION LIMITS for all HAZARDS listed in Table 201.101 shall apply.

HOME LIGHT THERAPY EQUIPMENT shall be classified in the following groups:

– Exempt Group (no photobiological HAZARD), if the emitted OPTICAL RADIATION does not exceed the EMISSION LIMITS for the Exempt Group specified in Table 201.101 for any applicable HAZARD, when assessed under the conditions of the time criteria (EXPOSURE TIMES) of Table 201.102 and the ANGLE OF ACCEPTANCE specified in Table 201.103;

– Risk Group 1 (low RISK), if the emitted OPTICAL RADIATION exceeds one or more EMISSION LIMITS for the Exempt Group and does not exceed the EMISSION LIMITS for Risk Group 1 specified in Table 201.101 for any applicable HAZARD, when assessed under the conditions of the time criteria (EXPOSURE TIMES) of Table 201.102 and the ANGLE OF ACCEPTANCE specified in Table 201.103; or

– Risk Group 2 (moderate RISK), if the emitted OPTICAL RADIATION exceeds one or more EMISSION LIMITS for Risk Group 1 and does not exceed the EMISSION LIMITS for Risk Group 2 specified in Table 201.101 for any applicable HAZARD, when assessed under the conditions of the time criteria (EXPOSURE TIMES) of Table 201.102 and the ANGLE OF ACCEPTANCE specified in Table 201.103.

NOTE 1 The time criteria are the maximum allowed EXPOSURE TIMES for the given wavelength ranges, EMISSION LIMITS and risk groups.

NOTE 2 IEC 62471:2006 recognizes Risk Group 3, where no EMISSION LIMITS apply. Therefore, the RISKS involved are considered too high for ME EQUIPMENT intended to be used in the HOME HEALTHCARE ENVIRONMENT.

Table 201.101 – EMISSION LIMITS for risk groups of HOME LIGHT THERAPY EQUIPMENT

HAZARD [a]	Wavelength range nm	Symbol [c]	EMISSION LIMIT			Units
			Exempt Group	Risk Group 1	Risk Group 2	
Actinic UV	180 to 400	E_S	0,001	0,003	0,03	$W \cdot m^{-2}$
Near UV	315 to 400	E_{UVA}	10	33	100	$W \cdot m^{-2}$
Blue light	300 to 700	L_B	100	10 000	4 000 000	$W \cdot m^{-2} \cdot sr^{-1}$
Retinal thermal	380 to 1 400	L_R	28 000/α [c]	N/A [d]	71 000/α [c]	$W \cdot m^{-2} \cdot sr^{-1}$
Retinal thermal, weak visual stimulus [b]	780 to 1 400	L_{IR}	6 000/α [c]	N/A [d]	N/A [d]	$W \cdot m^{-2} \cdot sr^{-1}$
Corneal/lens IR	780 to 3 000	E_{IR}	100	570	3 200	$W \cdot m^{-2}$

[a] The EMISSION LIMITS are based on eye and skin damage in the ultraviolet (UV) ranges and on eye damage in the visible and infrared (IR) ranges. Skin damage (such as erythema and burning) can also occur in the visible and IR ranges, but skin damage in these ranges is not covered in this document.

[b] Retinal damage in the wavelength range between 780 nm and 1 400 nm can be affected by absence of aversion response due to weak visual stimulus.

[c] The radiation quantities are defined in 4.3 of IEC 62471:2006. The ANGULAR SUBTENSE α is defined in 201.3.202.

[d] Retinal thermal HAZARDS L_R and L_{IR} do not change with time for EXPOSURE TIMES longer than 10 s. If the EMISSION LIMIT for L_R of the Exempt Group is exceeded (but not of Risk Group 2) for EXPOSURE TIMES up to 10 s, HOME LIGHT THERAPY EQUIPMENT is classified in Risk Group 2. If the EMISSION LIMIT for L_{IR} of the Exempt Group is exceeded for EXPOSURE TIMES up to 10 s, HOME LIGHT THERAPY EQUIPMENT needs to incorporate a skin detection device as specified in 201.10.103.

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Table 201.102 – Time criteria for risk groups of HOME LIGHT THERAPY EQUIPMENT

HAZARD	Wavelength range nm	Time s		
		Exempt Group	Risk Group 1	Risk Group 2
Actinic UV	180 to 400	30 000	10 000	1 000
Near UV	315 to 400	1 000	300	100
Blue-light	300 to 700	10 000	100	0,25
Retinal thermal	380 to 1 400	10	N/A	0,25
Retinal thermal, weak visual stimulus	780 to 1 400	10	N/A	N/A
Corneal/lens IR	780 to 3 000	1 000	100	10

Table 201.103 – Applicable ANGLE OF ACCEPTANCE for the assessment of emitted OPTICAL RADIATION from HOME LIGHT THERAPY EQUIPMENT

HAZARD	Wavelength range nm	ANGLE OF ACCEPTANCE γ rad		
		Exempt Group	Risk Group 1	Risk Group 2
Actinic UV	180 to 400	1,4	1,4	1,4
Near UV	315 to 400	1,4	1,4	1,4
Blue-light	300 to 700	0,11	0,011	0,001 7
Retinal thermal	380 to 1 400	0,011	N/A	0,001 7
Retinal thermal, weak visual stimulus	780 to 1 400	0,011	N/A	N/A
Corneal/Lens IR	780 to 3 000	1,4	1,4	1,4

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201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.1 General

201.7.1.2 *Legibility of markings

Replacement, at the end of the second sentence of the second paragraph of the compliance statement, of "1 m" by "0,33 m".

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.3 Consult ACCOMPANYING DOCUMENTS

Addition:

HOME LIGHT THERAPY EQUIPMENT classified in Risk Group 2 and HOME LIGHT THERAPY EQUIPMENT for which the emitted OPTICAL RADIATION exceeds the EMISSION LIMIT for the Exempt Group for the actinic UV HAZARD, the near UV HAZARD and/or the corneal/lens IR HAZARD shall be marked with safety sign ISO 7010-M002:2011-05 (see Table D.2, safety sign 10).

NOTE An overview of safety signs per HAZARD and per risk group is given in Table 201.C.102.

201.7.2.13 Physiological effects (safety signs and warning statements)

Addition:

HOME LIGHT THERAPY EQUIPMENT containing natural rubber latex shall be marked with symbol 5.4.5 of ISO 15223-1:2016 (see Table 201.D.1, symbol 101). The instructions for use shall also disclose any component containing natural rubber latex.

Compliance is checked by inspection.

Additional subclause:

201.7.2.13.101 * Markings and symbols for HOME LIGHT THERAPY EQUIPMENT

HOME LIGHT THERAPY EQUIPMENT for which the emitted OPTICAL RADIATION exceeds the EMISSION LIMIT for Risk Group 1 for the blue-light HAZARD shall be marked with safety sign ISO 7010-W027:2011-05 (see Table 201.D.2, safety sign 101).

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 102 of Table 201.D.2.

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 103 of Table 201.D.2.

HOME LIGHT THERAPY EQUIPMENT classified in Risk Group 2 and HOME LIGHT THERAPY EQUIPMENT for which the emitted OPTICAL RADIATION exceeds the EMISSION LIMIT for the Exempt Group for the corneal/lens IR HAZARD shall be marked with safety sign 104 of Table 201.D.2.

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NOTE An overview of safety signs per HAZARD and per risk group is given in Table 201.C.102.

201.7.9 ACCOMPANYING DOCUMENTS

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201.7.9.2 Instructions for use

201.7.9.2.2 Warnings and safety notices

Additional subclause:

201.7.9.2.2.101 * Additional warnings and safety notices

The instructions for use shall include

a) a warning statement to the effect: "WARNING: Do not leave the equipment unattended when it is switched on to avoid the risk of fire or burns."

b) a warning statement to the effect: "WARNING: This equipment is not intended for use by persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the equipment to avoid the risk of fire or burns."

c) a warning statement to the effect: "WARNING: This equipment is not intended for use by children. Children should be supervised to ensure that they do not play with the equipment to avoid the risk of fire and burns."

If applicable, the instructions for use shall include

a) a warning statement to the effect: "WARNING: If the mains cord is damaged, you shall have it replaced by [place MANUFACTURER'S name here], a service centre authorised by [place MANUFACTURER'S name here] or similarly qualified persons in order to avoid risk of electrocution."

b) a warning statement to the effect: "WARNING: Water and electricity are a dangerous combination! To avoid risk of electrocution,