EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-57

April 2011

ICS 11.040.50; 11.040.60

English version

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

(IEC 60601-2-57:2011)

Appareils électromédicaux -
Partie 2-57: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à source de lumière non-laser prévus pour des utilisations thérapeutiques, de diagnostic, de surveillance et de cosmétique/esthétique
(CEI 60601-2-57:2011)

Medizinische elektrische Geräte -
Teil 2-57: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten mit Nicht-Laser-Lichtquellen für die Anwendung in der Therapie, Diagnose, Überwachung und für kosmetische/ästhetische Zwecke
(IEC 60601-2-57:2011)

This European Standard was approved by CENELEC on 2011-03-07. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-57:2011 E

Foreword

The text of document 76/438/FDIS, future edition 1 of IEC 60601-2-57, prepared by IEC TC 76, Optical radiation safety and laser equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-57 on 2011-03-07.

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

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-12-07
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-03-07

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

- “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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-57:2011 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Addition:

Publication	Year	Title	EN/HD	Year
IEC 60947-3	-	Low-voltage switchgear and controlgear - Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	EN 60947-3	-
IEC 62471 (mod)	-	Photobiological safety of lamps and lamp systems	EN 62471	-
ISO 3864-2	-	Graphical symbols - Safety colours and safety signs - Part 2: Design principles for product safety labels	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EU Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

INTRODUCTION

This particular standard amends and supplements IEC 60601-1:2005 (third edition): *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*.

The requirements of this particular standard should be taken as the minimum to comply with, in order to achieve a reasonable level of safety and reliability during operation and application of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

An asterisk (*) notes clauses for which there is rationale comment in Annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of this particular standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment incorporating one or more sources of OPTICAL RADIATION in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and intended to create non-visual photobiological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications; hereafter referred to as light source equipment (LS EQUIPMENT).

This particular standard does not apply to equipment for sun tanning, for ophthalmic instruments or for infant phototherapy.

NOTE Safety requirements in this particular standard are intended to address only HAZARDS to the eye and skin; hazards to internal tissues are not included in its scope.

LS EQUIPMENT may consist of a single or multiple sources of OPTICAL RADIATION, with or without power supply, or may be incorporated into a complex system that includes optical, electrical or mechanical systems or sources of other radiation.

NOTE Annexes AA to EE have been included for purposes of general guidance and to illustrate many typical cases. However, the annexes should not be regarded as definitive or exhaustive.

201.1.2 Object

Replacement:

The objects of this particular standard are:

– to establish optical radiation safety, basic safety and essential performance requirements for LS EQUIPMENT;
– to specify requirements for the MANUFACTURER to supply information and establish procedures so that proper precautions can be adopted;
– to provide warning to individuals of HAZARDS associated with accessible OPTICAL RADIATION from LS EQUIPMENT through signs, labels and instructions;
– to reduce the possibility of injury by minimizing unnecessary accessible OPTICAL RADIATION; to provide means of improved control of the HAZARDS related to OPTICAL RADIATION through protective features and to assist safe use of LS EQUIPMENT;

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

– to protect persons against other HAZARDS resulting from the operation and use of LS 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 in Clause 201.2 of this particular standard.

All published collateral standards in the IEC 60601 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 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 is 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 particular standard 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 3.1 through 3.139, additional definitions in this particular standard 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 standard" 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 on page 33.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60947-3, *Low voltage switchgear and controlgear – Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units*

IEC 62471, *Photobiological safety of lamps and lamp systems*

ISO 3864-2, *Graphical symbols – Safety colours and safety signs – Part 2: Design principles for product safety labels.*

201.3 Terms and definitions

NOTE An index of defined terms used in this document is found beginning on page 34.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

Replacement:

201.3.18
CONTINUOUS OPERATION
operation with a continuous OPTICAL RADIATION output for a duration equal to or greater than 0,25 s for wavelengths in the range 400 to 700 nm and 10 s for all other wavelengths

Addition:

201.3.201
ANGLE OF ACCEPTANCE
γ
plane angle within which a detector responds to OPTICAL RADIATION

NOTE 1 THE ANGLE OF ACCEPTANCE may be controlled by apertures or optical elements.

NOTE 2 The ANGLE OF ACCEPTANCE is sometimes referred to as the field-of-view.

SI Unit: radian (rad)

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 In this particular standard subtended angles are denoted by the full included angle, not the half angle.

SI Unit: radian (rad)

201.3.203
EMERGENCY STOP
device intended to stop the LS EQUIPMENT OUTPUT immediately in case of emergency

201.3.204
EMISSION APERTURE
opening or window through which the OPTICAL RADIATION is emitted

201.3.205
EMISSION LIMIT
maximum accessible emission permitted for a particular risk group

201.3.206
EXPOSURE LIMIT
maximum level of exposure of the eye or skin that is not expected to result in adverse biological effects

NOTE EXPOSURE LIMITS are shown in Table BB.1

201.3.207
EXPOSURE TIME
PULSE DURATION (for a single pulse), duration of a pulse train or of a continuous emission of optical radiation incident upon the human or animal body during operation, maintenance or servicing of LS EQUIPMENT

SI Unit: second (s)

201.3.208
LS EQUIPMENT
ME EQUIPMENT which incorporates one or more sources of optical radiation in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and which is intended to create non-visual photo-biological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications

201.3.209
LS EQUIPMENT OUTPUT
either radiant power or radiant energy emitted by the LS EQUIPMENT

201.3.210
OCULAR HAZARD DISTANCE (OHD)
distance from an EMISSION APERTURE within which the projected radiant exposure or irradiance for a given EXPOSURE TIME equals the applicable EXPOSURE LIMIT value for the eye

SI Unit: m

201.3.211
OPTICAL RADIATION
electromagnetic radiation with wavelengths between 100 nm and 1 mm

201.3.212
PULSE/PULSED
accessible emission with the duration shorter than 0,25 s in the range 400 nm to 700 nm and shorter than 10 s at other wavelengths

201.3.213
PULSE DURATION
time increment measured between the half peak (50 %) power points at the leading and trailing edges of a PULSE

SI Unit: second (s)

201.3.214
PULSE INTERVAL
time between the end of one PULSE and the onset of the following PULSE, measured at the 50 % trailing and leading edges respectively

SI Unit: second (s)

201.3.215
PULSE TRAIN
series of PULSES where the total on time of the PULSES in any series of PULSES in any single exposure sequence does not exceed 0,25 s for wavelengths in the range 400 nm to 700 nm and does not exceed 10 s for all other wavelengths

201.3.216
READY
ready condition: the LS EQUIPMENT is capable of emitting OPTICAL RADIATION when the control switch is activated

201.3.217
READY INDICATOR
visible or audible signal that indicates when LS EQUIPMENT is in the ready condition; the purpose of the ready indicator is to make all persons present in the vicinity aware of the need to take precautions against hazardous optical radiation

201.3.218
SET VALUE
intended LS EQUIPMENT output incident on the treatment area, as set by the OPERATOR

201.3.219
SHORT WAVELENGTH BOUNDARY
wavelength at the 50 % point of the emission spectrum at its short wavelength edge

SI Unit: nm

201.3.220
SKIN HAZARD DISTANCE
distance from an EMISSION APERTURE within which the projected radiant exposure or irradiance for a given EXPOSURE TIME equals the applicable EXPOSURE LIMIT value for the skin

201.3.221
STAND-BY
stand-by condition: the power supply (SUPPLY MAINS or battery) is connected and the SUPPLY MAINS switch activated; the LS EQUIPMENT is not capable of emitting the OPTICAL RADIATION even if the control switch is activated

201.3.222
USER
person, who controls the delivery of the LS EQUIPMENT OUTPUT to the treatment area

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.1 General

Addition:

201.6.1.101 *Classification responsibilities

The MANUFACTURER shall provide the classification of LS EQUIPMENT.

The LS EQUIPMENT shall be classified on the basis of the emission of the accessible OPTICAL RADIATION over the full range of capability during operation at any time after manufacture and under every reasonably foreseeable single fault condition.

NOTE Classification of LS EQUIPMENT provides the basis for the range of control measures which the USER should take in order to minimize risk of excessive exposure to OPTICAL RADIATION.

201.6.1.102 *Classification rules

The classification is used to indicate the potential risk of adverse health effects.

For the purpose of classification rules, the following ranking of the risk groups, in order of increasing risk at a distance of 200 mm from the EMISSION APERTURE, shall be used. Assessment shall be made by the method specified in IEC 62471:

– Exempt Group – no photo-biological HAZARD;
– Risk Group 1 – low risk group; the risk is limited by normal behavioural limitations on exposure;
– Risk Group 2 – moderate risk group; the risk is limited by the aversion response to very bright light sources. However, such reflex responses do not occur universally;
– Risk Group 3 – high risk group; LS EQUIPMENT that may pose a risk even for momentary or brief exposure.

NOTE Risk Groups are described in IEC 62471.

201.6.1.102.1 Classification of continuous operation LS EQUIPMENT

a) Exempt Risk Group

CONTINUOUS OPERATION LS EQUIPMENT shall be assigned to the Exempt Risk Group if its accessible emission does not exceed the EMISSION LIMITS in any of the HAZARD spectral regions of Table 201.101 when assessed for the time criteria of Table 201.102 and the ANGLE OF ACCEPTANCE γ specified in Table 201.103.

b) Risk Group 1

CONTINUOUS OPERATION LS EQUIPMENT shall be assigned to Risk Group 1 if its accessible emission exceeds one or more EMISSION LIMITS for the Exempt Group as defined in Table 201.101 and does not exceed EMISSION LIMITS of Risk Group 1 in any of the HAZARD

spectral regions of Table 201.101 when assessed for the time criteria of Table 201.102 and the ANGLE OF ACCEPTANCE γ specified in Table 201.103.

c) Risk Group 2

CONTINUOUS OPERATION LS EQUIPMENT shall be assigned to Risk Group 2 if its accessible emission exceeds one or more EMISSION LIMITS for Risk Group 1 as defined in Table 201.101 and does not exceed EMISSION LIMITS of Risk Group 2 in any of the HAZARD spectral regions of Table 201.101 when assessed for the time criteria of Table 201.102 and the ANGLE OF ACCEPTANCE γ specified in Table 201.103.

d) Risk Group 3

CONTINUOUS OPERATION LS EQUIPMENT shall be assigned to Risk Group 3 if its accessible emission exceeds one or more EMISSION LIMITS for Risk Group 2 as defined in Table 201.101.

Table 201.101 – EMISSION LIMITS for risk groups of LS EQUIPMENT

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

NOTE 1 The list of the HAZARDS in Table 201.101 refers to eye damage and skin damage in the UV. Skin damage can also occur in the visible and IR, e.g. erythema or burning.

NOTE 2 Retinal damage in the wavelength range 780 nm to 1400 nm may be affected by absence of aversion response due to weak visual stimulus

[a] The retinal thermal HAZARDS L_R, L_{IR} do not change with time for EXPOSURE TIMES longer than 10 s. A consequence of this is that if the EMISSION LIMIT of Exempt Risk Group is exceeded for EXPOSURE TIME up to 10 s, the LS EQUIPMENT classified on the basis of the L_{IR} HAZARD, should be allocated to Risk Group 3. Similarly, LS EQUIPMENT classified on the basis of the retinal thermal HAZARD (L_R) should be allocated to Risk Group 2 or 3, as appropriate, if the EMISSION LIMIT of the Exempt Risk Group is exceeded for EXPOSURE TIME up to 10 s.

201.6.1.102.2 Classification of PULSED LS EQUIPMENT

For PULSED LS EQUIPMENT, classification criteria shall apply to the most restrictive of the requirements for a single PULSE, or any group of PULSEs within the time criteria of the applicable HAZARD region given in Table 201.102. EMISSION LIMITS for PULSED LS EQUIPMENT shall be calculated according to IEC 62471.

a) Exempt Risk Group

PULSED LS EQUIPMENT shall be assigned to the Exempt Risk Group if its accessible emission does not exceed EMISSION LIMITS in any of the HAZARD spectral regions of Table 201.101 when assessed for the time criteria of Table 201.102 and ANGLE OF ACCEPTANCE γ specified in Table 201.103.

b) Risk Group 1

PULSED LS EQUIPMENT shall be assigned to Risk Group 1 if its accessible emission exceeds one or more EMISSION LIMITS for the Exempt Group as defined in Table 201.101 and does not exceed the EMISSION LIMITS of Risk Group 1 in any of the HAZARD spectral regions of Table 201.101 when assessed for the time criteria of Table 202.102 and ANGLE OF ACCEPTANCE γ specified in Table 201.103.

c) Risk Group 2

PULSED LS EQUIPMENT shall be assigned to Risk Group 2 if its accessible emission exceeds one or more EMISSION LIMITS for Risk Group 1 as defined in Table 201.101 and does not exceed the EMISSION LIMITS of Risk Group 2 in any of the HAZARD spectral regions of Table 201.101 when assessed for the time criteria of Table 201.102 and the ANGLE OF ACCEPTANCE γ specified in Table 201.103.

d) Risk Group 3

PULSED LS EQUIPMENT shall be assigned to Risk Group 3 if its accessible emission exceeds one or more EMISSION LIMITS for Risk Group 2 as defined in Table 201.101.

Table 201.102 – Risk group time base criteria for classification of LS EQUIPMENT

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

Table 201.103 – Applicable ANGLE OF ACCEPTANCE for the assessment of accessible emission from LS EQUIPMENT

HAZARD	Wavelength range nm	Angle of acceptance γ rad		
		Exempt Risk Group	Risk Group 1	Risk Group 2
Actinic UV	180 – 400	1,4	1,4	1,4
Near UV	315 – 400	1,4	1,4	1,4
Blue-light	300 – 700	0,11	0,011	0,0017
Retinal Thermal	380 – 1 400	0,011	N/A	0,0017
Retinal Thermal, weak visual stimulus	780 – 1 400	0,011	N/A	N/A
Corneal/Lens IR	780 – 3 000	1,4	1,4	1,4

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

MANUFACTURERS of LS EQUIPMENT shall provide instructions for proper operation, including clear warnings concerning precautions to avoid possible exposure to hazardous OPTICAL RADIATION.

201.7.9.2 Instructions for use

201.7.9.2.13 Maintenance

Addition:

MANUFACTURERS of LS EQUIPMENT shall provide instructions for maintenance to be performed by the USER, including warnings concerning precautions to avoid possible exposure to hazardous OPTICAL RADIATION.

Additional subclauses:

201.7.9.2.101 Specific information for LS EQUIPMENT

201.7.9.2.101.1 Information on output

The MANUFACTURER of LS EQUIPMENT shall provide the following information for the USER:

– spectral irradiance or spectral radiant exposure for all intended configurations of LS EQUIPMENT;

– maximum output of OPTICAL RADIATION for all intended configurations of LS EQUIPMENT, measured at the treatment area. If the LS EQUIPMENT is designed for providing treatment in different treatment areas, these parameters shall be specified for each of the treatment areas;

– maximum variation of the output from the mean value across the treatment area for all intended configurations of the equipment;

– OCULAR HAZARD DISTANCE and/or SKIN HAZARD DISTANCE, when the LS EQUIPMENT is classified in excess of Risk Group 1.

For PULSED LS EQUIPMENT, for all intended operational settings of the equipment, the MANUFACTURER shall provide an additional statement of:

– PULSE DURATION of individual pulses;

– duration of a PULSE TRAIN;

– pulse interval;

– repetition rate;

– number of PULSES in a PULSE TRAIN.

201.7.9.2.101.2 Safety information

MANUFACTURERS of LS EQUIPMENT shall provide the following safety information in the USER instruction:

– instructions for installation, maintenance, check procedures and safe use, including clear warnings concerning precautions to avoid possible exposure to hazardous radiation or risk of fire;

– recommendations for training;

– legible reproductions (colour optional) of all required labels and HAZARD warnings affixed to the LS EQUIPMENT;

– a clear indication of all locations of EMISSION APERTURES;

– a list of controls, adjustments and procedures for operation and maintenance by the USER, including the warning "Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure";

– a note, saying that LS EQUIPMENT should be protected against unauthorised use, for example by removal of the key from the key switch;

– a recommendation for eye and skin protection for the USER and for the PATIENT/client.

NOTE The MANUFACTURER should provide a warning of risk of fire if the LS EQUIPMENT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. Some materials, e.g. darkly coloured clothing or cotton wool, when saturated with oxygen, may be ignited by the high temperatures produced in NORMAL USE of the LS EQUIPMENT.

Additional paragraphs:

201.7.101 Labelling of LS EQUIPMENT

201.7.101.1 Labelling requirements

The MANUFACTURER of LS EQUIPMENT shall provide product risk group marking. The label shall include the risk group number and wording according to Table 201.104.

NOTE Wording that conveys an equivalent meaning is acceptable.

Table 201.104 – Requirements for labelling of LS EQUIPMENT according to risk group classification

Hazard	Exempt Group	Risk Group 1	Risk Group 2	Risk Group 3
Actinic UV	Not required	CAUTION UV emitted from this device	CAUTION UV emitted from this device Eye or skin irritation may result	WARNING UV emitted from this device may be hazardous Avoid eye or skin exposure
Near UV	Not required	CAUTION UV emitted from this device	CAUTION UV emitted from this device Eye irritation may result	WARNING UV emitted from this device may be hazardous Avoid eye exposure
Blue-light	Not required	Not required	CAUTION The light emitted may be harmful to the eyes Do not stare at the light source	WARNING The light emitted may result in eye injury Do not look at the light source
Retinal Thermal	Not required	Not applicable	CAUTION The light emitted may be harmful to the eyes Do not stare at the light source	
Retinal Thermal, weak visual stimulus	Not required	Not applicable	Not applicable	WARNING IR emitted from this device may cause eye injury Avoid eye exposure
Corneal/ Lens IR	Not required	CAUTION IR emitted from this device Do not stare at the IR source	CAUTION IR emitted from this device may cause eye irritation Do not stare at the light source	

When LS EQUIPMENT emits OPTICAL RADIATION in more than one HAZARD spectral region, it shall be classified for the most restrictive case. If the OPTICAL RADIATION in other spectral regions exceeds the EMISSION LIMITS for the Exempt Group, appropriate warning shall be included in the product explanatory label.

NOTE For example, for the device classified as a Risk Group 3 product on the basis of a retinal IR HAZARD and emitting UV to the level of Risk Group 2, the legend of the label should indicate Risk Group 3, with the appropriate 'Warning' text; and show the 'Caution' text for the Risk Group 2 for the UV, but should not mention Risk Group 2 explicitly, as illustrated in Figure 201.1.

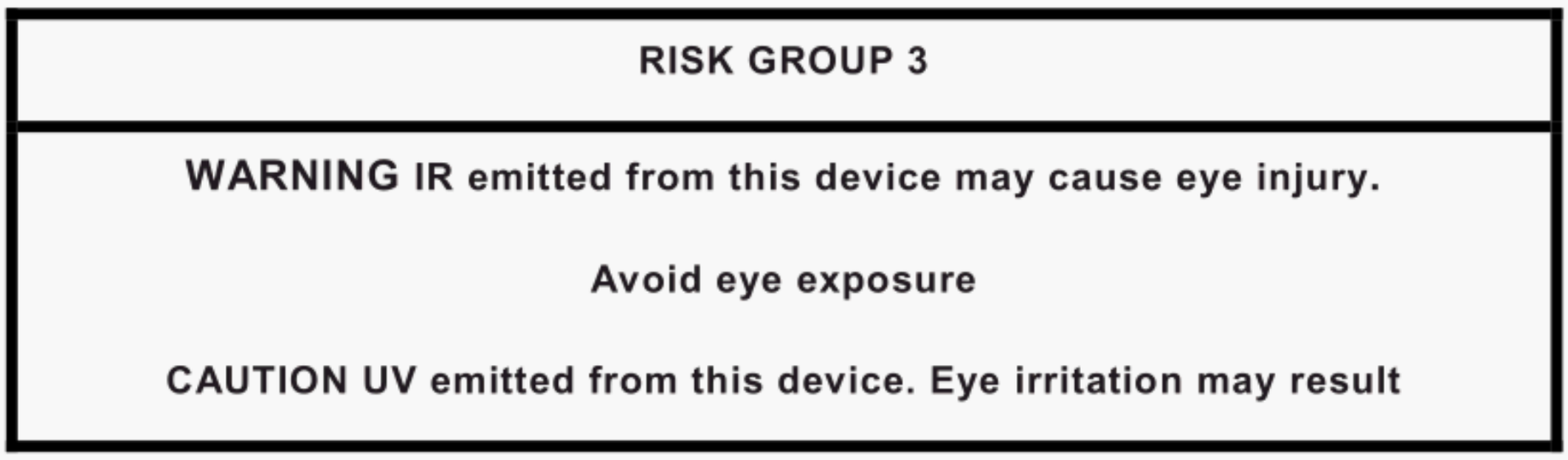


Figure 201.101 – Example of explanatory label for a device with multiple HAZARD spectral regions

201.7.101.2 Product label design and labelling information

LS EQUIPMENT classified in excess of the Exempt Group shall carry an explanatory label (Fig. 201.101) and warning label (Fig. 201.102) in accordance with the requirements of this standard and ISO 3864-2. The labels shall be durable, permanently affixed, legible, and clearly visible during operation, maintenance or service, according to their purpose. They shall be positioned so that they can be read without the necessity for human exposure to OPTICAL RADIATION in excess of the EXPOSURE LIMITS. Text borders and symbols shall be black on a yellow background.

If the size or design of the product makes labelling impractical, the label shall be included with the USER information or on the package.

NOTE 1 Direct printing or engraving of equivalent labels on the LS EQUIPMENT or panels is acceptable.

NOTE 2 Explanatory label may be of any size necessary to contain the required lettering and border. The minimum width of each border dimension should be 0,06 times the length of the shorter side of the label.

IEC 174/11

Figure 201.102 – Warning label – HAZARD symbol

201.7.101.3 EMISSION APERTURE label

Each LS EQUIPMENT classified in excess of Risk Group 1 shall have a label affixed close to each EMISSION APERTURE. The label(s) shall bear the words:

OPTICAL RADIATION APERTURE

or

APERTURE FOR OPTICAL RADIATION

or

AVOID EXPOSURE – OPTICAL RADIATION IS EMITTED FROM THIS APERTURE

201.7.101.4 Radiation output and standards information

The name and publication date of the standard to which the product was classified shall be included on the explanatory label or elsewhere in close proximity on the product. Each LS EQUIPMENT shall be described on the explanatory label by a statement of the maximum output of OPTICAL RADIATION, the PULSE DURATION range (if appropriate) and the emitted wavelength range.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.10.4 Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

Additional subclause:

201.8.10.4.101 Footswitch

Any foot-operated exposure control switch shall be shrouded to prevent unintentional operation. The force required to actuate the switch shall be not less than 10 N, applied over an area of 625 mm² anywhere on the operating surface of the footswitch. This force shall not exceed 50 N.

Compliance is checked by measurement of the actuating force.

NOTE HAND-HELD PARTS are covered in 8.10.4 of the general standard.

201.8.11 MAINS PARTS, components and layout

Additional subclause:

201.8.11.101 Cooling liquid

Where liquid is used in LS EQUIPMENT for cooling and where the liquid assumes the task of BASIC INSULATION to the SUPPLY MAINS, the conductivity of the liquid shall be such that the leakage current values required in 8.7 of the general standard are not exceeded in NORMAL USE. The conductivity of the liquid shall be continuously monitored by the LS EQUIPMENT. In case of leakage current exceeding the values required in 8.7 of the general standard as a result of increased liquid conductivity, the LS EQUIPMENT shall be switched off automatically from the SUPPLY MAINS.

Compliance is checked by inspection and functional tests.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies except as follows:

Additional subclauses:

201.10.101 Disabling device

LS EQUIPMENT may be fitted with a suitable device that disables the release of OPTICAL RADIATION in the absence of the target tissue.

If the LS EQUIPMENT is classified into a lower risk group by implementing such a device, the following requirement shall be met. Once an exposure has been completed, the equipment shall not be capable of emitting OPTICAL RADIATION again until the device has been re-activated.

201.10.102 Shield

Where the applicator is used in contact with the target area, LS EQUIPMENT of Risk Group 3 shall incorporate a means which prevents radiation being emitted from the applicator in a direction other than intended for the treatment.

LS EQUIPMENT may additionally incorporate a removable or fixed means which prevents USER exposure to radiation scattered from the target area.

201.10.103 Output uniformity

The spatial variation of the LS EQUIPMENT OUTPUT over the treatment area shall not deviate from the average irradiance or radiant exposure by more than ± 20% when the LS EQUIPMENT is Risk Group 3. A decrease of output greater than 20% is acceptable for the edge of the treatment area (20 % of the area).

Compliance testing: the detector area of the measuring device should not be larger than the typical absorption depth of the wavelengths incident on the target tissue. For visible and IR LS EQUIPMENT a detector area corresponding to 2 mm detector diameter may be chosen.

201.10.104 Controls and indicators

For the protection of the PATIENT, the OPERATOR, and other persons present, LS EQUIPMENT of Risk Group 3 shall incorporate:

a) Key-operated master control. The key shall be removable and the OPTICAL RADIATION shall not be accessible when the key is removed.

NOTE In this particular standard the term "key" includes any other control devices, such as magnetic cards, cipher combinations, computer passwords, etc.

b) Visible or audible READY INDICATOR, which shall be illuminated or audible when emission of the OPTICAL RADIATION is possible upon actuation of the control switch, to allow appropriate safety precautions to be taken.

c) OPTICAL RADIATION indicator

In addition to the READY INDICATOR, LS EQUIPMENT shall be equipped with a visible or an audible signal, which clearly indicates that emission of OPTICAL RADIATION is taking place.

If the indicators are of visible type, the READY INDICATOR and the OPTICAL RADIATION indicator shall be visible through protective eyewear recommended by the MANUFACTURER.

d) STAND-BY/READY control

LS EQUIPMENT shall be equipped with a STAND-BY/READY control. On initial switch-on the LS EQUIPMENT shall default to STAND-BY condition.

Compliance is checked by inspection.

201.10.105 Exposure termination

When the exposure termination is by means of a timer, for LS EQUIPMENT classified as Risk Group 3, protection against SINGLE FAULT CONDITIONS shall be provided by a safety device which is independent of the timer and is activated when the set time is exceeded by 20 %. The safety device shall terminate the OPTICAL RADIATION output and shall prevent further operation of the equipment.

NOTE A second timer may be a means of achieving compliance with this requirement.

Compliance is checked by inspection and measurements.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclause:

201.12.1.101 *Indication of LS EQUIPMENT OUTPUT

LS EQUIPMENT of Risk Group 3 shall display the USER selected value of the output of the OPTICAL RADIATION in SI units (use of submultiples, e.g. either cm^2 or m^2, is allowed).

Compliance is checked by inspection.

201.12.4.2 *Indication of parameters relevant to safety

Addition:

The LS EQUIPMENT OUTPUT and, where applicable, PULSE DURATION, emitted by the equipment shall not deviate from the pre-set indicated value by more than ± 20 %. A measured quantity, electrical or optical, which is directly related to the LS EQUIPMENT OUTPUT and PULSE DURATION, shall be monitored during operation. The monitoring shall be carried out at intervals shorter than the failure tolerance time. The indicated SHORT WAVELENGTH BOUNDARY for the LS EQUIPMENT shall not deviate from the SET VALUE by more than 5 %.

The LS EQUIPMENT OUTPUT emitted at the treatment area shall be checked each time the LS EQUIPMENT is switched on. One possible option is that the USER is able to perform this test according to instructions provided by the MANUFACTURER.

The LS EQUIPMENT shall not be able to be put into the READY state before the LS EQUIPMENT OUTPUT has been checked and the check has been validated each time the LS EQUIPMENT is switched to SUPPLY MAINS.

PULSE DURATION and SHORT WAVELENGTH BOUNDARY shall be checked at regular intervals. The test methods and the intervals shall be described in the instructions for use in accordance with 201.7.9.2.101.2.

Compliance is checked by inspection and measurements.

Additional subclause:

201.12.4.101 EMERGENCY STOP

LS EQUIPMENT classified as Risk Group 3 shall incorporate an EMERGENCY STOP. The EMERGENCY STOP shall immediately stop the emission of OPTICAL RADIATION. The EMERGENCY STOP shall be designed so as to be independent of all other LS EQUIPMENT stop systems. The switch shall be a red push-button device and be located in such a manner as to be readily visible and easily and quickly reached by the LS EQUIPMENT OPERATOR from the operating position. "EMERGENCY STOP" or symbol 101 of Table EE.1 shall be marked on or near the push-button.

If an EMERGENCY STOP according to IEC 60947-3 is incorporated in the LS EQUIPMENT, the EMERGENCY STOP for OPTICAL RADIATION is not required.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies except as follows:

201.13.1 Specific HAZARDOUS SITUATIONS

Additional subclause:

201.13.1.101 OPTICAL RADIATION HAZARDS

When applying the single fault conditions as described in 4.7 of the general standard and listed in 13.2 of the general standard and this particular standard, none of the HAZARDOUS SITUATIONS described in 13.1 of the general standard and this particular standard (inclusive) shall occur in the LS EQUIPMENT.

For LS EQUIPMENT of Risk Group 3, a single fault condition shall not result in an increase of accessible output greater than 100 % above the nominal value, or in an unintended release of OPTICAL RADIATION.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of this particular standard. Its purpose is to promote effective application of this particular standard by explaining the reasons for the requirements and provide additional guidance where appropriate.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.6.1.101 – Classification responsibilities and
subclause 201.6.1.102 – Classification rules

The time criterion for each optical radiation hazard used for risk group classification of LS EQUIPMENT is chosen so that the applicable EL is not exceeded during this time. LS EQUIPMENT is classified on the basis of the accessible emission over the full range of its intended use, under every foreseeable single fault condition and the time base criteria specified in table 201.102.

- *Exempt Group*

The LS EQUIPMENT that does not pose any of the following photo-biological hazards:

– an actinic ultraviolet HAZARD E_s within 8-hours exposure (30 000 s),
– a near-UV HAZARD E_{UVA} within 1 000 s,
– a retinal blue-light HAZARD L_B within 10 000 s,
– a retinal thermal HAZARD L_R within 10 s,
– an infrared radiation HAZARD, weak visual stimulus, L_{IR} within 10 s,
– an infrared radiation HAZARD for the eye E_{IR} within 1 000 s.

- *Risk Group 1 – Low risk*

The LS EQUIPMENT that does not pose any of the following hazards due to normal behavioural limitations on exposure:

– an actinic ultraviolet HAZARD E_s within 10 000 s,
– a near-UV HAZARD (E_{UVA}) within 300 s,
– a retinal blue-light HAZARD L_B within 100 s,
– a retinal thermal HAZARD L_R within 10 s,
– an infrared radiation HAZARD, weak visual stimulus, L_{IR} within 10 s,
– an infrared radiation HAZARD for the eye E_{IR} within 100 s.

- *Risk Group 2 – Moderate risk*

The LS EQUIPMENT that does not pose any of the following hazards due to aversion response against very bright light sources or against thermal discomfort:

– an actinic ultraviolet hazard E_s within 1 000 s,
– a near-UV hazard E_{UVA} within 100 s,
– a retinal blue-light hazard L_B within 0,25 s (aversion response),
– a retinal thermal hazard L_R within 0,25 s (aversion response),
– an infrared radiation hazard, weak visual stimulus, L_{IR} within 10 s,
– an infrared radiation hazard for the eye E_{IR} within 10 s.

- *Risk Group 3 – High risk*

The LS EQUIPMENT that may pose a hazard even for momentary or brief exposure. LS EQUIPMENT that exceeds the limits of Risk Group 2 should be classified as Risk Group 3 equipment.

The retinal thermal hazards $L_{R,}$ L_{IR} do not change with time for exposure durations longer than 10 s. A consequence of this is that if the emission limit L_{IR} of the Exempt Risk Group is exceeded for an exposure duration up to 10 s, the LS EQUIPMENT classified on the basis of the L_{IR} hazard is allocated to Risk Group 3. Similarly, LS EQUIPMENT classified on the basis of the retinal thermal hazard (L_R) is allocated to Risk Group 2 or 3, as appropriate, if the emission limit L_{IR} of the Exempt Risk Group is exceeded for exposure duration up to 10 s.

For LS EQUIPMENT classified in Risk Group 1 on the basis of E_s, E_{UVA}, L_B or E_{IR} HAZARDS, EMISSION LIMITS of the Exempt Risk Group for retinal HAZARDS L_R, L_{IR} should not be exceeded within 10 s.

For LS EQUIPMENT classified in Risk Group 2 on the basis of E_s, E_{UVA}, L_B or E_{IR} HAZARDS, EMISSION LIMITS of the Exempt Risk Group for retinal hazard L_{IR} (weak visual stimulus) should not be exceeded within 10 s.

Subclause 201.12.1.101 – Indication of LS EQUIPMENT OUTPUT

The display of the output is regarded important for comparison of treatment parameters of different LS EQUIPMENT. The photobiological effects also depend on other emission parameters, like wavelength range (filtering) and temporal characteristics. There are sometimes non-quantitative step controls of the output and the associated SI value is shown only in the accompanying literature.

When the LS EQUIPMENT is USER-controlled by setting target tissue parameters, e.g. the skin type or hair colour, and the LS EQUIPMENT derives the according output by an internal algorithm, then information on the actual output is important for the USER and needs to be displayed.

Subclause 201.12.4.2 – Indication of parameters relevant to safety

Failure tolerance time:

LS EQUIPMENT which terminates emission due to a fault conditions requires time to detect the fault and interrupt the emission. An excess exposure may be tolerated by the PATIENT or client for a certain time. This time is called failure tolerance time. The failure tolerance time depends on both the vulnerability of the target tissue and the emission characteristics of the LS EQUIPMENT. The failure tolerance time should be determined by the MANUFACTURER in the RISK MANAGEMENT FILE.

Annex BB
(informative)

Exposure limit Values

EXPOSURE LIMIT values (ELs) recommended by ICNIRP (International Commission for Non-Ionizing Radiation Protection) for non-coherent OPTICAL RADIATION are reproduced in Table BB.1 below.

Table BB.1 – EXPOSURE LIMIT values for non-coherent OPTICAL RADIATION

Wavelength nm	**EXPOSURE LIMIT value** (EL)	**Units**	**Comment**	**Part of the body**
200 to 400 (UVA, UVB and UVC)	H_{eff} = 30 Daily value 8 h	[J · m^{-2}]		**Eye** cornea conjunctiva lens **Skin**
315 to 400 (UVA)	H_{UVA} = 10^4 Daily value 8 h	[J · m^{-2}]		**Eye** lens
300 to 700 (Blue light)[a]	$L_B = \frac{10^6}{t}$ for t ≤10 000 s	L_B :[W · m^{-2} · sr^{-1}] t: [seconds]	for α ≥11 mrad	**Eye** retina
300 to 700 (Blue light)	L_B = 100 for t >10 000 s	[W · m^{-2} · sr^{-1}]		
300 to 700 (Blue light)	$E_B = \frac{100}{t}$ for t ≤10 000 s	E_B: [W · m^{-2}] t: [seconds]	for α <11 mrad	
300 to 700 (Blue light)	E_B = 0,01 t >10 000 s	[W · m^{-2}]		
380 to 1 400 (Visible and IRA)	$L_R = \frac{2{,}8 \cdot 10^7}{C_\alpha}$, for t >10 s	[W · m^{-2} · sr^{-1}]	C_α = 1,7 for α ≤1,7 mrad C_α = α for 1,7≤ α ≤100 mrad C_α = 100 for α >100 mrad λ_1= 380; λ_2= 1 400	**Eye** retina
380 to 1 400 (Visible and IRA)	$L_R = \frac{5 \cdot 10^7}{C_\alpha \cdot t^{0,25}}$, for 10 µs ≤t ≤10 s	L_R:[W · m^{-2} · sr^{-1}] t: [seconds]		
380 to 1 400 (Visible and IRA)	$L_R = \frac{8{,}89 \cdot 10^8}{C_\alpha}$, for t <10 µs	[W · m^{-2} · sr^{-1}]		
780 to 1 400 (IRA)	$L_R = \frac{6 \cdot 10^6}{C_\alpha}$, for t >10 s	[W · m^{-2} · sr^{-1}]	C_α = 11 for α ≤11 mrad C_α = α for 11≤ α ≤100 mrad C_α = 100 for α >100 mrad (**measurement field-of-view**: 11 mrad) λ_1= 780; λ_2= 1 400	
780 to 1 400 (IRA)	$L_R = \frac{5 \cdot 10^7}{C_\alpha \cdot t^{0,25}}$, for 10 µs ≤t ≤10 s	L_R: [W · m^{-2} · sr^{-1}] t: [seconds]		
780 to 1 400 (IRA)	$L_R = \frac{8{,}89 \cdot 10^8}{C_\alpha}$, for t <10 µs	L_R: [W · m^{-2} · sr^{-1}]		
780 to 3 000 (IRA and IRB)	E_{IR} = 18 000$^a t^{-0,75}$, for t ≤1 000 s	E_{IR}: [Wm^{-2}] t: [seconds]		**Eye** cornea lens
780 to 3 000 (IRA and IRB)	E_{IR} = 100, for t >1 000 s	[W m^{-2}]		

NOTE For steady fixation of very small sources with the ANGULAR SUBTENSE < 11 mrad, L_B can be converted to E_B. This normally applies only for ophthalmic instruments or a stabilised eye during anaesthesia. The maximum "stare time" is found by: $t_{max} = 100/E_B$ with E_B expressed in W · m^{-2}. Due to eye movements during normal visual tasks this does not exceed 100 s.

$$H_{eff} = \int_0^t \int_{\lambda=200\,nm}^{\lambda=400\,nm} E_\lambda(\lambda,t) \cdot S(\lambda) \cdot d\lambda \cdot dt$$

H_{eff} is only relevant in the range 200 nm to 400 nm

$$H_{UVA} = \int_0^t \int_{\lambda=315\,nm}^{\lambda=400\,nm} E_\lambda(\lambda,t) \cdot d\lambda \cdot dt$$

H_{UVA} is only relevant in the range 315 nm to 400 nm

$$L_B = \int_{\lambda=300\,nm}^{\lambda=700\,nm} L_\lambda(\lambda) \cdot B(\lambda) \cdot d\lambda$$

L_B is only relevant in the range 300 nm to 700 nm

$$E_B = \int_{\lambda=300\,nm}^{\lambda=700\,nm} E_\lambda(\lambda) \cdot B(\lambda) \cdot d\lambda$$

E_B is only relevant in the range 300 nm to 700 nm

$$L_R = \int_{\lambda=380\,nm}^{\lambda=1\,400\,nm} L_\lambda(\lambda) \cdot R(\lambda) \cdot d\lambda$$

L_R is only relevant in the range 380 nm to 1 400 nm

Spectral weighting $S(\lambda)$, $B(\lambda)$ and $R(\lambda)$ are given in Tables BB.2 and BB.3, respectively.

Table BB.2 – S(λ) [dimensionless], 200 nm to 400 nm

λ in nm	S (λ)	λ in nm	S(λ)	λ in nm	S(λ)	λ in nm	S(λ)
200	0,0300	250	0,4300	300	0,3000	350	0,000200
202	0,0371	252	0,4637	302	0,1629	352	0,000183
204	0,0459	254	0,5000	304	0,0849	354	0,000167
206	0,0551	256	0,5437	306	0,0454	356	0,000153
208	0,0643	258	0,5945	308	0,0260	358	0,000141
210	0,0750	260	0,6500	310	0,0150	360	0,000130
212	0,0824	262	0,7098	312	0,0081	362	0,000122
214	0,0906	264	0,7751	314	0,0042	364	0,000114
216	0,0995	266	0,8449	316	0,0024	366	0,000106
218	0,1093	268	0,9192	318	0,0016	368	0,000099
220	0,1200	270	1,0000	320	0,0010	370	0,000093
222	0,1316	272	0,9838	322	0,000670	372	0,000086
224	0,1444	274	0,9679	324	0,000520	374	0,000080
226	0,1583	276	0,9434	326	0,000479	376	0,000074
228	0,1737	278	0,9112	328	0,000440	378	0,000069
230	0,1900	280	0,8800	330	0,000410	380	0,000064
232	0,2089	282	0,8342	332	0,000383	382	0,000059
234	0,2292	284	0,7908	334	0,000355	384	0,000055
236	0,2510	286	0,7420	336	0,000327	386	0,000051
238	0,2744	288	0,6891	338	0,000303	388	0,000047
240	0,3000	290	0,6400	340	0,000280	390	0,000044
242	0,3227	292	0,5980	342	0,000263	392	0,000041
244	0,3471	294	0,5587	344	0,000248	394	0,000037
246	0,3730	296	0,4984	346	0,000231	396	0,000035
248	0,4005	298	0,3989	348	0,000215	398	0,000032
						400	0,000030
Refer to: Guidance on Limits of Exposure to Ultraviolet Radiation of Wavelength Between 180 nm and 400 nm (Incoherent Optical Radiation). *Health Physics*, 87 (2), 171-186, 2004 [3]							

Table BB.3 – B (λ), R (λ) [dimensionless], 300 nm to 1 400 nm

λ in nm	B (λ)	R (λ)
300 – <380	0,01	–
380	0,01	0,1
385	0,013	0,13
390	0,025	0,25
395	0,05	0,5
400	0,1	1
405	0,2	2
410	0,4	4
415	0,8	8
420	0,9	9
425	0,95	9,5
430	0,98	9,8
435	1	10
440	1	10
445	0,97	9,7
450	0,94	9,4
455	0,9	9
460	0,8	8
465	0,7	7
470	0,62	6,2
475	0,55	5,5
480	0,45	4,5
485	0,32	3,2
490	0,22	2,2
495	0,16	1,6
500	0,1	1
>500 – ≤600	$10^{0,02\cdot(450-\lambda)}$	1
>600 – ≤700	0.001	1
>700 – ≤1 050	–	$10^{0,002\cdot(700-\lambda)}$
>1 050 – ≤1 150	–	0,2
>1 150 – ≤1 200	–	$0,2\cdot10^{0,02\cdot(1\,150-\lambda)}$
>1 200 – 1 400	–	0,02
Refer to: ICNIRP Guidelines on Limits of exposure to broad-band incoherent optical radiation (0,38 to 3 μm). *Health Physics*, vol 73, no.3, 539-554 (1997) [4].		

Annex CC
(informative)

Protective eyewear for LS EQUIPMENT

Recommendations on selection of protective eyewear should take into account:

– ability to protect against specific workplace hazards;
– emergency controls and warnings should be clearly visible through protective eyewear;
– should fit properly and be reasonably comfortable to wear;
– should provide least restricted vision and movement;
– should be durable and cleanable;
– should allow unrestricted functioning of any other required PPE.

Additionally, if the USER needs prescribed correction lenses, the safety eyewear should not compromise the prescribed correction. It may be worn on top of the prescription glasses like goggles or it may contain a prescription glass insert/clip.

Different types of protective eyewear may be required for PATIENTS/clients and USERS. Protective eyewear for PATIENTS/clients may be opaque.

The requirements for protection against hazardous visible light and luminous transmission need to be balanced. Possible options include:

– selection of eyewear with attenuation only in the hazard wavelength range and high transmission outside hazardous spectral region;
– active filtering eyewear.

Further information on protective eyewear may be found in BS 8497-1:2008 [1] and BS 8497-2:2008 [2].

Annex DD
(informative)

Summary of MANUFACTURER'S requirements

Table DD.1 – Summary of MANUFACTURER'S requirements

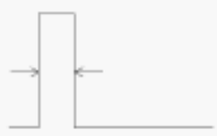
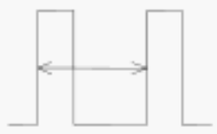
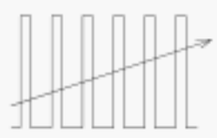
Requirements	Classification of risk group			
	Exempt Group	Risk Group 1	Risk Group 2	Risk Group 3
Description of risk group (refer to 201.6.1.102; Annex AA)	Safe under reasonably foreseeable conditions	Low risk - does not pose a hazard due to normal behavioural limitations on exposure	Moderate risk - does not pose a hazard due to aversion response to very bright light sources or due to thermal discomfort	High risk – may pose a hazard even for momentary or brief exposure
Labelling 201.7.101	Not required	Required for equipment emitting UV or IR radiation	Required	Required
Key control 201.10.104 a)	Not required	Not required	Not required	Required
EMERGENCY STOP 201.12.4.101; Annex EE	Not required	Not required	Not required	Required
OPTICAL RADIATION indicator 201.10.104 c)	Not required	Not required	Not required	Required
STAND BY/READY 201.10.104 d); Annex EE	Not required	Not required	Not required	Required
Automatic overexposure termination 201.10.105	Not required	Not required	Not required	Required
Hazard distance information 201.7.9.2.101.1	Not required	Not required	Required	Required
Information on LS EQUIPMENT OUTPUT 201.7.9.2.101.1	Required	Required	Required	Required
Safety information 201.7.9.2.101.2	Required	Required	Required	Required
NOTE The rationale behind the risk group classification is inadvertent worker's exposure. According to 12.4.1 of the general standard, MANUFACTURERS are responsible for providing a risk management file, including PATIENT risks. The MANUFACTURER'S risk assessments may determine that requirements which are applicable to higher risk groups may also be applied to lower risk groups.				

Annex EE
(informative)

Symbols on marking

Table EE.1 – Symbols, references and descriptions

The following symbols may be used on LS EQUIPMENT:

No.	Symbol	IEC reference	Description
101			Emergency LS EQUIPMENT stop
102		417-5266-a	STAND-BY/READY (STAND-BY)
103		417-5264-a	STAND-BY/READY (READY) [a]
104			CONTINUOUS OPERATION. The LS EQUIPMENT is set to a mode, where the EXPOSURE TIME is limited by THE LS EQUIPMENT OPERATOR actuating and releasing the switch
105			Single exposure. The LS EQUIPMENT is set to a mode, where one single exposure of a given duration is emitted when the switch is activated
106			Repeat exposure. The LS EQUIPMENT is set to a mode, where a series of exposures of a given duration and of a given pulse interval are emitted as long as the switch is activated
107			Exposure time
108			Repeat exposure pulse repetition time
109			Specialized pulsed mode. A pulsed mode of the light source equipment which may be used as an alternative to the mode of CONTINUOUS OPERATION
113			Optical fibre applicator
114			PRF, PULSE repetition frequency [rate]
NOTE The symbols either concur with the symbols contained in IEC/TR 60878:2003 [5] or are exclusive to IEC 60601-2-57. The above list is not to be considered as an exclusive list. Other symbols may be chosen from IEC/TR 60878 if appropriate.			
[a] This symbol is listed in Table D.1 No 16 of IEC 60601-1 as “ON” for part of the equipment. LS EQUIPMENT could make use of this symbol to indicate the “STANDBY” and “READY” states.			

Bibliography

[1] BS 8497-1:2008. *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications – Part 1: Specification for products*

[2] BS 8497-2:2008. *Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications – Part 2: Guidance on use*

[3] Guidance on Limits of Exposure to Ultraviolet Radiation of Wavelength Between 180 nm and 400 nm (Incoherent Optical Radiation). *Health Physics*, 87 (2), 171-186, 2004

[4] ICNIRP: Guidelines on limits of exposure to broad-band incoherent optical radiation (0,38 µm to 3 µm). *Health Physics* Vol. 73, No. 3, pp. 539-554, 1997

[5] IEC/TR 60878:2003, *Graphical symbols for electrical equipment in medical practice*

Index of defined terms used in this particular standard