

**SASO IEC 60601-2-57****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**

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### **INTRODUCTION**

The Saudi Standards, Metrology and Quality Organization (SASO) has adopted the International Standard IEC 60601-2-57Ed 1.0 /2011 "MEDICAL ELECTRICAL EQUIPMENT – Part 2-57: 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" issued by the International Electro technical Commission (IEC). It has been adopted without any technical modifications with a view to its approval as a Saudi standard.

**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<sup>1)</sup> 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 photo-biological 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;

<sup>1)</sup> 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 2.

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

$\gamma$

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** $\alpha$ 

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  $\gamma$  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  $\gamma$  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  $\gamma$  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<br>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            | $L_R$     | $28\,000/\alpha$ | N/A <sup>a</sup> | $71\,000/\alpha$ | $W \cdot m^2 \cdot sr^{-1}$ |
| Retinal thermal, weak visual stimulus | 780 – 1 400            | $L_{IR}$  | $6\,000/\alpha$  | N/A <sup>a</sup> | N/A <sup>a</sup> | $W \cdot m^2 \cdot sr^{-1}$ |
| 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

<sup>a</sup> 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  $\gamma$  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  $\gamma$  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  $\gamma$  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<br>nm | Time<br>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<br>nm | Angle of acceptance $\gamma$<br>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          |

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|                                       |             |       |       |        |
|---------------------------------------|-------------|-------|-------|--------|
| 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**

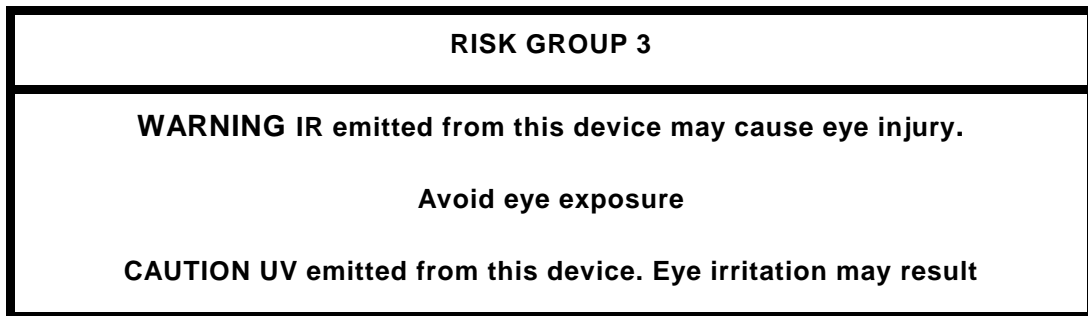
| Hazard     | Exempt Group | Risk Group 1                           | Risk Group 2  | Risk Group 3  |
|------------|--------------|--|---|---|
| Actinic UV | Not required | CAUTION<br>UV emitted from this device | CAUTION<br>UV emitted from this device<br>Eye or skin irritation may result | WARNING<br>UV emitted from this device may be hazardous<br>Avoid eye or skin exposure |
| Near UV    | Not required | CAUTION<br>UV emitted from this device | CAUTION<br>UV emitted from this device<br>Eye irritation may result         | WARNING<br>UV emitted from this device may be hazardous<br>Avoid eye exposure         |

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|                                       |              |   |   |  |
|---------------------------------------|--------------|---|---|--|
| Blue-light                            | Not required | Not required  | CAUTION<br>The light emitted may be harmful to the eyes<br>Do not stare at the light source         | WARNING<br>The light emitted may result in eye injury<br>Do not look at the light source |
| Retinal Thermal                       | Not required | Not applicable  | CAUTION<br>The light emitted may be harmful to the eyes<br>Do not stare at the light source         |  |
| Retinal Thermal, weak visual stimulus | Not required | Not applicable  | Not applicable  | WARNING<br>IR emitted from this device may cause eye injury<br>Avoid eye exposure        |
| Corneal/ Lens IR                      | Not required | CAUTION<br>IR emitted from this device<br>Do not stare at the IR source | CAUTION<br>IR emitted from this device may cause eye irritation<br>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.



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**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

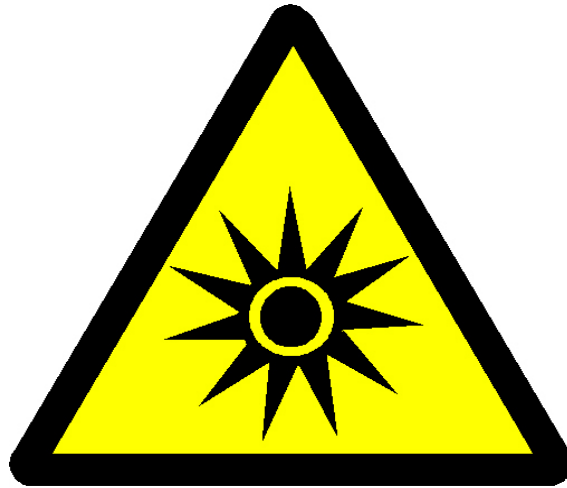
LS EQUIPMENT classified in excess of the Exempt Group shall carry an explanatory label (Fig. 201.101) and warning label (Fig. 201.102) in accordance with the requirements of this standard and ISO 3864-2. The labels shall be durable, permanently affixed, legible, and clearly visible during operation, 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 mm<sup>2</sup> 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  $\pm 20\%$  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<sup>2</sup> or m<sup>2</sup>, 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  $\pm 20\%$ . 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 A (informative)

### Particular guidance and rationale

#### A.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.

#### A.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

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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 B**  
(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<br>nm                        | EXPOSURE LIMIT value<br>(EL)   | Units  | Comment   | Part of the<br>body                           |
|---|--|--|---|---|
| 200 to 400<br>(UVA, UVB and UVC)        | $H_{\text{eff}} = 30$<br>Daily value 8 h   | $[J \cdot m^{-2}]$   |   | Eye cornea<br>conjunctiva<br>lens<br><br>Skin |
| 315 to 400<br>(UVA)                     | $H_{\text{UVA}} = 10^4$<br>Daily value 8 h   | $[J \cdot m^{-2}]$   |   | Eye lens                                      |
| 300 to 700<br>(Blue light) <sup>a</sup> | $L_B = \frac{10^6}{t}$<br>for $t \leq 10\,000$ s                                       | $L_B: [W \cdot m^{-2} \cdot sr^{-1}]$<br>$t: [\text{seconds}]$ | for $\alpha \geq 11$ mrad   | Eye retina                                    |
| 300 to 700<br>(Blue light)              | $L_B = 100$<br>for $t > 10\,000$ s   | $[W \cdot m^{-2} \cdot sr^{-1}]$                               |   |   |
| 300 to 700<br>(Blue light)              | $E_B = \frac{100}{t}$<br>for $t \leq 10\,000$ s  | $E_B: [W \cdot m^{-2}]$<br>$t: [\text{seconds}]$               | for $\alpha < 11$ mrad  | Eye retina                                    |
| 300 to 700<br>(Blue light)              | $E_B = 0,01$<br>$t > 10\,000$ s  | $[W \cdot m^{-2}]$   |   |   |
| 380 to 1 400<br>(Visible and IRA)       | $L_R = \frac{2,8 \cdot 10^7}{C_\alpha}$ , for $t > 10$ s                               | $[W \cdot m^{-2} \cdot sr^{-1}]$                               | $C_\alpha = 1,7$ for<br>$\alpha \leq 1,7$ mrad  | Eye retina                                    |
| 380 to 1 400<br>(Visible and IRA)       | $L_R = \frac{5 \cdot 10^7}{C_\alpha \cdot t^{0,25}}$ , for $10 \mu s \leq t \leq 10$ s | $L_R: [W \cdot m^{-2} \cdot sr^{-1}]$<br>$t: [\text{seconds}]$ | $C_\alpha = \alpha$ for<br>$1,7 \leq \alpha \leq 100$ mrad  |   |
| 380 to 1 400<br>(Visible and IRA)       | $L_R = \frac{8,89 \cdot 10^8}{C_\alpha}$ , for $t < 10 \mu s$                          | $[W \cdot m^{-2} \cdot sr^{-1}]$                               | $C_\alpha = 100$ for<br>$\alpha > 100$ mrad<br>$\lambda_1 = 380; \lambda_2 = 1\,400$  |   |
| 780 to 1 400<br>(IRA)                   | $L_R = \frac{6 \cdot 10^6}{C_\alpha}$ , for $t > 10$ s                                 | $[W \cdot m^{-2} \cdot sr^{-1}]$                               | $C_\alpha = 11$ for<br>$\alpha \leq 11$ mrad  |   |
| 780 to 1 400<br>(IRA)                   | $L_R = \frac{5 \cdot 10^7}{C_\alpha \cdot t^{0,25}}$ , for $10 \mu s \leq t \leq 10$ s | $L_R: [W \cdot m^{-2} \cdot sr^{-1}]$<br>$t: [\text{seconds}]$ | $C_\alpha = \alpha$ for<br>$11 \leq \alpha \leq 100$ mrad   |   |
| 780 to 1 400<br>(IRA)                   | $L_R = \frac{8,89 \cdot 10^8}{C_\alpha}$ , for $t < 10 \mu s$                          | $L_R: [W \cdot m^{-2} \cdot sr^{-1}]$                          | $C_\alpha = 100$ for<br>$\alpha > 100$ mrad<br><b>(measurement field-of-view:<br/>11 mrad)</b><br>$\lambda_1 = 780; \lambda_2 = 1\,400$ |   |
| 780 to 3 000<br>(IRA and IRB)           | $E_{\text{IR}} = 18\,000 a_t^{-0,75}$ , for $t \leq 1\,000$ s                          | $E_{\text{IR}}: [Wm^{-2}]$<br>$t: [\text{seconds}]$            |   | Eye cornea<br>lens                            |

780 to 3 000  
(IRA and IRB) $E_{IR} = 100$ , for  $t > 1\ 000$  s[W m<sup>-2</sup>]

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<sup>-2</sup>. Due to eye movements during normal visual tasks this does not exceed 100 s.

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

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

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

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

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

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

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

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

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

$L_R$  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<br>in nm | S(λ)   | λ<br>in nm | S(λ)   | λ<br>in nm | S(λ)   | λ<br>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 –  $B(\lambda)$ ,  $R(\lambda)$  [dimensionless], 300 nm to 1 400 nm

| $\lambda$<br>in nm   | $B(\lambda)$                      | $R(\lambda)$                                  |
|--|-----------------------------------|---|
| 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  | –                                 | $0,2 \cdot 10^{0,02 \cdot (1 150 - \lambda)}$ |
| >1 200 – 1 400   | –                                 | 0,02  |
| Refer to: ICNIRP Guidelines on Limits of exposure to broad-band incoherent optical radiation (0,38 to 3 $\mu\text{m}$ ). <i>Health Physics</i> , vol 73, no.3, 539-554 (1997) [4]. |                                   |   |

**Annex C**  
(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 D**  
(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<br>(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<br>201.7.101   | Not required                                 | Required for equipment emitting UV or IR radiation                                  | Required  | Required   |
| Key control<br>201.10.104 a)   | Not required                                 | Not required  | Not required  | Required   |
| EMERGENCY STOP<br>201.12.4.101; Annex EE   | Not required                                 | Not required  | Not required  | Required   |
| OPTICAL RADIATION indicator<br>201.10.104 c)   | Not required                                 | Not required  | Not required  | Required   |
| STAND BY/READY<br>201.10.104 d); Annex EE  | Not required                                 | Not required  | Not required  | Required   |
| Automatic overexposure termination<br>201.10.105   | Not required                                 | Not required  | Not required  | Required   |
| Hazard distance information<br>201.7.9.2.101.1   | Not required                                 | Not required  | Required  | Required   |
| Information on LS EQUIPMENT OUTPUT<br>201.7.9.2.101.1  | Required                                     | Required  | Required  | Required   |
| Safety information<br>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. |  |   |   |  |




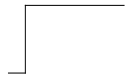
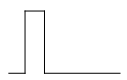
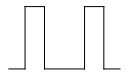
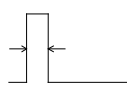
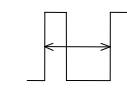


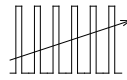


## Annex E (informative)

### 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) <sup>a</sup>  |
| 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.

<sup>a</sup> 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  $\mu\text{m}$  to 3  $\mu\text{m}$ ). *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

|                                    |                         |
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