BRITISH STANDARD

Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications

Part 2: Guidance on use

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Publishing and copyright information

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Contents

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 17 and a back cover.

Foreword

Publishing information

This part of BS 8497 is published by BSI and came into effect on 31 March 2008. It was prepared by Technical Committee PH/2/3, *Eye protection against lasers*. A list of organizations represented on this committee can be obtained on request to its secretary.

Information about this document

This is a new standard, which has been written to fill a need for the standardization of protective eyewear for users of intense light source (ILS) equipment.

Use of this document

As a guide, this British Standard takes the form of guidance and recommendations. It should not be quoted as if it were a specification and particular care should be taken to ensure that claims of compliance are not misleading.

Any user claiming compliance with this British Standard is expected to be able to justify any course of action that deviates from its recommendations.

It has been assumed in the preparation of this British Standard that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions in this standard are presented in roman (i.e. upright) type. Its recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Introduction

Protective eyewear for intense light source (ILS) equipment protects against excessive exposure to optical radiation during normal operation of the equipment and foreseeable accidental exposure due to equipment malfunctioning or human error. This includes accidental and cumulative exposure, and discomfort associated with viewing bright reflections.

1 Scope

This British Standard gives guidance and information to users, manufacturers and suppliers of ILS devices and safety advisors on the selection and safe use of eye protectors for humans and animals for cosmetic and medical applications used against excessive exposure to optical radiation in the spectral range 180 nm to 3 000 nm, with the exception of laser radiation.

This standard is not applicable to eye protectors for use with tanning equipment, ophthalmic instruments or other medical/cosmetic devices, the safety issues of which are addressed through other European and British standards.

2 Normative references

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.

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*

3 Terms and definitions

For the purpose of this British Standard, the terms and definitions given in BS 8497-1 and the following apply.

3.1 attenuation
decrease in the radiant flux as it passes through an absorbing or scattering medium

3.2 exposure limit values (ELVs)
level of exposure to the eye or skin that is not expected to result in adverse biological effects

3.3 intense pulsed light source (IPLS)
ILS that delivers its energy in the form of a single pulse or a train of pulses where each pulse is assumed to have a duration less than 0.25 s for wavelengths in the range 400 nm to 700 nm and 10 s for all other wavelengths

3.4 ocular hazard distance (OHD)
distance at which the beam irradiance, radiance or radiant exposure equals the appropriate ocular ELVs

3.5 pulse duration
time increment measured between the half peak (50%) of power points at the leading and trailing edges of a pulse

3.6 pulse separation
time between the end of one pulse and the onset of the following pulse, measured at the 50% trailing and leading edges

4 Optical radiation hazards

4.1 Risk assessment

4.1.1 The eye is at risk of injury from optical radiation in excess of the exposure limit values (ELVs) (see Annex A). A comparison of the predicted or measured radiation exposure with the applicable ELVs allows an assessment of a personal workplace exposure to optical radiation.

4.1.2 The risk assessment should include the following.

a) Determine the ELVs for exposure duration, type of hazard and emitting device configuration.

b) Calculate the spectrally weighted radiance using the data provided by the manufacturer of the ILS equipment. If this information is not available, measure the actual spectral irradiance or spectral radiance.

c) Compare the measured values with the ELVs.

4.1.3 If other measures are inadequate to control the risk of eye exposure in excess of any applicable ELVs, eye protection specifically designed for the wavelengths and output should be worn.

NOTE Personnel who might be at risk include the patient/client, ILS equipment operator, assisting staff and others.

4.1.4 See Annex B for a retinal thermal hazard assessment and Annex C for a worked example calculation.

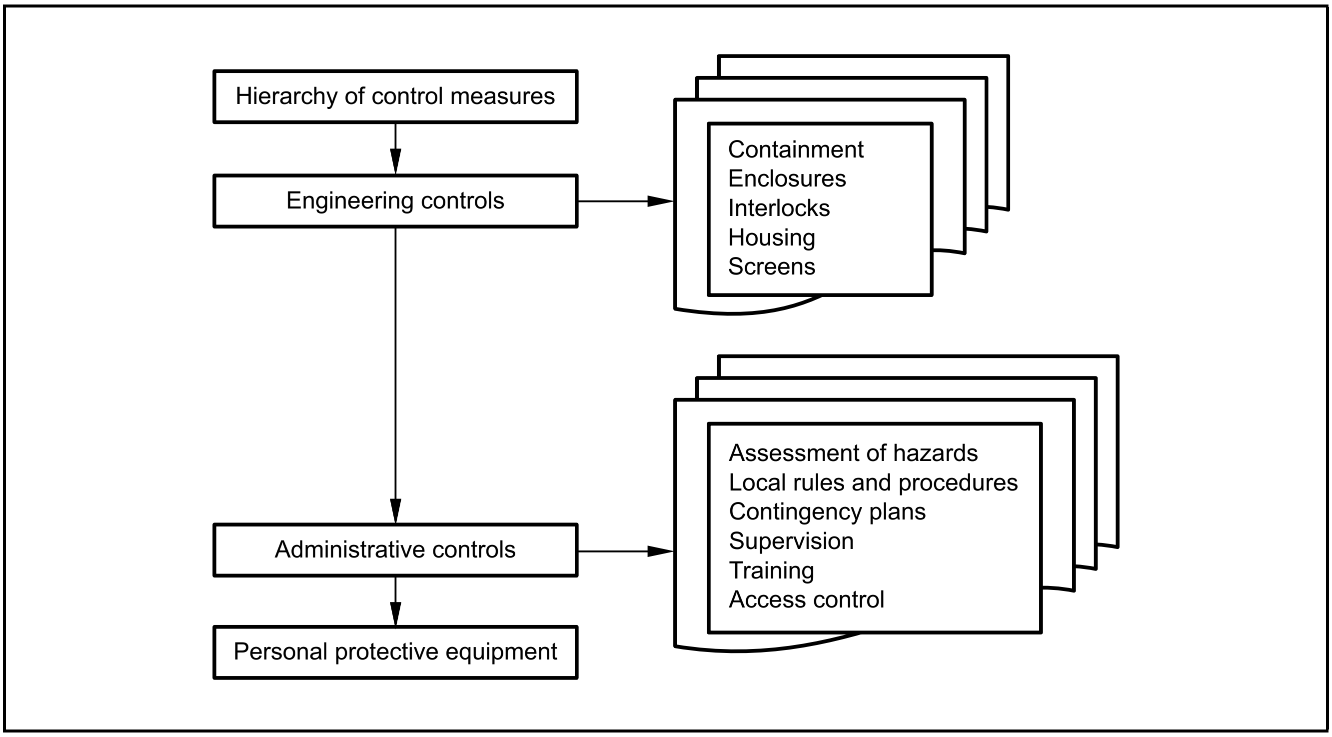
4.2 Control measures

4.2.1 Any person who is present within the hazard distance should be protected against eye or skin exposure to optical radiation above any applicable ELVs.

4.2.2 The extent of the skin and ocular hazard distance might vary according to the type of ILS equipment used and the optical properties of the applicators.

4.2.3 Exposure to optical radiation should be reduced, as far as reasonably practicable, by means of physical safeguards, such as engineering controls. Personal protection should only be used when engineering and administrative controls are impracticable or incomplete, in accordance with Figure 1.

Figure 1 **Hierarchy of control measures**



5 Eye protection

5.1 Protective eyewear

5.1.1 Reduction of unintended exposure should be included in the design specifications of the ILS equipment. Exposure to optical radiation should be reduced, as far as reasonably practicable, by means of physical safeguards, such as engineering controls.

5.1.2 When the treatment region is close to the eye, the patient's or client's protective eyewear should be selected carefully, as there will be a significant risk of exposure in excess of the ELVs. Consideration should also be given to the good fit of safety eyewear to prevent penetration of optical radiation from around the frame.

5.1.3 Different types of eye protection might be required for patients/clients, ILS equipment operators and supporting personnel.

5.1.4 An unambiguous and robust method of marking the ILS protective eyewear should be employed to ensure that there is a clear link to the particular ILS equipment device for which it has been specified.

5.1.5 A checklist to help select protective eyewear for the patient/client is given in Annex D.

5.1.6 A checklist to help select protective eyewear for the operator is given in Annex E.

5.2 Filter protection factor (FPF)

5.2.1 ELVs should be used to determine the required attenuation level of ILS protective filters because they refer to effective, i.e. spectrally weighted, radiance values.

5.2.2 Optical density or shade numbers should not be used for the characterization of ILS protective filters as they do not take into account the difference in the effect of different wavelengths on the eye.

5.2.3 FPF is a factor by which the protective filter attenuates the weighted ocular exposure. If the risk assessment demonstrates that ocular exposure limits are exceeded, the FPF of the protective eyewear should be adequate to ensure the exposure limit is not exceeded (see Annex F). This excess factor is likely to be different for a patient/client and operator, therefore, the FPF of protective eyewear for patient and operator would be different.

5.3 Luminous transmittance and colour perception

5.3.1 The luminous transmittance and the colour of the environment as seen through ILS protective filters (perceived colour) are important characteristics of protective eyewear which enable the operator to perform treatment without compromising non-optical radiation safety (see Annex G and Annex H).

5.3.2 Perceived colour depends on the spectral characteristics of the protective filter and illumination source. Thus, treatment might be performed under general light conditions (white light) or operating procedures might require an operator to observe the patient/client and control the equipment illuminated with radiation from ILS equipment. In these two cases, the colour of the environment (for example, equipment controls and blood) might appear different when seen through the same protective eyewear.

5.3.3 Colour is described as a (x, y) Commision Internationale de L'Eclairage (CIE) colour co-ordinate and might be presented in a CIE chromaticity chart (see Annex H). The (x, y) CIE co-ordinates take into account spectral characteristics of the filter and illumination source.

5.3.4 Red colour co-ordinates of protective filters mean that the visibility of equipment emergency controls and haemoglobin is substantially reduced.

6 User comfort and secondary safety issues

6.1 Peripheral leakage

Consideration should be given to the good fit of safety eyewear to prevent penetration of optical radiation from around the frame. This should be tested using a bright light prior to each use.

NOTE A patient's aversion response might be altered due to anaesthesia, sedation or other drugs.

6.2 Secondary reflections from eyewear frame and filters

Secondary reflections from frames or filters of protective eyewear might increase the risk of uncontrolled exposure of the user or others, therefore mirror-finish or high gloss filters and frames should not be used.

NOTE See BS 8497-1:2008, ***9.1****.*

6.3 Quality of filters and clarity of vision

6.3.1 Quality of filters of protective eyewear and clarity of vision should not limit the intended use of the ILS equipment, therefore, these characteristics are essential for an operator and unimportant for a patient/client. Patient/client protective eyewear may be opaque.

6.3.2 Filters of operator's eyewear should be free from any material or surface defects which are likely to impair the intended use, such as bubbles, scratches, inclusions, dull spots, scoring, excessive coloration or other defects.

6.4 Exposure to bright flashes below ELVs

6.4.1 For lower exposure levels (below ELVs), visual effects due to the temporary visual impairment might pose secondary safety hazards. Transient visual effects include disability (dazzle or veiling) glare, discomfort glare, startle (distraction) and after-images (flash blindness) (see Annex A).

6.4.2 Exposure to bright flashes cannot be corrected by the passive attenuation filters because passive filters attenuate ambient and flash level simultaneously.

6.4.3 Precautions should be taken against secondary safety hazards resulting from a temporary reduction in vision.

6.5 Overheating of eyewear

6.5.1 Excessive heating of eyewear frame and filters by absorbed radiation might cause ocular or cutaneous thermal damage in contact, especially for the patient/client.

6.5.2 The maximum temperature rise should not exceed 5 °C for the duration of treatment.

6.6 Additional considerations for active protective filters

6.6.1 Active filters of protective eyewear exhibit (directly or indirectly by applied voltage) a change of transmittance in response to an exposure to optical radiation. Consideration should be given to the response time of the active filter to ensure that it is appropriate for the ILS in use.

6.6.2 Only active filters that are designed, in the event of failure, to fail to a "safe state" should be used.

Annex A (informative) Ocular exposure to optical radiation

A.1 Exposure limit values (ELVs)

NOTE Attention is drawn to the Physical Agents (Artificial Optical Radiation) Directive) [1].

ELVs represent upper limits on exposure of the eye or skin that is not expected to result in adverse health effects. ELVs are set on the basis of experimental evidence and take into account uncertainties of that evidence. These levels are related to the wavelength of the radiation, the pulse duration or exposure time, the tissue at risk and, for radiation in the range of 380 nm to 1 400 nm, the size of the retinal image.

The limits for exposure require knowledge of the spectral radiance of the source, L_λ, and total irradiance, E, measured at the position of the eye or skin of the exposed person. Because ILS equipment can emit radiation as a series of pulses in a broad spectrum, calculation of the hazards can be complex.

The ocular hazard distance (OHD) should be taken into account when specifying the boundaries of the controlled area within which the access to optical radiation and activity of personnel is subject to control and supervision for the purpose of protection from optical radiation.

A.2 Exposures below ELVs

For lower exposure levels (below ELVs), visual effects due to temporary visual impairment might pose secondary safety hazards (see **6.4**).

Exposure to near UV/blue wavelength sources at exposure levels below ELVs (according to existing guidance) can induce a fluorescence in the lens of the eye with veiling glare intense enough to degrade visual performance and impair vision at normal indoor lighting levels.

Discomfort glare can develop in working environments where people are exposed to high luminance sources for long periods and might result in loss of visual efficiency. Discomfort glare depends on source brightness and the general field brightness controlling the adaptation level of the observer. CIE recommends the “glare constant” numerical scale as a criterion of discomfort glare, with 150 considered as “just uncomfortable”.

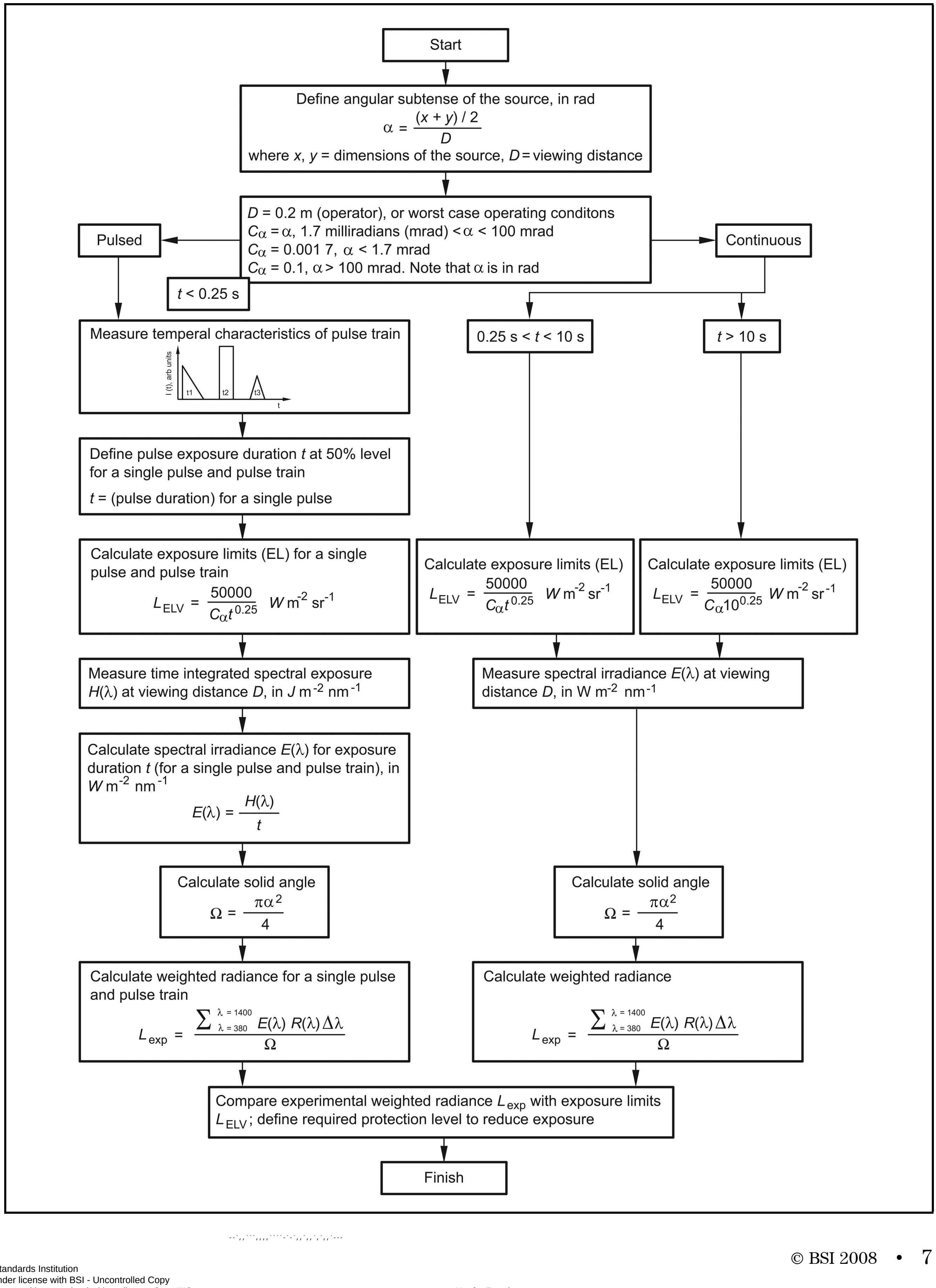
The relationship between the lighting of the work area and adjacent areas is also important. Large differences in brightness between the lighting of the work area and adjacent areas might cause visual discomfort or even compromise safety. The maximum recommended ratio of brightness of work area to adjacent areas is 10:1. If this ratio is above 10:1, consideration should be given to additional protective measures.

A.3 Example of an optical radiation hazard

See Annex B for a retinal thermal hazard assessment and Annex C for a worked example calculation.

Annex B (informative) Retinal thermal hazard – Assessment flowchart

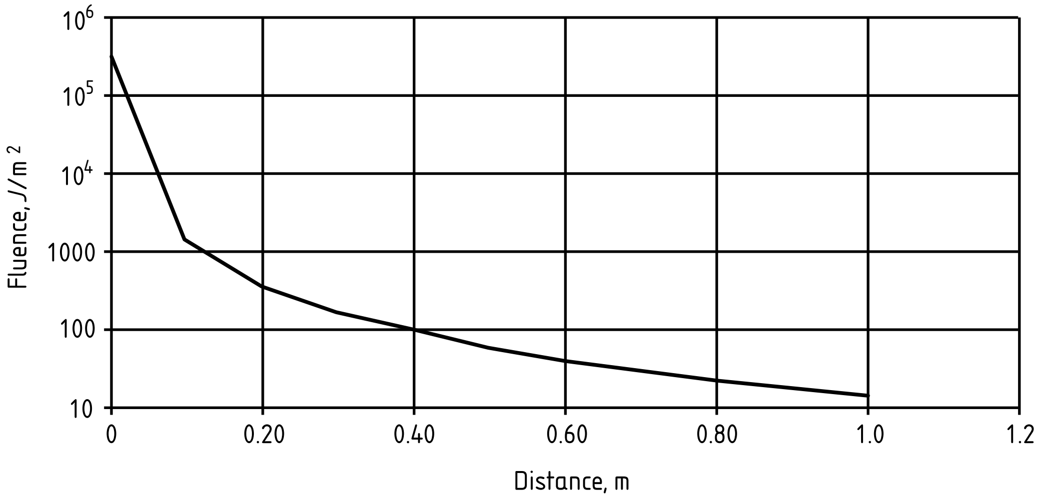
Figure B.1 **Flowchart for the assessment of retinal thermal hazard**



Annex C (informative) Retinal thermal hazard – Example calculation

C.1 IPLS device A is used for cosmetic treatment. The fluence of IPLS A measured at different distances from the device is shown in Figure C.1.

Figure C.1 **Decrease of the fluence with the distance away from IPLS A**



C.2 The following equation is used to calculate the ELV for retinal thermal hazard: $L_{\mathrm{ELV}} = \dfrac{50000}{C_\alpha t^{0.25}} \quad W\,\mathrm{m}^{-2}\,\mathrm{sr}^{-1}$

The information on exposure duration t and C_α is required.

C_α relates to the angular subtense of the source α as:

C_α = α, 1.7 milliradians (mrad) < α < 100 mrad;

C_α = 0.001 7, α < 1.7 mrad;

C_α = 0.100, α > 100 mrad.

NOTE α is in rad.

C.3 The longest and shortest dimensions of the IPLS emitting aperture (x, y) and viewing distance D are measured to calculate α. Dimensions of the IPLS emitting aperture are 10 mm × 30 mm (0.01 m × 0.03 m).

NOTE For the operator, the worst foreseeable case of accidental exposure is D = 0.2 m (arm's length).

C.4 The angular subtense of the source α is calculated: $\alpha = \dfrac{(x+y)/2}{D}$.

Angular subtense a calculated at different distances from the source is shown in Table C.1.

Table C.1 **Calculated angular subtense α at different distances from IPLS A**

Distance m	0.2	0.3	0.4	0.5	0.6	0.8	1.0
Angular subtense α, rad	0.1	0.067	0.05	0.04	0.033	0.025	0.02

C.5 To determine exposure duration t, the temporal characteristics of the pulse train are measured. Measurements of IPLS A result in the single pulse of 5 ms (0.005 s).

NOTE No spectral or angular information of signals is needed: intensity of the pulses may be measured in arbitrary units, and for a limited part of the emission spectrum and/or angular cone. It is important that detector response time is faster than pulse temporal parameters and linearity of a detector is also important.

C.6 ELV L_{ELV} is calculated: $L_{ELV} = \frac{50000}{C_\alpha t^{0.25}}$ $W\ m^{-2}\ sr^{-1}$

NOTE For all measurement distances in this example, 1.7 mrad $< \alpha <$ 100 mrad; therefore $C_\alpha = \alpha$ and ELV are expressed as radiance.

C.7 The calculation of retinal thermal ELVs is presented in Table C.2.

Table C.2 **Retinal thermal ELV calculated at different distances from IPLS A**

Distance m	0.2	0.3	0.4	0.5	0.6	0.8	1.0
ELV $W\ m^{-2}\ nm^{-1}$	1 880 000	2 806 000	3 761 000	4 701 000	5 698 000	7 521 000	9 402 000

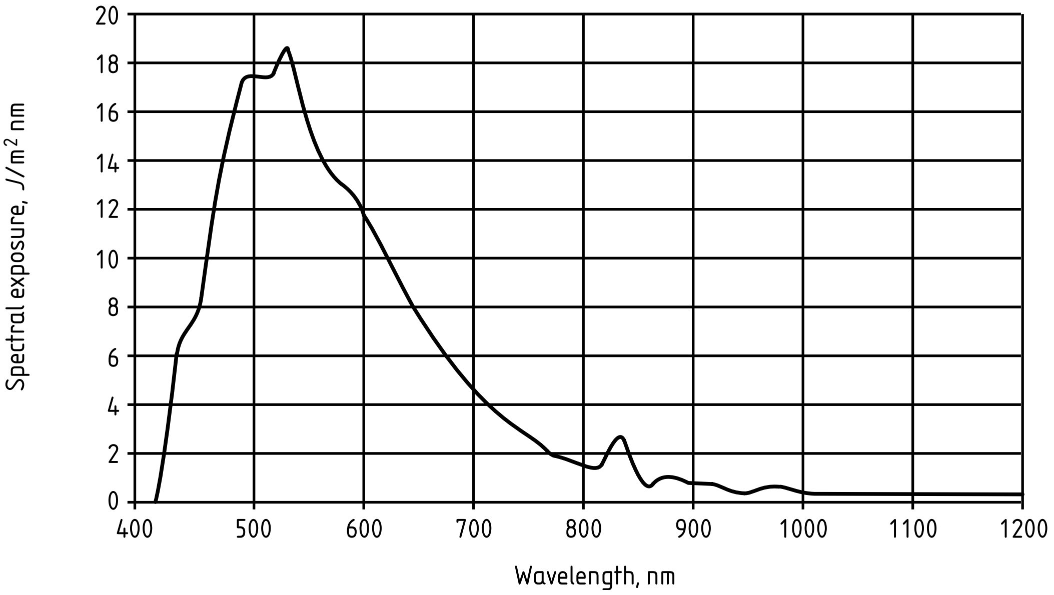
C.8 Time integrated spectral exposure $H(\lambda)$ is measured at 0.2 m from the device, in $J\ m^{-2}\ nm^{-1}$, using a spectroradiometer. The acquisition time is set longer than total pulse duration, i.e. over 5 ms.

NOTE 1 Measurement of spectral exposure rather than spectral irradiance is more practical for pulsed emission.

NOTE 2 The emission data is normally supplied by the ILS equipment manufacturer. If this is not available it needs to be measured.

C.9 Results of measurements of spectral exposure are illustrated in Figure C.3.

Figure C.2 **Measured spectral exposure of IPLS A 0.2 m from the device**



C.10 From measured spectral data $H(\lambda)$ (see Figure C.3) and exposure duration t (5 ms), the spectral irradiance $E(\lambda)$ in $W\ m^{-2}\ nm^{-1}$ is calculated: $E(\lambda) = \frac{H(\lambda)}{t}$

NOTE This spectral irradiance is non-weighted and integrated over full solid angle Ω.

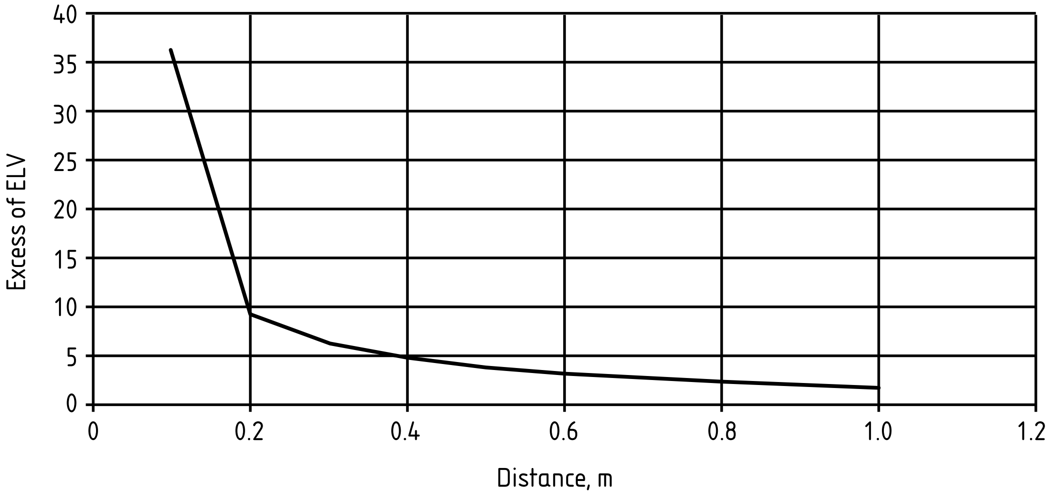
C.11 The solid angle Ω is calculated using angular subtense α from Table C.1: $\Omega = \frac{\pi\alpha^2}{4}$

C.12 From calculated spectral irradiance E(λ) and solid angle Ω, the weighted radiance L_{exp} is calculated at different distances from the device, using retinal thermal weighting function $R(\lambda)$:

$$L_{exp} = \frac{\sum_{\lambda=380}^{\lambda=1400} E(\lambda)R(\lambda)\Delta\lambda}{\Omega}$$

C.13 The measured weighted radiance L_{exp} is compared with calculated ELV L_{ELV}: (see Figure C.3).

Figure C.3 **Excess of measured weighted radiance over retinal thermal ELV for IPLS A**

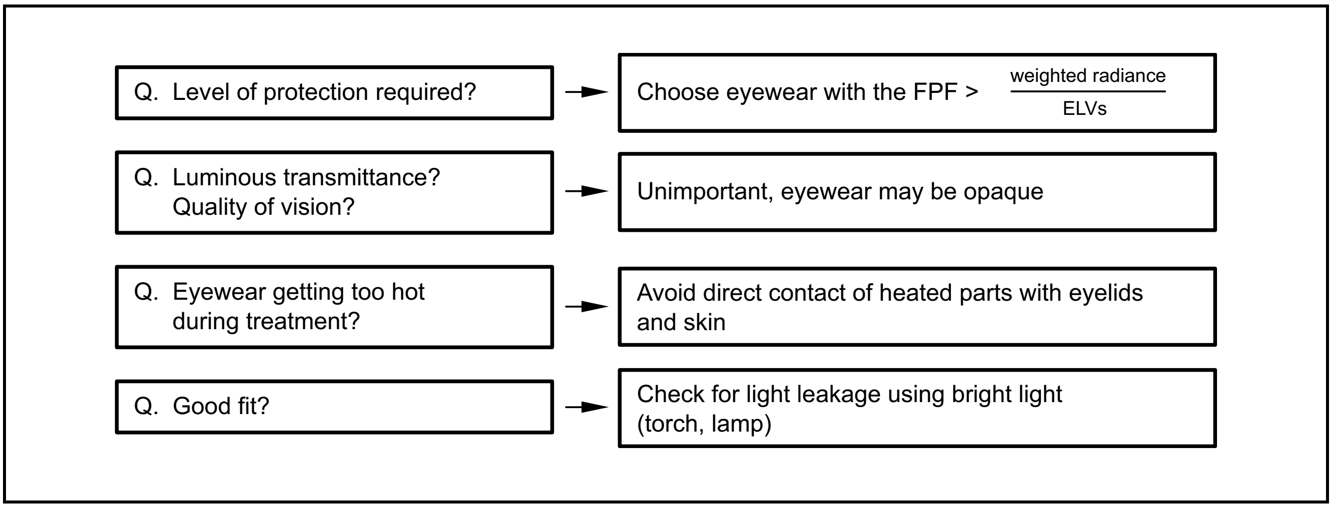


C.14 Results of the assessment indicate that the FPF of the protective eyewear for the operator of IPLS device A needs to be >10. The ELV is exceeded by a factor of 9.2 at 0.2 m which is considered to be a distance of foreseeable accidental exposure. At the distance of 1 m from this device, the retinal thermal ELV is exceeded by factor of 1.84, therefore personnel or patient/clients in the vicinity of 1 m would need to be protected from excessive exposure to optical radiation.

Annex D (informative) Protective eyewear for the patient/ client

If ELVs may be exceeded, based on the specification of the ILS equipment or risk assessment, the following checklist can be used.

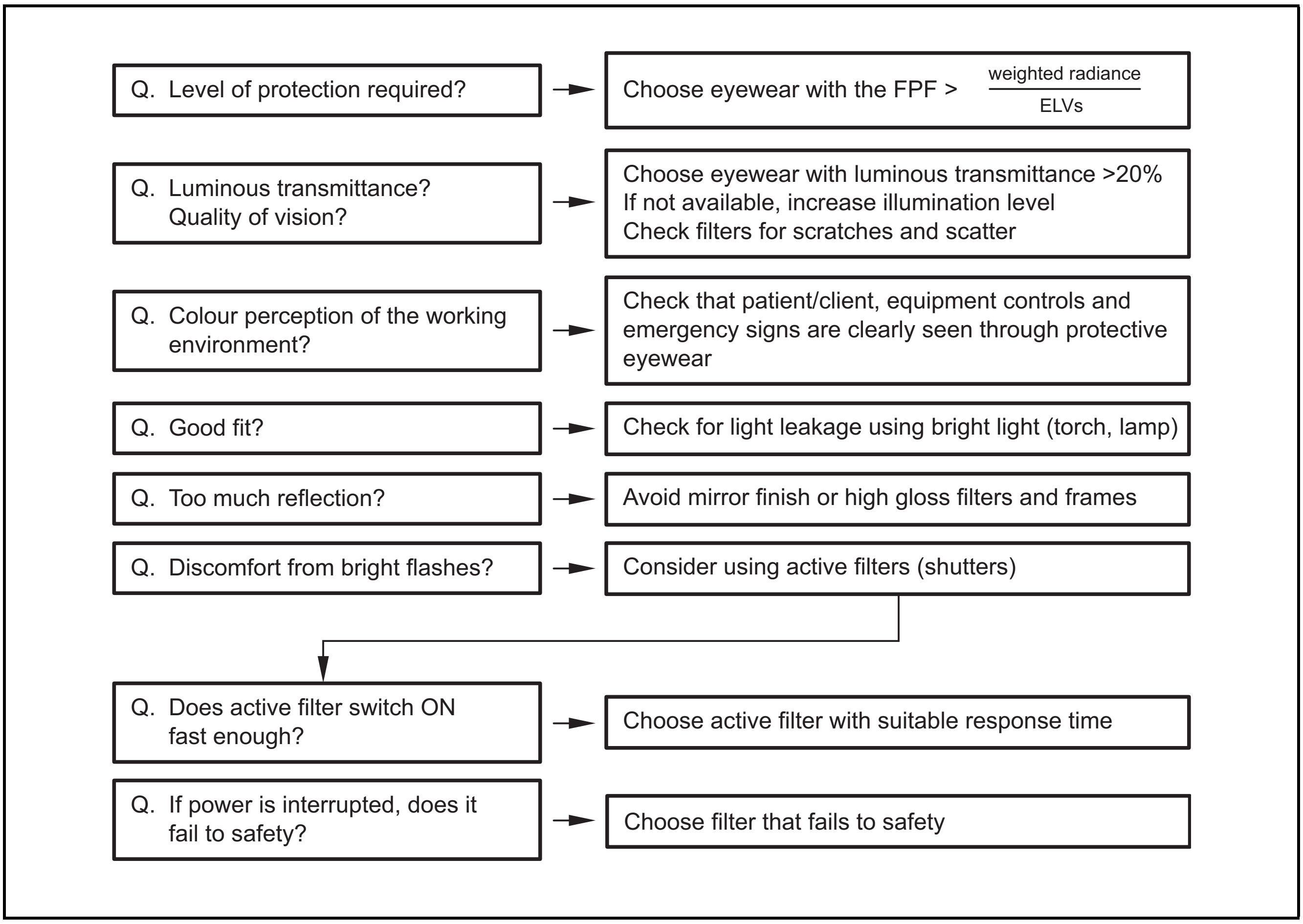
Figure D.1 **Checklist for a selection of protective eyewear for the patient/client**



Annex E (informative) Protective eyewear for the operator

If ELVs may be exceeded, based on the specification of the ILS equipment or risk assessment, the following checklist can be used.

Figure E.1 **Checklist for a selection of protective eyewear for the operator**



Annex F (informative) Filter protection factor

F.1 The filter protection factor (FPF) of ILS eyewear is a factor by which the filter attenuates the weighted ocular exposure.

F.2 The FPF of the eye protector, at the spectral range of emission of ILS equipment for which the eye protector is intended, is determined as:

$$FPF_{\mathrm{BL}} = \frac{\sum_{\lambda=300}^{\lambda=700} E(\lambda)B(\lambda)\Delta\lambda}{\sum_{\lambda=300}^{\lambda=700} E(\lambda)T(\lambda)B(\lambda)\Delta\lambda}$$

for blue light hazards;

$$FPF_{\mathrm{RTh}} = \frac{\sum_{\lambda=380}^{\lambda=1400} E(\lambda)R(\lambda)\Delta\lambda}{\sum_{\lambda=380}^{\lambda=1400} E(\lambda)T(\lambda)R(\lambda)\Delta\lambda}$$

for retinal thermal hazards;

$$FPF_{\mathrm{UV}} \frac{\sum_{\lambda=180}^{\lambda=400} E(\lambda)S(\lambda)\Delta\lambda}{\sum_{\lambda=180}^{\lambda=400} E(\lambda)T(\lambda)S(\lambda)\Delta\lambda}$$

for actinic ultra-violet hazards; and

$$FPF_{\mathrm{IR,lens}} = \frac{\sum_{\lambda=780}^{\lambda=3000} E(\lambda)\Delta\lambda}{\sum_{\lambda=780}^{\lambda=3000} E(\lambda)T(\lambda)\Delta\lambda}$$

for infra-red lens hazards;

where

$E(\lambda)$ is the spectral irradiance of the ILS device, in W m^{-2} nm^{-1};

$B(\lambda)$, $R(\lambda)$ and $S(\lambda)$ are blue light, retinal thermal and actinic ultra-violet hazard weighting functions, respectively;

$\Delta\lambda$ is the wavelength interval of the measurements, in nm;

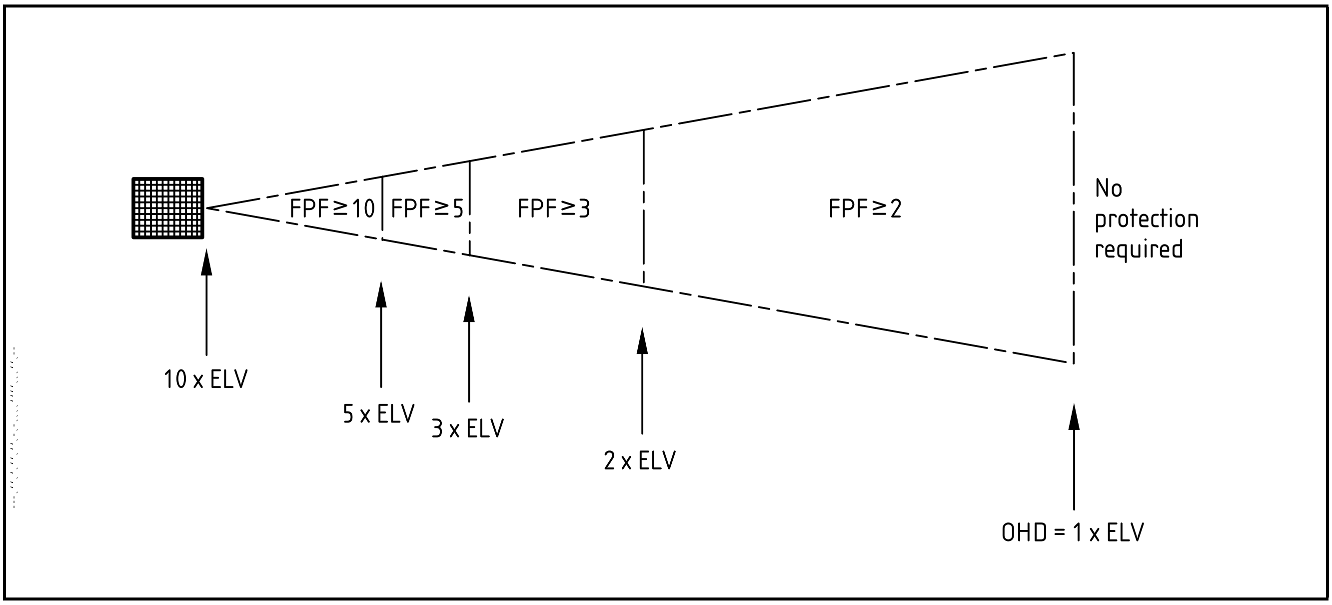
$T(\lambda)$ is the spectral transmittance of eye protector material at wavelength λ.

F.3 FPF quantifies the reduction of biologically effective ocular exposure and takes into account the effect of different wavelengths on the eye. To calculate FPF for a specific ILS device, both the emission spectrum of the ILS equipment and protective filter spectral attenuation are needed.

F.4 FPF directly relates to the risk assessment (see Clause **4**).

F.5 Minimal FPF of protective eyewear should be, at least, equal or higher than the required level of exposure reduction, as illustrated in Figure F.1.

Figure F.1 **Required level of eye protection on an ILS device that exceeds ELV by a factor of 10**



Annex G (informative)

Luminous transmittance

G.1 The luminous transmittance (T_V) of the protective filters is specified as:

$$T_V = \frac{\sum_{\lambda=380}^{\lambda=780} V(\lambda)T(\lambda)E(\lambda)\Delta\lambda}{\sum_{\lambda=380}^{\lambda=780} V(\lambda)E(\lambda)\Delta\lambda}$$

where

$E(\lambda)$ is the spectral radiance flux of the illumination source;

$V(\lambda)$ is spectral luminous efficiency;

$\Delta\lambda$ is the wavelength interval of the measurements, in nm;

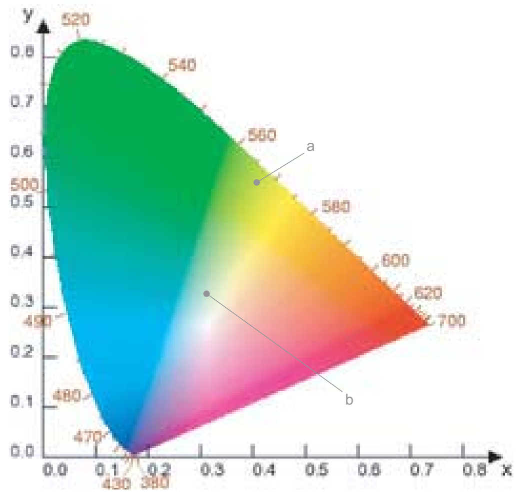
$T(\lambda)$ is the spectral transmittance of filter material at wavelength λ.

G.2 The luminous transmittance should be stated for the D65 standard illuminator. If an operator of ILS equipment is required to observe a patient/client or environment illuminated by the spectrally filtered ILS equipment, luminous transmittance should be specified for the ILS emission spectrum.

Annex H (informative) Colour perception of ILS protective eyewear – Example

The colour co-ordinates (x = 0.40; y = 0.53) of a protective filter illuminated with a white light (D65 illuminator) and the colour co-ordinates of the D65 illuminator (x = 0.3127; y = 0.3290) are given in Figure H.1.

Figure H.1 **Perceived colour of a white light viewed through a protective filter**



Key

A Protective filter illuminated with a D65 illuminator

B D65 white light illuminator

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For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS 6967, BS EN 165, *Glossary of terms for personal eye-protection*

BS EN 166, *Personal eye-protection – Specifications*

BS EN 175, *Personal protection – Equipment for eye and face protection during welding and allied processes*

BS EN 14255 (all parts), *Measurement and assessment of personal exposures to incoherent optical radiation*

BS ISO 10526, *CIE standard illuminants for colorimetry*

BS ISO/CIE 10527, *CIE standard colorimetric observers*

BS ISO 17166, *Erythema reference action spectrum and standard erythema dose*

Other publications

[1] EUROPEAN COMMUNITIES 2006/25/EC The Physical Agents (Artificial Optical Radiation) Directive. Luxembourg: Office for Official Publications of the European Communities, 2006.

Further reading

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CIE 55-1983, *Discomfort glare in the interior working environment*.[1)]

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CIE 109-1994. *A method of predicting corresponding colours under different chromatic and illuminance adaptations*.[1)]

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1) CIE publications are available to buy online at www.techstreet.com

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