BRITISH STANDARD

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

Part 1: Specification for products

ICS 13.340.20



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Contents

Foreword ii

Introduction 1

- 1 Scope 1
- **2** Normative references 1
- **3** Terms and definitions 1
- 4 Spectral transmittance 2
- **5** Luminous transmittance 2
- **6** Colour of the protective filters 3
- 7 Material and surface defects 3
- **8** Active filters 4
- **9** Construction of eye protectors 4
- 10 Labelling 4
- 11 Information to be supplied by the manufacturer 5

Annexes

Annex A (informative) Filter protection factor (FPF) 6

Annex B (informative) Calculation of FPF for protective eyewear -

Example 1 7

Annex C (informative) Calculation of FPF for protective eyewear -

Example 2 9

Annex D (informative) Spectral hazard weighting functions 12

Bibliography 15

List of figures

Figure B.1 – Spectral irradiance of ILS device A with different filtering attachments 7

Figure B.2 – Transmittance of eyewear protective filters 1, 2, 3 and 4 $\,$ 8

Figure C.1 – Spectral irradiance of ILS device B with interchangeable lamps 1, 2 and 3

Figure C.2 – Spectral transmittance of eyewear protective filters $5,\,6$ and 7-10

List of tables

Table B.1 – FPF of filters 1, 2 3 and 4 and different filtering attachments of ILS device A $\,9$

Table C.1 – FPF of filters 5, 6 and 7 and interchangeable lamps 1, 2 and 3 of ILS device B $\ 11$

Table D.1 – Ultra-violet hazard weighting function $S(\lambda)$ 12

Table D.2 – Blue light hazard B(λ) and retinal thermal hazard R(λ) weighting functions -13

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 15 and a back cover.

Foreword

Publishing information

This British Standard 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 equipment.

Presentational conventions

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

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 specifies performance, test methods and labelling of eye protectors used for ILS equipment used on humans and animals for cosmetic and medical applications 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 normative documents contain provisions which, through reference in this text, constitute provisions of this British Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the publication referred to applies.

BS EN 167:2002, Personal eye-protection – Optical test methods BS EN 168:2002, Personal eye-protection – Non-optical test methods

3 Terms and definitions

For the purpose of this British Standard, the following terms and definitions apply.

3.1 blue light hazard

potential for a photochemically induced retinal injury resulting from optical radiation exposure in the wavelength range 300 nm to 700 nm

3.2 filter protection factor (FPF)

factor by which the filter attenuates the weighted ocular exposure

NOTE Mathematical expressions for FPF are given in Annex A and example calculations in Annex B and Annex C.

3.3 infra-red eye lens hazard

potential for a thermal injury to cornea and lens of the eye resulting from optical radiation exposure in the wavelength range 780 nm to 3 000 nm

3.4 intense light source (ILS)

device incorporating one or more non-laser sources of optical radiation of the wavelength range 180 nm to 3 000 nm and intended for creating biological effects in humans and animals

NOTE It may operate in continuous or pulsed regime.

3.5 retinal thermal hazard

potential for a thermal retinal injury resulting from optical radiation exposure in the wavelength range 380 nm to 1 400 nm

3.6 ultra-violet hazard

potential for skin and ocular acute and chronic adverse effects resulting from optical radiation exposure in the wavelength range $180~\mathrm{nm}$ to $400~\mathrm{nm}$

4 Spectral transmittance

The spectral transmittance $t(\lambda)$ of the eye protector material shall be determined for normal incidence. The wavelength shall be determined within ± 2 nm.

Filters with angular dependent transmittance shall be measured at angles of incidence between 0° and 45° .

5 Luminous transmittance

5.1 The luminous transmittance (t_{V}) of the protective filters intended for use by the ILS operator shall be determined as:

$$t_{\rm V} = \frac{\sum_{\lambda=380}^{\lambda=780} V(\lambda) t(\lambda) E(\lambda) \Delta \lambda}{\sum_{\lambda=380}^{\lambda=780} V(\lambda) E(\lambda) \Delta \lambda}$$

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 .

5.2 Luminous transmittance, as determined in **5.1**, shall be stated for a D65 standard illuminator.

NOTE There are no requirements for the luminous transmittance of the filters of eye protectors intended for use by ILS equipment patients/clients; these filters may be opaque.

6 Colour of the protective filters

6.1 The Commision Internationale de L'Eclairage (CIE) colour co-ordinates (x, y) of the protective filters intended for use by the ILS operator shall be determined as:

$$x = \frac{X}{X + Y + Z}$$

and

$$y = \frac{Y}{X + Y + Z}$$

where

$$X = \sum_{380}^{780} E(\lambda)t(\lambda)\overline{x}(\lambda)\Delta\lambda$$

$$Y = \sum_{380}^{780} E(\lambda)t(\lambda)\overline{y}(\lambda)\Delta\lambda$$

$$Z = \sum_{380}^{780} E(\lambda)t(\lambda)\overline{z}(\lambda)\Delta\lambda$$

and

 \overline{x} , \overline{y} and \overline{z} are CIE colour matching functions;

 $E(\lambda)$ 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 .

6.2 The colour co-ordinates (x, y) shall be specified for a D65 standard illuminator in accordance with **6.1**.

NOTE 1 The colour co-ordinates (x, y) of the protective filters might be optionally presented on a CIE chromaticity chart.

NOTE 2 There are no requirements for the colour perception of the filters of eye protectors intended for use by ILS equipment patients/clients; these filters may be opaque.

7 Material and surface defects

When tested in accordance with BS EN 167:2002, Clause **5**, eye protectors intended for use by ILS equipment operators shall have a clear field of vision at least $\pm 40^{\circ}$ in the vertical and horizontal directions for each eye.

NOTE There are no requirements for the field of vision, material and surface defects of the filters of eye protectors intended for use by ILS equipment patients/clients; these filters may be opaque.

8 **Active filters**

- **8.1** In the case of protective filters that exhibit a change of transmittance in response to an exposure to incident optical radiation, the time taken by the eye protector to reach its full attenuation ("dark state") shall be determined and specified.
- 8.2 Active filters powered by mains or batteries shall fail to a safe state if the power supply is disconnected or malfunctions.
- 8.3 Active filters shall be tested to determine the maximum time to achieve full specified attenuation, for the whole spectral range of emission of the intended ILS equipment and angles of incidence between 0° and 45°.

Construction of eye protectors 9

9.1 Mirror-finish or high gloss filters and frames shall not be used.

NOTE Secondary reflections from frames or filters of protective eyewear, especially from concave surfaces, might increase the risk of uncontrolled exposure of the users.

- **9.2** Frames and side shields shall either:
- be opaque; or
- provide at least the same protection as the filter;

and be designed in such a way as to prevent the leakage of optical radiation around the edges of protective eyewear.

9.3 The removal of individual filters from the frame shall only be possible with the use of special tools.

If the filters consist of several individual filters (hybrid filters), they shall be assembled in such a way that they cannot be interchanged.

NOTE Hybrid filters should not delaminate after storage, when tested in accordance with BS EN 168:2002, Clause 5.

- **9.4** The resistance of filters and frames to ignition shall conform to BS EN 168:2002, Clause 7.
- **9.5** When tested in accordance with BS EN 168:2002, Clause 5 and Clause **6**, the transmittance increase shall be no more than 5%.

10 Labelling

Each ILS eye protector shall be clearly and permanently marked to indicate:

- model number;
- whether it is intended for the ILS patient/client only;
- manufacturer's identification.

If the information is marked on the filters, they shall not impair vision or the protective effect.

11 Information to be supplied by the manufacturer

Each ILS eye protector shall be supplied with printed user information in the language(s) of the country in which the eye protector is sold. This information shall include:

- a) a clear statement of the model number of the eye protection;
- b) a reproduction of the labelling in accordance with Clause **10** and an explanation of its meaning;
- c) spectral transmittance of the filters in tabular or graphic form at 2 nm intervals;
- d) for eye protectors intended for use by an ILS operator, luminous transmittance in accordance with Clause **5**;
- e) for eye protectors intended for use by an ILS operator, the CIE colour co-ordinates (x, y) of the protective filters in accordance with Clause **6**, with optional presentation on a CIE chromaticity chart;
- f) for active filters, maximum time to achieve specified attenuation, in accordance with Clause 8:
- g) for active filters powered by electrical mains or batteries, specification of power settings and power tolerances;
- h) instructions for use, care, storage, cleaning and disinfection of the eye protector;
- i) instructions for inspection and guidance on when the eye protector should be replaced;
- the name and address of the manufacturer or supplier of the eye protector;
- k) certification mark, if applicable.

Annex A (informative) Filter Annex A (informative) protection factor (FPF)

A.1 Neither optical density or shade numbers are suitable for characterization of ILS protective filters as these characteristics do not take into account the difference in the effect of different wavelengths on the eye, whereas exposure limit values (ELVs) (taken from the Physical Agents (Artificial Optical Radiation) Directive) refer to effective, e.g. spectrally weighted, radiance values.

A.2 FPF is defined as:

(A1)
$$FPF_{BL} = \frac{\sum_{\lambda=300}^{\lambda=700} E(\lambda)B(\lambda)\Delta\lambda}{\sum_{\lambda=300}^{\lambda=700} E(\lambda)t(\lambda)B(\lambda)\Delta\lambda}$$

for blue light hazards:

(A2)
$$FPF_{RTh} = \frac{\sum_{\lambda=380}^{\lambda=1400} E(\lambda)R(\lambda)\Delta\lambda}{\sum_{\lambda=380}^{\lambda=1400} E(\lambda)t(\lambda)R(\lambda)\Delta\lambda}$$

for retinal thermal hazards;

(A3)
$$FPF_{UV} \frac{\sum_{\lambda=180}^{\lambda=400} E(\lambda) S(\lambda) \Delta \lambda}{\sum_{\lambda=180}^{\lambda=400} E(\lambda) t(\lambda) S(\lambda) \Delta \lambda}$$

for actinic ultra-violet hazards; and

(A4)
$$FPF_{IR,lens} = \frac{\sum_{\lambda=780}^{\lambda=3000} E(\lambda) \Delta \lambda}{\sum_{\lambda=780}^{\lambda=3000} E(\lambda) t(\lambda) \Delta \lambda}$$

for infrared 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 .

A.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, the emission spectrum of the ILS equipment and protective filter spectral attenuation are needed.

A.4 FPF directly relates to the risk assessment. Key stages of such an assessment are to:

 a) calculate the weighted radiance using spectral irradiance of ILS equipment provided by the ILS equipment manufacturer (or measure actual spectral irradiance, if data is not available);

NOTE Spectral irradiance might be different for the operator of ILS equipment and patient/client.

- b) determine the ELVs for exposure duration and type of hazard;
- c) compare measured values with the ELVs.

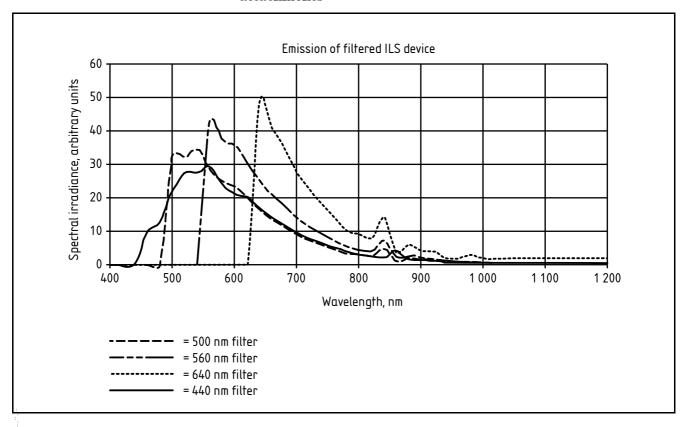
A.5 If the risk assessment demonstrates that retinal exposure limits are exceeded, protective eyewear should be worn. Minimal FPF of protective eyewear should be at least equal to or higher than the required level of exposure reduction. The required level of reduction of exposure is likely to be different for a patient/client and operator, therefore, FPF of protective eyewear for patient and operator might be different.

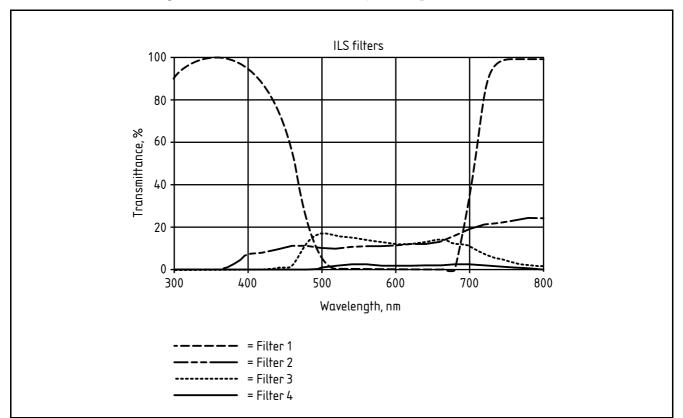
Annex B (informative)

Calculation of FPF for protective eyewear – Example 1

B.1 ILS device A for cosmetic applications is supplied with four different attachment tools, filtering spectral emission of the device at 440 nm, 500 nm, 560 nm and 640 nm, as illustrated in Figure B.1.

Figure B.1 Spectral irradiance of ILS device A with different filtering attachments





Transmittance of eyewear protective filters 1, 2, 3 and 4 Figure B.2

- B.3 FPF is calculated for blue light and retinal thermal hazards, using equations (A1) and (A2), correspondingly, where
- $E(\lambda)$ data is taken from Figure B.1;
- $B(\lambda)$ and $R(\lambda)$ are hazard weighting functions (see Annex D);
- $\Delta\lambda$ is the wavelength interval of the measurements (2 nm in this example);
- $t(\lambda)$ is the spectral transmittance of filters 1, 2 3 and 4 taken from Figure B.2.
- **B.4** FPFs for ultra-violet and infra-red lens hazards are not applicable for ILS device A because its spectral emission is very low in these hazard spectral regions.
- B.5 Calculated FPF values of the eyewear protective filters for different filtering attachments of ILS device A are presented in Table B.1.

440 nm 500 nm 560 nm 640 nm FPF for blue light hazard Filter 1 15 6 8 Filter 2 9 7 10 10 2 Filter 3 37 90 15 300 Filter 4 49 46 44 FPF for retinal thermal hazard Filter 1 7 8 11 10 Filter 2 9 8 7 6 Filter 3 7 3 3 10 Filter 4 95 48 52 55

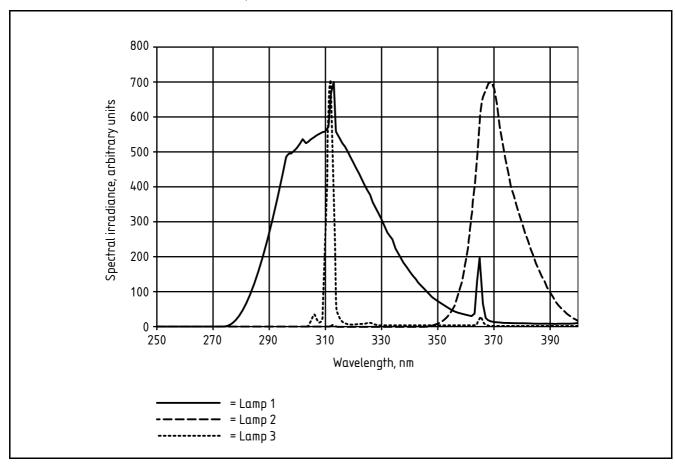
Table B.1 FPF of filters 1, 2 3 and 4 and different filtering attachments of ILS device A

Annex C (informative)

Calculation of FPF for protective eyewear – Example 2

C.1 ILS device B for medical applications is supplied with three interchangeable lamps: lamp 1, lamp 2 and lamp 3. Spectral irradiance of the lamps of ILS device B is shown in Figure C.1.

Figure C.1 Spectral irradiance of ILS device B with interchangeable lamps 1, 2 and 3



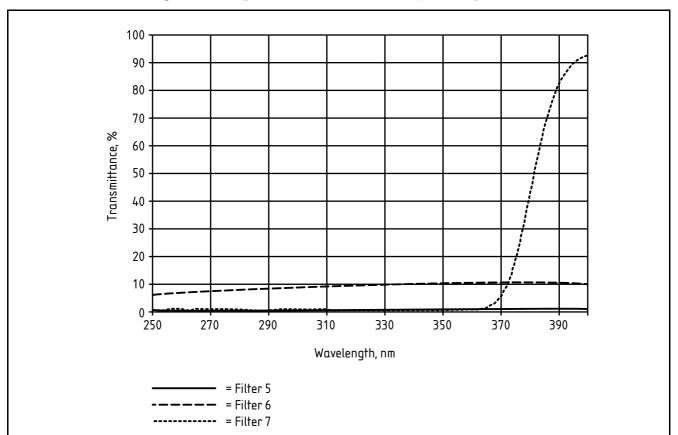


Figure C.2 Spectral transmittance of eyewear protective filters 5, 6 and 7

- C.3 FPF is calculated for blue light and ultra-violet hazards, using equations (A1) and (A3), correspondingly, where
- $E(\lambda)$ data is taken from Figure C.1;
- $B(\lambda)$ and $S(\lambda)$ are hazard weighting functions (see Annex D);
- $\Delta\lambda$ is the wavelength interval of the measurements (2 nm in this example);
- $t(\lambda)$ is spectral transmittance of filters 5, 6 and 7 taken from Figure C.2.
- C.4 FPFs for retinal thermal and infra-red lens hazards are not applicable for ILS device B because its spectral emission is very low in these hazard spectral regions.
- ${f C.5}$ Calculated FPF values of the eyewear protective filters for interchangeable lamps 1, 2 and 3 of ILS device B are presented in Table C.1.

Table C.1 FPF of filters 5, 6 and 7 and interchangeable lamps 1, 2 and 3 of ILS device B

	Lamp 1	Lamp 2	Lamp 3
		FPF for ultra-viol	et hazard
Filter 5	140	95	122
Filter 6	12	10	10
Filter 7	175	8	194
		FPF for blue ligh	ıt hazard
Filter 5	110	93	115
Filter 6	10	10	10
Filter 7	36	3	30

Spectral hazard weighting functions Annex D (informative)

For guidance, spectral hazard weighting functions $S(\lambda)$, $B(\lambda)$ and $R(\lambda)$, cited in the Physical Agents (Artificial Optical Radiation) Directive) for non-coherent optical radiation, are given in Table D.1 and Table D.2.

Ultra-violet hazard weighting function $S(\lambda)$ Table D.1

						<u> </u>		• •	
λ nm	S(\lambda)	λ nm	S(\lambda)	λ nm	S (λ)	λ nm	S(\lambda)	λ nm	$\mathbf{S}(\lambda)$
180	0.012 0	228	0.173 7	276	0.943 4	324	0.000 520	372	0.000 086
181	0.012 6	229	0.181 9	277	0.927 2	325	0.000 500	373	0.000 083
182	0.013 2	230	0.190 0	278	0.911 2	326	0.000 479	374	0.000 080
183	0.013 8	231	0.199 5	279	0.895 4	327	0.000 459	375	0.000 077
184	0.014 4	232	0.208 9	280	0.880 0	328	0.000 440	376	0.000 074
185	0.015 1	233	0.218 8	281	0.856 8	329	0.000 425	377	0.000 072
186	0.015 8	234	0.229 2	282	0.834 2	330	0.000 410	378	0.000 069
187	0.016 6	235	0.240 0	283	0.812 2	331	0.000 396	379	0.000 066
188	0.017 3	236	0.251 0	284	0.790 8	332	0.000 383	380	0.000 064
189	0.018 1	237	0.262 4	285	0.770 0	333	0.000 370	381	0.000 062
190	0.019 0	238	0.274 4	286	0.742 0	334	0.000 355	382	0.000 059
191	0.019 9	239	0.286 9	287	0.715 1	335	0.000 340	383	0.000 057
192	0.020 8	240	0.300 0	288	0.689 1	336	0.000 327	384	0.000 055
193	0.021 8	241	0.311 1	289	0.664 1	337	0.000 315	385	0.000 053
194	0.022 8	242	0.322 7	290	0.640 0	338	0.000 303	386	0.000 051
195	0.023 9	243	0.334 7	291	0.618 6	339	0.000 291	387	0.000 049
196	0.025 0	244	0.347 1	292	0.598 0	340	0.000 280	388	0.000 047
197	0.026 2	245	0.360 0	293	0.578 0	341	0.000 271	389	0.000 046
198	0.027 4	246	0.373 0	294	0.558 7	342	0.000 263	390	0.000 044
199	0.028 7	247	0.386 5	295	0.540 0	343	0.000 255	391	0.000 042
200	0.030 0	248	0.400 5	296	0.498 4	344	0.000 248	392	0.000 041
201	0.033 4	249	0.415 0	297	0.460 0	345	0.000 240	393	0.000 039
202	0.037 1	250	0.430 0	298	0.398 9	346	0.000 231	394	0.000 037
203	0.041 2	251	0.446 5	299	0.345 9	347	0.000 223	395	0.000 036
204	0.045 9	252	0.463 7	300	0.300 0	348	0.000 215	396	0.000 035
205	0.051 0	253	0.481 5	301	0.221 0	349	0.000 207	397	0.000 033
206	0.055 1	254	0.500 0	302	0.162 9	350	0.000 200	398	0.000 032
207	0.059 5	255	0.520 0	303	0.120 0	351	0.000 191	399	0.000 031
208	0.064 3	256	0.543 7	304	0.084 9	352	0.000 183	400	0.000 030
209	0.069 4	257	0.568 5	305	0.060 0	353	0.000 175		
210	0.075 0	258	0.594 5	306	0.045 4	354	0.000 167		
211	0.078 6	259	0.621 6	307	0.034 4	355	0.000 160		
212	0.082 4	260	0.650 0	308	0.026 0	356	0.000 153		
213	0.086 4	261	0.679 2	309	0.019 7	357	0.000 147		
214	0.090 6	262	0.709 8	310	0.015 0	358	0.000 141		
215	0.095 0	263	0.741 7	311	0.011 1	359	0.000 136		
216	0.099 5	264	0.775 1	312	0.008 1	360	0.000 130		
217	0.104 3	265	0.810 0	313	0.006 0	361	0.000 126		
-	1	1	1	1	_1			1	

Table D.1 Ultra-violet hazard weighting function S(λ) (continued)

λ nm	S (λ)	λ nm	S (λ)	λ nm	S (λ)	λ nm	S(λ)	λ nm	$\mathbf{S}(\lambda)$
218	0.109 3	266	0.844 9	314	0.004 2	362	0.000 122		
219	0.114 5	267	0.881 2	315	0.003 0	363	0.000 118		
220	0.120 0	268	0.919 2	316	0.002 4	364	0.000 114		
221	0.125 7	269	0.958 7	317	0.002 0	365	0.000 110		
222	0.131 6	270	1.000 0	318	0.001 6	366	0.000 106		
223	0.137 8	271	0.991 9	319	0.001 2	367	0.000 103		
224	0.144 4	272	0.983 8	320	0.001 0	368	0.000 099		
225	0.150 0	273	0.975 8	321	0.000 819	369	0.000 096		
226	0.158 3	274	0.967 9	322	0.000 670	370	0.000 093		
227	0.165 8	275	0.960 0	323	0.000 540	371	0.000 090		

Table D.2 Blue light hazard B(λ) and retinal thermal hazard R(λ) weighting functions

λ	Β(λ)	R(λ)
nm		
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

Blue light hazard B(λ) and retinal thermal hazard R(λ) weighting functions (continued) Table D.2

λ nm	Β(λ)	R(λ)
>500 − ≤600	10 ^{0.02} ·(450-λ)	1
>600 - ≤700	0.001	1
>700 - ≤1 050	_	10 ^{0.002} ·(700-λ)
>1050 - <1150	_	0.2
>1 150 – <1 200	_	0.2·10 ^{0.02·(1 150-λ)}
>1 200 – 1 400	_	0.02

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