
**Eye and face protection against
intense light sources used on humans
and animals for cosmetic and medical
applications —**

**Part 1:
Specification for products**

*Équipements ophtalmiques de protection contre les sources
lumineuses intenses utilisées sur les animaux et les humains pour des
applications médicales et cosmétiques —*

Partie 1: Spécifications des produits

STANDARDSISO.COM : Click to view the full PDF of ISO 12609-1:2021



STANDARDSISO.COM : Click to view the full PDF of ISO 12609-1:2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classes of ILS eye protectors	2
5 General requirements for ILS eye protectors	2
5.1 Ambient temperatures.....	2
5.2 Physiological compatibility.....	2
5.3 Construction and adjustment.....	3
5.4 Cleaning and/or disinfection.....	3
5.5 Headform(s).....	3
5.6 Mandatory and optional requirements.....	3
6 Transmittance	3
6.1 General.....	3
6.2 Luminous and spectral transmittance for F-scale numbers.....	4
6.3 Luminous and spectral transmittance for B-scale numbers.....	4
6.4 Uniformity of luminous transmittance and transmittance matching.....	5
7 Colour neutrality (optional requirement)	5
8 ILS eye protectors with autodarkening filters	5
8.1 General.....	5
8.2 Transmittance.....	6
8.3 Angular dependence of luminous transmittance.....	6
8.4 Switching time.....	6
9 Construction of ILS eye protectors	6
9.1 Area to be protected from ILS radiation.....	6
9.2 Frames and lateral protection.....	8
9.3 Material and surface quality.....	8
9.4 Field of view.....	8
9.5 Optical properties.....	8
9.5.1 Spherical and cylindrical power.....	8
9.5.2 Spatial deviation.....	9
9.5.3 Prismatic power of unmounted plano filters covering one eye.....	9
9.5.4 Prism imbalance for mounted filters and one-piece protectors.....	9
9.5.5 Narrow angle scatter.....	9
9.6 Resistance to ignition.....	9
9.7 Resistance to UV radiation.....	9
9.8 Resistance to thermal exposure.....	10
9.9 Basic impact level of complete ILS eye protectors.....	10
9.9.1 Complete protector.....	10
9.9.2 Failure criteria.....	10
9.9.3 ILS eye protectors with prescription inserts to carry corrective lenses.....	11
10 Marking	11
10.1 General.....	11
10.2 Mandatory markings.....	11
11 Information to be supplied by the manufacturer	12
Bibliography	13

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94 *Personal safety — Personal protective equipment*, Subcommittee SC 6, *Eye and face protection*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 85, *Eye protective equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12609-1:2013) which has been technically revised.

The main changes compared to the previous edition are as follows:

- Alignment to ISO 16321 series and ISO 18526 series.

A list of all parts in the ISO 12609 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Eye and face protection against intense light sources used on humans and animals for cosmetic and medical applications —

Part 1: Specification for products

1 Scope

This document specifies general requirements for operators' eye protectors for intense light source (ILS) equipment used on humans and animals for cosmetic and medical applications against excessive exposure to optical radiation in the spectral range 250 nm to 3 000 nm, with the exception of laser radiation.

This document is applicable to devices intended for patient protection during ILS procedures, except for treatment in the periorbital area. For guidance on patient eye protection during ILS procedures, see ISO/TR 22463.

For guidance on the use and selection of ILS eye protectors, see ISO 12609-2.

This document does not apply to:

- laser protectors, for which ISO 19818-1 applies;
- protectors for medically prescribed applications (not occupational), e.g. eye protection for severe dry eye, tints prescribed for medical conditions;
- protectors specifically intended for protection against only solar radiation and used in non-occupational environments for which the ISO 12312 (all parts) applies;
- protectors used with tanning equipment;
- protectors intended to protect against ionizing radiation, e.g. X-rays, for which IEC 61331-3 applies.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 4007, *Personal protective equipment — Eye and face protection — Vocabulary*

ISO 18526-1:2020, *Eye and face protection — Test methods — Part 1: Geometrical optical properties*

ISO 18526-2:2020, *Eye and face protection — Test methods — Part 2: Physical optical properties*

ISO 18526-3:2020, *Eye and face protection — Test methods — Part 3: Physical and mechanical properties*

ISO 18526-4, *Eye and face protection — Test methods — Part 4: Headforms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4007 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 intense light source

ILS

device incorporating one or more non-laser, pulsed or continuous, sources of optical radiation in the wavelength range 250 nm to 3 000 nm and intended to cause biological effects in humans and animals

3.2 opaque patient eye protector

protector made from a medium with spectral transmittance no more than 0,01 % in the waveband 250 nm to 3 000 nm

Note 1 to entry: This can be made of metal or intensely pigmented material.

4 Classes of ILS eye protectors

There are three classes of ILS eye protector

- a) F-scale eye protector where the scale number is determined by its luminous transmittance for CIE standard illuminant D65,
- b) B-scale protector where the scale number is determined by its blue-light transmittance, and
- c) Opaque eye protectors, for patient use only.

5 General requirements for ILS eye protectors

5.1 Ambient temperatures

ILS eye protectors described in this document are intended for use at normal ambient temperatures, (23 ± 5) °C.

5.2 Physiological compatibility

ILS eye protectors shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the health or safety of the wearer. The risks posed by substances leaking or evaporating from the ILS eye protector that can come into prolonged contact with the wearer shall be reduced by the manufacturer to within the limits of any applicable regulatory requirement.

Special attention shall be given to substances that are allergenic, carcinogenic, mutagenic or toxic to reproduction.

NOTE 1 Excessive pressure due to a poor fit on the head, chemical irritation and allergy are known to produce reactions. Rare or idiosyncratic reactions to any material are known to occur and the individual wearer is well advised to avoid those types of frame materials.

Substances recommended for cleaning, maintenance or disinfection shall be known to be unlikely to have any adverse effect upon the wearer when applied in accordance with the instructions given in the information to be supplied by the manufacturer.

Manufacturers/suppliers shall perform an appropriate risk analysis on potentially harmful substances contained in the ILS eye protector such that, when the ILS eye protector is used under the intended conditions and for the purposes intended, the health and safety of the wearer shall not be compromised.

The following are examples of documents that represent the appropriate information:

- a) specifications regarding the material(s);
- b) safety data sheets relating to the materials;
- c) information relating to the suitability of the materials for use with food, in medical devices, or other relevant applications;
- d) information relating to toxicological, allergenic, carcinogenic, toxic to reproduction, or mutagenic properties of the materials.

Specific national regulations with regard to the restriction of certain chemical substances are to be observed (for example the release of nickel).

5.3 Construction and adjustment

Areas of the ILS eye protector that may come into contact with the wearer during the intended use shall be free from projections, sharp edges or other features likely to cause discomfort or injury during use.

Any part of the ILS eye protector that can be adjusted or removed by the wearer for the purpose of replacement (in accordance with the instructions given in the information to be supplied by the manufacturer) shall favour adjustment, removal and attachment without the use of tools. Critical parts, such as the filters, shall not be removable by the wearer.

Any adjustment system incorporated in the ILS eye protector shall maintain the intended fit for the foreseeable conditions of use.

The test shall be carried out by physical inspection in accordance with ISO 18526-3:2020, 6.1.

5.4 Cleaning and/or disinfection

The ILS eye protectors shall be cleaned only once in accordance with the cleaning and/or disinfection procedures in the information to be supplied by the manufacturer before being subjected to testing.

5.5 Headform(s)

Unless the manufacturer specifies the headform(s) (in accordance with ISO 18526-4) that is/are compatible with the ILS eye protector, test methods where (a) headform(s) is/are required shall use the headform 1-M in accordance with ISO 18526-4 as the default.

5.6 Mandatory and optional requirements

In this document, both optional and mandatory requirements are described. Depending on the intended use and/or the manufacturer's claimed specification, some requirements marked as optional become mandatory.

6 Transmittance

6.1 General

The spectral transmittance, $\tau(\lambda)$, of the ILS protection filter at wavelengths between 250 nm and 3 000 nm shall be determined at normal incidence in accordance with ISO 18526-2:2020, Clause 6. The luminous transmittance, $\tau_{v,D65}$, shall be calculated in accordance with ISO 18526-2:2020, Clause 7 and the blue-light transmittance, τ_B , shall be calculated in accordance with ISO 18526-2:2020, 9.2. ILS protection filters shall fulfil the transmittance requirements of either the luminous transmittance, $\tau_{v,D65}$, based scale number designation (F-scale numbers) in accordance with 5.2 or the blue-light transmittance, τ_B , based scale number designation (B-scale numbers) in accordance with 5.3.

Filters with angularly dependent transmittance shall be measured at angles of incidence between 0° and at least 30° from the normal and tested in accordance with ISO 18526-2:2020, 17.8 and 17.9. ILS protection filters shall fulfil the transmittance requirements for the full angular range (-30° to +30°) of either the luminous transmittance, $\tau_{v,D65}$, based scale number designation (F-scale numbers) in accordance with 5.2 or the blue-light transmittance, τ_B , based scale number designation (B-scale numbers) in accordance with 5.3.

NOTE The spectral weighting functions $S(\lambda)$ and $B(\lambda)$ are given in ISO 4007:2018, Table A.1.

6.2 Luminous and spectral transmittance for F-scale numbers

The F-scale number of ILS eye protector shall be determined in accordance with Table 1 when tested in accordance with ISO 18526-2:2020, Clauses 6, 7 and 10.1.

Table 1 — Transmittance requirements for ILS protection filters; code letter F

Scale number	Spectral transmittance $\tau(\lambda)$			Luminous transmittance $\tau_{v,D65}$	Near IR transmittance τ_{NIR}
	250 nm $\leq \lambda \leq 315$ nm Maximum %	315 nm $< \lambda \leq 380$ nm Maximum %	380 nm $< \lambda \leq 450$ nm Maximum %	380 nm $< \lambda \leq 780$ nm %	780 nm $\leq \lambda \leq 3\ 000$ nm Maximum %
F1	0,1	0,4	$\tau_{v,D65}$	$100 \geq \tau_{v,D65} \geq 43,2$	50
F2				$43,2 > \tau_{v,D65} \geq 17,8$	
F3				$17,8 > \tau_{v,D65} \geq 8,5$	
F4				$8,5 > \tau_{v,D65} \geq 3,2$	
F5				$3,2 > \tau_{v,D65} \geq 1,2$	
F6				$1,2 > \tau_{v,D65} \geq 0,44$	

NOTE Emission by ILS equipment of optical radiation with wavelengths below 400 nm is negligible.

6.3 Luminous and spectral transmittance for B-scale numbers

In many types of ILS equipment, the blue spectral component of light poses the greatest risk.

The B-scale number of ILS eye protector shall be determined in accordance with Table 2 when tested in accordance with ISO 18526-2:2020, Clauses 6, 8.2, 9.2 and 10.1.

Table 2 — Transmittance requirements for ILS protection filters, code letter B

Scale number	Spectral transmittance $\tau(\lambda)$			Blue-light transmittance τ_B	Near IR transmittance τ_{NIR}
	250 nm $\leq \lambda \leq 315$ nm Maximum %	315 nm $< \lambda \leq 380$ nm Maximum %	380 nm $< \lambda \leq 450$ nm Maximum %	380 nm $< \lambda \leq 500$ nm %	780 nm $\leq \lambda \leq 3\ 000$ nm Maximum %
B1	0,1	0,4	—	$100 \geq \tau_B \geq 43,2$	50
B2			43,2	$43,2 > \tau_B \geq 17,8$	
B3			17,8	$17,8 > \tau_B \geq 8,5$	
B4			8,5	$8,5 > \tau_B \geq 3,2$	
B5			3,2	$3,2 > \tau_B \geq 1,2$	
B6			—	$1,2 > \tau_B$	

NOTE Emission by ILS equipment of optical radiation with wavelengths below 400 nm is negligible.

6.4 Uniformity of luminous transmittance and transmittance matching

ILS protection filters shall fulfil the following requirements for uniformity of transmittance:

- the relative variations of the luminous transmittance around the reference point(s), ΔF_R and ΔF_L , shall be measured in accordance with ISO 18526-2:2020, 7.4, as applicable. ΔF_R and ΔF_L (as appropriate) shall not exceed ± 10 %.
- the relative difference of the luminous transmittance, ΔP , between the right and left eye reference points shall be measured in accordance with ISO 18526-2:2020, 7.5. ΔP shall not exceed ± 15 %.

Changes of luminous transmittance that are caused by thickness variations due to the design of the filter are permitted. For verification, the procedure in accordance with the test method in ISO 18526-2:2020, 7.4.1.4 shall be used.

This requirement can be omitted for opaque patient eye protectors.

7 Colour neutrality (optional requirement)

If colour neutrality is claimed, the spectral transmittance between 450 nm and 650 nm shall be uniform, defined as being within ± 20 % of the mean transmittance value in this range.

The colour neutrality shall be tested in accordance with ISO 18526-2:2020, Clause 6.

8 ILS eye protectors with autodarkening filters

8.1 General

ILS eye protectors with autodarkening (electro-optical) filters switch from a light state (high transmittance) to a dark state (low transmittance) during the ILS procedures. Autodarkening eye protectors protect against the excessive exposure to optical radiation in the spectral range of 250 nm to 3 000 nm. ILS eye protectors with autodarkening filters combine passive UV and IR filters that protect against these respective hazards with an autodarkening filter technology that automatically attenuates the excessive radiation in the visible spectral range to safe and non-glaring levels.

ILS eye protectors with autodarkening filters are not intended for patient use.

NOTE In the light state, the protector enables the operator to recognize the required operational details during the treatment. As soon as bright light is reflected, mainly off the patient's skin or when the ILS source is pointed accidentally towards the eyes of the operator, the autodarkening filter switches to the dark state.

8.2 Transmittance

ILS eye protectors with autodarkening filters shall provide the required levels of spectral transmittance (250 nm to 450 nm) and near IR transmittance as specified in [Table 1](#) or [Table 2](#) in their light and dark states. The luminous transmittance or the blue-light transmittance shall be within the transmittance ranges for the shade numbers/categories claimed by the manufacturer for both light and dark states.

If the power supply is disconnected or malfunctions, ILS eye protectors with autodarkening filters powered by mains, batteries or photoelectric cells shall reduce the luminous transmittance (380 nm to 780 nm) to a maximum of 30 %. The spectral transmittance (250 nm to 450 nm) and the near IR transmittance requirements of scale number F2 or B2 specified in [Table 1](#) or [Table 2](#) shall also be fulfilled.

8.3 Angular dependence of luminous transmittance

Autodarkening filters with angularly dependent transmittance shall be measured at angles of incidence between 0° and at least 30° from the normal in accordance with ISO 18526-2:2020, 17.8, at a temperature of (23 ± 5) °C.

The maximum values of V_{15} and V_{30} of F-scale number and B-scale number autodarkening filters measured in white light (CIE standard illuminant A) shall not exceed the values given in [Table 3](#). The requirement shall apply to both the light and the dark states.

Table 3 — Angular dependence of luminous transmittance of autodarkening filters

Maximum value of V_{15}	Maximum value of V_{30}
7,20 (corresponding to 2 scale numbers)	51,75 (corresponding to 4 scale numbers)

8.4 Switching time

The time taken by an ILS eye protector with autodarkening filters to reach its maximum specified scale number ("dark state") in response to exposure to incident optical radiation shall not exceed 1 ms when determined in accordance with ISO 18526-2:2020, 17.11.

9 Construction of ILS eye protectors

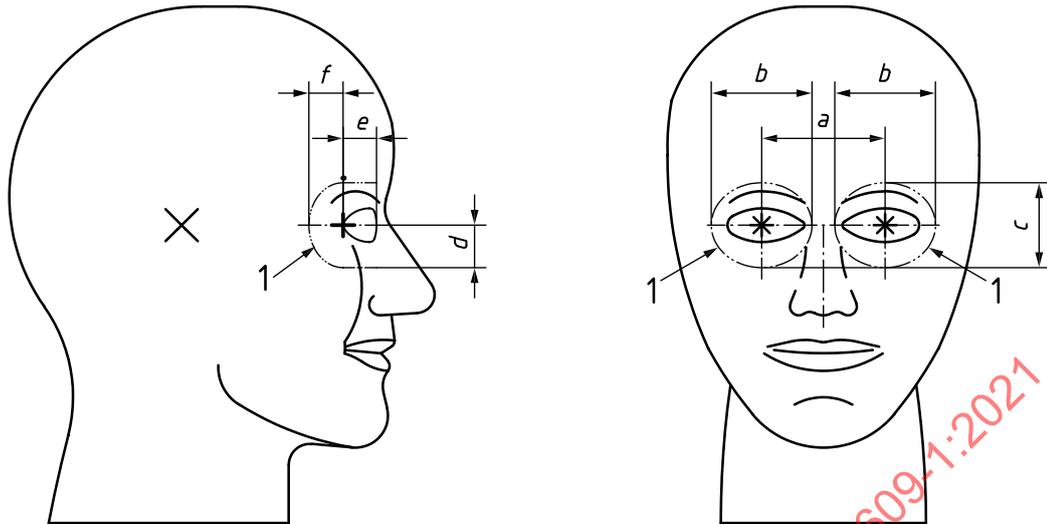
9.1 Area to be protected from ILS radiation

[Figure 1](#) and [Table 4](#) describe the minimum areas to be protected against optical radiation from the ILS.

The dimensions of the headform(s) are defined in ISO 18526-4.

When tested in accordance with ISO 18526-3:2020, 6.3, the ILS protector shall cover two ellipses projected on to the headform defined in [Table 4](#) and [Figure 1](#). These ellipses have a horizontal dimension of b and a vertical dimension of c , the centres of which are separated by dimension a . They are symmetrically placed on either side of the centre of the bridge of the headform nose, i.e. the vertical axis of symmetry midway between the corneal apices.

When tested from each side in accordance with ISO 18526-3:2020, 6.4, the ILS protector shall cover the area projected on to the headform as defined in [Table 4](#) and [Figure 1](#). This area is bounded by a semicircle of radius f centred on the lateral canthus, which is a distance, e , behind the corneal apex, and the horizontal lines through the top and bottom of the semicircle.



Key

- 1 areas to be protected
- * corneal apices and pupil centres
- + lateral canthus
- X resting point of the sides
- a to f* as defined in [Table 4](#).

NOTE A different interpupillary distance can be used if specified by the manufacturer in which case the values of *b*, *c*, *d* and *e* are adjusted in proportion.

Figure 1 — Areas of protection

Table 4 — Dimensions of minimum areas to be protected as illustrated in [Figure 1](#) (Tolerance on dimensions ±0,5 mm)

Dimensions in millimetres

Dimension	Headform				
	1-C6	1-C12	1-S	1-M	1-L
<i>a</i> ^a	54	58	60	64	68
<i>b</i>	29	32	36	40	42
<i>c</i>	21	22	25	28	29
<i>d</i>	10	11	12	14	15
<i>e</i>	7	8	9	12	13
<i>f</i>	10	10	10	10	10
—	—	—	2-S	2-M	2-L
<i>a</i>	—	—	63	64	70
<i>b</i>	—	—	33	35	40
<i>c</i>	—	—	23	24	28
<i>d</i>	—	—	12	12	14
<i>e</i>	—	—	7	8	9
<i>f</i>	—	—	10	10	10

NOTE There are no dimensions available for headforms 2-C12 and 2-C6.

^a Dimension *a* is the same as dimension *D* in ISO 18526-4:2020, Table 2 and Table 3.

9.2 Frames and lateral protection

Frames and lateral protection through which exposure to incident optical radiation could occur to the eyes shall provide at least the same level of protection as declared by the manufacturer or supplier for the minimum area to be protected in accordance with 9.1.

Thus, following requirements shall be satisfied when transmittances are measured in accordance with ISO 18526-2:2020, Clauses 6, 7 to 10.1:

- a) the luminous transmittance $\tau_{v,D65}$ or blue-light transmittance τ_B of the frame and lateral protection shall not exceed the value corresponding to the highest scale number of the ILS protection filter specified by the manufacturer (i.e. the darkest filter);
- b) the spectral transmittance requirements of the frame and lateral protection shall meet the requirements given in Table 1 or Table 2, as appropriate, corresponding to the highest scale number of the ILS protection filter specified by the manufacturer (i.e. the darkest filter).

9.3 Material and surface quality

Except for a marginal area 5 mm wide, filters shall be free from significant defects likely to impair vision when in use (such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation) when examined in accordance with ISO 18526-3:2020, 6.6.

9.4 Field of view

ILS eye protectors, in the as-worn position, shall have a minimum unobstructed field of view in front of each eye of 40° temporally and nasally in the horizontal meridian, and 40° superiorly and inferiorly in the vertical meridian, when measured at the corneal apex of the headform in accordance with ISO 18526-3:2020, 6.2.

9.5 Optical properties

9.5.1 Spherical and cylindrical power

The filters shall be tested at the reference points in the as-worn position in accordance with ISO 18526-1:2020, 6.1.

The spherical power and cylindrical power shall not exceed the tolerances given in Table 5.

Table 5 — Spherical, cylindrical power and prismatic power tolerances of ILS eye protectors

Spherical power	Cylindrical power	Additional requirements for mounted plano filters, one-piece and visor covering both eyes	Prismatic power of unmounted filters (in any direction)
Mean value of the focal powers (F_1, F_2) in the two principal meridians. $(F_1 + F_2)/2$	Absolute difference between the focal powers (F_1, F_2) in the two principal meridians. $ F_1 - F_2 $	The maximum difference between the measured spherical powers (F_R, F_L) of the right and left reference points. $ F_R - F_L $	
dioptries (D) ^a	dioptries (D)	dioptries (D)	prism dioptries (Δ) ^b
$\pm 0,12$	$\leq 0,12$	$\leq 0,18$	$\leq 0,25$
^a In some countries, the dimensional unit m^{-1} is used instead of the name dioptre or symbol D. ^b In some countries, the dimensional unit cm/m is used instead of the name prism dioptre or symbol Δ .			

This requirement can be omitted for opaque patient eye protectors.

9.5.2 Spatial deviation

If, during the measurements in accordance with ISO 18526-1:2020, 6.1, a doubling or other aberration of the image is observed, then the plano filter shall be further assessed in accordance with ISO 18526-1:2020, 6.3. The plano filter shall be free from irregular distortions likely to impair vision.

This requirement can be omitted for opaque patient eye protectors.

9.5.3 Prismatic power of unmounted plano filters covering one eye

The filters shall be tested at the reference point in the as-worn position in accordance with ISO 18526-1:2020, 6.1.

The prismatic power shall not exceed the values given in [Table 5](#).

This requirement can be omitted for opaque patient eye protectors.

9.5.4 Prism imbalance for mounted filters and one-piece protectors

The filters shall be tested in the as-worn position as specified in ISO 18526-1:2020, 6.2. Depending on the interpupillary distance (*PD*, represented as letter *a* in [Table 4](#)) of the specified headform(s), the respective diaphragm LB_2 shall be used.

The prism imbalance shall not exceed the values provided in [Table 6](#).

Table 6 — Prism imbalance

Horizontal		Vertical
Base out prism dioptres (Δ)	Base in prism dioptres (Δ)	prism dioptres (Δ)
1,00	0,25	0,25

This requirement can be omitted for opaque patient eye protectors.

9.5.5 Narrow angle scatter

After cleaning according to the manufacturer's instructions, the value of the reduced luminance coefficient shall not exceed $1,0 \text{ cd}\cdot\text{m}^{-2}\cdot\text{lx}^{-1}$ when measured in accordance with ISO 18526-2:2020, 14.2.

This requirement can be omitted for opaque patient eye protectors.

9.6 Resistance to ignition

All exterior parts of ILS eye protectors that are exposed when worn (excluding headbands) shall be tested in accordance with ISO 18526-3:2020, 6.10, and shall not ignite or continue to glow after removal of the heated rod.

9.7 Resistance to UV radiation

After exposure in accordance with ISO 18526-3:2020, 6.8.3:

- when calculated relative to the initial value, the relative change of luminous transmittance or blue-light transmittance shall not be greater than $\pm 10 \%$ (i.e. $|100 \cdot (\tau' - \tau) / \tau| \neq 10 \%$, where τ is the initial luminous or blue-light transmittance and τ' is the transmittance after UV radiation);
- the value of narrow angle scatter shall not exceed $1,0 \text{ cd}\cdot\text{m}^{-2}\cdot\text{lx}^{-1}$;
- any applicable UV and/or IR requirements for the initial $\tau_{v,D65}$ or τ_B shall continue to be satisfied.

For opaque patient eye protectors list items a) and b) can be omitted.

9.8 Resistance to thermal exposure

When tested in accordance with ISO 18526-3:2020, 6.7, no deformation of any part of the ILS eye protector shall be observed using an oven temperature of $(55 \pm 2) ^\circ\text{C}$ for (120^{+5}_0) min.

The test shall be verified by physical inspection in accordance with ISO 18526-3: 2020, 6.1.

9.9 Basic impact level of complete ILS eye protectors

9.9.1 Complete protector

Unless higher levels of impact protection at extremes of temperatures (see ISO 16321-1:2020, 7.10.2 and 7.11.2) are claimed, this Clause defines the minimum mechanical strength of complete ILS eye protectors and their filter assemblies.

Where a temperature different to the ambient range of $(23 \pm 5) ^\circ\text{C}$ is specified by the manufacturer, the appropriate temperature with accuracy of $\pm 2 ^\circ\text{C}$ shall be substituted for the relevant test condition.

Complete ILS eye protectors shall meet the requirements for the Basic Impact Level when tested in accordance with ISO 18526-3:2020, 7.3.1, using a steel ball with a diameter of $(25,40^{+0,05}_0)$ mm weighing $(66,8^{+0,5}_0)$ g and a drop height of $(1,27^{+0,03}_0)$ m.

There are four impact points defined with respect to the headform rather than the ILS eye protector. The ball is aimed at these impact points with the ILS eye protector in the as-worn position.

The four impact points are defined as follows:

- a) the left eye, frontal;
- b) the right eye, frontal;
- c) the left eye, lateral;
- d) the right eye, lateral.

Frontal impact: The ball is directed perpendicular to the frontal plane through the two corneal vertices (denoted by an asterisk, *, in [Figure 1](#)) to anywhere within an area of 10 mm radius centred on the corneal vertex. This is carried out for the right and left eyes.

Lateral impact (if appropriate): The ball is directed along a line through or parallel to that through the two lateral canthi (the location of the edge of the bony orbit and represented as + in [Figure 1](#)) to anywhere within an area of 10 mm radius centred on the lateral canthus. This is carried out for the right and left eyes.

The headform may be moved horizontally and vertically to select any single impact point lying within this 10 mm of the specified impact centres.

New ILS eye protectors may be used for each individual impact. In case of failure after multiple impacts on the same test sample, one new test sample for each individual impact point shall be used.

9.9.2 Failure criteria

After testing for protection from frontal and lateral impact in accordance with ISO 18526-3:2020, 7.3.1, at $(23 + 5) ^\circ\text{C}$, the following defects of the filter, protector housing or frame shall not be allowed when inspected in accordance with ISO 18526-3:2020, 6.1:

- a) cracking through the entire thickness into two or more pieces;
- b) the protector separates into two or more pieces;