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Ophthalmic instruments — Fundamental requirements and test methods —

Part 2: Light hazard protection

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —

Partie 2: Protection contre les dangers de la lumière

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15004-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition, together with ISO 15004-1, cancels and replaces ISO 15004:1997. All reference to light hazard (definitions 3.4 to 3.9, subclause 6.3, subclause 7.5, Annexes A, C and D of ISO 15004:1997) has essentially been moved to the present part of ISO 15004 and has been technically revised.

ISO 15004 consists of the following parts, under the general title *Ophthalmic instruments — Fundamental requirements and test methods*:

— *Part 1: General requirements applicable to all ophthalmic instruments*

— *Part 2: Light hazard protection*

Ophthalmic instruments — Fundamental requirements and test methods —

Part 2:
Light hazard protection

1 Scope

This part of ISO 15004 specifies fundamental requirements for optical radiation safety for ophthalmic instruments and is applicable to all ophthalmic instruments that direct optical radiation into or at the eye and for which there is a specific light hazards requirement section within their respective International Standards, i.e. all ophthalmic instruments listed in Annex B. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye. Where differences exist between this part of ISO 15004 and the light hazard requirements section of the respective vertical International Standard, then the vertical International Standard shall take precedence.

NOTE The emission limits are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. See Bibliography [1].

This part of ISO 15004 does not apply to radiation that is in excess of limits specified in ISO 15004 and that is intended for treatment of the eye.

This part of ISO 15004 classifies ophthalmic instruments into either Group 1 or Group 2 in order to distinguish instruments that are non-hazardous from those that are potentially hazardous.

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.

IEC 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1
aperture
aperture stop
opening that defines the area over which average optical emission is measured

NOTE For spectral irradiance measurements this opening is usually the entrance of a small sphere placed in front of the radiometer/spectroradiometer entrance slit.

3.1.2
continuous wave radiation source
CW radiation source
radiation source that is operated with a continuous output for a time greater than 0,25 s (i.e. a non-pulsed radiation source)

3.1.3
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

NOTE For an obscured or noncircular aperture, it has an area equivalent to that of a non-obscured circular aperture.

3.1.4
emission limit
maximum value of optical radiation output allowed

3.1.5
endoilluminator
device consisting of a light source and an associated fibre optic light guide that is intended for insertion into the eye to illuminate any portion of the interior of the eye

3.1.6
field of view
conical solid angle as "seen" by the detector, such as the eye or the radiometer/spectroradiometer, out of which the detector receives radiation

NOTE The field of view denotes the angle over which radiance is averaged (sampled) and should not be confused with the angular subtense of the source α which denotes source size.

3.1.7
Group 1 instrument

ophthalmic instrument for which no potential light hazard exists and that can be shown to fulfil the requirements of 5.2

3.1.8
Group 2 instrument
ophthalmic instrument for which a potential light hazard exists and that does not fulfil the requirements of 5.2

3.1.9
irradiance
E
⟨at a point on a surface⟩ quotient of the radiant power $\mathrm{d}\Phi$ incident on an element of a surface containing the point, by the area $\mathrm{d}A$ of that element, i.e.

$$E = \frac{\mathrm{d}\Phi}{\mathrm{d}A} \tag{1}$$

NOTE Irradiance is expressed in units of watts per square centimetre, W/cm^2.

3.1.10
manufacturer
natural or legal person who places the ophthalmic instrument on the market

3.1.11
maximum intensity
highest optical radiation emissions the instrument is capable of delivering under any and all conditions

3.1.12
operation microscope
stereo-microscope used for observation of surgical and other medical procedures, consisting of an illumination system and an observation system, including objective lens, variable or fixed power optical system, observation tube and eyepieces

3.1.13
optical radiation hazard
risk of damage to the eye by exposure to optical radiant energy

3.1.14
photoretinitis
retinal photochemically-induced injury resulting from a very intense retinal radiant exposure

NOTE The term photic maculopathy is also used to describe photoretinitis in the fovea-macular area of the retina.

3.1.15
pulsed light source
light source that delivers its energy in the form of a single pulse or a train of pulses where each pulse has a duration of less than 0,25 s

NOTE 1 A light source with a continuous train of pulses or modulated radiant energy where the peak radiated power is at least ten times the minimum radiated power is considered to be a pulsed light source.

NOTE 2 The pulse duration is the interval of time between the first and last instants at which the instantaneous value of a pulse reaches a specified fraction of its pulse magnitude or a specified threshold.

3.1.16
radiance
L
⟨in a given direction at a given point of a real or imaginary surface⟩ quantity defined by the formula

$$L = \frac{\mathrm{d}\Phi}{\mathrm{d}A \times \cos\theta \times \mathrm{d}\Omega} \tag{2}$$

where

$\mathrm{d}\Phi$ is the radiant power transmitted by an elementary beam passing through the given point and propagating in the solid angle $\mathrm{d}\Omega$ containing the given direction;

$\mathrm{d}A$ is the area of a section of that beam containing the given point;

θ is the angle between the normal to that section and the direction of the beam.

NOTE 1 The same definition holds for the time-integrated radiance L_i if, in the equation for L, the radiant power $\mathrm{d}\Phi$ is replaced by the radiant energy $\mathrm{d}Q$.

NOTE 2 Radiance is expressed in watts per steradian square centimetre, W/(sr·cm^2); time-integrated radiance is expressed in Joules per steradian square centimetre, J/(sr·cm^2).

3.1.17
radiant exposure
H
⟨at a point of a surface, for a given duration⟩ quotient of the radiant energy, $\mathrm{d}Q$, incident on an element of a surface containing the point over the given duration by unit area $\mathrm{d}A$ of that element

$$H = \frac{\mathrm{d}Q}{\mathrm{d}A} \tag{3}$$

Equivalently, the radiant exposure is defined as the integral of the irradiance, E, at a given point over a given duration, Δt

$$H = \int_{\Delta t} E \times \mathrm{d}t \tag{4}$$

NOTE Radiant exposure is expressed in Joules per square centimetre, J/cm^2.

3.1.18
scanning laser radiation
laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference

3.1.19
spectral irradiance
E_λ
quotient of the spectral radiant power d$\Phi(\lambda)$ in a wavelength interval dλ, incident on an element of a surface, by the area dA of that element and by the wavelength interval dλ

$$E_\lambda = \frac{\mathrm{d}\Phi(\lambda)}{\mathrm{d}A \times \mathrm{d}\lambda} \tag{5}$$

NOTE Spectral irradiance is expressed in watts per square centimetre nanometre, W/(cm^2·nm).

3.1.20
spectral radiance
L_λ
⟨for a wavelength interval dλ, in a given direction at a given point⟩ ratio of the spectral radiant power d$\Phi(\lambda)$ passing through that point and propagating within the solid angle dΩ in the given direction, to the product of the wavelength interval dλ and the areas of a section of that beam on a plane perpendicular to this direction (cos θ dA) containing the given point and to the solid angle dΩ

$$L_\lambda = \frac{\mathrm{d}\Phi(\lambda)}{\mathrm{d}A \times \cos\theta \times \mathrm{d}\Omega \times \mathrm{d}\lambda} \tag{6}$$

NOTE Spectral radiance is expressed in watts per steradian square centimetre nanometre, W/(sr·cm^2·nm).

3.2 Symbols

Symbols, quantities and units are listed in Table 1.

Table 1 — Symbols, quantities and units

Symbol	Quantity	Unit
E	irradiance (at a point on a surface)	W/cm^2
E_λ	spectral irradiance	W/(cm^2·nm)
L	radiance (in a given direction at a given point of a real or imaginary surface)	W/(sr·cm^2)
L_λ	spectral radiance (for a wavelength interval dλ, in a given direction at a given point)	W/(sr·cm^2·nm)
L_i	time-integrated radiance	J/(sr·cm^2)
H	radiant exposure (at a point of a surface, for a given duration)	J/cm^2
H_λ	spectral radiant exposure	J/(cm^2·nm)
$E_{\text{S-CL}}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_{\text{UV-CL}}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_{\text{A-R}}$	$A(\lambda)$ weighted retinal irradiance	W/cm^2
$E_{\text{IR-CL}}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm^2
$E_{\text{VIR-AS}}$	unweighted anterior segment visible and infrared radiation irradiance	W/cm^2
$E_{\text{VIR-R}}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm^2
$L_{\text{A-R}}$	$A(\lambda)$ weighted retinal radiance	W/(sr·cm^2)
$L_{i,\text{A-R}}$	$A(\lambda)$ weighted retinal time-integrated radiance	J/(sr·cm^2)
$L_{i,\text{VIR-R}}$	$R(\lambda)$ weighted, retinal visible and infrared radiation time-integrated radiance	J/(sr·cm^2)
$L_{\text{VIR-R}}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiance	W/(sr·cm^2)
$H_{\text{VIR-R}}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm^2
$H_{\text{IR-CL}}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm^2
$H_{\text{VIR-AS}}$	unweighted anterior segment visible and infrared radiation radiant exposure	J/cm^2
$H_{\text{S-CL}}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_{\text{UV-CL}}$	unweighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_{\text{A-R}}$	$A(\lambda)$ weighted retinal radiant exposure	J/cm^2
$S(\lambda)$	ultraviolet radiation hazard weighting function (see Annex A)	—
$A(\lambda)$	aphakic photochemical hazard weighting function (see Annex A)	—
$R(\lambda)$	visible and infrared radiation thermal hazard weighting function (see Annex A)	—
$\Delta\lambda$	summation interval	nm
t	exposure time; for pulsed instruments: exposure time for a single pulse and for any group of pulses the instrument is capable of producing	s
Δt	pulse width up to a time of 0,25 s	s
$E_\lambda \cdot t$	spectral radiant exposure	J/(cm^2·nm)
$(E_\lambda \cdot \Delta t)$	spectral radiant exposure at time Δt	J/(cm^2·nm)

4 Classification

For the purposes of this part of ISO 15004, ophthalmic instruments are classified into two groups in order to separate those instruments that are capable of presenting a potential hazard from those which do not. The two groups are named Group 1 and Group 2. They are defined as follows:

a) Group 1 instruments: ophthalmic instruments for which no potential light hazard exists. Ophthalmic instruments that can be shown to fulfil the requirements of 5.2.

b) Group 2 instruments: ophthalmic instruments for which a potential light hazard exists. Those ophthalmic instruments that do not fulfil the requirements of 5.2.

NOTE The classification process is outlined in the Classification flowchart (see Annex F).

5 Requirements

5.1 General

Ophthalmic instruments shall be so designed that the energy in all wavelengths be attenuated as much as possible in keeping with the intended use of the instrument.

If another device is used in combination with an ophthalmic instrument, the connecting system shall not degrade the optical radiation safety of either instrument, nor shall the optical radiation hazards of the combined system exceed the levels that are given in this part of ISO 15004.

Scanning instruments shall be evaluated using the pulsed instrument criteria when the scan lengths are greater than the diameter of the measurement aperture. Where the scan length is less than or equal to the measurement aperture, they shall be evaluated using the continuous wave criteria.

5.2 Requirements for classification as a Group 1 instrument

An ophthalmic instrument shall be classified in Group 1 if any or all of the following criteria apply.

a) An International Standard exists for the instrument type but no light hazard requirements are included in that International Standard.

b) Its components, e.g. lamps, light-emitting diodes, non-removable filters, lenses, fibres, etc., prevent emissions in excess of the limits specified for instruments in the Group 1 and certification of this exists. Such instruments shall be classified as Group 1 by virtue of the test certification by the manufacturer of the components themselves without the need for further measurements. If such components prevent some, but not all emissions specified for Group 1, then measurements shall be required only for the unblocked wavelengths, but not for the blocked wavelengths.

c) Its only sources of radiation are Class 1 lasers as classified under IEC 60825-1:2001.

d) Its emission values are equal to or less than the limit values given in 5.4. The test methods used for determination of compliance shall be in accordance with 6.2.

Existing International Standards that contain light hazard requirements are listed in Annex B. The limit values to determine Group 1 classification are based upon an expected exposure time for the instrument type under consideration. The Group 1 limit values given in 5.4 are based upon a 2 h exposure. These limits apply to all instruments except operation microscopes, endoilluminators, and instruments designed for continuous exposure. For operation microscopes and endoilluminators, the limits for Group 1 shall be further reduced by a factor of 2. For instruments designed for continuous exposure, the limits should be reduced by a factor equal to one half of the continuous exposure time, in hours, associated with the intended use of the instrument.

5.3 Requirements for Group 2 instruments

5.3.1 Group 2 instruments shall comply with the emission limits and guideline values given in 5.5.

5.3.2 The test methods used for determination of compliance shall be in accordance with 6.3 and 6.4. However, if components that are being used in the instrument, e.g. lamps, light-emitting diodes, non-removable filters, lenses, fibres, etc., prevent some, but not all emissions specified for Group 2, then provided that documentation of test certification of the respective components is available, measurements shall be required only for the unblocked wavelengths, but not for the blocked wavelengths.

5.3.3 Where provision is made to vary the brightness of the Group 2 instrument, an indication of the maximum intensity and fractions of maximum intensity shall be provided on the instrument.

5.3.4 Information shall be supplied with Group 2 instruments as specified in Clause 7.

5.4 Emission limits for determination of Group 1 classification

5.4.1 Continuous wave instruments

The emission limits specified in Table 2 relate to maximum corneal and lenticular or retinal irradiance or instrument radiance as applied directly to the continuous wave instrument's criteria. To evaluate the respective radiation hazard criteria, the equations given for them in Table 2 shall be used. See Table 1 for an explanation of the quantities used in the equations and for associated units.

If wavelengths 250 nm to 400 nm are not emitted by the source or are blocked by filtration, the measurements of Table 2, 5.4.1.1 and 5.4.1.2 are not required.

Table 2 — Group 1 limit values for continuous wave instruments

	Parameter	Wavelength nm	Equation	Limit
5.4.1.1	Weighted corneal and lenticular ultraviolet radiation irradiance, $E_{S\text{-}CL}$	250 to 400	$E_{S-CL} = \sum_{250}^{400} E_\lambda \times S(\lambda) \times \Delta\lambda$	0,4 μW/cm^2
		The corneal and lenticular ultraviolet radiation irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).		
5.4.1.2	Unweighted corneal and lenticular ultraviolet radiation irradiance, $E_{UV\text{-}CL}$	360 to 400	$E_{UV-CL} = \sum_{360}^{400} E_\lambda \times \Delta\lambda$	1 mW/cm^2
		The corneal and lenticular ultraviolet radiation irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).		

Table 2 (*continued*)

	Parameter	Wavelength nm	Equation	Limit
5.4.1.3	Retinal photochemical aphakic light hazard The limit values given in a) and b) are equivalent. It is only necessary to evaluate the retinal photochemical aphakic light hazard with **either** a) **or** b) below.			
a)	Weighted retinal irradiance, $E_{A\text{-}R}$	305 to 700	$E_{A-R} = \sum_{305}^{700} E_\lambda \times A(\lambda) \times \Delta\lambda$	220 µW/cm^2
		The retinal irradiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant power incident upon a circular area on the retina with a diameter of 0,18 mm ($2{,}54 \times 10^{-4}$ cm^2). However, if the instrument is intended to be used with an eye that is immobilized, a 0,03 mm ($7{,}07 \times 10^{-6}$ cm^2) diameter aperture shall be used instead of a 0,18 mm diameter aperture.		
b)	Weighted retinal radiance, $L_{A\text{-}R}$	305 to 700	$L_{A-R} = \sum_{305}^{700} L_\lambda \times A(\lambda) \times \Delta\lambda$	2 mW/(sr·cm^2)
		Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,011 rad. However, if the instrument is intended to be used with an eye that is immobilized, a field-of-view of 0,001 75 rad shall be used instead of the 0,011 rad field-of-view.		
5.4.1.4	Unweighted corneal and lenticular infrared radiation irradiance, $E_{IR\text{-}CL}$	770 to 2 500	$E_{IR-CL} = \sum_{770}^{2\,500} E_\lambda \times \Delta\lambda$	20 mW/cm^2
		The corneal irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).		
5.4.1.5	Unweighted anterior segment visible and infrared radiation irradiance, $E_{VIR\text{-}AS}$ **(for convergent beams only)**	380 to 1 200	$E_{VIR-AS} = \sum_{380}^{1\,200} E_\lambda \times \Delta\lambda$	4 W/cm^2
		The anterior segment irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area at the beam waist with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).		

Table 2 (*continued*)

	Parameter	Wavelength nm	Equation	Limit
5.4.1.6	Retinal visible and infrared radiation thermal hazard The limit values given in a) and b) are equivalent. It is only necessary to evaluate the retinal visible and infrared radiation thermal hazard with **either** a) **or** b) below.			
a)	Weighted retinal visible and infrared radiation thermal irradiance, $E_{\text{VIR-R}}$	380 to 1 400	$E_{\text{VIR-R}} = \sum_{380}^{1\,400} E_\lambda \times R(\lambda) \times \Delta\lambda$	0,7 W/cm^2
		The position of the highest irradiance found in the irradiated retinal area shall be found. The weighted retinal visible and infrared radiation irradiance value, $E_{\text{VIR-R}}$, shall then be calculated by dividing the spectral radiant power, $\Phi_{\text{VIR-R}}$, in watts, incident on the retina in a 0,03 mm circular disc centred on the position of highest irradiance by the area of this disc (7,07 × 10^{-6} cm^2). See Annex D for instructions on the way to make this calculation.		
b)	Weighted retinal visible and infrared radiation thermal radiance, $L_{\text{VIR-R}}$	380 to 1 400	$L_{\text{VIR-R}} = \sum_{380}^{1\,400} L_\lambda \times R(\lambda) \times \Delta\lambda$	6 W/(sr·cm^2)
		Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,001 75 rad.		

5.4.2 Pulsed instruments

The ultraviolet radiation limits for Group 1 pulsed instruments that can be operated in a continuous mode are the same as those for Group 1 continuous wave instruments. In such cases, the criteria for continuous wave instruments shall be modified by incorporating the time averaged values of repetitively pulsed instruments. The time averaged value is given by the ratio of the maximum energy that can be produced in a specific period of time to the time involved.

EXAMPLE 1 The time averaged limit for the weighted corneal and lenticular ultraviolet radiation irradiance $E_{\text{S-CL}}$ effective irradiance for an instrument that emits ten pulses in 5 s with an energy of 1 μJ/cm^2 per pulse is 10 μJ/cm^2/5 s = 2 μW/cm^2. This, therefore, would exceed the limit of 0,4 μW/cm^2 for the Group 1.

EXAMPLE 2 The time averaged irradiance for an instrument that emits two pulses in 10 s with an energy of 1 μJ/cm^2 per pulse would be 2 μJ/cm^2/10 s = 0,2 μW/cm^2. This is below the Group 1 limit of 0,4 μW/cm^2.

The emission limits specified in Table 3 relate to corneal, lenticular, anterior segment or retinal infrared radiation radiant exposure as applied directly to the pulsed instruments criteria. These criteria shall apply both to a single pulse and to any group of pulses. To evaluate the respective radiation hazard criteria, the equations given for them in Table 3 shall be used. See Table 1 for an explanation of the quantities used in the equations and for associated units.

Pulsed instruments shall be evaluated at their highest intensity output.

The nominal pulse duration, Δt, for pulsed instrument evaluation is determined by the time interval equal to the full width at half maximum of the pulse. The energy integration time, t, is the full pulse width for an individual pulse, and for multiple pulses, it is the time that includes each individual pulse and combination of pulses.