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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

Please see the administrative notes on page iii

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This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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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.

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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 15004-2:2007), which 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. It is applicable to all ophthalmic instruments that direct optical radiation into or at the eye and for which there is a light hazards requirement section within their respective International Standards. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye, as well as to those portions of therapeutic or surgical systems that direct optical radiation into or at the eye for diagnostic, illumination, measurement, imaging or alignment purposes.

This part of ISO 15004 does not apply to radiation that is intended for treatment of ocular tissues.

NOTE 1 In the case of the treatment beams of therapeutic devices, when conducting risk assessments for non-target tissues, the limits given in this International Standard can be applied to the treatment beam.

Where vertical (instrument-specific) International Standards contain specific light hazard requirements different from those given in this part of ISO 15004, then those in the vertical International Standard take precedence.

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.

NOTE 2 The emission limits are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. The limits and guidelines in this International Standard also take account of the likelihoods that eyes might be dilated and that eyes and heads might be stabilized during ophthalmic examinations. See Reference.[1]

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15004-1 and the following apply.

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

Note 1 to entry: 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, or can be, operated with a continuous output for a time that can be greater than 0,25 s (i.e. a non-pulsed radiation source)

3.1.3
dose-limited instrument
ophthalmic device, whose emission exceeds the Group 1 dose-rate (irradiance) limits, but through its design and construction cannot expose any given eye to radiation that reaches the cumulative exposure limits given in6.5 and Table 5 within a 24-hour period

Note 1 to entry: This instrument would then be a Group 1 instrument.

3.1.4
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

Note 1 to entry: For an obscured or non-circular aperture, it has an area equivalent to that of a non-obscured circular aperture.

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 1 to entry: 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 but does fulfil the requirements of 5.3

3.1.9
irradiance
E
⟨at a point on a surface⟩ quotient of the radiant power dΦ incident on an element of a surface containing the point, by the area dA of that element, i.e

$$E = \frac{d\varphi}{dA}$$

Note 1 to entry: 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

Note 1 to entry: Ultraviolet, visible, or infrared.

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

Note 1 to entry: 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 exposure of known duration of 0,25 s or less or a train of pulses where each pulse in that train has a duration of less than 0,25 s

Note 1 to entry: 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 to entry: 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.

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

$$L = \frac{d\varphi}{dA \times \cos\theta \times d\Omega}$$

where

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

dA 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 to entry: The same definition holds for the time-integrated radiance L_i if, in the formula for L, the radiant power dΦ is replaced by the radiant energy dQ.

Note 2 to entry: 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, dQ, incident on an element of a surface containing the point over the given duration by unit area dA of that element

$$H = \frac{dQ}{dA}$$

Note 1 to entry: Equivalently, the radiant exposure is defined as the integral of the irradiance, E, at a given point over a given duration, Δt

$$H = \int_{\Delta t} E \times dt$$

Note 2 to entry: Radiant exposure is expressed in Joules per square centimetre, J/cm^2.

3.1.18
scanning instrument
instrument that emits radiation having a time-varying direction, origin or pattern of propagation with regard to a stationary frame of reference

3.1.19
spectral irradiance
***E*$_\lambda$**
quotient of the spectral radiant power dΦ (λ) 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

$$E_\lambda = \frac{d\varphi(\lambda)}{dA \times d\lambda}$$

Note 1 to entry: Spectral irradiance is expressed in watts per square centimetre nanometre, W/(cm^2·nm).

3.1.20
spectral radiance
***L*$_\lambda$**
⟨for a wavelength interval dλ, in a given direction at a given point⟩ ratio of the spectral radiant power dΦ (λ) 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

$$L_\lambda = \frac{d\varphi(\lambda)}{dA \times \cos\theta \times d\Omega \times d\lambda}$$

Note 1 to entry: Spectral radiance is expressed in watts per steradian square centimetre nanometre, W/(sr·cm^2·nm).

3.1.21
time-limited instrument
ophthalmic device, whose maximum exposure duration is limited and known

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)
$E_{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_{A\text{-}R}$	$A(\lambda)$ weighted retinal irradiance	W/cm^2
$E_{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm^2
$E_{VIR\text{-}AS}$	unweighted anterior segment visible and infrared radiation irradiance	W/cm^2
$E_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm^2
$L_{A\text{-}R}$	$A(\lambda)$ weighted retinal radiance	W/(sr·cm^2)
$L_{i,A\text{-}R}$	$A(\lambda)$ weighted retinal time-integrated radiance	J/(sr·cm^2)
$L_{i,VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation time-integrated radiance	J/(sr·cm^2)
$L_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiance	W/(sr·cm^2)
$H_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm^2
$H_{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm^2
$H_{VIR\text{-}AS}$	unweighted anterior segment visible and infrared radiation radiant exposure	J/cm^2
$H_{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_{A\text{-}R}$	$A(\lambda)$ 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)	—
$B(\lambda)$	blue-light hazard 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; also: energy integration time; for pulsed instruments: the time to deliver a full pulse width for an individual pulse, and for multiple pulses, the time that includes each individual pulse and combination of pulses	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)
v_s	velocity of the scanning beam on the irradiated tissue surface	mm/s

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 but do fulfil those of 5.3.

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.

5.2 Requirements for classification as a Group 1 instrument

5.2.1 General

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, prevent emissions in excess of the limits specified for instruments in 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 to exceed the limits specified for Group 1, then measurements shall be required only for those parameters in Tables 2 and 3 where the components do not prevent the limits from being exceeded.

c) 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.

d) It is a dose-limited instrument by virtue of its construction and design, as defined in 3.1.3.

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 1 h exposure. These limits apply to all instruments except operation microscopes, endoilluminators, and instruments designed for continuous exposure. 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.

Time-limited instruments fulfil the Group 1 requirement for retinal photochemical aphakic light hazard weighted retinal irradiance, $E_{A\text{-}R}$, if their maximum exposure duration is less than the time to reach the recommended maximum exposure for photochemical aphakic retinal exposure, t_{max}, as per 6.5.3.

5.2.2 Requirements for classification as Group 1 for a scanning instrument

An ophthalmic instrument that images the retina or the anterior segment of the eye through the use of a small moving irradiated area shall be classified as a Group 1 instrument for retinal visible and infrared radiation thermal hazard if the total radiation energy entering the eye creates a weighted retinal visible and infrared radiation thermal irradiance less than or equal to limit given by Table 5, row 5.5.2.2, for a retinal image size of 0,03 mm and an exposure duration of 10 s, i.e. 1874 J/cm^2. Thus the energy entering the eye shall be less than or equal to 1,32 mW.

An ophthalmic instrument that scans the retina shall be classified as a Group 1 instrument for photochemical aphakic light hazard if the value of the aphakic weighted retinal irradiance, $E_{A\text{-}R}$, is equal to or less than the limit given by Table 2, row 5.4.1.3, where the value of the retinal spectral irradiance, E_λ, used to calculate $E_{A\text{-}R}$ shall be found by dividing the power entering the eye at each wavelength interval, $\Delta\lambda$, given in W, by the area of the irradiated retina, given in cm^2.

5.3 Requirements for Group 2 instruments

5.3.1 If an instrument does not fulfil all requirements for a Group 1 instrument, it shall be checked for compliance with Group 2 requirements only for those hazards for which it did not fulfil the requirements of Group 1. The reporting requirements of 7 b) need only be complied with if Group 1 requirements are not fulfilled for Table 2, row 5.4.1.1 - Weighted corneal and lenticular ultraviolet radiation irradiance or row 5.4.1.2 – Unweighted corneal and lenticular ultraviolet radiation radiant exposure or row 5.4.1.3 - Retinal photochemical aphakic light hazard, Weighted retinal irradiance.

Visible light is necessary for diagnosis of ocular pathology, and thus is commonly used in instruments such as direct and indirect ophthalmoscopes, slit-lamp microscopes, operation microscopes and endoilluminators. It is not reasonable to set limits on visible radiation that is needed for the diagnosis of disease or for visualization during ocular surgery. A surgeon may have to exceed an exposure level that is known to be potentially hazardous during an extended complicated surgery or a clinician may have to exceed an exposure level that is known to be potentially hazardous during an extended ocular examination for diagnosis of ocular pathology. With this in mind, the standard requires that the time to reach a potentially hazardous exposure be given, rather than to set a limit, so that clinicians are informed about potential optical radiation hazards that may be associated with the use of their instruments should they need to use an amount of radiation that has a high likelihood of causing ocular tissue damage.

5.3.2 A scanning instrument that does not fulfil the requirements of 5.2.2 for retinal visible and infrared radiation thermal hazard shall be checked for compliance with Group 2 using the pulsed and time-limited instrument requirements in Table 5, row 5.5.2.2. The value of pulse width Δt to be used in row 5.5.2.2 shall be found using the scan velocity, v_s, and the linear dimension of the beam cross-section in the scanning direction at the retina, d_r, in the formula

$$\Delta t = \frac{d_r}{v_s}$$

where v_s is the velocity of the scanning beam on the irradiated tissue surface expressed in mm/s.

If the value of d_r is less than 0,03 mm, set d_r at 0,03 mm.

For beams with a non-circular cross-section, the value of d_r shall be determined by averaging the maximum cross-section length with the minimum cross-section length. In this calculation, if the maximum cross-section length is greater than 1,2 mm, the value 1,2 mm shall be used as the maximum cross-section length.

When using the requirements of row 5.5.2.2 the value of N, the number of pulses, is the number of times the scan passes over the circular aperture of 0,03 mm on the retina.

A scanning instrument that does not fulfil the requirements of 5.2.2 for photochemical aphakic light hazard shall fulfil the requirements of 7 b) 1) for reporting time to reach the recommended maximum