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Oftalmični instrumenti - Osnovne zahteve in preskusne metode - 2. del: Zaščita pred nevarno svetlobo (ISO/DIS 15004-2:2014)

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO/DIS 15004-2:2014)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO/DIS 15004-2:2014)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumièrePlus de détails (ISO/DIS 15004-2:2014)

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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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

[Revision of first edition (ISO 15004-2:2007)]

ICS: 11.040.70

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Contents

Page

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, *Ohthalmic optics and instruments* and by Technical Committee CEN/TC 170, *Ophthalmic optics* in collaboration.

This second edition cancels and replaces the first edition (EN 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 and 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 In the case of ***the treatment beams of*** therapeutic devices, when conducting risk assessments for non-target tissues, the limits given in this 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 shall 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 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 standard also account for the likelihoods that eyes may be dilated and that eyes and heads may be stabilised during ophthalmic examinations. See Bibliography [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 exposure limits given in Table 5 and 6.5 within a 24-hour period.

3.1.4
time-limited instrument
ophthalmic device, whose maximum exposure duration is limited and known.

3.1.5
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

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

3.1.6
emission limit
maximum value of optical radiation output allowed

3.1.7
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

3.1.8
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.

3.1.9
Group 1 instrument
ophthalmic instrument for which no potential light hazard exists and that can be shown to fulfil the requirements of 5.2

3.1.10
Group 2 instrument
ophthalmic instrument for which a potential light hazard exists and that does not fulfil the requirements of 5.2

3.1.11
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.

$$E = \frac{d\phi}{dA} \quad (1)$$

Note 1 to entry: Irradiance is expressed in units of watts per square centimetre, W/cm^2.

3.1.12
manufacturer
natural or legal person who places the ophthalmic instrument on the market

3.1.13
maximum intensity
highest optical radiation emissions the instrument is capable of delivering under any and all conditions

3.1.14
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

3.1.15
optical radiation hazard
risk of damage to the eye by exposure to optical radiant energy

3.1.16
photoretinitis
retinal photochemically-induced injury 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.

3.1.17
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.

3.1.18
radiance
L
⟨in a given direction at a given point of a real or imaginary surface⟩ quantity defined by the formula

$$L = \frac{d\phi}{dA \times \cos\theta \times d\Omega} \tag{2}$$

where

- $d\Phi$ is the radiant power transmitted by an elementary beam passing through the given point and propagating in the solid angle $d\Omega$ 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 equation for L, the radiant power $d\Phi$ 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).

3.1.19
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

$$H = \frac{dQ}{dA} \tag{3}$$

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

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

Note 1 to entry: Radiant exposure is expressed in Joules per square centimetre, J/cm^2.

3.1.20
scanning instrument
instrument that emits radiation having a time-varying direction, origin or pattern of propagation with regard to a stationary frame of reference.

3.1.21
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

$$E_\lambda = \frac{d\phi(\lambda)}{dA \times d\lambda} \tag{5}$$

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

3.1.22
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

$$L_\lambda = \frac{d\phi(\lambda)}{dA \times \cos\theta \times d\Omega \times d\lambda} \tag{6}$$

Note 1 to entry: 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)
$E_\mathrm{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_\mathrm{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_\mathrm{A\text{-}R}$	$A(\lambda)$ weighted retinal irradiance	W/cm^2
$E_\mathrm{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm^2
$E_\mathrm{VIR\text{-}AS}$	unweighted anterior segment visible and infrared radiation irradiance	W/cm^2
$E_\mathrm{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm^2
$L_\mathrm{A\text{-}R}$	$A(\lambda)$ weighted retinal radiance	W/(sr·cm^2)
$L_{i,\mathrm{A\text{-}R}}$	$A(\lambda)$ weighted retinal time-integrated radiance	J/(sr·cm^2)
$L_{i,\mathrm{VIR\text{-}R}}$	$R(\lambda)$ weighted, retinal visible and infrared radiation time-integrated radiance	J/(sr·cm^2)
$L_\mathrm{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiance	W/(sr·cm^2)
$H_\mathrm{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm^2
$H_\mathrm{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm^2
$H_\mathrm{VIR\text{-}AS}$	unweighted anterior segment visible and infrared radiation radiant exposure	J/cm^2
$H_\mathrm{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_\mathrm{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_\mathrm{A\text{-}R}$	$A(\lambda)$ 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)