SLOVENSKI STANDARD
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Oftalmični instrumenti - Osnovne zahteve in preskusne metode - 2. del: Zaščita pred nevarno svetlobo (ISO 15004-2:2007)

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2007)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2007)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumiere (ISO 15004-2:2007)

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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English Version

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2007)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumière (ISO 15004-2:2007)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2007)

This European Standard was approved by CEN on 10 February 2007.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN ISO 15004-2:2007) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.

This document supersedes EN ISO 15004:1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 15004-2:2007 has been approved by CEN as EN ISO 15004-2:2007 without any modifications.

INTERNATIONAL STANDARD

ISO 15004-2

First edition
2007-02-15

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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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, $\mathrm{J/cm^2}$.

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 $\mathrm{d}\Phi(\lambda)$ in a wavelength interval $\mathrm{d}\lambda$, incident on an element of a surface, by the area $\mathrm{d}A$ of that element and by the wavelength interval $\mathrm{d}\lambda$

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

NOTE Spectral irradiance is expressed in watts per square centimetre nanometre, $\mathrm{W/(cm^2 \cdot nm)}$.

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

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

NOTE Spectral radiance is expressed in watts per steradian square centimetre nanometre, $\mathrm{W/(sr \cdot cm^2 \cdot nm)}$.

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	$W/(cm^2 \cdot nm)$
L	radiance (in a given direction at a given point of a real or imaginary surface)	$W/(sr \cdot cm^2)$
L_λ	spectral radiance (for a wavelength interval dλ, in a given direction at a given point)	$W/(sr \cdot cm^2 \cdot nm)$
L_i	time-integrated radiance	$J/(sr \cdot cm^2)$
H	radiant exposure (at a point of a surface, for a given duration)	J/cm^2
H_λ	spectral radiant exposure	$J/(cm^2 \cdot nm)$
$E_{S\text{-}CL}$	$S(\lambda)$ 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	$W/(sr \cdot cm^2)$
$L_{i,A\text{-}R}$	$A(\lambda)$ weighted retinal time-integrated radiance	$J/(sr \cdot cm^2)$
$L_{i,VIR\text{-}R}$	$R(\lambda)$ weighted, retinal visible and infrared radiation time-integrated radiance	$J/(sr \cdot cm^2)$
$L_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiance	$W/(sr \cdot cm^2)$
$H_{VIR\text{-}R}$	$R(\lambda)$ 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)	—
$R(\lambda)$	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	$J/(cm^2 \cdot nm)$
$(E_\lambda \cdot \Delta t)$	spectral radiant exposure at time Δt	$J/(cm^2 \cdot nm)$