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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

FDIS stage

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Foreword

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15004-2:2007), which has been technically revised.

The main changes are as follows:

— The terms and definitions include dose limited instruments and time limited instruments;

— The safe exposure limits have been reorganized into 4 tables (Tables 2 to 5), and the associated measurement conditions have been reorganized into a companion table (Table 6);

— A number of Group 1 exposure limits and Group 2 recommended maximum exposures (RMEs) have been updated to conform to recent research and relevant standards;

— The language has been clarified and simplified throughout the document, and a flowchart has been added as a guide to make the standard more accessible to first-time users;

— Clauses and associated exposure limits have been added for long-term repetitive exposures, such as may apply to extensive use of head-mounted displays by people with visual impairments;

— Provisions have been added to ensure that the exposure limits and RMEs applicable to specific devices are easily accessible to end users.

A list of all parts in the ISO 15004 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.

Introduction

Ophthalmic instruments are classified into two groups to distinguish instruments that can present a potential hazard from those that cannot. The two groups are named Group 1 and Group 2. They are defined as follows:

Group 1 instruments: ophthalmic instruments for which no potential light hazard exists when used as intended (see Clause 4).

Group 2 instruments: ophthalmic instruments for which a potential light hazard exists (see Clause 4).

Limits and guidelines for optical radiation exposure of the eye during ophthalmic examination can differ from those of non-ophthalmic applications. They can be more restrictive because of pupils dilation or retinal image stabilization, or less restrictive based on benefit/risk ratios. Furthermore, interruptions of exposure during surgical procedures mitigate the risk.

All group 2 instruments pose a potential risk of injury at the upper emission values of the instrument. This is true for both photochemical (where time is critical) and thermal, where transmission and absorption values can vary. Clinical judgement of individual susceptibility is also required.

NOTE 1 The basic limits and guidelines in this document are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. They also cover cases where pupils are dilated, or the image is stabilized on the retina during ophthalmic examinations.

NOTE 2 This document provides exposure limits for ocular tissues. The exposures can be calculated based upon the measured instrument emissions.

The flow chart in Figure 1 at the beginning of Clause 4 provides guidance on how to apply this document to any device to be tested or designed for light hazards conformity.

Ophthalmic instruments — Fundamental requirements and test methods —

Part 2:
Light hazard protection

1 Scope

This document 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. 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.

NOTE For the purpose of this document, optical radiation relates to the wavelength range of 250 nm to 2 500 nm.

This document does not apply to therapeutic radiation. However, in the case of the treatment beams of therapeutic devices, when conducting risk assessments for non-target tissues, the limits given in this document may be applied to those parts of the treatment beam that strike non-target tissue.

Where vertical (instrument-specific) International Standards contain specific light hazard requirements different from those given in ISO 15004-2, then those in the vertical International Standard take precedence.

This document classifies ophthalmic instruments into either Group 1 or Group 2 to distinguish instruments that are non-hazardous from those that are potentially hazardous.

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

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
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 integrating sphere placed in front of the radiometer/spectroradiometer entrance slit.

3.2
continuous exposure
continuous wave
CW
radiant exposure equal to or greater than 0,25 s duration

3.3
continuous wave instrument
CW instrument
ophthalmic instrument that is designed to expose the eye to one or more continuous wave radiation sources

3.4
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 equal or greater than 0,25 s (i.e. a non-pulsed radiation source)

3.5
dose-limited instrument
ophthalmic instrument whose emission could exceed the Group 1 exposure limits, but through its design and construction and accounting for multiple exposures within a 24-hour period, cannot under reasonably foreseeable conditions expose any given eye to radiation that exceeds the Group 1 cumulative exposure limits given in Table 2 and Table 3

Note 1 to entry: This instrument would otherwise be a Group 2 instrument; for example, some UV-Fluorescent diagnostic instruments.

Note 2 to entry: The maximal exposure duration of dose-limited instruments is 30 000 s.

3.6
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, the effective aperture is defined as the uniformly illuminated, unobscured circular aperture that transmits the same radiant flux.

3.7
emission limit
maximum permitted value of optical radiation output to which the eye is potentially exposed

3.8
exposure limit
maximum value of optical radiation exposed to which an ocular tissue is potentially exposed

3.9
endoilluminator
instrument 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

3.10
field-of-view
conical solid angle as “seen” by the detector, such as the eye or the radiometer/spectroradiometer, over which the detector receives radiation

Note 1 to entry: This is also referred to as acceptance angle.

Note 2 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.

Note 3 to entry: In this document, a plane angle is used to describe a circular symmetric solid angle field of view.

3.11
group 1 instrument
ophthalmic instrument for which no potential optical radiation hazard exists and that can be shown to fulfil Group 1 requirements

3.12
group 2 instrument
ophthalmic instrument for which a potential optical radiation hazard exists and that does not fulfil Group 1 requirements but does fulfil the Group 2 requirements

Note 1 to entry: Since Group 2 instruments do not fulfil the requirements of Group 1 instruments, special precautions are necessary.

3.13
immobilized eye
eye that is physically fixed or whose movements are compensated so that a retinal image does not move.

Note 1 to entry: For the purpose of this document, this term also refers to a retinal image stabilized by eye tracking technology. It does not refer to an eye that is maintaining voluntary fixation, e.g. during an ophthalmic examination.

3.14
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. given in Formula (1),

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

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

3.15
manufacturer
natural or legal person with responsibility for design or manufacture of an ophthalmic instrument with the intention of making the ophthalmic instrument available for use, under their name, whether or not such an ophthalmic instrument is designed or manufactured by that themself or on their behalf by another person

[SOURCE: ISO 13485:2016, 3.10, modified — The word "medical device" has been replaced by "ophthalmic instrument", neutered.]

3.16
maximum intensity
highest optical radiation intensity the instrument can deliver under normal conditions

3.17
operation microscope
stereo microscope used for observation of surgical and other medical procedures, consisting of an illumination system and an observation system

3.18
optical radiation hazard
hazard related to the risk of damage to the eye by exposure to optical radiant energy

3.19
pulse duration
time interval equal to the full width at half maximum of the pulse

3.20
pulsed instrument
ophthalmic instrument that emits radiation in the form of a single exposure of known duration of less than 0,25 s 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 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 pulsed radiation.

3.21
radiance
L
electromagnetic radiation emitted in a specified direction at a given point of a real or imaginary surface defined by Formula (2):

$$L = \frac{d\Phi}{dA \cdot cos\theta \cdot d\Omega} \quad (2)$$

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_t 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·cm²); time-integrated radiance is expressed in Joules per steradian square centimetre, J/(sr·cm²).

3.22
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 as expressed in Formula (3):

$$H = \frac{dQ}{dA} \quad (3)$$

equivalently, the radiant exposure is defined as the integral of the irradiance, E, at a given point over duration Δt as expressed in Formula (4):

$$H = \int_{\Delta t} E \cdot dt \quad (4)$$

Note 1 to entry: Radiant exposure is expressed in Joules per square centimetre, J/cm².

3.23
recommended maximum exposure
RME
group 2 radiant exposure value above which a substantial risk of permanent injury exists

Note 1 to entry: Added precautions are recommended.

3.24
scanning instrument
instrument that emits radiation having a time-varying direction, origin or pattern of propagation with regard to a stationary frame of reference

3.25
slit-lamp microscope
instrument consisting of a microscope and a swivelling illumination system providing a slit image

3.26
spectral irradiance
E_λ
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, as expressed in Formula (5):

$$E_\lambda = \frac{\mathrm{d}^2\Phi(\lambda)}{\mathrm{d}A \cdot \mathrm{d}\lambda} \quad (5)$$

Note 1 to entry: Spectral irradiance is expressed in watts per square centimetre nanometre, W/(cm²·nm).

3.27
spectral radiance
L_λ
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, as expressed in Formula (6):

$$L_\lambda = \frac{\mathrm{d}^2\Phi(\lambda)}{\mathrm{d}A \cdot \cos\theta \cdot \mathrm{d}\Omega \cdot \mathrm{d}\lambda} \quad (6)$$

Note 1 to entry: Spectral radiance is expressed in watts per steradian square centimetre nanometre, W/(sr·cm²·nm).

3.28
spectral radiant exposure
H_λ
quotient of the spectral radiant exposure dQ (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, given in Formula (7):

$$H_\lambda = \frac{\mathrm{d}^2Q(\lambda)}{\mathrm{d}A \cdot \mathrm{d}\lambda} \quad (7)$$

Note 1 to entry: Spectral radiant exposure is expressed in joules per square centimetre nanometre, J/(cm²·nm).

3.29
spot size
full-width half-maximum values of the dimension of an irradiated area

3.29.1
small spot
spot with a spot size ≤0,03 mm

Note 1 to entry: This applies where the minimum and maximum dimensions are less than or equal 0,03 mm.

3.29.2
intermediate spot
spot with at least one dimension between spot size >0,03 mm and <1,7 mm

Note 1 to entry: For the irradiated area with a non-circular cross-section, the value of spot size shall be determined by averaging the maximum and minimum cross-section lengths with the exception that where one dimension is greater than 1,7 mm, 1,7 mm is used for the averaging, the values are limited to no more than 1,7 mm and no less than 0,03 mm.

3.29.3
large spot
spot with a spot size ≥1,7 mm

Note 1 to entry: This applies where the minimum and maximum dimensions are both greater than or equal 1,7 mm.

3.30
time-limited instrument
ophthalmic instrument for which the maximum exposure duration for each subject per 24-hour period is limited by the manufacturer for each intended use and specified in the instructions for use

Table 1 — Symbols, quantities and units

Symbol	Quantity	Unit
E	irradiance (at a point on a surface)	W/cm²
E_λ	spectral irradiance	W/(cm²·nm)
L	radiance (in a given direction at a given point of a real or imaginary surface)	W/(sr·cm²)
L_λ	spectral radiance (for a wavelength interval dλ, in a given direction at a given point)	W/(sr·cm²·nm)
L_i	time-integrated radiance	J/(sr·cm²)
H	radiant exposure (at a point of a surface, for a given duration)	J/cm²
H_λ	spectral radiant exposure; the time-integral of spectral irradiance	J/(cm²·nm)
$E_{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm²
$E_{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm²
$E_{A\text{-}R}$	$A(\lambda)$ weighted retinal irradiance	W/cm²
$E_{B\text{-}R}$	$B(\lambda)$ weighted retinal irradiance	W/cm²
$E_{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm²
$E_{VIR\text{-}CL}$	unweighted anterior segment visible and infrared radiation irradiance	W/cm²
$E_{VIR\text{-}I}$	$R(\lambda)$ weighted iris visible and infrared radiation thermal irradiance	W/cm²
$E_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm²
$L_{A\text{-}R}$	$A(\lambda)$ weighted retinal radiance	W/(sr·cm²)
$L_{i,A\text{-}R}$	$A(\lambda)$ weighted retinal time-integrated radiance	J/(sr·cm²)
$L_{i,VIR\text{-}R}$	$R(\lambda)$ weighted, retinal visible and infrared radiation time-integrated radiance	J/(sr·cm²)
L_V	luminance (in a given direction point of a real or imaginary surface)	cd/cm²
$L_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiance	W/(sr·cm²)
$H_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm²
$H_{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm²
$H_{VIR\text{-}CL}$	unweighted anterior segment visible and infrared radiation radiant exposure	J/cm²