



**International  
Standard**

**ISO 15004-2**

**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*

**Second edition  
2024-12**

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CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://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.

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 document 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](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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](http://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.

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# 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 permitted value of optical radiation exposure 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  $\alpha$ , 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  $d\Phi$  incident on an element of a surface containing the point, by the area  $dA$  of that element, i.e. given in [Formula \(1\)](#),

$$E = \frac{d\Phi}{dA} \tag{1}$$

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

**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 themselves 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;

$\theta$  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,  $W/(sr \cdot cm^2)$ ; time-integrated radiance is expressed in Joules per steradian square centimetre,  $J/(sr \cdot cm^2)$ .

### 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  $\Delta t$  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,  $J/cm^2$ .

### 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**

$E_\lambda$   
quotient of the spectral radiant power  $d\Phi(\lambda)$  in a wavelength interval  $d\lambda$ , incident on an element of a surface, by the area  $dA$  of that element and by the wavelength interval  $d\lambda$ , as expressed in [Formula \(5\)](#):

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

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

**3.27**

**spectral radiance**

$L_\lambda$   
for a wavelength interval  $d\lambda$ , 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  $d\Omega$  in the given direction, to the product of the wavelength interval  $d\lambda$  and the areas of a section of that beam on a plane perpendicular to this direction ( $\cos \theta dA$ ) containing the given point and to the solid angle  $d\Omega$ , as expressed in [Formula \(6\)](#):

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

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

**3.28**

**spectral radiant exposure**

$H_\lambda$   
quotient of the spectral radiant exposure  $dQ(\lambda)$  in a wavelength interval  $d\lambda$ , incident on an element of a surface, by the area  $dA$  of that element and by the wavelength interval  $d\lambda$ , given in [Formula \(7\)](#):

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

Note 1 to entry: Spectral radiant exposure is expressed in joules per square centimetre nanometre,  $J/(cm^2 \cdot nm)$ .

**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  $\leq 0,03$  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  $\geq 1,7$  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/cm <sup>2</sup>
$E_{\lambda}$	spectral irradiance	W/(cm <sup>2</sup> ·nm)
$L$	radiance (in a given direction at a given point of a real or imaginary surface)	W/(sr·cm <sup>2</sup> )
$L_{\lambda}$	spectral radiance (for a wavelength interval $d\lambda$ , in a given direction at a given point)	W/(sr·cm <sup>2</sup> ·nm)
$L_i$	time-integrated radiance	J/(sr·cm <sup>2</sup> )
$H$	radiant exposure (at a point of a surface, for a given duration)	J/cm <sup>2</sup>
$H_{\lambda}$	spectral radiant exposure; the time-integral of spectral irradiance	J/(cm <sup>2</sup> ·nm)
$E_{S-CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm <sup>2</sup>
$E_{UV-CL}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm <sup>2</sup>
$E_{A-R}$	$A(\lambda)$ weighted retinal irradiance	W/cm <sup>2</sup>
$E_{B-R}$	$B(\lambda)$ weighted retinal irradiance	W/cm <sup>2</sup>
$E_{IR-CL}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm <sup>2</sup>
$E_{VIR-CL}$	unweighted corneal and lenticular visible and infrared radiation irradiance	W/cm <sup>2</sup>
$E_{VIR-I}$	$R(\lambda)$ weighted iris visible and infrared radiation thermal irradiance	W/cm <sup>2</sup>
$E_{VIR-R}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm <sup>2</sup>
$L_V$	luminance (in a given direction point of a real or imaginary surface)	cd/cm <sup>2</sup>
$H_{VIR-R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm <sup>2</sup>
$H_{IR-CL}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm <sup>2</sup>
$H_{VIR-CL}$	unweighted corneal and lenticular visible and infrared radiation radiant exposure	J/cm <sup>2</sup>
$H_{S-CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm <sup>2</sup>
$H_{UV-CL}$	unweighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm <sup>2</sup>
$H_{A-R}$	$A(\lambda)$ weighted retinal radiant exposure	J/cm <sup>2</sup>
$I(\lambda)$	iris radiation hazard weighting function (see Annex A)	—
$S(\lambda)$	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)	—
$R(\lambda)^a$	retinal radiation thermal hazard weighting function (see Annex A)	—
$\Delta\lambda$	wavelength summation interval	nm
$t$	exposure duration energy integration time;	s
$\Delta t$	pulse duration up to a time of 0,25 s	s
$v_s$	velocity of the scanning beam on the irradiated tissue surface	mm/s
$N$	number of pulses in a pulse train	—
$d_i$	iris spot size	mm

<sup>a</sup>  $R(\lambda)$  refers to  $R_A(\lambda)$  for aphakic eyes or  $R_p(\lambda)$  for phakic eyes, as appropriate.

NOTE For simplicity, “ $\tau(\lambda)$ ” is assumed to be 1,0 and “ $\tau_p(\lambda)$ ” is the re-normalized crystalline lens transmittance as specified in Table A.1.

Table 1 (continued)

Symbol	Quantity	Unit
$d_r$	retinal image dimension (diameter if image is circular) (see <a href="#">C.6</a> )	mm
$\tau(\lambda)$	aphakic spectral transmittance of ocular media	—
$\tau_p(\lambda)$	phakic spectral transmittance of ocular media	—
$Q$	radiant energy	J
$\Phi$	radiant power	W

<sup>a</sup>  $R(\lambda)$  refers to  $R_A(\lambda)$  for aphakic eyes or  $R_p(\lambda)$  for phakic eyes, as appropriate.

NOTE For simplicity, “ $\tau(\lambda)$ ” is assumed to be 1,0 and “ $\tau_p(\lambda)$ ” is the re-normalized crystalline lens transmittance as specified in [Table A.1](#).

## 4 Classification principles

### 4.1 General

[Figure 1](#) provides guidance in instrument classification.

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## 4.2 Group 1 instruments

Ophthalmic instruments for which no potential light hazard exists under conditions of intended use, i.e. ophthalmic instruments that can be shown to fulfil the requirements of [5.2](#).

NOTE An instrument that fulfils the requirements of [5.2](#) does not need to fulfill the requirements specified in [5.3](#).

## 4.3 Group 2 instruments

Ophthalmic instruments for which a potential light hazard exists, i.e. ophthalmic instruments that do not fulfil the requirements of [5.2](#) but do fulfil those of [5.3](#).

# 5 Requirements for classification

## 5.1 General

The following requirements are intended to ensure that ophthalmic instruments are so designed that the energy in all wavelengths is consistent with the safe use of the instrument. Ophthalmic instruments should be designed to exclude unnecessary radiation exposure to the eye. Therefore, ophthalmic instruments shall comply with the requirements for classification as Group 1 instruments (see [5.2](#)) unless higher emissions are necessary to achieve the intended clinical purpose.

Whilst some instruments, by the very nature of their design and their intended use, have the potential to be hazardous, others do not present such risks under any circumstances. This is the basis of classifying ophthalmic instruments into two separate groups.

For Group 2 instruments, this document requires the conditions 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 significant likelihood of causing ocular tissue damage.

NOTE 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. It is possible that a surgeon will have to exceed an exposure level that is known to be potentially hazardous during an extended complicated surgery or a clinician will have to exceed an exposure level that is known to be potentially hazardous during an extended ocular examination for diagnosis of ocular pathology.

The use of instruments for examination and treatment of very young children (e.g. younger than 2 years), may require special consideration due to the susceptibility to light hazards. For example, the aphakic weighting function should be used.

If one or more additional devices are intended to be used in combination with an ophthalmic instrument as specified by the manufacturer and in a way that could increase the optical radiation hazard, the combined system shall be tested to determine whether it fulfils the requirements for Group 1 or Group 2 limits.

## 5.2 Requirements for classification as a Group 1 instrument

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

**5.2.1** Its components, e.g. lamps, light-emitting diodes, non-removable filters, lenses, fibres, etc., prevent exposures more than the limits specified for instruments in the Group 1 and manufacturer's test certification or relevant documentation exists. Such instruments shall be classified as Group 1 by the manufacturer's test certification of the components themselves without the need for further measurements on the instrument itself. If such components prevent some, but not all exposures from exceeding the limits specified for Group 1, then measurements shall be required only for those parameters in [Table 2](#) where the limits can be exceeded.

Where more than one certified component is used, the manufacturer shall ensure that the combined radiation does not exceed the Group 1 limit.

**5.2.2** The emission values from any of the following instrument types are less than or equal to those given for the determination of Group 1 classification (see [5.4](#)):

- continuous wave instruments;
- pulsed instruments;
- time-limited instruments;
- scanning instruments;
- multiple source instruments;
- instruments for long-term repetitive daily use.

**5.2.3** It is a dose-limited instrument as defined in [3.5](#), for which the manufacturer shall demonstrate how its construction and design achieve the requirements of a Group 1 instrument.

### 5.3 Requirements for classification as a Group 2 instrument

An instrument shall be classified as a Group 2 instrument if [5.3.1](#) and [5.3.2](#) apply.

**5.3.1** The output level exceeds some or all the exposure limits of a Group 1 instrument (see [5.2](#)).

**5.3.2** Under its intended conditions of use, the output level is consistent with the exposure values in [Tables 4](#) and [5](#).

**5.3.3** For each operating mode where Group 1 limits are exceeded, the manufacturer shall document a justification and address the associated risks in the risk management file. A justification is not required if a vertical standard contains requirements for Group 2 instruments.

NOTE ISO 14971 provides a suitable risk management process.

**5.3.4** If an instrument has some operating modes that are dose limited (i.e. radiant emissions are prevented from exceeding Group 1 exposure limits) and others in which Group 2 exposures are possible, the requirements of [5.3.1](#) and [5.3.2](#) apply only for operating modes that are not dose limited.

### 5.4 Exposure limits for Group 1 classification

#### 5.4.1 Continuous wave instruments

The criteria for the exposure limits for continuous wave instruments relating to anterior segment and retinal irradiance are specified in [Table 2](#) and [Table 3](#).

NOTE The exposure limits for Group 1 continuous wave instruments are based on a maximum foreseeable use duration over a period of 5 000 s in a 24-hour period. Hence, the exposure limit for  $E_{S-CL}$  equals  $0,6 \mu\text{W}/\text{cm}^2$  (i.e.  $H_{S-CL} = 3,0 \text{ mJ}/\text{cm}^2$  over a period of  $t = 5\,000 \text{ s}$ ), and  $E_{A-R}$  equals  $440 \mu\text{W}/\text{cm}^2$  (i.e.  $H_{A-R} = 2,2 \text{ J}/\text{cm}^2$  over a period of  $t = 5\,000 \text{ s}$ ). For longer duration exposures, see [5.4.7](#).

#### 5.4.2 Pulsed instruments

Pulsed instruments shall be evaluated at their highest single-pulse output. For repetitively pulsed instruments, the cumulative effective (weighted) exposure for any given time interval shall not exceed the limit value for that time interval. The ultraviolet, visible, and infrared limits for Group 1 pulsed instruments shall be evaluated for the total cumulative effective exposure using the Group 1 criteria specified in [Tables 2](#) and [3](#).

The effective radiant exposure depends on the spectral composition of the radiation and shall be calculated as the sum of exposure values at all measurable wavelengths multiplied by the corresponding  $S(\lambda)$  weights

for corneal damage,  $A(\lambda)$  or  $B(\lambda)$  weights for photochemical damage, or  $R_A(\lambda)$  or  $R_B(\lambda)$  weights for thermal damage, as applicable.

The cumulative (time-integrated) radiant exposure is calculated as the maximum exposure per pulse times the number of pulses emitted during the total exposure time. The time-averaged irradiance is calculated as the ratio of the time integrated exposure divided by the total duration of the exposure.

If both photochemical and thermal injuries are possible, effective exposures shall be calculated using all applicable weighting functions (tabulated in [Annex A](#)), and the most restrictive limit (i.e. the limit corresponding to the lowest effective exposure) shall apply.

The exposure limits in [Table 2](#) and [Table 3](#) apply both to a single pulse and to any group of pulses.

NOTE Limits are not provided for exposure durations less than  $10^{-13}$  (100 fs) due to a lack of biological data. As an interim guideline, for shorter pulse durations, a conservative guideline would be to limit peak irradiances below the limit applicable to  $10^{-13}$  s.

EXAMPLE An instrument emits 100 pulses, each with a duration of 0,01 s into a retinal area with  $d_r = 0,1$  mm during a total exposure duration of 3 seconds. The pulses are monochromatic, with a wavelength of either 440 nm or 650 nm. From [Table 3](#), the thermal limit for 0,01 s duration pulses is 2,53 J/cm<sup>2</sup> and the photochemical limit is 2,2 J/cm<sup>2</sup>. For the 3 second total duration of the pulse train, the thermal limit is 182 J/cm<sup>2</sup> and the photochemical limit is 2,2 J/cm<sup>2</sup>.

For 440 nm pulses, the photochemical weight  $A(\lambda)$  is 1,0 and the thermal weight  $R(\lambda)$  is 2,0. Therefore, effective exposure values are equal to the measured values for comparison to the photochemical limit and twice the measured values for the thermal limit. The measured single-pulse exposure needed to match the 2,53 J/cm<sup>2</sup> thermal limit for 0,01 s duration pulses is 1,26 J/cm<sup>2</sup> and the photochemical limit is not applicable because the thermal RME is more restrictive. For the 3 second total duration of the pulse train, a measured cumulative exposure of 91 J/cm<sup>2</sup> (0,91 J/cm<sup>2</sup>/pulse) is needed to match the 182 J/cm<sup>2</sup> thermal limit because of the 2,0  $R(\lambda)$  value. However, these limits are irrelevant because the photochemical limit is 2,2 J/cm<sup>2</sup>, much more restrictive than the thermal limit.

For 650 nm pulses,  $A(\lambda)$  is 0,001 and  $R(\lambda)$  is 1,24. While the limits for weighted exposures are the same as for 440 nm, the relationship between the effective photochemical and thermal exposures is vastly different. The effective photochemical exposure is near zero, so the measured cumulative 3-second exposure would have to be 2 200 J/cm<sup>2</sup> to match the photochemical limit. In contrast a measured exposure of only 2,0 J/cm<sup>2</sup> is needed to match the single-pulse thermal limit of 2,53 J/cm<sup>2</sup>, and a measured cumulative exposure of 147 J/cm<sup>2</sup> matches the 3-second thermal limit of 182 J/cm<sup>2</sup>. Thus, the thermal limit is more restrictive for both single pulses and the three-second pulse train.

### 5.4.3 Time-limited instruments

The maximum exposure duration for Group 1 time-limited instruments is determined by the radiant power output of the instrument and the Group 1 limits in [Table 2](#) and [Table 3](#). This time limit applies to any given eye within a 24-hour period. The exposure duration shall be limited by the manufacturer to meet the requirements for each intended use.

### 5.4.4 Dose limited instruments

The exposure limits for dose-limited instruments are the Group 1 limits in [Table 2](#) and [Table 3](#), taking into account multiple exposures for any given eye within a 24-hour period.

### 5.4.5 Scanning instruments

If the radiant power exceeds the Group 1 limit for a static beam, do the following:

The value of pulse width  $\Delta t$  to be used as exposure duration in [Table 2](#) and [Table 3](#) shall be found using the scan velocity,  $v_s$ , and the linear dimension of the beam cross-section in the scanning direction at the irradiated tissue surface,  $d_s$ , in [Formula 8](#):

$$\Delta t = \frac{d_s}{v_s} \quad (8)$$

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

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

When using the requirements for pulsed instruments (see 5.4.2) 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 irradiated tissue surface.

The exposure over any portion of the scanned area shall not exceed the exposure limits that would apply to a spot size equivalent to that portion.

NOTE If the static beam exceeds the Group 1 limit, it can meet the Group 2 RME and therefore the manufacturer can choose the option to classify as Group 2 based on the output of the static beam.

### 5.4.6 Instruments with multiple sources

The optical radiation emissions from instruments that are designed to direct optical radiation on to the same point(s) in or on the eye from multiple light sources shall be below all applicable limits for each light source alone. For all intended consecutive and/or simultaneous use of the light sources, the limit that is applicable for each surface of the eye (cornea, lens, retina) is given by Formula (9):

$$\frac{H_1}{\text{Limit}_1} + \frac{H_2}{\text{Limit}_2} + \dots + \frac{H_i}{\text{Limit}_i} \leq 1 \quad (9)$$

If the limits are expressed in irradiance  $E$ , replace  $H$  by  $E$ .

where

$E$  is the quantity irradiance or effective irradiance <

$H$  is the quantity radiant exposure or effective radiant exposure;

$i$  is the index for the sources.

### 5.4.7 Instruments for long-term repetitive daily use

Instruments such as head-mounted displays that provide augmented or enhanced vision for low vision patients can be worn for many hours per day on a continuing basis and shall be Group 1. Such long-term repeated exposures will require exposure limits lower than those established for a 5 000 s duration. The 5 000 s duration has been established as a reasonably foreseeable maximum duration of use for clinical ophthalmic instruments. If ultraviolet radiation exposure is possible, the Group 1 limit for an 8-hour daily  $H_{S-CL}$  (250 nm to 400 nm) exposure shall be 0,1  $\mu\text{W}/\text{cm}^2$  ( $S(\lambda)$  weighted). Aphakic retinal irradiance,  $E_{A-R}$ , for visible light shall be limited to 10  $\mu\text{W}/\text{cm}^2$  ( $A(\lambda)$  weighted), and infrared retinal exposure,  $E_{VIR-R}$ , shall be limited to 10  $\text{mW}/\text{cm}^2$  ( $R(\lambda)$  weighted) (see 5.5.6 for exceptions).

NOTE In most cases, average irradiance will be below this limit to provide visual comfort. Different weighting functions are used for UV, visible, and IR spectral regions because the exposure limits are most restrictive for different mechanisms of damage in these regions.

## 5.5 Recommended maximum exposure (RME) values for Group 2 instruments

### 5.5.1 Continuous wave instruments

The criteria for calculating the recommended maximum exposures (RMEs) for continuous wave instruments relating to anterior segment and retinal irradiance are specified in Tables 4 and 5.

### 5.5.2 Pulsed instruments

Pulsed instruments shall be evaluated at their highest single-pulse output. For repetitively pulsed instruments, the cumulative effective (weighted) exposure for any given time interval shall not exceed the RME value for that time interval. The ultraviolet, visible, and infrared RMEs for Group 2 pulsed instruments shall be evaluated for the total cumulative effective exposure using the Group 2 criteria specified in Tables 4 and 5.

The effective radiant exposure depends on the spectral composition of the radiation and shall be calculated as the sum of exposure values at all measurable wavelengths multiplied by the corresponding  $S(\lambda)$  weights for corneal damage,  $A(\lambda)$  or  $B(\lambda)$  weights for photochemical damage, or  $R_A(\lambda)$  or  $R_B(\lambda)$  weights for thermal damage.

The cumulative (time-integrated) radiant exposure is calculated as the maximum exposure per pulse times the number of pulses emitted during the total exposure time. The time-averaged irradiance is calculated as the ratio of the time integrated exposure divided by the total duration of the exposure.

For any given measured exposure parameters, effective exposures shall be calculated using all applicable weighting functions, and the most restrictive RME (i.e. the RME corresponding to the lowest effective exposure) shall apply.

**EXAMPLE** An instrument emits 100 pulses, each with a duration of 0,01 s into a retinal area with  $d_r = 0,1$  mm during a total exposure duration of 3 s. The pulses are monochromatic, with a wavelength of either 440 nm or 650 nm. From [Table 5](#), the thermal RME for 0,01 s duration pulses is 3,5 J/cm<sup>2</sup> and the photochemical RME is not applicable because the thermal RME is more restrictive. For the 3 s total duration of the pulse train, the thermal RME is 251 J/cm<sup>2</sup> and the photochemical RME is 10 J/cm<sup>2</sup>.

For 440 nm pulses, the photochemical weight  $A(\lambda)$  is 1,0 and the thermal weight  $R(\lambda)$  is 2,0. Therefore, effective exposure values are equal to the measured values for comparison to the photochemical RME and twice the measured values for the thermal RME. The measured single-pulse exposure needed to match the 3,5 J/cm<sup>2</sup> thermal RME for 0,01 s duration pulses is 1,75 J/cm<sup>2</sup> and the photochemical RME is not applicable because the thermal RME is more restrictive. For the 3 s total duration of the pulse train, a measured integrated exposure of 125 J/cm<sup>2</sup> (1,25 J/cm<sup>2</sup>/pulse) is needed to match the 251 J/cm<sup>2</sup> thermal RME because of the 2,0  $R(\lambda)$  value. However, these RMEs are irrelevant because the photochemical RME is 10 J/cm<sup>2</sup>, much more restrictive than the thermal RME.

For 650 nm pulses,  $A(\lambda)$  is 0,001 and  $R(\lambda)$  is 1,24. While the RMEs for weighted exposures are the same as for 440 nm, the relationship between the effective photochemical and thermal exposures is vastly different. The effective photochemical exposure is near zero, so the measured integrated 3-second exposure would have to be 10 000 J/cm<sup>2</sup> to match the photochemical RME. In contrast a measured exposure of only 2,8 J/cm<sup>2</sup> is needed to match the single-pulse thermal RME of 3,5 J/cm<sup>2</sup>, and a measured integrated exposure of 202 J/cm<sup>2</sup> matches the 3-second thermal RME of 251 J/cm<sup>2</sup>. Thus, the thermal RME is much more restrictive for both single pulses and the three-second pulse train.

### 5.5.3 Time-limited instruments

The maximum exposure duration for Group 2 time-limited instruments is determined by the radiant power output of the instrument and the Group 2 exposure values in [Tables 4](#) and [5](#). This time limit applies to any given eye within a 24-hour period. The time limits shall be determined by the manufacturer for each intended use.

### 5.5.4 Scanning instruments

If the radiant power exceeds the Group 2 RME value for a static beam, do the following:

The value of pulse width  $\Delta t$  to be used in [Tables 4](#) and [5](#) 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,  $d_s$ , in [Formula \(10\)](#):

$$\Delta t = \frac{d_s}{v_s} \quad (10)$$

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

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

When using the requirements for pulsed instruments (see [5.5.2](#)) the number of pulses,  $N$ , is the number of times the scan passes over the circular aperture of 0,03 mm on the retina.

### 5.5.5 Instruments with multiple sources

The optical radiation emissions from instruments that are designed to direct optical radiation on to the same point(s) in or on the eye from multiple light sources shall be below all applicable RMEs for each light

source alone. For all intended simultaneous use and subsequent use for the ultraviolet radiation, the RME that is applicable for each surface of the eye (cornea, lens, retina) is given by [Formula \(11\)](#):

$$\frac{(E,H)_1}{RME_1} + \frac{(E,H)_2}{RME_2} + \dots + \frac{(E,H)_i}{RME_i} \leq 1 \quad (11)$$

where

- $E$  is the quantity irradiance or effective irradiance;
- $H$  is the quantity radiant exposure or effective radiant exposure;
- $i$  is the index for the sources.

### 5.5.6 Instruments for long-term repetitive daily use

Although head-mounted displays for long-term repetitive use would normally be Group 1 instruments, Group 2 exposures can be justified under extenuating conditions (e.g. irradiation of retinal implants in eyes with no photoreceptors). Long-term repeated exposures higher than the Group 1 limits can be necessary. In such cases, the exposure shall be limited to the minimum effective level.

## 5.6 Exposure limits and maximum recommended exposure values

[Table 2](#), [Table 3](#), [Table 4](#) and [Table 5](#), each on a single page, list the exposure limits for Group 1 and maximum recommended exposure values for Group 2.

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Table 2 — Group 1: cornea and lens exposure limits

Row	Location	Parameter and type	Radiometric formula	Wavelength nm	Exposure durations <sup>a</sup>				
					10 <sup>-13</sup> s to 10 <sup>-11</sup> s	>10 <sup>-11</sup> s to 10 <sup>-9</sup> s	>10 <sup>-9</sup> s to 10 s	>10 s to 25 s	>25 s to 5·10 <sup>3</sup> s
1	Cornea/ Lens (Photo-chemical)	Weighted radiant expo- sure	$H_{S-CL} = \sum_{250}^{400} H_{\lambda} \cdot S(\lambda) \cdot \Delta\lambda$	250 to 400	Not applicable. (Rows 2 and 3 are more restrictive)	3,0 mJ/cm <sup>2</sup> (0,3 mW/cm <sup>2</sup> for a duration of 10 s, 0,6 µW/cm <sup>2</sup> for a duration of 5·10 <sup>3</sup> s) For long-term exposures, see 5.4.7			
2	Cornea/ Lens (Thermal)	Unweighted UV radiant exposure	$H_{UV-CL} = \sum_{250}^{315} H_{\lambda} \cdot \Delta\lambda$	250 to 315	1 mJ/cm <sup>2</sup>	0,56·t <sup>1/4</sup> J/cm <sup>2</sup>	Not applicable. (Row 1 is more restrictive)		
3	Cornea/ Lens (Thermal)	Unweighted UV radiant exposure	$H_{UV-CL} = \sum_{315}^{400} H_{\lambda} \cdot \Delta\lambda$	315 to 400	6,0 mJ/cm <sup>2</sup>	1,1·t <sup>1/4</sup> J/cm <sup>2</sup>		100·t mJ/cm <sup>2</sup> (100 mW/cm <sup>2</sup> )	
4a	Cornea/ Lens (Thermal)	Unweighted VIS and IR radiant expo- sure	$H_{VIR-CL} = \sum_{400}^{1200} H_{\lambda} \cdot \Delta\lambda$	400 to 1 200	10 mJ/cm <sup>2</sup>	11·t <sup>1/4</sup> J/cm <sup>2</sup>		1,0·t J/cm <sup>2</sup> (1,0 W/cm <sup>2</sup> )	
4b									
5	Cornea/ Lens (Thermal, small beams)	Unweighted VIS and IR radiant expo- sure	$H_{VIR-CL} = \sum_{400}^{1200} H_{\lambda} \cdot \Delta\lambda$	400 to 1 200	20 mJ/cm <sup>2</sup>	23·t <sup>1/4</sup> J/cm <sup>2</sup>		4·t J/cm <sup>2</sup> (4 W/cm <sup>2</sup> )	

<sup>a</sup> Limits are not provided for exposure durations less than 10<sup>-13</sup> (100 fs) due to a lack of biological data. As an interim guideline, for shorter pulse durations, a conservative guideline would be to limit peak irradiances below the limit applicable to 10<sup>-13</sup> s.

NOTE 1 See Table 6 for measurement conditions and guidance.

NOTE 2 For rows 2 to 5: All thermal lens limits assume no concurrent iris exposure.

Table 3 — Group 1: iris and retina exposure limits

Row	Location	Parameter and type	Radiometric formula	Wave-length nm	Exposure durations <sup>a</sup>					
					10 <sup>-13</sup> s to 10 <sup>-10</sup> s	>10 <sup>-10</sup> s to 1,5·10 <sup>-6</sup> s	>1,5·10 <sup>-6</sup> s to 6,2·10 <sup>-4</sup> s	>6,2·10 <sup>-4</sup> s to 0,25 s	>0,25 s to 2,5·10 <sup>3</sup> s	>2,5·10 <sup>3</sup> s to 5·10 <sup>3</sup> s
6	Iris (averaged over 0,2 mm d) <sup>d</sup>	VIS/IR Thermal hazard	$H_{VIR-I} = \sum_{320}^{1400} H_{\lambda} \cdot I(\lambda) \cdot \Delta\lambda$	320 to 1 400	6 mJ/cm <sup>2</sup>	11 mJ/cm <sup>2</sup>	2-retinal limit (for d <sub>r</sub> >0,2 mm) <sup>d</sup>	1-retinal limit (d <sub>r</sub> >0,2 mm) <sup>d</sup>	0,5-retinal limit (for d <sub>r</sub> >0,2 mm) <sup>d</sup>	
7	Retina	Photo-chemical hazard: for aphakic eyes for phakic <sup>b</sup> eyes	$E_{A-R} = \sum_{305}^{700} E_{\lambda} \cdot A(\lambda) \cdot \Delta\lambda$ $E_{B-R} = \sum_{305}^{700} E_{\lambda} \cdot B(\lambda) \cdot \Delta\lambda$	305 to 700	Not applicable. Thermal limit is more restrictive. 2,2 J/cm <sup>2</sup> if t<5 000 s (0,44 mW/cm <sup>2</sup> for a duration of 5·10 <sup>3</sup> s). For long-term exposures, see 5.4.7.					
8	Retina (large spot >1,7 mm)		$H_{VIR-R} = \sum_{380}^{1400} H_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	2,0 mJ/cm <sup>2</sup>	3,5 mJ/cm <sup>2</sup>	100·t <sup>3/4</sup> J/cm <sup>2</sup>	2,5·t <sup>1/4</sup> J/cm <sup>2</sup>	5,0·t <sup>3/4</sup> J/cm <sup>2</sup>	0,7·t J/cm <sup>2</sup> (0,7 W/cm <sup>2</sup> )
9a	Retina (intermediate spot >0,085 to 1,7 mm)		$H_{VIR-R} = \sum_{380}^{1400} H_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	2,0 mJ/cm <sup>2</sup>	3,5 mJ/cm <sup>2</sup>	100·t <sup>3/4</sup> J/cm <sup>2</sup>	(2,5·t <sup>1/4</sup> J/cm <sup>2</sup> if t<(d <sub>r</sub> /3,4 mm) <sup>2</sup> s)	$\left(\frac{8 \cdot t^{3/4}}{d_r}\right) \frac{J}{cm^2}$ or $\left(\frac{1,2}{d_r}\right) \cdot t \frac{J}{cm^2}$	$\left[\frac{1,2}{d_r}\right] \frac{J}{cm^2}$ $\left[\frac{1,2}{d_r}\right] \frac{W}{cm^2}$
9b	Retina (intermediate spot >0,03 to 0,085 mm)		$H_{VIR-R} = \sum_{380}^{1400} H_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	170/d <sub>r</sub> μJ/cm <sup>2</sup>	300/d <sub>r</sub> μJ/cm <sup>2</sup>	$\left(\frac{7 \cdot t^{3/4}}{d_r}\right) \frac{J}{cm^2}$	$\left(\frac{1,7 \cdot t^{3/4}}{d_r}\right) \frac{J}{cm^2}$		
10	Retina (small spot ≤0,03 mm)		$Q_{VIR-R} = \sum_{380}^{1400} Q_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	40 nJ	80 nJ		1,7·t <sup>3/4</sup> mJ		0,3·t mJ (0,3 mW)

<sup>a</sup> For pulse durations less than 10<sup>-11</sup> s, replace R(λ) with a constant of 1,0 for all R(λ) less than 1. For exposure durations greater than 10 s, replace R(λ) with a constant of 1,0 for all R(λ) greater than 1.

<sup>b</sup> For instruments that will be only used on phakic eyes for persons over the age of 2, the blue-light hazard function B(λ) can be used instead of the aphakic photochemical hazard weighting function A(λ) to calculate the time to reach photochemical exposure limit.

<sup>c</sup> Limits are not provided for exposure durations less than 10<sup>-13</sup> (100 fs) due to a lack of biological data. As an interim guideline, for shorter pulse durations a conservative guideline would be to limit peak irradiances below the limit applicable to 10<sup>-13</sup> s.

<sup>d</sup> For calculated d<sub>r</sub> values < 0,2 mm, d<sub>r</sub> = 0,2 mm shall be used to calculate iris exposure.

NOTE See Table 6 for measurement conditions and guidance.

Table 4 — Group 2: cornea and lens RME values

Row	Location	Parameter and type	Radiometric formula	Wavelength nm	Exposure durations <sup>a</sup>			
					10 <sup>-13</sup> s to 10 <sup>-11</sup> s	>10 <sup>-11</sup> s to 10 <sup>-9</sup> s	>10 <sup>-9</sup> s to 10 s	>10 s to 5·10 <sup>3</sup> s
1	Cornea/Lens (Photo-chemical)	Weighted radiant exposure	$H_{S-CL} = \sum_{250}^{400} H_{\lambda} \cdot S(\lambda) \cdot \Delta\lambda$	250 to 400	Not applicable. (Rows 2 and 3 are more restrictive)	6,0 mJ/cm <sup>2</sup> (0,6 mW/cm <sup>2</sup> for a duration of 10 s, 1,2 μW/cm <sup>2</sup> for a duration of 5·10 <sup>3</sup> s)		
2	Cornea/Lens (Thermal)	Unweighted UV radiant exposure	$H_{UV-CL} = \sum_{250}^{315} H_{\lambda} \cdot \Delta\lambda$	250 to 315	2 mJ/cm <sup>2</sup>	1,1·t <sup>1/4</sup> J/cm <sup>2</sup>	Not applicable. (Row 1 is more restrictive)	
3	Cornea/Lens (Thermal)	Unweighted UV radiant exposure	$H_{UV-CL} = \sum_{315}^{400} H_{\lambda} \cdot \Delta\lambda$	315 to 400	12,0 mJ/cm <sup>2</sup>	2,2·t <sup>1/4</sup> J/cm <sup>2</sup>		200·t ml/cm <sup>2</sup> (200 mW/cm <sup>2</sup> )
4a	Cornea/Lens (Thermal)	Unweighted VIS and IR radiant exposure	$H_{VIR-CL} = \sum_{400}^{1200} H_{\lambda} \cdot \Delta\lambda$	400 to 1200	20 mJ/cm <sup>2</sup>	22·t <sup>1/4</sup> J/cm <sup>2</sup>		2,0·t J/cm <sup>2</sup> (2,0 W/cm <sup>2</sup> )
4b								6,0 mJ/cm <sup>2</sup>
5	Cornea/Lens (Thermal, small beams)	Unweighted VIS and IR radiant exposure	$H_{VIR-CL} = \sum_{400}^{1200} H_{\lambda} \cdot \Delta\lambda$	400 to 1200	40 mJ/cm <sup>2</sup>	For t ≤ 3 s 46·t <sup>1/4</sup> J/cm <sup>2</sup>	20·t J/cm <sup>2</sup> (20 W/cm <sup>2</sup> ) For t > 3 s	

<sup>a</sup> Limits are not provided for exposure durations less than 10<sup>-13</sup> (100 fs) due to a lack of biological data. As an interim guideline, for shorter pulse durations, a conservative guideline would be to limit peak irradiances below the limit applicable to 10<sup>-13</sup> s.

NOTE 1 For rows 2 to 5: All thermal lens RMEs assume no concurrent iris exposure.

NOTE 2 See Table 6 for measurement conditions and guidance.

Table 5 — Group 2 Iris and Retina RME Values

Row	Location	Parameter and type	Radiometric formula	Wave-length nm	Exposure durations <sup>a</sup>					
					10 <sup>-13</sup> s to 10 <sup>-10</sup> s	>10 <sup>-10</sup> s to 1,5·10 <sup>-6</sup> s	>6,2·10 <sup>-4</sup> s to 0,25 s	>0,25 s to 2,5·10 <sup>3</sup> s	>2,5·10 <sup>3</sup> s to 5·10 <sup>5</sup> s	
6	Iris (averaged over 0,2 mm d <sub>i</sub> ) <sup>d</sup>	VIS/IR Thermal hazard	$H_{VIR-I} = \sum_{320}^{1400} H_{\lambda} \cdot I(\lambda) \cdot \Delta\lambda$	320 to 1 400	8 mJ/cm <sup>2</sup>	15 mJ/cm <sup>2</sup>	2-retinal RME (for d <sub>i</sub> >0,2 mm) <sup>d</sup>	1-retinal RME (for d <sub>i</sub> >0,2 mm) <sup>d</sup>	0,5-retinal RME (for d <sub>i</sub> > 0,2 mm) <sup>d</sup>	
7	Retina	Photo-chemical Hazard: for aphakic eyes for phakic <sup>b</sup> eyes	$H_{A-R} = \sum_{305}^{700} H_{\lambda} \cdot A(\lambda) \cdot \Delta\lambda$ $H_{B-R} = \sum_{305}^{700} H_{\lambda} \cdot B(\lambda) \cdot \Delta\lambda$	305 to 700	Not applicable. Thermal limit is more restrictive. See 5.4.7.					
8	Retina (large spot >1,7 mm)		$H_{VIR-R} = \sum_{380}^{1400} H_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	2,8 mJ/cm <sup>2</sup>	5,0 mJ/cm <sup>2</sup>	140·t <sup>3/4</sup> J/cm <sup>2</sup>	3,5·t <sup>1/4</sup> J/cm <sup>2</sup>	7,0·t <sup>3/4</sup> J/cm <sup>2</sup>	1,0·t J/cm <sup>2</sup> (1,0 W/cm <sup>2</sup> )
9a	Retina (intermediate spot >0,085 to 1,7 mm)		$H_{VIR-R} = \sum_{380}^{1400} H_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	2,8 mJ/cm <sup>2</sup>	5,0 mJ/cm <sup>2</sup>	140·t <sup>3/4</sup> J/cm <sup>2</sup>	$\left(\frac{11}{d_r} \cdot t^{3/4}\right) \frac{J}{cm^2}$ or $(3,5 \cdot t^{1/4}) / cm^2$ if t < (d <sub>r</sub> /3,4 mm) <sup>2</sup> s	$\left(\frac{1,7}{d_r} \cdot t\right) \frac{J}{cm^2}$ or $\left[\frac{1,7}{d_r} \cdot W\right] \frac{W}{cm^2}$	
9b	Retina (intermediate spot >0,03 to 0,085 mm)	VIS/IR Thermal hazard <sup>a</sup>	$H_{VIR-R} = \sum_{380}^{1400} Q_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	240/d <sub>r</sub> μJ/cm <sup>2</sup>	420/d <sub>r</sub> μJ/cm <sup>2</sup>	$\left(\frac{10}{d_r} \cdot t^{3/4}\right) \frac{J}{cm^2}$			
10	Retina (small spot ≤0,03 mm)		$Q_{VIR-R} = \sum_{380}^{1400} Q_{\lambda} \cdot R(\lambda) \cdot \Delta\lambda$	380 to 1 400	56 nJ	100 nJ	2,3·t <sup>3/4</sup> mJ			0,4·t mJ (0,4 mW)

<sup>a</sup> For pulse durations less than 10<sup>-11</sup> s, replace R(λ) with a constant of 1,0 for all R(λ) less than 1. For exposure durations greater than 10 s, replace R(λ) with a constant of 1,0 for all R(λ) greater than 1.

<sup>b</sup> For instruments that will be only used on phakic eyes for persons over the age of 2, the blue-light hazard function B(λ) can be used instead of the aphakic photochemical hazard weighting function A(λ) to calculate the time to reach photochemical exposure limit.

<sup>c</sup> Limits are not provided for exposure durations less than 10<sup>-13</sup> (100 fs) due to a lack of biological data. As an interim guideline, for shorter pulse durations a conservative guideline would be to limit peak irradiances below the limit applicable to 10<sup>-13</sup> s.

<sup>d</sup> For calculated d<sub>i</sub> values < 0,2 mm, d<sub>i</sub> = 0,2 mm shall be used to calculate iris exposure.

NOTE See Table 6 for measurement conditions and guidance.

Table 6 — Measurement conditions and guidance for Tables 2 to 5

Row	Parameter	Measurement conditions
1	$H_{S-CL}$	The corneal and lenticular ultraviolet radiant exposure shall be evaluated by averaging the highest localized radiant power incident upon a circular area with a diameter of 3 mm ( $0,07 \text{ cm}^2$ ) at the corneal plane (see Annexes D, E).
2	$H_{UV-CL}$	The corneal radiation radiant exposure shall be evaluated by averaging the highest localized radiant power incident upon a circular area with a diameter of 1 mm ( $7,9 \cdot 10^{-3} \text{ cm}^2$ ) at the corneal plane (see Annexes D, E).
3, 4(a, b)	$H_{UV-CL}$ $H_{VIR-CL}$ $H_{IR-CL}$	The corneal radiant exposure shall be evaluated by averaging the radiant power incident upon the circular area of $9,6 \cdot 10^{-2} \text{ cm}^2$ (diameter=3,5 mm) for continuous exposure at the corneal plane that is centred on the location of the highest radiant exposure. For exposures less than 25 s, the measurement area is $7,9 \cdot 10^{-3} \text{ cm}^2$ (diameter =1,0 mm) (see Annexes D, E). Applies only if iris is not exposed. If iris is exposed, see row 6.
5	$H_{VIR-CL}$	This limit only applies to instruments that, in normal use, irradiate the eye with small beams $\leq 2$ mm diameter at any point between the anterior surface of the cornea and the posterior surface of the crystalline lens. The unweighted anterior segment irradiance shall be evaluated at the point of smallest beam diameter by locating the highest localized radiant power and averaging the radiant power within a circular area centred at that location having a diameter of 1,0 mm ( $7,9 \cdot 10^{-3} \text{ cm}^2$ ) (see Annexes D, E).
6	$H_{VIR-I}$	These values only apply to instruments that are intended to expose the iris. In determining the thermal exposure limit (Group 1) or RME (Group 2), the minimum beam spot diameter applicable to the iris, $d_i$ , is 0,2 mm. Iris thermal limits are based on retinal thermal limits where the iris spot size ( $d_i$ ) replaces retinal spot size ( $d_r$ ) in the calculation. For calculated $d_r$ values $< 0,2$ mm, $d_i = 0,2$ mm shall be used to calculate iris exposure.
7	$H_{A-R}$ $H_{B-R}$	The Group 1 photochemical limit for retinal exposure applies only to continuous wave and dose limited instruments. A time-limited or pulsed instrument does not qualify as a Group 1 instrument if it only meets this limit for a single retinal exposure. The retinal radiant exposure 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 ( $2,54 \cdot 10^{-4} \text{ cm}^2$ ), integrated over time duration $t$ . However, if the instrument is intended to be used with an eye that is immobilized, a 0,03 mm ( $7,07 \cdot 10^{-6} \text{ cm}^2$ ) diameter aperture shall be used instead of a 0,18 mm diameter aperture. See Annex D for instructions for this calculation. The retinal radiant exposure shall be at the radiant energy detectable through a 7 mm diameter aperture at the cornea. For instruments that produce a uniform beam on the retina with a diameter greater than 1 mm, an averaging aperture smaller than the beam diameter may be used to evaluate retinal irradiance instead of the apertures specified.
8	$H_{VIR-R}$ (Large spot $d_r \geq 1,7$ mm)	The retinal irradiance shall be evaluated by averaging the highest localized radiant power incident upon a circular area with a diameter of 0,03 mm ( $7,07 \cdot 10^{-6} \text{ cm}^2$ ) on the retina (see Annex D). For calculated $d_r$ values $> 1,7$ mm, $d_r = 1,7$ mm shall be used to calculate retinal exposure. The retinal radiant exposure shall be the radiant energy detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest radiant energy incident upon a retinal area with a diameter of 0,03 mm ( $7,07 \cdot 10^{-6} \text{ cm}^2$ ). See Annex D for instructions on the way to make this calculation.
9	$H_{VIR-R}$ (Intermediate spot $d_r > 0,03$ and $< 1,7$ mm)	The retinal radiant exposure shall be evaluated by averaging the highest radiant power incident upon a retinal area with a diameter of 0,03 mm ( $7,07 \cdot 10^{-6} \text{ cm}^2$ ). (Annex D). For instruments that produce a uniform irradiance profile on the retina with a diameter greater than 1 mm, a 1 mm diameter averaging aperture may be used to evaluate retinal irradiance instead of the apertures specified. The retinal radiant exposure shall be at the radiant energy detectable through a 7 mm diameter aperture at the cornea and shall be evaluated by averaging the highest localized radiant energy incident upon a circular area on the retina with a diameter of 0,03 mm ( $7,07 \cdot 10^{-6} \text{ cm}^2$ ). See Annex D for instructions on the way to make this calculation.
10	$Q_{VIR-R}$ , $\Phi_{VIR-R}$ (Small spot $d_r \leq 0,03$ mm)	Generally, this relates to laser or SLD radiation sources where the total beam radiant energy or power entering the eye is weighted by $R(\lambda)$ .

## 6 Test methods

### 6.1 General

All tests are type tests. All measurements shall be made at the instrument's intended working distance.

### 6.2 Classification of instruments into Group 1 or Group 2

The first step in determining whether an instrument with broadband radiant output is Group 1 or Group 2 shall be to measure the maximum radiation output of the instrument. If the maximum total radiant output

is below the Group 1 limit specified in [Table 2](#) or [3](#), the instrument is a Group 1 instrument, and no more measurements are needed.

NOTE The maximum radiation output of the instrument can be measured with a broadband radiometer, or with a Luminance or illuminance meter if the spectral distribution is known and limited to the visible waveband.

If the radiant output of any wavelength band exceeds the relevant Group 1 limit(s) shown in [Tables 2](#) or [3](#), the instrument shall fulfil the requirements of a Group 2 instrument.

The measurement methods specified in [Annex D](#) can be used. [Annex F](#) provides guidance.

### 6.3 Spectral measurements

Spectral irradiance, spectral radiance, spectral radiant exposure, and integrated spectral radiance measurements shall take into account potential errors related to variation in spectral weighting within the selected bandwidth of the monochromator.

The appropriate weighting factors tabulated in [Annex A](#) [ $A(\lambda)$  and/or  $R_A(\lambda)$ ] shall be applied. In the exceptional case of an instrument intended for use only on phakic eyes of patients over the age of 2 years,  $B(\lambda)$  replaces  $A(\lambda)$  and  $R_p(\lambda)$  replaces  $R_A(\lambda)$ . Total irradiance or radiant exposure values over a given spectral range are calculated by summing all the adjusted individual measurements over the range.

NOTE 1 If irradiance is measured over a bandwidth range, irradiance divided by the bandwidth is the spectral irradiance.

NOTE 2 The weighting function  $R(\lambda)$  is defined differently in different exposure duration ranges. See footnote <sup>a</sup> in [Table 3](#) and [Table 5](#).

Spectral measurements are not required for wavebands (e.g. UV or IR) that are known to be absent or filtered from the measured light source.

At all times, measurements shall be performed under the conditions defined in [Table 6](#).

### 6.4 Group 2 instruments: determination of time and number of pulses to reach recommended maximum exposure

#### 6.4.1 Determination of time $t_{\max}$ to reach the recommended maximum exposure for weighted corneal and lenticular ultraviolet radiation radiant exposure, $H_{S-CL}$

To determine the time to reach a potential optical radiation hazard for weighted corneal and lenticular ultraviolet radiation radiant exposure, [Formula \(12\)](#) shall be used:

$$t_{\max}(H_{S-CL}) = \frac{6 \cdot 10^{-3} \text{ J/cm}^2}{E_{S-CL}} \quad (12)$$

The corneal radiant exposure shall be evaluated by averaging the highest localized radiant power incident upon a circular area with a diameter of 3 mm (0,07 cm<sup>2</sup>) at the corneal plane.

#### 6.4.2 Determination of time $t_{\max}$ to reach the recommended maximum exposure for photochemical aphakic retinal radiant exposure

To determine the time to reach a significant optical radiation hazard for photochemical aphakic retinal exposure, [Formula \(13\)](#) shall be used.

$$t_{\max}(H_{A-R} = 10 \text{ J/cm}^2) = \frac{10 \text{ J/cm}^2}{E_{A-R}} \quad (13)$$

[Clause 7](#) requires a report of the time to reach a radiant exposure value of 10 J/cm<sup>2</sup>.

The limit for a Group 1 instrument is 2,2 J/cm<sup>2</sup> and above this value the potential risk increases.

To calculate  $t_{\max}$  for 2,2 J/cm<sup>2</sup> substitute 10 J/cm<sup>2</sup> by 2,2 J/cm<sup>2</sup> in [Formula \(13\)](#).

For instruments that will be used on phakic eyes of patients over the age of 2 years only, the blue-light hazard function  $B(\lambda)$  can be used, instead of the aphakic photochemical hazard weighting function  $A(\lambda)$  to calculate the time to reach maximum recommended photochemical exposure.

#### 6.4.3 Determination of the number of pulses necessary to reach the recommended maximum exposure for photochemical aphakic retinal exposure, $n_{\max}$ (for pulsed instruments)

To determine the number of pulses necessary to reach a significant optical radiation hazard for aphakic retinal exposure, [Formula \(14\)](#) shall be used:

$$n_{\max}(H_{A-R} = 10 \text{ J/cm}^2) = \frac{10 \text{ J/cm}^2}{H_{A-R} \text{ J/cm}^2 / \text{pulse}} = \frac{10 \text{ J/cm}^2}{\left[ \sum_{305}^{700} H_{\lambda} \text{ J/cm}^2 \cdot \Delta\lambda \cdot A(\lambda) \cdot \Delta\lambda \right] / \text{pulse}} \quad (14)$$

[Clause 7](#) requires a report of the number of pulses necessary to reach a radiant exposure value of 10 J/cm<sup>2</sup> designated  $n_{\max}(H_{A-R}=10 \text{ J/cm}^2)$ .

## 7 Information supplied by the manufacturer

### 7.1 Information provided on request

The manufacturer shall, on request, provide the user with a graph showing the relative spectral output of the instrument between 305 nm and 1 100 nm when the instrument is operating at maximum light intensity and maximum aperture or effective aperture. The spectral output shall be shown for the beam after it exits the instrument.

For Group 2 instruments, if the RME values are not directly given in the marking or via an electronic interface, the manufacturer shall provide RME information via an online link (see [7.3.3](#)). The URL shall remain stable for the expected service life of the instrument.

### 7.2 Accompanying documents

#### 7.2.1 General

Manufacturers shall provide accompanying documents that contains all relevant optical radiation safety information. It is the responsibility of the manufacturer to provide the safety information indicated below and to decide which additional information is relevant and, therefore, is provided.

#### 7.2.2 Dose-limited instruments

For instruments that are in Group 1 by being dose-limited, the manufacturer shall provide a description of how the design and construction meet the requirements for classification as a Group1 instrument.

#### 7.2.3 Cautionary statements

For Group 2 instruments, the following information and cautionary statements shall be provided in a prominent position in the user manual.

The cautionary statements below are provided as examples. The manufacturer may use modified wording as long as the same information is conveyed and no signal word of a lower warning level than CAUTION is used. If appropriate, several statements may be combined

### 7.2.3.1 Continuous wave and time-limited instruments

If the instrument does not fulfil the requirements of [Table 2](#), Row 1, the manufacturer shall provide the user with information concerning the time to reach a potential optical radiation hazard as determined in [6.4.1](#).

If the instrument does not fulfil the requirements of [Table 2](#), Row 3, the manufacturer shall provide the user with information concerning the time to reach a potential optical radiation hazard as determined in [6.4.2](#). A cautionary statement shall be included, and the following are examples:

#### CAUTIONARY STATEMENT:

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm<sup>2</sup> after \_\_\_\_ min. Although the risk of retinal injury just exceeding 2,2 J/cm<sup>2</sup> is low, caution is advised, as some patients are more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> (exposure duration exceeding \_\_\_\_ min) entail a significant risk of injury.**

### 7.2.3.2 Pulsed and time-limited pulsed instruments

If the instrument does not fulfil the requirements of Row 7, [Table 3](#) – Retinal photochemical aphakic light hazard, the manufacturer shall provide the user with information concerning either the number of pulses or the time to reach a potential optical radiation hazard as determined in [6.4.3](#), with either cautionary statement A or cautionary statement B:

#### CAUTIONARY STATEMENT:

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm<sup>2</sup> after \_\_\_\_ pulses or \_\_\_\_ min at a pulse rate of \_\_\_\_ pulses/sec. Although the risk of retinal injury at an exposure just exceeding 2,2 J/cm<sup>2</sup> is low, caution is advised., as some patients may be more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> (exceeding \_\_\_\_ pulses or \_\_\_\_ min at a pulse rate of \_\_\_\_ pulses/sec) entail a significant risk of injury.**

### 7.2.3.3 Multiple source instruments

For multiple source instruments with continuous wave output that can illuminate the same points on the retina: The manufacturer shall provide the user with information on how to determine the time to reach the recommended maximum exposure. This shall apply for the combination of light sources at various intensity settings. A cautionary statement shall be included, and the following are examples:

#### CAUTIONARY STATEMENT:

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to the summed light of spatially overlapping light sources from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm<sup>2</sup> after, e.g. \_\_\_\_ min for source 1, \_\_\_\_ min for source 2, ..... and \_\_\_\_ min for source *n*, if all sources are operating concurrently. Although the risk of retinal injury at a cumulative exposure just exceeding 2,2 J/cm<sup>2</sup> is low, as some patients may be more susceptible than others, caution is advised. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> (cumulative exposure duration exceeding 4,5 times the Group 1 limits) entail a significant risk of injury.**

NOTE 1 The exposure from all light sources is cumulative and additive.

NOTE 2 If the intensity of any of the light sources is reduced to 50 % of the maximum intensity, the exposure duration for that light source to reach the exposure limit is doubled. This linear relationship can be used to determine the time to reach the exposure limit for the combination of light sources at various intensity settings.

For instruments with multiple sources of pulsed light output that can illuminate the same points on the retina, the manufacturer shall provide the user with information on how to determine the number of pulses

to reach the recommended maximum exposure. This shall apply for the combination of light sources at various intensity settings. A cautionary statement shall be included, and the following are examples:

**CAUTIONARY STATEMENT:**

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light of spatially overlapping pulsed light sources from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm<sup>2</sup> after, e.g. \_\_\_\_\_ pulses for source 1, \_\_\_\_\_ pulses for 2, ..... and \_\_\_ pulses for source *n*. Although the risk of retinal injury at an exposure just exceeding 2,2 J/cm<sup>2</sup> is low, caution is advised, as some patients may be more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> (cumulative exposures from all sources exceeding 4,5 times the Group 1 limit) entail a significant risk of injury.**

NOTE 3 The exposure from all light sources is cumulative and additive.

NOTE 4 If the intensity of any of the light sources is reduced to 50 % of the maximum intensity, the number of pulses for that light source to reach the exposure limit is doubled. This linear relationship can be used to determine the time to reach the exposure limit for the combination of light sources at various intensity settings.

For multiple source instruments with continuous wave and pulsed light output that can illuminate the same points on the retina, the manufacturer shall provide information on how to determine the combination of the time and number of pulses to reach the maximum recommended exposure. This shall also apply for the combination of light sources at various intensity settings. A cautionary statement shall be included, and the following are examples:

**CAUTIONARY STATEMENT:**

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when all sources are operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm<sup>2</sup> after \_\_\_\_ min. Although the risk of retinal injury at an exposure just exceeding 2,2 J/cm<sup>2</sup> is low, caution is advised, as some patients may be more susceptible than others. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> (cumulative exposure duration exceeding \_\_\_\_ min) entail a significant risk of injury.**

NOTE 5 The exposure duration and number of pulses from all light sources is cumulative and additive.

NOTE 6 If the intensity of any of the light sources is reduced to 50 % of the maximum intensity, the exposure duration or number of pulses for that light source to reach the exposure limit is doubled. This linear relationship can be used to determine the time to reach the exposure limit for the combination of light sources at various intensity settings.

**7.2.3.4 Variable brightness**

Where provision is made to vary brightness, the manufacturer shall provide the user with information concerning the indication of the maximum intensity and fractions of maximum intensity.

**7.2.3.5 Operation microscopes, endoilluminators and slit lamps**

For operation microscopes and endoilluminators, the accompanying documents shall include the following cautionary statement:

**CAUTIONARY STATEMENT FOR OPERATION MICROSCOPES AND ENDOILLUMINATORS:**

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when operated at maximum intensity will potentially exceed the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> after \_\_\_\_ min unless additional action is taken by the user to minimize exposure.**

For slit lamps, the accompanying documents shall include the following cautionary statement:

**CAUTIONARY STATEMENT FOR SLIT LAMPS WHEN IMAGED TO THE RETINA:**

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument when operated at maximum intensity and focused on the retina at a fixed location will potentially exceed the recommended maximum exposure (RME) of 10 J/cm<sup>2</sup> after \_\_\_\_ min unless additional action is taken by the user to minimize exposure.**

#### 7.2.3.6 Instruments intended for phakic eyes of patients over the age of 2 years

If the instrument is only intended to be used with phakic eyes and a phakic spectral weighting function is used to show compliance with this document, the manufacturer shall include a cautionary statement in the accompanying documents that warns the user that the use of the instrument on aphakic eyes may be hazardous.

For instruments intended for the use on phakic eyes only, the accompanying documents shall include the following cautionary statement:

##### **CAUTIONARY STATEMENT FOR INSTRUMENTS INTENDED ONLY FOR PHAKIC EYES:**

**“CAUTION — Light output hazardous for aphakic or pseudophakic eyes.**

**This instrument is only intended to be used for phakic eyes. Using it on non-phakic eyes may lead to eye injury. Do not use the instrument for aphakic or pseudophakic eyes.”**

#### 7.2.3.7 Cautionary statements regarding risk of thermal injury

##### 7.2.3.7.1 Continuous wave and time-limited instruments

If the instrument does not fulfil the requirements of [Table 3](#), Rows 8 to 10, the manufacturer shall provide the user with information concerning the time to reach a potential optical radiation hazard at each of the available radiant output settings. A cautionary statement shall be included, and the following is an example:

##### **CAUTIONARY STATEMENT:**

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument may cause thermal retinal injury when operated at radiant outputs that produce weighted retinal intensities more than 0,7 W/cm<sup>2</sup>. Although the risk of retinal injury decreases with decreasing exposure duration and spot size for a given intensity, caution is advised, as the risk increases rapidly with increasing irradiance, and some patients are more susceptible than others. Exposures exceeding 1,0 W/cm<sup>2</sup> for more than 42 minutes entail a significant risk of injury.**

##### 7.2.3.7.2 Pulsed instruments

If the instrument does not fulfil the requirements of [Table 3](#), Rows 8 to 10, Weighted retinal thermal light hazard, the manufacturer shall provide the user with information concerning the potential optical radiation hazard at each of the available radiant output settings. A cautionary statement shall be included, and the following is an example:

##### **CAUTIONARY STATEMENT:**

**“CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to light from this instrument may cause thermal retinal injury when operated at intensities that produce retinal exposures that exceed the Group 1 limit for the exposure duration and spot size in use. Although the risk of retinal injury is low at the Group 1 limit and it decreases with decreasing exposure duration and spot size for a given intensity, caution is advised, as the risk increases rapidly with increasing intensity, and some patients are more susceptible to injury than others. Exposures exceeding the recommended maximum exposure (RME) for the exposure conditions in use entail a significant risk of injury.**

## 7.3 Marking

### 7.3.1 Radiation output

For all Group 2 instruments, where provision is made to vary the radiation output, the manufacturer shall provide on the instrument an indication of the maximum intensity and available intensity settings below maximum intensity.

### 7.3.2 Consult accompanying documents

Group 2 instruments shall be marked with the refer to instruction manual/booklet mandatory action safety sign ISO 7010-M002 (see [Annex F](#), symbol 1).

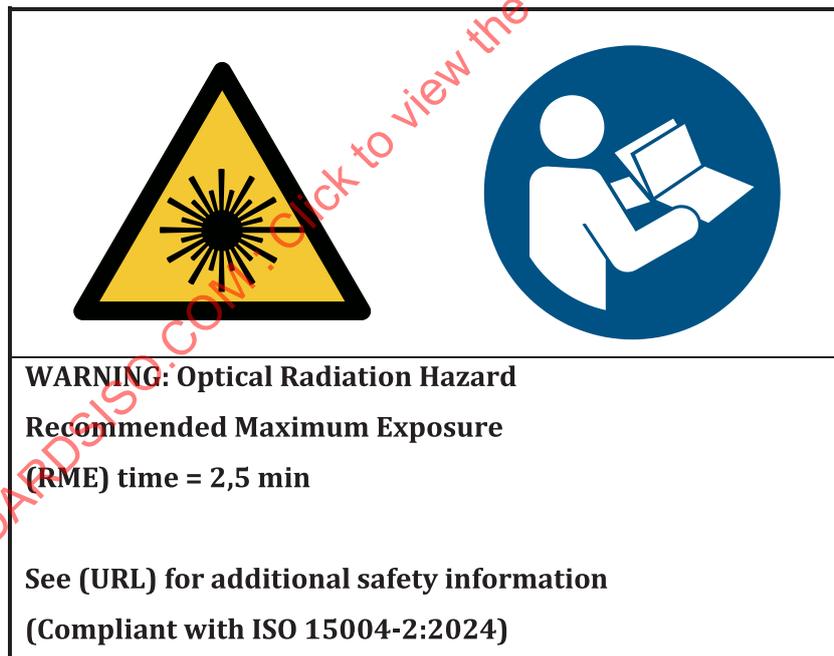
### 7.3.3 Safety information for optical radiation

Group 2 instruments shall be marked with a label indicating the time or the number of pulses to reach the Recommended Maximum Exposure for photochemical aphakic retinal radiant exposure (see [6.4.2](#) and [6.4.3](#)) – depending on what applies – or providing a link with access to this information. In addition, a dated reference to this document shall be given. Instruments with electronic user interfaces may fulfil this requirement by providing the RME information on the interface.

NOTE The link can be realised, for example by a QR code (see ISO/IEC 18004).

Group 2 instruments shall be marked with safety sign ISO 7010-W027 (see [Annex F](#), symbol 3).

If the ophthalmic instrument is a laser device, instead of safety sign ISO 7010-W027, the safety sign ISO 7010-W004 shall be used (see [Annex F](#), symbol 2).



**Figure 2 — Example optical radiation hazard warning label placed on Group 2 instruments emitting laser radiation fulfilling all requirements of [7.3.2](#) and [7.3.3](#)**

**Annex A**  
(normative)

**Spectral weighting functions**

Table A.1 provides the spectral weighting functions for retinal hazard analysis for both the aphakic and the phakic eye, the spectral transmittance of the crystalline lens of a young adult was used (see Column 4) in deriving the aphakic and phakic weighting function (see Columns 2 and 3).

NOTE  $R(\lambda)$  is defined differently in different exposure duration ranges. See footnote <sup>a</sup> in Table A.1.

**Table A.1 — Spectral weighting functions for retinal hazard analysis**

Wavelength nm	Iris or aphakic retinal thermal hazard weighting function <sup>a</sup> $R_A(\lambda)$ or $I(\lambda)$	Phakic retinal thermal hazard weighting function <sup>a</sup> $R_P(\lambda)$	Spectral transmittance of crystalline lens <sup>b</sup> $\tau_p(\lambda)$	Aphakic photochemical hazard weighting function $A(\lambda)$	Blue-light photochemical hazard function $B(\lambda)$
305	2,00	—	—	6,00	0,010
310	2,00	—	—	6,00	0,010
315	2,00	—	—	6,00	0,010
320	2,00	—	—	6,00	0,010
325	2,00	—	—	6,00	0,010
330	2,00	—	—	6,00	0,010
335	2,00	—	—	6,00	0,010
340	2,00	—	—	5,88	0,010
345	2,00	—	—	5,71	0,010
350	2,00	—	—	5,46	0,010
355	2,00	—	—	5,22	0,010
360	2,00	—	—	4,62	0,010
365	2,00	—	—	4,29	0,010
370	2,00	—	—	3,75	0,010
375	2,00	—	—	3,56	0,010
380	2,00	0,010	0,003	3,19	0,010
385	2,00	0,017	0,005	2,31	0,012 5
390	2,00	0,028	0,009	1,88	0,025
395	2,00	0,053	0,017	1,58	0,050
400	2,00	0,112	0,036	1,43	0,100
405	2,00	0,240	0,076	1,3	0,200
410	2,00	0,577	0,185	1,25	0,400
415	2,00	1,024	0,330	1,2	0,800
420	2,00	1,489	0,485	1,15	0,900
425	2,00	1,890	0,622	1,11	0,950
430	2,00	2,000	0,721	1,07	0,980
435	2,00	2,000	0,800	1,03	1,000
440	2,00	2,000	0,860	1	1,000
445	2,00	2,000	0,888	0,97	0,970
450	2,00	2,000	0,903	0,94	0,940

NOTE To calculate values of  $R(\lambda)$  for all wavelengths between 540 nm and 1 050 nm, the following relationship applies:  $R(\lambda) = 10^{0,002(700 - \lambda)}$ .

<sup>a</sup> For pulse durations less than  $10^{-11}$  s (10 ps), replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  less than 1. For exposure durations greater than 10 s, replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  greater than 1.

<sup>b</sup> Source: CIE 203:2012 (incl. Erratum) A Computerized Approach to Transmission and Absorption Characteristics of the Human Eye.

ISO 15004-2:2024(en)

Table A.1 (continued)

Wavelength nm	Iris or aphakic retinal thermal hazard weighting function <sup>a</sup> $R_A(\lambda)$ or $I(\lambda)$	Phakic retinal thermal hazard weighting function <sup>a</sup> $R_P(\lambda)$	Spectral transmittance of crystalline lens <sup>b</sup> $\tau_p(\lambda)$	Aphakic photochemical hazard weighting function $A(\lambda)$	Blue-light photochemical hazard function $B(\lambda)$
455	2,00	2,000	0,919	0,9	0,900
460	2,00	2,000	0,928	0,8	0,800
465	2,00	2,000	0,935	0,7	0,700
470	2,00	2,000	0,943	0,62	0,620
475	2,00	2,000	0,948	0,55	0,550
480	2,00	2,000	0,951	0,45	0,450
485	2,00	2,000	0,957	0,4	0,400
490	2,00	2,000	0,961	0,22	0,220
495	2,00	2,000	0,965	0,16	0,160
500	2,00	2,000	0,968	0,1	0,100
505	2,00	2,000	0,970	0,079	0,079
510	2,00	2,000	0,972	0,06	0,063
515	2,00	2,000	0,973	0,05	0,050
520	2,00	2,000	0,974	0,039 8	0,040
525	2,00	2,000	0,976	0,031	0,032
530	2,00	2,000	0,978	0,025	0,025
535	2,00	2,000	0,979	0,019 9	0,020
540	2,00	1,990	0,980	0,015 8	0,016
545	1,98	1,945	0,982	0,012 6	0,013
550	1,94	1,908	0,983	0,01	0,010
555	1,90	1,870	0,984	0,007 9	0,008
560	1,86	1,831	0,984	0,006 3	0,006
565	1,82	1,793	0,985	0,005	0,005
570	1,78	1,754	0,985	0,004	0,004
575	1,74	1,716	0,986	0,003 1	0,003
580	1,70	1,679	0,988	0,002 5	0,002
585	1,66	1,641	0,989	0,002	0,002
590	1,63	1,615	0,991	0,001 6	0,001
595	1,59	1,575	0,991	0,001 3	0,001
600	1,55	1,537	0,992	0,001	0,001
605	1,52	1,507	0,992	0,001	0,001
610	1,49	1,479	0,993	0,001	0,001
615	1,45	1,439	0,993	0,001	0,001
620	1,42	1,411	0,994	0,001	0,001
625	1,39	1,381	0,994	0,001	0,001
630	1,36	1,353	0,995	0,001	0,001
635	1,33	1,322	0,994	0,001	0,001
640	1,30	1,291	0,993	0,001	0,001
645	1,27	1,263	0,995	0,001	0,001
650	1,24	1,235	0,996	0,001	0,001
655	1,22	1,215	0,996	0,001	0,001
660	1,19	1,186	0,997	0,001	0,001
665	1,16	1,156	0,997	0,001	0,001

NOTE To calculate values of  $R(\lambda)$  for all wavelengths between 540 nm and 1 050 nm, the following relationship applies:  $R(\lambda) = 10^{0,002(700 - \lambda)}$ .

<sup>a</sup> For pulse durations less than  $10^{-11}$  s (10 ps), replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  less than 1. For exposure durations greater than 10 s, replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  greater than 1.

<sup>b</sup> Source: CIE 203:2012 (incl. Erratum) A Computerized Approach to Transmission and Absorption Characteristics of the Human Eye.

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Table A.1 (continued)

Wavelength nm	Iris or aphakic retinal thermal hazard weighting function <sup>a</sup> $R_A(\lambda)$ or $I(\lambda)$	Phakic retinal thermal hazard weighting function <sup>a</sup> $R_P(\lambda)$	Spectral transmittance of crystalline lens <sup>b</sup> $\tau_p(\lambda)$	Aphakic photochemical hazard weighting function $A(\lambda)$	Blue-light photochemical hazard function $B(\lambda)$
670	1,14	1,137	0,997	0,001	0,001
675	1,11	1,108	0,998	0,001	0,001
680	1,09	1,088	0,998	0,001	0,001
685	1,07	1,069	0,999	0,001	0,001
690	1,04	1,039	0,999	0,001	0,001
695	1,02	1,019	0,999	0,001	0,001
700	1,00	1,000	1,000	0,001	0,001
705	0,98	0,98	1,000	—	—
710	0,95	0,95	1,000	—	—
715	0,93	0,93	1,000	—	—
720	0,91	0,91	1,000	—	—
725	0,89	0,89	1,000	—	—
730	0,87	0,87	1,000	—	—
735	0,85	0,85	1,000	—	—
740	0,83	0,83	1,000	—	—
745	0,81	0,81	1,000	—	—
750	0,79	0,79	1,000	—	—
755	0,78	0,78	1,000	—	—
760	0,76	0,76	1,000	—	—
765	0,74	0,74	1,000	—	—
770	0,72	0,72	1,000	—	—
775	0,71	0,71	1,000	—	—
780	0,69	0,69	1,000	—	—
785	0,68	0,68	1,000	—	—
790	0,66	0,66	1,000	—	—
795	0,65	0,65	1,000	—	—
800	0,63	0,63	1,000	—	—
805	0,62	0,62	1,000	—	—
810	0,60	0,60	1,000	—	—
815	0,59	0,59	1,000	—	—
820	0,58	0,58	1,000	—	—
825	0,56	0,56	1,000	—	—
830	0,55	0,55	1,000	—	—
835	0,54	0,54	1,000	—	—
840	0,52	0,52	1,000	—	—
845	0,51	0,51	1,000	—	—
850	0,50	0,50	1,000	—	—
855	0,49	0,49	1,000	—	—
860	0,48	0,48	1,000	—	—
865	0,47	0,47	1,000	—	—
870	0,46	0,46	1,000	—	—
875	0,45	0,45	1,000	—	—
880	0,44	0,44	1,000	—	—

NOTE To calculate values of  $R(\lambda)$  for all wavelengths between 540 nm and 1 050 nm, the following relationship applies:  $R(\lambda) = 10^{0,002(700 - \lambda)}$ .

<sup>a</sup> For pulse durations less than  $10^{-11}$  s (10 ps), replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  less than 1. For exposure durations greater than 10 s, replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  greater than 1.

<sup>b</sup> Source: CIE 203:2012 (incl. Erratum) A Computerized Approach to Transmission and Absorption Characteristics of the Human Eye.

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Table A.1 (continued)

Wavelength nm	Iris or aphakic retinal thermal hazard weighting function <sup>a</sup> $R_A(\lambda)$ or $I(\lambda)$	Phakic retinal thermal hazard weighting function <sup>a</sup> $R_P(\lambda)$	Spectral transmittance of crystalline lens <sup>b</sup> $\tau_p(\lambda)$	Aphakic photochemical hazard weighting function $A(\lambda)$	Blue-light photochemical hazard function $B(\lambda)$
885	0,43	0,43	1,000	—	—
890	0,42	0,42	1,000	—	—
895	0,41	0,41	1,000	—	—
900	0,40	0,40	1,000	—	—
905	0,39	0,39	1,000	—	—
910	0,38	0,38	1,000	—	—
915	0,37	0,37	1,000	—	—
920	0,36	0,36	1,000	—	—
925	0,35	0,35	1,000	—	—
930	0,35	0,35	1,000	—	—
935	0,34	0,34	1,000	—	—
940	0,33	0,33	1,000	—	—
945	0,32	0,32	1,000	—	—
950	0,32	0,32	1,000	—	—
955	0,31	0,31	1,000	—	—
960	0,30	0,30	1,000	—	—
965	0,30	0,30	1,000	—	—
970	0,29	0,29	1,000	—	—
975	0,28	0,28	1,000	—	—
980	0,28	0,28	1,000	—	—
985	0,27	0,27	1,000	—	—
990	0,26	0,26	1,000	—	—
995	0,26	0,26	1,000	—	—
1 000	0,25	0,25	1,000	—	—
1 005	0,25	0,25	1,000	—	—
1 010	0,24	0,24	1,000	—	—
1 015	0,23	0,23	1,000	—	—
1 020	0,23	0,23	1,000	—	—
1 025	0,22	0,22	1,000	—	—
1 030	0,22	0,22	1,000	—	—
1 035	0,21	0,21	1,000	—	—
1 040	0,21	0,21	1,000	—	—
1 045	0,20	0,20	1,000	—	—
1 050	0,20	0,20	1,000	—	—
1 055	0,20	0,20	1,000	—	—
1 060	0,20	0,20	1,000	—	—
1 065	0,20	0,20	1,000	—	—
1 070	0,20	0,20	1,000	—	—
1 075	0,20	0,20	1,000	—	—
1 080	0,20	0,20	1,000	—	—
1 085	0,20	0,20	1,000	—	—
1 090	0,20	0,20	1,000	—	—
1 095	0,20	0,20	1,000	—	—

NOTE To calculate values of  $R(\lambda)$  for all wavelengths between 540 nm and 1 050 nm, the following relationship applies:  $R(\lambda) = 10^{0,002(700 - \lambda)}$ .

<sup>a</sup> For pulse durations less than  $10^{-11}$  s (10 ps), replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  less than 1. For exposure durations greater than 10 s, replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  greater than 1.

<sup>b</sup> Source: CIE 203:2012 (incl. Erratum) A Computerized Approach to Transmission and Absorption Characteristics of the Human Eye.

Table A.1 (continued)

Wavelength nm	Iris or aphakic retinal thermal hazard weighting function <sup>a</sup> $R_A(\lambda)$ or $I(\lambda)$	Phakic retinal thermal hazard weighting function <sup>a</sup> $R_P(\lambda)$	Spectral transmittance of crystalline lens <sup>b</sup> $\tau_p(\lambda)$	Aphakic photochemical hazard weighting function $A(\lambda)$	Blue-light photochemical hazard function $B(\lambda)$
1 100	0,20	0,20	1,000	—	—
1 105	0,20	0,20	1,000	—	—
1 110	0,20	0,20	1,000	—	—
1 115	0,20	0,20	1,000	—	—
1 120	0,20	0,20	1,000	—	—
1 125	0,20	0,20	1,000	—	—
1 130	0,20	0,20	1,000	—	—
1 135	0,20	0,20	1,000	—	—
1 140	0,20	0,20	1,000	—	—
1 145	0,20	0,20	1,000	—	—
1 150	0,20	0,20	1,000	—	—
1 155	0,20	0,20	1,000	—	—
1 160	0,20	0,20	1,000	—	—
1 165	0,20	0,20	1,000	—	—
1 170	0,20	0,20	1,000	—	—
1 175	0,20	0,20	1,000	—	—
1 180	0,20	0,20	1,000	—	—
1 185	0,20	0,20	1,000	—	—
1 190	0,20	0,20	1,000	—	—
1 195	0,20	0,20	1,000	—	—
1 200	0,20	0,20	1,000	—	—
1 205	0,20	0,20	1,000	—	—
1 210	0,20	0,20	1,000	—	—
1 215	0,20	0,20	1,000	—	—
1 220	0,20	0,20	1,000	—	—
1 225	0,20	0,20	1,000	—	—
1 230	0,20	0,20	1,000	—	—
1 235	0,20	0,20	1,000	—	—
1 240	0,20	0,20	1,000	—	—
1 245	0,20	0,20	1,000	—	—
1 250	0,20	0,20	1,000	—	—
1 255	0,20	0,20	1,000	—	—
1 260	0,20	0,20	1,000	—	—
1 265	0,20	0,20	1,000	—	—
1 270	0,20	0,20	1,000	—	—
1 275	0,20	0,20	1,000	—	—
1 280	0,20	0,20	1,000	—	—
1 285	0,20	0,20	1,000	—	—
1 290	0,20	0,20	1,000	—	—
1 295	0,20	0,20	1,000	—	—
1 300	0,20	0,20	1,000	—	—
1 305	0,20	0,20	1,000	—	—
1 310	0,20	0,20	1,000	—	—

NOTE To calculate values of  $R(\lambda)$  for all wavelengths between 540 nm and 1 050 nm, the following relationship applies:  $R(\lambda) = 10^{0,002(700 - \lambda)}$ .

<sup>a</sup> For pulse durations less than  $10^{-11}$  s (10 ps), replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  less than 1. For exposure durations greater than 10 s, replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  greater than 1.

<sup>b</sup> Source: CIE 203:2012 (incl. Erratum) A Computerized Approach to Transmission and Absorption Characteristics of the Human Eye.

Table A.1 (continued)

Wavelength nm	Iris or aphakic retinal thermal hazard weighting function <sup>a</sup> $R_A(\lambda)$ or $I(\lambda)$	Phakic retinal thermal hazard weighting function <sup>a</sup> $R_P(\lambda)$	Spectral transmittance of crystalline lens <sup>b</sup> $\tau_p(\lambda)$	Aphakic photochemical hazard weighting function $A(\lambda)$	Blue-light photochemical hazard function $B(\lambda)$
1 315	0,20	0,20	1,000	—	—
1 320	0,20	0,20	1,000	—	—
1 325	0,20	0,20	1,000	—	—
1 330	0,20	0,20	1,000	—	—
1 335	0,20	0,20	1,000	—	—
1 340	0,20	0,20	1,000	—	—
1 345	0,20	0,20	1,000	—	—
1 350	0,20	0,20	1,000	—	—
1 355	0,20	0,20	1,000	—	—
1 360	0,20	0,20	1,000	—	—
1 365	0,20	0,20	1,000	—	—
1 370	0,20	0,20	1,000	—	—
1 375	0,20	0,20	1,000	—	—
1 380	0,20	0,20	1,000	—	—
1 385	0,20	0,20	1,000	—	—
1,390	0,20	0,20	1,000	—	—
1 395	0,20	0,20	1,000	—	—
1 400	0,20	0,20	1,000	—	—

NOTE To calculate values of  $R(\lambda)$  for all wavelengths between 540 nm and 1 050 nm, the following relationship applies:  $R(\lambda) = 10^{0,002(700 - \lambda)}$ .

<sup>a</sup> For pulse durations less than  $10^{-11}$  s (10 ps), replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  less than 1. For exposure durations greater than 10 s, replace  $R(\lambda)$  with a constant of 1,0 for all  $R(\lambda)$  greater than 1.

<sup>b</sup> Source: CIE 203:2012 (incl. Erratum) A Computerized Approach to Transmission and Absorption Characteristics of the Human Eye.

Table A.2 — Spectral weighting functions for corneal hazard analysis

Wavelength nm	UV radiation hazard weighting function $S(\lambda)$
200	0,03
205	0,051
210	0,075
215	0,095
220	0,12
225	0,15
230	0,19
235	0,24
240	0,3
245	0,36
250	0,43
254	0,5
255	0,52
260	0,65
265	0,81
270	1
275	0,96
280	0,88
285	0,77

Table A.2 (continued)

Wavelength nm	UV radiation hazard weighting function $S(\lambda)$
290	0,64
295	0,54
297	0,46
300	0,3
303	0,12
305	0,06
308	0,03
310	0,02
313	$6,00 \times 10^{-3}$
315	$3,00 \times 10^{-3}$
316	$2,40 \times 10^{-3}$
317	$2,00 \times 10^{-3}$
318	$1,60 \times 10^{-3}$
319	$1,20 \times 10^{-3}$
320	$1,00 \times 10^{-3}$
322	$6,70 \times 10^{-4}$
323	$5,40 \times 10^{-4}$
325	$5,00 \times 10^{-4}$
328	$4,40 \times 10^{-4}$
330	$4,10 \times 10^{-4}$
333	$3,70 \times 10^{-4}$
335	$3,40 \times 10^{-4}$
340	$2,80 \times 10^{-4}$
345	$2,40 \times 10^{-4}$
350	$2,00 \times 10^{-4}$
355	$1,60 \times 10^{-4}$
360	$1,30 \times 10^{-4}$
365	$1,10 \times 10^{-4}$
370	$9,30 \times 10^{-5}$
375	$7,70 \times 10^{-5}$
380	$6,40 \times 10^{-5}$
385	$5,30 \times 10^{-5}$
390	$4,40 \times 10^{-5}$
395	$3,60 \times 10^{-5}$
400	$3,00 \times 10^{-5}$

## Annex B (informative)

### Measurement instruments

#### B.1 General

If the optical radiation emissions are sufficiently low, relatively simple and inexpensive optical radiation measurement instruments may be used to determine if an ophthalmic instrument is below the exposure limits specified in 5.4 (Group 1). Broadband meters that measure one of the spectrally weighted or non-weighted quantities are commercially available and may be used to directly measure potential optical radiation ocular and skin hazards. Spot luminance meters are also available to measure the quantity luminance. In general, if the luminance for a white light source is less than one candela per centimetre squared ( $1 \text{ cd/cm}^2$ ), spectral data would not be needed. Once the illuminance from an illuminance meter is measured, the spectral irradiance can be readily determined if the relative spectral power distribution is known. However, it is important to remember while performing these measurements that the measurements are to be averaged over a field-of-view of  $0,011 \text{ rad}$  ( $11 \text{ mrad}$  or  $0,63^\circ$ ). This means that at a distance of  $50 \text{ cm}$  from a light source, the field-of-view of the instrument must be emission-limited to a circular area with a diameter of  $5,5 \text{ mm}$ .

#### B.2 Method for finding the spectral irradiance function of a light source using available photometers and spectrometers or spectral power distribution information

It is often the case that the spectrum of a source is available either from specification supplied by its manufacturer or from measurements made by a spectrometer but that the absolute radiation values are not well specified or that the spectrum is given as relative values with respect to a maximum value, for instance. To use such spectral information to make the calculations required by this document the spectral irradiance or spectral radiant exposure absolute values are needed. To do this a scaling factor is needed, which when multiplied by the available spectral values, the absolute values needed are obtained. Such a scaling factor can be obtained using the method given below when the source has sufficient energy in the visible portion of the spectrum so that its luminance can be reliably measured using available instrumentation.

Measure the luminance of the source,  $L_v$ , with a calibrated photometer designed to make this measurement. Find the spectral radiance distribution function of the source,  $f(\lambda)$ , by measuring its spectral radiance distribution with a spectrometer or by using the published spectral distribution supplied by the manufacturer of the source.

The normalized values of  $f(\lambda)$  are calculated, using the un-normalized values of  $f(\lambda)$ , by first adding all the un-normalized values for the entire spectrum together and then dividing each of the un-normalized values by this sum.

Determine the proper scaling of the spectral radiance with the following method:

The luminance is given by [Formula \(B.1\)](#):

$$L_V = 683 \text{ lm / W} \times \int_{380}^{780} [L_\lambda \times V(\lambda)] d\lambda \quad L_V \approx 683 \text{ lm / W} \times \Delta\lambda \times \sum_{380}^{780} S \times f(\lambda) \times V(\lambda) \quad (\text{B.1})$$

where  $L_V = S \times f(\lambda)$  with  $f(\lambda)$ , the spectral power distribution function,  $S$  the desired scaling factor and  $V(\lambda)$  is the visibility function that is built into the meter's optical system. As  $L_V$  has been measured,  $S$ , is determined in [Formula \(B.2\)](#):

$$L_V = S \times 683 \text{ lm / W} \times \Delta\lambda \times \sum_{380}^{780} f(\lambda) \times V(\lambda) \quad (\text{B.2})$$

To calculate  $S$  the normalized values of  $f(\lambda)$  are used along with the values of  $V(\lambda)$  found in [Table B.1](#).

Using [B.2](#), value of  $S$  is determined by [Formula \(B.3\)](#):

$$S = \frac{L_V}{683 \text{ lm / W} \times \Delta\lambda \times \sum_{380}^{780} f(\lambda) \times V(\lambda)} \quad (\text{B.3})$$

Having found the value of  $S$ , form its product with  $f(\lambda)$  to give the spectral radiance function for the source  $L_\lambda = S \times f(\lambda)$  as given in [Formula \(B.4\)](#):

$$L_\lambda = \frac{L_V \times f(\lambda)}{683 \text{ lm / W} \times \sum_{380}^{780} f(\lambda) \times V(\lambda) \times \Delta\lambda} \quad (\text{B.4})$$

$L_\lambda$  is then used for all subsequent hazard evaluation calculations.

Note that photometers typically give the value of  $L_V$  in units of  $\text{cd/m}^2$ . To use the value of  $L_V$ , if given in units of  $\text{cd/m}^2$ , for the purposes of this document in [Formula \(B.4\)](#), its value needs to be multiplied by  $10^{-4}$  to convert its units to  $\text{cd/cm}^2$ .

**Table B.1 — Standard photopic visibility weighting function  $V(\lambda)$**

Wavelength nm	$V(\lambda)$
380	0,000 04
385	0,000 064
390	0,000 12
395	0,000 215
400	0,000 4
405	0,000 64
410	0,0012
415	0,002 18
420	0,004
425	0,007 26
430	0,011 6
435	0,016 84
440	0,023
445	0,029 8
450	0,038
455	0,048
460	0,06
465	0,073 9
470	0,091

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Table B.1 (continued)

Wavelength nm	$V(\lambda)$
475	0,112 6
480	0,139
485	0,169 3
490	0,208
495	0,258 6
500	0,323
505	0,389
510	0,503
515	0,608 2
520	0,71
525	0,793 2
530	0,862
535	0,914 9
540	0,954
545	0,980 3
550	0,99 5
555	1,000 2
560	0,995
565	0,978 6
570	0,952
575	0,915 4
580	0,87
585	0,816 3
590	0,757
595	0,694 9
600	0,631
605	0,566 8
610	0,503
615	0,441 2
620	0,381
625	0,321
630	0,265
635	0,217
640	0,175
645	0,138 2
650	0,107
655	0,08 16
660	0,061
665	0,044 6
670	0,032
675	0,023 2
680	0,017
685	0,011 92

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Table B.1 (continued)

Wavelength nm	$V(\lambda)$
690	0,008 2
695	0,005 72
700	0,004 1
705	0,002 91
710	0,002 1
715	0,001 483
720	0,001 05
725	0,000 736
730	0,000 52
735	0,000 36
740	0,000 25
745	0,000 172
750	0,000 12
755	0,000 084
760	0,000 06
765	0,000 042
770	0,000 03
775	0,000 02
780	0,000 01

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## Annex C (informative)

### Measurement methods for radiance/irradiance

#### C.1 Measurements to determine Group 1 status and to determine radiance/irradiance parameter values for Group 2 instruments

In order to determine if an ophthalmic instrument has Group 1 status it should not exceed any of the limits set forth in [Table 2](#) or [Table 3](#). To determine the spectral irradiance values or spectral radiant power values needed to calculate the limit parameter values of an ophthalmic instrument, either the methods given in this annex or equivalent methods should be used.

If an ophthalmic instrument is determined to have Group 2 status, the limits of [5.5](#) apply. To assess compliance with these limits, emission levels of the ophthalmic instrument should be determined, which requires measurement of spectral irradiance values and spectral radiant power values. This is done using either the methods given in this annex or equivalent methods.

#### C.2 Method to determine $E_{S-CL}$ , $E_{UV-CL}$ , $E_{IR-CL}$ and $E_{VIR-CL}$

Corneal spectral irradiance values,  $E_{\lambda}$  used to calculate  $E_{S-CL}$ ,  $E_{UV-CL}$ ,  $E_{IR-CL}$  and  $E_{VIR-CL}$  should be determined with a measuring instrument capable of measuring spectral irradiance or spectral radiant power over the specified wavelength band. The measuring instrument should be able to collect all radiant power over an area defined by the aperture described in [Table 6](#) that the tested ophthalmic instrument radiates into the plane where the cornea is placed during normal operation except in the case of  $E_{VIR-CL}$  where the measurement should be evaluated at the point of smallest beam diameter.

If the measuring instrument's output is in spectral radiant power, the spectral irradiance values assigned to the ophthalmic instrument should be taken to be the spectral radiant powers measured divided by the area that the ophthalmic instrument irradiates in the corneal plane.

If the measuring instrument's output is radiant power or irradiance, an additional measurement of the spectrum needs to be made. Then spectral radiant power or spectral irradiance is found by weighting the radiant power or irradiance by the spectrum measured.

#### C.3 Method to determine $E_{A-R}$

The retinal spectral irradiance values,  $E_{\lambda}$  needed to calculate  $E_{A-R}$  should be determined by first finding the spectral radiance of the ophthalmic instrument using one of the two following methods.

If, from knowledge of the ophthalmic instrument design, the area of the instrument exit pupil,  $A_{\text{exit}}$ , and the distance of the exit pupil from the corneal plane,  $D_p$ , is available, the effective illumination solid angle,  $\Omega_e$ , is determined by [Formula \(C.1\)](#):

$$\Omega_e = A_{\text{exit}} / D_p^2 \quad (\text{C.1})$$

The spectral radiance,  $L_\lambda$ , is then found from the spectral irradiance in the corneal plane,  $E_{\lambda-C}$ , as found using the method of [C.2](#) by [Formula \(C.2\)](#):

$$L_\lambda = E_{\lambda-C} / \Omega_e = E_{\lambda-C} D_p^2 / A_{\text{exit}} \quad (\text{C.2})$$

If  $\Omega_e$  is unknown, the measurement of spectral irradiance is made under the following controlled conditions. An aperture or effective aperture whose area,  $A$ , is small with respect to the beam cross

sectional area where it is placed is inserted into the beam between the ophthalmic instrument and the measuring plane. The spectral irradiance is measured using the method of [C.2](#). The spectral radiance,  $L_\lambda$ , is then found from the spectral irradiance,  $E_\lambda$ , by [Formula \(C.3\)](#):

$$L_\lambda = E_\lambda D^2 / A \quad (\text{C.3})$$

where  $D$  is the distance from the aperture or effective aperture, whose area is  $A$ , to the measurement plane.

These spectral radiance values should then be used to calculate the spectral irradiance values at the retina in the following way. The area of the pupil of the eye through which light passes in normal use of the ophthalmic instrument,  $A_p$ , should be determined. Its value can either be determined by knowledge of ophthalmic instrument design and usage or by measurement. If it is necessary to determine its value by measurement, the measurement should be made by placing a light-sensitive device such as a piece of photographic film or a CCD camera sensor in the plane where the pupil of the eye would be placed in normal instrument use and illuminating it to record the area illuminated. Then this illuminated area is measured and its value is taken to be  $A_p$ .

Calculation of retinal spectral irradiance should then be made by first assuming that the pupil lies at an optical distance,  $D_o$ , of 17 mm from the retina. The retinal spectral irradiance,  $E_\lambda$ , is then given by [Formula \(C.4\)](#):

$$E_\lambda = L_\lambda A_p / D_o^2 = L_\lambda A_p / 289 \quad (\text{C.4})$$

A third alternative method can be used for instruments, such as fundus cameras that produce a homogenous beam on the retina. The radiant power from the instrument is measured as in [C.2](#). By knowing the instrument's optical properties, the area into which this radiation falls is calculated. The retinal irradiance is then found by dividing the radiant power entering the eye by the area irradiated on the retina. Specific information on making the relevant calculations is found in [Annex D](#).

#### C.4 Method to determine $H_{S-CL}$ , $H_{UV-CL}$ , $H_{IR-CL}$ and $H_{VIR-CL}$

Corneal spectral radiant exposure values,  $H_\lambda$ , used to calculate  $H_{S-CL}$ ,  $H_{UV-CL}$ ,  $H_{IR-CL}$  and  $H_{VIR-CL}$  should be determined using a measuring instrument capable of measuring all the spectral radiant power that the tested ophthalmic instrument radiates during a single pulse.

The measurement should be taken by placing the measuring instrument so that its sensor collects all the radiation emitted by the tested ophthalmic instrument that falls in the plane where the cornea is placed during normal operation.

The spectral radiant exposure values are the measured spectral radiant power values divided by the measured irradiated area.

If the measuring instrument's output is radiant power or irradiance, an additional measurement of the spectrum needs to be made. Then spectral radiant power or spectral irradiance is found by weighting the radiant power or irradiance by the spectrum measured.

### C.5 Method to determine $H_{\text{VIR-R}}$ and $H_{\text{A-R}}$

The position of the highest radiant exposure found in the irradiated retinal area should be found. The weighted retinal visible and infrared radiation exposure value,  $H_{\text{VIR-R}}$ , should then be calculated by dividing the spectral radiant energy,  $Q_{\text{VIR-R}}$ , in joules, incident on the retina in a 0,03 mm diameter circular disc centred on the position of highest irradiance by the area of this disc ( $7,07 \times 10^{-6} \text{ cm}^2$ ).

Retinal spectral radiant exposure values,  $H_{\lambda}$ , used to calculate  $H_{\text{VIR-R}}$  and  $H_{\text{A-R}}$  should be determined by first finding the spectral radiance of the ophthalmic instrument using one of the two following methods.

**C.5.1** If from knowledge of the ophthalmic instrument design, the area of the instrument exit pupil,  $A_{\text{exit}}$ , and the distance of the exit pupil from the corneal plane,  $D_p$ , are available, the effective illumination solid angle,  $\Omega_e$ , is determined by [Formula C.5](#):

$$\Omega_e = \frac{A_{\text{exit}}}{D_p^2} \quad (\text{C.5})$$

The spectral radiance,  $L_{\lambda}$ , is then found from the spectral radiant exposure in the corneal plane,  $H_{\lambda\text{-c}}$ , as found using the method of [C.4](#) by [Formula \(C.6\)](#):

$$L_{\lambda} = \frac{H_{\lambda\text{-c}}}{\Omega_e \times t} = \frac{H_{\lambda\text{-c}} D_p^2}{A_{\text{exit}} \times t} \quad (\text{C.6})$$

If  $\Omega_e$  is unknown, the measurement of spectral radiant exposure is made under the following controlled conditions. An aperture or effective aperture whose area,  $A$ , is small with respect to the beam cross sectional area where it is placed is inserted into the beam between the ophthalmic instrument and the measuring plane. The spectral radiant exposure is measured using the method of [C.4](#). The spectral radiance,  $L_{\lambda}$ , is then found from the spectral radiant exposure,  $H_{\lambda}$ , by [Formula \(C.7\)](#):

$$L_{\lambda} = \frac{H_{\lambda} D^2}{A \times t} \quad (\text{C.7})$$

These spectral radiance values should then be used to calculate the spectral radiant exposure values at the retina in the following way. The area of the pupil of the eye through which light passes in normal use of the instrument,  $A_p$ , should be determined. Its value can either be determined by knowledge of ophthalmic instrument design and usage or by measurement. If it is necessary to determine its value by measurement, the measurement should be made by placing a light-sensitive device such as a piece of photographic film or a CCD camera sensor in the plane where the pupil of the eye would be placed in normal instrument use and illuminating it to record the area illuminated. Then this illuminated area is measured and its value is taken to be  $A_p$ .

Calculation of retinal spectral radiant exposure should then be made by first assuming that the pupil lies at an optical distance,  $D_o$ , of 17 mm from the retina. The retinal spectral radiant exposure,  $H_{\lambda}$ , is then given by [Formula \(C.8\)](#):

$$H_{\lambda} = \frac{L_{\lambda} A_p \times t}{D_o^2} = \frac{L_{\lambda} A_p \times t}{289} \quad (\text{C.8})$$

A third alternative method can be used for instruments, such as fundus cameras that produce a homogenous beam on the retina. The radiant power from the instrument is measured as in [C.2](#). By knowing the instrument's optical properties, the area into which this radiation falls is calculated. The retinal irradiance is then found by dividing the radiant power entering the eye by the area irradiated on the retina. Specific information on making the relevant calculations is found in [Annex D](#).

## C.6 Method to calculate $d_r$

To calculate the limit values  $E_{\text{VIR-R}}$  and  $L_{\text{VIR-R}}$  for continuous wave instruments and  $H_{\text{VIR-R}}$  and  $L_{\text{VIR-R}}$  for pulsed instruments, the dimension (in millimetres) of the source on the retinal surface,  $d_r$ , should be given a value. If the angular subtense of the source,  $\alpha$ , as viewed by the eye with the ophthalmic instrument positioned at its normal intended use distance from the eye, is known or has been measured,  $d_r$  is found using [Formula \(C.9\)](#):

$$d_r = 17 \cdot \tan \alpha \quad (\text{C.9})$$

where 17 mm is the distance from the nodal point of the standard eye to the retina.

Alternatively,  $d_r$  is found experimentally by forming an image of the source using a 17 mm focal length lens held at a distance from the ophthalmic instrument equal to the normal intended use position of the eye. The measured width of the image so formed in a plane 17 mm from the secondary principal plane of the lens is the value to use as  $d_r$ .

For beams with a non-circular cross-section, the value of  $d_r$  should 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 1,7 mm, the value 1,7 mm should be used as the maximum cross-section length.

NOTE Although laser safety standards define Gaussian beam diameter  $d_r$  at  $1/e$  points, this document uses full width at half maximum for uniformity between Gaussian and top hat beams.

## C.7 Example for determination of radiance from a measurement of irradiance

Diffuse light source, 15 mm in diameter, with a central hot spot with a diameter of 3 mm.

For this application, the eye is located a distance of 20 cm from the diffuse light source.

### C.7.1 Determination of radiance

Radiance can be determined by measuring the radiant power that is transmitted through two apertures spaced at a known distance,  $z$ , apart using the relationship given in [Formula \(C.10\)](#):

$$L = \frac{\Phi \cdot z^2}{A \cdot a} \quad (\text{C.10})$$

where

$L$  is the radiance;

$\Phi$  is the radiant power;

$a$  is the area of the first aperture;

$A$  is the area of the second aperture;

$z$  is the distance between the first aperture and the second aperture.

See [Figure C.1](#).

Only the radiation that is within a field-of-view of 11 mrad needs to be considered.

Determination of aperture size for field-of-view of 11 mrad.

In this application, the field-of-view of 11 mrad defines the diameter of the first aperture,  $d$ , that can be placed directly over the diffuse source at a distance  $z = 20$  cm from the nodal point of the eye, since the pupil of the eye is the field stop.

Thus,  $0,011 = \frac{d}{z}$  and  $d = 0,011 \times z = 2,2 \text{ mm}$

### C.7.2 Determination of irradiance

Irradiance is determined by measuring the radiant power that is transmitted through the second aperture with a diameter of 7 mm, at a distance  $z = 20 \text{ cm}$  from the light source. The irradiance is then equal to the radiant power divided by the area of a 7 mm aperture.

NOTE A 7 mm diameter aperture is used as specified for the measurement of the optical radiation incident on the eye.

Since,

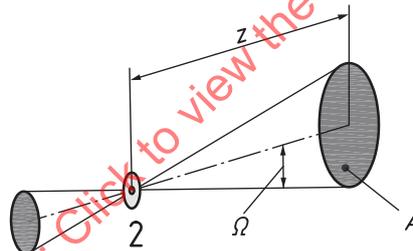
$$E = \frac{\Phi}{0,384 \text{ cm}^2} \quad (\text{C.11})$$

Formula (C.11) for radiance becomes Formula (C.12):

$$L = \frac{E \times z^2}{a} \quad (\text{C.12})$$

$$L = \frac{E \times (200)^2}{\pi(1,1)^2}$$

It is only necessary to measure the irradiance at distance  $z = 20 \text{ cm}$ , for the determination of the source radiance using an aperture of 2,2 mm over the hot spot of the diffuse source. This method takes the 11 mrad field-of-view into account.



#### Key

- $\Omega$  solid angle subtended by light source LS
- $A$  area of the second aperture
- $z$  distance between the first aperture (FS) and the second aperture (with area  $A$ )
- 1 first aperture
- 2 light source

Figure C.1 — Solid angle  $\Omega$  subtended by a light source

## Annex D (informative)

### Guidance on the direct measurement of irradiance

#### D.1 Measurements of irradiance in corneal or pupillary plane

To determine the spectral irradiance in the plane of the cornea or the pupil of the eye, the ophthalmic instrument is located in the intended position of use. The spectral irradiance is then determined by dividing the maximum spectral radiant power or radiant exposure that can be collected in a 1 mm diameter circular area in the applicable measurement plane by the area of the 1 mm aperture used.

#### D.2 Measurements of retinal irradiance

The spectral irradiance created in the plane of the retina by an ophthalmic instrument cannot be measured directly so it must be calculated, either from spectral radiance measurements or from spectral power measurements taken outside the eye.

If spectral radiance measurements are chosen, procedures given in [C.3](#) and [C.4](#) are to be used to make the measurements. A method using a photometer and the spectrum of the source is given in [B.2](#). Many ophthalmic instrument illumination systems are extended sources, by which it is meant that they illuminate a sizable area of the retina. For sources of this type it is important to make the spectral radiance measurements in the areas of the source with the highest intensity, rows 8 to 10 in [Tables 3](#) and [5](#) and rows 7 to 10 in [Table 6](#), all specify the size of the retinal area surrounding the highest intensity that is to be used to find the spectral radiance. However, as the measurements are taken outside the eye, a method is needed to set the area in terms of this situation. It is most convenient to first convert the required retinal areas to angular subtense values and then use these angular subtense values to set suitable limits on the measurement areas outside the eye. [Table D.1](#) gives the conversion from the retina areas, given as their diameter  $d$ , in millimetres, to the tangent of the angular subtense values using the standardized distance of 17 mm between the nodal point of the eye and the retina in [Formula \(D.1\)](#):

$$\tan \alpha = \frac{d}{17 \text{ mm}} \quad (\text{D.1})$$

**Table D.1 — Conversion from the retina areas**

Specified diameter of the retinal area mm	Tangent of the sub- tended angle
0,03	0,001 8
0,18	0,010 6
1	0,058 9

When using a photometer that measures in a small area and that allows to view the measured area and the measured value while taking the measurement, it is easy to make the spectral measurements in the areas of highest intensity. When a method, such as that given in [C.7](#), is used or when the source does not radiate in the visible portion of the spectrum, other methods are needed to ensure that measurements are taken in the source area of highest intensity. For instance, a CCD camera system that has sensitivity in the infrared portion of the spectrum can be used to find the areas of high intensity so the measurement apparatus can be directed at those areas. Once the apparatus is measuring in the correct general area of the source, its positioning can be iteratively changed until the highest intensity is found, at which point measurements are recorded.

Once the spectral radiance of the source  $L_\lambda$  has been measured, the retinal irradiance  $E_\lambda$  is calculated using [Formula \(C.4\)](#). The pupil area  $A_p$  to use in this formula is either the pupil entrance aperture area set by the instrument itself or, if the instrument does not set this area, the area of a 7 mm diameter disk (expressed in units of square centimetres).

If spectral power measurements are chosen to be used, the spectral power radiated by the instrument is measured at a distance from the instrument equal to that at which the pupil of the pupil is to be placed when the instrument is used. If the instrument sets the entrance aperture size of radiation entering the eye, the total power passing the measurement plane is recorded. If the instrument does not set the entrance aperture, the measurement of power passing through a 7 mm diameter aperture placed in the pupil plane is recorded.

Once spectral radiant power has been determined, it is then necessary to determine the spatial beam profile on the retina. The spatial beam profile of the radiation on the retina can be determined by direct measurements or by a combination of measurements and calculations using geometrical optics.

The area of the retina illuminated can be determined by geometrical optics for an ophthalmic instrument that produces a Maxwellian view with a circular beam waist at the pupillary plane of the eye. This is applicable for instruments that produce a homogenous beam on the retina. In this case, the cone angle is determined by measurements of the beam diameter,  $2x$  (where  $x$  is the radius), at a known distance,  $l$ , beyond the pupillary plane. The cone half angle,  $\theta$ , in this case is given by the [Formula \(D.2\)](#):

$$\theta = \tan^{-1}(x/l) \quad (D.2)$$

The radius,  $r$ , of the beam on the retina in centimetres, is given by the product,  $r = 1,7 \tan \theta = 1,7 (x / l)$ . In this case, the area on the retina is given by the product of  $\pi r^2$ .

In the case of a collimated beam incident on the cornea of the eye, the area to be used is either 0,03 mm, if the eye is immobilized, or 0,18 mm if the eye is not immobilized.

In the case of a divergent beam on the eye such as that from a direct ophthalmoscope, the area on the retina illuminated is given by [Formula \(D.3\)](#):

$$a_r = \Omega (1,7 \text{ cm})^2 \quad (D.3)$$

where  $\Omega$  is the solid angle subtended by the source in steradians.

$\Omega$  can be determined by measurements of the beam area at two distances from the exit aperture of the ophthalmic instrument. The beam areas at the two different distances can be used to determine the cone angle(s) from which the solid angle can be derived,

In this case, the solid angle  $\Omega$  is given by [Formula \(D.4\)](#):

$$\Omega = 2\pi(1 - \cos\alpha) \quad (D.4)$$

For evaluating photochemical hazards for divergent beams, the following procedures for a non-immobilized eye shall be used. The spectral irradiance on the retina is determined by dividing the maximum spectral radiant power or radiant exposure that can be collected in a 0,18 mm diameter circular retinal area by the area of the aperture used. For an immobilized eye, or for retinal thermal hazards, a 0,03 mm aperture shall be used. However, for instruments that produce a uniform beam on the retina with a diameter greater than 1 mm, a 1 mm diameter averaging aperture can be used to evaluate retinal irradiance instead of the apertures specified.

## Annex E (informative)

### Examples of measurement methods for specific ophthalmic instruments

#### E.1 Liquid crystal digital displays with LED backlighting

##### E.1.1 Measurement target: Liquid crystal chart (light source: white LED)

The liquid crystal chart uses white LEDs as the backlight for presentation of Landolt rings and Arabic numerals.

Since the emitted radiation from such charts is low, a luminance meter can be used as a sample screening method to determine whether strict measurements are required.

If the screening results are confirmed as low, further, measurements are not needed, and the chart can be classified as Group 1.

If there is any uncertainty, rigorous measurements will be required to determine Group classification.

##### E.1.2 Measuring method

Preparation:

- a) The measurement is performed in a dark room;
- b) set up the device as used in an ophthalmic examination setting and turn on the power;
- c) set the luminance at the maximum setting;
- d) record the measurement settings.

##### E.1.3 Brightness measurement: Luminance meter/colour luminance meter/spectral radiance meter

See [Figure E.1](#) for the test setup.

- a) Set up the luminance meter so that the reference position matches the eye's corneal position (2,5 m to 7 m) in the ophthalmic examination;
- b) Set the measurement angle of the luminance meter to 1°;
- c) Measure the luminance value
  - 1) An aperture is installed on the light emitting surface for evaluation at a measurement angle of 0,011 [rad]. (For example, when the inspection distance is 5 m, the aperture diameter is  $\varnothing 55$  mm);
  - 2) The measurement point of the luminance meter is adjusted to the aperture, and the measurement is performed after focusing;
  - 3) Set the luminance meter to the exposure duration at which the measured value stabilizes;
  - 4) If the measurement is not stable, measure multiple times and average;

5) Measure multiple points and evaluate with the highest value.

d) Calculate the corrected luminance value:

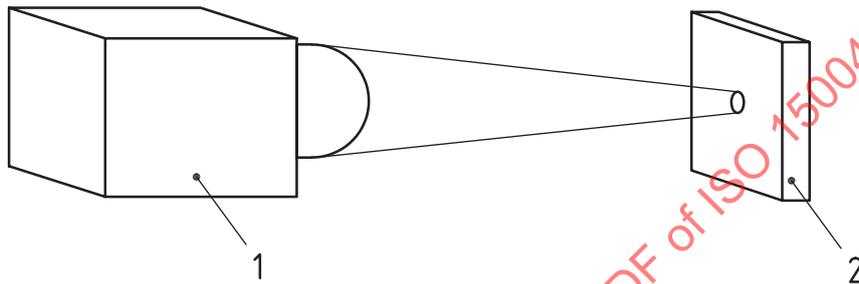
$$(\text{Corrected luminance value}) = (\text{measured luminance value}) \cdot (1^\circ/0,63^\circ)^2$$

e) Judge whether the requirements for the document are met by considering the uncertainty of measurement,

1) If the measured luminance value is 500 [cd/m<sup>2</sup>] and the measurement uncertainty is 10 %, (Corrected luminance value) = 500 · (1°/0,63°)<sup>2</sup> = 1 259,8 [cd/m<sup>2</sup>]

$$(\text{Corrected luminance value considering uncertainty}) = 1\,259,8 \cdot 1,10 = 1\,385,7 \text{ [cd/m}^2\text{]}$$

If the value does not exceed the specified value of 10 000 cd/m<sup>2</sup>, measurement for grouping is not needed, and it is classified as Group 1.



**Key**

- 1 luminance meter
- 2 surface of diffuse light source

**Figure E.1 — Test setup for the Brightness measurement**

**E.2 Fundus cameras**

**E.2.1 Measurement target:** Fundus camera (Example: Light source: Xenon lamp 420 nm – 1 000 nm/ Emission time: 0,002 s)

The fundus camera enables a view of the retina prior to photography by illuminating the retina with white light from a separate light source.

At the point of photography, a separate light source e.g. Xenon lamp, is flashed with an emission time of 0,002 s. Therefore, the instrument becomes a **pulsed instrument**.

Furthermore, fundus cameras are not intended to be used with an immobilized eye. Immobilized eye refers to situations where the eyes are physically fixed, such as during surgery.

**E.2.2 Measuring method**

Preparation:

- a) The measurement is performed in a dark room;
- b) Set up the instrument to be measured in the same way as used in an ophthalmic examination setting and turn on the power;
- c) Increase light output setting to maximum;
- d) Record the measurement settings.