BS EN ISO 15004-2:2024

BSI Standards Publication

Ophthalmic instruments — Fundamental requirements and test methods

Part 2: Light hazard protection

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National foreword

This British Standard is the UK implementation of EN ISO 15004-2:2024. It is identical to ISO 15004-2:2024. It supersedes BS EN ISO 15004-2:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/6, Ophthalmic instruments.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2024)

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European foreword

This document (EN ISO 15004-2:2024) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2025, and conflicting national standards shall be withdrawn at the latest by June 2025.

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Endorsement notice

The text of ISO 15004-2:2024 has been approved by CEN as EN ISO 15004-2:2024 without any modification.

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Foreword

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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).

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

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

The main changes are as follows:

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

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

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

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

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

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

A list of all parts in the ISO 15004 series can be found on the ISO website.

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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.

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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 α, which denotes source size.

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

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

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

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

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

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

3.14
irradiance
E
<at a point on a surface> quotient of the radiant power dΦ incident on an element of a surface containing the point, by the area dA of that element, i.e. given in Formula (1),

$$E = \frac{\mathrm{d}\Phi}{\mathrm{d}A} \tag{1}$$

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

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

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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):

$$L = \frac{\mathrm{d}\Phi}{\mathrm{d}A \cdot \cos\theta \cdot \mathrm{d}\Omega} \tag{2}$$

where

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

$\mathrm{d}A$ is the area of a section of that beam containing the given point;

θ is the angle between the normal to that section and the direction of the beam

Note 1 to entry: The same definition holds for the time-integrated radiance L_t if, in the equation for L, the radiant power $\mathrm{d}\Phi$ is replaced by the radiant energy $\mathrm{d}Q$.

Note 2 to entry: Radiance is expressed in watts per steradian square centimetre, W/(sr·cm^2); time-integrated radiance is expressed in Joules per steradian square centimetre, J/(sr·cm^2).

3.22
radiant exposure
H
at a point of a surface, for a given duration quotient of the radiant energy, $\mathrm{d}Q$, incident on an element of a surface containing the point over the given duration by unit area $\mathrm{d}A$ of that element as expressed in Formula (3):

$$H = \frac{\mathrm{d}Q}{\mathrm{d}A} \tag{3}$$

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

$$H = \int_{\Delta t} E \cdot \mathrm{d}t \tag{4}$$

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

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

3.26
spectral irradiance
E_λ
quotient of the spectral radiant power $\mathrm{d}\Phi(\lambda)$ in a wavelength interval $\mathrm{d}\lambda$, incident on an element of a surface, by the area $\mathrm{d}A$ of that element and by the wavelength interval $\mathrm{d}\lambda$, as expressed in Formula (5):

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

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

3.27
spectral radiance
L_λ
for a wavelength interval $\mathrm{d}\lambda$, in a given direction at a given point ratio of the spectral radiant power $\mathrm{d}\Phi(\lambda)$ passing through that point and propagating within the solid angle $\mathrm{d}\Omega$ in the given direction, to the product of the wavelength interval $\mathrm{d}\lambda$ and the areas of a section of that beam on a plane perpendicular to this direction ($\cos\theta\,\mathrm{d}A$) containing the given point and to the solid angle $\mathrm{d}\Omega$, as expressed in Formula (6):

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

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

3.28
spectral radiant exposure
H_λ
quotient of the spectral radiant exposure $\mathrm{d}Q(\lambda)$ in a wavelength interval $\mathrm{d}\lambda$, incident on an element of a surface, by the area $\mathrm{d}A$ of that element and by the wavelength interval $\mathrm{d}\lambda$, given in Formula (7):

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

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

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

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

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

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

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

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

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

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

Table 1 — Symbols, quantities and units

Symbol	Quantity	Unit
E	irradiance (at a point on a surface)	W/cm^2
E_λ	spectral irradiance	W/(cm^2·nm)
L	radiance (in a given direction at a given point of a real or imaginary surface)	W/(sr·cm^2)
L_λ	spectral radiance (for a wavelength interval dλ, in a given direction at a given point)	W/(sr·cm^2·nm)
L_i	time-integrated radiance	J/(sr·cm^2)
H	radiant exposure (at a point of a surface, for a given duration)	J/cm^2
H_λ	spectral radiant exposure; the time-integral of spectral irradiance	J/(cm^2·nm)
$E_{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation irradiance	W/cm^2
$E_{A\text{-}R}$	$A(\lambda)$ weighted retinal irradiance	W/cm^2
$E_{B\text{-}R}$	$B(\lambda)$ weighted retinal irradiance	W/cm^2
$E_{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation irradiance	W/cm^2
$E_{VIR\text{-}CL}$	unweighted corneal and lenticular visible and infrared radiation irradiance	W/cm^2
$E_{VIR\text{-}I}$	$R(\lambda)$ weighted iris visible and infrared radiation thermal irradiance	W/cm^2
$E_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation thermal irradiance	W/cm^2
L_V	luminance (in a given direction point of a real or imaginary surface)	cd/cm^2
$H_{VIR\text{-}R}$	$R(\lambda)$ weighted retinal visible and infrared radiation radiant exposure	J/cm^2
$H_{IR\text{-}CL}$	unweighted corneal and lenticular infrared radiation radiant exposure	J/cm^2
$H_{VIR\text{-}CL}$	unweighted corneal and lenticular visible and infrared radiation radiant exposure	J/cm^2
$H_{S\text{-}CL}$	$S(\lambda)$ weighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_{UV\text{-}CL}$	unweighted corneal and lenticular ultraviolet radiation radiant exposure	J/cm^2
$H_{A\text{-}R}$	$A(\lambda)$ weighted retinal radiant exposure	J/cm^2
$I(\lambda)$	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
Δt	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

[a] $R(\lambda)$ 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.

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Table 1 *(continued)*

Symbol	Quantity	Unit
d_r	retinal image dimension (diameter if image is circular) (see C.6)	mm
$\tau(\lambda)$	aphakic spectral transmittance of ocular media	—
$\tau_p(\lambda)$	phakic spectral transmittance of ocular media	—
Q	radiant energy	J
Φ	radiant power	W

[a] $R(\lambda)$ 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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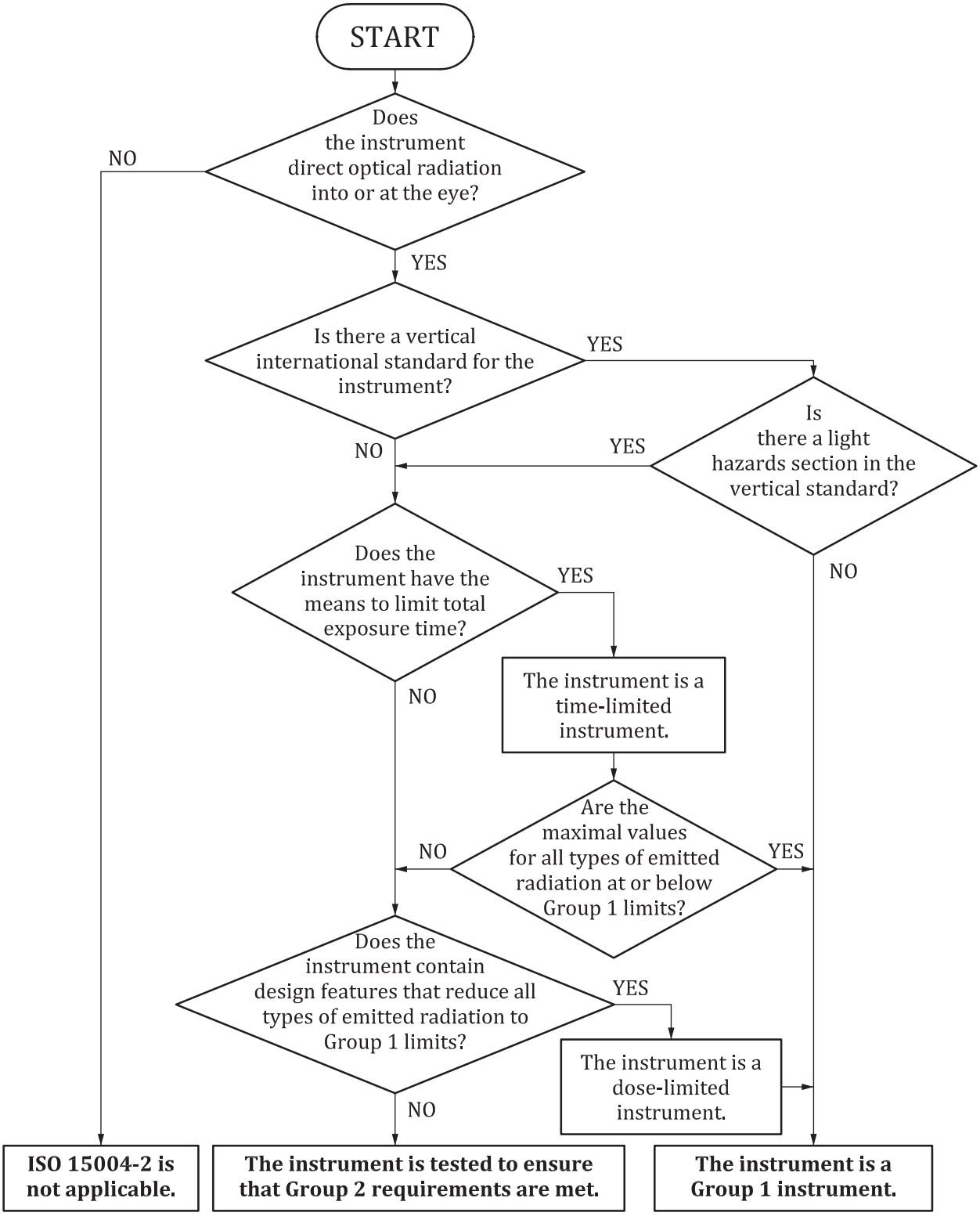

Figure 1 — Flow chart for guidance in instrument classification

Ophthalmic instruments are classified into two groups to separate 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:

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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.

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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 $E_{S\text{-}CL}$ equals 0,6 µW/cm^2 (i.e. $H_{S\text{-}CL}$ = 3,0 mJ/cm^2 over a period of t = 5 000 s), and $E_{A\text{-}R}$ equals 440 µW/cm^2 (i.e. $H_{A\text{-}R}$ = 2,2 J/cm^2 over a period of t = 5 000 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

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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^2 and the photochemical limit is 2,2 J/cm^2. For the 3 second total duration of the pulse train, the thermal limit is 182 J/cm^2 and the photochemical limit is 2,2 J/cm^2.

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^2 thermal limit for 0,01 s duration pulses is 1,26 J/cm^2 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^2 (0,91 J/cm^2/pulse) is needed to match the 182 J/cm^2 thermal limit because of the 2,0 $R(\lambda)$ value. However, these limits are irrelevant because the photochemical limit is 2,2 J/cm^2, 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^2 to match the photochemical limit. In contrast a measured exposure of only 2,0 J/cm^2 is needed to match the single-pulse thermal limit of 2,53 J/cm^2, and a measured cumulative exposure of 147 J/cm^2 matches the 3-second thermal limit of 182 J/cm^2. 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 Δt 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:

$$\Delta t = \frac{d_s}{v_s} \tag{8}$$

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):

$$\frac{H_1}{\text{Limit}_1}+\frac{H_2}{\text{Limit}_2}+\ldots+\frac{H_i}{\text{Limit}_i}\leq 1 \tag{9}$$

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 $H_{\text{S-CL}}$ (250 nm to 400 nm) exposure shall be 0,1 µW/cm^2 ($S(\lambda)$ weighted). Aphakic retinal irradiance, $E_{\text{A-R}}$, for visible light shall be limited to 10 µW/cm^2 ($A(\lambda)$ weighted), and infrared retinal exposure, $E_{\text{VIR-R}}$, shall be limited to 10 mW/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.

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