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Optics and optical instruments — Operation microscopes —

Part 2: Light hazard from operation microscopes used in ocular surgery

Optique et instruments d'optique — Microscopes chirurgicaux —

Partie 2: Danger de la lumière provenant des microscopes opératoires utilisés en chirurgie oculaire

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 10936 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 10936-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 10936 consists of the following parts, under the general title *Optics and optical instruments — Operation microscopes*:

— *Part 1: Requirements and test methods*

— *Part 2: Light hazard from operation microscopes used in ocular surgery*

Annexes A and B form a normative part of this part of ISO 10936. Annex C is for information only.

Optics and optical instruments — Operation microscopes —

Part 2:
Light hazard from operation microscopes used in ocular surgery

1 Scope

This part of ISO 10936 specifies requirements and test methods for optical radiation hazards from operation microscopes which are used during ocular surgery.

NOTE General requirements for operation microscopes and test methods for these requirements are specified in ISO 10936-1.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10936. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10936 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10936-1:2000, *Optics and optical instruments — Operation microscopes — Part 1: Requirements and test methods*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety,* including *Amendment 1:1991,* including *Amendment 2:1995.*

3 Terms and definitions

For the purposes of this part of ISO 10936, the following terms and definitions apply.

3.1
auxiliary beam
off-axis beam attached to or an integral part of the microscope and intended to illuminate the eye

3.2
corneal plane
plane that is perpendicular to the optical axis of the instrument and that is tangential to the corneal surface closest to the instrument when in normal use

3.3
photoretinitis
retinal photochemically induced injury resulting from intense retinal radiant exposure

NOTE Photic maculopathy is a term also used to describe photoretinitis in the fovea-macular area of the retina.

3.4
irradiance
E
at a point on a surface, the radiant energy flux incident on an element of the surface, divided by the area of that element

[ISO 31-6:1992]

NOTE Irradiance is expressed in milliwatts per square centimetre (mW/ cm^2).

3.5
main beam
axial beam exiting from the microscope

3.6
radiance
L
quotient of the radiant flux $d\Phi$ passing through a given point and propagating within the solid angle $d\Omega$ in a given direction Θ divided by the product of the area of a section of that beam on a plane perpendicular to the given direction containing the given point and the solid angle $d\Omega$ (see C.1)

NOTE Radiance is expressed in milliwatts per square centimetre per steradian [$mW/(cm^2 \cdot sr)$].

3.7
retinal hazard limit
limiting value of the spectrally-weighted source radiance of an ophthalmic instrument which, if exceeded, could cause damage at or to the retina

NOTE The effect of the radiance of a source (see 3.6) will decrease as the light beam passes through an optical system due to filtering, absorption or other loss mechanism. Thus, basing the retinal hazard on the source radiance ensures that the radiance at the retina cannot exceed the source radiance.

3.8
spectral radiance
$L_\lambda(\lambda)$
value of the radiance L (3.6) of an infinitesimal wavelength interval, at any given wavelength in the spectrum, divided by the range of that interval [$L_\lambda(\lambda) = \Delta L / \Delta\lambda$]

NOTE Spectral radiance is expressed in milliwatts per square centimetre per steradian per nanometer [$mW/(cm^2 \cdot sr \cdot nm)$].

3.9
spectrally-weighted photochemical aphakic source radiance
L_A
spectral radiance of the source integrated over the aphakic spectrum range 305 nm to 700 nm and weighted by $A(\lambda)$

$$L_A = \sum_{305}^{700} L_\lambda(\lambda) \cdot A(\lambda) \cdot \Delta\lambda \quad (1)$$

where $A(\lambda)$ is the spectral weighting function for the aphakic retinal hazard analysis (see annex A).

3.10
spectrally-weighted photochemical phakic source radiance
L_B
spectral radiance integrated over the phakic spectrum range 380 nm to 700 nm and weighted by $B(\lambda)$

$$L_B = \sum_{380}^{700} L_\lambda \ (\lambda) \cdot B(\lambda) \cdot \Delta\lambda \qquad (2)$$

where $B(\lambda)$ is the spectral weighting function for the phakic retinal hazard analysis (see annex A).

4 Requirements for optical radiation hazard

4.1 General

The operation microscope shall comply with the requirements specified in 4.2, 4.3 and 4.4.

The limit values given in 4.2 are considered acceptable with respect to the risks when weighted against the performances intended.

The requirements in IEC 60601-1 apply to this part of ISO 10936, with the exception of this clause which replaces clauses 32, 33 and 34 of IEC 60601-1.

4.2 Limit values

Limit values apply to radiation from the operation microscope used to illuminate, view or photograph the human eye with visible light (380 nm to 700 nm) and in which the full beam homogeneously illuminates a circular pupil of diameter 8 mm. These limits apply to each light source intended to illuminate the eye and attached to the operation microscope, including the main and auxiliary beams, and are as follows.

a) Short wavelength limit: the amount of radiant power exiting the instrument in the portion of the spectrum from 305 nm to 400 nm shall have an irradiance no greater than 0,05 mW/cm^2 as measured in the corneal plane when the operation microscope is operating at maximum intensity[1)] and at maximum aperture.

b) Long wavelength limit: the amount of radiant power exiting the instrument in the wavelength range 700 nm to 1100 nm shall not exceed either the amount of energy exiting the instrument in the range between 380 nm and 700 nm or 100 mW/cm^2, whichever value is the smaller. The energy shall be measured in the corneal plane when the instrument is operating at maximum intensity[1)] and maximum aperture.

If, due to stops or other obstructions of the beam, a pupil of less than 8 mm diameter is illuminated, the limit values may be increased by the ratio of the area of an 8 mm pupil divided by the true area illuminated.

It is recommended that the energy in the range of the spectrum below 420 nm be attenuated as much as possible.

For instruments with a large illuminating solid angle Ω over the designated spectral range 305 nm to 400 nm, i.e. $\Omega > 0{,}031$ sr, the limit values may be increased by the ratio of the true solid angle, expressed in steradians, divided by 0,031.

For instruments with non-pulsed radiation, the assumptions used to set the limit value for radiation shorter in wavelength than 400 nm are based on considerations of the typical spectral distribution of a 3000 K standard black body source, an illuminating solid angle at the corneal plane of 0,031 sr, a maximum exposure time of 5 min and the weighting factors for L_A (see annex A). The limit is set to ensure that the fraction of the photochemical hazard

1) Maximum intensity is the highest intensity the instrument is capable of delivering and, where overvoltage is provided, relates to that intensity. (See also 6.1 and 6.2.)

dose due to radiation shorter in wavelength than 400 nm is no greater than 1/8 of the total photochemical hazard dose over all wavelengths when that total dose is at the threshold limit for an 8 mm pupil.

Using the ACGIH (American Conference of Governmental Industrial Hygienists) guidelines, that threshold limit is 14 J/(cm^2 · sr). To convert from photochemical hazard weighted radiance to irradiance, over the designated spectral range 305 nm to 400 nm, the conversion factor 0,276 is used. Thus the limit is then found by the formula:

$$[14\ \text{J/(cm}^2 \cdot \text{sr)}] \times (0{,}031\ \text{sr}) \times [0{,}276/(300\ \text{s} \times 8)] = 0{,}05\ \text{mW/cm}^2 \quad (3)$$

For instruments with pulsed radiation, the limit is a total dose expressed in joules per square centimetre, and is found by the formula:

$$[14\ \text{J/(cm}^2 \cdot \text{sr)}] \times (0{,}031\ \text{sr}) \times (0{,}276/8) = 15\ \text{mJ/cm}^2 \quad (4)$$

For multiple pulses, the limit per pulse is then 15 mJ/cm^2 divided by the number of pulses.

4.3 Visible light

4.3.1 Variable light intensity

Where provision is made to vary the light intensity, the manufacturer shall calibrate the variable settings in relation to the spectrally-weighted (photochemical) phakic reference value[2)] of 500 mW/(cm^2 · sr), which shall be calibrated as 1,0. Each setting shall be quantified as a factor or portion of the reference intensity (e.g. 1,5; 1,25; 0,75; 0,5; 0,25 etc). A means of measuring the level of illumination between 380 nm and 700 nm with a relative uncertainty of ± 30 % shall be provided to ensure that the reference intensity setting can easily be recalibrated at 1,0.

The level of illumination referred to above covers any one of the following:

- irradiance over a specified wavelength range;
- radiance over a specified wavelength range;
- luminance over a specified wavelength range;
- illuminance over a specified wavelength range;
- spectral irradiance over a specified wavelength range;
- spectral radiance over a specified wavelength range.

The measurement means may be a separate external device or it may be incorporated into the microscope.

NOTE See annex B for information about the reference value of 500 mW/(cm^2 · sr).

4.3.2 Non-variable light intensity

For light sources which cannot be varied, the manufacturer shall indicate the calibration of the light intensity in relation to the spectrally-weighted (photochemical) phakic reference value[2)] of 500 mW/(cm^2 · sr).

2) This reference value relates to the use of an operation microscope with a 200 mm lens. See also annex B.

4.4 Retinal safety filter

4.4.1 A means (e.g. a filter which may be removable) shall be installed in the coaxial light path and for each auxiliary illuminator. This means shall reduce the spectrally-weighted phakic radiance to 20 % of its value without that means.

Removal of this means shall be indicated to the surgeon.

NOTE An automatic timing device may be incorporated to record the total time the filter means is out of the axial light path.

4.4.2 Removal of any retinal safety filter shall not expose the patient at the corneal plane to UV radiation greater than the limit values specified in 4.2.

5 Test methods

5.1 General

All tests described in this part of ISO 10936 are type tests.

5.2 Checking optical radiation safety

5.2.1 Determination of spectral irradiance

Spectral irradiance shall be measured with an uncertainty of less than ± 30 % at regular intervals over the effective portion of the spectrum. For aphakic photochemical hazard (L_A), the effective portion is 305 nm to 700 nm. For phakic photochemical hazard (L_B), the effective portion is 380 nm to 700 nm.

The intervals for spectral irradiance measurement should be centred on the values given in annex A with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement unit is milliwatts per square centimetre per nanometre [mW/(cm^2 · nm)]. This value should be recorded and, after being multiplied by the bandwidth, recorded as milliwatts per square centimetre (mW/ cm^2) for that interval (see also annex C).

5.2.2 Determination of irradiance

Irradiance shall be measured with an uncertainty of less than ± 30 % for the spectrum from 305 nm to 380 nm and ± 15 % between 380 nm and 1100 nm. For the short wavelength limit, the effective portion of the spectrum is from 305 nm to 400 nm. For the long wavelength limits, the effective portions of the spectrum are from 380 nm to 700 nm and from 700 nm to 1100 nm.

NOTE A spectroradiometer can be used to make these measurements.

5.3 Determination of beam cross-section

When determining the area of the beam cross-section which is required for several calculations, the measuring method used shall be capable of an accuracy of ± 30 %.

NOTE For irregular cross-sections, it may be appropriate to measure the area by exposing a piece of film and then measuring the area on the negative.

6 Information supplied by the manufacturer

6.1 The manufacturer shall provide the user with a graph for each light source (main beam and auxiliary beam) showing the relative spectral output of the instrument between 305 nm and 1100 nm when the operation