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Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety

Instruments ophtalmiques — Sondes endolumineuses — Exigences fondamentales et méthodes d'essai relatives à la sécurité vis-à-vis des rayonnements optiques

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Contents

Page

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15752 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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

Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety

1 Scope

This International Standard specifies optical radiation safety aspects of endoilluminators which are used to illuminate the interior of the eye during ocular surgery. This International Standard is not applicable to other active and non-active ophthalmic instruments and operating microscopes.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document 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.

IEC 60601-1:1988, *Medical Electrical Equipment — Part 1: General requirements for safety*.

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply:

3.1
aperture
opening, usually circular, through which light enters an optical system

3.1.1
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

NOTE For an obscured or noncircular aperture, it is the equivalent nonobscured circular aperture.

3.1.2
numerical aperture
NA
fibre aperture given by the index of refraction (of the medium in which the illuminated object lies) times the sine of the half angle of the cone of illumination

$NA = n' \sin u'$

where

n' is the index of refraction (of the medium in which the illuminated object lies) and

u' is the half angle of the cone of illumination

3.1.3
exiting aperture
portion of the endoilluminator light guide from which light from the endoilluminator light source emerges

3.2
endoilluminator
device consisting of an endoilluminator light source and an associated fibre optic endoilluminator light guide that is intended for insertion into the eye to illuminate any portion of the interior of the eye

3.3
endoilluminator light guide
device that transmits light from the endoilluminator light source into the eye

3.4
endoilluminator light source
device that produces and directs light into an endoilluminator light guide

3.5
irradiance
ratio of the radiant flux dΦ incident on an element of a surface by the area dA of that element

3.6
maximum intensity
highest intensity that can be delivered in any mode of operation including overvoltage

3.7
photoretinitis
retinal injury resulting from a very intense retinal radiant exposure

3.8
spectrally-weighted photochemical aphakic source irradiance
E_A
spectral irradiance of the source integrated over the aphakic spectrum range 305 nm to 700 nm and weighted by $A(\lambda)$ as given by the equation

$$E_A = \sum_{\lambda=305}^{\lambda=700} E_\lambda(\lambda) \cdot A(\lambda) \cdot \Delta\lambda \qquad (1)$$

where

$A(\lambda)$ is the spectral weighting function for the aphakic retinal hazard analysis, given in annex A,

$E_\lambda(\lambda)$ is the spectral irradiance produced by the source,

$\Delta\lambda$ is the summation interval.

4 Requirements

4.1 Design

Endoilluminators shall be so designed that, when used under the conditions intended by the manufacturer, the optical radiation risks associated with the use of the instrument are reduced to an acceptable level compatible with the generally acknowledged state of the art.

4.2 Limit values

Limit values apply to radiation from endoilluminators used to illuminate the interior of the eye with visible light.

— Short wavelength limit: the radiant power emitted from the exit aperture of an endoilluminator 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 at a distance of 5 mm in a plane perpendicular to the radiating fibre optic exiting aperture when the power supply is set to operate at maximum intensity.

— Long wavelength limit: the radiant power emitted from the exit aperture of an endoilluminator in the portion of the spectrum from 700 nm to 1100 nm shall not exceed 100 mW/cm^2, nor shall it exceed the irradiance in the range of the spectrum between 380 nm and 700 nm as measured at a distance of 5 mm in a plane perpendicular to the radiating fibre optic exiting aperture when the power supply is set to operate at maximum intensity.

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

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 at a distance of 5 mm from the exiting apertures of the recommended endoilluminator light guides in relation to an aphakic weighted irradiance reference value of 50 mW/cm^2, which shall be calibrated as 1. Each setting shall be quantified as a factor or portion of the reference intensity (e.g. 1,5; 1; 0,7; 0,5; 0,3; etc.).

4.3.2 Non-variable light intensity

For light sources which cannot be varied, the manufacturer shall calibrate the light intensity at a distance of 5 mm from the exiting apertures of the recommended light guides in relation to the aphakic weighted reference value of 50 mW/cm^2 referenced at a calibration setting of 1.

4.4 Light intensity measurement means

4.4.1 A calibrated means of measuring the aphakic weighted irradiance at a distance of 5 mm from the exiting apertures of recommended endoilluminator light guides shall be provided by the manufacturer of the endoilluminator light source. An appropriate measurement means is described in annex C. The measurement means shall be linear in response over a minimum of one decade.

4.4.2 The light guide manufacturer shall provide a means by which measurements described in 4.4.1 can be made under sterile conditions.

4.5 Retinal safety filter

4.5.1 A removable means (e.g. a filter) shall be installed in the endoilluminator light source before the endoilluminator light guide connector. This means shall reduce the spectral irradiance values at 440 nm to 50 % and at 400 nm to 1 % of their initial values without that means at the reference intensity of 1 (as defined in 4.3.1). An indicator shall be provided to display to the surgeon when the filtering means has been moved out of the light path.

4.5.2 Removal of any retinal safety filter should not result in exceeding the limit for short wavelength as specified in 4.2.

5 Method for the determination of spectral irradiance

Irradiance and spectrally weighted irradiance shall be determined with an uncertainty less than ± 30 % for the short wavelengths from 305 nm to 380 nm and ± 15 % for the visible spectrum from 380 nm to 700 nm.

NOTE A spectroradiometer can be used to make these measurements. The intervals should be centred on the values used in annex A with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement units are microwatts per square centimetre per nanometre (µW/cm^2/nm). This value is recorded and is also multiplied by bandwidth and recorded as microwatts per square centimetre (µW/cm^2) for that interval. If lamps with narrow spectral lines are used, the bandwidth measurements may need to be less than 5 nm.

6 Information supplied by the manufacturer

6.1 Information supplied by the manufacturer of an endoilluminator light source

6.1.1 The manufacturer of the endoilluminator light source shall provide the user with a graph showing the relative spectral output of the endoilluminator between 320 nm and 1100 nm with and without filters when the endoilluminator light source is operating at maximum light intensity with recommended endoilluminator light guides.

6.1.2 The manufacturer of the endoilluminator light source shall provide the user with the value for the spectrally-weighted aphakic irradiance of the endoilluminator at a distance of 5 mm in a plane perpendicular to the radiating fibre optic exiting aperture when the endoilluminator light source is set to operate at maximum light intensity with a specific endoilluminator light guide. The manufacturer shall specify the conditions under which the measurements were made, including the effective aperture, the numerical aperture and the material used in the light guide. The aphakic irradiance is determined by using the spectral weighting values given in annex A.

6.1.3 The manufacturer of the endoilluminator light source shall provide information on the meaning of spectrally-weighted aphakic retinal irradiance (see annex B).

6.1.4 The manufacturer of the endoilluminator light source shall provide information on the use of the variable light intensity control.

6.1.5 The manufacturer of the endoillumninator light source shall provide information on the risks associated with the replacement of components including light guides (see annex B).

6.2 Information supplied by the manufacturer of an endoilluminator light guide

The manufacturer of the endoilluminator light guide shall provide the user with the effective aperture, the numerical aperture and the material used in its endoilluminator light guide.

NOTE Additional documents may be required from the manufacturer according to IEC 60601-1.

7 Marking

7.1 Endoilluminator light source

The endoilluminator light source shall be permanently marked with at least the following information:

— name and address of manufacturer and/or trade name;

— model and serial number;

— any warnings and/or precautions to take;

— additional marking as required by IEC 60601-1, if applicable.

7.2 Endoilluminator light guide

The packaging of the endoilluminator light guide shall be marked with at least the following information:

— name and address of manufacturer and/or trade name;

— model and serial number, if applicable;

— any warnings and/or precautions to take;

— additional marking as required by IEC 60601-1, if applicable.