INTERNATIONAL STANDARD

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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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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 15752:2000), which has been technically revised.

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

1 Scope

This International Standard specifies optical radiation safety aspects of endoilluminator light sources and endoilluminator light guides which are used to illuminate the interior of the eye during ocular surgery.

2 Normative references

The following referenced documents are indispensable for the application 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 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15004-2 and the following apply.

3.1
exit 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

NOTE Adapted from ISO 15004-2:2007.

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

3.4
chandelier
endoilluminator light guide intended to be positioned adjacent to the sclera with an output divergence half-angle equal to or greater than 90°

3.5
pic
forceps
device incorporated into the tip of an endoilluminator light guide for tissue manipulation

3.6
standard (endoilluminator light guide)
collimated (endoilluminator light guide)
type of endoilluminator light guide with an output divergence half-angle equal to or less than 40°

3.7
wide angle (endoilluminator light guide)
diffusing (endoilluminator light guide)
type of endoilluminator light guide with an output divergence half-angle greater than 40° but less than 90°

3.8
endoilluminator light source
device that produces and directs light into an endoilluminator light guide

3.9
Group 1 instrument
ophthalmic instrument for which no potential light hazard exists and that can be shown to fulfil the requirements of ISO 15004-2:2007, 5.2

NOTE Adapted from ISO 15004-2:2007.

3.10
Group 2 instrument
ophthalmic instrument for which a potential light hazard exists and that does not fulfil the requirements of ISO 15004-2:2007, 5.2

NOTE Adapted from ISO 15004-2:2007.

4 Requirements

4.1 Optical radiation hazard with endoilluminator light sources

4.1.1 General

Endoilluminator light sources shall comply with the light hazard protection requirements given in ISO 15004-2.

4.1.2 Determination of classification group

The endoilluminator light source shall be classified as a Group 1 or Group 2 instrument as defined in ISO 15004-2:2007, Clause 4. The test methods given in Clause 5 of this International Standard, shall be used to make this determination.

4.1.3 Requirements for Group 1 instruments

If the status is determined to be Group 1, there are no further requirements.

4.1.4 Requirements for Group 2 instruments

If the status is determined to be Group 2, the endoilluminator light source shall comply with the requirements of ISO 15004-2:2007, 5.3 and Clause 7. In addition, Clause 6 of this International Standard shall apply.

Compliance with 5.3 of ISO 15004-2:2007 shall be verified using test methods given in Clause 5 of this International Standard.

4.2 Retinal protection

If the time to reach the aphakic weighted retinal radiant maximum exposure guideline is < 30 min at maximum output, a retinal protection means shall be installed in the instrument to increase the time to ⩾ 30 min.

The status of the protection means, whether enabled or disabled, shall be clearly evident to the user during surgery.

4.3 Stability of light intensity

The endoilluminator light source shall be designed to ensure that, when operated at maximum output, differences in output due to ageing, maintenance, servicing and correctly rated lamp and component replacements cannot reduce the time and/or number of pulses necessary to reach the maximum exposure guideline below the level determined in accordance with ISO 15004-2:2007, 6.5. This shall be applicable throughout the lifetime of the endoilluminator light source when maintained in accordance with the manufacturer's specifications.

Among other methods, this may be achieved by a risk management process.

5 Test methods

5.1 Determination of irradiance, spectral irradiance and spectrally weighted irradiance for Group 1 and Group 2 instruments

For endoilluminators that produce a uniform beam on the retina, with a diameter greater than 1 mm at the recommended use distance, the following shall apply.

For the determination of irradiance or spectrally weighted irradiance for standard/collimated light guides, the maximum radiant power or spectrally weighted radiant power for each light source at maximum intensity shall be determined over an averaging area of 1 mm in diameter at a distance of 15 mm from the exit aperture.

For the determination of irradiance or spectrally weighted irradiance for wide-angle/diffusing and chandelier light guides, the maximum radiant power or spectrally weighted radiant power for each light source at maximum intensity shall be determined over an averaging area of 1 mm in diameter at a distance of 18 mm from the exit aperture.

For the determination of irradiance or spectrally weighted irradiance for pic/forceps light guides, the maximum radiant power or spectrally weighted radiant power for each light source at maximum intensity shall be determined over an averaging area of 1 mm in diameter at a distance of 1 mm from the tip that is intended to be in contact with the macula.

A measurement aperture equal to the diameter of the gauge of the endoilluminator shall be used for endoilluminators that produce a uniform beam on the retina with a diameter of less than 1 mm at the recommended use distance.

Where the distance of use is not as specified above, measurements shall be made at the distance specified by the manufacturer.

Measurements shall be made in water or a saline solution. The spectrally weighted retinal irradiance at maximum intensity is equivalent to the value of the maximum spectrally weighted radiant power in a 1 mm diameter area divided by the area ($7{,}9 \times 10^{-3}$ cm^2).

For endoilluminators that do not produce a uniform beam on the retina at the recommended use distance, a measurement aperture of 0,03 mm shall be used.

5.2 Determination of half-angle

The output divergence half-angle shall be determined to be the angle at which the irradiance is equal to one half of the maximum irradiance when evaluated through a 1 mm aperture. The uncertainty in the angle shall be less than 1°.

A measurement aperture equal to the diameter of the gauge of the endoilluminator shall be used for endoilluminators that produce a uniform beam on the retina with a diameter of less than 1 mm at the recommended use distance.

For endoilluminators that do not produce a uniform beam on the retina at the recommended use distance, a measurement aperture of 0,03 mm shall be used.

5.3 Measurements to classify instruments in Group 1 or Group 2

In order to classify instruments in Group 1 or Group 2, 5.1 and 5.2 of this International Standard shall apply, together with ISO 15004-2:2007, 6.1, 6.2 and 6.4.

5.4 Group 2 instrument measurements

For Group 2 instrument measurements, 5.1 and 5.2 of this International Standard shall apply, together with ISO 15004-2:2007, 6.1, 6.3, 6.4, 6.5.1 and 6.5.2.

6 Information supplied by the manufacturer

6.1 General

For endoilluminators classified as Group 2, ISO 15004-2:2007, Clause 7, shall apply.

6.2 Information supplied by the manufacturer of Group 2 combination of endoilluminator light source and light guides

6.2.1 Manufacturers of combination endoilluminator light source and light guides shall provide the user with the exposure time(s) required to reach the aphakic weighted safety guideline with the endoilluminator light source set at maximum intensity and 50 % of maximum intensity, with and without the retinal protection means, for each light guide with which it is intended to be used. These guidelines shall be provided either on the endoilluminator light source or in/on the packaging of each light guide.

An example of information to be provided is given in Annex A.

6.2.2 The manufacturer of the endoilluminator light source shall provide the user, upon request, with a graph showing the relative spectral output of the endoilluminator between 320 nm and 1 100 nm, with and without the retinal protection means, when the endoilluminator light source is operating at maximum intensity with recommended endoilluminator light guides.

6.2.3 The manufacturer of the endoilluminator light source shall provide information on the risks associated with the replacement of components, including endoilluminator light guides.

6.3 Information supplied by the manufacturer of Group 2 endoilluminator light source

6.3.1 The manufacturer of the endoilluminator light source shall provide the user, upon request, with a graph showing the relative spectral output of the endoilluminator between 320 nm and 1 100 nm, with and without the retinal protection means, when the endoilluminator light source is operating at maximum intensity with recommended endoilluminator light guides.

6.3.2 The manufacturer of the endoilluminator light source shall provide information on the risks associated with the replacement of components, including endoilluminator light guides.

6.4 Information supplied by the manufacturer of endoilluminator light guides

Manufacturers of endoilluminator light guides shall provide the user with the exposure time(s) required to reach the aphakic spectrally weighted safety guideline for each light source with which it is intended to be used. The exposure times are to be specified with the endoilluminator light source set at maximum intensities and 50 % of maximum intensity for conditions with and without the retinal protection means in place. These guidelines shall be provided in/on the packaging of each light guide.

An example of information to be provided is given in Annex A.

7 Marking

7.1 Endoilluminator light source

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

a) name and address of manufacturer and/or trade name;

b) model and serial number;

c) information specified in 6.3;

d) any warnings and/or precautions to be taken;

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

7.2 Packaging of endoilluminator light guide

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

a) name and address of manufacturer and/or trade name;

b) model and serial number, if applicable;

c) information specified in 6.4;

d) any warnings and/or precautions to be taken;

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