INTERNATIONAL STANDARD

ISO 10936-2

Second edition
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Optics and photonics — Operation microscopes —

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

Optique et photonique — Microscopes chirurgicaux —

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

Reference number
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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.org
Web www.iso.org

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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 10936-2 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 10936-2:2001) which has been technically revised.

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

— *Part 1: Requirements and test methods*

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

Optics and photonics — 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 that 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 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 10936-1, *Optics and optical instruments — Operation microscopes — Part 1: Requirements and test methods*

ISO 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
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.

3.2
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 for optical radiation hazard

4.1 General

Operation microscopes shall comply with the light hazard protection requirements given in ISO 15004-2.

4.2 Determination of classification group

The operation microscopes shall be classified as Group 1 or Group 2 instruments as defined in ISO 15004-2:2007, Clause 4. The test methods given in Clause 5 of this part of ISO 10936 shall be used to make this determination.

4.3 Requirements for Group 1 instruments

4.3.1 General

The operation microscope shall comply with the requirements of ISO 15004-2:2007, 5.2.

4.3.2 Emission limits

The operation microscope shall comply with the requirements of:

— ISO 15004-2:2007, 5.4.1;

— and, if applicable, ISO 15004-2:2007, 5.4.2;

— and, if applicable, ISO 15004-2:2007, 5.4.3.

Compliance shall be verified using the test methods given in Clause 5 of this part of ISO 10936.

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

4.4 Requirements for Group 2 instruments

4.4.1 General

If the status is determined to be Group 2, the operation microscope shall comply with the requirements of ISO 15004-2:2007, 5.3. Compliance with ISO 15004-2:2007, 5.3, shall be verified using test methods given in Clause 5 of this part of ISO 10936.

4.4.2 Emission limits and guideline values

The operation microscope shall comply with the requirements of:

— ISO 15004-2:2007, 5.5.1;

— and, if applicable, ISO 15004-2:2007, 5.5.2;

— and, if applicable, ISO 15004-2:2007, 5.5.3.1;

— and, if applicable, ISO 15004-2:2007, 5.5.3.2.

4.4.3 Retinal protection device

If the time to reach the aphakic weighted retinal radiant maximum exposure guideline is < 30 min at maximum output, a retinal protection device shall be installed in the coaxial light path and for each auxiliary illuminator in the instrument. When activated, this device shall increase the time to reach the maximum exposure guideline either by a factor of no less than 5 or to a time ⩾ 30 min.

The status of the protection device, whether activated or unactivated, shall be clearly evident to the user during surgery.

4.4.4 Stability of light intensity

The operation microscope shall be designed to ensure that, when operated at maximum output, differences in output due to ageing, maintenance, servicing, and lamp and component replacements cannot reduce the time and/or number of pulses needed 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 device when maintained in accordance with the manufacturer's specifications.

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

5 Test methods

See ISO 15004-2:2007, 5.3.

For Group 1 instruments, ISO 15004-2:2007, 6.1, 6.2 and 6.4, using appropriate measurement methods as specified in ISO 15004-2:2007, Annex D and Annex E.

For Group 2 instruments, ISO 15004-2:2007, 6.3 and 6.4, using appropriate measurement methods as specified in ISO 15004-2:2007, Annex D and Annex E.

ISO 15004-2:2007, 6.5.1.

ISO 15004-2:2007, 6.5.2 (if applicable).

6 Additional information to be supplied by the manufacturer of Group 2 instruments

6.1 For continuous wave light sources that can be varied in intensity, the time needed to reach the maximum exposure guideline in accordance with ISO 15004-2:2007, 6.5.1, for the maximum setting and 50 % of the maximum setting, with and without the retinal protection device, shall be indicated in the user's manual (see ISO 15004-2:2007, Clause 7).

This information shall also be clearly evident to the user during surgery (see ISO 15004-2:2007, Clause 7). An example of how this information may be provided is given in Annex A.

6.2 Where applicable, for pulsed light sources that can be varied in intensity, the number of pulses needed to reach the maximum exposure guideline in accordance with ISO 15004-2:2007, 6.5.2, for the maximum setting and 50 % of the maximum setting, with and without the retinal protection device, shall be indicated in the user's manual (see ISO 15004-2:2007, Clause 7).

7 Marking

For the marking of operation microscopes, see ISO 10936-1.

Annex A
(informative)

Example of information regarding maximum retinal exposure guidelines to be provided to the user during surgery

Table A.1 — Maximum exposure guidelines

	Maximum output min	**50 % maximum output** min
Without retinal protection device	X	Y
With retinal protection device	Z	W
NOTE This information can be provided in the form of meaningful symbols.		

The light emitted from this instrument is potentially hazardous.

NOTE 1 Exposure times are for cumulative retinal exposure.

NOTE 2 Lower intensities increase the maximum exposure times in direct proportion to the decrease in intensities.

NOTE 3 Exposure times are given for clear media. Cloudy media and/or blood will increase these times.