DRAFT INTERNATIONAL STANDARD ISO/DIS 10936-2

ISO/TC **172**/SC **7** Secretariat: **DIN**

Voting begins on: **2008-03-25** Voting terminates on: **2008-08-25**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

[Revision of first edition (ISO 10936-2:2001)]

ICS 11.040.30; 37.020

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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 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 which are used during ophthalmic 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 Definitions

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

3.1
Group 1 instrument
ophthalmic instrument for which no potential light hazard exists

3.2
Group 2 instrument
ophthalmic instrument for which a potential light hazards exists

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 a Group 1 or Group 2 instrument as defined in ISO 15004-2:2007, Clause 4. The test methods given in this International Standard, i.e. ISO 10936-2, Clause 5, shall be used to make this determination.

4.3 Requirements for Group 1 instruments

If 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 by Clause 5 of this part of ISO 10936.

4.4.2 Retinal protection device

If the time to reach the aphakic weighted retinal radiant exposure 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 enabled, this device shall increase the time to reach the maximum exposure guideline either by a factor no less than 5 or to a time ≥ 30 min.

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

4.4.3 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, can not reduce the time and/or number of pulses 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

ISO 15004-2:2007, Clause 5.2 "Requirements for classification as a Group 1 instrument"

ISO 15004-2:2007, Clause 5.3 “Requirements for Group 2 instruments”

ISO 15004-2:2007, Clause 5.4.1 "Emission limits for determination of Group 1 classification – Continuous wave instruments"

ISO 15004-2:2007, Clauses 6.1, 6.2 and 6.4 "Test methods"

ISO 15004-2:2007, **(if applicable)** Clause 5.4.2 "Emission limits for determination of Group 1 classification – Pulsed instruments"

ISO 15004-2:2007, **(if applicable)** Clauses 6.1, 6.2 and 6.4 "Test methods"

ISO 15004-2:2007, **(if applicable)** Clause 5.5.3.1 "Determination of limits for multiple source instruments"

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

If status is determined to be Group 2, the following additional clauses are applicable:

ISO 15004-2:2007, Clause 5.5.1 "Emission limits and guideline values for Group 2 continuous wave instruments

ISO 15004-2:2007, Clauses 6.3 and 6.4 "Test methods"

ISO 15004-2:2007, **(if applicable)** Clause 5.5.2 "Emission limits for Group 2 pulsed instruments"

ISO 15004-2:2007, **(if applicable)** Clause 5.5.3.1 "Determination of limits for multiple source instruments"

ISO 15004-2:2007, **(if applicable)** Clause 5.5.3.2 "Guideline values for multiple source instruments"

ISO 15004-2:2007, **(if applicable)** Clauses 6.3 and 6.4 "Test methods"

ISO 15004-2:2007, Clause 6.5.1 "Time to reach a potential optical radiation hazard for aphakic retinal exposure for instruments with continuous light output"

ISO 15004-2:2007, **(if applicable)** Clause 6.5.2 "Determination of the number of pulses to reach a potential optical radiation hazard for aphakic retinal exposure for instruments with pulsed light output"

An example of how the measurements required in clauses 5.4.1, 5.5.1, and 5.5.2 may be made, is given in Annex B.

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

6.1 For continuous wave light sources which can be varied in intensity, the time to reach a potential light hazard according to 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 which can be varied in intensity, the number of pulses to reach a potential light hazard according to ISO 15004-2:2007, 6.5.2, for the maximum setting and at least one of the indicated lower settings, 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 marking of operation microscopes see ISO 10936-1.

Annex A
(informative)

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

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 could 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.

Annex B
(informative)

Fluid filled test eye

B.1 Description of the test eye

B.1.1 General

The fluid filled test eye is designed to simulate the human eye and to create images on a CCD camera array similar to images that fall on the human retina. The eye is comprised of a main body, a pupil/lens holding disk, an intraocular lens (IOL), a rear window assembly, a C-mount adapter and a CCD camera. These components are described below.

B.1.2 Main body

The main body of the test eye is best made of brass and has cemented into it the meniscus corneal shell. This shell acts as the cornea of the test eye in addition to acting as the anterior window of the water filled inner chamber of the test eye. The corneal shell is made of contact lens grade polymethylmethacrylate (PMMA) with an aspheric anterior surface and a spherical posterior surface. The anterior convex surface has a central radius of curvature of 7,8 mm with a conic constant of – 0,10. The central thickness of the shell is 0,5 mm. The posterior concave surface is spherical with a radius of curvature of 7,22 mm. The main body has a recessed area into which a pupil/lens holding disk is inserted. It is threaded to allow a window assembly to be screwed onto it thereby creating an inner, watertight chamber. A second threaded portion on the main body is for the attachment of the C-mount adapter.

B.1.3 Pupil/lens holding disk

The pupil aperture diameter is 7 mm. The disk is flat on one side and has a recessed central area on the other side. The edge lip of the recessed area is designed to hold the haptic loops of an intraocular lens (IOL). The pupil/lens holding disk fits in the eye with the flat surface closest to the corneal shell thus creating the pupil in the natural position and at the right distance from the cornea. The back of the disk acts as a seal for the eye when the rear window assembly is screwed tightly against it.

B.1.4 Intraocular lens implant

This lens is held in the pupil lens holding disk either by the elastic force of the haptic loops or by an adhesive at the edges.

B.1.5 Rear window assembly

The rear window assembly has a transparent window made of 1 mm thick microscope slide glass cemented into a brass body that is screwed onto the rear of the main body.

B.1.6 C-mount adapter

This adapter allows the test eye to be attached to a CCD camera at the correct distance from the CCD array surface.