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Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 10939:2007), of which it constitutes a minor revision with the following changes:

— technical correction of inconsistency in Table 1, Item No. 9 "Slit image": "Parallelism of the sides (for a slit image of 0,2 mm × 8,0 mm)";

— update of the dated normative reference to IEC 60601-1:2005 to include the Amendment AMD1: 2012, where appropriate.

Ophthalmic instruments — Slit-lamp microscopes

1 Scope

This document, together with ISO 15004-1 and ISO 15004-2, specifies requirements and test methods for slit-lamp microscopes to provide slit illumination and observation under magnification of the eye and its adnexa.

This document is not applicable to microscope accessories, e.g. photographic equipment and lasers.

This document takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

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

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
slit-lamp microscope
instrument consisting of a microscope and a swivelling illumination system providing a slit image

3.2
magnification
ratio of the viewing angle of an object, when observed through a magnifying system with the image at infinity, to that of the object, when observed by the naked eye at a reference viewing distance of 250 mm

Note 1 to entry: The magnification, Γ, can be calculated using the following formula:

$$\Gamma = \frac{\tan \sigma'}{\tan \sigma}$$

where

σ' is the angle at which an object is seen through the microscope;

σ is the angle at which the same object is seen without any instrument at a viewing distance of 250 mm.

Note 2 to entry: The magnification of the microscope comprises the magnifications of the complete system.

3.3
high eye point eyepiece
eyepiece in which the exit pupil is of sufficient clearance from the eyepiece to allow spectacles to be worn

4 Requirements

4.1 General

The slit-lamp microscope shall conform to the requirements specified in ISO 15004-1 and ISO 15004-2.

The slit-lamp microscope shall conform to the requirements specified in 4.2, 4.3 and 4.4. Compliance with these requirements is verified by type testing.

4.2 Optical requirements

The slit-lamp microscope shall conform to the requirements given in Table 1. These requirements shall be verified by use of measuring devices whose measuring errors are smaller than 10 % of the smallest value to be determined.

Test results shall be evaluated in accordance with general rules of statistics.

Table 1 — Requirements for optical properties

No.	Criterion	Requirement
1	Permissible tolerance of microscope magnification (see 3.2)	±5 %
2	Difference in magnification between left and right observation systems	≤3 %

[a] With the eyepiece for which the slit-lamp microscope is designed.

[b] This requirement does not apply to those slit-lamp microscopes where, due to the design, the mechanical axes of the eyepieces are not parallel to each other.

[c] For explanation of criterion No. 5, see Figure 1.

[d] Depth of field, expressed in millimetres:

$$d = \frac{\lambda}{2N^2} \cdot 10^{-6} + \frac{1}{7\Gamma \cdot N}$$

where

N is the numerical aperture;

Γ is the total magnification of the microscope (see 3.2);

λ is the reference wavelength in accordance with ISO 7944, expressed in nanometres.

[e] x is a weighting factor.

Table 1 *(continued)*

3	Angular difference in axis between left and right optical systems[a]	Vertically	Interpupillary distance between 60 mm and 66 mm	≤10′
			Interpupillary distance between 55 mm and <60 mm and between >66 mm and 72 mm	≤15′
		Horizontally	Convergence[b]	≤45′
			Divergence	≤10′
4	Shift in the object plane by change in magnification			≤0,4 mm
5	Focus tolerance for illumination system with respect to the mechanical rotation axis[c]		Axial[c]	Δa = ± 0,5 mm
			Lateral[c]	$(\Delta a)_\alpha$ = ± 0,35 mm
6	Tolerance for foci planes of left and right observation systems (ΔR, ΔL) including all magnifications with respect to the focus of illumination system (slit image) in any position [d e]			$\Delta R, \Delta L \leq x \cdot d$ x =2
7	Focus difference between the left and right observation systems [d e]			$\Delta(R, L) \leq x \cdot d$ x =2
8	Eyepiece	Calibration error of dioptre scale		±0,25 D at zero on the dioptre scale
		Range for interpupillary distance adjustment		55 mm to 72 mm
		Adjustment range (minimum)		−5,00 D to +5,00 D
				−4,00 D to +2,00 D for high eye point eyepieces
		Difference in axial positions of the exit pupils between left and right observation systems		≤1,5 mm
9	Slit image	Minimum width		≤0,2 mm
		Maximum length		≥8,0 mm
		Parallelism of the sides (for a slit image 0,2 mm × 8,0 mm)		≤0,5°
		Maximum width		Equal to slit length

[a] With the eyepiece for which the slit-lamp microscope is designed.

[b] This requirement does not apply to those slit-lamp microscopes where, due to the design, the mechanical axes of the eyepieces are not parallel to each other.

[c] For explanation of criterion No. 5, see Figure 1.

[d] Depth of field, expressed in millimetres:

$$d = \frac{\lambda}{2N^2} \cdot 10^{-6} + \frac{1}{7\Gamma \cdot N}$$

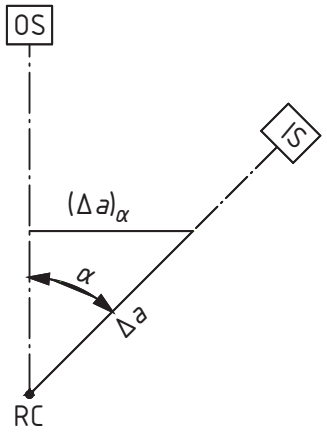
where

N is the numerical aperture;

Γ is the total magnification of the microscope (see 3.2);

λ is the reference wavelength in accordance with ISO 7944, expressed in nanometres.

[e] x is a weighting factor.



Key

$(\Delta a)_\alpha = \Delta a \sin\alpha$ for a rotational angle range up to $\alpha = 45°$

OS observation system

IS illumination system

RC rotational centre of OS and IS

Δa axial focus tolerance

Figure 1 — Explanation of criterion No. 5

4.3 Construction and function

4.3.1 General

The following requirements shall apply.

a) The parallel slit edges shall be smooth and free from any imperfections when observed using the highest magnification.

b) The slit image shall be evenly illuminated.

c) No contrast decrease in the slit image caused by reflections or scattered light shall be observed.

d) The brightness and colour transmission of the left and right optical systems shall be identical.

e) At the highest magnification, the resolving power in the centre of the field shall be at least 1 800 *N*.

Compliance with these requirements is checked by observation.

4.3.2 High eye point eyepiece

If the manufacturer states that the eyepiece is a high eye point eyepiece, the distance between the exit pupil of the observation system and the nearest part of the eyepiece shall be not less than 17 mm.

4.4 Optical radiation hazard with slit-lamp microscopes

This subclause replaces IEC 60601-1:2005 + AMD1:2012, 10.4, 10.5, 10.6 and 10.7.

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

It shall first be determined if the slit-lamp microscope is classified as a Group 1 or Group 2 instrument in accordance with ISO 15004-2:2007, Clause 4. The applicable clauses of ISO 15004-2 for slit-lamp microscopes are as follows:

a) for Group 1 slit-lamp microscopes:

   1) applicable requirements of ISO 15004-2:2007 are 5.1, 5.2 and 5.4;

   2) applicable test methods of ISO 15004-2:2007 are 6.1, 6.2, and 6.4;

   3) if status is determined to be Group 1, there are no further requirements; if status is determined not to be Group 1, the additional requirements given in b) are applicable;

b) for Group 2 slit-lamp microscopes:

   1) applicable requirements of ISO 15004-2:2007 are 5.1, 5.3 and 5.5;

   2) applicable test methods of ISO 15004-2:2007 are 6.1, 6.2, 6.3, 6.4, and 6.5;

   3) ISO 15004-2:2007, Clause 7, also applies.

If the intended use of the slit-lamp microscope includes the use of supplementary 90 D lenses, an arrangement shall be made for measurement of corneal and lenticular related exposure values. The 90 D lens (e.g. Volk lens) shall be at a position 7 mm behind the focus plane of the slit lamp with the maximum illumination field. The exposure measurement then is to arrange 7 mm behind the 90 D lens on the spot of the minimum size of the illumination field.

5 Accompanying documents

The slit-lamp microscope shall be accompanied by documents containing instructions for use. In particular, this information shall contain:

a) the name and address of the manufacturer;

b) if appropriate, a statement that the slit-lamp microscope in its original packaging conforms to the transport conditions as specified in ISO 15004-1;

c) any additional documents as specified in IEC 60601-1:2005 + AMD1:2012, 7.9;

d) a reference to this document, i.e. ISO 10939:2017, if the manufacturer or supplier claims compliance with it.

6 Marking

The slit-lamp microscope shall be permanently marked with at least the following information:

a) the name and address of the manufacturer or supplier;

b) the name and model of the slit-lamp microscope;

c) marking as required by IEC 60601-1:2005 + AMD1:2012.