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Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente

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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.

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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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.

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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:

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

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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.

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