INTERNATIONAL STANDARD

ISO 10936-1

Second edition
2017-08

Optics and photonics — Operation microscopes —

Part 1: Requirements and test methods

Optique et photonique — Microscopes chirurgicaux —

Partie 1: Exigences et méthodes d'essai

Reference number
ISO 10936-1:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 5, *Microscopes and endoscopes*.

This second edition cancels and replaces the first edition (ISO 10936-1:2000), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the normative references and the title have been updated;

— note from environmental conditions (4.3) has been removed;

— safety requirements (4.4) have been updated;

— the requirement depths of field and total visual magnification (see Table 1) have been clarified.

A list of all parts in the ISO 10936 series can be found on the ISO website.

Optics and photonics — Operation microscopes —

Part 1: Requirements and test methods

1 Scope

This document specifies requirements and refers to test methods for operation microscopes used for observation during surgical operation and treatment of patients.

It does not apply to accessories, e.g. photographic cameras.

NOTE Specific requirements with regard to optical radiation hazards from operation microscopes used in ocular surgery are given in ISO 10936-2.

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 7944, *Optics and optical instruments — Reference wavelengths*

ISO 8039, *Microscopes — Values, tolerances and symbols for magnification*

ISO 9022 (all parts), *Optics and photonics — Environmental test methods*

ISO 10934 (all parts), *Optics and optical instruments — Vocabulary for microscopy*

ISO 15227, *Optics and optical instruments — Microscopes — Testing of stereomicroscopes*

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 8039, ISO 10934 (all parts) and the following 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
operation microscope
stereomicroscope used for observation of surgical and other medical procedures, consisting of an illumination system and an observation system, including objective lens, variable or fixed power optical system, observation tube and eyepieces

EXAMPLE Colposcopes.

4 Requirements

4.1 General

The operation microscope shall conform to the requirements in 4.2, 4.3 and 4.4.

All requirements given below are minimum requirements. They apply to the reference wavelength according to ISO 7944.

4.2 Optical and mechanical requirements

The requirements in Table 1 apply.

Testing of optical and mechanical requirements shall be carried out in accordance with 5.2.

4.3 Environmental conditions

The operation microscope shall conform to the environmental requirements given in IEC 60601-1.

4.4 Safety

The requirements of IEC 60601-1 shall apply.

5 Test methods

5.1 General

All tests specified in this document are type tests.

5.2 Checking the optical and mechanical specifications

The requirements in 4.2 shall be checked with measuring devices the measuring uncertainty of which shall be smaller than 10 % of the value to be determined in accordance with ISO 15227.

Measurements shall be carried out in accordance with general rules of statistical evaluation.

5.3 Checking the environmental conditions

Testing of environmental conditions shall be carried out in accordance with ISO 9022 (all parts).

5.4 Checking the safety

Testing of safety shall be carried out in accordance with IEC 60601-1.

6 Marking

The operation microscope shall be permanently marked with at least the markings according to IEC 60601-1.

Table 1 — Requirements for optical and mechanical specifications

Criterion			Requirement
Tolerance of total magnification			± 7,5 %
Difference in magnification between left and right optical systems			≤ 1,5 %
Difference in axis between left and right optical systems[b]	vertical		≤ 15’
	horizontal[a]	convergence	≤ 45’
		divergence	≤ 10’
Shift of focusing planes by magnification change		axial object plane	$S_0 \leq 3 \cdot D_F$ [c,d]
Focus difference between left and right optical systems			$D_{L/R} \leq 1{,}5 \cdot D_F$ [c]
At highest magnification the resolving power in the centre of the field should be a minimum of			$1\,800 \cdot NA$ line pairs/mm
Difference in imaging rotation between right and left images			≤ 2°
Eyepiece	difference in exit pupil height between left and right optical systems		≤ 1,5 mm at 0 D on the dioptre scale
	calibration error of a dioptre scale, if used		±0,25 D at 0 D on the dioptre scale
	minimum range for interpupillary distance		55 mm to 75 mm
	minimum adjustment range	general	+5 D to –5 D
		high eye point	+2 D to –4 D

a This requirement does not apply to those operation microscopes where the mechanical axes of the eyepieces are not parallel to each other due to the design.

b Including a 10 × eyepiece at 0 D adjustment.

c The admissible axial shift of the focusing plane is determined by:

$$D_F = \frac{\lambda}{2 \cdot NA^2} + \frac{1}{7 \cdot M_{TOTVIS} \cdot NA}$$

where

D_F is the depth of field, in millimetres;

M_{TOTVIS} is the total visual magnification;

λ is the wavelength, in millimetres;

NA is the numerical aperture.

The second part of this equation is based on the resolution of the eye of 2’.

d S_0 is the shift of object plane, in millimetres.

Bibliography

[1] ISO 10936-2, *Optics and photonics — Operation microscopes — Part 2: Light hazard from operation microscopes used in ocular surgery*

[2] ISO 11883, *Optics and optical instruments — Microscopes — Marking of stereomicroscopes*