BRITISH STANDARD

BS ISO
10936-1:2000

Optics and optical instruments — Operation microscopes —

Part 1: Requirements and test methods

ICS 11.040.99

National foreword

This British Standard reproduces verbatim ISO 10936-1:2000 and implements it as the UK national standard.

The UK participation in its preparation was entrusted to Technical Committee LBI/33, Microscopes, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

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Summary of pages

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Optics and optical instruments — Operation microscopes —

Part 1: Requirements and test methods

Optique et instruments d'optique — Microscopes chirurgicaux —

Partie 1: Exigences et méthodes d'essai

Reference number
ISO 10936-1:2000(E)

Foreword

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International Standard ISO 10936-1 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 5, *Microscopes and endoscopes*.

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

— *Part 1: Requirements and test methods*

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

Optics and optical instruments — Operation microscopes —

Part 1: Requirements and test methods

1 Scope

This part of ISO 10936 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 normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10936. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10936 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 7944:1998, *Optics and optical instruments — Reference wavelengths.*

ISO 8039:1997, *Optics and optical instruments — Microscopes — Magnification*.

ISO 9022 (all parts), *Optics and optical instruments — Environmental test methods*.

ISO 10934 (all parts)[1)], *Optics and optical instruments — Vocabulary for microscopy*.

ISO 11883:1997, *Optics and optical instruments — Microscopes — Marking of stereomicroscopes*.

ISO 15227:2000, *Optics and optical instruments — Microscopes — Testing of stereomicroscopes*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety* (including Amendment 1:1991 and Amendment 2:1995.

IEC 60601-2-22:1995, *Medical electrical equipment — Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment*.

[1)] To be published.

3 Terms and definitions

For the purposes of this part of ISO 10936, the terms and definitions given in ISO 8039 and ISO 10934 and the following apply.

3.1
operation microscope
stereomicroscope used for observation of surgical and other medical procedures, consisting of an optical system of observation, including objective lens, variable or fixed power optical system, observation tube and eyepieces

EXAMPLE Colposcopes

4 Requirements

4.1 General

The operation microscope shall comply with the requirements given in 4.2 to 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 given 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 comply with the environmental requirements given in IEC 60601-1.

NOTE The test requirements given in ISO 10109-6 do not apply.

4.4 Safety

The requirements of IEC 60601-1 shall apply, with the following modification: 42.1 of IEC 60601-1 shall not apply.

5 Test methods

5.1 General

All tests specified in this part of ISO 10936 are type tests.

5.2 Checking the optical and mechanical specifications

The requirements according to 4.2 shall be checked with measuring devices the measuring error 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.

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	$S_0 \leqslant 3 \cdot D_F$ [c, d]
Focus difference between left and right optical systems			$D_{L/R} \leqslant 1{,}5 \cdot D_F$ [c]
At highest magnification the resolving power in the centre of the field should be a minimum of			1800 · 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:

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

where

D_F is the depth of field of lens, in millimetres;
$M_{TOT\ VIS}$ is the total visual magnification (highest value);
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.

Bibliography

[1] ISO 10109-6:1994, *Optics and optical instruments — Environmental requirements — Part 6: Test requirements for medical optical devices*

[2] ISO 10936-2:—[2)], *Optics and optical instruments — Operation microscopes — Part 2: Light hazard from operation microscopes used in ocular surgery.*

2) To be published.

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