INTERNATIONAL STANDARD

ISO 10939

First edition
1998-07-15

Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente

Reference number
ISO 10939:1998(E)

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.

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.

International Standard ISO 10939 was prepared by Techncial Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Ophthalmic instruments — Slit-lamp microscopes

1 Scope

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

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

This International Standard takes precedence over ISO 15004, if differences exist.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

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 The magnification, Γ, can be calculated using the following equation:

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

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 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.

4.2 Optical requirements

The slit-lamp microscope shall conform to the requirements given in table 1. These requirements are verified as described in 5.1.

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 %
3	Difference in axis betweeen left and right optical systems [1]	Vertical	Interpupillary distance between 60 mm and 66 mm	≤ 10'
		Vertical	Interpupillary distance between 55 mm and < 60 mm and between > 66 mm and 72 mm	≤ 15'
		Horizontal	Convergence [2]	≤ 45'
		Horizontal	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 [3]	Axial [3]		Δa = ± 0,5 mm
		Lateral [3]		$(\Delta a)_\alpha$ = ± 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			ΔR, $\Delta L \leq x \cdot d$ [4] $x = 2$ [5]
7	Focus difference between the left and right observation systems			$\Delta(R, L) \leq x \cdot d$ [4] $x = 2$ [5]
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
		Minimum length		≥ 8,0 mm
		Parallelism of the sides (for a slit image 0,2 mm x 0,8 mm)		≤ 0,5°
		Maximum width		Equal to slit length

Table 1 (concluded)

1) With the eyepiece for which the slit-lamp microscope is designed.

2) 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.

3) Explanation to criterion No. 5 (see also figure 1).

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

OS is the observation system;
IS is the illumination system;
RC is the rotational centre of OS and IS;
Δa is the axial focus tolerance.

4) 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 according to ISO 7944, expressed in nanometres.

5) x is a weighting factor.

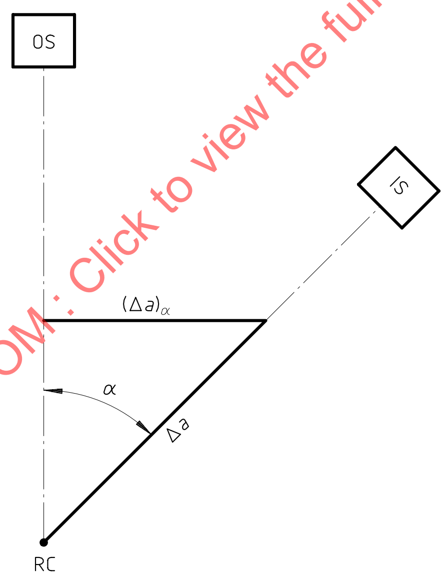

Figure 1 — Explanation to criterion No. 5

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 $1800 \cdot N$ line pairs/mm.

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

4.4.1 General

This clause replaces clauses 32, 33 and 34 of IEC 60601-1:1988.

The limit values given in items a) and b) of 4.4.2 shall apply to the radiation emerging from the slit-lamp microscope used to illuminate and view the human eye with visible light (380 nm to 700 nm) and in which the full beam homogeneously illuminates a circular pupil of 8 mm diameter (see notes 1 and 2 of 4.4.2).

NOTE The limit values given in 4.4.2 are considered acceptable with respect to the risks when weighted against the performances intended.

4.4.2 Limit values

a) Short wavelength limit:

The amount of radiant power exiting the slit-lamp microscope in the portion of the spectrum from 305 nm to 400 nm shall have an irradiance no greater than 0,22 mW/cm^2 as measured in the corneal plane when the slit-lamp microscope is operating at maximum intensity [1] and, if the aperture can be varied, at maximum aperture.

b) Long wavelength limit:

The amount of energy exiting the slit-lamp microscope in the wavelength range 700 nm to 1100 nm shall not exceed 100 mW/cm^2 nor shall it exceed the amount of energy exiting the slit-lamp microscope in the range between 380 nm and 700 nm. The energy shall be measured in the corneal plane when the slit-lamp microscope is operating at maximum intensity and maximum aperture.

NOTE 1 If due to stops or other obstructions of the beam, a circular pupil of less than 8 mm diameter is illuminated, the limit values may be increased by the ratio of the area of an 8 mm pupil divided by the true area illuminated.

NOTE 2 It is recommended that the energy in the range of the spectrum below 420 nm be attenuated as much as possible.

NOTE 3 For slit-lamp microscopes with non-pulsed radiation, the assumptions used to set the limit value for radiation shorter in wavelength than 400 nm are based on considerations of the typical spectral distribution of a 3000 K standard black body source, an illuminating solid angle at the corneal plane of 0,031 sr, a maximum exposure time of 5 min and the weighting factors for L_A (see annex A).

1) Maximum intensity is the highest brightness the slit-lamp microscope is capable of delivering, including the highest intensity achievable if overvoltage is provided.

The limit is set to ensure that the fraction of the photochemical hazard dose due to radiation shorter in wavelength than 400 nm is no greater than 1/8 of the total photochemical hazard dose over all wavelengths when that total dose is at the threshold limit for an 8 mm diameter pupil.

Using the American Conference of Governmental Industrial Hygienists (ACGIH) guidelines, that threshold limit is 14 J/(cm² · sr). To convert from photochemical hazard weighted radiance to irradiance, over the designated spectral range 305 nm to 400 nm, the conversion factor 0,276 is used. Thus the limit is then found by the formula

$$[14\ \text{J/(cm}^2 \cdot \text{sr)}] \times (0{,}031\ \text{sr}) \times [0{,}276/(300\text{s} \cdot 8)] = 0{,}05\ \text{mW/cm}^2$$

However, several of the assumptions used in determining the 0,05 mW/cm² limit are not valid for slit-lamp microscopes:

i) the pupil of the eye, assumed to have a diameter of 8 mm, is no longer the limiting stop in the system;

ii) the assumed solid angle subtended by the source at the retina of 0,173 9, based on an 8 mm pupil and used to create the ISO 15004 hazard weighting values, is no longer the effective solid angle experienced by the retina under the direct viewing situation of the slit-lamp microscope (the most hazardous condition);

iii) the solid angle of the source in the corneal plane assumed in the development of the 0,05 mW/cm² limit of 0,031 sr needs to be replaced by the actual solid angle subtended by the slit lamp exit aperture in the focal plane of the slit-lamp microscope.

Therefore, based on a cut-off of the UV radiation below 370 mm, the limit for radiation between 305 nm and 400 nm can be increased to 0,22 mW/cm².

4.4.3 Variable brightness

For slit-lamp microscopes where provision is made to vary the brightness, the manufacturer shall provide indications of the proportions of the maximum intensity.

4.4.4 Particular information

The manufacturer shall provide the user with a graph showing the relative spectral output of the slit-lamp microscope between 305 nm and 1100 nm when the instrument is operating at maximum light intensity and maximum aperture. The spectral output shall be shown for the beam after it exits the illumination system.

The manufacturer shall provide the user with the values for the spectrally-weighted photochemical source radiance, both phakic (L_B) and aphakic (L_A), measured in the beam exiting from the instrument when operating at maximum intensity and maximum aperture and determined by using the spectral weighting values given in Annex A.

The manufacturer shall provide information on the meaning of L_B and L_A to the user.

NOTE An example of such information is given in Annex B.

5 Test methods

All tests described in this International Standard are type tests.

5.1 Checking the optical requirements

The requirements specified in 4.2 shall be verified by use of measuring devices the measuring errors of which are smaller than 10 % of the smallest value to be determined.

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

5.2 Checking optical radiation safety for slit-lamp microscopes

5.2.1 Determination of spectral irradiance

Spectral irradiance shall be measured with an uncertainty of less than ±30% at regular intervals over the effective portion of the spectrum. For aphakic photochemical hazard (L_A), the effective portion is 305 nm to 700 nm. For phakic photochemical hazard (L_B), the effective portion is 380 nm to 700 nm.

NOTE The intervals for spectral irradiance measurement should be centred on the values given in Annex A with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement unit is milliwatts per square centimetre per nanometre [mW/(cm^2 · nm)]. This value should be recorded and, after being multiplied by the bandwidth, recorded as milliwatts per square centimetre (mW/cm^2) for that interval (see also Annex B).

5.2.2 Determination of irradiance

Irradiance shall be measured with an uncertainty of less than ± 30 % over the effective portions of the spectrum. For the short wavelength limit, the effective portion of the spectrum is from 305 nm to 400 nm. For the long wavelength limits, the effective portions of the spectrum are from 380 nm to 700 nm and 700 nm to 1100 nm.

NOTE A spectroradiometer can be used to make these measurements.

5.2.3 Determination of beam cross-section

When determining the area of the beam cross-section which is required for several caculations, the measuring method used shall be capable of an accuracy of ± 30 % (see B.2).

NOTE For irregular cross-sections, it may be appropriate to measure the area by exposing a piece of film and then measuring the area on the negative.

6 Accompanying documents

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

a) name and address of the manufacturer;

b) instructions for effective disinfection of the slit-lamp microscope, with particular reference to the disinfection of instruments to be returned to the manufacturer for repair and maintenance;

c) the information specified in 4.4.4;

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

e) any additional documents as specified in 6.8 of IEC 60601-1:1988.

7 Marking

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

a) name and address of manufacturer or supplier;

b) name and model of slit-lamp microscope;

c) marking as required by IEC 60601-1:1988;

d) a reference to this International Standard ISO 10939, if the manufacturer or supplier claims compliance with it.

Annex A
(normative)

Optical radiation hazard

A.1 Spectral weighting functions for retinal hazard analysis

Table A.1 gives spectral weighting functions for retinal hazard analysis

A.2 Determination of spectrally weighted source radiance

If spectral radiance $L_\lambda(\lambda)$ can only be measured relatively, but the total source radiance L can be measured absolutely, the following equation determines the spectrally-weighted photochemical aphakic source radiance L_A.

$$L_A = \frac{\sum_{305}^{700} L_\lambda(\lambda) \cdot A(\lambda) \cdot \Delta\lambda}{\sum_{305}^{700} L_\lambda(\lambda) \cdot \Delta\lambda} \cdot L \qquad \text{(A.1)}$$

If spectral radiance $L_\lambda(\lambda)$ can only be measured relatively, but the total source radiance L can be measured absolutely, the following equation determines the spectrally-weighted photochemical phakic source radiance L_B.

$$L_B = \frac{\sum_{380}^{700} L_\lambda(\lambda) \cdot B(\lambda) \cdot \Delta\lambda}{\sum_{380}^{700} L_\lambda(\lambda) \cdot \Delta\lambda} \cdot L \qquad \text{(A.2)}$$

NOTE $\Delta\lambda$ should be taken as 5 nm or 10 nm

Table A.1

Wavelength λ nm	Photochemical (blue-light) hazard function, B_λ	Photochemical aphakic hazard function, A_λ
305 to 335	-	6,00
340	-	5,88
345	-	5,71
350	-	5,46
355	-	5,22
360	-	4,62
365	-	4,29
370	-	3,75
375	-	3,56
380	0,006	3,19
385	0,012	2,31
390	0,025	1,88
395	0,050	1,58
400	0,10	1,43
405	0,20	1,30
410	0,40	1,25
415	0,80	1,20
420	0,90	1,15
425	0,95	1,11
430	0,98	1,07
435	1,00	1,03
440	1,00	1,00
445	0,97	0,97
450	0,94	0,94
455	0,90	0,90
460	0,80	0,80
465	0,70	0,70
470	0,62	0,62
475	0,55	0,55
480	0,45	0,45
485	0,40	0,40
490	0,22	0,22
495	0,16	0,16
500	0,10	0,10
510	0,063	0,063
520	0,040	0,043
530	0,025	0,025
540	0,016	0,016
550	0,010	0,010
560	0,006	0,006
570	0,004	0,004
580	0,002	0,002
590	0,001	0,001
600	0,001	0,001
610	0,001	0,001
620	0,001	0,001
630	0,001	0,001
640	0,001	0,001
650	0,001	0,001
660	0,001	0,001
670	0,001	0,001
680	0,001	0,001
690	0,001	0,001
700	-	-

Annex B
(informative)

Photometric measures

B.1 Radiance

The radiance L is given by the equation:

$$L = \frac{d^2\Phi}{d\Omega \cdot dA \cdot \cos\Theta} \qquad \text{(B.1)}$$

where

Θ is the angle between the normal to the element of the source surface and the direction of observation;

$d\Phi$ is the radiant flux leaving an element of the surface, expressed in milliwatts;

$d\Omega$ is the solid angle of an elementary cone containing the given direction, expressed in steradians;

dA is the element of the area of the radiant surface, expressed in square centimetres.

B.2 Example for determination of radiance

To find radiance L from irradiance measurement, the solid angle Ω subtended by the light source LS at the point of measurement has to be determined. This can be done by placing an aperture of known size which is much smaller than the beam size in the light beam at the measurement cross-section and measuring the area A of the beam passing through this field stop FS at a known distance z from the aperture (see figure B.1). The solid angle is then calculated approximately from the equation:

$$\Omega = \frac{A}{z^2} \qquad \text{(B.2)}$$

As the solid angle of the source will be the same for all wavelengths in general, the conversion from irradiance by dividing by the solid angle can be done as a final step in the total procedure.