INTERNATIONAL STANDARD

ISO 10943

First edition
1998-05-01

Ophthalmic instruments — Indirect ophthalmoscopes

Instruments ophtalmiques — Ophtalmoscopes indirects

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 10943 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 central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

Ophthalmic instruments — Indirect ophthalmoscopes

1 Scope

This International Standard, together with ISO 15004, specifies minimum requirements and test methods for hand-held, spectacle-type, and head-worn indirect ophthalmoscopes for observing indirect images of the eye fundus.

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

This International Standard is not applicable to condensing lenses used for indirect ophthalmoscopy or to accessories.

This International Standard is not applicable to table-mounted instruments such as Gullstrand ophthalmoscopes and their derivatives, nor to ophthalmoscopes primarily intended for image capture and/or processing such as those based on scanning laser techniques.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standards. 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 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods*

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

3 Définitions

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

3.1
indirect ophthalmoscope
optical instrument used with a condensing lens (hand-held or integral) to examine the eye, particularly the media and the fundus, by producing a real intermediate image which is viewed by the observer

3.2
monocular indirect ophthalmoscope
monocular ophthalmoscope which provides an illumination system and which is used with a condensing lens (hand-held or integral) in order to direct appropriately focused light into the patient's eye

NOTE - Such instruments may include corrective lenses or eyepieces to aid focusing by the observer of the real intermediate image produced by the condensing lens.

3.3
binocular indirect ophthalmoscope
binocular ophthalmoscope which provides an illumination system and which is used with a condensing lens in order to direct appropriately focused light into the patient's eye

NOTE 1 Such instruments also include a viewing system which allows the observer to examine the patient's retina by binocularly viewing the real intermediate image produced by the condensing lens.

NOTE 2 Such instruments may include corrective lenses or eyepieces to aid focusing of this image which is viewed by the observer.

3.4
condensing lens
plus-power lens used to condense the illuminating beam into the patient’s eye and to form a real inverted image of the retina thus illuminated

4 Requirements

4.1 General

The indirect ophthalmoscope shall conform to the requirements specified in ISO 15004.

The indirect ophthalmoscope shall conform to the specific requirements described in 4.2 to 4.4.

These requirements are verified as described in clause 5.

4.2 Optical and dimensional requirements

The requirements specified in table 1 and table 2 shall apply.

Table 1 — Optical and dimensional requirements where applicable

Criterion	Requirement
Interpupillary distance range	55 mm to 72 mm
Diameter 2r of the field of view [1) 2)]	≥ 100 mm
Diameter of largest illuminated spot [1)]	≤ 45 mm
Range of adjustment of headband size	520 mm to 640 mm

1) At 500 mm distance from the light exit.

2)

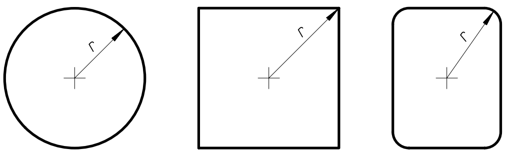

Table 2 — Requirements for optical accuracy where applicable

Criterion			Tolerance
Difference in axes' orientation between left and right optical systems	Vertical	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'
	Horizontal	Divergence in parallel systems	≤ 10'
		Convergence in parallel systems; in convergent systems deviation from the indicated angle	≤ 45'
Difference in magnification between left and right systems, where provided			≤ 5 %
Specified power of eyepieces or lenses where provided			± 0,09 D

4.3 Construction and function

4.3.1 The light output of the indirect ophthalmoscope shall be at least adjustable between the maximum and 10 % of the maximum.

4.3.2 The illuminance without a condensing lens and without filters at 500 mm distance from the exit aperture of the indirect ophthalmoscope shall be not less than 200 lx. Instruments with an integral condensing lens shall have equivalent illuminance.

4.3.3 No reflections or scattered light shall be visible.

4.3.4 The illumination system shall be capable of alignment with the viewing system to within 1° vertically.

4.3.5 No difference in brightness or colour between the left and right optical system shall be visible.

4.4 Optical radiation hazard with indirect ophthalmoscopes

4.4.1 General

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

4.4.2 Limit values

The limit values given in items a) and b) shall apply to the radiation emerging from the indirect ophthalmoscope used to illuminate and view the human eye with light from 380 nm to 700 nm and in which the full beam homogeneously illuminates a circular pupil of 8 mm (see notes 2 and 5).

NOTE 1 The limit values are considered acceptable with respect to the risks when weighted against the performances intended.

a) Short wavelength limit: The amount of radiant power exiting the indirect ophthalmoscope in the portion of the spectrum from 305 nm to 400 nm shall have an irradiance no greater than 0,05 mW/cm^2 as measured in the corneal plane when the instrument 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 indirect ophthalmoscope 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 indirect ophthalmoscope in the range between 380 nm and 700 nm. The energy shall be measured in the corneal plane when the instrument is operating at maximum intensity and maximum aperture.

NOTE 2 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 diameter pupil divided by the true area illuminated.

NOTE 3 It is recommended that the energy in the range of the spectrum below 420 nm be attenuated as much as possible.

NOTE 4 For indirect ophthalmoscopes with a large illuminating solid angle Ω over the designated spectral range 305 nm to 400 nm, i.e. $\Omega > 0{,}031$ sr, the limit values may be increased by the ratio of the true solid angle, expressed in steradians, divided by 0,031.

NOTE 5 For indirect ophthalmoscopes the assumptions used to set the limit value for radiation of wavelength shorter 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). The limit is set to ensure that the fraction of the photochemical hazard dose due to radiation of wavelength shorter 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 14J/(cm^2 · 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

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

4.4.3 Variable brightness

For indirect ophthalmoscopes where provision is made to vary the brightness, the manufacturer shall provide indications for the proportion 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 indirect ophthalmoscope 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 instrument.

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 C.

1) Maximum intensity is the highest brightness the indirect ophthalmoscope is capable of delivering, including the highest brightness achievable if overvoltage is provided.

5 Test methods

All tests described in this International Standard are type tests.

5.1 Checking the optical, mechanical and functional requirements

5.1.1 The requirements specified in 4.2 and 4.3 shall be verified by use of measuring devices with accuracy better than 10 % of the smallest value to be determined.

Measurements shall be carried out according to the general rules of statistical evaluation.

5.1.2 The requirements described in 4.3.3 and 4.3.5 shall be checked by observation.

5.2 Checking optical radiation safety for indirect ophthalmoscopes

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/(cm² · nm)]. This value should be recorded and, after being multiplied by the bandwidth, recorded as milliwatts per square centimetre (mW/cm²) 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 from 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 calculations, 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 indirect ophthalmoscope 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 indirect ophthalmoscope, 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 indirect ophthalmoscope 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;

f) a reference to this International Standard, i.e. ISO 10943, if the manufacturer or supplier claims compliance with it.

7 Marking

The indirect ophthalmoscope shall be permanently marked with at least the following information:

a) name of manufacturer or supplier;

b) name and model of indirect ophthalmoscope;

c) marking as required by IEC 60601-1.

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.