INTERNATIONAL STANDARD

ISO 10942

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Ophthalmic instruments — Direct ophthalmoscopes

Instruments ophtalmiques — Ophtalmoscopes directs

Foreword

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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 10942 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
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Ophthalmic instruments — Direct ophthalmoscopes

1 Scope

This International Standard, together with ISO 15004, specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus.

This International Standard takes precedence over the 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 15004:1997 *Ophthalmic instruments - Fundamental requirements and test methods*

IEC 60601-1:1988 *Medical eletrical equipment - Part 1: General requirements for safety*

3 Definitions

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

3.1
ophthalmoscope
optical instrument used to examine the external and internal parts of the eye, particularly the media and the fundus

3.2
direct ophthalmoscope
ophthalmoscope which provides an illuminating system, a viewing system and corrective lenses which allow the observer to view the patient's eye directly, that is without the formation of an intermediate image

3.3
viewing lens
lens which is positioned between the observer's eye(s) and the eye to be examined in order to achieve optimum focus, i.e. to correct for patient's and/or observer's refractive error and/or accommodation

NOTE - In direct ophthalmoscopes when a selection of such lenses is required, these are integrated with or mounted in a disc or other mechanical means by which the user may easily position the lens of choice centrally in the visual path.

3.4
auxiliary lens
additional corrective lens to facilitate access to higher refractive powers without requiring an excessive numbers of lenses

NOTE - Auxiliary lenses are normally integral with or mounted on a separate disc or other mechanical means and when required are used in conjunction with the viewing lenses.

3.5
ophthalmoscope graticule
pattern or target or graticule which can be optionally positioned in the illuminating light path within the instrument and which will be imaged on the retina for diagnostic, measurement or therapeutic purposes

NOTE - These can be fixed or focusable.

3.6
illuminating system
light source and associated lenses, mirrors and/or prism which serve to provide and project light into or onto the patient's eye

3.7
viewing system
those lenses and apertures which enable the observer to examine the patient's eye

3.8
field of view
angular field which is visible to a user when the entrance pupil is 12 mm behind the back surface of the ophthalmoscope, measured from the centre of the entrance pupil

See 6.1.3 and figure 1.

3.9
field of illumination
angular field which is illuminated and which is measured with its apex positioned at the image of the light source

4 Classification

Direct ophthalmoscopes shall be classified as follows:

Group A: Direct ophthalmoscopes that comply with all the requirements of this International Standard.

Group B: Direct opthalmoscopes that comply with the reduced requirements specified in table 1 and all other requirements specified in this International Standard except those in 5.4.2 and 5.4.4.

5 Requirements

5.1 General

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

The direct ophthalmoscope shall conform to the specific requirements specified in 5.2 to 5.5.

These requirements are verified as specified in clause 6.

5.2 Optical requirements

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

Table 1 — Requirements for optical specifications

Criterion	Requirements	
	Group A	Group B
Steps for the powers of viewing lenses	0, +1, +2, +3, +4, +6, +8, +10, +15, +20 D -1, -2, -3, -4, -6, -8, -10, -15, -20 D	10 steps in the range +10 D to 0 D to -10 D
Angle of field of view φ	≥ 6°	≥ 5°
Angle of field of illumination	≥ 9°	≥ 7°
Minimum diameter of the viewing system	3 mm	2,5 mm

Table 2 — Requirements for optical accuracy

Criterion		Tolerance
Accuracy of combined refractive power	0 D to +3 D 0 D to -3 D	± 0,37 D
	> +3 D to +10 D < 3 D to -10 D	± 0,50 D
	> +10 D to +15 D < -10 D to -15 D	± 0,75 D
	> +15 D < -15 D	± 1,00 D
Lens centration	0 D to +10 D 0 D to -10 D	1,0 mm
	> +10 D < -10 D	0,5 mm

5.3 Construction and function of the viewing system

5.3.1 The viewing lenses shall be arranged so that, as viewed from the operator's side:

a) increments of positive power, indicated by black or green figures, increase when the disc is turned clockwise;

b) increments of negative power, indicated by red figures, increase when the disc is turned anticlockwise.

5.3.2 The viewing lens control shall be provided with indexing stops for each lens power.

5.3.3 Left-hand and right-hand operation of the viewing lens control shall be possible.

5.4 Construction and function of the illumination system

5.4.1 The illuminating system shall be achromatic and provide uniform illumination of the fundus.

5.4.2 The intensity of the illuminating system of group A direct ophthalmoscopes shall be adjustable at least between the maximum and 10 % of the maximum.

5.4.3 The illuminance without filters at 200 mm distance from the exit aperture of the direct ophthalmoscope shall be not less than 150 lx.

5.4.4 Group A direct ophthalmoscopes shall have a minimum of two aperture stops in the illuminating system. These shall be a full aperture and a reduced aperture to facilitate viewing of the macula. Additionally a red-free filter shall be included.

NOTE - Other filters, apertures, fixation graticules, slits or half-circles are optional.

5.5 Optical radiation hazard with direct ophthalmoscopes

5.5.1 General

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

5.5.2 Limit values

The limit values given in items a) and b) shall apply to the radiation emerging from the direct 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 diameter (see notes 2 and 5).

NOTE 1 These 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 direct 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.

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

b) Long wavelength limit:

The amount of energy exiting the direct 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 direct 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 to 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 direct 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 direct 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 14 J/(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

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

5.5.3 Variable brightness

For direct ophthalmoscopes where provision is made to vary the brightness, the manufacturer shall provide indications for the proportion of the maximum intensity.

5.5.4 Particular information

The manufacturer shall provide the user with a graph showing the relative spectral output of the direct opthalmoscope 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 povide information on the meaning of L_B and L_A to the user.

NOTE - An example of such information is given in Annex C.

6 Test methods

All tests described in this International Standard are type tests.

6.1 Checking the optical and functional requirements

6.1.1 The requirements specified in 5.2 shall be verified by the 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.

NOTE - For measuring the refractive power according to table 2 the use of a focimeter in accordance with ISO 8598 [2] is recommended.

6.1.2 The requirements described in 5.3 and 5.4.1 shall be checked by observation.

6.1.3 For measuring the field of view, place the direct ophthalmoscope so that the back surface of the instrument is 12 mm in front of a pin-hole illuminated by a noncollimated light source.

It is essential that the divergent angle of the light source exceed the minimum angle of field-of-view specified in table 1.

Project the light patch onto a screen at a distance l (expressed in millimetres) from the pin-hole (see figure 1). Measure the diameter d (expressed in millimetres) of the fully illuminated, central core of the patch, disregarding the vignetted rim.

For the purposes of this measurement, use a 0,2 mm diameter pin-hole and calculate the angle of field-of-view, φ, from the expression:

$$\varphi = 2 \tan^{-1}[(d - 0{,}2) / 2\,l\,]$$

NOTE - If the projected light patch has a shape other than circular, the diameter of the smallest circle which will circumscribe the projected light patch is taken as the diameter d.

6.2 Checking optical radiation safety for direct ophthalmoscopes

6.2.1 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).

6.2.2 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.

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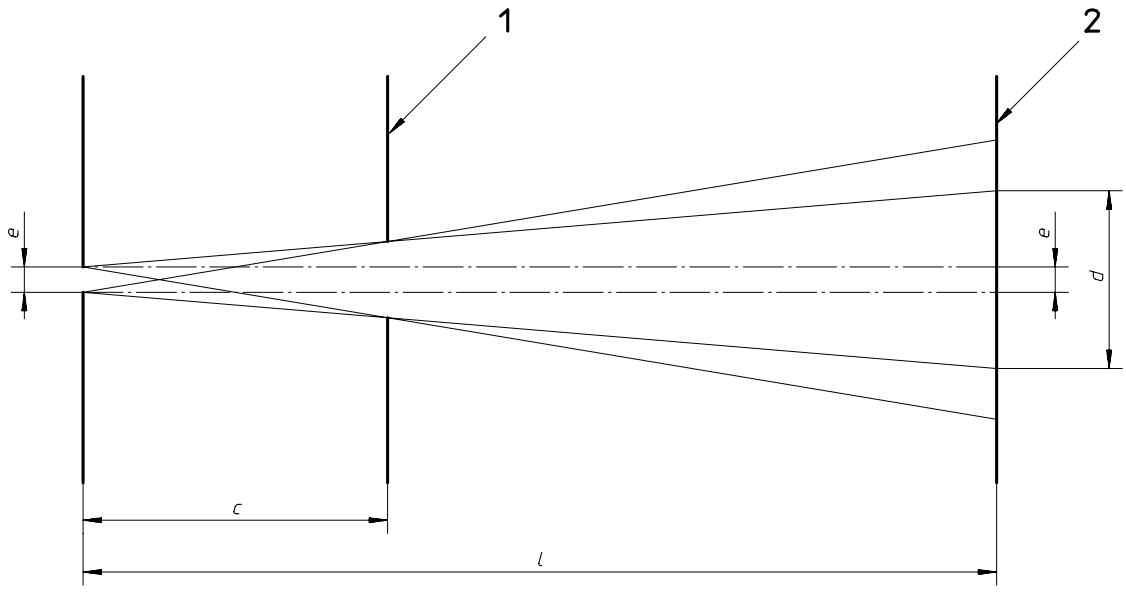
2) ISO 8598:1996, *Optics and optical instruments - Focimeters*



e = 0,2 mm
c = 12 mm

Key
1 Ophthalmoscope
2 Screen

Figure 1 — Test configuration for measuring the field of view

6.2.3 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.

7 Accompanying documents

The direct 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 direct ophthalmoscope, with particular reference to the disinfection of instruments to be returned to the manufacturer for repair and maintenance;

c) the information specified in 5.5.4;

d) if appropriate, a statement that the direct 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 10942, if the manufacturer or supplier claims complinace with it.