INTERNATIONAL STANDARD

ISO 10940

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Ophthalmic instruments — Fundus cameras

Instruments ophtalmiques — Appareils photographiques du fond de l'œil

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 10940 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

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Ophthalmic instruments — Fundus cameras

1 Scope

This International Standard, together with ISO 15004, specifies requirements and test methods for fundus cameras operating exclusively for photography of the fundus of the human eye. This International Standard is based upon techniques involving the direct effects of an optical image on a photographic emulsion.

This International Standard is not applicable to the following types of fundus camera:

- those designed to produce simultaneous stereoscopic photography;
- those using infrared radiation as a source of illumination for the observing system.

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 15004:1997 *Ophthalmic instruments - Fundamental requirements and test methods*

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

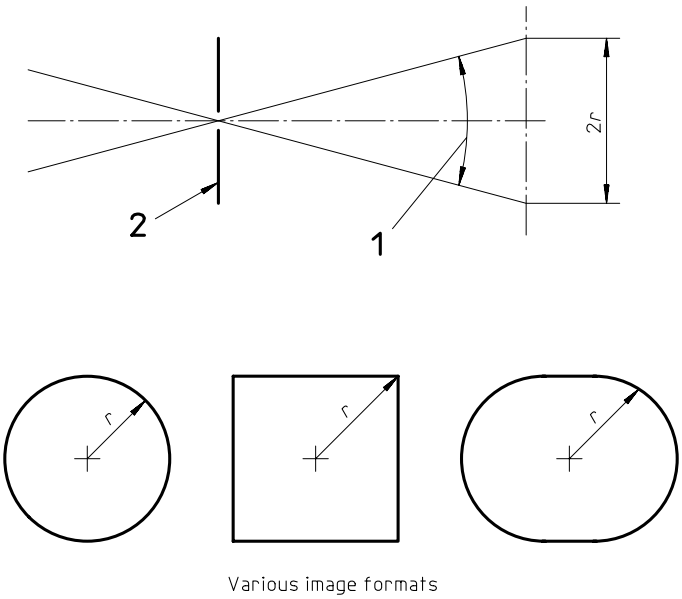
3 Definitions

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

3.1
resolving power of the fundus camera
minimum separation allowing recognition of two adjacent lines on the fundus, expressed as line pairs per millimetre (lp/mm)

3.2
field of view
photographic angular field of view
angle subtended at the exit pupil of the eye by the maximum dimension 2*r*

See figure 1.



Various image formats

Key
1 Angular field of view
2 Entrance pupil of instrument/exit pupil of eye

***r* for various formats**

3.3
magnification of photography
ratio of the size of the image on the photosensitive target to that of the fundus at the centre of the photographic field, assuming that the eye is emmetropic and that it has a focal length of 17 mm in air

3.4
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 fundus camera shall conform to the requirements specified in ISO 15004.

4.2 Optical requirements

The fundus camera shall conform to the requirements given in table 1. These requirements are verified as described in 5.1.

NOTE It is recommended that an oblique astigmatism compensator is provided for observation and photography of the periphery of the retina when using a fundus camera with an angular field-of-view of 30° or less.

Table 1 — Requirements for optical properties

Criterion		Minimum requirement	
Resolving power for camera with field of view	≤ 30°	centre	80 lp/mm
		middle (*r*/2)	60 lp/mm
		periphery (*r*)	40 lp/mm
	> 30°	centre	60 lp/mm
		middle (*r*/2)	40 lp/mm
		periphery (*r*)	25 lp/mm
Tolerance of field of view		± 7 %	
Tolerance of magnification of photography		± 7 %	
Range of dioptre adjustment of the optical finder		−5 D to +5 D	
		−4 D to +2 D for high eye point eyepieces	
Range of focus adjustment for compensation of patient's refractive error		−15 D to +15 D	

4.3 Construction and function

4.3.1 General

The instrument shall be designed in a way that there is no reflection nor stray light which is detrimental to the photography.

4.3.2 High eye point eyepiece

If the manufacturer states that the eyepiece is a high eye point eyepiece, the clearance shall be a minimum of 17 mm, as measured from that part of the eyepiece nearest the examiner's eye to the exit pupil of the instrument.

4.4 Optical radiation hazard with fundus cameras

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 fundus camera used to illuminate and view the human eye with visible light (380 nm to 700 nm) and in which the full beam homogeneously illuminates an 8 mm circular pupil (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 fundus camera 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 fundus camera 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 fundus camera in the range between 380 nm and 700 nm. The energy shall be measured in the corneal plane when the fundus camera 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 diameter 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 fundus cameras, when operated with non-pulsed radiation (in particular when using the alignment illumination), 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

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

NOTE 4 For fundus cameras, when operated with pulsed radiation, the limit is a total dose expressed in J/cm^2, and is found by the formula

$$[14\ \text{J/(cm}^2 \cdot \text{sr)}] \times (0{,}031\ \text{sr}) \times (0{,}276/8) = 15\ \text{mJ/cm}^2$$

For multiple pulses, the limit per pulse is then 15 mJ/cm^2 divided by the number of pulses.

NOTE 5 Fundus cameras often have illuminating solid angles larger than Ω = 0,031 sr. If this is the case, the limit values may be increased by the ratio of the true solid angle, expressed in steradians, divided by 0,031.

4.4.3 Variable brightness

For instruments 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 fundus camera between 305 nm and 1100 nm when the instrument is operating at maximum intensity and maximum aperture. The spectral output shall be shown for the beam after it exits the illumination system.

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

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.

5.1.1 Checking the resolving power

The resolving power shall be checked using a target which has black lines on a white ground. The black lines shall be equal in width to the white ground between them. The length of the lines shall be five times greater than their width and the reflectivity of the white ground shall be 1,4 times (or more) that of the reflectivity of the black lines.

Targets shall consist of two sets of three lines each. The lines in a set are parallel to one another. The lines of one set are perpendicular to the lines of the other set (see figure 2). In the central target the sets are oriented horizontally and vertically. In the peripheral target the sets are oriented radially and circumferentially.

Figure 2 — Test target for checking the resolving power

The test target images from the centre, middle and periphery used for checking resolving power as specified in table 1 for the three areas shall all be contained in the same photograph.

The test target shall be photographed at a distance of 1 m from the entrance pupil of the fundus camera. The light source used to illuminate the test target may be the normal fundus camera source or may be an external white light source. In either case, the light shall be filtered by a green filter with peak transmission wavelength between 520 nm and 560 nm and a half-peak bandwidth of less than 80 nm.

5.1.2 Checking the field of view

Check the field by photographing a screen placed 1 m from the entrance pupil of the fundus camera.

5.1.3 Checking the magnification of photography

Check the magnification by photographing a 100-mm scale held on a screen 1 m from the entrance pupil of the fundus camera. Measure the length of the image of the scale, L, in the resulting photograph. shall be expressed in millimetres. The magnification M is then found by using the formula

$$M = L/1,7$$

NOTE The value 1,7 results from the assumption that the eye has a focal length of 17 mm.

5.2 Checking optical radiation safety for fundus cameras

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 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 exposed area on the negative.

6 Accompanying documents

The fundus camera 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 fundus camera, 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.;

d) if appropriate, a statement that the fundus camera 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 fundus camera shall be permanently marked with at least the following information:

a) name and address of manufacturer or supplier;

b) name and model of fundus camera;

c) marking as required by IEC 60601-1;

d) a reference to this International Standard ISO 10940, if the manufacturer or supplier claims compliance with it.