INTERNATIONAL STANDARD

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Ophthalmic instruments — Fundus cameras

Instruments ophtalmiques — Appareils photographiques du fond de l'œil

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10940 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 10940:1998) which has been technically revised.

Ophthalmic instruments — Fundus cameras

1 Scope

This International Standard, together with ISO 15004-1 and ISO 15004-2, specifies requirements and test methods for fundus cameras operating for observing, photographing or recording electronic images of the fundus of the human eye in order to provide the image information for diagnosis. This International Standard is not applicable to the following instruments:

— those that contact the eye during the examination;

— those using scanning laser sources.

This International Standard takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

ISO 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

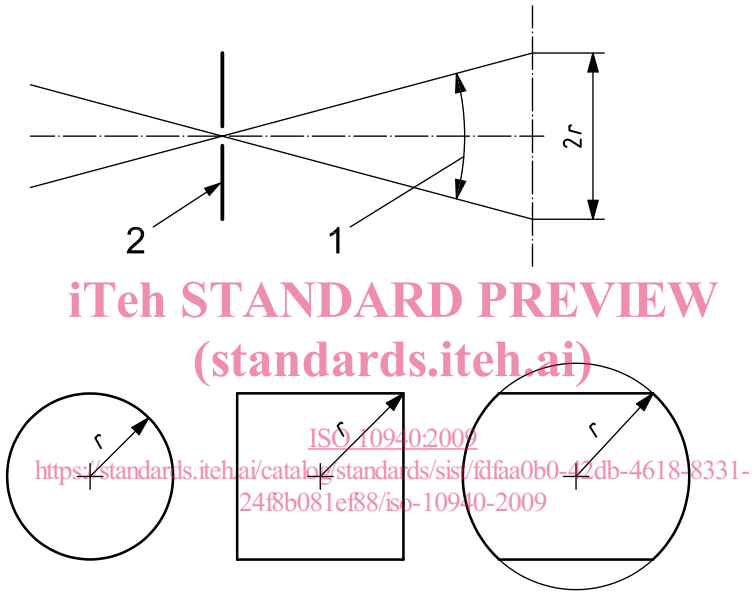
3.2
angular field of view
FOV
maximum image size displayed on the image plane, expressed as the angle subtended at the exit pupil of the eye by the maximum dimension $2r$

See Figure 1.

3.3
magnification of image
ratio of the size of an object at the centre on the image plane to that of the fundus, assuming that the eye is emmetropic and that it has a focal length of 17 mm in air

3.4
pixel pitch on the fundus
distance between two pixels (from centre to centre) of a digital image sensor theoretically projected on to the fundus, expressed in micrometres (μm), assuming that the eye is emmetropic and that it has a focal length of 17 mm in air

3.5
high eye point eyepiece
eyepiece in which the exit pupil is of sufficient clearance from the eyepiece to allow spectacles to be worn



Key
1 angular field of view
2 entrance pupil of instrument/exit pupil of eye

Figure 1 — Meaning of dimension r for various formats

4 Requirements

4.1 General

The fundus camera shall conform to the requirements specified in ISO 15004-1 and ISO 15004-2.

4.2 Optical properties

The fundus camera shall conform to the requirements given in Table 1.

When using near infrared light (NIR) for imaging (e.g. ICG application), the given limits for resolving power shall be reduced by a factor of 1,6.

It is recommended that an oblique astigmatism compensator be provided for observation and recording images of the periphery of the retina when using a fundus camera with an optical angular field $\leqslant 30°$.

Table 1 — Requirements for optical properties

Criterion		Requirement	
Resolving [a] power on the fundus for fundus camera optics	Field of view ⩽ 30°	centre	⩾ 80 lp/mm
		middle (r/2)	⩾ 60 lp/mm
		periphery (r)	⩾ 40 lp/mm
	Field of view > 30°	centre	⩾ 60 lp/mm
		middle (r/2)	⩾ 40 lp/mm
		periphery (r)	⩾ 25 lp/mm
Tolerance of angular field of view		± 5 %	
Tolerance of magnification of image [b]		± 7 %	
Tolerance of pixel pitch on fundus [c]		± 7 %	
Range of dioptre adjustment of the optical finder (when an optical finder is attached)		− 5 D to + 5 D	
		− 4 D to + 4 D for high eye point eyepieces	
Range of focus adjustment for compensation of patient's refractive error		− 15 D to + 15 D	

[a] To achieve the resolving power according this table, optical means are recommended. In the case of recording images, it is necessary to choose an appropriate medium (film or digital sensor).

[b] Only for fundus cameras recording on film.

[c] Only for fundus cameras recording on a digital sensor.

4.3 Construction and function

4.3.1 General

The instrument shall be designed in such a way that neither reflection nor stray light degrades the image.

4.3.2 High eye point eyepiece

If the manufacturer states that the eyepiece is a high eye point eyepiece, the clearance shall be ⩾ 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

This clause replaces 10.5, 10.6 and 10.7 of IEC 60601-1:2005. Fundus cameras shall comply with the light hazard protection requirements that are given in ISO 15004-2 in consideration of the following modality. (For guidance, see Annex A.)

It shall first be determined if the fundus camera is classified as a group 1 or group 2 instrument in accordance with ISO 15004-2:2007, Clause 4. The applicable clauses of ISO 15004-2:2007 for fundus cameras are as follows.

a) For group 1 fundus cameras:

   1) applicable requirements of ISO 15004-2:2007 are 5.1, 5.2 and 5.4 (except 5.4.3). For cameras with multiple sources designed to direct optical radiation on to the same point(s) of the eye at the same time, the following shall apply:

      i) the optical radiation emissions shall be below all applicable limits for each light source alone;

      ii) the resulting or combined radiation of the multiple sources shall be below all applicable limits of ISO 15004-2:2007, Table 2 or Table 3;

2) applicable test methods are given in ISO 15004-2:2007, 6.1, 6.2 and 6.4.

If status is determined to be group 1, there are no further requirements. If status is determined not to be group 1, the additional requirements given in b) are applicable.

b) For group 2 fundus cameras:

1) applicable requirements of ISO 15004-2:2007 are 5.1, 5.3, 5.5 (except 5.5.3). For cameras with multiple sources designed to direct optical radiation on to the same point(s) of the eye at the same time the following shall apply:

i) the optical radiation emissions shall be below all applicable limits for each light source alone;

ii) the resulting or combined radiation of the multiple sources shall be below all applicable limits or guideline values of ISO 15004-2:2007, Tables 4, 5 and 6;

iii) for intended consecutive and/or simultaneous use of pulsed and continuous light sources within an 8 h period, the sum of the ratios of the optical radiation emitted over the specified wavelength range according ISO 15004-2:2007, Tables 4, 5 and 6 to the applicable limit or guideline value shall be less than one. Only ratios of the same kind, i.e. related to the same hazard (e.g. photochemical, thermal or aphakic), shall be considered;

2) applicable test methods are given in ISO 15004-2:2007, 6.1, 6.2, 6.3, 6.4 and 6.5;

3) ISO 15004-2:2007, Clause 7.

If a fundus camera is capable of emitting more radiation in the visible or infrared wavelength range than specified for group 2 instruments, the manufacturer shall inform the user in the user manual about the potential hazard. See Annex B.

5 Test methods for checking the optical properties

5.1 General

All tests described in this International Standard are type tests.

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

5.2 Test target arrangement

5.2.1 Test target distance

The resolving power, the angular field of view, the magnification of image and the pixel pitch shall be checked using a test target in front of the fundus camera. The test target shall be used at a distance of 1 m from the entrance pupil of the fundus camera. The distance of 1 m shall be determined with a tolerance of $\leqslant$ 5 mm.

5.2.2 Test target illumination

The light source used to illuminate the test target may be the normal fundus camera light source or may be an external white light source. In either case, the light shall be filtered by a band-pass filter with peak transmission wavelength between 520 nm and 560 nm and a half-peak bandwidth of less than 80 nm. For NIR applications, the peak transmission wavelength shall be between 790 nm and 890 nm with a half-peak width of less than 120 nm.

5.2.3 Test target design

The test target for resolving power shall be in accordance with Figure 2, 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 5 × greater than their width and the reflectivity of the white ground shall be 1,4 × (or more) that of the reflectivity of the black lines. The targets shall consist of two sets of three lines each. The lines in a set shall be parallel to one another. The lines of one set shall be perpendicular to the lines of the other set (see Figure 2). In the central target, the sets shall be oriented horizontally and vertically. In the peripheral target, the sets shall be oriented radially and tangentially.

Figure 2 — Test target for checking the resolving power

5.3 Checking the resolving power of the fundus camera optics

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 image.

The limits specified in Table 1 are requirements for the optical performance of the fundus camera without a dedicated sensor (film or CCD), since this standard is not a standard for image sensors. Attention is to be paid to the fact that the resolving power of the medium used is not the limit for verification. It is recommended that visual means be used to check the resolving power in the image plane. If this is not possible, a sensor or film with appropriate resolution capability shall be chosen.

NOTE The resolving power on the fundus is given by using the factor 0,017 for an eye with a focal length of 17 mm.

5.4 Checking the angular field of view

The angular field of view shall be checked by taking an image of a graduated target (e.g. a scale, rule, measuring tape) placed 1 m from the entrance pupil of the fundus camera. The scale shall be perpendicular to the optical axis and centred to the field of view in accordance with Figure 1. Determine the distance $2r$, in millimetres, from edge to edge on the image of the visible scale. The angular field of view is found then by using Equation (1):

$$\text{FOV} = 2 \cdot \arctan(r/1\,000) \tag{1}$$

All distances shall be determined with a tolerance of $\leqslant$ 5 mm.

5.5 Checking the magnification of the image

The magnification of the image shall be checked by imaging a 100 mm graduated target scale held on a screen 1 m from the entrance pupil of the fundus camera. The length of the image of the scale, L, in the resulting image shall be measured. L shall be expressed in millimetres. The magnification of image M is then found by using Equation (2):

$$M = L/1{,}7 \tag{2}$$

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