
**Ophthalmic instruments — Fundus
cameras**

*Instruments ophtalmiques — Appareils photographiques du fond de
l'œil*

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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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

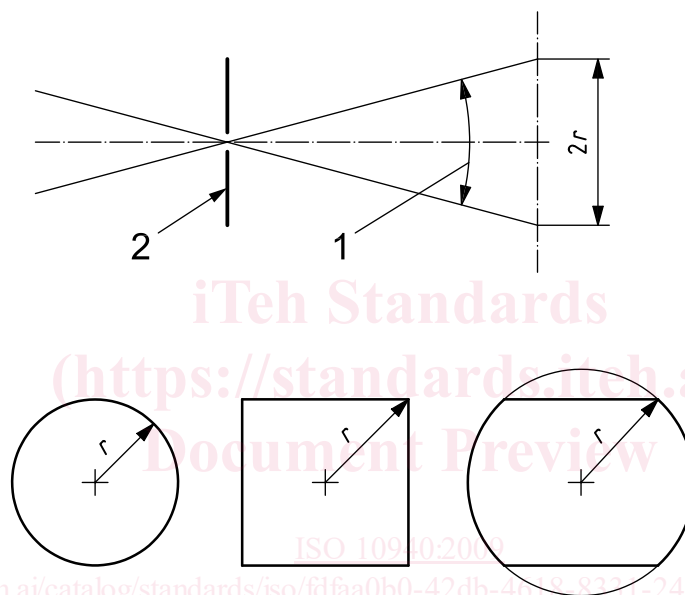
ratio of the size of an object at the centre on the image plane to that of the fundus, assuming that the eye is emmetropic and that it has a focal length of 17 mm in air

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 $\leq 30^\circ$.