SLOVENSKI STANDARD
SIST EN ISO 10940:2000

01-januar-2000

Oftalmiļ ni instrumenti - Kamere za slikanje oļ esnega ozadja (ISO 10940:1998)

Ophthalmic instruments - Fundus cameras (ISO 10940:1998)

Ophthalmische Instrumente - Funduskameras (ISO 10940:1998)

Instruments ophtalmiques - Appareils photographiques du fond de l'oeil (ISO 10940:1998)

Ta slovenski standard je istoveten z: **EN ISO 10940:1998**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 10940:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10940

May 1998

ICS 11.040.70

Descriptors: see ISO document

English version

Ophthalmic instruments - Fundus cameras (ISO 10940:1998)

Instruments ophtalmiques - Appareils photographiques du fond de l'oeil (ISO 10940:1998)

Ophthalmische Instrumente - Funduskameras (ISO 10940:1998)

This European Standard was approved by CEN on 9 March 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 10940:1998 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1998, and conflicting national standards shall be withdrawn at the latest by November 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10940:1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

ANNEX ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 15004	1997	Ophthalmic instruments - Fundamental requirements and test methods	EN ISO 15004	1997

ANNEX ZB (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptre" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Mesures).

Identification of the regulation:

Gesetz über die Einheiten im Meßwesen vom 02.07.1969 in der Fassung der Bakanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Meßwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9

INTERNATIONAL STANDARD

ISO 10940

First edition
1998-05-01

Ophthalmic instruments — Fundus cameras

Instruments ophtalmiques — Appareils photographiques du fond de l'œil

Reference number
ISO 10940:1998(E)

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.

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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*

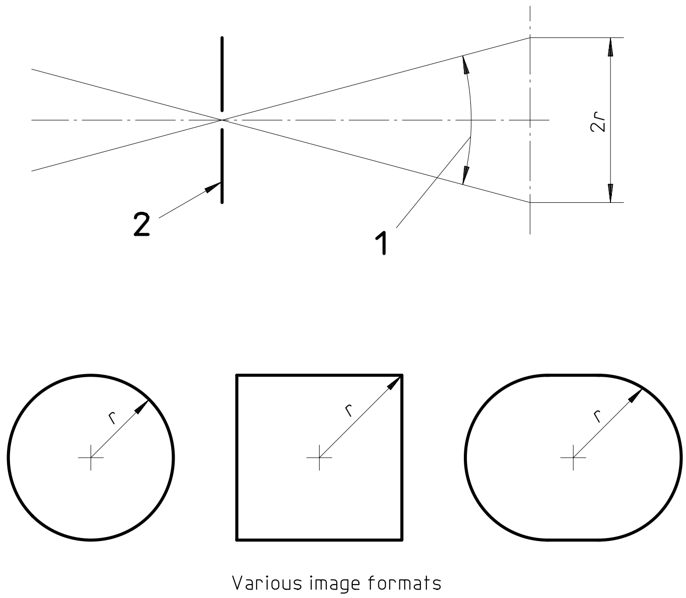
3 Definitions

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.



Key

1 Angular field of view

2 Entrance pupil of instrument/exit pupil of eye

Figure 1 — Meaning of dimension *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.