



SLOVENSKI STANDARD
SIST EN ISO 10942:2000
01-januar-2000

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Ophthalmic instruments - Direct ophthalmoscopes (ISO 10942:1998)

Ophthalmische Instrumente - Direkte Ophthalmoskope (ISO 10942:1998)

Instruments ophtalmiques - Ophtalmoscopes directs (ISO 10942:1998)

Ta slovenski standard je istoveten z: EN ISO 10942:1998

[SIST EN ISO 10942:2000](https://standards.iteh.ai/catalog/standards/sist/6e4e2c0a-2bfd-44b8-8836-8c87e9e287b6/sist-en-iso-10942-2000)

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ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 10942:2000 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10942

May 1998

ICS 11.040.70

Descriptors: see ISO document

English version

Ophthalmic instruments - Direct ophthalmoscopes (ISO
10942:1998)

Instruments ophtalmiques - Ophtalmoscopes directs (ISO
10942:1998)

Ophthalmische Instrumente - Direkte Ophthalmoskope
(ISO 10942:1998)

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.

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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 10942:1998 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 10942:1998 was approved by CEN as a European Standard without any modification.

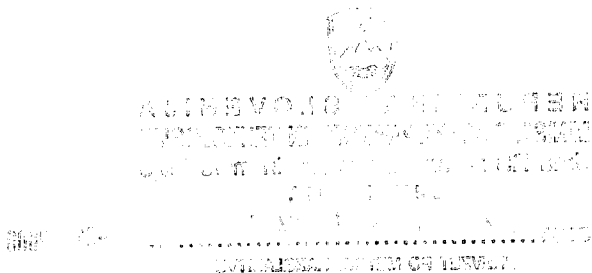
NOTE: Normative references to International Standards are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

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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

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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 "dioptré" 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 Measures).

Identification of the regulation:

Gesetz über die Einheiten im Meßwesen vom 02.07.1969 in der Fassung der Bekanntmachung 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
10942

First edition
1998-05-01

**Ophthalmic instruments — Direct
ophthalmoscopes**

Instruments ophtalmiques — Ophtalmoscopes directs

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Reference number
ISO 10942:1998(E)

ISO 10942:1998(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 10942 was prepared by Technical 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 — 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 electrical equipment - Part 1: General requirements for safety*
<https://standards.iteh.ai/catalog/standards/sist/6e4e2c0a-2bfd-44b8-8836-8c87e9e287b6/sist-en-iso-10942-2000>

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

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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 ophthalmoscopes 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	$\geq 6^\circ$	$\geq 5^\circ$
Angle of field of illumination	$\geq 9^\circ$	$\geq 7^\circ$
Minimum diameter of the viewing system	3 mm	2,5 mm

Table 2 — Requirements for optical accuracy
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Criterion	Tolerance
Accuracy of combined refractive power	$\pm 0,37$ D
	$\pm 0,50$ D
	$\pm 0,75$ D
	$\pm 1,00$ D
Lens centration	1,0 mm
	0,5 mm