SLOVENSKI PREDSTANDARD

oSIST prEN ISO 10943:2005

april 2005

Oftalmični instrumenti - Indirektni oftalmoskopi (ISO/DIS 10943:2005)

Ophthalmic instruments - Indirect ophthalmoscopes (ISO/DIS 10943:2005)

ICS 11.040.70

Referenčna številka
oSIST prEN ISO 10943:2005(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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prEN ISO 10943

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ICS

Will supersede EN ISO 10943:1998

English version

Ophthalmic instruments - Indirect ophthalmoscopes (ISO/DIS 10943:2005)

Instruments ophtalmiques - Ophtalmoscopes indirects (ISO/DIS 10943:2005)

Ophthalmische Instrumente - Indirekte Ophthalmoskope (ISO/DIS 10943:2005)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (prEN ISO 10943:2005) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 10943:1998.

Endorsement notice

The text of ISO 10943:2005 has been approved by CEN as prEN ISO 10943:2005 without any modifications.

DRAFT INTERNATIONAL STANDARD ISO/DIS 10943

ISO/TC **172**/SC **7** Secretariat: **DIN**

Voting begins on: **2005-02-03** Voting terminates on: **2005-07-03**

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Ophthalmic instruments — Indirect ophthalmoscopes

Instruments ophtalmiques — Ophtalmoscopes indirects

[Revision of first edition (ISO 10943:1998)]

ICS 11.040.70

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

Page

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 10943 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 (EN ISO 10943:1998) which has been technically revised.

Ophthalmic instruments — Indirect ophthalmoscopes

1 Scope

This International Standard, together with ISO 15004-1 and ISO 15004-2 specifies minimum requirements and test methods for hand-held, spectacle-type, and head-worn indirect ophthalmoscopes for observing indirect images of the eye fundus.

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

This International Standard is not applicable to condensing lenses used for indirect ophthalmoscopy or to accessories.

This International Standard is not applicable to table-mounted instruments such as Gullstrand ophthalmoscopes and their derivatives, nor to ophthalmoscopes primarily intended for image capture and/or processing such as those based on scanning laser techniques.

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:[1)] , *Ophthalmic instruments - Fundamental requirements and test methods – Part 2: Light hazard protection*

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

3 Terms and definitions

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

3.1
indirect ophthalmoscope
an optical instrument, which provides an illumination system and which is used with a condensing lens (hand-held or integral) to direct appropriately focused light into an eye in order to produce a real intermediate image that is viewed by an observer

NOTE Indirect ophthalmoscopes may be monocular or binocular.

1) To be published.

3.2
condensing lens
plus-power lens system used to focus the illuminating beam into an eye and to form a real inverted image of the retina thus illuminated

4 Requirements

4.1 General

The indirect ophthalmoscope shall conform to the requirements specified in ISO 15004-1 and ISO 15004-2.

The indirect ophthalmoscope shall conform to the specific requirements described in 4.2 to 4.4.

These requirements are verified as described in clause 5.

4.2 Optical and dimensional requirements

The requirements specified in table 1 and table 2 shall apply.

Table 1 — Optical and dimensional requirements where applicable for indirect ophthalmoscopes used with a hand-held condensing system

Criterion	Requirement
Interpupillary distance range	55 mm to 72 mm
Diameter 2 r of the field of view[A, B]	≥ 100 mm
Diameter of largest illuminated spot[A]	≥ 45 mm
Range of adjustment of headband circumference, if applicable	520 mm to 640 mm

A At 500 mm distance from the light exit.

B

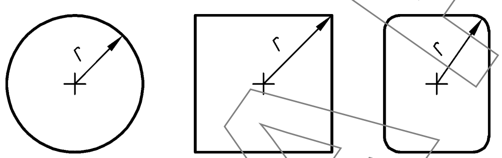

Table 2 Optical requirements for indirect ophthalmoscopes with integral condensing systems

Criterion	Requirement
Distance of focal point from end of instrument	15 mm to 20 mm
Diameter of beam at 500 mm from focal point	125 mm to 225 mm
Diameter of field of view at 500 mm from focal point	150 mm to 250 mm

