

**Oftalmilised instrumendid. Indirektsed oftalmoskoobid
(ISO 10943:2011)**

Ophthalmic instruments - Indirect ophthalmoscopes (ISO 10943:2011)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10943:2011 sisaldab Euroopa standardi EN ISO 10943:2011 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 13.08.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.08.2011.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 10943:2011 consists of the English text of the European standard EN ISO 10943:2011.

This standard is ratified with the order of Estonian Centre for Standardisation dated 13.08.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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English Version

**Ophthalmic instruments - Indirect ophthalmoscopes (ISO
10943:2011)**

Instruments optalmiques - Ophthalmoscopes indirects (ISO
10943:2011)

Ophthalmische Instrumente - Indirekte Ophthalmoskope
(ISO 10943:2011)

This European Standard was approved by CEN on 14 August 2011.

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

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Foreword

This document (EN ISO 10943:2011) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" 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of an identical text or by endorsement, at the latest by February 2012, and conflicting national standards shall be withdrawn at the latest by February 2012.

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

This document supersedes EN ISO 10943:2006.

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Endorsement notice

The text of ISO 10943:2011 has been approved by CEN as a EN ISO 10943:2011 without any modification.

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 15004-2:2007, *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

ophthalmoscope

optical instrument used to examine the external and internal parts of the eye, particularly the media and the fundus

3.2

indirect ophthalmoscope

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.