Oftalmilised instrumendid. Direktsed oftalmoskoobid

Ophthalmic instruments - Direct ophthalmoscopes



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO
10942:2006 sisaldab Euroopa standardi
EN ISO 10942:2006 ingliskeelset teksti.

This Estonian standard EVS-EN ISO 10942:2006 consists of the English text of the European standard EN ISO 10942:2006.

Käesolev dokument on jõustatud 31.07.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

This document is endorsed on 31.07.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.

Standard on kättesaadav Eesti standardiorganisatsioonist.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

Käesolev rahvusvaheline standard koos standardiga ISO/DIS 15004 esitab nõuded ja testimismeetodid käeshoitavatele direktsetele oftalmoskoopidele, mis on ette nähtud silmapõhja otseseks vaatlemiseks.

Scope:

This International Standard, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus. This International Standard takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

ICS 11.040.70

Võtmesõnad: jõudlus, klassifikatsioon, märgistus, oftalmiline instrumentaarium, oftalmoskoobid, optika, optiline instrumentaarium, tehnilised andmed, tehniliste andmete lehed, testimine, testimisvahendid, tüüptestimine (-testid)

EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10942

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ICS 11.040.70

Supersedes EN ISO 10942:1998

English Version

Ophthalmic instruments - Direct ophthalmoscopes (ISO 10942:2006)

Instruments ophtalmiques - Ophtalmoscopes directs (ISO 10942:2006)

Ophthalmische Instrumente - Direkte Ophthalmoskope (ISO 10942:2006)

This European Standard was approved by CEN on 9 March 2006.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

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Foreword

This document (EN ISO 10942:2006) 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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

This document supersedes EN ISO 10942:1998.

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

Endorsement notice

oved L. The text of ISO 10942:2006 has been approved by CEN as EN ISO 10942:2006 without any modifications.

INTERNATIONAL **STANDARD**

ISO 10942

Second edition 2006-06-01

Ophthalmic instruments — Direct ophthalmoscopes

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Foreword

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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 10942 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 10942:1998 and ISO 10942:1998/Cor.1:1998), which has been technically revised.

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Ophthalmic instruments — Direct ophthalmoscopes

1 Scope

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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:—¹⁾, 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

direct ophthalmoscope

ophthalmoscope which provides an illuminating system, an observation system and viewing lenses which allow the observer to visualize 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.

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¹⁾ To be published.