Opthalmic instruments - Tonometers

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8612:2009 sisaldab Euroopa standardi EN ISO 8612:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8612:2009 consists of the English text of the European standard EN ISO 8612:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.10.2009.	Date of Availability of the European standard text 01.10.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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English Version

Ophthalmic instruments - Tonometers (ISO 8612:2009)

Instruments ophtalmiques - Tonomètres (ISO 8612:2009)

Ophthalmische Instrumente - Augentonometer (ISO 8612:2009)

This European Standard was approved by CEN on 10 September 2009.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 8612:2009) 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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Endorsement notice

The text of ISO 8612:2009 has been approved by CEN as a EN ISO 8612:2009 without any modification.

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1 Scope

This International Standard, together with ISO 15004-1, specifies minimum requirements and the design compliance procedure for tonometers intended for routine clinical use in the estimation of intraocular pressure (IOP).

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

NOTE The true intraocular pressure is seldom directly measured since it would require invasion of the eye. Since the true IOP cannot be clinically measured, alternative methods are specified for determining a reference IOP (Annex A and Annex B).

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*

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
intraocular pressure
IOP
pressure within the eye

NOTE It is expressed in millimetres of mercury (mmHg), where 1 mmHg = 0,133 3 kPa.

3.2
reference tonometer
tonometer as described in Annex A

3.3
test tonometer
verified tonometer used in design compliance testing

3.4
reference IOP
IOP that is measured with a reference tonometer, as specified in Annex A, in accordance with the procedures given in Annex B