

## Opthalmic instruments - Tonometers

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8612:2009 sisaldab Euroopa standardi EN ISO 8612:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.12.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.10.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 8612:2009 consists of the English text of the European standard EN ISO 8612:2009.

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.

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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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## 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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 8612:2001.

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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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# Ophthalmic instruments — Tonometers

## 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