Opthalmic instruments - Tonometers

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 8612:2001 sisaldab Euroopa standardi EN ISO 8612:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 18.06.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 8612:2001 consists of the English text of the European standard EN ISO 8612:2001. This document is endorsed on 18.06.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

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

ICS 11.040.70

Võtmesõnad: definitions, ophtalmic optics, optical equipment, optical instruments, optics, specification (approval), specifications, testing, tonometers

EUROPEAN STANDARD
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EUROPÄISCHE NORM

EN ISO 8612

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English version

Ophthalmic instruments
Tonometers
(ISO 8612 : 2001)

Instruments ophtalmiques – Tonomètres (ISO 8612 : 2001)

Ophthalmische Instrumente – Tonometer (ISO 8612 : 2001)

This European Standard was approved by CEN on 2001-04-15.

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 Management Centre or to any CEN member.

The European Standards exist 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.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

International Standard

ISO 8612 : 2001 Ophthalmic instruments – Tonometers,

which was prepared by ISO/TC 172 'Optics and optical instruments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 170 'Ophthalmic optics', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by October 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8612 : 2001 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

1 Scope

This International Standard, together with ISO 15004, 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 the ISO 15004, if differences exist.

NOTE 1 The true intraocular pressure is seldom directly measured since it would require invasion of the eye. Since the true IOP cannot be known, the instrument (annex A) and method (annex B) for determining a reference IOP are instead specified.

NOTE 2 Clinical tonometers may employ different parameters or correlates in the indirect assessment of measured IOP. The manufacturer states the exact design parameters of the specific tonometer, and then, on the basis of design compliance testing as specified in 4.2, demonstrates that the specific design performs acceptably compared to the reference method. This process is referred to as certification.

The manufacturer also demonstrates, by methods specified in 4.3, that individual manufactured instruments perform the same (within defined limits) as the test tonometer. This process is referred to as verification.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 15004, *Ophthalmic instruments — Fundamental requirements and test methods.*

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

3 Terms and definitions

For the purposes of this International Standard, 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 = 1,333 hPa.

3.2
reference IOP
IOP that is measured with a reference tonometer, as specified in annex A, in accordance with the procedures given in annex B