



SLOVENSKI STANDARD SIST EN ISO 8612:2002

01-maj-2002

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Ophthalmic instruments - Tonometers (ISO 8612:2001)

Ophthalmische Instrumente - Tonometer (ISO 8612:2001)

Instruments ophtalmiques - Tonometres (ISO 8612:2001)

Ta slovenski standard je istoveten z: EN ISO 8612:2001

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ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8612

April 2001

ICS 11.040.70

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 15 April 2001.

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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 Management Centre has the same status as the official versions.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Page 2
EN ISO 8612:2001

Foreword

The text of the International Standard ISO 8612:2001 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of an identical text or by endorsement, at the latest by October 2001, and conflicting national standards shall be withdrawn at the latest by October 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, 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 Standards are listed in annex ZA (normative).

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Annex ZA (normative)
Normative references to international publications
with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 15004	1997	Ophthalmic instruments - Fundamental requirements and test methods	EN ISO 15004	1997

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INTERNATIONAL STANDARD

ISO
8612

First edition
2001-04-15

Ophthalmic instruments — Tonometers

Instruments ophtalmiques — Tonomètres

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Contents

Page

Foreword.....	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
5 Test methods	3
6 Accompanying documents	3
7 Additional information	4
8 Marking	4
Annex A (normative) Reference tonometer and method for determining reference IOP	5
Annex B (normative) Design compliance testing	11

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ISO 8612:2001(E)**Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8612 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition of ISO 8612 cancels and replaces ISO/TR 8612:1997, which has been technically revised.

Annexes A and B form a normative part of this International Standard.

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Ophthalmic instruments — Tonometers

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.

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2 Normative references

[SIST EN ISO 8612:2002](https://standards.iteh.ai/catalog/standards/sist/fc61b2b-cff4-4ec4-9334-178a719c19/sist-en-iso-8612-2002)

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