INTERNATIONAL STANDARD

ISO 8612

Second edition
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Ophthalmic instruments — Tonometers

Instruments ophtalmiques — Tonomètres

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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 2.

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 8612 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 8612:2001), which has been technically revised.

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

3.5
measured IOP
IOP reading provided by the test tonometer when used in accordance with the manufacturer's instructions

4 Requirements

4.1 General

4.1.1 The test tonometer shall conform to the general requirements specified in ISO 15004-1.

4.1.2 The test tonometer shall conform to the specific requirements specified in 4.2 to 4.4.

4.2 Design compliance testing (certification)

4.2.1 The manufacturer shall demonstrate, on the basis of design compliance testing as specified in Clause 5, that the test tonometer measurements, when compared to the reference tonometer measurements, meet the requirements as given in Table 1.

A tonometer that meets the requirements of Annex A for a reference tonometer need not undergo design compliance testing.

The requirements are met if not more than 5 % of the paired differences between the reference tonometer reading and the test tonometer reading for each pressure range are greater than the tolerance for that range in Table 1.

NOTE The tolerances given in Table 1 represent 1,96 times the standard deviation allowable for the paired measurement, and so account for not only the allowable error of the tonometer under test but also unavoidable error associated with the reference tonometer.

Table 1 — Requirements for tonometers

IOP range mmHg	Tolerance mmHg	Minimum number of eyes
7 to16	±5,0	40
> 16 to < 23	±5,0	40
⩾ 23	±5,0	40

4.2.2 The manufacturer shall analyse the data, taken in the course of design compliance testing as specified in Clause 5, using the total least squares method for the regression, and make available, as required in Clause 7, the slope, the offset and the standard deviation of the regression line.

4.3 Verification (instrument compliance)

4.3.1 The manufacturer shall develop a method and test apparatus to confirm that the design requirements of 4.2 are met by each manufactured tonometer. Each tonometer shall be verified with this method and apparatus. This method and test apparatus shall be the same as those used to measure and verify the test tonometer in 4.2.

4.3.2 The permissible error of the test apparatus shall be less than or equal to one-half of the permissible tolerance as given in Table 1.

4.4 Construction and function

4.4.1 The surfaces of the tonometer that are intended to come into contact with the cornea shall be:

a) composed of non-toxic, stable and non-oxidative material which is inert to ocular tissue, tears and appropriate pharmacological agents;

b) designed either to facilitate disinfection or for single patient use;

c) free of surface irregularities and imperfections when viewed with unmagnified corrected vision.

4.4.2 The tonometer shall permit the measurement of IOP throughout the range 7 mmHg to 50 mmHg. The scale or display shall either provide a direct measurement of a value whose relationship to IOP is known or give a numerical reading corresponding to the IOP value.

Readings of IOP less than 7 shall be displayed either by their numerical value or by a “low reading” indication. Readings of IOP greater than 50 shall be displayed either by their numerical value or by a “high reading” indication.

5 Test methods

5.1 This International Standard describes type testing (certification) and individual device testing (verification).

5.2 The reference IOP shall be determined as described in Annex A.

5.3 Design compliance testing shall be performed as described in Annex B.

6 Accompanying documents

The tonometer shall be accompanied by documents containing instructions for use together with maintenance procedures and their frequency of application. In particular, this information shall contain:

a) name and address of the manufacturer;

b) instructions for effective disinfection of the tonometer where applicable;

c) contra-indications for the use of the tonometer;

d) a list of accessories suitable for use with the tonometer;

e) if appropriate, any additional documents as specified in 7.9 of IEC 60601-1:2005;

f) a reference to this International Standard, i.e. ISO 8612:2009, if the manufacturer or supplier claims compliance with it.

7 Additional information

Upon request, the manufacturer shall provide information on the operating principles of the certified tonometer.

8 Marking

The tonometer shall be permanently marked with at least the following information:

a) name of manufacturer or supplier;

b) name and model of tonometer;

c) if applicable, marking as required by IEC 60601-1.

Annex A
(normative)

Reference tonometer and method for determining reference IOP

A.1 Specifications of the reference applanation tonometer

A.1.1 General

The reference tonometer shall be a mechanical-optical applanation tonometer that measures the force required to produce a given area of applanation.

A.1.2 Area of applanation

The area of applanation shall be circular with a diameter of 3,06 mm. The manufacturing tolerance for the diameter of the applanation circle shall be ±0,02 mm.

A.1.3 Surface of tonometer head

The front (contact) surface of the tonometer head shall have a diameter of at least 6,0 mm and shall be smooth to the touch. When examined by unmagnified corrected vision under direct illumination, the surface shall be free from surface imperfections (free from fissures, cracks and dents) that could damage the eye. Over a central area of not less than 4 mm diameter, the front surface shall be a plane structure with a “peak to valley” deviation from a plane surface of less than 3,0 µm. The outer edge of this tonometer head shall be smoothed. The front surface flatness requirement shall be verified using the method given in A.2.3.6 or an alternate equivalent method.

A.1.4 Measuring force

The measuring force shall be continuously adjustable within a minimum range extending from 0 mN to 49,0 mN, without the use of auxiliary weights. The measured value of the force shall be clearly legible on a linearly divided scale or a digital indication.

The change of force required to move the tonometer head in the opposite direction (reverse span) at the point of transition shall not exceed 0,49 mN.

A.1.5 Display

If lines are used as graduations on the measuring scale, they shall be straight, of equal width, and shall be engraved or otherwise permanently marked. No line shall be wider than 1/4 of the distance between two lines.

If a digital display is used, the increments shall be $\leqslant$ 1 mmHg.

One scale unit shall represent either 0,98 mN or 1,96 mN. The main scale graduations shall be numbered with a value. The width of the reference mark shall be no greater than the smallest width of the graduation lines on the measuring scale.

A.1.6 Tolerance for measurement of force

When the tonometer head is adjusted to the verification position, the tolerance for the measured value of the force within the measuring range shall be ±1,5 % of the nominal value or ±0,49 mN, whichever is greater, over a temperature range from 15 °C to 30 °C.

A.2 Verification of reference tonometer

A.2.1 General

The reference tonometer shall be verified using the apparatus given in A.2.2 or an alternative equivalent method.

A.2.2 Apparatus

A.2.2.1 **Optical limit gauge**, consisting of a left line and two right vertical lines divided horizontally by a dashed line, for testing the applanation circle diameter (see Figure A.1). The distance between the right lines corresponds to twice the value of the tolerances of the applanation circle diameter specified in A.1.2.

Dimensions in millimetres

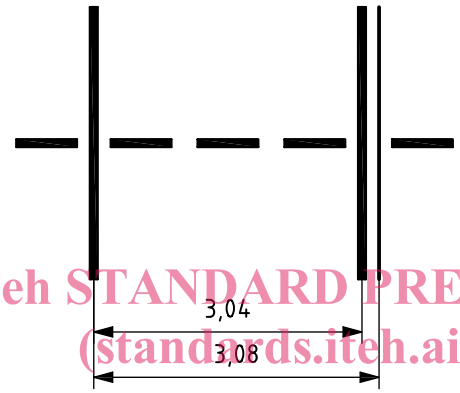


Figure A.1 — Optical limit gauge for verifying diameter of the applanation circle of 3,06 mm

A.2.2.2 **Balance**, of 0,01 g/scale division sensitivity for a) testing the measuring force, b) testing the reverse span for transitional movement of the tonometer head into the opposite direction, and c) for checking the position of the measuring arm with reference to its freedom of movement at equilibrium of forces.

A.2.2.3 **Flatness tester**, comprising a low pressure sodium lamp, a glass optical flat (flatness tolerance of $< 1/8$ wave at 589 nm) and a 10× magnifier lens for determining the flatness of the central 4 mm of the reference tonometer head (see Figure A.2).

A.2.3 Verification procedures

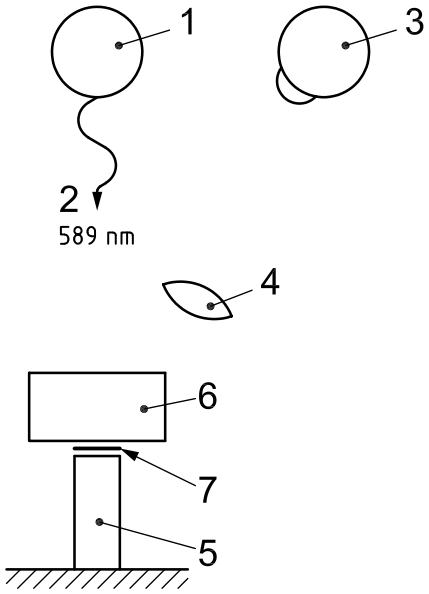
A.2.3.1 General

The reference tonometer shall be verified using the method given below or an equivalent method.

A.2.3.2 Diameter of the applanation circle

Substitute the optical limit gauge (A.2.2.1) for the examined eye. Orient the dividing line of the prisms so that it coincides with the dashed line. The action of the doubling prisms is to displace the images of the lines above and below the dividing line by a combined distance equal to the applanation circle diameter, so that they appear to come into coincidence (see Figure A.3). For a tonometer head without doubling prisms, determine the applanation circle diameter using a lined square that is verified by direct comparison with the optical gauge.

The tonometer shall comply with the tolerance requirements if the transposed lower half-line lies within the lateral interval delineated by the upper right line pair (Figure A.3).



Key

1 low pressure sodium lamp, e.g. SOX18 (ANSI L69)
2 radiation of wavelength 589 nm
3 observer
4 magnifier, 10×
5 tonometer tip under test
6 glass optical flat, 1/8 wave
7 interference fringes

Figure A.2 — Optical apparatus for verifying 3 µm flatness of the reference tonometer head

Dimensions in millimetres

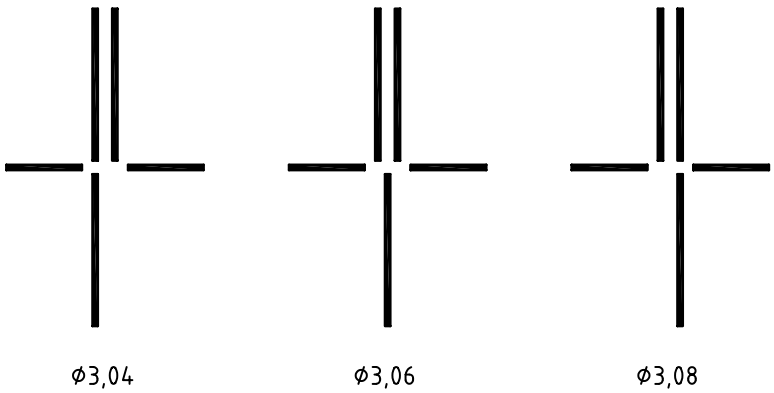


Figure A.3 — Verification of tolerance limits for diameter of the applanation circle, here for diameter values of 3,04 mm, 3,06 mm and 3,08 mm