INTERNATIONAL STANDARD

ISO 8612

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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 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.

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.

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

3.3
measured IOP
IOP reading provided by the tonometer when used in accordance with the manufacturer's instructions

3.4
reference tonometer
tonometer as described in annex A

3.5
test tonometer
verified tonometer used in design compliance testing

4 Requirements

4.1 General

The tonometer shall conform to the general requirements specified in ISO 15004.

The 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.

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 the 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 7 a), 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 that were used to measure and verify the test tonometer in 4.2. Details of the method and test apparatus shall be made available in accordance with the requirements of clause 7.

4.3.2 The permissible error of the test apparatus shall be 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) smooth when felt with the finger, and be free of surface imperfections that would damage the eye or prevent adequate disinfection, when examined by unmagnified corrected vision under specular reflection.

4.4.2 The tonometer shall permit the measurement of IOP throughout the range 7 to 50. 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 IOPs less than 7 shall be displayed either by their numerical value or by a "low reading" indication. Readings of IOPs greater than 50 shall be displayed either by their numerical value or by a "high reading" indication.

5 Test methods

5.1 All tests described in this International Standard are type tests.

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, with particular reference to the disinfection of instruments to be returned to the manufacturer for repair and maintenance;

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

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

e) if appropriate, a statement that the tonometer in its original packaging conforms to the transport conditions as specified in ISO 15004;

f) if appropriate, any additional documents as specified in 6.8 of IEC 60601-1:1988;

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

7 Additional information

The manufacturer shall provide the following information upon request:

a) information on the operating principles of the certified tonometer, specific protocol for design compliance testing (annex B), specific results of design compliance testing with statistical evaluation;

b) documentation describing the verification test apparatus, verification procedures and its own verification test results for that tonometer;

c) a full specification for the apparatus required for verification, sufficient to allow the purchaser or purchaser's representative to construct or acquire such test apparatus.

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 which 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 pressure body

The front surface of the pressure body shall be smooth to the touch, and, when examined by unmagnified corrected vision under direct illumination, shall be free from surface imperfections that could damage the eye, and shall have a diameter of at least 6,0 mm.

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 pressure body 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 less than or equal to 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 not be greater than the smallest width of the graduation lines on the measuring scale.

A.1.6 Tolerance for measurement of force

When the pressure body 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 Apparatus

A.2.1.1 Optical limit gauge, consisting of a left and two right vertical lines which are 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.2.1.2 Balance, of 0,01 g/scale division sensitivity for a) testing the measuring force, b) testing the reverse span for transitional movement of the pressure body 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 Verification procedures

A.2.2.1 General

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

A.2.2.2 Diameter of the applanation circle

Substitute the optical limit gauge (A.2.1.1) 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 (Figure A.2). For a pressure body 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.2).

Dimensions in millimetres

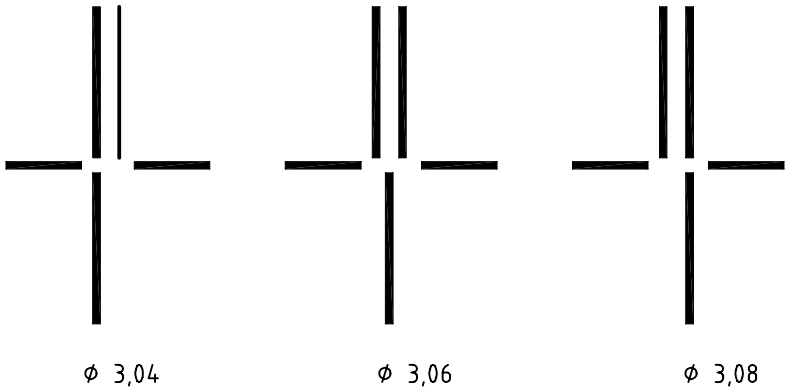


Figure A.2 — Verification of tolerance limits for diameter of the applanation circle, here for diameter values of 3,04 mm, 3,06 mm and 3,08 mm

A.2.2.3 Measuring force, reverse span and central position of the tonometer arm

The measuring force, reverse span and central position of the tonometer are verified by using the tonometer balance system (see Figure A.3) as follows.

NOTE Numbers in parentheses in the following instructions refer to Figure A.3.

Attach the applanation tonometer to the balance system by means of a holding device. Align one of the contact wheels to the tonometer pressure body (1, 2 or 3) using a three-coordinate fine adjustment, so that the contact wheel touches the centre of the pressure-body applanation surface and presses against it with enough force such that the balance pointer (5) is aligned to the zero index mark. The tonometer pressure setting for this step shall be in the centre of the measuring range, midway between the front and back overloading stops. Check the balance system for freedom of movement by loading the balance with a 0,5 g weight (4) and ensuring that the pointer swings to the lower balance stop.

After ensuring freedom of movement of the balance system, remove the 0,5 g weight. Next, ensure that the balance system responds freely to changes in the tonometer pressure setting as follows;

Adjust the applanation tonometer to a value which corresponds to an IOP of 10 mmHg.

Symmetrically align the pressure body with the contact wheel without touching it.

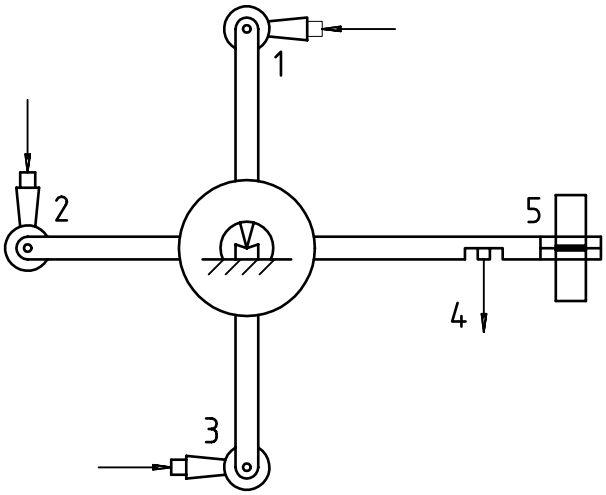
Move the pressure body towards the contact wheel until the balance swings clearly over its zero point.

Adjust the applanation tonometer to a value which corresponds to an IOP of 0 mmHg.

Successively place weights in increments of 1 g on the balance, from 1 g up to the maximum load. Increase the measuring force of the tonometer as the weights are added to the balance, until the pointer again coincides with the zero index mark.

Then carry out the test starting with the maximum weight and decreasing the tonometer measuring force. Adjustment and checking of the applanation tonometer shall be carried out using a low-vibration device.

The tonometer shall comply with the requirements specified in A.1.4 and A.1.6 if the deviations of the various values of the measuring force from nominal values, as displayed by the tonometer scale, do not exceed the tolerance values, and if the change of force required to move the pressure body in the reverse direction (reverse span) does not exceed the value specified in A.1.4.



Key

1, 2, 3 Contact wheels and pressure bodies at the different measuring positions
4 Balance weight
5 Pointer and zero index

Figure A.3 — Arrangement for verifying the measuring force

A.2.2.4 Width of lines on the measuring drum

The tonometer shall comply with the requirements specified in A.1.5, if the measured width is less than or equal to the width of the standard line.

A.2.2.5 Variation of measuring-force scale reading between 15 °C and 30 °C

The test should, in general, be carried out only once for each reference tonometer.

Place the tonometer, mounted on the tonometer balance, in a room in which the temperature can be adjusted. Monitor the scale readings as a function of temperature.

The tonometer shall comply with the requirements specified in A.1.6 if, throughout the temperature range, the scale readings do not vary by more than the permitted limits.

A.2.3 Test certificate

The results of verification testing, carried out in accordance with this International Standard, shall be recorded in a test certificate provided by the manufacturer in the countries where no legal verification is available. An example of a test certificate is illustrated in Figure A.4.

Tonometer Test Certificate

Tonometer No.: _____ Date: _____

Sender: _____ Tester: _____

Manufacturer: _____ Controller: _____

Diameter of applanation circle, nominal 3,06 mm or _____ ± 0,02 mm

a) Pressure body No.1 _____ mm b) Pressure body No. 2 _____ mm

MEASURING FORCE

Initial state: The tonometer arm shall be adjusted symmetrically in the free space available for movement with reference to the verification position.

Nominal requirement	**Error**	
	Horizontal	**Vertical**
9,81 ± 0,49 mN	_____ mN	_____ mN
19,61 ± 0,49 mN	_____ mN	_____ mN
29,42 ± 0,49 mN	_____ mN	_____ mN
39,23 ± 0,59 mN	_____ mN	_____ mN
49,03 ± 0,74 mN	_____ mN	_____ mN
58,84 ± 0,88 mN	_____ mN	_____ mN
68,65 ± 1,03 mN	_____ mN	_____ mN
78,45 ± 1,18 mN	_____ mN	_____ mN

Reverse span at the transition of pressure body movement into the opposite direction:

0,49 mN maximum _____ mN

Position of measuring arm relative to its free play at equilibrium of force:

Middle _____

Remarks: _____

_____

_____

Result: _____ Verified _____ Not verified

Signature: _____

Figure A.4 — Example of a test certificate

A.3 Protocol for using the reference tonometer

The following procedure shall be carried out when using the reference tonometer in the design compliance testing specified in annex B.

a) Anaesthetize the selected eye of the subject.

b) Stain with sodium fluorescein.

NOTE Steps a) and b) may be combined by using an anaesthetic to which sodium fluorescein has already been added.

c) Set the tonometer drum to a force corresponding to an IOP of 10 mmHg.

If possible, do not touch the eyelid with the fingers in order to open the palpebral aperture. If the palpebral aperture is not wide enough to allow the tonometer cone to make contact, instruct the subject to open his/her eyes wider.

d) Direct the subject to view a distance fixation point. If distance fixation cannot be maintained and near fixation is used, this fact should be recorded.

e) Measure the intraocular pressure for the mean of the ocular pulse and remove the tonometer from the eye.

f) Repeat steps c) ,d) and e) if the measurement was not valid because:

1) the patient felt a sensation;

2) the eyelid was touched;

3) the fluorescein ring was too broad or too thin;

4) any other circumstances suggest that the measurement may have been inaccurate.

g) If there is any evidence that the anaesthetic is no longer fully effective, re-administer the anaesthetic.

h) Repeat steps c), d), e) and f) if a series of multiple measurements is suggested. After the first measurement for a given subject has been taken, all valid subsequent measurements shall be recorded when a series of multiple measurements are desired. If any interruption to the consecutive readings occurs, then recommence the procedure.