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.