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Ophthalmic instruments – Impression and Applanation Tonometers

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Foreword

This Recommendation was developed by the OIML Working Group “Tonometer” of Technical Committee 18 “Medical Measuring Instruments” between 2005 and 2010.

Tonometers have been used for many years to measure the intraocular pressure of an individual's eye. An accurate measurement of this pressure is an extremely important diagnostic tool, especially for Glaucoma.

Generally accepted requirements are laid down in this Recommendation. It describes also the testing of impression and applanation tonometers based on the experience gathered in the past. Most of this experience and knowledge to setup requirements and test procedures was collected for more than 30 years in the Physikalisch-Technische Bundesanstalt, Berlin, Germany by Kai Jessen, Hans-Joachim Thiemich and Rudi Drahn and in the German Verification Offices by Hubert Dudek. Also most of the special test equipment was designed by these experts.

1. Scope

This Recommendation specifies requirements for the design compliance and construction of impression and applanation tonometers, which are used for the determination of the intraocular pressure (IOP) in clinical application. It refers solely to those applanation tonometers, which measure the force necessary to applanate the cornea with a pressure body to a given diameter, according to the method developed by Hans Goldmann.

2. Terminology

For the purposes of this Recommendation the following terms and definitions apply.

2.1 Design compliance

The compliance of a tonometer according to the design and the construction of the manufacturer.

2.2 Intraocular pressure (IOP)

The pressure within the eye front chamber, given in millimeters of mercury (mmHg)

3. Description of the category of instrument

3.1 Impression tonometer

The impression tonometer designed by Hjalmar Schiøtz measures the indentation of the cornea by a plunger of defined mass.

3.2 Applanation tonometer

Applanation tonometer measure either the force necessary to applanate the cornea with a pressure body to a given diameter, or determine the diameter of the applanated cornea area with a known measuring force.

4. Units of the measurement

The IOP is measured in millimeters of mercury (mmHg). The scale is divided in arbitrary units, a conversion rule or table must be provided.

For impression tonometers the correlation between indentation and IOP was determined by Friedenwald (Friedenwald JS (1957). Tonometer Calibration. Trans Am Acad Ophthal Otol 61, pp108-123).

5. Requirements

5.1 General

Those parts of the tonometer, that are intended to contact the cornea shall be made of stainless and acid-resistant steel, or of material which is inert to tissues.

5.2 Environmental condition

5.2.1 Devices in use

Tonometers shall comply with all requirements specified in this Recommendation at

- temperature between 15 °C and 35 °C,
- relative humidity between 10 % and 90 % (non-condensing)

Testing shall be carried out in accordance with 6.1.

5.2.2 Influence of storage

Tonometers shall comply with all requirements specified in this Recommendation after storage at

- temperature between -10 °C and 55 °C,
- relative humidity between 10 % and 95 % (non-condensing)

Testing shall be carried out in accordance with 6.2.

5.3 Accompanying documents

The manufacturers shall provide a user's instruction, which include instructions for disinfection and maintenance. The user's instructions for impression tonometer shall include a conversion table from scale value to IOP.

5.4 Inscriptions

Each tonometer shall bear the following information:

- name of manufacturer or trade mark;
- serial number.

Each instrument and its necessary accessories, except for the pressure body of the applanation tonometers, shall be marked with an individual serial number. However, in case marking is likely to deteriorate their function, the list of instruments or accessories shall be alternatively attached.

Applanation tonometer shall indicate near the scale the value of the force given in mN equivalent with the smallest scale interval on the scale.

Testing shall be carried out by visual inspection.

5.5 Specific requirements for impression tonometer

5.5.1 Mass of the tonometer and additional masses

The mass of the tonometer, without handle, shall be $(16,5 \pm 0,5)$ g. The additional masses to extend the measuring range shall be as follows:

- additional mass with inscription 7.5: $2,00 \text{ g} \pm 0,02 \text{ g}$
- additional mass with inscription 10.0: $4,50 \text{ g} \pm 0,02 \text{ g}$
- additional mass with inscription 15.0: $9,50 \text{ g} \pm 0,02 \text{ g}$

Note: The inscriptions 7.5, 10.0 and 15.0 on the additional masses are used, because the effective mass of the lever-pointer-plunger system together with the additional mass is as inscribed on the additional mass.

Testing shall be carried out in accordance with 6.3.

5.5.2 Effective mass

The effective mass of the lever-pointer-plunger system when the tonometer is in a vertical position shall be as follows:

- 5,50 g \pm 0,15 g when indicating scale division 5
- 5,50 g \pm 0,20 g when indicating scale division 10

Testing shall be carried out in accordance with 6.4.

5.5.3 Friction between plunger and plunger sleeve

The friction between plunger and plunger sleeve shall not interfere significantly the result of the measurement.

Testing shall be carried out according 6.5.

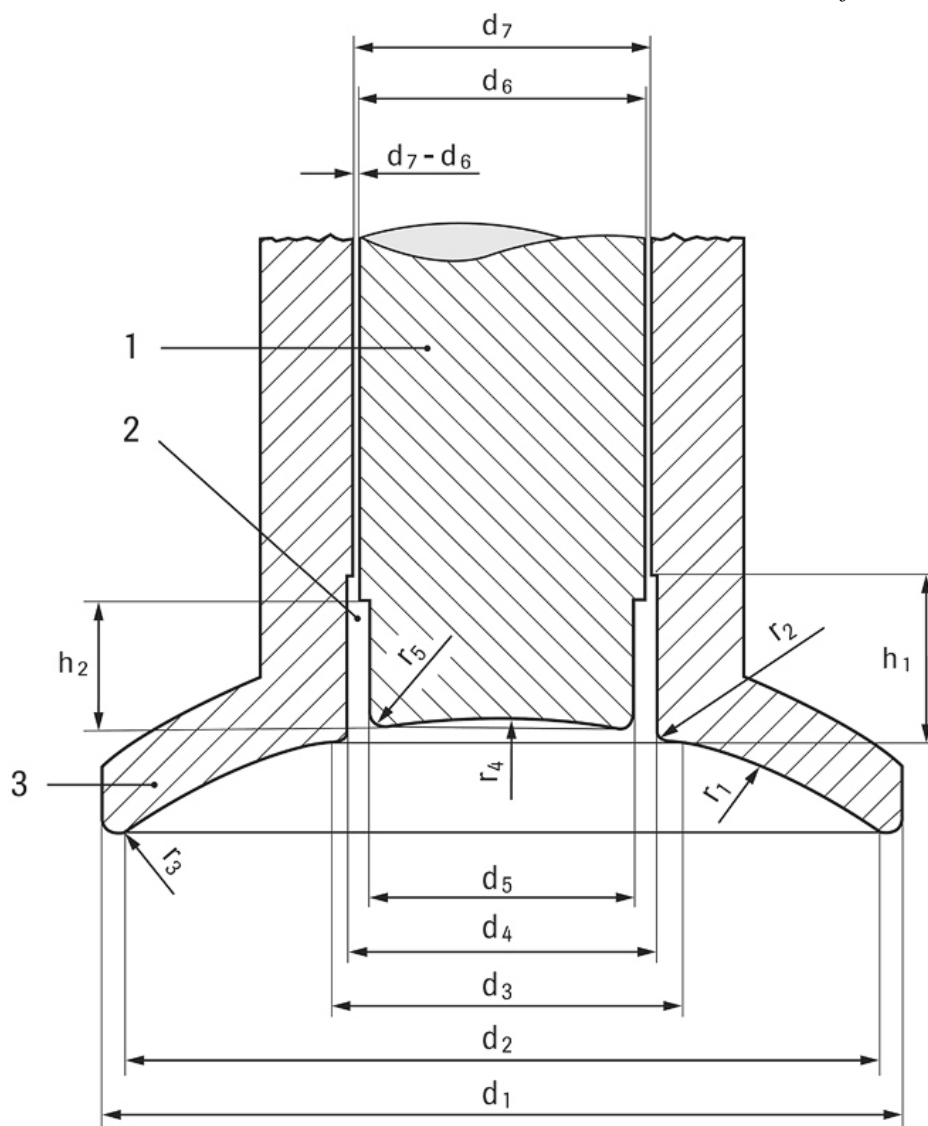
5.5.4 Surface

The front (contact) surfaces of the footplate and plunger shall be smooth to the touch, and, when examined by unaided corrected vision, shall be free from surface imperfections that could damage the eye. The outer edge of the footplate and the inside edge of the recess or counterbore shall be rounded (cf. 5.5.5).

Testing shall be carried out by visual inspection.

5.5.5 Dimensions of footplate and plunger

The footplate and the plunger shall comply with the dimensions given in table 1 and 2.



Key

- 1 Plunger
- 2 Air gap
- 3 Footplate

- r_1 : radius of curvature of the spherical front surface of the footplate
- r_2 : minimum radius of the inside edge curvature of the footplate
- r_3 : minimum radius of the outside edge curvature of the footplate
- r_4 : radius of curvature of the spherical front surface of the plunger
- r_5 : radius of the edge curvature of the plunger

- d_1 : Outer diameter of the footplate
- d_2 : outside diameter of the spherical front Surface of the footplate
- d_3 : diameter of the transition circle of the footplate
- d_4 : diameter at the front surface up to the height of the footplate
- d_5 : diameter of the plunger at the front surface up to the height of 1,5 mm
- d_6 : diameter of the plunger up the height of 1,5 mm
- d_7 : diameter of the bore of the footplate
- h_1 : height of the bore hole of the footplate
- h_2 : height of the crank under 1,5 mm of the plunger diameter

Figure 1: Schematic drawing of footplate and plunger of the impression tonometer

Table 1: Dimensions of footplate for impression tonometer (cf. fig. 1)

items of footplate	dimension (mm)
diameter (d ₁)	10,1 ± 0,2
radius of curvature of the spherical front surface (r ₁)	15,00 ± 0,25
outside diameter of the spherical front surface (d ₂)	9,0 + 0,1
minimum radius of the outside edge curvature (r ₃)	0,2
either - diameter (d ₄) of the recess or counterbore on the front surface up to the height (h ₁)	3,3 - 0,1
- minimum radius of the inside edge curvature (r ₂)	0,2
or - diameter of the bore hole at the transition between footplate curvature and the edge curvature of the recess or counterbore (central area) (d ₃)	3,7 - 0,1
minimum height of the recess or counterbore on the front surface (h ₁)	≥ 1,5

Table 2: Dimensions of plunger for impression tonometer (cf. fig. 1)

items of plunger	dimension (mm)
minimum diameter (d ₄) at the front surface up to the height (h ₁) of 1,5 mm	3,00 ± 0,03
minimum height(h ₂) at the front surface with the diameter (d ₅)	1,5
radius of curvature of the spherical front surface (r ₄)	15,00 ± 0,75
radius of the edge curvature (r ₅)	0,25 ± 0,03
maximum extension of the plunger below the spherical footplate	3,0

Table 3: Dimensions of plunger sleeve and plunger (cf. fig. 1)

	dimension (mm)
maximum difference $d_7 - d_6$ [d_7 : diameter in the footplate of the plunger sleeve, d_6 : diameter of the plunger]	0,05

Testing shall be carried out according 6.6 and 6.7.

5.5.6 Plunger

For impression tonometer designed according Schioetz applies: At some point between the scale indications 5 and 10, the plunger axis and the lower surface of the lever shall form a right angle at the point of contact.

Testing shall be carried out by visual inspection.

5.5.7 Scale

The scale shall be arranged parallel or inclined to the axis of the plunger.

The scale shall be divided into at least 15 equal scale divisions (from -1 to 15 or from 0 to 15 respectively). The scale shall show integers only.

The distance between two adjacent lines shall be equal to a plunger displacement of 0,05 mm. The permissible error limits for different displacements are given in table 4.

Table 4: Displacement and its permissible error limits of the plunger of impression tonometers.

scale division (from – to)	plunger displacement and its permissible error limits (mm)
0 - 5	0,25 ± 0,01
0 - 10	0,50 ± 0,02
0 - 15	0,75 ± 0,03
0 - 18	0,90 ± 0,05
-1 - 15	0,80 ± 0,03

The division of the scale shall consist of straight lines, of equal width, and directed in the axis of the pointer. No line shall neither be wider than $\frac{1}{4}$ of the distance between two lines nor more than 0,25 mm.

Testing shall be carried out by visual inspection and according 6.8.

5.5.8 Pointer

The pointer shall not be wider than the smallest width of a scale line. If the Pointer moves over the scale, it shall overlap the shortest lines by at least one-third. The tip shall not extend beyond the scale lines. The distance between pointer and the plane of the scale shall not be greater than 1,0 mm at any point of the scale. The pointer shall not grind on the plane of the scale.

Testing shall be carried out by visual inspection and according 6.9.

5.5.9 Position of use of the tonometer

When the tonometer is picked up without restraint at the holding point of the handle, the axis shall be in the vertical position.

Testing shall be carried out by visual inspection.

5.5.10 Test block

Each single tonometer shall have a test block whose curvature is $(16,00 \pm 0,05)$ mm to test that the indication is $0,0 \pm 0,2$ on the scale when put on the test block.

Testing shall be carried out by visual inspection.

5.6 Specific requirements for applanation tonometer

Note: The applanation tonometer measures the force necessary to applanate the Cornea with a pressure body to a given diameter. Instruments with different measuring principle are not in the scope of this Recommendation (cf. 1.). The measurement of the force is usually indicated on a scale.

5.6.1 Diameter of applanation circle

The diameter of the applanation circle shall be $(3,06 \pm 0,02)$ mm.

Testing shall be carried out in accordance with 6.10.

5.6.2 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.

Testing shall be carried out by visual inspection.

5.6.3 Diameter of the pressure body

The pressure body shall have a diameter of at least 6,0 mm at the area to contact the cornea.

Testing shall be carried out in accordance with 6.11.

5.6.4 Measuring force

The measuring force shall be continuously adjustable within the minimum range extending from 0,0 mN to 49,0 mN, without the use of auxiliary masses. The measured value of the force shall be clearly legible.

Testing shall be carried out by visual inspection.

5.6.5 Accuracy of the measuring force

When the pressure body is adjusted to the verification position, the permissible error of the force within the measuring range shall be not more than $\pm 1,5$ % of the nominal value or $\pm 0,49$ mN whichever is greater.

Testing shall be carried out in accordance with 6.12.

5.6.6 Effect of hysteresis

The effect of hysteresis for the measuring force shall not exceed 0,29 mN.

Testing shall be carried out in accordance 6.12.

5.6.7 Scale

Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width, and shall be engraved or otherwise permanently marked. No line shall be wider than $\frac{1}{4}$ of the distance between two lines.

One scale mark shall represent either 0,1 or 0,2 scale divisions. The scale graduations at 0, 1, 2, 3 etc. shall be numbered with an integer value. The scale shall be linearly divided. The conversion factor between scale value and force in mN shall be 9,81.

Note: At an applanation circle of 3,06 mm (cf. 5.6.1) the conversion factor between scale value and IOP in mmHg is 10,0.

Each fifth scale mark shall have greater length. The width of the reference mark shall not be greater than the width of the graduation lines on the measuring scale.

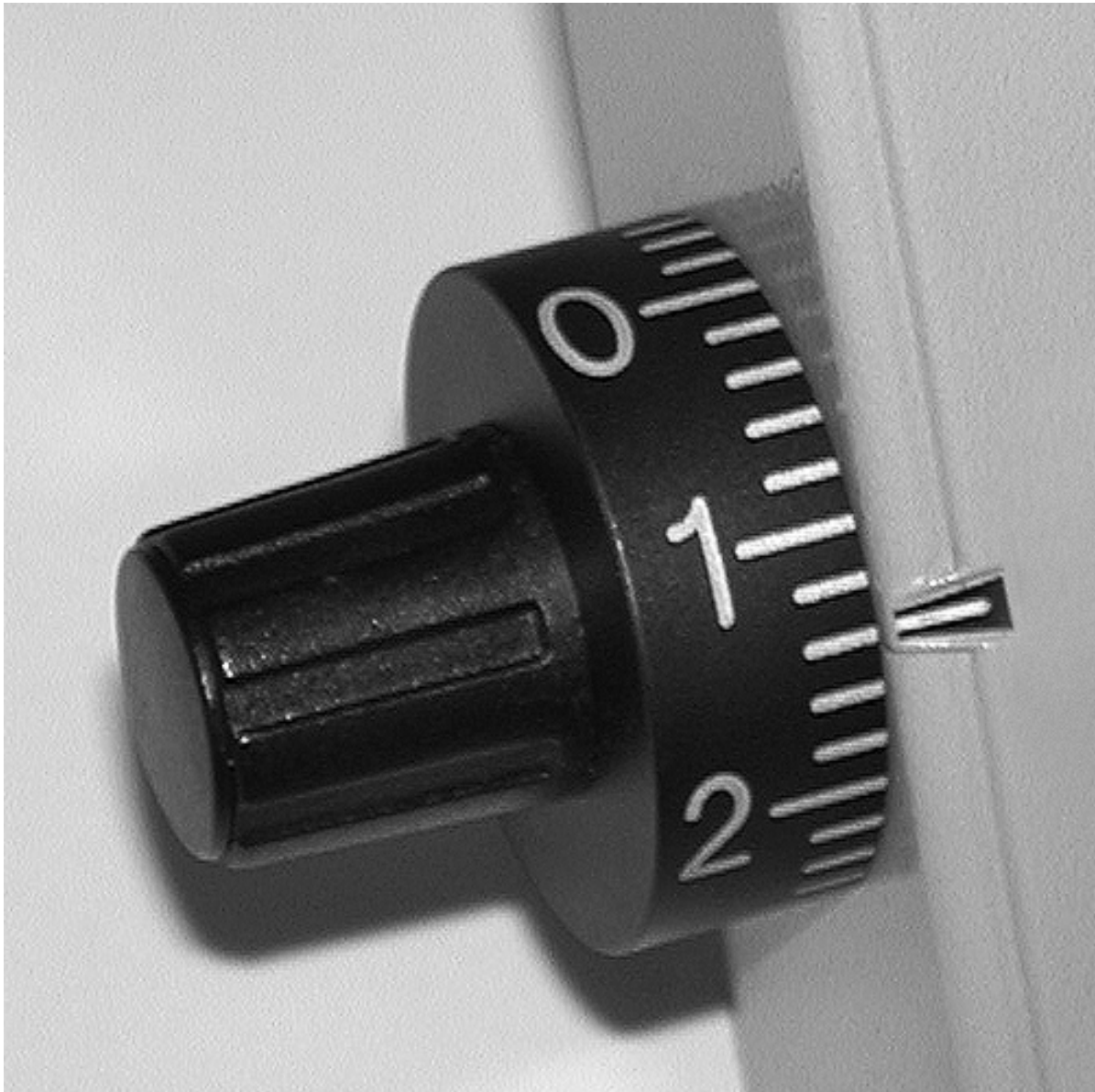


Figure 2: Example of a scale for an applanation tonometer (the unit mN is not shown here).

Testing shall be carried out by visual inspection.

5.6.8 Mechanical strength

Hand-held applanation tonometer shall fall freely once from each of three different starting

orientations from a height of 1 m onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base. Test on the requirement given in 5.6.5 and 5.6.6.

All other applanation tonometer shall fall freely once from each of three different starting orientations from a height of 5 cm onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base. Test on the requirement given in 5.6.5 and 5.6.6.

Note: Drop tests with impression tonometer are not performed, because the damage should be visible for the user.

6. Test methods

6.1 Influence of environmental conditions on the performance for devices in use

Under at least 3 different sets of environmental conditions described in 5.2.1, tests shall be performed

- for impression tonometer on the requirements given in 5.5.3 (test procedure: 6.5) and 5.5.7, table 4 “Displacement and its permissible error limits of the plunger of impression tonometers” (test procedure: 6.8),
- for applanation tonometer on the requirements given in 5.6.5 (test procedure: 6.12) and 5.6.6 (test procedure: 6.12).

6.2 Influence of storage on the performance

After being subject to at least 2 different sets of environmental conditions described in 5.2.2 for 24 h each, tests shall be performed

- for impression tonometer on the requirements given in 5.5.3 (test procedure: 6.5) and 5.5.7, table 4 “Displacement and its permissible error limits of the plunger of impression tonometers” (test procedure: 6.8),
- for applanation tonometer on the requirements given in 5.6.5 (test procedure: 6.12) and 5.6.6 (test procedure: 6.12).

6.3 Measurement of the mass of the impression tonometer and additional masses

6.3.1 Apparatus

6.3.1.1 Balance with a measurement uncertainty equal or less than 50 mg.

6.3.1.2 Balance with a measurement uncertainty equal or less than 2 mg.

Note: For the measurement of the different masses either two balances (as described above) or one balance (measurement uncertainty equal or less than 2 mg) can be used.

6.3.2 Procedure

The mass of the tonometer, without the handle, is measured with the balance (6.3.1.1).

The additional masses are measured with the balance (6.3.1.2).

6.3.3 Expression of results

Express the results as the differences of measured masses and the values given in 5.5.1.

6.4 Measurement of the effective mass of the impression tonometer

6.4.1 Apparatus

6.4.1.1 Balance with a measurement uncertainty equal or less than 10 mg.

6.4.2 Procedure

The effective mass of the lever-pointer-plunger system with the tonometer in a vertical position is determined by the balance (6.4.1.1).

6.4.3 Expression of results

Express the results as the difference of measured mass and the value given in 5.5.2.

6.5 Determination of the friction between plunger and plunger sleeve of the impression tonometer

6.5.1 Apparatus

6.5.1.1 Goniometer

6.5.2 Procedure

When the tonometer is moved slowly and uniformly from the horizontal position into the vertical position with the plunger on the upper stop, the plunger shall begin to slide into the footplate hole before the angle of the tonometer axis relative to the horizontal exceeds 25 degrees. During this manoeuvre, the lever shall not touch the plunger. The tonometer shall be able to slide easily in its handle, see figure 3a and 3b.

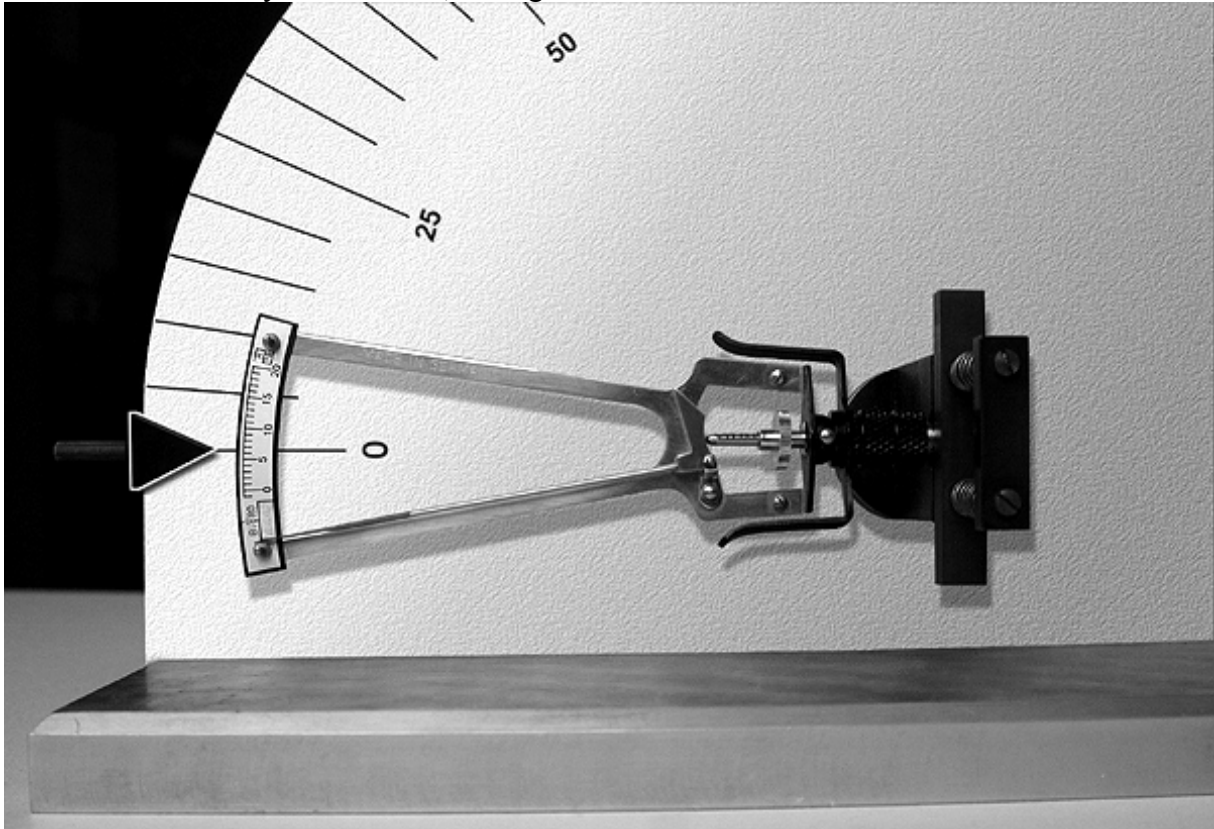


Figure 3a: Tonometer at horizontal position

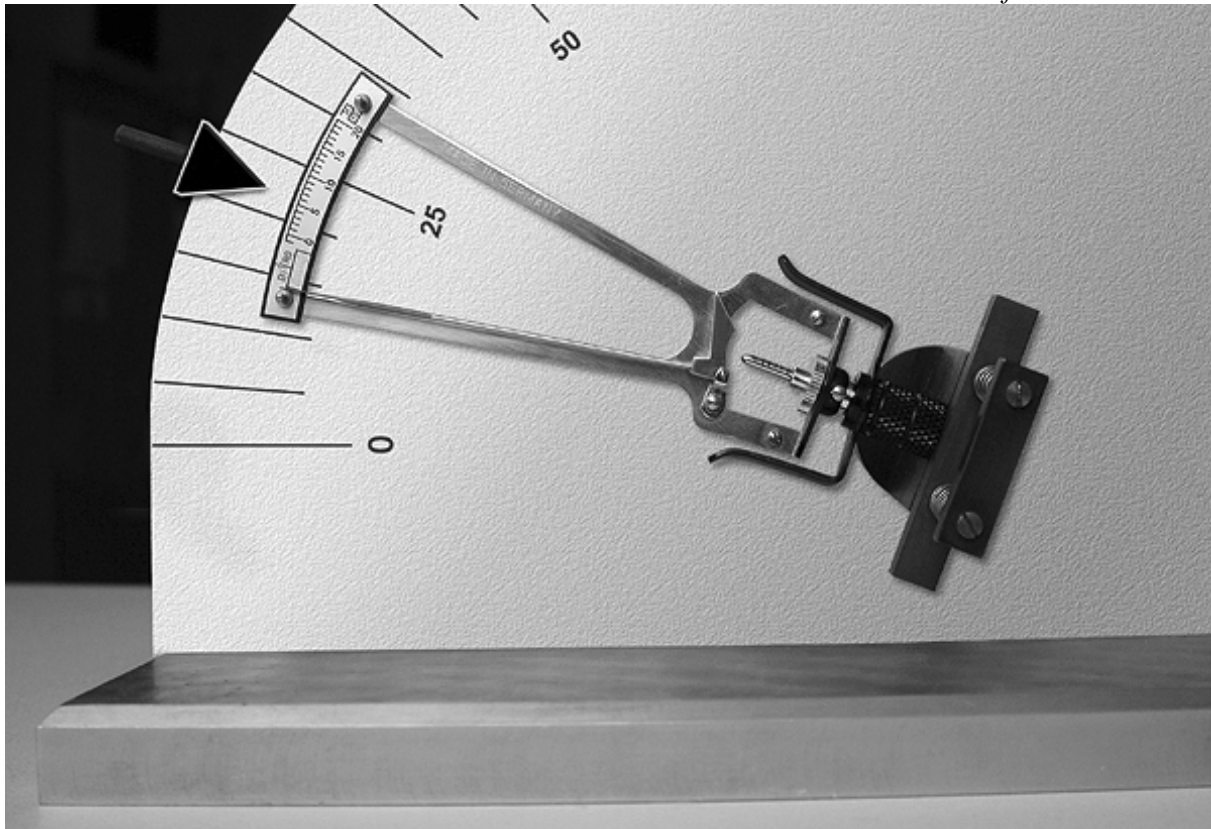


Figure 3b: The plunger begins to slide into the footplate hole before the angle of the tonometer axis relative to the horizontal exceeds 25 degrees.

6.6 Measurement of the dimensions of footplate and plunger of the impression tonometer

6.6.1 Apparatus

6.6.1.1 Length measuring instrument with a measurement uncertainty equal or less than 0,01 mm.

6.6.2 Procedure

Measure the lengths, diameters and radiuses given in table 1 with length measuring instrument(s) (6.6.1.1).

6.6.3 Expression of results

Express the results as the differences of measured length and the values given in 5.5.5.

6.7 Test of the curvature of the footplate and plunger of the impression tonometer

6.7.1 Apparatus

6.7.1.1 Length measuring instrument with a measurement uncertainty equal or less than 0,01 mm.

6.7.1.2 Test block with radius of curvature of $(14,75 \pm 0,05)$ mm

6.7.1.3 Test block with radius of curvature of $(16,00 \pm 0,05)$ mm

6.7.2 Procedure

Measure the lengths, diameters and radiuses given in table 2 with length measuring instrument(s) (6.7.1.1).

When the instrument is tested on a test block whose radius of curvature is $(14,75 \pm 0,05)$ mm, the pointer shall indicate $-1,0 \pm 0,2$ on the scale. When tested on a block whose radius of curvature is $(16,00 \pm 0,05)$ mm, it shall indicate $0,0 \pm 0,2$ on the scale.

With the tonometer in position on the test block, the scale reading shall not vary by more than 0,4 scale divisions when the plunger is rotated or moved laterally, or when the lever is moved laterally.

Note: The two test blocks are required to check the interaction of the plunger and the footplate.

6.7.3 Expression of results

Express the results as the differences of measured length and the values given in 5.5.5. The measurements with the test blocks shall be expressed as maximum scale readings.

6.8 Test of the displacement of the plunger for impression tonometers

6.8.1 Apparatus

6.8.1.1 Length measuring instrument with a measurement uncertainty equal or less than 0,002 mm.

6.8.2 Procedure

Measure the displacements of the plunger given in table 3 with the length measuring instrument (6.8.1.1).

6.8.3 Expression of results

Express the results as the differences of measured displacements and the values given in 5.5.7.

6.9 Test of the distance between the scale and the pointer of the impression tonometer

6.9.1 Apparatus

6.9.1.1 Gauge of 1,00 mm with a measurement uncertainty of 0,02 mm or less.

6.9.2 Procedure

Test the distance between the scale and the pointer of the impression tonometer with the gauge (6.9.1.1) at 3 different scale positions, smallest, largest scale marking and in-between. The gauge shall not or only hardly fit between scale and pointer.

6.10 Determination of the diameter of applanation circle of the applanation tonometer

6.10.1 Apparatus

6.10.1.1 Length measuring instrument (e.g. reticule of lines in combination with a microscope) with a measurement uncertainty equal or less than 0,004 mm.

6.10.2 Procedure

Determine the diameter of the applanation circle with the length measuring instrument (6.10.1.1) in two directions, perpendicular to each other.

6.10.3 Expression of results

Express the result as the differences of measured lengths and the value given in 5.6.1. If a reticule of lines with the indication of the minimum and maximum value is used, it is sufficient to state that the diameter stays in the required limits.

6.11 Determination of the diameter of the pressure body of the applanation tonometer

6.11.1 Apparatus

6.11.1.1 Length measuring instrument with a measurement uncertainty equal or less than 0,1 mm.

6.11.2 Procedure

Determine the diameter of the pressure body with the length measuring instrument (6.11.1.1) in two directions, perpendicular to each other.

6.11.3 Expression of results

Express the result as the differences of measured lengths and the value given in 5.6.3.

6.12 Measurement of the accuracy of the measuring force of the applanation tonometer and the effect of hysteresis of the applanation tonometer

6.12.1 Apparatus

6.12.1.1 Force measuring instrument (e.g. a balance) with a measurement uncertainty equal or less than 0,15 mN.

6.12.2 Procedure

Increase the force in steps of not more than 10 mN by adjusting the dial of the applanation tonometer and measure this force with the force measuring instrument (6.12.1.1). When the upper limit of the measuring range is attained, the force is decreased on the same force levels that were measured when increasing the force.

6.12.3 Expression of results

Express the result as the differences of adjusted forces of the applanation tonometer and the measured forces to determine the accuracy of the measurement. To determine the hysteresis error, calculate the difference of the measured forces when increasing the force and when decreasing the force.

Annex A Test report format for impression tonometer

Notes: This Annex is informative with regard to implementation of OIML Rxxx in national regulations; however, use of the Test Report Format is mandatory for the application of the Recommendation within the OIML Certificate System.

References to the requirements of OIML Rxxx are given in brackets.

A.1 Name and address of testing laboratory (laboratories)

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.....

A.2 Reference to this Recommendation

OIML Rxx, year of edition 201__

A.3 Identification of the pattern to which the test report applies

As an example common and trade names and model, and a brief description including drawings, diagrams, and inscriptions, specifically including the following:

- Type of tonometer and characteristics

Impression tonometer: mechanical / mechanical-electrical

- measuring range,

IOP: from mmHg to mmHg

scale : from scale div. toscale div.

A.4 Identification of samples tested (e.g. serial number)

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.....
.....
.....
.....

A.5 Name and address of manufacturer

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.....

A.6 Name and address of applicant if different from manufacturer

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.....
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A.7 Dates of the test period: Start..... End.....

A.8 Location or name of laboratory, where the tests were performed, if different from the address given in A.1 :

.....
.....
.....
.....
.....

A.9 Information and identification

A.9.1 List of documents submitted for the evaluation:

Pass: Fail:

A.9.2 Operating manual, clear and complete instructions:

Pass: Fail:

A.9.3 Operating manual, compliance with the requirements:

Pass: Fail:

A.10 Summary of tests carried out as specified conditions specified in this Recommendation.

A.10.1 General tests

- Test of visible defects or damages:

Pass: Fail:

- Measurements and units (4):

Pass: Fail:

Comments:

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A.10.2 Specific requirements for impressiontonometer (5.5)

- A.10.2.1** Tonometer mass without handle (5.5.1):

16,5 ± 0,5 g

Pass: Fail:

- A.10.2.2** additional mass with inscription 7.5 (5.5.1):

2,00 g ± 0,02 g

Pass: Fail:

- A.10.2.3** additional mass with inscription 10.0 (5.5.1):

4,50 g ± 0,02 g

Pass: Fail:

- A.10.2.4** additional mass with inscription 15.0 (5.5.1):

9,50 g ± 0,02 g

Pass: Fail:

A.10.3 Effective mass (5.5.2)

- A.10.3.1** Scale division 5 (5.5.2) for the effective mass

5,50 g ± 0,15 g

Pass: Fail:

- A.10.3.2** Scale division 10 (5.5.2) for the effective mass

5,50 g ± 0,20 g

Pass: Fail:

A.10.4 Friction between plunger and plunger sleeve

A.10.4.1 Surface (5.5.4)

Testing shall be carried out by visual inspection

Pass: Fail:

A.10.5 Dimensions of footplate and plunger (5.5.5)

Items of footplate

A.10.5.1 diameter (d_1)

10,1 mm \pm 0,2 mm

Pass: Fail:

A.10.5.2 radius of curvature of the spherical front surface (r_1)

15,00 mm \pm 0,25 mm

Pass: Fail:

A.10.5.3 outside diameter of the spherical front surface (d_2)

9,0 mm + 0,1 mm

minimum radius of the outside edge curvature (r_3) 0,2 mm

Pass: Fail:

A.10.5.4 either - diameter (d_4) of the recess or counterbore

on the front surface up to the height (h_1) 3,3 mm - 0,1 mm

minimum radius of the inside edge curvature (r_2) 0,2 mm

Pass: Fail:

A.10.5.5 or -diameter of the bore hole at the transition between foot-plate curvature and the edge curvature of the recess or counterbore (central area) (d_3)

3,7 mm - 0,1 mm

Pass: Fail:

A.10.5.6 minimum height of the recess or counterbore

on the front surface (h_1) \geq 1,5 mm

Pass: Fail:

Items of plunger

10.5.7 minimum diameter (d_4) at the front surface up to the height (h_1) of 1,5 mm

3,00 mm \pm 0,03 mm

Pass: Fail:

10.5.8 minimum height(h_2) at the front surface
with the diameter (d_5)

1,5 mm

Pass: Fail:

10.5.9 radius of curvature of the spherical front surface (r_4) 3,00 mm \pm 0,03 mm

Pass: Fail:

10.5.10 radius of the edge curvature (r_5) 0,25 mm \pm 0,03 mm

Pass: Fail:

10.5.11 maximum extension of the plunger below
the spherical footplate

3,0 mm

Pass: Fail:

Dimension of plunger sleeve and plunger

10.5.12 maximum difference $d_7 - d_6$

[d_7 : diameter in the footplate of the plunger sleeve,
 d_6 : diameter of the plunger]

0,05 mm

Pass: Fail:

A.10.6 Plunger (5.5.6)

For impression tonometer designed according Schioetz applies: At some point between the scale indications 5 and 10, the plunger axis and the lower surface of the lever shall form a right angle at the point of contact. Testing shall be carried out by visual inspection

Pass: Fail:

A.10.7 Scale (5.5.7)

10.7.1 The scale shall be arranged parallel or inclined to the axis of the plunger.

Pass: Fail:

A.10.7.2 The scale shall be divided into at least 15 equal scale divisions (from -1 to 15 or from 0 to 15 respectively). The scale shall show integers only.

Pass: Fail:

Scale division

The distance between two adjacent lines shall be equal to a plunger displacement of 0,05 mm. The permissible error limits for different displacements

Plunger displacement and its permissible error

Scale division from 0 to 5	0,25 mm ± 0,01 mm
	Pass: <input type="checkbox"/> Fail: <input type="checkbox"/>
Scale division from 0 to 10	0,50 mm ± 0,02 mm
	Pass: <input type="checkbox"/> Fail: <input type="checkbox"/>
Scale division from 0 to 15	0,75 mm ± 0,03 mm
	Pass: <input type="checkbox"/> Fail: <input type="checkbox"/>
Scale division from 0 to 18	0,90 mm ± 0,05 mm
	Pass: <input type="checkbox"/> Fail: <input type="checkbox"/>
Scale division from -1 to 15	0,80 ± 0,03
	Pass: <input type="checkbox"/> Fail: <input type="checkbox"/>

The division of the scale shall consist of straight lines, of equal width, and directed in the axis of the pointer. No line shall neither be wider than ¼ of the distance between two lines nor more than 0,25 mm.

Pass: Fail:

A.10.8 Pointer (5.5.8)

The pointer shall not be wider than the smallest width of a scale line. If the Pointer moves over the scale, it shall overlap the shortest lines by at least one-third. The tip shall not extend beyond the scale lines. The distance between pointer and the plane of the scale shall not be greater than 1,0 mm at any point of the scale. The pointer shall not grind on the plane of the scale

Pass: Fail:

A.10.9 Position of use the tonometer (5.5.9)

When the tonometer is picked up without restraint at the holding point of the handle, the axis shall be in the vertical position.

Pass: Fail:

A.10.10 Test block

Each single tonometer shall have a test block whose curvature is 16,00 mm \pm 0,05 mm to test that the indication is $0,0 \pm 0,2$ on the scale when put on the test block.

Pass: Fail:

Annex B Test report format for applanation tonometer

Notes: This Annex is informative with regard to implementation of OIML Rxxx in national regulations; however, use of the Test Report Format is mandatory for the application of the Recommendation within the OIML Certificate System.

References to the requirements of OIML Rxxx are given in brackets.

B.1 Name and address of testing laboratory (laboratories)

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.....
.....
.....
.....
.....

B.2 Reference to this Recommendation

OIML Rxxx, year of edition: 201

B.3 Identification of the pattern to which the test report applies

As an example common and trade names and model, and a brief description including drawings, diagrams, and inscriptions, specifically including the following:

- Type of tonometer and characteristics,
pressure body / diameter:
- measuring range,
IOP: from mmHg to mmHg
scale: from scale div. to scale div.

B.4 Identification of samples tested (e.g. serial number)

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B.5 Name and address of manufacturer

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B.6 Name and address of applicant if different from manufacturer

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B.7 Dates of the test period: Start..... End.....

B.8 Location or name of laboratory, where the tests were performed, if different from the address given in B.1 :

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.....
.....
.....

B.9 Information and identification

B.9.1 List of documents submitted for the evaluation:

Pass: Fail:

B.9.2 Operating manual, clear and complete instructions:

Pass: Fail:

B.9.3 Operating manual, compliance with the requirements:

Pass: Fail:

B.10 Summary of tests carried out as specified conditions specified in this Recommendation.

B.10.1 General tests

- Test of visible defects or damages:

Pass: Fail:

- Measurements and units (4):

Pass: Fail:

Comments:

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B.10.2. Specific requirements for applanation tonometer (5.6)

Note: The applanation tonometer measures the force necessary to applanate the Cornea with a pressure body given to a diameter. The measurement of the force is given on a scale.

B10.2.1 Diameter of applanation circle (5.6.1), nominal 3,06 mm ± 0,02 mm

Pressure body no 1:

Pass: Fail:

Pressure body no 2:

Pass: Fail:

B.10.2.2 Surface of pressure body (5.6.2)

Testing shall be carried out by visual inspection

Pass: Fail:

B.10.2.3 Diameter of the pressure body (5.6.3)

The pressure body shall have a diameter of a least 6,0 mm at the area to contact the cornea.

Pass: Fail:

B.10.2.4 Measuring force (5.6.4)

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

Nominal force in mN	Error horizontal position * in mN	Error vertical position * in mN
0,00 ± 0,49		
9,81 ± 0,49		
19,61 ± 0,49		
29,42 ± 0,49		
39,23 ± 0,59		
49,03 ± 0,74		
58,84 ± 0,88 **		
68,65 ± 1,03 **		
78,45 ± 1,18 **		
* Chose the position permissible for the tonometer, e.g. both. ** Nominal forces, if the range exceeds 49 mN.		

The measuring force shall be continuously adjustable within the minimum range extending from 0,0 mN to 49,0 mN, without the use of auxiliary masses. The measured value of the force shall be clearly legible.

Pass: Fail:
Pass: Fail:

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

Pass: Fail:

B.10.2.5 Accuracy of the measuring force (5.6.5)

Nominal force in mN	Measuring force, increasing steps in mN	Measuring force, decreasing steps in mN	Difference (decreasing –increasing) in mN
0,00 ± 0,49			
9,81 ± 0,49			
19,61 ± 0,49			
29,42 ± 0,49			
39,23 ± 0,59			
49,03 ± 0,74			
58,84 ± 0,88 *			
68,65 ± 1,03 *			
78,45 ± 1,18 *			

** Nominal forces, if the range exceeds 49 mN

When the pressure body is adjusted to the verification position, the permissible error of the force within the measuring range shall be not more than ± 1,5 % of the nominal value or ± 0,49 mN whichever is greater.

Pass: Fail:

B.10.2.6 Effect of hysteresis (5.6.6)

The effect of hysteresis for the measuring force shall not exceed 0,29 mN.

Pass: Fail:

B.10.2.7 Scale (5.6.7)

Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width, and shall be engraved or otherwise permanently marked. No line shall be wider than ¼ of the distance between two lines.

Pass: Fail:

Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width, and shall be engraved or otherwise

permanently marked. No line shall be wider than $\frac{1}{4}$ of the distance between two lines.

Pass: Fail:

Each fifth scale mark shall have greater length. The width of the reference mark shall not be greater than the width of the graduation lines on the measuring scale.

Pass: Fail:

B.10.2.8 Mechanical strength (5.6.8)

Hand-held applanation tonometer shall fall freely once from each of three different starting orientations from a height of 1 m onto a 50 mm \pm 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base. Test on the requirement given in 5.6.5 and 5.6.6.

Pass: Fail:

All other applanation tonometer shall fall freely once from each of three different starting orientations from a height of 5 cm onto a 50 mm \pm 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base. Test on the requirement given in 5.6.5 and 5.6.6.

Pass: Fail:

B.11 Date of the test report:

.....

Test report number:

.....

Signature of the person(s) responsible for the test:

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