
Ophthalmic instruments -
Impression and applanation tonometers.

Part 1: Metrological and technical requirements

Instruments ophtalmiques - tonomètres d'empreinte et d'aplanation.

Partie 1: Exigences métrologiques et techniques



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Ophthalmic instruments – Impression and applanation tonometers

Part 1 – Metrological and technical requirements

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 applications. When referring to applanation tonometers, which measure the force necessary to applanate the cornea over a given diameter using the flat contact side of a pressure body, this Recommendation covers the method developed by Hans Goldmann.

2 Terminology

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

2.1 design compliance

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

2.2 intraocular pressure (IOP)

pressure within the eye front chamber, given in millimetres of mercury (mmHg) or kilopascals (kPa)

3 Introduction

Tonometers have been used for many years to measure the intraocular pressure of an individual's eye. Accurate measurement of this pressure is extremely important for diagnosis and monitoring, especially for glaucoma.

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

The international standard ISO 8612 *Ophthalmic instruments – Tonometers* specifies clinical test methods (design compliance tests) by comparing tonometers with reference applanation tonometers. It is mainly intended to test non-contact tonometers ("air puff" tonometers). This Recommendation specifies designs for impression and applanation tonometers which have shown to be appropriate for diagnosis and monitoring.

4 Description of the category of instrument

4.1 Impression tonometer

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

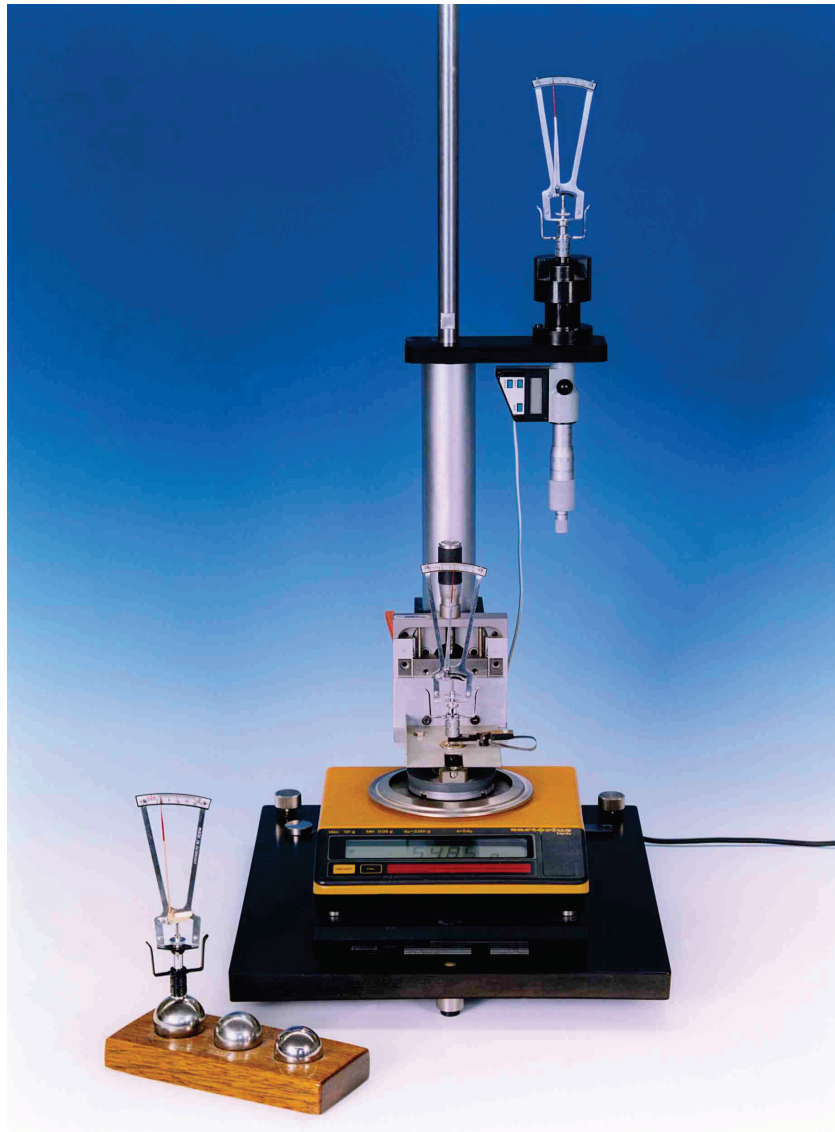


Figure 1 – Impression tonometer and test gauges

4.2 Applanation tonometer

An applanation tonometer measures the force necessary to applanate the cornea over a given diameter using the flat contact side of a pressure body.



Figure 2 – Applanation tonometer and test setup (using a balance)



Figure 3 – Detailed view of applanation tonometer test setup (using a balance)

5 Units of measurement

The IOP is measured in millimetres of mercury (mmHg) or in kilopascals (kPa). If the scale of the tonometer is divided into arbitrary units, a conversion rule or table must be provided.

Note: This Recommendation gives examples in mmHg only since this is the unit used in most cases.

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).

6 Requirements

6.1 General

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

6.2 Environmental conditions

6.2.1 Devices in use

Tonometers shall comply with all the requirements specified in this Recommendation at

- temperatures between 10 °C and 35 °C,
- relative humidity between 30 % and 90 % (non-condensing).

Testing shall be carried out in accordance with R 145-2, 1.

6.2.2 Influence of storage

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

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

Testing shall be carried out in accordance with R 145-2, 2.

6.3 Accompanying documents

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

6.4 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 an applanation tonometer, shall be marked with an individual serial number. However, if marking is likely to deteriorate its function, the list of instruments or accessories shall be provided with the instrument.

Each applanation tonometer shall indicate, near the scale, the value of the force in mN which is equivalent to the smallest scale interval on the scale.

Testing shall be carried out by visual inspection.

6.5 Specific requirements for impression tonometers

6.5.1 Mass of the tonometer and additional masses

The mass of the tonometer, without the handle, shall be $16.5 \text{ g} \pm 0.5 \text{ g}$. 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 are used on the additional masses because this value corresponds to the effective mass, in grams, of the lever-pointer-plunger system together with the additional mass.

Testing shall be carried out in accordance with R 145-2, 3.

6.5.2 Effective mass

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

- $5.50 \text{ g} \pm 0.15 \text{ g}$ when indicating scale division 5;
- $5.50 \text{ g} \pm 0.20 \text{ g}$ when indicating scale division 10.

Testing shall be carried out in accordance with R 145-2, 4.

6.5.3 Friction between the plunger and the plunger sleeve

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

Testing shall be carried out in accordance with R 145-2, 5.

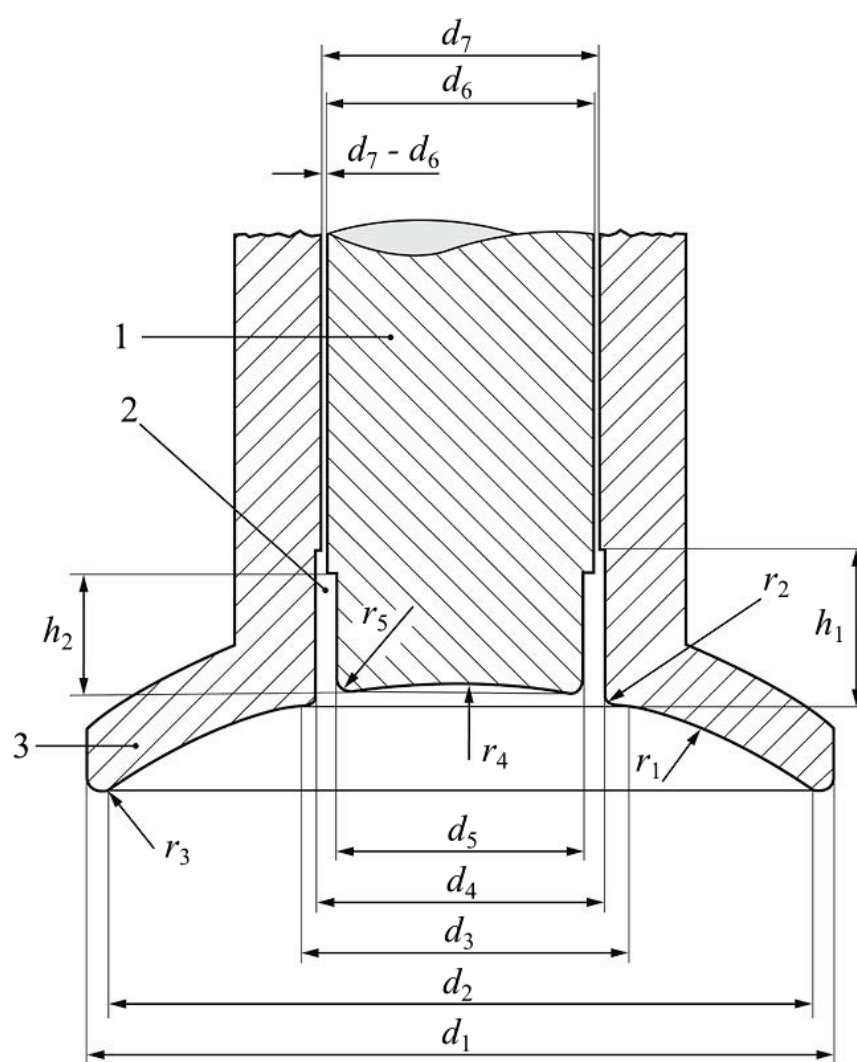
6.5.4 Surface

The front contact surfaces of the footplate and the plunger shall be smooth to the touch, and, when examined by unaided corrected vision under direct illumination, 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 (see 6.5.5).

Testing shall be carried out by visual inspection.

6.5.5 Dimensions of the footplate and plunger

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



Key

1	Plunger	d_1	Outer diameter of the footplate
2	Air gap	d_2	Outside diameter of the spherical front surface of the footplate
3	Footplate	d_3	Diameter of the transition circle of the footplate
r_1	Radius of curvature of the spherical front surface of the footplate	d_4	Diameter at the front surface up to the height of the footplate
r_2	Minimum radius of the inside edge curvature of the footplate	d_5	Diameter of the plunger from the front surface up to the height of h_2
r_3	Minimum radius of the outside edge curvature of the footplate	d_6	Diameter of the plunger above the height of h_2
r_4	Radius of curvature of the spherical front surface of the plunger	d_7	Diameter of the bore of the footplate
r_5	Radius of the edge curvature of the plunger	h_1	Height of the bore hole of the footplate
		h_2	Height of the reduced diameter section of the plunger

Figure 4 – Schematic drawing of the footplate and the plunger of an impression tonometer

Table 1 – Dimensions of the footplate for an impression tonometer (see Figure 3)

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	$9.0^{+0.1}_0$
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 , and minimum radius of the inside edge curvature, r_2	$3.3^{0}_{-0.1}$
or: diameter of the bore hole at the transition between the footplate curvature and the edge curvature of the recess or counterbore (central area), d_3	0.2
	$3.7^{0}_{-0.1}$
Minimum height of the recess or counterbore on the front surface, h_1	≥ 1.5

Table 2 – Dimensions of the plunger for an impression tonometer (see Figure 3)

Items of plunger	Dimension (mm)
Minimum diameter, d_4 , at the front surface up to the height h_1	3.00 ± 0.03
Minimum height, h_2 , at the front surface with 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 the plunger sleeve and the plunger (see Figure 3)

	dimension (mm)
Maximum difference, $d_7 - d_6$	0.05
where: d_7 = diameter of the plunger sleeve in the footplate, d_6 = diameter of the plunger	

Testing shall be carried out in accordance with R 145-2, 6 and R 145-2, 7.

6.5.6 Plunger

For impression tonometers designed according to Schiøtz, at some point between 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.

6.5.7 Scale

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

The scale may begin at -1 or at 0 .

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

The distance between two adjacent lines shall be equal to a plunger displacement of 0.05 mm. The maximum permissible errors for different displacements are given in Table 4.

Table 4 – Displacement and maximum permissible error of the plunger of impression tonometers

Scale division (from – to)	Plunger displacement and its maximum permissible error (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 divisions marked on the scale shall consist of straight lines, of equal width, arranged on the axis of the pointer. No line shall be thicker than $\frac{1}{4}$ of the distance between two lines, nor thicker than 0.25 mm.

Testing shall be carried out by visual inspection and in accordance with R 145-2, 8.

6.5.8 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 of their length. The tip shall not extend beyond the scale lines. The distance between the 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 touch the plane of the scale.

Testing shall be carried out by visual inspection and in accordance with R 145-2, 9.

6.5.9 Position of use of the tonometer

When the tonometer is held in its operating position by the handle, its axis shall be in the vertical position so that friction, which may adversely affect the measurement, is minimized.

Testing shall be carried out by visual inspection.

6.5.10 Test block

Each tonometer shall have a test block whose radius of curvature is $16.00 \text{ mm} \pm 0.05 \text{ mm}$ to test that the indication is 0.0 ± 0.2 on the scale when the tonometer is put on the test block.

Testing shall be carried out by visual inspection.

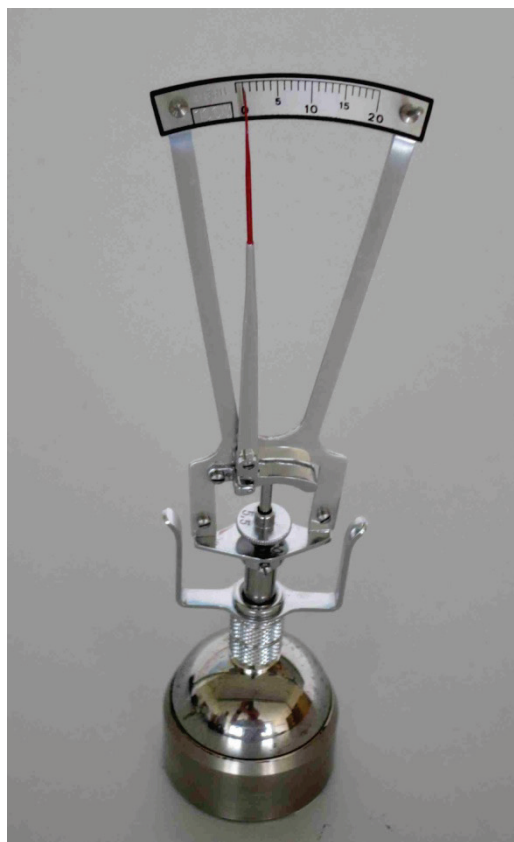


Figure 5 – Impression tonometer placed on the test block, indicating 0.0 on the scale

6.6 Specific requirements for applanation tonometers

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

6.6.1 Diameter of the applanation circle

The diameter of the applanation circle shall be $3.06 \text{ mm} \pm 0.02 \text{ mm}$.

Testing shall be carried out in accordance with R 145-2, 10.

6.6.2 Surface of the pressure body

The front contact surface of the pressure body shall be smooth to the touch, and, when examined by unaided corrected vision under direct illumination, shall be free from surface imperfections that could damage the eye.

Testing shall be carried out by visual inspection.

6.6.3 Diameter of the pressure body

The pressure body shall have a diameter of at least 6.0 mm at the area which comes into contact with the cornea.

Testing shall be carried out in accordance with R 145-2, 11.

6.6.4 Measuring force

The measuring force shall be continuously adjustable over the minimum range 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.

6.6.5 Accuracy of the measuring force

The maximum permissible error of the force over the measuring range shall be $\pm 1.5\%$ of the nominal value, or ± 0.49 mN, whichever is the greater.

Testing shall be carried out in accordance with R 145-2, 12.

6.6.6 Effect of hysteresis

The effect of hysteresis for the measuring force shall not exceed 0.29 mN.

Testing shall be carried out in accordance with R 145-2, 12.

6.6.7 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 the scale value and the force in mN shall be 9.81.

Note: For an applanation circle of 3.06 mm diameter (see 6.6.1), the conversion factor between the scale value and the IOP in mmHg is 10.0.

Every fifth scale mark shall be longer. The width of the reference mark shall not be greater than the width of the graduation lines on the measuring scale.

Testing shall be carried out by visual inspection.

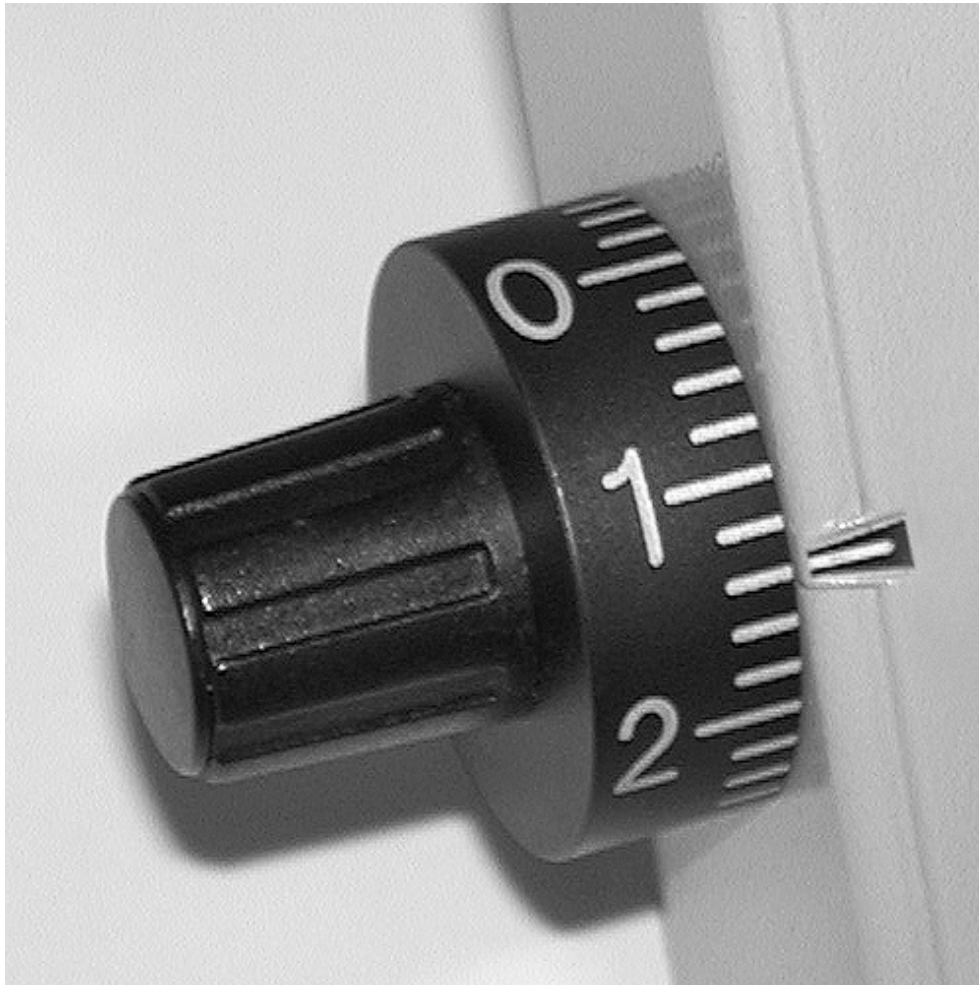


Figure 6 – Example of a scale for an applanation tonometer

6.6.8 Mechanical strength

Hand-held applanation tonometers shall operate correctly following a free fall from a height of 1 m onto a $50\text{ mm} \pm 5\text{ mm}$ thick hardwood board (hardwood $> 600\text{ kg/m}^3$) lying flat on a concrete or similar rigid base. This requirement shall apply to a fall from a starting position in any of the three axes of orientation.

All other applanation tonometers shall operate correctly following a free fall from a height of 5 cm onto a $50\text{ mm} \pm 5\text{ mm}$ thick hardwood board (hardwood $> 600\text{ kg/m}^3$) lying flat on a concrete or similar rigid base. This requirement shall apply to a fall from a starting position in any of the three axes of orientation.

In either case, correct operation following the falls shall be verified by checking that the tonometer still complies with the requirements of 6.6.5 and 6.6.6.

Note: Drop tests are not performed on impression tonometers, because the damage should be visible to the user.