STANDARD OPERATING PROCEDURE

“mechanical and electronic contact ocular tonometers”

This document is based on the General Measure No. 0111-OOP-C038-13.

1 Basic definitions

For the purposes of this Procedure, the terms and definitions according to VIM and VIML and the definitions below shall apply.

1.1 ocular tonometer
an apparatus for measuring intraocular pressure

1.2 contact ocular tonometer
an ocular tonometer for measuring intraocular pressure by means of direct or indirect contact of the measuring device with the cornea of the eye

1.3 intraocular pressure (IOP)
the pressure inside the eye measured in millimetres of mercury (mmHg) or kilopascals (kPa)

1.4 impression method of measuring intraocular pressure
the application of a static load of a defined mass to the footplate of an impression tonometer in vertical direction and the simultaneous pressing of a contact plunger along the axis of the footplate using weights of a defined total weight causing indentation of the cornea and thus vertical displacement of the plunger whereby intraocular pressure can be determined

1.5 impression (Schiøtz) ocular tonometer
an ocular tonometer for measurement using the impression method by direct contact of the plunger with the cornea of the eye along the axis of the footplate at a defined static load

1.6 applanation method of measuring intraocular pressure
force is exerted by the contact head or a contact sensor on the cornea causing a constant flattening of the cornea of a defined diameter, on the basis of which intraocular pressure can be determined by measuring the force exerted; alternatively, a constant force of a defined magnitude is exerted on the cornea by the applanation head causing a flattening of the cornea whereby intraocular pressure can be determined by measuring the diameter of the flattened area

1.7 Goldmann applanation ocular tonometer
an ocular tonometer for measurement using the applanation method by direct contact of the applanation head with the cornea creating an applanation diameter of 3.06 mm under slit illumination

NOTE This includes ocular tonometers placed on a slit lamp or mobile designs with a mechanical scale or display.

1.8 electronic contact ocular tonometer
an ocular tonometer for measuring intraocular pressure either by means of direct contact or indirect contact of a sensor with the cornea of the eye

2 Metrological requirements and technical requirements

Medical devices with a measuring function must be designed and manufactured in such a way as to provide adequate accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy shall be indicated by the manufacturer so that the devices do not compromise the clinical condition, health or safety of the patient when used under the specified conditions and for their intended purpose.

If the limits of accuracy and the conditions under which they apply are not indicated by the manufacturer, the metrological requirements provided below, which fall within the scope of the relevant requirements under European standards, shall be applied.

2.1 Rated operating conditions

The rated operating conditions shall be specified by the manufacturer. If not specified by the manufacturer, the requirements for the maximum permissible error of the device must be complied with at least within the ambient temperature range of 15 °C to 35 °C and relative humidity range of 10% to 90%.

2.2 Measuring interval

The minimum measuring interval of a contact ocular tonometer must be within the range of 7 mmHg to 50 mmHg, but no greater than 80 mmHg, as per the manufacturer's specifications.

Intraocular pressure indicated by an electronic contact ocular tonometer which is less than 7 mmHg must be displayed in the form of a number or indicated as "low value". Readouts higher than 50 mmHg must be displayed in the form of a number or indicated as "high value".

2.3 Maximum permissible error of an applanation ocular tonometer

The maximum permissible error of indication of intraocular pressure shall be specified by the manufacturer. If not specified by the manufacturer, the maximum permissible errors given in Table 1 shall apply.

Table 1 – Maximum permissible errors

Measuring range	Maximum permissible error
7 mmHg to ≤ 16 mmHg	±1.5 mmHg
> 16 mmHg to < 23 mmHg	±2.0 mmHg
≥ 23 mmHg	±3.0 mmHg

3 Technical requirements

If not indicated by the manufacturer in the specifications of the measuring instrument or if not indicated differently from those provided below, the technical requirements provided below, which are proportionate to the relevant requirements under European standards, shall apply.

3.1 Impression ocular tonometers

The accuracy of the impression method for measuring intraocular pressure is dependent on adherence to mass and longitudinal parameters.

3.1.1 Mass parameters

The specific mass of the tonometer and additional masses shall be determined according to Table 2.

Table 2 – Mass parameters of the impression ocular tonometer

Mass of the tonometer, without handle		(16.5 ± 0.5) g
Additional masses with inscription	7.5	(2.00 ± 0.02) g
	10.0	(4.50 ± 0.02) g
	15.0	(9.50 ± 0.02) g
NOTE The inscriptions 7.5, 10.0 and 15.0 on the additional masses indicate the sum of the actual masses and the effective mass of 5.5 g.		

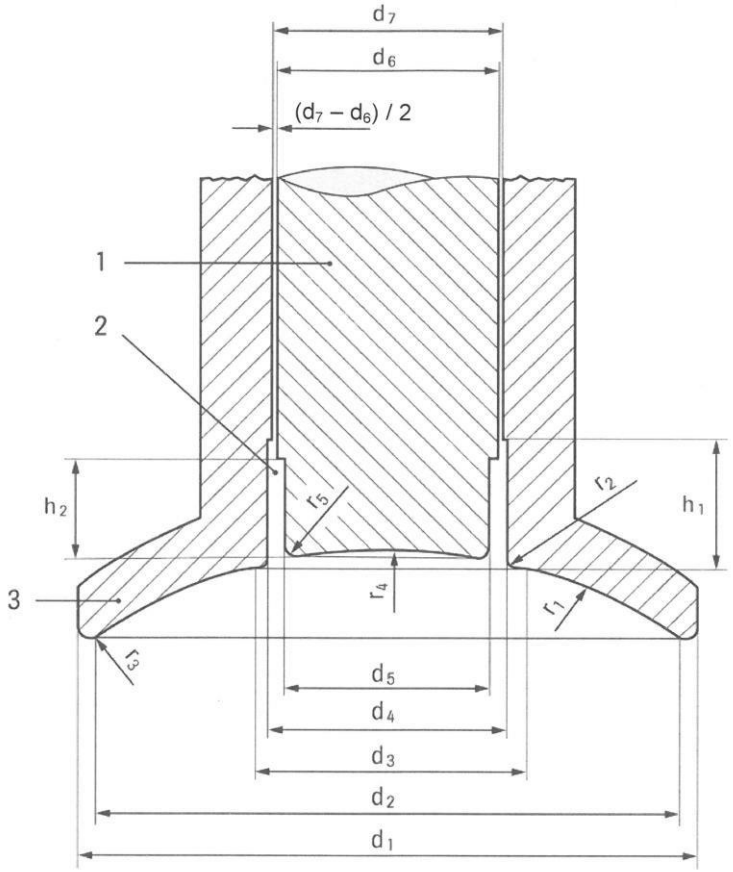
3.1.2 Effective mass

The effective mass is the sum of the masses of the lever, pointer and plunger in the vertical position and shall be:

(5.50 ± 0.15) g when indicating scale division 5,

(5.50 ± 0.20) g when indicating scale division 10.

3.1.3 Longitudinal parameters of the plunger and the footplate



Key

1 Plunger
2 Air gap between the plunger and the footplate
3 Footplate

Figure 1 - Dimensions of the footplate and the plunger of the impression ocular tonometer

Table 3 - Dimensions of the footplate for the impression ocular tonometer

Footplate item	Dimensions (mm)
diameter (d_1)	10.1 ± 0.2
radius of curvature of the spherical front surface (r_1)	15.00 ± 0.25
minimum outer diameter of the spherical front surface (d_2) minimum radius of the outer edge curvature (r_3) either – inner diameter (d_4) of the footplate recess up to the height (h_1) – minimum radius of the inner edge curvature (r_2) or – diameter of the bore hole at the transition to the recess (d_3) between (r_1) and the inner edge (r_2)	9.0 + 0.1 0.2 3.3 – 0.1 0.2 3.7 – 0.1
minimum height of the recess (h_1)	≥ 1.5

Table 4 - Dimensions of the plunger for the impression ocular tonometer

Plunger item	Dimensions (mm)
plunger diameter (d_4) at the height (h_2)	3.00 ± 0.03
minimum height (h_2)	1.5
radius of the spherical front surface of the plunger (r_4)	15.00 ± 0.75
radius of the edge curvature (r_5)	0.25 ± 0.03
maximum extension of the plunger below the curvature of the footplate	3.0

The clearance between the plunger and the footplate shall be half of the difference between the inner diameter of the footplate d_7 and the guiding diameter of the plunger d_6 and shall not exceed 0.05 mm.

3.1.4 Scale

The scale must be inclined to the axis of the plunger. The scale must be divided into at least 15 linearly distributed divisions from –1 to 15 or from 0 to 15. A single scale division must be equal to a plunger displacement of 0.05 mm.

Table 5 - Displacement of the plunger of the impression ocular tonometer

Scale divisions in total from – to	Plunger displacement mm	Permissible error limit 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

3.1.5 Pointer

The distance between the pointer and the scale must not be greater than 1.0 mm at any point of the scale.

3.1.6 Footplate with the contact plunger

The friction between the plunger along the axis of the footplate and the plunger sleeve must not influence the result of the measurement. The plunger must begin to move within the footplate before the angle of the axis of the impression ocular tonometer relative to the horizontal position exceeds 25°.

The contact surface of the plunger and the footplate must be ground and polished. The surface must be smooth and without protrusions and scratches that could damage the cornea of the eye or influence measurement results.

3.1.7 Position of use of the impression ocular tonometer

Between the 5th and 10th scale division, the plunger axis and the plane through the surface of the lever must form a right angle at the point of contact.

3.1.8 Test block of the impression ocular tonometer

Every single impression ocular tonometer must be equipped with a test block whose curvature is either (as per the manufacturer) $R_k = (16.00 \pm 0.05)$ mm, for which the indication on the scale of the tonometer must be (0.0 ± 0.2), or a standard block $R_k = (15.00 \pm 0.05)$ mm, for which the indication on the scale of the tonometer must be (-1.0 ± 0.2).

3.2 Applanation ocular tonometers

3.2.1 Diameter of the applanation circle of the Goldmann tonometer

The diameter of the applanation circle shall be (3.06 ±0.02) mm.

3.2.2 Surface of the prismatic head or the pressure measuring sensor

The front surface of the prismatic head or the pressure measuring sensor must be smooth for contact with the cornea and without any protrusions. The surface of the head must be smooth and without any protrusions and scratches, which could damage the eye or optically influence measurement results.

3.2.3 Diameter of the prismatic head

The prismatic head must have a diameter of at least 6.0 mm in the area of direct contact with the cornea of the eye.

3.2.4 Measuring force requirements

The measuring force must be continuously adjustable within the minimum range extending from 9.81 mN to 49.0 mN, without the use of auxiliary masses. The measured value of the force must be clearly legible.

3.2.5 Accuracy of the measuring force

When the prismatic head is adjusted to the verification position, the permissible error of the force within the measuring interval must not be greater than ±1.5% of the nominal value or greater than ±0.49 mN.

3.2.6 Hysteresis effect

The effect of hysteresis for the measuring force must not exceed ±0.49 mN.

3.2.7 Mass of the prismatic head

Mass shall be specified by the manufacturer according to the type of the tonometer.

3.2.8 Scale

The conversion factor between scale value and force in mN shall be 9.81. The minimum permissible range shall be 10 mmHg to 50 mmHg, the maximum permissible range shall be 0 mmHg to 80 mmHg. Where 0.1 scale division is used, one scale unit shall represent 0.98 mN, where 0.2 scale division is used, it shall represent 1.96 mN.

Where the scale is displayed on a display, the above range in mmHg shall apply.

3.2.9 Shape of the arm and position of the prismatic head

The geometric shape of the arm, the position of the prismatic head and the permissible tolerances shall be determined by the manufacturer in the specifications.

4 Measuring instrument markings

Each ocular tonometer must bear, at least, the following markings:

- name of the manufacturer or supplier,
- name and type of the ocular tonometer,
- serial number.

Each ocular tonometer, with the exception of the prismatic applanation head, must be marked with the same serial number.

5 Subsequent verification

5.1 Verification of impression ocular tonometers

5.1.1 Overview of the tests performed

Subsequent verification of impression ocular tonometers shall comprise the following tests performed sequentially:

- visual inspection,
- accuracy test,
    - check of the specific masses of the impression tonometer,
    - check of the effective mass of the impression tonometer,
    - check of the dimensions of the footplate, plunger and pointer,
    - check of plunger displacement,
    - test of the friction between the plunger and the footplate.

5.1.2 Visual inspection

The purpose of the visual inspection shall be to check:

- that the ocular tonometer submitted for verification conforms to the approved type or design of the measuring instrument for which conformity was declared when it was placed on the market,
- that the measuring instrument is complete and the serial numbers on the tonometer and all of its components are identical,
- the surface and shape of the plunger for damage, protrusions and scratches using optical equipment,
- that it shows no obvious signs of damage or contamination,

- the surface of the test block (see Article 3.1.8) for damage, protrusions and scratches,
- completeness and legibility of the required inscriptions and markings referred to in Ch. 4.

5.1.3 Test equipment

The following equipment shall be used for the tests:

a) scales with an upper limit of the measuring interval of at least 18 g and maximum permissible error of less than 0.005 g,

b) two micrometers, one with an upper limit of the measuring interval of at least 5 mm and the other up to 25 mm, with maximum permissible error of less than 0.003 mm,

c) a calliper with an upper limit of the measuring interval of up to 150 mm and maximum permissible error of less than 0.02 mm,

d) testing blocks with the radius R_k:

1 $R_k = (15.00 \pm 0.05)$ mm,

2 $R_k = (16.00 \pm 0.05)$ mm,

3 $R_k = (14.75 \pm 0.05)$ mm,

e) a protractor with a maximum permissible error of less than 2°,

f) a projection microscope with magnification of at least 80×.

5.1.4 Accuracy test

The accuracy test shall comprise checks and tests referred to below in Articles 5.1.4.1 to 5.1.4.5.

If all longitudinal and mass parameters are complied with, including friction between the plunger and the footplate, correct function and accuracy of the measuring instrument are guaranteed.

5.1.4.1 Check of the specific masses of the impression tonometer

The mass parameter values referred to in Article 3.1.1 shall be checked by weighing.

5.1.4.2 Check of the effective mass of the impression tonometer

The effective mass values of the tonometer in the vertical position referred to in Article 3.1.2 shall be checked by weighing.

5.1.4.3 Check of the dimensions of the footplate, plunger and pointer

The dimensions of the impression ocular tonometer according to the manufacturer's specifications or according to Articles 3.1.3, 3.1.5, 3.1.7 and Tables 3 and 4 shall be checked.

5.1.4.4 Plunger displacement test

Plunger displacement as specified under Article 3.1.4 and Table 5 shall be measured using a micrometer and compliance with the permissible error limit shall be observed.

5.1.4.5 Test of the friction between the plunger and the footplate

When the impression tonometer is placed into the horizontal position and moved slowly into the vertical position with the plunger at the upper stop, the tonometer must begin to move downwards before the angle of the tonometer axis relative to the horizontal exceeds 25° as referred to in Article 3.1.6.

5.2 Verification of Goldmann applanation ocular tonometers

5.2.1 Overview of the tests performed

Subsequent verification of applanation ocular tonometers shall comprise the following tests performed sequentially:

- visual inspection,
- accuracy test,
  - check of the diameter of the applanation circle of the prismatic head,
  - check of the front diameter of the prismatic head,
  - test of accuracy of the measuring force and its hysteresis.

5.2.2 Visual inspection

The purpose of the visual inspection shall be to check:

- that the ocular tonometer submitted for verification conforms to the approved type or design of the measuring instrument for which conformity was declared when it was placed on the market,
- that it shows no obvious signs of damage or contamination,
- the surface of the prismatic head,
- completeness and legibility of the required inscriptions and markings referred to in Chapter 4.

5.2.3 Test equipment

The following equipment shall be used for the tests:

a) force measuring test equipment with an upper limit of the measuring interval of at least 80 mN and with a maximum permissible error of less than 0,17 mN for the range of 9 mN to 50 mN and 0.20 mN for the range of over 50 mN;

b) a microscope with magnification of at least 10× and with a cross-hair reticule;

c) a glass-etched reticule with a maximum permissible error of less than ±0.002 mm.

5.2.4 Accuracy test

The accuracy test shall comprise tests specified by the manufacturer or tests and checks referred to below in Articles 5.2.4.1 to 5.2.4.5.

If all the defined technical parameters and force values are complied with, including the force hysteresis value, correct function and accuracy of the measuring instrument are guaranteed.

5.2.4.1 Check of the diameter of the applanation circle of the prismatic head

The diameter of the applanation circle shall be determined in two directions, perpendicular to each other.

The measured value must meet the requirements under Article 3.2.1.

5.2.4.2 Check of the front diameter of the prismatic head

The diameter of the prismatic head shall be determined in two directions, perpendicular to each other.

The measured value must meet the requirements under Article 3.2.3.

5.2.4.3 Test of accuracy of the measuring force and hysteresis

The test of the measuring force values shall be performed on a test bench using a force measuring instrument or on a pointer system using measuring weights. The test shall be performed with the prismatic head in the verification position continuously from the minimum to the maximum value and

back to the initial position; the measuring force error within the whole range must not be more than ±1.5% of the nominal value or ±0.49 mN.

Two measurements shall be performed. The measured values shall be recorded and the results shall be used to calculate hysteresis, which must not be more than ±0.49 mN. The measurement results must take the uncertainty of the measuring equipment into account.

5.3 Verification of electronic contact ocular tonometers

5.3.1 Overview of the tests performed

Subsequent verification of electronic contact ocular tonometers shall comprise the following tests performed sequentially:

- visual inspection,
- accuracy tests,
- determination of hysteresis.

5.3.2 Visual inspection

The purpose of the visual inspection shall be to check:

- that the ocular tonometer submitted for verification conforms to the approved type or design of the measuring instrument for which conformity was declared when it was placed on the market,
- that it shows no obvious signs of damage or contamination,
- the surface and dimensions of the contact sensor according to the manufacturer's specifications,
- the required functions, including zeroing of the measuring instrument, as per the manufacturer's specifications,
- completeness and legibility of the required inscriptions and markings referred to in Chapter 4.

5.3.3 Test equipment

The tests shall be performed using test equipment supplied by the manufacturer for the given type of the electronic contact ocular tonometer.

5.3.4 Accuracy test

The procedure for testing electronic contact ocular tonometers, which measure by means of direct contact with the cornea or without direct contact through the eyelid, shall be specified by the manufacturer.

The test of accuracy of the intraocular pressure values in mmHg shall be performed on a test bench.

The test shall be performed with the contact sensor in the verification position from 7 mmHg to 50 mmHg, unless otherwise specified by the manufacturer. The pressure values indicated on the display must fall within the limits below, unless otherwise specified by the manufacturer:

7 mmHg to ≤ 16 mmHg	±1.5 mmHg
> 16 mmHg to < 23 mmHg	±2.0 mmHg
≥ 23 mmHg	±3.0 mmHg

Three measurements shall be performed.

5.3.5 Hysteresis test

The measured values shall be used to calculate hysteresis, which must not be more than ±1 mmHg.

ANNEXES

Annex 1: Sample test protocol for impression tonometers

Annex 2: Sample test protocol for applanation tonometers