inTENSE, Deliverable 8

Good practice guidelines for traceable IOP metrology

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1. Contact tonometers

1.1. Impression tonometers

1.1.1. Requirements placed on facilities

The metrological verification shall be performed at following ambient conditions:

Ambient temperature: 15 °C to 35 °C

Relative air humidity: 10 % to 85 %

Air conditioning of the testing laboratory is not necessary for the metrological verification.

The testing laboratory must be free of external disturbances (eg. vibrations from traffic or machinery, direct sunlight, etc.)

1.1.2. Requirements placed on measurement and test equipment

A weight balance shall be used for determining the effective masses of the lever-pointer-plunger system and of the mass of the tonometer without a holder (minimum requirements).

Measurement range: 5 g up to at least 18 g

Measurement uncertainty*: ≤ 0,050 g

Weight balance to determine the mass of the additional weights (minimum requirements):

Measurement range: 1,5 g up to at least 10 g

Measurement uncertainty*: ≤ 0,005 g

Length measuring instrument to determine the plunger displacement (minimum requirements):

Measurement range: from 0 mm up to at least 5 mm

Measurement uncertainty* 0,003 mm

Test blocks:

1st sphere: Radius of curvature: 16,00 mm

Measurement uncertainty*: ≤ 0,05 mm

2nd sphere: Radius of curvature: 14,75 mm

Measurement uncertainty*: ≤ 0,05 mm

Goniometer to determine the friction:

Measurement uncertainty*: 2°

** Measurement uncertainty for k = 2*

1.1.3. Content and scope of the metrological verification

1.1.3.1. Initial check

The person conducting the metrological verification must be provided with the instructions for use of the device to be verified. The device that is subject to metrological verification must either bear CE marking including the identification number of the conformity assessment body (i. e. notified body) or the national type-approval mark where CE marking is not applicable. All components of the device must comply with the description in the instructions for use and Declaration of Conformity or type approval. Scales, labels and descriptions must comply either with the manufacturer's specifications or with the specifications for type-approved devices as specified in national law.

The device must be clean and free of obvious defects.

Measurement devices that were not placed on the market as medical devices but have a medical intended purpose as defined in Article 2, (12) of the Medical Devices Regulation (MDR) [1], must also be subjected to metrological verification.

1.1.3.2. Metrological verifications

The compliance with the manufacturer's specifications – or, in the case of older devices placed on the market prior the MDD (Medical Devices Directive) [4] came into force – with the specifications in the national type approval certificate must be checked.

Visual inspection

Tonometers must be checked to ensure that they bear the prescribed markings, in particular the CE markings with the number of the conformity assessment body (i. e. notified body). In addition, impression tonometers must be checked for friction between the plunger and the plunger sleeve of the tonometer, the integrity (including the smoothness) of the surfaces and the edges of the footplate and the plunger and, in the case of purely mechanical impression tonometers, the mechanical condition of the pointer (not bent out of shape, distance to the scale approx. 1 mm). As the individual components of impression tonometers are usually not interchangeable, at least the plunger, the nut (if any) and the lever-pointer-plunger system must be clearly marked as parts of one system, e.g. by identical serial numbers.

Verification procedure

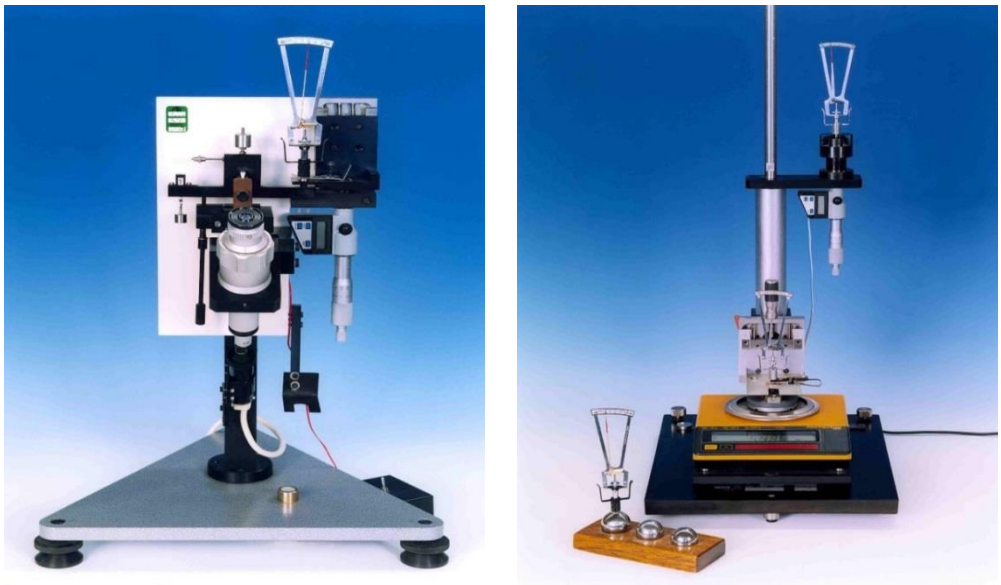

Figure 1: Test equipment used for the verification of impression tonometers.
Left: Mechanical beam balance to determine the mass of the tonometers as well as a micrometre screw gauge for measuring the plunger displacement of the tonometer.
Right: Electronic balance to determine the tonometer masses as well as a micrometre screw gauge for measuring the plunger displacement of the tonometer.
Right, frontal: Test blocks for the verification of the zero indication.

Weighing procedures for impression tonometers

The weighing procedures shall be performed by involving a mechanical beam balance and/or an electronic balance (Figure 1).

The total mass of the tonometer without the holder shall be determined. Unless otherwise specified, it shall be (including the indication of the limit value of maximum permissible measurement error):

16,5 g ± 0,5 g

The effective mass of the lever-needle-scale system shall be determined at the scale divisions 5 and 10. Unless otherwise specified, it shall be (including the indication of the limit value of the maximum permissible measurement deviation):

at scale division 5: 5,50 g ± 0,15 g

at scale division 10: 5,50 g ± 0,20 g

The mass of the additional weights used to extend the measuring range of the tonometer *(*Figure 1, *right frontal)* must be verified prior to the verification of the scale readings; the masses commonly used are listed in Table 1:

Table 1: Common masses of the additional weights

Marking	**Mass (g)**	**Maximum permissible measurement error (g)**
7,5	2,00	± 0,02
10	4,50	± 0,02
15	9,50	± 0,02

Zero indication and displacement of the plunger

The zero indication shall be verified by means of two test blocks with a radius of curvature of 14,75 and 16,00 mm respectively (Figure 1) and shall:

a) Indicate -1,0 when the foot plate is placed on a test block of 14,75 mm radius of curvature.

b) Indicate 0,0 when the foot plate is placed on a test block of 16,00 mm radius of curvature.

The indication shall comply with maximum permissible errors specified in Table 2.

Table 2: Zero indicator measured on test blocks

Radius of the test block (mm)	**Indication of the tonometer (scale values)**	**Maximum permissible measurement error (scale values)**
14,75	-1,0	± 0,2
16,00	0,0	± 0,2

The plunger displacement shall be verified for all scale values indicated in Table 3 by means of a micrometre screw gauge. It shall comply with the maximum permissible errors specified in Table 3.

Table 3: Plunger displacement and indication of the impression tonometer

Scale values	Plunger displacement (mm)	Maximum permissible measurement error (mm)
-1 to 5	0,30	± 0,01
-1 to 10	0,55	± 0,02
-1 to 15	0,80	± 0,03
-1 to 18	0,95	± 0,05

Determination of the friction between the plunger and the plunger sleeve

When the tonometer moves smoothly and continuously from the horizontal to the vertical position with the plunger in the upper position (see Figure 2, left-hand side), the plunger shall slide downwards into the hole of the footplate at 25°inclination at the latest. During this test, the lever-pointer system must not touch the plunger (i.e. the pointer should be secured against movement), see Figure 2, right-hand side.

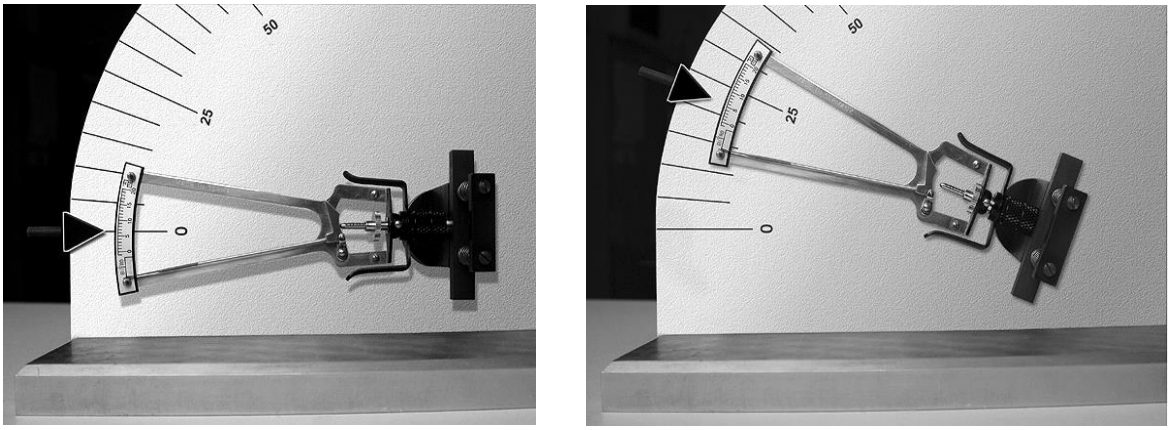

Figure 2: Left: Tonometer in the horizontal position with the plunger in the upper position, indication below the scale value 0.
Right: The plunger slides down into the hole of the footplate at an angle of less than 25°. Please note that the lever-pointer system does not touch the plunger and is still in its initial position.

1.2. Applanation tonometers

1.2.1. Requirements placed on facilities

The metrological verification shall be performed at following ambient conditions:

Ambient temperature: 15 °C to 35 °C

Relative air humidity: 10 % to 85 %

Air conditioning of the testing laboratory is not necessary for the metrological verification.

The testing laboratory must be free of external disturbances (eg. vibrations from traffic or machinery, direct sunlight, etc.)

1.2.2. Requirements placed on measurement and test equipment

The following test equipment shall be used for the verification of applanation tonometers:

- For the determination of the diameter of the applanation circle of the tonometer prism:

Glass reticle:

Measurement uncertainty (for $k = 2$) : $\leq 0{,}002$ mm

Microscope:

At least 10-fold magnification

- For testing the measuring force, test equipment which complies with the following minimum requirements:

Measurement range: 9 mN up to a minimum of 80 mN

Measurement uncertainty in the measurement range of 9 mN to 50 mN: $\leq 0{,}17$ mN

Measurement uncertainty in the measurement range above 50 mN: $\leq 0{,}20$ mN

1.2.3. Content and scope of the metrological verification

1.2.3.1. Initial check

The person conducting the metrological verification must be provided with the instructions for use of the device to be verified. The device that is subject to metrological verification must either bear CE marking including the identification number of the conformity assessment body (i. e. notified body) or the national type-approval mark where CE marking is not applicable. All components of the device must comply with the description in the instructions for use and Declaration of Conformity or type approval. Scales, labels and descriptions must comply either with the manufacturer's specifications or with the specifications for type-approved devices as specified in national law.

The device must be clean and free of obvious defects.

Measurement devices that were not placed on the market as medical devices but have a medical intended purpose as defined in Article 2, (12) of the Medical Devices Regulation (MDR) [1], must also be subjected to metrological verification.

1.2.3.2. Metrological verifications

The compliance with the manufacturer's specifications – in the case of older devices placed on the market prior the MDD (Medical Devices Directive) [4] came into force – with the specifications in the national type approval certificate must be checked.

Visual inspection

Tonometers must be checked to ensure that they bear the prescribed markings, in particular the CE markings with the number of the conformity assessment body (i. e. notified body).

Verification procedure

Verification of the diameter of the applanation circle of the tonometer prism

The diameter of the applanation circle shall be tested for all tonometer prisms used by means of a suitable reticle. The manufacturer of the applanation tonometer must specify the suitable type of tonometer prism and the nominal value of the diameter of the applanation circle.

In general, the diameter of the applanation circle of the tonometer prism has the following dimensions (with the specification of the maximum permissible measurement error):

3,06 mm ± 0,2 mm.

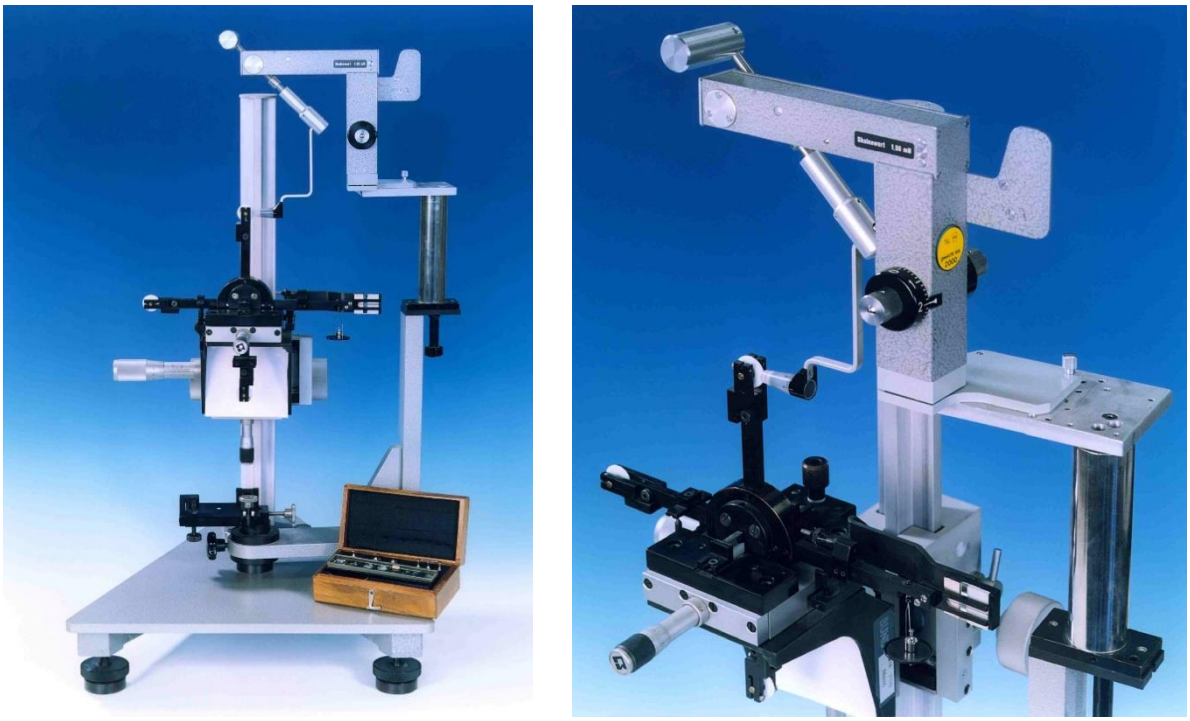

Figure 3: Cross beam balance for the verification of applanation tonometers.
Left: Overall view with tonometer; Right: Detailed view with tonometer

Verification of the tonometer prism

The entire contact surface of the tonometer prism shall be even, smoothly polished and free of scratches. The peripheries of this surface shall be free of protrusions and fragment fractures.

Verification of the measuring force of the tonometer

In the following, the verification of the measuring force using a cross beam balance is described as this device is the most frequently used test equipment. Other force measuring devices can be used if they are suitable and metrologically traceable, e.g. the optical-interference test equipment manufactured by SIOS Meßtechnik company, Ilmenau.

The tonometer shall be aligned in such a way that the contact wheel of the cross-beam balance lies centrally against the tonometer prism. To ensure that measurements are taken in the centre of the horizontal travel range of the tonometer prism and that measurement errors are avoided when the margins are reached, the procedure described below shall be followed:

- The weighing pan must be loaded with a weight of 1 g;
- The tonometer must be set to scale value 2 (corresponding to a force of 19,61 mN);
- The displacement of the pointer on the beam balance must be observed;
- The tonometer must be set to scale value 0 (corresponding to a force of 0 mN);
- The displacement of the pointer on the balance must be observed;

- The horizontal alignment of the tonometer is accurate when the displacements in the upward and downward directions are symmetrical, otherwise the described adjustment procedure must be repeated.

Note: The permissible movement of the prism is limited by a front and rear stopper. For safety reasons, all known applanation tonometers are additionally equipped with an overload protection.

After the adjustment has been completed, the verification is performed in the upwards and downwards direction in increments of 1 scale division (corresponding to a force of 9,81 mN) within the measurement range specified by the manufacturer (see Table 4).

Note: If a prism with an applanation circle diameter of 3,06 mm ± 0,02 mm is used, 10 mmHg correspond to the tonometer scale division of 1 or to a force of 9,81 mN.

The hysteresis error of the force must be determined at all measuring points when the prism movement returns from the tonometer and moves in the opposite direction (downward movement). The manufacturer's specifications must be used for the verification. Unless otherwise specified by the manufacturer, the value 0,49 mN shall apply for the reversal hysteresis.

Tonometers with the ability to perform measurements in any desired position, must be tested in the vertical and horizontal direction. The preparations for the verification as well as the verification procedure in the horizontal direction must be carried out analogously to the verification in the vertical direction.

Table 4: Verification steps for the measurement force of the tonometer. The manufacturer's specifications for the measurement range must be taken into account.

Reference force (mN)	**Maximum permissible measurement error (mN)**	**Permissible setting range* at the tonometer (scale values)**
9,81	± 0,49	0,95 – 1,05
19,61	± 0,49	1,95 – 2,05
29,42	± 0,49	2,95 – 3,05
39,23	± 0,59	3,94 – 4,06
49,03	± 0,74	4,92 – 5,08
58,84	± 0,88	5,91 – 6,09
68,65	± 1,03	6,90 – 7,10
78,45	± 1,18	7,88 – 8,12

*) The scale values specified in this table apply only to prisms with an applanation circle diameter of 3,06 mm (reference value).

2. Non-contact tonometers (NCT)

2.1. Requirements placed on facilities

The metrological verification shall be performed at following ambient conditions:

Ambient temperature: 15 °C to 35 °C

Relative air humidity: 10 % to 85 %

Air conditioning of the testing laboratory is not necessary for the metrological verification.

The testing laboratory must be free of external disturbances (eg. vibrations from traffic or machinery, direct sunlight, etc.)

2.2. Requirements placed on measurement and test equipment

PTB test equipment (PTB-jig, flapper):

Measurement range (minimum requirements): 10 mmHg to 50 mmHg

Measurement uncertainty* in the measurement range of 10 mmHg to 15 mmHg: $\leq$ 0,4 mmHg

Measurement uncertainty* in the measurement range of 15 mmHg to 30 mmHg: $\leq$ 0,5 mmHg

Measurement uncertainty* in the measurement range of 30 mmHg to 50 mmHg: $\leq$ 0,8 mmHg

** Measurement uncertainty for k = 2*

Note: To ensure the internal quality assurance of the long-term stability of the PTB-jig/flapper, it is strongly recommended to test it from time to time, e.g. every 6 weeks, always using the same (reference) non-contact tonometer.

2.3. Content and scope of the metrological verification

2.3.1. Condition check

The person conducting the metrological verification must be provided with the instructions for use of the device to be verified. The device that is subject to metrological verification must either bear CE marking including the identification number of the conformity assessment body (i. e. notified body) or the national type-approval mark where CE marking is not applicable. All components of the device must comply with the description in the instructions for use and Declaration of Conformity or type approval. Scales, labels and descriptions must comply either with the manufacturer's specifications or with the specifications for type-approved devices as specified in national law.

The device must be clean and free of obvious defects.

Measurement devices that were not placed on the market as medical devices but have a medical intended purpose as defined in Article 2, (12) of the Medical Devices Regulation (MDR) [1], must also be subjected to metrological verification.

2.3.2. Metrological verifications

The compliance with the manufacturer's specifications – or in the case of older devices placed on the market prior the MDD (Medical Devices Directive) [4] came into force– with the specifications in the national type approval certificate must be checked.

Visual inspection

Tonometers must be checked to ensure that they bear the prescribed markings, in particular the CE markings with the number of the conformity assessment body (i. e. notified body).

Verification procedure

In contrast to applanation and impression tonometers, where the traceability to national standards is ensured, for NCTs this procedure is not technically feasible. To ensure the traceability of NCTs, transfer standards are used to compare the tonometer to be tested to an identically manufactured device which was previously clinically tested in conformity with ISO 8612. Test equipment allowing the simulation of IOP measurements are used as transfer standards in the verification of NCTs.

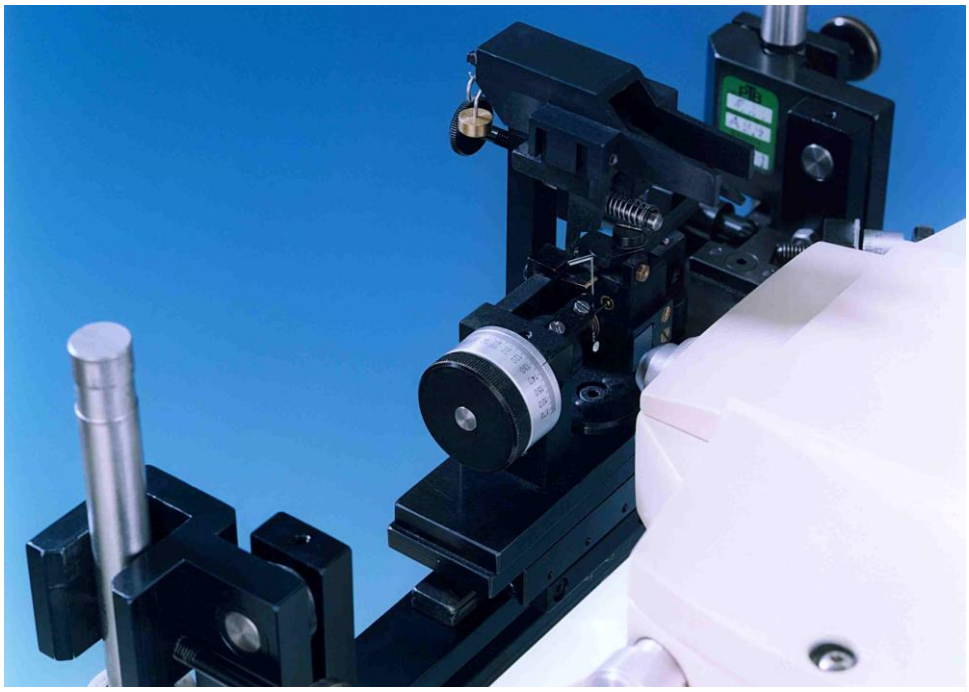

Figure 4: PTB-jig (flapper) for the metrological verification of non-contact tonometers

The verifications shall be carried out periodically and after every repair.

Different set-ups and devices to test non-contact tonometers exist and new ones are being developed. All available IOP test equipment cannot be mentioned here, currently the most commonly used are

- PTB-jig (flapper) (Figure 4)
- mechanical phantom eye (“rubber eye”)
- electronic phantom eye

Other test equipment specified by the manufacturer can be used if its suitability has been confirmed by a test certificate issued by an NMI (e.g. PTB, CMI).

The manufacturer shall define the reference values required for the periodical metrological checks (e.g. MTK in Germany, BTK in Czech Republic) by using clinically tested NCT and a compatible test equipment. Thus, the manufacturer of the tonometer to be verified knows the

reference values that this tonometer type must display during the simulated measurement. The reference values are only valid for certain non-contact tonometer – test equipment combinations; as a rule, they are not transferable to other types of tonometers. If the reference values are not evident from the accompanying instructions for use or from other supplementary documents, they shall be obtained from the manufacturer.

Test procedure

The verification procedure is considered appropriate if compliance with 6.4.1. of the OIML Recommendation RXXX [3] is demonstrated.

Alternatively, the following procedure shall be followed:

10 repeated measurements shall be performed for one value in each of the three IOP ranges specified in the Table 5. This one value, at which the verification is performed, is specified by the manufacturer for the IOP test equipment used.

For any temperature-humidity combination in the temperature range from 10 °C to 40 °C and the relative humidity range from 10% to 90% (non-condensing), the maximum permissible measurement error Δx (the difference between the indicated value of the device under test and the reference value) of the arithmetic mean and the standard deviation $s(\Delta)$ shall comply with the following requirements:

- for the reference value in the low range: $|\Delta x_{low}| \leq 0{,}13\ kPa\ (1{,}0\ mmHg)$; $s(\Delta x_{low}) \leq 0{,}13\ kPa\ (1{,}0\ mmHg)$
- for the reference value in the intermediate range: $|\Delta x_{intermediate}| \leq 0{,}20\ kPa\ (1{,}5\ mmHg)$; $s(\Delta x_{intermediate}) \leq 0{,}20\ kPa\ (1{,}5\ mmHg)$
- for the reference value in the high range: $|\Delta x_{high}| \leq 0{,}27\ kPa\ (2{,}0\ mmHg)$; $s(\Delta x_{high}) \leq 0{,}27\ kPa\ (2{,}0\ mmHg)$

Table 5: Definition of the IOP measuring range

IOP range		
	kPa	**mmHg**
low	0,93 to 2,13	7,0 to 16,0
intermediate	2,13 to < 3,07	> 16,0 to < 23,0
high	≥ 3,07	≥ 23,0

Requirements for test equipment

The IOP test equipment shall prove sufficiently small error limits and measurement uncertainties. The error limits are considered to be sufficiently small if they do not exceed one third of the error limits of the NCT to be tested. Manufacturers may specify smaller permissible limits for their IOP test equipment. Manufacturer specifications with values higher than the state of the art (see table Table 5) shall not be accepted for IOP test equipment intended for metrological control.

3. References

[1] MDR, The European Union Medical Device Regulation (Council Regulation 2017/745 of 5 April 2017 concerning medical devices, OJ No L 117/1 of 2017-05-05)

[2] ISO 8612, Ophthalmic Instruments – Tonometers (2009)

[3] OIML R-XXX

[4] MDD, The Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993 [1] concerning medical devices)