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The present document is the first Committee Draft (1CD was developed by Project Group 2 of OIML TC 18 Medical measuring instruments.) and was drawn up on the basis of the conclusions of comments from member nations on the Working Draft circulated on the 15th of January 2020.

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Ophthalmic instruments – Non-contact tonometers

Part 1 – Metrological and technical requirements

1 Introduction

Non-contact tonometers have been used for many years to measure the intraocular pressure. Accurate measurement of the IOP is important as chronically high IOP is considered the main risk factor for glaucoma development and progression.

The Recommendation references the international standard ISO 8612 Ophthalmic instruments – Tonometers with respect to the clinical investigation of non-contact tonometers.

Note: ISO 8612 uses the term “design compliance testing” for clinical investigation.

To ensure the traceability of non-contact tonometers, this Recommendation proposes a series of requirements and test procedures meant to compare the performance of individual non-contact tonometers to the, in its performance and safety components, identically manufactured clinically tested device in conformity with ISO 8612 (commonly known as golden unit).

Additional requirements concerning environmental influences on the performance and mechanical strength are specified.

2 Scope

This Recommendation specifies minimum requirements and test procedures for the design compliance, construction and performance of non-contact tonometers (NCT), which are used for the estimation of the intraocular pressure (IOP) of human subjects in clinical applications.

The requirements and test procedures for applanation and impression tonometers are described in the OIML Recommendation R 145.

Note: Non-contact tonometers do not measure directly the intraocular pressure; the IOP is estimated by investigating the response of the eye to an air pulse generated by a non-contact tonometer.

In the mandatory Annex B of this Recommendation, minimum requirements and test procedures for the design compliance, construction and performance of IOP testing equipment are specified.

3 Terms and definitions

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

3.1 intraocular pressure (IOP)

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

3.2 non-contact tonometer (NCT)

tonometer that uses an air pulse to determine the IOP, without mechanical contact with the eye.

3.3 reference tonometer

Goldman applanation tonometer that complies with Annex A of ISO 8612.

3.4 IOP testing equipment

equipment able to simulate intraocular pressure and which is used for the testing and verification of non-contact tonometers.

Note: The most common types of IOP testing equipment for non-contact tonometers are described in the informative Annex B.

3.5 Hand-held

device intended to be supported by the hand during normal use.

4 Description of the category of instrument

Non-contact tonometers use the applanation principle. The applanation of a predefined area of the cornea is achieved by the application of an air pulse. An optical sensor registers when the applanation is achieved and the IOP is calculated based on the force needed to applanate the cornea.

The main components of a non-contact tonometer (air-puff tonometer) are: a pneumatic system that generates a rapid puff of air directed to the eye surface, a light emitter that sends for instance a beam of light under a specified angle and a light detector collecting the light reflected by the cornea at a specified angle of incidence.

5 Units of measurement

The IOP shall be indicated in kilopascals (kPa) or in millimetres of mercury (mmHg).

6 Metrological requirements

6.1 IOP measuring range and resolution

The non-contact tonometers shall be capable of indicating IOP at least in the range 0.0 kPa to 5.3 kPa (0 mmHg to 40 mmHg). If the manufacturer claims a broader range, the compliance with this Recommendation shall be proven for the entire range.

The resolution of the display shall be at least 0.1 kPa (1 mmHg).

Check compliance with the requirements consulting the instructions for use or by confirmation by the manufacturer.

6.2 Environmental conditions

6.2.1 Devices in use

Non-contact tonometers shall comply with all the requirements specified in 6.4.1 at

- temperatures between 10 °C and 40 °C,
- relative humidity between 10 % and 90 % (non-condensing).

Testing shall be carried out in accordance with Clause 1 of R XXX-2.

6.2.2 Storage of non-contact tonometers

Non-contact tonometers shall comply with all requirements specified in 6.4.1 after storage at

- temperatures between –20 °C and 60 °C,
- relative humidity between 10 % and 90 % (non-condensing).

Testing shall be carried out in accordance with Clause 2 of R XXX-2.

6.3 Clinical investigation

The manufacturer shall demonstrate, on the basis of design compliance testing as specified in Clause 4.2 of ISO 8612, that at least 95 % of the paired differences between the reference tonometer reading and the test tonometer reading, meet the requirements given in Table 1.

Table 1
The maximum permissible measurement error
for the paired differences reference tonometer - test tonometer

IOP range			**maximum permissible measurement error**	
	kPa	**mmHg**	**kPa**	**mmHg**
low	0.93 to 2.13	7.0 to 16.0	± 0.67	± 5.0
intermediate	2.13 to < 3.07	> 16.0 to < 23.0	± 0.67	± 5.0
high	≥ 3.07	≥ 23.0	± 0.67	± 5.0

Note: ISO 8612 uses the term "tolerance" as "maximum permissible measurement error". This recommendation opts for the use of the term "maximum permissible measurement error" as recommended in the International vocabulary of metrology - Basic and general concepts and associated terms (VIM, 4.26).

6.4 Stability

The repeatability test in Clause 6.4.1 shall be performed as the initial test (prior to all other tests required by this Recommendation).

The intermediate measurement precision test in Clause 6.4.2 shall be performed as the final test (following all other tests required by this Recommendation).

6.4.1 Repeatability

Ten repeated measurements shall be performed for one value in each of the three IOP ranges specified in the Table 1. This value is specified by the manufacturer for the IOP testing 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: $|\Delta x_{high}| \leq 0.27\ kPa\ (2.0\ mmHg)$; $s(\Delta x_{high}) \leq 0.27\ kPa\ (2.0\ mmHg)$

Testing shall be carried out in accordance with Clause 1 of R XXX-2

Note: This Clause does not require new measurements if the measurements from Clause 6.2 have already been recorded.

6.4.2 Intermediate measurement precision

The repeatability test in Clause 6.4.1 shall be repeated and complied with.

Testing shall be carried out in accordance with Clause 3 of R XXX-2

7 Technical requirements

7.1 Mechanical strength of non-contact tonometers

Hand-held non-contact tonometers shall operate correctly following a free fall from a height of 1.0 ± 0.1 m as specified in Clause 4 of R xxx-2.

Correct operation following the fall shall be verified by checking that the tonometer still complies with the requirements in Clause 6.4.

Testing shall be carried out in accordance with Clause 4 of R XXX-2

8 Metrological controls

8.1 Inscription of the device

Each tonometer shall bear the following information:

- name of manufacturer or trademark;
- serial number;
- measuring unit;
- type approval number (if applicable).

Testing shall be carried out by visual inspection.

8 .2 Accompanying documents

The manufacturers shall provide a user's instruction manual, which includes:

- the description of the device and its accessories,

- instructions for use and maintenance,
- information concerning clinical investigation according to ISO 8612 Ophthalmic instruments – Tonometers,
- reference to the current Recommendation.

Testing shall be carried out by visual inspection.

8.3 Verification

In the case of non-contact tonometers, traceability to national standards is technically not feasible. Instead, traceability is ensured via a transfer standard, to an identically manufactured device in its performance and components and clinically tested in conformity with ISO 8612. IOP testing equipment allowing the simulation of IOP measurements is used as transfer standards in the (re)verification of non-contact tonometers.

The verifications shall be periodically performed and after repair. The reverification period shall not exceed two years.

The (re)verification shall be carried out in accordance to Clause 1 of R XXX-2 at any room temperature between 10 °C and 40 °C and relative humidity between 10 % and 90 %.

Note: Examples for such IOP testing equipment can be found in Annex B. The use of different IOP testing equipment is permissible as long as the manufacturer can prove compliance with the current Recommendation.

Annex A

IOP testing equipment

(Mandatory)

A.1 Requirements for IOP testing equipment

The IOP testing 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 exceed these requirements, i.e. to specify smaller permissible limits for their IOP testing equipment. Manufacturer specifications below the state of the art shall not be acceptable for IOP testing equipment intended for metrological control.

Note: Examples for such IOP testing equipment can be found in Annex B. The use of different IOP testing equipment is permissible as long as the manufacturer can prove compliance with the current Recommendation.

The IOP testing equipment shall be periodically verified according to A.1.1. The reverification period is one year unless otherwise specified by the manufacturer, but not more than three years.

A.1.1 IOP testing equipment in use

The IOP testing equipment shall comply with all the requirements specified in this Recommendation at

- temperatures between 10 °C and 40 °C,
- relative humidity between 10 % and 90 % (non-condensing).

Check compliance with Clause 6.4.1.

Testing shall be carried out in accordance with Clause 1 of R XXX-2

A1.2 Storage of IOP testing equipment

The test equipment shall comply with all the requirements specified in this Recommendation at

- temperatures between 10 °C and 40 °C,
- relative humidity between 10 % and 90 % (non-condensing).

Check compliance with Clause 6.4.1.

Testing shall be carried out in accordance with Clause 2 of R XXX-2

A1.3 Mechanical stability

Perform at least 1 000 repeated measurements with the IOP testing equipment, equally distributed in the three measurement ranges specified in Table 1.

Check compliance with 6.4.1.

Testing shall be carried out in accordance with Clause 4 of R XXX-2

A1.4 Mechanical strength of IOP testing equipment

The hand-held IOP testing equipment shall operate correctly following a free fall from a height of 1.0 m ± 0.1 m onto a 50 mm ± 5 mm thick hardwood board (density > 600 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.

IOP testing equipment that cannot comply with these requirements shall be marked accordingly and shall be subject to performance checks prior to each use.

Check compliance with 6.4.1.

Testing shall be carried out in accordance with Clause 4 of R XXX-2

Annex B

IOP testing equipment to simulate the measurement of the intraocular pressure

(Informative)

The IOP testing equipment to simulate the measurement of the intraocular pressure shall fulfil at least the following requirements:

- The non-contact tonometer to be tested in the same configuration as it is used on human subjects.
- The IOP testing equipment to be stable (see Clause 10).

Note: The procedure on how to attach the IOP testing equipment to the non-contact tonometer should be part of the testing.

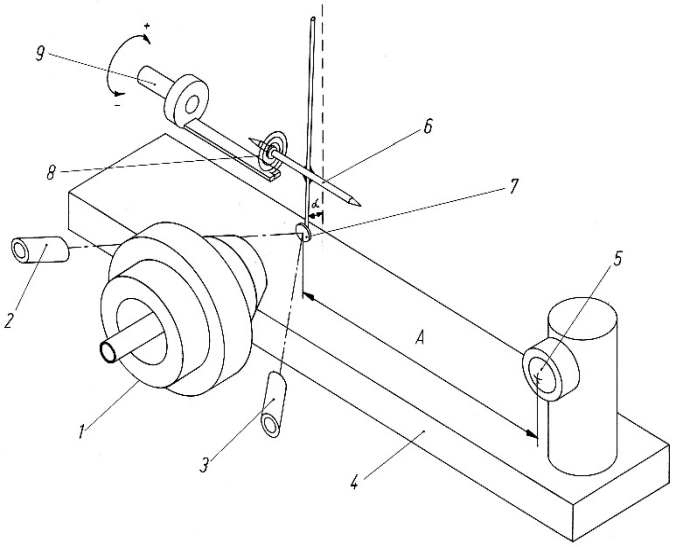
Those components important for the simulation to be traceable to national standards.

Different set-ups to test non-contact tonometers exist and new ones are being developed. As a presentation of all available IOP testing equipment is not feasible, this Recommendation will concentrate on the three most commonly used set-ups:

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

PTB flapper

The German Metrology Institute PTB (Physikalisch-Technische Bundesanstalt) has developed in the 1980s a mechanical device able to simulate an IOP measurement. The scheme of this IOP testing equipment is shown in Figure 1. This device simulates the applanation of a human eye by means of the kinematic movement of a small circular mirror (7). The device uses a mirror and lever system, wherein the tonometer air pulse is directed at the mirror mounted on a lever to angularly displace the lever about a pivot axis. By changing the torque, different IOP values can be simulated.



Where:

1: nozzle of the non-contact tonometer

2, 3: light source and light detector of the NCT

4: mount

5: lens to adjust the distance non-contact tonometer – mirror

6: rotating axis

7: mirror

8: spring

9: adjustment of the torque

A: distance to move the test jig distant adjustment to the dynamic test position

Figure 1 - Schematic drawing of the PTB flapper

Note: The PTB flapper requires special mounting to be attached to the non-contact tonometer.

Mechanical phantom eye (“rubber eye”)

The mechanical phantom eye shall simulate the shape and the biomechanical properties of the cornea, it is made of soft silicon rubber and fabricated with different thicknesses. The aging effect of the elastic material shall be investigated, and periodic checks are strongly recommended. An example of a mechanical phantom eye is shown in Figure 2.

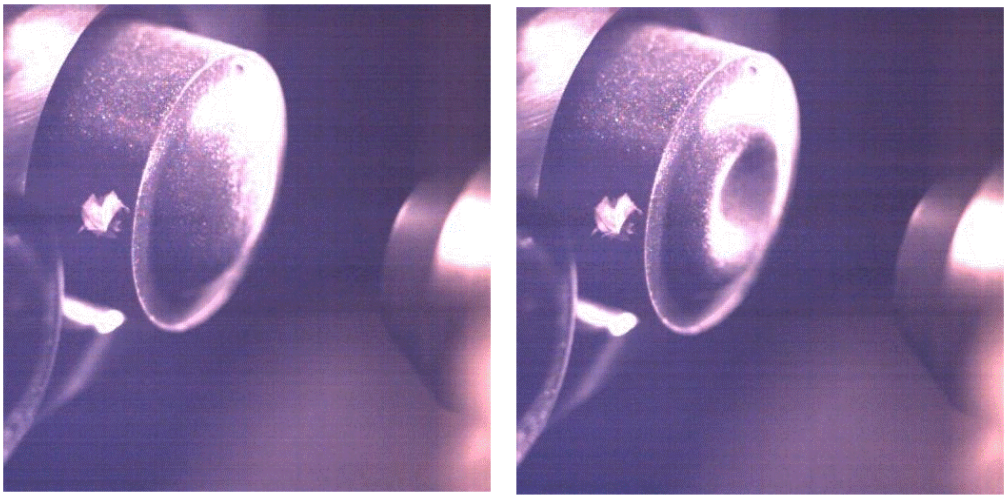


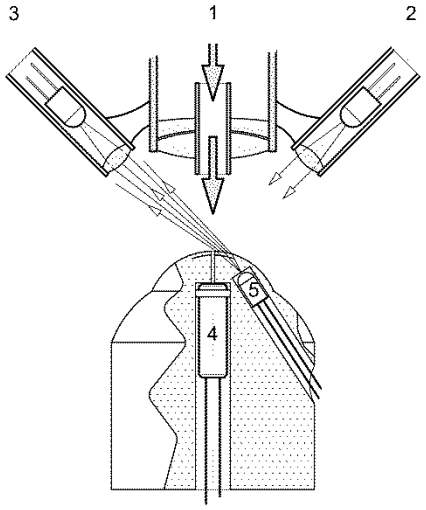
Figure 2 - Representation of a mechanical phantom eye
(in both cases shown on the left side of the picture)

left: in the resting phase; right: during the measurement

Note: Usually this mechanical phantom eye can be attached to the non-contact tonometer easily.

Electronic phantom eye

The electronic phantom eye (Figure 3) is a device, which is made from rigid material. Its exterior design resembles a cornea. Inside it has a pressure transducer and a light source. Depending on the pressure applied by the air puff, measured by the pressure transducer of the electronic phantom eye, the light source flashes. This flash simulates the reflection signal expected by the non-contact tonometer. The electronic phantom eye is mechanically stable and easy to attach to the non-contact tonometer.



Where

1: nozzle of the non-contact tonometer

2, 3: light source and light detector of the NCT

4: pressure transducer of the electronic phantom eye

5: light source of the electronic phantom eye

Figure 3 - Schematic drawing of an electronic phantom eye