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Foreword

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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. This publication was developed by Project Group 2 of OIML TC 18 Medical measuring instruments.

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Ophthalmic instruments – Non-contact tonometers

Part 2 – Test ~~procedures~~methods

1 Influence of environmental conditions on performance for devices in use and repeatability

1.1 ~~Apparatus~~Test equipment

- IOP testing equipment as described in R xxx-1, A.1
- Climatic chamber with non-uniformity of temperature within ± 1 °C, instability of temperature of ± 1 °C, non-uniformity of relative humidity of ± 5 %, instability of relative humidity of ± 5 %

1.2 ~~Test method~~Procedure

Proceed as follows:

- The IOP testing equipment shall be kept at room temperature, outside of the climatic chamber.
- For each of the following temperature-humidity combinations, the device to be tested shall be placed in the climatic chamber for at least 1 hour (or the time specified in the instructions for use) in order to reach steady performance conditions:
 - $12\text{ °C} \pm 2\text{ °C}, 20\% \pm 10\%$
 - $25\text{ °C} \pm 2\text{ °C}, 50\% \pm 10\%$
 - $38\text{ °C} \pm 2\text{ °C}, 80\% \pm 10\%$
- After steady performance conditions ~~are~~reached, the IOP testing equipment shall be attached.
- For each of the ranges specified in ~~Table~~ 1, set the IOP testing equipment to one arbitrary chosen reference value.
- For each temperature-humidity combination as indicated in b), perform ~~10~~ten repeated measurements in each of the measurement ranges in Table 1 and record the data:

Table 1 - Definition of the IOP ranges

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

If during the measurement the climatic chamber has to be open for more than 2 minutes, the steady performance conditions shall be ensured by repeating b) to e).

1.3 ~~Expression~~ Presentation of results

For each measuring range and for each temperature-humidity combination, separately calculate the results as the difference between the indicated value of the device under test and the reference value. Check compliance with the requirements in R xxx-1, 6.4.1.

2 Influence of storage on the performance

2.1 ~~Test equipment~~ Apparatus

- IOP testing equipment as described in R xxx-1, A.1
- Climatic chamber with non-uniformity of temperature within ± 1 °C, instability of temperature of ± 1 °C, non-uniformity of relative humidity of ± 5 %, instability of relative humidity of ± 5 %.

2.2 ~~Test method~~ Procedure

The packed devices under test shall be subject to the following storage procedure:

- Store the device under test for at least 24 h at $-18\text{ °C} \pm 2\text{ °C}$ ambient temperature and $20\% \pm 10\%$ relative humidity
- Store the device under test for 1 h at room temperature
- Store the device under test for at least 24 h at $58\text{ °C} \pm 2\text{ °C}$ ambient temperature and $80\% \pm 10\%$ relative humidity
- Wait at least one hour at room temperature before performing the following step.

Perform the procedure described in 1.2.

2.3 ~~Expression~~ Presentation of results

For each measuring range and for each temperature-humidity combination, separately calculate the results as the difference between the indicated value of the device under test and the reference value.

Check compliance with the requirements in Rxxx-1, 6.4.1.

3 Intermediate measuring precision

After all tests were performed, repeat Clause 1, exclusively at $25\text{ °C} \pm 2\text{ °C}$ room temperature and $50\% \pm 10\%$ relative humidity.

For each measuring range, separately calculate the results as the difference between the indicated value of the device under test and the reference value.

Check compliance with the requirements in R xxx-1, 6.4.1.

4 Mechanical strength of non-contact tonometers

4.1 Test equipmentApparatus

- IOP testing equipment as described in Rxxx-1, A.1
- Hardwood board with a thickness of $50\text{ mm} \pm 5\text{ mm}$ and a density $> 600\text{ kg/m}^3$

4.2 Test methodProcedure

Examine the type of non-contact tonometer (hand-held or other types). Non-contact tonometers containing a hand-held component shall undergo both testing procedures.

After the applicable tests 4.2.1-4.2.3 were performed, repeat Clause 1, exclusively at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ room temperature and $50\% \pm 10\%$ relative humidity.

4.2.1 Hand-held NCT

Allow the hand-held NCT to fall freely six times (once on each side) from a height of $1.0\text{ m} \pm 0.1\text{ m}$ onto the hardwood board lying flat on a concrete or similar rigid base.

~~**4.2.2 Non-hand-held NCT**~~

~~Allow the hand-held NCT to fall freely six times (once on each side) from a height of $50\text{ mm} \pm 5\text{ mm}$ onto the hardwood board lying flat on a concrete or similar rigid base.~~

~~**4.2.3**~~**4.2.2 NCT containing a hand-held measuring component**

Allow the non-portable part of the NCT to fall freely six times (once on each side) from a height of $50\text{ mm} \pm 5\text{ mm}$ onto the hardwood board lying flat on a concrete or similar rigid base.

Allow the hand-held component of the NCT to fall freely six times (once on each side) from a height of $1.0\text{ m} \pm 0.1\text{ m}$ onto the hardwood board lying flat on a concrete or similar rigid base.

4.3 PresentationExpression of results

For each measuring range, separately calculate the results as the difference between the indicated value of the device under test and the reference value.

Check compliance with the requirements in Rxxx-1, 6.4.1

~~Mandatory~~ Annex A

~~IOP testing equipment~~

(Mandatory)

A.1 Requirements for IOP testing equipment

A.2 IOP testing equipment in use

A.2.1 ~~Test equipment~~Apparatus

- At least ~~5~~five non-contact tonometers compatible with the IOP testing equipment
- Climatic chamber with non-uniformity of temperature within ± 1 °C, instability of temperature of ± 1 °C, non-uniformity of relative humidity of ± 5 %, instability of relative humidity of ± 5 %.

A.2.2 ~~Test method~~Procedure

Proceed as follows:

- a) The NCTs shall be kept at room temperature, outside of the climatic chamber.
- b) For each of the following temperature-humidity combinations, the IOP testing equipment to be tested shall be placed in the climatic chamber for at least ~~1~~one hour (or the time specified in the instructions for use) in order to reach steady performance conditions:
- c) $12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, $20\text{ \%} \pm 10\text{ \%}$
- d) $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, $50\text{ \%} \pm 10\text{ \%}$
- e) $38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, $80\text{ \%} \pm 10\text{ \%}$
- f) After steady performance conditions are reached, the IOP testing equipment shall be attached to the NCT.
- g) For each of the ranges specified in table xxx, set the IOP testing equipment to one arbitrary chosen reference value.
- h) For each temperature-humidity combination as indicated in b), perform ~~10~~ten repeated measurements in each of the measurement ranges in Table 1 and record the data:
- i) Repeat b) - e) for each of the ~~5~~five NCTs.

If the measurement takes more than ~~2~~two minutes, the IOP testing equipment shall be placed in the climatic chamber again for at least ~~1~~one hour, the steady performance conditions shall be ensured by repeating b) to e).

A.2.3 ~~Presentation~~Expression of results

For each NCT individually, for each measuring range and for each temperature-humidity combination, separately calculate the results as the difference between the indicated value of the device under test and the reference value. Check compliance with the requirements in R xxx-1, 6.4.1.

For each measuring range and for each temperature-humidity combination:

- a) separately calculate the results as the difference between the indicated value of the device under test and the reference value;

A.3 Storage of IOP testing equipment

A.3.1 Test equipment~~Apparatus~~

- A non-contact tonometer compatible with the IOP testing equipment
- Climatic chamber with non-uniformity of temperature within $\pm 1\text{ }^{\circ}\text{C}$, instability of temperature of $\pm 1\text{ }^{\circ}\text{C}$, non-uniformity of relative humidity of $\pm 5\%$, instability of relative humidity of $\pm 5\%$;

A.3.2 Test method~~Procedure~~

The IOP testing equipment under test shall be subject to the following storage procedure:

- a) Store the IOP testing equipment for at least 24 h at $-18\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ ambient temperature and $20\% \pm 10\%$ relative humidity
- b) Store the IOP testing equipment for 1 h at room temperature
- c) Store the IOP testing equipment for at least 24 h at $58\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ ambient temperature and $80\% \pm 10\%$ relative humidity
- d) Wait at least one hour at room temperature before performing the following step;

Perform the procedure described in A 2.2 a) – e), for one IOP testing equipment only.

A.3.4 Presentation~~Expression~~ of results

For each measuring range and for each temperature-humidity combination, separately calculate the results as the difference between the indicated value of the device under test and the reference value. Check compliance with the requirements in R xxx-1, 6.4.1.

A.3.5 Mechanical strength of IOP testing equipment

The mechanical strength check for the IOP testing equipment shall be performed in conformity with the requirements indicated by the manufacturer in the instructions for use.

Compliance with the requirements in R XXX-1, 6.4.1 shall be checked prior and consequent to the strength check, exclusively at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ room temperature and $50\% \pm 10\%$ relative humidity. The strength check shall be performed by considering the worse-case specified by the manufacturer for the IOP testing equipment.

A.4 Mechanical stability

A.4.1 Test equipment~~Apparatus~~

- At least one non-contact tonometer, but none of the five non-contact tonometers used in A.2, compatible with the IOP testing equipment
- At least five non-contact tonometers compatible with the IOP testing equipment

A.4.2 Test method~~Procedure~~

The IOP testing equipment under test shall be subject to the following procedure:

- Attach the non-contact tonometer, not used in A.2, to the IOP testing equipment~~.~~
- Perform 1_000 IOP measurements, equally distributed in the three measurement ranges.
Note: more than one non-contact tonometer may be used~~.~~
- Perform the procedure described in A.2.2 with the same five non-contact tonometers and the IOP testing equipment at the same reference IOP values in each IOP pressure range used in A.2~~.~~

A.4.3 Presentation~~Expression~~ of results

For each NCT individually, for each measuring range and for each temperature-humidity combination, separately calculate the results as the difference between the indicated value of the device under test and the reference value. Check compliance with the requirements in R xxx-1, 6.4.1.

For each measuring range and for each temperature-humidity combination:

- a) separately calculate the results as the difference between the indicated value of the device under test and the reference value;
- b) average the results obtained in a) for all NCTs.

Check compliance with the requirements in R xxx-1, A.1.3.