



First Committee Draft (CD)

Project:	New Recommendation
Title:	Ophthalmic instruments – Non-contact tonometers Part 4: Type evaluation report format
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Convenership:	Germany
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☐ Discussion at (date and place of meeting):

☒ Comments by: 10 November 2020

☐ Vote (P-members only) and comments by:

Contents (to be finalised later)

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Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Project Groups linked to Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

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. OIML Publications may be downloaded from the OIML website in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization's headquarters:

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Internet: www.oiml.org

Ophthalmic instruments – Non-contact tonometers

Part 4 – Type evaluation report format

Note 1: Section I of the document summarises the test results for non-contact tonometers, while Section II of the document summarises the test results for the testing equipment used for the testing of non-contact tonometers.

Note 2: For series type approvals of either non-contact tonometers or testing equipment used for the testing of non-contact tonometers, a minimum of two devices shall be tested in order to ensure that the devices are produced with sufficient and consistent metrological.

I Type evaluation report format for non-contact tonometers

1 General

This type evaluation report format is informative with regard to the implementation of OIML R xxx in national regulations; however, use of the type evaluation report format is mandatory for the application of this Recommendation within the OIML Certificate System.

References to the requirements of OIML R xxx-1 are given in brackets.

1.1 Name and address of the certification body

1.2 Reference to this Recommendation

When referring to the whole Recommendation:	OIML R xxx
When referring to the metrological and technical requirements:	OIML R xxx-1
When referring to the test procedures:	OIML R xxx-2
When referring to the test report format:	OIML R xxx-3
When referring to the type evaluation report format:	OIML R xxx-4

1.4 Identification of the samples tested (e.g. serial number)

1.5 Name and address of the manufacturer

1.6 Name and address of the applicant (if different from the manufacturer)

1.7 Dates of the test period

Start:

End:

1.8 Location or name of the certification body at which the type evaluation was performed (if different from the address given in 1.1)

1.9 Information and identification**1.9.1 Inscription of the device (R xxx-1, 8.1)**

Name of the manufacturer or trademark:

Pass: ☐ Fail: ☐

Serial number:

Pass: ☐ Fail: ☐

Type approval number (if applicable)

Pass: ☐ Fail: ☐**1.9.2 Accompanying documents (R xxx-1, 8.2)**

Description of the device and its accessories:

Pass: ☐ Fail: ☐

Instruction for use and maintenance:

Pass: ☐ Fail: ☐

Clinical investigation according to ISO 8612

Pass: ☐ Fail: ☐**1.10 Summary of metrological requirements according to this Recommendation****1.10.1 IOP measuring range and resolution (R xxx-1, 6.1)**IOP range: 0.0 kPa ~~to~~ 5.3 kPa (0 mmHg ~~to~~ 40 mmHg)Pass: ☐ Fail: ☐

Resolution: 0.1 kPa (1 mmHg)

Pass: ☐ Fail: ☐

1.10.2 Influence of environmental conditions on performance for devices in use and repeatability (R xxx-2, 1)

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
H Low	0.13 ± 0.13	1.0 ± 1.0		
i Intermediate	0.2 ± 0.2	1.5 ± 1.5		
h High	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
Low	0.13 ± 0.13	1.0 ± 1.0		
Intermediate	0.2 ± 0.2	1.5 ± 1.5		
High	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
H Low	0.13 ± 0.13	1.0 ± 1.0		
i Intermediate	0.2 ± 0.2	1.5 ± 1.5		
h High	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.10.3 Influence of storage on the performance (R xxx-2, 2)

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
L ow	0.13 ± 0.13	1.0 ± 1.0		
I ntermediate	0.2 ± 0.2	1.5 ± 1.5		
H igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
L ow	0.13 ± 0.13	1.0 ± 1.0		
I ntermediate	0.2 ± 0.2	1.5 ± 1.5		
H igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
low	0.13 ± 0.13	1.0 ± 1.0		
intermediate	0.2 ± 0.2	1.5 ± 1.5		
high	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

1.10.4 Intermediate measuring precision

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.11 Mechanical strength (Rxxx-2, 4)

1.11.1 Hand-held non-contact tonometer

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.11.2 NCT containing a hand-held measuring component

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH = 50 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
low	0.13 ± 0.13	1.0 ± 1.0		
intermediate	0.2 ± 0.2	1.5 ± 1.5		
high	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

2 Details of type evaluation report

Date of the type evaluation report:

.....

Type evaluation report number:

.....

Signature of the person(s) responsible for the certification:

.....

II Type evaluation report for testing equipment (R xxx-1, ~~Mandatory~~ Annex A)

1 General

This type evaluation report format is informative with regard to the implementation of OIML R xxx in national regulations; however, use of the type evaluation report format is mandatory for the application of this Recommendation within the OIML Certificate System.

References to the requirements of OIML R xxx-1 are given in brackets.

1.1 Name and address of the certification body

1.2 Reference to this Recommendation

When referring to the whole Recommendation:	OIML R xxx
When referring to the metrological and technical requirements:	OIML R xxx-1
When referring to the test procedures:	OIML R xxx-2
When referring to the test report format:	OIML R xxx-3
When referring to the type evaluation report format:	OIML R xxx-4

1.3 Photo(s)

1.4 Identification of the samples tested (e.g. serial number, type of device)

1.5 Name and address of the manufacturer

1.6 Name and address of the applicant (if different from the manufacturer)

1.7 Dates of the test period

Start:

End:

1.8 Location or name of the certification body at which the type evaluation was performed
(if different from the address given in 1.1)

1.9 Summary of metrological requirements according to this Recommendation

1.9.1 IOP testing equipment in use

1.9.1.1 Tonometer 1

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
H Low	0.13 \pm 0.13	1.0 \pm 1.0		
I Intermediate	0.2 \pm 0.2	1.5 \pm 1.5		
h High	0.27 \pm 0.27	2.0 \pm 2.0		

Pass: ☐

Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> Low	0.13 ± 0.13	$1.0 \pm \underline{1.0}$		
<u>i</u> Intermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> High	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> Low	0.13 ± 0.13	$1.0 \pm \underline{1.0}$		
<u>i</u> Intermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> High	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

1.9.1.2 Tonometer 2

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> Low	0.13 ± 0.13	$1.0 \pm \underline{1.0}$		
<u>i</u> Intermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> High	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.9.1.3 Tonometer 3

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

1.9.1.4 Tonometer 4

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
$\underline{\text{H}}_{\text{Low}}$	0.13 ± 0.13	$1.0 \pm \underline{1.0}$		
$\underline{\text{i}}_{\text{Intermediate}}$	0.2 ± 0.2	1.5 ± 1.5		
$\underline{\text{h}}_{\text{High}}$	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
$\underline{\text{H}}_{\text{Low}}$	0.13 ± 0.13	$1.0 \pm \underline{1.0}$		
$\underline{\text{i}}_{\text{Intermediate}}$	0.2 ± 0.2	1.5 ± 1.5		
$\underline{\text{h}}_{\text{High}}$	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.9.1.5 Tonometer 5

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
$\underline{\text{H}}_{\text{Low}}$	0.13 ± 0.13	$1.0 \pm \underline{1.0}$		
$\underline{\text{i}}_{\text{Intermediate}}$	0.2 ± 0.2	1.5 ± 1.5		
$\underline{\text{h}}_{\text{High}}$	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> Low	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> Intermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> High	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> Low	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> Intermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> High	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

1.9.2 Storage of IOP testing equipment

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> Low	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> Intermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> High	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.9.3 Mechanical strength

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.9.4 Mechanical stability

1.9.4.1 Tonometer 1

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
L ow	0.13 ± 0.13	1.0 ± 1.0		
I ntermediate	0.2 ± 0.2	1.5 ± 1.5		
H igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50 % \pm 10 %

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
L ow	0.13 ± 0.13	1.0 ± 1.0		
I ntermediate	0.2 ± 0.2	1.5 ± 1.5		
H igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80% $\pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.9.4.2 Tonometer 2

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20% $\pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% $\pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH = $80\% \pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

1.9.4.3 Tonometer 3

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH = $20\% \pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH = $50\% \pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= $80\% \pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
$\underline{\text{H}}_{\text{Low}}$	0.13 ± 0.13	1.0 ± 1.0		
$\underline{\text{i}}_{\text{Intermediate}}$	0.2 ± 0.2	1.5 ± 1.5		
$\underline{\text{h}}_{\text{High}}$	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

1.9.4.4 Tonometer 4

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= $20\% \pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
$\underline{\text{H}}_{\text{Low}}$	0.13 ± 0.13	1.0 ± 1.0		
$\underline{\text{i}}_{\text{Intermediate}}$	0.2 ± 0.2	1.5 ± 1.5		
$\underline{\text{h}}_{\text{High}}$	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= $50\% \pm 10\%$

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
$\underline{\text{H}}_{\text{Low}}$	0.13 ± 0.13	1.0 ± 1.0		
$\underline{\text{i}}_{\text{Intermediate}}$	0.2 ± 0.2	1.5 ± 1.5		
$\underline{\text{h}}_{\text{High}}$	0.27 ± 0.27	2.0 ± 2.0		

Pass: ☐ Fail: ☐

$t = 38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 80% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

1.9.4.5 Tonometer 5

$t = 12\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 20% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, RH= 50% \pm 10%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
<u>H</u> ow	0.13 ± 0.13	1.0 ± 1.0		
<u>i</u> ntermediate	0.2 ± 0.2	1.5 ± 1.5		
<u>h</u> igh	0.27 ± 0.27	2.0 ± 2.0		

Pass:

☐

Fail:

☐

$t = 38_{-}\text{C} \pm 2_{-}\text{C}$, RH= 80_{-}% \pm 10_{-}%

IOP range	Requirement $ \Delta x_{req} \pm s(\Delta x_{req})$		Measurement $ \Delta x_{meas} \pm s(\Delta x_{meas})$	
	kPa	mmHg	kPa	mmHg
L ow	0.13 \pm 0.13	1.0 \pm 1.0		
i ntermediate	0.2 \pm 0.2	1.5 \pm 1.5		
h igh	0.27 \pm 0.27	2.0 \pm 2.0		

Pass: ☐ Fail: ☐

2 Details of type evaluation report

Date of the type evaluation report:

Type evaluation report number:

Signature of the person(s) responsible for the certification: