



**First Committee Draft (CD)**

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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:

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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.

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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 15<sup>th</sup> of January 2020.

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## **Ophthalmic instruments – Non-contact tonometers**

### **Part 3 – Test report format**

*Note:* 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.

## **I Test report for non-contact tonometer**

### **1 General**

This test report format is informative with regard to the implementation of OIML R xxx in national regulations; however, use of the test 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 testing laboratory (laboratories)**

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#### **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)**

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**1.5 Name and address of the manufacturer**

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

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**1.7 Dates of the test period**

Start: 

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End: 

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**1.8 Location or name of the laboratory at which the tests were performed (if different from the address given in 1.1)**

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**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 (Rxxx-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 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
<del>H</del> Low	$0.13 \pm 0.13$	$1.0 \pm 1.0$		
<del>I</del> Intermediate	$0.2 \pm 0.2$	$1.5 \pm 1.5$		
<del>H</del> High	$0.27 \pm 0.27$	$2.0 \pm 2.0$		

Pass: ☐ Fail: ☐

## 2 Details of test report

Date of the test report:

Test report number:

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

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

### 1 General

This test report format is informative with regard to the implementation of OIML R xxx in national regulations; however, use of the test 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 testing laboratory (laboratories)

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#### 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 approval mark, type of device)**

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**1.5 Name and address of the manufacturer**

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

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**1.7 Dates of the test period**

Start: 

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End: 

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**1.8 Location or name of the laboratory at which the tests were performed (if different from the address given in 1.1)**

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**1.9 Summary of metrological requirements according to this Recommendation**

**1.9.1 IOP testing equipment in use**

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ , 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
<del>l</del> Low	$0.13 \pm 0.13$	$1.0 \pm 1.0$		
<del>i</del> Intermediate	$0.2 \pm 0.2$	$1.5 \pm 1.5$		
<del>h</del> High	$0.27 \pm 0.27$	$2.0 \pm 2.0$		

Pass: ☐ Fail: ☐

**1.9.2 Mechanical stability**

$t = 25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ , 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
<del>H</del> Low	$0.13 \pm 0.13$	$1.0 \pm 1.0$		
<del>i</del> Intermediate	$0.2 \pm 0.2$	$1.5 \pm 1.5$		
<del>h</del> High	$0.27 \pm 0.27$	$2.0 \pm 2.0$		

Pass:

☐

Fail:

☐**2 Details of test report**

Date of the test report:

Test report number:

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