
Ophthalmic instruments -
Impression and applanation tonometers.

Part 3: Test report format

Instruments ophtalmiques - tonomètres d'empreinte et d'aplanation.

Partie 3: Format du rapport d'essais



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Foreword

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Ophthalmic instruments – Impression and applanation tonometers

Part 3 – Test report format

1 Impression tonometers

This test report format is informative with regard to the implementation of OIML R 145 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 145-1 are given in brackets.

The impression tonometer designed by Hjalmar Schiøtz measures the indentation of the cornea by a plunger of defined mass and dimensions.

1.1 Name and address of the testing laboratory (laboratories)

1.2 Reference to this Recommendation

When referring to the whole Recommendation:	OIML R 145:2015
When referring to the metrological and technical requirements:	OIML R 145-1:2015
When referring to the test procedures:	OIML R 145-2:2015
When referring to the test report format:	OIML R 145-3:2015

1.3 Identification of the type to which the test report applies

As an example: common and trade names and model, and a brief description including drawings, diagrams, and inscriptions, specifically including the following:

Type of tonometer and characteristics

Impression tonometer:	mechanical	☐	electro-mechanical	☐
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Measuring range

IOP:	from	_____	mmHg	to	_____	mmHg
------	------	-------	------	----	-------	------

Scale:	from	_____	scale divisions	to	_____	scale divisions
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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 laboratory at which the tests were performed (if different from the address given in 1.1)

1.9 Information and identification**1.9.1 List of documents submitted for the evaluation**Pass: ☐ Fail: ☐**1.9.2 Operating manual**

Clear and complete instructions:

Pass: ☐ Fail: ☐

Compliance with the requirements:

Pass: ☐ Fail: ☐**1.10 Summary of tests carried out according to this Recommendation****1.10.1 General tests**

Test for visible defects or damage:

Pass: ☐ Fail: ☐

Units of measurement (R 145-1, 5):

Pass: ☐ Fail: ☐

Comments:

1.10.2 Mass of the tonometer and additional masses (R 145-1, 6.5.1)

1.10.2.1 Tonometer mass without the handle:

 $16.5 \pm 0.5 \text{ g}$ Pass: ☐ Fail: ☐

1.10.2.2 Additional mass with inscription 7.5:

 $2.00 \text{ g} \pm 0.02 \text{ g}$ Pass: ☐ Fail: ☐

1.10.2.3 Additional mass with inscription 10.0:

 $4.50 \text{ g} \pm 0.02 \text{ g}$ Pass: ☐ Fail: ☐

1.10.2.4 Additional mass with inscription 15.0:

 $9.50 \text{ g} \pm 0.02 \text{ g}$ Pass: ☐ Fail: ☐

1.10.3 Effective mass (R 145-1, 6.5.2)1.10.3.1 Scale division 5 for the effective mass $5.50 \text{ g} \pm 0.15 \text{ g}$ Pass: ☐Fail: ☐1.10.3.2 Scale division 10 for the effective mass $5.50 \text{ g} \pm 0.20 \text{ g}$ Pass: ☐Fail: ☐**1.10.4 Friction between the plunger and the plunger sleeve (R 145-1, 6.5.3)**

<i>Requirement:</i>	R 145-1, 6.5.3	The friction between the plunger and the plunger sleeve shall not interfere significantly with the result of the measurement.
<i>Test procedure:</i>	R 145-2, 5	

Pass: ☐Fail: ☐**1.10.5 Surface (R 145-1, 6.5.4)**

<i>Requirement:</i>	R 145-1, 6.5.4	The front contact surfaces of the footplate and the plunger shall be smooth to the touch, and, when examined by unaided corrected vision under direct illumination, shall be free from surface imperfections that could damage the eye. The outer edge of the footplate and the inside edge of the recess or counterbore shall be rounded.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐Fail: ☐**1.10.6 Dimensions of the footplate and the plunger (6.5.5)****Footplate dimensions (Table 1)**1.10.6.1 Diameter, d_1 : $10.1 \text{ mm} \pm 0.2 \text{ mm}$ Pass: ☐Fail: ☐1.10.6.2 Radius of curvature of the spherical front surface, r_1 : $15.00 \text{ mm} \pm 0.25 \text{ mm}$ Pass: ☐Fail: ☐1.10.6.3 Outside diameter of the spherical front surface, d_2 : $9.0_0^{+0.1}$ Minimum radius of the outside edge curvature, r_3 :

0.2 mm

Pass: ☐Fail: ☐

1.10.6.4	either a): Diameter, d_4 , of the recess or counterbore on the front surface up to the height, h_1 :	$3.3_{-0.1}^0$ mm		
	Minimum radius of the inside edge curvature, r_2 :	0.2 mm		
		Pass: ☐	Fail: ☐	
	or b): Diameter of the bore hole at the transition between foot-plate curvature and the edge curvature of the recess or counterbore (central area), d_3 :	$3.7_{-0.1}^0$ mm		
		Pass: ☐	Fail: ☐	
1.10.6.5	Minimum height of the recess or counterbore on the front contact surface, h_1 :	≥ 1.5 mm		
		Pass: ☐	Fail: ☐	

Plunger dimensions (Table 2)

1.10.6.6	Minimum diameter, d_4 , at the front contact surface up to the height, h_1 , of 1.5 mm:	$3.00 \text{ mm} \pm 0.03 \text{ mm}$		
		Pass: ☐	Fail: ☐	
1.10.6.7	Minimum height, h_2 , at the front contact surface with the diameter, d_5 :	1.5 mm		
		Pass: ☐	Fail: ☐	
1.10.6.8	Radius of curvature of the spherical front contact surface, r_4 :	$15.00 \text{ mm} \pm 0.75 \text{ mm}$		
		Pass: ☐	Fail: ☐	
1.10.6.9	Radius of the edge curvature, r_5 :	$0.25 \text{ mm} \pm 0.03 \text{ mm}$		
		Pass: ☐	Fail: ☐	
1.10.6.10	Maximum extension of the plunger below the spherical footplate:	3.0 mm		
		Pass: ☐	Fail: ☐	

Plunger sleeve and plunger dimensions (Table 3)

1.10.6.11	Maximum difference, $d_7 - d_6$ [d_7 : diameter in the footplate of the plunger sleeve, d_6 : diameter of the plunger]:	0.05 mm		
		Pass: ☐	Fail: ☐	

1.10.7 Plunger (R 145-1, 6.5.6)

<i>Requirement:</i>	R 145-1, 6.5.6	For impression tonometers designed according to Schiøtz, at some point between scale indications 5 and 10, the plunger axis and the lower surface of the lever shall form a right angle at the point of contact.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

1.10.8 Scale (R 145-1, 6.5.7)**1.10.8.1**

<i>Requirement:</i>	R 145-1, 6.5.7	The scale shall be arranged parallel to or inclined to the axis of the plunger.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

1.10.8.2

<i>Requirement:</i>	R 145-1, 6.5.7	The scale shall be divided into at least 15 equal scale divisions (for instance from -1 to 15 or from 0 to 15). The scale shall show integers only.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

1.10.9 Scale divisions**1.10.9.1**

<i>Requirement:</i>	R 145-1, 6.5.7	The distance between two adjacent lines shall be equal to a plunger displacement of 0.05 mm. The maximum permissible errors for different displacements are given in R 145-1, Table 4.
<i>Test procedure:</i>	R 145-2, 8	

Plunger displacement and its maximum permissible errors (Table 4)

Scale division from 0 to 5:

0.25 mm $\pm$ 0.01 mmPass: ☐ Fail: ☐

Scale division from 0 to 10:

0.50 mm $\pm$ 0.02 mmPass: ☐ Fail: ☐

Scale division from 0 to 15:

0.75 mm $\pm$ 0.03 mmPass: ☐ Fail: ☐

Scale division from 0 to 18:

0.90 mm $\pm$ 0.05 mmPass: ☐ Fail: ☐

Scale division from -1 to 15:

0.8 mm $\pm$ 0.03 mmPass: ☐ Fail: ☐

1.10.9.2

<i>Requirement:</i>	R 145-1, 6.5.7	The divisions marked on the scale shall consist of straight lines, of equal width, arranged on the axis of the pointer. No line shall be thicker than $\frac{1}{4}$ of the distance between two lines, nor thicker than 0.25 mm
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐**1.10.10 Pointer (R 145-1, 6.5.8)**

<i>Requirement:</i>	R 145-1, 6.5.8	The pointer shall not be wider than the smallest width of a scale line. If the pointer moves over the scale, it shall overlap the shortest lines by at least one-third of their length. The tip shall not extend beyond the scale lines. The distance between the pointer and the plane of the scale shall not be greater than 1.0 mm at any point of the scale. The pointer shall not touch the plane of the scale.
<i>Test procedure:</i>	Visual inspection R 145-2, 9	

Pass: ☐ Fail: ☐

1.10.11 Position of use of the tonometer (R 145-1, 6.5.9)

<i>Requirement:</i>	R 145-1, 6.5.9	When the tonometer is held in its operating position by the handle, its axis shall be in the vertical position so that friction, which may adversely affect the measurement, is minimized.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐**1.10.12 Test block (R 145-1, 6.5.10)**

<i>Requirement:</i>	R 145-1, 6.5.10	Each tonometer shall have a test block whose radius of curvature is $16.00 \text{ mm} \pm 0.05 \text{ mm}$ to test that the indication is 0.0 ± 0.2 on the scale when the tonometer is put on the test block.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

2 Applanation tonometers

This test report is informative with regard to the implementation of OIML R 145 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 145 are given in brackets.

The applanation tonometer measures the force necessary to applanate the cornea over a given diameter using the flat contact side of a pressure body. The measurement of the force is given on a scale.

2.1 Name and address of the testing laboratory (laboratories)

2.2 Reference to this Recommendation

When referring to the whole Recommendation:	OIML R 145:2015
When referring to the metrological and technical requirements:	OIML R 145-1:2015
When referring to the test procedures:	OIML R 145-2:2015
When referring to the test report format:	OIML R 145-3:2015

2.3 Identification of the type to which the test report applies

As an example: common and trade names and model, and a brief description including drawings, diagrams, and inscriptions, specifically including the following:

Type of tonometer and characteristics

Applanation tonometer: pressure body / diameter: _____

Measuring range

IOP: from _____ mmHg to _____ mmHg

Scale: from _____ scale divisions to _____ scale divisions

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

2.5 Name and address of the manufacturer

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

2.7 Dates of the test period

Start:

End:

2.8 Location or name of the laboratory at which the tests were performed (if different from the address given in 2.1)

2.9 Information and identification**2.9.1 List of documents submitted for the evaluation**Pass: ☐ Fail: ☐**2.9.2 Operating manual**

Clear and complete instructions:

Pass: ☐ Fail: ☐

Compliance with the requirements:

Pass: ☐ Fail: ☐**2.10 Summary of tests carried out according to this Recommendation****2.10.1 General tests**

Test for visible defects or damage:

Pass: ☐ Fail: ☐

Units of measurement (R 145-1, 5):

Pass: ☐ Fail: ☐

Comments:

2.10.2 Diameter of the applanation circle (R 145-1, 6.6.1)

<i>Requirement:</i>	R 145-1, 6.6.1	The diameter of the applanation circle shall be 3.06 mm $\pm$ 0.02 mm.
<i>Test procedure:</i>	R 145-2, 10	

Pressure body no 1:

Pass: ☐ Fail: ☐

Pressure body no 2:

Pass: ☐ Fail: ☐

2.10.3 Surface of the pressure body (R 145-1, 6.6.2)

<i>Requirement:</i>	R 145-1, 6.6.2	The front contact surface of the pressure body shall be smooth to the touch, and, when examined by unaided corrected vision under direct illumination, shall be free from surface imperfections that could damage the eye.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

2.10.4 Diameter of the pressure body (R 145-1, 6.6.3)

<i>Requirement:</i>	R 145-1, 6.6.3	The pressure body shall have a diameter of at least 6.0 mm at the area which comes into contact with the cornea.
<i>Test procedure:</i>	R 145-2, 11	

Pass: ☐ Fail: ☐

2.10.5 Measuring force (R 145-1, 6.6.4)

<i>Requirement:</i>	R 145-1, 6.6.4	The measuring force shall be continuously adjustable over the minimum range from 0.0 mN to 49.0 mN, without the use of auxiliary masses. The measured value of the force shall be clearly legible.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

Position of measuring arm relative to its free play at equilibrium of force: middle:

Pass: ☐ Fail: ☐

2.10.6 Accuracy of the measuring force (R 145-1, 6.6.5)

<i>Requirement:</i>	R 145-1, 6.6.5	The maximum permissible error of the force over the measuring range shall be $\pm 1.5\%$ of the nominal value, or ± 0.49 mN, whichever is the greater.
<i>Test procedure:</i>	R 145-2, 12	

Nominal force (mN)	Measuring force, increasing steps (mN)	Measuring force, decreasing steps (mN)	Difference (decreasing – increasing) (mN)
9.81 ± 0.49			
19.61 ± 0.49			
29.42 ± 0.49			
39.23 ± 0.59			
49.03 ± 0.74			
$58.84 \pm 0.88^*$			
$68.65 \pm 1.03^*$			
$78.45 \pm 1.18^*$			
* Nominal forces to be used if the range exceeds 49 mN			

Pass: ☐ Fail: ☐
2.10.7 Effect of hysteresis (R 145-1, 6.6.6)

<i>Requirement:</i>	R 145-1, 6.6.6	The effect of hysteresis for the measuring force shall not exceed 0.29 mN.
<i>Test procedure:</i>	R 145-2, 12	

Pass: ☐ Fail: ☐

2.10.8 Scale (R 145-1, 6.6.7)**2.10.8.1**

<i>Requirement:</i>	R 145-1, 6.6.7	Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width, and shall be engraved or otherwise permanently marked. No line shall be wider than $\frac{1}{4}$ of the distance between two lines.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

2.10.8.2

<i>Requirement:</i>	R 145-1, 6.6.7	One scale mark shall represent either 0.1 or 0.2 scale divisions. The scale graduations at 0, 1, 2, 3, etc. shall be numbered with an integer value. The scale shall be linearly divided. The conversion factor between the scale value and the force in mN shall be 9.81.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

2.10.8.3

<i>Requirement:</i>	R 145-1, 6.6.7	Every fifth scale mark shall be longer. The width of the reference mark shall not be greater than the width of the graduation lines on the measuring scale.
<i>Test procedure:</i>	Visual inspection	

Pass: ☐ Fail: ☐

2.10.9 Mechanical strength (R 145-1, 6.6.8)**2.10.9.1**

<i>Requirement:</i>	R 145-1, 6.6.8 R 145-1, 6.6.5 & R 145-1, 6.6.6 to be met after falls	Hand-held applanation tonometers shall operate correctly following a free fall from a height of 1 m onto a 50 mm $\pm$ 5 mm thick hardwood board (hardwood > 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.
<i>Test procedure:</i>	R 145-2, 12	

Pass: ☐ Fail: ☐

2.10.9.2

<i>Requirement:</i>	R 145-1, 6.6.8 R 145-1, 6.6.5 & R 145-1, 6.6.6 to be met after falls	All other applanation tonometers shall operate correctly following a free fall from a height of 5 cm onto a 50 mm $\pm$ 5 mm thick hardwood board (hardwood > 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.
<i>Test procedure:</i>	R 145-2, 12	

Pass: ☐ Fail: ☐

3 Details of test report

Date of the test report:

.....

Test report number:

.....

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

.....