INTERNATIONAL RECOMMENDATION

OIML R 145-2

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Ophthalmic instruments - Impression and applanation tonometers.

Part 2: Test procedures

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

Partie 2: Procédures d'essais

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

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Ophthalmic instruments – Impression and applanation tonometers

Part 2 – Test methods

1 Influence of environmental conditions on performance for devices in use

Under at least three different sets of environmental conditions described in R 145-1, 6.2.1, tests shall be performed

- for impression tonometers according to the requirements given in R 145-1, 6.5.3 (test procedure: R 145-2, 5) and R 145-1, 6.5.7, Table 4 “Displacement and maximum permissible error of the plunger of impression tonometers” (test procedure: R 145-2, 8),
- for applanation tonometers according to the requirements given in R 145-1, 6.6.5 (test procedure: R 145-2, 12) and R 145-1, 6.6.6 (test procedure: R 145-2, 12).

2 Influence of storage on the performance

After being subject to at least two different sets of environmental conditions described in R 145-1, 6.2.2 for 24 h each, tests shall be performed

- for impression tonometers according to the requirements given in R 145-1, 6.5.3 (test procedure: R 145-2, 5) and R 145-1, 6.5.7, Table 4 “Displacement and permissible error limits of the plunger of impression tonometers” (test procedure: R 145-2, 8),
- for applanation tonometers according to the requirements given in R 145-1, 6.6.5 (test procedure: R 145-2, 12) and R 145-1, 6.6.6 (test procedure: R 145-2, 12).

3 Measurement of the mass of the impression tonometer and additional masses

3.1 Apparatus

3.1.1 Balance with a measurement uncertainty less than or equal to 50 mg.

3.1.2 Balance with a measurement uncertainty less than or equal to 2 mg.

Note: For the measurement of the different masses, either two balances (as described above) or one balance (with a measurement uncertainty less than or equal to 2 mg) may be used.

3.2 Procedure

The mass of the tonometer, without the handle, is measured with the balance (3.1.1).

The additional masses are measured with the balance (3.1.2).

3.3 Expression of results

Express the results as the differences between the measured masses and the values given in R 145-1, 6.5.1.

4 Measurement of the effective mass of the impression tonometer

4.1 Apparatus

Balance with a measurement uncertainty less than or equal to 10 mg.

4.2 Procedure

The effective mass of the lever-pointer-plunger system with the tonometer in a vertical position is determined using the balance (4.1).

4.3 Expression of results

Express the results as the differences between the measured mass and the value given in R 145-1, 6.5.2.

5 Determination of the friction between the plunger and the plunger sleeve of the impression tonometer

5.1 Apparatus

Goniometer.

5.2 Procedure

When the tonometer is moved slowly and uniformly from the horizontal position into the vertical position with the plunger on the upper stop, the plunger shall begin to slide into the footplate hole before the angle of the tonometer axis relative to the horizontal exceeds 25°. During this manoeuvre, the lever shall not touch the plunger. The tonometer shall be able to slide easily in its handle, see Figures 1 and 2.

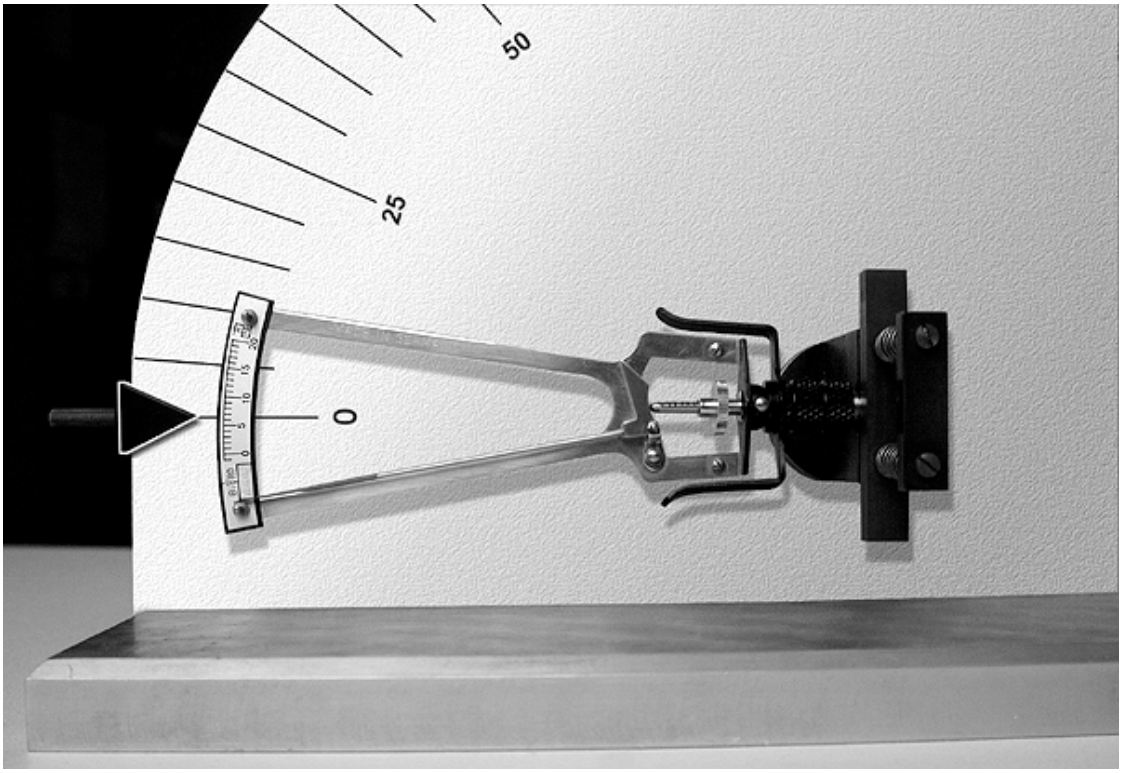

Figure 1 – Tonometer in the horizontal position

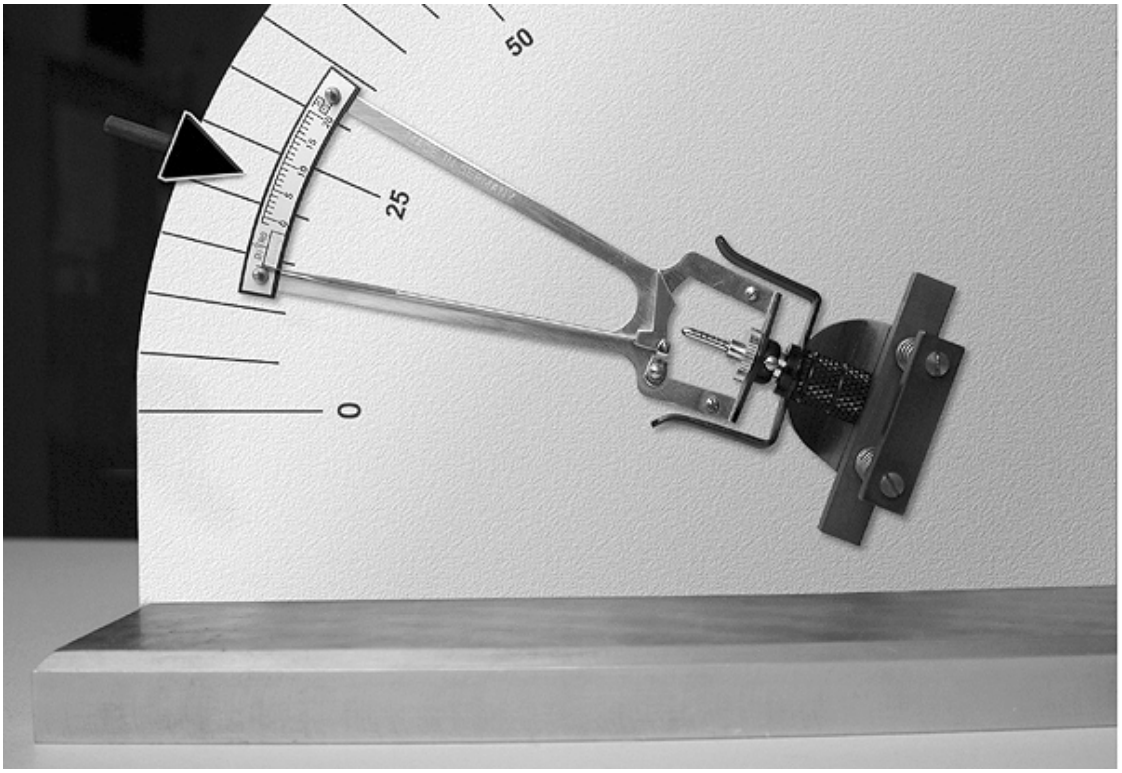

Figure 2 – The plunger begins to slide into the footplate hole before the angle of the tonometer axis relative to the horizontal exceeds 25°

6 Measurement of the dimensions of the footplate and the plunger of the impression tonometer

6.1 Apparatus

Length measuring instrument with a measurement uncertainty less than or equal to 0.01 mm.

6.2 Procedure

Measure the lengths, diameters and radii given in R 145-1, 6.5.5, Table 1 with the length measuring instrument(s) (6.1).

6.3 Expression of results

Express the results as the differences between the measured dimensions and the values given in R 145-1, 6.5.5.

7 Test of the curvature of the footplate and the plunger of the impression tonometer

7.1 Apparatus

7.1.1 Length measuring instrument with a measurement uncertainty less than or equal to 0.01 mm.

7.1.2 Test block with a radius of curvature of 14.75 mm ± 0.05 mm (special test block for negative scale values).

7.1.3 Test block with a radius of curvature of 16.00 mm ± 0.05 mm (as mentioned in R 145-1, 6.5.10).

7.2 Procedure

Measure the lengths, diameters and radii given in R 145-1, 6.5.5, Table 2 with the length measuring instrument(s) (7.1.1).

When the instrument is tested on a test block whose radius of curvature is 14.75 mm ± 0.05 mm, the pointer shall indicate –1.0 ± 0.2 on the scale. When tested on a test block whose radius of curvature is 16.00 mm ± 0.05 mm, it shall indicate 0.0 ± 0.2 on the scale.

With the tonometer in position on the test block, the scale reading shall not vary by more than 0.4 scale divisions when the plunger is rotated or moved laterally, or when the lever is moved laterally.

Note: The two test blocks are required to check the interaction of the plunger and the footplate.

7.3 Expression of results

Express the results as the differences between the measured dimensions and the values given in R 145-1, 6.5.5. The measurements with the test blocks shall be expressed as maximum scale readings.

8 Test of the displacement of the plunger for impression tonometers

8.1 Apparatus

Length measuring instrument with a measurement uncertainty less than or equal to 0.002 mm.

8.2 Procedure

Measure the displacements of the plunger given in Table 3 with the length measuring instrument (8.1).

8.3 Expression of results

Express the results as the differences between the measured displacements and the values given in R 145-1, 6.5.7.

9 Test of the distance between the scale and the pointer of the impression tonometer

9.1 Apparatus

Gauge block of 1.00 mm with a measurement uncertainty less than or equal to 0.02 mm.

9.2 Procedure

Test the distance between the scale and the pointer of the impression tonometer with the gauge block (9.1) at three different scale positions: smallest, largest scale marking, and in-between. The gauge shall not, or only just, fit between the scale and the pointer.

10 Determination of the diameter of the applanation circle of the applanation tonometer

10.1 Apparatus

Length measuring instrument (e.g. reticule of lines in combination with a microscope) with a measurement uncertainty less than or equal to 0.004 mm.

10.2 Procedure

Using the length measuring instrument (10.1), determine the relative displacement between the two halves of an image in contact with the applanating surface of the pressure body in two directions, perpendicular to each other.

Note: More details are given in ISO 8612:2009 *Ophthalmic instruments – Tonometers*, A.2.

10.3 Expression of results

Express the results as the differences between the measured diameters and the values given in R 145-1, 6.6.1. If a reticule of lines with the indication of the minimum and maximum value is used, it is sufficient to state that the diameter stays within the required limits.

11 Determination of the diameter of the pressure body of the applanation tonometer

11.1 Apparatus

Length measuring instrument with a measurement uncertainty less than or equal to 0.1 mm.

11.2 Procedure

Determine the diameter of the pressure body with the length measuring instrument (11.1) in two directions, perpendicular to each other.

11.3 Expression of results

Express the results as the differences between the measured diameters and the values given in R 145-1, 6.6.3.

12 Measurement of the accuracy of the measuring force of the applanation tonometer and the effect of hysteresis of the applanation tonometer

12.1 Apparatus

Force measuring instrument (e.g. a balance) with a measurement uncertainty less than or equal to 0.15 mN.

12.2 Procedure

Increase the force in steps of not more than 10 mN by adjusting the dial of the applanation tonometer and measure this force with the force measuring instrument (12.1). When the upper limit of the measuring range is attained, the force is decreased to the same force levels that were measured when increasing the force.

12.3 Expression of results

Express the results as the differences of adjusted forces of the applanation tonometer and the measured forces to determine the accuracy of the measurement. To determine the hysteresis error, calculate the difference of the measured forces when increasing and decreasing the force.