INTERNATIONAL STANDARD

ISO 10343

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Ophthalmic instruments — Ophthalmometers

Instruments ophtalmiques — Ophtalmomètres

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10343 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 10343:1997), which has undergone minor revision to update normative references.

Ophthalmic instruments — Ophthalmometers

1 Scope

This International Standard, together with ISO 15004-1, specifies requirements and test methods for continuously or digitally indicating ophthalmometers. Certain types of ophthalmometer (designated as code 1 in Table 1) are capable of measuring radii of curvature of contact lenses as described in ISO 18369-3:2006, 4.1. It is assumed that the local corneal front surface and both contact lens surfaces are spherical or toroidal.

This International Standard takes priority over ISO 15004-1, if differences exist.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8429, *Optics and optical instruments — Ophthalmology — Graduated dial scale*

ISO 15004-1:2006, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
ophthalmometer
instrument designed to measure and indicate the radii of curvature and principal meridians of the human cornea's central area and of contact lenses

3.2
distance-dependent ophthalmometer
ophthalmometer in which the result of measurement is influenced by the distance between the instrument and the surface to be measured

3.3
toroidal surface
surface having two orthogonal, circular “principal meridians”, one maximum and one minimum, and generated by a circular arc rotating about an axis which is in the same plane as the arc but which does not pass through its centre of curvature

3.4
principal curvature direction
direction in which the radius of curvature of the reflecting surface to be measured is at its minimum or maximum

3.5
corneal refraction
value of corneal refractive power calculated by use of the equation:

$$F = (n-1)\cdot 1\,000/r$$

where

F is the corneal refraction, expressed per metre;

r is the radius of the front surface of the cornea, in millimetres;

n is the assumed refractive index of cornea (system including the tear film).

4 Requirements

4.1 General

The ophthalmometer shall conform to the requirements specified in ISO 15004-1.

4.2 Radius of curvature measurements

The ophthalmometer shall conform to requirements given in Table 1. Conformity shall be verified as described in 5.2.

Table 1 — Requirements for measurement of radius of curvature

Criterion		Type code	Requirement
Measuring range		code A	5,5 mm to 10,0 mm
		code B	6,5 mm to 9,4 mm
Radii readings for	continuously indicating instruments	code 1	scale interval of 0,05 mm
		code 2	scale interval of 0,1 mm
	digitally indicating instruments		increment 0,02 mm
Measurement accuracy (twice the standard deviation, i.e. 2σ)		code 1	±0,015 mm
		code 2	±0,05 mm

4.3 Measurement of direction of principal meridians

The ophthalmometer shall conform to requirements given in Table 2. Conformity shall be verified as described in 5.2.

Table 2 — Requirements for measurement of direction of principal meridians

Criterion		Requirement
Measuring range		0° to 180°
Meridian direction reading	continuously indicating scales	scale interval 5°
	digitally indicating scales	increment 1°
Measurement accuracy using test device (twice the standard deviation, i.e. 2σ)	for principal meridional differences in radii of curvature $\leqslant$ 0,3 mm	±4°
	for principal meridional differences in radii of curvature $>$ 0,3 mm	±2°
Angular indications shall be in accordance with ISO 8429.		

4.4 Eyepiece adjustment (if applicable)

The dioptric adjustment range for distance-dependent instruments shall be a minimum of −4 D to +4 D, for which the scale from −3 D to +2 D shall be calibrated.

5 Test methods

5.1 General

All tests described in this International Standard are type tests.

5.2 Checking optical requirements

Conformity to the requirements specified in 4.2 and 4.3 shall be verified by use of measuring devices the measuring error of which is less than 10 % of the smallest value to be determined.

Test results shall be evaluated according to the general rules of statistics.

Conformity to the requirements of 4.2 shall be verified using three spherical test surfaces, one chosen from each of three radii ranges: $\leqslant$ 6,8 mm, 7,5 mm to 8,1 mm and $\geqslant$ 9,1 mm. These test surfaces shall have the following properties:

a) uncertainty of sphere radius of curvature $\leqslant$ 1 µm;

b) local departure from sphericity $\leqslant$ 0,5 µm;

c) surface roughness $\leqslant$ 0,05 µm;

d) diameter of effective surface $\geqslant$ 6 mm.

Conformity to the requirements of 4.3 shall be verified with two test devices as described in Table 3. To fulfil the requirements of 4.3, each test device shall be used to measure in four different orientations, namely 0°, 45°, 90° and 135°. The orientation of the test devices shall be referenced to a local horizontal as established by a spirit level. One example of this test device is described in Annex A.

Table 3 — Parameters for test device

Type	Maximum principal radius of curvature	Difference between principal radii	Precision with which principal meridional axis is known
1	8,0 mm ± 0,2 mm	0,2 mm ± 0,07 mm	±1°
2	8,0 mm ± 0,2 mm	0,4 mm ± 0,07 mm	±0,5°

6 Accompanying documents

The ophthalmometer shall be accompanied by documents containing instructions for use and any necessary precautions. In particular, these documents shall contain the following information:

a) name and address of the manufacturer;

b) instructions as to effective disinfection of the ophthalmometer with particular reference to instruments returned to the manufacturer for repair and maintenance;

c) the assumed refractive index, n, of the cornea used in calculating corneal refraction;

d) if appropriate, a statement that the ophthalmometer in its original packaging conforms to the transport conditions as specified in 5.3 of ISO 15004-1:2006;

e) any additional documents as specified in IEC 60601-1.

7 Marking, labelling and packaging

The ophthalmometer shall be permanently marked with at least the following information:

a) name and address of manufacturer or supplier;

b) name, model, serial number and type code according to 4.2;

c) additional marking as required by IEC 60601-1;

d) a reference to this International Standard, i.e. ISO 10343:2009, if the manufacturer or supplier claims compliance with it.

Annex A
(informative)

Test devices and test configuration for checking meridional axes and ophthalmometer position

Figure A.1 depicts one of two lenses, each of non-critical centre thickness, having one plano and one toroidal surface, with optical and mechanical centres of curvature coaxial. The radii of curvature of the toroidal surface should be of the following design:

$r_1 = 8{,}00 \text{ mm} \pm 0{,}2 \text{ mm}$

$r_2 < r_1$

The radii of curvature difference for each of the two test lenses cited in Table 3 is as follows:

Type 1: 0,2 mm ± 0,07 mm

Type 2: 0,4 mm ± 0,07 mm

Each lens is mounted in a holder whose mechanical axis is coincident and parallel with the test lens' optical axis. As indicated in Figure A.1, the holder is an octagonal cylinder composed of four pairs of parallel plano surfaces, each of which is equidistant from, and parallel to, the holder's mechanical axis. Each toric test lens is mounted so that its principal meridians are perpendicular to an orthogonal pair of holder plano reference surfaces within the following tolerances:

Type 1: ±1°

Type 2: ±0,5°

The angular precision of the lens mounting can be verified by a setup as shown in Figure A.2. A low-energy visible laser beam of approximately 10 mm diameter is directed normally to the test lens' plano surface. A small real aerial image is formed by the test lens. A suitable positive lens, placed at a convenient axial distance from the first image, can be used to project enlarged line images on to a screen. If test lens holder and screen reference line are commonly referenced by spirit level, the orientation of the test lens in the holder can be verified.