INTERNATIONAL STANDARD

ISO 10343

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Ophthalmic instruments — Ophthalmometers

Instruments ophtalmiques — Ophtalmomètres

Reference number
ISO 10343:1997(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

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

Annex A of this International Standard is for information only.

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Ophthalmic instruments — Ophthalmometers

1 Scope

This International Standard, together with ISO 15004, specifies requirements and test methods for continuously or digitally indicating ophthalmometers. Certain types of ophthalmometers (designated as code 1 in table 1) are capable of measuring radii of curvature of contact lenses as described in ISO 10338[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, if differences exist.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Internatinal Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of the IEC and ISO maintain registers of currently valid International Standards.

ISO 8429:1986, *Optics and optical instruments — Ophthalmology — Graduated dial scale.*

ISO 15004:— [2], *Ophthalmic instruments — Fundamental requirements and test methods.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Definitions

For the purposes of this International Standard, the following 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 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

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1) ISO 10338:1996, *Optics and optical instruments — Contact lenses — Determination of curvature.*

2) To be published.

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 minimum or maximum

3.5 corneal refraction
value of corneal refractive power calculated using the equation:

$$F = (n-1) \cdot 1000 / r$$

where

F is the corneal refraction, expressed per metre;

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

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

4 Requirements

4.1 General

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

4.2 Radius of curvature measurements

The ophthalmometer shall conform to requirements given in table 1. Conformity shall be verified as described in 5.1.

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 5.1.

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

All tests described in this International Standard are type tests.

5.1 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 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 local horizontal as established by a bubble 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, this information shall contain:

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;

e) any additional documents as specified in IEC 601-1.

7 Marking

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 601-1;

d) a reference to this International Standard, i.e. ISO 10343, 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 noncritical 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 are:

Type 1: 0,2 mm ± 0,07 mm

Type 2: 0,4 mm ± 0,07 mm

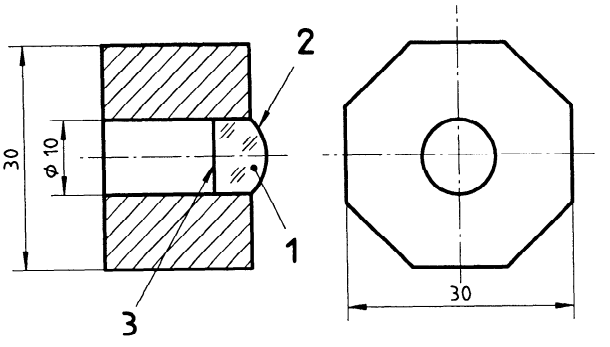
Each lens is mounted in a holder whose mechanical axis is coincident and parallel with the test lens' optical axis. As indicated in figure A.1, the holder is an octagonal cylinder composed of four pairs of parallel plano surfaces, each of which is equidistant from and parallel to the holder's mechanical 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°

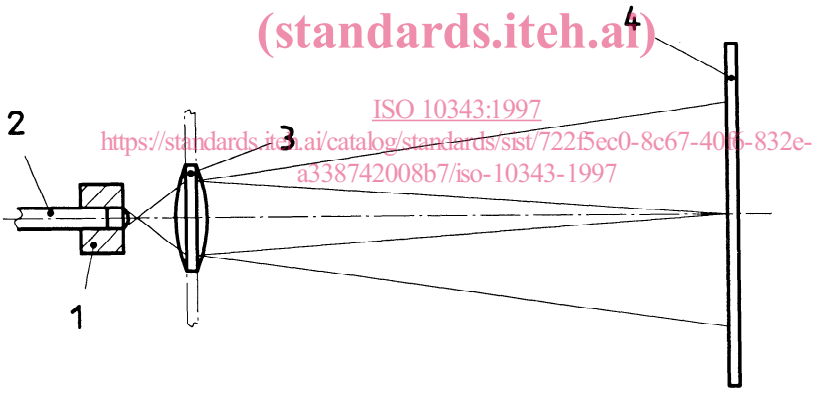
The angular precision of the lens mounting can be verified by a setup as shown in figure A.2. A low-energy visible laser beam of approximately 10 mm diameter is directed normally to the test lens' plano surface. A small real aerial image(s) is formed by the test lens. A suitable positive lens, placed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

Dimensions in millimetres



1 Test lens
2 Toroidal surface
3 Plano surface

Figure A.1 — Test device



1 Test device
2 Laser beam
3 Projector
4 Screen

Figure A.2 — Test configuration

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