भारतीय मानक **IS 18572 : 2024**

Indian Standard

नेत्र संबंधी उपकरण — नेत्रमापी यंत्र

(ISO 10343 : 2014, संशोधित)

Ophthalmic Instruments — Ophthalmometers

(ISO 10343 : 2014, MOD)

ICS 11.040.70

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भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI - 110002
www.bis.gov.in www.standardsbis.in

April 2024 **Price Group 6**

Ophthalmic Instruments and Appliances Sectional Committee, MHD 05

NATIONAL FOREWORD

This Indian Standard which is modified adoption of ISO 10343 : 2014 'Ophthalmic instruments — Ophthalmometers' issued by the International Organization for Standardization (ISO) was adopted by Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 8429 Optics and optical instruments — Ophthalmology — Graduated dial scale	IS 13783 : 1993/ISO 8429 : 1986 Optics and optical instruments — Ophthalmology — Graduated dial scale	Identical
IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (IEC 60601-1 : 2020 MOD) (*third revision*)	Modified
ISO 15004-1 : 2006 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments	IS 18638-1 : 2024 Ophthalmic instruments — Fundamental requirements and test methods: Part 1 General requirements applicable to all ophthalmic instruments (ISO 15004-1 : 2020 MOD)	Modified

In this Standard, reference to ISO 15004-1 : 2006 has been modified to IS 18638-1:2024 which is a modified adoption of ISO 15004-1 : 2020. ISO 15004-1 : 2020 is a revision of ISO 15004-1 : 2006, ISO 15004-1 : 2006 has been withdrawn by ISO.

In this Standard, reference to IEC 60601-1 has been modified to IS13450 (Part 1) : 2024 which is a modified adoption of IEC 60601-1 : 2020.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

This standard also makes a reference to the BIS Certification Marking of the product, details of which is given in National Annex B.

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Indian Standard

OPHTHALMIC INSTRUMENTS — OPHTHALMOMETERS

(ISO 10343 : 2014, MOD)

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 have sufficient resolution and range (see Table 2) to adequately measure the radii of curvature of contact lenses complying with ISO 18369-3:2006, 4.1.3, and Clause 5. 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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
keratometric constant
conversion value equal to 337,5 used to convert corneal curvature from inverse millimetres (mm^{-1}) to keratometric dioptres

[SOURCE: ISO 19980:2012, 3.11]

3.6
keratometric dioptres
KD
value of curvature, expressed in inverse millimetres (mm^{-1}), multiplied by the keratometric constant 337,5

[SOURCE: ISO 19980:2012, 3.12]

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 or Table 2. Conformity shall be verified as described in 5.2. If the instrument conforms to the requirement of Table 1 it is a "Type B" ophthalmometer. If the instrument conforms to the requirements of Table 2 it is a "Type A" ophthalmometer. Type A and Type B ophthalmometers have sufficient resolution and range to adequately measure human corneas. Type A ophthalmometers have sufficient resolution and range (see Table 2) to adequately measure the radii of curvature of contact lenses complying with ISO 18369-3:2006, 4.1.3, and Clause 5. It is assumed that the local corneal front surface and both contact lens surfaces are spherical or toroidal.

Table 1 — Requirements for measurement of radius of curvature and curvature for Type B ophthalmometers (applicable to human corneas only)

Criterion		Requirement
Measuring range		6,5 mm to 9,4 mm (52,0 KD to 36,0 KD)
Indications given in terms of radii of curvature	continuously indicating instruments	scale interval of 0,1 mm (0,25 KD)
	digitally indicating instruments	increment 0,02 mm (0,125 KD)
Measurement accuracy (twice the standard deviation, i.e. 2σ)		±0,05 mm

Table 2 — Requirements for measurement of radius of curvature and curvature for Type A ophthalmometers (applicable to contact lenses and human corneas)

Criterion		Requirement
Measuring range		6,5 mm to 9,4 mm (52,0 KD to 36,0 KD)
Indications given in terms of radii of curvature	continuously indicating instruments	scale interval of 0,02 mm (0,125 KD)
	digitally indicating instruments	increment 0,02 mm (0,125 KD)
Measurement accuracy (twice the standard deviation, i.e. 2σ)		±0,025 mm

4.3 Measurement of direction of principal meridians

The ophthalmometer shall conform to requirements given in Table 3. Conformity shall be verified as described in 5.2.

Table 3 — 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 ≤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: ≤6,8 mm, 7,5 mm to 8,1 mm and ≥9,1 mm. These test surfaces shall have the following properties:

a) uncertainty of sphere radius of curvature ≤1 µm;

b) local departure from sphericity ≤0,5 µm;

c) surface roughness ≤0,05 µm;

d) diameter of effective surface ≥6 mm.

Conformity to the requirements of 4.3 shall be verified with two test devices as described in Table 4. 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 4 — 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) if appropriate, a statement that the ophthalmometer in its original packaging conforms to the transport conditions as specified in ISO 15004-1:2006, 5.3;

d) 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 according to 4.2;

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

d) a reference to this International Standard, i.e. ISO 10343:2014, if the manufacturer or supplier claims compliance with it.

Annex A
(informative)

Test devices and test configuration for checking meridional axesand 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 4 is as follows:

— Type 1: 0,2 mm ± 0,07 mm

— Type 2: 0,4 mm ± 0,07 mm

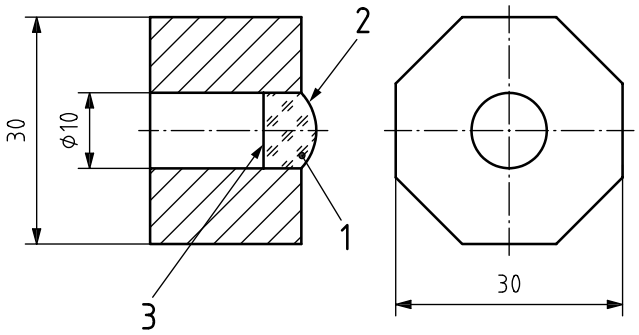
Each lens is mounted in a holder whose mechanical axis is coincident and parallel with the test lens' optical axis. As indicated in Figure A.1, the holder is an octagonal cylinder composed of four pairs of parallel plano surfaces, each of which is equidistant from, and parallel to, the holder's mechanical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

a) Type 1: ±1°

b) 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.

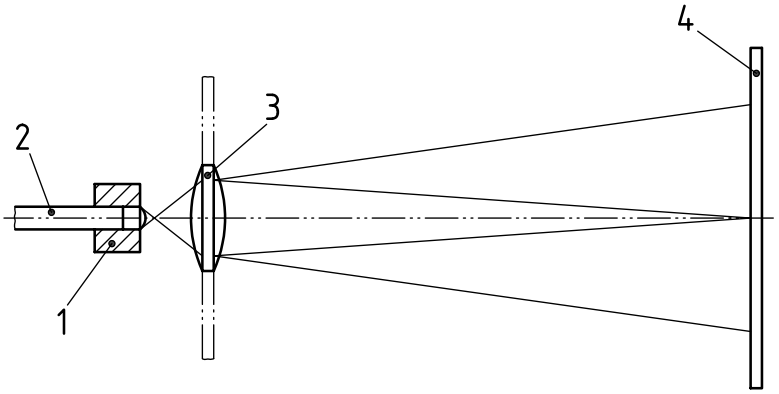
Dimensions in millimetres



Key

1 test lens
2 toroidal surface
3 plano surface

Figure A.1 — Test device



Key

1 test device
2 laser beam
3 projector
4 screen

Figure A.2 — Test configuration

Bibliography

[1] ISO 18369-3:2006, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

[2] ISO 19980:2012, *Ophthalmic instruments — Corneal topographers*

NATIONAL ANNEX B

(*National Foreword*)

B-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

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Amendments Issued Since Publication

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BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	: 601/A, Konnectus Tower -1, 6th Floor, DMRC Building, Bhavbhuti Marg, New Delhi 110002	2323 7617
Eastern	: 8th Floor, Plot No 7/7 & 7/8, CP Block, Sector V, Salt Lake, Kolkata, West Bengal 700091	2367 0012 2320 9474
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