

---

---

नेत्र सम्बन्धी उपकरण — आई  
रीफ्रैक्टोमीटर

Ophthalmic Instruments — Eye  
Refractometers

ICS 11.040.70

© BIS 2014



भारतीय मानक ब्यूरो  
BUREAU OF INDIAN STANDARDS  
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली-110002  
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG  
NEW DELHI-110002  
[www.bis.org.in](http://www.bis.org.in) [www.standardsbis.in](http://www.standardsbis.in)

## NATIONAL FOREWORD

This Indian Standard which is identical with ISO 10342 : 2010 'Ophthalmic instruments — Eye refractometers' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and 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 and terminologies 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'.
- 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 the following International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is listed below along with its degree of equivalence for the edition indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60601-1 : 2005 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2008 Medical electrical equipment : Part 1 General requirements for basic safety and essential performance	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 7944 : 1998	Optics and optical instruments — Reference wavelengths
ISO 8429 : 1986	Optics and optical instruments — Ophthalmology — Graduated dial scale
ISO 13666 : 1998	Ophthalmic optics — Spectacle lenses — Vocabulary
ISO 15004-1 : 2006	Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments

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, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Indian Standard*

**OPHTHALMIC INSTRUMENTS — EYE  
REFRACTOMETERS**

## **1 Scope**

This International Standard, together with ISO 15004-1, specifies requirements and test methods for eye refractometers using an objective measuring principle. It is limited to the measurement of spherocylindrical refractive error.

This International Standard takes precedence 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 7944, *Optics and optical instruments — Reference wavelengths*

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

ISO 13666, *Ophthalmic optics — Spectacle lenses — Vocabulary*

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

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

## **3 Terms and definitions**

For the purposes of this document, the terms and definitions given in ISO 13666 as well as the following apply.

### **3.1**

#### **eye refractometer**

instrument with continuous or digital readout used for measuring the refractive errors of the eye

### **3.2**

#### **tolerance**

range of permissible difference between mean measured value and nominal value

## 4 Requirements

### 4.1 General

The eye refractometer shall conform to the general requirements specified in ISO 15004-1.

### 4.2 Optical requirements

The eye refractometer shall conform to the requirements given in Table 1 or Table 2.

The dioptric powers indicated in the requirements shall be referenced to the specific wavelengths used,  $\lambda = 546,07 \text{ nm}$  or  $\lambda = 587,56 \text{ nm}$  as required in ISO 7944.

The indication of the readings of cylinder power shall be possible in plus or minus cylinder convention.

**Table 1 — Requirements for continuously indicating eye refractometers**

Criterion	Measuring range	Maximum scale interval	Test device <sup>a</sup>	Tolerance
Spherical vertex power	-15 D to +15 D (maximum meridional vertex power)	0,25 D	0 D, $\pm 5$ D, $\pm 10$ D	$\pm 0,25$ D
			$\pm 15$ D	$\pm 0,50$ D
Cylindrical vertex power	0 D to 6 D	0,25 D	Sphere: approx. 0 D Cylinder: -3 D Axis: 0°, 90°	$\pm 0,25$ D
Cylinder axis <sup>b</sup> for cylinder power	0° to 180°	5°		$\pm 5^\circ$
<sup>a</sup> The refractive error of the test device shall not differ by more than 1,0 D from the nominal value above. <sup>b</sup> Cylinder axis shall be indicated as specified in ISO 8429.				

**Table 2 — Requirements for digitally indicating eye refractometers**

Criterion	Measuring range	Maximum scale interval	Test device <sup>a</sup>	Tolerance
Spherical vertex power	-15 D to +15 D (maximum meridional vertex power)	0,25 D	0 D, $\pm 5$ D, $\pm 10$ D	$\pm 0,25$ D
			$\pm 15$ D	$\pm 0,50$ D
Cylindrical vertex power	0 D to 6 D	0,25 D	Sphere: approx. 0 D Cylinder: -3 D Axis: 0°, 90°	$\pm 0,25$ D
Cylinder axis <sup>b</sup> for cylinder power	0° to 180°	1°		$\pm 5^\circ$
<sup>a</sup> The refractive error of the test device shall not differ by more than 1,0 D from the nominal value above. <sup>b</sup> Cylinder axis shall be indicated as specified in ISO 8429.				

### 4.3 Measuring range

The eye refractometer shall have a minimum measuring range for vertex power of -15 D to +15 D.

Eye refractometers that indicate cylindrical power shall have a minimum measuring range for cylinder power of 0 D to 6 D.

The eye refractometer shall have an axis direction range of 0° to 180°.

#### 4.4 Eyepiece (if applicable)

The dioptric adjustment range of the operator's eyepiece shall be a minimum of  $-4$  D to  $+4$  D.

### 5 Test methods

#### 5.1 General

All tests described in this International Standard are type tests.

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

#### 5.2 Checking the vertex power

The vertex power accuracy requirements as specified in Tables 1 and 2 shall be verified using the special test device specified in Annex A.

Test measurements for spherical vertex power shall be made at least every 5 D over the claimed measuring range of the instrument, i.e. at  $-15$  D,  $-10$  D,  $-5$  D,  $0$  D,  $+5$  D,  $+10$  D,  $+15$  D.

Test measurements for cylindrical vertex power shall be made at 3 D.

#### 5.3 Checking the cylinder axis

The astigmatic accuracy requirements, as specified in Tables 1 or 2, shall be verified using the special test device specified in Annex A. The orientation of the cylinder axis of the test device shall be known to within a tolerance of  $\pm 1^\circ$ .

Measurements shall be made in the two principal meridians. These two measurements shall give measurements for axis and power within the tolerances given in Tables 1 and 2.

### 6 Accompanying documents

The eye refractometer 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 for effective disinfection of the eye refractometer with particular reference to instruments returned to the manufacturer for repair and maintenance;
- c) if appropriate, a statement that the eye refractometer in its original packaging conforms to the transport conditions as specified in 5.3 of ISO 15004-1:2006;
- d) any additional documents as specified in 7.9 of IEC 60601-1:2005;
- e) instructions for checking the calibration of the instrument.

## **7 Marking**

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

- a) name and address of manufacturer or supplier;
- b) name and model of eye refractometer;
- c) additional marking as required by IEC 60601-1;
- d) reference to this International Standard, i.e. ISO 10342:2010, if the manufacturer or supplier claims compliance with it;
- e) reference wavelength.

## Annex A (normative)

### Test device for eye refractometers

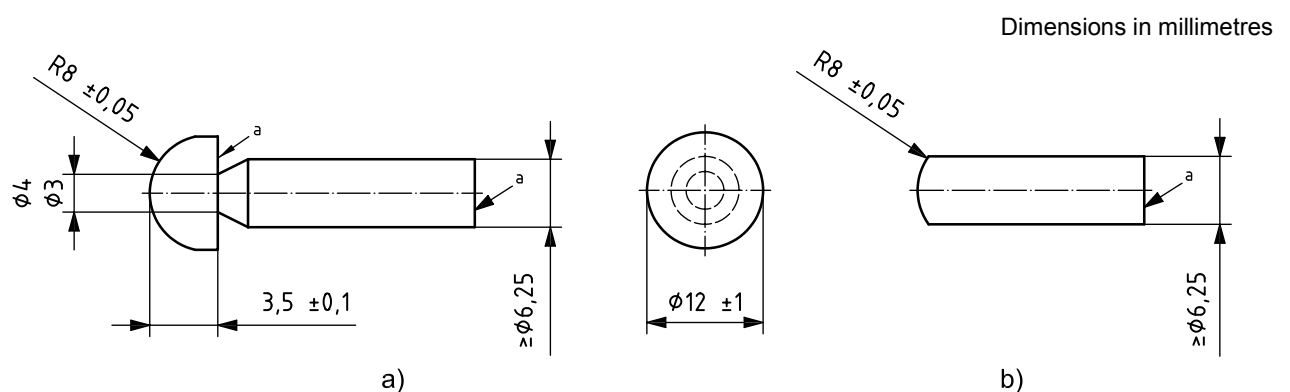
#### A.1 Design specifications

The test device shall be made of optical glass, with the Abbe number,  $\nu$ , in the range 58 to 60, as shown in Figure A.1. The spherical front surface shall be polished to an optical finish and the plano back surface should be lightly frosted. All other surface shall be clear but may be roughly finished.

For testing the spherical vertex power accuracy of the eye refractometer, the test device shall be used as shown in Figure A.1 a) or b). If the eye refractometer does not provide an artificial pupil, type a) with a pupil diameter between 3 mm and 4 mm should be used.

For testing the cylinder axis and cylinder power accuracy, the device with front toric surface shall be used. If cylinder power/axis is tested by adding a cylindrical lens to the spherical test device, a thin rigid toric lens with an 8 mm base curve may be fixed on to the front surface of the device. The orientation of the cylinder axis shall be marked so that the device may be oriented in use. When the test device is modified in this fashion, it can only be used to measure the astigmatic difference and the axis direction.

The test device shall be placed in a suitable holder and attached to the eye refractometer so that its optical axis is parallel to that of the eye refractometer to a tolerance of  $\pm 1^\circ$ .



a Painted dark grey.

NOTE The reflection rates of painted fundus of model eye should be similar to that of the human fundus.

Figure A.1 — Test device

#### A.2 Accuracy of refractive power

The refractive power of the test devices used to verify the spherical vertex power of eye refractometers shall be known to  $\pm 0,06$  D. The wavelength used for the calculation and the vertex distance shall be specified.

Calculated nominal power value should be given to the second decimal place.

### A.3 Determination of refractive power

When the test device is to be used to verify the accuracy of eye refractometers that are of different types but have the same type of indication (digital or continuous), the refractive power value shall be determined by one of the following methods.

- a) Measure the refractive power using precision retinoscopy on an optical bench or a collimating telescope together with a refractor head. When the refractive power of the test device is determined using this method, an aperture with a diameter of no more than 3 mm shall be placed coincident with the front surface to minimize the effects of spherical aberration.
- b) Measure the length,  $s'$ , the radius of curvature of the front surface,  $r$ , and the index of refraction of the material,  $n$ , and calculate the refractive power using ray tracing in the following way. Find a point on the optical axis such that a bundle of rays, filling a 3 mm pupil in the plane of the refracting surface of the device, form the smallest root mean square (rms) spot on the diffuse back surface of the device. The refractive power of the device is then found as follows:

$$P = 1/d$$

where

$P$  is the refractive power of the device, expressed in dioptres;

$d$  is the distance of the point source from the refracting surface, expressed in metres.

NOTE The spherical refractive power,  $P$ , of the test device is a function of its length,  $s'$ , the radius of curvature of the front surface,  $r$ , and the index of refraction,  $n$ , of the material from which the test device is constructed. While it is possible to calculate the paraxial power of the test device, this value is not representative of its performance in use. This is because of the spherical aberration of the device and of the fact that eye refractometers in general sample an annular portion of the periphery of the pupil. Therefore the paraxial value, which is more representative of human vision, differs from the measured value. The measured value is best predicted by finding an optimum image point by a ray tracing technique in which a point source of rays is found for which the smallest root mean square (rms) spot size falls on the diffuse surface of the test device for a 3 mm pupil size. The reciprocal of the distance, expressed in metres, of this point source from the curved surface of the test device is then the expected refractive power of the device when measured by an eye refractometer.



## Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

### Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

### Review of Indian Standards

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 latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc No.: MHD 05 (0200).

### Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

### 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.org.in

#### Regional Offices:

	Telephones
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	{ 2323 7617 2323 3841
Eastern : 1/14 C.I.T. Scheme VII M, V. I. P. Road, Kankurgachi KOLKATA 700054	{ 2337 8499, 2337 8561 2337 8626, 2337 9120
Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160022	{ 260 3843 260 9285
Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600113	{ 2254 1216, 2254 1442 2254 2519, 2254 2315
Western : Manakalaya, E9 MIDC, Marol, Andheri (East) MUMBAI 400093	{ 2832 9295, 2832 7858 2832 7891, 2832 7892

**Branches:** AHMEDABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE. DEHRADUN. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KOCHI. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAJKOT. VISAKHAPATNAM.