

---

---

## Ophthalmic instruments — Refractor heads

*Instruments ophtalmiques — Têtes de réfracteurs*

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO 10341:2012](https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ce-4d71-b232-f79b254df643/iso-10341-2012)

<https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ce-4d71-b232-f79b254df643/iso-10341-2012>



## iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10341:2012

<https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ee-4d71-b232-f79b254df643/iso-10341-2012>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

## 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.

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 10341 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 10341:2009), of which Tables 2, 3 and 4 have been technically revised.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10341:2012

<https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ee-4d71-b232-f79b254df643/iso-10341-2012>

## **iTeh STANDARD PREVIEW** **(standards.iteh.ai)**

ISO 10341:2012

<https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ee-4d71-b232-f79b254df643/iso-10341-2012>

# Ophthalmic instruments — Refractor heads

## 1 Scope

This International Standard specifies requirements and test methods for refractor heads used for the determination of refractive errors and binocular functions of the human eye.

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

[ISO 10341:2012](https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ce-4d71-b232-f79b254df643/iso-10341-2012)

## 3 Terms and definitions

<https://standards.iteh.ai/catalog/standards/sist/f8a478e7-38ce-4d71-b232-f79b254df643/iso-10341-2012>

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

### 3.1

#### **refractor head**

instrument providing a means of positioning spherical and cylindrical lenses, prisms and other optical devices in front of a subject's eyes for the purpose of determining refractive error and binocular functions

### 3.2

#### **reference plane**

plane at which the readings and the power tolerances of the refractor head apply

### 3.3

#### **reference distance**

distance between the reference plane of the refractor head and the corneal vertex

## 4 Requirements

### 4.1 General

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

### 4.2 Measuring ranges

The requirements specified in Table 1 for refractor heads shall apply.

Table 1 — Measuring ranges for refractor heads

Criterion	Minimum measuring ranges for each side
Spherical power	0 D to +15 D in steps of 0,25 D 0 D to -15 D in steps of 0,25 D
Astigmatic power	0 D to 5 D in steps of 0,25 D in plus or minus cylinder form
Cylinder axis <sup>a</sup>	0° to 180° indicated in 5° steps; in addition, readings or estimates to 1° shall be possible
Prismatic power <sup>b</sup>	0 Δ to 10 Δ in steps of 1 Δ, or continuously
Prism base <sup>a</sup>	0° to 360° indicated in 5° steps; in addition, readings or estimates to 1° shall be possible. Indication of the prism base by horizontal and vertical components is allowed as an alternative
<sup>a</sup> Cylinder axis and prism base settings shall be indicated according to ISO 8429.	
<sup>b</sup> The combined prismatic powers of both sides shall be at least 30 Δ.	

### 4.3 Optical requirements

The requirements specified in Tables 2 to 7 shall apply. Powers shall be measured in the reference plane. Conformance shall be verified as described in 5.2.

The dioptric powers indicated in Tables 2, 3 and 5 shall be referenced to the wavelength  $\lambda = 546,07$  nm or alternatively  $\lambda = 587,56$  nm in accordance with ISO 7944.

If the requirements are not met for both wavelengths, the reference wavelength used shall be indicated.

The requirements for spherical power are given in Table 2.

iTeH STANDARD PREVIEW  
(standards.iteh.ai)

Table 2 — Tolerances on spherical power

Indicated spherical power (absolute)	mean power $\frac{S_1 + S_2}{2}$	Tolerance on residual astigmatism $ S_1 - S_2 $
D	D	D
0,00 to 3,00	±0,06	0,03
> 3,00 to 6,00	±0,09	
> 6,00 to 9,00	±0,12	
> 9,00 to 12,00	±0,15	0,06
> 12,00 to 15,00	±0,18	
> 15,00 to 20,00	±0,25	
> 20,00	±0,35	
NOTE $S_1$ and $S_2$ refer to the vertex powers in the principal meridians.		

The requirements for cylindrical power are given in Table 3.

**Table 3 — Tolerances on cylindrical power**

Indicated cylindrical power D	Tolerance D
≤ 0,50	0,06
> 0,50 to 1,00	0,09
> 1,00 to 3,00	0,12
> 3,00 to 6,00	0,18
> 6,00	0,25

The requirements on centration of lens combinations are given in Table 4.

**Table 4 — Tolerances of prismatic effect of spherical and cylindrical lenses relative to the centre point of the aperture in the combined optical mechanical system (not including crossed cylinders)**

Indicated power (absolute) D	Tolerance Δ
0,00	0,12
> 0,00 to 6,00	0,25
> 6,00 to 12,00	0,37
> 12,00	0,62

The requirements for rotary and fixed prisms are given in Table 5.

ISO 10341:2012  
https://standards.iteh.ai/catalog/standards/sist/iso/10341/2012-07-01/iso-10341-2012-07-01-0232-179b254d1b43/iso-10341-2012

Indicated power Δ	Tolerance
≤ 5,00	±0,25 Δ
> 5,00	±5 %

NOTE The indicated prismatic power refers to an incident ray parallel to the axis of the optical system.

The requirements for axis and base direction are given in Table 6.

**Table 6 — Tolerances on cylinder axis and prism base setting**

Criterion	Indicated power (absolute)	Tolerance
Cylinder axis <sup>a</sup> (excluding crossed cylinders)	> 0 D to 0,25 D	±5°
	> 0,25 D to 1 D	±3°
	> 1 D	±2°
Prism base setting <sup>a</sup>	≤ 1 Δ	±5°
	> 1 Δ to 10 Δ	±3°
	> 10 Δ	±2°

NOTE Zero direction for cylinder axis and prism base is defined as the line connecting the aperture centres when the instrument is adjusted for zero height difference between both sides.

<sup>a</sup> Cylinder axis and prism base settings shall be indicated according to ISO 8429.

The requirements for calibration accuracy are given in Table 7.

**Table 7 — Tolerances on reference and pupillary distance values**

Criterion	Tolerance mm
Scale for reference distance	±0,5
Scale for pupillary distance	±0,5

#### 4.4 Construction and function

These requirements shall be verified as described in 5.3.

- a) Minimum free aperture for all lenses within the refractor head shall be 16 mm; however, for prisms with a power of 6 Δ and more, the aperture may be reduced to a minimum of 11 mm.
- b) The manufacturer shall indicate the reference plane for the instrument and shall make provision for the measurement of the reference distance of each side.
- c) There shall be at least a device provided to allow for occlusion and dissociation. A Jackson crossed cylinder shall be installed on each side.
- d) The interpupillary distance shall be continuously adjustable in a minimum range from 50 mm to 75 mm.
- e) The adjustable range of the forehead rest shall be at least 10 mm.
- f) The instrument shall be designed and constructed to eliminate all detrimental internally reflected or stray light.
- g) The structures of the lens chamber shall not interfere with the visual function of the patient when viewing the target.
- h) The instrument shall be designed and constructed so that when the lenses and accessories are positioned in front of the viewing aperture, they shall be positively aligned and centred.

### 5 Test methods

#### 5.1 General

All tests specified in this International Standard are type tests.

#### 5.2 Checking optical requirements

Conformance to the requirements specified in 4.3 shall be tested by using a device that does not exceed a measuring error of 0,01 D or 20 % of the given tolerance for vertex power, whichever is greater, and of 0,5° for cylinder axis direction and prism base setting. Measurement shall be made at the aperture centre, and referred to the reference plane.

NOTE An example is given in Annex A.

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

#### 5.3 Checking construction and function

Conformance to the requirements specified in 4.4 shall be checked by observation.



## 6 Information supplied by the manufacturer



### 6.1 Accompanying documents

The refractor head shall be accompanied by documents containing instructions for use and any necessary precautions. In particular, this information shall contain:

- name and address of the manufacturer;
- instructions for effective disinfection of the refractor head with particular reference to instruments returned to the manufacturer for repair and maintenance;
- if appropriate, a statement that the refractor head in its original packaging conforms to the transport conditions as specified in 5.3 of ISO 15004-1:2006;
- any additional documents as specified in IEC 60601-1.

### 6.2 Marking of the auxiliary wheel

The following letters or symbols shall be used, as appropriate:

MR		Maddox rods
SS	or 	Stenopaic slit
PH	or 	Pinhole
BL	or 	Occluder
FL		Frosted lens
CL	or 	Cross line
RF		Red filter
GF		Green filter
PF		Polarization filter
OA		Open aperture
RL		Retinoscopic lens

### 6.3 Identification of the refractor head

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

- name and address of manufacturer or supplier;
- name, model and serial number of instrument;
- if appropriate, reference wavelength used;
- additional markings as required by IEC 60601-1;
- a reference to this International Standard, i.e. ISO 10341:2012, if the manufacturer or supplier claims compliance with it.