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Ophthalmic instruments — Refractor heads

Instruments ophtalmiques — Têtes de réfracteurs

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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
Web www.iso.org

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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 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.

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*

3 Terms and definitions

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 [a]	0° to 180° indicated in 5° steps; in addition, readings or estimates to 1° shall be possible
Prismatic power [b]	0 Δ to 10 Δ in steps of 1 Δ, or continuously
Prism base [a]	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

[a] Cylinder axis and prism base settings shall be indicated according to ISO 8429.

[b] 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 λ = 546,07 nm or alternatively λ = 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.

Table 2 — Tolerances on spherical power

Indicated spherical power (absolute)	Tolerance on	
	mean power $\frac{S_1+S_2}{2}$	residual astigmatism $\lvert S_1-S_2 \rvert$
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	0,06
> 9,00 to 12,00	±0,15	
> 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.

Table 5 — Tolerances on prismatic power

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 [a] (excluding crossed cylinders)	> 0 D to 0,25 D	±5°
	> 0,25 D to 1 D	±3°
	> 1 D	±2°
Prism base setting [a]	≤ 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.		
[a] 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:

a) name and address of the manufacturer;

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

c) 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;

d) 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:

a) name and address of manufacturer or supplier;

b) name, model and serial number of instrument;

c) if appropriate, reference wavelength used;

d) additional markings as required by IEC 60601-1;

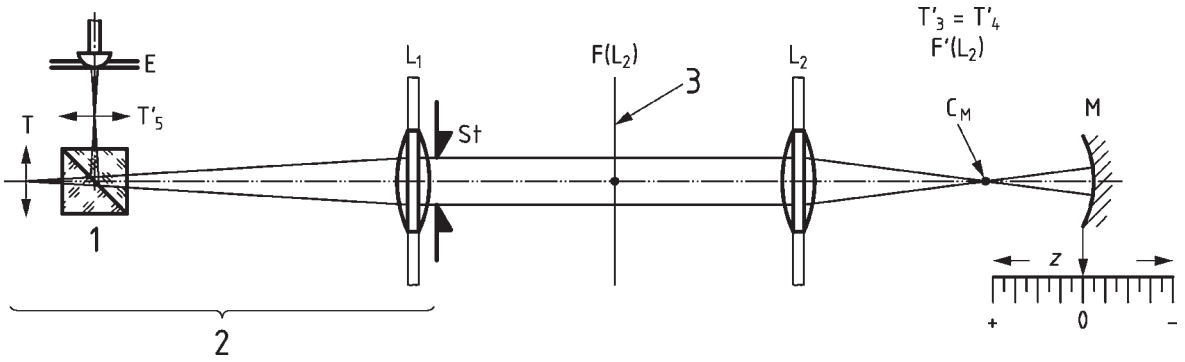
e) a reference to this International Standard, i.e. ISO 10341:2012, if the manufacturer or supplier claims compliance with it.

Annex A
(informative)

Example of test device for checking accuracy of refractor head elements

A.1 Determination of spherical and cylindrical power

For testing and determining the tolerances of spherical and cylindrical elements of the refractor head, 5.2 states that the uncertainty of the testing device is not to exceed 20 % of the given tolerance of the optical elements. A simplified design of a device for testing these elements is shown in Figure A.1. Commercial lensmeters or focimeters conforming to ISO 8598:1996 do not comply with this requirement.



Key

1	beam splitter
2	autocollimating telescope
3	reference plane for refractor head
F	focal point
M	mirror
C_M	centre of curvature of the mirror M
E	eyepiece
L_1, L_2	objective lenses
St	stop
T	target
T′	target image
z	movement of the mirror

Figure A.1 — Set up for a refractor head test device

The example in Figure A.1 shows the ray tracing when the refractor head power is zero. The lenses L_1 and L_2 are high quality compound objectives. L_1 and eyepiece E form an autocollimating telescope with a minimum magnification of ×15. The stop St reduces the diameter of the measuring bundle to 7 mm. Lens L_1 of this collimating telescope forms an image T'_1 of target T at infinity. The refractor head is adjusted to the measuring device so that its reference plane matches the front focal point $F(L_2)$ of the lens L_2 and both optical axes coincide. The front surface of refractor head is facing the autocollimating telescope.

As in this example the refractor head has zero power, it forms image $T'_2 = T'_1$ at infinity. Lens L_2 forms another image T'_3 at its back focal point $F'(L_2)$. This real image also forms another real image T'_4 coincidentally

produced by concave mirror M which is movable along the axis of the test equipment, and whose position is indicated by the precision scale. The coincident images are produced at the centre of curvature C_M of mirror M and coincidence is achieved by movement z of the mirror. The rays are then reflected back along their original paths, thereby forming image T'_5 on a graticule viewed through eyepiece E. The vertex power S of the combined optical elements of the refractor head is calculated by

$$S = z\left(\frac{1}{f}\right)^2$$

wherein $(1/f)$ is the power of lens L_2. As the rays pass through the optical elements of the refractor head twice (once each way), the measuring accuracy will be twice that of normal focimeters. Refractive errors, therefore, are lowered.

A.2 Prism power and base setting

Prism power and base setting may easily be determined by a laser beam transmitted through the lens. The direction of the beam is to be indicated as described in this International Standard.

Bibliography

[1] ISO 8598:1996, *Optics and optical instruments — Focimeters*

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