INTERNATIONAL STANDARD

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Ophthalmic instruments — Refractor heads

Instruments ophtalmiques — Têtes de réfracteurs

Reference number
ISO 10341:1997(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 10341 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 — 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, if differences exist.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International 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 listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7944:—[1], *Optics and optical instruments — Reference wavelengths.*

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

ISO 13666:—[2], *Ophthalmic optics — Spectacle lenses — Vocabulary.*

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 definitions given in ISO 13666 and the following apply.

3.1 refractor head: Instrument providing 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.

1) To be published. (Revision of ISO 7944:1984)

2) To be published.

4 Requirements

4.1 General

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

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[1)]	0° to 180° indicated in 5° steps; in addition, readings or estimates to 1° shall be possible.
Prismatic power[2)]	0 Δ to 10 Δ in steps of 1 Δ, or continuously.
Prism base[1)]	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.

1) Cylinder axis and prism base settings shall be indicated according to ISO 8429.
2) 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 5.1.

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.

Table 2 — Tolerances on spherical power

Indicated spherical power (absolute) D	Tolerance on	
	mean power $\frac{S_1 + S_2}{2}$ D	residual astigmatism $\lvert S_1 - S_2 \rvert$ 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	
> 12,00 to 15,00	± 0,18	
> 15,00	± 0,25	

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

Meridian of highest absolute power (nominal value) D	**Indicated cylindrical power** D				
	⩽ 0,50	> 0,50 to 1,00	> 1,00 to 3,00	> 3,00 to 6,00	> 6,00
	Tolerance D				
0,00 to 5,00	0,06	0,06	0,06	0,09	0,12
> 5,00 to 10,00					
> 10,00 to 15,00			0,09	0,12	0,18
> 15,00		0,09	0,12	0,18	0,25
NOTE — The tolerance for the meridian with the higher absolute power, given in table 2, is valid for both meridians in addition to the cylinder tolerances of table 3.					

The requirements on centring 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	0,50

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[1] (excluding crossed cylinders)	> 0 D to 0,25 D	± 5°
	> 0,25 D to 1 D	± 3°
	> 1 D	± 2°
Prism base direction[1]	≤ 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.		
1) 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 5.2.

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 over 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

All tests specified in this International Standard are type tests.

5.1 Checking optical requirements

Conformance to the requirements specified in 4.3 shall be tested by using a device which 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.

5.2 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:—[3];

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

6.2 Marking of the auxiliary wheel

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

MR	Maddox rods
SS or I	Stenopaic slit
PH or ○	Pinhole
BL or ●	Occluder
FL	Frosted lens
CL or ⊕	Cross line

3) To be published.

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 601-1;

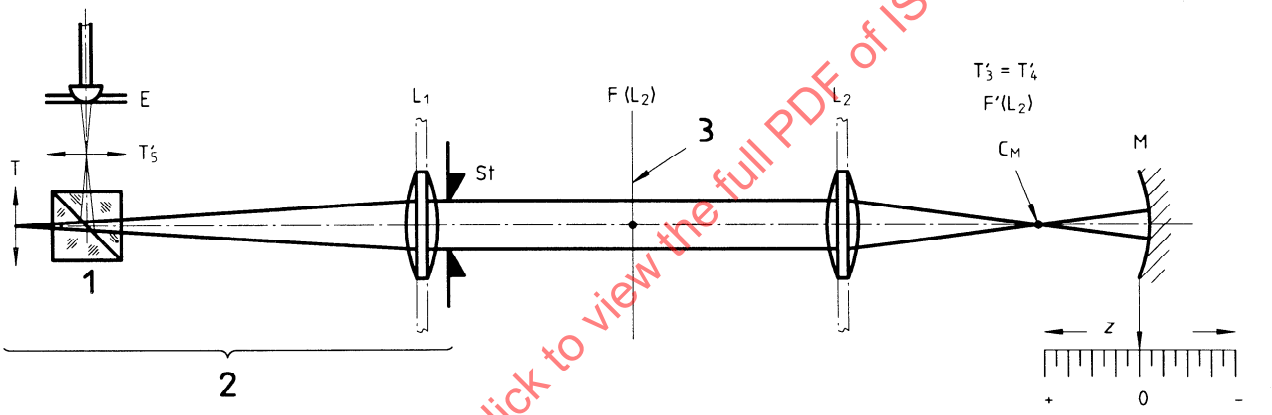
e) a reference to this International Standard, i.e. ISO 10341, if the manufacturer or supplier claims compliance with it.

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, subclause 5.1 of this International Standard 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[4] do not comply with this requirement.



Key

1	Beam splitter	E	Eyepiece
2	Autocollimating telescope	L_1, L_2	Objective lenses
3	Reference plane of refractor head	St	Stop
F	Focal point	T	Target
M	Mirror	T′	Target image
C_M	Centre of curvature		

Figure A.1 — Setup 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 the refractor head is facing the autocollimating telescope.

4) ISO 8598: *Optics and optical instruments — Focimeters.*