Foreword

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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 10342 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A forms an integral part of this International Standard.

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Ophthalmic instruments — Eye refractometers

1 Scope

This International Standard, together with ISO 15004, specifies requirements and test methods for eye refractometers.

This International Standard takes precedence 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 indicated 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 — General 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 definition apply.

3.1 eye refractometer: Instrument with continuous or digital readout used for measuring the refractive errors of the eye.

4 Requirements

4.1 General

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

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

2) To be published.

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 wavelengths λ = 546,07 nm or λ = 587,56 nm as required in ISO 7944.

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

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	Accuracy - double standard deviation
Spherical and cylindrical vertex power		0,00 D to ± 10,00 D	0,25 D	± 0,25 D
		> 10,00 D (absolute)	0,50 D	± 0,50 D
Cylinder axis *) for cylinder power	0,25 D to 0,50 D	0° to 180°	5°	± 10°
	> 0,50 D to 3,00 D			± 5°
	> 3,00 D			± 3°
*) Cylinder axis shall be indicated as specified in ISO 8429.				

Table 2 - Requirements for digitally indicating eye refractometers

Criterion		Measuring range	Maximum scale interval	Deviation from the nominal value of the test device
Spherical and cylindrical vertex power		0,00 D to ± 10,00 D	0,25 D	± 0,25 D
		> 10,00 D (absolute)	0,50 D	± 0,50 D
Cylinder axis *) for cylinder power	0,25 D to 0,50 D	0° to 180°	1°	± 10°
	> 0,50 D to 3,00 D			± 5°
	> 3,00 D			± 3°
*) 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 which 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 minimal of - 4 D to + 4 D.

5 Test methods

All tests described in this International Standard are type tests.

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

5.1 Checking the vertex power

The vertex power accuracy requirements as specified in table 1 or table 2 shall be verified using the special test device specified in Annex A. For digitally indicating instruments, nominal values of the test device shall be integer multiples of 0,25 D.

Test measurements 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.

5.2 Checking the cylinder axis

The astigmatic accuracy requirements, as specified in table 1 or table 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 within a tolerance of 20 % of that given in table 1 or 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 clause 5.3 of ISO 15004;

d) any additional documents as specified in 6.8 of IEC 601-1:1988.

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 601-1;

d) a reference to this International Standard ISO 10342, if the manufacturer or supplier claims compliance with it.

Annex A (normative)

Test device for eye refractometers

A.1 Design specifications

The test device shall be made of polymethylmethacrylate (PMMA) or optical glass as shown in Figure A.1. If the test device is made of glass, the Abbe number, ν, shall lie in the range 58 to 60. The spherical front surface shall be polished to an optical finish and the plano back surface should be lightly frosted. All other surfaces 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.

For testing the cylinder axis accuracy and the cylindrical vertex power accuracy, a toric contact lens with an 8 mm base curve shall be fixed onto 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 with a tolerance of ± 1°.

Dimensions in millimetres

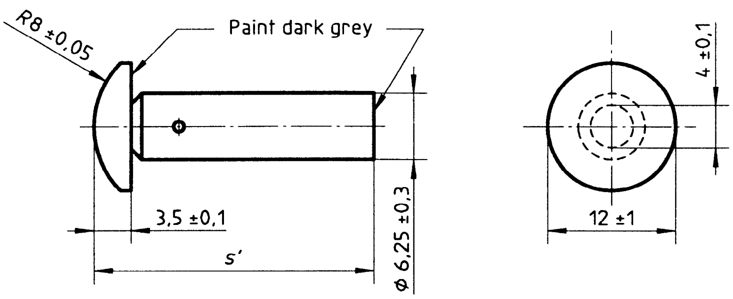

Figure A.1 - Test device

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 ± 0,06 D.

Test devices which are to be used to verify the spherical vertex power accuracy of digitally reading eye refractometers shall be constructed with length, s', such that the refractive power is within ± 0,06 D of an integer multiple of 0,25 D.

A.3 Determination of refractive power

When the test device is to be used to verify the accuracy of eye refractometers which 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.

1) 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.

2) 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, forms the smallest root mean square (rms) spot of the diffuse back surface of the device. The refractive power of the device is then found by:

$$P = 1/d$$

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 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 curved surface of the test device is then the expected refractive power of the device when measured by an eye refractometer.

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