INTERNATIONAL STANDARD

ISO 12865

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Ophthalmic instruments — Retinoscopes

Instruments ophtalmiques — Rétinoscopes

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 12865 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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1 Scope

This International Standard, together with ISO 15004, specifies minimum requirements and test methods for hand-held streak and spot retinoscopes for use in objective determination of the refractive errors of the eye.

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 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods*

IEC 60601-1:1988, *Medical electrical equipment — Part 1 : General requirements for safety*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1
retinoscope
ophthalmic instrument designed to assess objectively refractive errors of the eye by reflecting a beam of light into it from a mirror and observing the movement of the retinal reflex across the pupil

NOTE - A retinoscope usually consists of an illuminating system that produces a beam of light including a mirror with either a semireflective or a perforated highly reflective coating, a viewing system and a power supply for the light source.

3.2
streak retinoscope
retinoscope capable of producing a beam of light of rectangular cross-section with adjustable focusing

3.3
spot retinoscope
retinoscope capable of producing a beam of light of approximately circular cross-section

NOTE - The spot image focus may be adjustable.

4 Requirements

4.1 General

The retinoscope shall conform to the requirements specified in ISO15004.

The retinoscope shall conform to the specific requirements specified in 4.2 to 4.4.

These requirements are verified as specified in clause 5.

4.2 Optical and mechanical requirements

The requirements specified in table 1 shall apply.

Table 1 -— Requirements for optical and mechanical specifications

Retinoscope	Criterion	Requirement
Streak retinoscope	Rotation	≥ 190°
	Distance of real image[1)] of lamp filament adjustable to	≤ 450 mm
	Distance of virtual image[1)] of lamp filament adjustable to	≤ 450 mm
	Length of streak image[2)]	≥ 30 mm
	Thickness of streak image[2)]	≤ 1,5 mm
	Deviation from linearity of the streak image at the focus[2)]	≤ 2 mm
	Rotational decentring of centre of streak image[2)]	≤ 10 mm
Spot retinoscope	Distance of virtual image[1)] of lamp filament	≤ 1000 mm
	Spot diameter at 500 mm distance[1)]	≤ 25 mm

1) All distances are measured from the light exit of the instrument.
2) When focused at 500 mm.

4.3 Construction and function

4.3.1 General

a) When projecting the light beam onto a white surface and looking through the instrument, no internal reflection or scattered light shall be visible.

b) The light output shall be adjustable, continuously or in steps, from zero to its maximum.

4.3.2 Streak retinoscopes

a) The streak image shall be continuously rotatable within the limits specified in table 1.

b) The streak imaging bundle of light shall be continuously adjustable from convergent to divergent within the image distances specified in table 1.

c) The streak image shall be evenly illuminated and free from discoloration and distortion.

NOTE - An index stop at the infinite focus is optional.

4.4 Optical radiation hazard with retinoscopes

4.4.1 General

This clause replaces clauses 32, 33 and 34 of IEC 60601-1:1988.

4.4.2 Limit values

The limit values given in items a) and b) shall apply to the radiation emerging from the retinoscope used to illuminate and view the human eye with light from 380 nm to 700 nm and in which the full beam homogeneously illuminates a circular pupil of 8 mm diameter (see notes 2 and 4).

a) Short wavelength limit:

The radiance of the light source in the portion of the spectrum from 305 nm to 400 nm shall be no greater than 1,6 mW/(cm^2 · sr) as measured in the beam exiting the retinoscope with the instrument operating at maximum intensity[1)].

NOTE 1 For retinoscopes with a small illuminating solid angle, i.e. $\Omega << 0{,}031$ sr, the limit value of illumination is given by the radiance of the light source instead of an irradiance value in the corneal plane.

b) Long wavelength limit:

The amount of energy exiting the retinoscope in the wavelength range 700 nm to 1100 nm shall not exceed 100 mW/cm^2, nor shall it exceed the amount of energy exiting the retinoscope in the range between 380 nm and 700 nm. The energy shall be measured in the corneal plane when the instrument is operating at maximum intensity[1)].

NOTE 2 If, due to stops or other obstructions of the beam, a circular pupil of diameter less than 8 mm is illuminated, the limit values may be increased by the ratio of the area of an 8 mm diameter pupil divided by the true area illuminated.

NOTE 3 It is recommended that the energy in the range of the spectrum below 420 nm be attenuated as much as possible.

NOTE 4 For retinoscopes, the assumptions used to set the limit value for radiation of wavelength shorter than 400 nm are based on considerations of the typical spectral distribution of a 3000 K standard black-body source, a maximum exposure time of 5 min and the weighting factors for L_A (see Annex A). The limit is set to ensure that the fraction of the photochemical hazard dose due to radiation of wavelength shorter than 400 nm is no greater than 1/8 of the total photochemical hazard dose over all wavelengths when that total dose is at the threshold limit for an 8 mm diameter pupil.

Using the American Conference of Governmental Industrial Hygienists (ACGIH) guidelines, that threshold limit is 14 J/(cm² · sr). To convert from photochemical hazard weighted radiance to radiance over the designated spectral range (305 nm to 400 nm), the conversion factor 0,276 is used. Thus the limit is then found by the formula

$$[14 \text{ J/(cm}^2 \cdot \text{sr)}] \times [0{,}276/(300 \text{ s} \times 8)] = 1{,}6 \text{ mW/(cm}^2 \cdot \text{sr)}$$

1) Maximum intensity is the highest brightness the retinoscope is capable of delivering, including the highest brightness achievable if overvoltage is provided.

4.4.3 Variable brightness

For retinoscopes where provision is made to vary the brightness, the manufacturer shall provide indications of the proportions of the maximum intensity.

4.4.4 Particular information

The manufacturer shall provide the user with a graph showing the relative spectral output of the retinoscope between 305 nm and 1100 nm when the instrument is operating at maximum light intensity. The spectral output shall be shown for the beam after it exits the instrument.

The manufacturer shall provide the user with the values for the spectrally weighted photochemical source radiance, both phakic L_B and aphakic L_A, measured in the beam exiting from the instrument when operating at maximum intensity and determined by using the spectral weighting values given in Annex A.

The manufacturer shall provide information on the meaning of L_B and L_A to the user.

NOTE - An example of such information is given in Annex C.

5 Test methods

All tests described in this International Standard are type tests.

5.1 Checking the optical, mechanical and functional requirements

5.1.1 The requirements specified in 4.2 shall be verified by use of measuring devices with accuracy better than 10 % of the smallest value to be determined.

5.1.2 Concerning virtual image distance, check compliance with table 1 by placing

a) a +3,00 D lens at the light exit of a streak retinoscope; or
b) a +2,00 D lens at the light exit of a spot retinoscope

and determine whether it is possible to produce a sharp image of the streak or spot, respectively, at a distance of 1000 mm or less from the retinoscope.

5.1.3 The requirements specified in 4.3.1 and 4.3.2 shall be checked by observation.

5.2 Checking optical radiation safety for retinoscopes

5.2.1 Determination of spectral radiance

Spectral radiance of the light source shall be measured with an uncertainty of less than ± 50 % in the beam exiting the retinoscope at regular intervals over the effective portions of the spectrum. For aphakic photochemical hazard L_A the effective portion is 305 nm to 700 nm. For phakic photochemical hazard L_B the effective portion is 380 nm to 700 nm. If necessary, radiance may be calculated from spectral irradiance (see 5.2.2) and solid angle (see Annex B).

5.2.2 Determination of spectral irradiance

Spectral irradiance shall be measured with an uncertainty of less than ± 30 % at regular intervals over the effective portion of the spectrum. For aphakic photochemical hazard L_A the effective portion is 305 nm to 700 nm. For phakic photochemical hazard L_B the effective portion is 380 nm to 700 nm.

NOTE - The intervals for spectral irradiance measurement should be centred on the values given in Annex A with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement unit is milliwatts per square centimetre per nanometre [mW/(cm² · nm)]. This value should be recorded and, after being multiplied by the bandwidth, recorded as milliwatts per square centimetre (mW/cm²) for that interval (see also Annex B).

5.2.3 Determination of beam cross-section

When determining the area of the beam cross-section, which is required for several calculations, the measuring method used shall be capable of an accuracy of ± 30 % (see B.2).

NOTE - For irregular cross-sections, it may be appropriate to measure the area by exposing a piece of film and then measuring the area on the negative.

6 Accompanying documents

The retinoscope shall be accompanied by documents containing instructions for use. In particular this information shall contain:

a) name and address of the manufacturer;

b) instructions for effective disinfection of the retinoscope, with particular reference to the disinfection of instruments to be returned to the manufacturer for repair and maintenance;

c) the information specified in 4.4.4;

d) if appropriate, a statement that the retinoscope in its original packaging conforms to the transport conditions as specified in ISO 15004;

e) any additional documents as specified in 6.8 of IEC 60601-1:1988;

f) a reference to this International Standard, i.e. ISO 12865, if the manufacturer or supplier claims compliance with it.

7 Marking

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

a) name of manufacturer or supplier;

b) name and model of retinoscope;

c) marking as required by IEC 60601-1.

Annex A
(normative)

Optical radiation hazard

A.1 Spectral weighting functions for retinal hazard analysis

Spectral weighting functions for retinal hazard analysis are given in table A.1

A.2 Determination of spectrally-weighted source radiance

If spectral radiance $L_\lambda(\lambda)$ can only be measured relatively, but the total source radiance L can be measured absolutely, the following equation determines the spectrally-weighted photochemical aphakic source radiance L_A.

$$L_A = \frac{\sum_{305}^{700} L_\lambda(\lambda) \cdot A(\lambda) \cdot \Delta\lambda}{\sum_{305}^{700} L_\lambda(\lambda) \cdot \Delta\lambda} \cdot L \qquad \text{(A.1)}$$

If spectral radiance $L_\lambda(\lambda)$ can only be measured relatively, but the total source radiance L can be measured absolutely, the following equation determines the spectrally-weighted photochemical phakic source radiance L_B.

$$L_B = \frac{\sum_{380}^{700} L_\lambda(\lambda) \cdot B(\lambda) \cdot \Delta\lambda}{\sum_{380}^{700} L_\lambda(\lambda) \cdot \Delta\lambda} \cdot L \qquad \text{(A.2)}$$

NOTE - $\Delta\lambda$ should be taken as 5 nm or 10 nm.

Table A.1

Wavelength λ nm	**Photochemical (blue-light) hazard function**, $B(\lambda)$	**Photochemical aphake hazard function**, $A(\lambda)$
305 to 335	-	
340	-	
345	-	
350	-	
355	-	
360	-	
365	-	
370	-	
375	-	
380	0,006	
385	0,012	
390	0,025	
395	0,050	
400	0,10	
405	0,20	
410	0,40	
415	0,80	
420	0,90	
425	0,95	
430	0,98	
435	1,00	
440	1,00	
445	0,97	
450	0,94	
455	0,90	
460	0,80	
465	0,70	
470	0,62	
475	0,55	
480	0,45	
485	0,40	
490	0,22	
495	0,16	
500	0,10	
510	0,063	
520	0,040	
530	0,025	
540	0,016	
550	0,010	
560	0,006	
570	0,004	
580	0,002	
590	0,001	
600	0,001	
610	0,001	
620		
630		
640		
650		
660		
670		
680		
690		
700		