

# INTERNATIONAL STANDARD

# ISO 12865

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## Ophthalmic instruments — Retinoscopes

*Instruments ophtalmiques — Skiascopes*

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

This second edition cancels and replaces the first edition (ISO 12865:1998), which has been technically revised.

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# Ophthalmic instruments — Retinoscopes

## 1 Scope

This International Standard, together with ISO 15004-1, 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 15004-1, 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 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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## 3 Terms and definitions

For the purposes of this document, the following terms and 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 semi-reflective 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 and orientation

### 3.3

#### **spot retinoscope**

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

NOTE The spot image focus can be adjustable.

## 4 Requirements

### 4.1 General

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

The retinoscope shall conform to the specific requirements specified in 4.2 to 4.3.

These requirements shall be verified as specified in Clause 5.

### 4.2 Optical and mechanical requirements

The requirements specified in Table 1 apply.

**Table 1 — Requirements for optical and mechanical specifications**

Retinoscope	Criterion	Requirement
Streak retinoscope	Rotation	$\geq 190^\circ$
	Distance from the instrument to which the real image <sup>a</sup> of the lamp filament is adjustable	$\leq 450$ mm
	Distance from the instrument to which the virtual image <sup>a</sup> of the lamp filament is adjustable	$\leq 450$ mm
	Length of streak image <sup>b</sup>	$\geq 30$ mm
	Width of streak image <sup>b</sup>	$\leq 1,5$ mm
	Deviation from linearity of the streak image at the focus <sup>b</sup>	$\leq 2$ mm
	Rotational decentring of centre of streak image <sup>b</sup>	$\leq 10$ mm
Spot retinoscope	Distance of virtual image <sup>a</sup> of lamp filament	$\leq 1\ 000$ mm
	Spot diameter at 500 mm distance <sup>a</sup>	$\leq 25$ mm
<sup>a</sup> All distances are measured from the light exit of the instrument.		
<sup>b</sup> 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 beam luminous intensity 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.

### 4.3.3 Spot retinoscopes

- a) The spot image shall be circular, evenly illuminated and free from discolouration.
- b) If focusable, the imaging bundle shall be continuously adjustable from convergent to divergent within the image distances specified in Table 1 for streak retinoscopes.

## 5 Test methods

**5.1** All tests described in this International Standard are type tests.

**5.2** 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.

**5.2.1** 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 1 000 mm or less from the retinoscope.

**5.2.2** The requirements specified in 4.3.1 to 4.3.3 shall be checked by observation.

## 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) if appropriate, a statement that the retinoscope in its original packaging conforms to the transport conditions as specified in ISO 15004-1;
- c) any additional documents as specified in 7.9 of IEC 60601-1:2005;
- d) a reference to this International Standard (ISO 12865:2006), 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.

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