INTERNATIONAL STANDARD

ISO 10943

Fourth edition
2023-01

Ophthalmic instruments — Indirect ophthalmoscopes

Instruments ophtalmiques — Ophtalmoscopes indirects

Reference number
ISO 10943:2023(E)

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Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with by the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 10943:2011), which has been technically revised.

The main changes are as follows:

— revision of the dated references;

— editorial update of the whole document.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Ophthalmic instruments — Indirect ophthalmoscopes

1 Scope

This document, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held, spectacle-type, and head-worn indirect ophthalmoscopes for observing indirect images of the eye fundus.

This document takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

This document is not applicable to condensing lenses used for indirect ophthalmoscopy or to accessories.

This document is not applicable to table-mounted instruments such as Gullstrand ophthalmoscopes and their derivatives, nor to ophthalmoscopes primarily intended for image capture and/or processing such as those based on scanning laser techniques.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

ISO 15004-2, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005+A1:2012+A2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
ophthalmoscope
optical instrument used to examine the external and internal parts of the eye, particularly the media and the fundus

3.2
indirect ophthalmoscope
optical instrument, which provides an illumination system and which is used with a condensing lens (hand-held or integral) to direct appropriately focused light into an eye in order to produce a real intermediate image that is viewed by an observer

Note 1 to entry: Indirect ophthalmoscopes may be monocular or binocular.

3.3
condensing lens
plus-power lens system used to focus the illuminating beam into an eye and to form a real inverted image of the retina thus illuminated

4 Requirements

4.1 General

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

The indirect ophthalmoscope shall conform to the specific requirements described in 4.2 to 4.4.

These requirements shall be verified as described in Clause 5.

4.2 Optical and dimensional requirements

The requirements specified in Tables 1, 2 and 3 shall apply.

Table 1 — Optical and dimensional requirements for indirect ophthalmoscopes used with a hand-held condensing system

Criterion	Requirement
Interpupillary distance range	55 mm to 72 mm
Diameter 2*r* of the field of view[ab]	≥100 mm
Diameter of largest illuminated spot[a]	≥45 mm
Range of adjustment of headband circumference, if applicable	520 mm to 640 mm

[a] At 500 mm distance from the light exit.

[b] Definition of *r* for different fields of view:

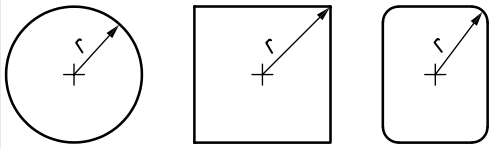

Table 2 — Optical requirements for indirect ophthalmoscopes with integral condensing systems

Criterion	Requirement
Distance of focal point from end of instrument	15 mm to 20 mm
Diameter of beam at 500 mm from focal point	125 mm to 225 mm
Diameter of field of view at 500 mm from focal point	150 mm to 250 mm

Table 3 — Requirements for optical accuracy for binocular indirect ophthalmoscopes

Criterion			Tolerance
Difference in axes' orientation between left and right optical systems	vertical	interpupillary distance between 60 mm and 66 mm	≤10'
		interpupillary distance between 55 mm and 60 mm and between 66 mm and 72 mm	≤15'
	horizontal	divergence in parallel systems	≤10'
		convergence in parallel systems; in convergent systems, deviation from the indicated angle	≤45'

Table 3 *(continued)*

Criterion	Tolerance
Difference in magnification between left and right systems, where provided	≤5 %
Specified power of eyepieces or lenses where provided	±0,12 D

4.3 Construction and function

4.3.1 The minimum adjustable range of the light output of the indirect ophthalmoscope shall be from maximum to 10 % of the maximum.

4.3.2 No reflections or scattered light shall be visible as determined by observation.

4.3.3 The illumination system shall be capable of alignment with the viewing system to within 1° vertically.

4.3.4 For binocular systems, no difference in brightness or colour between the left and right optical system shall be visible.

4.3.5 The defocused illumination beam shall be homogeneous and achromatic as determined by visual inspection.

4.4 Optical radiation hazard with indirect ophthalmoscopes

This subclause replaces IEC 60601-1:2005+A1:2012+A2:2020, 10.4, 10.5, 10.6 and 10.7.

Indirect ophthalmoscopes without an integral condensing system shall be evaluated and tested with the condensing lens of a design specified by the manufacturer of the indirect ophthalmoscope to be used with the instrument that represents the most unfavourable condition with respect to light safety. This lens shall be positioned from the reflecting surface of the indirect ophthalmoscope at the position correct for it (in accordance with manufacturer's instructions) to be placed when used to examine the human eye.

The indirect ophthalmoscope shall conform to the light hazard protection requirements and test methods given and specified in ISO 15004-2.

The applicable clauses and subclauses of ISO 15004-2:2007 for indirect ophthalmoscopes are as follows:

a) classification in accordance with ISO 15004-2:2007, Clause 4;

b) for Group 1 indirect ophthalmoscopes:

   1) ISO 15004-2:2007, 5.1, 5.2, 5.4.1, 6.1, 6.2 and 6.4 are applicable;

   2) if status is determined to be Group 1, there are no further requirements;

   3) if status is determined not to be Group 1, the additional requirements given in c) are applicable;

c) for Group 2 indirect ophthalmoscopes:

   1) ISO 15004-2:2007, 5.5.1, 6.3, 6.4, 6.5 and Clause 7 are applicable, and

   2) additionally, ISO 15004-2:2007, 6.3, for instruments with variable light intensity.

5 Test methods: optical, mechanical and functional requirements

5.1 All tests described in this document are type tests.

5.2 The requirements specified in 4.2, 4.3.1, 4.3.3 and 4.3.4 shall be verified by use of measuring devices with accuracy better than 10 % of the smallest value to be determined.

Measurements shall be carried out according to general rules of statistical evaluation.

5.3 The requirements described in 4.3.2 and 4.3.5 shall be verified with taking measurement uncertainty into account, see ISO/IEC Guide 98-3.

6 Accompanying documents

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

a) name and address of the manufacturer;

b) any additional documents as specified in IEC 60601-1:2005+A1:2012+A2:2020, 7.9;

c) a reference to this document (ISO 10943:2023), if the manufacturer or supplier claims conformity with it;

d) specifications of condensing lenses that can be safely used with the instrument, including diameter and power.

7 Marking

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

a) name of manufacturer or supplier;

b) name and model of indirect ophthalmoscope;

c) marking as required by IEC 60601-1.

Bibliography

[1] ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

ICS 11.040.70

Price based on 5 pages