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# Ophthalmic instruments — Indirect ophthalmoscopes

*Instruments ophtalmiques — Ophtalmoscopes indirects*

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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).

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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.


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# 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.

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**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:

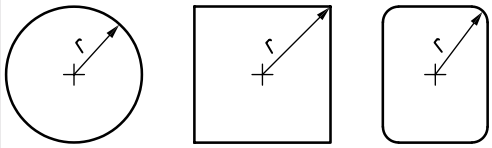


**Table 2 — Optical requirements for indirect ophthalmoscopes with integral condensing systems**

| 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' |


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