
**Ophthalmic instruments — Indirect
ophthalmoscopes**

Instruments ophtalmiques — Ophtalmoscopes indirects

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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.