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Ophthalmic instruments — Direct ophthalmoscopes

Instruments ophtalmiques — Ophtalmoscopes directs

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Foreword

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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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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with 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 third edition cancels and replaces the second edition (ISO 10942:2006), which has been technically revised.

The main changes compared to the previous edition 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 — Direct ophthalmoscopes

1 Scope

This document, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus.

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

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, *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 terminological 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
direct ophthalmoscope
ophthalmoscope (3.1) which provides an illuminating system, an observation system and viewing lenses which allow the observer to visualize the patient's eye directly, that is without the formation of an intermediate image

3.3
viewing lens
lens which is positioned between the observer's eye(s) and the eye to be examined in order to achieve optimum focus, i.e. to correct for patient's and/or observer's refractive error and/or accommodation

Note 1 to entry: In direct ophthalmoscopes when a selection of such lenses is required, these are integrated with or mounted in a disc or other mechanical means by which the user can easily position the lens of choice centrally in the visual path.

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3.4
auxiliary lens
additional *viewing lens* (3.3) to facilitate access to higher refractive powers without requiring an excessive number of lenses

Note 1 to entry: Auxiliary lenses are normally integral with or mounted on a separate disc or other mechanical means and when required are used in conjunction with the viewing lenses.

3.5
ophthalmoscope graticule
pattern or target or graticule which can be optionally positioned in the illuminating light path within the instrument and which will be imaged on the retina for diagnostic, measurement or therapeutic purposes

Note 1 to entry: These can be fixed or focusable.

3.6
illuminating system
light source and associated lenses, mirrors and/or prism which serve to provide and project light into or onto the patient's eye

3.7
viewing system
lenses and apertures which enable the observer to examine the patient's eye

3.8
field of view
angular field which is visible when the entrance pupil is 12 mm behind the back surface of the *ophthalmoscope* (3.1), measured from the centre of the entrance pupil

Note 1 to entry: See 6.2.3 and Figure 1.

3.9
field of illumination
angular field which is illuminated and which is measured with its apex positioned at the image of the light source

4 Classification

Direct ophthalmoscopes shall be classified as follows:

a) Group A: Direct ophthalmoscopes that comply with all the requirements of this document.

b) Group B: Direct ophthalmoscopes that comply with the reduced requirements specified in Table 1 and all other requirements specified in this document except those in 5.4.2 and 5.4.3.

5 Requirements

5.1 General

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

The direct ophthalmoscope shall conform to the specific requirements specified in 5.2 to 5.5.

These requirements shall be verified as specified in Clause 6.

5.2 Optical requirements

The requirements specified in Table 1 and Table 2 shall apply.

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