भारतीय मानक
Indian Standard

IS 18882 : 2024

(*Superseding IS/ISO 10943 : 2011*)

नेत्र संबंधी उपकरण — अप्रत्यक्ष नेत्रदर्शी

(ISO 10943 : 2023, संशोधित)

(पहला पुनरीक्षण)

Ophthalmic Instruments — Indirect Ophthalmoscopes

(ISO 10943 : 2023, MOD)

(First Revision)

ICS 11.040.70

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August 2024 **Price Group 6**

NATIONAL FOREWORD

This Indian Standard (First Revision) which is modified adoption of ISO 10943 : 2023 'Ophthalmic instruments — Indirect ophthalmoscopes' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 2018 as IS/ISO 10943 : 2011 'Ophthalmic instruments — Indirect ophthalmoscopes'. The first revision has been undertaken to align it with latest edition of ISO 10943.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Standard*	*Degree of Equivalence*
ISO 15004-1 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments	IS 18638 (Part 1) : 2024 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1 : 2020, MOD)	Modified
ISO 15004-2 Ophthalmic instruments Fundamental requirements and test methods — Part 2: Light hazard protection	IS 18638 (Part 2) : 2024/ ISO 15004-2 : 2007 Opthalmic instruments and test methods: Part 2 Light hazard protection	Identical
IEC 60601-1:2005+A1 : 20122+A2 : 2020 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (IEC 60601-1 : 2020, MOD) (*third revision*)	Modified

In this standard, reference to IEC 60601-1 has been modified to IS 13450 (Part 1) : 2024 which is a modified adoption of IEC 60601-1 : 2020.

In this Standard, reference to ISO 15004-1 has been modified to IS 18638 (Part 1) : 2024 which is a modified adoption of ISO 15004-1 : 2020.

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Indian Standard

OPHTHALMIC INSTRUMENTS — INDIRECT OPHTHALMOSCOPES

(ISO 10943 : 2023, MOD)

(First Revision)

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:

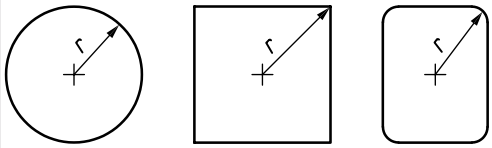

Table 2 — Optical requirements for indirect ophthalmoscopes with integral condensing systems

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)*

NATIONAL ANNEX A

(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

(*Continued from second cover*)

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*). The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

This standard also makes a reference to the BIS certification marking of the product, details of which is given in National Annex A.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

This Indian Standard has been developed from Doc No.: MHD 05 (25357).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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