
**Ophthalmic instruments —
Synoptophores**

Instruments ophtalmiques — Synoptophores

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10944 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 10944:1998), which has undergone minor revision in order to update normative references.

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Ophthalmic instruments — Synoptophores

1 Scope

This International Standard, together with ISO 15004-1, specifies minimum requirements and test methods for synoptophores (also called major amblyoscopes or synoptometers) used to test, measure, train and develop the patient's binocular vision and to measure horizontal, vertical and cyclo deviation in different positions of gaze.

This International Standard takes precedence over ISO 15004-1, if differences exist.

2 Normative references

The following referenced documents are indispensable for the application 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 15004-1:2006, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

IEC 60601-1:2005, *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.

3.1

synoptophore

instrument designed to present interchangeable targets to each eye and with the ability to move targets independently in order to present them at different versional and vergence positions

NOTE Target configuration and location along with other instrument features are used to test, measure and train binocular vision.

3.2

visual targets for simultaneous perception

targets used to form two different images, one on each retina, which cannot be fused into a single image

3.3

visual targets for fusion

targets used to form two similar images, one on each retina, which are capable of being fused, and in which control points are often incorporated in order to assess if either eye is suppressing the relevant image

3.4

visual targets for stereoscopic vision

targets used to test and/or measure stereoscopic acuity in which image pairs, having common reference points, are fused in vision to give a stereoscopic effect

3.5 arm

rotatable structural member of the synoptophore intended to carry the ocular systems, targets and illumination system

4 Requirements

4.1 General

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

The synoptophore shall conform to the specific requirements described in 4.2 and 4.3.

These requirements shall be verified as described in Clause 5.

4.2 Optical and mechanical requirements

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

Table 1 — Requirements for adjustment ranges and graduation of scales

Criterion		Requirement
Interpupillary distance	adjustable range	45 mm to 75 mm
	graduation	< 1 mm
Horizontal movement of each arm independently	outwardly	40°
	inwardly	40°
	graduation	1° or 2Δ ^a
Vertical rotation of each arm independently	angle of elevation	15°
	angle of depression	20°
Torsional movement of visual targets (cyclo-)	clockwise range	20°
	anti-clockwise range	20°
	graduation	1°
Chin-rest height	adjustable range from chin-rest top to eyepiece centres	75 mm to 125 mm

^a Δ = prism dioptre equivalent correction at the patient's eye. The actual linear tolerance will depend on the optical path length of the ocular arms.

Table 2 — Adjustment tolerances

Interpupillary distance setting		± 0,5 mm
Lateral alignment of targets at zero setting		± 0,5° or ± 1Δ ^a
Vertical alignment of targets at zero setting		± 0,125° or ± 0,25Δ ^a
Torsional alignment of targets at zero setting		± 0,5°
Alignment of targets throughout the horizontal movement range with both arms locked together	vertically	± 10'
	laterally	± 0,5°
	torsionally	± 10'

^a The tolerances given are expressed in degrees when the scale is graduated in degrees, and in prism dioptres when graduated in prism dioptres.