INTERNATIONAL STANDARD

ISO 12867

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Ophthalmic instruments — Trial frames

Instruments ophtalmiques — Montures d'essai

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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.

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 12867 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 12867:1998), which has undergone minor revision to update the normative references.

Ophthalmic instruments — Trial frames

1 Scope

This International Standard, together with ISO 15004-1, specifies minimum requirements and test methods for trial frames for holding trial case lenses, complying with ISO 9801, in front of a subject's eyes in order to assess visual acuity and facilitate optical correction of vision.

This International Standard is applicable to lens holders mounted on headbands, bracket-mounted frames and frames mounted in the manner of spectacles with supports on the ears and the bridge of the nose. It is applicable to all types of trial frame, including half-eye and rotating lens holders.

This International Standard is not applicable to refractor heads (see ISO 10341).

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 8429, *Optics and optical instruments — Ophthalmology — Graduated dial scale*

ISO 9801, *Ophthalmic instruments — Trial case lenses*

ISO 15004-1:2006, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
trial frame
frame consisting of two interconnected lens holders and means for holding them in a required position in front of the subject's eyes

3.2
reduced-aperture trial frame
trial frame designed to hold reduced-aperture trial lenses

3.3
full-aperture trial frame
trial frame designed to hold both full-aperture trial lenses and reduced-aperture trial lenses

3.4
half-eye trial frame
trial frame whose lens holders consist of the lower half-segment only and which are designed to hold full- or reduced-aperture trial lenses

3.5
lens holder
unit designed to hold a number of trial case lenses in front of one eye

3.6
bridge piece
part of the mounting which supports the trial frame on, and part of which is in contact with, the subject's nose

3.7
side
part of the trial frame which uses the subject's ear to retain the frame against the face

4 Requirements

4.1 General

The trial frame shall conform to the requirements specified in ISO 15004-1:2006, except Clauses 5 and 6.

4.2 Mechanical requirements

4.2.1 General

The trial frame shall conform to the requirements specified in 4.2.2 to 4.2.10.

These requirements are verified as specified in Clause 5.

4.2.2 Lens holders

The trial frame shall have the means of positioning each of two lens holders, one before each eye of the subject. Each lens holder shall have the means of retaining in position a combination of at least three lenses, each in a separate compartment spaced along the geometrical axis of the lens holder.

4.2.3 Interpupillary distance

The spacing of the centres of the lens holders shall be adjustable to coincide with the interpupillary distance, and to maintain the lenses in position.

4.2.4 Lens rotation

It shall be possible to rotate one lens in each holder smoothly about its optical axis (see Table 1).

4.2.5 Sides

The sides, if not adjustable, shall be parallel in a vertical direction.

4.2.6 Bridge piece adjustment

The bridge piece shall be so constructed as to enable the vertex distance to be varied, and the centre of the lenses to be raised or lowered with respect to the interpupillary line.

4.2.7 Axis scale

The trial frame shall have a scale indicating cylinder axis and prism base for each lens holder. It shall extend to at least 180°. The scale direction shall increase from the horizontal, anticlockwise, in accordance with ISO 8429. The scale divisions shall be no greater than 5°.

4.2.8 Lens holder alignment

The geometrical axes of the lens holders shall be parallel to within 2°; the relative axial displacement of the lens holders shall be no more than 0,5 mm.

4.2.9 Dimensions and tolerances

Table 1 gives the interpupillary range, minimum aperture and lens rotation for lens holders.

Table 1 — Range and minimum aperture

Parameter	Full and reduced apertures	Half-eye
Interpupillary distance range	55 mm to 75 mm	59 mm to 67 mm
Minimum clear aperture	20 mm	20 mm
Minimum lens rotation	180°	180°
NOTE Interpupillary distance range for children's trial frames is not included.		

The lens holders shall be so arranged that when trial lenses in accordance with ISO 9801 are placed in them, the lens axes shall be parallel within 2,5° and shall coincide within a tolerance circle of 1 mm diameter. The lenses shall not be able to move laterally or axially within 0,2 mm of their central position.

4.2.10 Construction

The trial frame shall contain no surfaces, sharp edges or corners which could cause injury to the subject under normal conditions of use.

4.3 Materials

Components of the trial frame which are designed to come into direct contact with the skin of the patient or user shall be made of materials that are neither toxic nor known to create significant allergic reactions, when used as intended by the manufacturer.

Materials used in the construction shall be of noncorrosive composition or suitably surface-treated to render them noncorrosive in clinical atmospheric conditions.

5 Test methods

5.1 General

All tests described in this International Standard are type tests.

5.2 Checking of mechanical requirements

The requirements of 4.2.2 to 4.2.7 and 4.2.10 shall be checked by observation.

5.3 Checking of parallelism of geometrical axes of lens holders

Any suitable method capable of measuring the parallelism of the geometrical axes to an accuracy of ± 0,5° or better may be used.

Examples are given in Annex A.

5.4 Checking of coincidence of lens holder planes

Any suitable method capable of measuring the distance between the lens holder's planes to an accuracy of 0,1 mm or better may be used.

A suitable method of carrying out the test is, for example, to fit one of the discs (see Figure A.1) with an arm (A) parallel to, and at a known distance from, the disc's plane, and long enough to reach the geometrical axis of the lens holder. Measure the distance between the arm and the disc in the other lens holder using a calliper with an accuracy of 0,1 mm or better.

6 Accompanying documents

The trial frame shall be accompanied by documents containing instructions for use. In particular, this information shall include:

a) name and address of the manufacturer;

b) instructions for effective disinfection of the trial frame, with particular reference to the disinfection of trial frames returned to the manufacturer for repair and maintenance;

c) model of trial frame, if applicable;

d) a reference to this International Standard, i.e. ISO 12867:2010, if the manufacturer claims compliance with it.

7 Marking

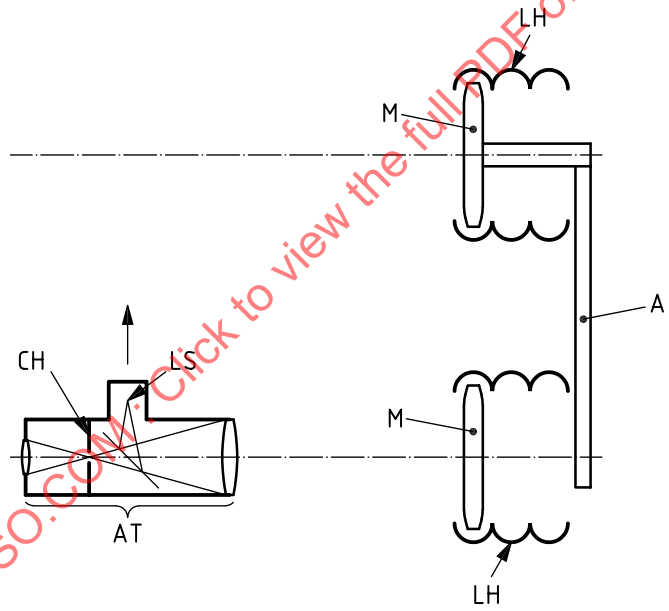
The trial frame shall be permanently marked with at least the name of the manufacturer or supplier.

Annex A
(informative)

Examples of test methods for checking parallelism of geometrical axes of lens holders

A.1 Method 1: checking parallelism of geometrical axes with a collimated telescope

Insert a plane mirror (M) (e.g. of diameter 38 mm) into each lens holder (LH) (see Figure A.1). Use an autocollimation telescope (AT) mounted on a slide in order to move it perpendicular to the geometrical axis of one lens holder. Align the telescope when directed towards the first mirrored disc, then move and direct it towards the second and measure the displacement of the light source's (LS) image in the cross-hair (CH) plane of the telescope. From this displacement, calculate the angular deviation from parallel. (In Figure A.1, "A" indicates an arm serving as an auxiliary means to determine the relative and actual displacement of the lens holders.)



Key

A arm
M plane mirror
LH lens holder
AT autocollimation telescope
LS light source
CH cross-hair

Figure A.1 — Test configuration for checking parallelism of holders