EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 12870

May 2018

ICS 11.040.70

Supersedes EN ISO 12870:2014

English Version

Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2016)

Optique ophtalmique - Montures de lunettes - Exigences et méthodes d'essai (ISO 12870:2016)

Augenoptik - Brillenfassungen - Anforderungen und Prüfverfahren (ISO 12870:2016)

This European Standard was approved by CEN on 26 April 2018.

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Ref. No. EN ISO 12870:2018: E

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3.2
natural organic material
material that has not been synthesized from other raw organic materials and, when processed, remains essentially in its original state

Note 1 to entry: Processing in this case is defined as cutting, shaping, laminating, bonding, bending, polishing and heating.

EXAMPLE Natural horn, bamboo and wood.

3.3
custom-made spectacle frame
spectacle frame made to special order for a named patient

EXAMPLE Spectacle frames specially manufactured for wearers with unusual facial characteristics.

4 Requirements

4.1 General

The requirements applicable to different types of spectacle frames are given in Table 1. All spectacle frame types covered by this International Standard shall comply with the requirements identified as "general" (g). Requirements marked "O" are optional, but can be required by legislation in some countries.

Table 1 — Requirements applicable to different types of spectacle frames

Frame type	Subclause[a]											
	4.2.1	4.2.2	4.2.3	4.2.4	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10
Rimless and semi-rimless mounts	g	g	O	O	O	O	g	g	g	g	g	O
All other frame types[b]	g	g	O	O	g	g	g	g	g	g	g	O

Key	
g	Frame type shall meet the requirements of this subclause in order to comply with this International Standard.
O	Compliance with this subclause is optional.
4.2.1	Construction
4.2.2	General physiological compatibility
4.2.3	Nickel release
4.2.4	Clinical evaluation
4.3	Measurement system
4.4	Dimensional tolerances on nominal size
4.5	Tolerance on screw threads
4.6	Dimensional stability at elevated temperature
4.7	Resistance to perspiration
4.8	Mechanical stability
4.9	Resistance to ignition
4.10	Resistance to optical radiation

[a] Under European legislation, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.5, 4.6, 4.7, 4.8 and 4.9 cover some essential requirements.

[b] "All other frame types" include plastics and metal spectacle frames, including folding spectacle frames, that have a rim that completely surrounds the lens periphery.

4.2 Physiological compatibility

4.2.1 Construction

When tested under the inspection conditions given in 7.2, areas of the spectacle frame that can, either by design or accident, come into contact with the wearer should be smooth, without sharp protuberances, and all edges should be rounded.

4.2.2 General physiological compatibility

Spectacle frames shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the health (and safety) of the wearer. The risks posed by substances leaking (migrating) from the device that might come into prolonged contact with the skin shall be reduced by the manufacturer to a practicable minimum and within the limits of any appropriate regulatory requirement. Special attention shall be given to substances that are known to be allergenic, carcinogenic, mutagenic or toxic to reproduction.

NOTE 1 The following list, which is given for information, provides examples of documents that can be examined when checking the innocuousness of materials:

— specification of the materials used;

— safety data sheets relating to the materials;

— information relating to the suitability of the materials for use with food, in medical devices, or other relevant applications;

— information relating to investigations into the allergenic, carcinogenic, toxicological or mutagenic properties of the materials, or their toxicity with regard to reproduction;

— information relating to ecotoxicological and other environmental investigations on the materials.

NOTE 2 Reactions can be generated by excessive pressure, for example, due to a poor fit on the face, chemical irritation or allergy. Rare or idiosyncratic reactions can occur to any material and indicate the need for the individual to avoid particular types of frames.

NOTE 3 In some countries, specific material properties are mandatory.

4.2.3 Nickel release

Those parts of metal spectacle frames and those metal parts of combination spectacle frames that come into direct and prolonged contact with the skin of the wearer shall not have a nickel release greater than 0,5 µg/cm^2/week when tested in accordance with ISO/TS 24348 or, equivalently, EN 16128.

The parts to be tested shall include the following:

— the front (rims, bridge and, if applicable, brace bar and any nasal bearing surfaces including metal nose pads), excluding pad arms and lugs;

— the sides including metal collets, but excluding the joints and areas intended to be protected by plastic end covers (tips);

— metal decorative trims, if fitted on the inside of plastic sides and plastic end covers.

See ISO/TS 24348 or, equivalently, EN 16128 for further details.

NOTE 1 Annex C provides brief information about European requirements and legislation.

NOTE 2 If only indicative information on the extent of nickel release is required, such information can be obtained by performing one of the tests specified in CEN/CR 12471. See NOTE 2 of Annex C.

4.2.4 Clinical evaluation

If a spectacle frame is manufactured using materials (e.g. plastics, alloys, coatings or pigments) not previously used in spectacle frame manufacture, the clinical evaluation shall be made according to the appropriate International Standard(s), either using the spectacle frame itself or using studies where the identical material is used in other medical devices.

4.3 Measurement system

The stated nominal dimensions of the spectacle frame shall be in accordance with the measuring system specified in ISO 8624.

4.4 Dimensional tolerances on nominal size

When measured with a linear measuring device that is accurate to at least 0,1 mm, the following tolerances shall apply to the marked dimensions of the unglazed spectacle frame using the boxed lens measurement method described in ISO 8624:

a) horizontal boxed lens size: ±0,5 mm;

b) distance between lenses: ±0,5 mm;

c) overall length of side: ±2,0 mm.

To improve the accuracy of measurement of overall length of side, it is recommended that the drop be physically straightened. Sinuosity in the intended vertical plane, or pronounced curvature in the intended horizontal plane in the part of the side before the earbend, should be ignored. The overall length of side should be taken as the length of the straight line between the dowel screw and the end of the side. Gentle bowing of the side to go round the width of the head should be straightened. For sides without a hinged joint, the side should be held open at $(90\,^{0}_{-5})°$ to the front or to that part of the side that is attached to the front, and the length is measured from the end of the side to the front, minus 10 mm. See ISO 8624:2011, Figures 2 and 3 for an illustration of overall length of side.

To simplify the edging of lenses for any single frame model, tighter tolerances in the lens aperture size from one frame to another of the same nominal size may be a matter of agreement between supplier and purchaser.

4.5 Tolerance on screw threads

The tolerances on the screw threads used in the spectacle frame shall conform to ISO 11381.

4.6 Dimensional stability at elevated temperature

When the spectacle frame with test lenses fitted is tested in accordance with 8.2, the distance between the tips of the sides shall not alter by more than +6 mm or −12 mm. For small spectacle frames where the tip of the side is less than 100 mm from the back plane of the front, these tolerances are reduced to +5 mm or −10 mm.

4.7 Resistance to perspiration

When the spectacle frame is tested in accordance with 8.3, there shall be

a) no spotting or colour change (except for loss of gloss on surface) anywhere on the frame, excluding joints and screws, after testing for 8 h, and

b) no corrosion, surface degradation or separation of any coating layer on the parts liable to come into prolonged contact with the skin during wear, i.e. the insides of the sides, bottom and lower parts of the rim and the inside of the bridge, after testing for a total of 24 h.

Such defects shall be visible under the inspection conditions described in 7.2.

If the spectacle frame is made from natural materials and the manufacturer recommends a cream or wax for its maintenance, then, before testing, the frame(s) shall be prepared with this cream or wax in accordance with the manufacturer's instructions. At the end of the test, if the frame fails to meet this requirement when checked for colour change or surface degradation, use the cream or wax and wait for one day before checking again for colour change or surface degradation. If the frame has recovered its original appearance, the spectacle frame is considered to have passed the test; if the frame remains discoloured, the frame is considered to have failed the test.

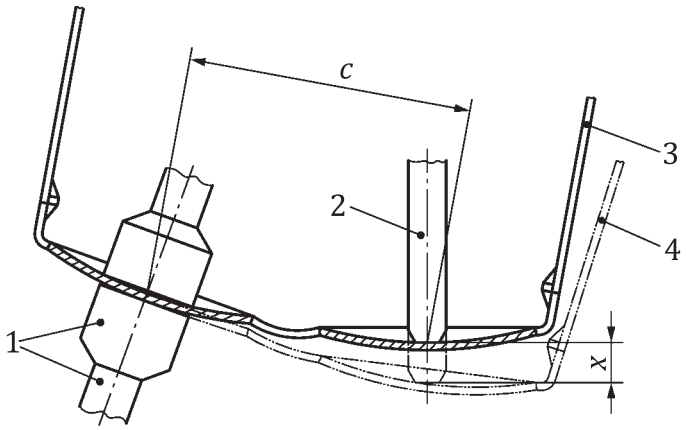
4.8 Mechanical stability

4.8.1 Bridge deformation

When tested in accordance with 8.4, the spectacle frame with the test lenses fitted shall not

a) fracture or crack at any point, or

b) be permanently deformed from its original configuration by more than 2 % of the distance, *c*, between the boxed centres of the spectacle frame, i.e. the residual deformation, *x*, shall not exceed 0,02*c* (see Figure 1).



Key

1 annular clamp
2 pressure peg
3 original position
4 residual deformation, *x*

Figure 1 — Permanent deformation of bridge

4.8.2 Lens retention characteristics

The spectacle frame shall be considered to demonstrate acceptable lens retention characteristics if, when tested in accordance with 8.4, neither test lens is dislodged wholly or partially from its original location in the groove or mount.

4.8.3 Endurance

When tested in accordance with 8.5, the spectacle frame with the test lenses fitted shall not

a) fracture at any point,

b) be permanently deformed from its original position by more than 5 mm after 500 cycles,

c) require more than light finger pressure to open and close the sides (except for frames fitted with sprung joints), or

d) have a side that closes under its own weight at any point in the opening/closing cycle (for frames not fitted with sprung joints), or for sides fitted with sprung joints, the side shall still support its weight in the open position (i.e. opened to the fullest natural extent without activating the spring mechanism).

4.9 Resistance to ignition

When the spectacle frame is tested in accordance with 8.6, there shall be no continued combustion after withdrawal of the test rod.

4.10 Resistance to optical radiation

When tested in accordance with 8.7, there shall be no

a) colour change greater than grade 3 on the grey scale in ISO 105-A02, or

b) loss of lustre on bright surfaces,

when compared with an untested sample under the inspection conditions described in 7.2.

5 Selection of test samples

5.1 General

The minimum level of conformity testing requires that two test specimens of each spectacle frame model shall be selected at random. These specimens shall be selected by the manufacturer or its representative, and shall be identified as test sample 1 and test sample 2. They shall be conditioned as described in Clause 6 before testing as described in Clauses 7 and 8.

In some regions, local legislation requires a spectacle frame model to comply with regulatory requirements throughout the duration of its supply to the market. When compliance with this International Standard is claimed, the manufacturer or its representative has the responsibility, by any chosen means, for example use of ISO 13485, ISO 14971 and/or this International Standard, to ensure that the compliance of the spectacle frame model continues throughout its duration of supply, and not only at its first launch on the market.

5.2 Testing for nickel release

For metal and combination spectacle frames, two additional test samples shall be selected at random and shall be conditioned and tested as specified in ISO/TS 24348 or, equivalently, EN 16128.

5.3 Change in spectacle frame model

If a range of spectacle frame models is made from the same material(s), following the same manufacturing procedures, including surface treatments, it is acceptable to perform, from Table 2, test sequences 4 (see 8.3), 8 (see 8.6) and, if required, 9 (see 8.7) and/or 10 on only one of the spectacle frame models.

6 Preparation and conditioning of test samples

6.1 Test lenses

Prior to testing for the requirements described in 4.6 to 4.10, test samples 1 and 2 shall be fitted with a pair of suitable test lenses.