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Ophthalmic optics — Spectacle frames — Requirements and test methods

Optique ophtalmique — Montures de lunettes — Exigences et méthodes d'essai

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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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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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 fifth edition cancels and replaces the fourth edition (ISO 12870:2016), which has been technically revised.

The main changes are as follows:

— rimmed clip-ons, prescription inserts, and frames made by additive manufacture are now included in the scope;

— additional terms and definitions;

— clarification of the tests to be applied for the physiological properties of custom-made frames in Table 1 (in 4.1);

— some re-arrangement of and additional text in 4.2;

— simplification of the text in 4.2 to make it more general, and addition of a note on magnets;

— additional wording has been added to 4.8.3 and 8.5 to emphasize that the apparatus prevents rotational movements of the "fixed" side;

— minor changes to 4.2.1, 6.1, 8.5.2.3, 8.6, 8.7 (with a new Annex D), Clause 9 and 10.3;

— 4.5 has been made optional, while the original 10.5 and 10.6 are now in a Note to 4.2.1;

— a new 10.5 refers to an informative Annex E on frame handling information.

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.

Ophthalmic optics — Spectacle frames — Requirements and test methods

1 Scope

This document specifies fundamental requirements and their test methods for unglazed spectacle frames designed for use with prescription lenses. It is applicable to spectacle frames at the point of sale by the manufacturer or supplier to the retailer.

This document is applicable to:

— all mass-produced spectacle frame types, including rimless mounts, semi-rimless mounts and folding spectacle frames;

— spectacle frames made with additive manufacturing, for example, 3D printing;

— spectacle frames made from natural organic materials;

— the frame or mount of clip-ons designed specifically for attachment to particular models of spectacle frame, but not to their lenses or filters to which ISO 16034 or ISO 12312-1 apply;

— prescription inserts designed for attachment to particular models of, for example, eye protector, sunglass or diving mask.

Parts of this document are applicable to custom-made frames – see 3.1.3 and Table 1.

NOTE See Annex A for recommendations on the design of spectacle frames and terms to be used when describing metal frames.

This document is not applicable to spectacle frames used in eye protection, where ISO 16321-1 applies, or to sunglasses with afocal filters, where ISO 12312-1 applies.

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 105-A02, *Textiles — Tests for colour fastness — Part A02: Grey scale for assessing change in colour*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7998, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary*

ISO 8624, *Ophthalmic optics — Spectacle frames — Measuring system and vocabulary*

ISO 11380, *Optics and optical instruments — Ophthalmic optics — Formers*

ISO 11381, *Ophthalmic optics — Spectacle frames — Screw threads*

EN 16128, *Ophthalmic optics — Reference method for the testing of spectacle frames and sunglasses for Nickel release*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7998 and ISO 8624 and the following 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 General terms

3.1.1
spectacle frame model
spectacle frame produced to a common design, using the same materials (but not necessarily the same pigmentation) and surface treatment

3.1.2
mass-produced frame
frame that is based on standardized dimensions/designs and is typically produced in a continuous production run or homogenous batch

Note 1 to entry: A homogeneous batch will be made to the same specifications using the same machine/ equipment set-up.

Note 2 to entry: A mass-produced frame is not designed for a particular individual, but may have to be adapted to fit the wearer's facial features during dispensing, and will be adapted by fitting it with spectacle lenses.

[SOURCE: Adapted from IMDRF N49:2018, 4.7 and 4.8]

3.1.3
custom-made frame
frame made to a written request from a person authorized by national law for the sole use of a particular individual to address the specific anatomo-physiological features, pathological condition or frame colour or design request of the individual for whom it is intended

Note 1 to entry: Frames that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made.

Note 2 to entry: A custom-made frame is intended for a case where an individual's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an alternative device available on the market.

[SOURCE: IMDRF N49:2018, 4.2, definition abbreviated to fit ISO Rules.]

3.1.4
principal component
<of a frame> rims, bridge, lugs and sides

Note 1 to entry: For a frame of which the front is made of plastic materials, the rims, bridge and lugs can be machined from or moulded in a single piece of material.

3.1.5
trained observer
person trained in the testing of frames who has a binocular decimal visual acuity of at least 1,0 (6/6 or 20/20) and wearing the appropriate refractive correction, if necessary, for the observation distance of the test

[SOURCE: ISO 4007:2018, 3.11.1, modified by replacing "with" by "who has" and "eye and face protectors" with "frames", and the addition of "the" before "testing".]

3.1.6
test lens
lens as described in 6.1 to be mounted into the frame for testing the frame's requirements

3.2 Types of frame

3.2.1
plastics frame
frame of which the *principal components* (3.1.4) of the front are made of a plastics material

3.2.2
frame made of natural organic materials
frame of which the *principal components* (3.1.4) of the frame are made of *natural organic materials* (3.3.1)

Note 1 to entry: For the purposes of terminology, a frame from natural organic materials has the same construction as a plastics frame, the material having some properties similar to those of a plastic material.

3.2.3
metal frame
frame of which the *principal components* (3.1.4) of the frame are made of metal

3.2.4
folding frame
frame hinged at the bridge, and possibly in the sides, so as to fold into a small space

3.2.5
combination frame
frame of which the front and/or sides are made of at least two different categories of material

Note 1 to entry: The *non-principal components* (A.9.2) are excluded from consideration in this definition.

Note 2 to entry: Categories of material include, but are not limited to, metal, plastic and natural organic materials.

Note 3 to entry: This includes the original meaning of the term when the combination depended only on the construction of the front.

3.2.6
mount for rimless and semi-rimless spectacles
mount of which the front is made of metal or of a plastic material or a *natural organic material* (3.3.1) having similar properties, or a combination of both, and in which the lenses are not or only partially surrounded by a protecting rim

3.2.7
mixed frame
frame in which the components liable to come into close and prolonged contact with the skin are made of at least two different categories of material

Note 1 to entry: All components are included, both *principal components* (3.1.4) and *non-principal components* (A.9.2).

Note 2 to entry: Categories of material include, but are not limited to, metal, plastic and natural organic materials.

Note 3 to entry: This definition is used only for descriptions for testing purposes, not for frame categorization when marketing or in catalogues.

3.2.8
clip-on
pair of lenses/filters or a one-piece lens or filter designed to clip on over the front of or behind a pair of spectacles

Note 1 to entry: For the purposes of this document, the term is restricted to designs with a rim that fits on the front.

[SOURCE: ISO 4007:2018, 3.5.1.14, modified by the addition of the note 1 to entry.]

3.2.9
prescription insert
device for carrying prescription lenses that is intended to be attached on the inside of the protector between the eyes of the wearer and the protective lens

Note 1 to entry: Prescription inserts can be used with eye and face protectors for occupational use, sunglasses, diving goggles, augmented reality devices, etc.

[SOURCE: ISO 4007:2018, 3.5.1.15, modified by the addition of the note to entry.]

3.3 Term describing frame materials

3.3.1
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.

3.3.2
rolled-gold covering
covering achieved using a method by which a layer of gold alloy is bonded to a sheet or bar of base metal, the whole then being subjected to reduction by rolling

Note 1 to entry: The proportion of gold is designated by its nominal thickness, in micrometres, and by the fineness of the gold alloy covering the base metal, for example, 40 µm nominal thickness of 500 fineness gold alloy. In accordance with ISO 3160-1, the range of nominal thicknesses, in micrometres, are 5 µm, 10 µm, 20 µm, 40 µm and 80 µm, with a tolerance of –20 %, and the fineness is defined as the proportion of pure gold contained in the gold alloy, normally expressed in thousandths (41,67 thousandths = 1 carat).

Note 2 to entry: To clarify that the frame is made from rolled-gold material, the initials L or RG can also be marked on the frame.

[SOURCE: ISO 3160-1:1998, 3.1, modified by the addition of the notes which have been developed from the standard, including ISO 3160-1:1998, 3.5.]

3.3.3
rolled-gold spectacle frame
frame of which each of the metal *principal components* (3.1.4) is made of a material with a rolled-gold covering

3.3.4
titanium frame
frame of which each of the metal *principal components* (3.1.4) is made of an alloy containing at least 70 % titanium by mass and has a non-nickel containing coating

3.3.5
pure titanium frame
frame of which each of the metal *principal components* (3.1.4) is made of an alloy containing at least 90 % titanium by mass and has a non-nickel containing coating

3.3.6
memory-metal frame
frame of which some of the metal *principal components* (3.1.4) are made of an alloy with specific flexibility characteristics

Note 1 to entry: The rims might be made of monel or similar material, or a titanium alloy.

Note 2 to entry: Some memory-metal alloys contain at least 40 % titanium (mass fraction).

3.3.7
titanium niobium frame
Ti-Nb frame
frame of which some of the metal *principal components* (3.1.4) are made of an alloy containing at least 50 % and less than 70 % titanium by mass and contains the element niobium

Note 1 to entry: Niobium and other elements are included in order to decrease Young's modulus to 80 GPa or less for specific flexibility characteristics. The alloy and its surface coating do not contain the element nickel.

Note 2 to entry: The rims are probably made of titanium, usually β-titanium. β-titanium material is a titanium alloy containing at least 70 % titanium by mass with specific 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 document shall comply with the requirements identified as "general" (g). Requirements marked "O" are optional, but can be required by legislation in some countries.

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 conformity with this document is claimed, the manufacturer or its representative has the responsibility, by any chosen means, 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.

Table 1 — Requirements applicable to different types of spectacle frame

Production method	Frame type	Subclause/Clause[a]													
		4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	9
Mass-produced frame[b]	Mounts for rimless and semi-rimless spectacles	g	g	g	O	g	O	g[c]	O	g	g	g	g	O	g
	Rimmed clip-ons, prescription inserts	g	g	g	O	g	g	g	N	N	g	N	g	O	O
	All other frame types[d]	g	g	g	O	g	g	g	O	g	g	g	g	O	g
Custom-made frame[b]	Mounts for rimless and semi-rimless spectacles	g	g	g	O	g	O	N	O	N	N	N	g	O	O
	Rimmed clip-ons, prescription inserts	g	g	g	O	g	g	O	N	N	N	N	g	O	O
	All other frame types[d]	g	g	g	O	g	g	O	O	N	N	O[e]	g	O	O

Key				
g		Frame type shall meet the requirements of this subclause in order to conform with this document.		
O		Conformity with this subclause is optional.		
N		Not applicable		
4.2		Construction	4.9	Tolerance on screw threads
4.3		Risk analysis	4.10	Dimensional stability at elevated temperature
4.4		Biological compatibility	4.11	Resistance to perspiration
4.5		Nickel release	4.12	Mechanical stability
4.6		Clinical evaluation	4.13	Resistance to ignition
4.7		Measurement system	4.14	Resistance to optical radiation
4.8		Dimensional tolerances on nominal size	Clause 9	Marking

[a] Under European legislation, 4.2, 4.3, 4.4, 4.5, 4.6, 4.9, 4.10, 4.11, 4.12, 4.13 and Clause 9 cover some essential requirements.

[b] The manufacturer shall inform the test laboratory of the production method.

[c] Horizontal boxed lens size is optional for rimless mounts.

[d] "All other frame types" include plastics, metal, combination frames and frames made of natural organic materials, including folding frames, that have a rim that completely surrounds the lens periphery.

[e] Only 4.12.1 and 4.12.2 can be applied.