INTERNATIONAL STANDARD

ISO 18369-2

Second edition
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Ophthalmic optics — Contact lenses —

Part 2: Tolerances

Optique ophtalmique — Lentilles de contact —

Partie 2: Tolérances

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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 18369-2 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 18369-2:2006), of which Clause 7 and Table 4 have been technically revised.

ISO 18369 consists of the following parts, under the general title *Ophthalmic optics — Contact lenses*:

— *Part 1: Vocabulary, classification system and recommendations for labelling specifications*

— *Part 2: Tolerances*

— *Part 3: Measurement methods*

— *Part 4: Physicochemical properties of contact lens materials*

Introduction

ISO 18369 is applicable to contact lenses, which are devices worn over the front surface of the eye in contact with the preocular tear film. This part of ISO 18369 covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers and fluorosiloxanes, etc. Soft contact lenses are easily deformable and require support for proper shape. A very large subset of soft contact lenses consists of transparent hydrogels containing water in concentrations greater than 10 %. Soft contact lenses can also be made of non-hydrogel materials, e.g. flexible polysiloxanes (silicone elastomers).

ISO 18369 is applicable to determining allowable tolerances of parameters and properties important for the proper functioning of contact lenses as optical devices. ISO 18369 includes tolerances for single vision contact lenses, bifocal lenses, lenses that alter the flux density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling and/or opaque tints) and lenses that significantly attenuate ultraviolet radiation (UV-absorbing lenses). ISO 18369 covers contact lenses designed with spherical, toric and aspheric surfaces, and recommended methods for the specification of contact lenses.

Ophthalmic optics — Contact lenses —

Part 2: **Tolerances**

1 Scope

This part of ISO 18369 specifies the tolerance limits of the principal optical and physical parameters of rigid, soft and rigid scleral contact lenses.

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 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-3:2006, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

ISO 18369-4:2006, *Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

4 Tolerances for rigid contact lenses

When tested as described in ISO 18369-3, the dimensional and optical properties of corneal and scleral rigid contact lenses shall be as specified, within the appropriate tolerance limits given in Tables 1 and 2. Each dimension and optical property specified shall be determined using a test method with measurement reproducibility better than one-half the tolerance limit specified for the property. For fenestration, truncation and displacement, measured values shall not differ from the specified values by more than 10 %.

5 Tolerances for soft contact lenses

When tested as described in ISO 18369-3, the dimensional and optical properties for soft contact lenses shall be as specified, within the appropriate tolerance limits given in Table 3. Each dimension and optical property specified shall be determined using a test method with measurement reproducibility better than one-half the tolerance limit specified for the property. For truncation and displacement, measured values shall not differ from the specified values by more than 10 %.

6 Conditioning of contact lenses prior to testing

Contact lenses shall be equilibrated as specified in the relevant test method cited in ISO 18369-3 or as specified by the manufacturer. Lenses made of hydrogel materials shall be equilibrated in the standard saline described in ISO 18369-3 or an equivalent solution for the particular method of measurement.

7 Oxygen permeability (Dk)

Oxygen permeability (Dk) is determined indirectly knowing the oxygen transmissibility (Dk/t) of the material. The tolerance for Dk is ± 20 % for all types and designs of contact lenses. Test methods for oxygen permeability are specified in ISO 18369-4.

8 Transmittance of ultraviolet radiation

For contact lenses claimed to attenuate ultraviolet radiation, total transmittance of ultraviolet radiation through the contact lens shall conform to those amounts specified in Table 4. Such lenses shall be categorized as “Class 1” or “Class 2” absorbers, according to the measured ultraviolet radiation transmittance.

9 Requirements for finish

9.1 General

Acceptance and failure criteria for inclusions, surface imperfections, fenestrations (when indicated), edge contour and finish shall be documented by the manufacturer.

9.2 Inclusions and surface imperfections

When examined as specified in ISO 18369-3, the contact lens shall not exhibit any inclusions or surface imperfections which could interfere with its intended functional use.

9.3 Fenestrations

The front and back edges of the holes shall appear finished in the style specified by the manufacturer when examined under 7× magnification.

9.4 Edge contour and finish

When examined under 7× magnification, the contact lens edge shall meet the quality characteristics described by the manufacturer with respect to shape, smoothness and polish.

10 Additional properties

When a manufacturer claims additional contact lens properties (e.g. aspherical design), the properties shall be described by the manufacturer together with appropriate measurement methods and tolerances.

Table 1 — Dimensional tolerances for rigid contact lenses

Dimensions in millimetres

Property	Tolerance limit			Relevant method
	Corneal contact lens		Scleral contact lens	
	PMMA	Gas permeable		
Back optic zone radius	±0,025	±0,05	±0,10	ISO 18369-3:2006, 4.1
Back optic zone radii of toroidal surfaces [a] [b]				ISO 18369-3:2006, 4.1
where 0 < Δr ≤ 0,2	±0,025	±0,05	±0,12	
where 0,2 < Δr ≤ 0,4	±0,035	±0,06	±0,13	
where 0,4 < Δr ≤ 0,6	±0,055	±0,07	±0,15	
where Δr > 0,6	±0,075	±0,09	±0,17	
Back optic zone diameter [c]	±0,20	±0,20	±0,20	ISO 18369-3:2006, 4.3
Back scleral radius (of preformed lens)	—	—	±0,10	ISO 18369-3:2006, 4.1
Basic or primary optic diameter	—	—	±0,20	ISO 18369-3:2006, 4.3
Back or front peripheral radius (where measurable) [c]	±0,10	±0,10	±0,10	ISO 18369-3:2006, 4.1
Back peripheral diameter [c]	±0,20	±0,20	±0,20 (for preformed lenses)	ISO 18369-3:2006, 4.3
Total diameter [b]	±0,10	±0,10	±0,25	ISO 18369-3:2006, 4.3
Front optic zone diameter [c]	±0,20	±0,20	±0,20	ISO 18369-3:2006, 4.3
Bifocal segment height	−0,10 to +0,20	−0,10 to +0,20	−0,10 to +0,20	ISO 18369-3:2006, 4.3
Centre thickness	±0,02	±0,02	±0,10	ISO 18369-3:2006, 4.4
Vertex clearance from cast (for impression scleral lenses)	—	—	±0,02	ISO 18369-3:2006, 4.1

[a] Δr is the difference between the radii of the two principal meridians.

[b] The tolerance applies to each meridian.

[c] These tolerances apply only to contact lenses with spherical surfaces and distinct curves; they are for a finished contact lens and any blending may make measurement difficult.

Table 2 — Optical tolerances for rigid contact lenses

Dimension	Tolerance limit	Relevant method
Back vertex power in the weaker meridian		ISO 18369-3:2006, 4.2
0 to ±5,00 D	±0,12 D	
over ±5,00 D to ± 10,0 D	±0,18 D	
over ±10,00 D to ± 15,0 D	±0,25 D	
over ±15,00 D to ± 20,0 D	±0,37 D	
over ±20,00 D	±0,50 D	
Prismatic error (measured at geometrical centre of the optic zone)		—
Back vertex power 0 to 6 D	0,25 cm/m	
Back vertex power over 6 D	0,50 cm/m	
Specified prism	±0,25 cm/m	—
Optical centration for scleral lenses only (maximum error)	0,50 mm	ISO 18369-3:2006, 4.3
Cylinder power		ISO 18369-3:2006, 4.2
to 2,00 D	±0,25 D	ISO 18369-3:2006, 4.2
over 2,00 D to 4,00 D	±0,37 D	
over 4,00 D	±0,50 D	
Cylinder axis	±5°	ISO 18369-3:2006, 4.2

Table 3 — Dimensional and optical tolerances for soft contact lenses

Property	Tolerance limits	Relevant method
Back optic zone radius [a] [b]	±0,20 mm	ISO 18369-3:2006, 4.1
Sagitta at specified diameter [a]	±0,05 mm	ISO 18369-3:2006, 4.1
Total diameter	±0,20 mm	ISO 18369-3:2006, 4.3
Optic zone diameter	±0,20 mm	ISO 18369-3:2006, 4.3
Centre thickness [c]		ISO 18369-3:2006, 4.4
$t_C \le 0{,}10$ mm	$\pm[0{,}010 \text{ mm} + 0{,}10\ t_C]$	
$t_C > 0{,}10$ mm	$\pm[0{,}015 \text{ mm} + 0{,}05\ t_C]$	
Back vertex power		ISO 18369-3:2006, 4.2
$\lvert F'_v \rvert \le 10$ D	±0,25 D	
$10 \text{ D} < \lvert F'_v \rvert \le 20$ D	±0,50 D	
$\lvert F'_v \rvert > 20$ D	±1,00 D	
Prismatic error [d]		—
$\lvert F'_v \rvert \le 6$ D	0,25 cm/m	
$\lvert F'_v \rvert > 6$ D	0,50 cm/m	
Prescribed optical prism [e]		—
$\lvert F'_v \rvert \le 6$ D	±0,25 cm/m	
$\lvert F'_v \rvert > 6$ D	±0,50 cm/m	
Prism axis	±5°	

Table 3 *(continued)*

Property	Tolerance limits	Relevant method
Cylinder power		ISO 18369-3:2006, 4.2
$\lvert F'_c \rvert \leq 2$ D	±0,25 D	
2 D < $\lvert F'_c \rvert \leq 4$ D	±0,37 D	
$\lvert F'_c \rvert > 4$ D	±0,50 D	
Cylinder axis	±5°	ISO 18369-3:2006, 4.2

[a] Tolerance is applicable when this property is the one specified by the manufacturer as the expression of the back surface curvature.

[b] Tolerance is applicable when the step between successive back optic zone radii is 0,40 mm or greater. For smaller steps the tolerance is equal to half the design step (e.g. back optic zone radius design step 0,30 mm, tolerance ± 0,15 mm).

[c] Examples of tolerance calculations:

Nominal thickness	Tolerance	
0,035 mm	± [0,010 + 0,004]	= ± 0,014 mm
0,070 mm	± [0,010 + 0,007]	= ± 0,017 mm
0,150 mm	± [0,015 + 0,008]	= ± 0,023 mm
0,300 mm	± [0,015 + 0,015]	= ± 0,030 mm

[d] Prismatic error is measured at the geometrical centre of the optical zone.

[e] The reference for the prism axis in toric lenses is the axis of the base-apex line.

Table 4 — Tolerance limits of material and contact lens physical properties

Property		Tolerance limits		Relevant method
Luminous transmittance (τ_V) [a b]		±5 % absolute [c]		ISO 18369-3:2006, 4.6
Ultraviolet radiation transmittance τ_{UV} [d e]	Class 1 absorber	UVB 280 nm to 315 nm	UVA 316 nm to 380 nm	ISO 18369-3:2006, 4.6
		$\tau_{UVB} < 0{,}01\ \tau_V$	$\tau_{UVA} < 0{,}10\ \tau_V$	
	Class 2 absorber	UVB 280 nm to 315 nm	UVA 316 nm to 380 nm	ISO 18369-3:2006, 4.6
		$\tau_{UVB} < 0{,}05\ \tau_V$	$\tau_{UVA} < 0{,}50\ \tau_V$	
Oxygen permeability (Dk)		±20 % [b]		ISO 18369-2:2006, 7 and ISO 18369-4:2006, 4.4
Refractive index		±0,005 (soft contact lenses) or ± 0,002 (rigid contact lenses)		ISO 18369-4:2006, 4.5
Water content		±2 % absolute [c]		ISO 18369-4:2006, 4.6

[a] τ_V is the luminous transmittance of the contact lens, the average transmittance summated over the wavelengths of the visible spectrum.

[b] The tolerance percentage applies to the property nominal value.

[c] ± x % absolute means that the limit is the declared value ± x %, e.g. 48 % to 52 % for a declared 50 % at ± 2 %, or 80 % to 90 % for a declared 85 % at ± 5 %.

[d] τ_{UVA} and τ_{UVB} are the average ultraviolet radiation transmittances of the contact lens, summated over the wavelengths shown.

[e] This requirement is applicable only to contact lenses for which UV absorption is claimed.

