
**Ophthalmic optics — Contact lenses —
Part 2:
Tolerances**

*Optique ophtalmique — Lentilles de contact —
Partie 2: Tolérances*





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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This third edition cancels and replaces the second edition (ISO 18369-2:2012), which has been technically revised.

A list of all parts in the ISO 18369 series can be found on the ISO website.

Ophthalmic optics — Contact lenses —

Part 2: Tolerances

1 Scope

This document specifies the tolerance limits of the principal optical and physical parameters of rigid corneal, rigid scleral and soft contact lenses at the time of manufacture.

These tolerances might not apply to other purposes, for example, shelf-life studies.

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

ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

ISO 18369-4:2017, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

4 General

4.1 Tolerance limits for contact lenses

When tested as described in ISO 18369-3, the dimensional and optical properties for contact lenses shall be as specified within the appropriate tolerance limits given in [Table 1](#), [Table 2](#) and [Table 3](#).

When tested as described in ISO 18369-4, the material properties for contact lenses shall be as specified, within the appropriate tolerance limits given in [Table 4](#).

4.2 Conformance criteria for testing products

There are three meaningful methods to determine the conformance of contact lens parameters to specified tolerances:

- a) 100 % inspection — a method to determine conformance to a specified value, including tolerances based on evaluation of each item in the population to be evaluated;
- b) acceptance sampling — a method to assign a product to a specified conformance level (e.g. acceptance quality limit and limiting quality);
- c) statistical estimation of performance — process assessment where a representative sample is determined and used to estimate performance.

Conformance can be based on supplier data for lens lots supplied or third-party audits.

4.3 Conditioning of contact lenses prior to testing

Contact lenses shall be equilibrated in standard saline or packaging solution, unless otherwise specified in the relevant test method specified in ISO 18369-3 or ISO 18369-4.

4.4 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.

4.5 Requirements for finish

4.5.1 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.

4.5.2 Fenestrations

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

4.5.3 Edge contour and finish

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

4.6 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.

5 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 [Table 1](#) and [Table 2](#).

For fenestration, truncation and displacement, measured values shall not differ from the specified values by more than 10 %.

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 18369-3:2017, 4.2
Back optic zone radii of toroidal surfaces ^{a,b}				ISO 18369-3:2017, 4.2
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 18369-3:2017, 4.4
Back scleral radius (of preformed lens)	—	—	±0,10	ISO 18369-3:2017, 4.2
Basic or primary optic diameter	—	—	±0,20	ISO 18369-3:2017, 4.4
Back or front peripheral radius (where measurable) ^c	±0,10	±0,10	±0,10	ISO 18369-3:2017, 4.2
Back peripheral diameter ^c	±0,20	±0,20	±0,20 (for preformed lenses)	ISO 18369-3:2017, 4.4
Total diameter ^b	±0,10	±0,10	±0,25	ISO 18369-3:2017, 4.4
Front optic zone diameter ^c	±0,20	±0,20	±0,20	ISO 18369-3:2017, 4.4
Bifocal segment height	−0,10 to +0,20	−0,10 to +0,20	−0,10 to +0,20	ISO 18369-3:2017, 4.4
Centre thickness	±0,02	±0,02	±0,10	ISO 18369-3:2017, 4.5
^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 there is a possibility that any blending makes measurement difficult.				

Table 2 — Optical tolerances for rigid contact lenses

Dimension	Tolerance limit	Relevant method
Label back vertex power (F'_L) in the weaker meridian		
$ F'_L \leq 5,00$ D	$\pm 0,12$ D	ISO 18369-3:2017, 4.3
$5,00$ D < $ F'_L \leq 10,00$ D	$\pm 0,18$ D	
$10,00$ D < $ F'_L \leq 15,00$ D	$\pm 0,25$ D	
$15,00$ D < $ F'_L \leq 20,00$ D	$\pm 0,37$ D	
$ F'_L > 20,00$ D	$\pm 0,50$ D	
Optical centration for scleral lenses only (maximum error)	0,50 mm	ISO 18369-3:2017, 4.4
Cylinder power		
to 2,00 D	$\pm 0,25$ D	ISO 18369-3:2017, 4.3
over 2,00 D to 4,00 D	$\pm 0,37$ D	
over 4,00 D	$\pm 0,50$ D	
Cylinder axis	$\pm 5^\circ$	ISO 18369-3:2017, 4.3

6 Tolerances for soft contact lenses

Contact lenses shall be equilibrated in standard saline or packaging solution unless otherwise stated in the relevant test method specified in ISO 18369-3 or ISO 18369-4.

The results for any test shall include information concerning the solution used (standard saline or packaging solution).

Where a manufacturer is unable to comply with one or more requirements specified in this document, a deviation from this document is permitted provided that there are clinical data (see ISO 11980) and that a risk assessment (see ISO 14971) has been carried out to support the product's safety and performance.

This proviso only applies to stock soft lenses when justified and validated by statements from the manufacturer. It does not apply to custom specified lenses.

A manufacturer may have a lens design including specified tolerances which may differ from those in this document. As part of the design file, the manufacturer will have clinical data and will have carried out a risk assessment.

Table 3 — Parameter tolerances for soft contact lenses

Dimension	Tolerance limits	Relevant method
Back optic zone radius/equivalent posterior radius of curvature/base curve equivalent	$\pm 0,20$ mm	ISO 18369-3:2017, 4.2
Sagitta	$\pm 0,05$ mm ^a	ISO 18369-3:2017, 4.2
Total diameter	$\pm 0,20$ mm	ISO 18369-3:2017, 4.4
Centre thickness, t_C ^b		
$t_C \leq 0,10$ mm	$\pm(0,010 \text{ mm} + 0,10 t_C)$	ISO 18369-3:2017, 4.5
$t_C > 0,10$ mm	$\pm(0,015 \text{ mm} + 0,05 t_C)$	
Label back vertex power (F'_L)		
$ F'_L \leq 10,00$ D	$\pm 0,25$ D	ISO 18369-3:2017, 4.3
$10,00 \text{ D} < F'_L \leq 20,00$ D	$\pm 0,50$ D	
$ F'_L > 20,00$ D	$\pm 1,00$ D	
Cylinder power (F'_c)		
$ F'_c \leq 2,00$ D	$\pm 0,25$ D	ISO 18369-3:2017, 4.3
$2,00 \text{ D} < F'_c \leq 4,00$ D	$\pm 0,37$ D	
$ F'_c > 4,00$ D	$\pm 0,50$ D	
Cylinder axis	$\pm 5^\circ$	ISO 18369-3:2017, 4.3
^a The sagitta tolerance is only applicable when this parameter is the one used to describe the posterior surface of the lens.		
^b Examples of tolerance calculations:		
Nominal thickness	Tolerance	
0,035 mm	$\pm[0,010 + 0,004] = \pm 0,014$ mm	
0,070 mm	$\pm[0,010 + 0,007] = \pm 0,017$ mm	
0,150 mm	$\pm[0,015 + 0,008] = \pm 0,023$ mm	
0,300 mm	$\pm[0,015 + 0,015] = \pm 0,030$ mm	

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

Property		Tolerance limits		Relevant method
Spectral transmittance in the visible region (τ_{VIS}) ^{a,b}		±5 % absolute ^c		ISO 18369-3:2017, 4.8
Ultraviolet radiation transmittance ^{d,e}	Class 1 absorber	UVB 280 nm to 315 nm	UVA 315 nm to 380 nm	ISO 18369-3:2017, 4.8
		$\tau_{UVB} < 1,0 \%$	$\tau_{UVA} < 10,0 \%$	
	Class 2 absorber	UVB 280 nm to 315 nm	UVA 315 nm to 380 nm	ISO 18369-3:2017, 4.8
		$\tau_{UVB} < 5,0 \%$	$\tau_{UVA} < 50,0 \%$	
Oxygen permeability (<i>Dk</i>)		±20 % ^b		ISO 18369-4:2017, 4.4
Refractive index		±0,005 (soft contact lenses) ±0,002 (rigid contact lenses)		ISO 18369-4:2017, 4.5
Water content		±2 % absolute ^c		ISO 18369-4:2017, 4.6
^a τ_{VIS} is the spectral transmittance of the contact lens, the average transmittance summated over the wavelengths of the visible spectrum (380 nm to 780 nm).				
^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_{UVB} and τ_{UVA} 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.				

Bibliography

- [1] ISO 11980, *Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations*
- [2] ISO 14534, *Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements*
- [3] ISO 14971, *Medical devices — Application of risk management to medical devices*

