INTERNATIONAL STANDARD

**ISO 8321-1**

Second edition
2002-09-15

# Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses —

## Part 1: **Rigid corneal and scleral contact lenses**

*Optique ophtalmique — Spécifications relatives aux propriétés des matériaux et aux propriétés optiques et dimensionnelles des lentilles de contact —*

*Partie 1: Lentilles cornéennes et verres scléraux rigides*



Reference number
ISO 8321-1:2002(E)

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Printed in Switzerland

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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 3.

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 part of ISO 8321 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8321-1 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 8321-1:1991), which has been technically revised to include requirements for refractive index, transmittance and oxygen permeability and transmissibility and to include reference to International Standards providing relevant test methods.

ISO 8321 consists of the following parts, under the general title *Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses*:

— *Part 1: Rigid corneal and scleral contact lenses*

— *Part 2: Single-vision hydrogel contact lenses*

Annex A of this part of ISO 8321 is for information only.

# Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses —

## Part 1: Rigid corneal and scleral contact lenses



## 1 Scope

This part of ISO 8321 specifies requirements for rigid corneal and scleral contact lenses including tolerance limits for material, optical and dimensional properties.

A method for presenting the specification of contact lenses is described in annex A.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8321. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8321 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8320-1:—[1)], *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses*

ISO 8320-2, *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products*

ISO 8599, *Optics and optical instruments — Contact lenses — Determination of the spectral and luminous transmittance*

ISO 9337-1, *Contact lenses — Determination of back vertex power — Part 1: Method using focimeter with manual focusing*

ISO 9338, *Optics and optical instruments — Contact lenses — Determination of the diameters*

ISO 9339-1, *Optics and optical instruments — Contact lenses — Determination of the thickness — Part 1: Rigid contact lenses*

ISO 9340, *Optics and optical instruments — Contact lenses — Determination of strains for rigid contact lenses*

ISO 9341, *Optics and optical instruments — Contact lenses — Determination of inclusions and surface imperfections for rigid contact lenses*

ISO 9913-1, *Optics and optical instruments — Contact lenses — Part 1: Determination of oxygen permeability and transmissibility by the FATT method*

1) To be published.

ISO 9913-2, *Optics and optical instruments — Contact lenses — Part 2: Determination of oxygen permeability and transmissibility by the coulometric method*

ISO 9914, *Optics and optical instruments — Contact lenses — Determination of refractive index of contact lens materials*

ISO 10338, *Optics and optical instruments — Contact lenses — Determination of curvature*

## 3 Terms and definitions

For the purposes of this part of ISO 8321, the terms and definitions given in ISO 8320-1 and ISO 8320-2 apply.

## 4 Requirements for dimensions and optical properties

### 4.1 Tolerances

When tested as described in 4.2 and 4.3, the dimensional and optical properties shall be as specified, within the appropriate tolerance limits given in Tables 1 and 2, and the material physical properties as given in Table 3.

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

### 4.2 Test methods

Each dimension and optical property specified shall be determined using a test method with a measurement tolerance limit better than one-half the tolerance limit specified for the property.

The International Standards which specify the relevant test methods are listed in Tables 1, 2 and 3.

### 4.3 Conditioning of contact lenses prior to testing

Contact lenses shall be equilibrated as specified in the relevant test method or as stated by the manufacturer.

### 4.4 Additional properties

When a manufacturer claims additional contact lens properties (e.g. aspherical design), he should describe these properties, where possible, together with appropriate measurement methods and the tolerances.

## 5 Requirements for finish

### 5.1 Inclusions and surface imperfections

When examined as specified in ISO 9341, the contact lens shall not exhibit any inclusions or surface imperfections which could interfere with its intended functional use.

### 5.2 Strains

When examined as specified in ISO 9340, the corneal contact lens or its shell, or the corneal portion of a scleral contact lens or its shell, shall appear uniform, not counting the marginal zone of not more than 0,3 mm wide.



 

### 5.3 Fenestrations

The front and back edges of the holes shall appear finished in the style specified by the manufacturer when examined under 5 × magnification.

### 5.4 Edge contour and finish

When examined under 6 × magnification, the contact lens edge shall meet the quality characteristics described by the manufacturer with respect to shape, smoothness and polish.

**Table 1 — Dimensional tolerances of corneal contact lenses and scleral contact lenses**

Dimensions in millimetres

| Property | Tolerance limits | | | Relevant standard |
|---|---|---|---|---|
| | Corneal contact lens | | Scleral contact lens | |
| | PMMA | Gas permeable | | |
| Back optic zone radius | ± 0,025 | ± 0,05 | ± 0,10 | ISO 10338 |
| Back optic zone radii of toroidal surfaces [a, b] | | | | |
| where 0 < $\Delta r \leqslant$ 0,2 | ± 0,025 | ± 0,05 | ± 0,12 | |
| where 0,2 < $\Delta r \leqslant$ 0,4 | ± 0,035 | ± 0,06 | ± 0,13 | |
| where 0,4 < $\Delta r \leqslant$ 0,6 | ± 0,055 | ± 0,07 | ± 0,15 | |
| where $\Delta r$ > 0,6 | ± 0,075 | ± 0,09 | ± 0,17 | |
| Back optic zone diameter [c] | ± 0,20 | ± 0,20 | ± 0,20 | |
| Back scleral radius (of preformed lens) | — | — | ± 0,10 | |
| Basic or primary optic diameter | — | — | ± 0,20 | |
| Back or front peripheral radius (where measurable) | ± 0,10 | ± 0,10 | ± 0,10 | |
| Back peripheral diameter [c] | ± 0,20 | ± 0,20 | ± 0,20 (for preformed lenses) | |
| Total diameter [b] | ± 0,10 | ± 0,10 | ± 0,25 | ISO 9338 |
| Front optic zone diameter [c] | ± 0,20 | ± 0,20 | ± 0,20 | |
| Bifocal segment height* | − 0,10 to + 0,20 | − 0,10 to + 0,20 | − 0,10 to + 0,20 | |
| Centre thickness | ± 0,02 | ± 0,02 | ± 0,10 | ISO 9339-1 |
| Vertex clearance from cast (for impression scleral lenses) | — | — | ± 0,02 | |

a $\Delta r$ 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.

* This value is currently under review by an ad hoc project group.

**Table 2 — Optical tolerances of corneal contact lenses and scleral contact lenses**

| Dimension | Tolerance limits | Relevant standard |
|---|---|---|
| Back vertex power in the weaker meridian | | ISO 9337-1 |
| 0 to ± 5,00 D | ± 0,12 D | |
| over ± 5,00 D to ± 10,00 D | ± 0,18 D | |
| over ± 10,00 D to ± 15,00 D | ± 0,25 D | |
| over ± 15,00 D to ± 20,00 D | ± 0,37 D | |
| over ± 20,00 D | ± 0,50 D | |
| Prismatic error<br>(measured at geometrical centre of the optic zone) | | |
| Back vertex power 0 to 6 D | 0,25 Δ | |
| Back vertex power over 6 D | 0,50 Δ | |
| Specified prism | ± 0,25 Δ | |
| Optical centration for scleral lenses only (maximum error) | 0,50 mm | |
| Cylinder power | | |
| to 2,00 D | ± 0,25 D | |
| over 2,00 D to 4,00 D | ± 0,37 D | |
| over 4,00 D | ± 0,50 D | |
| Cylinder axis | ± 5° | |

**Table 3 — Tolerance limits of material and contact lens physical properties**

| Property | | Tolerance limits | | Relevant standard |
|---|---|---|---|---|
| Refractive index | | ± 0,002 | | ISO 9914 |
| Luminous transmittance $\tau_v$ [a, b] | | ± 5 % absolute [c] | | ISO 8599 |
| UV radiation transmittance $\tau_{uv}$ [d, e] | Class 1 absorber | UV-A<br>316 nm to 380 nm | UV-B<br>280 nm to 315 nm | ISO 8599 |
| | | $\tau_{uv} < 0{,}10\ \tau_v$ | $\tau_{uv} < 0{,}01\ \tau_v$ | |
| | Class 2 absorber | UV-A<br>316 nm to 380 nm | UV-B<br>280 nm to 315 nm | ISO 8599 |
| | | $\tau_{uv} < 0{,}50\ \tau_v$ | $\tau_{uv} < 0{,}05$ | |
| Oxygen permeability and transmissibility [b] | | ± 20 % | | ISO 9913 (both parts) |

[a] $\tau_v$ is the luminous transmittance of the contact lens. It is an average transmission summated over the wavelengths of the visible spectrum.

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

[c] $\pm x$ % absolute means that the tolerance limit is the declared value $\pm x$ %, e.g. 45 % to 55 %, 80 % to 90 %.

[d] $\tau_{uv}$ is the ultraviolet radiation transmittance of the contact lens. It is an average transmission summated over the wavelengths shown.

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

# Annex A
(informative)

# Recommended method for presenting the specification of rigid contact lenses

## A.1 General

The contact lens is viewed from the front, as if on the eye.

All linear dimensions are in millimetres (mm).

Additional specific requirements, such as degree of blending of transitions, edge form and material tint, may be included as “Additional notes” to the specification.

Front surface geometry and thicknesses are not always included in the specification. In such instances, the manufacturer will need to allocate appropriate values to these parameters.

The specification may include a description of the material from which the contact lens is to be fabricated.

Examples of the method of presenting specifications are given in A.2.

## A.2 Examples

### A.2.1 Example 1: Tri-curve corneal contact lens with fenestration

| $r_0$ | | $\varnothing_0$ | | $r_1$ | | $\varnothing_1$ | | $r_2$ | | $\varnothing_T$ | $F'_V$ |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 7,60 | : | 7,00 | / | 8,30 | : | 8,80 | / | 12,25 | : | 9,20 | – 6,00 |
| (see Note 1) | | (see Note 2) | | (see Note 3) | | (see Note 4) | | (see Note 5) | | (see Note 6) | (see Note 7) |

or

| | | | | |
|---|---|---|---|---|
| $r_0$ | 7,60 | : | 7,00 | $\varnothing_0$ |
| $r_1$ | 8,30 | : | 8,80 | $\varnothing_1$ |
| $r_2$ | 12,25 | : | 9,20 | $\varnothing_T$ |
| $F'_V$ | | – 6,00 | | (see Note 7) |
| $\varnothing_{a0}$ | | 7,40 | | (see Note 8) |
| $t_c$ | | 0,10 | | (see Note 9) |

1 fenestration 0,3 mm, 2 mm from edge (see Note 10).

or

| | | | |
|---|---|---|---|
| $r_0$ | 7,60 | | (see Note 1) |
| $F'_V$ | – 6,00 | | (see Note 7) |
| $\varnothing_T$ | 9,20 | | (see Note 6) |
| $t_c$ | 0,10 | | (see Note 9) |
| $r_1$ | 8,30/7,00 | $\varnothing_0$ | (see Notes 2, 3 and 11) |
| $r_2$ | 12,25/8,80 | $\varnothing_1$ | (see Notes 4, 5 and 11) |
| $\varnothing_{a0}$ | 7,40 | | (see Note 8) |

NOTE 1 This is the back optic zone radius ($r_0$).

NOTE 2 This is the back optic zone diameter ($\varnothing_0$).

NOTE 3 This is the first back peripheral radius ($r_1$).

NOTE 4 This is the first back peripheral diameter ($\varnothing_1$).

NOTE 5 This is the second back peripheral radius ($r_2$).

NOTE 6 This is the total diameter ($\varnothing_T$).

NOTE 7 This is the back vertex power in air.

NOTE 8 This is the specified value of front of the optic zone diameter.

NOTE 9 This is the specified value of the centre thickness.

NOTE 10 This is the specified fenestration, hole diameter 0,3 mm, hole centre 2 mm from edge of the contact lens.

NOTE 11 In this form of the specification only, the radius and width of the peripheral curves may be specified; in this example as 8,30/0,9 and 12,25/0,2 respectively.



### A.2.2 Example 2: Corneal contact lens with a back toroidal surface and a spherical front surface

| $r_0$ | | $\varnothing_0$ | | $r_1$ | | $\varnothing_1$ | | $r_2$ | | $\varnothing_2$ | | $r_3$ | | $\varnothing$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $\frac{8,20}{7,60}$ | : | 7,50 | / | $\frac{8,70}{8,10}$ | : | 8,30 | / | $\frac{9,20}{8,60}$ | : | 9,10 | / | $\frac{9,70}{9,10}$ | : | 9,50 |

(see Note 12)

+ 0,75 along 8,20 radius (see Note 13).

or

| | | |
|---|---|---|
| $r_0$ | 8,20/7,60 | (see Note 12) |
| | + 0,75 | (see Note 13) |
| $\varnothing$ | 9,50 | |
| $t_c$ | 0,15 | |
| $r_1$ | 8,70/8,10 | |
| $\varnothing_0$ | 7,50 | |
| $r_2$ | 9,20/8,60 | |
| $\varnothing_1$ | 8,30 | |
| $r_3$ | 9,70/9,10 | |
| $\varnothing_2$ | 9,10 | |

NOTE 12 A toroidal surface is specified by the radii of curvature in its two principal meridians, the radius in the flatter meridian being written first, or above the line, and the radius in the steeper meridian second, or below it. The zone diameter is specified for the flatter principal meridian.

NOTE 13 The back vertex power in air is specified along the flatter principal meridian.

### A.2.3 Example 3: Peripheral back toric contact lens

| | | | | | |
|---|---|---|---|---|---|
| $r_0$ | 7,80 | : | 7,00 | $\varnothing_0$ | |
| $r_1$ | $\frac{8,80}{8,20}$ | : | 8,40 | $\varnothing_{01}$ | (see Note 14) |
| $r_2$ | $\frac{11,00}{10,40}$ | : | 9,00 | $\varnothing_T$ | |

$F'_V = +\,15,00$ (see Note 15)

$\varnothing_{a0} = 7,40$ (see Note 16)

or

| | | |
|---|---|---|
| 7,80<br>+ 15,00 | $r_0$ | (see Note 15) |
| 9,00 | $\varnothing_T$ | |
| 0,25 | $t_c$ | |
| 8,80/8,20 | $r_1$ | (see Note 14) |
| 7,00 | $\varnothing_0$ | |
| 11,00/10,40 | $r_2$ | |
| 8,40 | $\varnothing_1$ | |

$\varnothing_{a0} = 7,40$ (see Note 16)

NOTE 14 The toroidal peripheral surface is specified by the radii of curvature in its two principal meridians. The zone diameter is specified for the flatter principal meridian.

NOTE 15 This is the back vertex power in air.

NOTE 16 This is the specified value of the front optic zone diameter.

### A.2.4 Example 4: Front toric corneal contact lens

| $r_0$ | | $\varnothing_0$ | | $r_1$ | | $\varnothing_1$ | | $r_2$ | | $\varnothing_T$ |
|---|---|---|---|---|---|---|---|---|---|---|
| 7,95 | : | 7,60 | / | 9,20 | : | 8,80 | / | 11,00 | : | 9,30 |

– 3,50/– 1,50 × 180 1,5Δ Base 280°

$t_c$ = 0,30

or

| | |
|---|---|
| 7,95 | $r_0$ |
| – 3,50/– 1,50 × 180 | (see Note 17) |
| 9,30 | $\varnothing_T$ |
| 0,30 | $t_c$ |
| 9,20/7,60 | $r_1/\varnothing_0$ |
| 11,00/8,80 | $r_2/\varnothing_1$ |
| 1,5 Δ Base 280° | (see Note 18) |

NOTE 17 This is the back vertex power in air.

NOTE 18 The is the power and orientation of the specified prism. It is assumed that in wear the prism will locate with its base downwards (i.e. at 280°).

### A.2.5 Example 5: Bitoric corneal contact lens

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| C3 | 8,00 | : | 7,50 | / | 9,95 | : | 9,00 | / | 12,75 | : | 9,50 |
| | 7,40 | | | | 8,85 | | | | 10,65 | | |

– 4,00 along 8,00 radius (see Note 19).

Work + 1,50 cylinder having its axis parallel to 8,00 radius to give final back vertex powers in air of – 4,00 and – 2,50 (see Note 20).

or

8,00/7,40
– 4,00/+ 1,50 (see Note 21)
9,50
0,15
9,95/8,85
7,50
12,75/10,75
9,00

NOTE 19 The back vertex power in air is specified along the flatter meridian.

NOTE 20 The front surface cylinder axis is specified in relation to the flatter meridian.

NOTE 21 The back vertex power in air is specified in sphere/cylinder form, the flatter principal meridian being taken as the axis of the cylinder.

## A.2.6 Bifocal contact lenses

### A.2.6.1 General

Unless the segment(s) specified are circular, a diagram should be included in the prescription.

### A.2.6.2 Example 6: Solid front surface concentric bifocals (see Figure A.1)

8,10:8,00
8,80:8,80
10,75:9,20
+ 2,50 Add + 2,00 (see Note 22).
Central segment 3,00 mm diameter (see Note 23).

NOTE 22 This is the back vertex power in air of the distance portion together with the near addition.

NOTE 23 This is the diameter of the distance portion.

Dimensions in millimetres

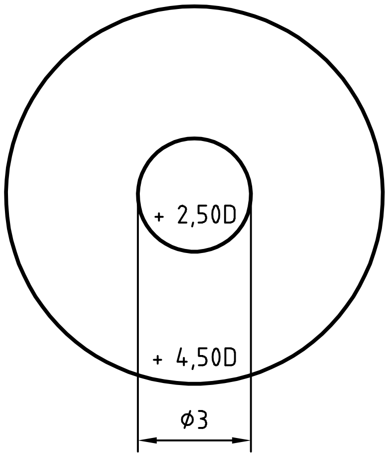


**Figure A.1 — Example 6** (A.2.6.2)

**A.2.6.3 Example 7: Fused crescent segment bifocals** (see Figure A.2)

7,85:8,00

8,60:9,00

9,70:10,00

| | | |
|---|---|---|
| + 1,50 | Add + 2,00 | (see Note 24) |
| 1,5 Δ | Base 270° | (see Note 25) |

or

7,85

+ 1,50

10,00

0,30

8,60/8,00

9,70/9,00

| | | | |
|---|---|---|---|
| Add + 2,00 | 1,5Δ | Base 90° | (see Note 25) |

Segment 7,5 mm, wide, height 3,75 mm (see Note 26).

Truncate 0,75 mm along 5 inferior (see Note 27).

NOTE 24 This is the back vertex power of the distance portion, together with the near addition.

NOTE 25 This is the specified prism.

NOTE 26 This is the segment size and position.

NOTE 27 This is the specified truncation.