INTERNATIONAL STANDARD

ISO 8321-1

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Optics and optical instruments — Contact lenses —

Part 1: Specification for rigid corneal and scleral contact lenses

Optique et instruments d'optique — Lentilles de contact —
Partie 1: Spécification des lentilles cornéennes et des verres scléraux rigides

Reference number
ISO 8321-1:1991(E)

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.

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.

International Standard ISO 8321-1 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Sub-Committee SC 8, *Ophthalmic optics*.

ISO 8321 consists of the following parts, under the general title *Optics and optical instruments — Contact lenses*:

— *Part 1: Specification for rigid corneal and scleral contact lenses*

— *Part 2: Specification for soft corneal and scleral contact lenses*

Annexes A and B of this part of ISO 8321 are for information only.

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Optics and optical instruments — Contact lenses —

Part 1:
Specification for rigid corneal and scleral contact lenses

1 Scope

This part of ISO 8321 specifies requirements for contact lenses as supplied by a manufacturer according to a prescription from a practitioner. A recommended method for presenting the prescription of contact lenses is described in annex A.

This part of ISO 8321 applies to rigid corneal and scleral contact lenses including those manufactured of gas permeable materials. It does not apply to soft contact lenses in a dry state. Annex B covers related aspects that cannot be the basis for requirements in this part of ISO 8321.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8321. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8321 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols.*

ISO 9340:—[1], *Optics and optical instruments — Contact lenses — Determination of strains.*

ISO 9341:—[1], *Optics and optical instruments — Contact lenses — Determination of inclusions and surface imperfections.*

3 Definitions

For the purposes of this part of ISO 8321, the definitions given in ISO 8320 apply.

4 Recommendation for method of prescription

The prescription for each lens is assumed to be in accordance with the recommended method described in annex A .

5 Requirements for dimensions and optical properties

5.1 Tolerances

When tested as described in 5.2 and 5.3 the dimensional and optical properties shall be as prescribed, within the appropriate tolerances detailed in tables 1 and 2.

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

1) To be published.

5.2 Methods of test

Each dimension and optical property specified shall be determined using a calibrated measuring instrument with a precision better than one-half of the tolerance specified for the property.

5.3 Test environment

Lenses shall be tested while in the physico-chemical environment stated by the manufacturer (see clause 8).

Table 1 — Dimensional tolerances of corneal lenses and scleral lenses

Dimensions in millimetres

Dimension	Corneal		Scleral
	Poly(methyl methacrylate) [PMMA]	Gas permeable	
Back optic zone radius	±0,025	±0,05	±0,010
Back optic zone radii of toroidal surfaces (see notes 1 and 2)			
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 (see note 3)	±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 (see note 3)	±0,20	±0,20	±0,20 (for preformed lenses)
Total diameter (see note 2)	±0,10	±0,10	±0,25
Front optic zone diameter (see note 3)	±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
Vertex clearance from cast (for impression scleral lenses)	—	—	±0,02

NOTES

1 Δr is the difference between the radii of the two principal meridians.

2 The tolerance applies to each meridian.

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

6 Requirements for finish

6.1 Inclusions and surface imperfections

When examined as described in ISO 9341, the lens shall be free of inclusions or surface imperfections which interfere with its intended functional use.

6.2 Strain

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

6.3 Fenestrations

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

6.4 Edge profile

When examined under × 10 magnification, the edge profile shall appear to be as prescribed, uniform in section and free from blemishes.

7 Requirements for delivey of lenses from the manufacturer to the practitioner

7.1 Lenses shall be delivered in the state most appropriate for their intended functional use.

7.2 The manufacturer shall label the immediate container with at least the following information:

a) the lens prescription;

b) the lens batch code.

Table 2 — Optical tolerances of corneal lenses and scleral lenses

Dimension	Corneal or scleral (including gas permeable)
Back vertex power in the weaker meridian	
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 (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
Prescribed prism	± 0,25 Δ
Optical centration for scleral lenses only (maximum error)	0,50 mm
Cylinder power	
up 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°

8 Information provided by the manufacturer to the practitioner

The following additional information shall be provided by the manufacturer to the practitioner:

a) the solution, if any, in which the lens is delivered;

b) whether sterile;

c) the type of material of which the lens is made;

d) the methods recommended by the manufacturer for the practitioner's and patient's use for cleaning, disinfection and storage of the lens;

e) the recommended conditions of testing and measurement, if different from those specified in the relevant International Standards;

f) where appropriate, the expiry date or the date of manufacture.

Annex A
(informative)

Recommended method for presenting the prescription of contact lenses

A.1 General

The 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, are included as "Additional Notes".

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

The prescription prescribes the material from which the lens is to be fabricated.

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

A.2 Examples

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

r_0		ϕ_0	/	r_1	:	ϕ_1	/	r_2	:	ϕ_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	ϕ_0
r_1	8,30 :	8,80	ϕ_1
r_2	12,25 :	9,20	ϕ_T
F'_v	−6,00		(see note 7)
ϕ_{a_0}	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)
ϕ_T	9,20		(see note 6)
t_c	0,10		(see note 9)
r_1	8,30/7,00	ϕ_0	(see notes 2, 3 and 11)
r_2	12,25/8,70	ϕ_1	(see notes 4, 5 and 11)
ϕ_{a_0}	7,40		(see note 8)

NOTES

1 Back optic zone radius (r_0).

2 Back optic zone diameter (ϕ_0).

3 First back peripheral radius (r_1).

4 First back peripheral diameter (ϕ_1).

5 Second back peripheral radius (r_2).

6 Total diameter (ϕ_T).

7 Back vertex power in air.

8 Prescribed value of front of optic zone diameter.

9 Prescribed value of centre thickness.

10 Prescribed fenestration, hole diameter 0,3 mm, hole centre 2 mm from edge of lens.

11 In this form of the specification **only**, the radius and width of the peripheral curves may be specified; in this example as 8,30/0,90 and 12,25/0,20 respectively.

A.2.2 Example 2: Corneal lens with a back toroidal surface

r_0		ϕ_0		r_1		ϕ_1		r_2		ϕ_2		r_3		ϕ
8,20 / 7,60	:	7,50	/	8,70 / 8,10	:	8,30	/	9,20 / 8,60	:	9,10	/	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)
ϕ	9,50	
t_c	0,15	
r_1	8,70/8,10	
ϕ_0	7,50	
r_2	9,20/8,60	
ϕ_1	8,30	
r_3	9,70/9,10	
ϕ_2	9,10	

NOTES

12 A toroidal surface is prescribed 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.

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

A.2.3 Example 3: Peripheral back toric lens

r_0	7,80	:	7,00	ϕ_0	
r_1	8,80 / 8,20	:	8,40	ϕ_{01}	(see note 14)
r_2	11,00 / 10,40	:	9,00	ϕ_T	

$F'_v = +15{,}00$ (see note 15)

$\phi_{a_0} = 7{,}40$ (see note 16)