INTERNATIONAL STANDARD

ISO 8321-2

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

Part 2: Single-vision hydrogel contact lenses

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

Partie 2 : Lentilles de contact en hydrogel unifocales

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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.

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.

International Standard ISO 8321-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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 2: Single-vision hydrogel contact lenses

1 Scope

This part of ISO 8321 specifies requirements for hydrated single-vision hydrogel 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 ISO and IEC maintain registers of currently valid International Standards.

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

ISO 8599:1994, *Optics and optical instruments — Contact lenses — Determination of the spectral and luminous transmittance*.

ISO 9337-1:1999, *Contact lenses — Determination of back vertex power — Part 1: Method using focimeter with manual focusing*.

ISO 9338:1996, *Optics and optical instruments — Contact lenses — Determination of the diameters*.

ISO 9339-2:1998, *Optics and optical instruments — Contact lenses — Determination of thickness — Part 2: Hydrogel contact lenses*.

ISO 9913-1:1996, *Optics and optical instruments — Contact lenses — Part 1: Determination of oxygen permeability and transmissibility with the FATT method*.

ISO 9914:1995, *Optics and optical instruments — Contact lenses — Determination of refractive index of contact lens materials*.

ISO 10338:1996, *Optics and optical instruments — Contact lenses — Determination of curvature*.

ISO 10339:1997, *Ophthalmic optics — Contact lenses — Determination of water content of hydrogel lenses*.

ISO 10344:1996, *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing*.

[1] To be published. (Revision of ISO 8320:1986)

3 Terms and definitions

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

4 Requirements for dimensions and optical properties

4.1 Test methods

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

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

4.2 Conditioning of contact lenses prior to testing

Contact lenses shall be conditioned in accordance with the relevant test method.

4.3 Tolerances

When tested as described in 4.1 and 4.2 the dimensional and optical properties shall be as specified, within the appropriate tolerance limits given in Table 1 and the material physical properties as given in Table 2.

5 Requirement for finish

5.1 Criteria

Acceptance and failure criteria for inclusions, surface imperfections, edge contour and finish shall be documented by the manufacturer.

5.2 Inclusions and surface finish

When examined at ×10 magnification in standard saline solution according to ISO 10344, the contact lens shall not exhibit any inclusions or surface imperfections which could interfere with its intended functional use.

5.3 Edge contour and finish

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

Table 1 — Dimensional and optical tolerances

Property	Tolerance limits	Relevant International Standard
Back optic zone radius [a] [b]	± 0,20 mm	ISO 10338
Sagitta at specified diameter [a]	± 0,05 mm	ISO 10338
Total diameter	± 0,20 mm	ISO 9338
Optic zone diameter	± 0,20 mm	ISO 9338
Centre thickness $\leqslant$ 0,10 mm > 0,10 mm	 ± [0,010 mm + 0,10 t_c] [c] ± [0,015 mm + 0,05 t_c] [c]	ISO 9339-2
Back vertex power $\lvert F'_v \rvert \leqslant 10$ D 10 D < $\lvert F'_v \rvert \leqslant 20$ D $\lvert F'_v \rvert > 20$ D	 ± 0,25 D ± 0,50 D ± 1,00 D	ISO 9337-1
Prismatic error [d] $\lvert F'_v \rvert \leqslant 6$ D $\lvert F'_v \rvert > 6$ D	 0,25 cm/m 0,50 cm/m	ISO 9337-1
Specified optical prism [e] $\lvert F'_v \rvert \leqslant 6$ D $\lvert F'_v \rvert > 6$ D Direction of specified optical prism	 ± 0,25 cm/m ± 0,50 cm/m ± 5°	ISO 9337-1
Cylinder power $\lvert F'_c \rvert \leqslant 2$ D 2 D < $\lvert F'_c \rvert \leqslant 4$ D $\lvert F'_c \rvert > 4$ D	 ± 0,25 D ± 0,37 D ± 0,50 D	
Direction of cylinder axis	± 5°	

[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] = ± 0,03 mm

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

[e] The reference for the prismatic direction in toric lenses is the basic axis on apex.

Table 2 — Tolerance limits of material and contact lens physical properties

Property		Tolerance limits		Relevant International Standard
Refractive index		± 0,005		ISO 9914
Luminous transmittance (τ_V) [a, b]		± 5 % absolute [c]		ISO 8599
Ultraviolet radiation transmittance τ_{UV} [d, e]	Class 1 absorber	UV - B 280 nm to 315 nm	UV - A 316 nm to 380 nm	ISO 8599
		$\tau_{UV} < 0,01\ \tau_V$	$\tau_{UV} < 0,10\ \tau_V$	
	Class 2 absorber	UV - B 280 nm to 315 nm	UV - A 316 nm to 380 nm	
		$\tau_{UV} < 0,05\ \tau_V$	$\tau_{UV} < 0,50\ \tau_V$	
Water content [b]		± 2 % absolute [c]		ISO 10339
Oxygen permeability [b]		± 20 %		ISO 9913-1

[a] τ_V is the luminous transmittance of the contact lens. It is an average transmittance summed 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. 45 % to 55 %, 80 % to 90 %.

[d] τ_{UV} is the ultraviolet radiation transmittance of the contact lens. It is an average transmittance summed 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 specifications of single-vision hydrogel contact lenses

A.1 General

Hydrogel contact lenses are at times available in a limited range of parameters. The range of parameters corresponds to a standard contact lens design. The specifications of a hydrogel contact lens should give the contact lens type and the relevant dimensions necessary to uniquely identify the contact lens. In the specifications of a non-standard contact lens design, all the parameters necessary to define that contact lens should be specified. Examples of the method of presenting specifications are given in clause A.2.

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

All linear dimensions are given 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.

A.2 Examples

A.2.1 Example 1: Bicurve hydrogel contact lens

r_0	:	$Ø_0$	/	r_1	:	$Ø_T$	/	F'_v
8,80		12,00		9,50		14,00		– 4,00
(see note 1)		(see note 2)		(see note 3)		(see note 4)		(see note 5)

or

r_0	8,80	:	$Ø_0$	12,00
r_1	9,50	:	$Ø_T$	14,00
F'_v	– 4,00			(see note 5)
$Ø_{ao}$	8,00			(see note 6)
t_c	0,06			(see note 7)

NOTE 1 Back optic zone radius (r_0)

NOTE 2 Back optic zone diameter ($Ø_0$)

NOTE 3 First back peripheral radius (r_1)