



SLOVENSKI STANDARD
SIST EN ISO 8321-1:2000
01-januar-2000

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Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses (ISO 8321-1:1991)

Optik und optische Instrumente - Kontaktlinsen - Teil 1: Grundanforderungen für harte Korneal- und Skleralkontaktlinsen (ISO 8321-1:1991)

Optique et instruments d'optique - Lentilles de contact - Partie 1: Spécification des lentilles cornéennes et des verres scléreaux rigides (ISO 8321-1:1991)

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Ta slovenski standard je istoveten z: EN ISO 8321-1:1996

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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EUROPEAN STANDARD

EN ISO 8321-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 1996

ICS 11.040.70

Descriptors: See ISO document

English version

**Optics and optical instruments - Contact lenses -
Part 1: Specification for rigid corneal and scleral
contact lenses (ISO 8321-1:1991)**

Optique et instruments d'optique - Lentilles de contact - Partie 1: Spécification des lentilles cornéennes et des verres scléraux rigides (ISO 8321-1:1991)

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REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZNANOST IN TEHNOLOGIJO
Urad RS za standardizacijo in meroslovje
LJUBLJANA

SIST.....EN ISO 8321-1.....

PREVZET PO METODI RAZGLASITVE

-01- 2000

This European Standard was approved by CEN on 1996-07-26. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard from ISO/TC 172 „Optics and optical instruments“ of the International Organization for Standardization (ISO) has been taken over as a European Standard by the Technical Committee CEN/TC 170 „Ophthalmic optics“, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 1997, and conflicting national standards shall be withdrawn at the latest by February 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom

Endorsement notice

The text of the International Standard ISO 8321-1:1991 was approved by CEN as a European Standard with Annex ZA (informative).

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ANNEX ZA (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptré" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Measures).

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Identification of the regulation: **(standards.iteh.ai)**

Gesetz über die Einheiten im Meßwesen vom 02.07.1969 in der Fassung der Bekanntmachung vom 22.04.1985, and

<https://standards.iteh.ai/catalog/standards/sist/132936c8-2139-4e62-9044-32621af98d87/sist-en-iso-8321-1-2000>

Ausführungsverordnung zum Gesetz über Einheiten im Meßwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9

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INTERNATIONAL STANDARD

ISO
8321-1

First edition
1991-08-15

Optics and optical instruments — Contact lenses —

Part 1:

**Specification for rigid corneal and scleral contact
lenses**

<https://standards.iteh.ai/32621a98487/sist-en-iso-8321-1-2000>
Optique et instruments d'optique — Lentilles de contact —
**Partie 1: Spécification des lentilles cornéennes et des verres scléreaux
rigides**



Reference number
ISO 8321-1:1991(E)

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.

ISO 8321-1:1991(E)**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).

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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	$\pm 0,025$	$\pm 0,05$	$\pm 0,010$
Back optic zone radii of toroidal surfaces where $0 < \Delta r \leq 0,2$ where $0,2 < \Delta r \leq 0,4$ where $0,4 < \Delta r \leq 0,6$ where $\Delta r > 0,6$ (see notes 1 and 2)	$\pm 0,025$ $\pm 0,035$ $\pm 0,055$ $\pm 0,075$	$\pm 0,05$ $\pm 0,06$ $\pm 0,07$ $\pm 0,09$	$\pm 0,12$ $\pm 0,13$ $\pm 0,15$ $\pm 0,17$
Back optic zone diameter (see note 3)	$\pm 0,20$	$\pm 0,20$	$\pm 0,20$
Back scleral radius (of preformed lens)	—	—	$\pm 0,10$
Basic or primary optic diameter	—	—	$\pm 0,20$
Back or front peripheral radius (where measurable)	$\pm 0,10$	$\pm 0,10$	$\pm 0,10$
Back peripheral diameter (see note 3)	$\pm 0,20$	$\pm 0,20$	$\pm 0,20$ (for preformed lenses)
Total diameter (see note 2)	$\pm 0,10$	$\pm 0,10$	$\pm 0,25$
Front optic zone diameter (see note 3)	$\pm 0,20$	$\pm 0,20$	$\pm 0,20$
Bifocal segment height	$-0,10$ to $+0,20$	$-0,10$ to $+0,20$	$-0,10$ to $+0,20$
Centre thickness	$\pm 0,02$	$\pm 0,02$	$\pm 0,10$
Vertex clearance from cast (for impression scleral lenses)	—	—	$\pm 0,02$

NOTES

- Δr is the difference between the radii of the two principal meridians.
- The tolerance applies to each meridian.
- 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.