
**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 scléaux rigides



Reference number
ISO 8321-1:2002(E)

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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.