SLOVENSKI STANDARD
SIST EN ISO 9339-1:2000

01-januar-2000

Optika in optiļ ni instrumenti - Kontaktne leļ e - Ugotavljanje debeline - 1. del: Trde kontaktne leļ e (ISO 9339-1:1996)

Optics and optical instruments - Contact lenses - Determination of the thickness - Part 1: Rigid contact lenses (ISO 9339-1:1996)

Optik und optische Instrumente - Kontaktlinsen - Bestimmung der Dicke - Teil 1: Formstabile Kontaktlinsen (ISO 9339-1:1996)

Optique et instruments d'optique - Lentilles de contact - Détermination de l'épaisseur - Partie 1: Lentilles de contact rigides (ISO 9339-1:1996)

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ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 9339-1:2000 **en**

EUROPEAN STANDARD
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English version

Optics and optical instruments - Contact lenses - Determination of the thickness - Part 1: Rigid contact lenses (ISO 9339-1:1996)

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Optik und optische Instrumente - Kontaktlinsen - Bestimmung der Dicke - Teil 1: Formstabile Kontaktlinsen (ISO 9339-1:1996)

This European Standard was approved by CEN on 22 June 1998.

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This European Standard exists 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 Technical Committee ISO/TC 172 "Optics and optical instruments" of the International Organization for Standardization (ISO) has been taken over as an European Standard by 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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, 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 9339-1:1996 has been approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 9339-1

First edition
1996-08-15

Optics and optical instruments — Contact lenses — Determination of the thickness —

Part 1: Rigid contact lenses

Optique et instruments d'optique — Lentilles de contact — Détermination de l'épaisseur —

Partie 1: Lentilles de contact rigides

Reference number
ISO 9339-1:1996(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 9339-1 was prepared jointly by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 9339 consists of the following parts, under the general title *Optics and optical instruments — Contact lenses — Determination of the thickness*:

— *Part 1: Rigid contact lenses*

— *Part 2: Hydrogel contact lenses*

Annex A forms an integral part of this part of ISO 9339.

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Optics and optical instruments — Contact lenses — Determination of the thickness —

Part 1:
Rigid contact lenses

1 Scope

This part of ISO 9339 specifies a method for the determination of the thickness (e.g. centre thickness, junction thickness, edge thickness) of rigid contact lenses.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9339. 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 9339 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 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.*

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

3 Definitions

For the purposes of this part of ISO 9339, the definitions given in ISO 8320 apply.

4 Requirements

4.1 Precision

The method described in annex A has been found to have a reproducibility R of better than 0,01 mm, when determined in accordance with ISO 5725-2.

4.2 Measuring temperature

The results obtained by the test method shall be unaffected by the temperature during measurements.

4.3 Test method

The method described in annex A, which complies with 4.1 and 4.2, or a method shown to be equivalent.

Annex A
(normative)

Dial gauge method for rigid contact lenses

A.1 Principle

The thickness of rigid contact lenses is measured by means of a dial gauge.

A.2 Apparatus

A.2.1 Dial gauge, graduated with a scale with intervals not exceeding 0,01 mm, and with a reproducibility R equal to or better than 0,01 mm over the range 0 mm to 5 mm.

The measuring face of the dial gauge shall be spherical with a radius of between 1,2 mm and 5,0 mm. The measuring face shall apply a force not exceeding 1,4 N on the contact lens to be tested.

NOTE — These limits are selected to minimize the elastic deformation of the contact lens to be tested.

A.2.2 Anvil or similar plane surface with smooth surface.

A.2.3 Calibration test pieces shall consist of high precision engineering shims, the thickness of each being known to within ± 0,005 mm, and traceable to a calibrated standard unit of measurement. Three test pieces shall be used having the following nominal thicknesses:

a) just less than the minimum expected in the determination of the thickness;

b) just greater than the maximum expected in the determination of the thickness;

c) approximately midway between a) and b).

A.3 Conditioning

The rigid contact lens and the measuring instrument shall be maintained during the test at a temperature of (20 ± 5) °C.

A.4 Procedure

A.4.1 Calibration of the dial gauge

Mount the dial gauge with its plunger just in contact with the anvil. Place each calibrated shim successively between the plunger and the anvil and take 10 independent measurements of the shim thickness. Calculate the mean reading for each shim. From the mean values for the three determinations, prepare a calibration curve.

A.4.2 Measurement of the contact lens thickness

A.4.2.1 Mount the dial gauge (A.2.1) vertically above a horizontal plane surface.

A.4.2.2 Allow the measuring surface of the gauge to rest on the plane surface [see figure A.1 a)] and record the reading on the gauge. Alternatively, it may be preferable to zero the dial gauge.

Then place the contact lens with the anterior surface on the plane surface and beneath the dial gauge [see figure A.1 b)] and record the reading on the gauge.

Record the thickness as the difference between the two readings.

A.4.2.3 Repeat 4.2.2 two times to obtain three independent measurements. Correct each measurement using the calibration curve obtained in A.4.1.

The term "independent" means that after each measurement the lens is removed from the surface and then replaced.

A.4.2.4 The thickness of the contact lens shall be calculated as the arithmetic mean of the three determinations.

A.5 Test report

The test report shall contain at least the following information: