SLOVENSKI STANDARD
SIST EN ISO 10338:2000

01-januar-2000

Optika in optiį ni instrumenti - Kontaktne leį e - Ugotavljanje ukrivljenosti (ISO 10338:1996)

Optics and optical instruments - Contact lenses - Determination of curvature (ISO 10338:1996)

Optik und optische Instrumente - Kontaktlinsen - Bestimmung der Krümmung (ISO 10338:1996)

Optique et instruments d'optique - Lentilles de contact - Détermination de la courbure (ISO 10338:1996)

Ta slovenski standard je istoveten z: EN ISO 10338:1997

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 10338:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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Descriptors: See ISO document

English version

Optics and optical instruments - Contact lenses - Determination of curvature (ISO 10338:1996)

Optique et instruments d'optique - Lentilles de contact - Détermination de la courbure (ISO 10338:1996)

Optik und optische Instrumente - Kontaktlinsen - Bestimmung der Krümmung (ISO 10338:1996)

This European Standard was approved by CEN on 23 November 1997.

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.

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

Ref. No. EN ISO 10338:1997 E

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 June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

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 10338:1996 has been approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 10338

First edition
1996-07-15

Optics and optical instruments — Contact lenses — Determination of curvature

Optique et instruments d'optique — Lentilles de contact — Détermination de la courbure

Reference number
10338:1996(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 10338 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A to C form an integral part of this International Standard. Annex D is for information only.

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Optics and optical instruments — Contact lenses — Determination of curvature

1 Scope

This International Standard describes methods for the determination of curvature of contact lenses.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard 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 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions.*

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 5725-3:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method.*

ISO 5725-4:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method.*

ISO 5725-6:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 6: Use in practice of accuracy values.*

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

ISO 10344:—[1)], *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8320 apply.

4 Test methods

The test methods specified in detail in annexes A to C to this International Standard are listed in table 1, together with a statement of their reproducibility when applied to either rigid or hydrogel contact lenses.

1) To be published.

Table 1 — Test methods

Annex	Test method/application	Reproducibility, R (ISO 5725)
A	Optical microspherometry Spherical rigid lenses	 ± 0,015 mm in air
B	Ophthalmometry Spherical rigid lenses Spherical rigid lenses Spherical hydrogel lenses (38 % water content, t_c > 0,1 mm)	 ± 0,015 mm in air ± 0,025 mm in saline solution ± 0,050 mm in saline solution
C	Sagittal height method Hydrogel lenses (38 % water content, t_c > 0,1 mm) Hydrogel lenses (55 % water content, t_c > 0,1 mm) Hydrogel lenses (70 % water content, t_c > 0,1 mm)	 ± 0,050 mm in saline solution ± 0,100 mm in saline solution ± 0,200 mm in saline solution

Annex A
(normative)

Determination of radius of curvature using the optical microspherometer

A.1 Scope

This annex specifies a method for determining the radius of curvature of rigid contact lenses using the optical microspherometer.

A.2 Principle

The optical microspherometer consists essentially of a microscope fitted with a vertical illuminator. Light from the target T [figure A.1 a)] is reflected down the

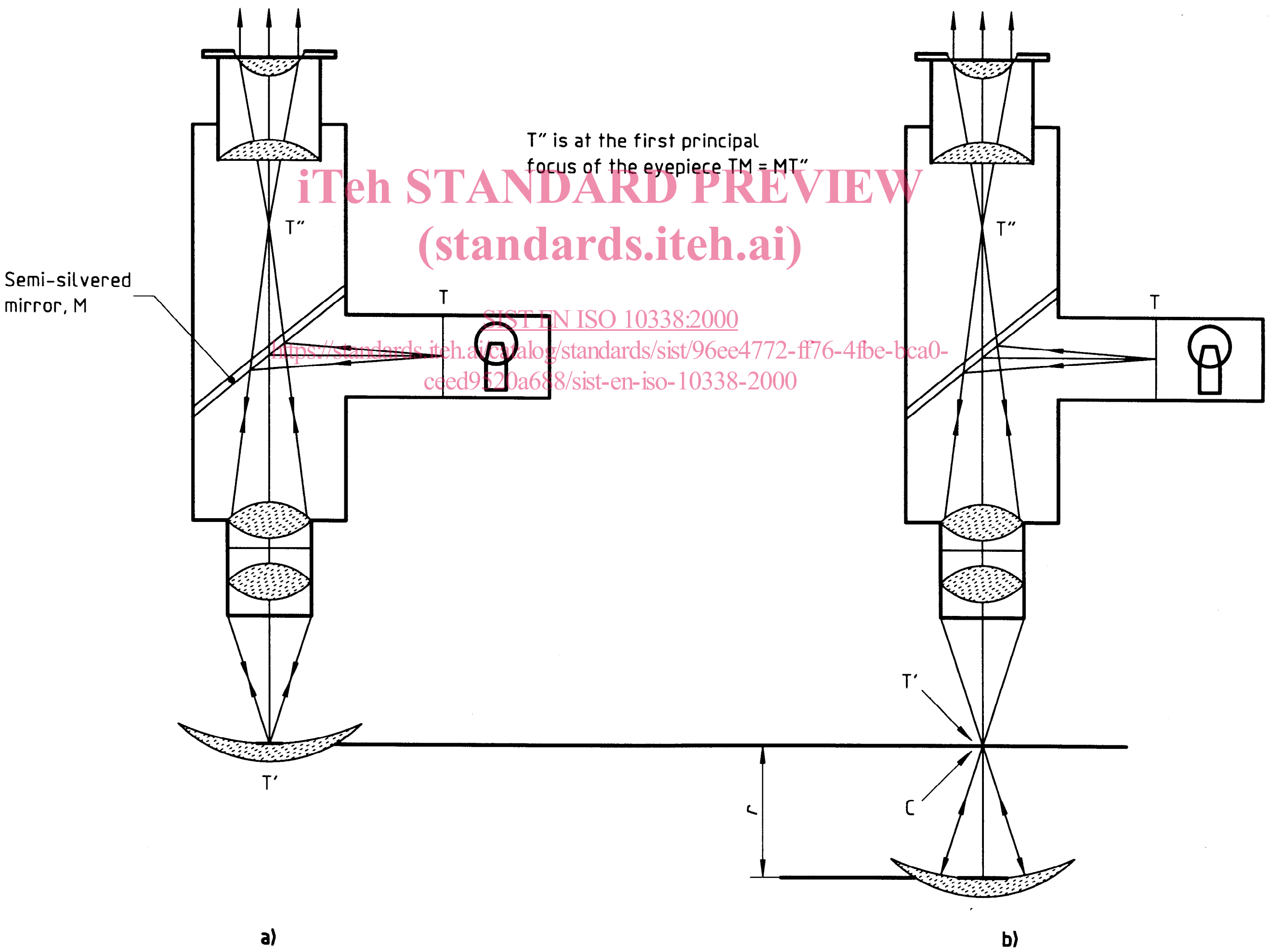

Figure A.1 — Optical microspherometer showing the images of target T

the microscope tube by the semi-silvered mirror M and passes through the microscope objective to form an image of the target at T′. If the focus coincides with the lens surface, then light is reflected back along the diametrically opposite path to form images both at T and T″. T″ coincides with the first principal focus of the eyepiece when a sharp image of the target is seen by the observer.

The distance between the microscope and the lens surface is increased by either raising the microscope or lowering the stage until the image formed by the objective (T′) coincides with C, the centre of curvature of the surface [see figure A.1 b)]. Light from target T strikes the surface normally and is reflected back along its own path to form images at T and T″ as before. The distance through which the microscope of stage has been moved is equal to the radius (*r*) of curvature of the surface.

A.3 Apparatus

A.3.1 Optical microspherometer, comprising an optical microscope fitted with a vertical illuminator and a target, and having a fine focus adjustment. The adjustment control shall allow fine movement of the microscope or of its stage. The adjustment gauge shall have a linear scale.

A.3.1.1 The objective lens shall have a magnification of not less than × 6,5 and a numerical aperture of not less than 0,25.

A.3.1.2 The total magnification of the microscope shall be not less than × 65.

A.3.1.3 The real image of the target object formed by the microscope shall be not greater than 1,2 mm in diameter.

A.3.1.4 The scale interval for the gauge shall be not more than 0,02 mm.

A.3.1.5 The accuracy of the gauge shall be ± 0,010 mm for readings of 2,00 mm or more at a temperature of 20 °C ± 5 °C. The repeatability of the gauge (see note 1) shall be ± 0,003 mm.

NOTES

1 The term "gauge" refers to both analogue and digital instruments.

2 "Repeatability" means the closeness of agreement between mutually independent test results obtained under repeatability conditions.

3 The gauge mechanism should incorporate some means for eliminating backlash (retrace). If readings are taken in one direction, this source of error need not be considered.

A.3.2 Test plates, concave and made of crown glass, to be used for calibration. Three test plates shall be used having radii of curvature in the range 6,30 mm to 6,70 mm, 7,80 mm to 8,20 mm and 9,30 mm to 9,70 mm. The test plates shall have radii accurately known to ± 0,007 5 mm.

A.4 Procedure

A.4.1 Calibration

Using the test plates described in A.3.2, mount each so that the optical axis of the microscope is normal to the test surface. Adjust the separation of microscope and stage so that the image of the target is focused on the surface [figure A.1 a)] and a clear image of the target is seen in the microscope. Set the gauge to read zero. Increase the separation between the microscope and the stage until a second clear image of the target is seen in the microscope. The microscope and the surface now occupy the position shown in figure A.1 b). Record the distance shown on the gauge as the radius of curvature. Take ten independent measurements from each test plate and calculate the arithmetic mean for each set. Plot the results on a calibration curve and use this to correct the results obtained in A.4.2.

NOTE 4 The term "independent" means that the test plate or lens is to be removed from the instrument and remounted between each reading.

A.4.2 Measurement

A.4.2.1 Carry out the measurements on the test lens in air at 20 °C ± 5 °C.

A.4.2.2 Mount the lens so that the optical axis of the microscope is normal to that part of the lens surface of which the radius is to be measured. Three independent readings shall be made as described in A.4.1. Correct the arithmetic mean of this set of measurements, using the calibration curve obtained in A.4.1, and record the result to the nearest 0,01 mm.

Annex B
(normative)

Determination of radius of curvature using the ophthalmometer

B.1 Scope

This annex specifies a method for determining the radius of curvature of rigid or hydrogel contact lenses, using an ophthalmometer.

B.2 Principle

In ophthalmometry, radius of curvature is derived indirectly by measuring the angular size of the reflected image formed by the surface being measured of an object of known angular size. Figure B.1 shows schematically a typical optical system in which light from two targets arranged at a known angle is reflected by the central area of the surface being measured. The two images formed are observed through a short-focus telescope fitted with a doubling system. The amount of doubling required to superimpose the two central images of the four observed in the telescope field is a measure of the angular size of the reflected images.

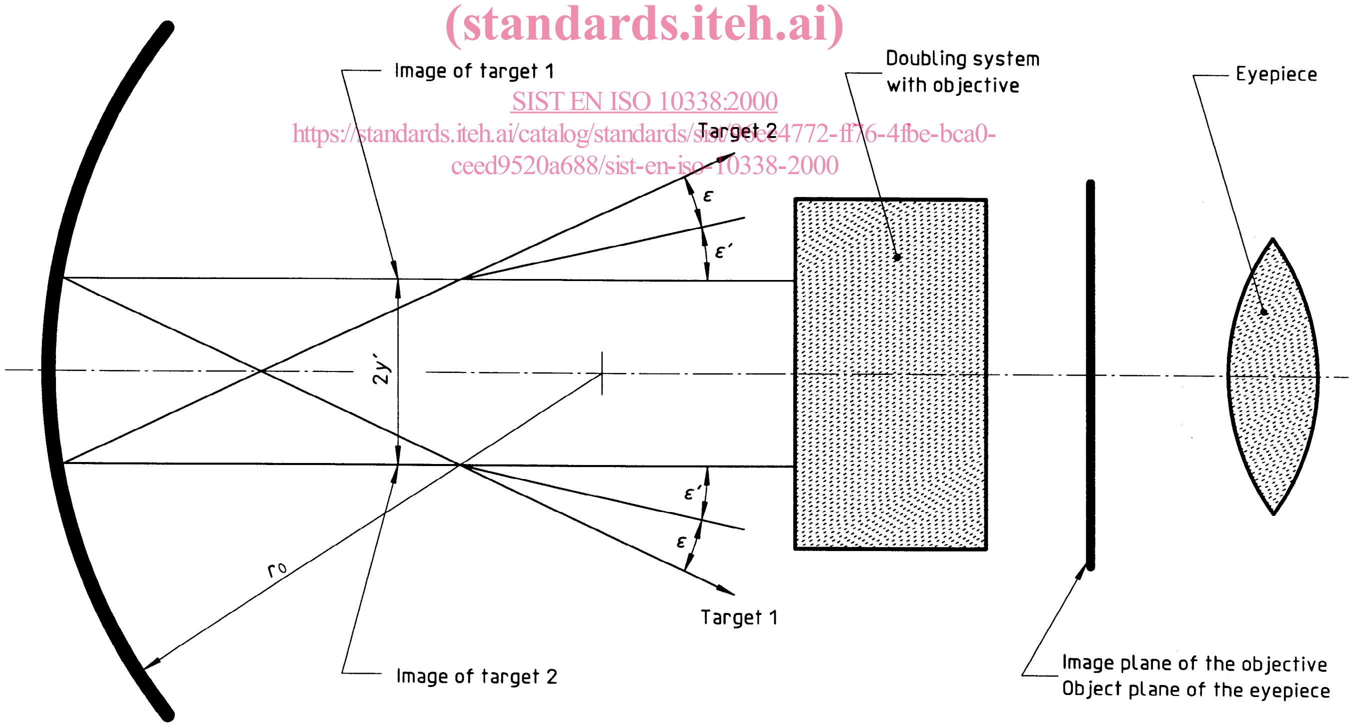

Figure B.1 — Measuring principle