

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)



Documents
Document Sharing Hub

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.

© ISO 1996

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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	$\pm 0,015$ mm in air
B	Ophthalmometry Spherical rigid lenses Spherical rigid lenses Spherical hydrogel lenses (38 % water content, $t_c > 0,1$ mm)	$\pm 0,015$ mm in air $\pm 0,025$ mm in saline solution $\pm 0,050$ 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)	$\pm 0,050$ mm in saline solution $\pm 0,100$ mm in saline solution $\pm 0,200$ 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

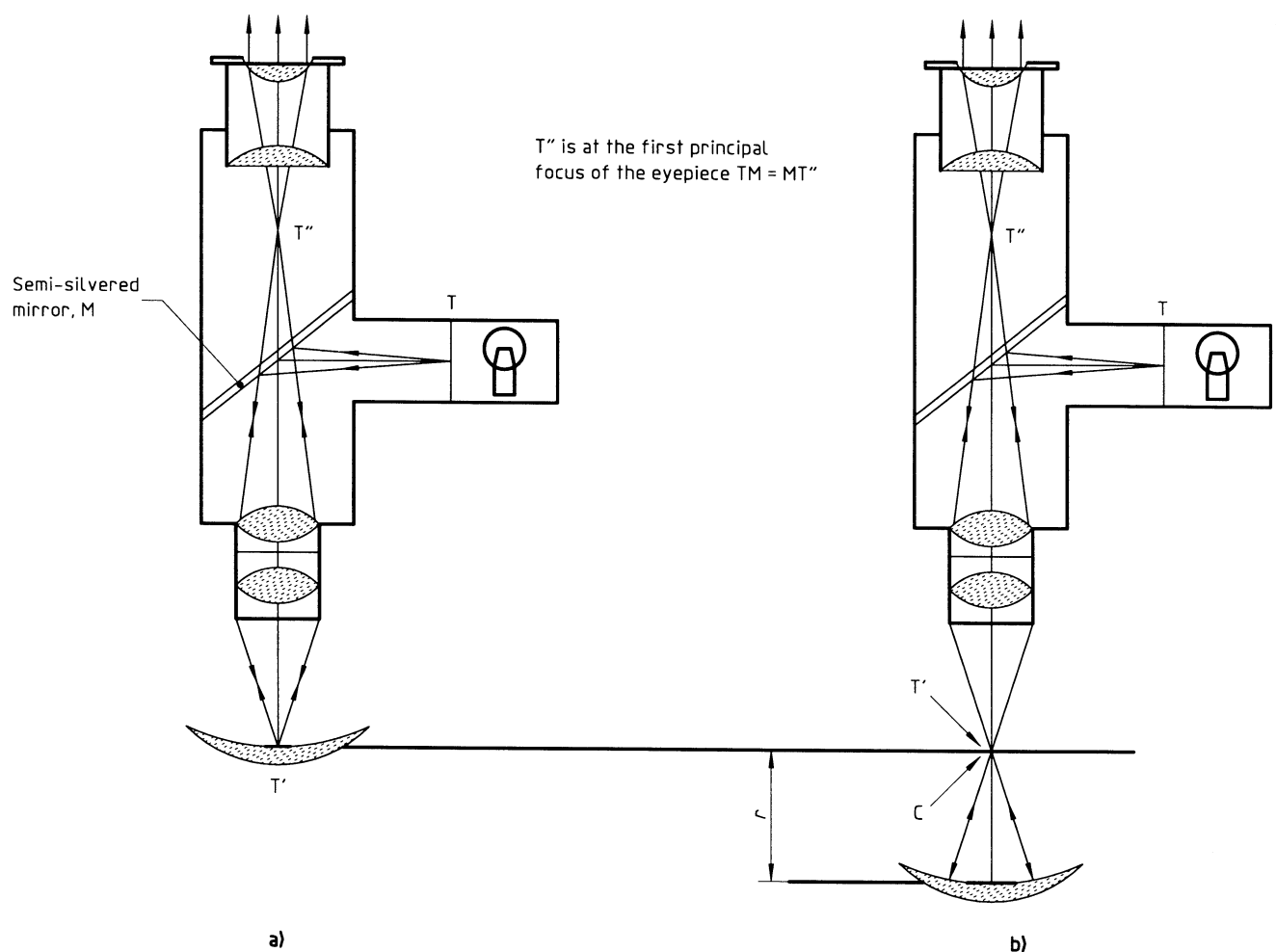


Figure A.1 — Optical microspherometer showing the images of target T

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 $\times 6,5$ 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 $\times 65$.

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 $\pm 0,010$ mm for readings of 2,00 mm or more at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$. The repeatability of the gauge (see note 1) shall be $\pm 0,003$ 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 $\pm 0,007\text{ }5$ 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 re-mounted between each reading.

A.4.2 Measurement

A.4.2.1 Carry out the measurements on the test lens in air at $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$.

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.