INTERNATIONAL STANDARD

ISO 9339-2

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

Part 2:
Hydrogel contact lenses

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

Partie 2: Lentilles de contact en hydrogel

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@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.

Draft International Standards adopted by the technical committees are circulated to 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 9339-2 was prepared by Technical Committee 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 thickness*:

— *Part 1: Rigid contact lenses*

— *Part 2: Hydrogel contact lenses*

Annex A of this part of ISO 9339 is for information only.

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

Part 2:
Hydrogel contact lenses

1 Scope

This part of ISO 9339 describes a method for the determination of thickness of soft (hydrogel) contact lenses by means of a low-force gauge.

NOTE 1 This method is suitable for comparison of thickness between contact lenses, but may not be indicative of the absolute thickness of a contact lens.

NOTE 2 ISO 9339-1 is applicable for the determination of 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 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols.*

ISO 10344:1996, *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing.*

3 Definitions

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

3.1
precision
closeness of agreement between independent test results obtained under stipulated conditions

[ISO 3534-1]

3.2
repeatability
precision under repeatability conditions

[ISO 3534-1]

3.3
repeatability conditions
conditions in which independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time

[ISO 3534-1]

3.4
reproducibility
precision under reproducibility conditions

[ISO 3534-1]

3.5
reproducibility conditions
conditions in which test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment

[ISO 3534-1]

3.6
reproducibility standard deviation
s_R
standard deviation of test results obtained under reproducibility conditions

[ISO 3534-1]

NOTE It is a measure of the dispersion of the distribution of test results under reproducibility conditions.

3.7
reproducibility limit
R
value less than or equal to which the absolute difference between two test results obtained under reproducibility conditions may be expected to lie with a probability of 95 %

[ISO 3534-1]

4 Principle

The thickness of soft contact lenses is measured using a mechanical gauge which exerts a force of not more than 0,015 N (1,5 g).

5 Apparatus

5.1 Low-force mechanical gauge, for measuring positional linear displacement in the range 0 mm to 1 mm, comprising a rigid frame in which are mounted a sensor and an anvil and capable of measuring a displacement to an accuracy of 0,001 mm.

The sensor is fitted with a tip with a diameter of not less than 2 mm and with a flat surface perpendicular to the direction of movement of the sensor. The sensor acts against a spring exerting a maximum force of 0,015 N when displaced by 1 mm from its unrestrained position (i.e. rest).

The anvil which supports the test lens beneath the sensor has a convex surface with a radius of 7,0 mm to 8,0 mm and a diameter of 14 mm to 16 mm.

NOTE 1 Preferably the movement of the sensor should be damped to avoid it impacting on the anvil or test lens.

NOTE 2 The anvil may be marked with concentric rings of diameters 12,5 mm and 15 mm to assist in centring the test lens when measuring the geometrical-centre thickness.

5.2 Calibration test pieces, consisting of high precision engineering shims, the thickness of each being known to within ± 0,000 5 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 expected minimum thickness to be measured;

b) just greater than the expected maximum thickness to be measured; and

c) approximately midway between a) and b).

6 Conditioning of contact lenses before testing

Each contact lens to be tested shall be equilibrated in standard saline solution in accordance with ISO 10344 at a temperature of 20,0 °C ± 5 °C for 30 min unless otherwise specified by the manufacturer**,** in which case the manufacturer's instructions shall be followed.

7 Procedure

7.1 Calibration of the low-force gauge

At a temperature of 20 °C ± 5 °C, calibrate the low-force mechanical gauge (5.1) by carrying out the following procedure.

a) Place each test piece successively between the sensor and the anvil, lower the sensor gently and record the value.

b) Repeat a) four more times to obtain five measurements for each test piece.

c) Calculate the mean value for each test piece and compute the calibration relationship.

d) Single calibration values are only valid (i.e. acceptable) if they do not differ from the mean value by more than 0,001 mm.

NOTE The preferred method of computing a calibration relationship is to use a least squares fit, e.g. linear regression.

7.2 Measurement of contact lens thickness

To determine the geometrical-centre thickness, carry out the following procedure at a temperature of 20 °C ± 5 °C.

a) With the sensor raised, remove the contact lens from the equilibrating standard saline solution and place it on the anvil. Align the contact lens so that its rim lies concentrically with the anvil edge or, if present, with the concentric rings (see 5.1, note 2).

b) Lower the sensor gently on to the contact lens, ensuring that this step follows step a) in the shortest possible time to minimize dehydration of the contact lens, and record the value.

c) Repeat steps a) and b) four more times to obtain five independent measurements of the contact lens geometrical centre thickness. Correct each observed value using the calibration regression relationship and record the corrected values.

d) Calculate the arithmetic mean of the five corrected values.

NOTE 1 The thickness of soft contact lenses may be determined at any position within the contact lens, but normally the thickness at the geometrical centre is required.

NOTE 2 Contact lens decentration should be less than 1 mm.

NOTE 3 The term 'independent' means that after each measurement the contact lens is removed from the gauge and re-equilibrated in the saline solution before the next measurement.

8 Expression of results

The thickness of the contact lens shall be reported as the mean of the five corrected values obtained from 7.2 d), together with an indication of the position at which the measurement was made.

9 Precision

The precision data for the measurement of thickness of soft contact lenses using a low-force gauge were determined in accordance with ISO 5725:1986. These data are shown in table 1.

Table 1 — Precision data

Thickness range mm	Reproducibility mm	
	s_R	R
0,04 to 0,60	0,006	0,017
NOTE These precision data were derived from measurements of geometrical-centre thickness. These data may not be applicable to excessively thin or thick soft contact lenses.		

An estimate of the value of the reproducibility standard deviation, s_R, was obtained using tests in three laboratories. It has been used to show that single test results on the same test lens, measured under reproducibility conditions, may be expected to agree with one another to within 0,017 mm in 95 % of tests.

The measurement tolerance, MT, of the method is given by:

$$MT = \frac{1{,}96\, s_R}{\sqrt{N}}$$

where

s_R is the reproducibility standard deviation;

N is the number of replicate measurements required;

1,96 is the Student's t factor for 95 % confidence level.

The formula may be rearranged to give:

$$N = (1{,}96\, s_R / MT)^2$$

NOTE If a product tolerance of, for example, 0,02 mm is required, then the measurement tolerance MT should be set to one-half of that value, 0,01 mm in this example, and the above calculation performed to obtain the number of readings required to specify the thickness to ± 0,02 mm at the 95 % confidence level.

10 Test report

The test report shall contain at least the following information:

a) the name of the laboratory which performed the test;

b) all necessary details for identification of the soft contact lens to which the report applies;

c) a reference to this part of ISO 9339;

d) the thickness of the contact lens, expressed in millimetres, the position on the contact lens at which the measurements were made and the temperature of measurement;

e) the date on which the test was performed;

f) identification of the equipment or apparatus used.