INTERNATIONAL STANDARD

ISO 9338

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

Optique et instruments d'optique — Lentilles de contact — Détermination des diamètres

Reference number
ISO 9338:1996(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 9338 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A forms an integral part of ISO 9338. Annex B is for information only.

International Organization for Standardization
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Optics and optical instruments — Contact lenses — Determination of the diameters

1 Scope

This International Standard describes methods for the determination of contact lens diameters.

Annex A describes a projection method which is suitable for both soft and rigid contact lenses. Annex B describes a method which is suitable only for rigid 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 edition indicated was 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 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.*

BS 3625:1963 (1994), *Specification for eyepiece and screen graticules for the determination of the particle size of powders.*

BS 3406 Part 4:1993, *Methods for determination of particle size distribution — Guide to microscope and image analysis methods.*

3 Definitions

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

4 Requirements

4.1 Measuring precision

The minimum reproducibility shall be ± 0,05 mm.

4.2 Measuring temperature

The measurements shall be done at a temperature in the range of 18 °C to 35 °C. The chosen measuring temperature shall be stated in the test report.

5 Test report

The test report shall contain at least the following information:

a) the identification of the contact lens tested;

b) a reference to this International Standard;

c) the measuring temperature;

d) the diameter of the contact lens;

e) the date of the measurements.

Annex A
(normative)

Determination of diameter of a contact lens using the projection method

A.1 Principle

The diameter of the lens is determined from an enlarged projection of the lens on a screen in comparison with a calibrated scale.

A.2 Apparatus and reagents

A.2.1 Projection system

The projection system, as shown in figure A.1 shall be capable of measuring to ± 0,05 mm over a range of 0 mm to 17 mm.

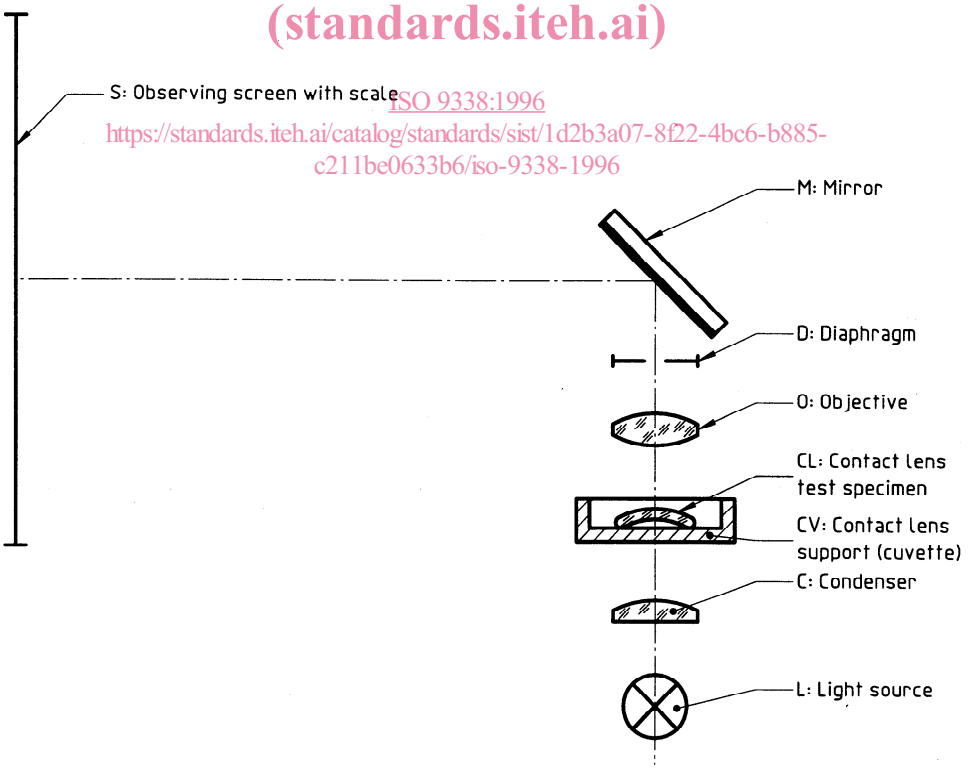


Figure A.1 — Principle of the apparatus

The contact lens support CV is placed horizontally and can be adjusted vertically. The scale of the screen S represents a linear magnification of at least x 15 and permits a measurement accuracy of 0,05 mm for the contact lens diameter. The apparatus has a telecentric path of rays which is ensured by positioning the diaphragm D in the rear focal plane of the objective O.

A.2.2 Test graticule

A microscope graticule as specified in BS 3625, or an equivalent graticule with a diameter of at least 15 mm shall be used for calibration as recommended in BS 3406 Part 4.

A.2.3 Reagent

Conditioning and measurement of soft contact lenses shall be made in saline solution as specified in ISO 10344.

A.3 Conditioning

A.3.1 For hydrogel lenses, each contact lens shall be fully hydrated and stabilized in saline solution. The measuring solution and the contact lens shall be stabilized before the test and maintained during the test at the chosen temperature within ± 1 °C.

A.3.2 For rigid lenses, each contact lens shall be stabilized before the test and maintained during the test at the chosen temperature.

A.4 Procedure

A.4.1 Calibration

Place the calibration graticule in the test specimen position. Adjust and stage the separation of the calibration graticule so that the image of the graticule is focused on the scale S of the observing screen (see figure A.1).

Take ten independent readings of the calibration graticule at lengths of 5 mm, 7 mm, 9 mm, 11 mm, 13 mm and 15 mm. The term "independent" means that the calibration graticule shall be repositioned and refocused after each reading.

Calculate the arithmetic mean of each set. Plot the results on a calibration curve and use this to correct the results obtained in A.4.2.

A.4.2 Measurement

Place the conditioned contact lens at the appropriate temperature in the contact lens support CV (see figure A.1) and centre the image of the contact lens on the scale S. Determine both the minimum and maximum diameters by three independent readings. The term "independent" means in this case that the contact lens shall be repositioned after each reading. Take care not to deform the contact lens during the determination. Calculate each diameter by taking the arithmetic mean of the six readings and adjust this value by using the calibration curve obtained in A.4.1.

Annex B
(informative)

Determination of the total diameter of rigid contact lenses with a V-groove diameter gauge

B.1 Principle

When a circular disc slides into a V-groove, it stops at a distance from the apex of the groove determined by the diameter of the disc and the included angle of the V-groove. The reading of the diameter is obtained from the location of the superior edge of the lens on a scale engraved for this purpose in the centre or edge of the groove.

B.2 Apparatus and tools

B.2.1 V-groove

An example of a V-groove diameter gauge capable of measuring to ± 0,05 mm over a range from 7 mm to 11 mm is shown in figure B.1.

For engraved markings, the scale should be inscribed for diameters in the range 7,0 mm to 11,0 mm. The graduation lines should be placed at diameter intervals of 0,10 mm with a longer line at each interval of 0,50 mm and a more prominent line at each interval of 1,00 mm.

B.2.2 Calibration discs

Three discs accurately made from a hard, durable material, e.g. aluminium or a suitable plastics material, with diameters of 7,50 mm ± 0,01 mm, 9,50 mm ± 0,01 mm and 10,50 mm ± 0,01 mm should be used for calibration.

B.3 Conditioning

The rigid contact lens should be stabilized before the test and maintained during the test at the chosen temperature.

B.4 Procedure

B.4.1 Calibration

Position the calibration discs in the V-groove diameter gauge so that the disc touches each side of the groove. Take ten independent readings of each disc. The term "independent" means that the calibration discs should be repositioned after each reading. Calculate the arithmetic mean of each set. Plot the results on a calibration curve and use this to correct the results obtained in B.4.2.

B.4.2 Measurement

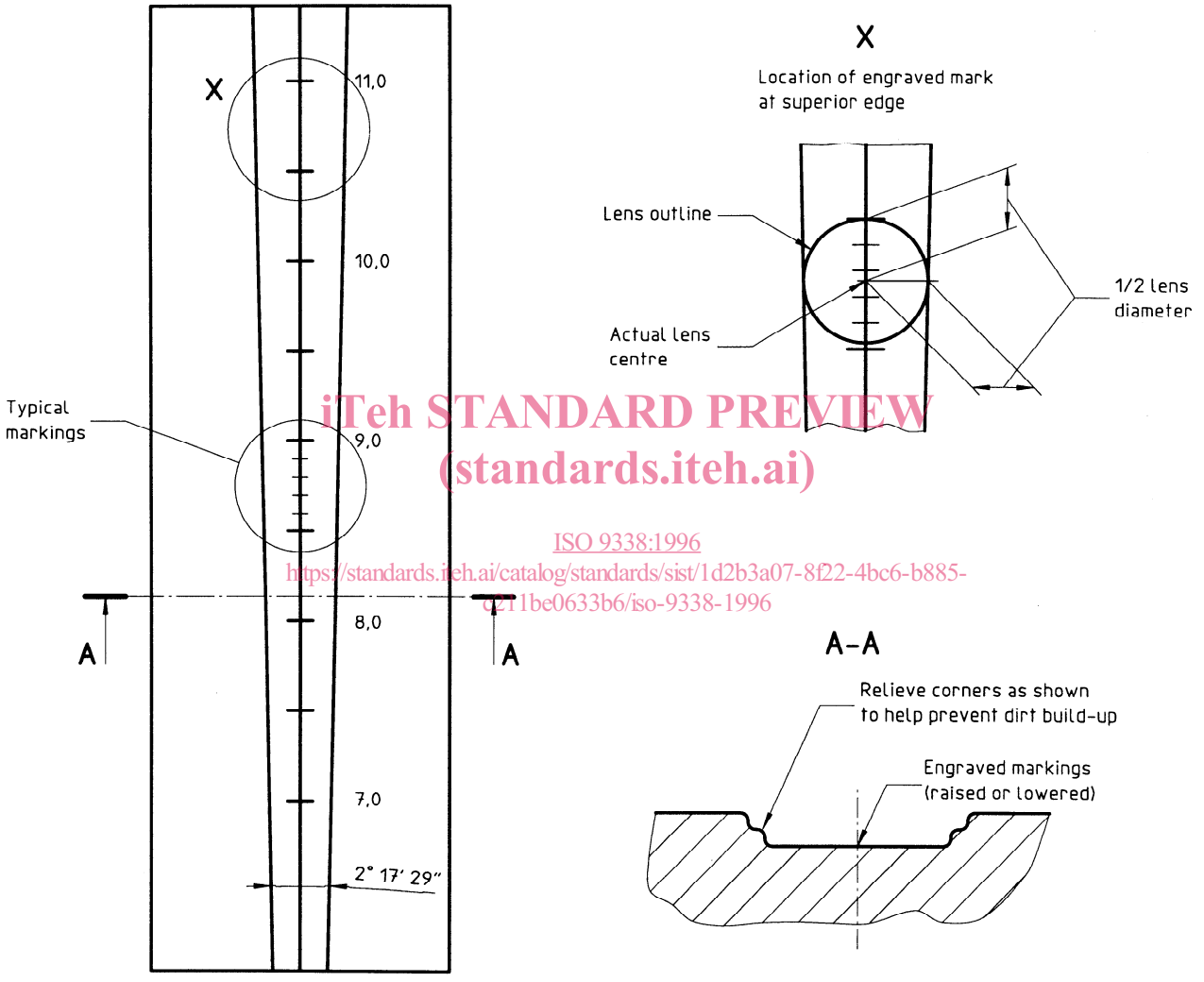
Place a dry contact lens of uniform diameter into the large end of the V-groove diameter gauge. Allow the lens to slide down the groove under its own weight by raising the wide end of gauge by approximately 45°.

By interpolation, determine the diameter from the location of the superior edge of the lens (see figure B.1, detail X) against the engraved scale.

Take three independent readings. The term "independent" means that the contact lens should be removed from the gauge after each reading. Take care not to deform the contact lens during the determination. Calculate the total diameter by taking the arithmetic mean of the three readings and adjusting this value by using the calibration curve obtained in B.4.1.

NOTE — Since the scale is defined in units of 0,1 mm, smaller intervals of measurement require interpolation.

Dimensions in millimetres



Depth of groove: 1,0 mm ± 0,25 mm

Length of groove: 100,0 mm ± 0,25 mm

Angle of groove: $2\arctan\left(\frac{11{,}0 - 7{,}0}{200}\right) = 2°17'29''$

Width of groove

Large end: 11,0 mm ± 0,01 mm

Small end: 7,0 mm ± 0,01 mm

Figure B.1 — Example of a V-groove diameter gauge with scale on centreline of groove

Dimensions in millimetres

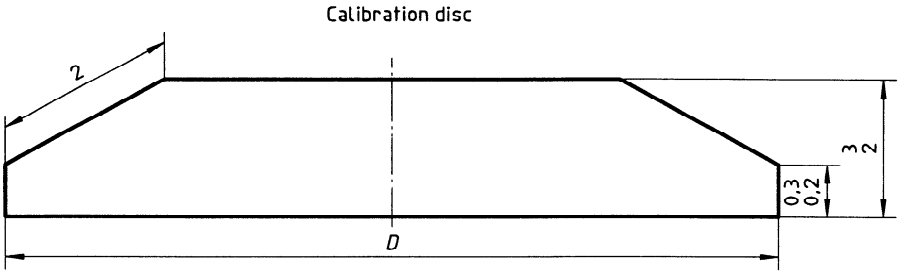


Figure B.2 — Example of a calibration disc

B.4.3 Precision limits of measurement

Since the diameter reading is obtained from a visual sighting of the lens edge against the engraved scale, the precision of this method is a function of the visual capabilities of the observer. Using the expression for the change in diameter which results from a change in position along the engraved scale, it is found that a change of 0,225 mm along the scale is equivalent to a change of 0,01 mm of diameter. Assuming that a distance of 0,38 mm would be easily discernible, a precision of 0,015 mm in measurement is obtained. In addition, since the engraved markings are equivalent to 0,1 mm in diameter, 1/4 of this distance can be easily judged. It is reasonable, therefore, to set the precision for this type of gauge as

$$P_L = \frac{0{,}75\sin\alpha/2}{1+\sin\alpha/2}$$

where P_L is the precision limit.

B.5 Calculations for V-groove specifications

The geometrical relationships of a V-groove are illustrated in the figure B.3. From this geometrical drawing, the following algebraic relationships between the diameter of the disc (D), the distance from the apex (L) and the wedge angle (α) are found.

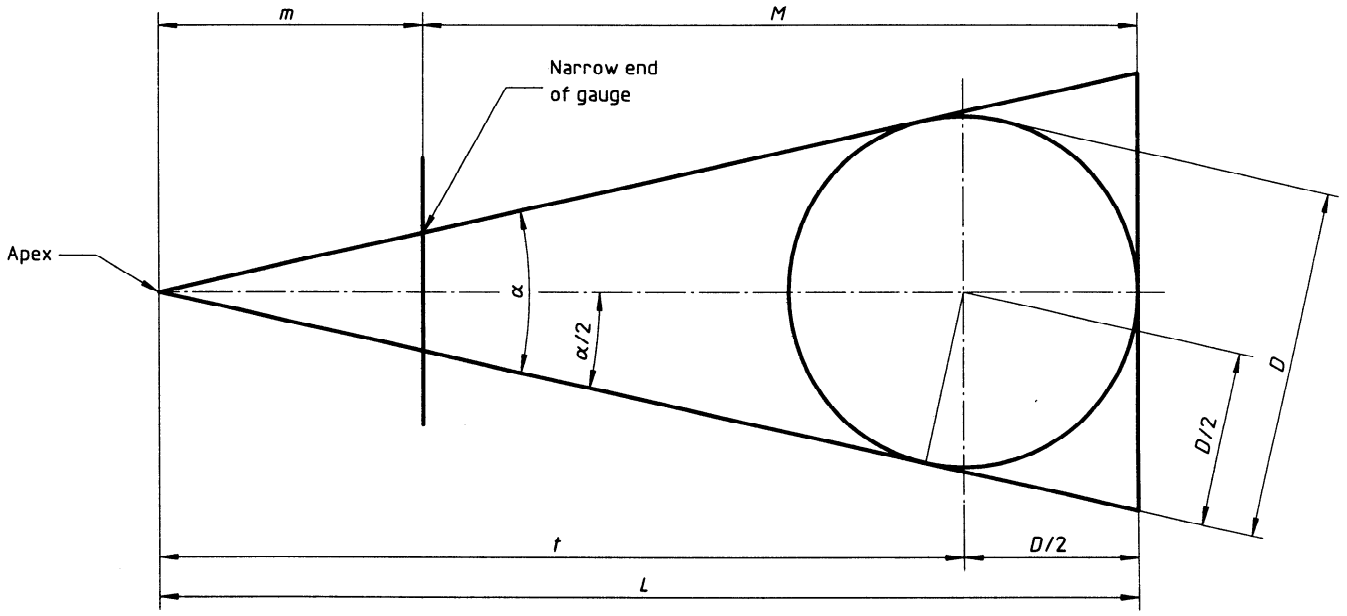


Figure B.3 — Geometrical relationships of a V-groove diameter gauge