INTERNATIONAL STANDARD

ISO 10338

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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

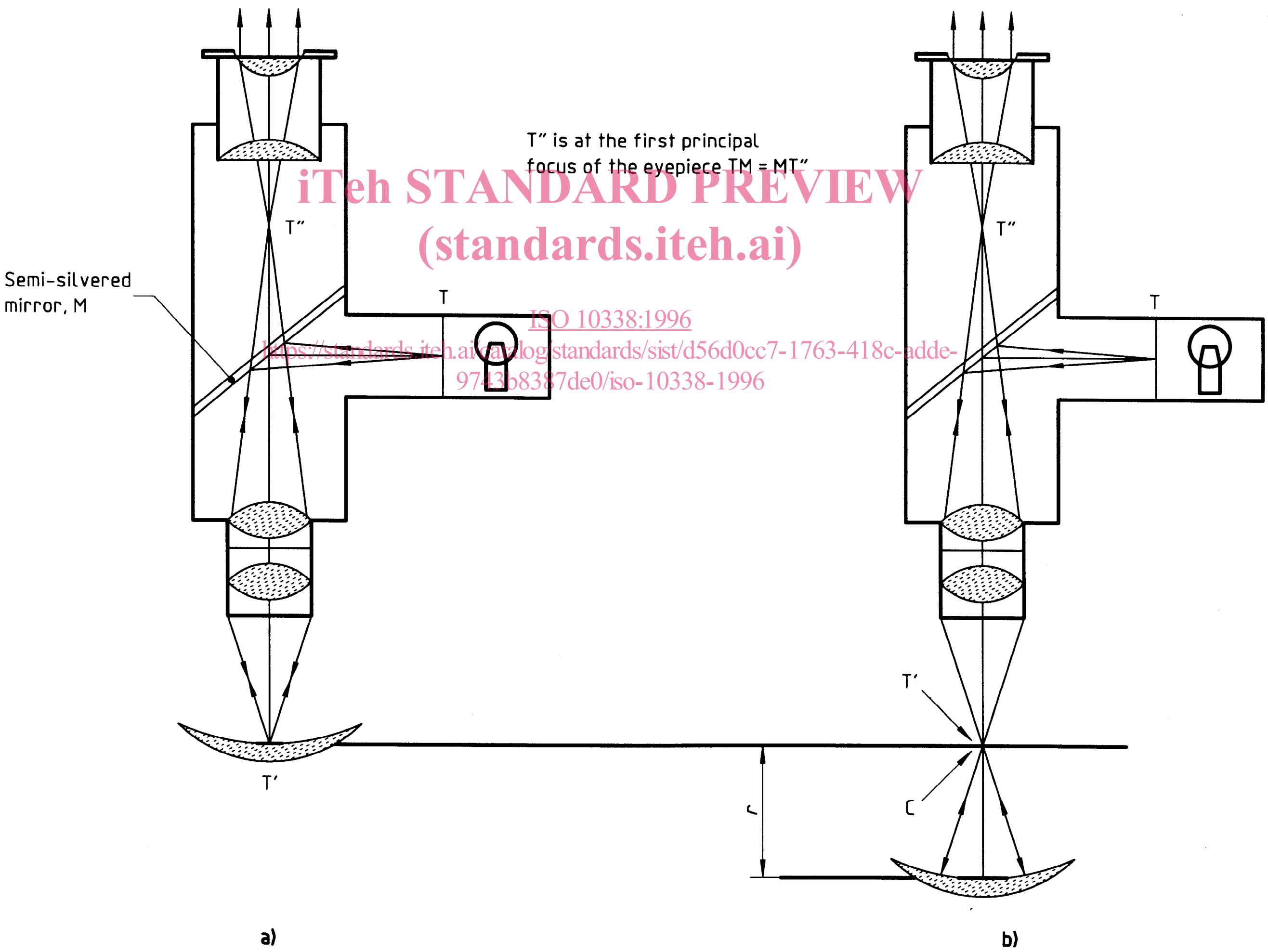


Figure A.1 — Optical microspherometer showing the images of target T

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.

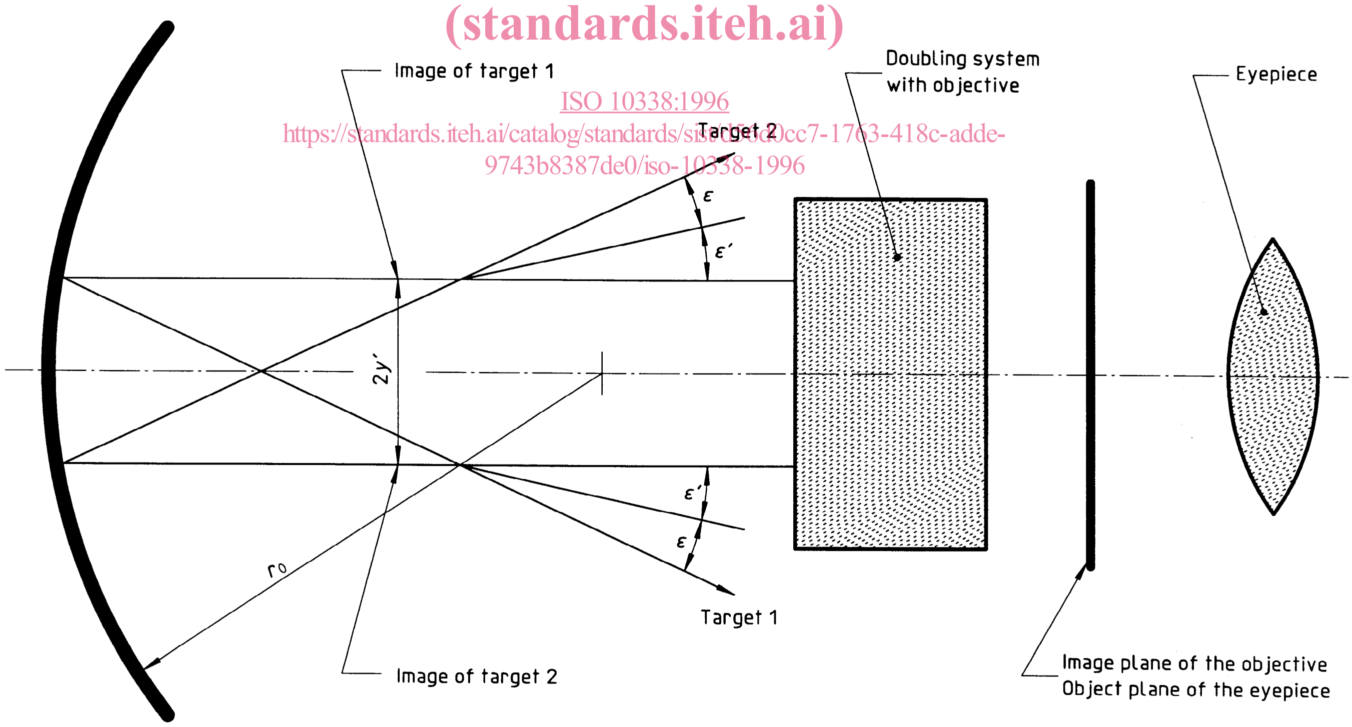


Figure B.1 — Measuring principle

The radius of curvature shall be derived to a first approximation, assuming the surface is spherical in the area measured, from the following equation:

$$r_0 = \frac{-y'}{\sin \varepsilon}$$

where

r_0 is the radius of curvature;

y' is half the distance between the reflected images;

ε is the angle of incidence.

Figure B.2 shows an adaptation of the optical system of figure B.1 to measure rigid (hard) contact lenses in air.

When the measurement is made in a wet cell, the radius of curvature is derived from:

$$r_0 = \frac{-y'n}{\sin \varepsilon}$$

where

r_0 is the radius of curvature;

y' is half the distance between the reflected images;

ε is the angle of incidence;

n is the refractive index of the saline solution.

Figure B.3 shows an adaptation of the optical system of figure B.1 to measure contact lenses in solution.

B.3 Apparatus

B.3.1 Ophthalmometer, having a total magnification of not less than × 20 and a scale interval of not more than 0,02 mm.

B.3.2 Lens holders, capable of supporting the lens without strain or deformation.

B.3.2.1 Measurements in air

The lens shall be supported in a holder which does not produce strain or deformation (see figure B.2)

B.3.2.2 Measurements in wet cell

The lens shall be supported without deformation in a cell with an optically plane surface through which the measurement is made. The cell shall be at least 5 mm larger than the diameter of the lens [see figure B.3 a)].

Alternatively, the lens shall be supported on a short tube, having a diameter in the range 8,0 mm to 10,0 mm, with the back surface upwards. Hydraulic pressure is equalized by a hole in the tube. The cell is filled with saline and closed with an optically parallel flat glass lid [see figure B.3 b)].

B.3.3 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.

B.3.4 Constant temperature bath, capable of control at 20 °C ± 1,0 °C.

B.4 Procedure

B.4.1 Calibration

Using the test plates (B.3.3) mounted in a lens holder (B.3.2), carry out ten determinations of the curvature of each plate, and calculate the arithmetic mean for each. Plot the means on a calibration curve and use this to correct the test measurements. Use saline solution conforming to ISO 10344 when calibrating the instrument for the measurement of lenses in solution.

NOTE 5 The term "independent" means that the test plate or lens is to be removed from the instrument and remounted between each reading.

B.4.2 Measurement

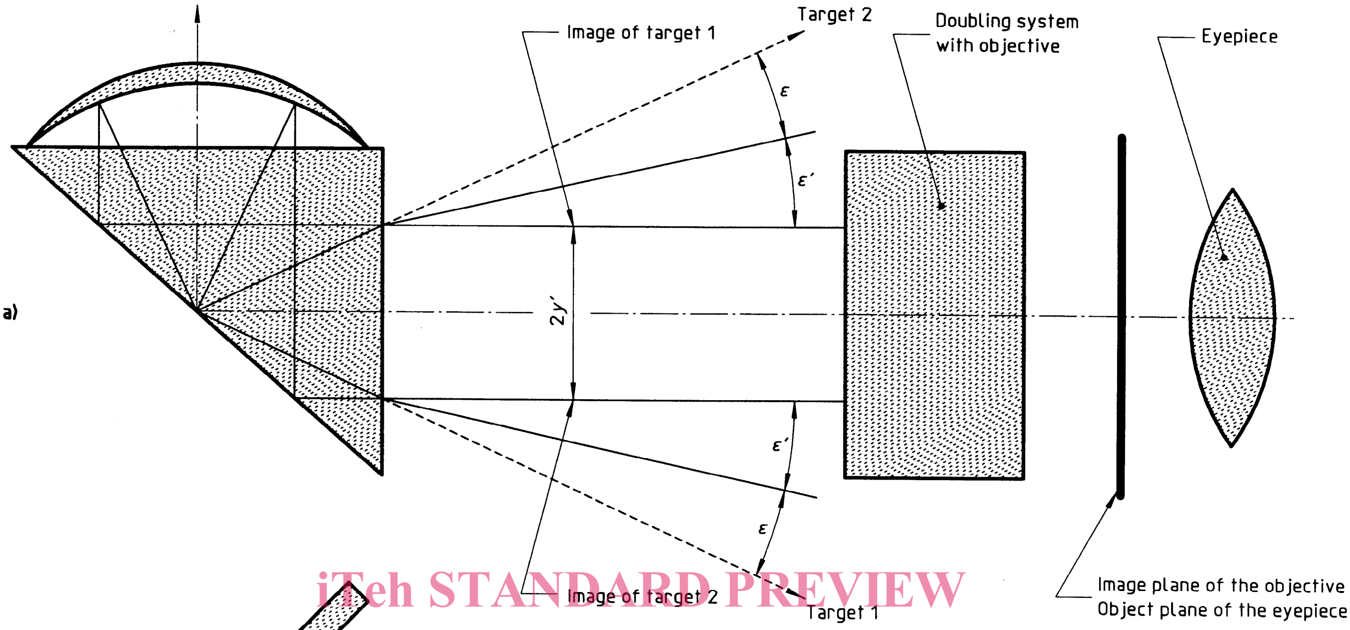
B.4.2.1 Measurement in air

Carry out the measurements on the finished products in air at a temperature of 20 °C ± 5 °C, taking a set of 3 independent readings. Report the test results as the arithmetic mean of the set of measurements, corrected using the calibration curve obtained in B.4.1.

B.4.2.2 Measurement in solution

This method is applicable only to measurement in central area. Suspend the lens to be tested in saline solution according to ISO 10344 and equilibrate it. Fill the cell with the same solution at a temperature of 20 °C ± 0,5 °C, and take a set of 3 independent readings. Report the test results as the arithmetic mean of the set of measurements, corrected using the calibration curve obtained in B.4.1.

a)



b)

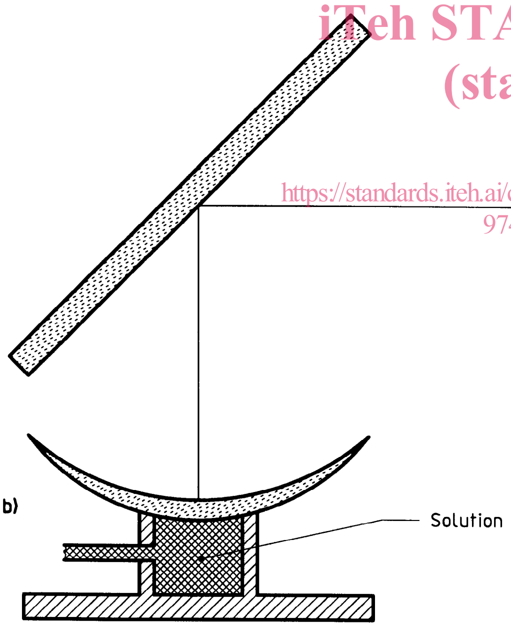


Figure B.2 — Measuring arrangements in air

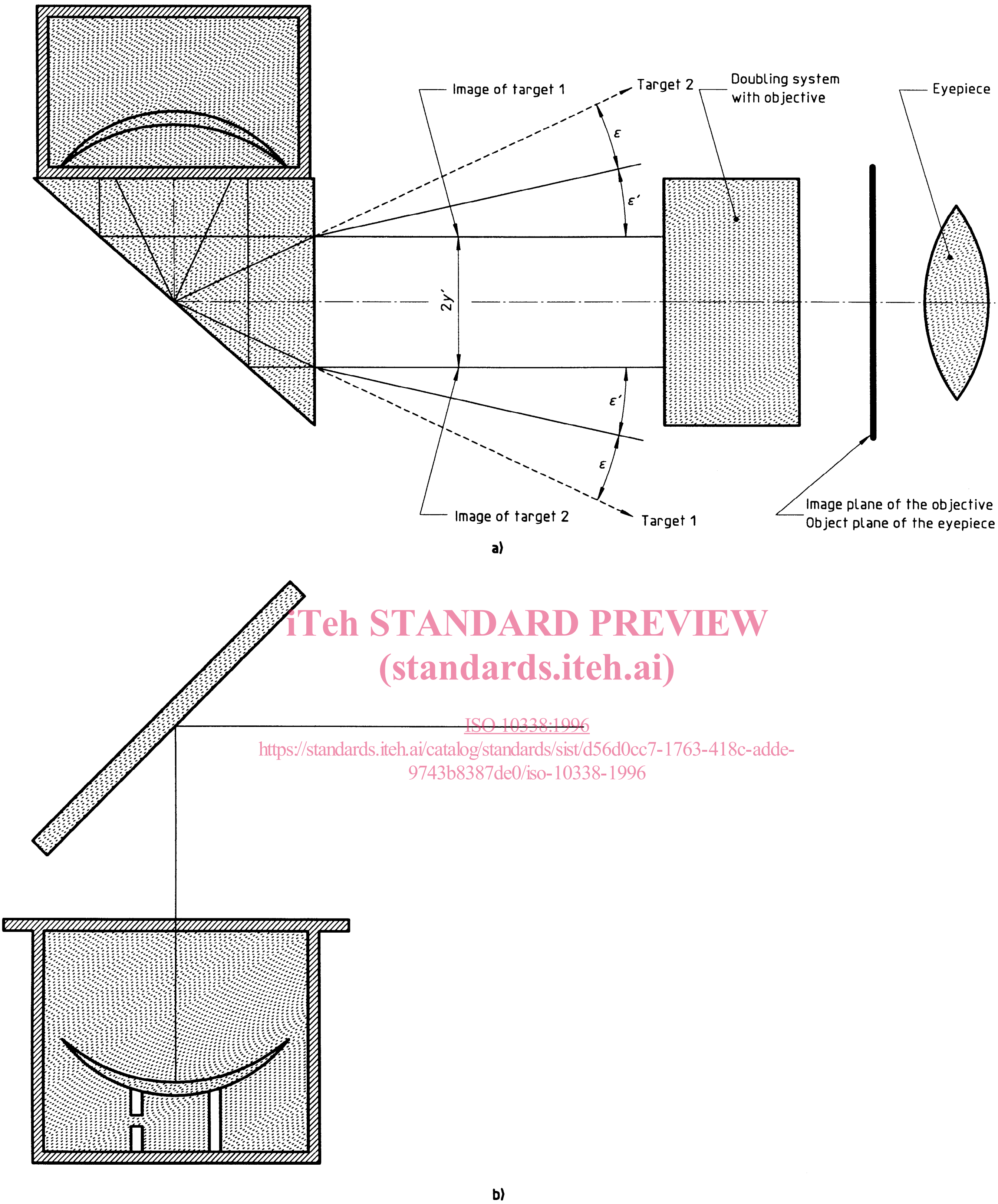


Figure B.3 — Measuring arrangements with wet cells

Annex C
(normative)

Determination of radius of curvature from sagitta

C.1 Scope

This annex specifies methods for determining the

— sagitta above a given chord diameter,

— total sagitta of the lens,

— curvature related to hydrogel contact lenses.

Curvature refers to the radius of curvature of a spherical surface. Equivalent spherical curvature refers to the calculated curvature using the sagitta formula (see C.2) when an aspherical surface is present.

NOTE 6 Toric surfaces cannot be measured using this method.

C.2 Principle

The sagitta s of a spherical lens surface is measured from a chord y of known length (see figure C.1).

From figure C.1, the radius of curvature r is given by the expression:

$$r = 0{,}5\,s + 0{,}125\,\frac{y^2}{s}$$

If the total lens sagitta is required, then y is the total diameter of the lens.

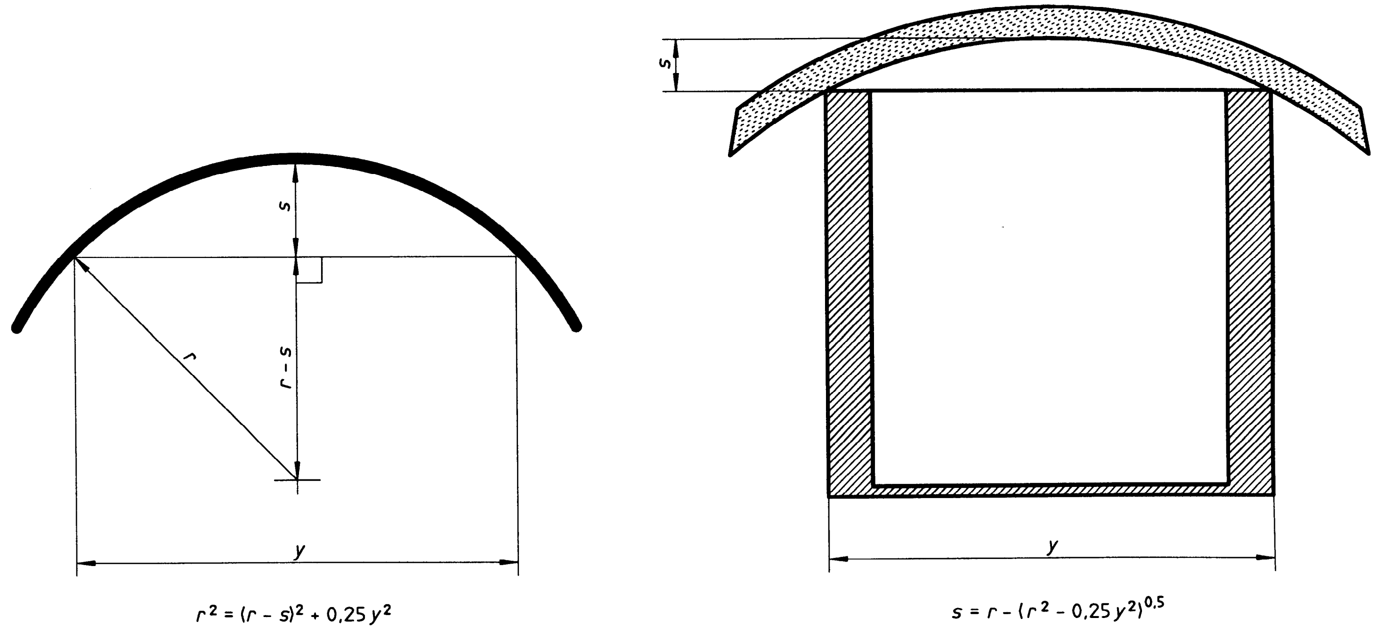


Figure C.1 — The geometry of sagittal measurement