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Ophthalmic optics — Contact lenses —

Part 3:
Measurement methods

Optique ophtalmique — Lentilles de contact —

Partie 3: Méthodes de mesure

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 18369-3:2006), which has been technically revised.

A list of all parts in the ISO 18369 series can be found on the ISO website.

Ophthalmic optics — Contact lenses —

Part 3: Measurement methods

1 Scope

This document specifies the methods for measuring the physical and optical properties of contact lenses specified in ISO 18369-2, i.e. radius of curvature, label back vertex power, diameter, thickness, inspection of edges, inclusions and surface imperfections and determination of spectral transmittance. This document also specifies the equilibrating solution and standard saline solution for testing of contact lenses.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 9342-1, *Optics and optical instruments — Test lenses for calibration of focimeters — Part 1: Test lenses for focimeters used for measuring spectacle lenses*

ISO 18369-1:2017, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Methods of measurement for contact lenses

4.1 General

Clause 4 specifies methods for measuring finished contact lens parameters.

Clause 4 is applicable to testing laboratories, suppliers and users of contact lens products or services, in which measurement results are used to demonstrate compliance to specified requirements.

Alternative test methods and equipment may be used provided the accuracy and precision are equivalent to or more capable than the test methods described.

Each method should be capable of measurement with a precision [repeatability and reproducibility (R&R)] of ≤30 % of the allowed tolerance range[8].

Lenses should be equilibrated by soaking in standard saline or packaging solution for sufficient time that the parameter to be measured remain constant within the ability of the method to measure the parameter.

NOTE The process might be influenced by the nature of the lens material, volume of the solution used for equilibration and the nature of the solution used to hydrate the lens (if any).

The nature of the equilibration solution (i.e. standard saline solution or packaging solution) and the equilibration process should be identified in the test report.

Many methods require use of specific temperature ranges and this should be considered when equilibrating the lenses for testing.

4.2 Radius of curvature

4.2.1 General

There are two generally accepted instruments for determining the radius of curvature of rigid contact lens surfaces. These are the optical microspherometer (see 4.2.2) and the ophthalmometer with contact lens attachment.

The ophthalmometer method measures the reflected image size of a target placed at a known distance in front of a rigid or soft lens surface, and the relationship between curvature and magnification of the reflected image is then used to determine the back optic zone radius (see Annex C).

For hydrogel contact lenses, sagittal depth can be measured using ultrasonic, mechanical and optical methods that are available and are applicable to hydrogel contact lens surfaces as indicated in 4.2.3 and Table 1. Sagittal depth can also be used to determine equivalent radius of curvature.

The sagittal methods are generally not recommended instead of radius measurement for rigid spherical surfaces because aberration, toricity and other errors are masked during sagitta measurement. Sagittal depth of rigid aspheric surfaces can be useful.

In addition to these measurement methods, a method using interferometry and applicable to rigid contact lenses is given in Annex A for information.

Table 1 — Reproducibility values for different test methods

Refer to	Test method/application	Reproducibility, R[a]
4.2.2	Optical spherometry	
	Spherical rigid lenses	±0,015 mm in air
Annex C	Ophthalmometry	
	Spherical rigid lenses	±0,015 mm in air
	Spherical rigid lenses	±0,025 mm in saline solution
	Spherical hydrogel lenses	
	(38 % water content, t_c > 0,1 mm)	±0,050 mm in saline solution
4.2.3	Sagittal height method	
	Hydrogel contact lenses[b]	
	38 % water content, t_c > 0,1 mm	±0,05 mm in saline solution
	55 % water content, t_c > 0,1 mm	±0,10 mm in saline solution
	70 % water content, t_c > 0,1 mm	±0,20 mm in saline solution[c]

NOTE This table provides reproducibility for spherical rigid lenses because this type of lens was included in the ring test carried out. However, in general, the values equally apply to aspheric and toric rigid lenses.

[a] R is the reproducibility as defined in ISO 18369-1:2017, 3.1.12.9.3.

[b] The three water contents given in this table were the ones used to conduct the ring test. For other water content lenses, extrapolation can be used.

[c] The reproducibility is equal to the tolerance and, therefore, the sagittal height method is not relevant for water contents of 70 % and above.

4.2.2 Optical spherometry (rigid contact lenses)

4.2.2.1 Principle

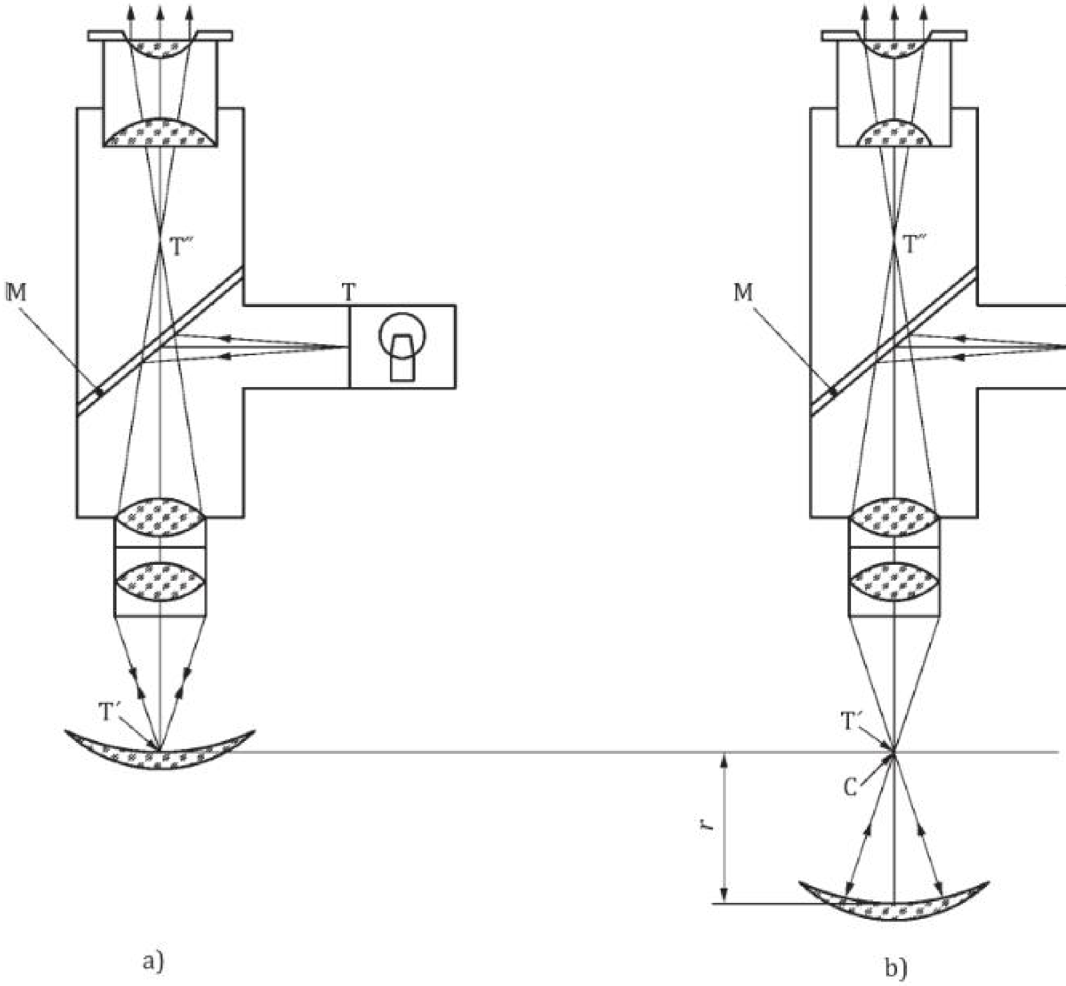
The microspherometer locates the surface vertex and the aerial image (centre of curvature) with the Drysdale principle, as described below. The distance between these two points is the radius of curvature for a spherical surface and is known as the apical radius of curvature for an aspheric surface derived from a conic section. The microspherometer can be used to measure radii of the two primary meridians of a rigid toric surface and with a special tilting attachment, eccentric radii can be measured as found in the toric periphery of a rigid aspheric surface. When the posterior surface is measured, the back optic zone radius is that which is verified.

The optical microspherometer consists essentially of a microscope fitted with a vertical illuminator. See Figure 1. Light from the target, T, is reflected down 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 at T and T″. The image at T″coincides with the first principle focus of the eyepiece when a sharp image is seen by the observer [Figure 1 a)]. This is referred to as the "surface image".

The distance between the microscope and the lens surface is increased by either raising the microscope or lowering the lens on the microscope stage until the image (T′) formed by the objective coincides with C (the centre of curvature of the surface). Light from the target T strikes the lens' surface normally and is reflected back along its own path to form images at T and T′ as before [Figure 1 b)]. A sharp image of the target is again seen by the observer. This is referred to as the "aerial image". The distance through which the microscope or stage has been moved is equal to the radius (r) of curvature of the surface. The distance of travel is measured with an analogue or digital distance gauge incorporated in the instrument.

In the case of a toric test surface, there is a radius of curvature determined in each of two primary meridians aligned with lines within the illuminated microspherometer target.

It is also possible to measure the front surface radius of curvature by orienting the lens such that its front surface is presented to the microscope. In this instance, the aerial image is below the lens, such that the microscope focus at T′ need be moved down from its initial position at the front surface vertex in order to make T′ coincide with C.



Key

C centre of curvature of the surface to be measured

T target

T′ image of T at a self-conjugate point

T″ image of T′ located at the first principal focus of the eyepiece, TM = MT″

M semi-silvered mirror

r radius of curvature of the surface

Figure 1 — Optical system of a microspherometer

4.2.2.2 Instrument specification

The optical microspherometer shall have an optical microscope fitted with a vertical illuminator and a target and have 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.

The objective lens shall have a minimum magnification of ×6,5 with a numerical aperture of not less than 0,25. The total magnification shall not be less than ×30. The real image of the target formed by the microscope shall not be greater than 1,2 mm in diameter.

The scale interval for the gauge shall not be more than 0,02 mm. The accuracy of the gauge shall be ±0,010 mm for readings for 2,00 mm or more at a temperature of 20 °C to 25 °C. The repeatability of the gauge (see Note 1 and Note 2) shall be ±0,003 mm.

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.

The illuminated target is typically composed of four lines intersecting radially at the centre, separated from each other by 45°.

The microspherometer shall include a contact lens holder that is capable of holding the contact lens surface in a reference plane that is normal to the optic axis of the instrument. The holder shall be adjustable laterally, such that the vertex of the contact lens surface may be centred with respect to the axis. The contact lens holder shall allow neutralization of unwanted reflections from the contact lens surface not being measured.

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

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

4.2.2.3 Calibration

Calibration (determining the measuring accuracy) shall be carried out using at least three concave spherical radius test plates over the range to be tested.

EXAMPLE Three concave spherical radius test plates made from crown glass:

— Plate 1: 6,30 mm to 6,70 mm;

— Plate 2: 7,80 mm to 8,20 mm;

— Plate 3: 9,30 mm to 9,70 mm.

The test plates have radii accurately known to ±0,007 5 mm.

Calibration shall take place at a temperature of 20 °C to 25 °C and after the instrument has had sufficient time to stabilize.

Mount the first test plate so that the optical axis of the microscope is normal to the test surface. Adjust the separation of the microscope and stage so that the image of the target is focused on the surface and a clear image of the target is seen through 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 surface now occupy the position seen in Figure 1 b).

Both images shall have appeared in the centre of the field of view. If this does not occur, move the test surface laterally and/or tilted until this does occur. Record the distance shown on the gauge when the second image is in focus as the radius of curvature.

Take at least 10 independent measurements (see Note) and calculate the arithmetic mean for each set. Repeat this procedure for the other two test plates. Plot the results on a calibration curve and use this to correct the results obtained in 4.2.2.4.

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

4.2.2.4 Measurement method

Carry out the measurements on the test lens in air at 20 °C to 25 °C.

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 measurements shall be made. Correct the arithmetic mean of this set of measurements using the calibration curve obtained in 4.2.2.3 and record the result to the nearest 0,01 mm.

In the case of a toric surface, the contact lens shall not only be centred, but also rotated such that the two primary meridians are parallel to lines of the target within the microspherometer. The measurement procedure described shall be carried out for each of the two primary meridians.

In the case of an aspheric surface, where the apical radius of curvature shall be measured, the procedure is the same as for a spherical surface with the exception that placement of the surface vertex at the focus of the microscope has to be more precise. At this point, there shall be no toricity noticeable in the aerial image.

NOTE 1 The equivalent spherical radius of curvature of an aspheric surface can be determined by measurement of the sagittal depth (s) of the surface over the optic zone (y) using the methods employed in 4.2.3. The sagittal depth is converted to an equivalent spherical radius using Formula (1):

$$r = \frac{s}{2} + \frac{y^2}{8s} \tag{1}$$

where s is the sagittal depth, in millimetres, and y is the chord distance, in millimetres.

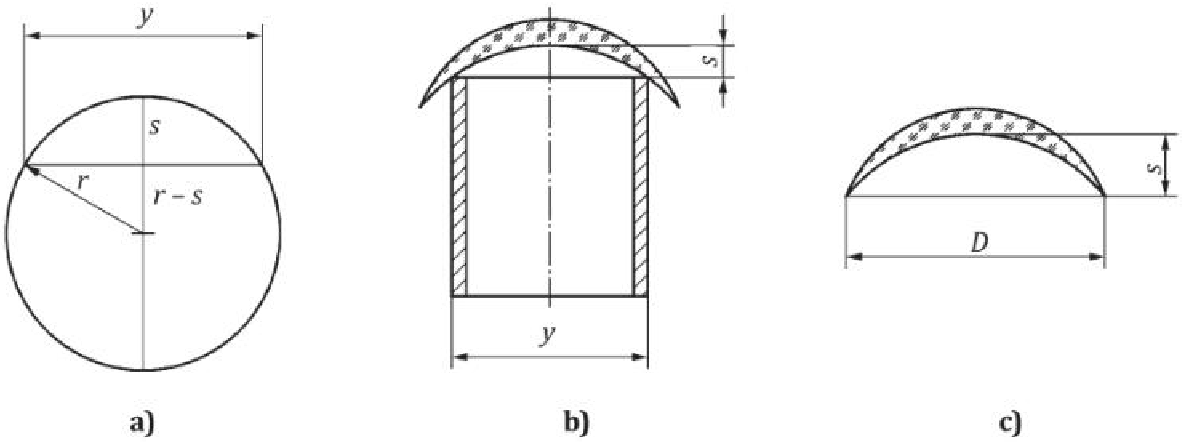
NOTE 2 This method is independent of eccentricity (e) and can be used to verify those equivalent radii calculated using eccentricity values. In addition, this method of determining the equivalent radius is applicable to aspheric surfaces that are not based on conic sections.

NOTE 3 Eccentricity of a conoidal aspheric surface can be computed from the sagittal and apical radii of curvature measured at chord diameters (y) away from the apex of the surface. Although the apex of these surfaces appears spherical when centred in the microspherometer, the surfaces become progressively toric as the point of measurement is brought away from the apex (as the chord diameter, y, is increased). As there is a known relationship between apical radius, eccentricity, chord diameter and sagittal radius for any conoidal surface, eccentricity and its consistency over the surface can be evaluated.

4.2.3 Sagittal height method

4.2.3.1 Principle

Sagittal depth is the distance from the vertex of the contact lens surface to a chord drawn across the surface at a known diameter. For the determination of the sagittal depth of the back optic zone, the contact lens is positioned concave side down against a circular contact lens support of fixed outside (chord) diameter (see Figure 2).



Key

r radius of curvature of lens

s sagittal depth

y outside (chord) diameter of lens support

D total diameter

Figure 2 — Measurement of sagittal depth of a soft contact lens

A soft contact lens shall be equilibrated in standard saline solution (see 4.9) before measurement. The equivalent posterior radius of curvature can also be determined using sagittal depth measurement.

The following three types of method may be used for posterior sagittal depth measurement of soft lenses.

a) Optical comparator

The vertical distance between the back vertex of the lens and the chord is measured visually under magnification. It can be difficult to accurately detect the back vertex of the contact lens using an optical comparator. An alternative method to measuring the posterior sagitta is to measure the total sagitta of the contact lens and subtract the centre thickness.

b) Mechanical or optical sensor

This method introduces a central vertical probe that is extended so that it just touches the back surface vertex, its length from the chord equals the sagittal depth [see Figure 2 b) and Figure 3]. An optical sensor can also be used to measure the distance from the lens support plane to the lens back surface vertex.

c) Ultrasound

Sagitta can also be ultrasonically assessed by measuring the time of travel through standard saline of an ultrasonic pulse from an ultrasonic transducer to the back vertex and by reflection back to the transducer. The resultant measured sagittal depth is, therefore, half of the distance calculated by multiplication of the time by the velocity of sound in saline at the temperature involved and then subtraction of the vertical height from the transducer to the top of the lens support.

Radius of curvature for a spherical surface ($e = 0$), or apical radius of curvature for a conicoidal surface with specified eccentricity ($e > 0$), can be calculated from the sagittal depth using the appropriate formula (see Table 2).

Table 2 — Summary of radius of curvature formulae in terms of sagittal depth (S), eccentricity (e), chord diameter (y) and lens total diameter (D)

Sphere	$r = \frac{S}{2} + \frac{y^2}{8S}$	Figure 2 a)
Ellipsoid	$r_a = \frac{\left(pS^2 + y^2/4\right)}{2S}$	where the shape factor $p = 1 - e^2$
Sphere (EPC method)	$r = \frac{S}{2} + \frac{D^2}{8S}$	Figure 2 c)

4.2.3.2 Instrument specification

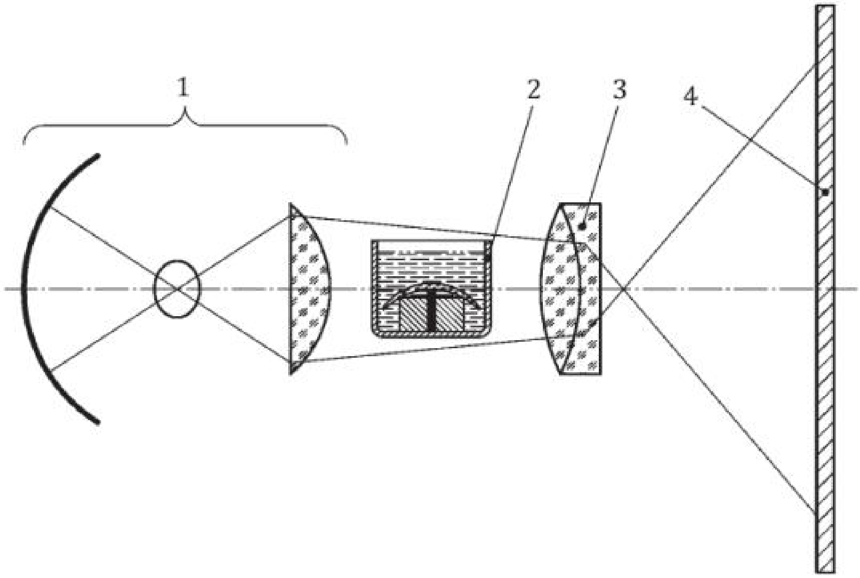
4.2.3.2.1 The optical comparator. This shall have a minimum magnification of 10× and shall have incorporated a soft lens wet cell with a lens support appropriate to the radius being measured. For back optic zone radius, a hollow cylindrical contact lens support sized for the back optic zone radius should be used. In the measurement of equivalent posterior radius of curvature, a flat stage sized to allow slight overhang of the contact lens is optimal.

In order to measure total posterior sagitta, the contact lens shall rest horizontally with its concave (posterior) surface against the circular outside edge of the flat-rimmed support. The cylindrical support shall be constructed in such a way as to provide a chord diameter (y) appropriate to the posterior surface lens design when a soft lens is centred on the support. The flat stage support shall be sized to allow the contact lens to overhang approximately 0,100 mm when centred on the stage. This overhang will allow more accurate measurement of lens total diameter.

4.2.3.2.2 Mechanical analyser. The instrument shall allow the contact lens, lens support and probe to be focused together. It shall allow the operator to see that the contact lens is centred on the support so that the probe approaches along the lens axis and, finally, just touches the back vertex of the lens (see Figure 3 and Figure 4). This is the end point required to obtain a measurement value. The distance travelled by a solid mechanical probe from the plane of the lens support to the lens back surface vertex is the sagittal depth (S). An optical sensor can also be used to measure the distance from the lens support plane to the lens back surface vertex.

A reticule or digital readout should display minimal increments of ≤10 % of the sagittal tolerance and should be capable of measuring sagittal depth with a precision (R&R) of ≤30 % of the allowed tolerance. Resolution greater than 10 % can be used but will affect determination of accuracy, precision, process capability and gauge capability.

The temperature of the wet cell and contact lens shall be maintained at 20 °C ± 1,0 °C.



Key

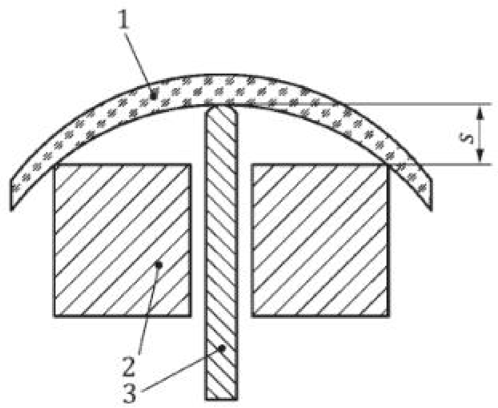
1 illumination system

2 wet cell with test sample

3 imaging lens

4 projection screen

Figure 3 — Principle of the mechanical analyser



Key

s sagittal depth

1 contact lens

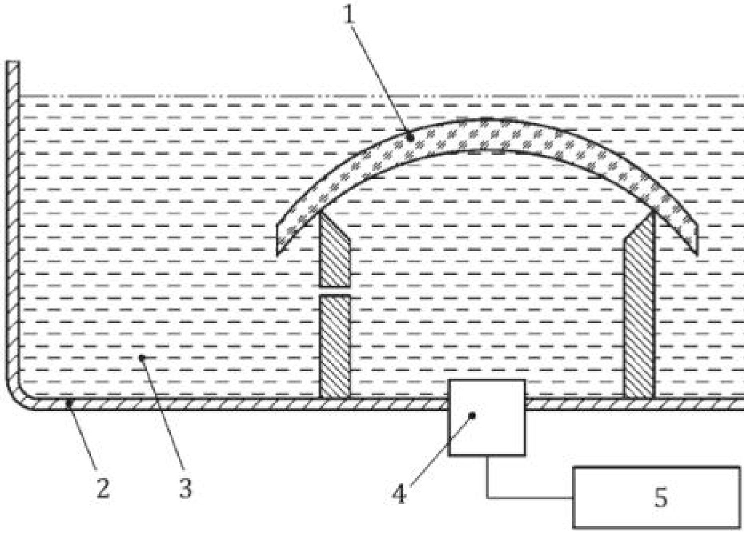
2 lens support

3 probe

Figure 4 — Detail of the mechanical analyser showing the lens support and probe

4.2.3.2.3 Ultrasound method. In the case of ultrasonic measurement of sagittal depth, the requirements for the wet cell and support are shown in Figure 5. An ultrasonic transducer shall be fitted under the centre of the contact lens support. It should have a frequency greater than 18 MHz, beam width of 2,0 mm or less at focus and a focal length of 15 mm to 50 mm.

The temperature of the wet cell and contact lens shall be maintained at 20 °C ± 0,5 °C because ultrasound method is temperature dependent as well as material dependent.



Key

1 contact lens

2 container

3 saline solution

4 transducer

5 ancillary equipment

Figure 5 — Ultrasonic measurement of sagittal depth in a wet cell

4.2.3.3 Calibration

Instrument calibration shall be carried out to assure measuring accuracy to known standards and multiple instrument equivalence using three height test plates. The test plates shall be chosen so as to determine the measuring accuracy over the desired range of contact lens sagittal heights. The actual heights shall be known to within 0,002 mm.

Calibration can also be carried out using rigid single curve test pieces of known accuracy.

EXAMPLE Three concave spherical radius test plates made from crown glass:

— Plate 1: 6,30 mm to 6,70 mm;

— Plate 2: 7,80 mm to 8,20 mm;

— Plate 3: 9,30 mm to 9,70 mm.

The test plates have radii accurately known to ±0,007 5 mm.

Calibration shall take place in a wet cell with a temperature of 20 °C ± 1,0 °C after the instrument has had sufficient time to stabilize and after the calibration pieces have been equilibrated in standard saline solution within the wet cell.

Each test plate shall be measured from the same direction three times and the arithmetic mean calculated. Differences between calculated and actual radius shall be used to construct a correction calibration curve.

4.2.3.4 Measurement method

The lens shall be allowed to equilibrate in standard saline (see 4.9).

The temperature of the lens and surrounding saline after stabilization shall be 20 °C ± 1,0 °C except for the ultrasound method which shall be 20 °C ± 0,5 °C.

Allow the contact lens to float down by gravity over the contact lens support in saline solution, taking care to centre the lens over the support. When measuring the sagittal depth of aspheric surfaces, particular attention should be paid to accurate centration of the lens on the support.

The measurement shall be recorded to the nearest 0,01 mm and shall be converted to radius of curvature or apical radius of curvature using the formulae shown in Table 2.

A minimum of three independent measurements are used to obtain an arithmetic mean value.

4.3 Label back vertex power

4.3.1 General

Label back vertex power of a single power contact lens is the dioptric power as measured with a focimeter as specified in 4.3.2, calibrated as specified in 4.3.3 using the measurement method given in 4.3.4 or 4.3.5. Proper design of the contact lens stop, calibration and measurement apertures and calibration standards are all necessary to properly measure the label back vertex power of contact lenses.

Label back vertex power can also be determined by immersing the lens in saline solution. Examples of techniques that can be employed are given in Annex B.

4.3.2 Focimeter specification

4.3.2.1 Focimeter, having a minimum range of −20,00 D to +20,00 D with a minimum measuring accuracy of ±0,06 D, and capable of manual focusing. Other focimeters may be used provided the readings derived are shown to be equivalent to those of a manually focusing focimeter. A focimeter conforming to ISO 8598-1 can be used.

4.3.2.2 Lens supports allowing centration of the contact lens optic zone around the optical axis of the focimeter.

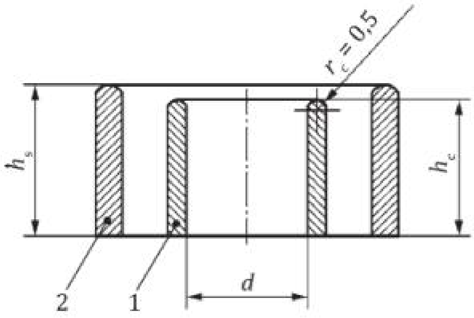
Two interchangeable lens supports are used. These are

1) a support that allows calibration with spherical aberration-free (spectacle-type) lenses in the vertex plane of the focimeter, and

2) an alternative smaller and shorter support of 4,0 mm to 5,0 mm in diameter so that the back vertex of a contact lens can also be positioned in the vertex plane of the focimeter. See the example in Figure 6. This will provide the appropriate vertex power by compensating for the sagittal depth change due to a back optic zone radius of 8,00 mm in a contact lens (see Figure 7 for illustration). Contact lenses with a back optic zone radius value substantially different from this can require further distance correction. An example of paddle support is shown in Annex D.

NOTE Although the contact lens stop will reduce sagittal errors, it will have little effect on reducing spherical aberration.

Dimensions in millimetres



$h_s - h_c = 0,55$ mm

Key

h_c height of contact lens support

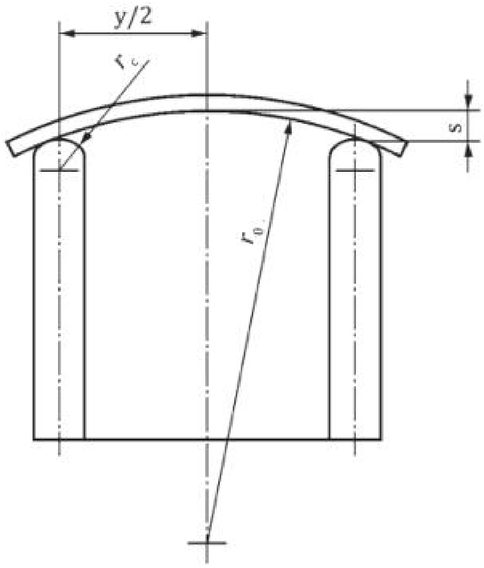
h_s height of spectacle lens support

r_c radius of contact lens support

1 contact lens support (4,0 mm to 5,0 mm in diameter)

2 spectacle lens support

Figure 6 — Example of focimeter stops for calibration and power measurement



Key

s sagittal depth of back central optic zone

$y/2$ semichord length (chord diameter = y)

r_0 back optic zone radius (base curve radius)

r_c radius of contact lens stop

Figure 7 — Contact lens resting on a contact lens stop

4.3.3 Calibration

Instrument calibration shall be carried out to assure measuring accuracy to known standards using spherical test lenses with minimal spherical aberration as specified in ISO 9342-1. The label back vertex

Measurements shall be taken along meridians or extensions of meridians passing through the geometrical centre of the rigid contact lens. Three measurements of the appropriate zone diameter or width shall be taken along the meridian of the length to be measured and the arithmetic mean shall be taken as the measurement along that meridian. Adjust this value using the calibration curve if necessary.

4.5 Thickness

4.5.1 General

Thickness, measured through the section of a contact lens, shall be made with a dial gauge for rigid lenses (see 4.5.2) and with a "low-force" dial gauge for soft contact lenses (see 4.5.3).

Optical methods using a microspherometer or a projection comparator can be used for comparison of thickness between contact lenses, but might not be indicative of the absolute thickness of a contact lens, and the precision has not been verified by inter-laboratory testing.

4.5.2 Dial gauge method

4.5.2.1 Instrument specification

The measuring face of the dial gauge shall be spherical with a radius between 1,2 mm and 5,0 mm depending on the lens to be measured. The radius and measuring force applied to the lens specimen shall not exceed the limit of the lens material so as to prevent undue compression of the specimen during testing. The dial gauge shall be capable of being set to zero using a fixed stop so that the surfaces of the contact lens at the point where the thickness is to be measured shall be in contact with the adjustable stylus and the fixed stop. The dial gauge readout should display minimal increments of ≤10 % of the thickness tolerance being measured and should be capable of measuring thicknesses with a precision (R&R) of 30 % of the allowed tolerance. Resolution greater than 10 % can be used but will affect determination of accuracy, precision, process capability and gauge capability.

4.5.2.2 Calibration

Instrument calibration shall be carried out to assure measuring accuracy to known standards and multiple instrument equivalence using multiple precision engineering discs. These discs shall be made from a hard, non-compressible material (e.g. steel, hard plastic). The discs shall be chosen so as to determine the measuring accuracy over the desired range of measured thicknesses. The actual thickness of these discs shall be traceable to a national or International Standard and known to within 0,002 mm.

Calibration shall take place at a temperature of 20 °C to 25 °C and after the instrument and calibration discs have had sufficient time to stabilize.

Place each calibration shim between the stylus and the fixed stop. Record the calibration shim thickness to the nearest 0,002 mm. Take three independent readings and calculate the arithmetic mean. Differences between calculated and actual calibration shim thickness shall be used to construct a correction calibration curve if the results fail to meet the calibration accuracy criteria.

4.5.2.3 Measurement method

The dial gauge shall be maintained at a temperature of 20 °C to 25 °C during the measurement.

Place the test specimen convex side down between the stylus and the fixed stop at the point to be measured as shown in Figure 12. Record the thickness to the nearest 0,002 mm. Take three independent readings, taking care not to deform the lens during the measurement. Calculate the thickness by taking the arithmetic mean of the readings and adjust this value using the calibration curve.

4.9.2.2 Formula example using USP substances

The following formula for USP substances shall be applicable to the finished solution:

a) sodium chloride USP (NaCl): 8,300 g;

b) monobasic sodium phosphate monohydrate USP ($NaH_2PO_4 \cdot H_2O$): 0,467 g;

c) dibasic sodium phosphate heptahydrate USP ($Na_2HPO_4 \cdot 7H_2O$): 4,486 g;

d) water according to ISO 3696:1987, Grade 3 (H_2O): completed to 1 000 ml.

4.9.2.3 Formula example using Ph Eur substances

The following formula for Ph Eur substances shall be applicable to the finished solution:

a) natrII chloridum Ph Eur (NaCl): 8,300 g;

b) natrII dihydrogenophosphas dihydricus Ph Eur ($NaH_2PO_4 \cdot 2H_2O$): 0,528 g;

c) dinatrII phosphas dodecahydricus Ph Eur ($Na_2HPO_4 \cdot 12H_2O$): 5,993 g;

d) water according to ISO 3696:1987, Grade 3 (H_2O): completed to 1 000 ml.

4.9.2.4 Formula example using anhydrous substances

The following formula for anhydrous substances shall be applicable to the finished solution:

a) NaCl 8,300 g;

b) NaH_2PO_4 0,406 g;

c) Na_2HPO_4 2,376 g;

d) water according to ISO 3696:1987, Grade 3 (H_2O): completed to 1 000 ml.

4.9.3 Preparation procedure

The hydrated phosphates of sodium can vary in the number of molecules of water of hydration, depending on the type and period of exposure to the atmosphere. This will affect their formula mass and the formulations given may not achieve the required molarity, and, therefore, a pH of 7,4 ± 0,1. In this sense, the saline is not a "standard" until provision has been made to adjust the solution using a pH-meter calibrated by standardized reference solutions. To adjust the solution, either aqueous orthophosphoric acid (e.g. 5 mol/l) or aqueous sodium hydroxide (e.g. 5 mol/l) should be added after the ingredients have been dissolved in the water. Only a small amount of adjustment (less than 1 ml/l) is required to formulate the solution.

Sequentially, add the three ingredients to 70 % of the water (700 ml in the examples given in 4.9.2.2, 4.9.2.3 and 4.9.2.4), ensuring that all are completely dissolved by proper mixing.

Test this solution with a calibrated pH-meter and adjust by addition of drops of either acid or alkali to a pH of 7,4 ± 0,1. Dilute the adjusted solution with water to a volume of 1 000 ml, mix thoroughly and test the pH again. If necessary, add more acid or alkali.

If anhydrous ingredients are used, adjustment of the pH by addition of acid and alkali is not required. However, it is good practice to check the pH of the final solution before use.

4.9.4 Packaging and labelling

If the saline is to be retained, it shall be packaged in autoclavable containers, preferably of neutral glass and sterilized by a validated process. The closures shall be airtight.

Labelling shall include

a) a reference to this document (i.e. ISO 18369-3:2017),

b) a description (e.g. standard saline for contact lens testing), and

c) the date of preparation.

If the saline is not to be stored, it shall be used within 24 h of preparation and need not be autoclaved.

5 Test report

When any test method has been carried out in accordance with the specification detailed in this document, a test report shall be prepared and shall contain at least the following information:

a) the name of the laboratory carrying out the test;

b) all necessary details for the identification of the contact lens tested;

c) a reference to this document (i.e. ISO 18369-3:2017) and relevant subclause;

d) any deviations from the specified method;

e) the test result, including, where possible, an estimation of the error;

f) the date of test and the name of the responsible person.

Annex A
(informative)

Measurement of rigid contact lens curvature using interferometry

A.1 General

This annex suggests a method for the measurement of the curvature of contact lenses by interferometry.

In order to evaluate an interference fringe pattern, it is necessary to quantify the deviation of the fringe pattern from some ideal, best-fitting pattern. For contact lens surface evaluation, a best-fitting conicoidal spherical surface is normally used.

A.2 Measuring principle and apparatus

One basic setup for testing front and/or back curvatures of rigid contact lenses is the Twyman-Green interferometer shown in Figure A.1.

A collimated laser beam is separated by a beam splitter (3) into a test beam and a reference beam. The latter is reflected at a very accurate reference mirror (4) and arrives at the interferometer's exit where a computer-generated hologram (5) is placed in case of an aspherical test surface.

The test beam passes through a lens system (2) consisting of a high-aperture objective (6) and one or several additional lenses (7) in order to introduce a spherical shape of the wavefront fitting the test surface (8). When reflected back, the light takes almost the same path and interferes with the reference beam at the interferometer's exit. When different aspherical surfaces are tested, a computer-generated hologram can be used to transform the aberrated diffraction order, since the hologram is not plane. It can thus interfere with the undiffracted light of the reference beam to produce an interference pattern with either perfectly straight fringes or no fringes at all.

A.3 Precision

Any shape deviation of a surface tested introduces a curved or irregular fringe pattern which can be interpreted as a contour level map of the deviations from the ideal surface. Adjacent fringes have an altitude difference of half the wavelength used, e.g. 633,2 nm for a He-Ne laser.

Applying automatic fringe analysis techniques by means of computer-controlled video- or CCD-cameras will rapidly measure the shape deviations of either the entire surface or a large part of it depending on its ratio of diameter to vertex radius and on the numeric aperture of the objective (6).

The obtained shape accuracy is better than 300 nm. The accuracy of the vertex radius is the same as the resolution of the distance gauge.

A.4 Test specimens

The test specimens shall be normal production finished rigid contact lenses.

A.5 Procedure

Position the surface of the contact lens to be measured very precisely in relation to the focus of the objective (6) by a distance gauge of 0,001 mm resolution.

B.3.1.3 The instrument shall have a positioning mechanism for the cuvettes containing the contact lenses designed so that the lens being measured is located centrally in the measuring system.

B.3.2 Eight spherical test standards or contact lenses, with the label back vertex powers of the calibrating lenses spaced so as to determine the measuring accuracy over a broad range of label back vertex powers. Minimum requirements for this purpose include four plus lenses and four minus lenses to cover the power ranges of the contact lenses to be measured. The powers of the calibration lenses shall be traceable to a national or international standard.

B.3.3 Calibrated cuvettes, such that the optical properties of the walls of the cuvettes used in the measurement shall not influence the outcome of the test.

B.3.4 Standard saline solution, conforming to 4.9. The refractive index of the saline solution shall be known correct to three places of decimals.

B.4 Procedure

B.4.1 Conditioning of lenses prior to testing

Condition each test lens prior to testing as follows: immerse in a vial filled with standard saline solution (B.3.4) and maintain at a temperature of 20 °C ± 1,0 °C for 30 min. If 30 min is not a sufficient time for the lens polymer to equilibrate, the lens manufacturer should state the time required.

B.4.2 Calibration

B.4.2.1 At a temperature of 20 °C to 25 °C and using the spherical test lenses (B.3.2) arranged in calibrated cuvettes (B.3.3), follow the manufacturer's instructions to calibrate the instrument.

The average measured power for each lens should be within ±0,04 D of the nominal value.

B.4.2.2 Take three independent readings and record the arithmetic mean.

"Independent reading" means a reading that is obtained in a manner not influenced by any previous reading; the test lens should be removed from the instrument between each reading.

B.4.2.3 Plot the results on a calibration curve.

NOTE The preferred method of plotting a calibration curve is to use a linear least squares best fit.

B.4.3 Measurement of label back vertex power

B.4.3.1 Transfer the lens from its equilibrating vial to a cuvette (B.3.3) filled with standard saline solution (B.3.4) at a temperature of 20 °C ± 1,0 °C, using a lens lift.

B.4.3.2 Make sure the lens is not inverted.

B.4.3.3 Place the cuvette in the positioning mechanism (B.3.1.3) as specified by the instrument manufacturer.

B.4.3.4 Follow the instrument manufacturer's instructions to obtain a reading of the label back vertex power of the lens being measured.

B.4.4 Number of readings required

B.4.4.1 General

The number of readings required for spherical hydrogel soft lenses is given in Table B.1. The number of readings required for each of the power-related dimensions of toric hydrogel soft lenses is given in Table B.2.

NOTE The number of readings required will depend on the tolerance limit of the dimension being measured and the reproducibility of the test method as assessed by an inter-laboratory test. Table B.1 and Table B.2 are based on the outcome of inter-laboratory tests as given in B.4.6.

B.4.4.2 Spherical lenses

Take the number of independent readings (see B.4.2.2) of the label back vertex power, as specified in Table B.1 and calculate the arithmetic mean. Use the calibration curve (B.4.2.3) to determine the corrected arithmetic mean.

B.4.4.3 Toric lenses

Take the number of independent readings (see B.4.2.2) of the toric power-related parameters, as specified in Table B.2 and calculate the arithmetic mean. Use the calibration curve (B.4.2.3) to determine the corrected arithmetic mean.

Table B.1 — Number of readings required for spherical soft lenses

Parameter	Tolerance limit	Number of measurements	
		Moiré deflectometer	Hartmann instrument
Label back vertex power			
0 to ±10,00 D	±0,25 D	2	1
over ±10,00 D to ±20,00 D	±0,50 D	1	1
over ±20,00 D	±1,00 D	1	1

Table B.2 — Number of readings required for toric soft lenses

Parameter	Tolerance limit	Number of measurements	
		Moiré deflectometer	Hartmann instrument
Sphere power			
0 to ±10,00 D	±0,25 D	7	2
over ±10,00 D to ±20,00 D	±0,50 D	2	2
over ±20,00 D	±1,00 D	2	2
Cylinder power			
up 2,00 D	±0,25 D	2	2
over 2,00 D to 4,00 D	±0,37 D	1	2
over 4,00 D	±0,50 D	1	2
Axis direction	±5°	2	3

B.4.5 Expression of results

B.4.5.1 Spherical lenses

The label back vertex power of the lens in dioptres shall be reported as the corrected arithmetic mean determined as described in B.4.4.2.

B.4.5.2 Toric lenses

The sphere and cylinder powers of the lens in dioptres and the axis direction in degrees shall be reported as the corrected arithmetic mean(s) determined as described in B.4.4.3.

B.4.6 Reproducibility data

B.4.6.1 Spherical soft contact lenses

Reproducibility data for the measurement of label back vertex power of spherical soft lenses is given in Table B.3.

NOTE The values for reproducibility (R) and reproducibility standard deviation (S_R) were determined by an interlaboratory test conducted in accordance with ISO 5725 during 1996 and 1997 involving four and five independent laboratories, respectively, and 21 sample lenses.

Single results on identical test lenses reported by two laboratories will differ by more than the reproducibility value R on average not more than once in 20 cases in the normal and correct operation of the method.

Table B.3 — Reproducibility data for spherical soft contact lenses

Parameter	Reproducibility	
	S_R	R
Label back vertex power, Moiré deflectometer	0,090 3 D	0,252 8 D
Label back vertex power, Hartmann instrument	0,025 3 D	0,070 8 D

B.4.6.2 Toric soft contact lenses

Reproducibility data for the measurement of label back vertex power of toric soft contact lenses are given in Table B.4.

NOTE The values for reproducibility (R) and reproducibility standard deviation (S_R) were determined by an interlaboratory test conducted in accordance with ISO 5725 during 1996 and 1997 involving five independent laboratories and 8 and 19 sample lenses, respectively.

Single results on identical test lenses reported by two laboratories will differ by more than the reproducibility value R on average not more than once in 20 cases in the normal and correct operation of the method.

Table B.4 — Reproducibility data for toric soft contact lenses

Parameter	Reproducibility			
	Moiré deflectometer		Hartmann instrument	
	S_R	R	S_R	R
Sphere power	0,157 9 D	0,442 1 D	0,064 9 D	0,181 7 D
Cylinder power	0,093 D	0,260 4 D	0,087 1 D	0,243 9 D
Axis direction	1,22°	3,416°	2,016°	5,644 8°

Annex C
(informative)

Measurement of the radius of curvature of contact lenses using the ophthalmometer

C.1 Ophthalmometer

Spherical and toric surfaces of contact lenses can be measured using the ophthalmometer (see ISO 10343). For the purpose of determining the radius of curvature of a spherical rigid surface, the instrumentation shall be calibrated as described in C.4 and the measuring accuracy determined as per the recommended procedure.

C.2 Principle

The ophthalmometer is a short-focus telescope with a doubling system and is primarily designed to measure the curvature of the central cornea of the eye. For contact lens measurements, a special lens-holding attachment is required that will position the contact lens to be measured so that its back surface is perpendicular to the optical axis of the ophthalmometer. The curvature of the contact lens is then determined by using the doubling system provided in the ophthalmometer, which operates on the basis of determination of reflected image size for an object of known size and distance and the relationship of image size to radius of curvature of mirror surfaces. The ophthalmometer provides a radius of curvature for an area of the surface having a chord diameter of approximately 3,0 mm. The optically important components of an ophthalmometer are shown in Figure C.1.

The radius of curvature shall be derived to a first approximation assuming the surface is spherical in the area measured from Formula (C.1):

$$r_0 = \frac{-y'n}{\sin\varepsilon} \tag{C.1}$$

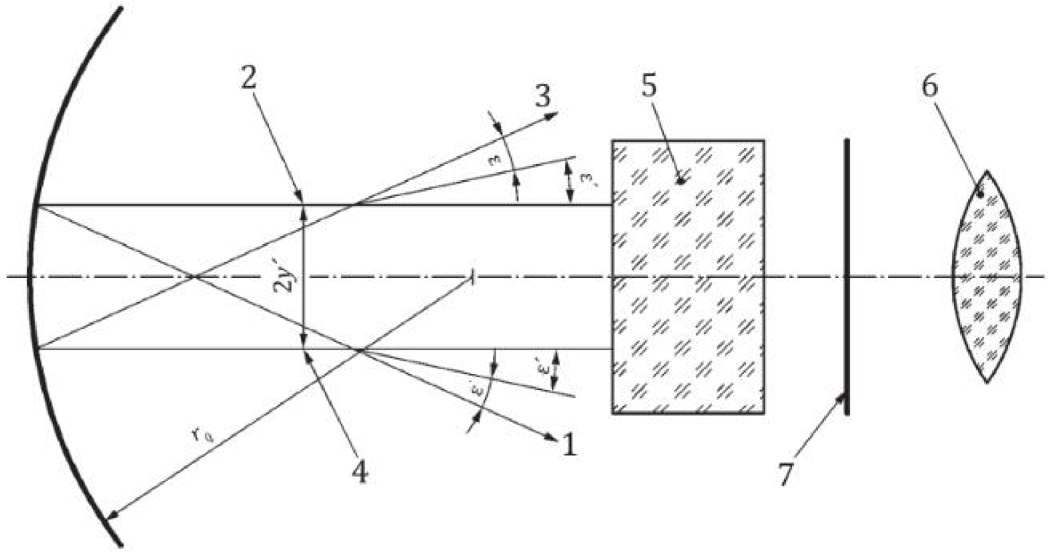
where

r_0 is the radius of curvature;

y' is half the distance between reflected images;

ε is the angle of incidence;

n is the refractive index of immersion medium (n = 1 for measurements in air).



Key

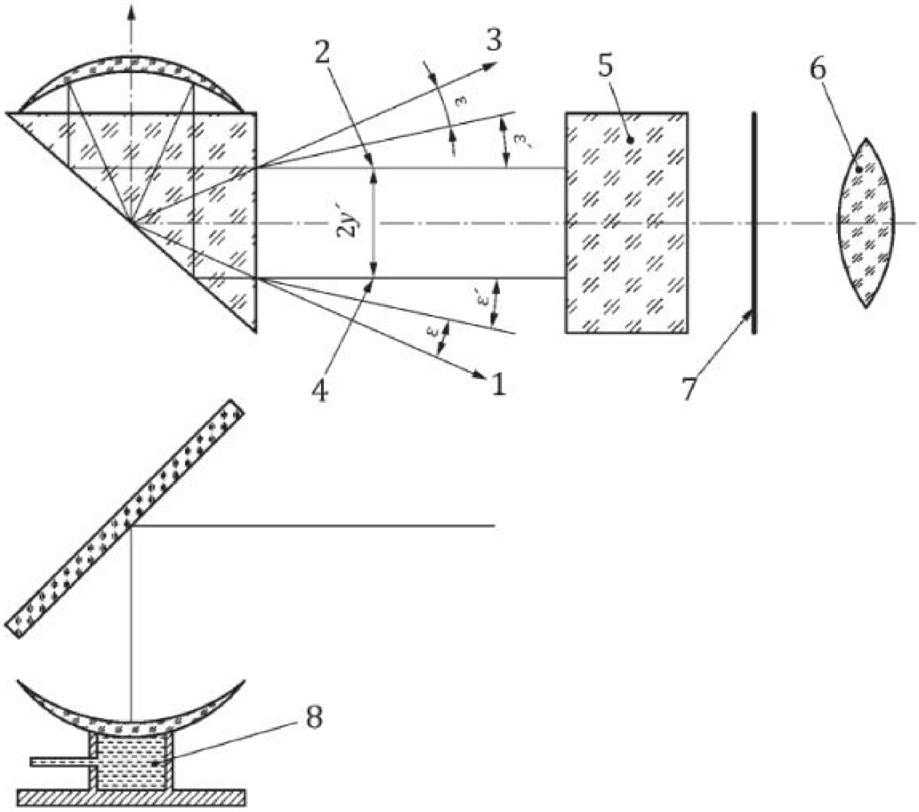
r_0	radius of curvature
$2y'$	distance between reflected images
ε, ε'	angles of incidence
1	Target 1
2	image of Target 1
3	Target 2
4	image of Target 2
5	doubling system with objective
6	eyepiece
7	image plane of the objective = object plane of the eyepiece

Figure C.1 — Optical system of an ophthalmometer

C.3 Instrument specifications

The ophthalmometer shall have a lighted target positioned so that it will reflect from an optical surface placed perpendicular to the axis of the optical system. A special lens-holding attachment is necessary so that the contact lens is held in the proper location and orientation (see Figure C.2 and Figure C.3, which are indicative of posterior surface measurement of contact lenses). The adjustable optical doubling system of the ophthalmometer shall be capable of assessing the size of the reflected image of a target of fixed size and distance, or target size shall be sufficiently adjustable with a fixed doubling system so as to attain a reflected image of fixed size. The ophthalmometer shall be capable of measurement of the two primary meridians of a toric surface. The total magnification of the instrument shall not be less than ×20.

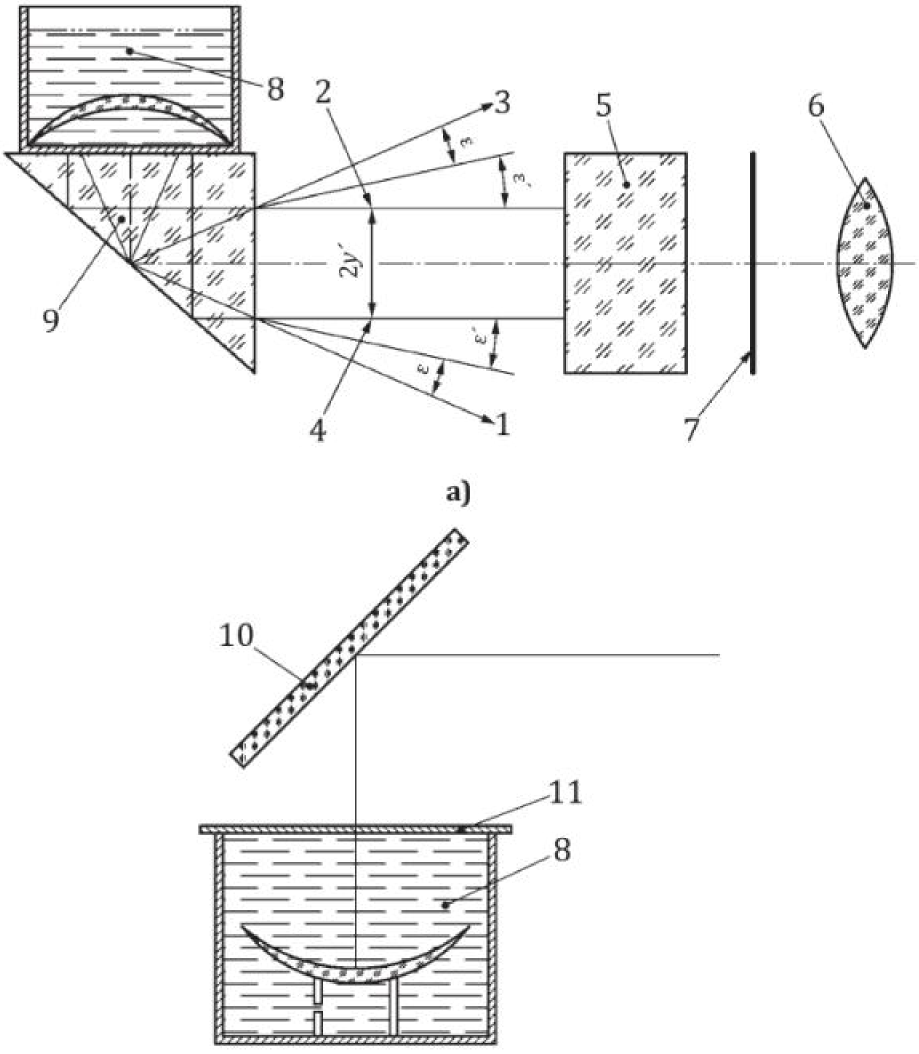
The scale interval shall be not more than 0,02 mm. If the scale is in dioptres, the maximum scale interval shall be 0,25 D. An instrument-specific conversion chart is used to change power values to radii of curvature.



Key

ε, ε′	angles of incidence
2y′	distance between reflected images
1	Target 1
2	image of Target 1
3	Target 2
4	image of Target 2
5	doubling system with objective
6	eyepiece
7	image plane of the objective = object plane of the eyepiece
8	solution

Figure C.2 — Ophthalmometer arrangement for measurement in air



Key

ε, ε'	angles of incidence
$2y'$	distance between reflected images
1	Target 1
2	image of Target 1
3	Target 2
4	image of Target 2
5	doubling system with objective
6	eyepiece
7	image plane of the objective = object plane of the eyepiece
8	saline solution
9	prism
10	front surface silvered mirror
11	transparent removable lid

Figure C.3 — Ophthalmometer arrangement for measurement in a wet cell

C.4 Calibration

For calibration of the ophthalmometer, use the test plates specified in 4.2.2.3.

Calibration shall take place at a temperature of 20 °C to 25 °C and after the instrument has had sufficient time to stabilize.

Use standard saline solution (see 4.9) when calibrating the instrument for the measurement of lenses in solution.

Each test piece shall be measured from the same direction at least 10 times and the arithmetic mean shall be calculated. Differences between calculated and actual radius shall be used to construct a correction calibration curve if applicable.

C.5 Measurement method

NOTE Rigid contact lenses are generally and more easily measured in air but can also be measured in a wet cell, if desired.

Carry out the measurements at a temperature of 20 °C to 25 °C and after stabilization of test piece and test equipment at that temperature.

Hold the rigid contact lens to be measured in the contact lens attachment, perpendicular to the optical axis of the ophthalmometer.

Make three independent readings of the radius, recorded to the nearest 0,01 mm. Take the arithmetic mean of the three readings (corrected using the calibration curve) as the radius of curvature of the spherical surface. In the case of a toric surface, determine three readings and the arithmetic mean for each of the two primary meridians. Correct each arithmetic mean using the calibration curve and take it as the radius of curvature of the meridian.

C.6 Measurement of soft lenses in a wet cell using an ophthalmometer

This method is only applicable to measurement in the central area.

Equilibrate the soft lens in standard saline solution (see 4.9) at 20 °C ± 1,0 °C. Suspend it in standard saline solution during measurement in the wet cell (see Figure C.3). Carry out the measurements of the soft lens and the saline solution in the wet cell at a temperature of 20 °C ± 1,0 °C.

Position the soft contact lens to be measured by the contact lens attachment, perpendicular to the optical axis of the ophthalmometer.

Make three independent readings of the radius, recorded to the nearest 0,01 mm. Take the arithmetic mean of the three readings as the radius of curvature of the spherical surface. In the case of a toric surface, determine three readings and the arithmetic mean for each of the two primary meridians in the reflected image. Correct all values using the calibration curve.

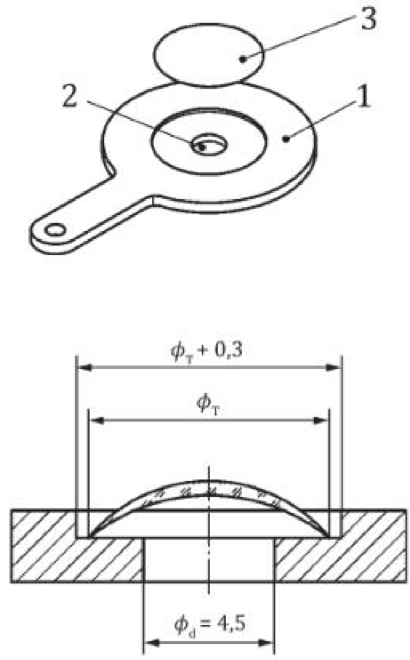
Annex D
(informative)

Paddle support for focimeters used for power measurements of contact lenses

Figure D.1 shows an example of a suitable paddle support. In this design, the blotted contact lens is placed on a paddle which both centres the lens relative to the axis of the focimeter and provides the aperture over which the label back vertex power is measured.

The paddle with contact lens is placed onto an adjustable paddle stage. See Figure D.2 and Figure D.3. This adjustability allows the contact lens back vertex to be positioned in the vertex plane of the focimeter.

Dimensions in millimetres



Key

1 paddle

2 aperture

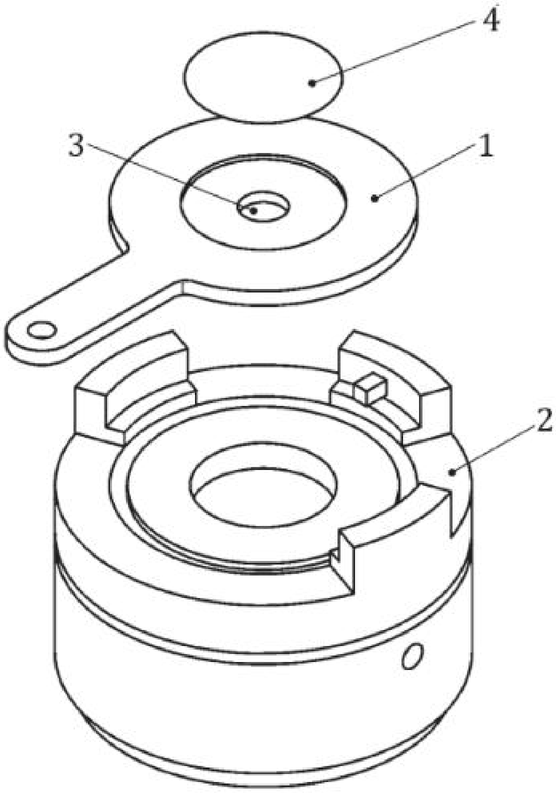
3 contact lens

$Ø_T$ diameter of contact lens

$Ø_d$ diameter of aperture

NOTE The paddle is fitted into a support stage; see Figure D.2 and Figure D.3.

Figure D.1 — Example of a paddle support for a contact lens



Key

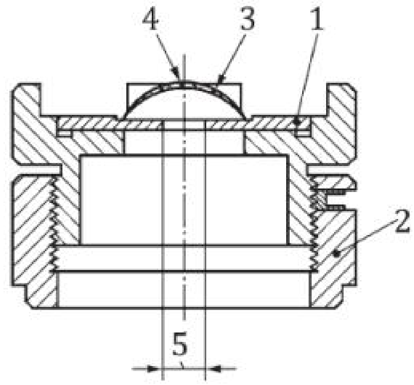
1 paddle

2 adjustable paddle stage

3 aperture

4 contact lens

Figure D.2 — Example of paddle and support stage for the focimeter



Key

1 paddle

2 adjustable paddle stage

3 contact lens

4 back vertex

5 aperture

Figure D.3 — Cross section showing a contact lens, paddle and support stage

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1) ISO 5725 was cancelled and replaced by ISO 5725-1, ISO 5725-2, ISO 5725-3, ISO 5725-4, ISO 5725-5 and ISO 5725-6.

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