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ISO 18369-3

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Ophthalmic optics — Contact lenses

Part 3: Measurement methods

Optique ophtalmique — Lentilles de contact

Partie 3: Méthodes de mesure

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18369-3 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition cancels and replaces ISO 8599:1994, ISO 9337-1:1999, ISO 9337-2:2004, ISO 9338:1996, ISO 9339-1:1996, ISO 9339-2:1998, ISO 9341:1996, ISO 10338:1996 and ISO 10344:1996, which have been technically revised.

ISO 18369 consists of the following parts, under the general title *Ophthalmic optics — Contact lenses*:

— *Part 1: Vocabulary, classification system and recommendations for labelling specifications*

— *Part 2: Tolerances*

— *Part 3: Measurement methods*

— *Part 4: Physicochemical properties of contact lens materials*

Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the preocular tear film. This part of ISO 18369 covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Soft contact lenses are easily deformable and require support for proper shape. A very large subset of soft contact lenses consists of transparent hydrogels containing water in concentrations greater than 10 %. Soft contact lenses can also be made of non-hydrogel materials, e.g. flexible polysiloxanes (silicone elastomers).

The ISO 18369 series is applicable to determining allowable tolerances of parameters and properties important for proper functioning of contact lenses as optical devices. The ISO 18369 includes tolerances for single-vision contact lenses, bifocal lenses, lenses that alter the flux density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling, and/or opaque tints), and lenses that significantly attenuate ultraviolet radiation (UV-absorbing lenses). The ISO 18369 series of standards covers contact lenses designed with spherical, toric, and aspheric surfaces, and recommended methods for the specification of contact lenses.

Ophthalmic optics — Contact lenses

Part 3:
Measurement methods

1 Scope

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

2 Normative references

The following referenced documents are indispensable for the application 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 18369-1, *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.

4 Methods of measurement for contact lenses

4.1 Radius of curvature

4.1.1 General

There are two generally accepted instruments for determining the radius of curvature of rigid contact lens surfaces. These are the optical microspherometer (see 4.1.2) and the ophthalmometer with contact lens attachment (see 4.1.3).

The ophthalmometer method (see 4.1.3) measures the reflected image size of a target placed 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.

Ultrasonic, mechanical, and optical measurements of sagittal depth are applicable to hydrogel contact lens surfaces as indicated in 4.1.4 and Table 1, but are generally not recommended instead of radius measurement for rigid spherical surfaces because aberration, toricity and other errors are masked during measurement. Sagittal depth of rigid aspheric surfaces can be useful, however, as indicated in 4.1.2.4.

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

Table 1 — Test methods, application and reproducibility

Subclause	Test method/application	Reproducibility [a, b] R
4.1.2	Optical microspherometry	
	Spherical rigid lenses	± 0,015 mm in air
4.1.3	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
4.1.4	Sagittal height method	
	Hydrogel lenses (38 % water content, $t_C > 0,1$ mm)	± 0,050 mm in saline solution
	Hydrogel lenses (55 % water content, $t_C > 0,1$ mm)	± 0,100 mm in saline solution
	Hydrogel lenses (70 % water content, $t_C > 0,1$ mm)	± 0,200 mm in saline solution

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

[a] The reproducibility of any method should be half or less of the product tolerance specified in ISO 18369-2 in order to verify the tolerance.

[b] Reproducibility, R, as defined in ISO 5725-1[1].

4.1.2 Microspherometer

4.1.2.1 Principle

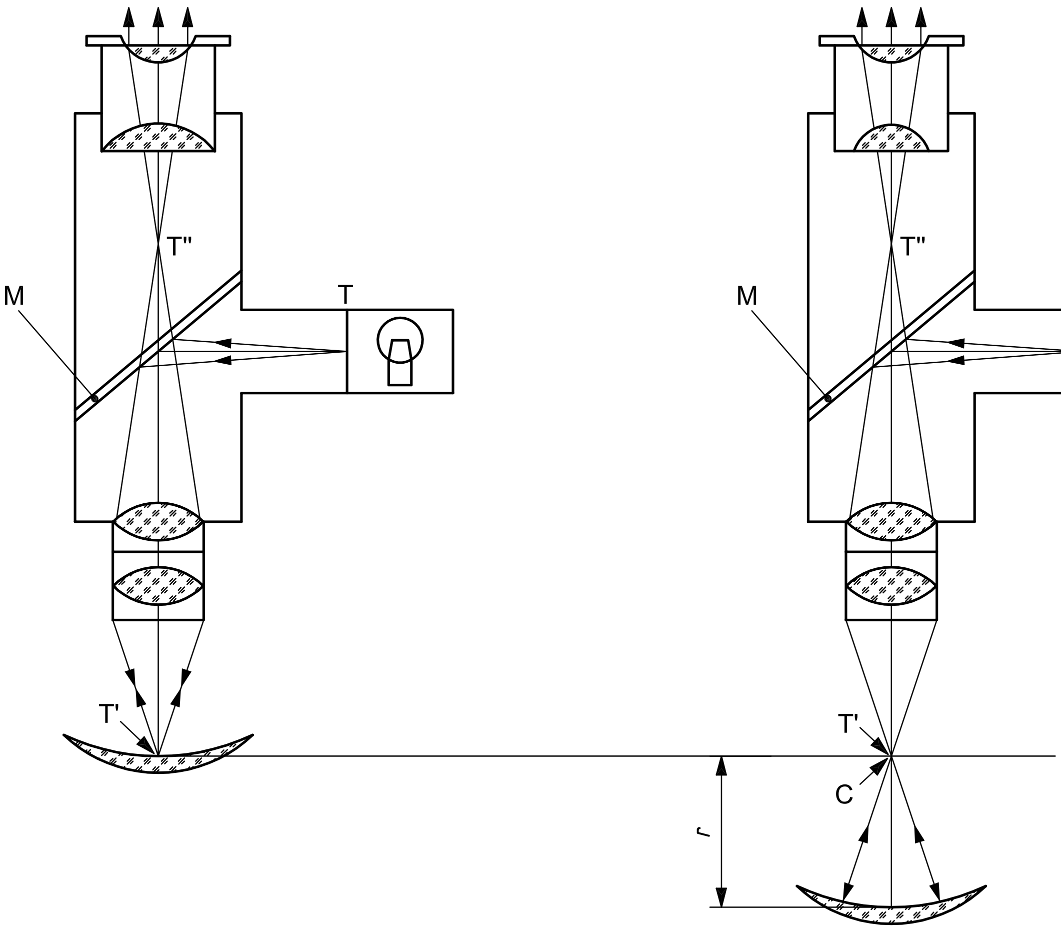
The microspherometer locates the surface vertex and the aerial image (centre of curvature) with the Drysdale principle, as described below. The distance between these two points is the radius of curvature for a spherical surface, and is known as the apical radius of curvature for an aspheric surface 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. Light from the target T (Figure 1) 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

4.1.2.2 Instrument specification

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.

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 ×65. 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 ± 5 °C. The repeatability of the gauge (see NOTES 1 and 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 comprised of 4 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 analog and digital gauges.

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

4.1.2.3 Calibration

4.1.2.3.1 Calibration (determining the measuring accuracy) shall be carried out using the following 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 shall have radii accurately known to ± 0,007 5 mm.

4.1.2.3.2 Calibration shall take place in a room with an ambient temperature of 20 °C ± 5 °C and after the instrument has had sufficient time to stabilize.

4.1.2.3.3 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 ten 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 4.1.2.4.

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.

4.1.2.4 Method of measurement

Carry out the measurements on the test lens in air at 20 °C ± 5 °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 as described in 4.1.2.3.3. Correct the arithmetic mean of this set of measurements using the calibration curve obtained in 4.1.2.3.3 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 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 ($2\,h$) using the methods employed in 4.1.4. The sagittal depth is converted to an equivalent spherical radius using the equation

$$r = \frac{s}{2} + \frac{h^2}{2s} \qquad (1)$$

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.

4.1.3 Ophthalmometer method

4.1.3.1 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 2.

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

$$r_0 = \frac{-y'n}{\sin\varepsilon} \qquad (2)$$

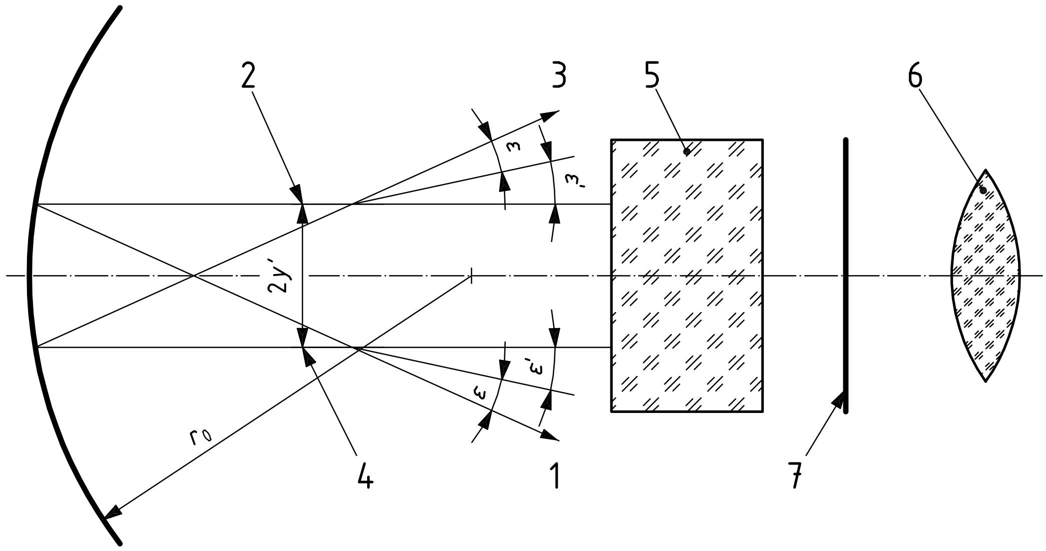
where

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 2 — Optical system of an ophthalmometer

4.1.3.2 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 Figures 3 and 4, 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 must 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.

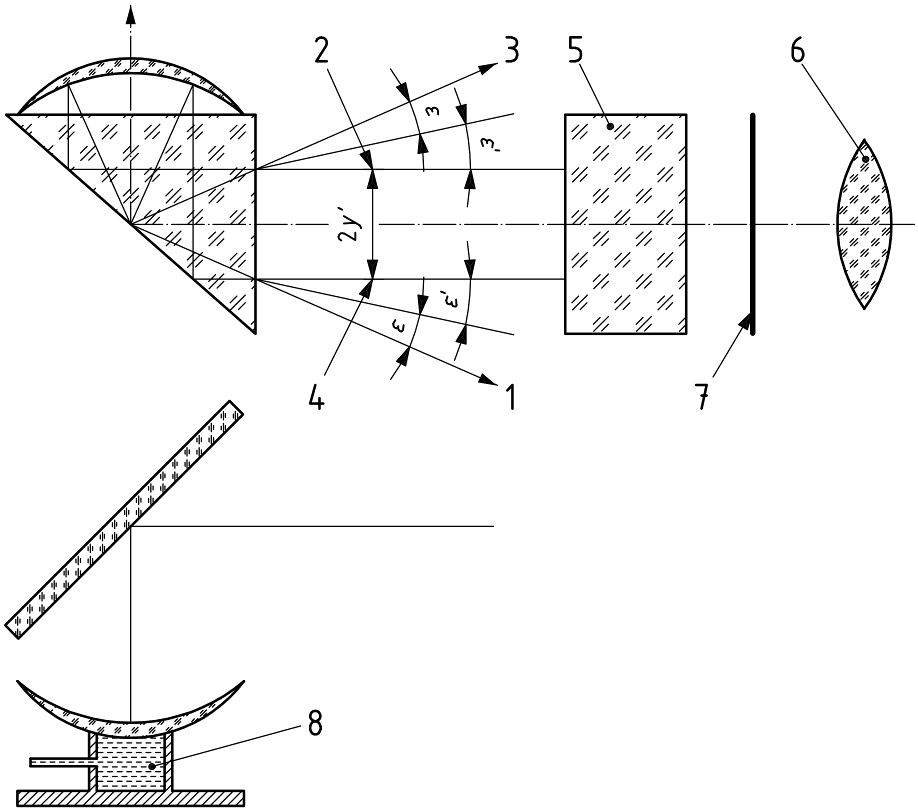
The scale interval shall be not more than 0,02 mm. If the scale is in dioptres the maximum scale interval shall be 0,25 D. An instrument-specific conversion chart is used to change power values to radii of curvature.

4.1.3.3 Calibration

4.1.3.3.1 For calibration of the ophthalmometer use the test plates specified in 4.1.2.3.1.

4.1.3.3.2 Calibration shall take place in a room with an ambient temperature of 20 °C ± 5 °C and after the instrument has had sufficient time to stabilize. Use standard saline solution (see 4.7) when calibrating the instrument for the measurement of lenses in solution.

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



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 3 — Ophthalmometer arrangement for measurement in air

4.1.3.4 Method of measurement

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

4.1.3.4.1 Measurement in air

Carry out the measurements at an ambient temperature of 20 °C ± 5 °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 determinations of the radius, recorded to the nearest 0,01 mm. Take the arithmetic mean of the three determinations (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 mean for each of the two primary meridians. Correct each mean using the calibration curve and take it as the radius of curvature of the meridian.

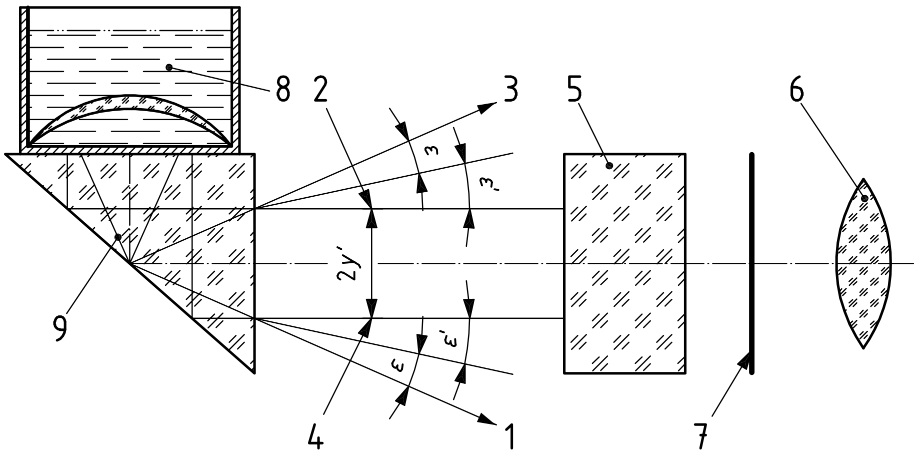
4.1.3.4.2 Measurement in a wet cell

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

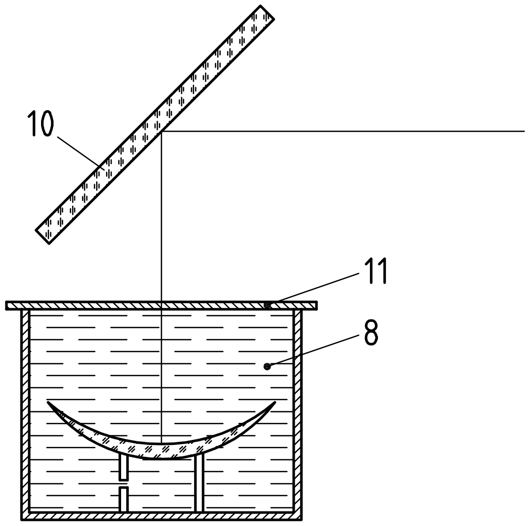
Equilibrate the soft lens in standard saline solution (see 4.7) at 20 °C ± 0,5 °C. Suspend it in standard saline solution during measurement in the wet cell. Carry out the measurements at an ambient temperature of the soft lens and the saline solution in the wet cell of 20 °C ± 0,5 °C.

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

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



a)



b)

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 4 — Ophthalmometer arrangement for measurement in a wet cell

4.1.4 Measurement of sagittal depth

4.1.4.1 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 rested concave side down against a circular contact lens support of fixed outside (chord) diameter (see Figure 5). A hydrogel contact lens would be equilibrated in standard saline solution (see 4.7) before measurement.

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

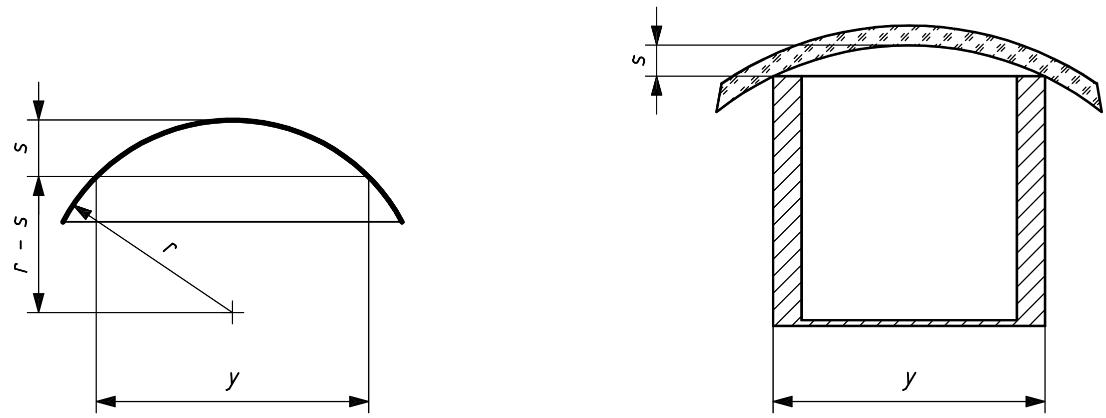
a) With use of the optical comparator, the vertical distance between the back vertex and the chord is measured visually under magnification.

b) The mechanical method introduces a vertical probe that is extended to the back surface vertex, its length from the chord when touching the back surface equal to the sagittal depth (see Figure 7).

c) This distance 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 conoidal surface with specified eccentricity ($e > 0$), may be calculated from the sagittal depth using the appropriate equation.

Using the methods specified in a) to c), the day-to-day repeatability for contact lenses should be expected to be 0,05 mm for lenses with a low water content (less than 38 %), 0,1 mm for lenses with a medium water content (38 % to 54 %) and 0,2 mm for lenses with a high water content (greater than 54 %).



$r^2 = (r - s)^2 + 0{,}25\, y^2$

$s = r - (r^2 - 0{,}25\, y^2)^{0{,}5}$

Key

r radius of curvature of lens

s sagittal depth

y outside (chord) diameter of lens support

Figure 5 — Geometry of sagittal depth measurement

4.1.4.2 Instrument specification

4.1.4.2.1 Optical comparator

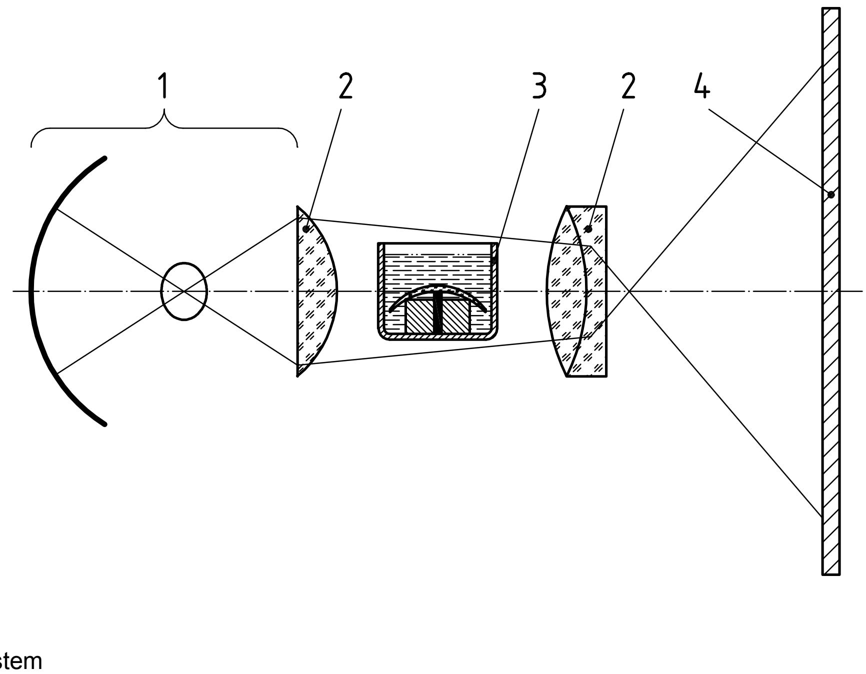
The optical comparator shall have a minimum magnification of ×10, and shall have incorporated a wet cell with a hollow cylindrical contact lens support. As shown in Figure 5, the contact lens shall rest horizontally with its concave (back) surface centred against the circular outside edge of the flat-rimmed support. The support shall be constructed in such a way as to provide a chord diameter (y) of at least 8,0 mm. In the example shown (Figure 5), the preferred chord diameter (y) of the support is 10,0 mm. A graticule marked in minimal increments of 0,01 mm shall be used, so that sagittal depth can be visually determined with a repeatability of ± 0,02 mm or better when used to measure sagittal depths within the central portion of the contact lens (when the contact lens is properly centred on its support). The instrument shall have a means of controlling the wet cell temperature.

NOTE A magnification exceeding ×50 will increase the reproducibility of the method, but the test method has not been verified by an interlaboratory test.

4.1.4.2.2 Spherometer

The spherometer projects the profiles of the contact lens, lens support and probe onto a screen (see Figure 6). The projection system shall have a magnification of at least ×10 and 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 7). This is the endpoint required to obtain a measurement value. The distance travelled by a solid mechanical probe (tracer pin or sensor) from the plane of the lens support to the lens back surface vertex is the sagittal depth (s). Analogue or digital gauges shall have a precision of at least 0,01 mm.

The requirement for the wet cell and support shall be the same as that already noted (see 4.1.4.2.1).



Key

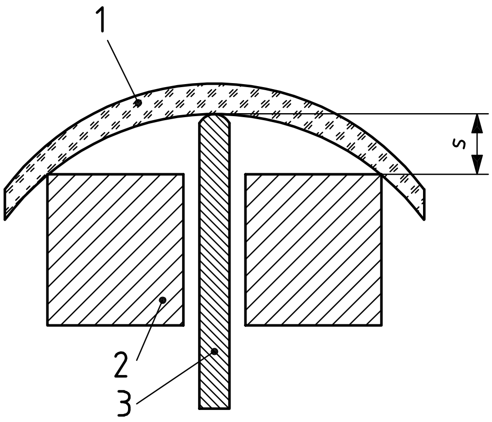
1 illumination system

2 lens

3 measuring cell with test sample

4 screen

Figure 6 — Principle of the mechanical analyser for the wet cell



Key

s sagittal depth

1 contact lens

2 lens support

3 probe

Figure 7 — Detail of the mechanical analyser showing the lens support and probe

4.1.4.2.3 Ultrasound unit

The ultrasonic transducer shall be fitted under the centre of the contact lens support (see Figure 8). It shall have a frequency (f) greater than 18 MHz, bandwidth of 1,4 $f \pm$ 5 MHz, beam width of 2,0 mm or less at focus, and a focal length of 25 mm to 50 mm. An ancillary electronic apparatus shall enable the correct electronic signal to be applied to the transducer. The interval timer shall be able to record times to 0,01 µs. A variable gate time is recommended in order that averaged time can be used. It should be noted that sound reflections occur from both surfaces of the contact lens and any other acoustic surface present. The ancillary apparatus shall be able to reject or ignore the unwanted reflection signal.

The requirement for the wet cell and support shall be the same as that already indicated (see 4.1.4.2.1).

Regardless of its construction, the repeatability of the ultrasound unit with wet cell shall be ± 0,02 mm or better when used to measure sagittal depths within the central portion of the contact lens (when the contact lens is properly centred on its support).

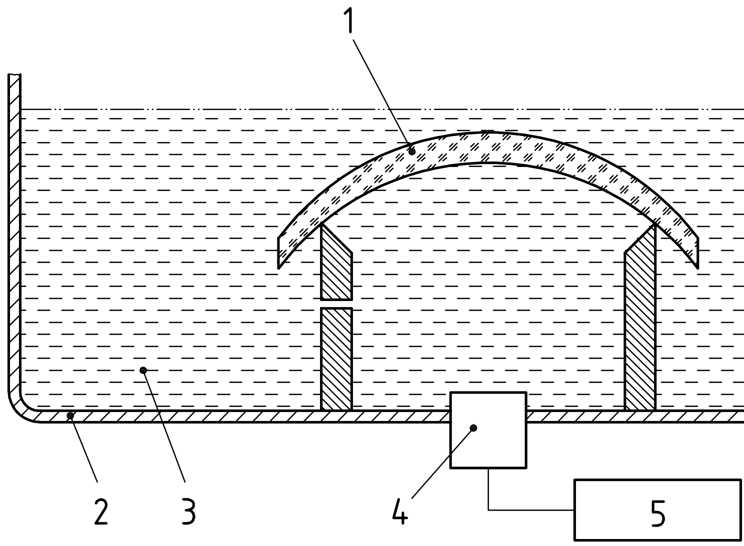
4.1.4.3 Calibration

Calibration (determining the measuring accuracy) shall be carried out using three rigid spherical concave radius gauges made of polymethylmethacrylate or glass. The gauges shall be spaced so as to determine the measuring accuracy over a broad range of measurement. Minimum requirements for this purpose include gauges at 7,50 mm ± 0,1 mm, 8,50 mm ± 0,1 mm and 9,50 mm ± 0,1 mm. The actual radius shall be known to within 0,01 mm.

NOTE It is convenient for these reference pieces to be planoconcave in form and to have a central thickness of 3 mm and a diameter of 12 mm.

Calibration shall take place at an ambient temperature of 20 °C ± 5 °C for optical comparator and spherometer methods and at 20 °C ± 0,5 °C for the ultrasound method, after the instrument has had sufficient time to stabilize, and after the gauges have been equilibrated in standard saline within the wet cell.

Each gauge shall be measured from the same direction at least 20 times and the arithmetic mean shall be calculated. Differences between calculated and actual radius shall be used to construct a calibration curve, if applicable.



Key

1 contact lens

2 container

3 saline solution

4 transducer

5 ancillary equipment

Figure 8 — Ultrasonic measurement of sagittal depth in a wet cell

4.1.4.4 Method of measurement

Allow the contact lens to be measured 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. Allow the lens to equilibrate in standard saline (see 4.7) for at least 30 min at 20 °C ± 0,5 °C prior to measurement. Carry out the measurement at a temperature of the lens and surrounding saline after stabilization of 20 °C ± 0,5°C.

The measurement shall consist of three separate determinations of the sagittal depth with the optical comparator, mechanical method, or ultrasound unit, recorded to the nearest 0,01 mm. Take the arithmetic mean of the three sagittal depth measurements as the sagittal depth (s) of the contact lens surface.

4.1.4.5 Conversion of sagittal depth to radius of curvature

When desired, sagittal depth (s) can be converted to radius of curvature (for spherical surfaces) or equivalent spherical radius of curvature (for aspheric surfaces) over the diameter of measurement ($2y$) using the equation

$$r = \frac{s}{2} + \frac{y^2}{2s} \tag{3}$$

The radius of curvature is then obtained from the calibration curve by inserting the arithmetic mean sagittal depth.

4.2 Back vertex power

4.2.1 General

The back vertex power of rigid contact lenses shall be determined in air by use of a focimeter. See 4.2.2 for the focimeter method of measurement.

The back vertex power of soft contact lenses shall either be determined in air by use of a focimeter (see 4.2.2) or shall be determined by immersing the lenses in saline solution with the Moiré deflectometer or with the Hartmann method (see 4.2.3 and Annex B).

4.2.2 Focimeter method of measurement

4.2.2.1 Instrument specification

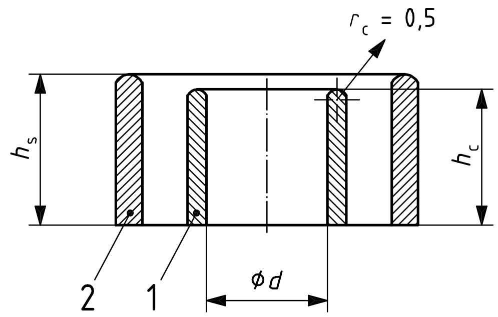
The focimeter used shall have a minimum range of –20,00 D to +20,00 D with a minimum measuring accuracy of ± 0,06 D, and shall be capable of manual focusing. Other focimeters may be used provided the readings derived are shown to be equivalent to those of a manually focusing focimeter. A focimeter conforming to ISO 8598:1996 may be used, but will require modification of the lens support as specified below.

The increased sagittal depth of contact lenses compared to spectacle lenses, and the limited diameter of the optic zone of contact lenses, will not allow proper positioning of the back vertex and optic zone of a contact lens at the spectacle lens stop usually provided with the focimeter. Therefore, the focimeter shall be modified with a special contact lens support (see Figure 9). The contact lens support (contact lens stop) for use in place of the spectacle lens stop shall be designed so that the contact lens rests on the supporting ring only as shown in Figure 10.

Figure 9 shows an example of a suitable support. Its central aperture has a diameter of 4,50 mm ± 0,50 mm and projects 0,55 mm ± 0,02 mm less than the spectacle lens stop which it replaces. The radius r_c of the annular surface that contacts the posterior surface of the contact lens is 0,50 mm. 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. Lenses with a back optic zone radius value substantially different from this may require further vertex distance correction.

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

Dimensions in millimetres

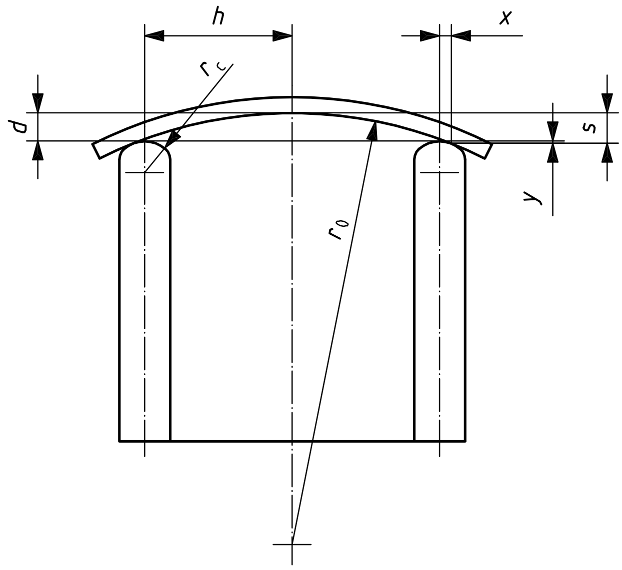


$h_s - h_c = (0{,}55 \pm 0{,}02)$ mm $d = 4{,}50$ mm $\pm$ 0,50 mm

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
2 spectacle lens support

Figure 9 — Contact lens support (stop) for the focimeter



Key

s sagittal depth of back central optic zone

h semichord length (chord diameter = $2h$)

r_0 back optic zone radius (base curve radius)

r_c radius of lens stop

Figure 10 — Contact lens resting on a contact lens stop

4.2.2.2 Focimeter calibration

Use six spherical test lenses having a nominal back vertex power within one dioptre of −20,00 D, −15,00 D, −10,00 D, −5,00 D, +5,00 D, +10,00 D, +15,00 D, and +20,00 D respectively. The actual back vertex powers of these test lenses shall be traceable to a national or International Standard.

At a temperature of 20 °C ± 5 °C and using the spherical test lenses calibrate the focimeter fitted with the appropriate lens stop.

Place each test lens centrally with its back surface against the appropriate lens stop, and focus the focimeter to obtain the clearest possible image. Record the focimeter reading. Take three independent readings within 30 s and record the mean. Plot the results on a calibration curve.

NOTE The term “independent” means that the test lens is removed from the instrument and remounted between each reading.

4.2.2.3 Focimeter measurement of rigid and non-hydrogel lenses

Before making the measurement, rigid lenses shall be maintained at a temperature of 20 °C ± 5 °C for at least 30 min. During the measurement, maintain the focimeter and contact lens support at an ambient temperature of 20 °C ± 5 °C. Place the contact lens with its posterior surface against the contact lens support to properly position the back vertex as the reference point for measurement. It is important that the back vertex be centred in the pupil of the lens stop and lens surfaces be clean and free of debris or solution. Take four independent readings of the back vertex power. Calculate the mean and, using the calibration curve, determine the corrected mean.

4.2.2.4 Focimeter measurement of hydrogel lenses

Equilibrate the hydrogel lenses in standard saline solution (4.7) for at least 30 min at 20 °C ± 0,5 °C prior to measurement. Blot the lens with a lint-free absorbent cloth or filter paper, thus removing surface liquid, and place it upon the contact lens support within 10 s. The process shall be the same as that in 4.2.2.3. Place the posterior surface of the lens appropriately on the support.

For spherical hydrogel lenses, take five independent readings of the back vertex power, calculate the mean and, using the calibration curve, determine the corrected mean.

For toric hydrogel contact lenses, take 19 independent readings to determine the mean spherical power to within ± 0,25 D. Take 17 independent readings to determine the mean cylinder power to within ± 0,25 D. Take 7 independent readings to determine the mean cylinder axis to within ± 5°.

These criteria for toric hydrogel contact lenses have been established by an international interlaboratory test. Fewer readings may be taken if the values are not required to the precision noted above.

4.2.3 Measurement of hydrogel contact lenses by immersion in saline

The test methods (Moiré deflectometer method and Hartmann method) are specified in Annex B and are listed in Table 2, together with a statement of their reproducibility when applied to spherical or toric hydrogel contact lenses.

Table 2 — Test methods for measurement of back vertex power

Type of lens/parameter	Reproducibility					
	in air		by immersion in saline solution			
	s_R	R	s_R	R	s_R	R
	Focimeter	**Focimeter**	**Moiré**	**Moiré**	**Hartmann**	**Hartmann**
Spherical hydrogel lenses						
Back vertex power	0,143 D (for power range $\lvert F'_V \rvert \leqslant 10$)	0,400 D (for power range $\lvert F'_V \rvert \leqslant 10$)	0,090 3 D	0,252 8 D	0,025 3 D	0,070 8 D
Toric hydrogel lenses						
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°

s_R standard deviation of the reproducibility

R reproducibility

4.3 Diameters and widths

4.3.1 Total diameter

4.3.1.1 General

Measurement of the total diameter of rigid contact lenses shall be made by either the V-groove gauge method specified in 4.3.1.2 or the projection comparator method specified in 4.3.1.3.

Measurement of the total diameter of soft contact lenses shall be made using the projection comparator method specified in 4.3.1.3.

The minimum reproducibility of any method shall be ± 0,05 mm.

4.3.1.2 V-groove gauge method

4.3.1.2.1 Principle

When a circular disc slides into a V-groove (see Figures 11 and 12 for an example of a V-groove gauge), 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.

4.3.1.2.2 V-Groove specification

The groove specifications shall be capable of measuring to ± 0,05 mm over a range from 7 mm to 11 mm. The groove shall be engraved at its edge or in its centre, with a scale for reading off diameters. The scale should be inscribed for diameters in the range of 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. An example of a V-groove gauge is shown in Figures 11 and 12.

4.3.1.2.3 Calibration

4.3.1.2.3.1 Calibration discs

Three discs made from a hard, durable material, e.g. aluminium or a suitable plastic, accurately machined to diameters of 10,50 mm, 9,50 mm, and 7,50 mm (± 0,01 mm), shall be used to calibrate the groove for initial location of engraved markings (see Figure 13).

4.3.1.2.3.2 Calibration procedure

Maintain the diameter gauge at a temperature of 20 °C ± 5 °C during 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. Plot the results on a calibration curve and use this to correct the results obtained in 4.3.1.2.4. Diameter readings to within ± 0,02 mm are deemed acceptable for ongoing calibration purposes.

4.3.1.2.4 Measurement

Maintain the diameter gauge at a temperature of 20 °C ± 5 °C during measurement.

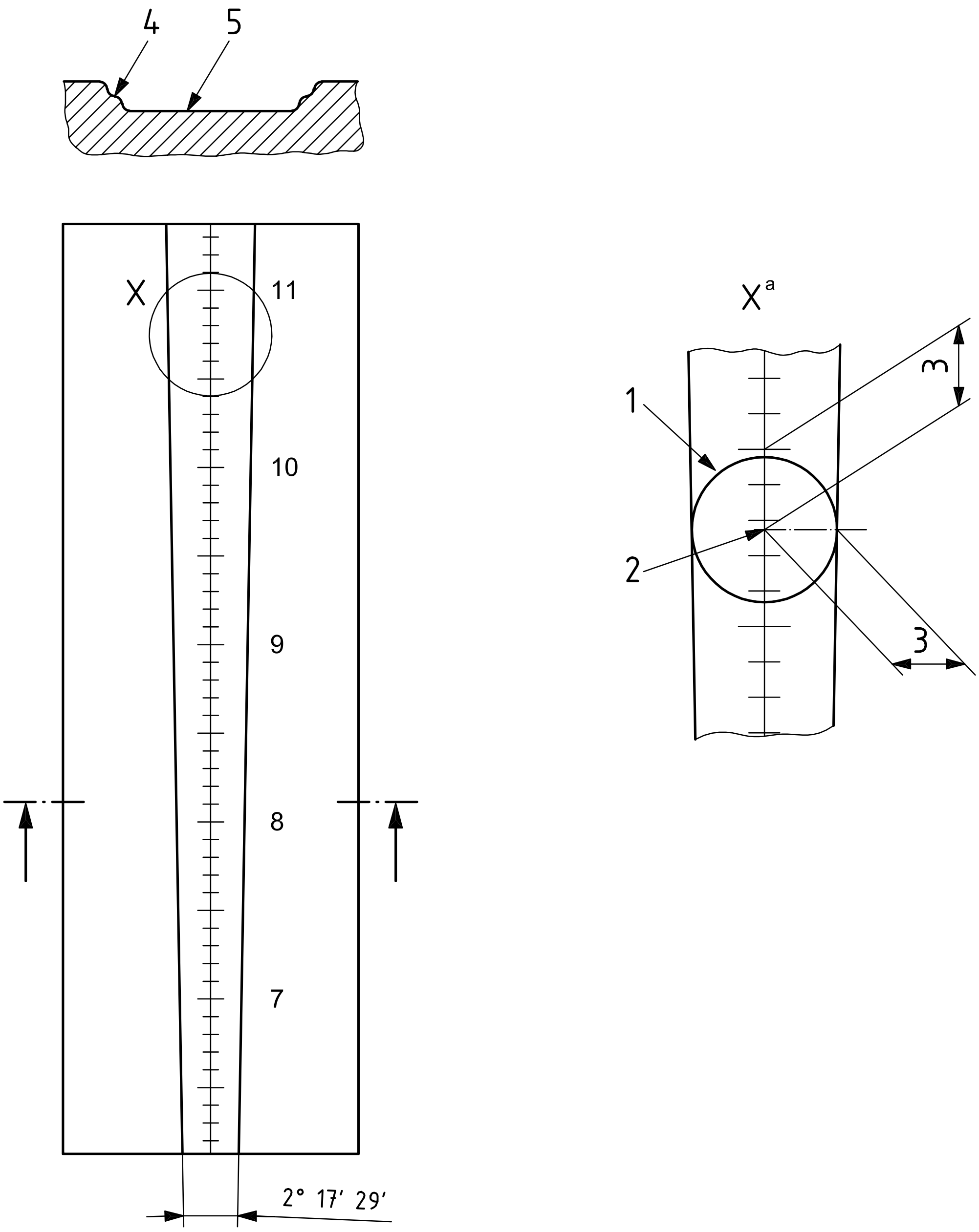
Place the dry rigid contact lens in the wide end of the groove and incline the groove to approximately 45° such that the lens is allowed to slide slowly due to gravity, without any undue exterior pressure from fingertip, etc., towards the narrow end of the groove. As the lens slides into progressively narrower portions of the groove, some friction against the back surface and edges of the groove slows its fall due to gravity. The lens falls until it attains a fixed position between the upper and lower edges of the groove at a point where the groove width is equal to the lens diameter. Read off the diameter from the location of the superior edge of the lens on the groove's scale engraved for this purpose.

By rotating the lens, determine the maximum and minimum diameters by three independent measurements, taking care not to deform the lens during the measurement. Calculate the total diameter by taking the arithmetic mean of the six readings and adjust this value using the calibration curve. This assumes that the lens is intended to have a uniform diameter, if this is not the case calculate the average of the maximum and minimum diameters separately.

4.3.1.2.5 Expected reproducibility of results

Since the diameter reading is obtained from a visual sighting of the lens edge against the engraved scale, the precision of this method is dependent upon the visual capabilities of the observer. However, the change in position along the engraved scale is proportional to the reciprocal of the sine of the included (groove) angle (25:1 in the illustration). Since the engraved markings are 2,5 mm apart a diameter change of 0,01 mm would be equivalent to a distance of 0,25 mm along the diameter scale. Assuming that a distance of 0,38 mm would be easily discernible, a repeatability of 0,015 mm in measurement is obtained. In addition, since the engraved markings are in increments of 0,1 mm, 1/4 of this distance can be easily judged. It is reasonable, therefore, to set the precision limit for this type gauge equal to 0,75 sin (0,5β), where β is the included (groove) angle. For the groove specifications shown in Figure 11 this would correspond to an accuracy limit of 0,75 sin (1,145) = 0,015 mm.

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

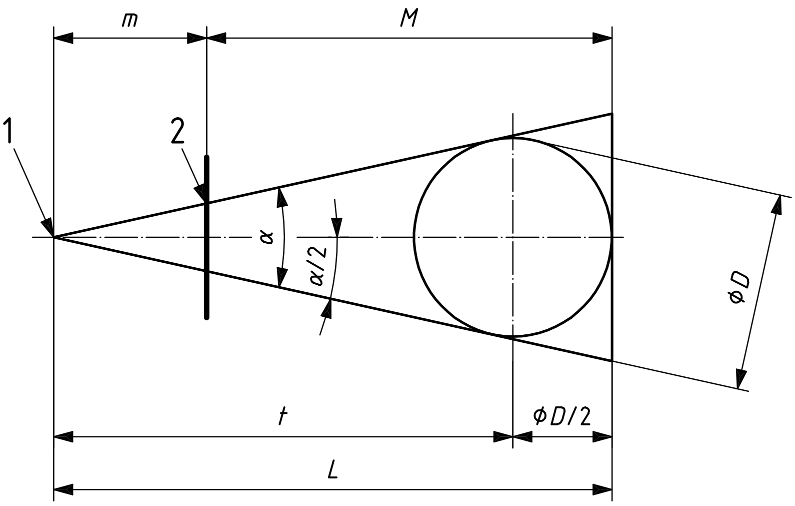
Small end: 7,0 mm ± 0,01 mm

Key

1 lens outline
2 actual lens centre
3 1/2 lens diameter
4 relieve corners as shown to help prevent dirt build-up
5 engraved markings (raised or lowered)

[a] Location of engraved mark at superior edge.

Figure 11 — Example of V-Groove diameter gauge (not to scale)



Key

1 apex

2 narrow end of groove

Figure 12 — Geometry of the V-groove diameter gauge

Dimensions in millimetres

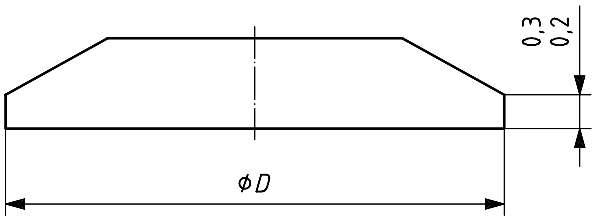


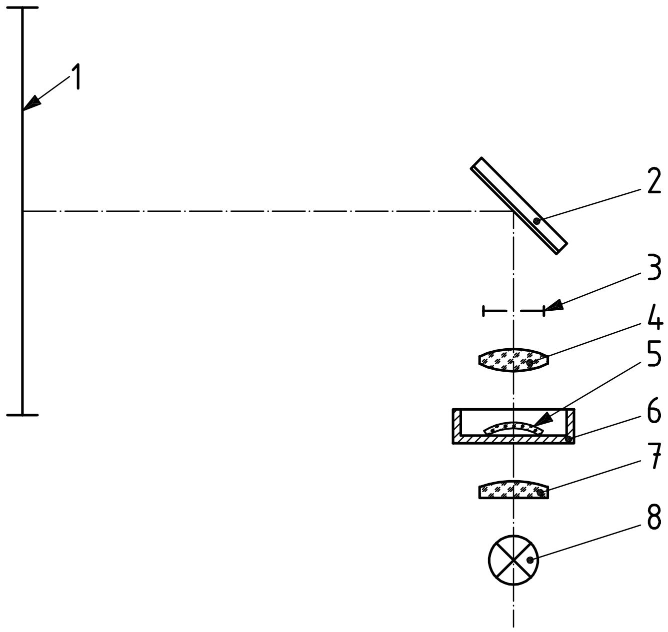
Figure 13 — Example of calibration disc

4.3.1.3 Projection comparator method

4.3.1.3.1 Projection comparator specification

The principle of the projection comparator is shown in Figure 14. The projection system shall be capable of measuring to ± 0,05 mm over a range of 0 mm to 17 mm. Referring to Figure 14, the contact lens support (6) is placed horizontally and can be adjusted vertically. The scale of the screen (1) represents a linear magnification of at least ×15 and permits 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 (3) in the rear focal plane of the objective (4).

The diameter of the lens is either taken from linear markings on the screen, or from a marked glass scale (similar to a microscope graticule) under the lens within the support which is projected onto the screen.



Key

1 observing screen with scale
2 mirror
3 diaphragm
4 objective
5 contact lens test specimen
6 contact lens support (cuvette)
7 condenser
8 light source

Figure 14 — Principle of the projection comparator

4.3.1.3.2 Calibration

4.3.1.3.2.1 Calibration discs

Use the calibration discs specified in 4.3.1.2.3.1, plus two more discs of 13,0 mm and 15,0 mm for soft lens measurement.

4.3.1.3.2.2 Calibration procedure

Maintain the projection comparator at a temperature of 20 °C ± 5 °C during calibration. Place the calibration disc in the test specimen position. Adjust and stage the projection comparator so that the image of the calibration disc is focused on the scale of the observing screen. Take 10 independent readings of each calibration disc. Calculate the arithmetic mean of each set. Plot the results on a calibration curve and use this to correct the results obtained in 4.3.1.3.3. Diameter readings to within ± 0,02 mm are deemed acceptable for ongoing calibration purposes.

4.3.1.3.3 Measurement

For hydrogel lenses, equilibrate the lens to be tested in standard saline solution (see 4.7) at a temperature of 20 °C ± 0,5 °C for 30 min, unless otherwise specified by the manufacturer.

Maintain the projection comparator at a temperature of 20 °C ± 5 °C during measurement of a lens in air.

Place the contact lens on the support. For a soft lens cover with standard saline solution (4.7) at a temperature of 20 °C ± 0,5 °C. Re-fill the contact lens support with standard saline solution at the same temperature prior to each measurement, unless the support is fitted with a temperature control system.

By rotating the lens, determine the maximum and minimum diameters by three independent measurements, taking care not to deform the lens during the measurement. Calculate the total diameter by taking the arithmetic mean of the six readings and adjust this value using the calibration curve. This assumes that the lens is intended to have a uniform diameter; if this is not the case calculate the average of the maximum and minimum diameters separately.

Should the diameters of any two of the four measured meridians of a soft lens be different by more than 0,4 mm the soft lens shall be characterized as being “out-of-round”.

4.3.2 Zone diameters and width

4.3.2.1 General

The diameters and widths of contact lens zones (e.g. optic zone diameters, secondary and peripheral curve diameters or widths) may be measured with a projection comparator (see 4.3.1.3) or for rigid lenses in air a hand-held magnifier (see 4.3.2.2). Such measurements are difficult since the edges of these zones are often “blended” so that the zones merge into each other.

4.3.2.2 Method using a hand-held scale magnifier

4.3.2.2.1 Scale magnifier specification

The scale magnifier shall have a minimum magnification of ×7. The magnifier shall have a suitable scale through the centre of the field of view and shall have minimum scale divisions of 0,10 mm.

4.3.2.2.2 Calibration

Calibration discs of known diameter shall be used to determine the accuracy of the magnifier and calibration discs of different sizes shall be used to determine the accuracy along different portions of the scale (see 4.3.1.2.3.1 for specification of calibration discs). Provisions shall be made to provide correction factors where necessary. Consideration shall be made of the focusing accuracy of the magnifier during calibration and shall be included in the correction factors.

4.3.2.2.3 Measurement

Maintain the scale magnifier at an ambient temperature of 20 °C ± 5 °C during measurement.

Take measurements along meridians or extensions of meridians passing through the geometrical centre of the rigid contact lens. Take three measurements of the appropriate zone diameter or width along the meridian of the length to be measured. Take the arithmetic mean as the measurement along that meridian.

4.4 Thickness

4.4.1 General

Thickness, measured through the section of a contact lens, shall be made with a dial gauge for rigid lenses (see 4.4.2) and with a “low-force” dial gauge for soft contact lenses (see 4.4.3).

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

4.4.2 Dial gauge method

4.4.2.1 Instrument specification

The measuring face of the dial gauge shall be spherical with a radius between 1,2 mm and 5,0 mm. The measuring face shall apply a force not exceeding 1,4 N on the lens. Minimum scale increments shall not exceed 0,01 mm, and with a reproducibility (R) equal to or better than 0,01 mm over the range 0 mm to 5 mm. 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.

4.4.2.2 Calibration

4.4.2.2.1 Calibration shims

High-precision engineering shims, the thickness of each being known to within ± 0,005 mm, and traceable to a calibrated standard unit of measurement, are required for calibration. Three test pieces shall be used having the following nominal thicknesses:

a) just less than the minimum expected in the determination;

b) just greater than the maximum expected in the determination;

c) approximately midway between a) and b).

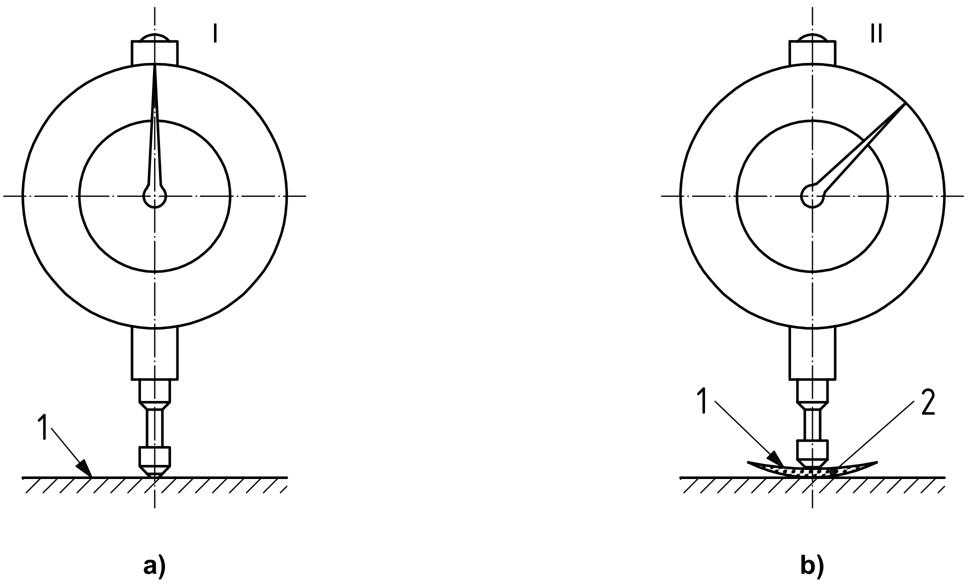
4.4.2.2.2 Calibration procedure

Place each calibrated shim (see 4.4.2.2.1) successively between the plunger and the anvil and take five independent measurements of the shim thickness. Calculate the mean reading for each shim. From the mean values of the three determinations prepare a calibration curve.

4.4.2.3 Measurement

Maintain the dial gauge at an ambient temperature of 20 °C ± 5 °C during measurement.

Take three independent measurements at the point to be measured. See Figure 15. Correct each measurement using the calibration curve obtained in 4.4.2.2.2. Calculate the thickness of the contact lens as the arithmetic mean of the three determinations.



Key

1 measuring face

2 contact lens

Figure 15 — Measurement of centre thickness with a dial gauge

4.4.3 Low-force mechanical gauge method

4.4.3.1 Instrument specification

The gauge measures positional linear displacement and comprises a rigid frame in which are mounted a sensor and an anvil capable of measuring displacement to an accuracy of 0,001 mm. The sensor is fitted with a flat tip with a diameter of at least 2,0 mm and the force exerted by the sensor shall not exceed 0,015 N (1,5 g) 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. The movement of the sensor may be damped and the anvil may be marked with concentric rings to aid lens centration.

4.4.3.2 Calibration

Calibration of the low-force gauge is performed as noted in 4.4.2.2, except that the thickness of the test shims shall be known to within ± 0,000 5 mm.

4.4.3.3 Measurement

Maintain the low-force mechanical gauge at an ambient temperature of 20 °C ± 5 °C during measurement.

Equilibrate the lens to be tested in standard saline solution (4.7) at a temperature of 20 °C ± 0,5 °C for 30 min, unless otherwise specified by the manufacturer.

Take five independent measurements at the point to be measured. Ensure the measurement is carried out within the shortest possible time to minimize dehydration of the lens, and that the contact lens is returned to the saline solution between each measurement. Correct each measurement using the calibration curve obtained in 4.4.3.2. Calculate the thickness of the contact lens as the arithmetic mean of the five determinations.

Reproducibility for thickness of hydrogel contact lenses is shown in Table 3.

Table 3 — Reproducibility of measurement of hydrogel contact lens thickness using a low-force thickness gauge

Thickness range mm	**Reproducibility** [a] mm	
	s_R	R
0,04 to 0,60	0,006	0,017

[a] These precision data were derived from measurements of geometrical-centre thickness. These data may not be applicable to excessively thin or thick contact lenses.

4.5 Inspection of edges, inclusions and surface imperfections

4.5.1 Edge inspection

Finished edge thickness and shape shall be assessed by visual examination under direct illumination at ×7 magnification.

The observer shall be skilled in the inspection of contact lens edges.

4.5.2 Determination of inclusions and surface imperfections

4.5.2.1 General

The method for inclusions shall be capable of resolving any inclusion greater than 3 µm in the lens material, such as non-homogeneities or bubbles. The method for surface imperfections shall be capable of resolving any surface imperfection greater than 9 µm such as scratches or pitting.

Surface markings intentionally made are not regarded as surface imperfections.

4.5.2.2 Instrument specification and test conditions

Two separate enlarging magnifiers shall be used. For the observation of inclusions a magnifier of ×6 shall be used, and for the observation of surface imperfections, a magnifier of ×2 shall be used.

The illumination of the contact lens to be examined shall be 350 lx ± 35 lx including the room illumination.

See Figure 16 for an example of suitable apparatus.

The contact lens and measuring device shall be maintained at a temperature of 20 °C ± 5°C.

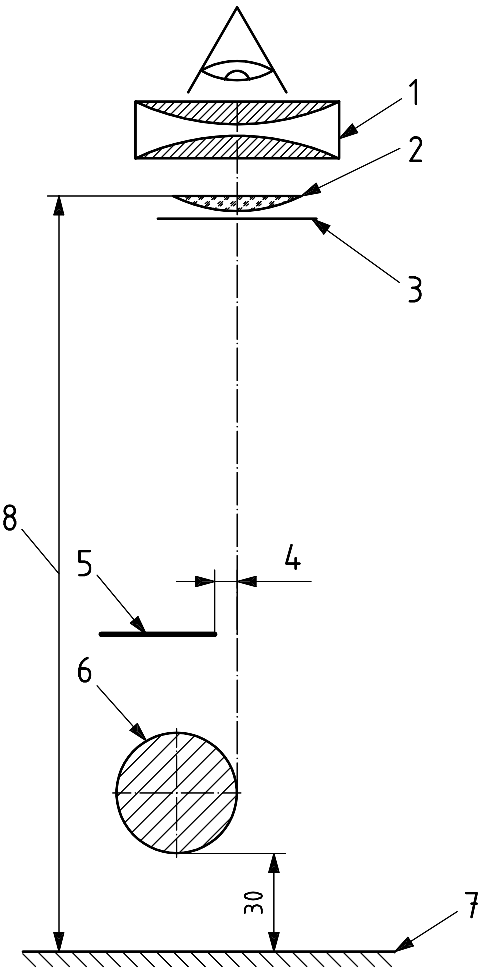
4.5.2.3 Method of inspection

Place the contact lens on the support (see Figure 16), ensuring that the lens is not significantly deformed. With the aid of the magnifier, view the lens at a light-dark border and record the defects as indicated in Table 4.

The observer shall be skilled in the recognition of contact lens defects.

Other methods, which fulfil the requirements of 4.5.2, are also allowed.

Dimensions in millimetres



Key

1 magnifying device
2 contact lens
3 contact lens support
4 adjustable width of luminous area
5 diaphragm
6 fluorescent lamp
7 plate 150 mm × 360 mm, matt black
8 control distance approximately 400 mm

Figure 16 — Example of measurement apparatus

Table 4 — Rating scheme for designating the size of defects

Class	Size of defects
0	Not visible under ×6 magnification
1	Not visible under ×2 magnification
2	Visible under ×6 magnification
3	Visible under ×2 magnification

4.6 Determination of spectral and luminous transmittance

4.6.1 Principle

4.6.1.1 Spectral transmittance, $\tau(\lambda)$ is the ratio of the transmitted spectral radiant flux $\phi_{\mathrm{e}\lambda\mathrm{t}}(\lambda)$, to the incident spectral radiant flux $\phi_{\mathrm{e}\lambda\mathrm{i}}(\lambda)$ In practice, the measurement of spectral transmittance $\tau(\lambda)$ is taken over a small range of wavelength $\Delta\lambda$, for which the associated radiant flux $\Delta\phi_{\mathrm{e}\lambda}(\lambda)$ is given by $\Delta\phi_{\mathrm{e}\lambda}(\lambda) = \phi_{\mathrm{e}\lambda}(\lambda) \times \Delta\lambda$.

The spectral transmittance $\tau(\lambda)$ is determined by measuring the radiant flux relative to the wavelength both with and without the contact lens and calculated from Equation (4).

$$\tau(\lambda) = \frac{\Delta\phi_{\mathrm{e}\lambda\mathrm{t}}(\lambda)}{\Delta\phi_{\mathrm{e}\lambda\mathrm{i}}(\lambda)} = \frac{\phi_{\mathrm{e}\lambda\mathrm{t}}(\lambda)\times\Delta\lambda}{\phi_{\mathrm{e}\lambda\mathrm{i}}(\lambda)\times\Delta\lambda} \qquad (4)$$

4.6.1.2 Luminous transmittance, τ_{v} is the ratio of transmitted luminous flux ϕ_{vt} to incident luminous flux ϕ_{vi}. In the case of luminous transmittance, the relative spectral luminous efficiency function $V(\lambda)$ of the human eye is the criterion for the assessment of the radiation. The luminous flux is the radiant flux weighted spectrally by the relative spectral luminous efficiency function $V(\lambda)$ and integrated over the visible range of wavelengths as given in Equation (5):

$$\tau_{\mathrm{v}} = \frac{\phi_{\mathrm{vt}}}{\phi_{\mathrm{vi}}} = \frac{\int_{380\,\mathrm{nm}}^{780\,\mathrm{nm}} \phi_{\mathrm{e}\lambda}(\lambda)\times\tau(\lambda)\times V(\lambda)\times \mathrm{d}\lambda}{\int_{380\,\mathrm{nm}}^{780\,\mathrm{nm}} \phi_{\mathrm{e}\lambda}(\lambda)\times V(\lambda)\times \mathrm{d}\lambda} \qquad (5)$$

In practice, the integral is approximated using one of two methods:

a) by summations using spectral transmittance data weighted by the product of the spectral distribution of a specified radiant source and the relative spectral luminous efficiency function [see Equation (6)]; or

b) by measurements with a photometer having a response function that approximates the source-relative spectral luminous efficiency function product.

If spectral data are used, the spacing between successive wavelengths for the summation shall not exceed 10 nm ($\Delta\lambda = 10$ nm):

$$\tau_{\mathrm{v}} = \frac{\phi_{\mathrm{vt}}}{\phi_{\mathrm{vi}}} = \frac{\sum_{380\,\mathrm{nm}}^{780\,\mathrm{nm}} \phi_{\mathrm{e}\lambda}(\lambda)\times\tau(\lambda)\times V(\lambda)\times \Delta\lambda}{\sum_{380\,\mathrm{nm}}^{780\,\mathrm{nm}} \phi_{\mathrm{e}\lambda}(\lambda)\times V(\lambda)\times \Delta\lambda} \qquad (6)$$

When the spacing is smaller than 10 nm, a linear interpolation is permissible.

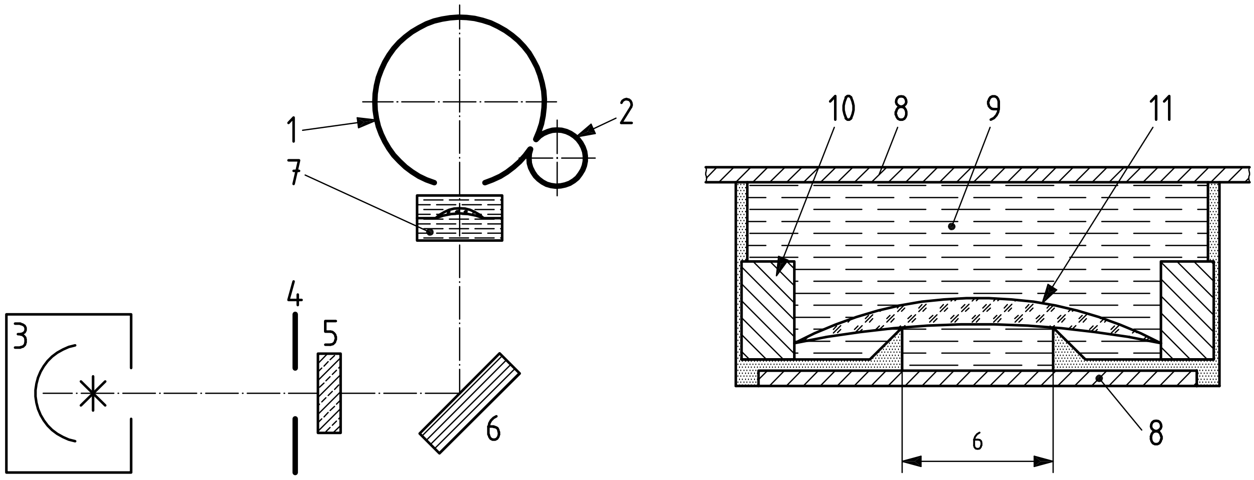
4.6.1.3 The **reference light source** shall be reported. CIE standard illuminant A is recommended, but CIE-C or D65 may be used, as the differences for light unsaturated tints are small.

4.6.2 Instrument specification, test conditions and procedure

The apparatus shown in Figure 17, or an apparatus that will yield equivalent results, shall be used for the determination of spectral and luminous transmittance. For spectral measurements, the bandwidth shall not exceed 10 nm.

The accuracy of the apparatus shall be specified in the test report.

Dimensions in millimetres



a) **Apparatus for determination of spectral and luminous transmittance**

b) **Example of a cuvette for holding saline and a soft contact lens**

Key

1 integrating sphere
2 receiver
3 lamp
4 diaphragm
5 filter
6 mirror
7 cuvette with contact lens
8 quartz glass plate
9 saline solution
10 centring ring
11 contact lens

Figure 17 — Apparatus for determination of spectral and luminous transmittance

Measurements of soft contact lenses shall be made with the lens fully hydrated and surrounded by standard saline solution (see 4.7) in the measuring cuvette.

The measurements of rigid contact lenses are made in air. Place the rigid contact lens as close to the entrance port of the integrating sphere as possible.

The transmittance measurements shall be made inside the central optic zone of the contact lens. Intended values shall be measured both with and without the contact lens. $\tau(\lambda)$ and/or τ_v shall be calculated using Equations (4), (5) or (6).

Luminous transmittance of many lenses has been measured in air. To correct these values to “measured in standard saline solution” values, the difference in surface reflection between the lens immersed in saline solution and in air has to be taken into account. This is done by using the Fresnel transmittance formula for a dielectric interface under normal incidence [Equation (7)]:

$$T = \frac{4 \times n_1 \times n_2}{(n_1 + n_2)^2} \quad (7)$$

where

T is the interfacial transmittance;

n_1, n_2 are the refractive indices of the two materials.

The converted luminous transmittance is then calculated as follows:

$$\tau_{\text{saline}} = M \times \tau_{\text{air}} \tag{8}$$

where

$$M = \left[\frac{(n_{\text{saline}}) \times (n_{\text{air}} + n_{\text{cl}})^2}{(n_{\text{air}}) \times (n_{\text{saline}} + n_{\text{cl}})^2} \right]^2$$

n_{air} is equal to 1;

n_{saline} is refractive index of standard saline solution;

n_{cl} is refractive index of contact lens material.

4.7 Saline solution for contact lens testing

4.7.1 General

This subclause specifies a standard saline solution for use, when required, in conducting test methods specified in ISO 18369 or other International Standards. The specified solution is applicable to the equilibrating of either a contact lens or a contact lens material prior to testing, and also to the immersion of the test item during testing. It is not intended for the purpose of packaging finished contact lenses, but is similar to many commercially used contact lens packaging solutions.

If a solution not complying with this subclause is used for testing, results may vary and the composition of the solution used should be declared.

The standard saline solution shall be phosphate-buffered at a pH of 7,4 ± 0,1 and have a nominal osmolarity of 310 mOsm/kg ± 5 mOsm/kg. It shall be prepared using either; hydrated sodium phosphate salts that comply with the requirements of monographs in current Official Pharmacopoeia (such as the US Pharmacopoeia (USP), the European Pharmacopoeia (Ph Eur); or various National Pharmacopoeia); or anhydrous sodium phosphate salts of a purity equivalent to specified reagent for general laboratory work (SLR). The liquid phase is water complying with ISO 3696:1987, Grade 3 or any purer standardized grade. Water shall be either freshly prepared or sterilized within 24 h of preparation of the standard solution.

4.7.2 Formulation

4.7.2.1 Formulation in molarities

The following molar concentrations shall be applicable to the finished solution:

a) sodium chloride (NaCl) 1,420 × 10^{-1} mol/l;

b) sodium dihydrogen phosphate (NaH_2PO_4) 3,384 × 10^{-3} mol/l;

c) disodium phosphate (Na_2HPO_4) 1,673 × 10^{-2} mol/l.

4.7.2.2 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.

4.7.2.3 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.

4.7.2.4 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.

4.7.3 Preparation procedure

The hydrated phosphates of sodium may 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 in 4.7.2.1, 4.7.2.2 and 4.7.2.3 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 (e.g. BS 1647 and BS 3145). 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 4.7.2.1, 4.7.2.2 and 4.7.2.3), ensuring that all are completely dissolved by proper mixing.

Test this solution with a calibrated pH-meter and adjust by dropwise addition 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.

4.7.4 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 International Standard (i.e. ISO 18369-3:2006),

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

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 part of ISO 18369, 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 part of ISO 18369 (ISO 18369-3:2006), 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 determination 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

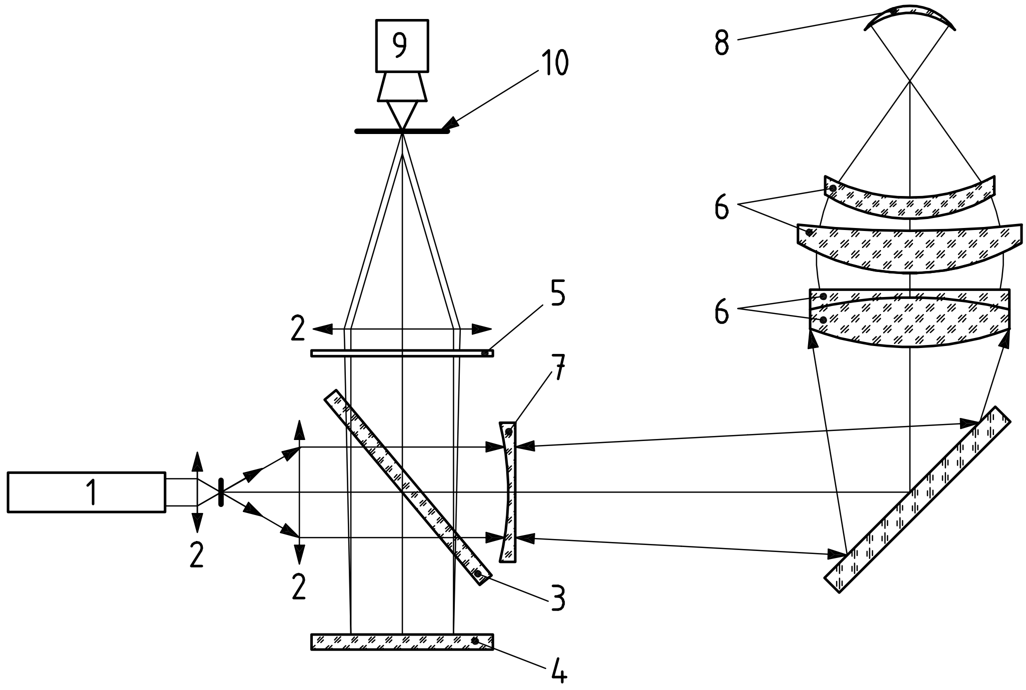
Any shape deviation of a surface tested introduces a curved or irregular fringe pattern which can be interpreted as a contour level map of the deviations from the ideal surface. Adjacent fringes have an altitude difference of half the wavelength used, e.g. 633,2 nm for a He-Ne laser.

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.



Key

1	laser	6	high-aperture objective
2	L1, L2, L3 lens system	7	lens
3	beam splitter	8	test surface (of the contact lens)
4	reference mirror	9	camera
5	computer-generated hologram	10	diaphragm

Figure A.1 — Measuring principle with a Twyman-Green interferometer

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.

Control the focusing by visual adjustment of the interference pattern to a minimum of fringes.

Axially move the contact lens by an amount equal to its vertex radius. In this position, perform the interference fringe analysis.

Calculate the best-fitting vertex radius as well as the conicoidal constant from the result of the fringe analysis. Derive the residual deviations from the ideal conicoidal surface.

Annex B
(informative)

Determination of back vertex power of soft contact lenses immersed in saline using the Moiré deflectometer or Hartmann methods

B.1 General

This annex specifies a method for determining the back vertex power of soft contact lenses immersed in saline using the Moiré deflectometer or the Hartmann method.

B.2 Principle

B.2.1 The Moiré deflectometer is a quantitative instrument for mapping ray deflections of a beam passed through or reflected off a test object. The technique is based on the Moiré effect, a phenomenon that causes a fringe pattern to appear when two gratings are placed at a small angle to each other. The fringe pattern is detected by a CCD camera and digitized. Digital information relating to the fringe pattern is relayed through the electro-optical interface to the control software for analysis. The resulting image is displayed on a visual display unit.

The system is calibrated so that when there is no contact lens in the cuvette, the beam is collimated and straight vertical fringes are observed. When a contact lens is inserted in the cuvette, the fringes deviate from the vertical. The laser light source is translated by means of a servomotor under software control until the fringes are restored to the vertical. The power of the cuvette-contact lens combination is determined from the distance the laser travels, from which the dioptric power of the lens being measured is calculated. It is necessary to calculate the back vertex power of the contact lens in air based on the parameters of the cuvette, saline and contact lens.

B.2.2 The Hartmann test is used to measure the power-related components of optical elements that are placed in the path of a beam of light which then passes through a screen containing a number of microlenses. Typically, the screen consists of an array of microlenses arranged in a square matrix. The measuring system is arranged so that a reference image is taken before the optical element to be measured is placed in the system. The image produced by the microlenses is memorized; this acts as the reference image. The optical element to be measured is then introduced to the system; the image of the microlenses is altered by the power-related parameters of the element being measured. It can be shown that the transverse aberrations of the image of the microlenses are a function of the power-related parameters of the element being measured. An algorithm is used to calculate the power-related parameters of the element being measured.

B.3 Apparatus and reagent

B.3.1 **Moiré deflectometer or Hartmann instrument**, having the following capabilities:

B.3.1.1 The diameter of the central aperture through which the power is measured shall be adjustable and at least be capable of being set to 4,50 mm ± 0,50 mm.

B.3.1.2 The instrument shall have a measuring range of at least −20,00 D to +20,00 D.

This requirement should apply to the powers in air; suitable allowance should be made in the system for the power of lenses immersed in saline.

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 lenses, with the nominal back vertex power of each test lens being within one dioptre of −20,00 D, −15,00 D, −10,00 D, −5,00 D, +5,00 D,+10,00 D, +15,00 D and +20,00 D. The powers of the test lenses shall be traceable to a national or International Standard. The following parameters shall be known for each of the test lenses, to the accuracy given:

— centre thickness to ± 0,01 mm;

— base curve to ± 0,05 mm;

— diameter to ± 0,05 mm;

— refractive index correct to three places of decimals.

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

B.3.4 Standard saline solution, conforming to 4.7. 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 ± 0,5 °C for 30 min.

If 30 min is not 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 ± 5 °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 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 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 ± 5 °C, using a lens lift.

B.4.3.2 Make sure the lens is not everted.

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 back vertex power of the lens being measured.

B.4.4 Number of readings required

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 interlaboratory test. Tables B.1 and B.2 are based on the outcome of interlaboratory tests as given in B.4.6.

B.4.4.1 Spherical lenses

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

B.4.4.2 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 mean. Use the calibration curve (B.4.2.3) to determine the corrected mean.

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

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

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

Parameter	Tolerance limit	Number of measurements Moiré	Number of measurements Hartmann
Sphere power			
0 to ± 10 D	± 0,25 D	7	2
over ± 10 D to ± 20 D	± 0,50 D	2	2
over ± 20 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 back vertex power of the lens in dioptres shall be reported as the corrected mean value determined as described in B.4.4.1.

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 mean value(s) determined as described in B.4.4.2.

B.4.6 Reproducibility data

B.4.6.1 Spherical soft contact lenses

Reproducibility data for the measurement of 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 [2] during 1996 and 1997 involving four and five independent laboratories respectively and 21 sample lenses.

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

Parameter	Reproducibility	
	s_R	R
Back vertex power, Moiré	0,090 3 D	0,252 8 D
Back vertex power, Hartmann	0,025 3 D	0,070 8 D

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.

B.4.6.2 Toric soft contact lenses

Reproducibility data for the measurement of 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 [2] 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		Hartmann	
	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°

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1) ISO 5725:1986 was cancelled and replaced by ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998 and ISO 5725-6:1994.

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