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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

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.

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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](http://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.

This corrected version of ISO 18369-3:2017 incorporates the following corrections.

- The last sentence of the Scope has been revised to clarify that the equilibrating solution is standard saline solution.
- “International Standard” has been replaced by “international standard” in five instances.
- “test specimen position” has been replaced by “contact lens support (cuvette)” in two instances.
- “calibration shim” has been replaced by “calibration disc” in six instances.
- “saline” has been replaced by “saline solution” throughout the text.
- In 4.2.2.1, third paragraph, second sentence,  $T'$  has been replaced by  $T''$ .
- In Table 1, “ $t_c$ ” has been replaced by “ $t_C$ ”.
- In the key of Figure D.1, the symbol of the diameters has been replaced by “ $\varnothing$ ”.
- Additional minor editorial changes have been made to improve clarity.

# 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, i.e. 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  $\leq 30$  % of the allowed tolerance range<sup>[8]</sup>.

Lenses should be equilibrated by soaking in standard saline solution 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, the 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, $R^a$
<a href="#">4.2.2</a>	Optical spherometry Spherical rigid lenses	$\pm 0,015$ mm in air
<a href="#">Annex C</a>	Ophthalmometry Spherical rigid lenses Spherical rigid lenses Spherical hydrogel lenses (38 % water content, $t_c > 0,1$ mm)	$\pm 0,015$ mm in air $\pm 0,025$ mm in saline solution $\pm 0,050$ mm in saline solution
<a href="#">4.2.3</a>	Sagittal height method Hydrogel contact lenses <sup>b</sup> 38 % water content, $t_c > 0,1$ mm 55 % water content, $t_c > 0,1$ mm 70 % water content, $t_c > 0,1$ mm	$\pm 0,05$ mm in saline solution $\pm 0,10$ mm in saline solution $\pm 0,20$ mm in saline solution <sup>c</sup>
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

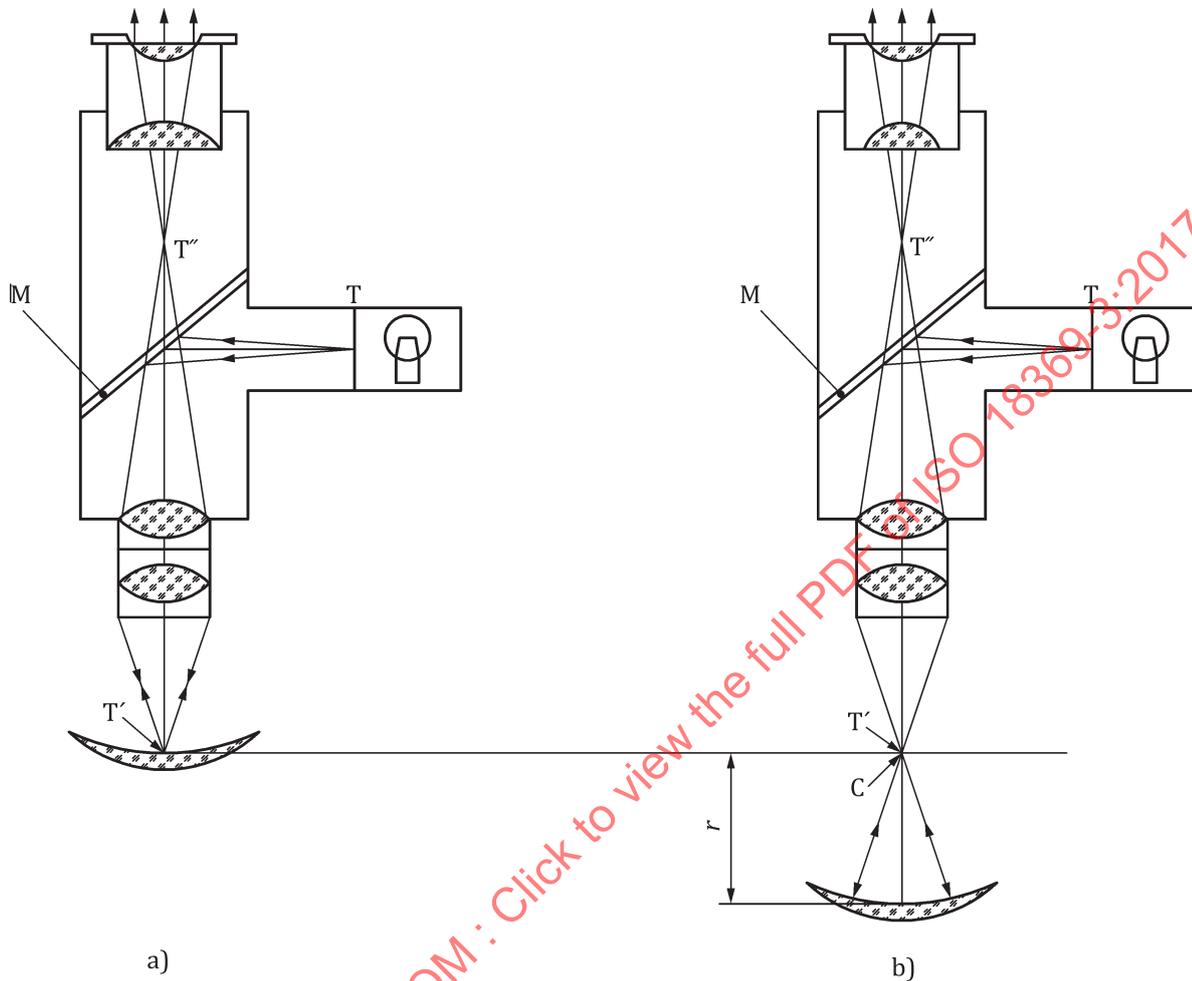
The microspherometer locates the surface vertex and the aerial image (centre of curvature) with the Drysdale principle, as described below. The distance between these two points is the radius of curvature for a spherical surface and is known as the apical radius of curvature for an aspheric surface derived 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  $\times 6,5$  with a numerical aperture of not less than 0,25. The total magnification shall not be less than  $\times 30$ . 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  $\pm 0,010$  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  $\pm 0,003$  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  $45^\circ$ .

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 optical 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 optical axis of the instrument. 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  $\pm 0,0075$  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.

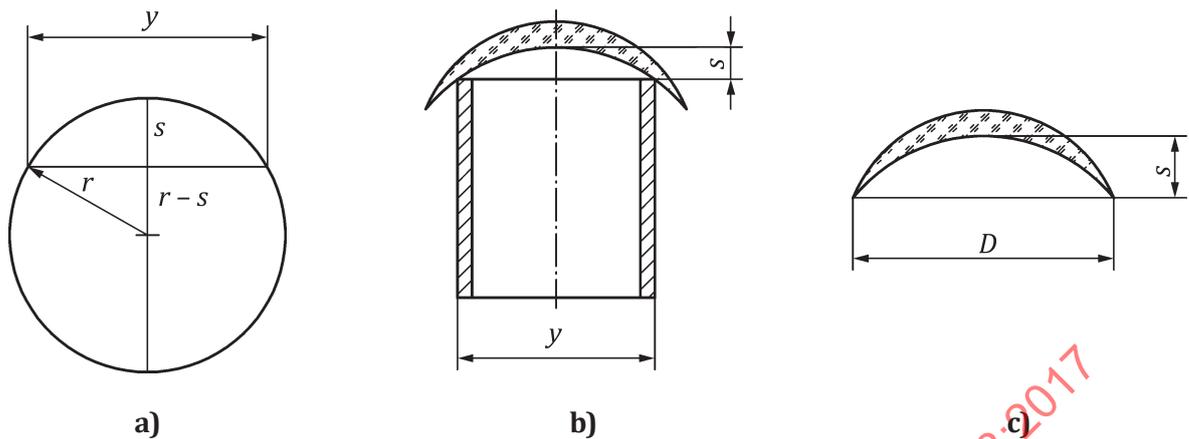
NOTE 2 This method is independent of eccentricity ( $e$ ) and can be used to verify those equivalent radii calculated using eccentricity values. In addition, this method of determining the equivalent radius is applicable to aspheric surfaces that are not based on conic sections.

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

**4.2.3.2 Instrument specification**

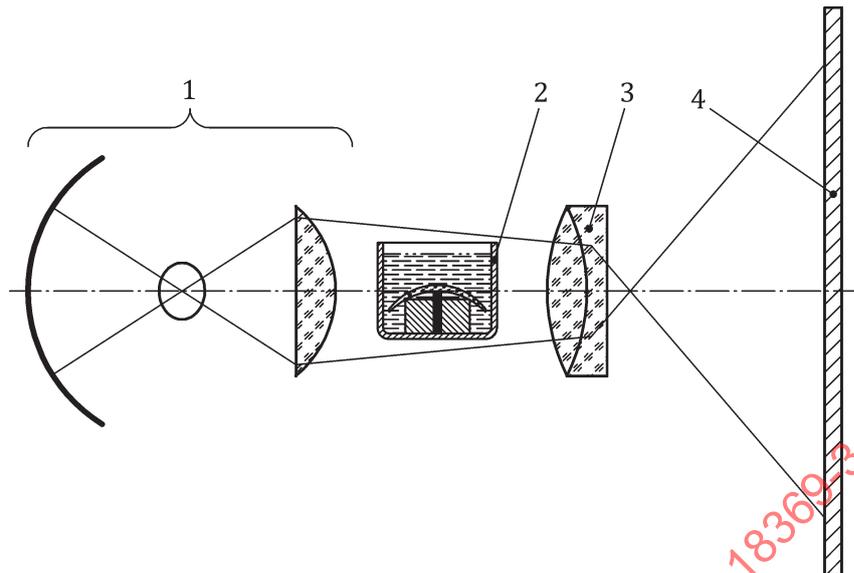
**4.2.3.2.1 Optical comparator.** This shall have a minimum magnification of 10× and shall have incorporated a soft lens wet cell with a lens support appropriate to the radius being measured. For back optic zone radius, a hollow cylindrical contact lens support sized for the back optic zone radius should 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.

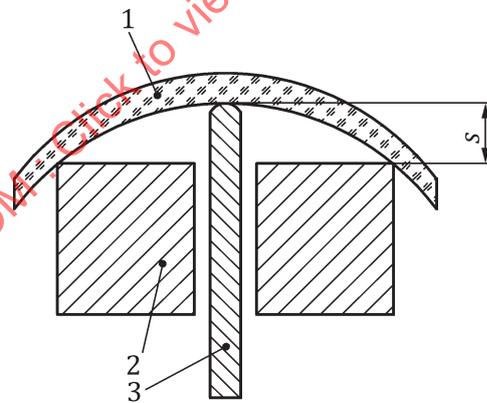
The temperature of the wet cell and contact lens shall be maintained at 20 °C ± 1,0 °C.



**Key**

- 1 illumination system
- 2 wet cell with test sample
- 3 imaging lens
- 4 projection screen

**Figure 3 — Principle of the mechanical analyser**



**Key**

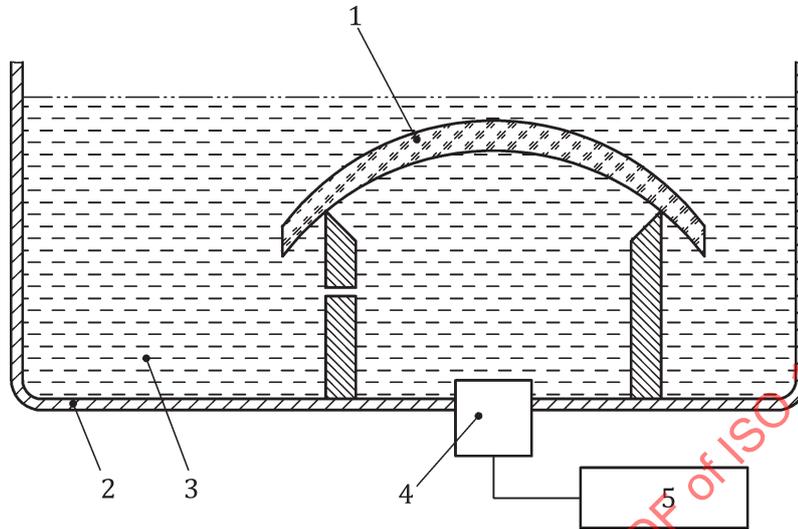
- $s$  sagittal depth
- 1 contact lens
- 2 lens support
- 3 probe

**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  $20\text{ }^{\circ}\text{C} \pm 0,5\text{ }^{\circ}\text{C}$  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  $\pm 0,0075\text{ mm}$ .

Calibration shall take place in a wet cell with a temperature of  $20\text{ }^{\circ}\text{C} \pm 1,0\text{ }^{\circ}\text{C}$  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 solution (see [4.9](#)).

The temperature of the lens and surrounding saline solution after stabilization shall be  $20\text{ °C} \pm 1,0\text{ °C}$  except for the ultrasound method which shall be  $20\text{ °C} \pm 0,5\text{ °C}$ .

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

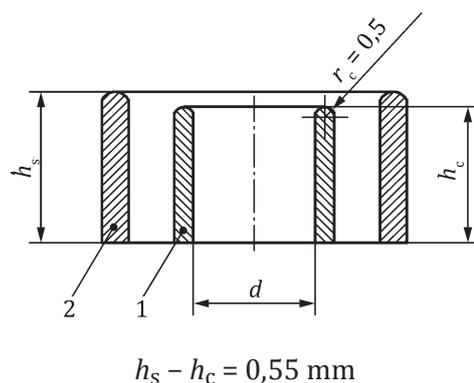
**4.3.2.1 Focimeter**, having a minimum range of  $-20,00\text{ D}$  to  $+20,00\text{ D}$  with a minimum measuring accuracy of  $\pm 0,06\text{ D}$ , and capable of manual focusing. Other focimeters may be used provided the readings derived are shown to be equivalent to those of a manually focusing 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

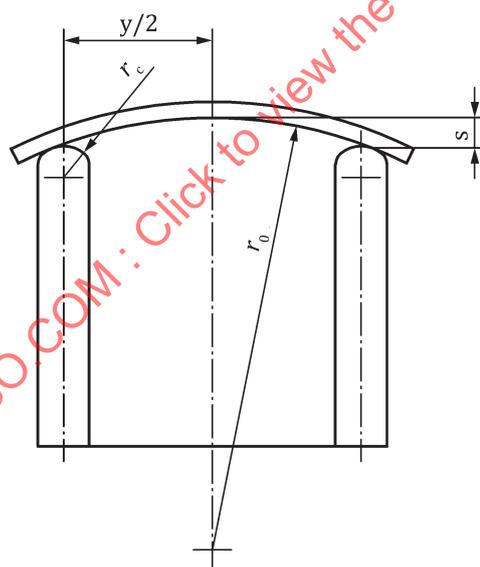
- 1) a support that allows calibration with spherical aberration-free (spectacle-type) lenses in the vertex plane of the focimeter, and
- 2) an alternative smaller and shorter support of 4,0 mm to 5,0 mm in diameter so that the back vertex of a contact lens can also be positioned in the vertex plane 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.

**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

powers of the calibration lenses shall be 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 range of the focimeter, e.g. -5,00 D; -10,00 D; -15,00 D; -20,00 D; +5,00 D; +10,00 D; +15,00 D; +20,00 D. The actual label back vertex power of these lenses shall be traceable to a national or international standard and known to within 0,03 D.

At a temperature of 20 °C to 25 °C and using the spherical test lenses, calibrate the focimeter fitted with the appropriate spectacle 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 to the nearest 0,06 D or less. Take three independent readings and record the arithmetic mean. Differences between calculated and actual label back vertex power shall be used to construct a correction calibration curve, if the results fail to meet the calibration accuracy criteria.

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

#### 4.3.4 Focimeter measurement of rigid lenses

Before making the measurement, rigid lenses shall be maintained at a temperature of 20 °C to 25 °C for at least 30 min. During the measurement, maintain the focimeter and contact lens support at a temperature of 20 °C to 25 °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 of the contact lens is centred on the optical axis of the focimeter and lens surfaces be clean and free of debris or solution. Take four independent readings of the label back vertex power. Calculate the arithmetic mean and, using the calibration curve, determine the corrected arithmetic mean.

#### 4.3.5 Focimeter measurement of hydrogel lenses

Equilibrate the hydrogel lenses. See ISO 18369-1:2017, 3.1.1.21.

Blot the lens with a lint-free absorbent cloth or filter paper to remove surface liquid, and place it upon the contact lens support within 10 s. The process shall be the same as that in 4.3.4. Place the posterior surface of the lens appropriately on the lens support.

Multiple independent readings may be taken to minimize measurement error. Calculate the arithmetic mean if necessary and, using the calibration curve, determine the corrected arithmetic mean. When measuring multiple times, take care that the lens is not distorted or damaged. Also, note the order of multiple measurements to confirm that there is no measurement trend that might be the result of lens distortion or damage.

#### 4.3.6 Measurement of hydrogel contact lenses by immersion in saline solution

The test methods (Moiré deflectometer method and Hartmann method) are specified in [Annex B](#) and are listed in [Table 3](#), together with a statement of their reproducibility when applied to spherical or toric hydrogel contact lenses.

NOTE The data in [Table 3](#) was the result of a ring test.

**Table 3 — Reproducibility for label back vertex power test methods**

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
<b>Spherical hydrogel lenses</b>						
Label back vertex power	0,143 D (for power range $ F'_L  \leq 10$ )	0,400 D (for power range $ F'_L  \leq 10$ )	0,090 3 D	0,252 8 D	0,025 3 D	0,070 8 D
<b>Toric hydrogel lenses</b>						
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.						

### 4.3.7 Addition power measurement

At the present time, measurement methods for determining the addition power of soft lenses and rigid lenses have not been adequately developed and ring tested.

## 4.4 Diameters and widths

### 4.4.1 Total diameter

#### 4.4.1.1 General

Measurement of the overall diameter of rigid contact lenses shall be made by either the V-groove gauge method (see 4.4.1.2) or the projection comparator method (see 4.4.1.3). Measurements of the overall diameter of soft contact lenses shall be made using the projection comparator method (see 4.4.1.3).

The V-groove gauge or projection comparator should have a scale or digital readout display with minimal increments of  $\leq 10$  % of the overall diameter tolerance and should be capable of measuring total diameters with a precision (R&R) of  $\leq 30$  % of the allowed tolerance.

Resolution greater than 10 % can be used but will affect determination of accuracy, precision, process capability and gauge capability.

#### 4.4.1.2 V-groove gauge method

##### 4.4.1.2.1 Principle

When a circular disc slides into a V-groove (see Figure 8 and Figure 9 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.

##### 4.4.1.2.2 V-Groove specification

The groove specifications shall be capable of measuring to  $\pm 0,05$  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 Figure 8 and Figure 9.

#### 4.4.1.2.3 Calibration

Instrument calibration shall be carried out to assure measuring accuracy to known standards and multiple instrument equivalence using three calibration discs (see [Figure 10](#)). These discs shall be made from a hard, durable material (e.g. steel, aluminium or hard plastic). The discs shall be chosen so as to determine the measuring accuracy over the desired range of contact lens overall diameters. Minimum requirements for this purpose are discs with nominal diameters of 10,50 mm, 9,50 mm and 7,50 mm ( $\pm 0,01$  mm). The actual diameters of these discs shall be traceable to a national or international standard and known to within 0,010 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.

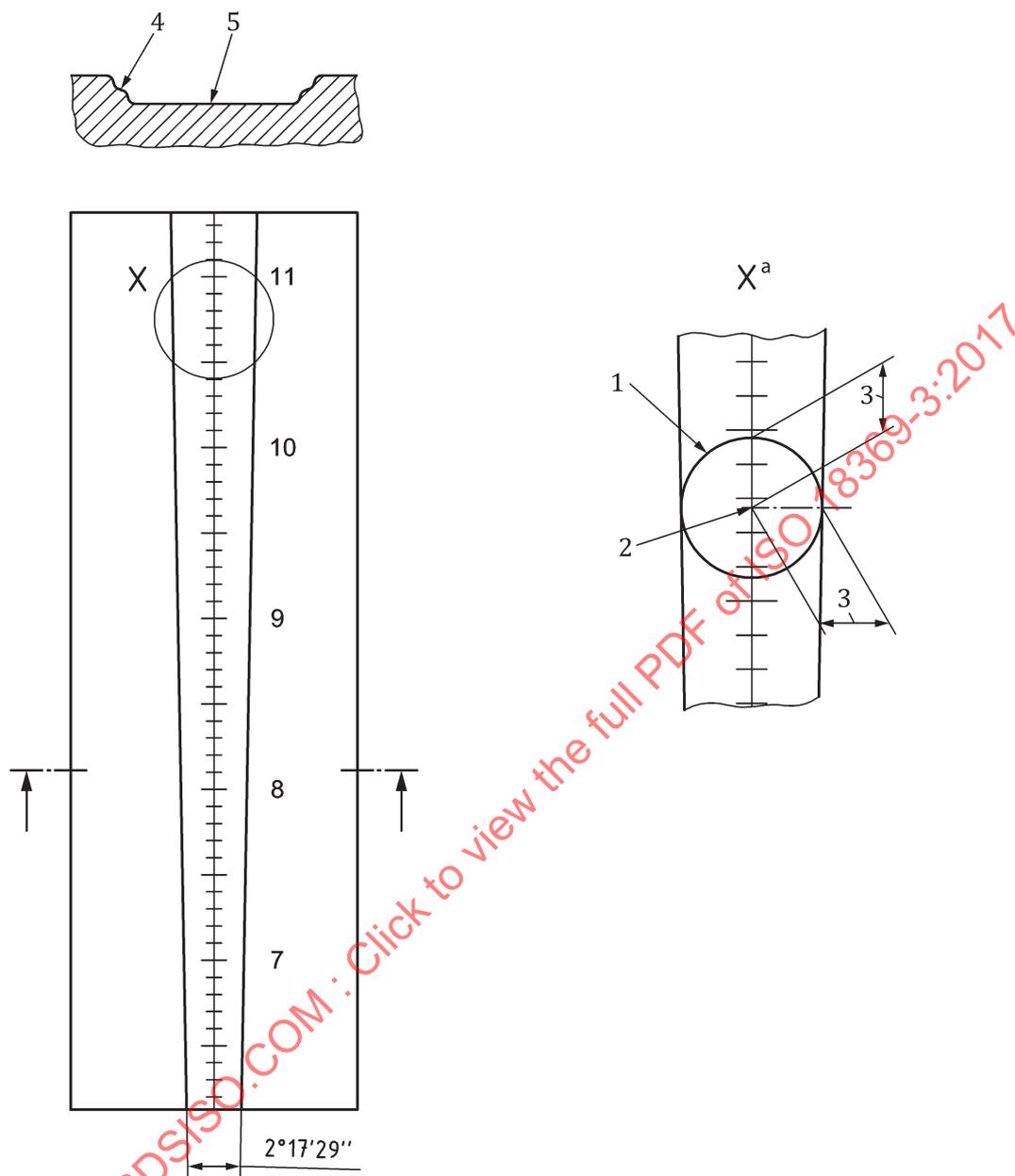
Position the calibration discs in the V-groove diameter gauge so that the disc touches each side of the groove under no external force. Record the V-groove reading to the nearest 0,025 mm. Take three independent readings and calculate the arithmetic mean. Differences between calculated and actual calibration disc size shall be used to construct a correction calibration curve if the results fail to meet the calibration accuracy and precision criteria.

#### 4.4.1.2.4 Measurement method

The V-groove gauge shall be maintained at a temperature of 20 °C to 25 °C during the 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.



Depth of groove: 1,0 mm ± 0,25 mm

Length of groove: 100,0 mm ± 0,25 mm

Angle of groove:  $2 \arctan \left( \frac{11,0 - 7,9}{200} \right) = 2^\circ 17' 29''$

Width of groove:

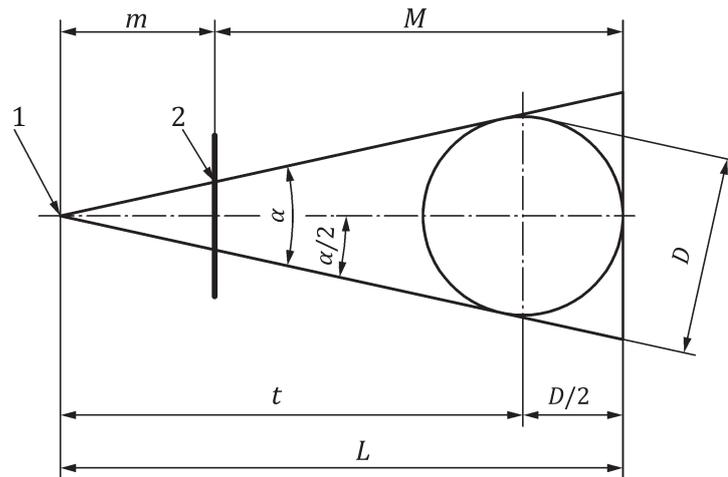
Large end: 11,0 mm ± 0,01 mm

Small end: 7,0 mm ± 0,01 mm

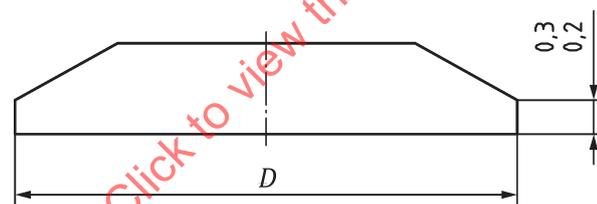
**Key**

- 1 lens outline
- 2 actual lens centre
- 3 1/2 lens diameter
- a Location of engraved mark at superior edge.
- 4 relieve corners as shown to help prevent dirt build-up
- 5 engraved markings (raised or lowered)

**Figure 8 — Example of V-groove diameter gauge (not to scale)**

**Key**

- 1 apex
- 2 narrow end of groove
- $D$  lens diameter
- $\alpha$  angle of groove

**Figure 9 — Geometry of the V-groove diameter gauge**

Dimensions in millimetres

**Key**

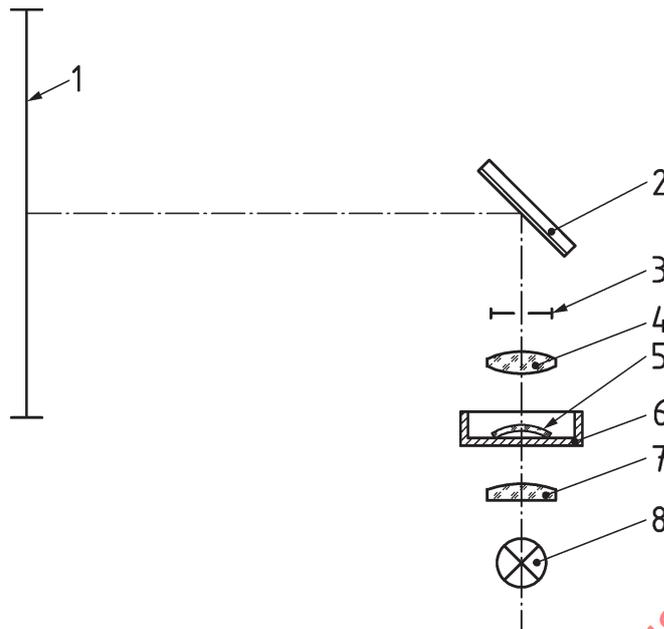
- $D$  diameter of the calibration disc

**Figure 10 — Example of calibration disc****4.4.1.3 Projection comparator method****4.4.1.3.1 Projection comparator specification**

The principle of the projection comparator is shown in [Figure 11](#). The projection system shall be capable of measuring to  $\pm 0,05$  mm over a range of 0 mm to 17 mm. Referring to [Figure 11](#), 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  $\times 15$  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 measurement 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, or from a digital readout to the lens stage.

The projection comparator shall incorporate a soft lens wet cell with a lens support. The wet cell shall be filled with standard saline solution. The temperature of the wet cell and contact lens shall be maintained at  $20\text{ }^{\circ}\text{C} \pm 1,0\text{ }^{\circ}\text{C}$ .



**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 11 — Principle of the projection comparator**

As shown in [Figure 11](#), the contact lens shall rest horizontally with its concave (back) surface against the contact lens support. A reticule or digital readout should display minimal increments of  $\leq 10\%$  of the tolerance measured and should be capable of measuring overall diameter (or zone diameter or width) with a precision (R&R) of  $\leq 30\%$  of the allowed tolerance. Resolution greater than  $10\%$  can be used but will affect determination of accuracy, precision, process capability and gauge capability.

**4.4.1.3.2 Calibration**

Instrument calibration shall be carried out to assure measuring accuracy to known standards and multiple instrument equivalence using three calibration discs. These discs shall be made from a hard, durable and corrosion-resistant material (e.g. stainless steel). The discs shall be chosen so as to determine the measuring accuracy over the desired range of contact lens zones and widths measured. The actual diameters of these discs shall be traceable to a national or international standard and known to within  $0,005\text{ mm}$  at a temperature of  $20\text{ }^\circ\text{C} \pm 1,0\text{ }^\circ\text{C}$ .

Calibration shall take place in a wet cell with a temperature of  $20\text{ }^\circ\text{C} \pm 1,0\text{ }^\circ\text{C}$  after the instrument has had sufficient time to stabilize and after the calibration discs have been equilibrated in standard saline solution within the wet cell.

Place the calibration disc in the contact lens support (cuvette). Adjust the stage and projection comparator so that the image of the calibration disc is focused on the scale of the observation screen. Record the calibration disc diameter to the nearest  $0,020\text{ mm}$ . Take three independent readings and calculate the arithmetic mean. Differences between calculated and actual calibration disc size shall

be used to construct a correction calibration curve if the results fail to meet the calibration accuracy criteria.

#### 4.4.1.3.3 Measurement method

The projection comparator shall be maintained at a temperature of 20 °C to 25 °C. The temperature of the wet cell, standard saline solution and contact lens shall be maintained at 20 °C ± 1,0 °C. Place the contact lens in the contact lens support (cuvette) and allow to equilibrate. Equilibration times are a function of lens material and thickness and shall be determined by the manufacturer.

Adjust the stage and projection comparator so that the image of the contact lens is focused on the scale of the observation screen. Record the contact lens diameter (or zone diameter) to the nearest 0,020 mm. If required to improve precision, take three independent readings taking care not to deform the lens during the measurement and calculate the diameter (or zone diameter) by taking the arithmetic mean of the readings and adjust this value using the calibration curve.

#### 4.4.2 Zone diameters and widths

##### 4.4.2.1 General

The diameters and widths of contact lens zones (e.g. optic zone diameters, secondary and peripheral curve diameters or widths) can be measured with a projection comparator according to the method described in [4.4.1.3](#), or for rigid lenses in air with a hand-held magnifier according to the method described in [4.4.2.2](#). Such measurements are difficult since the edges of these zones are often “blended” so that the zones merge into each other.

##### 4.4.2.2 Hand-held magnifier

###### 4.4.2.2.1 Hand-held magnifier specifications

The hand-held magnifier shall have a minimum magnification power of ×7 for the measurement of zone diameters and widths of rigid lenses in air. The magnifier should have a suitable scale through the centre of the field of view with minimal increments of ≤10 % of the tolerance measured and should be capable of measuring zone diameters and widths 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.

###### 4.4.2.2.2 Calibration

Instrument calibration shall be carried out to assure measuring accuracy to known standards and multiple instrument equivalence using multiple calibration discs. These discs shall be made from a hard, durable and corrosion-resistant material (e.g. steel, aluminium or hard plastic). The discs shall be chosen so as to determine the measuring accuracy over the desired range of measured features. The actual diameters of these discs shall be traceable to a national or international standard and known to within 0,01 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 the calibration disc under the hand-held magnifier. Record the calibration disc diameter to the nearest 0,010 mm. Take three independent readings and calculate the arithmetic mean. Differences between calculated and actual calibration disc size shall be used to construct a correction calibration curve if the results fail to meet the calibration accuracy criteria.

Consideration shall be made of the focusing accuracy of the magnifier during calibration and shall be included in the correction calibration curve.

#### 4.4.2.2.3 Measurement method

The hand-held magnifier shall be maintained at a temperature of 20 °C to 25 °C during the measurement.

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 measurement, 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 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  $\leq 10$  % 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 disc between the stylus and the fixed stop. Record the calibration disc thickness to the nearest 0,002 mm. Take three independent readings and calculate the arithmetic mean. Differences between calculated and actual calibration disc thickness shall be used to construct a correction calibration curve if the results fail to meet the calibration accuracy criteria.

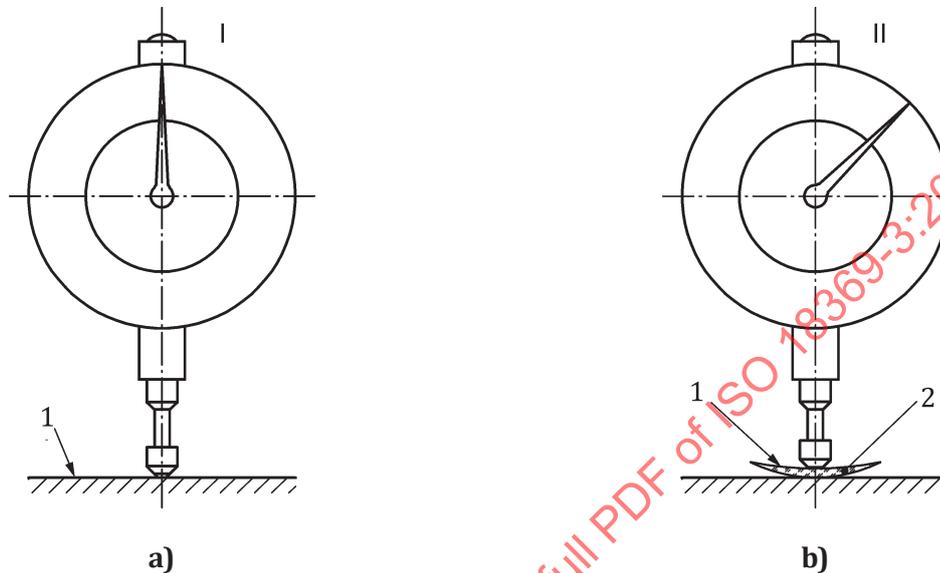
##### 4.5.2.3 Measurement method

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.

When measuring multiple times, take care that the lens is not distorted or damaged. Also, record the order of multiple measurements to confirm that there is no measurement trend that might be the result of lens distortion or damage.



#### Key

- 1 measuring face
- 2 contact lens

Figure 12 — Measurement of centre thickness with a dial gauge

### 4.5.3 Low-force mechanical gauge method

#### 4.5.3.1 Instrument specification

The low-force mechanical gauge should be used to measure thickness of hydrogel contact lenses. The mechanical gauge is comprised of a rigid frame in which a sensor is mounted to measure linear displacement. The sensor shall be fitted with a flat tip with a diameter of at least 2,0 mm.

The measuring force applied to the specimen shall not exceed the limit of the lens material so as to prevent undue compression of the specimen during testing. The force exerted by the sensor should be minimal and shall not exceed 0,015 N (less than 1,5 g) when displaced by 1 mm from its unrestrained position (i.e. rest). A contact lens support shall be located beneath the sensor and have a radius of 7,0 mm to 9,0 mm and an overall diameter between 14 mm and 18 mm. A contact lens support with a flat surface may also be used provided that the diameter is large enough to support the lens. The gauge shall be capable of being set to zero at the lens support so that the surfaces of the contact lens are at the point where the thickness is to be measured and are in contact with the sensor tip and the lens support. The size and shape of the lens support may be optimized to aid lens centration, measurement accuracy and repeatability.

The gauge readout should display maximum increments of 1  $\mu\text{m}$  being measured and should be capable of measuring thicknesses with a precision (R&R) of  $\leq 30\%$  of the allowed tolerance. Resolution greater than 10 % can be used but will affect determination of accuracy, precision, process capability and gauge capability.

#### 4.5.3.2 Calibration

Measurement accuracy of the low-force mechanical gauge is dependent on measurement force and sensor accuracy. Instrument calibration shall be carried out to assure measuring accuracy to known standards and multiple instrument equivalence using a 0,3 g to 3,0 g precision dynamometer, or other appropriate instrument, for example, a load cell, and multiple precision engineering discs.

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

To verify or calibrate sensor force, zero the sensor and remove the lens support. Position the dynamometer measuring tip beneath the sensor tip and slowly lower the sensor tip, allowing the dynamometer to stop the fall as it comes to a position near the zero position. It can be necessary to place discs beneath the dynamometer to achieve the correct height. Take three independent readings of sensor force and calculate the arithmetic mean. Adjustment of the sensor force to the desired level can be made by moving the sensor counterweight. Make the appropriate adjustment and repeat the force measurement. Replace the lens support.

The precision engineering discs shall be made from a hard, non-compressible material (e.g. steel). 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 0,001 mm.

Place each calibration disc between the sensor tip and the lens support. Record the calibration disc thickness to the nearest 0,001 mm. Take three independent readings and calculate the arithmetic mean. Differences between calculated and actual calibration disc thickness shall be used to construct a correction calibration curve if the results fail to meet the calibration accuracy criteria.

#### 4.5.3.3 Measurement method

The low-force mechanical gauge shall be maintained at a temperature of 20 °C to 25 °C during the measurement.

Equilibrate the lenses.

Place on the contact lens support within 10 s to minimize dehydration of the lens.

Record the thickness to the nearest 0,001 mm. Multiple measures may be taken to reduce measurement variation, returning the lens to the standard saline solution between each measurement. Calculate the thickness by taking the arithmetic mean of the readings and adjust this value using the calibration curve.

When measuring multiple times, take care that the lens is not distorted or damaged. Also, note the order of multiple measurements to confirm that there is no measurement trend that might be the result of lens distortion or damage.

#### 4.6 Edge inspection

Finished edge thickness and shape shall be assessed by visual examination under direct illumination with at least  $\times 7$  magnification.

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

Automated visual technologies or other systems may be used provided the systems are qualified for accuracy and precision.

#### 4.7 Determination of inclusions and surface imperfections

Investigations for surface irregularities, e.g. scratches, pitting, etc. and inclusions in the lens material such as heterogeneities, bubbles and the like can be made with hand-held magnification of at least

×7 or with a projection comparator. More reproducible observations can be made with controlled illumination and background lighting conditions.

Automated visual technologies or other systems may be used, provided the systems are qualified for accuracy and precision.

## 4.8 Spectral transmittance

### 4.8.1 General

Spectral transmittance  $\tau(\lambda)$  is the ratio of the transmitted spectral radiant flux  $\phi_{\text{et}}(\lambda)$  to the incident spectral radiant flux  $\phi_{\text{ei}}(\lambda)$ . In practice, the measurement of spectral transmittance  $\tau(\lambda)$  is taken over a small range of wavelength  $\Delta\lambda$ .

The spectral transmittance  $\tau(\lambda)$  is determined by measuring the spectral radiant flux both with and without the contact lens and calculated from [Formula \(2\)](#):

$$\tau(\lambda) = \frac{\Delta\phi_{\text{et}}(\lambda)}{\Delta\phi_{\text{ei}}(\lambda)} = \frac{\phi_{\text{et}}(\lambda) \times \Delta\lambda}{\phi_{\text{ei}}(\lambda) \times \Delta\lambda} \quad (2)$$

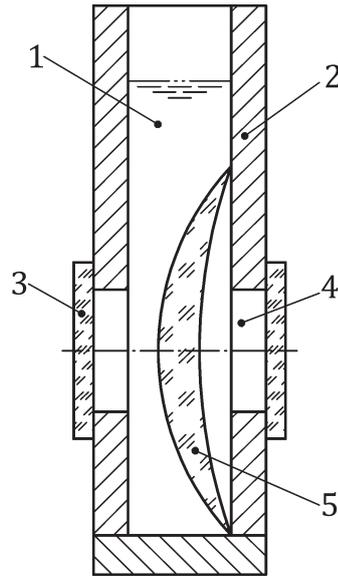
### 4.8.2 Instrument specification, test conditions and procedure

A spectrophotometer or integrating sphere shall be used. For spectral measurements, the bandwidth shall not exceed 10 nm. The beam shall be centred in the aperture.

The instrument shall be capable of measurement in the visible spectrum (380 nm to 780 nm) and, if necessary, in the ultraviolet regions of the spectrum.

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

A cuvette is needed to hold the contact lens and saline solution. [Figure 13](#) shows a typical design. The lens should be centred in the cuvette so that the transmission of the central optic zone is measured.



**Key**

- 1 saline solution
- 2 cuvette
- 3 transparent cover plate
- 4 aperture to restrict beam to the central optic zone
- 5 contact lens under test

**Figure 13 — Design of a typical cuvette used for spectral transmission measurement**

If a single beam spectrophotometer is used, measurements shall be taken using the cuvette filled with standard saline solution but without the contact lens. This effectively "zeroes" the instrument before measurement of a fully hydrated soft contact lens is made with the lens surrounded by standard saline solution (see 4.9) in the cuvette.

The measurements of rigid contact lenses are made in air.

The transmittance measurements shall be made inside the central optic zone of the contact lens.

If an integrating sphere is used, then the lens is positioned as close as possible to the entry port.

To correct values measured in air to "measured in standard saline solution" values, or vice versa, 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 [see Formula (3)]:

$$T = \frac{4 \times n_1 \times n_2}{(n_1 + n_2)^2} \tag{3}$$

where

- $T$  is the interfacial transmittance;
- $n_1, n_2$  are the refractive indices of the two materials.

## 4.9 Saline solution for testing

### 4.9.1 General

This subclause 4.9 specifies a standard saline solution to be used for the test methods specified in the ISO 18369 series. This saline solution is used for bringing hydrogel contact lenses and materials to chemical, thermal and dimensional equilibration prior to testing and as a holding medium while measurements are made.

For technical reasons, some manufacturers need to pack their lenses in a packaging solution that has a different composition from the “standard” saline solution. The properties and parameters of lenses can be different when measured in the two different solutions. Therefore, in order to measure the “label values” of a contact lens, the measurements might need to be made using “packaging solution”.

The type of saline solution used in the testing shall be documented in the report.

The standard saline solution shall be phosphate-buffered at a pH of  $7,4 \pm 0,1$  and have a nominal osmolarity of  $310 \text{ mOsm/kg} \pm 5 \text{ mOsm/kg}$ . 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 saline solution.

### 4.9.2 Formulation

#### 4.9.2.1 Formulation in molarities

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

- a) sodium chloride (NaCl)  $1,420 \times 10^{-1} \text{ mol/l}$ ;
- b) sodium dihydrogen phosphate ( $\text{NaH}_2\text{PO}_4$ )  $3,384 \times 10^{-3} \text{ mol/l}$ ;
- c) disodium phosphate ( $\text{Na}_2\text{HPO}_4$ )  $1,673 \times 10^{-2} \text{ mol/l}$ .

#### 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 ( $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$ ): 0,467 g;
- c) dibasic sodium phosphate heptahydrate USP ( $\text{Na}_2\text{HPO}_4 \cdot 7\text{H}_2\text{O}$ ): 4,486 g;
- d) water according to ISO 3696:1987, Grade 3 ( $\text{H}_2\text{O}$ ): 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 ( $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ ): 0,528 g;
- c) dinatrii phosphas dodecahydricus Ph Eur ( $\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$ ): 5,993 g;
- d) water according to ISO 3696:1987, Grade 3 ( $\text{H}_2\text{O}$ ): 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<sub>2</sub>PO<sub>4</sub> 0,406 g;
- c) Na<sub>2</sub>HPO<sub>4</sub> 2,376 g;
- d) water according to ISO 3696:1987, Grade 3 (H<sub>2</sub>O): 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  $7,4 \pm 0,1$ . In this sense, the saline solution 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  $7,4 \pm 0,1$ . 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 solution 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 solution for contact lens testing), and
- c) the date of preparation.

If the saline solution 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.

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## 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 rigid 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.

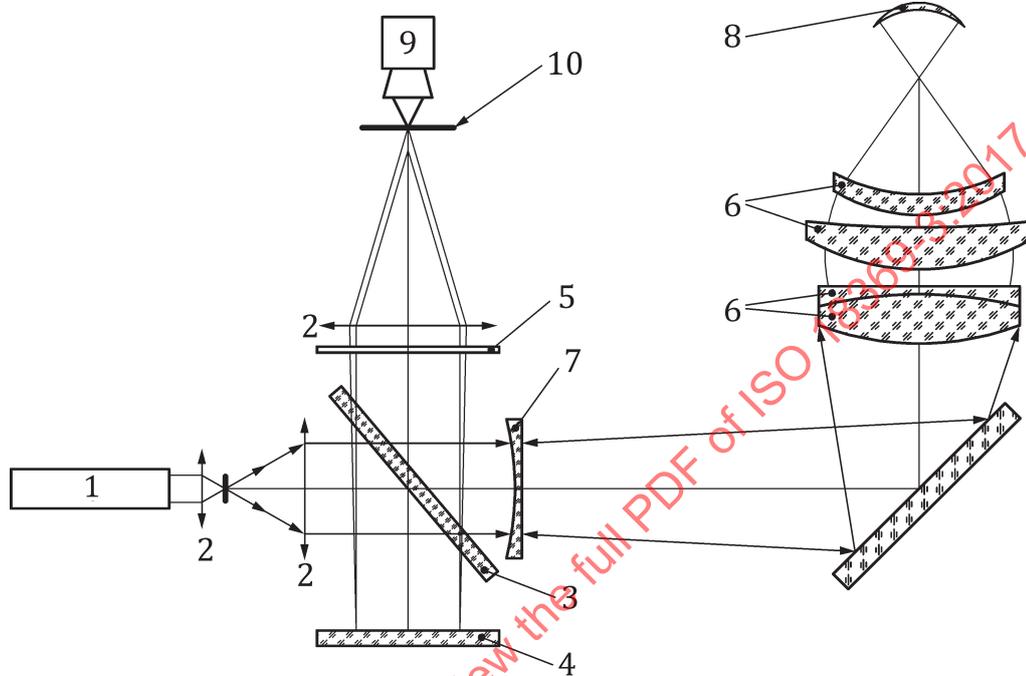
#### A.5 Procedure

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.

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.



**Key**

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

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

## Annex B (informative)

# Measurement of label back vertex power of soft contact lenses immersed in saline solution using the Moiré deflectometer or Hartmann methods

### B.1 General

This annex specifies a method for the measurement of the label back vertex power of soft contact lenses immersed in saline solution 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 label back vertex power of the contact lens in air based on the parameters of the cuvette, saline solution 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  $4,50 \text{ mm} \pm 0,50 \text{ mm}$ .

**B.3.1.2** The instrument shall have a measuring range that is capable for the test articles being measured. 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 solution.

**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  $20\text{ °C} \pm 1,0\text{ °C}$  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  $20\text{ °C}$  to  $25\text{ °C}$  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  $\pm 0,04\text{ D}$  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  $20\text{ °C} \pm 1,0\text{ °C}$ , 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
<b>Label back vertex power</b>			
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
<b>Sphere power</b>			
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
<b>Cylinder power</b>			
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
<b>Axis direction</b>	±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](#).