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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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Contents

Page

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

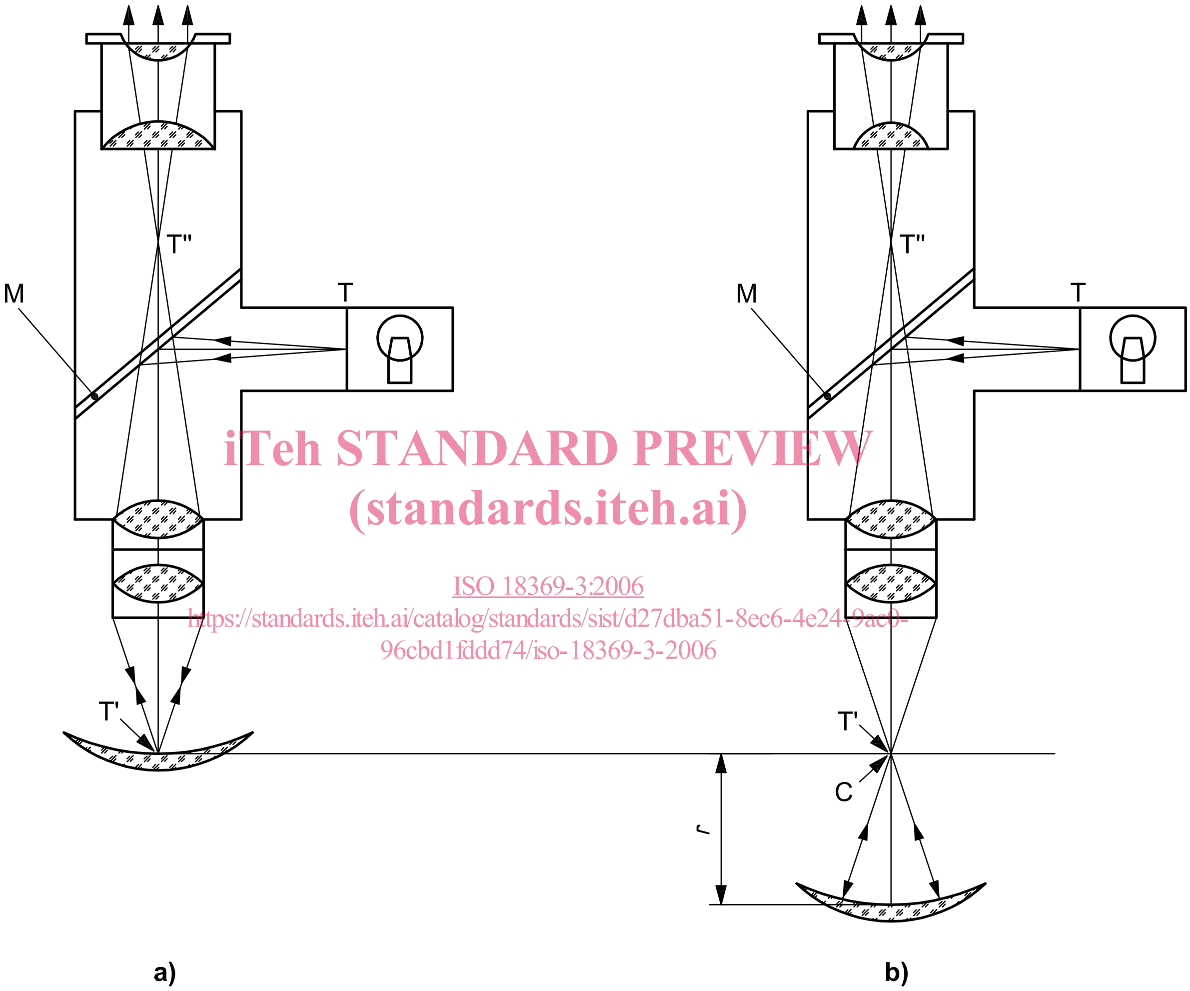
The microspherometer locates the surface vertex and the aerial image (centre of curvature) with the Drysdale principle, as described below. The distance between these two points is the radius of curvature for a spherical surface, and is known as the apical radius of curvature for an aspheric surface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

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

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

$$r_0 = \frac{-y'n}{\sin\varepsilon} \tag{2}$$

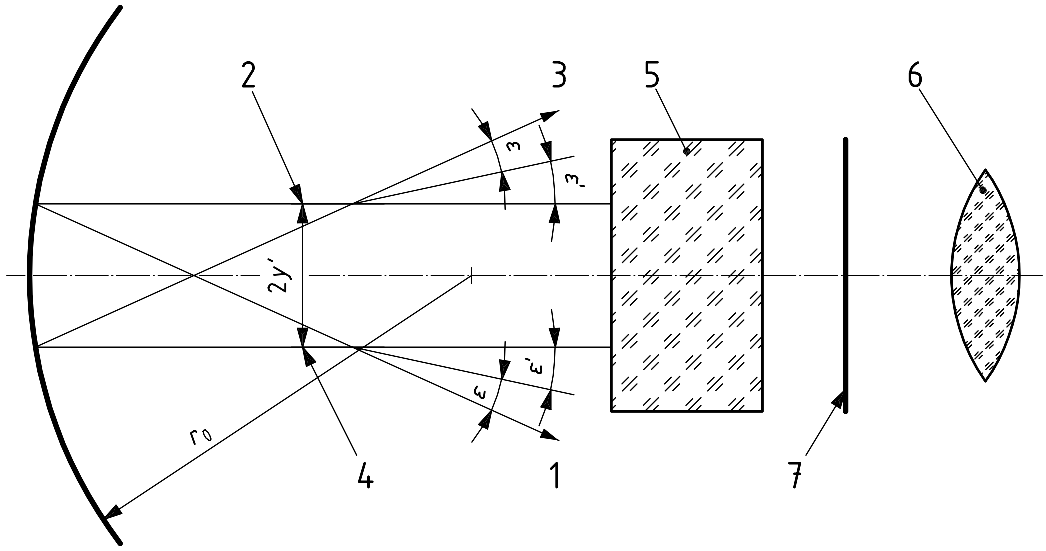
where

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.

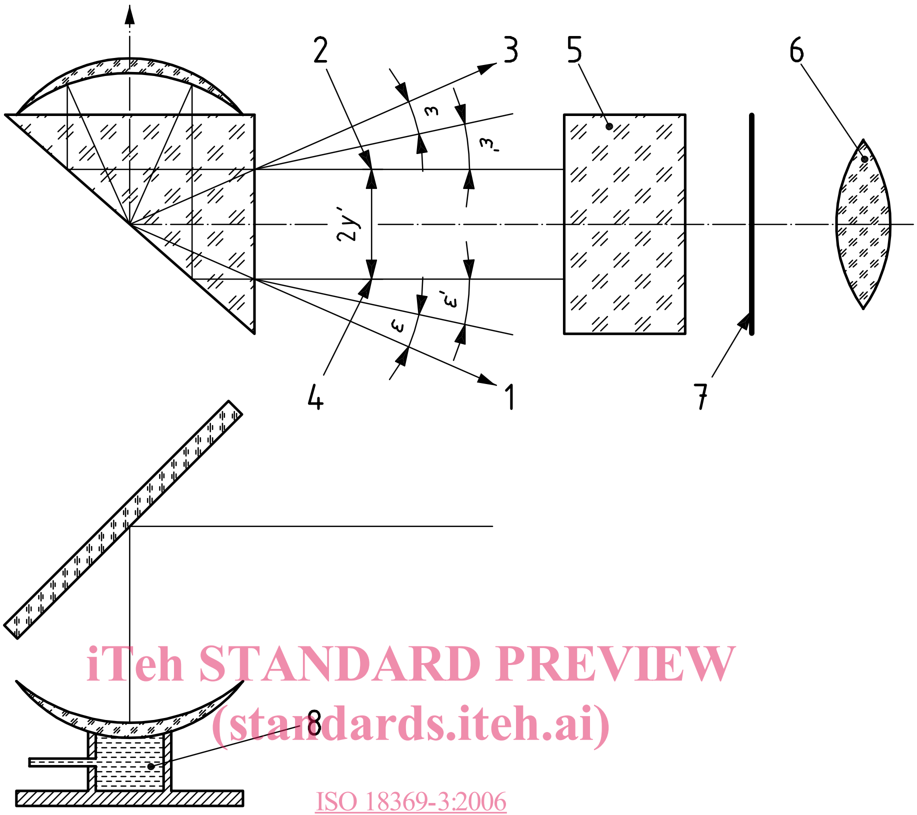
The scale interval shall be not more than 0,02 mm. If the scale is in dioptres the maximum scale interval shall be 0,25 D. An instrument-specific conversion chart is used to change power values to radii of curvature.

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