SLOVENSKI STANDARD
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Očesna optika - Kontaktne leče - 3. del: Merilne metode (ISO 18369-3:2017)

Ophthalmic optics - Contact lenses - Part 3: Measurement methods (ISO 18369-3:2017)

Augenoptik - Kontaktlinsen - Teil 3: Messverfahren (ISO 18369-3:2017)

Optique ophtalmique - Lentilles de contact - Partie 3: Méthodes de mesure (ISO 18369-3:2017)

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Ophthalmic optics - Contact lenses - Part 3: Measurement methods (ISO 18369-3:2017)

Optique ophtalmique - Lentilles de contact - Partie 3: Méthodes de mesure (ISO 18369-3:2017)

Augenoptik - Kontaktlinsen - Teil 3: Messverfahren (ISO 18369-3:2017)

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 18369-3:2017) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.

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

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The text of ISO 18369-3:2017 has been approved by CEN as EN ISO 18369-3:2017 without any modification.

INTERNATIONAL STANDARD

ISO 18369-3

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Ophthalmic optics — Contact lenses —

Part 3:
Measurement methods

Optique ophtalmique — Lentilles de contact —

Partie 3: Méthodes de mesure

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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).

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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.

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

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

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

Ophthalmic optics — Contact lenses —

Part 3:
Measurement methods

1 Scope

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

2 Normative references

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

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

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

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

3 Terms and definitions

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

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

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

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

4 Methods of measurement for contact lenses

4.1 General

Clause 4 specifies methods for measuring finished contact lens parameters.

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

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

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

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

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

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

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

4.2 Radius of curvature

4.2.1 General

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

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

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

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

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

Table 1 — Reproducibility values for different test methods

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

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

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

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

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

4.2.2 Optical spherometry (rigid contact lenses)

4.2.2.1 Principle

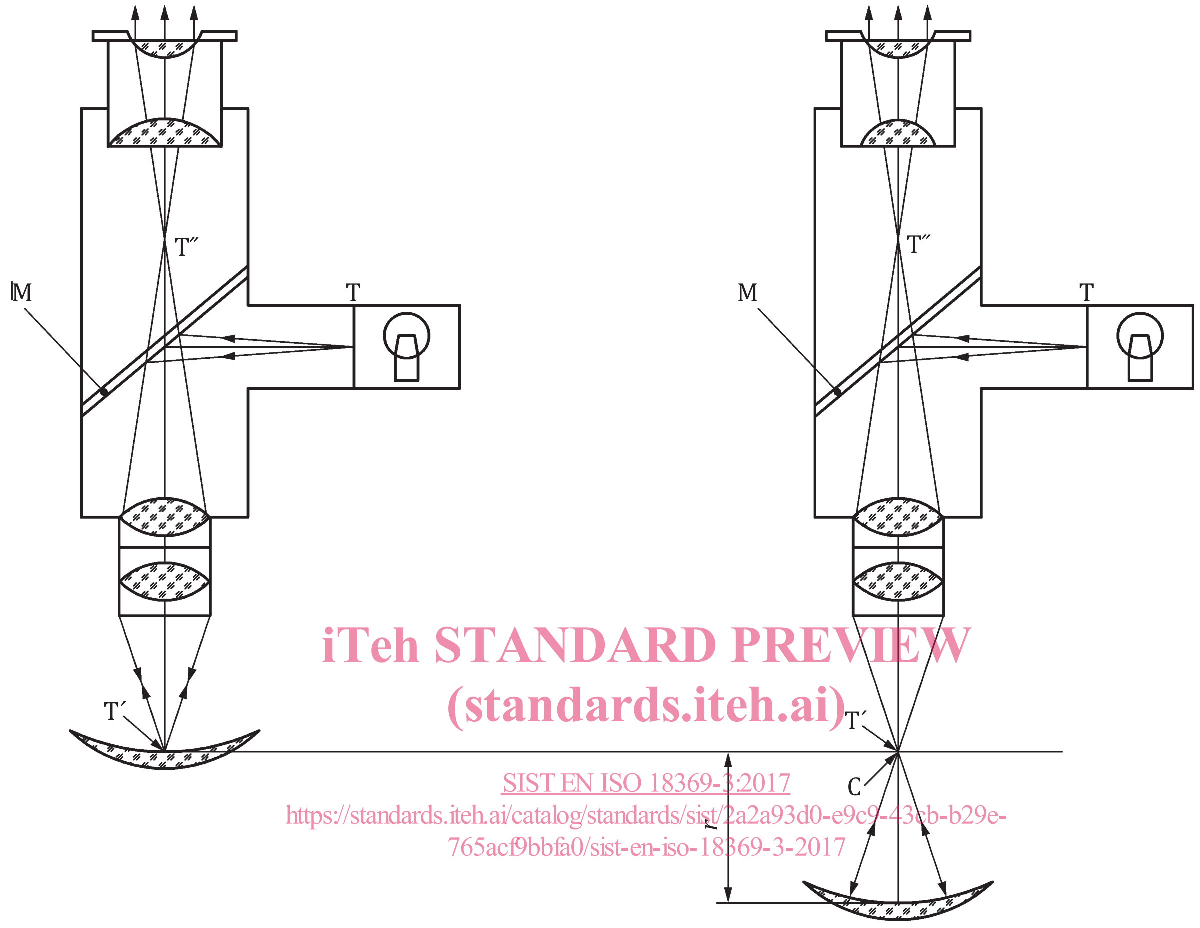
The microspherometer locates the surface vertex and the aerial image (centre of curvature) with the Drysdale principle, as described below. The distance between these two points is the radius of curvature for a spherical surface and is known as the apical radius of curvature for an aspheric surface derived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

The optical microspherometer consists essentially of a microscope fitted with a vertical illuminator. See Figure 1. Light from the target, T, is reflected down the microscope tube by the semi-silvered mirror, M, and passes through the microscope objective to form an image of the target at T′. If the focus coincides with the lens surface, then light is reflected back along the diametrically opposite path to form images at T and T″. The image at T″coincides with the first principle focus of the eyepiece when a sharp image is seen by the observer [Figure 1 a)]. This is referred to as the “surface image”.

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

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

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



a) b)

Key

C centre of curvature of the surface to be measured

T target

T′ image of T at a self-conjugate point

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

M semi-silvered mirror

r radius of curvature of the surface

Figure 1 — Optical system of a microspherometer

4.2.2.2 Instrument specification

The optical microspherometer shall have an optical microscope fitted with a vertical illuminator and a target and have a fine focus adjustment. The adjustment control shall allow fine movement of the microscope or of its stage. The adjustment gauge shall have a linear scale.

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

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

The gauge mechanism should incorporate some means for eliminating backlash (retrace). If readings are taken in one direction, this source of error need not be considered.

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

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

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

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

4.2.2.3 Calibration

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

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

— Plate 1: 6,30 mm to 6,70 mm;

— Plate 2: 7,80 mm to 8,20 mm;

— Plate 3: 9,30 mm to 9,70 mm.

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

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

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

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

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

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

4.2.2.4 Measurement method

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

Mount the lens so that the optical axis of the microscope is normal to that part of the lens surface of which the radius is to be measured. Three independent measurements shall be made. Correct the