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Foreword

This document (EN ISO 18369-3:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

This document supersedes EN ISO 10338:1997, EN ISO 10344:1998, EN ISO 8599:1996, EN ISO 9337-1:2000, EN ISO 9337-2:2004, EN ISO 9338:1998, EN ISO 9339-1:1998, EN ISO 9339-2:1998, EN ISO 9339-2:1998.

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Endorsement notice

The text of ISO 18369-3:2006 has been approved by CEN as EN ISO 18369-3:2006 without any modifications.

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.

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

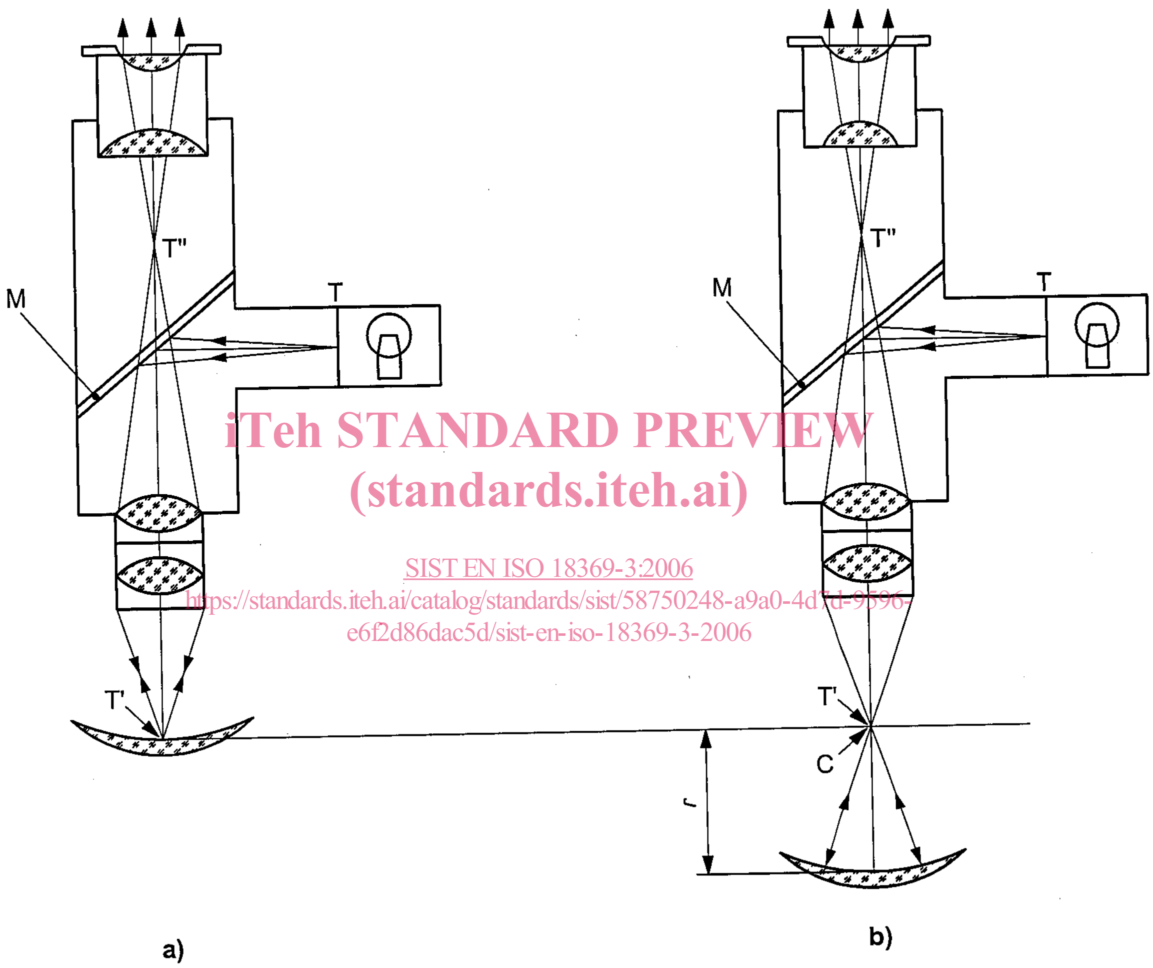
The microspherometer locates the surface vertex and the aerial image (centre of curvature) with the Drysdale principle, as described below. The distance between these two points is the radius of curvature for a spherical surface, and is known as the apical radius of curvature for an aspheric surface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