Ophthalmic optics - Contact lenses - Part 3: Measurement methods (ISO 18369-3:2017, Corrected version 2017-10-01)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18369-3:2017 sisaldab Euroopa standardi EN ISO 18369-3:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18369-3:2017 consists of the English text of the European standard EN ISO 18369-3:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.09.2017.	Date of Availability of the European standard is 20.09.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 18369-3

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English Version

Ophthalmic optics - Contact lenses - Part 3: Measurement methods (ISO 18369-3:2017, Corrected version 2017-10-01)

Optique ophtalmique - Lentilles de contact - Partie 3: Méthodes de mesure (ISO 18369-3:2017, Version corrigée 2017-10-01)

Augenoptik - Kontaktlinsen - Teil 3: Messverfahren (ISO 18369-3:2017, korrigierte Fassung 2017-10-01)

This European Standard was approved by CEN on 1 July 2017.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.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.

This document supersedes EN ISO 18369-3:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 18369-3:2017, Corrected version 2017-10-01 has been approved by CEN as EN ISO 18369-3:2017 without any modification.

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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.

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 “⌀”.

—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 ≤30 % of the allowed tolerance range[8].