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Ophthalmic optics — Contact lenses —

Part 1: Vocabulary, classification system and recommendations for labelling specifications

Optique ophtalmique — Lentilles de contact —

Partie 1: Vocabulaire, système de classification et recommandations pour l'étiquetage des spécifications

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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).

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).

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 18369-1:2006), which has been technically revised. It also incorporates the Amendment ISO 18369-1:2006/Amd 1:2009.

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

This corrected version of ISO 18369-1:2017 incorporates the following corrections.

—"optic axis" has been replaced by "optical axis" in two instances.

—"saline" has been replaced by "saline solution" throughout the text.

—"lens" has been replaced by "contact lens" wherever applicable.

—In Clause 3, cross-references of the terms have been corrected.

—In 3.1.2.1.31, "back central optic radius" has been replaced by "back central optic zone radius".

—In 3.1.2.3, NOTE 3, "See Figure 2" has been replaced by "See Figure 1".

—In 3.1.2.4.1, "geometrical centre" has been replaced by "geometric centre".

—In 3.1.2.4.4, h, "lens geometric centre" has been replaced by "geometric centre", and "exposed sample area" has been replaced by "contact lens".

—In 3.1.2.4.4, t_{HM}, "test sample" has been replaced by "contact lens".

—In 3.1.2.4.4, "t_0 to $_h$" has been replaced by "t_0 to t_h", and "exposed sample area" has been replaced by "contact lens".

—In 3.1.5.14, "space between the back of the contact lens (3.1.1.1)" has been replaced by "space between the back surface of the scleral contact lens (3.1.1.3)".

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—In 3.1.6.13, the SOURCE has been changed to read “[SOURCE: ISO 13666:2012, 15.2, modified — “by the material” has been replaced with “by the contact lens (3.1.1.1)”, and Note 1 to entry has been added.]”.

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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 document covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape. Soft contact lenses are easily deformable and require support for proper shape.

Clause 3 contains the terms and definitions primarily used in the contact lens field. A list of terms having special symbols is given in Table 1.

The list of terms and definitions does not include all ISO terms, definitions, and symbols used in the contact lens field. It is intended to be a convenient reference source from which the contents have been compiled from the text of this and other ISO standards applicable to the manufacture, evaluation, measurement, labelling and marketing of contact lenses and contact lens care products. An alphabetical index was added for rapid finding of terms.

Words are grouped under several topics by reference number according to the general category into which each word logically fits. The preferred form of each term is listed on the first line after its reference number. Other admitted forms have been placed on subsequent lines after the preferred form. All admitted terms are given in bold-faced type. A few obsolete and superseded terms are listed for historical reference and convenience and to aid comprehension but are indicated as deprecated and are no longer to be used. Obsolete and superseded terms are not in bold-faced type so that they may be clearly identified as terms used historically.

Contact lenses are primarily used for the correction of refractive errors but they can also be used for therapeutic purposes and cosmetic reasons. The materials used are divided into two main categories, rigid and soft. The former is composed mainly of corneal lenses and to a lesser extent, scleral lenses. Both types can be made from gas-permeable materials or non-gas permeable materials. Soft lenses are manufactured primarily from hydrogel materials. A small number of lenses incorporate both a rigid material and a soft material.

In terms of vision correction, contact lenses can be made as single-vision, bifocal, multifocal or progressive lenses. Surface designs can be spherical, aspheric, toric or “complex”.

Wearing modality can be daily wear, flexible wear, or extended wear. Typical replacement schedules for soft lenses are daily, two weekly, or monthly. Rigid lenses and some soft lenses are replaced less often, for example, once a year.

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Ophthalmic optics — Contact lenses —

Part 1: Vocabulary, classification system and recommendations for labelling specifications

1 Scope

This document identifies and defines the terms applicable to the physical, chemical and optical properties of contact lenses, their manufacture and uses. It provides a vocabulary of terms and, when appropriate, the international symbol and abbreviation associated with a specific term. This document also defines the terms relating to contact lens care products. It also incorporates the classifications of contact lens materials and gives recommendations for the labelling of the specifications of contact lenses.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and symbols

For the purposes of this document, the following terms and definitions 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

3.1 Terms and definitions

3.1.1 Basic terms

3.1.1.1
contact lens
ophthalmic lens designed to be worn on the front surface of the eye

Note 1 to entry: This term includes contact lenses of plano power.

3.1.1.2
corneal contact lens
intralimbal contact lens
contact lens (3.1.1.1) having a *total diameter* (3.1.2.3.1) less than the visible iris diameter and designed to be worn in its entirety on the cornea

3.1.1.3
scleral contact lens
contact lens (3.1.1.1) whose *scleral zone* (3.1.5.12) is supported on the bulbar conjunctiva and whose *optic zone* (3.1.2.1.17) vaults over the cornea

Note 1 to entry: In some cases, the *back optic zone* (3.1.2.2.1) will have minimal corneal touch.

Note 2 to entry: Terms such as mini-scleral, semi-scleral and corneo-scleral can be found in the contact lens literature to describe lenses of different parameters.

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