INTERNATIONAL STANDARD

ISO 18369-1

Second edition
2017-08

Corrected version
2017-10

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

Reference number
ISO 18369-1:2017(E)

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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)”.

— 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.]".

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.

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.

Note 3 to entry: See 3.1.5 for specific terms concerning scleral contact lenses.

3.1.1.4
lenticular contact lens
contact lens (3.1.1.1) having a front *optic zone* (3.1.2.1.17) made smaller than the *total diameter* (3.1.2.3.1)

Note 1 to entry: This construction is conventionally used to reduce the *centre thickness* (3.1.2.4.1) of a *positive power contact lens* (3.1.2.1.13) or reduce the edge thickness of a *negative power contact lens* (3.1.2.1.14).

3.1.1.5
contact shell
contact lens (3.1.1.1) not designed to correct vision

3.1.1.6
scleral shell
rigid *contact shell* (3.1.1.5) with a *scleral zone* (3.1.5.12)

Note 1 to entry: See 3.1.5 for specific terms concerning scleral shells.

3.1.1.7
rigid contact lens
contact lens (3.1.1.1) which, in its final state and under normal conditions, retains its form without support and has a *water content* (3.1.6.11) less than 10 %

Note 1 to entry: Rigid contact lenses are made of non-hydrogel rigid materials which can flex slightly but do not substantially conform to the shape of the cornea when on the eye.

3.1.1.8
rigid gas-permeable contact lens
RGP contact lens
DEPRECATED: hard gas-permeable contact lens
contact lens (3.1.1.1) manufactured from a rigid material containing one or more gas-permeable polymers in sufficient concentrations to facilitate transport of oxygen through the lens and having a *Dk* equal to or greater than 10 *Dk* units

Note 1 to entry: For an explanation of the meaning of *Dk* and *Dk* units, see 3.1.6.8.

3.1.1.9
soft contact lens
contact lens (3.1.1.1) made of a hydrogel material or non-hydrogel material which, in its hydrated final state and under normal conditions, contains a known *water content* (3.1.6.11), is easily deformable and may not retain its form without support

3.1.1.10
hydrogel contact lens
DEPRECATED: hydrophilic contact lens
contact lens (3.1.1.1) made of water-absorbing material having equilibrium *water content* (3.1.6.11) greater than or equal to 10 % in standard saline solution as specified in ISO 18369–3 at 20 °C

3.1.1.11
composite contact lens
contact lens (3.1.1.1) composed of two or more different materials

EXAMPLE Laminated lens, fused segment lens, lens with a rigid centre and a flexible periphery.

3.1.1.12
surface-treated contact lens
contact lens (3.1.1.1) whose surfaces have been modified to make the surface characteristics different to those of the bulk material

3.1.1.13
bifocal contact lens
multifocal contact lens (3.1.1.14) having two *optic zones* (3.1.2.1.17), usually for distance and near-vision correction

Note 1 to entry: See 3.1.4 for specific terms concerning bifocal contact lenses.

3.1.1.14
multifocal contact lens
contact lens (3.1.1.1) designed to provide two or more zones of different corrective powers

Note 1 to entry: See 3.1.4 for specific terms concerning multifocal contact lenses.

3.1.1.15
progressive power contact lens
varifocal power contact lens
contact lens (3.1.1.1) designed to provide correction for more than one viewing range in which the power changes continuously, rather than discretely, over a part or the whole of the lens

Note 1 to entry: See 3.1.4 for specific terms concerning progressive power contact lenses.

3.1.1.16
spherical aberration
attribute of an optical system due to variation in the focusing between peripheral and paraxial rays

3.1.1.17
contact lens accessory

article intended specifically by its manufacturer to be used with a *contact lens* (3.1.1.1) to enable the contact lens to be used in accordance with its *intended purpose* (3.1.9.1)

Note 1 to entry: This term includes all devices to clean, handle, store or manipulate lenses for intended use.

Note 2 to entry: This definition does not include the *primary packaging* (3.1.9.7), e.g. vials, *blister packs* (3.1.9.5) or mailers, intended by the manufacturer to be used only for shipment of the contact lenses.

3.1.1.18
contact lens care product
contact lens accessory (3.1.1.17) intended for use in maintaining the safety and *performance* (3.1.9.2) of a *contact lens* (3.1.1.1) after opening and removal of the contact lens from its *primary container* (3.1.9.7)

Note 1 to entry: See 3.1.9 and 3.1.11 for specific terms concerning contact lens care products and the hygienic management of contact lenses.

3.1.1.19
suction cup
handheld device designed with a small concave flexible tip intended to aid the insertion of a *contact lens* (3.1.1.1) onto or removal from the eye by means of suction

Note 1 to entry: A suction cup is designed primarily for use with rigid *corneal contact lenses* (3.1.1.2) and *scleral contact lenses* (3.1.1.3).

3.1.1.20
contact lens container
storage container
contact lens case
storage case
device in which *contact lenses* (3.1.1.1) are stored either dry (rigid corneal and scleral lenses), or in a suitable solution (rigid gas permeable lenses, hydrogel and other soft lenses), by the user after removal from the *primary container* (3.1.9.7) or the eye

3.1.1.21
equilibration
conditioning of a lens or lens material in a test solution at a specified temperature until the parameters of the lens or material remain stable

Note 1 to entry: Lenses are equilibrated by soaking in an appropriate volume of solution for sufficient time that the parameters to be measured remain constant on repeated measures within the capability of the method to measure the parameter.

Note 2 to entry: The key solution parameters, e.g. pH and *osmolality* (3.1.6.5), are included in the test report.

Note 3 to entry: The equilibration conditions will be determined by the test laboratory.

3.1.2 Terms related to contact lens parameters and design

3.1.2.1 General terms

3.1.2.1.1
dioptre
D
unit of measure of the refractive power of a lens

Note 1 to entry: The power of a lens is equal to the reciprocal of a lens' focal length measured in metres.

Note 2 to entry: The symbol D is the preferred unit of measure abbreviation over the symbol m^{-1}, as D is an established international abbreviation.

3.1.2.1.2
front vertex
point on the anterior contact lens surface which lies also on the optical axis of the central *optic zone* (3.1.2.1.17)

3.1.2.1.3
paraxial front vertex power
F_V
reciprocal of the paraxial front vertex focal length

Note 1 to entry: See ISO 13666.

Note 2 to entry: The front vertex power is expressed in *dioptres* (3.1.2.1.1). This theoretical value is often used during a design process. Paraxial powers are used in ray-tracing through an optical system and are limited to very small ray angles and heights.

3.1.2.1.4
paraxial back vertex power
F'_V
reciprocal of the paraxial back vertex focal length

Note 1 to entry: See ISO 13666.

Note 2 to entry: The back vertex power is expressed in *dioptres* (3.1.2.1.1). This theoretical value is often used during the design process. Paraxial powers are used in ray-tracing through an optical system and are limited to very small ray angles and heights.

3.1.2.1.5
label front vertex power
F_L
reciprocal of the front vertex focal length over the *optic zone* (3.1.2.1.17) in air, expressed in *dioptres* (3.1.2.1.1)

Note 1 to entry: The front vertex focal length is the distance from the front vertex to the optimal focus over the optic zone, when measured as specified in ISO 18369–3:2017, 4.3.

Note 2 to entry: The measurement of front vertex focal length will be affected by *spherical aberration* (3.1.1.16).

3.1.2.1.6
label back vertex power
F'_L
reciprocal of the back vertex focal length over the *optic zone* (3.1.2.1.17) in air, expressed in *dioptres* (3.1.2.1.1)

Note 1 to entry: The back vertex focal length is the distance from the back vertex to the optimal focus over the optic zone, when measured as specified in ISO 18369–3:2017, 4.3.

Note 2 to entry: The measurement of back vertex focal length will be affected by *spherical aberration* (3.1.1.16).

3.1.2.1.7
cylinder power
F'_C
difference in back vertex power between the two principal meridians of maximum and minimum radii of curvature of a lens measured in air, expressed in *dioptres* (3.1.2.1.1)

3.1.2.1.8
cylinder axis
meridian 90° to the meridian of maximum *cylinder power* (3.1.2.1.7)

Note 1 to entry: This axis is defined by the angle, in degrees, between the horizontal plane and the cylinder axis.

3.1.2.1.9
prismatic error
unintended optical prism in a *contact lens* (3.1.1.1), expressed in *prism dioptres* (3.1.12.10)

3.1.2.1.10
power profile
localized optical power as a function of radial distance from the centre of the lens

3.1.2.1.11
prescribed optical prism
intended optical prism within a *contact lens* (3.1.1.1), expressed in *prism dioptres* (3.1.12.10)

3.1.2.1.12
prism axis
defined by the angle, in degrees, between the horizontal plane and the base of the prism

3.1.2.1.13
positive power contact lens
plus-power contact lens
contact lens (3.1.1.1) which causes parallel incident light, incident on a single *optic zone* (3.1.2.1.17), to converge to a real focus

Note 1 to entry: Positive power contact lenses are typically used for hyperopic patients.

3.1.2.1.14
negative power contact lens
minus-power contact lens
contact lens (3.1.1.1) which causes parallel light, incident on a single *optic zone* (3.1.2.1.17), to diverge from a virtual focus

Note 1 to entry: Negative power contact lenses are typically used for myopic patients.

3.1.2.1.15
plano contact lens
afocal contact lens
contact lens (3.1.1.1) whose back vertex power is zero

3.1.2.1.16
liquid lens
fluid lens
tear lens
lacrimal lens
refractive element formed by the liquid between the *back optic zone* (3.1.2.2.1) of the *contact lens* (3.1.1.1) and the cornea

3.1.2.1.17
optic zone
area of a *contact lens* (3.1.1.1) which has a prescribed optical effect

Note 1 to entry: The prescribed optical effect is contributed jointly by the central anterior and posterior surface curvatures of the contact lens.

Note 2 to entry: The term may be qualified by either the prefix "back" or "front" in the case of a surface with a single optical component. In the case of an *alternating image bifocal contact lens* (3.1.4.15), the term may be qualified by either the prefix "distance" or "near". In the case of a *concentric multifocal contact lens* (3.1.4.4), the term may be qualified by the prefix "central" or "peripheral".

Note 3 to entry: The term may be qualified by the prefix "central" or "peripheral".

3.1.2.1.18
peripheral zone
region of specified dimensions surrounding the *optic zone(s)* (3.1.2.1.17) but with no prescribed refractive effect

Note 1 to entry: There can be more than one peripheral zone.

3.1.2.1.19
displacement of optic
d
decentration of the *optic zone* (3.1.2.1.17) relative to the contact lens *edge* (3.1.2.1.34)

Note 1 to entry: See 3.1.5 for application to *scleral contact lenses* (3.1.1.3).

3.1.2.1.20
geometric centre
C
centre of the circle containing the contact lens *edge* (3.1.2.1.34)

Note 1 to entry: For a *scleral contact lens* (3.1.1.3), the geometric centre is taken as the centre of the *optic zone* (3.1.2.1.17). For a truncated contact lens, the geometric centre is taken as the centre of the circle that contains the circular portion of the edge.

3.1.2.1.21
conic section
one of a group of plane geometric curves at the intersection of a plane with a cone

Note 1 to entry: Conic sections have eccentricities (*e*) ranging from zero to positive infinity. The group includes the following two-dimensional curves: circle, *ellipse* (3.1.2.1.26), parabola, and *hyperbola* (3.1.2.1.27).

3.1.2.1.22
conoidal surface
surface described by rotating a *conic section* (3.1.2.1.21) about its axis

Note 1 to entry: These surfaces include spheres, ellipsoids, paraboloids and hyperboloids.

Note 2 to entry: The term "conoidal" in the contact lens field usually refers to surfaces that are not spherical.

3.1.2.1.23
eccentricity
e
value descriptive of a *conic section* (3.1.2.1.21) and the rate of curvature change away from the apex of the curve

Note 1 to entry: Circle ($e = 0$), *ellipse* (3.1.2.1.26) ($0 < e < 1$), parabola ($e = 1$) and *hyperbola* (3.1.2.1.27) ($e > 1$). In order to signify use of an *oblate* (3.1.2.1.24) curve of the ellipse, *e* is sometimes given a negative sign that is not used in contact lens computations. Otherwise, use of the *prolate* (3.1.2.1.25) curve of the ellipse is assumed.

3.1.2.1.24
oblate
<surface or curve> becoming progressively steeper away from the apex

Note 1 to entry: Oblate is the opposite of *prolate* (3.1.2.1.25).

3.1.2.1.25
prolate
<surface or curve> becoming progressively flatter away from the apex

Note 1 to entry: Prolate is the opposite of *oblate* (3.1.2.1.24).

3.1.2.1.26
ellipse
locus of points in a plane whose combined distance from two fixed points (the two foci) in the plane is constant

Note 1 to entry: This is a *conic section* (3.1.2.1.21) having an *eccentricity* (3.1.2.1.23) greater than zero and less than one ($0 < e < 1$), formed by sectioning a cone with a plane in such a way that the angle of the plane with respect to the cone's base is less than the angle of the cone's side with respect to the base. Each ellipse has a *prolate* (3.1.2.1.25) curve and an *oblate* (3.1.2.1.24) curve. Use of the prolate curve is assumed unless otherwise indicated. Although *e* is the same for both prolate and oblate curves, *e* is sometimes given a minus sign not used in contact lens computations in order to signify use of the oblate elliptical curve.

3.1.2.1.27
hyperbola
locus of points in a plane whose distance from a fixed point in the plane (the focus) divided by its distance from a fixed line in the plane (the directrix) is a positive constant greater than one

Note 1 to entry: This is a *conic section* (3.1.2.1.21) having an *eccentricity* (3.1.2.1.23) greater than one ($e > 1$), formed by sectioning a cone with a plane in such a way that the angle of the plane with respect to the cone's base is greater than the angle of the cone's side with respect to the base. Hyperbolas are *prolate* (3.1.2.1.25) curves.

3.1.2.1.28
optical decentration
positioning of the optical centre at a point other than the *geometric centre* (3.1.2.1.20) of the *optic zone* (3.1.2.1.17) or *central optic zone* (3.1.4.5)

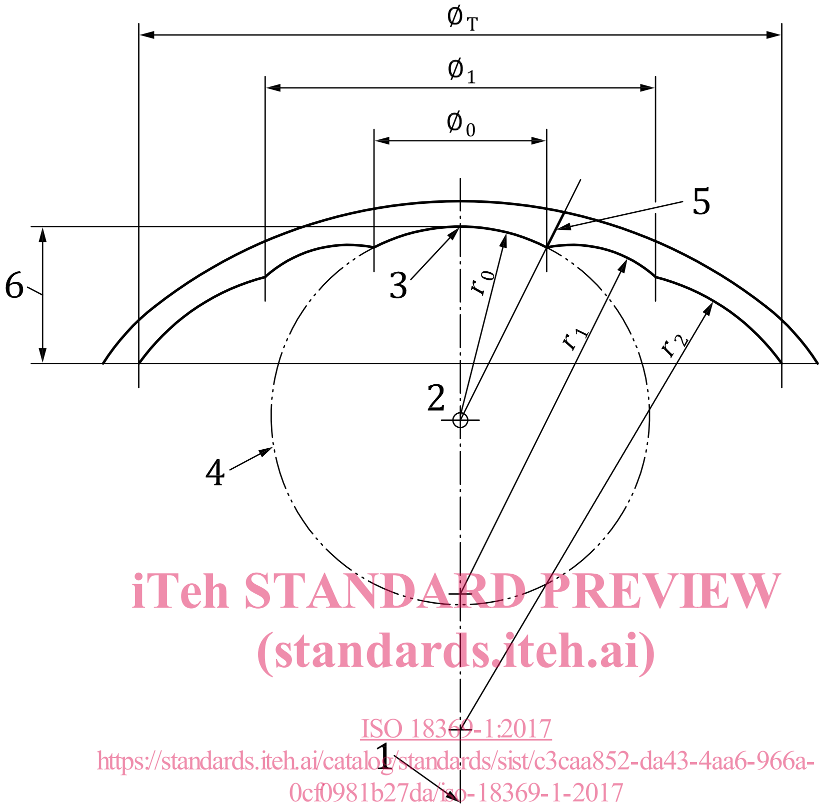
3.1.2.1.29
contact lens axis
line passing through the geometric centre, perpendicular to a plane containing the *edge* (3.1.2.1.34) of a *contact lens* (3.1.1.1)

Note 1 to entry: See Figure 1.

3.1.2.1.30
back vertex
point on the posterior contact lens surface which also lies on the optical axis of the central *optic zone* (3.1.2.1.17)

3.1.2.1.31
vertex sphere
imaginary *spherical surface* (3.1.2.1.41) touching the *back vertex* (3.1.2.1.30)

Note 1 to entry: The radius of curvature of the vertex sphere is the same as the steepest back optic zone radius, back central optic zone radius, or back vertex radius of an aspheric lens (see Figure 1).



Key

1 contact lens axis
2 centre of vertex sphere
3 back vertex
4 vertex sphere
5 peripheral junction thickness, t_{PJ0}
6 overall posterior sagitta

Figure 1 — Schematic representation of a tri-curve contact lens including symbols of the main parameters describing its back surface

3.1.2.1.32
sagitta
sagittal depth
sagittal height
maximum distance from a chord which is perpendicular to the axis of rotation of a surface, to the curved surface

3.1.2.1.33
overall posterior sagitta
distance along the *contact lens axis* (3.1.2.1.29) from the *back vertex* (3.1.2.1.30) to a plane containing the contact lens *edge* (3.1.2.1.34)

3.1.2.1.34
edge
most peripheral part of a *contact lens* (3.1.1.1) which is contiguous with the front and back surfaces

3.1.2.1.35
edge form
edge profile
shape of the *edge* (3.1.2.1.34) in a plane containing the *contact lens axis* (3.1.2.1.29)

3.1.2.1.36
bevel
narrow front or back *peripheral zone* (3.1.2.1.18), of a single spherical or aspherical curvature, adjacent to the *edge* (3.1.2.1.34) of a *contact lens* (3.1.1.1)

3.1.2.1.37
radial lift
l_R
distance between a specified point on the back surface of a *contact lens* (3.1.1.1) and the *vertex sphere* (3.1.2.1.31) measured along a radius of curvature of the vertex sphere

Note 1 to entry: See Figure 2 a).

3.1.2.1.38
radial edge lift
l_{ER}
distance between a point on the back surface of a *contact lens* (3.1.1.1) at the *edge* (3.1.2.1.34) and the *vertex sphere* (3.1.2.1.31) measured along the radius of curvature of the latter

Note 1 to entry: See Figure 2 b).

Note 2 to entry: This is often a value computed by the manufacturer and can be altered by the edging process.

3.1.2.1.39
axial lift
l_A

distance between a specified point on the back surface of a *contact lens* (3.1.1.1) and the *vertex sphere* (3.1.2.1.31) measured parallel to the *contact lens axis* (3.1.2.1.29)

Note 1 to entry: See Figure 2 a).

3.1.2.1.40
axial edge lift
l_{EA}
distance between a point on the back surface of a *contact lens* (3.1.1.1) at the *edge* (3.1.2.1.34) and the *vertex sphere* (3.1.2.1.31), measured parallel to the *contact lens axis* (3.1.2.1.29)

Note 1 to entry: See Figure 2 b).

Note 2 to entry: This is often a value computed by the manufacturer and can be altered by the edging process.