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ISO 18369-1

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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

Reference number
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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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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.

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 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: Note1 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

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* (3.1.2.1.34) 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 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 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 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* (3.1.1.1) surface which lies also on the optic axis of the *central optic zone* (3.1.4.5)

3.1.2.1.3
paraxial front vertex power
F_V
reciprocal of the paraxial *front vertex* (3.1.2.1.2) 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* (3.1.2.1.30) 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* (3.1.2.1.2) 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* (3.1.2.1.30) 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* (3.1.2.1.30) 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* (3.1.2.1.30) 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 translating *bifocal contact lens* (3.1.1.13), 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 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* (3.1.1.1) *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* (3.1.1.1) 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* (3.1.1.1) 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)

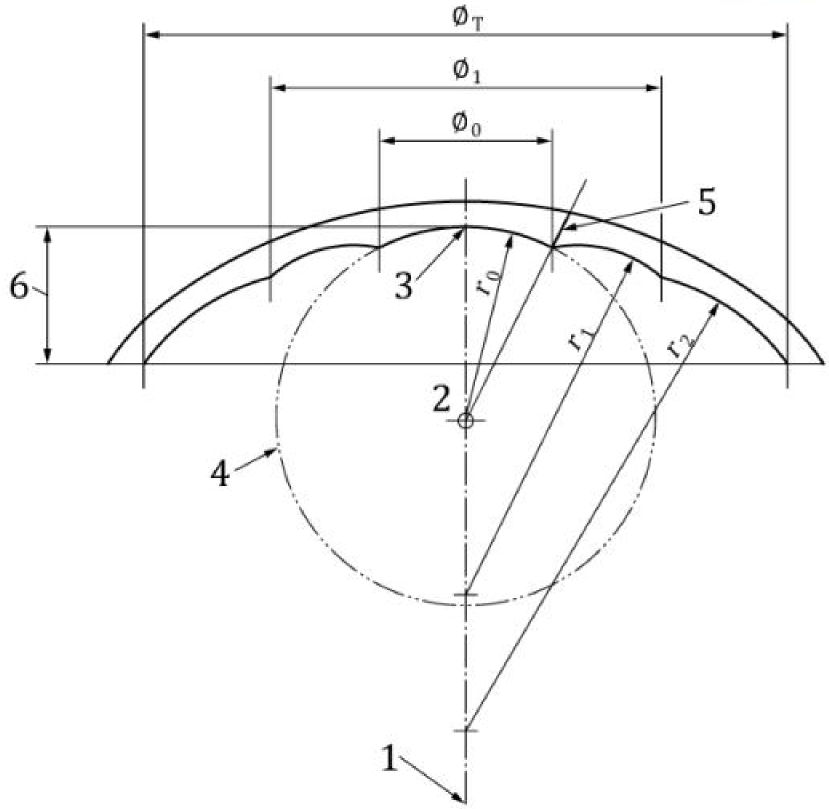
3.1.2.1.29
contact lens axis
line passing through the geometric centre, perpendicular to a plane containing the *edge* (3.1.2.1.34) of a *contact lens* (3.1.1.1)

Note 1 to entry: See Figure 1.

3.1.2.1.30
back vertex
point on the posterior *contact lens* (3.1.1.1) surface which also lies on the optic axis of the *central optic zone* (3.1.4.5)

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* (3.1.2.2.3), back central optic 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* (3.1.1.1) *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.

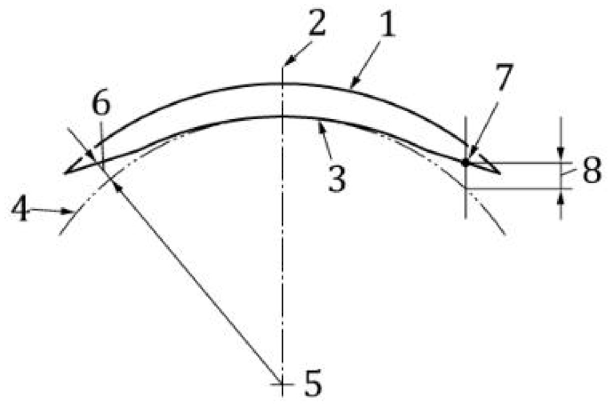
3.1.2.1.39
axial lift
l_{A}
distance between a specified point on the back surface and the vertex sphere measured parallel to the *contact lens axis* (3.1.2.1.29)

Note 1 to entry: See Figure 2 a).

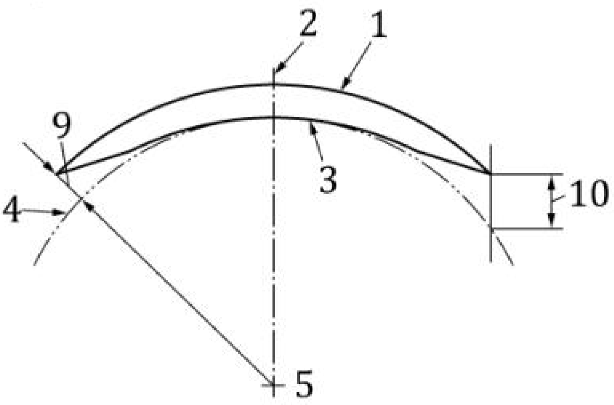
3.1.2.1.40
axial edge lift
l_{EA}
distance between a point on the back of a *contact lens* (3.1.1.1) at the *edge* (3.1.2.1.34) and the vertex sphere, measured parallel to the *contact lens axis* (3.1.2.1.29)

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.



a) Difference between radial and axial lift



b) Difference between radial and axial edge lift

Key

1 contact lens front surface

2 lens axis

3 contact lens back surface

4 vertex sphere

5 centre of vertex sphere

6 radial lift, l_R

7 specified point (see NOTE)

8 axial lift, l_A

9 radial edge lift, l_{ER}

10 axial edge lift, l_{EA}

NOTE The specified point's position on the lens back surface is measured at right angles to the lens axis from the extreme edge of the lens (for radial edge lift) or from the lens centre (for radial lift).

Figure 2 — Difference between lift and edge lift

3.1.2.1.41

spherical surface

surface having the same radius of curvature for meridians in all directions

Note 1 to entry: Surfaces which are not spherical would normally be termed aspheric or toroidal.

3.1.2.1.42

sagittal radius of curvature

radius of curvature in the sagittal plane at a specified off-axis point on the surface

Note 1 to entry: The radius at a specified point on the surface is equal to the distance along the normal at that point to its intersection with the axis of rotation.

Note 2 to entry: The sagittal plane is perpendicular to the tangential plane.

3.1.2.1.43
tangential radius of curvature
radius of curvature in the tangential plane at a specified off-axis point on a surface

Note 1 to entry: The tangential plane contains both the off-axis point and the optical axis.

3.1.2.1.44
bi-curve contact lens
contact lens (3.1.1.1) whose back surface is composed of two intersecting spherical zones

3.1.2.1.45
tri-curve contact lens
contact lens (3.1.1.1) whose back surface is composed of three intersecting coaxial spherical zones

Note 1 to entry: See Figure 1.

3.1.2.1.46
multi-curve contact lens
contact lens (3.1.1.1) with a back surface that is composed of more than three intersecting spherical zones

3.1.2.1.47
aspheric contact lens
contact lens (3.1.1.1) with its front or *back optic zone* (3.1.2.2.1) of aspheric form

Note 1 to entry: See 3.1.3 for specific terms concerning aspheric contact lenses.

3.1.2.1.48
toric contact lens
contact lens (3.1.1.1) with front and/or *back optic zone* (3.1.2.2.1) of toroidal form

3.1.2.1.49
bi-toric contact lens
contact lens (3.1.1.1) having both front and *back optic zones* (3.1.2.2.1) of toroidal form

3.1.2.1.50
toroidal zone
zone having a surface with its maximum and minimum radii of curvature perpendicular to each other

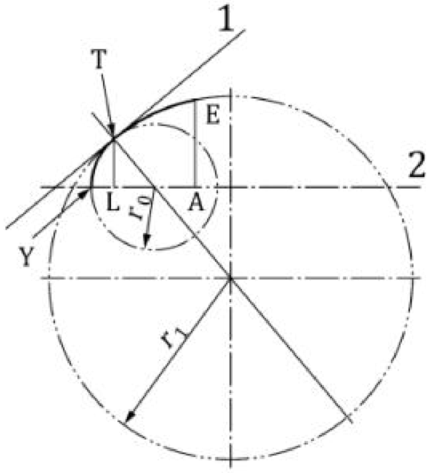
3.1.2.1.51
toric periphery contact lens
contact lens (3.1.1.1) with one or more back *peripheral zones* (3.1.2.1.18) of toroidal form that surround a spherical *back optic zone* (3.1.2.2.1)

3.1.2.1.52
junction
intersection of two adjacent zones

Note 1 to entry: This applies to both back and front surfaces.

3.1.2.1.53
tangential junction
junction (3.1.2.1.52) where the curvatures of adjacent zones have a common tangent

Note 1 to entry: See Figure 3.



Key

1 tangent common to both circles

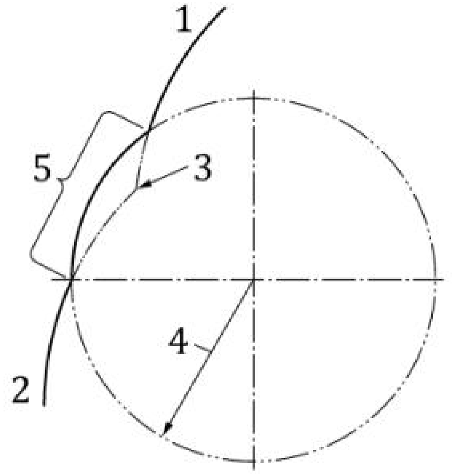
2 contact lens axis

NOTE This is an example of a back surface of a contact lens. It is a bi-curve surface with a tangential junction, T. The back peripheral zone would be formed by rotating the arc TE around the lens axis; the back optic zone is formed by rotating the arc YT around the lens axis. The back optic zone diameter is 2 LT; the total diameter is 2 EA; the overall posterior sagitta is YA.

Figure 3 — Example of a tangential junction

3.1.2.1.54
transition
transition zone
junction (3.1.2.1.52) which has been modified to smooth the change between adjacent curvatures

Note 1 to entry: See Figure 4.



Key

1 zone A

2 zone B

3 original junction of zone A and zone B

4 radius of curvature of the transition

5 transition

Figure 4 — Example of a transition on the back surface of a contact lens

3.1.2.1.55
blend
polished, smoothed *junction* (3.1.2.1.52) or *transition zone* (3.1.2.1.54) between two different adjacent surface curvatures

Note 1 to entry: This typically applies to the junction (transition) between posterior zones.

Note 2 to entry: This does not constitute the formation of an *aspheric zone* (3.1.3.1).

3.1.2.1.56
ballast
rotationally asymmetrical distribution of thickness for the purpose of effecting rotational orientation of a *contact lens* (3.1.1.1) on the eye

Note 1 to entry: The most common method of achieving ballast in contact lenses is with the use of base-down vertical prism.

3.1.2.1.57
prism ballast
vertical prism used to create a *wedge design* (3.1.2.1.58) that will help stabilize the rotation and orientation of a *contact lens* (3.1.1.1) on the eye

Note 1 to entry: A vertical prism can also be used to correct a vertical hyperphoria or hypertropia.

Note 2 to entry: The asymmetrical distribution of thickness, rather than the effect of mass, is responsible for the rotational orientation of the contact lens that incorporates prism.

3.1.2.1.58
wedge design
rotationally asymmetric distribution of thickness to effect the required rotational orientation of a *contact lens* (3.1.1.1) on the eye, or to improve the centration of a high-riding lens

Note 1 to entry: One common way of creating a wedge design is to incorporate base-down vertical prism into a contact lens.

3.1.2.1.59
peripheral thinning
slab-off
thinning, towards the *edge* (3.1.2.1.34), of the front periphery of the *contact lens* (3.1.1.1), in one or more discrete areas

Note 1 to entry: This is normally applied to achieve contact lens rotational stabilization. It is different from both *ballast* (3.1.2.1.56) and a *lenticular contact lens* (3.1.1.4) construction.

3.1.2.1.60
truncation
inferior *edge* (3.1.2.1.34) of a *contact lens* (3.1.1.1) that has a straight line or near straight line

Note 1 to entry: See Figure 8.

Note 2 to entry: This construction is typically used in toric and multifocal contact lenses.

3.1.2.1.61
fenestration
specified hole which passes through a *contact lens* (3.1.1.1)

3.1.2.1.62
carrier
part of a plus or minus *lenticular contact lens* (3.1.1.4) peripheral to the front *optic zone(s)* (3.1.2.1.17)

Note 1 to entry: The carrier can be negative, positive or parallel in construction, but it is radially symmetrical.

Note 2 to entry: In Figure 5, the carriers are represented with flat surfaces for clarity, but in reality, they are composed of curved surfaces.

3.1.2.1.63
negative carrier
minus carrier
carrier (3.1.2.1.62) having an *edge* (3.1.2.1.34) thickness that is greater than the *junction* (3.1.2.1.52) thickness

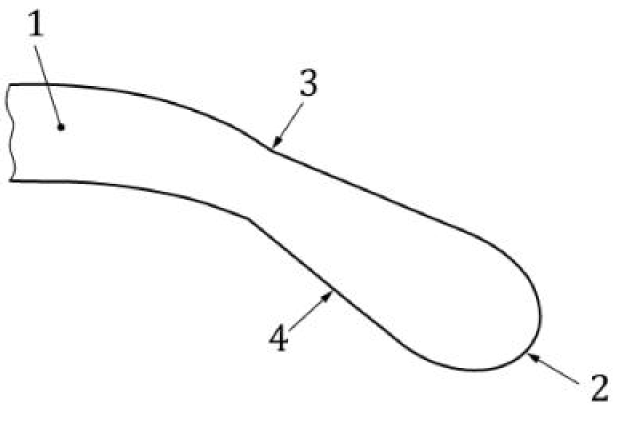
Note 1 to entry: See Figure 5 a).

3.1.2.1.64
parallel carrier
plano carrier
carrier (3.1.2.1.62) having an *edge* (3.1.2.1.34) thickness and *junction* (3.1.2.1.52) thickness that are equal

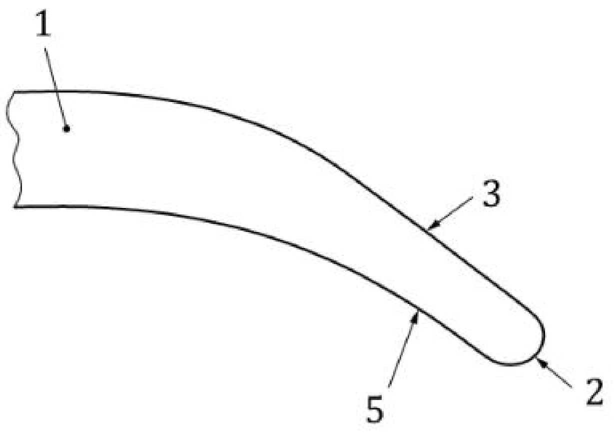
Note 1 to entry: See Figure 5 b).

3.1.2.1.65
positive carrier
plus carrier
carrier (3.1.2.1.62) having an *edge* (3.1.2.1.34) thickness that is less than the *junction* (3.1.2.1.52) thickness

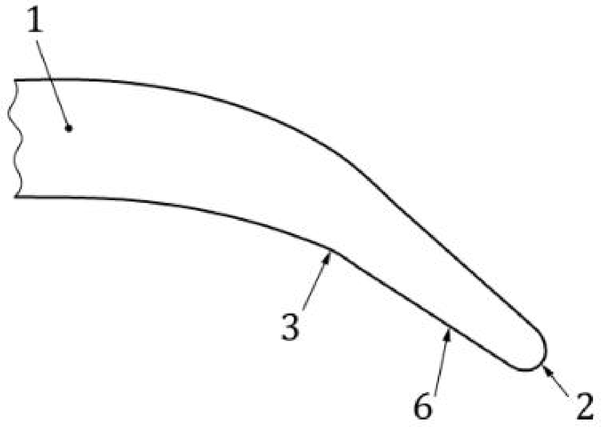
Note 1 to entry: See Figure 5 c).



a) Negative or minus carrier



b) Parallel or plano carrier



c) Positive or plus carrier

Key

1 optic zone
2 edge
3 junction
4 negative carrier
5 parallel carrier
6 positive carrier

NOTE Figures are not to scale.

Figure 5 — Examples of carriers

3.1.2.2 Terms related to the radius of curvature

NOTE 1 Radii relating to zones on the back surface of the lens are designated by a numerical subscript starting with zero (r_0). The subscript becomes numerically larger from the lens centre to the lens edge. See Figure 1.

NOTE 2 Radii relating to the front surface of the lens have a double subscript, the first part of which is the letter "a". The second part is a number from zero upward, for example, r_{a2}.

NOTE 3 In the case of an *aspheric zone* (3.1.3.1), a mathematical equation or expression can be used to describe the curvature of the zone.

3.1.2.2.1
back optic zone
posterior surface area of a single-vision *contact lens* (3.1.1.1) which contributes to the prescribed optical effect

Note 1 to entry: This area is sometimes called the back central optic zone of a concentric back surface *bifocal contact lens* (3.1.1.13) or *multifocal contact lens* (3.1.1.14), which has more than one *optic zone* (3.1.2.1.17).

3.1.2.2.2
equivalent posterior radius of curvature
EPC
base curve equivalent
BCE
spherical radius of curvature of a *contact lens* (3.1.1.1) computed from the *overall posterior sagitta* (3.1.2.1.33) of a contact lens

Note 1 to entry: The EPC would normally only apply to *soft contact lenses* (3.1.1.9).

3.1.2.2.3
back optic zone radius
base curve radius
r_0
radius of curvature of the *back optic zone* (3.1.2.2.1) of a surface with a single refractive element

Note 1 to entry: On a *toroidal zone* (3.1.2.1.50) there will be two radius values.

Note 2 to entry: The term "base curve" used in a *contact lens* (3.1.1.1) context is not to be confused with the same term when used in a spectacle lens context (see ISO 13666).

3.1.2.2.4
back central optic zone radius
r_0
radius of curvature of the back central optic zone of a *multifocal contact lens* (3.1.1.14)

Note 1 to entry: See Figure 1.

3.1.2.2.5
back peripheral optic zone radius
$r_1, r_2, \ldots$
radius of curvature of a back *peripheral optic zone* (3.1.4.6) of a *multifocal contact lens* (3.1.1.14)

Note 1 to entry: See Figure 1.

3.1.2.2.6
back peripheral radius
$r_1, r_2, \ldots$
radius of curvature of the back *peripheral zone* (3.1.2.1.18)

Note 1 to entry: This term may be preceded by first, second, third, etc.

Note 2 to entry: See Figure 1.

3.1.2.2.7
front optic zone radius
r_{a0}
radius of curvature of the front *optic zone* (3.1.2.1.17) of a surface with a single refractive element

3.1.2.2.8
front central optic zone radius
r_{a0}
radius of curvature of the front *central optic zone* (3.1.4.5) of a *multifocal contact lens* (3.1.1.14)

3.1.2.2.9
front peripheral optic zone radius
$r_{a1}, r_{a2}, \ldots$
radius of curvature of a front *peripheral optic zone* (3.1.4.6) of a *multifocal contact lens* (3.1.1.14)

3.1.2.2.10
front peripheral radius
$r_{a1}, r_{a2}, \ldots$
radius of curvature of a front *peripheral zone* (3.1.2.1.18)

Note 1 to entry: This term may be preceded by first, second, third, etc.

3.1.2.3 Terms related to diameter

NOTE 1 In cases of elliptical shapes, the maximum and minimum sizes are used for measurement purposes.

NOTE 2 Elliptical zones that are toroidal, or adjacent to a *toroidal zone* (3.1.2.1.50), have their diameter specified on the flattest meridian.

NOTE 3 In lenses with concentric posterior surface zones, the zones are qualified by a subscript number from zero starting with the innermost zone ($\varnothing_0$). See Figure 2. On the anterior surface the number is always preceded by the letter "a", for example ($\varnothing_{a0}$).

3.1.2.3.1
total diameter
overall diameter
$\varnothing_T$
maximum external dimension of the finished *contact lens* (3.1.1.1) or shell

3.1.2.3.2
optic zone diameter
maximum diameter of the specified *optic zone* (3.1.2.1.17)

Note 1 to entry: The optic zone of a *toric periphery contact lens* (3.1.2.1.51) is usually elliptical in shape.

3.1.2.3.3
back optic zone diameter
$\varnothing_0$
diameter of the *back optic zone* (3.1.2.2.1) on a surface with a single optical component

Note 1 to entry: On a *toroidal zone* (3.1.2.1.50), there will be two values.

3.1.2.3.4
back central optic zone diameter
$\varnothing_0$
diameter of the posterior central optic zone of a *concentric multifocal contact lens* (3.1.4.4)

3.1.2.3.5
back peripheral optic zone diameter
$\varnothing_1$, $\varnothing_2$, ...
diameter of a posterior peripheral optic zone of a *concentric multifocal contact lens* (3.1.4.4)

3.1.2.3.6
back peripheral zone diameter
$\varnothing_1$, $\varnothing_2$, ...
diameter of a back *peripheral zone* (3.1.2.1.18)

Note 1 to entry: This term may be preceded by first, second, third, etc.

3.1.2.3.7
front optic zone diameter
$\varnothing_{a0}$
diameter of the front *optic zone* (3.1.2.1.17) on a surface with a single refractive element

3.1.2.3.8
front central optic zone diameter
$\varnothing_{a0}$
diameter of the anterior *central optic zone* (3.1.4.5) of a *multifocal contact lens* (3.1.1.14)

3.1.2.3.9
front peripheral optic zone diameter
$\varnothing_{a1}$, $\varnothing_{a2}$, ...
diameter of an anterior *peripheral optic zone* (3.1.4.6) of a *multifocal contact lens* (3.1.1.14)

3.1.2.3.10
front peripheral zone diameter
$\varnothing_{a1}$, $\varnothing_{a2}$, ...
diameter of a front *peripheral zone* (3.1.2.1.18)

Note 1 to entry: This term may be preceded by first, second, third, etc.

Note 2 to entry: In cases of elliptical shapes, the maximum and minimum sizes are used for measurement purposes.

Note 3 to entry: Elliptical zones that are toroidal, or adjacent to a *toroidal zone* (3.1.2.1.50), have their diameter specified on the flattest meridian.

Note 4 to entry: In lenses with concentric posterior surface zones, the zones are qualified by a subscript number from zero, starting with the innermost zone ($\varnothing_0$); see Figure 1. On the anterior surface, the number is always preceded by the letter "a", for example, $\varnothing_{a0}$.

3.1.2.4 Terms related to thickness

NOTE It is common in France to use the symbol *e* for *épaisseur*, rather than *t* for thickness.

3.1.2.4.1
centre thickness
geometric centre thickness
t_C
axial thickness (3.1.2.4.5) or *radial thickness* (3.1.2.4.7) of a *contact lens* (3.1.1.1) or shell along its axis at the geometrical centre

Note 1 to entry: The minimum centre thickness of a minus lens is determined by the *critical thickness* (3.1.2.4.2) of the contact lens material.

3.1.2.4.2
critical thickness
minimum thickness of a *contact lens* (3.1.1.1) at a point or points of thickness determined by lens geometry or design

Note 1 to entry: The critical thickness of a conventional contact lens of minus power is usually at its centre. The critical thickness of a conventional contact lens of plus power is usually at the *edge* (3.1.2.1.34) of the most plus meridian. A plus-lenticular lens with minus carrier usually has its critical thickness at the front lenticular *junction* (3.1.2.1.52).

Note 2 to entry: The critical thickness is determined by stability, durability, flexibility, and/or fragility of the lens material.

3.1.2.4.3
optical centre thickness
t_O
thickness of the *contact lens* (3.1.1.1) at its optical centre

Note 1 to entry: This symbol is used only if the optical centre does not coincide with the *geometric centre* (3.1.2.1.20).

3.1.2.4.4
harmonic mean thickness
t_{HM}
thickness of a rotationally symmetric *contact lens* (3.1.1.1) calculated from a series of (h + 1) *radial thickness* (3.1.2.4.7) measurements at intervals of equal annular area from the centre point (point 0) to the edge point (point h) of the circular zone by the expression:

$$t_{HM} = \frac{h+1}{\frac{1}{t_0}+\frac{1}{t_1}+\frac{1}{t_2}+\frac{1}{t_3}+\ldots+\frac{1}{t_h}}$$

where

h	is a series of concentric circles indicating zones of equal surface area from the lens geometric centre to the edge of the exposed sample area;
t_{HM}	is the harmonic mean thickness of a radially symmetric test sample;
t_0 to t_h	are the radial thicknesses measured at intervals of equal area from the centre (t_0) to the edge (t_h) of the exposed sample area.

Note 1 to entry: The number of zones is equal to h + 1.

Note 2 to entry: For spherical lenses, the average thickness, in millimetres, of a rotationally symmetric contact lens central zone where the anterior and posterior surfaces are not parallel can be calculated from the expression:[23]

$$\frac{1}{t_{HM}} = \frac{-4,606\left(n-1\right)}{d^2F\times 10^{-3}}\ \log_{10}\left\{1-\left[d^2F\times 10^{-3}\right]/\,2\,\left[n-1\right]\,t_c\right\}$$

where

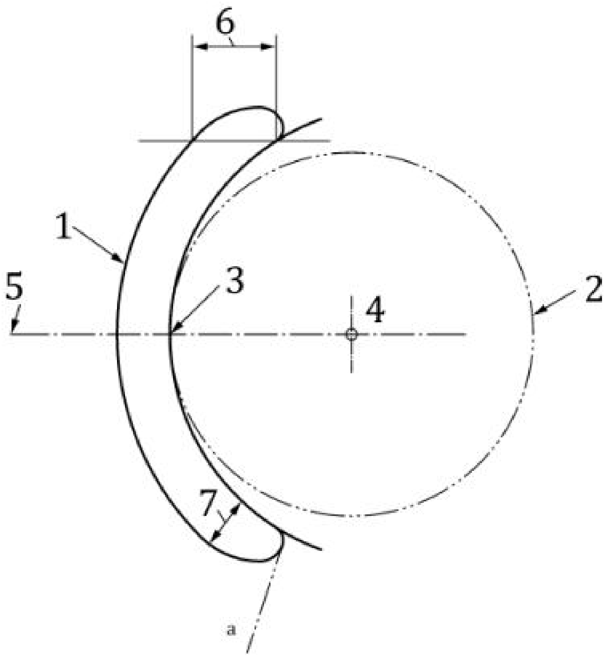
n	is the refractive index;
F	is the lens power, in dioptres;
$2d$	is the diameter of the central zone, in mm;
t_C	is the centre thickness, in mm.

3.1.2.4.5
axial thickness
t_A
thickness of a *contact lens* (3.1.1.1) along a line parallel to the lens axis, at a specified position

3.1.2.4.6
axial edge thickness
t_{EA}
thickness at the extremity of the *peripheral zone* (3.1.2.1.18) (edge) of a *contact lens* (3.1.1.1) measured parallel to the lens axis

Note 1 to entry: This value is often computed by the manufacturer on the basis of an uncut edge and can be altered by the edging process.

Note 2 to entry: See Figure 6, key 6.



Key

1 front surface of contact lens
2 vertex sphere
3 back vertex
4 centre of vertex sphere
5 contact lens axis
6 axial edge thickness, t_{EA}
7 radial edge thickness, t_{ER}

a The radial edge thickness would normally be measured 0,2 mm to 0,8 mm from the edge of the contact lens.

Figure 6 — Difference between radial and axial edge thickness

3.1.2.4.7
radial thickness
t_R
thickness of a *contact lens* (3.1.1.1) along a line which passes through the centre of the vertex sphere and intersects the lens at a specified point

3.1.2.4.8
radial edge thickness
$t_{ER(x)}$
thickness of the *contact lens* (3.1.1.1) measured normal to the front surface at a specified distance, *x*, from the *edge* (3.1.2.1.34)

Note 1 to entry: See Figure 6, key 7.

EXAMPLE $t_{ER(0.2)}$ indicates the radial edge thickness is measured 0,2 mm from the contact lens edge.

3.1.2.4.9
carrier junction thickness
t_{CJ}
radial thickness (3.1.2.4.7) at the carrier *junction* (3.1.2.1.52)

Note 1 to entry: To indicate the zone concerned, the subscript is followed by the number of the inner zone.

3.1.2.4.10
peripheral junction thickness
t_{PJ}
radial thickness (3.1.2.4.7) of the *contact lens* (3.1.1.1) measured at a specified *junction* (3.1.2.1.52)

Note 1 to entry: The subscript may be followed by a number to indicate the junction concerned. See Figure 1.

3.1.3 Terms related to aspheric contact lenses

3.1.3.1
aspheric zone
zone with surface having a form generated by the rotating of a curve of continuously varying radius about the *contact lens axis* (3.1.2.1.29)

3.1.3.2
bi-aspheric contact lens
contact lens (3.1.1.1) having both front and *back optic zones* (3.1.2.2.1) of aspheric form

3.1.3.3
aspheric periphery contact lens
contact lens (3.1.1.1) with one or more back peripheral *aspheric zones* (3.1.3.1) and a spherical *back optic zone* (3.1.2.2.1)

3.1.3.4
aspheric bi-curve contact lens
contact lens (3.1.1.1) whose back surface is composed of two intersecting coaxial *aspheric zones* (3.1.3.1)

3.1.3.5
aspheric tri-curve contact lens
contact lens (3.1.1.1) whose back surface is composed of three intersecting coaxial *aspheric zones* (3.1.3.1)

3.1.3.6
aspheric multi-curve contact lens
contact lens (3.1.1.1) whose back surface is composed of more than three intersecting coaxial *aspheric zones* (3.1.3.1)

3.1.3.7
apical radius of curvature
radius of curvature at the apex of an aspheric surface having a *sagittal depth* (3.1.2.1.32) that is approximately equal to the sagittal depth of the aspheric surface in a small area surrounding its apex

3.1.4 Terms related to bifocal and multifocal contact lenses

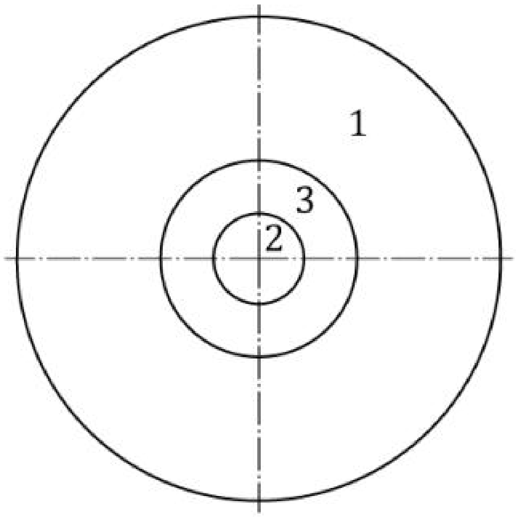
3.1.4.1
addition power
addition
add
difference between the average vertex power of the most plus (or least minus) portion and the average vertex power of the least plus (or most minus) portion of the *contact lens* (3.1.1.1)

3.1.4.2
progressive optical zone
aspheric zone (3.1.3.1) designed to provide a continuous change of surface power

3.1.4.3
concentric bifocal contact lens
contact lens (3.1.1.1) having two *optic zones* (3.1.2.1.17) of different power, each having coincident *geometric centres* (3.1.2.1.20)

Note 1 to entry: See Figure 7.

Note 2 to entry: This excludes diffractive *bifocal contact lenses* (3.1.1.13).



Key

1 carrier

2 central optic zone

3 peripheral optic zone

Figure 7 — Surface of a solid, concentric bifocal contact lens

3.1.4.4
concentric multifocal contact lens
contact lens (3.1.1.1) having two or more *optic zones* (3.1.2.1.17) of different power, each having coincident *geometric centres* (3.1.2.1.20)

3.1.4.5
central optic zone
innermost *optic zone* (3.1.2.1.17) of a concentric bifocal or other *multifocal contact lens* (3.1.1.14)

3.1.4.6
peripheral optic zone
optic zone (3.1.2.1.17) surrounding the *central optic zone* (3.1.4.5) of a *concentric multifocal contact lens* (3.1.4.4)

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

3.1.4.7
centre distance contact lens
CD contact lens
multifocal or *progressive power contact lens* (3.1.1.15) where the maximum minus (or minimum plus) power is found in the *central optic zone* (3.1.4.5) of the lens

3.1.4.8
centre near contact lens
CN contact lens
multifocal or *progressive power contact lens* (3.1.1.15) where the maximum plus (or minimum minus) power is found in the *central optic zone* (3.1.4.5) of the lens

3.1.4.9
solid bifocal contact lens
one-piece bifocal contact lens
non-composite bifocal contact lens
bifocal contact lens (3.1.1.13) formed from only one material

3.1.4.10
solid multifocal contact lens
one-piece multifocal contact lens
non-composite multifocal contact lens
multifocal contact lens (3.1.1.14) formed from only one material

3.1.4.11
fused segment contact lens
multifocal contact lens (3.1.1.14) made from materials of different *refractive indices* (3.1.6.3)

3.1.4.12
segment height
vertical distance of the segment extreme point above the horizontal tangent to the *contact lens* (3.1.1.1) periphery at its lowest point

Note 1 to entry: See Figure 8.

Note 2 to entry: This dimension does not apply to concentric and diffractive *multifocal contact lenses* (3.1.1.14).

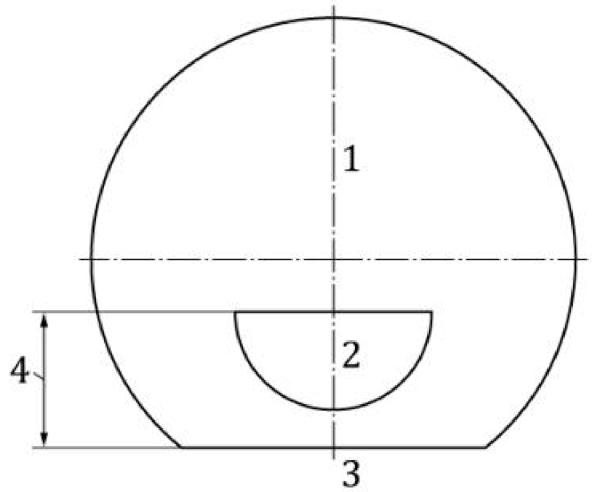
3.1.4.13
diffractive bifocal contact lens
simultaneous image *bifocal contact lens* (3.1.1.13) which utilizes diffraction, as well as refraction, to focus retinal images of distant and near objects

3.1.4.14
simultaneous image multifocal contact lens
DEPRECATED: simultaneous vision contact lens
bifocal contact lens (3.1.1.13) or *multifocal contact lens* (3.1.1.14) whose *performance* (3.1.9.2) does not primarily depend on lens movement for different viewing distances

Note 1 to entry: It is intended that two or more zones continually cover the pupil area.

3.1.4.15
alternating image bifocal contact lens
translating bifocal contact lens
DEPRECATED: alternating vision bifocal contact lens
DEPRECATED: translating vision bifocal contact lens
bifocal contact lens (3.1.1.13) whose *performance* (3.1.9.2) depends primarily on movement of the *contact lens* (3.1.1.1) to position either the near or the distance portion in front of the pupil

Note 1 to entry: See Figure 8.



Key

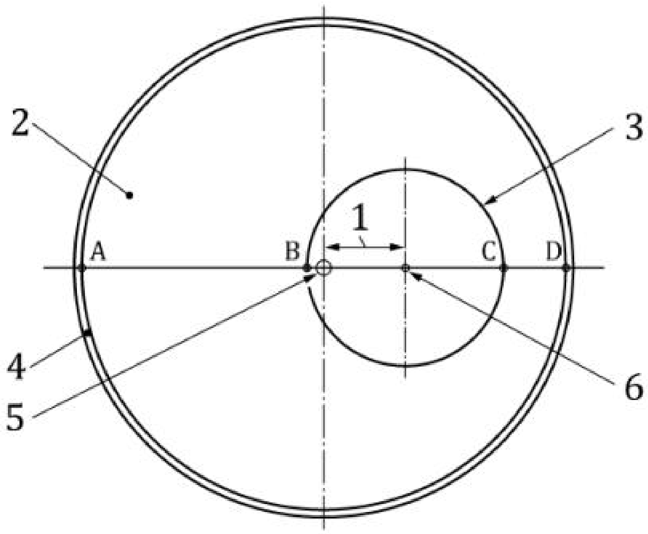
1 distance optic zone

2 near optic zone

3 truncation

4 segment height

Figure 8 — Example of an alternating image bifocal contact lens



Key

1 displacement of optic, $d = (AB - CD)/2$

2 scleral zone

3 optic-scleral junction

4 edge

5 centre of circle enclosing edge

6 centre of circle enclosing the optic zone

NOTE The distance AD is the back scleral size.

Figure 9 — Posterior view of a scleral contact lens or shell

3.1.5 Terms related to scleral contact lenses and shells

3.1.5.1
impression scleral contact lens
scleral contact lens (3.1.1.3), the back surface of which has been produced by moulding from a cast of the eye of the wearer

3.1.5.2
impression scleral shell
scleral shell (3.1.1.6), the back surface of which has been produced by moulding from a cast of the eye of the wearer

3.1.5.3
impression tray
type of shell used to hold impression material in contact with the eye

3.1.5.4
preformed scleral contact lens
scleral contact lens (3.1.1.3), not an impression lens, the back surface of which is of a specified form

3.1.5.5
back scleral size
maximum internal dimension of the back scleral surface before the sharp edges have been rounded

Note 1 to entry: See Figure 9, where the distance AD is the back scleral size.

3.1.5.6
displacement of optic
d
half of the difference between the maximum and minimum *scleral chords* (3.1.5.10)

Note 1 to entry: See Figure 9.

Note 2 to entry: This assumes a round *contact lens* (3.1.1.1) with a round *optic zone* (3.1.2.1.17).

3.1.5.7
primary optic diameter
diameter of the *optic zone* (3.1.2.1.17) before any *transition* (3.1.2.1.54) is added

Note 1 to entry: See Figure 9.

Note 2 to entry: In a case where the optic zone is not circular, the longest chord passing through the *geometric centre* (3.1.2.1.20) is used.

3.1.5.8
primary optic plane
plane perpendicular to the lens axis and containing the *primary optic diameter* (3.1.5.7)

3.1.5.9
primary sagitta
distance along the lens axis from the *back vertex* (3.1.2.1.30) of the *optic zone* (3.1.2.1.17) to the *primary optic plane* (3.1.5.8)

3.1.5.10
scleral chord
distance in a specified meridian from the optic-scleral junction to the junction of the back scleral surface with the *edge* (3.1.2.1.34)

Note 1 to entry: See Figure 9, where distances AB and CD are examples of scleral chords.

3.1.5.11
scleral thickness
thickness of the *scleral zone* (3.1.5.12) measured normal to the front scleral surface at any specified point

3.1.5.12
scleral zone
zone of a scleral lens (or shell) designed to lie in front of the sclera

3.1.5.13
channel
specified groove in a *scleral contact lens* (3.1.1.3) or shell

Note 1 to entry: This normally allows interchange of tear fluid from the optic portion to the external eye.

3.1.5.14
scleral lens vault
space between the back of the *contact lens* (3.1.1.1) and the ocular surface

3.1.6 Terms related to contact lens material properties

3.1.6.1
tensile modulus of elasticity
constant ratio between the tensile stress (the force per unit cross sectional area of the sample) and the tensile strain, (the linear change in sample dimension divided by the original dimension), in the range of linear elastic behaviour of the material

Note 1 to entry: The tensile modulus is obtained from the initial linear portion of the stress versus strain plot. The stress-strain behaviour of a material is temperature and strain-rate dependent.

Note 2 to entry: The tensile modulus in conjunction with the lens shape and dimensions can affect the clinical *performance* (3.1.9.2) of the lens, for example, how well the lens conforms to the eye.

3.1.6.2
dimensional stability
degree to which a contact lens maintains its original dimensions over time, expressed in percent change of the original dimension

3.1.6.3
refractive index
index of refraction
ratio of the speed of light in a vacuum to the speed of that same light in a material

Note 1 to entry: Historically, the index of refraction is reported at specific spectral lines, such as 589,3 nm (sodium D-line), 587,6 nm (helium d-line) or 546,1 nm (mercury e-line).

3.1.6.4
permeability coefficient
P
"constant" of permeability for gases in polymeric membranes:

$$P = \frac{V \times t}{A \times \Delta p \times t_{\Delta p}}$$

where

V is the volume of gas, in cm^3;

t is the thickness;

A is the surface area, in cm^2;

$t_{\Delta p}$ is the time, in seconds, during which the polymeric membrane is subject to the difference in pressure;

Δp is the difference in pressure, in ml × mm of mercury.

3.1.6.5
osmolality
concentration of an osmotic solution, expressed in terms of osmoles of solute per kilogram of solvent (osmol/kg)

3.1.6.6
osmolarity
concentration of an osmotic solution expressed as osmoles of solute per litre of solution (osmol/l)

Note 1 to entry: Osmolarity is a measure of all substances dissolved in the solution and is measured by colligative properties such as freezing point depression and vapour pressure.

3.1.6.7
conductivity
measure of the effect of the presence of dissolved substances in a solution to conduct electricity

Note 1 to entry: Conductivity does not measure the same solution properties as either *osmolality* (3.1.6.5) or *osmolarity* (3.1.6.6) and does not produce equivalent results. Conductivity only measures those substances that produce ions and does not measure dissolved substances that do not produce ions.

3.1.6.8
oxygen permeability
Dk
oxygen flux (3.1.6.9), *j*, under specified conditions through *contact lens* (3.1.1.1) material of unit thickness when subjected to unit pressure difference

Note 1 to entry: This is the most commonly used gas permeability for contact lens materials.

Note 2 to entry: Oxygen permeability, *Dk*, is expressed in units of 10^{-11} (cm^2/s) [ml O_2/(ml × mmHg)]. For simplicity, the units for *Dk* are referred to as barrer or "*Dk* units".

Note 3 to entry: Oxygen permeability is a physical property of the material and is not a function of the shape or thickness of a contact lens or material sample.

Note 4 to entry: mmHg have been used since the early developments of *soft contact lenses* (3.1.1.9) and *Dk* units based on this non-SI pressure unit are readily and widely understood and used by practitioners and the contact lens industry. The calculated numerical value for *Dk* will depend on whether units of mmHg or hPa were used in the *Dk* calculation.

3.1.6.9
oxygen flux
j
net volume of oxygen gas passing through a unit area of sample *contact lens* (3.1.1.1) material per unit time under specified conditions, including temperature, sample thickness and partial pressures of oxygen on both sides of the sample

Note 1 to entry: A convenient unit of oxygen flux for contact lens material is μl/(cm^2 · s).

3.1.6.10
oxygen transmissibility
Dk/t
oxygen permeability (3.1.6.8), *Dk*, divided by the thickness, *t*, in centimetres, of the measured sample under specified conditions

Note 1 to entry: Oxygen transmissibility, *Dk*/t, is expressed in units of 10^{-9} (cm/s) [mlO_2/(ml × mmHg)]. For simplicity, the units for *Dk*/t are referred to as "*Dk*/t units".

Note 2 to entry: Unlike permeability, oxygen transmissibility depends upon the thickness and, therefore, the cross-sectional shape or design of a contact lens or material sample.

3.1.6.11
water content
w_{water}
amount of water (expressed as a percentage by mass fraction) present in a hydrated *contact lens* (3.1.1.1) under specified conditions of temperature, pH and *osmolarity* (3.1.6.6)

Note 1 to entry: The term is most commonly used when dealing with hydrogel materials.

Note 2 to entry: Water content influences many of the physical properties of hydrogel materials as well as various parameters of the finished contact lens.

Note 3 to entry: Measurements of water content are carried out using ISO standard saline according to ISO 18369-3. Use of packaging solution for the purpose of *labelling* (3.1.9.8) can provide different results.

3.1.6.11.1
low water content contact lens
hydrogel contact lens (3.1.1.10) having a *water content* (3.1.6.11), w_{water}, that is greater than or equal to 10 % and less than 50 % ($10\ \% \le w_{water} < 50\ \%$)

3.1.6.11.2
high water content contact lens
hydrogel contact lens (3.1.1.10) having a *water content* (3.1.6.11) , w_{water}, that is greater than or equal to 50 % ($w_{water} \ge 50\ \%$)

3.1.6.12
ionic
contact lens (3.1.1.1) material having a positive or negative charge at the pH of interest

Note 1 to entry: Hydrogel lens materials in Groups 3 and 4 are considered ionic if they contain greater than 0,5 % weight of a charged monomer or oligomer at any pH in the range 6,0 to 8,0.

Note 2 to entry: Hydrogel lens materials in Group 5 are considered ionic if they contain a charged monomer or oligomer at any pH within the range pH 6,0 to 8,0.

3.1.6.13
spectral transmittance
$\tau(\lambda)$
ratio of the spectral radiant flux transmitted by the *contact lens* (3.1.1.1) to the incident spectral flux at any specified wavelength (λ)

Note 1 to entry: The visible spectral transmittance is summated over the range 380 nm to 780 nm.

[SOURCE: ISO 13666:2012, 15.2, modified — Note 1 to entry has been added.]

3.1.6.14
UV-absorbing contact lens
UV-blocking contact lens
UV-filtering contact lens
contact lens (3.1.1.1) having a specification in compliance with either *Class 1* (3.1.6.14.3) or *Class 2* (3.1.6.14.4)

3.1.6.14.1
UVA
radiation of wavelengths between 315 nm and 380 nm

Note 1 to entry: See ISO 20473.

3.1.6.14.2
UVB
radiation of wavelengths between 280 nm and 315 nm

3.1.6.14.3
Class 1
classification for a *contact lens* (3.1.1.1) whose spectral transmittance of *UVA* (3.1.6.14.1) (τ_{UVA}) < 10,0 % and whose spectral transmittance of *UVB* (3.1.6.14.2) (τ_{UVB}) < 1,0 %

3.1.6.14.4
Class 2
classification for a *contact lens* (3.1.1.1) whose spectral transmittance of *UVA* (3.1.6.14.1) (τ_{UVA}) < 50,0 % and whose spectral transmittance of *UVB* (3.1.6.14.2) (τ_{UVB}) < 5,0 %.

3.1.6.15
contact angle
angle formed by an intersection of the tangents at the solid-liquid-gaseous interface comprised of a *contact lens* (3.1.1.1) material, a known liquid, and air, under specified conditions

Note 1 to entry: The contact angle is formed between a tangent to the air/liquid interface and a tangent to the liquid/solid interface.

3.1.6.15.1
advancing contact angle
contact angle (3.1.6.15) created when the liquid has been moving along a solid surface

3.1.6.15.2
equilibrium contact angle
contact angle (3.1.6.15) created when there has been no movement of the liquid across the solid surface for a substantial time period

3.1.6.15.3
receding contact angle
contact angle (3.1.6.15) created when the liquid has been moving away from an area of solid surface which was previously wet

3.1.7 Terms related to tinted contact lenses

3.1.7.1
tinted contact lens
contact lens (3.1.1.1) with some coloration for a specified or an intended use

3.1.7.2
opaque tinted contact lens
eye-masking tinted contact lens
contact lens (3.1.1.1) with sufficient colour in order to mask all or most of the natural iris colour

Note 1 to entry: This is a colloquial term and not all such lenses are completely opaque.

3.1.7.3
enhancing tint
coloration which is added to a *contact lens* (3.1.1.1) in order to alter the apparent iris colour of the wearer

3.1.7.4
handling tint
visibility tint
coloration added to a *contact lens* (3.1.1.1) which is intended to improve the visibility of the lens during handling but which is not intended to have any apparent effect on iris colour

3.1.8 Terms related to contact lens manufacture

3.1.8.1
lathe-cut contact lens
turned contact lens
contact lens (3.1.1.1) primarily manufactured by removal of material with a lathe

3.1.8.2
spin-cast contact lens
contact lens (3.1.1.1) manufactured by a process where a concave mould containing monomer is spun around a vertical axis

3.1.8.3
moulded contact lens
contact lens (3.1.1.1) manufactured primarily in a mould

3.1.8.4
truncate
remove a specified part of the *contact lens* (3.1.1.1) periphery in order to make it non-circular

3.1.9 Terms related to packaging and labelling of contact lenses and contact lens care products

3.1.9.1
intended purpose
use for which a product is intended according to the information supplied by the manufacturer on the *labelling* (3.1.9.8), in the instructions and/or in promotional materials

3.1.9.2
performance
suitability of a product to achieve its *intended purpose* (3.1.9.1)

3.1.9.3
multi-dose solution
liquid preparation in a *primary container* (3.1.9.7) whose volume allows the user to expel an appropriate amount of the product on more than one occasion

3.1.9.4
unit dose
contact lens care solution packaged within a *primary container* (3.1.9.7) that contains sufficient product intended for only one use

3.1.9.5
blister pack
disposable *primary container* (3.1.9.7) consisting of a thin moulded depression of material containing a product sealed with appropriate material

3.1.9.6
tamper-evident package
package having an indicator or barrier to entry which, if damaged, breached or missing, can reasonably be expected to provide evidence to practitioners or users that the package may have been opened

3.1.9.7
primary packaging
primary container
element of the packaging system that maintains the sterility or cleanliness of the product

Note 1 to entry: See ISO 11134.

Note 2 to entry: Primary packaging is intended for storage and protection of the finished product for the duration of the labelled *shelf - life* (3.1.9.10) or until the integrity of the package has been compromised.

3.1.9.8
labelling
all information given on any label, the *primary container* (3.1.9.7), the secondary carton or in a leaflet supplied with the product

3.1.9.9
expiration date
expiry date
end date of period of time, designated by the manufacturer, beyond which the product should not be first used

3.1.9.10
shelf - life
specified period of time from the date of manufacture of a product to its labelled *expiration date* (3.1.9.9)

3.1.9.11
discard date
DEPRECATED: in-use period
specified period of time from first use to when the product should be discarded

3.1.9.12
in-use stability
ability of a *contact lens* (3.1.1.1) or *contact lens care product* (3.1.1.18) to retain its *performance* (3.1.9.2) and safety from first opening to its *discard date* (3.1.9.11)

3.1.9.13
batch
defined quantity of bulk, intermediate or finished product that is intended or purported to be uniform in character and quality, and which has been produced during a defined cycle of manufacture

Note 1 to entry: Refer to ISO 15223 (all parts) or EN 980 for applicable symbols.

3.1.10 Terms related to contact lens usage and wear modality

3.1.10.1
disposable contact lens
contact lens (3.1.1.1) intended for a single use (wearing period)

Note 1 to entry: A disposable contact lens is not intended to be reused. It is intended to be discarded after removal from the eye.

Note 2 to entry: Depending on the contact lens wear modality, "a single use" can refer to a single use in daily or extended or flexible wear.

3.1.10.2
reusable contact lens
contact lens (3.1.1.1) intended to be worn more than once, according to the manufacturer's instructions

Note 1 to entry: Manufacturers' instructions would conventionally include *contact lens cleaning* (3.1.11.13), *rinsing* (3.1.11.18) and *disinfection* (3.1.11.18).

3.1.10.3
replacement frequency
time period recommended by the manufacturer for discarding a *contact lens* (3.1.1.1)

Note 1 to entry: The replacement frequency is determined starting from the first use of the lens until the recommended time for discarding is reached.

3.1.10.3.1
frequent replacement contact lens
planned replacement contact lens (3.1.10.3.2) for which the replacement period is three months or less

3.1.10.3.2
planned replacement contact lens
contact lens (3.1.1.1) for which the manufacturer has recommended a replacement period

3.1.10.4
contact lens wear modality
prescribed form or manner in which a *contact lens* (3.1.1.1) is worn

3.1.10.4.1
daily wear
contact lens wear modality (3.1.10.4) in which a *contact lens* (3.1.1.1) is worn only during waking periods

3.1.10.4.2
extended wear
contact lens wear modality (3.1.10.4) in which a *contact lens* (3.1.1.1) is worn continuously during successive waking and sleeping periods

Note 1 to entry: Extended wear is designed for use over a defined period which is determined individually for lens materials and is labelled for that duration of use.

3.1.10.4.3
flexible wear
variable wearing modality where the wearer uses a *contact lens* (3.1.1.1), designed to support *extended wear* (3.1.10.4.2), for both daily wear and extended wear on different occasions

3.1.10.4.4
orthokeratology contact lens
contact lens (3.1.1.1) specifically designed for reshaping the corneal epithelium during wear

3.1.10.5
cosmetic contact lens
prosthetic contact lens
decorative contact lens
contact lens (3.1.1.1) specifically designed to change or mask the appearance of the eye

Note 1 to entry: Cosmetic lenses are devices which can also be used for therapeutic purposes.

3.1.10.6
cosmetic contact shell
contact lens (3.1.1.1) shell specifically designed to change or mask the appearance of the eye

Note 1 to entry: Cosmetic shells are devices which can also be used for therapeutic purposes.

3.1.10.7
bandage contact lens
protective contact lens
therapeutic contact lens
contact lens (3.1.1.1) designed to protect, maintain, or aid in restoring integrity of ocular tissue

Note 1 to entry: This type of contact lens can be designed to include a refractive element.

3.1.10.8
trial contact lens
diagnostic contact lens
contact lens (3.1.1.1) only used by a practitioner or fitter for the purpose of selecting the appropriate contact lens parameters for the intended wearer

3.1.10.9
multipatient use trial contact lens
trial contact lens (3.1.10.8) permitted to be used on more than one person

Note 1 to entry: For care of multipatient trial lenses, refer to ISO/TS 19979.

3.1.11 Terms related to contact lens hygienic management and contact lens care products

3.1.11.1
active ingredient
component present in sufficient quantity that relates to an *intended purpose* (3.1.9.1)

3.1.11.2
antimicrobial activity
ability to kill/destroy/inactivate microorganisms, prevent their proliferation and/or prevent their pathogenic action

3.1.11.3
antimicrobial agent
compound capable of *antimicrobial activity* (3.1.11.2)

3.1.11.4
neutralization
process by which active ingredients (e.g. hydrogen peroxide) in a *contact lens care product* (3.1.1.18) which can compromise ocular tissue are rendered inactive and/or non-toxic

Note 1 to entry: There is no implication that pH 7,0 has been achieved by this process.

3.1.11.5
neutralizing agent
chemically active ingredient(s) capable of *neutralization* (3.1.11.4)

3.1.11.6
surfactant
agent that modifies the surface energy (surface tension) of a solution

Note 1 to entry: Surfactants are common ingredients used in the formulation of contact lens cleaners.

3.1.11.7
preservative
component intended to prevent the growth of microorganisms in or on a product

3.1.11.8
stasis
inhibition of microbial growth

3.1.11.9
bioburden
population of viable microorganisms on a raw material, component, a finished product and/or a package

Note 1 to entry: Bioburden is expressed as the total viable count (TVC), or colony forming units (CFU, cfu) per lens, lens case or tablet, or CFU per millilitre of solution.

[SOURCE: ISO/TS 11139:2006, 2.2, modified]

3.1.11.10
sterile
free of viable microorganisms

Note 1 to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven. The nature of microbial death is described by an exponential function. Therefore, the presence of viable microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

Note 2 to entry: Refer to ISO 15223 (all parts) or EN 980 for applicable symbols.

[SOURCE: ISO/TS 11139:2006, 2.43, modified]

3.1.11.11
sterility assurance level
SAL
probability of a viable microorganism being present on a product unit after sterilization

Note 1 to entry: SAL is normally expressed as a negative power (n) of 10, in the form 10^{-n}.

[SOURCE: ISO/TS 11139:2006, 2.46, modified]

3.1.11.12
hygienic management
procedure by which *contact lenses* (3.1.1.1) are maintained in a condition for safe reuse

3.1.11.13
contact lens cleaning
process of removing surface contaminants from a *contact lens* (3.1.1.1)

Note 1 to entry: Cleaning is usually the first step in the *hygienic management* (3.1.11.12) of a *reusable contact lens* (3.1.10.2). Chemical agents, e.g. *surfactants* (3.1.11.6), are often employed in contact lens cleaning products to facilitate the removal of foreign matter from a contact lens.

3.1.11.14
contact lens care regimen
series of processes specified by the *contact lens* (3.1.1.1) or care product manufacturer and used by the contact lens wearer to maintain ocular health, lens condition, comfort and vision

3.1.11.15
contact lens disinfection
chemical or physical process to reduce the number of viable microorganisms on a *contact lens* (3.1.1.1) to a level which is neither harmful to ocular health nor to the quality of contact lenses and *contact lens accessories* (3.1.1.17)

Note 1 to entry: Bacterial spores, acanthamoeba, some fungal spores, prions and some viruses might not necessarily be inactivated during the contact lens disinfection process.

3.1.11.15.1
contact lens disinfecting agent
chemically or physically active ingredient in *contact lens disinfection* (3.1.11.15)

3.1.11.15.2
contact lens disinfecting product
product that possesses biocidal activity (kills, destroys, or inactivates), meeting the primary criteria of the stand-alone test specified in ISO 14729

3.1.11.15.3
contact lens disinfecting regimen
contact lens care regimen (3.1.11.14) designed to meet both the secondary criteria of the stand-alone test and the regimen test as specified in ISO 14729

3.1.11.16
abrasive cleaner
suspension in sufficient concentration used to facilitate *contact lens cleaning* (3.1.11.13) by friction enhancement

3.1.11.17
enzymatic cleaner
protein or lipid remover
liquid or solid preparation containing one or more enzymes as active ingredients with the *intended purpose* (3.1.9.1) of reducing adsorbed and absorbed proteins and/or lipids on a *contact lens* (3.1.1.1)

Note 1 to entry: Enzymatic cleaners are optional *contact lens care products* (3.1.1.18) recommended for use in the hygienic management of contact lenses.

3.1.11.18
rinsing
removal of physical and chemical contaminants from a *contact lens* (3.1.1.1) by allowing the flow of a suitable liquid over the surfaces of the lens

Note 1 to entry: A minimum time for rinsing lenses is generally recommended by the manufacturer in the *labelling* (3.1.9.8) of a rinsing solution to achieve its *intended purpose* (3.1.9.1).

3.1.11.19
soaking
immersion of a *contact lens* (3.1.1.1) in a specified solution for a specified time

Note 1 to entry: A minimum time for soaking lenses is generally recommended by the manufacturer in the *labelling* (3.1.9.8) of a soaking or storage solution to achieve its *intended purpose* (3.1.9.1).

3.1.11.20
soaking solution
storage solution
liquid preparation with the *intended purpose* (3.1.9.1) of keeping a *contact lens* (3.1.1.1) in a condition suitable for reuse while the lens is not in the eye

Note 1 to entry: Soaking solutions can contain *preservatives* (3.1.11.7).

3.1.11.21
conditioning solution
liquid preparation formulated for *soaking* (3.1.11.19) and storage of a *contact lens* (3.1.1.1) for the *intended purpose* (3.1.9.1) of maintaining the lens in a condition suitable for reuse

Note 1 to entry: Conditioning solutions are generally formulated with antimicrobial agents and viscosity agents and are primarily intended for use in the hygienic management of *rigid contact lenses* (3.1.1.7).

3.1.11.22
wetting solution
liquid preparation applied to *contact lenses* (3.1.1.1) to improve the short-term hydrophilicity of the lens surface

Note 1 to entry: Because these solutions contain ingredients to affect wettability including viscosity agents, they can also act to improve lubrication.

3.1.11.23
lubricating and rewetting solution
rewetting drops
liquid preparation intended for occasional use directly in the eye by a *contact lens* (3.1.1.1) wearer for alleviating discomfort of lens wear and improving lens tolerance by physical means

Note 1 to entry: The term "comfort drops" is sometimes also used but is deprecated because it is a registered trademark of a *contact lens care product* (3.1.1.18) in some countries and is no longer a generic term.

3.1.11.24
multipurpose solution
DEPRECATED: combination solution
liquid preparation which has more than one claimed function in the hygienic management of a *contact lens* (3.1.1.1)

3.1.11.25
packaging solution
shipping solution
liquid preparation used by the *contact lens* (3.1.1.1) manufacturer or practitioner to dispatch or store lenses in a *primary container* (3.1.9.7)

3.1.12 Miscellaneous terms

3.1.12.1
aphakia
condition where the natural crystalline lens of the eye is absent

3.1.12.2
biocompatibility
ocular biocompatibility
property of a material that will not cause an allergenic, hypersensitive, irritative, or toxic reaction when it is in contact with human ocular tissue or pre-ocular tear film

3.1.12.3
clinical investigator
individual and/or institution responsible for the conduct of a clinical investigation who and/or which takes the clinical responsibility for the well-being of the subjects involved

Note 1 to entry: Whether this is an individual or an institutional responsibility can depend on national legislation.

3.1.12.4
elution
less aggressive form of extraction for removing chemicals from a *contact lens* (3.1.1.1) material

Note 1 to entry: Generally, the process of elution uses either distilled water, saline, cottonseed oil or tissue culture media as solvents, room temperature as a specified condition and extended time periods (e.g. 24 h to 72 h) for removing or greatly diluting the presence of some chemicals or imputed impurities from the contact lens material.

3.1.12.5
extractable substance
leachable substance
residual substance
chemical removed from the material composing a *contact lens* (3.1.1.1), during the process of *extraction* (3.1.12.6)

3.1.12.6
extraction
process of removing residual chemicals that are present in materials by using a specified solvent, for a specified time, under specified conditions

Note 1 to entry: The process of extraction is typically associated with aggressive conditions such as short time periods (e.g. 1 h) and high solvent temperatures (e.g. 37 °C) for removing chemicals from a material.

3.1.12.7
inoculum
suspension of known microorganisms

3.1.12.8
accuracy
closeness of agreement between the test result and the accepted reference value (true value)

Note 1 to entry: When applied to a set of observed values, accuracy describes a combination of random components (precision) and a common systematic error component (trueness).

Note 2 to entry: The use of the term "precision" for "accuracy" is to be avoided.

3.1.12.9
precision
closeness of agreement between mutually independent test results obtained under stipulated conditions

Note 1 to entry: See ISO 3534-1.

Note 2 to entry: Precision depends only on the distribution of random errors and does not relate to the true or accepted reference value of the parameter tested. Repeatability and reproducibility are concepts of precision. See the appropriate part of ISO 5725.

3.1.12.9.1
repeatability
closeness of agreement between mutually independent test results obtained following the same test procedure on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time

3.1.12.9.2
inter-laboratory reproducibility
closeness in agreement between mutually independent test results obtained following the same test procedure on the same test material in different laboratories, on equivalent equipment by different operators within short intervals of time

Note 1 to entry: In cases where the inter-laboratory reproducibility is used, traditional *reproducibility* (3.1.12.9.3) is termed "intermediate precision".

3.1.12.9.3
reproducibility
closeness of agreement between mutually independent test results obtained following the same test procedure on identical test material in different laboratories by different operators using different equipment

3.1.12.10
prism dioptre
Δ
pdpt
unit of prismatic deviation, equal to 100 tan δ, where δ is the angle of deviation in degrees (°)

Note 1 to entry: Prism dioptre is expressed in centimetres per metre (cm/m).

[SOURCE: ISO 13666:2012, 10.11, modified]

3.1.12.11
ophthalmometer
keratometer
instrument used to measure the radius of curvature of the primary front and back curve of a *contact lens* (3.1.1.1)

3.1.12.12
radiuscope
microspherometer
instrument used to measure a radius of curvature of a *contact lens* (3.1.1.1)

Note 1 to entry: The instrument is typically used to measure the *back optic zone radius* (3.1.2.2.3) of a *rigid contact lens* (3.1.1.7).

3.1.12.13
V-gauge
V-groove diameter gauge
V-groove
device used to measure the total diameter of *rigid contact lenses* (3.1.1.7)

3.2 Symbols

Table 1 — Symbols

Symbol	Term	Reference
r_0	back optic zone radius	3.1.2.2.3
r_0	back central optic zone radius	3.1.2.2.4
r_1, r_2	back peripheral optic zone radius	3.1.2.2.5
r_1, r_2	back peripheral radius	3.1.2.2.6
r_{a0}	front optic zone radius	3.1.2.2.7
r_{a0}	front central optic zone radius	3.1.2.2.8
r_{a1}, r_{a2}	front peripheral optic zone radius	3.1.2.2.9
r_{a1}, r_{a2}	front peripheral radius	3.1.2.2.10
e	eccentricity	3.1.2.1.23
$\varnothing_0$	back optic zone diameter	3.1.2.3.3
$\varnothing_0$	back central optic zone diameter	3.1.2.3.4
$\varnothing_1, \varnothing_2$	back peripheral optic zone diameter	3.1.2.3.5
$\varnothing_1, \varnothing_2$	back peripheral zone diameter	3.1.2.3.6
$\varnothing_{a0}$	front optic zone diameter	3.1.2.3.7
$\varnothing_{a0}$	front central optic zone diameter	3.1.2.3.8
$\varnothing_{a1}, \varnothing_{a2}$	front peripheral optic zone diameter	3.1.2.3.9
$\varnothing_{a1}, \varnothing_{a2}$	front peripheral zone diameter	3.1.2.3.10
$\varnothing_T$	total diameter	3.1.2.3.1
t_A	axial thickness[a]	3.1.2.4.5
t_{EA}	axial edge thickness[a]	3.1.2.4.6
t_{CJ}	carrier junction thickness[a]	3.1.2.4.9
t_C	geometric centre thickness[a]	3.1.2.4.1
t_O	optical centre thickness[a]	3.1.2.4.3
t_{HM}	harmonic mean thickness[a]	3.1.2.4.4
t_{PJ}	peripheral junction thickness[a]	3.1.2.4.10
t_R	radial thickness[a]	3.1.2.4.7
$t_{ER(x)}$	radial edge thickness[a]	3.1.2.4.8
l_A	axial lift	3.1.2.1.39
l_{EA}	axial edge lift	3.1.2.1.40
l_R	radial lift	3.1.2.1.37
l_{ER}	radial edge lift	3.1.2.1.38
D	dioptre	3.1.2.1.1
F'_v	paraxial back vertex power	3.1.2.1.4
F_v	paraxial front vertex power	3.1.2.1.3
F'_L	label back vertex power	3.1.2.1.6
F_L	label front vertex power	3.1.2.1.5
d	displacement of optic	3.1.2.1.19, 3.1.5.6
$\tau(\lambda)$	spectral transmittance	3.1.6.13
Dk	oxygen permeability	3.1.6.8

a In France, it is common to use the abbreviation *e* for *épaisseur*, rather than *t* for thickness.

Table 1 *(continued)*

Symbol	Term	Reference
Dk/t	oxygen transmissibility	3.1.6.10
P	permeability coefficient	3.1.6.4
j	oxygen flux	3.1.6.9
a In France, it is common to use the abbreviation *e* for *épaisseur*, rather than *t* for thickness.		

4 Classification of contact lens materials

4.1 The specific name of a contact lens material is given as a seven-part coding as follows:

1	2	3	4	5	6	7
prefix	stem	series	group suffix	(*Dk*)	(water content)	modification code

For hydrogel lens materials, the classification denotes whether the material is ionic and the range in which the water content falls. For non-hydrogel lens materials, the classification indicates the presence/absence of silicone/fluorine and oxygen permeability grouping. For both types of material, the presence or absence of surface modifications is indicated.

4.2 The prefix is a term used to designate a specific identity of monomers and crosslinking agents. Use of this prefix, which is administered by the United States Adopted Names (USAN) Council, is optional outside the United States of America.[1)]

4.3 Two types of stem are used. The filcon stem is affixed to the prefix for materials that contain equal to or greater than 10 % water by mass. The focon stem is affixed to the prefix for materials which contain less than 10 % water by mass.

NOTE By definition, non-hydrogel soft contact lens materials containing <10 % water do not readily fit into this classification system. Based on historical considerations, these materials have been given the filcon stem but do not readily conform to the groups in Table 3.

4.4 The series suffix is also administered by the USAN Council and is used in cases in which the original ratio of monomers of an existing contact lens material is changed to make a new contact lens material. In this case, the capital letter "A" is added after the stem designation. Subsequent changes in ratio of identical monomers are designated by the next letter of the alphabet. These letters are used to differentiate polymers of identical monomeric components but with different ratios.

4.5 The group suffix, represented by Arabic numerals, indicates the range of water content measured according to ISO 18369-4 and ionic content for filcon materials. For focon materials, it indicates the presence or absence of silicone/fluorine.

1) United States Adopted Names Council, c/o American Medical Association, P.O. Box 10970, Chicago, Illinois, USA, 60610 ; phone (312) 464-4046, http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council.page?.

4.6 For non-hydrogel materials, the group suffixes in Table 2 apply. For hydrogel materials, the group suffixes in Table 3 apply.

Table 2 — Classification of non-hydrogel materials

Group suffix	Material
1	Materials not containing silicone or fluorine
2	Materials containing silicone but not fluorine
3	Materials containing silicone and fluorine
4	Materials containing fluorine but not silicone
NOTE Polymer formulations can also contain initiators, catalysts, tints, UV absorbers, fillers and wetting agents which can be present in the final material. For clarity and simplicity, these additives have been omitted from the stated composition.	

Table 3 — Classification of hydrogel materials

Group suffix	Hydrogel material	Description
1	Low water content, non-ionic	Materials which contain less than 50 % water and which contain 0,5 wt % or less of monomers that are ionic at pH 6 to pH 8
2	High water content, non-ionic	Materials which contain 50 % or more water and which contain 0,5 wt % or less of monomers which are ionic at pH 6 to pH 8
3	Low water content, ionic	Materials which contain less than 50 % water and which contain greater than 0,5 wt % of monomers which are ionic at pH 6 to pH 8
4	High water content, ionic	Materials which contain 50 % water or more and which contain greater than 0,5 wt % of monomers which are ionic at pH 6 to pH 8
5[a]	Enhanced oxygen permeable materials (e.g. silicone hydrogels, silicone elastomers)	Materials having oxygen permeability (*Dk*) greater than 40 *Dk* units (using mmHg) and that have a *Dk* greater than that expected on the basis of the material's water content alone.
5A	Ionic subgroup	A subgroup of Group 5 which contains monomers or oligomers which are ionic at pH 6 to pH 8
5B	High water subgroup	A subgroup of Group 5 which contains 50 % water or more and no ionic monomer or oligomer at pH 6 to pH 8
5C	Low water subgroup	A subgroup of Group 5 which contains less than 50 % water and no ionic monomer or oligomer at pH 6 to pH 8
[a] It is currently understood that Group 5 lens materials are biphasic polymers containing a hydrophilic phase and a hydrophobic phase. The hydrophobic phase may affect the properties of the material in addition to the oxygen permeability. At this time, insufficient data are available to sub-classify the material based on a description of the hydrophobic phase. Until such time as further classification of the hydrophobic phase can be made, users should carry out a risk assessment to define the appropriate materials to include in care product evaluation.		

4.7 Oxygen permeability is expressed in *Dk* units using mmHg.

4.8 Water content is expressed as the percentage of water by weight in the material.

4.9 The modification code, designated by a lower case "m", denotes that the lens from Groups 1 to 4 hydrogels and Groups 1 to 4 rigid materials has a modified surface which has characteristics different from the bulk of the material. The modification code is only used if the contact lens has been subjected to a surface modification process. Examples include

— plasma treatment,

— acid/base hydrolysis, and/or

— incorporation of a material which migrates to the surface.

Certain types of tinted lenses may also be considered surface modified.

For Group 5 polymers, the modification code, designated by the lower case "c" or "w" denotes that the lens has a modified surface that has characteristics different from the bulk material. A modification code is only used if the contact lens has been subjected to a surface modification process.

The modification code "c" should only be used if the surface has been chemically modified (e.g. bonded surface modification or plasma treatment).

The modification code "w" should only be used for materials having releasing or internal wetting agents using semi-interpenetrating networks.

NOTE Modification codes for hydrogels are for lenses as manufactured and do not include any additive included in the packaging solution.

4.10 Examples of classification by code

EXAMPLE 1 Hydrogel material.

A hydrogel material whose formulation has the USAN code "cromo", of monomer ratio modification "A", containing 78 % water, 0,3 weight % ionic monomers and exhibiting an oxygen permeability of 42 *Dk* units is classified by the following code:

cromofilcon A 2 (42) [78 %]

EXAMPLE 2 Silicone hydrogel material

A silicone hydrogel material whose formulation has the USAN code of "aero" of monomer ratio formulation B containing 46 % water, no ionic monomers or oligomers at pH 7,0, showing an oxygen permeability of 100 *Dk* units and having a self-releasing wetting agent is classified by the following code:

aerofilcon B 5C (100) [46 %] w

EXAMPLE 3 Rigid (non-hydrogel) material

A non-hydrogel material whose formulation has the USAN code "Fluorsil", containing both silicone and fluorine, exhibiting an oxygen permeability of 132 *Dk* units and subjected to plasma treatment is classified by the following code:

fluorsilfocon 3 (132) m

Annex A
(informative)

Specification of rigid contact lenses

A.1 General

The contact lens is viewed from the front, as if on the eye. All linear dimensions are in millimetres (mm). Additional specific requirements, such as degree of blending of transitions, edge form and material tint, can be included as "Additional notes" to the specification.

Front surface geometry and thickness are sometimes not included in the specification. In such instances, the manufacturer will need to allocate appropriate values to these parameters. The specification can include a description of the material from which the contact lens is to be fabricated.

A diagram should be included in the specification of a bifocal contact lens.

Examples of the methods of presenting specifications are given in A.2. See Table 1 for the explanation of symbols used in these examples.

A.2 Examples

A.2.1 Example 1: Tri-curve corneal contact lens with fenestration

Figure A.1 provides three examples (bordered) of alternative presentation of the specification of a tri-curve corneal contact lens with fenestration.

	r_0	$⌀_0$ / r_1	$⌀_1$ / r_2	$⌀_T$	F'_L	t_C
	7,60	7,00 / 8,30	8,80 / 12,25	9,20	−6,00	0,10
Specified fenestration	1 fenestration: 0,30 mm diameter, 2 mm from edge					

a) Alternative 1

r_0 : $⌀_0$	7,60 : 7,00
r_1 : $⌀_1$	8,30 : 8,80
r_2 : $⌀_T$	12,25 : 9,20
F'_L	−6,00
$⌀_{a0}$	7,40
t_C	0,10
Specified fenestration	1 fenestration: 0,3 mm diameter, 2 mm from edge

b) Alternative 2

r_0	7,60
F'_L	−6,00
$⌀_T$	9,20
t_C	0,10
r_1 / $⌀_0$	8,30 / 7,00
r_2 / $⌀_1$	12,25 / 8,80
$⌀_{a0}$	7,40
Specified fenestration	1 fenestration:0,3 mm diameter, 2 mm from edge

c) Alternative 3

NOTE In this form of the specification only (see Alternative 3), the radius and width of the peripheral curves can be specified; in this example, as 8,30/0,9 and 12,25/0,2, respectively.

Figure A.1 — Presentations of specification for a tri-curve corneal contact lens with fenestration

A.2.2 Example 2: Tri-curve corneal contact lens with fenestration

Figure A.2 provides two examples (bordered) of alternative presentation of the specification for a corneal contact lens with a toric back surface and a spherical front surface.

r_0	$⌀_0$ / r_1	$⌀_1$ / r_2	$⌀_2$ / r_3	$⌀_T$	F'_L
8,20 7,60	7,50 / 8,70 8,10	8,30 / 9,20 8,60	9,10 / 9,70 9,10	9,50	+0,75

a) Alternative 1

r_0	8,20 / 7,60
F'_L	+0,75
$⌀_T$	9,50
t_C	0,15
r_1	8,70 / 8,10
$⌀_0$	7,50
r_2	9,20 / 8,60
$⌀_1$	8,30
r_3	9,70 / 9,10
$⌀_2$	9,10

b) Alternative 2

NOTE 1 A toroidal surface is specified by the radii of curvature in its two principal meridians, the radius in the flatter meridian being written first, or above the line, and the radius in the steeper meridian second, or below it. The zone diameter is specified for the flatter principal meridian.

NOTE 2 The back vertex power in air is specified along only the flatter principal meridian (in this example, +0,75 along the 8,20 meridian). This is only appropriate for a toric corneal lens with a back toric surface and a spherical front surface.

Figure A.2 — Presentations of specification for a corneal contact lens with a toric back surface and a spherical front surface

A.2.3 Example 3: Peripheral back toric contact lens

Figure A.3 provides two examples (bordered) of alternative presentation of the specification for a peripheral back toric contact lens.

r_0 : $\varnothing_0$	7,80 : 7,00
r_1 : $\varnothing_1$	8,30 : 8,40 8,20
r_2 : $\varnothing_T$	11,00 : 9,00 10,40
F'_L	+15,00
$\varnothing_{a0}$	7,40

a) Alternative 1

r_0	7,80
F'_L	+15,00
$\varnothing_T$	9,00
t_C	0,25
r_1	8,80 / 8,20
$\varnothing_0$	7,00
r_2	11,00 / 10,40
$\varnothing_1$	8,40
$\varnothing_{a0}$	7,40

b) Alternative 2

NOTE The toroidal peripheral surface is specified by the radii of curvature in its two principal meridians. The zone diameter is specified for the flatter principal meridian.

Figure A.3 — Presentations of specification for a peripheral back toric contact lens

A.2.4 Example 4: Front toric corneal contact lens

Figure A.4 provides two examples (bordered) of alternative presentation of the specification for a front toric corneal contact lens.

	r_0	$\varnothing_0$ / r_1	$\varnothing_1$ / r_2	$\varnothing_T$
	7,95	7,60 / 9,20	8,80 / 11,00	9,30
F'_L	−3,50 / −1,50 × 180			
Prescribed prism[a]	1,5$^{\Delta}$ Base 270			
t_C	0,30			

a) Alternative 1

r_0	7,95
F'_L	−3,50 / −1,50 × 180
$\varnothing_T$	9,30
t_C	0,30
r_1 / $\varnothing_0$	9,20 / 7,60
r_2 / $\varnothing_1$	11,00 / 8,80
Prescribed prism[a]	1,5$^{\Delta}$ Base 270

b) Alternative 2

a It is assumed that in wear the prism will locate with its base downwards (i.e. at 270°).

Figure A.4 — Presentations of specification for a front toric corneal contact lens

A.2.5 Example 5: Bi-toric corneal contact lens

Figure A.5 provides two examples (bordered) of alternative presentation of the specification for a bi-toric corneal contact lens.

r_0	$\varnothing_0$ / r_1	$\varnothing_1$ / r_2	$\varnothing_T$	F'_L
8,00 7,40	7,50 / 9,95 8,85	9,00 / 12,75 10,65	9,50	−2,50 −4,00

a) Alternative 1

r_0	8,00 / 7,40
F'_L	−2,50 / −4,00
$\varnothing_T$	9,50
t_C	0,15
r_1	9,95 / 8,85
$\varnothing_0$	7,50
r_2	12,75 / 10,65
$\varnothing_1$	9,00

b) Alternative 2

NOTE The back vertex powers in air are specified along both the flatter and steeper meridians (in this example, −2,50 along the 8,00 meridian and −4,00 along the 7,40 meridian).

Figure A.5 — Presentations of specification for a bi-toric corneal contact lens

A.2.6 Example 6: Solid front surface concentric bifocals

Figure A.6 provides an example (bordered) of the presentation of the specification for a solid front surface concentric bifocals contact lens. Figure A.7 gives the diagram that forms part of the specification.

r_0 : $\varnothing_0$	8,10 : 8,00
r_1 : $\varnothing_1$	8,80 : 8,80
r_2 : $\varnothing_T$	10,75 : 9,20
F'_L of distance portion together with near addition	+2,50 Add +2,00
Diameter of distance position	Central from segment 3,00 mm diameter

Figure A.6 — Presentation of specification for a solid front surface concentric bifocals contact lens

Dimensions in millimetres

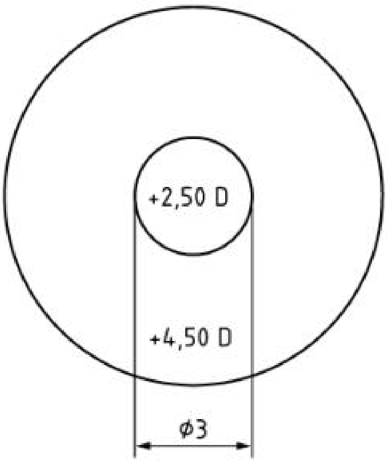


Figure A.7 — Example 6

A.2.7 Example 7: Fused crescent segment bifocals

Figure A.8 provides two examples (bordered) of alternative presentation of the specification for a fused crescent segment bifocals contact lens. Figure A.9 gives the diagram that forms part of the specification.

r_0 : $\varnothing_0$	7,85 : 8,00
r_1 : $\varnothing_1$	8,60 : 9,00
r_2 : $\varnothing_T$	9,70 : 10,00
F'_L of distance portion together with near addition	+1,50 Add +2,00
Prescribed prism	1,5$^\Delta$ Base 270
Segment size and position	Segment 7,5 mm wide, height 3,75 mm
Specified truncation	Truncate 0,75 mm along 5 inferior

a) Alternative 1

r_0	7,85
F'_L	+1,50
$\varnothing_T$	10,00
t_C	0,30
r_1 / $\varnothing_0$	8,60 / 8,00
r_2 / $\varnothing_1$	9,70 / 9,00
Near addition; Prescribed prism	Add +2,00 1,5$^\Delta$ Base 270
Segment size and position	Segment 7,5 mm wide, height 3,75 mm
Specified truncation	Truncate 0,75 mm along 5 inferior

b) Alternative 2

Figure A.8 — Presentations of specification for a fused crescent segment bifocal contact lens

Dimensions in millimetres

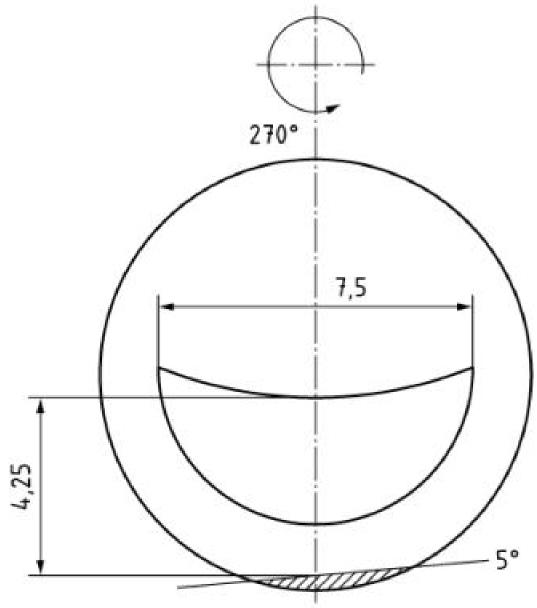


Figure A.9 — Example 7

A.2.8 Example 8: Preformed scleral contact lens

Figure A.10 provides an example (bordered) of the presentation of the specification for a preformed scleral contact lens.

r_0	$⌀_0$ / r_1	$⌀_1$ / r_2 [a]	$⌀_T$ [b]	[c]	d[d]	F'_L
8,50	12,50 / 11,00	14,00 / 13,00	23,00 × 21,00	L30	*d*1,00 in	−8,00

a Back scleral radius.

b Total diameter: long and short axes.

c Orientation of long axis in standard axis notation.

d Displacement of optic (in this example, 1,00 mm towards the nose).

Figure A.10 — Presentation of specification for a preformed scleral contact lens

A.2.9 Example 9: Impression scleral contact lens

Figure A.11 provides an example (bordered) of the presentation of the specification for an impression scleral contact lens.

	r_0	$\varnothing_0$ / r_1	$\varnothing_1$
	8,50	8,75 / 10,00	10,50
Vertex clearance	Vertex clearance 0,25		
Specification of back scleral size	Back scleral size as indicated on cast.		
F'_L	−1,00		

Figure A.11 — Presentation of specification for an impression scleral contact lens

Annex B
(informative)

Specification of soft contact lenses

B.1 General

Hydrogel contact lenses are at times available in a limited range of parameters. The range of parameters corresponds to a standard contact lens design. The specifications of a hydrogel contact lens should give the contact lens type and the relevant dimensions necessary to uniquely identify the contact lens. In the specification of a non-standard contact lens design, all the parameters necessary to define that contact lens should be specified.

As with rigid contact lenses, the soft contact lens is viewed from the front, as if on the eye. All linear dimensions are given in millimetres (mm). Additional specific requirements, such as degree of blending of transitions, edge form and material tint, are included as "Additional notes".

Front surface geometry and thickness are seldom included in the specification. In such instances, the manufacturer will need to allocate appropriate values to these parameters. It is assumed that during wear any prism will locate with its base downwards.

Examples of the method of presenting specifications are given in B.2. See Table 1 for the explanation of symbols used in these examples.

B.2 Examples

B.2.1 Example 1: Bi-curve hydrogel contact lens

Figure B.1 provides two examples (bordered) of alternative presentation of the specification for a bi-curve hydrogel contact lens.

r_0	$\varnothing_0$ / r_1	$\varnothing_T$	F'_L
8,80	12,00 / 9,50	14,00	−4,00

a) Alternative 1

r_0 : $\varnothing_0$	8,80 : 12,00
r_1 : $\varnothing_T$	9,50 : 14,00
F'_L	−4,00
$\varnothing_{a0}$	8,00
t_C	0,06

b) Alternative 2

Figure B.1 — Presentations of specification for a bi-curve hydrogel contact lens

B.2.2 Example 2: Front toric hydrogel contact lens

Figure B.2 provides two examples (bordered) of alternative presentation of the specification for a front toric hydrogel contact lens.

	r_0	$\varnothing_0$ / r_1	$\varnothing_T$
	8,70	12,50 / 9,70	14,50
F_L	−3,50 / −1,50 × 180		
Prescribed prism	1,5$^\Delta$ Base 270		
t_C	0,30		

a) Alternative 1

r_0 : $\varnothing_0$	8,70 : 12,50
r_1 : $\varnothing_T$	9,70 : 14,50
t_C	0,30
F_L	−3,50 / −1,50 × 180
Prescribed prism	1,5 $^\Delta$ Base 270

b) Alternative 2

Figure B.2 — Presentations of specification for a front toric hydrogel contact lens

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Alphabetical index of terms

A

B

ICS 01.040.11; 11.040.70

Price group A