INTERNATIONAL STANDARD

ISO 18369-1

First edition
2006-08-15

Ophthalmic optics — Contact lenses —

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

Optique ophtalmique — Lentilles de contact —

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

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18369-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition cancels and replaces ISO 8320-1:2003, ISO 8320-2:2001 and ISO 11539:1999, which have been technically revised. Furthermore, together with ISO 18369-2, it cancels and replaces ISO 8321-1:2002 and ISO 8321-2:2000, which have been technically revised.

ISO 18369 consists of the following parts, under the general title *Ophthalmic optics — Contact lenses*:

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

— *Part 2: Tolerances*

— *Part 3: Measurement methods*

— *Part 4: Physicochemical properties of contact lens materials*

Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the preocular tear film. This part of ISO 18369 covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Soft contact lenses are easily deformable and require support for proper shape. A very large subset of soft contact lenses consists of transparent hydrogels containing water in concentrations greater than 10 %. Soft contact lenses can also be made of non-hydrogel materials, e.g. flexible polysiloxanes (silicone elastomers).

The ISO 18369 series is applicable to determining allowable tolerances of parameters and properties important for proper functioning of contact lenses as optical devices. The ISO 18369 series includes tolerances for single vision contact lenses, bifocal lenses, lenses that alter the flux density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling, and/or opaque tints), and lenses that significantly attenuate ultraviolet radiation (UVR absorbing lenses). The ISO 18369 series covers contact lenses designed with spherical, toric, and aspheric surfaces, and recommended methods for the specification of contact lenses.

The vocabulary portion (2.1) of this part of ISO 18369 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 fitted. 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 as an aid to 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.

Figure 1 gives a schema of the classification and provides examples. It does not take into account all possible characteristics (hence resulting qualifiers) used in contact lens designation. Combinations of more than one qualifier are often used in contact lens designation.

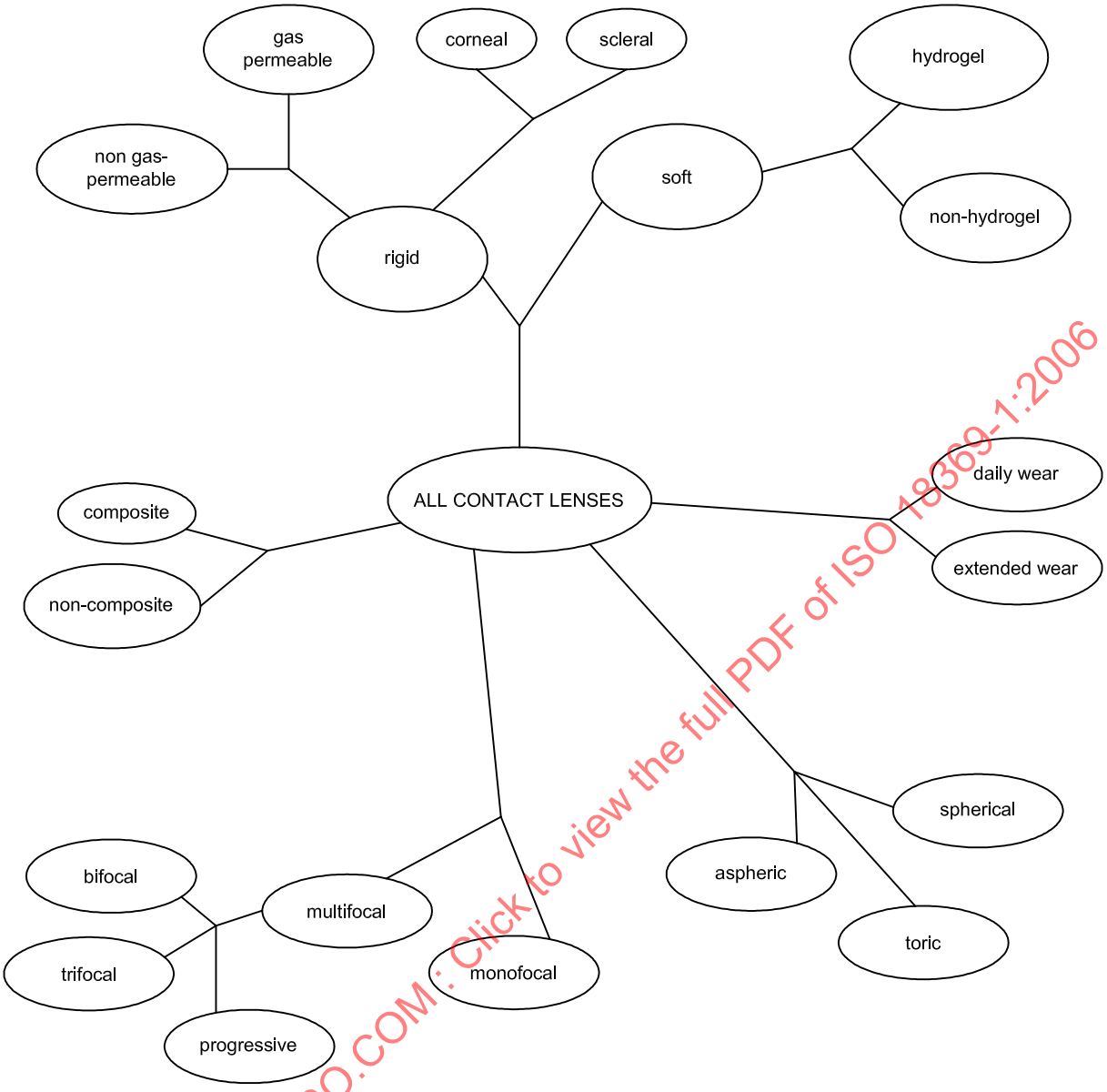


Figure 1 — Classification of contact lenses according to various characteristics leads to various qualifiers used in their designation

Ophthalmic optics — Contact lenses —

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

1 Scope

This part of ISO 18369 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 part of ISO 18369 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 Terms, definitions and symbols

2.1 Terms and definitions

2.1.1 Basic terms

2.1.1.1
contact lens
any ophthalmic lens designed to be worn on the front surface of the eye

NOTE This term includes contact lenses of plano power.

2.1.1.2
corneal contact lens
contact lens having a total diameter less than the visible iris diameter and designed to be worn in its entirety on the cornea

2.1.1.3
scleral contact lens
contact lens designed to be worn in front of the cornea and on the adjacent portion of the surrounding bulbar conjunctiva

NOTE See 2.1.5 for specific terms concerning scleral contact lenses.

2.1.1.4
lenticular contact lens
contact lens having a front optic zone made smaller than the total diameter

NOTE This construction is conventionally used to reduce the centre thickness of a positive power contact lens or reduce the edge thickness of a negative power contact lens.

2.1.1.5
contact shell
contact lens not designed to correct vision

2.1.1.6
scleral shell
rigid contact shell with a scleral zone

NOTE See 2.1.5 for specific terms concerning scleral shells.

2.1.1.7
rigid contact lens
hard contact lens
contact lens which, in its final form and under normal conditions, retains its form without support

2.1.1.8
rigid gas-permeable contact lens
RGP contact lens
hard gas-permeable contact lens (deprecated)
rigid contact lens which contains one or more components in the contact lens polymer in sufficient concentration to permit oxygen transmission through the contact lens

2.1.1.9
soft contact lens
contact lens which requires support to maintain its form

2.1.1.10
hydrogel contact lens
hydrophilic contact lens (deprecated)
contact lens made of water-absorbing material having equilibrium water content greater than or equal to 10 % in standard saline solution at 20 °C

NOTE Standard saline solution is prepared as specified in ISO 18369-3.

2.1.1.11
composite contact lens
contact lens composed of two or more different materials

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

2.1.1.12
surface treated contact lens
contact lens whose surfaces have been modified to make the surface characteristics different to those of the bulk material

2.1.1.13
bifocal contact lens
multifocal contact lens having two optic zones, usually for distance and near-vision correction

NOTE See 2.1.4 for specific terms concerning bifocal contact lenses.

2.1.1.14
multifocal contact lens
contact lens designed to provide two or more zones of different corrective powers

NOTE See 2.1.4 for specific terms concerning multifocal contact lenses.

2.1.1.15
progressive power contact lens
varifocal power contact lens
contact lens 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 See 2.1.4 for specific terms concerning progressive power contact lenses.

2.1.1.16
contact lens accessory
article intended specifically by its manufacturer to be used with a contact lens to enable the lens to be used in accordance with its intended purpose

NOTE This term includes all devices recommended for use in the hygienic management of contact lenses, for hydrating contact lenses, or alleviating discomfort of contact lens wear by physical means.

2.1.1.17
contact lens care product
contact lens accessory intended for use in maintaining the safety and performance of a contact lens after opening and removal of the lens from its primary container

NOTE See 2.1.9 and 2.1.11 for specific terms concerning contact lens care products and the hygienic management of contact lenses.

2.1.1.18
other accessory for contact lenses
item used for handling contact lenses or as a part of a contact lens care regimen excluding contact lens care products

EXAMPLE Suction cup used to aid in the insertion of a contact lens onto or removal from the surface of the eye.

NOTE This definition does not include the primary packaging (e.g. vials, blister packs or mailers) intended by the manufacturer to be used only for shipment of the contact lenses.

2.1.1.19
suction cup
hand-held device designed with a small concave flexible tip intended to aid the insertion of a contact lens onto or removal from the eye by means of suction

NOTE A suction cup is designed primarily for use with rigid corneal contact lenses.

2.1.1.20
contact lens container
storage container
contact lens case
storage case
container in which contact lenses are stored either dry or in a suitable solution by the user after removal from the primary container or the eye

2.1.2 Contact lens parameters and design

2.1.2.1 General terms

2.1.2.1.1
front vertex power
F_v
reciprocal of the paraxial front vertex focal length

[ISO 13666:1998]

NOTE The front vertex power is expressed in dioptres.

2.1.2.1.2
back vertex power
F'_v
reciprocal of the paraxial back vertex focal length

[ISO 13666:1998]

NOTE The back vertex power is expressed in dioptres.

2.1.2.1.3
positive power contact lens
plus-power contact lens
contact lens which causes parallel incident light (incident on a single optic zone) to converge to a real focus

2.1.2.1.4
negative power contact lens
minus-power contact lens
contact lens which causes parallel light (incident on a single optic zone) to diverge from a virtual focus

2.1.2.1.5
plano contact lens
afocal contact lens
contact lens whose back vertex power is zero

2.1.2.1.6
liquid lens
fluid lens
tear lens
lacrimal lens
refractive element formed by the liquid between the back optic zone of the contact lens and the cornea

NOTE The liquid element of this lens is typically composed of tear fluid.

2.1.2.1.7
optic zone
that part of a contact lens which has a prescribed optical effect

NOTE 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, the term may be qualified by either the prefix “distance” or “near”. In the case of a concentric multifocal contact lens, the term may be qualified by the prefix “central” or “peripheral”.

2.1.2.1.8
peripheral zone
region with no prescribed refractive effect, of specified dimensions, surrounding the optic zone(s)

NOTE There can be more than one peripheral zone.

2.1.2.1.9
displacement of optic
d
⟨non-scleral lenses⟩ displacement of the optic zone relative to the lens periphery

NOTE This term does not apply to scleral contact lenses.

2.1.2.1.10
geometric centre
C
centre of the circle containing the contact lens edge

NOTE For a scleral contact lens, the geometric centre is taken as the centre of the optic zone. For a truncated contact lens, the geometric centre is taken as the centre of the circle that contains the circular portion of the edge.

2.1.2.1.11
optical decentration
positioning of the optical centre at a point other than the geometric centre of the optic zone or central optic zone

2.1.2.1.12
contact lens axis
line passing through the geometric centre, perpendicular to a plane containing the edge of a contact lens

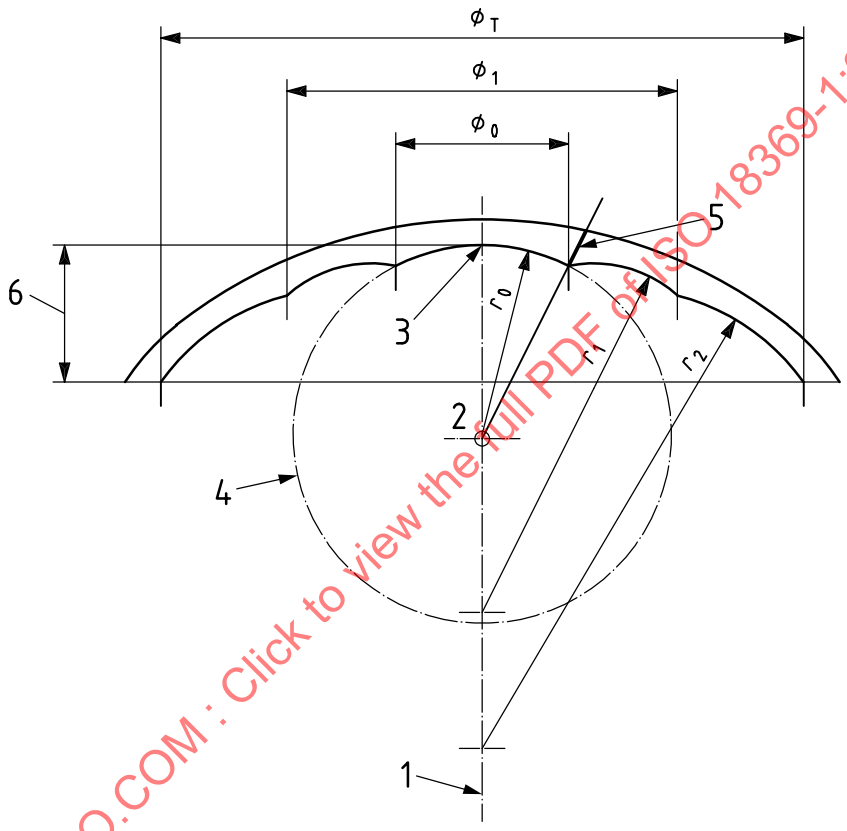
See Figure 2.

2.1.2.1.13
back vertex
point on the posterior contact lens surface lying on the contact lens axis

See Figure 2.

2.1.2.1.14
vertex sphere
imaginary spherical surface touching the back vertex

NOTE The radius of curvature of the vertex sphere is the same as the steepest back optic zone radius, back central optic radius, or back vertex radius of an aspheric lens (see Figure 2).



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

2.1.2.1.15
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

2.1.2.1.15.1
overall posterior sagitta
distance along the contact lens axis from the back vertex to a plane containing the contact lens edge

See Figure 2.

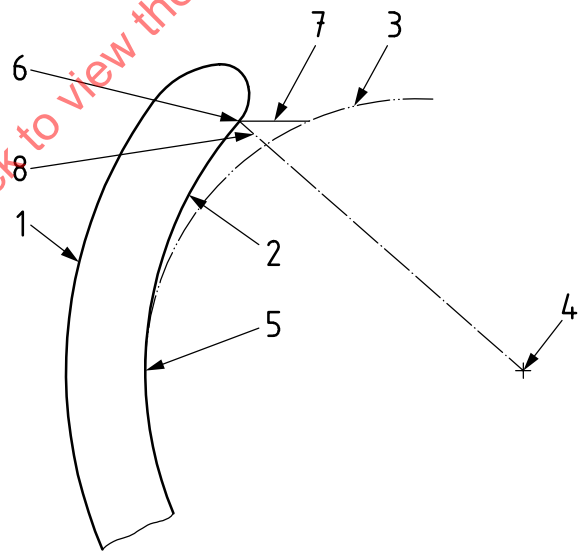
2.1.2.1.16
edge
that part of a contact lens which is contiguous with the front and back surfaces

2.1.2.1.17
edge form
edge profile
profile of the edge in a plane containing the contact lens axis

2.1.2.1.18
bevel
narrow back peripheral zone, of a single spherical or aspherical curvature, adjacent to the edge of a contact lens

2.1.2.1.19
radial lift
l_R
distance between a specified point on the back surface of a contact lens and the vertex sphere measured along a radius of curvature of the latter

See Figure 3.



Key
1 front surface of contact lens
2 back surface of contact lens
3 vertex sphere
4 centre of vertex sphere
5 junction
6 specified point on the back surface of the contact lens; for radial and axial edge lift, specified point at the edge of the contact lens
7 axial lift, l_A
8 radial lift, l_R

Figure 3 — The difference between radial and axial lift

2.1.2.1.20
radial edge lift
l_{ER}
distance between a point on the back surface of a contact lens at the edge and the vertex sphere measured along the radius of curvature of the latter

See Figure 3.

NOTE This is often a value computed by the manufacturer and may be altered by the edging process.

2.1.2.1.21
axial lift
l_A
distance between a specified point on the back surface and the vertex sphere measured parallel to the contact lens axis

See Figure 3.

2.1.2.1.22
axial edge lift
l_{EA}
distance between a point on the back of a contact lens at the edge and the vertex sphere, measured parallel to the contact lens axis

See Figure 3.

NOTE This is often a value computed by the manufacturer and may be altered by the edging process.

2.1.2.1.23
spherical surface
⟨non-aspheric⟩ surface described by rotating a circle about a line containing its centre

2.1.2.1.24
spherical surface
⟨non-toric⟩ surface having the same radius of curvature for meridians in all directions

2.1.2.1.25
sagittal radius of curvature
radius of curvature in the sagittal plane at a specified off-axis point on the surface

NOTE 1 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 The sagittal plane contains the normal to the surface at the specified point, but does not contain the axis of rotation, being perpendicular to the tangential plane.

2.1.2.1.26
tangential radius of curvature
radius of curvature in the tangential plane at a specified off-axis point on a surface

NOTE The tangential plane contains both the normal to the surface at the point specified and the axis of rotation.

2.1.2.1.27
bi-curve contact lens
contact lens whose back surface is composed of two intersecting spherical zones

2.1.2.1.28
tri-curve contact lens
contact lens whose back surface is composed of three intersecting coaxial spherical zones

2.1.2.1.29
multi-curve contact lens
contact lens with a back surface that is composed of more than three intersecting spherical zones

2.1.2.1.30
aspheric contact lens
contact lens with its front or back optic zone of aspheric form

NOTE See 2.1.3 for specific terms concerning aspheric contact lenses.

2.1.2.1.31
toric contact lens
contact lens with front and/or back optic zone of toroidal form

2.1.2.1.32
bi-toric contact lens
contact lens having both front and back optic zones of toroidal form

2.1.2.1.33
toroidal zone
zone having a surface with its maximum and minimum radii of curvature perpendicular to each other

2.1.2.1.34
toric periphery contact lens
contact lens with one or more back peripheral zones of toroidal form that surround a spherical back optic zone

2.1.2.1.35
junction
intersection of two adjacent zones

NOTE This applies to both back and front surfaces.

2.1.2.1.36
tangential junction
junction where the curvatures of adjacent zones have a common tangent

See Figure 4.

2.1.2.1.37
transition
transition zone
junction which has been modified to smooth the change between adjacent curvatures

See Figure 5.

2.1.2.1.38
blend
polished, smoothed junction or transition zone between two different adjacent surface curvatures, typically applied at the junction (transition) between posterior zones

cf. **transition** (2.1.2.1.37)

NOTE This does not constitute the formation of an aspheric zone.

2.1.2.1.39
ballast
rotationally asymmetrical distribution of thickness for the purpose of effecting rotational orientation of a contact lens on the eye

NOTE The most common method of achieving ballast in contact lenses is with the use of base-down vertical prism.

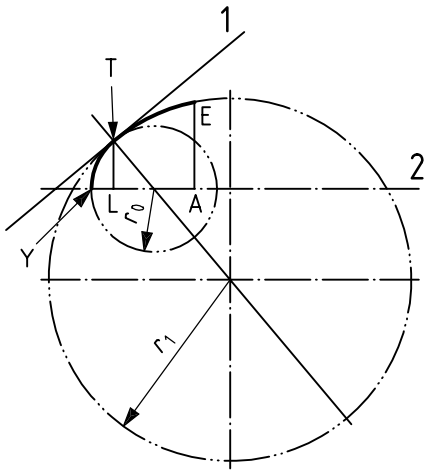
2.1.2.1.40
prism ballast
vertical prism used to create a wedge design that will help stabilize the rotation and orientation of a contact lens on the eye

NOTE 1 A vertical prism may also be used to correct a vertical hyperphoria or hypertropia.

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

2.1.2.1.41
wedge design
rotationally asymmetric distribution of thickness to effect the required rotational orientation of a contact lens on the eye, or to improve the centration of a high-riding lens

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



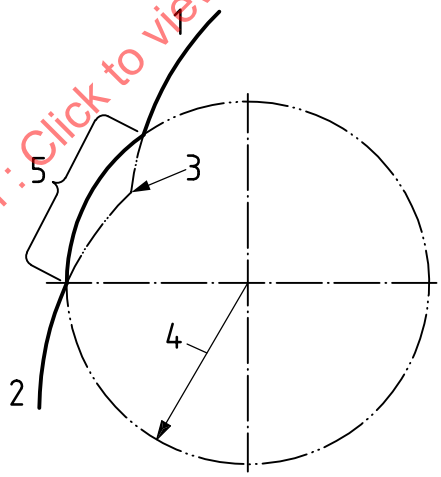
Key

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 4 — Example of a tangential junction



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 5 — Example of a transition on the back surface of a contact lens

2.1.2.1.42
peripheral thinning
slab-off
thinning, towards the edge, of the front periphery of the contact lens, in one or more discrete areas

NOTE This is normally applied to achieve contact lens rotational stabilization. It is different from both ballast and a lenticular contact lens construction.

2.1.2.1.43
truncation
altered portion of the edge, after a contact lens has been truncated

2.1.2.1.44
fenestration
specified hole which passes through a contact lens

2.1.2.1.45
carrier
that part of a plus or minus lenticular contact lens peripheral to the front optic zone(s)

NOTE The carrier may be negative, positive or parallel in construction, but it is radially symmetrical.

2.1.2.1.46
negative carrier
minus carrier
carrier having an edge thickness that is greater than the junction thickness

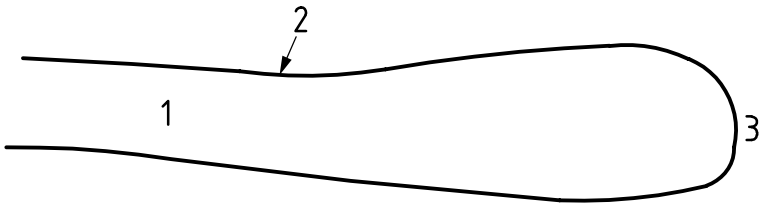
See Figure 6 a).

2.1.2.1.47
parallel carrier
plano carrier
carrier having an edge thickness and junction thickness that are equal

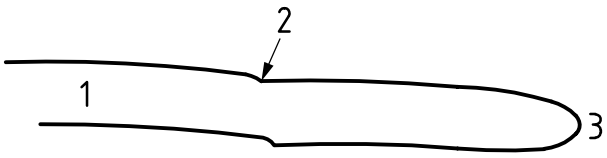
See Figure 6 b).

2.1.2.1.48
positive carrier
plus carrier
carrier having an edge thickness that is less than the junction thickness

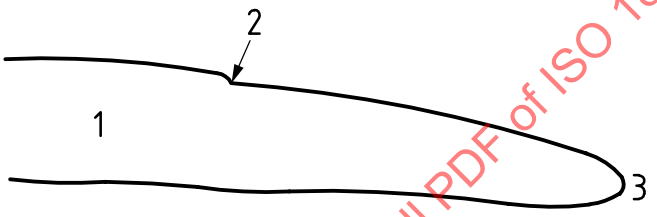
See Figure 6 c).



a) Negative carrier



b) Parallel carrier



c) Positive carrier

Key

1 optic zone
2 junction
3 edge

Figure 6 — Different types of carrier

2.1.2.2 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 larger from the lens centre to the lens edge. See Figure 2.

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, a mathematical equation or expression may be used to describe the curvature of the zone.

2.1.2.2.1
back optic zone radius
base curve radius

r_0

radius of curvature of the back optic zone of a surface with a single refractive element

NOTE 1 On a toroidal zone there will be two radius values.

NOTE 2 The term “base curve” used in a contact lens context must not be confused with the same term when used in a spectacle lens context (see ISO 13666:1998).

2.1.2.2.2
back central optic zone radius

r_0

radius of curvature of the back central optic zone of a multifocal contact lens

2.1.2.2.3
back peripheral optic zone radius
$r_1, r_2, \ldots$
radius of curvature of a back peripheral optic zone of a multifocal contact lens

2.1.2.2.4
back peripheral radius
$r_1, r_2, \ldots$
radius of curvature of the back peripheral zone

NOTE This term may be preceded by first, second, third, etc.

2.1.2.2.5
front optic zone radius
r_{a0}
radius of curvature of the front optic zone of a surface with a single refractive element

2.1.2.2.6
front central optic zone radius
r_{a0}
radius of curvature of the front central optic zone of a multifocal contact lens

2.1.2.2.7
front peripheral optic zone radius
$r_{a1}, r_{a2}, \ldots$
radius of curvature of a front peripheral optic zone of a multifocal contact lens

2.1.2.2.8
front peripheral radius
$r_{a1}, r_{a2}, \ldots$
radius of curvature of a front peripheral zone

NOTE This term may be preceded by first, second, third, etc.

2.1.2.3 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, 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 ($Ø_0$). See Figure 2. On the anterior surface the number is always preceded by the letter "a", for example ($Ø_{a0}$).

2.1.2.3.1
total diameter
overall diameter
$Ø_T$
maximum external dimension of the finished contact lens or shell

2.1.2.3.2
optic zone diameter
maximum diameter of the specified optic zone

NOTE The optic zone of a toric periphery contact lens is usually elliptical in shape.

2.1.2.3.3
back optic zone diameter
$Ø_0$
diameter of the back optic zone on a surface with a single optical component

NOTE On a toroidal zone there will be two values.

2.1.2.3.4
back central optic zone diameter
$Ø_0$
diameter of the posterior central optic zone of a concentric multifocal contact lens

2.1.2.3.5
back peripheral optic zone diameter
$Ø_1$, $Ø_2$, ...
diameter of a posterior peripheral optic zone of a concentric multifocal contact lens

2.1.2.3.6
back peripheral zone diameter
$Ø_1$, $Ø_2$, ...
diameter of a back peripheral zone

NOTE This term may be preceded by first, second, third, etc.

2.1.2.3.7
front optic zone diameter
$Ø_{a0}$
diameter of the front optic zone on a surface with a single refractive element

2.1.2.3.8
front central optic zone diameter
$Ø_{a0}$
diameter of the anterior central optic zone of a multifocal contact lens

2.1.2.3.9
front peripheral optic zone diameter
$Ø_{a1}$, $Ø_{a2}$, ...
diameter of an anterior peripheral optic zone of a multifocal contact lens

2.1.2.3.10
front peripheral zone diameter
$Ø_{a1}$, $Ø_{a2}$, ...
diameter of a front peripheral zone

NOTE This term may be preceded by first, second, third, etc.

2.1.2.4 Thickness

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

2.1.2.4.1
geometric centre thickness
t_C
thickness of the contact lens or shell at its geometric centre

2.1.2.4.2
optical centre thickness
t_O
thickness of the contact lens at its optical centre

NOTE This symbol is used only if the optical centre does not coincide with the geometric centre.

2.1.2.4.3
harmonic mean thickness

t_{HM}
thickness of a rotationally symmetric contact lens calculated from a series of (h + 1) radial thickness 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

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

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;

$t_{0 \text{ to } h}$ 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 The number of zones is equal to h + 1.

2.1.2.4.4
axial thickness

t_A
thickness of a contact lens along a line parallel to the lens axis, at a specified position

2.1.2.4.5
axial edge thickness

t_{EA}
axial thickness at a defined distance from the edge

See Figure 7.

2.1.2.4.6
radial thickness

t_R
thickness of a contact lens along a line which passes through the centre of the vertex sphere and intersects the lens at a specified point

2.1.2.4.7
radial edge thickness

$t_{ER(x)}$
thickness of the lens measured normal to the front surface at a specified distance x from the edge

See Figure 7.

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

2.1.2.4.8
carrier junction thickness

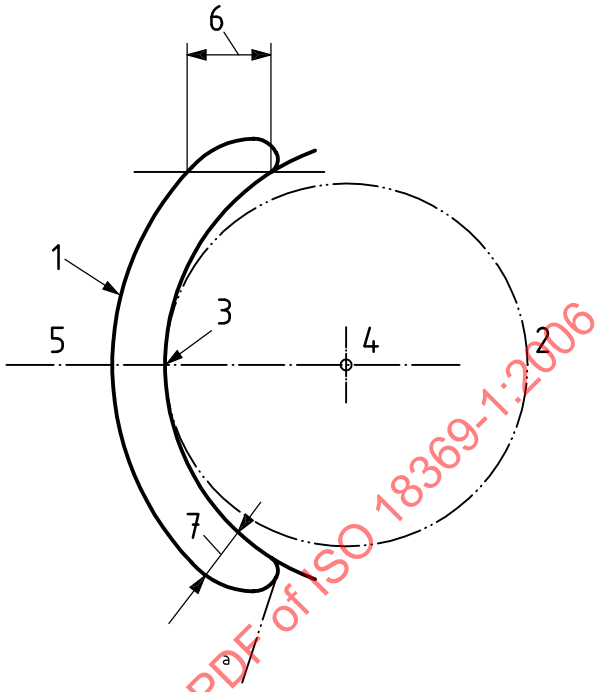
t_{CJ}
radial thickness at the carrier junction

NOTE To indicate the zone concerned, the subscript is followed by the number of the inner zone.

2.1.2.4.9
peripheral junction thickness

t_{PJ}
radial thickness of the contact lens measured at a specified junction

NOTE The subscript may be followed by a number to indicate the junction concerned. See Figure 2.



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 7 — The difference between radial and axial edge thickness

2.1.3 Aspheric contact lenses

2.1.3.1
aspheric zone
zone with surface having a form generated by the rotating of a curve of continuously varying radius about the contact lens axis

2.1.3.2
bi-aspheric contact lens
contact lens having both front and back optic zones of aspheric form

2.1.3.3
aspheric periphery contact lens
contact lens with one or more back peripheral aspheric zones and a spherical back optic zone

2.1.3.4
aspheric bi-curve contact lens
contact lens whose back surface is composed of two intersecting coaxial aspheric zones

2.1.3.5
aspheric tri-curve contact lens
contact lens whose back surface is composed of three intersecting coaxial aspheric zones

2.1.3.6
aspheric multi-curve contact lens
contact lens whose back surface is composed of more than three intersecting coaxial aspheric zones

2.1.3.7
apical radius of curvature
radius of curvature at the apex of an aspheric surface having a sagittal depth that is approximately equal to the sagittal depth of the aspheric surface in a small area surrounding its apex

2.1.4 Bifocal and multifocal contact lenses

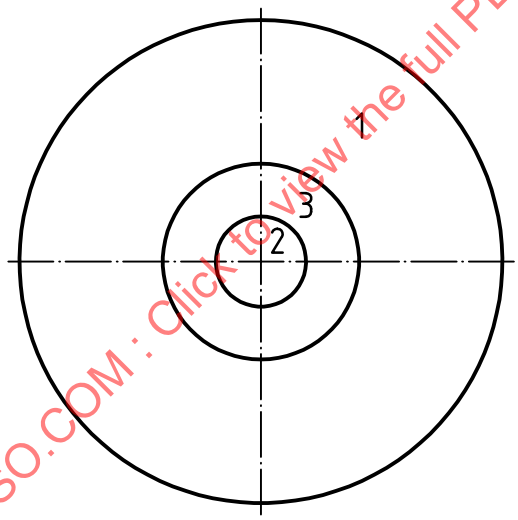
2.1.4.1
addition power
addition
add
difference between the vertex power of the near portion and the vertex power of the distance portion

2.1.4.2
progressive optical zone
aspheric zone designed to provide a continuous change of surface power

2.1.4.3
concentric bifocal contact lens
contact lens having two optic zones of different power, each having coincident geometric centres

See Figure 8.

NOTE This excludes diffractive bifocal contact lenses.



Key
1 carrier
2 central optic zone
3 peripheral optic zone

Figure 8 — The surface of a solid, concentric bifocal contact lens

2.1.4.4
concentric multifocal contact lens
contact lens having two or more optic zones of different power, each having coincident geometric centres

2.1.4.5
central optic zone
innermost optic zone of a concentric bifocal or other multifocal contact lens

2.1.4.6
peripheral optic zone
optic zone surrounding the central optic zone of a concentric multifocal contact lens

NOTE There can be more than one peripheral optic zone.

2.1.4.7
centre distance contact lens
CD contact lens
multifocal or progressive power contact lens where the maximum minus (or minimum plus) power is found in the central optic zone of the lens

2.1.4.8
centre near contact lens
CN contact lens
multifocal or progressive power contact lens where the maximum plus (or minimum minus) power is found in the central optic zone of the lens

2.1.4.9
solid bifocal contact lens
one-piece bifocal contact lens
non-composite bifocal contact lens
bifocal contact lens formed from only one material

2.1.4.10
solid multifocal contact lens
one-piece multifocal contact lens
non-composite multifocal contact lens
multifocal contact lens formed from only one material

2.1.4.11
fused segment contact lens
multifocal contact lens made from materials of different refractive indices

2.1.4.12
segment height
vertical distance of the segment extreme point above the horizontal tangent to the contact lens periphery at its lowest point

See Figure 9.

NOTE This dimension does not apply to concentric and diffractive multifocal contact lenses.

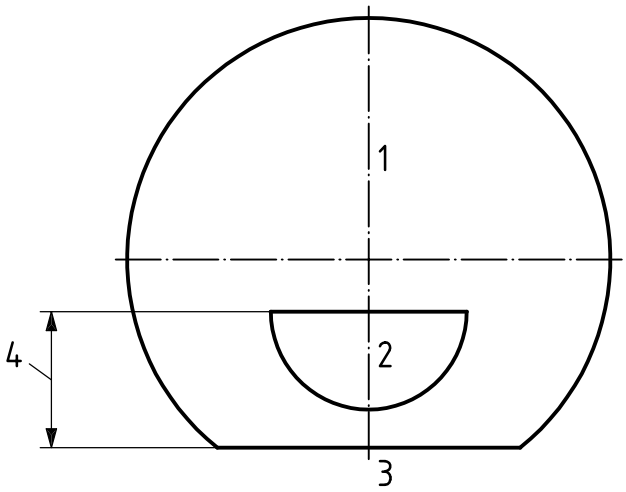
2.1.4.13
diffractive bifocal contact lens
simultaneous image bifocal contact lens which utilizes diffraction as well as refraction to focus retinal images of distant and near objects

2.1.4.14
simultaneous image multifocal contact lens
simultaneous vision contact lens (deprecated)
bifocal or multifocal contact lens whose performance does not primarily depend on lens movement for different viewing distances

NOTE It is intended that two or more zones continually cover the pupil area.

2.1.4.15
alternating image bifocal contact lens
translating bifocal contact lens
alternating vision bifocal contact lens (deprecated)
translating vision bifocal contact lens (deprecated)
bifocal contact lens whose performance depends primarily on movement of the contact lens to position either the near or the distance portion in front of the pupil

See Figure 9.



Key

1 distance optic zone
2 near optic zone
3 truncation
4 segment height

Figure 9 — Example of an alternating image bifocal contact lens

2.1.5 Scleral contact lenses and shells

2.1.5.1
impression scleral contact lens
scleral contact lens, the back surface of which has been produced by moulding from a cast of the eye of the wearer

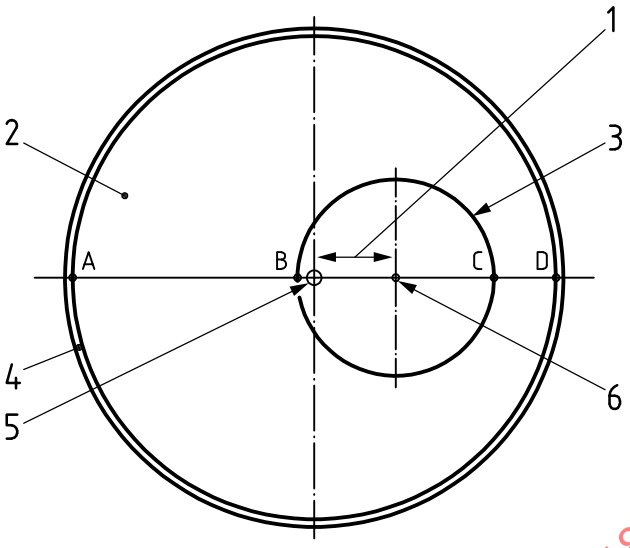
2.1.5.2
impression scleral shell
scleral shell, the back surface of which has been produced by moulding from a cast of the eye of the wearer

2.1.5.3
impression tray
type of shell used to hold impression material in contact with the eye

2.1.5.4
preformed scleral contact lens
scleral contact lens, not an impression lens, the back surface of which is of a specified form

2.1.5.5
back scleral size
maximum internal dimension of the back scleral surface before the sharp edges have been rounded

See Figure 10.



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
7 back scleral size = AD

Figure 10 — Posterior view of a scleral contact lens or shell

2.1.5.6
displacement of optic
d

⟨scleral lenses⟩ half of the difference between the maximum and minimum scleral chords

See Figure 10.

NOTE This assumes a round contact lens with a round optic zone.

2.1.5.7
primary optic diameter
diameter of the optic zone before any transition is added

See Figure 10.

NOTE In a case where the optic zone is not circular, the longest chord passing through the geometric centre is used.

2.1.5.8
primary optic plane
plane perpendicular to the lens axis and containing the primary optic diameter

2.1.5.9
primary sagitta
distance along the lens axis from the back vertex of the optic zone to the primary optic plane

2.1.5.10
scleral chord
distance in a specified meridian from the optic-scleral junction to the junction of the back scleral surface with the edge

NOTE See Figure 10, where distances AB and CD are examples of scleral chords.

2.1.5.11
scleral thickness
thickness of the scleral zone measured normal to the front scleral surface at any specified point

2.1.5.12
scleral zone
zone of a scleral lens (or shell) designed to lie in front of the sclera

2.1.5.13
channel
specified groove in a scleral contact lens or shell

2.1.6 Contact lens material properties

2.1.6.1
dimensional stability
degree to which a contact lens maintains its original dimensions over time

2.1.6.2
gas permeability
P
gas flux, j, under specified conditions through contact lens material of unit thickness when subjected to unit pressure difference

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

where

V is the volume, expressed in centimetres cubed, of gas;

t is the axial thickness, expressed in centimetres, of the contact lens material;

A is the surface area, expressed in centimetres squared;

Δp is the difference in pressure, expressed in hectopascals;

$t_{\Delta p}$ is the time, expressed in seconds, during which the contact lens material is subjected to the difference in pressure.

2.1.6.3
oxygen permeability
Dk
oxygen flux, j, under specified conditions through contact lens material of unit thickness when subjected to unit pressure difference

NOTE 1 This is the most commonly used gas permeability for contact lens materials.

NOTE 2 Oxygen permeability, Dk, is expressed in units of 10^{-11} (cm^2/s) [ml O_2/(ml · hPa)], or equivalently, 10^{-11} (cm^3 O_2 · cm)/(cm^2 · s · hPa). For simplicity, the units for Dk are referred to as "Dk units".

NOTE 3 For Dk units in terms of mmHg instead of hPa (760 mmHg = 1 013,25 hPa) multiply the numerical value obtained using hPa by 1,333 22.

NOTE 4 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.

2.1.6.4
oxygen flux
j

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

NOTE A convenient unit of oxygen flux for contact lens material is $\mu l/(cm^2 \cdot s)$.

2.1.6.5
oxygen transmissibility
Dk/t

oxygen permeability, *Dk*, divided by the thickness, *t*, in centimetres, of the measured sample under specified conditions

NOTE 1 Oxygen transmissibility, *Dk/t*, is expressed in units of 10^{-9} (cm/s) [ml O_2/(ml · hPa)], or equivalently, 10^{-9} (cm^3 O_2)/(cm^2 · s · hPa). For simplicity, the units for *Dk/t* are referred to as "*Dk/t* units".

NOTE 2 For *Dk/t* units in terms of mmHg instead of hPa (760 mmHg = 1 013,25 hPa) multiply the numerical value obtained using hPa by 1,333 22.

NOTE 3 Unlike permeability, oxygen transmissibility depends upon the thickness and, therefore, the cross-sectional shape or design of a contact lens or material sample.

2.1.6.6
water content

amount of water (expressed as a percentage by mass fraction) present in a hydrated contact lens under specified conditions of temperature

NOTE 1 The term is most often used when dealing with hydrogel materials.

NOTE 2 Water content influences many of the physical properties of hydrogel materials as well as various parameters of the finished contact lens.

2.1.6.6.1
low water content contact lens

hydrogel contact lens having a water content, w_{water}, that is greater than or equal to 10 % and less than 50 % [10 % $\leqslant w_{water} <$ 50 %]

2.1.6.6.2
mid water content contact lens

hydrogel contact lens having a water content, w_{water}, that is greater than or equal to 50 % and less than or equal to 65 % [50 % $\leqslant w_{water} \leqslant$ 65 %]

2.1.6.6.3
high water content contact lens

hydrogel contact lens having a water content that is greater than 65 % [$w_{water} >$ 65 %]

2.1.6.7
ionic

containing greater than 1 % (expressed as mole fraction) monomers which are ionic at pH 7,2

2.1.6.8
non-ionic

containing less than or equal to 1 % (expressed as mole fraction) monomers which are ionic at pH 7,2

2.1.6.9
spectral transmittance
τ_λ
ratio of the spectral radiant flux transmitted by the contact lens to the incident spectral flux at any specified wavelength (λ)

[ISO 13666:1998]

2.1.6.10
luminous transmittance
τ_V
ratio of the luminous flux transmitted by the lens to the incident luminous flux

[ISO 13666:1998]

NOTE 1 In order to calculate this, it is necessary to know the spectral luminous efficiency.

NOTE 2 It is necessary to specify the light source (e.g. D65 or illuminant A).

NOTE 3 An average transmittance summed over the wavelengths of a visible spectrum is given by the formula

$$\tau_V = 1/400 \int_{380\ nm}^{780\ nm} \tau(\lambda)\,d\lambda$$

2.1.6.11
UV-absorbing contact lens
UV-blocking contact lens
UV-filtering contact lens
contact lens having a specification in compliance with either Class 1 or Class 2

NOTE See 2.1.6.11.3 and 2.1.6.11.4.

2.1.6.11.1
UVA
radiation of wavelengths between 316 nm and 380 nm

2.1.6.11.2
UVB
radiation of wavelengths between 280 nm and 315 nm

2.1.6.11.3
Class 1
classification for a contact lens whose luminous transmittance of UVA (τ_{UVA}) < 10 % of τ_V and whose luminous transmittance of UVB (τ_{UVB}) < 1 % of τ_V

2.1.6.11.4
Class 2
classification for a contact lens whose luminous transmittance of UVA ($\tau_{UVA)}$ < 50 % of τ_V and whose luminous transmittance of UVB (τ_{UVB}) < 5 % of τ_V

2.1.6.12
contact angle
angle formed by an intersection of the tangents at the solid-liquid-gaseous interface comprised of a contact lens material, a known liquid, and air, under specified conditions

NOTE The contact angle is formed between a tangent to the air/liquid interface and a tangent to the liquid/solid interface.

2.1.6.13
advancing contact angle
contact angle created when the liquid has been moving towards a dry solid surface

2.1.6.14
equilibrium contact angle
contact angle created when there has been no movement of the liquid across the solid surface for a substantial time period

2.1.6.15
receding contact angle
contact angle created when the liquid has been moving away from an area of solid surface which was previously wet

2.1.7 Tinted contact lenses

2.1.7.1
tinted contact lens
contact lens with some colouration for a specified or an intended use

2.1.7.2
opaque tinted contact lens
eye-masking tinted contact lens
contact lens with sufficient colour in order to mask all or most of the natural iris colour

NOTE This is a colloquial term and not all such lenses are completely opaque.

2.1.7.3
enhancing tint
colouration which is added to a contact lens in order to alter the apparent iris colour of the wearer

2.1.7.4
handling tint
visibility tint
colouration added to a contact lens 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

2.1.8 Contact lens manufacture

2.1.8.1
lathe-cut contact lens
turned contact lens
contact lens primarily manufactured by removal of material with a lathe

2.1.8.2
spin-cast contact lens
contact lens manufactured by a process where a concave mould containing monomer is spun around a vertical axis

2.1.8.3
moulded contact lens
contact lens manufactured primarily in a mould

2.1.8.4
truncate
to remove a specified part of the contact lens periphery in order to make it non-circular

2.1.9 Packaging and labelling of contact lenses and contact lens care products

2.1.9.1
intended purpose
use for which a product is intended according to the information supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials

2.1.9.2
performance
suitability of a product to achieve its intended purpose

2.1.9.3
multi-dose solution
liquid preparation in a primary container whose volume allows the user to expel an appropriate amount of the product on more than one occasion

2.1.9.4
unit dose
contact lens care solution packaged within a primary container that contains sufficient product intended for only one use

2.1.9.5
blister pack
disposable primary container consisting of a thin moulded depression of material containing a product sealed with appropriate material

2.1.9.6
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

2.1.9.7
primary packaging
primary container
element of the packaging system that maintains the sterility or cleanliness of the product

[ISO 11134:1994]

NOTE Primary packaging is intended for storage and protection of the finished product for the duration of the labelled shelf-life or until the integrity of the package has been compromised.

2.1.9.8
labelling
all information given on any label, the primary container, the secondary carton or in a leaflet supplied with the product

2.1.9.9
expiration date
expiry date
end date of period of time, designated by the manufacturer, beyond which the product should not be first used

2.1.9.10
shelf-life
specified period of time from the date of manufacture of a product to its labelled expiration date

2.1.9.11
discard date
in-use period (deprecated)
specified period of time from first use to when the product should be discarded

2.1.9.12
in-use stability
ability of a contact lens or contact lens care product to retain its performance and safety from first opening to its discard date

2.1.9.13
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

[ISO 11137:1995]

NOTE Refer to ISO 15223 or EN 980 for applicable symbols.

2.1.10 Contact lens usage and wear modality

2.1.10.1
disposable contact lens
contact lens intended for a single use (wearing period)

NOTE A disposable contact lens is not intended to be reused. It is intended to be discarded after removal from the eye.

2.1.10.2
reusable contact lens
contact lens intended to be reprocessed for reuse according to the manufacturer's instructions between periods of wear

NOTE Reprocessing of a reusable contact lens would conventionally include contact lens cleaning and disinfection.

2.1.10.3
replacement frequency
time period recommended by the manufacturer for discarding a contact lens

NOTE The replacement frequency is determined starting from the first use of the lens until the recommended time for discarding is reached.

2.1.10.3.1
frequent replacement contact lens
planned replacement contact lens for which the replacement period is three months or less

2.1.10.3.2
planned replacement contact lens
contact lens for which the manufacturer has recommended a replacement period

2.1.10.4
contact lens wear modality
prescribed form or manner in which a contact lens is worn

2.1.10.4.1
daily wear
contact lens wear modality in which a contact lens is worn only during waking periods

2.1.10.4.2
extended wear
contact lens wear modality in which a contact lens is worn continuously during successive waking and sleeping periods

2.1.10.5
cosmetic contact lens
contact lens specifically designed to change or mask the appearance of the eye

NOTE Cosmetic lenses are devices which can also be used for therapeutic purposes.

2.1.10.6
cosmetic contact shell
contact lens shell specifically designed to change or mask the appearance of the eye

NOTE Cosmetic shells are devices which can also be used for therapeutic purposes.

2.1.10.7
bandage contact lens
protective contact lens
therapeutic contact lens
contact lens designed to protect, maintain, or aid in restoring integrity of ocular tissue

NOTE This type of contact lens can be designed to include a refractive element.

2.1.10.8
trial contact lens
diagnostic contact lens
contact lens only used by a practitioner or fitter for the purpose of selecting the appropriate contact lens parameters for the intended wearer

2.1.10.8.1
multipatient use trial contact lens
trial contact lens permitted to be used on more than one person

2.1.11 Contact lens hygienic management and contact lens care products

2.1.11.1
active ingredient
component present in sufficient quantity that relates to an intended purpose

2.1.11.2
antimicrobial activity
ability to kill/destroy/inactivate microorganisms, prevent their proliferation and/or prevent their pathogenic action

2.1.11.3
antimicrobial agent
compound capable of antimicrobial activity

2.1.11.4
neutralization
process by which active ingredients (e.g. hydrogen peroxide) in a contact lens care product which can compromise ocular tissue are rendered inactive and/or non-toxic

NOTE There is no implication that pH 7,0 has been achieved by this process.

2.1.11.5
neutralizing agent
chemically active ingredient(s) capable of neutralization

2.1.11.6
surfactant
agent that modifies the surface energy (surface tension) of a solution

NOTE Surfactants are common ingredients used in the formulation of contact lens cleaners.

2.1.11.7
preservative
component intended to prevent the growth of microorganisms in or on a product

2.1.11.8
stasis
inhibition of microbial growth

2.1.11.9
bioburden
population of viable microorganisms on a raw material, component, a finished product and/or a package

[ISO 11134:1994]

NOTE Bioburden is expressed as the total viable count (TVC), or colony forming units (CFU, cfu) per lens or tablet, or CFU per millilitre of solution.

2.1.11.10
sterile
free of viable microorganisms

[ISO 11135:1994]

NOTE 1 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 Refer to ISO 15223 or EN 980 for applicable symbols.

2.1.11.11
sterility assurance level
SAL
probability of a viable microorganism being present on a product unit after sterilization

[ISO 11135:1994]

NOTE SAL is normally expressed as a negative power (n) of ten, in the form 10^{-n}.

2.1.11.12
hygienic management
procedure by which contact lenses are maintained in a condition for safe reuse

2.1.11.13
contact lens cleaning
process of removing surface contaminants from a contact lens

NOTE Cleaning is usually the first step in the hygienic management of a reusable contact lens. Chemical agents (e.g. surfactants) are often employed in contact lens cleaning products to facilitate the removal of foreign matter from a contact lens.

2.1.11.14
contact lens care regimen
series of processes specified by the contact lens or care product manufacturer and used by the contact lens wearer to maintain ocular health, lens condition, comfort and vision

2.1.11.15
contact lens disinfection
chemical or physical process to reduce the number of viable microorganisms on a contact lens to a level which is neither harmful to ocular health nor to the quality of contact lenses and accessories

NOTE Bacterial spores, acanthamoeba, some fungal spores, prions and some viruses might not necessarily be inactivated during the contact lens disinfection process.

2.1.11.15.1
contact lens disinfecting agent
chemically or physically active ingredient in contact lens disinfection

2.1.11.15.2
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 14729:2001

2.1.11.15.3
contact lens disinfecting regimen
contact lens care regimen designed to meet both the secondary criteria of the stand-alone test and the regimen test as specified in ISO 14729:2001

2.1.11.16
abrasive cleaner
suspension in sufficient concentration used to facilitate cleaning of contact lenses by friction enhancement

2.1.11.17
enzymatic cleaner
protein or lipid remover
liquid or solid preparation containing one or more enzymes as active ingredients with the intended purpose of reducing adsorbed and absorbed proteins and/or lipids on a contact lens

NOTE Enzymatic cleaners are optional contact lens care products recommended for use in the hygienic management of contact lenses.

2.1.11.18
rinsing
act of removing physical and chemical contaminants from a contact lens by allowing the flow of a suitable liquid over the surfaces of the lens

NOTE A minimum time for rinsing lenses is generally recommended by the manufacturer in the labelling of a rinsing solution to achieve its intended purpose.

2.1.11.19
soaking
act of immersing a contact lens in a specified solution for a specified time

NOTE A minimum time for soaking lenses is generally recommended by the manufacturer in the labelling of a soaking or storage solution to achieve its intended purpose.

2.1.11.20
soaking solution
storage solution
liquid preparation with the intended purpose of keeping a contact lens in a condition suitable for reuse while the lens is not in the eye

NOTE Soaking solutions can contain preservatives.

2.1.11.21
conditioning solution
liquid preparation formulated for soaking and storage of a contact lens for the intended purpose of maintaining the lens in a condition suitable for reuse

NOTE 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.

2.1.11.22
wetting solution
liquid preparation applied to contact lenses to improve the short-term hydrophilicity of the lens surface

NOTE Because these solutions normally contain viscosity increasing agents, they can also act to improve lubrication between the eyelid and the contact lens.

2.1.11.23
eye drops
lubricating and rewetting solution
rewetting drops
liquid preparation intended for occasional use directly in the eye by a contact lens wearer for alleviating discomfort of lens wear and improving lens tolerance by physical means

NOTE The term “comfort drops” is sometimes also used but is deprecated because it is a registered trademark of a contact lens care product in some countries and is no longer a generic term.

2.1.11.24
multipurpose solution
combination solution (deprecated)
liquid preparation which has more than one claimed function in the hygienic management of a contact lens

2.1.11.25
packaging solution
shipping solution
liquid preparation used by the contact lens manufacturer or practitioner to dispatch or store lenses in a primary container

2.1.12 Miscellaneous

2.1.12.1
aphakia
condition where the natural crystalline lens of the eye is absent

2.1.12.2
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 preocular tear film

2.1.12.3
clinical investigator
individual and/or institution responsible for the conduct of a clinical investigation who and/or which takes the clinical responsibility for the wellbeing of the subjects involved

[ISO 14155-1:2003]

NOTE Whether this is an individual or an institutional responsibility can depend on national legislation.

2.1.12.4
elution
less aggressive form of extraction for removing chemicals from a contact lens material

NOTE 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.

2.1.12.5
extractable substance
leachable substance
residual
chemical removed from the material composing contact lenses, during the process of extraction

2.1.12.6
extraction
process of removing residual chemicals that are present in materials by using a specified solvent, for a specified time, under specified conditions

NOTE 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.

2.1.12.7
inoculum
suspension of known microorganisms

2.1.12.8
accuracy
closeness of agreement between the test result and the accepted reference value (true value)

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

2.1.12.9
precision
closeness of agreement between mutually independent test results obtained under stipulated conditions

[ISO 3534-1:1993]

NOTE 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.)

2.1.12.9.1
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

NOTE The value of repeatability is expressed as the difference between test results below which the absolute difference between two single test results can be expected to lie with a probability of 95 %.

2.1.12.9.2
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

NOTE The value of reproducibility is expressed as the difference between test results below which the absolute difference between two single test results can be expected to lie with a probability of 95 %.

2.1.12.10
prism dioptre
Δ
pdpt
unit of prismatic deviation, equal to 100 tan δ, where δ is the angle of deviation in degrees (°)

[ISO 13666:1998]

NOTE Prism dioptre is expressed in centimetres per metre (cm/m).

2.1.12.11
ophthalmometer
keratometer
instrument used to measure the radius of curvature of the primary front and back curve of a contact lens

2.1.12.12
radiuscope
microspherometer
instrument used to measure a radius of curvature of a contact lens

NOTE The instrument is typically used to measure the back optic zone radius of a rigid contact lens.

2.2 Symbols

Table 1 — Symbols

Symbol	Term	Reference
r_0	Back optic zone radius	2.1.2.2.1
r_0	Back central optic zone radius	2.1.2.2.2
r_1, r_2	Back peripheral optic zone radius	2.1.2.2.3
r_1, r_2	Back peripheral radius	2.1.2.2.4
r_{a0}	Front optic zone radius	2.1.2.2.5
r_{a0}	Front central optic zone radius	2.1.2.2.6
r_{a1}, r_{a2}	Front peripheral optic zone radius	2.1.2.2.7
r_{a1}, r_{a2}	Front peripheral radius	2.1.2.2.8
$Ø_0$	Back optic zone diameter	2.1.2.3.3
$Ø_0$	Back central optic zone diameter	2.1.2.3.4
$Ø_1$, $Ø_2$	Back peripheral optic zone diameter	2.1.2.3.5
$Ø_1$, $Ø_2$	Back peripheral zone diameter	2.1.2.3.6
$Ø_{a0}$	Front optic zone diameter	2.1.2.3.7
$Ø_{a0}$	Front central optic zone diameter	2.1.2.3.8
$Ø_{a1}$, $Ø_{a2}$	Front peripheral optic zone diameter	2.1.2.3.9
$Ø_{a1}$, $Ø_{a2}$	Front peripheral zone diameter	2.1.2.3.10
$Ø_T$	Total diameter	2.1.2.3.1
t_A	Axial thickness[a]	2.1.2.4.4
t_{EA}	Axial edge thickness[a]	2.1.2.4.5
t_{CJ}	Carrier junction thickness[a]	2.1.2.4.8
t_C	Geometric centre thickness[a]	2.1.2.4.1
t_O	Optical centre thickness[a]	2.1.2.4.2
t_{HM}	Harmonic mean thickness[a]	2.1.2.4.3
t_{PJ}	Peripheral junction thickness[a]	2.1.2.4.9
t_R	Radial thickness[a]	2.1.2.4.6
t_{ER}	Radial edge thickness[a]	2.1.2.4.7
l_A	Axial lift	2.1.2.1.21
l_{EA}	Axial edge lift	2.1.2.1.22
l_R	Radial lift	2.1.2.1.19
l_{ER}	Radial edge lift	2.1.2.1.20
F'_v	Back vertex power	2.1.2.1.2
F_v	Front vertex power	2.1.2.1.1
d	Displacement of optic	2.1.2.1.9
τ_V	Luminous transmittance	2.1.6.10
τ_λ	Spectral transmittance	2.1.6.9
Dk	Oxygen permeability	2.1.6.3
Dk/t	Oxygen transmissibility	2.1.6.5
j	Oxygen flux	2.1.6.4

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

3 Classification of contact lens materials

3.1 The specific name of a contact lens or contact lens material is given as a **six-part coding** as follows:

(prefix) (stem) (series) (group suffix) (*Dk* range) (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 (see 3.7).

3.2 The **prefix** is a term assigned to a material to designate a specific chemical formulation. Use of this prefix, which is administered by the United States Adopted Names (USAN) Council, is optional outside the United States of America.[1)]

3.3 Two types of **stems** 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.

3.4 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.

3.5 The **group** suffix, represented by Roman 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.

3.5.1 For **hydrogel** materials, the group suffixes in Table 2 shall apply.

Table 2 — Group suffixes for hydrogel materials

Group suffix	Hydrogel material	Description
I	Low water content, non-ionic	Materials which contain less than 50 % water and which contain 1 % or less (expressed as mole fraction) of monomers that are ionic at pH 7,2
II	Mid and high water content, non-ionic	Materials which contain 50 % water or more, and which contain 1 % or less (expressed as a mole fraction) of monomers which are ionic at pH 7,2
III	Low water content, ionic	Materials which contain less than 50 % water and which contain greater than 1 % (expressed as a mole fraction) of monomers which are ionic at pH 7,2
IV	Mid and high water content, ionic	Materials which contain 50 % water or more, and which contain greater than 1 % (expressed as a mole fraction) of monomers which are ionic at pH 7,2
NOTE Low water content is defined as less than 50 % water (< 50 %); mid water content is from 50 % to 65 % water, inclusive (50 % to 65 % water); and high water content is greater than 65 % water (> 65 %). Hence, group suffixes II and IV include all materials having water content of 50 % or greater.		

1) United States Adopted Names Council, c/o American Medical Association, P.O. Box 10970, Chicago, Illinois, USA, 60610 ; phone (312) 464-4046.

3.5.2 For **non-hydrogel** materials, the group suffixes in Table 3 shall apply.

Table 3 — Group suffixes for non-hydrogel materials

Group suffix	Non-hydrogel material
I	Materials which do not contain either silicone or fluorine
II	Materials which contain silicone but not fluorine
III	Materials which contain both silicone and fluorine
IV	Materials which contain 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.	

3.6 Oxygen permeability range (*Dk* range), presented as a numeric designation, which categorizes the *Dk* of the material in ranges that are considered to be of significance in contact lens wear. For contact lenses and contact lens materials, the oxygen permeability is measured according ISO 18369-4. The permeability range is then denoted in the classification by the number corresponding to the categories in Table 4.

Table 4 — Oxygen permeability range

Category	*Dk* units using hPa	*Dk* units using mmHg
0	< 0,75 *Dk* unit	< 1 *Dk* unit
1	0,75 *Dk* unit to 11,75 *Dk* units	1 *Dk* unit to 15 *Dk* units
2	12,0 *Dk* units to 22,5 *Dk* units	16 *Dk* units to 30 *Dk* units
3	22,75 *Dk* units to 45,0 *Dk* units	31 *Dk* units to 60 *Dk* units
4	45,25 *Dk* units to 75,0 *Dk* units	61 *Dk* units to 100 *Dk* units
5	75,25 *Dk* units to 112,5 *Dk* units	101 *Dk* units to 150 *Dk* units
6	112,75 *Dk* units to 150,0 *Dk* units	151 *Dk* units to 200 *Dk* units
7, etc.	increasing in increments of 37,5 *Dk* units	increasing in increments of 50 *Dk* units

3.7 The **modification** code, designated by a lower case “m”, denotes that the lens has a modified surface which has different characteristics from the bulk of the material. This suffix is only used if the contact lens has been subjected to a surface modification process. Examples include:

— plasma treatment,

— acid/base hydrolysis,

— incorporation of a material which migrates to the surface, etc.

Certain types of tinted lenses may also be considered surface modified. In the case of an unmodified surface, this suffix is omitted.

3.8 Examples of classification by code:

EXAMPLE 1 Hydrogel material.

Hydrogel material whose formulation has the USAN code “Cromo”, of monomer ratio modification “A”, containing 78 % water, 0,6 % mole fraction ionic monomers and exhibiting an oxygen permeability of 42 *Dk* units is classified by the following code:

Cromofilcon A II 3

EXAMPLE 2 Non-hydrogel material.

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 III 6 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, may 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 may 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 for a tri-curve corneal contact lens with fenestration.

	r_0	:	$\varnothing_0$	/	r_1	:	$\varnothing_1$	/	r_2	:	$\varnothing_T$	F'_v	t_C
	7,60	:	7,00	/	8,30	:	8,80	/	12,25	:	9,20	–6,00	0,10
Specified fenestration	1 fenestration: 0,3 mm diameter, 2 mm from edge												

a) Alternative 1

r_0 : $\varnothing_0$	7,60	: 7,00
r_1 : $\varnothing_1$	8,30	: 8,80
r_2 : $\varnothing_T$	12,25	: 9,20
F'_v	–6,00	
$\varnothing_{a0}$	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'_v	–6,00
$\varnothing_T$	9,20
t_C	0,10
r_1 / $\varnothing_0$	8,30 / 7,00
r_2 / $\varnothing_1$	12,25 / 8,80
$\varnothing_{a0}$	7,40
Specified fenestration	1 fenestration: 0,3 mm diameter, 2 mm from edge

In this form of the specification only, the radius and width of the peripheral curves may be specified; in this example as 8,30/0,9 and 12,25/0,2 respectively.

c) Alternative 3

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

A.2.2 EXAMPLE 2 — Corneal contact lens with a toric back surface and a spherical front surface

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	:	$\varnothing_0$	/	r_1	:	$\varnothing_1$	/	r_2	:	$\varnothing_2$	/	r_3	:	$\varnothing_T$	F'_v
$\frac{8,20}{7,60}$	:	7,50	/	$\frac{8,70}{8,10}$	:	8,30	/	$\frac{9,20}{8,60}$	:	9,10	/	$\frac{9,70}{9,10}$	:	9,50	+0,75

a) Alternative 1

r_0	8,20 / 7,60
F'_v	+0,75
$\varnothing_T$	9,50
t_C	0,15
r_1	8,70 / 8,10
$\varnothing_0$	7,50
r_2	9,20 / 8,60
$\varnothing_1$	8,30
r_3	9,70 / 9,10
$\varnothing_2$	9,10

b) Alternative 2

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.

The back vertex power in air is specified along only the flatter principal meridian (in this example, +0,75 along 8,20 radius). 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	:	$\varnothing_1$	$\frac{8,80}{8,20}$	:	8,40
r_2	:	$\varnothing_T$	$\frac{11,00}{10,40}$	:	9,00
F'_v			+15,00		
$\varnothing_{a0}$			7,40		

a) Alternative 1

r_0	7,80
F'_v	+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

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