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

Reference number
ISO 18369-1:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

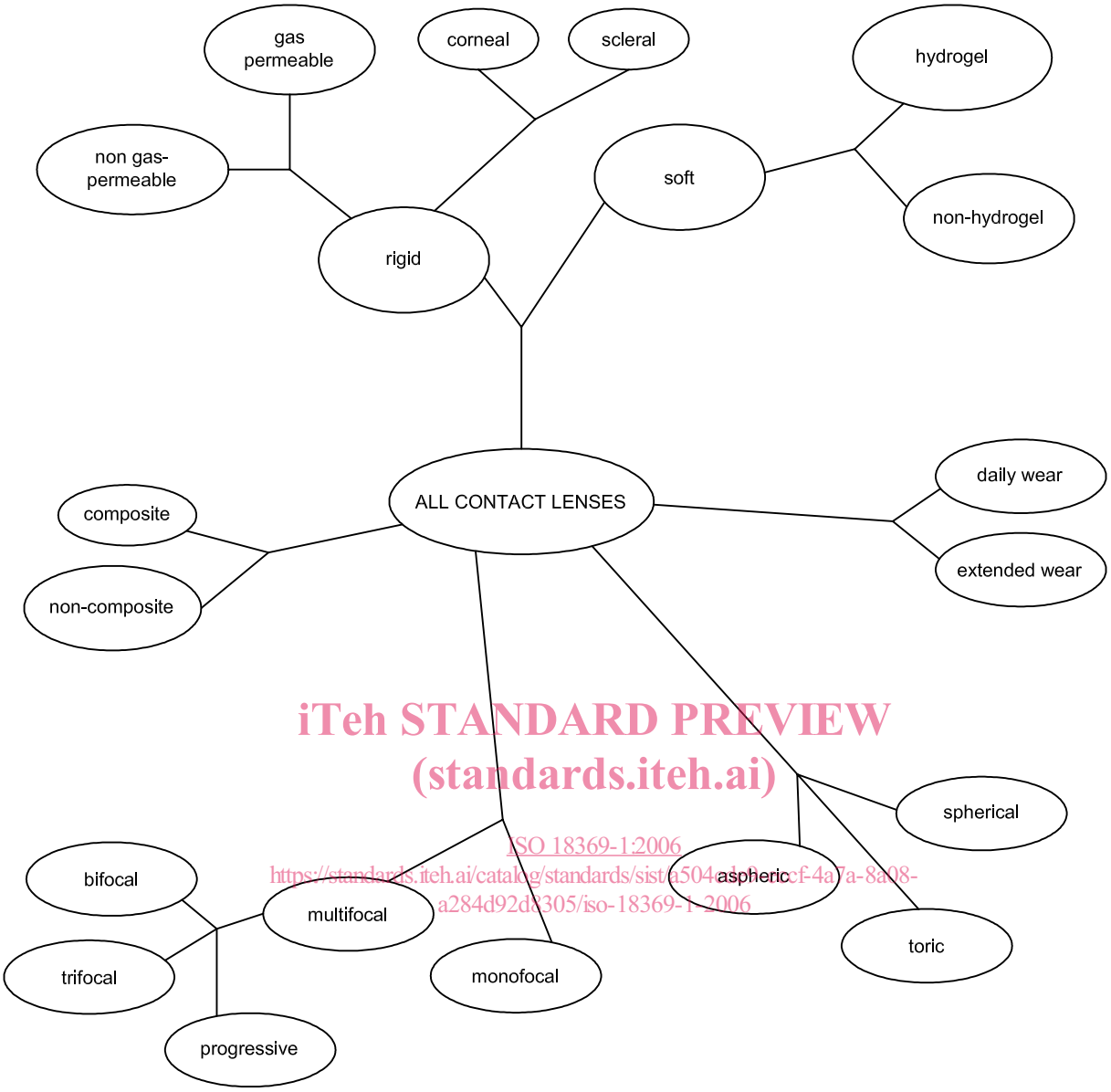


Figure 1 — Classification of contact lenses according to various characteristics leads to various qualifiers used in their designation

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

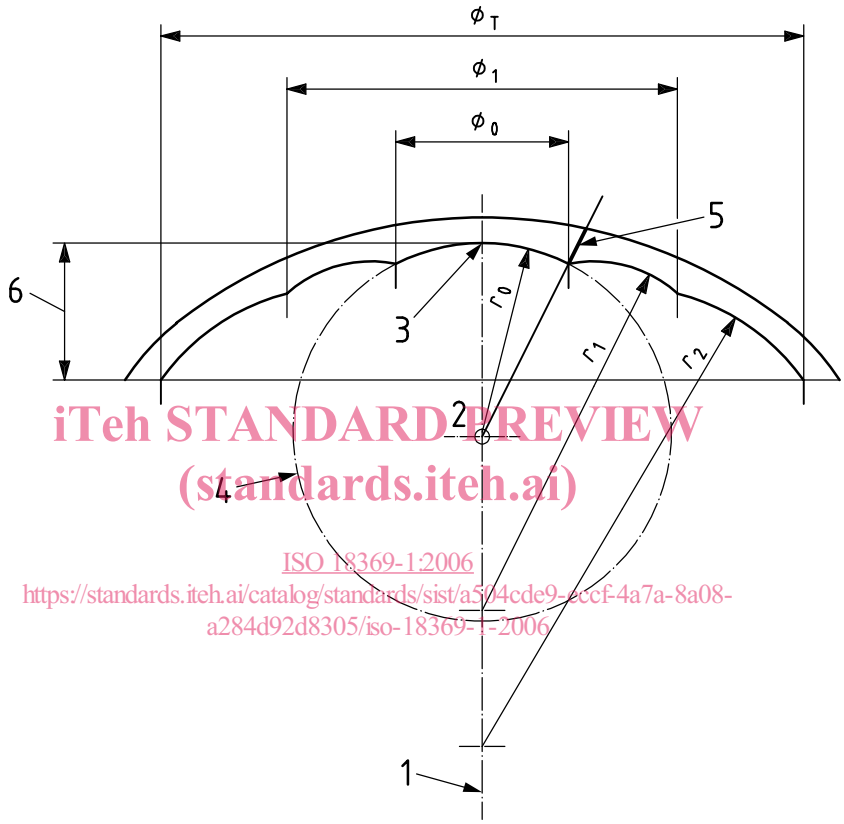
See Figure 2.

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.

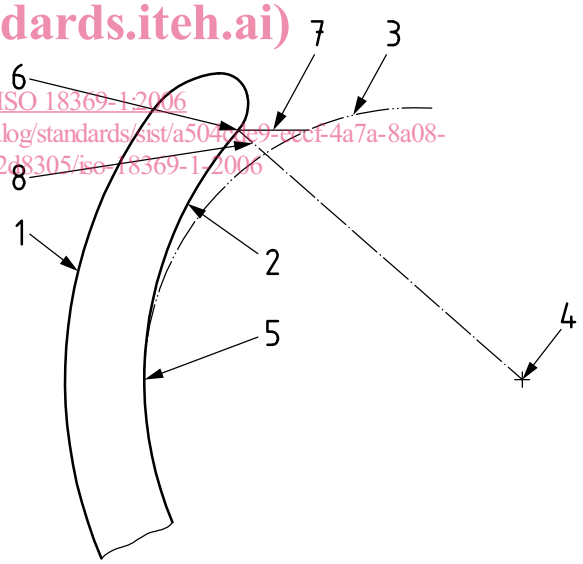
2.1.2.1.16
edge
that part of a contact lens which is contiguous with the front and back surfaces

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.

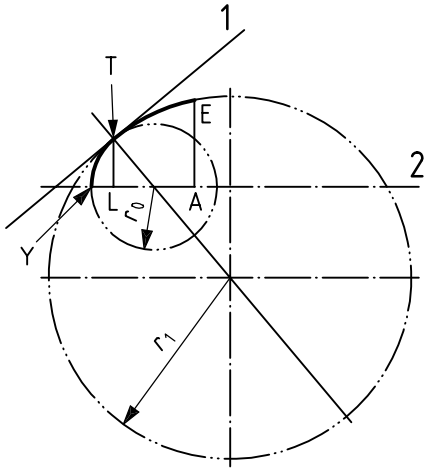
2.1.2.1.40
prism ballast
vertical prism used to create a wedge design that will help stabilize the rotation and orientation of a contact lens on the eye

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.



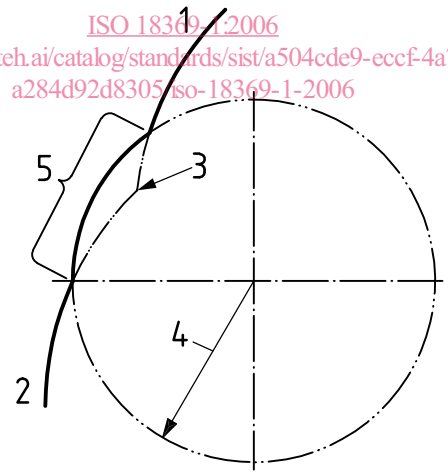
Key

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