

# Ophthalmic optics — Contact lenses —

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

ICS 01.040.11; 11.040.70

## National foreword

This British Standard is the UK implementation of EN ISO 18369-1:2006+A1:2009. It is identical with ISO 18369-1:2006, incorporating amendment 1:2009. It supersedes BS EN ISO 18369-1:2006 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/172, Ophthalmic optics, to Subcommittee CH/172/9, Contact lenses and contact lens care products.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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|              |                                                                                                                      |
|              |                                                                                                                      |

English Version

**Ophthalmic optics - Contact lenses - Part 1: Vocabulary,  
classification system and recommendations for labelling  
specifications (ISO 18369-1:2006)**

Optique ophtalmique - Lentilles de contact - Partie 1:  
Vocabulaire, système de classification et recommandations  
pour l'étiquetage des spécifications (ISO 18369-1:2006)

Augenoptik - Kontaktlinsen - Teil 1: Begriffe, Einteilung von  
Kontaktlinsenmaterialien und Empfehlungen für die  
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## **Foreword**

This document (EN ISO 18369-1:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

This document supersedes EN ISO 8320-1:2003, EN ISO 8320-2:2001 and EN ISO 11539:1999 and partly supersedes EN ISO 8321-1:2002 and EN ISO 8321-2:2000.

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## **Endorsement notice**

The text of ISO 18369-1:2006 has been approved by CEN as EN ISO 18369-1:2006 without any modifications.

NOTE: A-Deviations are given in Annex ZA (informative)

## **Foreword to amendment A1**

This Amendment (EN ISO 18369-1:2006/A1:2009) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics" the secretariat of which is held by DIN.

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The text of ISO 18369-1:2006/Amd 1:2009 has been approved by CEN as a EN ISO 18369-1:2006/A1:2009 without any modification.

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## Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the precorneal 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.

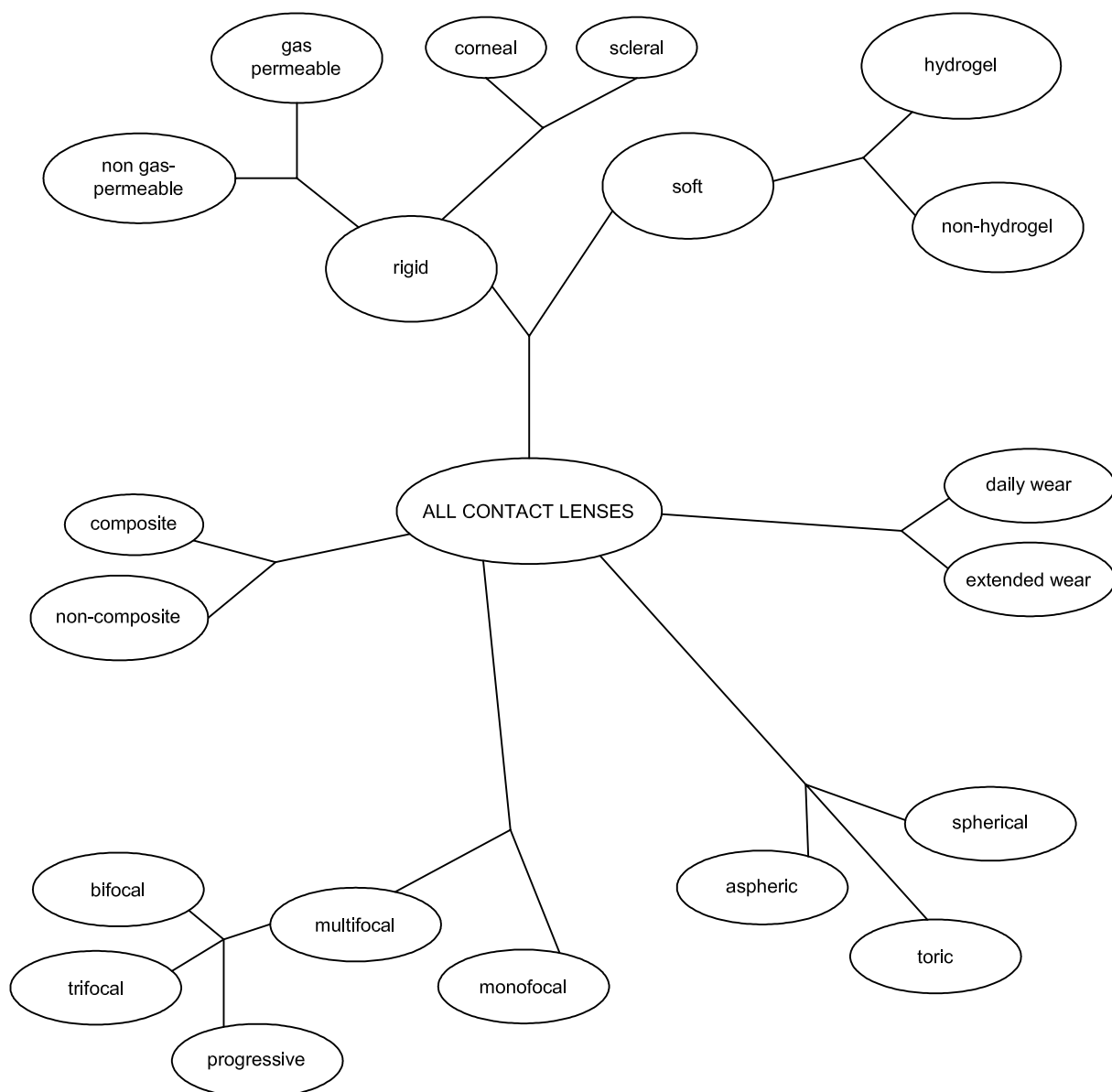


**Figure 1 — Classification of contact lenses according to various characteristics leads to various qualifiers used in their designation**

# 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**

##### **lacrimonal 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

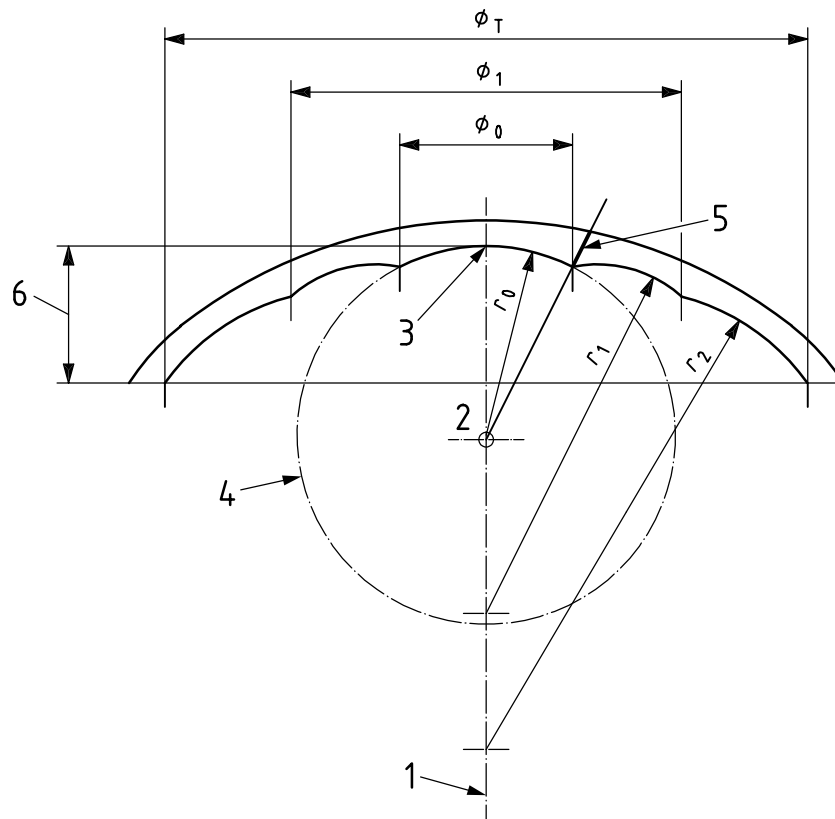
See Figure 2.

#### 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,  $l_R$

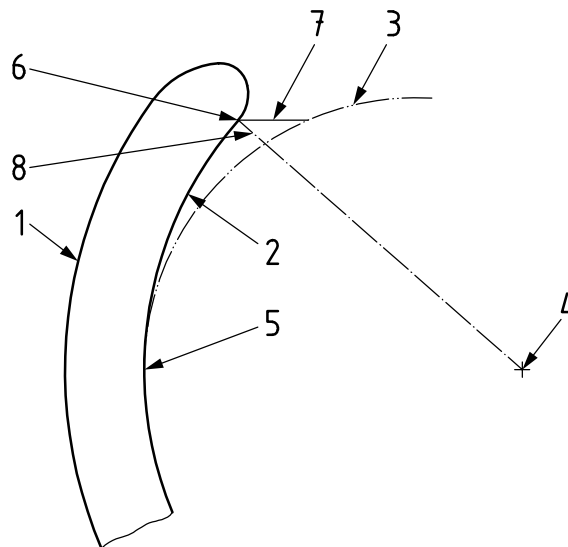


Figure 3 — The difference between radial and axial lift

#### 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.

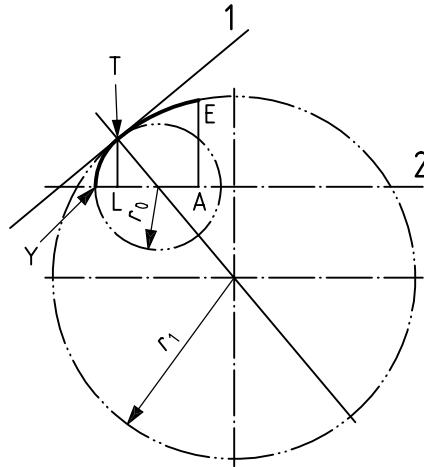
NOTE 2 The asymmetrical distribution of thickness, rather than the effect of mass, is responsible for the rotational orientation of the contact lens that incorporates prism.

**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.

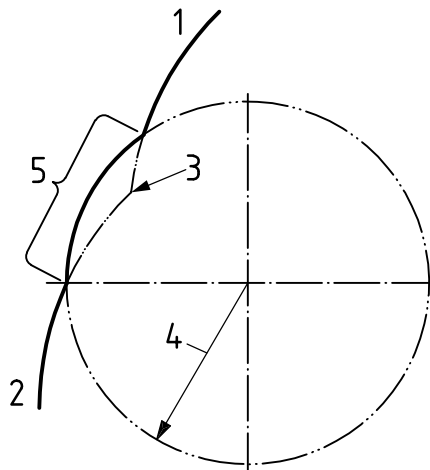


**Key**

- 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).