INTERNATIONAL STANDARD

ISO 11979-3

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Ophthalmic implants — Intraocular lenses —

Part 3:
Mechanical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —

Partie 3: Propriétés mécaniques et méthodes d'essai

Reference number
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Contents

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

International Standard ISO 11979 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

— *Part 1: Vocabulary*

— *Part 2: Optical properties and test methods*

— *Part 3: Mechanical properties and test methods*

— *Part 4: Labelling and information*

— *Part 5: Biocompatibility*

— *Part 6: Shelf-life and transport stability*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

Annexes A to G form a normative part of this part of ISO 11979. Annexes H and I are for information only.

Introduction

This part of ISO 11979 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ISO 11979-7 [1]. Because of the complexity of this analysis, detailed descriptions and examples have been given in annex I.

Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards, it is then up to the parties using the standard to modify or develop corresponding methods, and give rationale and validation for them in a spirit that is consistent with this International Standard.

In the cases where different tolerances have been given depending on material or design, they reflect an already existing situation with well-established products.

NOTE It always was and still is the intention of the Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards become available.

Ophthalmic implants — Intraocular lenses —

Part 3:
Mechanical properties and test methods

1 Scope

This part of ISO 11979 specifies requirements and test methods for certain mechanical properties of intraocular lenses (IOLs).

It is applicable to all types of IOLs intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular IOL design.

NOTE For certain designs and certain applications, a specific test method described in this part of ISO 11979 may not be applicable. In such instances, the IOL manufacturer should devise corresponding test methods and provide validation and rationale for them.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 11979-1:—[1)], *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary.*

ISO 11979-2:—[1)], *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods.*

ISO 11979-4:—[1)], *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information.*

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 11979-1 apply. For the convenience of the reader, some of these terms and definitions are reproduced here.

3.1
body
central part of an intraocular lens incorporating the optic

See Figure 1.

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1) To be published.

3.2
clear optic
diameter of the circle, concentric with the optical axis of an intraocular lens, containing only features of the intraocular lens belonging to the optical design

See Figure 1.

3.3
in situ
in equilibrium with aqueous humour at 35 °C

See also ISO 11979-2.

3.4
multipiece intraocular lens
intraocular lens assembled from separate loop and body components

NOTE An intraocular lens with a body and two loops is often referred to as a three-piece intraocular lens.

3.5
one-piece intraocular lens
intraocular lens in which the haptic is an integral part of the body

3.6
optic decentration
lateral displacement of the optic due to compression of the haptic(s), measured as distance between the geometric centre of the clear optic and the centre of a cylinder of a specified diameter to which the intraocular lens is confined

See Figure C.1.

3.7
optic tilt
angle between the optical axis of the intraocular lens in the uncompressed state and that in the compressed state, with the intraocular lens being confined to a specified diameter

3.8
overall diameter
diameter of the cylinder circumscribing an intraocular lens, be it haptic or optic, with the axis of the cylinder coincident with the optical axis of the intraocular lens

See Figure 1.

3.9
positioning hole
hole, whether penetrating or not, intended to be used for surgical manipulation

See Figure 1.

3.10
sagitta
maximum distance between the planes, normal to the optical axis, which contact respectively the most anterior and the most posterior points, be it haptic or optic, of an uncompressed intraocular lens

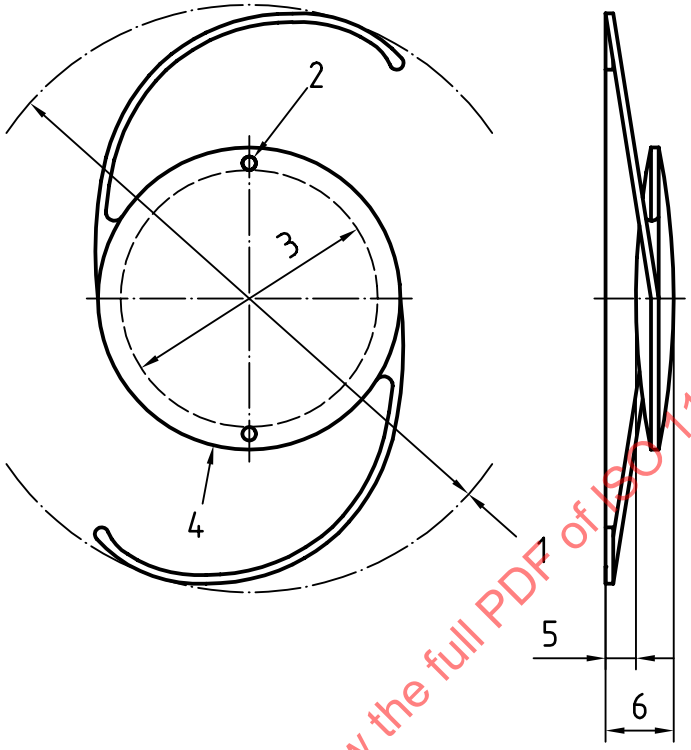
See Figure 1.

3.11
vault height
distance between the plane, normal to the optical axis, containing the vertex of the iris-proximal optical surface and the plane, normal to the optical axis, containing the most iris-proximal point of the uncompressed haptic of an intraocular lens

See Figure 1.

NOTE 1 The iris-proximal side of the intraocular lens refers to the intended position as implanted.

NOTE 2 The vault height is positive if the distance defined is in the direction towards the retina as implanted, and negative if not.



Key

1 Overall diameter
2 Positioning holes
3 Clear optic
4 Body
5 Vault height
6 Sagitta

Figure 1 — Indicative illustration of some dimensional parameters of an intraocular lens

4 Requirements

4.1 General

Properties of IOLs that do not change their dimensions after implantation shall be determined at 23 °C ± 2 °C and relative humidity (RH) 50 % RH ± 10 % RH. For all other IOLs, properties shall be determined at *in situ* conditions within the temperature tolerance of ± 2 °C. The precise composition of the solution used shall be reported in all cases.

IOLs which are intended for clinical manipulations of folding or other optic deformation shall undergo such manipulations prior to being tested, to ensure maintenance of critical performance parameters after manipulation. Since the lens thickness is critical in these manipulations, samples of the highest and lowest dioptric power shall be included. Applicable mechanical and optical properties, defined elsewhere in this International Standard, shall be measured. The folding or other deformation shall correspond to the configuration required by the IOL for actual implantation, and this condition shall be maintained for a minimum of 3 min. The folding or other deformation shall be performed by the same method and instrumentation, or their equivalent, as intended for clinical use. The IOL shall be allowed to return to its original and designed configuration. Compliance with applicable mechanical and optical requirements shall be demonstrated at (24 ± 2) h after release from folding or other deformation.

For each of the methods described below, tests shall be performed on a minimum of three IOL lots. If dioptric power affects the property tested, the lots shall comprise one each of low, medium and high dioptric powers. The minimum sample size for each test shall be 10 IOLs per lot. The lots shall be representative of IOLs being marketed. In all cases, the sampling criteria applied shall be reported.

4.2 Tolerances and dimensions

For all types of IOLs except multi-piece posterior chamber IOLs, the tolerance on the overall diameter shall be ± 0,20 mm. For multi-piece posterior chamber IOLs, the tolerance on the overall diameter shall be ± 0,30 mm.

NOTE For symmetrically designed IOLs with two haptics, the overall diameter equals the distance between haptic vertices.

The tolerance on the vault height shall be as follows:

a) for anterior chamber IOLs, ± 0,15 mm;

b) for posterior chamber IOLs with polypropylene loop(s), ± 0,35 mm; and

c) for other IOLs, ± 0,25 mm.

The tolerance on the sagitta shall be as follows:

a) for anterior chamber IOLs, ± 0,25 mm;

b) for posterior chamber IOLs with polypropylene loop(s), ± 0,45 mm; and

c) for other IOLs, ± 0,35 mm.

The tolerance on the clear optic shall be ± 0,10 mm.

The tolerance on the dimensions of the body shall be ± 0,10 mm. For ellipsoid IOLs, the dimensions of the body shall be reported as (short axis) × (long axis).

The tolerance on the diameter of the positioning hole shall be (+0,05/0,00) mm.

Dimensions for which tolerances are given above shall be specified in the manufacturer's design documentation. Some dimensions may vary with dioptric power, hence different specifications may apply to individual powers of an intraocular lens design. Some dimensions, as specified in ISO 11979-4, shall be given in the labelling of the product.

4.3 Compression force

Using the method described in annex A, the compression force shall be measured and reported as follows:

a) for IOLs intended for capsular bag placement, at a diameter of 10 mm;

b) for IOLs intended for sulcus placement, at a diameter of 11 mm;

c) for IOLs intended for both capsular bag and sulcus placement, both at a diameter of 10 mm and at a diameter of 11 mm; and

d) for anterior chamber IOLs, at the minimum and maximum intended compressed diameters recommended by the manufacturer in the product literature.

4.4 Axial displacement in compression

Using the method described in annex B, the axial displacement in compression shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

In addition, for anterior chamber IOLs, the vault height and the sagitta in the compressed state shall be given in the product literature as a function of dioptric power at the minimum and maximum intended compressed diameters, as specified in 4.3.

4.5 Optic decentration

Using the method described in annex C, the optic decentration shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

If the sum of the arithmetic mean and two standard deviations of the optic decentration exceeds 10 % of the clear optic, it shall be demonstrated that the modulation transfer function of the IOL in a model eye in accordance with ISO 11979-2 is within the limits specified therein, at an optic decentration equal to the sum of the arithmetic mean and two standard deviations for the whole range of dioptric powers being marketed.

4.6 Optic tilt

Using the method described in annex D, the optic tilt shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

If the sum of the arithmetic mean and two standard deviations of the optic tilt exceeds 5°, it shall be demonstrated that the modulation transfer function of the IOL in a model eye in accordance with ISO 11979-2 is within the limits specified therein, at an optic tilt equal to the sum of the arithmetic mean and two standard deviations for the whole range of dioptric powers being marketed.

4.7 Angle of contact

Using the method described in annex E, the angle of contact shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

NOTE The angle of contact is a measured approximation of the total haptic contact with the supporting ocular tissue.

4.8 Compression force decay

Using the method described in annex F, the compression force decay shall be tested and reported at the same diameters that were used for the measurement of compression force (see 4.3).

NOTE 1 The loops of IOLs are designed to exert some pressure on eye structures as a means of keeping the IOL in position and should continue to do so for some time after implantation.

Results shall be reported as residual compression force after 24 h in compression at each required compressed diameter under *in situ* conditions within the temperature tolerance of ± 2 °C.

NOTE 2 Reduction in compression force may in part be caused by water uptake by the haptic material.

4.9 Dynamic fatigue durability

All loops shall be capable of withstanding, without breaking, 250 000 cycles of near-sinusoidal deformation of ± 0,25 mm around the compressed distance.

Using the method described in annex G, fatigue testing shall be performed as follows:

a) for IOLs intended for capsular bag placement, at a compressed distance of 5,0 mm between the testing plate and the centre of the optic;

b) for IOLs intended for sulcus placement, at a compressed distance of 5,5 mm between the testing plate and the centre of the optic;

c) for IOLs intended for both capsular bag and sulcus placement, at a compressed distance of 5,0 mm between the testing plate and the centre of the optic; and

d) for anterior chamber IOLs, at two different compressed distances between the testing plate and the centre of the optic, corresponding to half the minimum intended compressed diameter and half the maximum intended compressed diameter, respectively, as recommended by the manufacturer in the product literature.

This test shall be carried out only for IOL designs in which the loop will be in a compressed state when implanted. The frequency shall be between 1 Hz and 10 Hz.

NOTE Higher frequencies may be used if it is verified that the loop follows the testing plate without lag at all times.

No loop tested shall break.

4.10 Loop strength

The IOL manufacturer shall provide evidence that the loops of an IOL design are capable of withstanding surgical manipulations without failure.

A test method useful for many designs is given in annex H.

4.11 Surface and bulk homogeneity

The IOL shall be essentially free from defects (see note) and all edges shall appear smooth when viewed at 10× magnification with a stereomicroscope using optimal lighting conditions.

NOTE By defects are meant deviations from surface and bulk homogeneity that are not intended features of the design, including all kinds of surface defects such as scratches, digs, protrusions, cracks, roughness, etc., as well as bulk defects such as inclusions, bubbles, striae, discoloration, etc.

5 Supplementary information available from the manufacturer

In addition to the information specified in ISO 11979-4, the manufacturer shall have on record the information required by the tests specified in this part of ISO 11979, as well as the evidence of loop strength required by 4.10.

Annex A
(normative)

Measurement of compression force

A.1 Principle

The force exerted by the loops is measured when the IOL is confined to a prescribed diameter with the movement of the body being unrestricted.

A.2 Apparatus

A diagram of the apparatus is shown in Figures A.1 and A.2 and comprises the following.

A.2.1 **Two anvils** with faces having a radius of 5,00 mm ± 0,02 mm or 5,50 mm ± 0,02 mm, as appropriate, and constructed from a low-friction material to minimize loop rotational constraint;

A.2.2 **Device** capable of measuring force with an accuracy of ± 0,1 mN.

A.3 Procedure

A.3.1 Carry out the testing with the IOL in the horizontal plane.

NOTE Testing in the vertical plane leads to asymmetrical distribution of force between the loops due to the mass of the IOL.

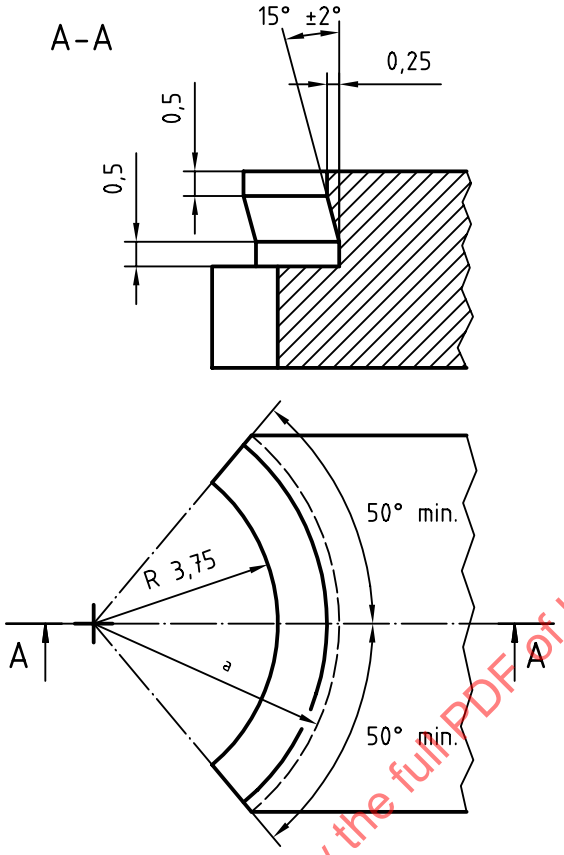
A.3.2 Set the anvils to a distance approximately equal to the overall dimension of the IOL and place the IOL between the anvils.

A.3.3 Locate the IOL in the uncompressed state so that the line of compression bisects the angle of contact in the compressed state or, in the case of IOLs where there are multiple contacts, so that the line of compression bisects the angle of contact from the extremes in the compressed state (see Figure A.3).

A.3.4 Close the anvils to the prescribed diameter.

A.3.5 Read the compression force after allowing between 10 s and 30 s for the IOL to stabilize.

Dimensions in millimetres



a R = 5 mm ± 0,02 mm or 5,50 mm ± 0,02 mm

Figure A.1 — Anvil

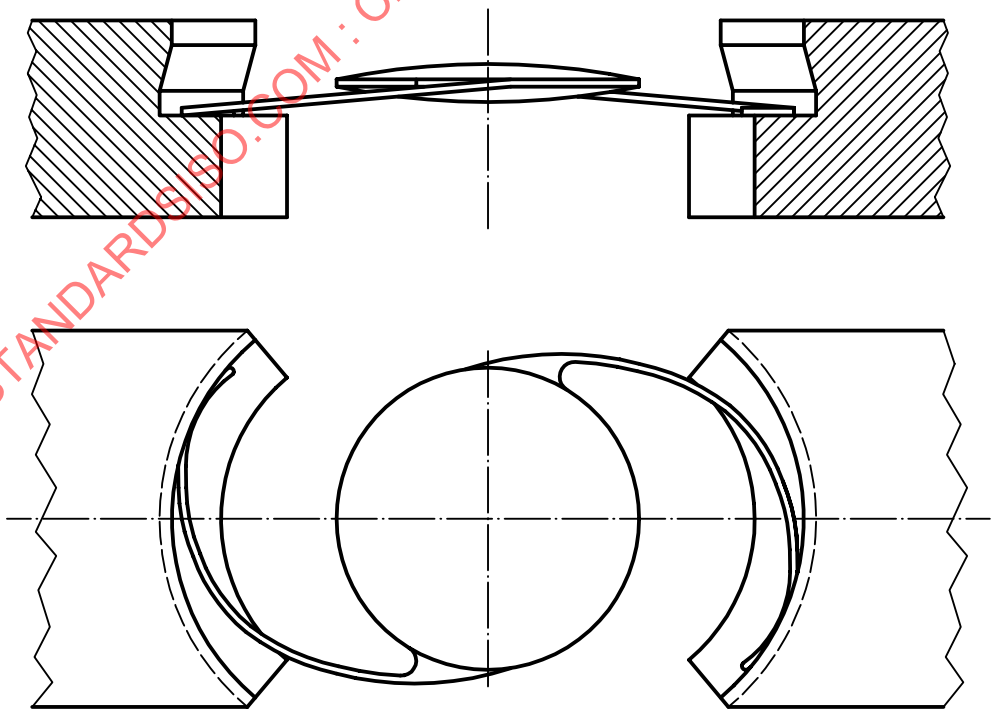
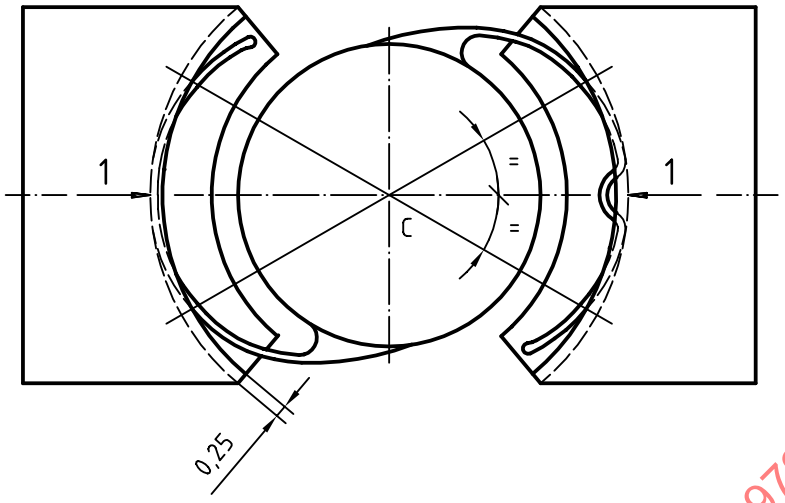


Figure A.2 — Arrangement for measurement of compression force

Dimensions in millimetres



Key

1 Compression
C Centre of curvature of anvil faces

Figure A.3 — IOL in compressed state between anvils
(showing an IOL with two different types of loops)

A.4 Precision

The repeatability (r) and the reproducibility (R) are given by the equations:

$$r = -0,4 + 0,46 \times F$$

$$R = -0,4 + 0,55 \times F$$

where F is the compression force, expressed in millinewtons.

NOTE Definitions of repeatability and reproducibility are found in ISO 5725[2]. The equations were derived as the result of interlaboratory tests conducted in accordance with ISO 5725[2]. The variability due to measurement and population is inseparable, due to the sampling method used for the tests.

A.5 Expression of results

The test report shall contain at least the following information:

a) test diameter;

b) identification of the test sample;

c) number of IOLs tested;

d) arithmetic mean and standard deviation of test readings; and

e) date of the test.

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2) ISO 5725:1986. A revised version of ISO 5725 has since been published in several parts (see [2] to [7]).

Annex B
(normative)

Measurement of axial displacement in compression

B.1 Principle

Taking the uncompressed state as reference, displacement along the optical axis is measured when the IOL is compressed to a specified diameter.

B.2 Apparatus

B.2.1 Cylindrical well, with an inner diameter within ± 0,04 mm of that specified, with a base for loop location and a rim that allows viewing the IOL from the side, and constructed from a low-friction material to minimize loop rotational constraint (see Figure B.1). Alternatively, two anvils with faces having a radius within ± 0,02 mm of that specified, and produced from a low-friction material to minimize loop rotational constraint, e.g. as described in A.2.

B.2.2 Profile projector, accurate to 0,01 mm.

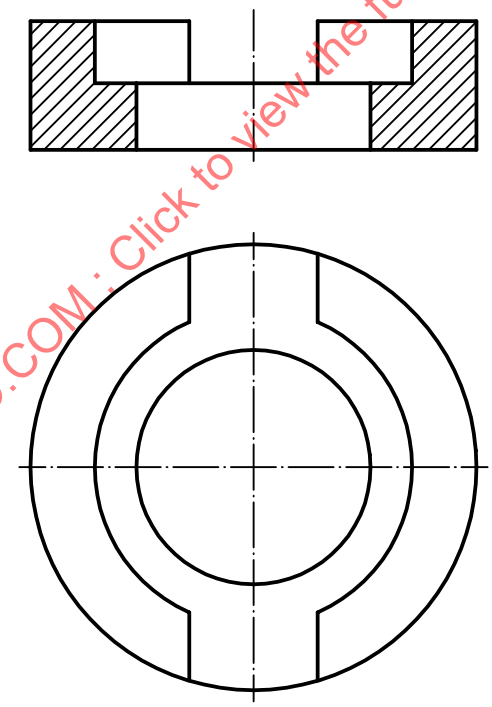


Figure B.1 — Cylindrical well for determination of axial displacement in compression

B.3 Procedure

B.3.1 Measure the distance l_0 shown in Figure B.2 by means of the profile projector with the IOL in the uncompressed state.

B.3.2 Place the IOL in the well (B.2.1) and centre the IOL manually as well as can be done visually, without exerting excessive force. Alternatively, place the IOL between the anvils (B.2.1) and close the anvils to the specified diameter as described in A.3.2, A.3.3 and A.3.4.

NOTE Placement of the IOL in the well induces asymmetrical forces on the loops, as in implantation. However, surgeons routinely centre the IOL manually after implantation. This is the rationale explaining why manual centration is permissible with the first method.

B.3.3 Measure the distance l shown in Figure B.3 by means of the profile projector.

B.3.4 Calculate the axial displacement $l - l_0$.

NOTE The sign convention is that a positive value indicates movement toward the retina as implanted.

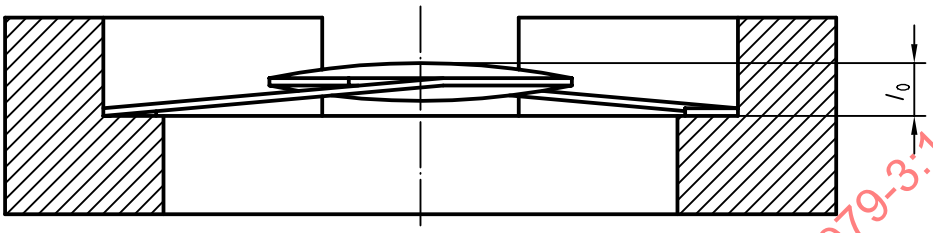
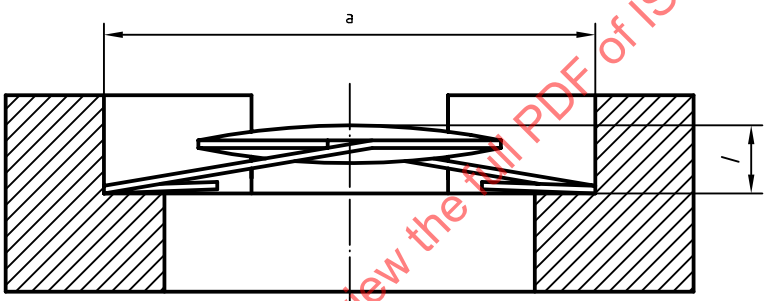


Figure B.2 — Cylindrical well with the IOL in uncompressed state

Dimensions in millimetres



a ∅ 10,00 ± 0,04 or ∅ 11,00 ± 0,04

Figure B.3 — Cylindrical well with the IOL in compressed state

B.4 Precision

The repeatability and reproducibility (see ISO 5725[2)] for definitions) are expected to be 0,2 mm and 0,3 mm, respectively.

NOTE Definitions of repeatability and reproducibility are found in ISO 5725[2)]. The quantities were derived as the result of interlaboratory tests conducted in accordance with ISO 5725[2)]. The variability due to measurement and population is inseparable, due to the sampling method used for the tests.

2) ISO 5725:1986. A revised version of ISO 5725 has since been published in several parts (see [2] to [7]).

B.5 Expression of results

The test report shall contain at least the following information:

a) test diameter;

b) identification of the test sample;

c) number of IOLs tested;

d) arithmetic mean and standard deviation of test readings; and

e) date of the test.

Annex C
(normative)

Measurement of optic decentration

C.1 Principle

Optic decentration is measured with the IOL confined to a specified diameter.

C.2 Apparatus

C.2.1 Cylindrical well, with an inner diameter within ± 0,04 mm of that specified, with a base for loop location, and constructed from a low-friction material to minimize loop rotational constraint. Alternatively, two anvils with faces having a radius within ± 0,02 mm of that specified, and produced from a low-friction material to minimize loop rotational constraint, e.g. as described in A.2.

C.2.2 Profile projector, accurate to 0,01 mm.

C.3 Procedure

C.3.1 Place the IOL in the well (C.2.1), ensuring that the loops are seated on the base (see Figure C.1), and centre the IOL manually as well as can be done visually, without exerting excessive force. Alternatively, place the IOL between the anvils (C.2.1) and close the anvils to the specified diameter as described in A.3.2, A.3.3 and A.3.4.

NOTE Placement of the IOL in the well induces asymmetrical forces on the loops, as during implantation. However, surgeons routinely centre the IOL manually after implantation. This is the rationale explaining why manual centration is permissible with the first method.

C.3.2 Measure the optic decentration C–C′ as shown in Figure C.1 using the profile projector.

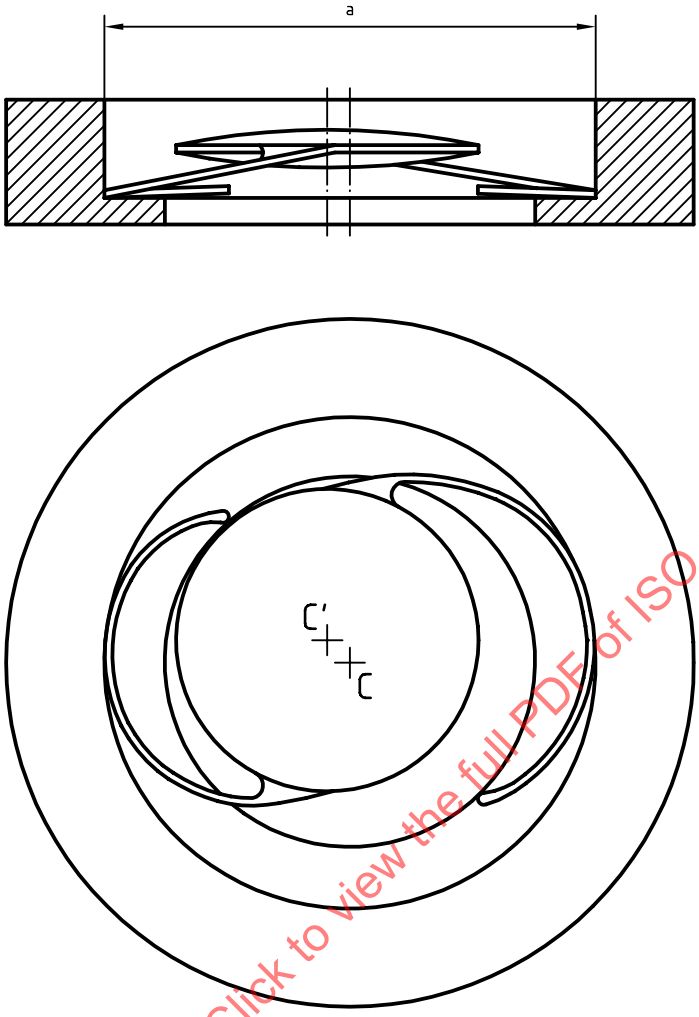
C.4 Precision

The repeatability and reproducibility (see ISO 5725[2)] for definitions) are both expected to be 0,2 mm.

NOTE Definitions of repeatability and reproducibility are found in ISO 5725[2)]. The quantities were derived as the result of interlaboratory tests conducted in accordance with of ISO 5725[2)]. The variability due to measurement and population is inseparable, due to the sampling method used for the tests.

2) ISO 5725:1986. A revised version of ISO 5725 has since been published in several parts (see [2] to [7]).

Dimensions in millimetres



Key

C Centre of well
C′ Centre of optic

a ∅ 10,00 ± 0,04 or ∅ 11,00 ± 0,04

Figure C.1 — Determination of optic decentration

C.5 Expression of results

The test report shall contain at least the following information:

a) test diameter;

b) identification of the test sample;

c) number of IOLs tested;

d) arithmetic mean and standard deviation of test readings; and

e) date of the test.

Annex D
(normative)

Measurement of optic tilt

D.1 Principle

Optic tilt is measured with the IOL confined to a specified diameter.

D.2 Apparatus

D.2.1 Cylindrical well, with an inner diameter within ± 0,04 mm of that specified, with a base for loop location, and constructed from a low-friction material to minimize loop rotational constraint. Alternatively, two anvils with faces having a radius within ± 0,02 mm of that specified, and produced from a low-friction material to minimize loop rotational constraint, e.g. as described in A.2.

D.2.2 Microscope, with a height gauge accurate to 0,01 mm.

D.2.3 *x*/*y*-Translation stage, fitted with position gauges accurate to 0,01 mm.

D.3 Procedure

D.3.1 Define the x and y axes of the Cartesian coordinates for the IOL as shown in Figure D.1, with the origin of coordinates at the centre of the optic, and with the x axis in the direction of the minimum distance between parallel planes, also parallel to the optical axis, that can be constructed to confine the optic.

D.3.2 Mark four intersections between the edge of the optic and each axis of the coordinates (P, Q, R and S in Figure D.1).

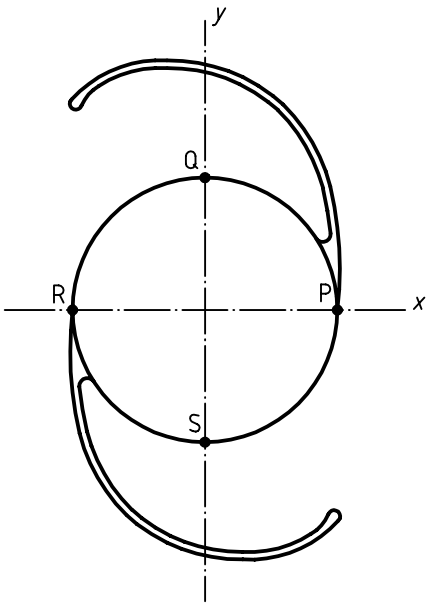
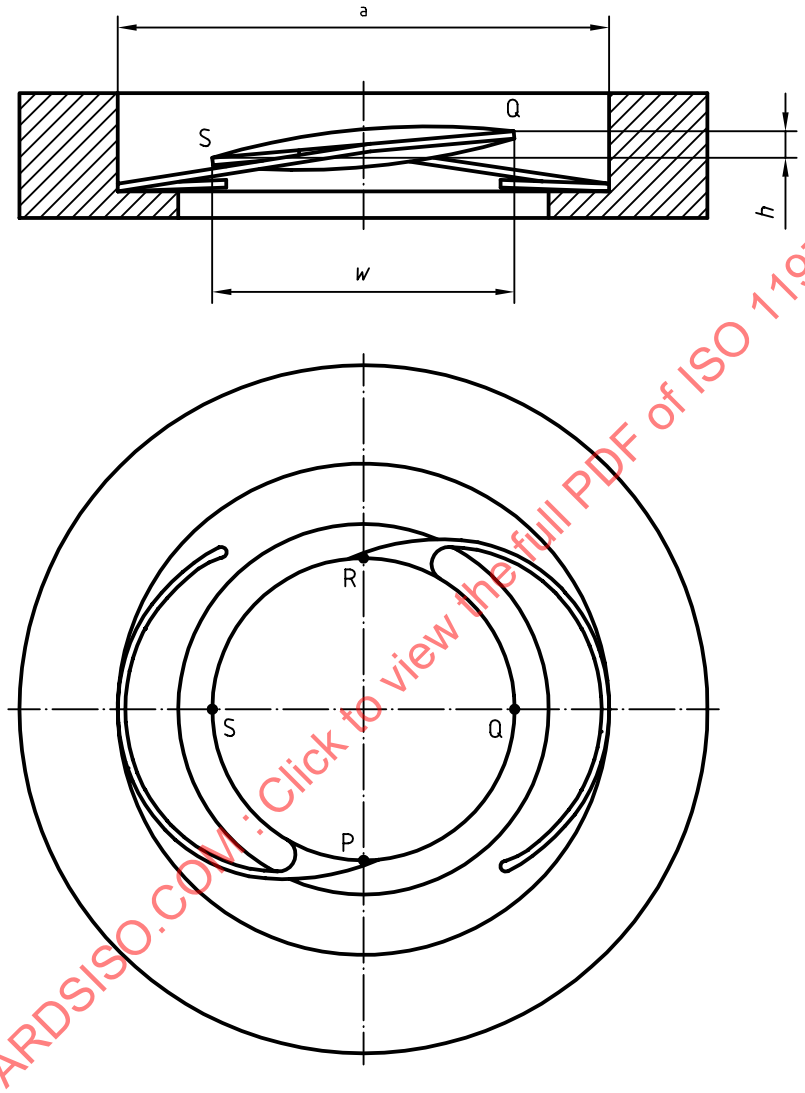


Figure D.1 — Points for determination of optic tilt

D.3.3 Place the IOL in the well (D.2.1), ensuring that the loops are seated on the base (see Figure D.2), and centre the IOL manually as well as can be done visually, without exerting excessive force. Alternatively, place the IOL between the anvils (D.2.1) and close the anvils to the specified diameter as described in A.3.2, A.3.3 and A.3.4.

NOTE Placement of the IOL in the well induces asymmetrical forces on the loops, as during implantation. However, surgeons routinely centre the IOL manually after implantation. This is the rationale explaining why manual centration is permissible with the first method.

Dimensions in millimetres



a ∅ 10,00 ± 0,04 or ∅ 11,00 ± 0,04

Figure D.2 — Determination of optic tilt

D.3.4 Measure horizontal and vertical distances between points Q and S (w and h in Figure D.2) and those between points P and R using the microscope with a height gauge and the translation stage with x and y gauges.

D.3.5 Calculate the tilt of the line QS (h/w in Figure D.2) and that of the line PR.

D.3.6 Calculate the optic tilt by using:

$$\text{optic tilt} = \tan^{-1}[\{(\text{tilt of line QS})^2 + (\text{tilt of line PR})^2\}^{0,5}]$$

D.4 Precision

The repeatability and reproducibility (see ISO 5725[2)] for definitions) are expected to be 1° and 2°, respectively.

NOTE Definitions of repeatability and reproducibility are found in ISO 5725[2)]. The quantities were derived as the result of interlaboratory tests conducted in accordance with ISO 5725[2)]. The variability due to measurement and population is inseparable, due to the sampling method used for the tests.

D.5 Expression of results

The test report shall contain at least the following information:

a) test diameter;

b) identification of the test sample;

c) number of IOLs tested;

d) arithmetic mean and standard deviation of test readings; and

e) date of the test.

2) ISO 5725:1986. A revised version of ISO 5725 has since been published in several parts (see [2] to [7]).

Annex E
(normative)

Measurement of angle of contact

E.1 Principle

An approximation of the total loop contact with the supporting ocular tissue is measured when the IOL is confined to a specified diameter.

E.2 Apparatus

E.2.1 Cylindrical well, with an inner diameter within ± 0,04 mm of that specified, with a base for loop location, and constructed from a low-friction material to minimize loop rotational constraint. Alternatively, two anvils with faces having a radius within ± 0,02 mm of that specified, and produced from a low-friction material to minimize loop rotational constraint, e.g. as described in A.2.

E.2.2 Device for measuring angles, accurate to 0,5°.

E.3 Procedure

E.3.1 Place the IOL in the well (E.2.1), ensuring that the loops are seated on the base (see Figure E.1), and centre the IOL manually as well as can be done visually, without exerting excessive force. Alternatively, place the IOL between the anvils (E.2.1) and close the anvils to the specified diameter as described in A.3.2, A.3.3 and A.3.4.

NOTE Placement of the IOL in the well induces asymmetrical forces on the loops, as during implantation. However, surgeons routinely centre the IOL manually after implantation. This is the rationale explaining why manual centration is permissible with the first method.

E.3.2 Measure the angle of contact, i.e. the angle between the points where the clearance between loop and well wall (or anvil faces) is 0,25 mm. If the loop makes multiple contacts, report the sum of the angles of contact as measured for each loop (see Figure E.1).

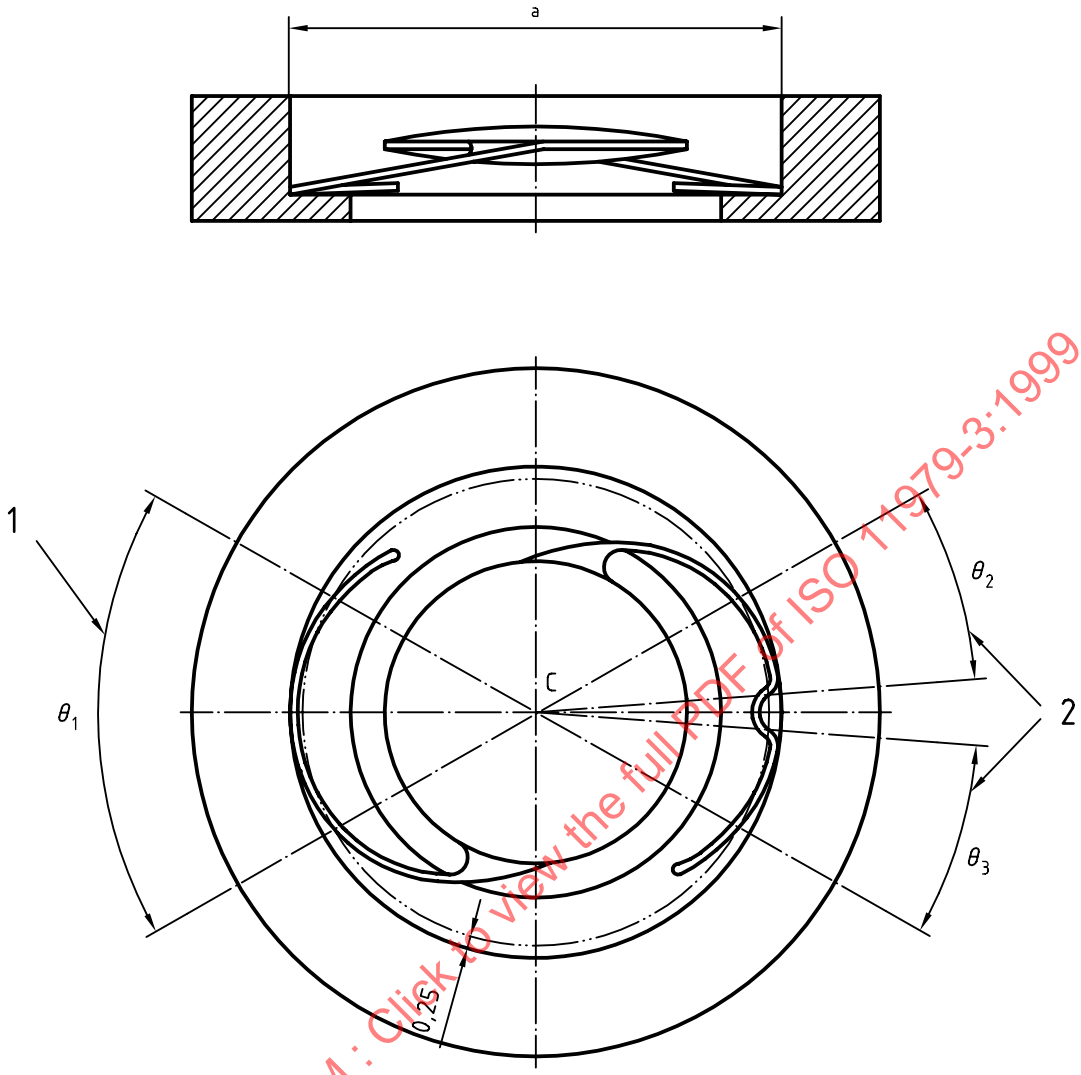
E.4 Precision

The repeatability and reproducibility (see ISO 5725[2)] for definitions) are expected to be 3° and 8°, respectively.

NOTE Definitions of repeatability and reproducibility are found in ISO 5725[2)]. The quantities were derived as the result of interlaboratory tests conducted in accordance with ISO 5725[2)]. The variability due to measurement and population is inseparable, due to the sampling method used for the tests.

2) ISO 5725:1986. A revised version of ISO 5725 has since been published in several parts (see [2] to [7]).

Dimensions in millimetres



Key

1 Angle of contact = θ_1
2 Angle of contact = $\theta_2 + \theta_3$
C Centre of well

a ∅ 10,00 ± 0,04 or ∅ 11,00 ± 0,04

Figure E.1 — Determination of angle of contact

E.5 Expression of results

The test report shall contain at least the following information:

a) test diameter;

b) identification of the test sample;

c) number of IOLs tested;

d) arithmetic mean and standard deviation of test readings, for each type of loop; and

e) date of the test.

Annex F
(normative)

Measurement of compression force decay

F.1 Principle

Measurement of residual compression force when the IOL has been confined to a specified diameter under *in situ* conditions for a specified time.

NOTE The precision of this method has not been explicitly evaluated, but the two measurements of compression force have the same precision as stated in A.4.

F.2 Apparatus

F.2.1 Cylindrical well, with an inner diameter within ± 0,04 mm of that specified, with a base for loop location, submerged under *in situ* conditions.

F.2.2 Thermostatted bath, accurate to ± 2 °C into which the well containing the IOL can be submerged under simulated *in situ* conditions.

F.3 Procedure

F.3.1 Use IOLs which have not been previously used for any other testing involving compression or other deformation of the loops.

F.3.2 Measure the compression force using the method described in annex A.

F.3.3 Within 30 min after the compression force measurement, place the IOL in the well (F.2.1) and immerse in the thermostatted bath for 24 h ± 30 min.

F.3.4 Remove the IOL from the well and measure the compression force 20 min ± 5 min after removal, using the method described in annex A.

F.4 Expression of results

The test report shall contain at least the following information:

a) test diameter;

b) identification of the test sample;

c) number of IOLs tested;

d) arithmetic mean and standard deviation of test readings before immersion;

e) arithmetic mean and standard deviation of test readings after immersion; and

f) date of the test.

Annex G
(normative)

Testing of dynamic fatigue durability

G.1 Principle

Fatigue testing is carried out by compressing the IOL to a specified dimension and giving cyclic compressive loading to the loop.

G.2 Apparatus

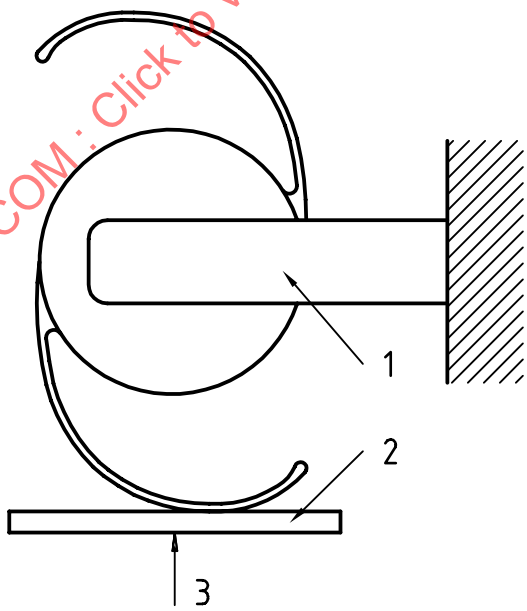
A diagram of the apparatus is shown in Figure G.1 and comprises:

G.2.1 Clamp.

G.2.2 Testing plate, with a flat surface, produced from a low-friction material to minimize haptic frictional constraint.

G.2.3 Device capable of producing 250 000 cycles of near-sinusoidal compressive loading at an amplitude of 0,5 mm perpendicular to the testing plate.

NOTE Figure G.1 shows the arrangement of the apparatus.



Key

1 Clamp
2 Testing plate
3 Compression

Figure G.1 — Arrangement for testing dynamic fatigue durability

G.3 Procedure

G.3.1 Clamp the body so that the optical axis is parallel to the testing plate (G.2.2) and the line of compression corresponds to the line which bisects the angle of contact as described in A.3.3.

G.3.2 Compress the IOL to the appropriate dimension.

G.3.3 Perform the cyclic compression on the haptic for 250 000 cycles at an amplitude of 0,5 mm.

G.3.4 Check whether the loop has broken.

G.4 Expression of results

The test report shall contain at least the following information:

a) dimension of compression;

b) identification of the test sample;

c) number of IOLs tested;

d) number of loops tested, for each type of loop;

e) number of loops broken, for each type of loop; and

f) date of the test.

Annex H
(informative)

Measurement of loop pull strength

H.1 Principle

Determination of maximum force sustainable in tension colinear with the loop at its junction with the optic.

H.2 Apparatus

H.2.1 Tensometer capable of measuring force with a resolution accuracy of ± 0,01 N and capable of producing extension rates between 1 mm/min and 6 mm/min.

H.3 Procedure

H.3.1 Clamp the optic so that the direction of pull is tangential to the loop at the loop/optic junction (see Figure H.1).

H.3.2 Set the extension rate in the range between 1 mm/min and 6 mm/min and activate the tensometer.

H.3.3 Pull the IOL until the loop breaks or separates from the optic, or until the pull force reaches 0,25 N. Discard results if the loop breaks in the clamp.

NOTE It is customary in tensile testing to discard results when sample breaks in the clamp, since it can then be inferred that the clamping has influenced the result.

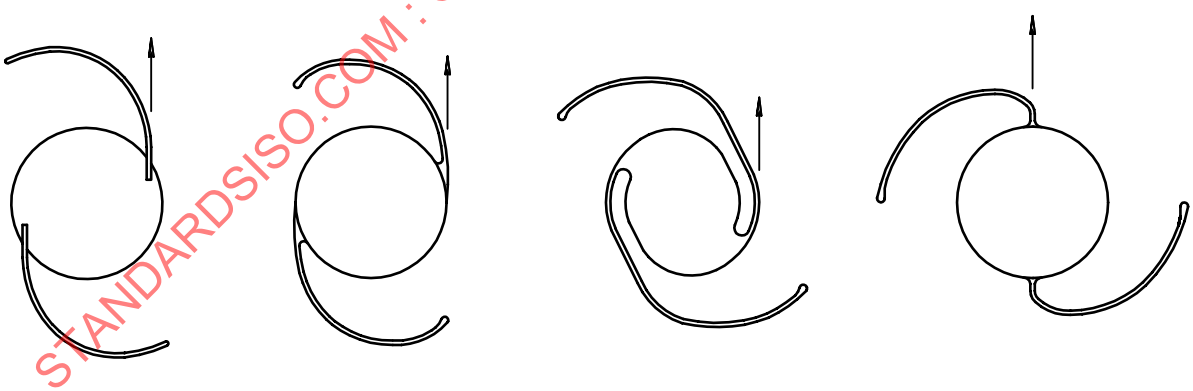


Figure H.1 — Direction of pull

H.4 Expression of results

The test report shall contain at least the following information:

a) identification of the test sample;

b) number of IOLs tested;

c) number of loops tested, for each type of loop;

d) number of loops broken with a pull force of less than 0,25 N for each type of loop; and

e) date of the test.

Annex I
(informative)

Mechanical data analysis

I.1 Principle

Mechanical data, i.e. compression force, compression force after decay and angle of contact, can be used to assess whether a modified IOL is a Level A modification of a parent IOL, as described in ISO 11979-7 [1].

This annex describes in detail, with the help of examples, the application of the two methods of analysis given in ISO 11979-7, i.e. the comparison of a modified model to a single parent model and the comparison of a modified model to all parent models of a sponsor.

I.2 Terms and definitions

For the purposes of this annex only, the following terms and definitions apply.

NOTE 1 For the definition of “parent intraocular lens model”, see ISO 11979-1.

NOTE 2 A parent IOL model should have undergone a clinical investigation involving at least 100 subjects at each reporting form, either in a full clinical investigation or in the limited investigation of a Level B modification (see ISO 11979-7 [1]). A Level A modified IOL model which was added to the clinical investigation of the parent model could itself only be considered a parent IOL model if that Level A modified model was investigated with a minimum of 100 subjects at each form and if the results of a statistical and clinical analysis indicate that there is no significant difference between its clinical performance and the clinical performance of its parent model.

I.2.1
open-loop IOL
IOL model which contains two loops, each loop having one end attached to the body of the IOL and the other end free

I.2.2
closed-loop IOL
IOL model which contains two loops, each loop having both ends attached to the body of the optic

I.2.3
hybrid open-loop/closed-loop IOL
IOL model which contains two loops, with one loop having one end attached to the body of the IOL and the other end free, and the other loop having both ends attached to the body of the IOL

I.3 Procedures

I.3.1 General

A sponsor may use either of two alternative methods to determine that a modified model is a Level A modification. If a sponsor determines, using either method, that the modified model is not a Level A modification of the parent model(s), the sponsor should also determine that the modified model is not a Level A modification using the other method of analysis, before deciding to conduct a clinical investigation of the modified model.

I.3.2 Mechanical comparison between a single model and a modified version of that model

I.3.2.1 General

For comparisons between a modified model and a single parent model, which is either currently undergoing a clinical investigation or has completed a clinical investigation, the sponsor should demonstrate that the mechanical properties of the modified lens are not significantly different from those of that parent model.

The following general restrictions apply.

— In no case should the change in loop configuration or overall diameter associated with the modified model result in a greater than 40 % change in angle of contact compared to the parent model at the applicable compressed diameters.

— A model of either the open-loop, closed-loop, or hybrid open/closed-loop types should be compared only to the same type of model.

— Models of the open-loop or closed-loop type having dissimilar loops should have each loop assessed separately, and then each loop on the modified model should be compared to the corresponding loop on the parent model that it most closely resembles.

— The maximum standard deviation associated with the parent's and the modified model's compression force values (initial and after decay) that may be used for the analysis is restricted to 20 % of the mean force value.

The analysis between the modified model and the sponsor's parent model should include the following comparisons:

— compression force divided by angle of contact per loop;

— compression force after decay divided by angle of contact per loop.

For each test needed for the analysis, the lens should be evaluated at 10,0 mm compressed diameter if the modified lens is only for capsular bag fixation, at 11,0 mm if it is only for ciliary sulcus fixation, or at both diameters if it is for both.

The sponsor should determine the force necessary to compress the parent model and the modified model to the required overall diameter(s) (see annex A for method). The mean force value (F), and the standard deviation (σ) should be calculated. From this data, the upper force boundaries (UFB_p) and lower force boundaries (LFB_p) should be calculated using these equations for the parent model:

$$UFB_p = F_p + \sigma_p \qquad \text{(when } F_p \geqslant 1100 \times 10^{-5} \text{ N)}$$

$$UFB_p = F_p + 3\sigma_p - [(F_p - 800 \times 10^{-5}\ \text{N})/150 \times 10^{-5}\ \text{N}]\sigma_p \qquad \text{(when } 800 \times 10^{-5}\ \text{N} < F_p < 1100 \times 10^{-5}\ \text{N)}$$

$$UFB_p = F_p + 3\sigma_p \qquad \text{(when } F_p \leqslant 800 \times 10^{-5}\ \text{N)}$$

$$LFB_p = F_p - 3\sigma_p \qquad \text{(when } F_p \geqslant 150 \times 10^{-5}\ \text{N)}$$

$$LFB_p = F_p - (F_p/50 \times 10^{-5}\ \text{N})\sigma_p \qquad \text{(when } F_p < 150 \times 10^{-5}\ \text{N)}$$

NOTE The compression force values 150×10^{-5} N and 800×10^{-5} N represent the lower and upper boundaries, respectively, containing most of the IOL models that have demonstrated acceptable clinical performance. Since much less is known about the clinical performance of IOL models outside these boundaries, a more conservative approach has been taken with parent models with loop flexibilities outside these boundaries to minimize the difference between the parent and the modified model. The equations above accomplish this in the following manner:

— by using $3\sigma_p$ only with parent models that display mean compression force values between 150×10^{-5} N and 800×10^{-5} N;

— by decreasing the σ_p used in the LFB_p equation in a continuous manner until it equals $0 \times \sigma_p$ at 0 mean compression force with parent models that display mean compression force values below 150×10^{-5} N;

— by decreasing the σ_p used in the UFB_p equation with parent models that display mean compression force values above 800×10^{-5} N in a continuous manner until it equals $1 \times \sigma_p$ at a mean compression force value of 1100×10^{-5} N; and

— by using σ_p with parent models that display mean compression force values above 1100×10^{-5} N.

The upper force boundaries (UFB_m) and lower force boundaries (LFB_m) should be calculated using these equations for the modified model:

$$UFB_m = F_m + \sigma_m$$

$$LFB_m = F_m - \sigma_m$$

As stated above, for both the parent and modified models, the maximum standard deviation is restricted to 20 % of *F*.

The sponsor should determine the angle of contact (*AC*) associated with the loops of the parent models and the modified model when the lenses are compressed to the required overall diameter(s) (see annex E for method). The *UFB* and the *LFB* divided by the mean *AC* at the compressed overall diameter(s) determine the range of force values per degree of *AC* associated with the parent lens and the modified lens at the compressed diameter(s).

For the modified lens to be considered a Level A modification of the parent model, the following is required.

— The mean AC_m associated with the loops of the modified model at the required compressed overall diameter(s) should be within ± 40 % of the mean AC_p associated with the loops on the parent model at each of the compressed overall diameters.

— Some part of the range defined by the UFB_m/AC_m and the LFB_m/AC_m for the modified lens should overlap the range defined by the UFB_p/AC_p and the LFB_p/AC_p for the parent model at each of the compressed overall diameters, both initially and after decay.

The two examples below illustrate hypothetical results using this method of analysis to demonstrate that a modified lens is a Level A modification of the parent lens.

I.3.2.2 EXAMPLE 1

The sponsor has four open-loop posterior chamber parent models which are indicated for both ciliary sulcus and capsular bag fixation:

Model 1: C-loop (14,0 mm overall diameter)

Model 2: modified C-loop (12,0 mm overall diameter)

Model 3: J-loop (13,5 mm overall diameter)

Model 4: modified J-loop (13,0 mm overall diameter)

The sponsor has taken a minimum of 10 samples of each of the models, and has determined the compression force necessary to compress each model to an overall diameter of 10 mm. The mean force values (*F*), and the standard deviations (σ) were calculated. From these data the upper force boundaries (*UFB*) and lower force boundaries (*LFB*) were calculated according to the equations and procedure above.

The *AC* associated with each loop when the lens was compressed to 10 mm was measured and the mean value was determined. Next, the *UFB* and *LFB* were divided by the mean *AC*. These values determine the range of force values per degree of *AC* associated with a lens when compressed to 10 mm overall diameter.

The procedures described above were repeated for an overall compression diameter of 11 mm and for 10 mm and 11 mm of overall compressed diameter after decay.

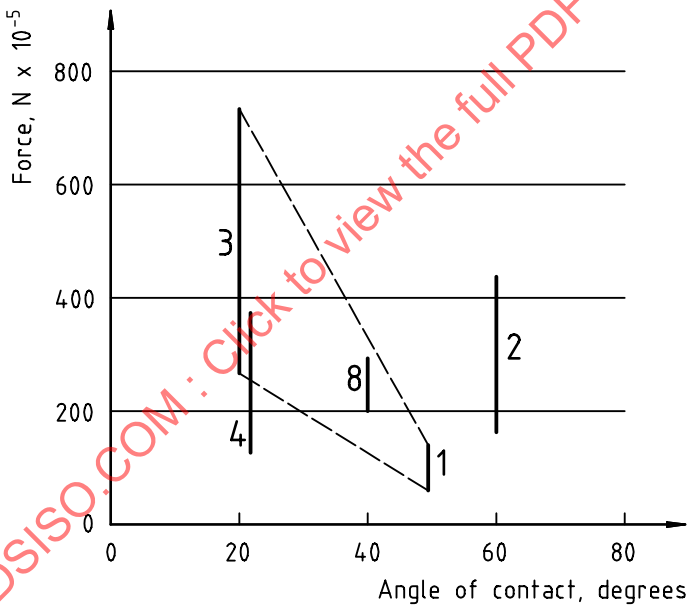
Table I.1 lists the data associated with the four hypothetical models at 10 mm overall constrained diameter, and Figure I.1 shows the bar chart derived from those data.

Table I.1 — Mechanical data for Models 1 to 4 at 10 mm

Model	1	2	3	4
F	90×10^{-5} N	300×10^{-5} N	500×10^{-5} N	250×10^{-5} N
σ	25×10^{-5} N	45×10^{-5} N	75×10^{-5} N	40×10^{-5} N
UFB	44×10^{-5} N [a]	435×10^{-5} N	725×10^{-5} N	370×10^{-5} N
LFB	58×10^{-5} N [a,b]	165×10^{-5} N	275×10^{-5} N	130×10^{-5} N
AC	50°	60°	20°	22°
UFB/AC	2,9	7,3	36	17
LFB/AC	1,2	2,8	14	5,9

[a] $\sigma > 0{,}2F$, therefore σ was restricted to $0{,}2F$.

[b] $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p/50 \times 10^{-5}\ \text{N})\sigma_p$ was used.



Key

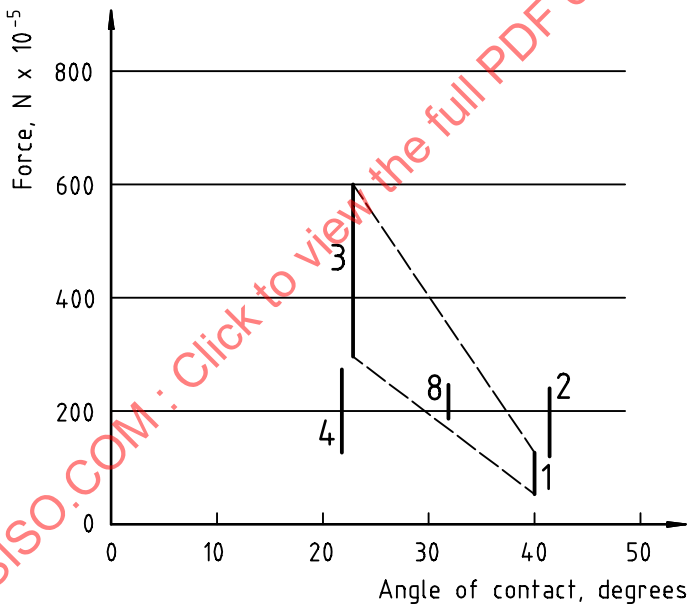
1 Model 1
2 Model 2
3 Model 3
4 Model 4
8 Model 8

Figure I.1 — *FIAC* range for Models 1 to 4 at 10 mm of Example 1
(dotted lines and reference to Model 8 pertain to Example 3)

Table I.2 lists the data associated with the four hypothetical models at 11 mm overall constrained diameter, and Figure I.2 shows the bar chart derived from those data.

Table I.2 — Mechanical data for Models 1 to 4 at 11 mm

Model	1	2	3	4
F	80×10^{-5} N	180×10^{-5} N	450×10^{-5} N	200×10^{-5} N
σ	16×10^{-5} N	$20 \times 10^{\times 5}$ N	50×10^{-5} N	25×10^{-5} N
UFB	128×10^{-5} N	240×10^{-5} N	600×10^{-5} N	275×10^{-5} N
LFB	54×10^{-5} N [a]	120×10^{-5} N	300×10^{-5} N	125×10^{-5} N
AC	40°	42°	23°	22°
UFB/AC	3,2	5,7	26	12
LFB/AC	1,4	2,9	13	5,7
a $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p/50 \times 10^{-5}\ \text{N})\sigma_p$ was used.				



Key

1 Model 1
2 Model 2
3 Model 3
4 Model 4
8 Model 8

Figure I.2 — *FIAC* range for Models 1 to 4 at 11 mm of Example 1
(dotted lines and reference to Model 8 pertain to Example 3)