BS EN ISO 11979-3:2012

BSI Standards Publication

Ophthalmic implants — Intraocular lenses

Part 3: Mechanical properties and test methods (ISO 11979-3:2012)

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National foreword

This British Standard is the UK implementation of EN ISO 11979-3:2012. It supersedes BS EN ISO 11979-3:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/7, Eye implants.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Ophthalmische Implantate - Intraokularlinsen - Teil 3: Mechanische Eigenschaften und Prüfverfahren (ISO 11979-3:2012)

This European Standard was approved by CEN on 30 November 2012.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 11979-3:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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

This document supersedes EN ISO 11979-3:2006.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11979-3:2012 has been approved by CEN as a EN ISO 11979-3:2012 without any modification.

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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 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 11979-3 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-3:2006), which has been technically revised in order to include relevant requirements and test methods for toric intraocular lenses and accommodating intraocular lenses.

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*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

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[7]. Because of the complexity of this analysis, detailed descriptions and examples have been given in ISO/TR 22979[8]. 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 part of ISO 11979.

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

INTERNATIONAL STANDARD ISO 11979-3:2012(E)

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.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 apply.

4 Requirements

4.1 General

For all IOLs, the mechanical properties shall be determined at *in situ* conditions. The precise composition of the solution used shall be reported in all cases. Alternative test conditions, e.g. room temperature conditions, may be used if a justification to deviate from *in situ* is given. The alternative test conditions shall be specified in the test reports.

For each of the methods described below, tests shall be performed on a minimum of three IOL lots of medium dioptric power. If dioptric power affects the property tested, the lots shall comprise one each of low, medium and high dioptric powers. For toric intraocular lenses, half of each of these three lots shall contain intraocular lenses with the highest cylindrical power, and the other half shall contain intraocular lenses with the lowest cylindrical power. 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. Means and standard deviations shall be reported for the pooled samples.

If, for certain designs and certain applications, a specific test method described in this part of ISO 11979 is not applicable, the IOL manufacturer can devise a corresponding test method and provide a validation and rationale for it.

For accommodating IOLs (AIOLs) the theoretical mechanism of action to change the power of the eye shall be described e.g. the change of curvature or the movement of lens elements under compression. The general factors determining this action shall be characterized and specified. Further mechanical testing over a range that includes the maximum and minimum limits of the theoretical mechanism of

action shall be performed. If the dynamic response to the mechanism of action is time dependent, this time dependency shall be characterized.

4.2 Tolerances and dimensions

The tolerances for overall diameter, vault height and sagitta are given in Table 1.

Table 1 — Tolerances of overall diameter, vault height and sagitta

Test method	Overall diameter	Vault height	Sagitta
Anterior chamber IOLs	±0,20 mm	±0,15 mm	±0,25 mm
Multi piece posterior chamber IOLs	±0,30 mm	±0,35 mm	±0,45 mm
Other IOLs	±0,20 mm	±0,25 mm	±0,35 mm

The tolerance on the clear optic shall be ± 0,15 mm. The diameter of the clear optic shall be greater than 4,25 mm in any meridian. 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 nominal $\left(\begin{smallmatrix}+0,05\\0\end{smallmatrix}\right)$ 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.

4.3 Clearance analysis (anterior chamber lenses only)

An empirical analysis of anatomic placement shall be performed for anterior chamber lenses to evaluate the most proximate points with relation to the anatomical structures of the eye. The clearance of the anterior surface of the IOL optic in relation to the endothelial layer of the cornea shall be determined for the lens at its minimum recommended diameter in its compressed state. In addition the separation between the posterior surface of the IOL optic and the iris shall be determined. For phakic IOLs, the separation between the posterior surface of the IOL optic and the crystalline lens shall also be determined. These results shall be considered in the risk analysis. The theoretical eye model in Annex I can be used in the evaluation.

The manufacturer shall strive for a clearance of at least 1 mm under worst-case conditions, i.e. conditions which would result in the minimum amount of clearance.

4.4 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, with the haptics compressed to a diameter of 10 mm;

b) for IOLs intended for sulcus placement, with the haptics compressed to a diameter of 11 mm;

c) for IOLs intended for both capsular bag and sulcus placement, with the haptics compressed to both a diameter of 10 mm and a diameter of 11 mm;

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

4.5 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 4.4).

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 4.4.

4.6 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 4.4).

The sum of the arithmetic mean and two standard deviations of the optic decentration shall not exceed 10 % of the clear optic.

4.7 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 4.4).

The sum of the arithmetic mean and two standard deviations of the optic tilt shall not exceed 5°.

4.8 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 4.4).

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

4.9 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 4.4).

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

Results shall be reported as residual compression force after 24 h ± 2 h in compression at each required compressed diameter.

4.10 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;

d) for anterior chamber IOLs, at a distance between the testing plate and the centre of the optic, corresponding to half the maximum intended compressed diameter 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.

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

No loop tested shall break.

For IOLs designed to move axially under compression, additional testing shall be considered.

4.11 Surgical manipulation

The IOL manufacturer shall provide evidence that the loops of an IOL design are capable of withstanding surgical manipulations without failure. An appropriate test method and specification shall be established by the manufacturer to ensure that the device does not fail at typical deformations. A test method, useful for some designs with loops, is given in Annex H.

4.12 Surface and bulk homogeneity

The IOL shall be essentially free from defects, i.e. 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. The lens shall be inspected at 10 × magnification under optimal lighting conditions; any questionable or critical areas shall be viewed at higher magnification.

5 Recovery of properties following simulated surgical manipulation

The testing in this clause applies only to IOLs of which the optic is intended to be folded or compressed during implantation. Perform testing on 10 lenses of each of the dioptric powers with the smallest and largest cross-sectional dimensions. In practice this will typically be 10 lenses with the lowest and 10 lenses with the highest dioptric power. For toric intraocular lenses, half of each of these lens groups shall contain intraocular lenses with the highest cylindrical power, and the other half shall contain intraocular lenses with the lowest cylindrical power. Follow the instructions supplied by the manufacturer, using recommended lubricants and instrumentation. To determine the acceptable time during which the lens is allowed to be kept deformed prior to implantation, maintain the deformed state for a period of time. This time shall not be shorter than 3 min. Times in excess of 20 min need not be investigated. The time used shall be reported.

After release from the deformed state, allow the lens to relax at *in situ* conditions up to 24 h ± 2 h. The time used shall be reported. Subsequently:

a) measure dioptric power and image quality in accordance with ISO 11979-2;

b) measure overall diameter and sagitta in accordance with 4.2;

c) inspect for surface and bulk homogeneity in accordance with 4.12.

The results shall be reported and are acceptable if they remain within manufacturing specifications of the product.

6 Additions for accommodating IOLs (AIOLs)

6.1 Designs comprising multiple optical elements shall be evaluated on the alignment of the optics relative to each other in terms of centration. The effects of decentration on the optical performance of the AIOL shall be used to determine appropriate tolerances.

6.2 Designs comprising multiple optical elements shall be evaluated on the alignment of the optics relative to each other in terms of tilt. The effects of optic tilt on the optical performance of the AIOL shall be used to determine appropriate tolerances.

6.3 Using the principle described in 4.10, the theoretical motion of the AIOL in the eye shall be replicated for at least 1 million cycles. In addition to evaluating any damage of the AIOL after this treatment, the mechanical characteristics that determine the performance of the AIOL shall be assessed and shall not be found altered to an extent that can be clinically significant. Any other dynamic properties influencing the performance of the AIOL shall be evaluated. If the theoretical action does not include a radial compression of the haptic of 0,5 mm (±0,25 mm), the test in 4.10 shall be additionally performed.

6.4 If indicated by risk analysis and assessment, additional testing can be required to demonstrate the effect of aging on the continued functionality of the device. If the lens is meant to move or change shape, testing must elucidate the effect of ageing on movement or shape change (or other changes, such as refractive index).

6.5 Mechanical characteristics that affect the ability of an AIOL to function shall be demonstrated not to change to an extent that can be clinically significant following simulated surgical manipulation for implantation.

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, constructed from a low-friction material to minimize loop rotational constraint, and aligned relatively with each other.

A.2.2 **Device**, capable of measuring force accurate to at least ± 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 of 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

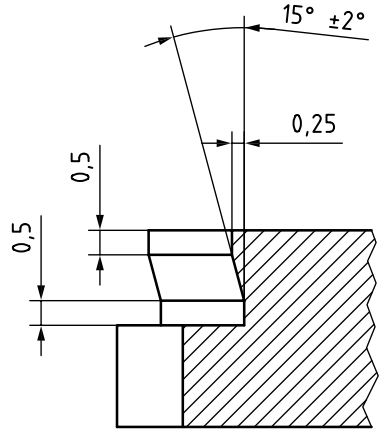


Figure A.1 — Anvil

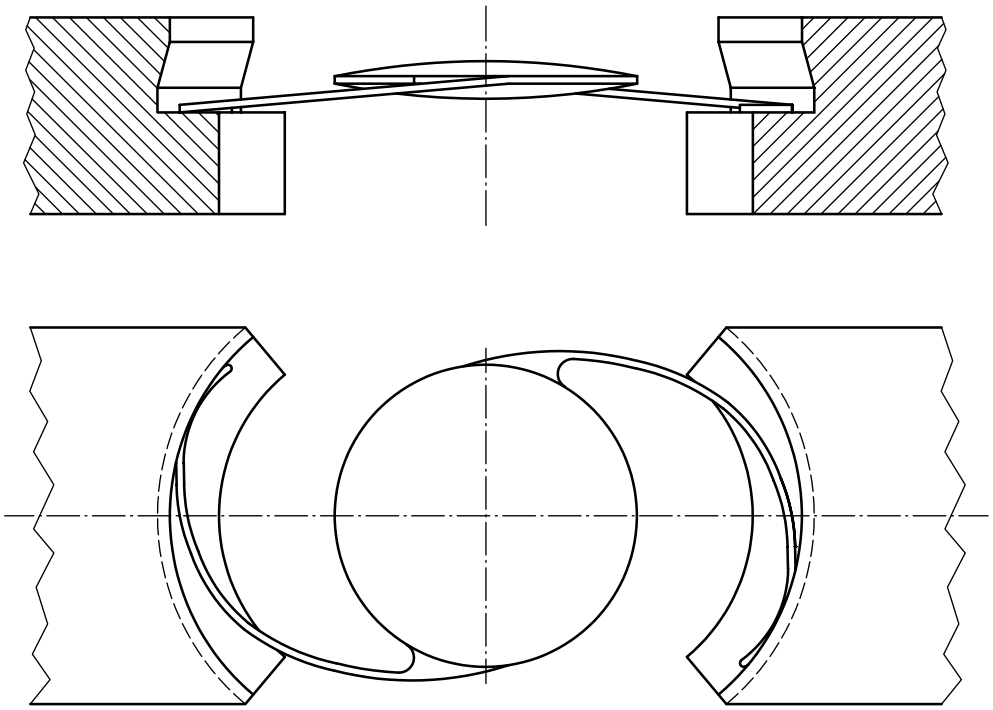
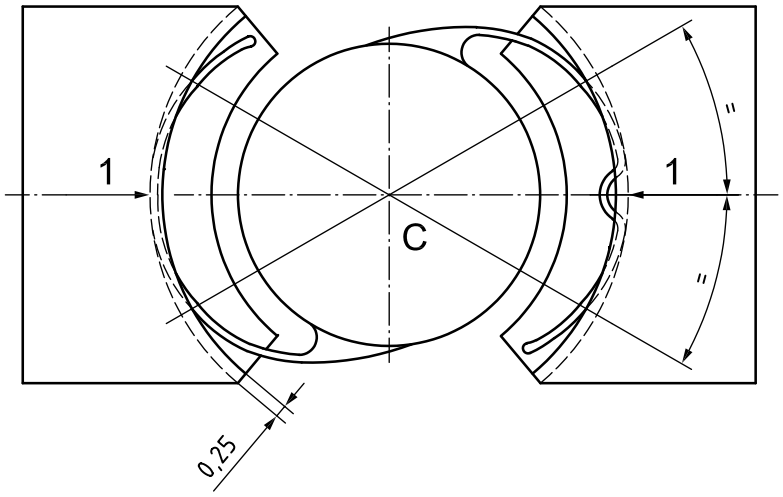


Figure A.2 — Arrangement for measurement of compression force

Dimensions in millimetres



Key

1 direction of 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 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) test diameter;

c) identification of the test sample;

d) number of IOLs tested;

e) arithmetic mean and standard deviation of test readings;

f) any alternative test conditions;

g) date of the test.

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, produced from a low-friction material to minimize loop rotational constraint, and aligned relatively with each other, e.g. as described in A.2.

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

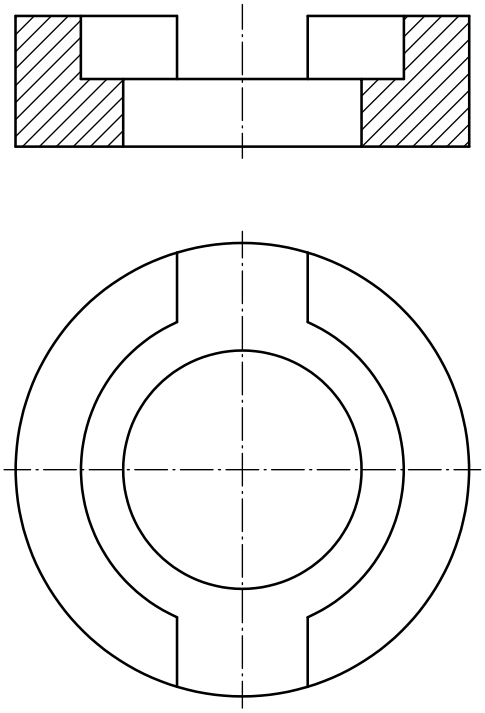


Figure B.1 — Cylindrical well for determination of axial displacement in compression

B.3 Procedure

B.3.1 Place the IOL in the well (B.2.1) and measure the distance h_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.

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

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

B.3.4 Calculate the axial displacement $h - h_0$.

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

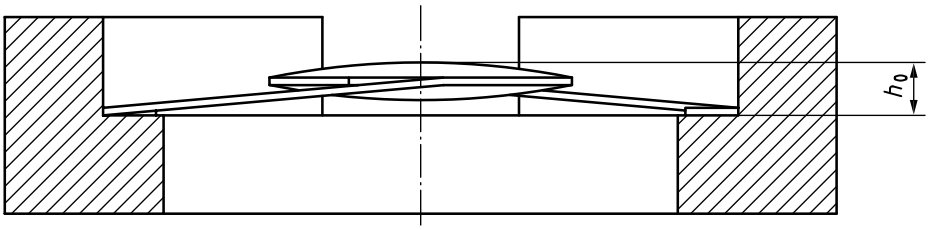
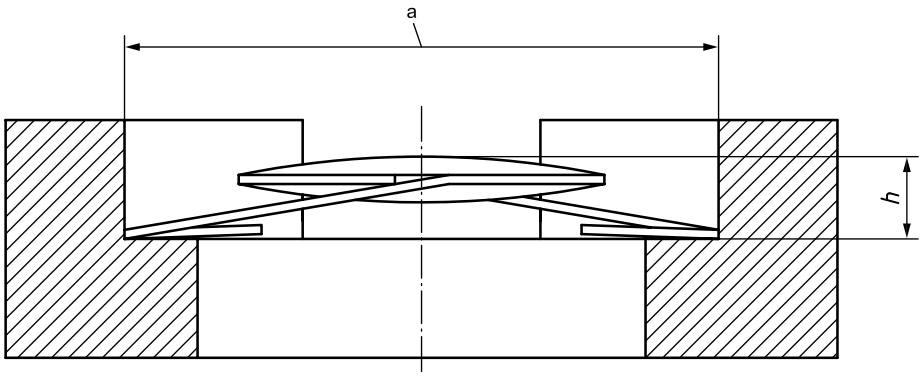


Figure B.2 — Cylindrical well with the IOL in uncompressed state

Dimensions in millimetres



[a] Ø 10,00 ± 0,04 or Ø 11,00 ± 0,04.

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

B.4 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) test diameter;

c) identification of the test sample;

d) number of IOLs tested;

e) arithmetic mean and standard deviation of test readings;

f) any alternative test conditions;

g) 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, produced from a low-friction material to minimize loop rotational constraint, and aligned relatively with each other, e.g. as described in A.2.

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

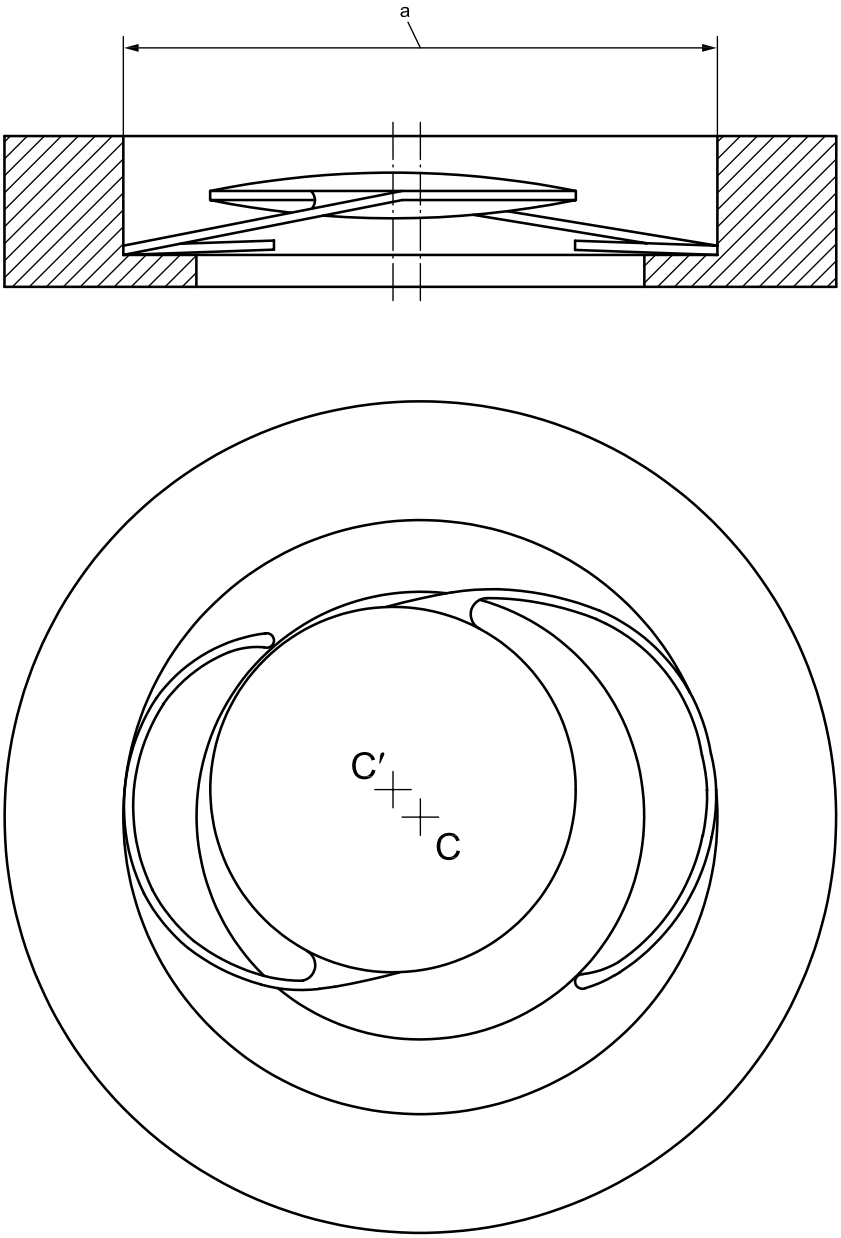
C.3 Procedure

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.

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

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



Key

C	centre of well
C′	centre of optic
a	Ø 10,00 ± 0,04 or Ø 11,00 ± 0,04.

Figure C.1 — Determination of optic decentration

C.4 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) test diameter;

c) identification of the test sample;

d) number of IOLs tested;

e) arithmetic mean and standard deviation of test readings;

f) any alternative test conditions;

g) 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, produced from a low-friction material to minimize loop rotational constraint, and aligned relatively with each other, 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.

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).

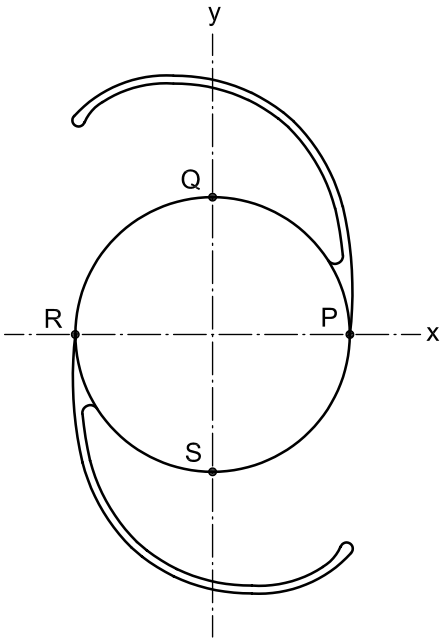


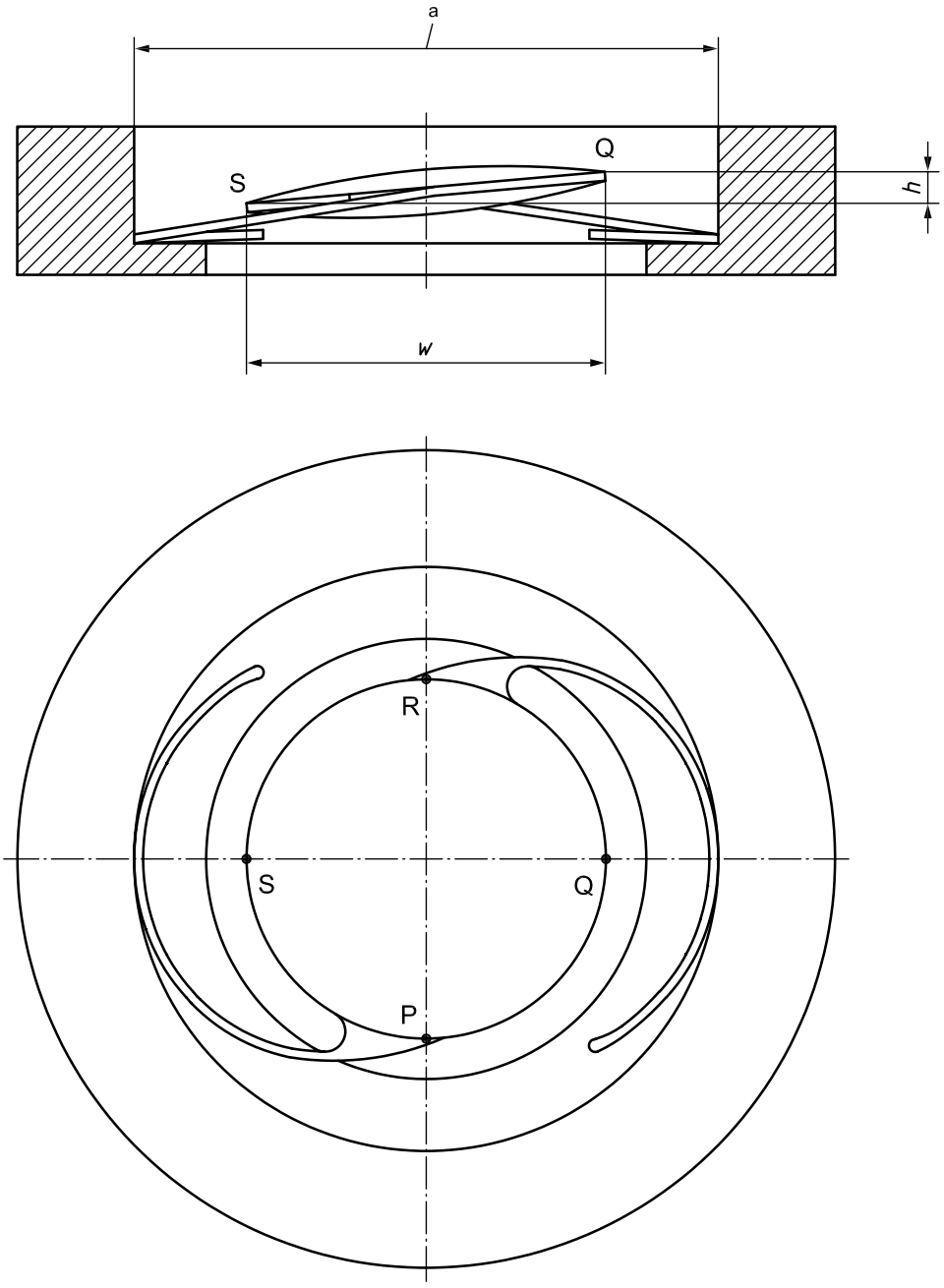
Figure D.1 — Points for determination of optic tilt

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. Ensure that the base of the well or anvils, where the loops will be seated, is parallel with the *x*/*y*-translation stage.

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

Dimensions in millimetres



a Ø 10,00 ± 0,04 or Ø 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 slope, s_1, of the line QS (h/w as shown in Figure D.2) and the slope, s_2, of the line PR.

D.3.6 Calculate the optic tilt, θ, expressed in degrees, by using:

$$\theta = \tan^{-1}\sqrt{s_1^2 + s_2^2}$$

where

s_1 is the tilt of the line QS;

s_2 is the tilt of the line PR.

D.4 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) test diameter;

c) identification of the test sample;

d) number of IOLs tested;

e) arithmetic mean and standard deviation of test readings;

f) any alternative test conditions;

g) date of the test.

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, produced from a low-friction material to minimize loop rotational constraint, and aligned relatively with each other, e.g. as described in A.2.

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

E.3 Procedure

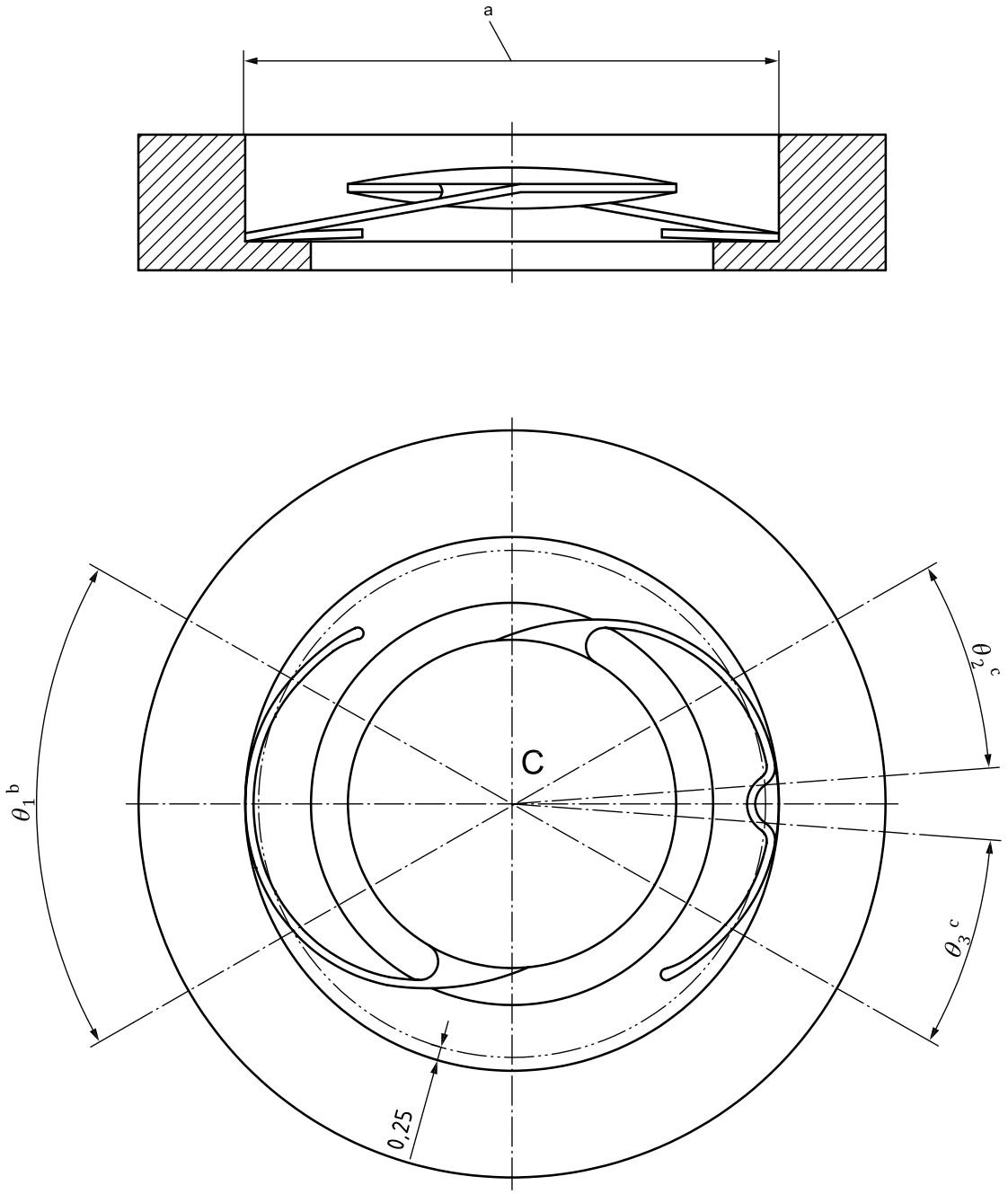
E.3.1 Place the IOL in the well (E.2.1), ensuring that the loops are seated on the base (see Figure E.1), and centre the IOL manually as well as can be done visually, without exerting excessive force.

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.

Placement of the IOL in the well or between the anvils induces asymmetrical forces on the loops, as during implantation. However, surgeons routinely centre the IOL manually after implantation. This is the rationale why manual centration is permissible with this 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).

Dimensions in millimetres



Key

C centre of well

a Ø 10,00 ± 0,04 or Ø 11,00 ± 0,04.

b Angle of contact = θ_1.

c Angle of contact = $\theta_2 + \theta_3$.

Figure E.1 — Determination of angle of contact

Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) test diameter;

c) identification of the test sample;

d) number of IOLs tested;

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

f) any alternative test conditions;

g) date of the test.

Annex F
(normative)

Testing 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 method of measurement of compression force has the same precision as the method in Annex A.

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.

F.2.2 Thermostatically controlled bath capable of keeping the well submerged at *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 bath for 24 h ± 60 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 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) test diameter;

c) identification of the test sample;

d) number of IOLs tested;

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

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

g) any alternative test conditions;

h) 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

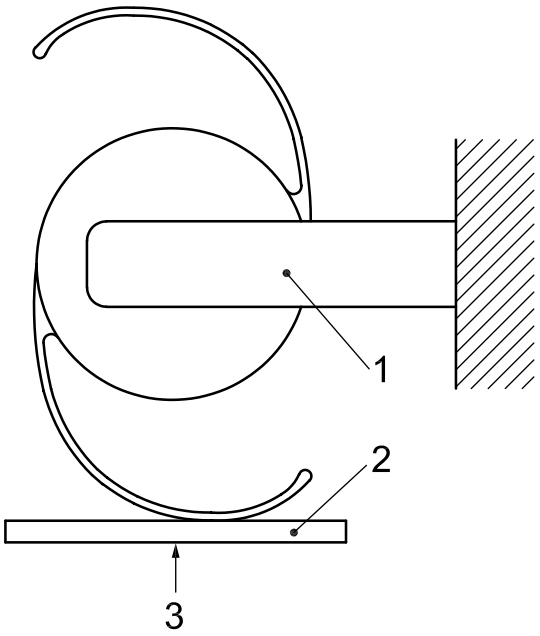
A diagram of the apparatus is shown in Figure G.1 and comprises the following.

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 with a peak-to-peak displacement 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 ± 0,25 mm around the compression distance.

G.3.4 Check whether the loop has broken.

G.4 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) dimension of compression;

c) identification of the test sample;

d) number of IOLs tested;

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

f) number of loops broken, for each type of loop;

g) any alternative test conditions;

h) date of the test.

Annex H
(informative)

Measurement of loop pull strength

H.1 Principle

Determination of maximum force sustainable in tension collinear 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 the sample breaks in the clamp, since it can then be inferred that the clamping has influenced the result.

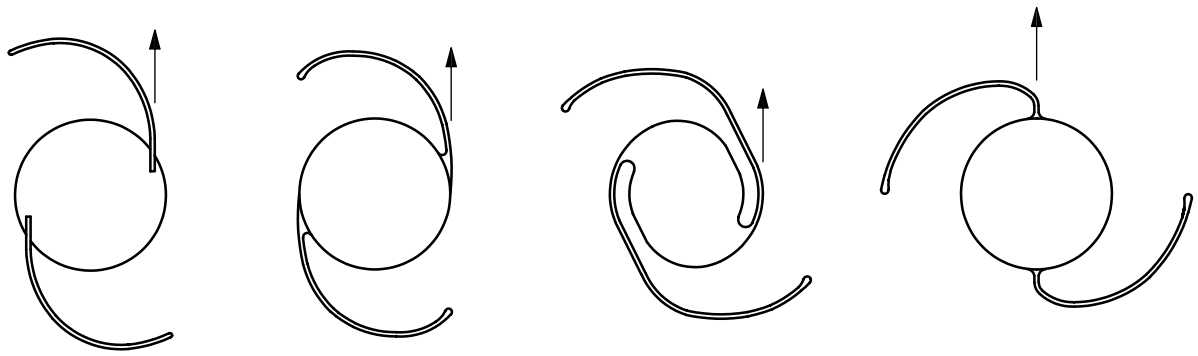


Figure H.1 — Direction of pull

H.4 Test report

Report at least the following:

a) reference to this part of ISO 11979;

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 with a pull force of less than 0,25 N for each type of loop;

f) any alternative test conditions;

g) date of the test.

Annex I
(informative)

Clearance analysis

I.1 Principle

To draft the IOL design into a theoretical schematic model of the anterior chamber of the eye. The analysis takes into account the clearance between the IOL, optic and haptics, and the cornea and the iris. In case of phakic IOLs, the clearance between IOL and crystalline lens is also considered.

I.2 Schematic model of the anterior chamber

I.2.1 A model that can be used for a clearance analysis is shown in Figure I.1.

Figure I.1 is intended to be used as an indication of clearance only. It is not intended for optical analysis.

Dimensions in millimetres

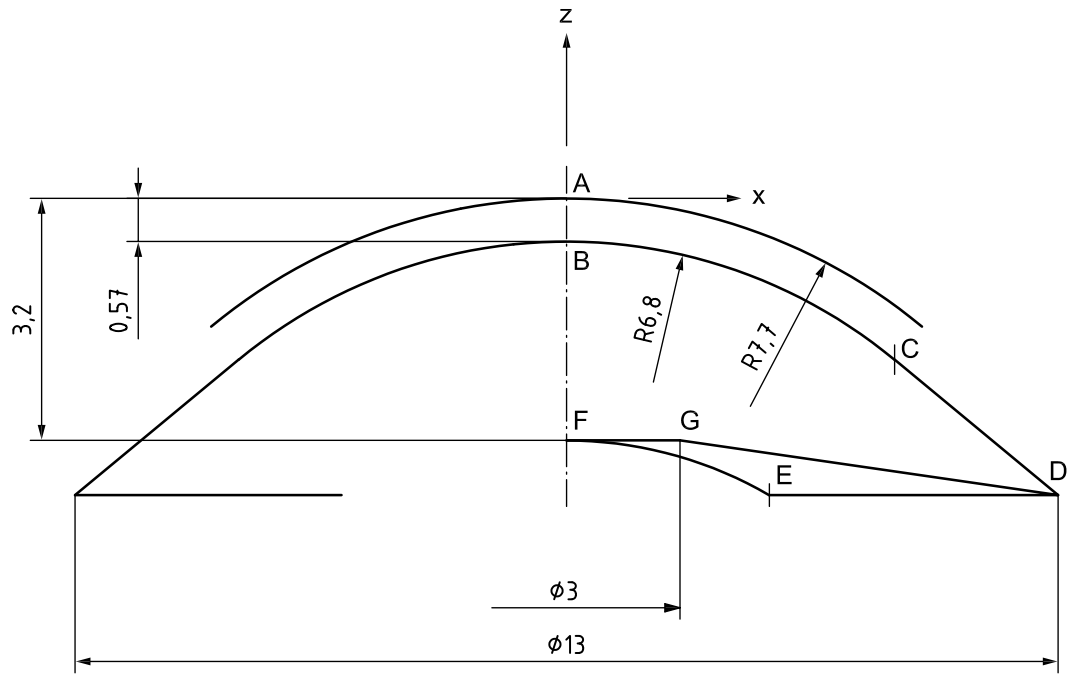


Figure I — 1 — Schematic anterior chamber for clearance analysis

I.2.2 The model is rotationally symmetric around the z-axis. For intraocular lenses with a complex three-dimensional design, the three-dimensional model is used. The geometric eye model consists of the following elements.

a) **Central anterior corneal surface (central part) A:**

   i) Circle segment.

   ii) Position of vertex (x; z): (0,00; 0,00).

   iii) Radius of curvature: 7,70 (see Reference [9]).

iv) Position of centre point (x; z): (0,00; –7,70).

b) **Central posterior corneal surface B – C:**

i) Circle element.

ii) Position of vertex (*x*; *z*): (0,00; –0,57) (see Reference [10]).

iii) Radius of curvature: 6,80 (see Reference [9]).

iv) Position of centre point (*x*; *z*): (0,00; –7,37).

c) **Peripheral posterior cornea C – D:**

i) A line element tangent to the central posterior cornea at Point C and through the anterior chamber angle D.

ii) Position of D: (6,50; –3,70)

iii) Position of C: (4,08; –1,93)

iv) Point D is the location of the anterior chamber angle. The *x* coordinate is half the angle-to-angle diameter. The angle-to-angle diameter is set equal to the white-to-white diameter + 1 mm. The white-to-white diameter is 12 mm as measured by Wang and Auffarth[11]. Point D is located at the intersection of the iris with the cornea. The position of the iris is estimated by the average anterior chamber depth of aphakic eyes. The average anterior chamber depth was determined by Hoffer on 400 subjects[12].

d) **Iris of aphakic eyes D – E:**

i) Line element perpendicular to the z-axis through point D.

NOTE For phakic eyes the anterior chamber angle is usually smaller.

e) **Accommodated anterior lens E – F (part of clearance analysis of phakic IOLs):**

i) The following values and coordinates are based upon a crystalline lens in the state of 10 D of accommodation.

ii) Circle element.

iii) Position of vertex (*x*; *z*): (0,00; –3,20) (see Reference [9]).

iv) Radius of curvature: 5,33 (see Reference [9]).

v) Position of centre point (*x*; *z*): (0,00;–8,53).

vi) The eye model can be adapted to test inclusion and exclusion criteria. A study by Hoffer[12] shows the variation in anterior chamber depth in phakic eyes. The study reports an average anterior chamber depth of 3,24 mm with a standard deviation of 0,44 mm, determined on 6 950 eyes, 72 years average in age (standard deviation 10 years).

f) **Iris of phakic eyes D –G (part of clearance analysis of phakic IOLs):**

i) A line element from the central anterior iris G (pupil size 3 mm) to the anterior chamber angle D.

ii) Position of Point G: (1,50; –3,20)

I.3 Procedure

I.3.1 Construct the schematic model of the anterior chamber on paper or in a CAD system.

I.3.2 Draw in the schematic model the anterior chamber lens at the intended position. If the IOL is intended for a smaller or larger angle-to-angle diameter, it should be drawn at that diameter. If the lens is compressed in the eye, it should be drawn in its compressed shape, taking the axial displacement under compression into account.

I.3.3 Measure the minimum distance of the lens body to the posterior surface of the cornea.

I.3.4 For a clearance analysis of phakic lenses, the state of accommodation should be considered. Measure the minimum distance between the lens body and the iris and crystalline lens, while the crystalline lens is in the accommodated state [see I.2.2 e)].

I.3.5 Perform the procedure for the extreme sizes of the range of lenses offered. In practice, this will typically be the lenses with the lowest and the highest dioptric power.

During accommodation, the central iris is displaced anteriorly and this should be taken in the clearance analysis.

I.4 Test report

Report at least the following:

a) reference to this part of ISO 11979;

b) intended angle-to-angle diameter;

c) axial displacement under compression of the lens that is being analysed;

d) indication or description of the most proximate point(s) of the lens body to the posterior surface of the cornea and report the clearance between the lens body and cornea;

e) indication or description of the nearest point(s) of the lens body to the anterior surfaces of the crystalline lens and iris (phakic eyes only);

f) clearance between the lens body and anterior surfaces of crystalline lens and iris (phakic eyes only);

g) schematic drawings of the anterior eye chamber with the lens model under evaluation;

h) schematic drawings of the anterior eye chamber with the lens models that are used for comparison in the risk analysis;

i) any alternative test conditions.

Annex J
(informative)

Precision

The values and equations for precision of the test methods in Annexes A to E were derived as the result of interlaboratory tests completed in 1994 on IOLs with a mechanical behaviour typical for that time. The tests were conducted in accordance with ISO 5725:1986[1]. The variability due to measurement and population is inseparable, due to the sampling method used for the tests. A revised version of ISO 5725:1986 can be found in ISO 5725-1:1994[2] ISO 5725-2:1994[3] ISO 5725-3:1994[4] ISO 5725-4:1994[5] ISO 5725-6:1994[6]. Definitions of precision, repeatability and reproducibility are found in ISO 5725-1:1994[2].

The values and equations for precision of the tests methods are given in Table J.1. The repeatability and reproducibility for compression force were established on lenses with forces in the range 1 mN to 8 mN.

Table — J.1 — Repeatability and reproducibility

Test method	Annex	Repeatability r	Reproducibility R
Compression force	A	$-0,4 + 0,46 \times F$[a]	$-0,4 + 0,55 \times F$[a]
Axial displacement in compression	B	0,2 mm	0,3 mm
Optic decentration	C	0,2 mm	0,2 mm
Optic tilt	D	1°	2°
Angle of contact	E	3°	8°

[a] F is the compression force, expressed in mN.

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[2] ISO 5725-1: 1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

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[7] ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

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[9] Gullstrand A *Helmholtz's Treatise on Physiological Optics*. Southall J.P.C., ed. New York, Dover, 1962

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[11] Wang L., & Auffarth G.U. White-to-white corneal diameter measurements using the Eyemetrics program of the Orbscan topography system. *Dev. Ophthalmol.* 2002, **34** pp. 141–146

[12] Hoffer K.J. Biometry of 7,500 cataractous eyes. *Am. J. Ophthalmol.* 1980, **90** pp. 360–368

1) ISO 5725:1986 has been cancelled and replaced by ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998 and ISO 5725-6:1994.

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