
**Ophthalmic implants — Intraocular
lenses —**

Part 3:
Mechanical properties and test methods

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 3: Propriétés mécaniques et méthodes d'essai*
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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 <https://standards.iteh.ai/catalog/standards/sist/6c3ee1aa-0856-40aa-b632-3183cf9c015b/iso-11979-3-1999>

— 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.

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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.

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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.

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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.

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**multi-piece 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.

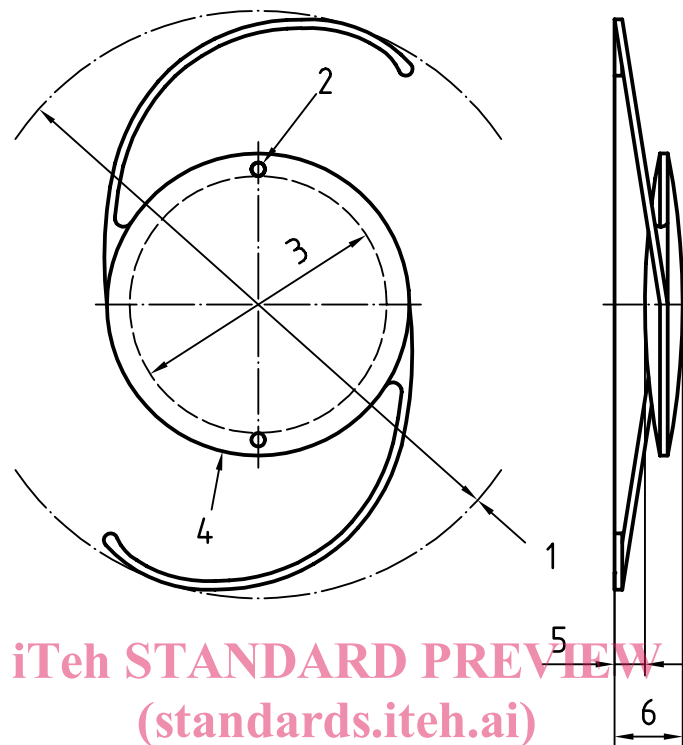
3.11**vault height**

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

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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 $23\text{ °C} \pm 2\text{ °C}$ and relative humidity (RH) $50\% \text{ RH} \pm 10\% \text{ RH}$. For all other IOLs, properties shall be determined at *in situ* conditions within the temperature tolerance of $\pm 2\text{ °C}$. 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 $(24 \pm 2)\text{ h}$ 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 $\pm 0,20$ mm. For multi-piece posterior chamber IOLs, the tolerance on the overall diameter shall be $\pm 0,30$ 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, $\pm 0,15$ mm;
- b) for posterior chamber IOLs with polypropylene loop(s), $\pm 0,35$ mm; and
- c) for other IOLs, $\pm 0,25$ mm.

The tolerance on the sagitta shall be as follows:

- a) for anterior chamber IOLs, $\pm 0,25$ mm;
- b) for posterior chamber IOLs with polypropylene loop(s), $\pm 0,45$ mm; and
- c) for other IOLs, $\pm 0,35$ mm.

The tolerance on the clear optic shall be $\pm 0,10$ mm.

The tolerance on the dimensions of the body shall be $\pm 0,10$ mm. For ellipsoid IOLs, the dimensions of the body shall be reported as (short axis) \times (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 (standards.iteh.ai)

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 $\pm 0,25$ 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.

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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 $5,00 \text{ mm} \pm 0,02 \text{ mm}$ or $5,50 \text{ mm} \pm 0,02 \text{ mm}$, 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 $\pm 0,1 \text{ mN}$.

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.