INTERNATIONAL STANDARD

ISO 11979-9

First edition
2006-09-01

Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

Implants ophtalmiques — Lentilles intraoculaires —
Partie 9: Lentilles intraoculaires multifocales

Reference number
ISO 11979-9:2006(E)

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

Published in Switzerland

Contents

Page

Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 11979-9 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, 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*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

Ophthalmic implants — Intraocular lenses —

Part 9:
Multifocal intraocular lenses

1 Scope

This part of ISO 11979 is applicable to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g. far and near).

NOTE The term “near vision” as used in this part of ISO 11979 includes useful vision at a distance of claimed benefit; e.g. near and/or intermediate distances.

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*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

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

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1, ISO 14155-1 and ISO 14155-2 apply.

4 Physical requirements

4.1 General

This clause is applicable to the physical properties of multifocal intraocular lenses (MIOLs) in the assembled or final form, as intended for implantation in the human eye.

4.2 Tolerances and dimensions

For tolerances and dimensions, the requirements of ISO 11979-3 apply, together with the following additional requirement that the manufacturer shall establish tolerances with respect to the optical design.

5 Optical requirements

5.1 General

This clause is applicable to the optical properties and performance requirements of MIOLs in their final form, as intended for implantation in the human eye.

5.2 Dioptric power

For dioptric power, ISO 11979-2 applies to the far power of an MIOL and to any distinct near power(s).

Two alternative methods for the determination of dioptric power, given in ISO 11979-2, can be applied to MIOLs. For each near image plane, these methods are modified as follows:

a) for the determination of dioptric power from measured back focal length, once the microscope is focused on the far image plane and the distance from the back vertex of the MIOL to the distant focal point is determined, focus the microscope on the near image plane and determine the distance from the back vertex of the MIOL to the near focal point;

b) for the determination of dioptric power from measured magnification, once the microscope is focused on the far image plane and the linear dimension, h_{image}, in the image is determined, focus the microscope on the near image plane and determine the linear dimension, h_{image}, in the image.

Depending on the MIOL optic design the correction formulas given in ISO 11979-2 could be invalid. In such cases, the manufacturer shall derive and justify corrections that result in dioptric powers that are consistent with power labelling of monofocal IOLs.

If the focusing conditions of ISO 11979-2 are not appropriate for the particular design, another focusing condition shall be developed with justification.

5.3 Imaging quality

The imaging quality shall be evaluated for the far power and any claimed near power(s) or power range. The imaging quality specifications apply in all meridians.

For designs that have no distinct near power, a specification describing the through-focus response performance shall be developed.

The manufacturer shall demonstrate that all available powers meet the imaging quality specifications.

The imaging quality of a MIOL shall be evaluated by modulation transfer function (MTF) testing in the eye model described in ISO 11979-2 with the following additions:

ISO 11979-2 is modified such that best focus for the power under evaluation is obtained by maximizing the MTF at 50 cycles/mm with a (3 ± 0,25) mm aperture. Using that focus, record the MTF values at the following conditions:

a) small aperture (2 mm to 3 mm), 25 cycles/mm and 100 cycles/mm, for the far power;

b) small aperture (2 mm to 3 mm), 25 cycles/mm and 100 cycles/mm, for the near power(s) or power range;

c) large aperture (4 mm to 5 mm), 25 cycles/mm and 50 cycles/mm, for the far power.

The converging beam from the model cornea described in ISO 11979-2 exposes a central diameter of the MIOL (± 0,1 mm) to, interchangeably, either the small or the large aperture that is chosen to best control the MTF performance.

In order to best control the MTF performance of the MIOL, the small and large apertures used for testing shall be chosen and defined for the lens model over the range of apertures provided above with a tolerance of ± 0,25 mm. The manufacturer shall have the option of setting the minimum MTF specification based on the area under the curve between the two spatial frequencies or on the MTF value for each individual spatial frequency.

The minimum MTF specification shall be set such that it results in acceptable visual outcome, verifiable, or to be verified, by clinical data.

NOTE 1 The minimum MTF specification is typically set as the mean value minus an acceptable level of deviation, e.g. mean value minus two standard deviations.

NOTE 2 The apertures above represent the exposed diameter of the test MIOL and can differ from the aperture stop of the optical bench.

NOTE 3 It can be necessary to have a different imaging quality specification for each combination of test aperture and focus.

5.4 Additional optical characterization

5.4.1 Optical design

Tests that shall be performed to characterize the MIOL optical design are described in Annex A.

5.4.2 Spectral transmittance

For spectral transmittance, ISO 11979-2 applies.

6 Clinical investigation

6.1 General

If clinical evaluation, in accordance with ISO 14155-1, together with risk assessment, in accordance with ISO 14971, identifies the need for a clinical investigation, the requirements of ISO 14155-1, ISO 14155-2 and ISO 11979-7 apply, with additional requirements given in 6.2.

NOTE Considerations for the risk analysis regarding modifications to one or more existing designs are found in ISO/TR 22979 [1].

6.2 Additional requirements for the clinical investigation plan

The requirements for the clinical investigation plan of ISO 11979-7 apply. In addition to the study variables given in ISO 11979-7, the following shall be considered:

a) near visual acuity (VA), with best distance correction;

b) uncorrected near VA;

c) uncorrected distance VA;

d) quality of vision survey;

e) defocus evaluation;

f) fundus visualization;

g) contrast sensitivity;

h) functional performance.

NOTE 1 Information regarding a design of the clinical investigation can be found in Annex B.

NOTE 2 Information regarding determination of sample sizes for the clinical investigation is provided in Annex C.

7 Information supplied by the manufacturer

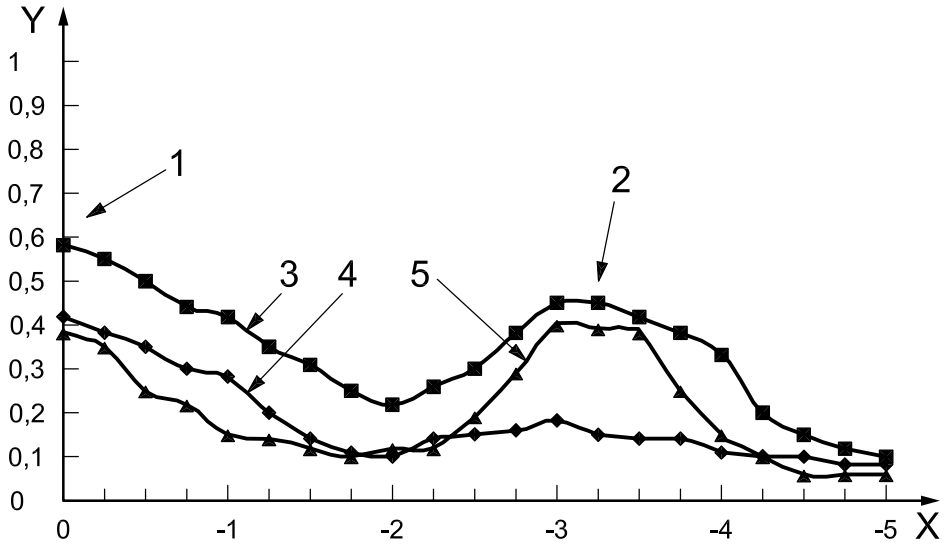
The requirements for the information supplied by the manufacturer given in ISO 11979-4 apply, with the following additional information that shall be made available to the user:

a) a summary of the results of the clinical investigation, if any;

b) a graph of the MTF through focus response performance of the MIOL in the model eye, using the conditions described in Annex A of this part of ISO 11979 (see example in Figure 1); informative text shall accompany the figure explaining that the MTF values in the graph describe the MIOL optical performance in a standardized model eye at 50 cycles/mm as the focus is gradually shifted from that of a far object to increasingly nearer objects and that higher numbers indicate better performance;

c) a graph of the spectral transmittance through the MIOL in the range of 300 nm to 1 100 nm.

The general requirements for information provided by the manufacturer with medical devices specified in EN 1041 [2] should be considered. Symbols can be used instead of text, where appropriate. When symbols are used, the requirements of ISO 15223 [3] and EN 980 [4] should be considered.



Key

X defocus (dioptres)
Y modulation ratio at 50 cycles/mm
1 far object
2 near object
3 3 mm pupil size
4 2 mm pupil size
5 4,5 mm pupil size

Figure 1 — Example of MTF through focus response for multiple pupil sizes

Annex A
(normative)

Optical characterization

A.1 Theoretical evaluation

Make a theoretical evaluation of, or measure, the percentage of light energy going to the images produced by the far power and by each near power (or power range) as a function of aperture from 2,0 mm to 4,5 mm at maximum intervals of 0,5 mm, for the cases when the lens is centred, decentred 0,5 mm, and decentred 1,0 mm. When determining the percentage of light energy going to each of the images, include any unrefracted light, and any other light that does not usefully contribute to the intended image, in the total light energy. Report the results in the form of separate graphs for each case.

A.2 Optical testing

This testing will confirm that the actual performance of the lens is similar to its theoretical performance.

Use ten representative samples each of low, medium and high power manufactured MIOLs for testing in the model eye defined in ISO 11979-2 with the following additions.

a) Modulation transfer function (MTF) testing:

Generate MTF through-frequency curves at different apertures for the images formed by the far power and by each near power (or power range) with the lens on-axis, decentred 1,0 mm, and tilted 5°. Do this for aperture sizes 2 mm, 3 mm, and 4,5 mm (± 0,25 mm) at the position of the lens. Focus to give maximum modulation ratio for 50 cycles/mm in each case. Report the results in the form of graphs, averaging MTF on-axis curves for each power tested.

For this MTF testing, ten representative samples each of low, medium and high power manufactured MIOLs are used for the on-axis condition. Each MIOL with the median performance for the on-axis condition from the low, medium and high power groups are used for the subsequent decentred and tilted conditions. Therefore, a total of 30 lenses (10 low, 10 medium, and 10 high power) are used for the on-axis condition, and a total of 3 lenses (1 low, 1 medium, and 1 high power) are used for the decentred and tilted conditions.

In each case, the performance should be compared to that of a similar monofocal lens.

b) MTF through-focus-response testing:

Generate the MTF through-focus-response of the MIOL at 50 cycles/mm with 2 mm, 3 mm, and 4,5 mm ± 0,25 mm apertures. Focus to maximum MTF at 50 cycles/mm for an object at infinity and then measure MTF at positions in image space that correspond with increasingly closer object distances down to that corresponding with 20 cm.

c) Recovery of properties following simulated surgical manipulation:

The testing in this clause applies only to lenses for which the optic is intended to be folded or compressed during implantation. ISO 11979-3 applies with the following additions.

To evaluate the combined effects of haptic compression and folding and/or injection, as applicable, first simulate implantation using the maximum recommended time for the MIOL to be held in the folder/injector, and then place the lens in a holder that constrains the haptics to 10 mm diameter (for posterior chamber MIOLs) or the minimum expected constrained diameter (for anterior chamber MIOLs).

Immerse the lens in its holder in aqueous at 35 °C for a minimum of 24 h. Then, while maintaining the constraint, place the lens in the model eye. Thereafter focus to maximum MTF at 50 cycles/mm and measure through-frequency MTF. Do this for apertures of 3 mm and 4,5 mm at the positions of the lens.

Report the results in the form of a graph averaging the through frequency MTF of the lenses measured. The maximum recommended time for the MIOL to be held in the folder/injector is stated in the report.