INTERNATIONAL STANDARD

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Ophthalmic implants — Intraocular lenses —

Part 2: Optical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —
Partie 2: Propriétés optiques 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.

Attention is drawn to the possibility that some of the elements of this part of ISO 11979 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11979-2 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, B and C form a normative part of this part of ISO 11979. Annexes D, E, F and G are for information only.

Introduction

This part of ISO 11979 contains several test methods for which associated requirements are given and one test method for which no requirement is formulated. The former are directly connected to the optical functions of intraocular lenses. The latter, the test for spectral transmittance, has been provided for those interested in information about UV transmission and in specific situations, e.g. when using laser light sources for medical diagnosis and treatment.

Extensive interlaboratory testing has been carried out before setting the limits specified. Some basic problems were encountered.

The accuracy in the determination of dioptric power has an error that is not negligible in relation to the half-dioptre steps in which intraocular lenses are commonly labelled. The dioptric power tolerances take this fact into account. Hence the limits set may lead to some overlap into the next labelled power, especially for high dioptre lenses. Reference [1] gives further discussion on this subject.

The majority of lenses hitherto implanted have been made from poly(methyl methacrylate) (PMMA), and were qualified using the method described in annex B. Thus the general clinical experience is associated with this level. The method in annex B is limited in its applicability, however. The limits for the more general method in annex C have been set in terms of MTF in an eye model, following two approaches. The first is by correlation to the method and limit in annex B. Further discussion can be found in reference [2]. The second is set as a percentage of what is calculated as theoretical maximum for the design, with the rationale that a minimum level of manufacturing accuracy be guaranteed. For common PMMA lenses, these two limits correspond well with each other. For lenses made of materials with lower refractive index, or with certain shape factors, or for extreme power lenses in general, the latter limit is lower than the former. However, such lenses are already in use, indicating clinical acceptance. The question arises which is the absolute lowest limit that is compatible with good vision. No definite answer can be found, but following clinical data presented to the working group, an absolute lower limit has been set for the calculation method.

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. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-2 and EN ISO 11979-2). For those parts where no identical versions exist, 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 on clinical investigations become available.

Ophthalmic implants — Intraocular lenses —

Part 2:
Optical properties and test methods

1 Scope

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

It is applicable but not limited to non-toric, monofocal intraocular lenses intended for implantation into the anterior segment of the human eye, excluding corneal implants.

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 6328: —[1)], *Photography — Photographic materials — Determination of ISO resolving power.*

ISO 9334:1995, *Optics and optical instruments — Optical transfer function — Definitions and mathematical relationships.*

ISO 9335:1995, *Optics and optical instruments — Optical transfer function — Principles and procedures of measurement.*

ISO 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary.*

U.S. Mil Std 150-A-1961, *Photographic lenses.*

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 9334 and ISO 11979-1 apply.

NOTE Some definitions from ISO 11979-1 are reproduced for information in annex G.

1) To be published. (Revision of ISO 6328:1982)

4 Requirements

4.1 General

All requirements stated below shall apply to the finished product as marketed. If applicable, the lens shall be positioned as intended for use.

NOTE 1 The methods specified below are reference methods. Alternative methods demonstrated to produce results that are equivalent to those obtained with the reference methods may also be used.

NOTE 2 Any validated procedures that ensure that IOLs are within the tolerances specified may be used in quality control.

4.2 Dioptric power

When determined by one of the methods described in annex A, the dioptric power as stated by the manufacturer (e.g. on the label of the IOL) shall, in any meridian, be within the tolerance limits specified in Table 1.

NOTE Astigmatism is implicitly limited by the requirement that dioptric power be within the tolerance limits of Table 1 in all meridians.

Table 1 — Tolerances on dioptric power

Nominal dioptric power range [a] D	Tolerance on dioptric power D
0 to ⩽ 15	± 0,3
> 15 to ⩽ 25	± 0,4
> 25 to ⩽ 30	± 0,5
> 30	± 1,0
[a] The ranges apply to positive as well as to negative dioptric powers.	

4.3 Imaging quality

Imaging quality shall be determined either according to the method described in annex B or to the method described in annex C.

NOTE The method of annex C is more general. It can be used e.g. for extreme dioptric powers and for materials which swell in aqueous humour, for which cases the method of annex B is not suitable.

a) If determined in accordance with annex B, the resolution efficiency of the IOL shall be no less than 60 % of the diffraction-limited cut-off spatial frequency. In addition, the image shall be free of aberrations other than those due to normal spherical aberration.

b) If determined in accordance with annex C, the modulation transfer function (MTF) value of the system of model eye with IOL shall, at 100 mm^{-1}, meet either of the two conditions given below:

   1) be greater or equal to 0,43;

   2) be greater or equal to 70 % of that calculated as maximum attainable for the system of model eye with the specific IOL design and power in question, but in any case greater or equal to 0,28.

NOTE 1 Spatial frequency has the dimension of reciprocal length, mm^{-1}. It is often referred to as line-pairs per mm or c/mm, where c denotes cycles.

NOTE 2 The approval levels given above correspond well with each other for PMMA lenses in the range 10 D to 30 D.

NOTE 3 Examples of calculation of maximum attainable MTF at 100 mm^{-1} are given in C.5.

4.4 Spectral transmittance

For each type of IOL, the spectral transmittance in the range 300 nm to 1200 nm shall be on record for the IOL with a dioptric power of 20 D or its equivalent. The spectrum shall be recorded with a spectrophotometer using a 3 mm aperture. The spectrophotometer shall have a bandwidth of not more than 5 nm and be accurate to ± 2 % in transmittance.

The sample shall be either an actual IOL or a flat piece of the IOL optic material, having an average thickness equal to that of the central 3 mm of the 20 D IOL and having undergone the same production treatment as the finished IOL, including sterilization. IOLs made of materials that change transmittance properties *in situ* shall be measured with the IOL under simulated *in situ* conditions.

NOTE Guidance can be found in ISO 8599 [3] for the measurement. The definition for *in situ* conditions is found in ISO 11979-1 (see also annex G).

Annex A
(normative)

Measurement of dioptric power

A.1 General

Three alternative methods for the determination of dioptric power are given below. Their applicability is limited to spherical lenses.

NOTE 1 For more details about optical measurement and calculations, see references [4], [5] in the Bibliography, or similar textbooks on optics.

NOTE 2 For non-spherical lenses, dioptric power should be designated in a way consistent with the procedure given in this annex.

Irrespective of method used, the value of dioptric power is determined at 35 °C ± 2 °C for light of wavelength 546 nm ± 10 nm. For the methods in A.3 and A.4, the aperture is no less than 3 mm in diameter.

A.2 Determination of dioptric power by calculation from measured dimensions

Measure the surface radii using a special radius meter or general purpose interferometer. Measure the lens thickness with a micrometer or similar device.

Calculate the dioptric power, using the equation:

$$D = D_f + D_b - (t_c/n_{IOL}) \cdot D_f \cdot D_b \quad \text{(A.1)}$$

where, at the conditions in question,

D is the dioptric power, in dioptres, of the IOL;

D_f is the dioptric power, in dioptres, of the front surface of the IOL;

D_b is the dioptric power, in dioptres, of the back surface of the IOL;

t_c is the central thickness, in metres, of the IOL;

n_{IOL} is the refractive index of the IOL optic material.

NOTE 1 Equation (A.1) is often referred to as the "thick lens equation".

Calculate D_f from the equation:

$$D_f = (n_{IOL} - n_{med})/r_f \quad \text{(A.2)}$$

where, at the conditions in question,

n_{med} is the refractive index of the surrounding medium;

r_f is the radius, in metres, of the front surface of the IOL.

Calculate D_b from the equation:

$$D_b = (n_{med} - n_{IOL})/r_b \quad \text{(A.3)}$$

where, at the conditions in question, r_b is the radius, in metres, of the back surface of the IOL.

NOTE 2 With respect to the incidence of light, a convex radius is positive and a concave radius is negative.

NOTE 3 These equations assume that there is exact alignment of front and back surfaces along the optical axis.

NOTE 4 ISO 9914 [6] describes a method that may be used to determine n_{IOL}, which should be known to the third decimal place.

Use n_{med} = 1,336, and the dimensions and refractive index of the IOL under *in situ* conditions to obtain the dioptric power *in situ*, D_{aq}, from equation (A.1).

If the measured dimensions and the refractive index of the IOL were not obtained under *in situ* conditions, proper corrections therefore should be made.

A.3 Determination of dioptric power from measured back focal length

A.3.1 Principle

The back focal length (BFL) is the distance from the back vertex of the IOL to the focal point with parallel light incident on-axis upon the IOL.

NOTE 1 The position of the focal point is dependent on the spatial frequency focused at. It is not coincident with the paraxial focal point of the lens under measurement if there is spherical aberration. The focus found is often referred to as "best focus".

In order to obtain the paraxial focal length from the measured BFL, corrections have to be made for the distance from the back vertex to the back principal plane of the IOL, and for the distance from the paraxial focal point to the best focal point.

NOTE 2 BFL and the two corrections are all vector quantities. The positive direction is that of the optical axis towards the image.

A.3.2 Apparatus

A.3.2.1 Optical bench, such as that illustrated in Figure A.1, used to determine BFL.

NOTE It is a matter of convenience whether to use a straight bench or employ a mirror as illustrated in Figure A.1.

The target is at the focus of the collimator, so that parallel light is incident upon the IOL. The focal length of the collimator should be more than ten times that of the IOL. The collimator is an achromat that is virtually free of aberrations for the wavelength band transmitted by the filter. The filter should transmit green light with the transmittance peak close to 546 nm.

The microscope is connected to a position-measuring device so that its position along the optical axis can be determined with an accuracy of 0,01 mm.

A.3.3 Procedure

Mount the IOL on the optical bench just behind the aperture.

Focus the microscope at the back surface of the IOL and note the position of the microscope.

Focus the microscope at the image of the target and note the position of the microscope.

NOTE 1 Focusing should be done at a spatial frequency close to 0,3 of the cut-off frequency of the IOL.

The distance from the back vertex of the IOL to the focal point is the back focal length, BFL, of the IOL.

NOTE 2 The procedure given here assumes that measurement is done in air at normal ambient conditions of a laboratory. The calculations assume that the dimensions of the IOL are not appreciably different under *in situ* conditions. Should that not be the case, BFL should be measured with the IOL under simulated *in situ* conditions, with appropriate changes in the calculations.