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ISO 11979-2

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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

Reference number
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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 $\leqslant$ 15	$\pm$ 0,3
$>$ 15 to $\leqslant$ 25	$\pm$ 0,4
$>$ 25 to $\leqslant$ 30	$\pm$ 0,5
$>$ 30	$\pm$ 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.

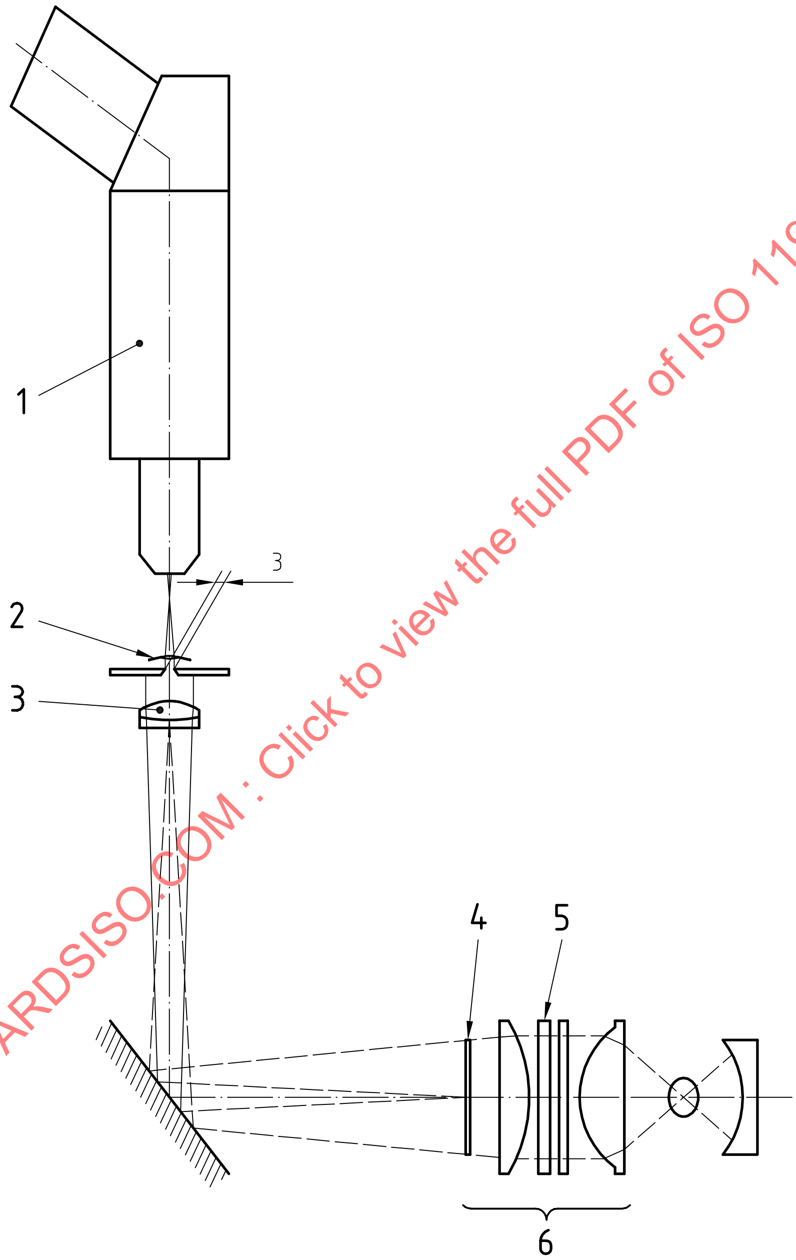
Calculate the distance from the back vertex of the IOL to the back principal plane of the IOL by using the equation:

$$-A_2H'' = (D_f / D) \cdot (n_{med} / n_{IOL}) \cdot t_c \qquad \text{(A.4)}$$

where n_{med} = 1 for measurement in air.

NOTE 3 A_2H'' is a vector that can be positive or negative. The quantity $-A_2H''$ is added to BFL as a correction.

Dimensions in millimetres



Key

1 Microscope
2 IOL
3 Collimator
4 USAF Target
5 Dichroïc Filter
6 Condenser

Figure A.1 — Optical bench with IOL

Calculate the defocus, *Def*, the distance from the paraxial focal point to the focal point found (best focus) by using the equation:

$$-Def = -LSA/2 \quad \text{(A.5)}$$

where *LSA* is the longitudinal spherical aberration, expressed in millimetres. This is the vector from the back paraxial focal point to the intersection of a meridional ray at the pupillary margin with the optical axis.

NOTE 4 *Def* is a vector that can be positive or negative. The quantity –*Def* is added to BFL as a correction.

LSA can be calculated by ray trace procedures that are not explicitly given in this part of ISO 11979.

NOTE 5 The user of this part of ISO 11979 is referred to the optics literature [4], [5] for methods on how to calculate *LSA*.

NOTE 6 Equation (A.5) is a simplification. A more exact calculation of defocus can be obtained by means of optical design calculation programmes. In such calculations the position of the best focal point depends on the spatial frequency focused at.

It is permissible under this part of ISO 11979 to calculate *Def* by other procedures, such as those available in optical design calculation programmes, provided that the correctness of the programme has been verified.

Add the two corrections to BFL to obtain the paraxial focal length in air, f_{air} (in metres), and calculate the dioptric power in air, D_{air}, by using the equation:

$$D_{air} = n_{med} / f_{air} \quad \text{(A.6)}$$

where $n_{med} = 1$ for measurement in air.

Compute the conversion ratio, Q, using the equation:

$$Q = D_{aq,nom} / D_{air,nom} \quad \text{(A.7)}$$

where $D_{aq,nom}$ and $D_{air,nom}$ are calculated from equation (A.1) using nominal dimensions for the IOL and appropriate values for n_{med} and n_{IOL}.

NOTE 7 In general, the value of n_{IOL} is influenced by temperature and water uptake by the IOL optic material.

Finally calculate the dioptric power *in situ*, D_{aq}, by using the equation:

$$D_{aq} = D_{air} \cdot Q \quad \text{(A.8)}$$

NOTE 8 Table A.1 gives examples of the magnitude of the corrections.

A.4 Determination of dioptric power from measured magnification

A.4.1 Principle

The concept of lens power relates to the magnification of a lens. One method (the principle of the focal collimator) to utilize magnification to determine dioptric power is given here.

A.4.2 Apparatus

A.4.2.1 Optical bench, such as that illustrated in Figure A.1.

A.4.2.2 The target in this case has a measurable linear dimension, such as the distance between two lines. The microscope has some means, such as a reticule, to measure the same linear dimension in the image.

A.4.3 Procedure

Determine the linear dimension, h_{target}, of the target.

Determine the focal length, F, of the collimator.

NOTE 1 These two determinations need not be repeated every time.

NOTE 2 The ratio F/h_{target} may be obtained by measurement of calibrated lenses in lieu of the IOL.

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

Focus the microscope on the image and measure the linear dimension, h_{image}, in the image.

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

Calculate the focal length of the IOL, f, by using the equation:

$$f = (F/h_{target}) \cdot h_{image} \qquad \text{(A.9)}$$

Add the correction for defocus (see A.3.2) to f to obtain the paraxial focal length, f_{air}, and continue according to the procedure described in A.3.2 from equation (A.6).

NOTE 4 The focal length, f, in equation (A.9) may also be measured on a so-called nodal slide bench.

A.5 Precision

The repeatability and the reproducibility are functions of dioptric power, and are expected to be about 0,5 % and 1 %, respectively, of the dioptric power (see annex D).

Table A.1 — Examples of calculated corrections under various assumptions about optic shape, IOL power and refractive indices

Assumed refractive indices

Air:	1
Aqueous humour:	1,336
PMMA [a]	
— at room temperature:	1,493
— under *in situ* cond.:	1,4915
Silicone	
— at room temperature:	1,418
— under *in situ* cond.:	1,415

Assumed dimensions [mm]

IOL optic diameter:	6
IOL edge thickness:	0,3
Aperture stop:	3

Defocus due to spherical aberration [b]

r_f mm	r_b mm	t_c mm	BFL mm	$-A_2H''$ mm	$-Def$ mm	$-LSA/2$ mm	D_{air} D	D_{aq} D
PMMA SYMMETRIC BICONVEX								
31,069	–31,069	0,59	31,35	0,20	0,06	0,06	31,64	10,00
20,695	–20,695	0,74	20,77	0,25	0,09	0,09	47,36	15,00
15,504	–15,504	0,89	15,46	0,30	0,11	0,12	63,00	20,00
12,386	–12,386	1,04	12,31	0,35	0,08	0,15	78,50	25,00
10,304	–10,304	1,19	10,13	0,41	0,11	0,17	93,86	30,00
PMMA CONVEX-PLANO								
15,550	plane	0,59	31,10	0,40	0,04	0,04	31,70	10,00
10,367	plane	0,74	20,47	0,50	0,06	0,06	47,55	15,00
7,775	plane	0,90	15,09	0,60	0,08	0,09	63,41	20,00
6,220	plane	1,07	11,80	0,72	0,10	0,11	79,26	25,00
5,183	plane	1,26	9,59	0,84	0,08	0,13	95,12	30,00
PMMA MENISCUS								
9,742	25,917	0,60	30,51	0,64	0,13	0,13	31,97	10,00
7,427	25,917	0,76	20,01	0,70	0,12	0,13	48,00	15,00
6,003	25,917	0,93	14,68	0,80	0,13	0,14	64,08	20,00
5,039	25,917	1,12	11,47	0,91	0,09	0,16	80,21	25,00
4,343	25,917	1,33	9,24	1,05	0,08	0,18	96,42	30,00
SILICONE SYMMETRIC BICONVEX								
15,775	–15,775	0,88	18,63	0,30	0,10	0,12	52,56	10,00
10,500	–10,500	1,18	12,25	0,42	0,10	0,17	78,31	15,00
7,858	–7,858	1,49	9,05	0,54	0,08	0,22	103,41	20,00
6,269	–6,269	1,83	7,09	0,67	0,08	0,27	127,62	25,00
5,205	–5,205	2,20	5,73	0,83	0,08	0,31	150,59	30,00

[a] Poly(methyl methacrylate).

[b] $-Def$, defocus to maximum MTF at 100 mm^{-1}, was calculated by means of the DOTF module of Sigma PC Version 1.7 (Kidger Optics, Crowborough, UK). This value was used to obtain D_{air} and D_{aq}. The value using equation (A.5), i.e. $-LSA/2$, is given for comparison.

Annex B
(normative)

Measurement of resolution efficiency

B.1 Principle

The resolution limit of an IOL, expressed as a percentage of the diffraction-limited cut-off spatial frequency of an ideal lens having the same focal length, is determined under identical conditions of aperture, wavelength and surrounding medium.

B.2 Apparatus

B.2.1 Optical bench, e.g. as illustrated in Figure A.1, having the following features:

a) a collimator achromat which is virtually free from aberrations in combination with the light source used, having a focal length preferably at least ten times that of the IOL being measured;

b) a target known as the U.S. Air Force 1951 Resolution Target (U.S. Mil Std 150-A-1961: Photographic lenses, §5.1.1.7; see Figure B.1), diffusely illuminated by a monochromatic light source of 546 nm ± 10 nm, and being in the focal plane of the collimator;

c) an aperture stop of 3,0 mm ± 0,1 mm, placed at most 3 mm in front of the IOL being measured;

d) a surrounding medium of air;

e) a microscope objective with a numerical aperture greater than 0,3 and capable of magnifying 10× to 20×; and

f) an eye-piece magnifying about 10×.

B.3 Procedure

Place the IOL on the optical bench, taking care to centre it as well as possible on the optical axis of the bench.

By moving the microscope objective, focus the image of the target to obtain the best possible overall balance between coarse and fine patterns (see Figure B.1).

Then determine the finest pattern (group, element) for which both horizontal and vertical bars are resolved, with the additional requirement that all coarser patterns are also resolved. Refer to 5.3.5.1 of ISO 6328:— regarding how to determine if a pattern is resolved. Further examine the image for aberrations other than spherical aberration.

NOTE The appearance of such other aberrations are termed in many descriptive ways for which there are no proper definitions. Some commonly used words are streaking, ghosting, haze and flare.

B.4 Calculations

The spatial frequency, ν, expressed in reciprocal millimetres, for the finest pattern resolved is calculated from the equation:

$$\nu = (F/f) \times 2^{[G + (E - 1)/6]} \qquad \text{(B.1)}$$

where

G denotes the group of the pattern;

E denotes the element within that group of the pattern;

F is the focal length, in millimetres, of the collimator;

f is the focal length, in millimetres, of the IOL.

The diffraction limited cut-off frequency, ω, expressed in reciprocal millimetres, is calculated by the equation:

$$\omega = (2n \cdot \sin u)/\lambda \qquad \text{(B.2)}$$

where

n is the refractive index of the surrounding medium;

λ is the wavelength of the light, in millimetres;

u is the vertex angle of the marginal ray.

For small angles the expression, in reciprocal millimetres, can be reduced to the equation:

$$\omega = (nd)/(f\lambda) \qquad \text{(B.3)}$$

where d is the diameter of the aperture stop, in millimetres.

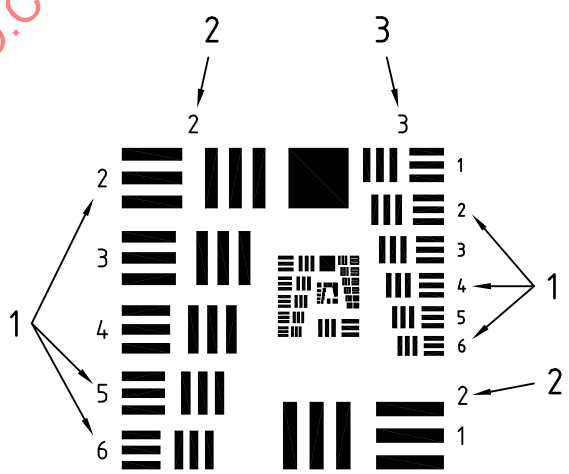
The resolution efficiency, RE, expressed as a percentage of the cut-off spatial frequency, is calculated from the equation:

$$RE = 100 \times 2^{[G + (E-1)/6]} \times (F\lambda)/(nd) \qquad \text{(B.4)}$$

NOTE In the case under consideration, $n = 1$ (air), $d = 3$ mm, and $\lambda = 0{,}000\,546$ mm.

B.5 Precision

The repeatability and reproducibility expected with this method are 20 % and 30 % of the cut-off frequency, respectively (see annex E).



Key

1 Element number

2 Group 2

3 Group 3

Figure B.1 — U.S. Air Force 1951 Resolution Target with groups 0 and 1 omitted

Annex C
(normative)

Measurement of MTF

C.1 Principle

The modulation transfer function (MTF) is measured using monochromatic light with the IOL placed in a model eye.

NOTE Reference [7] gives a general introduction to the optical transfer function. ISO 9334 and ISO 9335 give the standardization framework for MTF instrumentation and measurement.

C.2 Apparatus

C.2.1 Model eye, having the following features:

NOTE 1 A discussion about model eyes can be found in [8], which, however, was not available when this particular model eye was formulated.

a) the IOL front surface is placed at a plane between 27 mm and 28 mm in front of the focal point of the model cornea itself, taking the refractive index of the image space to be 1,336;

NOTE 2 For the calculation of the location of this plane, the model eye is assumed infinitely deep so that the image falls within the liquid with which the model eye is filled.

b) the converging beam from the model cornea exposes the central circular 3,0 mm ± 0,1 mm of the IOL;

NOTE 3 An obvious way is to place a 3,0 mm aperture just in front of the IOL.

NOTE 4 An alternative that offers practical advantages is to place the aperture in front of the cornea. The diameter of the aperture is chosen, depending on the cornea, so as to expose the required central circle of the IOL. This geometry is permissible only for measurement on-axis.

c) the IOL is placed in a liquid medium contained between two flat windows;

d) the difference in refractive index between the IOL and the liquid medium is within 0,005 units of that under *in situ* conditions;

NOTE 5 For practical testing purposes, physiological saline may in many cases be used as a substitute for aqueous humour.

NOTE 6 In case no interaction occurs between the IOL optic material and aqueous humour, pure water can be used.

e) the model cornea is virtually aberration free in combination with the light source used, so that any aberrations of the system are due to the IOL;

NOTE 7 A suitable model eye is illustrated in Figure C.1. Dimensions and glass types are given in Table C.1.

f) the image plane falls in air, beyond the last window.

a) Without IOL
(as described in Table C.1)

b) With a 30 D PMMA IOL at the correct position
(note that the image plane moves closer to the last window, but remains behind it, with the IOL in place)

Figure C.1 — Model eye

Table C.1 — Design of a model eye fulfilling the requirements of C.2.1

Dimensions in millimetres

Surface number	Surface radius	Separation space	Diameter	Material/ Medium
1	24,590		16	
		5,21		SSK4
2	–15,580		16	
		1,72		SF8
3	–90,200		16	
		3,0		air
4	plane		32	
		6,0		BK7 window
5	plane		32	
		6,25		liquid
6	plane		3,0	aperture
		10,0		liquid
7	plane		32	
		6,0		BK7 window
8	plane		32	
		9,25		air
9	plane			image plane

NOTE — The design given here utilizes Melles-Griot LAO 034 as model cornea. SSK4, SF8 and BK7 are codes for glasses from Schott. This information is given for the convenience of users of this part of ISO 11979 and does not constitute an endorsement by ISO of these products. Equivalent lenses and glasses may be used if they can be shown to lead to the same results.

C.2.2 Optical bench

The model eye is mounted on an optical bench for measurement of MTF conforming to the requirements of ISO 9335. The light source is by filtration or otherwise confined to 546 nm ± 10 nm.

With the apparatus described, measurement can be carried out at ambient temperature if the IOL dimensions do not deviate appreciably from those under *in situ* conditions. Otherwise the measurement should be carried out at the *in situ* temperature.

C.3 Procedure

Place the model eye (C.2.1) on the optical bench (C.2.2). Ensure that the IOL is in the correct position, and that the whole unit is well aligned with the optical axis of the bench, and focused to obtain maximum MTF at 100 mm^{-1}. Record this MTF value.

C.4 Precision

The repeatability and reproducibility expected with this method is 0,09 and 0,19 modulation units, respectively (see annex E).

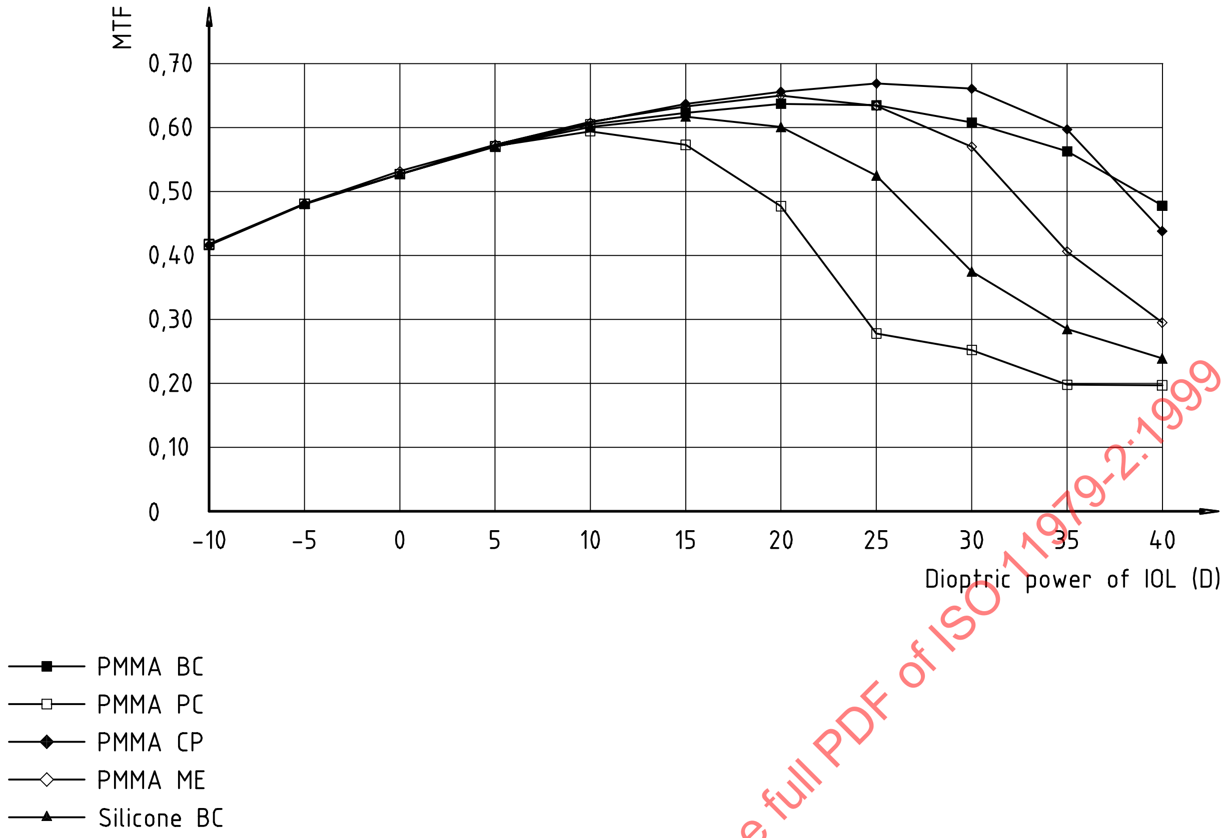
C.5 Examples of calculated MTF under various assumptions

The calculations all assume the use of the model eye described in Table C.1 in which an IOL with perfect spherical surfaces as designed is placed with its front apex at plane 6. The aperture stop is 3 mm. The separation between the front surface of the IOL and that of the last glass window remains totally 10 mm, except for the very highest dioptric powers where it is reduced so that the image may fall beyond the window. The IOLs all have 6 mm optic diameter with a 0,3 mm edge. The refractive index of the liquid is 1,336, those for the materials apply under *in situ* conditions and are given in Table C.2. Defocus was made to best focus at 100 mm^{-1} to the nearest 0,01 mm.

NOTE For these calculations, the DOTF option of the programme WinSIGMA Level 1 (Kidger Optics, Crowborough, UK) was used. Verification calculations using other software are reported in annex F.

Table C.2 — Calculated MTF values at 100 mm^{-1} of the system of model eye with IOL for selected cases

Dioptric power D	IOL front radius mm	IOL back radius mm	IOL central thickness mm	MTF
PMMA SYMMETRIC BICONVEX (n = 1,4915)				
–10	–31,100	31,100	0,01	0,42
0	plane	plane	0,30	0,53
15	20,695	–20,695	0,74	0,62
30	10,304	–10,304	1,19	0,61
PMMA CONVEX-PLANO (n = 1,4915)				
15	10,367	plane	0,74	0,64
30	5,183	plane	1,26	0,66
SILICONE SYMMETRIC BICONVEX (n = 1,415)				
15	10,500	–10,500	1,18	0,62
30	5,204	– 5,204	2,20	0,38



NOTE BC biconvex, PC plano-convex, CP convex-plano, ME meniscus (with an assumed –6 D back surface power)

Figure C.2 — Calculated MTF values at 100 mm^{-1} of the system of model eye with IOL for various designs

Annex D
(informative)

Precision of dioptric power determination

An interlaboratory test on the determination of dioptric power was conducted for the preparation of this part of ISO 11979. It involved 10 laboratories and seven IOLs, spanning the dioptric power range 10 D to 30 D. The detailed results of the interlaboratory test have been published [1].

In the interlaboratory test, the repeatability was found to be about 0,5 % of the dioptric power measured, while the reproducibility was found to be about 1 % of the dioptric power, using the procedure described in A.2. The significance of these results can be expressed as follows.

If a person makes a single determination of the dioptric power of an IOL, the chance that a repeated measurement, using the same apparatus and with the time lapse between the two occasions short (repeatability conditions), would be within 0,5 % of the first one is 95 %, assuming normal and correct operation of the measurement and calculation procedures.

If a person at one laboratory makes a single determination of the dioptric power of an IOL, and another person at another laboratory with a different piece of apparatus (reproducibility conditions), tries to reproduce this single measurement, the chance that the second person's result would be within 1 % of the first one's is 95 %, assuming normal and correct measurement and calculation procedures.

NOTE The tolerances given in Table 1 include manufacturing tolerances as well as errors due to the limited measurement precision. A manufacturer should take this into account when setting internal tolerances to assure that IOLs put on the market are found in compliance with this part of ISO 11979 when tested by independent laboratories. An in-depth discussion of this topic can be found in [1].