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Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia (ISO/DIS 11979-7:2023)

Ophthalmische Implantate - Intraokularlinsen - Teil 7: Klinische Prüfungen von Intraokularlinsen für die Korrektion von Aphakie (ISO/DIS 11979-7:2023)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques de lentilles intraoculaires pour la correction de l'aphakie (ISO/DIS 11979-7:2023)

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Part 7:
Clinical investigations of intraocular lenses for the correction of aphakia

Implants ophtalmiques — Lentilles intraoculaires —

Partie 7: Investigations cliniques de lentilles intraoculaires pour la correction de l'aphakie

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This fourth edition cancels and replaces the third edition (ISO 11979-7:2018), which has been technically revised.

The main changes are as follows:

— development of definitions of the terms “depth of focus” and “functional vision” as used in describing the clinical function of IOLs at certain focal points or over a range of focal points;

— development of classifications of non-accommodative posterior chamber “Simultaneous Vision Range” (SVL) lenses that include the subtypes of MIOL (Multifocal), EDF (Extended Depth of Focus) and FVR (Full Visual Range) IOLs, and defining each of these IOL types to allow differentiation among the lens types based on clinical and safety performance measures,

— establishment of guidelines for clinical testing of newly defined IOL types as listed above as well as related novel lens types, with alignment of testing methodologies among the lens types;

— alignment of clinical testing updates with 11979-2 Optical and 11979-4 Labelling documents;

— alignment of newly developed terminology with 11979-1 Vocabulary;

— alignment of clinical testing updates with ISO/TR 22979 guidance document.

A list of all parts in the ISO 11979 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Intraocular lenses (IOLs) are used to correct residual refractive errors in subjects who have aphakia. Such residual refractive errors typically include sphere and astigmatism but may also correct for a lack of accommodation. Different designs of IOLs can be used to correct for specific refractive errors. In the case where an IOL is designed to provide more than one type of refractive correction, that IOL will have to satisfy each of the separate requirements of those correction designs.

This document provides requirements and recommendations for intraocular lens investigations of new IOL models. In the case where an IOL model is a modification of a parent IOL model, a risk analysis can be used in order to determine the appropriate level of testing.

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations of intraocular lenses for the correction of aphakia

1 Scope

This document specifies the particular requirements for the clinical investigations of intraocular lenses that are implanted in the eye in order to correct aphakia.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

3 Terms and definitions and abbreviated terms

3.1 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.2 Abbreviated terms

UDVA	uncorrected distance visual acuity
UIVA	uncorrected intermediate visual acuity
UNVA	uncorrected near visual acuity
CDVA	corrected distance visual acuity
CIVA	corrected intermediate visual acuity

CNVA corrected near visual acuity

DCIVA distance corrected intermediate visual acuity

DCNVA distance corrected near visual acuity

4 Justification for a clinical investigation

A risk analysis shall be implemented in accordance with ISO 14971. If the risk analysis identifies the need for a clinical investigation, the requirements of ISO 14155 shall apply, with additional requirements given in this document.

If a new IOL model is a modification of a parent IOL for which the safety and performance have already been established through clinical investigation in accordance with this document, then a limited or no additional clinical investigation shall suffice.

The outcomes of optical evaluation performed according to Annex C in ISO 11979-2 may be used to include or exclude characteristics to be studied in a clinical investigation.

ISO/TR 22979[1] provides guidance in determining the need for a clinical investigation.

5 Ethical considerations

For clinical investigations of medical devices for human subjects, the ethical requirements in ISO 14155 apply.

6 General requirements

6.1 General

There are four main categories of intraocular lenses that are determined by optical design and/or clinical characteristics or performance:

a) monofocal (IOL);

b) toric (TIOL);

c) simultaneous vision lens (SVIOL): non accommodative lenses that provide simultaneous vision at multiple distances:

   — multifocal (MIOL); lens implants that emphasize optical and functionally useful acuity levels at far, but when compared to the monofocal control lens, also have improved optical and clinical performances at near focal distances;

   — extended depth of focus (EDF IOL); lens implants that emphasize optical and functionally useful acuity levels at far but also from far through intermediate focal distances;

   — full visual range IOL (FVR IOL) lens implants that emphasize optical and functionally useful acuity levels at far but also from far through intermediate and up to near focal distances.

d) Accommodating (AIOL).

The same basic requirements apply to all of the IOL types. Additional requirements apply to SVIOL, EDF, TIOL, and AIOL lenses.

There is a further subdivision depending on anatomic placement of the IOL:

— posterior chamber; and

— anterior chamber.

Posterior chamber lenses are placed behind (posterior to) the iris. Anterior chamber lenses are placed in front of (anterior to) the iris. Additional requirements apply in the case of anterior chamber lenses.

6.2 Design of a clinical investigation

6.2.1 Requirements for all types of IOL

A clinical investigation shall be designed to compare the rates of adverse events and visual acuities above defined thresholds of the model IOL to the results of historical data. Annex A provides general guidance for the design of a clinical investigation of IOLs. Historical data can be found in Annex E.

6.2.2 Additional requirements for toric IOLs (TIOL)

Prior to any clinical investigation of a toric intraocular lens, the rotational stability of a mechanically and geometrically equivalent non-toric version of that IOL model shall be demonstrated.

The following performance criteria for rotational stability shall be fulfilled:

The IOL rotation is defined as the difference in postoperative orientation of the meridian defined by the IOL axis indicator between that intended on the day of surgery (Form 0) and that measured at Form 4 and subsequent Forms. See A.3 for recommendations on reporting periods. The absolute value of the rotation shall be less than 10° in 90 % of the cases and less than 20° in 95 % of the cases.

Subsequently, if found necessary by risk analysis (e.g. to assess the clinical performance of low cylinder power TIOLs), a clinical investigation can be performed using the toric version of the model.

Subjects that undergo a secondary surgery to correct postoperative IOL rotational misalignment shall have their clinical results prior to the secondary surgery carried forward as the final results for that subject, and examinations scheduled to be performed later in the clinical investigation shall be performed prior to the secondary surgery, wherever possible. (See Annex D.)

Additional elements for investigations of TIOLs are outlined in Annex B.

6.2.3 Additional requirements for Simultaneous Vision IOL (SVIOL) including MIOL, EDF and FVR lenses

6.2.3.1 General

For SVIOL optical designs, a clinical investigation shall evaluate the safety and performance of vision at far as well as any additional intended defined focal distances (e.g., intermediate and/or near). Clinically significant acuity shall be defined as ≤ 0,20 logMAR. All visual acuity items in the table relate to mean monocular photopic visual acuity.

Intermediate visual performance shall be assessed with best distance correction at 66 cm. Near visual performance shall be assessed with best distance correction at 40 cm. Additional testing distances may be used based on the lens design. [1]

NOTE 1 In order to minimize pseudo-accommodation, the monofocal IOL used for the control group should be aspheric, commercially available and one for which the selection has been justified.

Depth of focus testing shall be performed as described in Annex F.3. If depth of focus testing results meet the requirements listed in Table 1 then the requirements are satisfied. However, if depth of focus testing visual acuity fails to meet the requirements for EDF IOL at -1,5D, or in the case of the FVR lens at either -1,5D or -2,5D, then a conversion factor may be calculated and applied to the entire defocus curve (see notes 4 and 5 in Table 1.) to see if the “converted” acuities meet the stated requirements. This conversion factor shall only be used to adjust the defocus curve to evaluate compliance to the

requirement that the visual acuity from CDVA to -1,5 D (EDF) or -2,5 D (FVR) is ≤ 0,20 logMAR at any defocus data point.

The specific effectiveness requirements are related to the type of SVL as listed table 1 shall be met.

Table 1 — Additional requirements for Simultaneous Visions IOLs

Category	FAR	INTERMEDIATE	NEAR
SVIOL all types	Δ (mesopic CS) ≤ 0,3 log units at any frequency[1]		
MIOL	CDVA ≤ 0,20 logMAR[2]		DCNVA superior to control
EDF IOL	CDVA non-inferior to control 0,1 logMAR level	DCIVA ≤ 0,20 logMAR	
EDF IOL		DCIVA superior to control	
EDF IOL	Defocus range (0,2) ≥0,5D greater than control[3]		
EDF IOL	*Visual acuity from CDVA to -1,5 D defocus ≤ 0,20 logMAR at any defocus data point*[4]		
			Annex A CDVA non-inferior to control **0,1** logMAR level
FVR IOL	CDVA non-inferior to control 0,1 logMAR level		
FVR IOL		DCIVA ≤ 0,20 logMAR	DCNVA ≤ 0,20 logMAR
FVR IOL		DCIVA superior to control	DCNVA superior to control
FVR IOL	*Visual acuity from CDVA to -2,5 D defocus ≤ 0,20 logMAR at any defocus data point*[5]		

1. Δ refers to difference with control, tested without glare.

2. Visual performance shall meet or exceed 0,20 logMAR in order to prevent performance values to be rounded down to 0,20 logMAR.

3. See Annex F.3 for depth of focus testing

4. Since factors such as subject fatigue and optotype minification can have a slight detrimental impact on a subject's visual acuity performance during the defocus curve testing (as compared to the chart testing at that distance), the defocus testing visual acuity levels may need to be adjusted by a conversion factor.

The conversion factor (CF) is defined as the logMAR VA difference between the defocus curve VA at 1,5D and DCIVA at 66 cm. Typically, the CF is a positive value indicating that defocus VA is worse than DCIVA. However, sometimes it can be negative value as well. The CF is noted below is only applicable for this requirement and the adjusted defocus curve cannot be applied towards other requirements noted in Table 1.

Table 1 *(continued)*

Category	FAR	INTERMEDIATE	NEAR
If the mean defocus curve VA at 1,5 is not worse than the DCIVA (i.e., it is either better or same), then no adjustment is needed, and the requirement as noted above should be followed for the test IOL. On the other hand, if the mean defocus curve VA at 1,5D is worse than the DCIVA at 66 cm then a conversion factor shall be applied prior to assessing whether the test IOL met the requirement in Table 1. The new defocus testing visual acuity for any data point from BCDVA (0D) to -1,5 D defocus is the measured value (in logMAR) adjusted by the conversion factor. The adjusted defocus testing visual acuity shall meet the requirement in Table 1. For example, if DCIVA is 0,15 logMAR and VA with the defocus curve at 1,5D is 0,20 log MAR, then it is clear that the defocus curve VA is worse than DCIVA. This difference (i.e., 0,05 logMAR) is the conversion factor. The factor is then applied to the mean defocus curve by adjusting the mean defocus curve by this difference. In this instance, the entire defocus curve is shifted up by this magnitude. This adjusted defocus curve is now checked against the requirement in Table 1 to ensure the performance target is met. [5] Since factors such as subject fatigue and optotype minification can have a slight detrimental impact on a subject's visual acuity performance during the defocus curve testing (as compared to the chart testing at that distance), the defocus testing visual acuity level may need to be adjusted by a conversion factor. The conversion factor (CF) is defined as the logMAR VA largest of the differences between the defocus curve VA at 1,5D or 2,5D and DCNVA at 66 cm or 40 cm, respectively. Typically, the CF is a positive value indicating that defocus VA is worse than DCNVA. However, sometimes it can be negative value as well. The CF is noted below is only applicable for this requirement and the adjusted defocus curve cannot be applied towards other requirements noted in Table 1. If the mean defocus curve VAs at 1,5D and 2,5D are not worse than the DCIVA and DCNVA (i.e., it is either better or same), then no adjustment is needed, and the requirement as noted above should be followed for the test IOL. On the other hand, if the mean defocus curve VA at one (or both) of the induced defocus levels (namely 1,5D or 2,5D) is worse than the corresponding DCNVA (at 66 cm or 40 cm respectively), then a conversion factor (i.e. the largest difference between the two test distance comparisons) is applied prior to assessing whether the test IOL meets the requirement in Table 1. The new defocus testing visual acuity for any data point from BCDVA (0D) to -2,5 D defocus is the measured value (in logMAR) adjusted by the conversion factor. The adjusted defocus testing visual acuity shall meet the requirement in Table 1. For example, if DCIVA is 0,12 logMAR and DCNVA is 0,15 logMAR and VA with the defocus curve at 1,5D is 0,10 logMAR and at 2,5D is 0,20 log MAR, then it is clear that the defocus curve VA is worse than the chart VA at both distances. The largest difference between the two test distances is 0,05 logMAR. This shall be the conversion factor and subsequently applied to the mean defocus curve by adjusting the mean defocus curve by this difference. In this instance, the entire defocus curve is shifted up by this magnitude. This adjusted defocus curve is now checked against the requirement in Table 1 to ensure the performance target is met.			

6.2.3.2 Depth of Focus testing

Depth of focus evaluations shall be performed on all SVIOL types. See Annex F for additional guidance.

6.2.3.3 Safety Requirements

The mean mesopic far contrast sensitivity (without glare) for all SVIOL shall be no worse than 0,3 log units below that of the control at any test spatial frequency. Annex C identifies additional safety and performance requirements for consideration.

NOTE The 0,3 log unit at one spatial frequency is from review of the ***Summary of Safety and Effectiveness Documents (SEED's)*** of approved MIOL's in the US.

6.2.4 Additional requirements for accommodating IOLs (AIOL)

A controlled clinical investigation of an AIOL shall evaluate the accommodative amplitude and the additional safety and performance aspects related to the risk assessment. Annex D identifies safety and performance aspects for consideration. Annex F includes defocus testing guidance. The clinical investigation plan shall include at least one objective method to measure accommodative amplitude.

The investigation enrolment shall consist of two phases (see Annex D). The second phase shall begin only if the first phase has demonstrated that the IOL design provides an average of at least 1,0 D of objective accommodation. In order for the design to be designated as an AIOL, the overall investigation shall demonstrate objective accommodation of 1,0 D or more at the point of accommodative stability (see Annex D).

Additional elements for AIOLs are outlined in Annex D.

6.2.5 Additional requirements for anterior chamber IOLs

A clinical investigation of an anterior chamber IOL shall evaluate the change in endothelial cell density, hexagonality and coefficient of variation of endothelial cell area, the clearance between the surfaces of the anterior chamber IOL and the posterior surface of the cornea and the iris, the anterior chamber angle (including observations of pigment and synechiae), and any additional safety and performance aspects related to the risk assessment.

6.3 Characteristics of clinical investigations

6.3.1 General

The clinical investigation plan shall provide information regarding characteristics to be studied, and instructions regarding the methods and documentation of these characteristics. Whenever possible, objective methods, such as photographic imaging, shall be used.

If additional claims are to be made, additional corresponding characteristics shall be studied.

If several types of IOLs are combined, the characteristics of each IOL subtype in the combination shall be fully considered.

6.3.2 Characteristics to be studied for all types of IOL

The following characteristics shall be considered:

a) CDVA;

b) Manifest (subjective) refraction

c) visual acuity at all intended distances with far correction;

d) intraocular pressure;

e) corneal status;

f) signs of intraocular inflammation;

- anterior chamber cells;
- anterior chamber flare;
- cystoid macular oedema;
- hypopyon; and
- endophthalmitis.

g) pupillary block;

h) retinal detachment;

i) status of anterior and posterior capsule;

j) IOL decentration[2];

k) IOL tilt[2];

l) IOL discoloration;

m) IOL opacity;

n) glistenings in IOL; and

o) visualization of posterior pole through IOL.

6.3.3 Additional characteristics to be studied for toric IOL

a) IOL rotational stability; and

b) corneal astigmatism;

— prior to surgery;

— intended surgical position (Form 0); and

— post-surgical.

6.3.4 Additional characteristics to be studied for SVIOLs

a) Depth of focus testing;

b) Uncorrected visual acuity at far and intermediate and/or near, as applicable to the type of IOL;

c) Intermediate and/or near visual acuity with best distance correction, as applicable to the type of IOL;

d) Patient reported outcome (PRO) survey to assess visual symptoms related to the optical properties of the IOL for Bilateral implantation of SVIOL;

e) Rate of secondary surgical interventions;

f) Contrast sensitivity (at far).

6.3.5 Additional characteristics to be studied for accommodating IOL

a) objective accommodative amplitude;

b) uncorrected visual acuity at distance, intermediate and near;

c) visual acuity at near and intermediate using far correction;

d) additional refraction (over distance correction) required to achieve any improvement in near visual acuity;

e) contrast sensitivity;

f) pupil size;

g) PRO survey to assess visual symptoms related to the optical properties of the IOL;

h) Rate of secondary surgical interventions.