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Ophthalmic implants — Intraocular lenses —

Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes

Implants ophtalmiques — Lentilles intraoculaires —

Partie 10: Investigations cliniques de lentilles intraoculaires pour la correction de l'amétropie des yeux phaques

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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 on 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 the following URL: 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 second edition cancels and replaces the first edition (ISO 11979-10:2006) and its amendment (ISO 11979-10:2006/Amd 1:2014), which has been technically revised.

The main changes compared to the previous edition are as follows.

— modified the scope to include phakic multifocal and phakic toric intraocular lenses;

— added references to the requirements in ISO 11979-6, ISO 11979-7, and ISO 11979-8;

— modified the clinical requirements to include those for phakic multifocal and phakic toric intraocular lenses; and

— modified the informative Annex A to include elements associated with the clinical investigation of phakic multifocal and phakic toric intraocular lenses.

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

Introduction

Phakic intraocular lenses are used to correct refractive errors in patients with a non-cataractous crystalline lens. They are typically used for patients with higher amounts of myopia or hyperopia. Originally, they contained a spherical monofocal optic to correct spherical errors but later variations utilized a toric optic to also correct refractive astigmatism. Phakic intraocular lenses with a multifocal optic can be used to correct presbyopia in patients that have lost the ability to accommodate.

The requirements and recommendations in the ISO series of standards for aphakic intraocular lenses for the most part also apply to phakic intraocular lenses. Those standards should be reviewed for guidance that would also be applicable to phakic intraocular lenses (e.g. shelf-life testing, biocompatibility testing, etc.).

This document provides requirements and recommendations for phakic intraocular lens investigations of new models. Risk analysis should be used to determine the investigational design, if needed, for models that are modifications of parent phakic models. For modifications of a parent phakic model refer to ISO/TR 22979.

Ophthalmic implants — Intraocular lenses —

Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes

1 Scope

This document specifies requirements for any intraocular lenses to be implanted in the anterior segment of the eye with the primary indication to modify its refractive power.

There are three main categories of phakic intraocular lenses depending on the optical design:

a) Phakic monofocal (PIOL);

b) Phakic multifocal (PMIOL); and

c) Phakic toric (PTIOL).

Each of these categories is further designated for implantation in either the anterior or posterior chamber of the anterior segment of the eye.

The basic phakic IOL requirements apply to all the types. Additional requirements apply to PMIOL and PTIOL designs.

This document addresses specific clinical requirements for phakic IOLs that are not addressed in the other parts of ISO 11979.

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

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

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of lenses for the correction of aphakia*

ISO 11979-8, *Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements*

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, 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 terminological databases for use in standardization at the following addresses:

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

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

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 Optical requirements

The applicable requirements of ISO 11979-2 shall apply.

5 Mechanical requirements

The applicable requirements of ISO 11979-3 shall apply.

6 Biocompatibility requirements

The applicable requirements of ISO 11979-5 shall apply.

7 Shelf-life and transport stability requirements

The requirements of ISO 11979-6 shall apply.

8 Fundamental requirements

The requirements of ISO 11979-8 shall apply.

9 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 phakic IOL model is a modification of a parent phakic 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 can suffice. ISO/TR 22979[1] provides guidance in determining the need for a clinical investigation.

10 General clinical requirements

10.1 General

The requirements for a clinical investigation given in ISO 14155 shall apply, with additional requirements given below.

10.2 Design of a clinical investigation

10.2.1 Requirements for all types of phakic IOLs

A non-controlled clinical investigation shall be designed to investigate the safety and performance of PIOL designs, and PTIOL designs of higher cylinder power.

A controlled clinical investigation shall be designed to investigate the safety and performance of PMIOL designs, and PTIOL designs of lower cylinder power (i.e. cylinder powers of 1,5 D or less).

The primary safety endpoint for all phakic IOL investigations is endothelial cell density.

NOTE In the case of the non-controlled clinical investigations, data describing changes in endothelial cell density over time for levels of ametropia similar to the levels for the subjects in the investigation from either literature or from a sub-study of non-operated eyes will be useful in assessing the significance of the endothelial cell density changes in the study subjects.

10.2.2 Additional requirements for PTIOLs

During the clinical investigation of a PTIOL, the rotational stability 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 and that measured at the final reporting period for the investigation. Absolute rotation shall be less than 10° in 90 % of the cases, and less than 20° in 95 % of the cases.

The clinical performance of low cylinder power PTIOLs shall be demonstrated compared to the non-toric control PIOL.

In such a clinical investigation, subjects that undergo secondary surgery to correct postoperative phakic 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 be performed prior to the secondary surgery, if possible.

The TIOL clinical design provisions in ISO 11979-7 shall be used to determine the additional evaluations needed to be incorporated into the general phakic clinical investigational design described in Annex A to evaluate the performance of the PTIOL design.

10.2.3 Additional requirements for PMIOLs

For PMIOL designs, a clinical investigation shall evaluate the safety and performance of vision at far distance and near distances, and at any intended intermediate focal distances. The MIOL clinical design recommendations in ISO 11979-7 shall be used to determine the additional evaluations needed to be incorporated into the general phakic IOL clinical investigation design described in Annex A to evaluate the visual performance of the PMIOL design.

In all cases, the clinical investigation plan shall include defocus evaluation.

10.3 Characteristics

10.3.1 General

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

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

If several types of phakic IOLs are combined, the characteristics of all of them shall be considered.

10.3.2 Characteristics applying to the clinical evaluations for all types of phakic IOLs

a) UDVA;

b) CDVA;

c) subjective refraction;

d) contrast sensitivity;

e) pupil size;

f) intraocular pressure;

g) corneal status, including endothelial cell density status;

i) signs of inflammation:

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

j) pupillary block;

k) retinal detachment;

l) status of anterior and posterior capsule;

m) status of the crystalline lens;

n) status of anterior chamber angle;

o) status of iris;

p) anterior chamber depth;

q) IOL decentration;

r) IOL tilt;

s) IOL discoloration; and

t) IOL opacity.

If justified by the risk analysis, cycloplegic refraction shall be considered for all phakic IOL investigations.

10.3.3 Additional characteristics applying to PTIOLs

a) keratometry; and

b) IOL axis mark rotation.

10.3.4 Additional characteristics applying to PMIOLs

a) UNVA, and if applicable UIVA;

b) DCNVA, and if applicable DCIVA;

c) subject questionnaire;

d) defocus evaluation; and

e) fundus visualization.

10.4 Duration of the investigation

The minimum duration of the clinical investigations shall be 3 years (see Annex A for visit window tolerances) for all parent phakic IOLs which are not modifications of a model for which safety and performance data have been established through clinical investigation.

When a phakic IOL is a modification of a parent phakic IOL, ISO/TR 22979 is used as guidance to determine the need for a clinical investigation.

All subjects in a clinical investigation that have not been discontinued shall complete all visits of the investigation. The clinical investigation shall be considered completed when all subjects that have been enrolled in the investigation, including subjects whose phakic IOL was removed or replaced, have either completed follow-up according to the protocol or have past the final visit window.

10.5 Enrolment

To minimize the risks associated with the clinical investigation of a new phakic IOL, subject enrolment shall occur in stages. The subject data from each stage shall be evaluated and found acceptable by the sponsor and the coordinating investigator (and by the regulatory body, where applicable) prior to the continuation of the clinical investigation. Guidance on phased enrolment is included in Annex A.

10.6 Bilateral implantation

Any plans for fellow eye implantation shall be described in the clinical investigation plan. Bilateral implantation shall not be implemented until initial safety and performance data have been collected, evaluated and confirmed by the sponsor and coordinating investigator (and by risk analysis, if applicable).

When implantation of fellow eyes is permitted, the clinical investigation plan shall specify the time period between implantation of first eye and fellow eye, based upon risk analysis.

Both the first and second eye of each subject shall be included in the analyses of endothelial cell loss, adjusted for the correlation between eyes. The primary statistical analyses of other adverse events shall be performed using only using the first implanted eye for each subject; secondary analyses shall include all implanted eyes. For performance endpoints, the primary analyses shall be performed using only the first implanted eye for each subject.

The review of data from at least 50 eyes with six months of follow-up is recommended prior to fellow eye implantation. Risk analysis can allow an earlier implantation in fellow eyes if sufficiently justified by previous clinical experience.

10.7 Surgical technique

The clinical investigation plan shall contain descriptions of the surgical technique, the intraoperative use of ophthalmic viscosurgical devices, and the use of preoperative, intraoperative and postoperative medications. Any deviation shall be recorded on the case report forms.

For PTIOLs, the clinical investigation plan shall specify the type and location of the incision. The estimated effect of the incision on the corneal astigmatism shall be used in the protocol for choosing the appropriate cylindrical power.

If a specific calculation procedure is to be used to determine the appropriate power for implantation, the calculation procedure and its derivation shall also be included in the clinical investigation plan. Clinical data shall be evaluated at intervals during the investigation to refine the power calculation procedure, if necessary.

10.8 Examination and treatment of subjects

The reporting periods are described in Annex A.

The clinical investigation plan shall describe how subject visits and ophthalmic adverse events that occur between standard reporting periods will be handled in the data analyses.

10.9 Adverse events reports

Serious adverse events and all adverse device effects shall be reported using a special case report form and forwarded to the sponsor as required. A drop in visual performance shall be considered as a serious ophthalmic adverse event (e.g. a drop in CDVA of two or more lines; a drop in quality of vision from glare/ reduction in contrast sensitivity associated with the development of a cataract). All other adverse events shall be reported using either the standard visit case report form or specific adverse event forms and be collected during monitoring.

10.10 Inclusion and exclusion criteria

10.10.1 General criteria for all phakic IOLs

The following are general criteria for all phakic IOLs. Additional criteria shall be included depending on the risk analysis for the particular IOL model.

10.10.1.1 Inclusion criteria

The following inclusion criteria shall be considered:

a) adult;

b) meets specified refractive criteria (spherical and cylindrical components);

c) meets specified minimum CDVA in each eye;

d) UDVA 0,5 logMAR or worse;

e) less than 0,75 D difference between cycloplegic and subjective refractions;

f) stable ametropia (±0,75 D), as expressed by subjective refraction spherical equivalent for a minimum of 12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history;

g) to control the influence of contact lenses on the refraction, current contact lens wearer needs to demonstrate a stable refraction (±0,5 D), expressed as subjective refraction spherical equivalent, on two consecutive examination dates and stability of the refraction is determined by the following criteria:

   1) contact lenses were not worn for at least 2 weeks (rigid and toric contact lenses) or 3 days (soft contact lenses) prior to the first refraction;

   2) two refractions were performed at least 7 days apart;

h) subject, who is expected to have residual postoperative cylindrical refractive error of < 1,0 D, has been given the opportunity to experience his/her best spectacle vision with the anticipated correction; and

i) signed informed consent form.

10.10.1.2 Exclusion criteria

The following exclusion criteria shall be considered:

a) previous intraocular and corneal surgery;

b) an acute or chronic disease or illness that would increase the operative risk or confound the outcome(s) of the study;

c) systemic medications being taken that can confound the outcome of the study or increase the risk to the subject;

d) ocular condition that can predispose for future complications;

e) less than the minimum endothelial cell density (ECD) at time of enrollment as described by Table 1;

f) coefficient of variation of endothelial cell area > 0,45 (in both eyes)[2];

g) percent hexagonality of endothelial cell shape ≤ 45 %[2];

h) pregnancy and lactation;

i) monocular subject;

j) insufficient space for the intended implant;

k) concurrent participation in another drug or device investigation; and

l) no cataract of any grade.

Table 1 — Recommended minimum endothelial cell density (ECD) for investigation

Age at time of enrolment years	**Minimum endothelial cell density** cells/mm^2
21 to 25	2 950
26 to 30	2 650
31 to 35	2 400
36 to 45	2 200
≥ 46	2 000
NOTE With the rate of endothelial cell density decrease unknown during the clinical investigation, minimum endothelial cell density values were selected for this table that are based on conservative assumptions in order to protect the subjects in the investigation. The recommended endothelial cell density (ECD) in this table represents the average minimum ECD necessary to leave 1 000 cells/mm^2 at 72 years of age assuming a 10 % surgical decrease and a yearly rate of decrease of 2 %.	

10.10.2 Additional criteria for PTIOLs

The following are additional inclusion criteria that shall be considered for all PTIOLs. Additional criteria shall be included depending on the risk analysis for the particular PTIOL model.

a) subjective refractive cylinder within the range defined in the clinical investigation plan;

b) subjective refractive cylinder demonstrated by no systematic change in refractive power over 12 months; and

c) expected dilated pupil size at least large enough to visualize the axis markings for posterior chamber phakic IOLs.

10.10.3 Additional criteria for multifocal IOLs

The following are additional exclusion criteria that shall be considered for all PMIOLs. Additional criteria shall be included depending on the risk analysis for the particular PMIOL model:

a) subjects with ocular disorders, other than cataract, that could potentially cause future acuity losses to a level of 0,66 logMAR or worse in either eye;

b) subjects who are expected to require retinal laser treatment;

c) greater than 1,0 D of pre-operative corneal astigmatism;

d) irregular astigmatism or suspected corneal ectasia; and

e) inability to achieve secure lens placement in the designated location.

11 Information supplied by the manufacturer

The requirements of ISO 11979-4 apply.

In addition, the contraindications criteria in the labelling should include a modification of Table 1 based on the upper 90 % confidence interval associated with the actual acute and chronic rate of endothelial cell density decrease determined from the clinical investigation rather than the assumed yearly rate of 2 % decrease used in Table 1. If other factors (e.g. anterior chamber depth) are determined to influence the rate of endothelial cell density decrease, these factors should be incorporated into the modification of the table so that a minimum endothelial cell density based on age and these other factors is provided to show in which patients the phakic IOL is contraindicated.

The labelling shall also include a histogram with the frequency distribution of % endothelial cell changes in increments of 5 % between pre-operative and final reporting form levels.

Annex A
(informative)

Elements in a phakic IOL clinical investigation

A.1 General

The following are elements of a clinical investigation plan (CIP) which can assist in collecting data for the purpose of determining the safety and performance of all types of phakic IOLs.

A.2 Investigation design

A.2.1 General

The suggested clinical investigation design is an uncontrolled study for PIOL designs, and PTIOL designs of higher cylinder power. A controlled clinical investigation is designed to investigate the safety and performance of PMIOL designs, and PTIOL designs of lower cylinder power (i.e. cylinder powers of 1,5 D or less). Guidance is provided in ISO 11979-7.

Minimum study duration of three years and sample size of 300 is recommended to adequately evaluate the acute and chronic changes in endothelial cell density (and associated adverse events such as corneal haze, decompensation, secondary surgical reintervention, etc.) and the rate of cataract development. The clinical investigation plan should inform subjects and investigators that longer term follow-up could be necessary.

To take into account that some subjects are lost to follow-up during the course of the clinical investigation (including deceased subjects and subjects who have the IOL explanted), enrol about 420 subjects. Significantly larger numbers of subjects are not to be enrolled, in order to minimize exposure to the risks of a new IOL.

To assist in achieving a balance in the number of subjects from each investigator, each surgeon contributes a minimum of 20 subjects, but no more than 25 % of the subjects in the investigation. Guidance for accountability is provided in ISO 11979-7.

A.2.2 Primary endpoint

The recommended primary safety endpoint is endothelial cell density. Sample size guidance is provided in Annex B.

A.2.3 Enrolment

For clinical studies of a single refractive indication, the following phased enrollment plans are recommended.

a) Phase I: 10 subjects (unilaterally implanted), followed for 6 months;

b) Phase II: 50 additional subjects (unilaterally implanted), followed for 6 months; and

c) Phase III: remainder of the subjects.

Depending on the design of the phakic IOL, a different phase-in can be appropriate. The data from each stage is evaluated and found acceptable by the sponsor and the principal investigator prior to proceeding to the next stage.

NOTE Previous clinical experience, i.e. results from well-documented clinical investigations, can be used as a justification to support faster enrolment.

A.2.4 Standardization of procedures

Define criteria for evaluation of all studied variables. Define testing conditions for all measurements. Before commencing the investigation, instruct and train all investigators to use these in order to obtain data that can be combined for the purpose of statistical analysis.

The minimum number of completed case report forms for each reporting period is 300.

A.3 Reporting periods

The time frames for the reporting periods are defined below:

a) Preoperative (Preop);

b) Operative (Op);

c) Day 1 (1 day);

d) Week 1 (5 to 9 days);

e) Month 1 (3 to 5 weeks);

f) Month 3 (10 to 14 weeks);

g) Month 6 (21 to 26 weeks);

h) Month 12 (11 to 14 months);

i) Month 18 (17 to 21 months);

j) Month 24 (23 to 27 months);

k) Month 30 (29 to 33 months); and

l) Month 36 (35 to 39 months).

A.4 Clinical tests

The recommended examination schedule for PIOL designs is given in Table A.1.

Table A.1 — Recommended PIOL examination schedule

Study	Preop	Op	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36
UDVA	X		X	X	X	X	X	X		X		X
CDVA	X			X	X	X	X	X		X		X
DCNVA	X							X				X
Subjective refraction	X	X[a]		X	X	X	X	X		X		X
Cycloplegic refraction	X					X		X		X		X
Axial length	X											
Anterior chamber[b]	X						X					X
Intraocular pressure	X	X[c]	X	X	X	X	X	X	X	X	X	X
Slit lamp exam[d]	X		X	X	X	X	X	X		X		X
Status of crystalline lens	X					X	X	X	X	X	X	X
Gonioscopic exam.	X						X	X		X		X
Fundus exam. with dilated pupil	X				X			X		X		X
Mesopic pupil size	X						X					X
Pachymetry of corneal thickness	X	X[e]					X					X
Keratometry[f]	X	X						X				X
Subject questionnaire	X						X	X	X	X	X	X
Specular microscopy	X						X	X	X[g]	X	X[g]	X
Sub-studies												
Contrast sensitivity[h]	X						X					X
Clearance analysis[i]	X					X						

[a] For contact lens wearers.

[b] Distance from the posterior surface of the cornea to the anterior surface of the crystalline lens.

[c] Post-surgery operative day IOP measurements are considered if pupillary block is a possible complication.

[d] Tilt and decentration of the PIOL are included in the slit lamp assessment.

[e] If required for the surgical procedure.

[f] To establish preoperative refractive stability for contact lens wearers and to demonstrate postoperative corneal stability, where necessary.

[g] These evaluations are optional (in the case of specular microscopy data, they can be useful to demonstrate the trend associated with the outcomes given the variability of the ECD measurements).

[h] Contrast sensitivity testing is performed on all subjects preoperatively and repeated postoperatively on those subjects that are part of the contrast sensitivity sub-study and on all subjects that develop crystalline lens opacity at all remaining visits. The testing is performed under mesopic and mesopic with glare conditions.

[i] Methods such as anterior segment optical coherence tomography, ultrasonic biomicroscopy or Scheimpflug photography can be used.

The additional clinical examinations recommended for PTIOL designs are given in Tables A.2.

Table A.2 — Recommended additional PTIOL examination schedule

Study	Preop	Op	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36
IOL axis orientation		X	X	X	X	X	X	X		X		X

The additional clinical examinations recommended for PMIOL designs are given in Table A.3. Additionally, the subject questionnaire should add questions regarding the quality of the subject's vision as described in ISO 11979-7. Guidance for the defocus evaluation sub-study is provided in ISO 11979-7.

Table A.3 — Recommended additional PMIOL examination schedule

Study	Preop	Op	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36
UNVA						X	X	X		X		X
Photopic pupil size	X						X					
Sub-studies												
Defocus evaluation[a]							X			X		X
Far contrast sensitivity – Photopic with glare							X			X		X

[a] Subjects in the defocus study should come from the three pupil size categories defined in ISO 11979-7. If 10 subjects are not available in some pupil size categories, then the maximum number available is used.

A.5 Evaluations

A.5.1 General

Procedures for general evaluations are described in ISO 11979-7. Other evaluations specific to phakic IOLs are described below.

A.5.2 Crystalline lens status

The crystalline lens should be evaluated preoperatively and at each of the postoperative intervals after 1 month. The level of evaluation should be commensurate with the risk of lens opacities/lens changes identified by the risk analysis performed by the manufacturer.

For phakic IOLs where the design or surgical procedure could lead to lens changes, a grading system[3][4][5] or quantitative method should be used to evaluate all eyes for lens changes and to evaluate those changes over time.

When lens opacity is observed, photographs should also be taken when first observed and at each subsequent visit to document any progression of the opacity. Also, when crystalline lens opacities are detected, contrast sensitivity testing is performed on that subject at each postoperative evaluation after the opacity is observed.

A.5.3 Aqueous cell and flare assessment

The slit lamp examination includes the measurement of aqueous cell and flare by a standard grading system[6].

A.5.4 Measurement of intraocular pressure

Intraocular pressure is measured using Goldmann applanation tonometry. Other methods can be used with a scientific justification, provided that all investigators use the same method.