PUBLISHED DOCUMENT

PD ISO/TR
22979:2006

Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

ICS 11.040.70

BSI
British Standards

National foreword

This Published Document is the UK implementation of ISO/TR 22979:2006.

The UK participation in its preparation was entrusted by Technical Committee CH/172, Ophthalmic optics, to Subcommittee CH/172/7, Eye implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 January 2008

ISBN 978 0 580 54820 8

Amendments issued since publication

Amd. No.	Date	Comments

TECHNICAL REPORT

ISO/TR 22979

First edition
2006-02-01

Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

Implants ophtalmiques — Lentilles intraoculaires — Directives relatives à l'évaluation de la nécessité d'investigation clinique pour les modifications de dessin des lentilles intraoculaires

Reference number
ISO/TR 22979:2006(E)

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Foreword

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Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

1 Scope

This Technical Report provides guidance on the application of Parts 3, 7 and 9 of the ISO 11979 series of International Standards for intraocular lenses (IOLs). It addresses factors to be considered in a risk analysis of the significance of modifications to anterior and posterior chamber, monofocal and multifocal, intraocular lenses. It also suggests methods of data analysis and interpretation that can be used to determine the need for and the design of a clinical investigation.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

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

4 Monofocal lenses

4.1 General

Monofocal IOLs that are modifications of a parent IOL, have different requirements for clinical investigations depending on the magnitude of the modifications. This Technical Report provides considerations for the risk analysis to determine which of the following are needed.

a) No clinical investigation.

b) Limited clinical investigation of 100 subjects followed up to and including Form 4, see ISO 11979-7.

c) Full clinical investigation as defined in ISO 11979-7.

4.2 Modification levels (categories)

4.2.1 Level A modifications

Level A modifications are minor modifications for which all safety and performance questions can be adequately addressed by non-clinical testing. Level A modifications require no clinical investigation.

4.2.2 Level B modifications

Level B modifications are modifications that raise safety and/or performance questions that can be adequately addressed with a limited clinical investigation.

4.2.3 Level C modifications

Level C modifications are modifications that raise safety and/or performance questions that can only be addressed with a full clinical investigation.

4.3 Clinical investigation with multiple IOL models

More than one IOL model can be studied in the same clinical investigation provided that the models are Level A modifications of each other. A model qualifies as a parent only if it has been investigated in a minimum of 100 subjects as defined in ISO 11979-1.

4.4 Mechanical data analysis

4.4.1 General

The mechanical data analysis method in this clause can be used to determine whether a modified posterior chamber IOL is a Level A modification.

The testing to characterize the mechanical characteristics of an IOL is described in ISO 11979-3. The data from the compression force, compression force decay and angle of contact testing is used to determine the difference in mechanical behaviour between the parent IOL(s) and a modification of the parent IOL(s).

Two methods of mechanical data analysis that can be considered to determine the differences between a modified IOL and parent IOL(s) are outlined in 4.4.2 and 4.4.3. A detailed description of the methods with examples is given in Annex B.

4.4.2 Comparison to a single parent IOL model

For comparison between a modified model and a single parent model, the manufacturer assesses whether the mechanical properties of the modified IOL are similar to those of the parent model.

4.4.3 Comparison to multiple parent IOL models

For comparison between a modified model and multiple parent models, the manufacturer assesses whether the mechanical properties of the modified IOL fall inside the ranges of mechanical characteristics defined by the parent models.

5 Multifocal lenses

5.1 General

This clause provides guidance to the risk analysis to assess whether a clinical investigation is warranted with regard to modifications of a multifocal IOL (MIOL) model. A modified MIOL can be compared to both monofocal and multifocal parents for mechanical properties, but only to multifocal parents for optical properties.

5.2 Addition of a parent multifocal optic to a parent monofocal model

5.2.1 General

The factors below are considered when adding a parent multifocal optic to a parent monofocal model. When a significant additional risk is identified, a clinical investigation, designed to address the specific risk area, is considered.

5.2.2 Material

Determine whether any characteristic of the monofocal lens material has an impact on the performance of the multifocal optic. If the material of the monofocal parent is different from that of the approved MIOL, a clinical study is considered, particularly if the optical or mechanical testing results in clinical concerns.

5.2.3 Mechanical design

Determine whether the design or placement of the monofocal parent affects the optical performance expected with the multifocal design. The risk analysis comprises the following.

a) The potential for increased variability in IOL centration (i.e. tilt and decentration) due to the monofocal parent's IOL body and haptic design. The comparison includes analysis of clinical study reports of centration issues and mechanical differences in IOL design.

b) Optical sensitivity to IOL decentration and tilt are evaluated using methods outlined in ISO 11979-2 by comparison of the decentration and tilt characteristics of the new multifocal design to the parent multifocal design.

c) Evaluation of the potential for changes in the predictability and stability of post-operative refraction.

5.3 Modification of the optical design geometry of a parent multifocal optic

The following factors are considered when modifying the geometry of a multifocal optic of a parent MIOL model.

a) A change in the fundamental technology creating the multiple powers (e.g. diffraction versus refraction) is a change to the multifocal parent design and a clinical investigation is performed as specified in ISO 11979-9.

b) Minor modifications to a parent multifocal design can be made to enhance or optimize performance. Optical bench testing as defined in ISO 11979-9, including measurement of the modulation transfer function (MTF) as function of spatial frequency (through-frequency MTF) and as function of defocus (through-focus MTF), is performed and analysed to assess the potential for significant changes in clinical function. Additional analysis is performed to assess specific concerns raised with the design modification. When an additional risk is identified, a clinical investigation is considered that is designed to address the specific risk area.

Annex A
(informative)

Examples of modifications to a parent IOL model

A.1 General

Modifications to an IOL that has undergone a clinical investigation can be classified in one of three categories depending on the level of modification: Level A, Level B or Level C. The applicable criteria to determine what level of modification has occurred to the parent model are described below.

The applicability column indicates the type of IOL that the modification is applicable to:

— P designates posterior chamber IOLs, excluding one-piece plate designs;

— A designates anterior chamber IOLs;

— PL designates posterior chamber IOLs made from flexible materials that are of a one-piece plate design.

A modified model may have various combinations of the modifications listed below, as long as all the applicable criteria are met.

A.2 Level A modifications

The Level A modifications are listed in Tables A.1 to A.3. Modifications in Table A.3 differ from the other modifications in that they involve material/design substitutions of parent models only.

Table A.1 — Change in loop configuration

Modification	Applicability	Mechanical data analysis
Mirror-image version of a model	P/A/PL	No
Change in overall diameter Addition of a size specific to patients with a certain anterior chamber width.	A	No
Changes in loop features Changes such as the addition of notches or the addition of eyelets or rounded ends to loops.	P/A	No
Change in loop angulation Changes to a design with the body angulated posterior to the loops resulting in a change in sagitta value up to a maximum of 1,6 mm for the 20 D version of the model.	P	No
Change in overall diameter	P	Yes
Change in loop thickness or width	P	Yes
Change in loop configuration (shape)	P	Yes

Table A.2 — Change in optic configuration

Modification	Applicability	Mechanical data analysis
Change in dioptric power range Whereby the IOL of any power in the range that the manufacturer makes available meets ISO 11979. The clearance between the surface of the anterior chamber IOL and the ocular tissue is a subject for consideration for each new power range, see ISO 11979-3.	P/A/PL	No
Change in optic or body size and addition of tabs to the periphery of the optic Changes in body circumference design or optic size if the length is not less than 5,0 mm along any meridian (e.g. going from a circular to an ovoid body) and not greater than 7,5 mm along any meridian.	P/PL	No
Change of clear optic Any obstruction that interferes with the performance of the optic, provided that the clear optic diameter is greater than 4,25 mm.	P/A/PL	No

Table A.3 — Interchanging IOL materials and designs

Modification	Applicability	Mechanical data analysis
Interchanging materials and design from parent IOLs Assuming that the interchange is within the limits of a Level A modification mechanically.	P	Yes

A.3 Level B modifications

The Level B modifications are listed in Tables A.4 and A.5.

Table A.4 — Change in loop configuration or material

Modification	Applicability	Mechanical data analysis
Change in loop configuration Including change in overall diameter, loop thickness or width, when not meeting the Level A criteria mechanically. If the change in loop configuration of the modified lens appears to have the potential to cause different or greatly increased safety concerns as compared to the parent model(s), it is considered to be a Level C modification.	P	Yes
Change to new loop material This is a change in loop material to a material that is new to the manufacturer, but is a material the long-term safety of which as a loop material can be supported by the ophthalmic literature, provided that the articles disclose the identity of the material used and the manufacturer uses the identical material.	P	Yes

Table A.5 — Change in optic material or configuration

Modification	Applicability	Mechanical data analysis
Change in body material This is a change in body material to a material that is new to the manufacturer, but is a material the long-term safety of which as a body material can be supported by the ophthalmic literature, provided that the articles disclose the identity of the material used and the manufacturer uses the identical material.	P	Not applicable
Change in body or optic diameter This is a change in body or optic diameter outside the range from 5,0 mm to 7,5 mm. Evaluations of models that incorporate optics less than 5,0 mm in diameter should include clinical testing to evaluate the effects of glare on the subject's visual acuity that may result from the small optic.	P	Not applicable

A.4 Level C modifications

Modifications not described in A.2 or A.3 are Level C modifications.

Annex B
(informative)

Mechanical data analysis

B.1 Principle

The methods in this annex apply to two-looped lens models only. Mechanical data, i.e. compression force, compression force after decay and angle of contact, can be used to assess whether a modified IOL is a Level A modification of a parent IOL, as described in Annex A.

B.2 Terms and definitions

The following terms and definitions in this paragraph apply for this Annex only.

B.2.1
open-loop IOL
IOL model which contains two loops, each loop having one end attached to the body of the IOL and the other end free

B.2.2
closed-loop IOL
IOL model, which contains two loops, each loop having both ends attached to the body of the optic

B.2.3
hybrid open-loop/closed-loop IOL
IOL model which contains two loops, with one loop having one end attached to the body of the IOL and the other end free, and the other loop having both ends attached to the body of the IOL

B.3 Mechanical comparison methods

B.3.1 General

For comparisons between a modified model and a single parent model, which is either currently undergoing a clinical investigation or has completed a clinical investigation, the manufacturer demonstrates that the mechanical properties of the modified lens are not significantly different from those of the parent model.

For comparisons between a modified model and multiple parent models, the manufacturer demonstrates that the mechanical properties of the modified lens are not significantly different from the range of properties associated with the parent models.

The analysis between the modified model and the manufacturer's parent model(s) includes the following comparisons:

— compression force divided by angle of contact per loop;

— compression force after decay divided by angle of contact per loop.

For each test needed for the analysis, the lens is evaluated at 10,0 mm compressed diameter if the modified lens is only for capsular bag fixation, at 11,0 mm if it is only for ciliary sulcus fixation, or at both diameters if intended for both capsular bag and ciliary sulcus fixation.

B.3.2 Restrictions

B.3.2.1 The method of comparison with a single parent model includes the following restrictions.

— A model of either the open-loop, closed-loop, or hybrid open/closed-loop types is only compared to the same type of model.

— For models of the open-loop or closed-loop type having dissimilar loops, each loop is assessed separately, and then each loop on the modified model is compared to the corresponding loop on the parent model that it most closely resembles.

B.3.2.2 The method of comparison with multiple parents includes the following restrictions.

— An open-loop model or the open loop of a hybrid open-loop/closed-loop model is only compared to the properties associated with open-loop parent models.

— A closed-loop model or the closed loop of a hybrid open-loop/closed-loop model is only compared to the properties associated with closed-loop parent models.

— For models of the open-loop or closed-loop type having dissimilar loops (and therefore different angles of contact) each loop is compared separately to the appropriate (i.e. open-loop or closed-loop) graph of properties associated with the parent models.

B.3.3 Calculations

The manufacturer determines the force necessary to compress the parent model and the modified model to the applicable overall diameter(s) (see ISO 11979-3 for the test method). The mean force value F and the standard deviation σ are determined for the parent model and the modified model for the applicable overall diameters.

The force spread value f in the equations is set equal to 20 % of the mean force value (0,2 F) or to the standard deviation σ provided that σ is lower than (0,2 F).

From this data, the upper force boundaries UFB_p and lower force boundaries LFB_p are calculated using the following equations for the parent model:

$UFB_p = F_p + f_p$ (when $F_p \geqslant 1\,100 \times 10^{-5}$ N)

$UFB_p = F_p + 3f_p - [(F_p - 800 \times 10^{-5}) / 150 \times 10^{-5}]f_p$ (when $800 \times 10^{-5} < F_p < 1\,100 \times 10^{-5}$ N)

$UFB_p = F_p + 3f_p$ (when $F_p \leqslant 800 \times 10^{-5}$ N)

$LFB_p = F_p - 3f_p$ (when $F_p \geqslant 150 \times 10^{-5}$ N)

$LFB_p = F_p - (F_p / 50 \times 10^{-5})f_p$ (when $50 \times 10^{-5} < F_p < 150 \times 10^{-5}$ N)

$LFB_p = F_p - f_p$ (when $F_p \leqslant 50 \times 10^{-5}$ N)

The upper force boundaries UFB_m and lower force boundaries LFB_m are calculated using the following equations for the modified model:

$UFB_m = F_m + f_m$

$LFB_m = F_m - f_m$

B.3.4 Background of the calculations

The compression force values 150×10^{-5} N and 800×10^{-5} N represent the lower and upper boundaries, respectively, containing most of the IOL models that have demonstrated acceptable clinical performance. Since much less is known about the clinical performance of IOL models outside these boundaries, a more conservative approach has been taken with parent models with loop flexibilities outside these boundaries to minimize the difference between the parent and the modified model. The equations above accomplish this in the following manner for the parent models:

— by using $3 f_p$ only with parent models that have mean compression force values between 150×10^{-5} N and 800×10^{-5} N;

— by decreasing the multiplier of f_p used in the LFB_p equation with parent models that have mean compression force values below 150×10^{-5} N in a continuous manner until it equals 1 at a mean compression force value of 50×10^{-5} N;

— by using f_p with parent models that have mean compression force values below 50×10^{-5} N;

— by decreasing the multiplier of f_p used in the UFB_p equation with parent models that have mean compression force values above 800×10^{-5} N in a continuous manner until it equals 1 at a mean compression force value of 1100×10^{-5} N;

— by using f_p with parent models that have mean compression force values above 1100×10^{-5} N.

B.3.5 Analysis of a single parent comparison

The manufacturer determines the angle of contact AC associated with the loops of the parent model and the modified model when the lenses are compressed to the required overall diameter(s), see ISO 11979-3. The UFB and the LFB divided by the mean AC at the compressed overall diameter(s) determine the range of force values per degree of AC associated with the parent lens and the modified lens at the compressed diameter(s).

For the modified lens to be considered a Level A modification of the parent model, the following criteria apply.

— The mean AC_m associated with the loops of the modified model at the applicable compressed overall diameter(s) is within $\pm$ 40 % of the mean AC_p associated with the loops on the parent model at each of the compressed overall diameters.

— Some part of the range defined by the UFB_m/AC_m and the LFB_m/AC_m for the modified lens overlaps the range defined by the UFB_p/AC_p and the LFB_p/AC_p for the parent model at each of the compressed overall diameters, both initially and after decay.

Example 1 and Example 2 in B.4 illustrate hypothetical results using this method of analysis to demonstrate that a modified lens is a Level A modification of the parent lens.

B.3.6 Analysis of a multiple parent comparison

The manufacturer determines the angle of contact AC associated with the loops of the parent models and the modified model when the lenses are compressed to the required overall diameter(s), see ISO 11979-3 for method.

Then for each parent model, the manufacturer graphs the force values as a function of loop AC for each overall diameter and condition.

For hybrid open-loop/closed-loop parent models the properties are separated into their open-loop and their closed-loop components and the data is added to the corresponding graph.

For the modified lens to be considered a Level A modification of the parent models, the following applies:

— Part of the force range for the modified model falls within the boundary ranges defined by the force characteristics of any two of the manufacturer's parent models that are separated by not more than 30° of AC for the loop type in question. It is not necessary that the same two parent models be used for the comparisons under all of the test conditions.

Example 3 in B.4 illustrates hypothetical results using this method of analysis to demonstrate that a modified lens is a Level A modification of the multiple parent lens models.

B.4 Examples

B.4.1 Example 1: Single parent comparison (IOLs with symmetrical loops)

Example 1 discusses the testing necessary to demonstrate the Level A relationship between two open-loop models with symmetrical loops. The manufacturer, in this example, has designed a new model (Model 5) by modifying a parent IOL model (Model 2), with modified C haptics and an overall diameter of 12 mm, by increasing the overall diameter from 12,0 mm to 14,0 mm and by modifying the shape of the loop to a different form of modified C-loop. To determine if Model 5 is a Level A modification of Model 2, the manufacturer has evaluated the mechanical characteristics of the new model.

The manufacturer has taken a minimum of 10 samples of each of the models, and has determined the compression force necessary to compress each model to an overall diameter of 10 mm. The mean force values F, and the standard deviations σ were determined. From these data the upper force boundaries UFB and lower force boundaries LFB were calculated according to the equations and procedure in B.3, in which the force spread values f were set equal to the standard deviations σ.

The AC associated with each loop when the lens was compressed to 10 mm was measured and the mean value was determined. Next, the UFB and LFB were divided by the mean AC. These values determine the range of force values per degree of AC associated with a lens when compressed to 10 mm overall diameter.

The procedures described above were repeated for an overall compression diameter of 11 mm and for 10 mm and 11 mm after decay. Table B.1 and B.2 show the data associated with the two hypothetical models.

Table B.1 — Mechanical data for Model 2

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	300×10^{-5} N	180×10^{-5} N	130×10^{-5} N	80×10^{-5} N
σ	45×10^{-5} N	20×10^{-5} N	20×10^{-5} N	12×10^{-5} N
UFB	435×10^{-5} N	240×10^{-5} N	190×10^{-5} N	116×10^{-5} N
LFB	165×10^{-5} N	120×10^{-5} N	78×10^{-5} N [a]	61×10^{-5} N [a]
AC	60°	42°	62°	44°
UFB/AC	7,3	5,7	3,1	2,6
LFB/AC	2,8	2,9	1,3	1,4

[a] $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p/50 \times 10^{-5})\ \sigma_p$ was used.

Table B.2 — Mechanical data for Model 5 (modification of Model 2)

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	450×10^{-5} N	250×10^{-5} N	220×10^{-5} N	120×10^{-5} N
σ	70×10^{-5} N	55×10^{-5} N	30×10^{-5} N	20×10^{-5} N
UFB	520×10^{-5} N	300×10^{-5} N [a]	250×10^{-5} N	140×10^{-5} N
LFB	380×10^{-5} N	200×10^{-5} N [a]	190×10^{-5} N	100×10^{-5} N
AC	70°	52°	74°	55°
UFB/AC	7,5	5,8	3,4	2,6
LFB/AC	5,4	3,8	2,6	1,8

[a] $\sigma > 0{,}2\ F$, therefore f was set equal to $0{,}2\ F$.

Based on these data, the proposed Model 5 was compared with parent Model 2. The following comparisons form the elements necessary to conclude that Model 5 is a Level A modification of Model 2:

— The mean AC_m for Model 5, 70° (10 mm) and 52° (11 mm), is within 40 % of the mean AC_p for Model 2, i.e. 60° (10 mm) and 42° (11 mm).

— The LFB/AC_m to UFB/AC_m range for Model 5 overlaps the range defined by the UFB/AC_p and the LFB/AC_p for Model 2 at all four test conditions: 10 mm and 11 mm compressed overall diameters and 10 mm and 11 mm compressed overall diameters after decay.

Therefore Model 5 does not need to undergo a clinical investigation, provided it is otherwise in compliance with all relevant parts of ISO 11979.

If Model 2 was undergoing a clinical investigation, this analysis could have been used to determine that Model 5 was a Level A modification of Model 2 and could therefore be added to its clinical investigation.

NOTE The same testing is performed to demonstrate the Level A relationship between two closed-loop models with symmetrical loops.

B.4.2 Example 2: Single parent comparison for IOLs with asymmetric loops

Example 2 discusses the testing necessary to demonstrate the Level A relationship between two open-looped models with asymmetrical loops, two closed-loop models with asymmetrical loops, or two hybrid open-loop/closed-loop models.

The manufacturer, in this example, has modified a hybrid closed-loop/open-loop parent model, Model 6, by changing the configuration of both the open-loop and the closed-loop, and reducing the overall diameter of the model from 14 mm to 12,5 mm. The new model is designated Model 7. In cases like this, in which a model possesses asymmetrical loops, the mechanical characteristics have to be determined for each loop separately. The characteristics of the closed loops of Model 6 and 7 are first compared, and then the characteristics of the open loops of Models 6 and 7 are compared.

Table B.3 and Table B.4 provide the mechanical characteristics of the closed loops on Models 6 and 7, respectively.

Table B.3 — Mechanical data for the closed loop on Model 6

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	900×10^{-5} N	750×10^{-5} N	450×10^{-5} N	375×10^{-5} N
σ	110×10^{-5} N	100×10^{-5} N	80×10^{-5} N	60×10^{-5} N
UFB	1157×10^{-5} N [a]	1050×10^{-5} N	690×10^{-5} N	555×10^{-5} N
LFB	570×10^{-5} N	450×10^{-5} N	210×10^{-5} N	195×10^{-5} N
AC	65°	64°	66°	65°
UFB/AC	18	16	11	8,5
LFB/AC	8,8	7	3,2	3
[a] $F_p > 800 \times 10^{-5}$ N, therefore $UFB_p = F_p + 3\ \sigma_p - [(F_p - 800\ \times 10^{-5}) / 150 \times 10^{-5}]\ \sigma_p$ was used.				

Table B.4 — Mechanical data for the closed loop on Model 7

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	700×10^{-5} N	600×10^{-5} N	350×10^{-5} N	250×10^{-5} N
σ	100×10^{-5} N	70×10^{-5} N	50×10^{-5} N	25×10^{-5} N
UFB	800×10^{-5} N	670×10^{-5} N	400×10^{-5} N	275×10^{-5} N
LFB	600×10^{-5} N	530×10^{-5} N	300×10^{-5} N	225×10^{-5} N
AC	50°	48°	51°	49°
UFB/AC	16	14	7,8	5,6
LFB/AC	12	11	5,9	4,6

Table B.5 and Table B.6 below provide the mechanical characteristics of the open-loops on Models 6 and 7, respectively.

Table B.5 — Test data for the open loop on Model 6

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	900×10^{-5} N	750×10^{-5} N	450×10^{-5} N	375×10^{-5} N
σ	110×10^{-5} N	100×10^{-5} N	80×10^{-5} N	60×10^{-5} N
UFB	1157×10^{-5} N [a]	1050×10^{-5} N	690×10^{-5} N	555×10^{-5} N
LFB	570×10^{-5} N	450×10^{-5} N	210×10^{-5} N	195×10^{-5} N
AC	40°	35°	41°	36°
UFB/AC	29	30	17	15
LFB/AC	14	13	5,1	5,4
[a] $F_p > 800 \times 10^{-5}$ N, therefore $UFB_p = F_p + 3\ \sigma_p - [(F_p - 800 \times 10^{-5})/150 \times 10^{-5}]\ \sigma_p$ was used.				

Table B.6 — Test data for the open loop on Model 7

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	700×10^{-5} N	600×10^{-5} N	350×10^{-5} N	250×10^{-5} N
σ	100×10^{-5} N	70×10^{-5} N	50×10^{-5} N	25×10^{-5} N
UFB	800×10^{-5} N	670×10^{-5} N	400×10^{-5} N	275×10^{-5} N
LFB	600×10^{-5} N	530×10^{-5} N	300×10^{-5} N	225×10^{-5} N
AC	46°	41°	47°	42°
UFB/AC	17	16	8,5	6,6
LFB/AC	13	13	6,4	5,4

It is noted that for Tables B.3 to B.6, the force value necessary to compress the open-loop and closed-loop of each model are, of course, identical (Tables B.3 and B.5; Tables B.4 and B.6). This is because for the measurement both the haptics of the IOL are compressed between anvils and the force measured is exerted by both haptics.

The force boundaries for the parent model in Tables B.3 and B.5 were derived using 3f, except in the cases where $F > 800 \times 10^{-5}$ N. The force boundaries for the modified model in Tables B.4 and B.6 were derived using force spread value f. For the parent model and the modified model the force spread value f was set equal to the standard deviation σ.

Based upon the following analysis of the data, it can be concluded that new Model 7 is a Level A modification of parent Model 6:

— The mean AC_m for new Model 7, 50° (10 mm) and 48° (11 mm) is within 40 % of the mean AC_p for parent Model 6, 65°(10 mm) and 64° (11 mm) for the closed loops.

— The mean AC_m for new Model 7, 46° (10 mm) and 41° (11 mm) is within 40 % of the mean AC_p for parent Model 6, 40° (10 mm) and 35° (11 mm) for the open loops.

— The LFB/AC_m to UFB/AC_m range for Model 7 overlaps the range defined by the UFB/AC_p and the LFB/AC_p for Model 6 at all of the test conditions: 10 mm and 11 mm compressed overall diameters, and 10 mm and 11 mm compressed overall diameters after decay, for both the open-loop and closed-loop comparisons.

B.4.3 Example 3: Multiple parents

The manufacturer has four open-loop posterior chamber parent models, which are indicated for both ciliary sulcus and capsular bag fixation:

— Model 1: C-loop (14,0 mm overall diameter);

— Model 2: modified C-loop (12,0 mm overall diameter);

— Model 3: J-loop (13,5 mm overall diameter);

— Model 4: modified J-loop (13,0 mm overall diameter).

All relevant models of the manufacturer's lens product range are considered. Tables B.7 to B.10 list the mechanical data associated with the four hypothetical models. The manufacturer constructs graphs of the compression properties associated with these four hypothetical parent models (see Figures B.1 to B.4). The force spread value is set equal to the standard deviation σ for each model.

The data associated with the four parent models at 10 mm constrained overall diameter is listed in Table B.7. Figure B.1 shows the bar chart derived from those data.

Table B.7 — Mechanical data for Models 1 to 4 at 10 mm

Parameter	Model			
	1	2	3	4
F	90×10^{-5} N	300×10^{-5} N	500×10^{-5} N	250×10^{-5} N
σ	25×10^{-5} N	45×10^{-5} N	75×10^{-5} N	40×10^{-5} N
UFB	144×10^{-5} N [a]	435×10^{-5} N	725×10^{-5} N	370×10^{-5} N
LFB	58×10^{-5} N [a, b]	165×10^{-5} N	275×10^{-5} N	130×10^{-5} N
AC	50°	60°	20°	22°
UFB/AC	2,9	7,3	36	17
LFB/AC	1,2	2,8	14	5,9

[a] $\sigma > 0{,}2\ F$, therefore f was restricted to $0{,}2\ F$.

[b] $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p/50 \times 10^{-5})\ \sigma_p$ was used.

Table B.8 lists the data associated with the four parent models at 11 mm constrained overall diameter and Figure B.2 shows the bar chart derived from those data.

Table B.8 — Mechanical data for Models 1 to 4 at 11 mm

Parameter	Model			
	1	2	3	4
F	80×10^{-5} N	180×10^{-5} N	450×10^{-5} N	200×10^{-5} N
σ	16×10^{-5} N	20×10^{-5} N	50×10^{-5} N	25×10^{-5} N
UFB	128×10^{-5} N	240×10^{-5} N	600×10^{-5} N	275×10^{-5} N
LFB	54×10^{-5} N [a]	120×10^{-5} N	300×10^{-5} N	125×10^{-5} N
AC	40°	42°	23°	22°
UFB/AC	3,2	5,7	26	12
LFB/AC	1,4	2,9	13	5,7

[a] $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p/50 \times 10^{-5})\ \sigma_p$ was used.

Table B.9 lists the data associated with the four parent models at 10 mm constrained overall diameter after decay and Figure B.3 shows the bar chart derived from those data.

Table B.9 — Mechanical data for Models 1 to 4 at 10 mm after decay

Parameter	Model			
	1	2	3	4
F	50×10^{-5} N	130×10^{-5} N	240×10^{-5} N	120×10^{-5} N
σ	12×10^{-5} N	20×10^{-5} N	30×10^{-5} N	20×10^{-5} N
UFB	80×10^{-5} N [a]	190×10^{-5} N	330×10^{-5} N	180×10^{-5} N
LFB	40×10^{-5} N [a, b]	78×10^{-5} N [b]	150×10^{-5} N	72×10^{-5} N [b]
AC	52°	62°	22°	24°
UFB/AC	1,5	3,1	15	7,5
LFB/AC	0,8	1,3	6,8	3,0

[a] $\sigma > 0{,}2\ F$, therefore σ was restricted to $0{,}2\ F$.

[b] $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p / 50 \times 10^{-5})\sigma_p$ was used.

Table B.10 lists the data associated with the four parent models at 11 mm constrained overall diameter after decay, and Figure B.4 shows the bar chart derived from those data.

Table B.10 — Mechanical data for Models 1 to 4 at 11 mm after decay

Parameter	Model			
	1	2	3	4
F	45×10^{-5} N	80×10^{-5} N	200×10^{-5} N	90×10^{-5} N
σ	10×10^{-5} N	12×10^{-5} N	25×10^{-5} N	15×10^{-5} N
UFB	72×10^{-5} N [a]	116×10^{-5} N	275×10^{-5} N	135×10^{-5} N
LFB	37×10^{-5} N [a, b]	61×10^{-5} N [c]	125×10^{-5} N	63×10^{-5} N [c]
AC	42°	44°	25°	24°
UFB/AC	1,7	2,6	11	5,6
LFB/AC	0,9	1,4	5	2,6

[a] $\sigma > 0{,}2\ F$, therefore σ was restricted to $0{,}2\ F$.

[b] $F < 50 \times 10^{-5}$ N, therefore $LFB = F_p - \sigma_p$ was used.

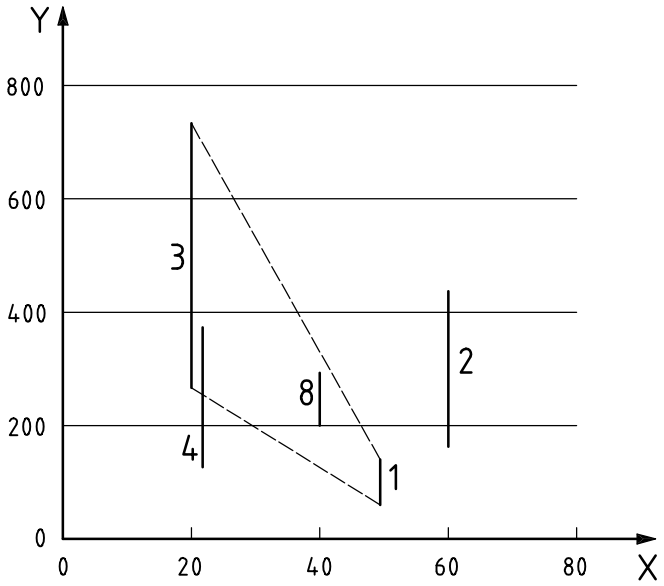
[c] $F < 150 \times 10^{-5}$ N, therefore $LFB = F_p - (F_p/50 \times 10^{-5})\ \sigma_p$ was used.

In this example, the manufacturer has modified one of the open-loop parent models and designated it Model 8. The modified model differs from its parent model in loop configuration and overall diameter. To determine if Model 8 is a Level A modification, its compression properties were determined and found as given in Table B.11. As always, one time the force spread value f (here set equal to the standard deviation σ) from the mean was used to define the force boundaries for this modified model.

Table B.11 — Mechanical data for new Model 8

Parameter	Compressed diameter			
	10 mm	11 mm	10 mm after decay	11 mm after decay
F	250×10^{-5} N	220×10^{-5} N	120×10^{-5} N	100×10^{-5} N
σ	40×10^{-5} N	30×10^{-5} N	20×10^{-5} N	15×10^{-5} N
UFB	290×10^{-5} N	250×10^{-5} N	140×10^{-5} N	115×10^{-5} N
LFB	210×10^{-5} N	190×10^{-5} N	100×10^{-5} N	85×10^{-5} N
AC	40°	32°	42°	34°

The data in Table B.11 for Model 8 are incorporated in Figures B.1 to B.4, from which it can be concluded that Model 8 is a Level A modification of the manufacturer's open-loop parent models and therefore does not have to undergo a clinical evaluation. This conclusion is based on the following elements. The force ranges for Model 8 overlap the boundary ranges associated with two parent models which are no more than 30° of AC different from each other under all the test conditions (at 10 mm and 11 mm, and at 10 mm and 11 mm after decay).



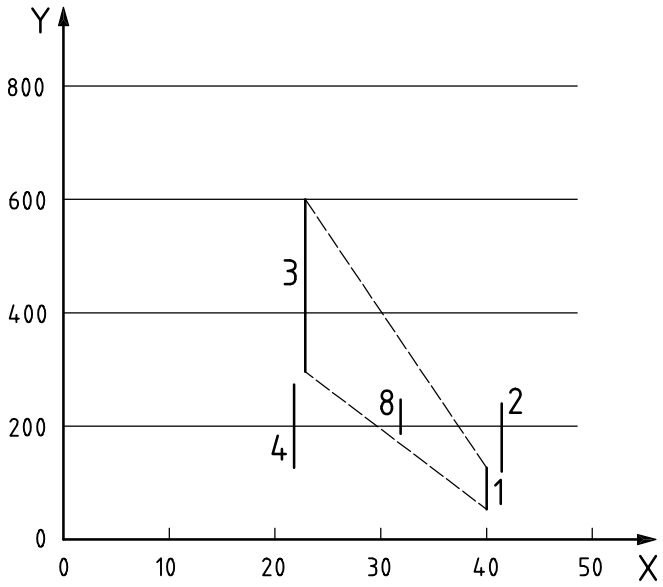
Key

X Angle of contact, degrees

Y Force, 10^{-5} N

1 Model 1
2 Model 2
3 Model 3
4 Model 4
8 Model 8

Figure B.1 — F/AC range for Models 1 to 4 at 10 mm of Example 3



Key

X Angle of contact, degrees

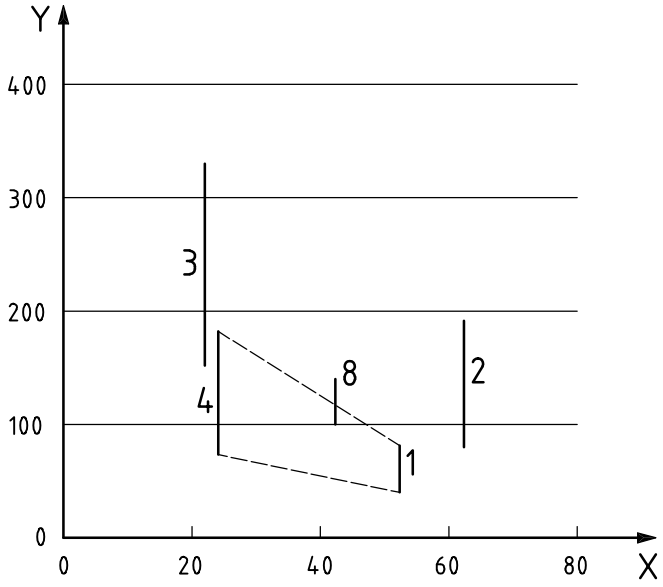
Y Force, 10^{-5} N

1 Model 1 4 Model 4

2 Model 2 8 Model 8

3 Model 3

Figure B.2 — *FlAC* range for Models 1 to 4 at 11 mm of Example 3



Key

X Angle of contact, degrees

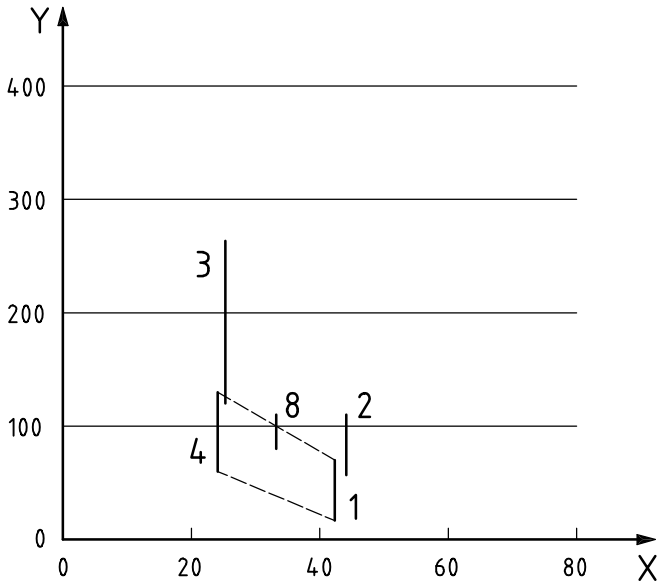
Y Force, 10^{-5} N

1 Model 1 4 Model 4

2 Model 2 8 Model 8

3 Model 3

Figure B.3 — *FlAC* range for Models 1 to 4 at 10 mm, after decay of Example 3



Key

X Angle of contact, degrees

Y Force, 10^{-5} N

1 Model 1
2 Model 2
3 Model 3
4 Model 4
8 Model 8

Figure B.4 — *FlAC* range for Models 1 to 4 at 11 mm after decay of Example 3

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