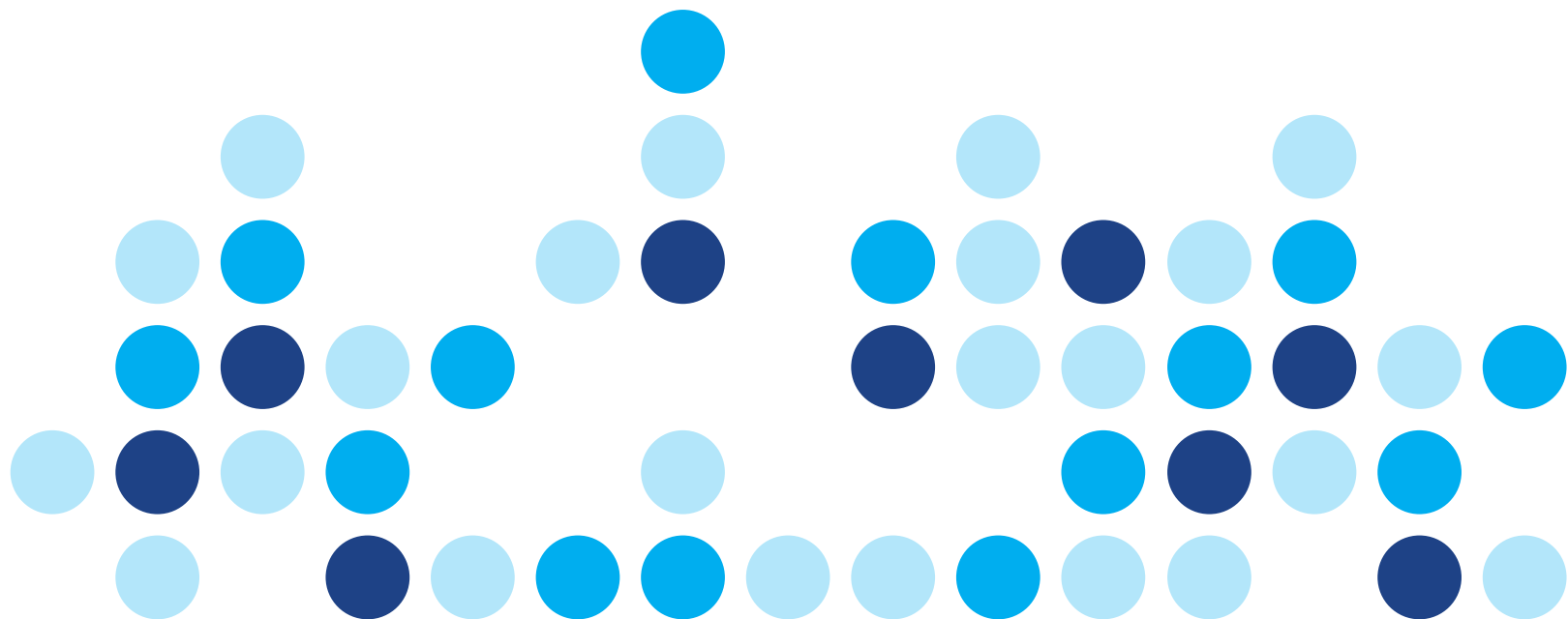


IOL Lens Constant Optimization

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Key Takeaways:

- Utilizing accurate Lens Constants for specific IOL models and employing an appropriate new generation IOL formula can improve the refractive outcome of a cataract procedure
- Manufacturer recommended lens constants, either theoretically calculated or refined with initial clinical data, or independent websites provided clinical lens constants, such as those from ULIB, are starting points for individual surgeons when working with a new IOL model (Figure 1)
- Personalization of lens constants is a critically important step for individual surgeons to further improve and optimize refractive outcomes and patient satisfaction. A simple suggested protocol is provided in Fig 2
- Resources and tools are available to support individual surgeons on lens constant personalization

Introduction:

With the evolution of intraocular lens (IOL) technology, cataract surgery has advanced from the replacement of a cloudy crystalline lens with a standard-power IOL for simply restoring the patient's basic refractive state, to an advanced refractive-cataract surgical procedure.¹ These changes have been supplemented with advanced methods for IOL power calculation, developments in cataract diagnostic instrumentation, cataract surgical equipment and surgical techniques. Refractive cataract surgery is now able to provide patients the opportunity to regain excellent vision and to be less dependent on spectacles. With the use of premium IOLs growing worldwide, including toric, bifocal, extended depth of focus and accommodative IOLs, patients' demand for spectacle independence continues to increase.

Currently, most cataract surgeons can achieve refractive outcomes within ± 0.50 D of the predicted postoperative spherical equivalent (SE) in 70-75% of cases. Reportedly, the top 1% of surgeons can attain this level of accuracy in 90% of cases.² IOL power calculation accuracy is essential for the success of reaching refractive targets. Achieving accuracy depends on 1) the accuracy of the biometric data, 2) the accuracy of manufacturer's IOL power quality control, and 3) the accuracy of the IOL power formulas used to obtain the proper lens power.³ Among these factors, the selection of the most appropriate IOL power formula including the use of an accurate lens constant are recognized being critical for delivering optimized refractive outcomes. However, the process of obtaining an accurate optimized lens constant is not easily understood.

This white paper aims to 1) describe the different lens constants that are used for IOL power formulas; 2) explain the role of initial lens constants provided by the manufacturer for new IOL models; 3) emphasize the importance of lens constant optimization and personalization; 4) provide information on the resources or tools to help surgeons obtain more accurate personalized lens constants.

Lens Constants in IOL Power Calculation Formulas

Lens constants are specific adjustment factors that improve the precision of the IOL power calculation by including the effective lens position (ELP) prediction, with the goal of improving the post-operative refractive outcome.

With the advanced optical biometry technology for axial length measurement, the ultimate accuracy of preoperative IOL power calculation relies heavily on the precise prediction of the ELP. The primary source of IOL power calculation prediction error is the inaccurate estimation of postoperative ELP.⁴

ELP describes the effective IOL position in the eye and is defined as the distance from corneal vertex to the principal plane of the IOL (Figure 2). The term ELP was recommended to the FDA in 1995 to avoid the confusion with the anatomical anterior chamber depth (ACD) and the pseudophakic ACD, which was previously used to describe the IOL position.⁵

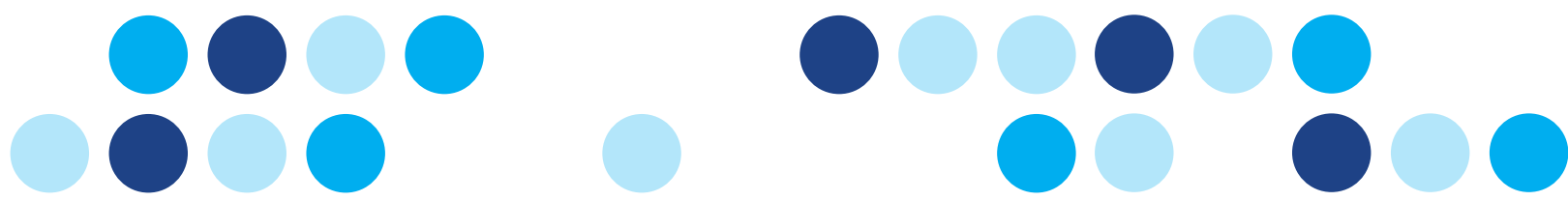


Table 1: Lens Constants in commonly used IOL power formulas

IOL Formula	Principle	Preoperative Measurable Variables	Lens Constant
Holladay I	Vergence	AL, K	Surgeon Factor (SF)
SRK/T	Vergence	AL, K	A-constant
Hoffer Q	Vergence	AL, K	pACD
Haigis	Vergence	AL, K, ACD	a0, a1, a2
Holladay II	Vergence	AL, K, HWTW, Refraction (previous), ACD, LT, Age	ACD#
Barrett Universal II	Vergence	AL, K, ACD, WTW*, LT*	Lens factor (LF)
Olson	Ray Tracing	AL, K, ACD, LT	C-constant or Olsen ACD#
Hill-RBF	Artificial Intelligence (AI)	AL, K, ACD, WTW*, LT*	A-constant (for optical biometry)
ORA SYSTEM®	Modified refractive vergence/AI	ASE, AL, K, WTW,	ORA SYSTEM® specific Surgeon Factor

AL: axial Length;

K: central corneal power;

pACD: personalized anterior chamber depth

ACD: pre-op anterior chamber depth (phakic),

HWTW: horizontal limbal white to white

LT: lens thickness (crystalline lens)

ORA: Optiwave® Refractive Analysis

ASE: aphakic spherical equivalent

*optional variables

not measured ACD

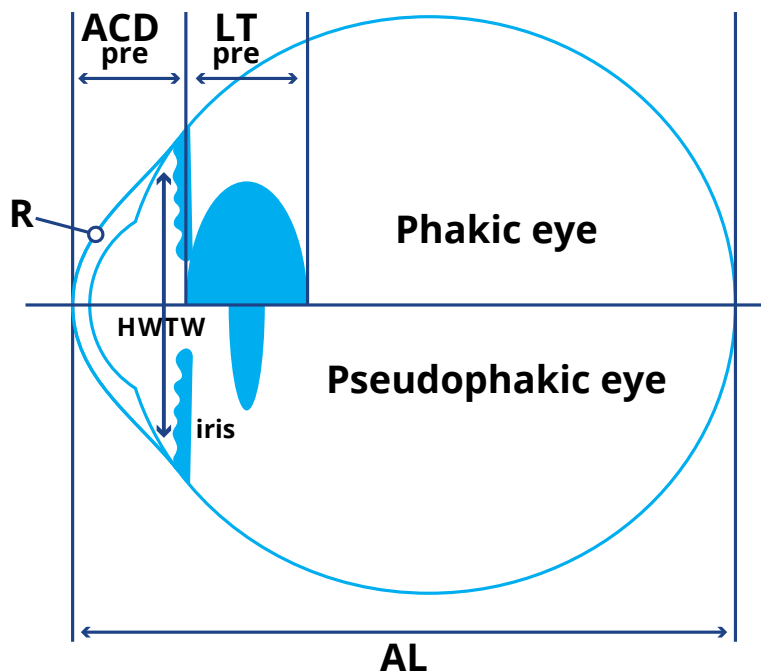


Figure 3: Measurements used in the prediction of postoperative ELP

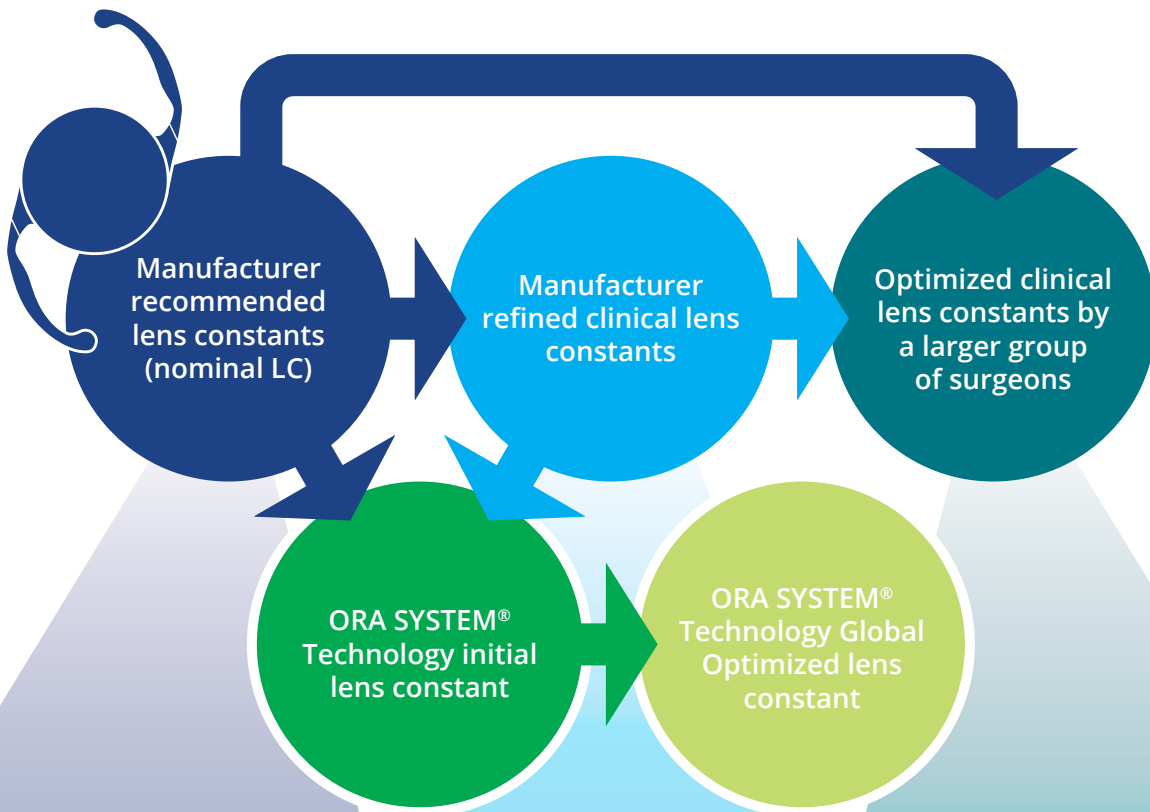
AL= Axial Length; ACD_{pre} (preoperative ACD)= anatomical anterior chamber depth + central corneal thickness; HWTW= Horizontal limbal white to white; R= Corneal radius of curvature (used to calculate K)

Different IOL power calculation formulas use different algorithms incorporating measured preoperative variables (Figure 3, Table 1) and lens constants to predict the ELP and the IOL power. More detailed information on different lens constants can be found in Appendix A.



Figure 1: Lens Constant (LC) Optimization (Global)

With Preoperative IOL Power Formula

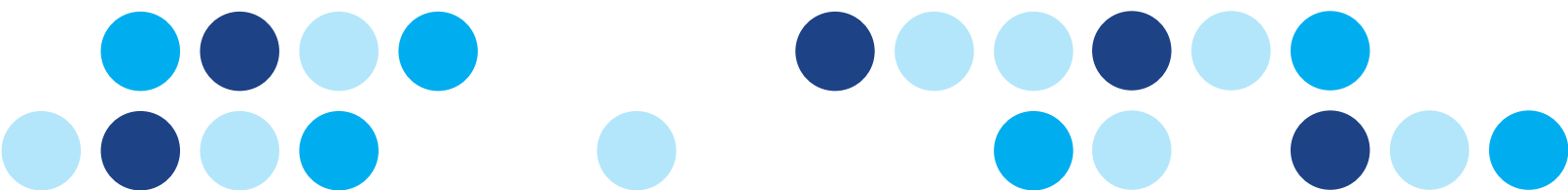


- Each IOL has its own manufacturer recommended LC based on its design and material
- A starting point when there is no manufacturer refined clinical lens LC or other clinical optimized LC.
 - e.g. ReSTOR® IOL 2.5 (SV25T0), Nominal A constant: 119.1

- Provided by the manufacturer utilizing some clinical outcomes data (back-calculation with postoperative MRSE, preoperative biometry measurement, IOL power in specific IOL formula)
- A better starting point compared to the manufacturers' theoretical recommended LC
 - e.g. ReSTOR® IOL 2.5 (SV25T0), refined clinical A –constant: 119.3 (from US clinical trial results of 294 eyes at 14 clinical sites with optical biometer using SRK/T formula)

- Provided by independent websites such as ULIB, IOLCON, which utilize data from a group of contributing surgeons (back-calculation with postoperative MRSE, preoperative biometry measurement, IOL power with specific IOL formula)
- Depending on the number of participating cases, number of surgeons and the range of AL, K, ACD of eyes included, it might be a better starting point than the initial manufacturer recommended lens constants. The more cases and the more surgeons involved, the more accurate the optimized LCs will be
 - e.g. ReSTOR® IOL 2.5 (SV25T0): two A constants for SRK/T formula are listed in ULIB with IOLMASTER*. One is 119.5, which is derived from two surgeons with 70 cases. It is considered to be less accurate than the Alcon clinical refined A-constant

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With Intraoperative ORA SYSTEM® Technology



- Based on the manufacturer recommended lens constants or refined clinical lens constants if present, ORA SYSTEM® Technology software generates an initial lens constant and a set of regression coefficients for the new IOL
 - e.g. ReSTOR® IOL 2.5 (SV25T0): surgeon selects lens model and the algorithm inserts the LC into the formula
- ORA SYSTEM® Technology software generates ORA SYSTEM® Technology global optimized Lens constant and associated regression coefficients with the data entered by participating surgeons
 - With ≥ 100 surgeries (≥ 10 day post-op) per lens
 - ≥ 3 surgeons with ≥ 15 surgeries per surgeon
 - No surgeon with $> 50\%$ of surgeries
- With the increase number of cases from different surgeons, the ORA SYSTEM® Technology global optimized lens constant and regression coefficients are updated quarterly for each IOL model

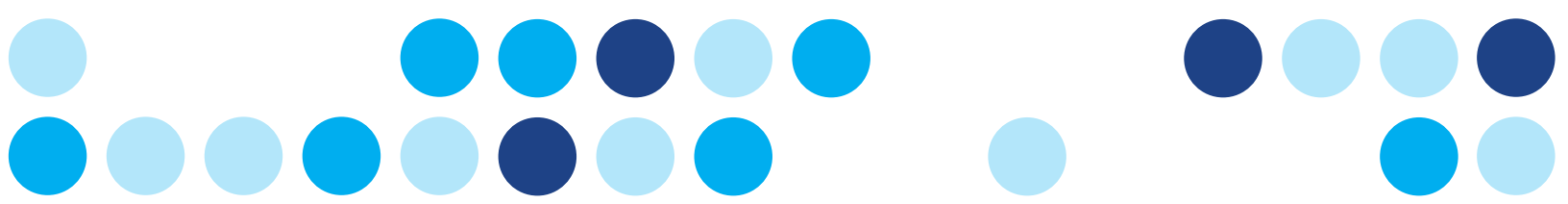


Figure 2: Lens Constant Personalization

With Preoperative IOL Power Formula



Starting LC Selection for an IOL of Interest

- 1) Manufacturer refined clinical LC
- 2) Optimized LC from a group of surgeons
- 3) Nominal Lens Constant present – when no other appropriate clinical LC present

Example: ReSTOR® IOL 2.5 (SV25T0): A-constant 119.3 (refined clinical lens constant from Alcon clinical trial)

- 1) Select an advanced IOL Power Formula

- 2) Convert the known initial LC to the LC used in the selected IOL formula*

Example:

- 1) Barrett Universal II formula
- 2) Convert A-constant 119.3 to LF using ASCRS online Tool, LF= 2.04

Conduct 20-30 cases

- 1) Use same biometer and keratometer to conduct pre-op measurements and select the IOL power using the selected IOL formula
- 2) Use same surgical technics to conduct cataract surgery with IOL implantation and
- 3) Collect post-op manifest refractive outcome at 4-10 weeks postop
- 4) Exclude the cases that have complication or best corrected distance VA is worse than 20/25

Personalized LC determination*

- 1) Back-calculate LC for each case#
- 2) Determine the mean and SD of LC
- 3) Determine the personalized LC for the selected IOL formula

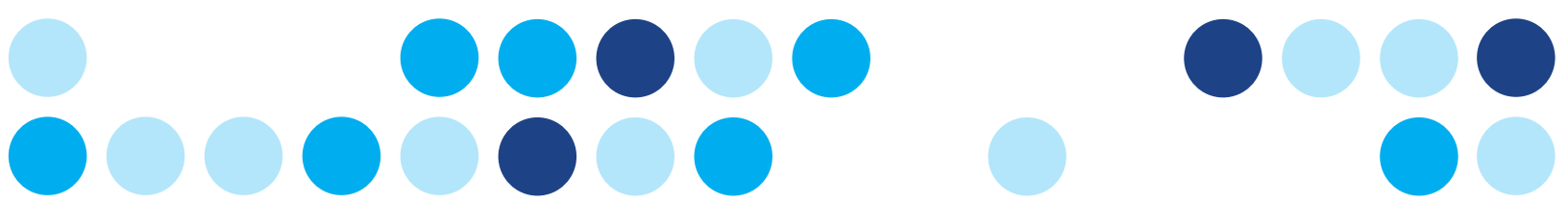
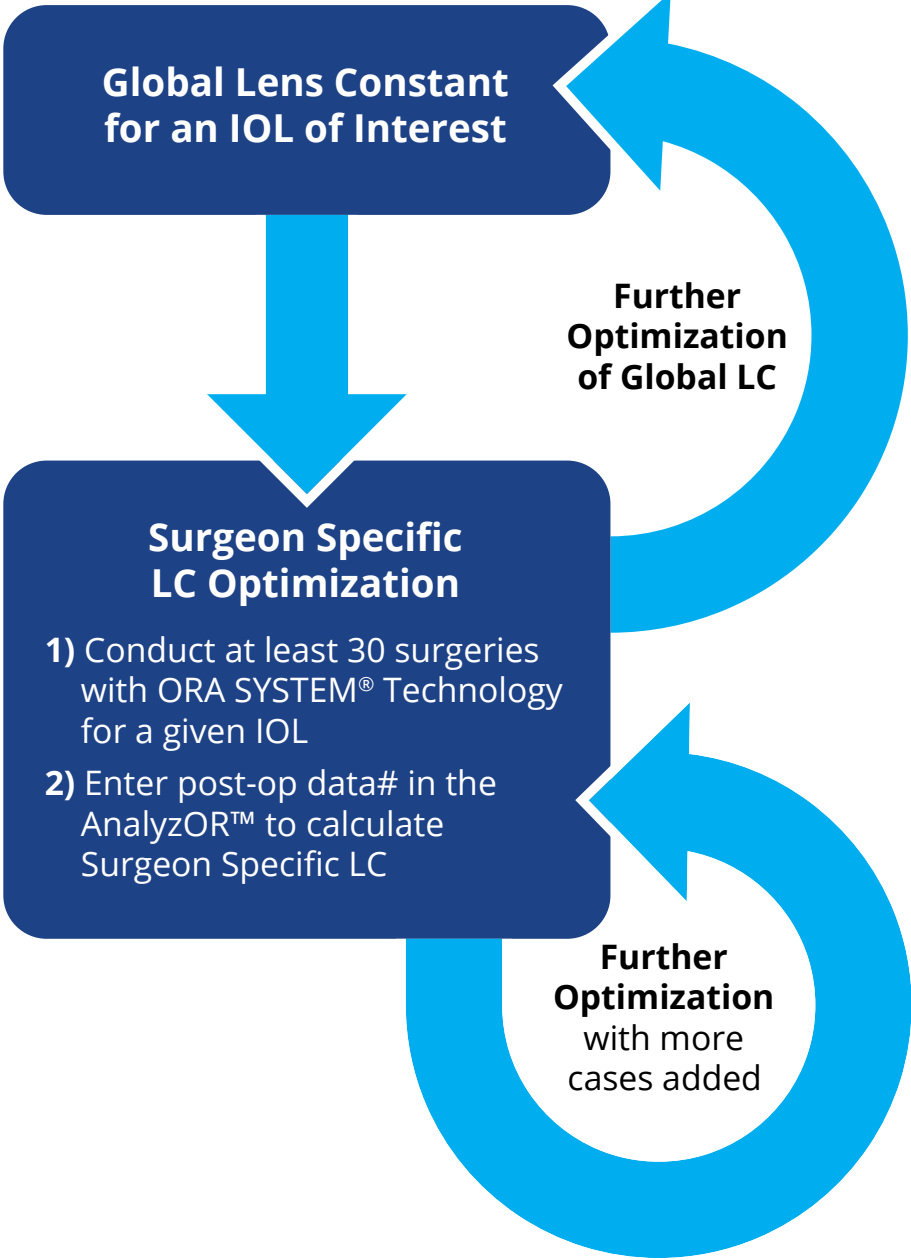
Further Optimization

Add more cases

*Resources are available to complete this step (See text)
Data needed to back-calculate LC (Table 3)



With Intraoperative ORA SYSTEM® Technology



Manufacturer Recommended Lens Constants:

Each IOL model has unique optic and haptic geometry, and distinct optical properties. The IOL power required for a given eye may not be the same with different IOL models based on these unique optical characteristics. Therefore, for every unique IOL model, a theoretical lens constant may be calculated using a population-average model eye by the IOL manufacturer. For example, the A constant used in the SRK/T formula based on whether ultrasonic or optical biometry measurements is used. The theoretically derived Lens Constant is often verified by comparing to a control IOL on the bench. Based on these bench results, the manufacturer may label the IOL model with a nominal, provisional, or recommended lens constant value.⁶ Such nominal and recommended lens constants are used as the starting point in clinical practice.

Lens Constant Optimization

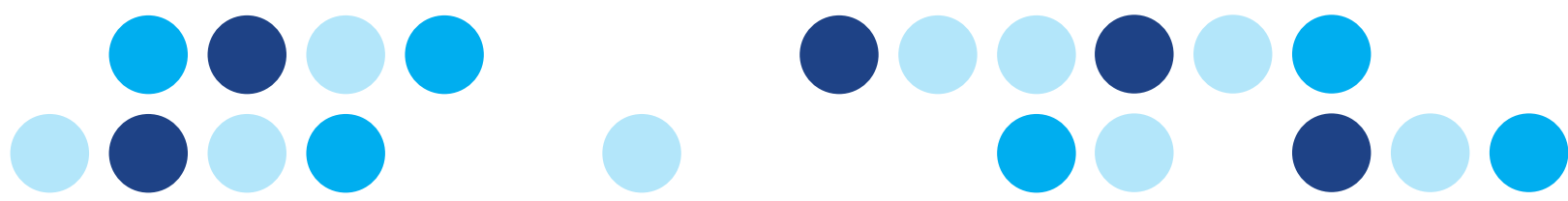
Lens constants are used to improve the prediction accuracy of ELP and the IOL power. The value of the lens constants may be affected by many factors. In addition to the IOL design itself, other factors such as different diagnostic instrumentation or variations in surgical technique may all lead to variation of the calculated ELP. Table 2 lists the potential factors that may contribute to the change of Lens Constants for a particular IOL model in a specific clinical situations.

Table 2: Factors that contributes to the value of Lens Constants

Formula	Different formula uses different lens constants
IOL	<ul style="list-style-type: none">• IOL material• IOL design, including optic and haptic design⁷• IOL type e.g. anterior or posterior chamber, one piece or three piece
Diagnostic instrument	Systemic error from diagnostic equipment e.g. ultrasonic biometry, optical biometry, Keratometry
Surgical Factors (Any surgical steps that may affect final ELP)	<ul style="list-style-type: none">• Capsulorhexis size and centration• Incision size, position• Inadequate OVD removal• Preoperative and postoperative medication• Post op capsular bag contraction and fibrosis (patient/surgical dependent)

1. Clinical lens constant optimization by the IOL manufacturers

Ideally, after determining the theoretical lens constant for a particular IOL, the manufacturer might refine the lens constant based on clinical outcomes. Ideally, this requires approximately 10 to 20 surgeons to perform a specific number of cataract surgeries (≥ 50 each) using the recommended theoretical lens constant and utilizing standard surgical techniques. The refractive outcomes of the surgery, specifically the post-operative manifest refraction spherical equivalent, is used to optimize the lens constant, and to obtain a refined clinical lens constant.⁸ The exact number of cases depends on the variability of the clinical data, but a standard error of the mean of less than 0.1 diopter has been proposed to ensure statistical accuracy.⁵ Included cases should have high quality preoperative measurements, no complications during surgery and post-operative best corrected distance visual acuity (BCDVA) should be 20/40 or better. The refraction should be measured when it is considered stable, 4-10 weeks after the surgery.⁹ Dr. Li Wang from Baylor College of Medicine recommends using a post-operative BCDVA cutoff at 20/25 or better to further improve the accuracy of lens constant optimization. With this information, manufacturers may



update this clinical refined lens constant on the IOL box labeling or in other company documentation.

2. Clinical lens constants provided by independent websites

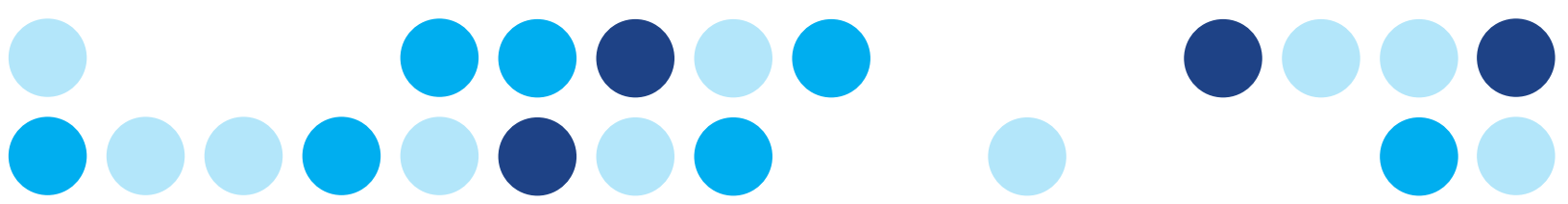
Since 2001, The User Group for Laser Interference Biometry (ULIB), originated and overseen by Dr. Wolfgang Haigis of the University of Würzburg, collected, refined and optimized lens constants for many different types of IOLs using clinical data contributed by participating surgeons.¹⁰ Optimized lens constants based on the different biometers are searchable on the website. Some surgeons use these lens constants as a starting point rather than using the manufacturer recommended ones. Understanding any limitations on how these optimized lens constants presented on ULIB were derived, such as the number of cases, the range of axial lengths, number of surgeons contributing the data, etc. is important. ULIB also provides a service to help surgeons personalize their own lens constants. However, the latest revision of the ULIB website was on July 12, 2016. Another similar website, IOL Con by Steinbeis Vision Research (<https://iolcon.org/>) is providing a service similar to ULIB.

3. Personalized Lens Constant by individual surgeon

The manufacturer recommended lens constants, either the theoretically calculated or the clinically refined lens constant, are the starting point for a personalized lens constant which is specific to each individual lens model and surgeon. Using the lens constants listed on the ULIB or IOL Con as a starting point is another option after careful consideration as stated in the previous section.

Surgeons are highly encouraged to develop their own personalized lens constant for a given IOL using the advanced formula to account for practice-specific variables to further improve refractive outcomes.^{5,11,12} Since each surgeon may use different biometers, keratometers, and surgical techniques, these may result in differences in the ELP in individual patient. Below are the recommended steps to conduct lens constant personalization (Figure 2):

1. It is recommended that each surgeon conducts at least 20-30 uneventful cases with the specific IOL model of interest
2. Select a specific IOL formula and determine the starting point of the associated lens constant. If the known starting lens constant is not the lens constant used in the selected IOL power formula, simple conversion can be done using the conversion formulas (Appendix A), or at the ULIB or IOL Con websites (conversion among A-constant, SF, pACD and Haigis Lens Constants) and at ASCRS Online Tool website (between A-constant and LF with Barrett Universal Formula; suggested starting A constant with Hill-RBF calculator). Some modern biometers can also provide lens constant conversion with their built-in software.
3. Collect stable post-op manifest refraction 4-10 weeks after surgery.
4. The personalized lens constant can then be generated by the back-calculation method using the stable post-operative manifest refraction and the preoperative measurements (e.g. AL, K, ACD, HWTW, LT etc.) with the selected formula.⁵
5. It is recommended to repeat the personalization process when more cases, including more anatomically non-average eyes, are available. The actual number of cases needed by a single surgeon to personalize a lens constant is influenced by targeting a standard error of the mean of less than ± 0.25 D. Cases included should be uncomplicated case as described previously.



Currently, multiple resources are available to help individual surgeons conduct lens constant personalization. Table 3 contains the information individual surgeons need for the lens constant personalization.

Table 3: Data needed for Lens Constant Optimization or Personalization

Require Information	Comment
Post-op Manifest Refraction (Sphere, Cylinder, Axis, 4- 10 weeks)	
Post-operative Uncorrected and Best corrected distance visual acuity (UCDVA, BCDVA)	<ul style="list-style-type: none"> • BCDVA \geq UCDVA • BCDVA \geq 20/25
Pre-op measurements: AL, Ks (Steep/Flat Ks, Steep Axis), ACD, LT, HWTW	Some parameters are options depends on the IOL power formula selected. For ORA SYSTEM [®] , all these are optional
Power of implanted IOL	
IOL power formula used for pre-op power calculation	

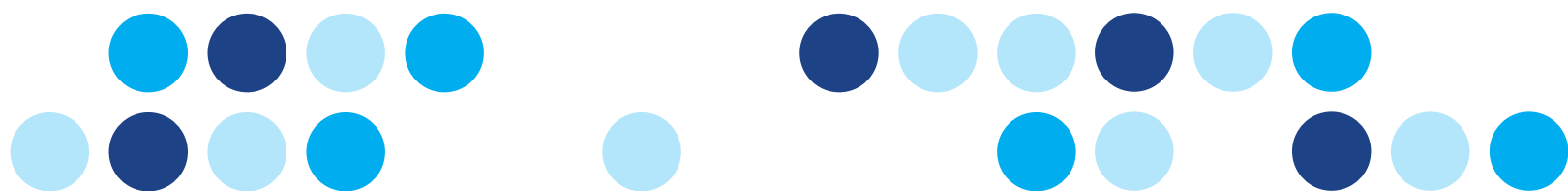
1. Biometer systems such as IOLMASTER 500* or the LenSTAR*, provide a lens constant optimization option in the instrument's software. Surgeons may enter their post-operative refraction data for a certain number of cases. The number of cases required may differ depending on the specific instrument and software. This information can be obtained by contacting the biometer manufacturers.

IOL MASTER 700* currently does not provide lens constant optimization on the device, however, it can be conducted through the use of Zeiss Veracity software.

2. Iolcon.org provides lens constant optimization and lens constant conversion with instruction on the website: <https://iolcon.org/>. ULIB used to provide similar service at <http://ocusoft.de/ulib/index.htm>.
3. Dr. Warren Hill provides free lens constants optimization for the Haigis Formula with instructions on his website: <https://www.doctor-hill.com/iol-main/haigis.htm>.
4. Holladay IOL Consultant Software & Surgical Outcomes Assessment also provide lens constant personalization service with subscription. Information can be found at <http://www.hicsoap.com/>.
5. Users may utilize the cloud-based component of the ORA SYSTEM[®], the AnalyzOR™ Technology, to further optimize IOL specific Surgeon Factor and regression coefficients to deliver improved outcomes. Through input of surgeon's post-op data, surgeons may obtain one of two optimized lens constants, the ORA SYSTEM[®] Global Lens Optimization Constant or the more refined ORA SYSTEM[®] Personalized Surgeon Factor.

ORA SYSTEM[®] Global Lens Optimization Constant:

Similar to the manufacturer recommended clinical lens constants, ORA SYSTEM[®] Global Lens Optimization Constant is generated using a group of surgeons' post-op data, i.e. at least 100 surgeries with post-op data of ≥ 10 days after surgery, from at least 3 surgeons with ≥ 15 cases each, with no one surgeon having more than 50% of all cases. All cases included in the optimization analysis need to have 1) post-op best correct distance visual acuity (BCDVA) better than 20/40; 2) post-op BCDVA \geq post-op UCDVA, and 3) an absolute ORA SYSTEM[®] Technology predicted error less than 2.75 D. Furthermore, for each lens model which meets the criteria above, Regression Coefficients are optimized for different types of surgical groups based on the history of post-keratorefractive status and anatomical features. Unlike the typical manufacturer recommended clinical lens constants, the ORA SYSTEM[®] Global Lens



Optimization Constant and model specific regression coefficients are refined with additional post-op data and updated in AnalyzOR™ Technology every three months.

ORA SYSTEM® Technology Personalized Surgeon Factor:

Similar to personalized lens constants for different IOL formulas, surgeons can generate their own ORA SYSTEM® Technology personalized surgeon factor by entering their own post-op refractive outcomes into AnalyzOR™. For a particular IOL model, at least 30 cases are required. As more data is entered, this ORA SYSTEM® Technology Personalized Surgeon Factor can be continuously refined and updated to further improve post-op refractive outcomes.

Conclusion:

Selecting the appropriate IOL power formula and using accurate lens constants are critical steps in improving postoperative refractive outcomes. Manufacturer recommended lens constants, either calculated theoretically or optimized clinically with the data from a group of surgeons, are a starting point for individual surgeons. Lens Constant personalization is a critically important step for each surgeon to further improve their patients' refractive outcomes. Resources or tools are available to help each individual surgeon conduct lens constant optimizations.

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Appendix A: List of lens constants used in different IOL power formulas

1. A-constant:

The A-constant was an empirically derived lens constant that originated in 1980 with linear regression formulas SRK

SRK	$P = A - 0.9K - 2.5AL$; A = IOL specific A-constant; P = IOL power
SRKII	$P = A1 - 0.9K - 2.5AL$; A1 = A-constant optimized based on AL

and SRKII:

It was also used in the later developed SRK/T formula. The A-constant is the most familiar lens constant known to ophthalmic surgeons and lens manufacturers. Most manufacturers will provide an A-constant for each new IOL model. The A-constant does not directly give information about the position of the IOL. However, it can be converted to an ELP by the regression equation shown below:

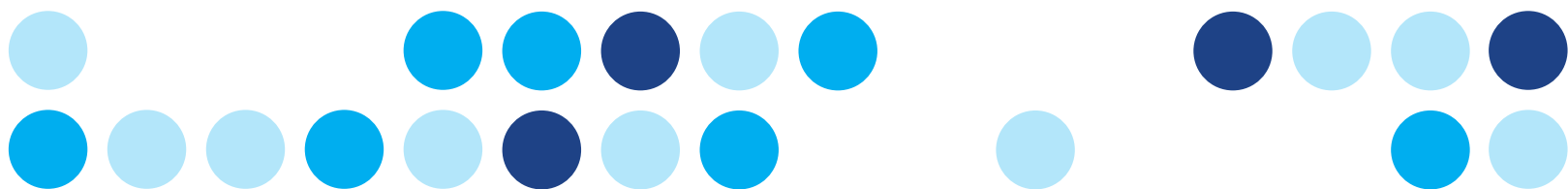
$$ELP = [(A\text{-constant} * 0.5663) - 62.005] / 0.9704^5$$

The SRK/T A-constant (for optical Biometry) is also used for the Hill-RBF IOL power calculator.¹³

2. Surgeon Factor (SF):

The Surgeon Factor (SF) was introduced as the lens constant for the Holladay 1 formula in 1988.¹⁴ It is the distance from the pseudophakic anterior iris plane to the principal plane of the thin IOL. It can be converted to ELP using the following equation:

$$ELP = (\text{Surgeon Factor} + 3.595) / 0.9704^5$$



3. Personalized Anterior Chamber Depth (pACD):

The Hoffer Q formula was introduced in 1993 and used pACD as its lens factor, which is the equivalent to ELP in the thin lens model.

Conversion Formula	
A Constant to pACD or ACD	$pACD = 0.58357 * A\text{-constant} - 63.896^8$
A Constant to SF	$SF = (A\text{-constant} * 0.5663) - 65.600^8$
A Constant to a0	$a0 = 0.62467 * A\text{-constant} - 68.747 - 3.687^{16}$ $a1 = 0.4, a2 = 0.1^{16}$

4. a0, a1 and a2:

The Haigis formula was developed by Wolfgang Haigis in 2004. It uses three lens constants (a0, a1 and a2) in addition to the pre-operative biometry measurement (ACD, AL) to predict ELP.

$$ELP = a0 + (a1 * ACD) + (a2 * AL)$$

ACD = measured phakic anterior chamber depth; AL = axial length

These three lens constants (a0, a1, and a2) are developed based on multiple linear regression analysis. The function of the a0 constant is equivalent to what the A-constant, Surgeon Factor or pACD do for the SRK/T, Holladay I and Hoffer Q formulas, respectively. The a1 is the coefficient of the measured ACD and the a2 is the coefficient of the measured AL. Both a1 and a2 are used to vary the shape of the power prediction curve, changing the power based on the central corneal power, anterior chamber depth, axial length and individual lens geometry. The geometry of many IOL models may not be the same for all powers and it is helpful if a formula is able to take this information into account¹²

5. C-constant (Olsen ACD):

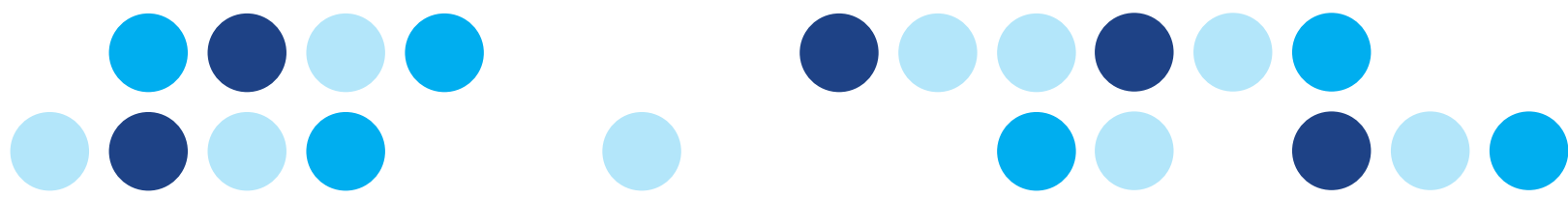
The concept of the C-constant was developed by Dr. Olson as a method to predict ELP from the preoperative dimension and position of the natural crystalline lens.¹⁵ It is defined as a ratio of the distance between the center of IOL (post-op) and the preoperative anterior lens capsule to the preoperative crystalline lens thickness.

$$C = (ACD_{post} + TIOL/2 - ACD_{pre}) / LT_{pre}$$

The prediction of IOL position with the C-constant is used in Olsen's ray tracing-assisted IOL power calculation.

6. Lens Factor (LF):

The Lens Factor, introduced in the Barrett Universal formula¹¹, describes the distance between the iris plane and the second principle plane of the IOL (in the thick lens model). Together with AL and K, the Lens Factor helps to predict the ELP.



7. Lens constant used in ORA SYSTEM® Technology

ORA SYSTEM® Technology that allows surgeons to confirm the preoperative calculated IOL power using an intraoperative wavefront aberrometer at the time of cataract surgery. It uses the IOL specific Surgeon Factor and the specific regression coefficient to deliver a more predictable outcome in ORA SYSTEM®. The regression coefficient is assigned from the linear regression formula (RANSAC) based on the anatomical features, including AL, K, WTW and aphakic spherical equivalent (ASE).

$ELP = \text{ORA SYSTEM}^{\circledR} \text{ Specific Surgeon Factor} + \text{WaveTec Factor}$

The WaveTec Factor is derived from 3rd order polynomial equation based on the measured ASE

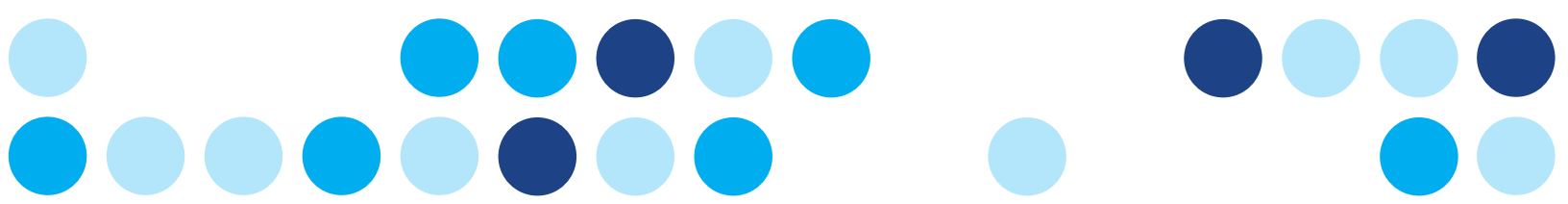
Conversion of lens constants used in different formulas

Simple conversion equations are available to calculate one lens constant to another for a particular IOL model.^{8,15}

Biometer Manufacturers and IOL calculation software developed after 1988 started to program the conversion relationships into the software or hard-wired them into the instruments [8]. The conversion can also be found at the ULIB (<http://ocusoft.de/scripts2/ciolc.php>), IOL Con (<https://iolcon.org/lensesTable.php>) and ASCRS Online Tool Websites. Although ULIB website has not been updated in recent years, the lens constant conversion can still be carried out, and it still contains the information for old IOL models.

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ORA SYSTEM[®] With Verifeye[®]+ Technology

Important Product Information

INTENDED USE: The ORA SYSTEM[®] Technology is designed to be used during ophthalmic surgery. Wavefront data is obtained, analyzed, and presented to the user via a cart mounted LCD touchscreen, within a period that does not impede the surgical procedure

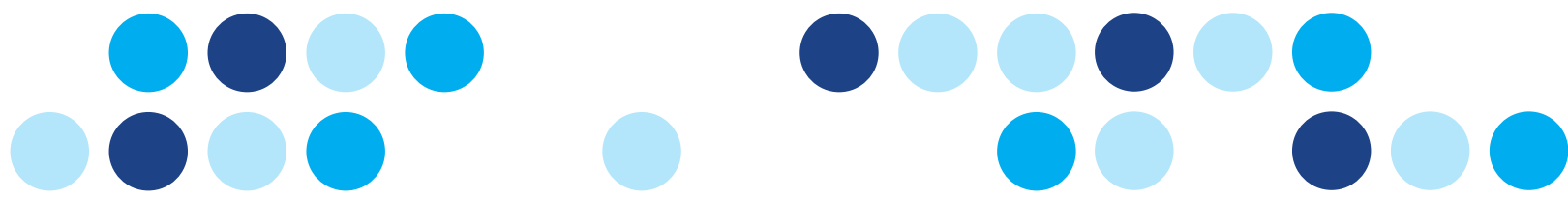
The ORA SYSTEM[®] Technology is intended for use in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements).

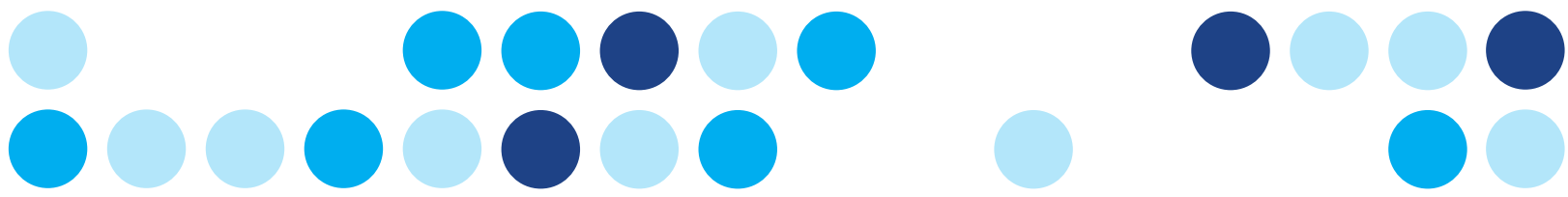
The safety and effectiveness of using the data from the ORA SYSTEM[®] Technology have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.

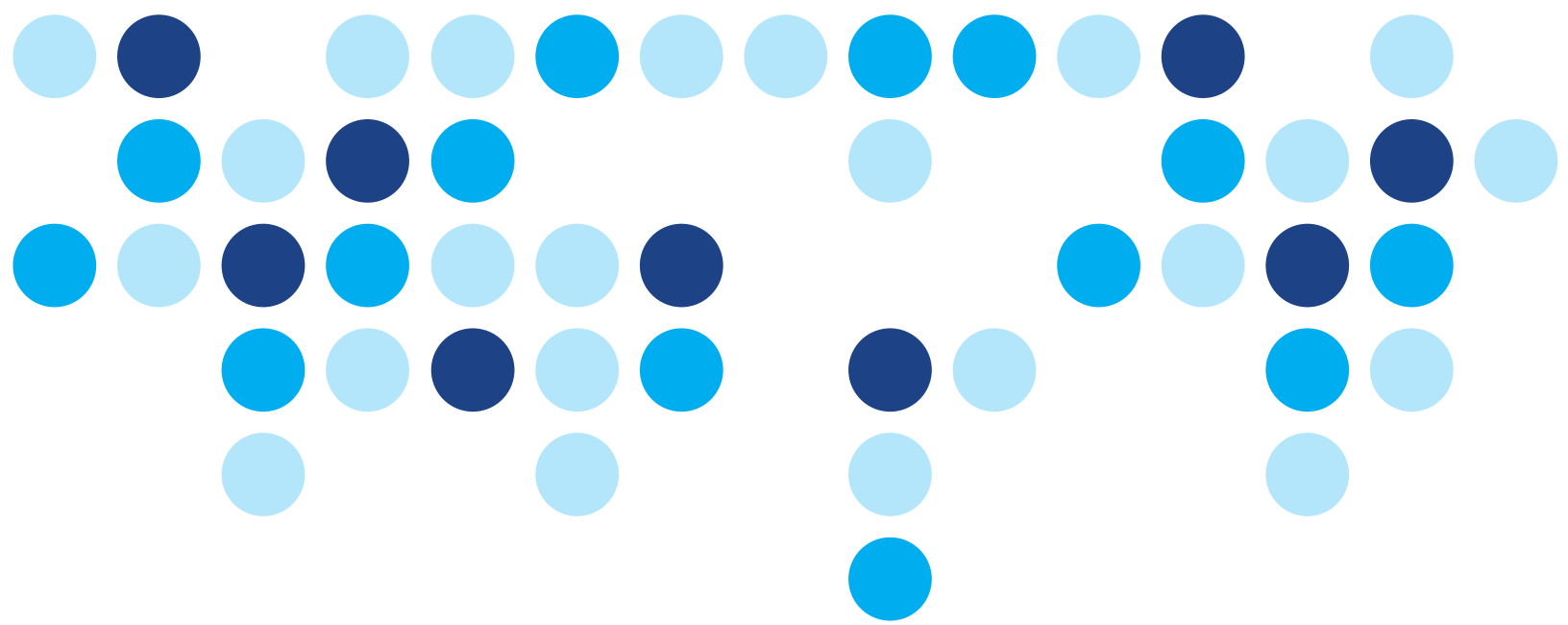
U.S. Federal law restricts this device to sale by or on the order of a physician or ophthalmologist.

CAUTIONS:

- It will be difficult to obtain accurate, consistent, and reliable measurements if any of the following conditions or situations exists:
- Patients having progressive retinal pathology such as diabetic retinopathy, macular degeneration, or any other pathology that the physician deems would interfere with patient fixation.
- Patients having corneal pathology such as Fuchs', EBMD, keratoconus, advanced pterygium impairing the cornea, or any other pathology that the physician deems would interfere with the measurement process.
- Patient's for which the preoperative regimen includes residual viscous substances left on the corneal surface such as lidocaine gel or viscoelastics.
- Visually significant media opacity, such as prominent floaters or asteroid hyalosis, will limit or prohibit measurement process. Image quality indicator will indicate when this is an issue.
- Patients having received retro or peribulbar block, or any other treatment that impairs their ability to visualize the fixation light.
- Utilization of Iris hooks during an ORA SYSTEM[®] Technology image capture will yield inaccurate measurements.







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