

STAARVision Instruction Guide

STAAR Surgical Company - Moran Research and Consulting, Inc.

Introduction

The STAARVision PPOS is a secure, private, HIPAA compliant web service where surgeons can perform IOL calculations as well as maintain and analyze their surgical outcome data. This tool will help you and your patients achieve the maximum possible benefits of the Visian ICL™ technology. The STAARVision web-service provides a centralized utility for physicians to perform complex Lens calculations, track and maintain patient data, generate outcome statistics and reports, order lenses and to facilitate communication with the STAAR Surgical customer Service Department.

Course and Proctoring information

Visian ICL certification is a mandatory requirement for physicians who are interested in implanting the Visian ICL lens.

Physician certification for implantation of the Visian ICL is part of STAAR Surgical Company's ongoing commitment to excellence in ophthalmology. A physician becomes eligible for certification after attending a Certified Visian ICL Training Course. Once eligible, the physician will complete their certification by successfully selecting, implanting and managing five surgical procedures with the support of an on-site STAAR Application Specialist.

Certification courses in the US and the Dominican Republic are part of a two-step certification program. The first step in the process is a one-day course consisting of a 4 hour didactic presentation, lens loading, wet lab, live surgery observation and examination of postoperative patients.

To schedule proctoring with an Applications Specialist, a physician must first contact their local STAAR Representative. The representative will confirm that the physician has five appropriate candidates for Visian ICL surgery and will assist in scheduling an Applications Specialist for proctoring.

The Applications Specialist will contact the physician to arrange the logistics of the certification. Several important factors shall be discussed during this call including:

- Receiving a physician PIN for access to WWW.STAARVISION.COM, the website for Visian ICL calculation and on-line ordering
- Scheduling appropriate surgical and clinical staff trainings
- Scheduling a pre-surgical time to review the surgical steps and the Visian ICL loading procedure
- Reviewing a pre-surgical check-list of the required instrumentation
- Reviewing potential Visian ICL candidates for accurate patient selection

Please keep in mind when requesting a proctoring date that the certification process usually requires three days:

- Day one - train staff and review all necessary surgical steps
- Day two - perform live surgery
- Day three - one-day postoperative patient review and answer any remaining questions

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Additionally, peripheral YAG iridectomies must be performed one to two weeks prior to surgery. Also remember that careful selection of patients is critical to successful certification.

Minimum Computer Requirements

You will need an internet connected computer with at least 256 MB RAM and a "browser" such as Microsoft Internet Explorer 6.0 or better and an email account. The screen resolution should be set at no less than 1024 x 768 for the best user experience.

Calculator registration and setup

In preparation for calculation training and the ordering process with the Applications Specialist, complete the Quick Start Guide at the end of this document. The Quick Start Guide requires information regarding the equipment used to obtain measurements and is necessary for the initial setup of the STAARVISION account. Having this form completed will help expedite the training and ordering process for the first lenses. Close follow up and entry of postoperative data is required for the first 20 cases. This information is tracked via STAARVISION and will be required for continuous lens ordering.



Login Name and Pin Number

Navigate your browser to WWW.STAARVISION.COM to start the registration process. Under the Register/Login section, click on the underlined word "here" to proceed to the registration section.

Click the register button (note- this page is also the login page). As part of the registration process, please read, understand and agree to the "Application Terms of Service". Click the "I agree" selection and then the "SUBMIT" button.

Enter the appropriate information on the form. All entries must be complete before clicking the "SUBMIT" button.

If the entered data is incorrect or incomplete, a warning will be displayed. If all information is correct, but you still receive a warning, please contact STAAR Surgical's customer service department. Throughout this guide, yellow entryboxes or yellow dropdown lists are required fields.

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Set-Up Parameters

Using the values recorded on the “Quick Start Guide”, enter the information on the form. Click “SUBMIT” and then “Continue” to proceed.

My Preferences (change password)

Diagnostic Preferences

Refractive Vertex Distance: 12.50 Instrument Index: * Default: 1.3375

Corneal Power Technique: Please select

ACD Technique: Please select

Axial Length Technique: Please select

* If you are unsure which value to use, select the default: 1.3375

Surgical Technique

Incision Type: Please select

Incision Location: Please select

What brand of A-scan do you use?

Manufacturer:

Model:

What brand of keratometer or topographer do you use?

Manufacturer:

Model:

How do you measure endothelial cell density?

Technique: Please select

Manufacturer:

Model:

How do you measure WTW (horizontal corneal limbus to limbus diameter)?

Technique: Please select

Manufacturer:

Model:

Update

Shipping and Billing Information

Enter the information regarding your billing address. As a default, this will also be your shipping information. Click “Update” to proceed.

My Profile

First name: *

Last name: *

Address: *

Address 2:

ZIP: *

City: *

State: *

Country: * Please select

Email: * test@account.com

Email on file: test@account.com

Tel: *

Fax:

Update Cancel

Multiple Shipping and Billing Addresses

If your shipping information is different than your billing information or you may have multiple locations for a billing or shipping address, then click “Profile” under the Settings section.

Previz® STAAR Vision Account

Instructions: To add a patient, document a visit or perform a calculation click "Patient Records".

Patients	Reports	Settings	Support
Patient Records	Outcome Analysis	Profile	Help / QuickStart
Practice Overview	ICL Indication	Preferences	Technical Support
Lens Orders		Manage Users	ICL Fax Form

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Select the “Manage my shipping addresses” or “Manage my billing addresses”

Select “Add new shipping/billing address”

Enter information in the spaces provided and click “Save”

Manage Shipping Addresses

Short Name	Address	Action
123 Billing Address	Test Account	Edit
Default	123 Billing Address Suite 200 Billing City, CA 90000, United States Tel: 626 303 7902	

[Add new shipping address](#)

My Profile

First name: *

Last name: *

Address: *

Address 2:

ZIP: *

City: *

State: *

Country: *

Email: *

Email on file:

Tel: *

Fax:

* Required: [Manage my shipping addresses](#)

* Required: [Manage my billing addresses](#)

Calculation

Select “Patient Records” under the “Patients” section.

You can review existing patients by searching by last name or by using the drop down list. Clicking Advanced Search will allow for further refined searches by MRN (ID), Name or Date of Birth.

To add a new patient record, click “Add New Patient”. The Demographic Data section will ask for:

- MRN – Medical Record Number. This number is required and is a free-form field. Use a number that references this patient.
- Last Name – Patient Last Name. This value is required and is a free-form field.
- First Name – Patient First Name. This value is required and is a free-form field.
- Gender- Patient Gender. This value is required and is selectable.
- DOB – Patient Date of Birth. This value is required and the format is displayed in the text boxes. (MM-DD-YYYY)
- Click “Save” to save this patient record.
- A confirmation message will appear “Demographic data has been saved”

Patients

[Patient Records](#)

[Practice Overview](#)

[Lens Orders](#)

Patient List [Help](#)

Enter Last Name or ID:

Select Patient from List or Add New:

Demographic Data [Help](#)

MRN:

Last Name:

First Name:

Gender: Male Female

Date of Birth:

Click the “[Click here to continue](#)”.

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Select “OS” or “OD”, the default is “OD”

Enter the Visit Date in the space provided. You can also click the underlined “Visit Date:” to choose a date from a calendar popup.

Click the down arrow on the drop down list under “UCVA” and make an appropriate selection.

Manifest/Cyclo/SCTL – only one of these refractions is required to perform the calculation.

Required fields

Sphere	Valid range: -20 to 20 diopters
Cylinder	Valid range: -10 to 10 diopters
Axis	Valid range: 0 to 180 degrees
BCVA	Best Corrected Visual Acuity: Select from the drop down list.
K Readings	Valid Range: 30 to 55 diopters
K Axis	Valid range: 0 to 180 degrees. The K2 Axis will automatically be populated with a value 90 degrees from the K1 Axis.
ECC	Endothelium Cell Count, Valid range: 500 – 5000
ACD	Anterior Chamber Depth, Valid Range: 2.8 to 7 mm. For purposes of lens power calculation, ACD is measured from Corneal Epithelium to Crystalline lens. For Lens Sizing, the ACD is determined by subtracting the pachymetry from the ACD. This value must be equal or greater than 3.0 mm.
WTW	White to White, Valid Range: 10 to 14 mm
Pach um	Pachymetry in microns, Valid range: 350 to 700
AC Angle	Select a Grade from 0 (closed) to 4 (wide open).

Optional Values

Enter Cycloplegic or SCTL values in combination with or instead of Manifest Refraction.

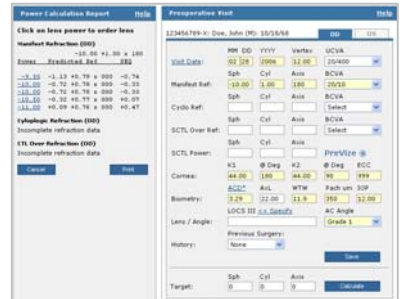
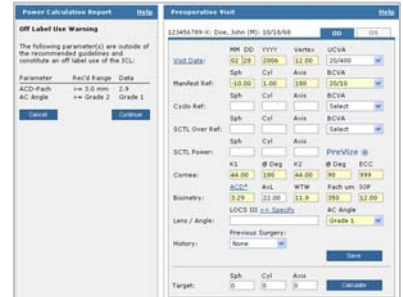
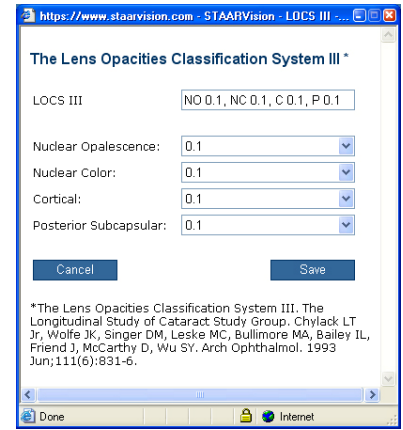
Axl	Axial Length, Valid range: 19 to 35
Vertex	Back Vertex Distance, may be changed from your default value that was set in “Preferences”
IOP	Intraocular Pressure, Valid range: 10 to 60

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LOCS Lens Opacities Classification System- Click “<< Specify”. Valid Ranges are 0.1 (clear) to 6.9 (opaque). Click “Save” when your choices are complete. The LOCS value will be transferred to the calculation page.

Click “Calculate” to display lens powers.

When values are outside of the FDA labeling, an off-label message will appear. Click “Cancel” to return to the calculation entry or click “Continue” to proceed. A chart of lens powers is displayed along with Predicted Refraction and SEQ (Spherical Equivalent). Select “Print” to print this calculation with all patient data and lens powers. Select the desired lens power to place the lens order.



Lens Ordering

Enter the purchase order number. A PO number is required by Customer Service to place the order. Verify that the correct billing, shipping and alternate contact info is correct. Specify the date that ICL delivery is desired. You may enter comments regarding your order in the space provided.

Click “Order” to send an email with this data to STAAR Surgical’s Customer Service Department. A confirmation email will be sent as verification of your order.

ICL Order

PO Number:

Patient:

Eye:

Model:

Power:

Predicted Ref:

SEQ:

DEQ:

Ship order to:

Alt contact:

Bill order to:

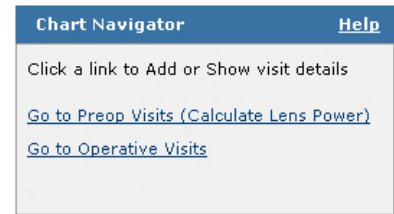
Date ICL Delivery is Desired:

Comments:

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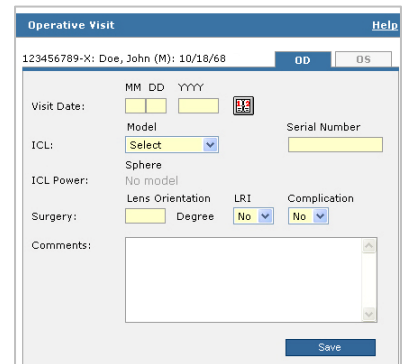
Surgical and Postop Information

Close follow up and entry of postoperative data is required for the first 20 surgical cases. STAARVision allows you to store pre-operative, operative and post-operative visits to help track your ICL patients. After an order is placed, the menu system in the Chart Navigator will add the following option: “[Go to Operative Visits](#)”. You cannot enter post-operative visits until an operative visit is complete.



Operative Visit

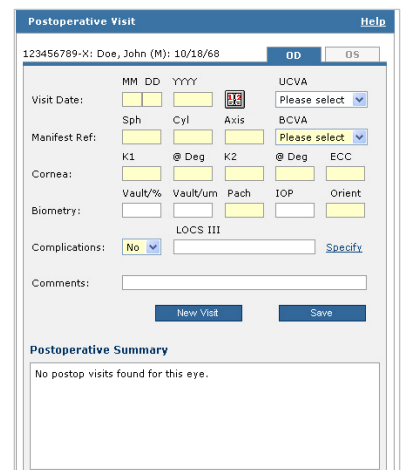
Click “[Go to Operative Visits](#)” to enter operative data. Select the calendar icon to select the surgical date. Select the ICL Model using the drop-down arrow. Enter the Serial number for that ICL Model. Select the ICL Power that was used. Enter the Lens Orientation in Degrees (0-180). Note if a Limbal Relaxing Incision was done or if there were any complications during surgery. Use the comment section to elaborate if necessary. Click “Save” to save the record



A new option appears in the Chart Navigator: “[Go to Postoperative Visits](#)”

Postoperative Visit

Click “[Go to Postoperative Visits](#)” to enter Postoperative information. Select the calendar icon to select the postoperative date. Select the uncorrected visual acuity (UCVA) using the drop-down arrow. Enter the Manifest Sphere, Cylinder and Axis. Select the best corrected visual acuity (BCVA) using the drop-down arrow. Enter the keratometry values. Enter the Endothelial Cell Count (ECC) measurement. Vault/% is the percentage of vault compared with the corneal thickness. In some instances, this may be greater than 100%. Enter the vault in microns. Enter the Pachymetry. Click “Save” to save this record. Click “New Visit” to add another postoperative record.



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Outcomes Analysis

STAARVision provides useful reporting tools to monitor your success with the Visian ICL. To use the reporting functions, you must enter postoperative data. The minimum required post-operative information should be the Manifest Refraction, BCVA, and LOCS Score. When the postoperative data is complete, the post-operative record will be included in the Outcomes Analysis Report.

The screenshot shows a navigation menu with four main sections:

- Patients:** Patient Records, Practice Overview, Lens Orders
- Reports:** Outcome Analysis, ICL Indication
- Settings:** Profile, Preferences, Manage Users
- Support:** Help / QuickStart, Technical Support, ICL Fax Form

Quick View Statistics

IOL Model	Patients	Postoperative Eyes	Postoperative Mean Values					
			Age	Post Rx	UCVA	BCVA	Abs Error	Error
MICL126	1	0	41.27	0.00			0.00	0.00
MICL132	4	1	43.72	-0.26		20/23	1.32	-1.26

[Refresh](#)

Review the Quick View Statistics and verify that Postoperative Eyes exist. Click “Outcome Analysis” in the Reports section to view the report screen.

Outcome Summary

ICL Model: Correction: Time Interval: Postop from: Postop to: [Refresh](#)

Select the desired parameters to customize the report output:

ICL Model – All, 12.1, 12.6, 13.2 or 13.7

Correction – Corrected or Uncorrected

Time Interval – Preoperative or Postoperative

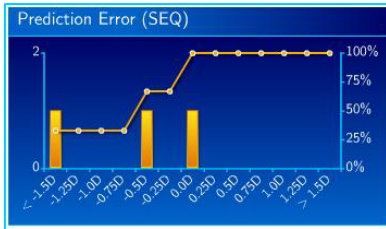
Post-Op From and Post-Op To – a range of days after operative surgery

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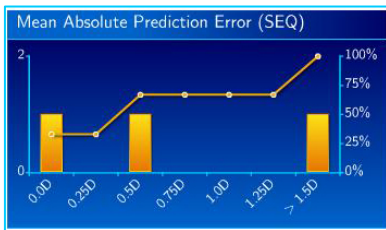
Preoperative



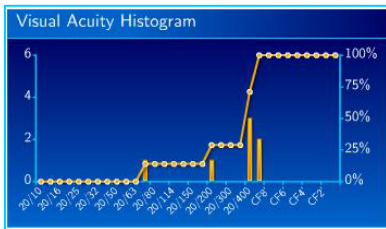
Spherical Equivalent



Prediction Error – expected error predicted by the calculation

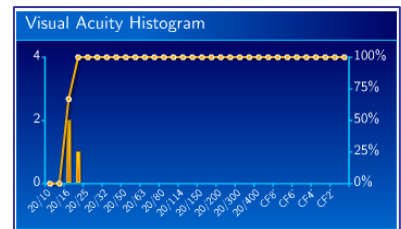
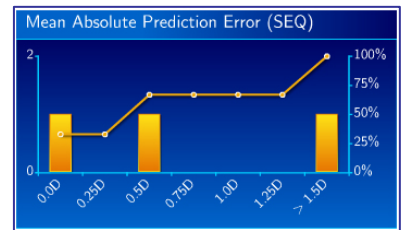
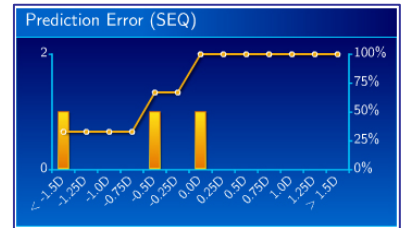
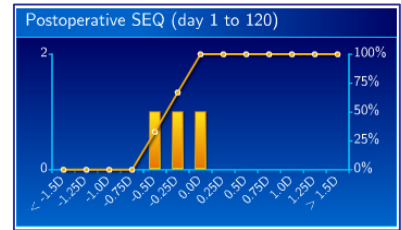


Mean Absolute Prediction Error– All values are converted to positive values and averaged in quarter diopter increments



Visual Acuity Histogram – Patient (corrected or uncorrected) Visual Acuity

Postoperative



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STAAR Surgical Visian ICL®**

Please complete this Profile Form before you access your www.STAARVision.com account. This information will be used in the registration process. Save the completed form for your records. You will also need this form if you call the help line.

Surgeon Profile Form

1. Enter your STAAR Surgical Registration Code (PIN)

_____ (if unknown, contact STAAR Surgical Customer Support)

2. Select a username

_____ (your choice, at least six characters, no spaces)

3. Select a password

_____ (your choice, at least six characters, no spaces)

4. Enter a valid email address

_____ (evaluation and approval notice will be sent here)

5. What technique do you use to measure corneal power?

- a) Manual Keratometry b) Auto Keratometry c) Topography

6. What technique do you use to measure phakic anterior chamber depth?

- a) Immersion A-scan b) Contact A-scan c) Optical (IOL Master)

7. What technique do you use to measure axial length?

- a) Immersion A-scan b) Contact A-scan c) Optical (IOL Master)

8. What type of incision do you use?

- a) Clear Cornea b) Near Clear Cornea c) Scleral Tunnel d) Other

9. Where do you make your surgical incision?

- a) Temporal b) Superior c) Steep Axis d) Other

10. What brand A-Scan Unit do you use?

Manufacturer _____ Model _____

11. What brand Keratometry/Topographer do you use to measure corneal power?

Manufacturer _____ Model _____

12. How do you measure endothelial cell density?

Manufacturer _____ Model _____



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13. Shipping Addresses. You can enter an unlimited number of addresses and add or change them later in Profile.

Short Name: _____ (how you refer to the full address)

First Name: _____

Last Name: _____

Facility Name: _____

Address: _____

City: _____

State: _____

Zip: _____

Country: _____

Tel: _____

Fax: _____

14. Billing Addresses. You can enter an unlimited number of addresses.

Short Name: _____ (how you refer to the full address)

First Name: _____

Last Name: _____

Facility Name: _____

Address: _____

City: _____

State: _____

Zip: _____

Country: _____

Tel: _____

Fax: _____