arcscan
Imaging ahead of the curve

User Manual

ArcScan Insight® ® 100

Foreword

This manual and the equipment described herein are for use by qualified medical professionals trained in the use and care of the device. It is intended as a guide for using the ArcScan Insight® 100. The contents of this document may not be disclosed to third parties, copied, or duplicated in any form, in whole or in part, without the prior written permission of ArcScan.

> ***Caution:*** *Federal Law (USA) restricts this device to sale by or on the order of a physician.*

Equipment covered in this manual:
ArcScan Insight® 100

Manufacturer:
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Golden, CO 80401
USA

For information call:
720.750.7909

Translations for this manual may be provided upon request.

CE 2797

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Conventions Used in this Manual

Warning: *Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.*
Caution: *Indicates a hazardous situation, which, if not avoided, may result in minor or moderate injury.*
Notice: *Indicates a hazard, which may result in product damage.*

Table of Contents

Chapter 1: Introducing the ArcScan Insight® 100

This chapter includes information about:

- The purpose of the instrument
- When the instrument should not be used
- General warnings and precautions
- System components and accessories

Caution: *Read all warnings, cautions, and instructions provided with this system before using.*
Caution: *Read the instructions, warnings, and cautions provided with accessories before using. Specific instructions for accessories are not included in this manual.*
Caution: *Medical electrical equipment, such as the ArcScan Insight® 100, needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and placed into service according to the EMC information provided.*
Caution: *Portable and mobile RF communications equipment can adversely affect the performance of medical electrical equipment.*
Caution: *Disposal of the instrument at end of life must be according to hospital or clinic regulation.*

About the Instrument

The ArcScan Insight® 100 is a precision ultrasound device for imaging and biometry of the eye. It uses a 20-60 MHz transducer that scans the eye in an arc whose curvature approximates the anterior ocular surfaces. The ArcScan Insight® 100 acquires data in a series of one or more meridional planes separated by equal angular intervals. These data produce images of the cornea or anterior segment at specific meridians on which measurements can be made. Specifically, the ArcScan Insight® 100 can measure the thickness of the cornea and its individual layers, the epithelium, stroma, and surgically induced surfaces. Measurements can also be made of the anatomic structures comprising the anterior of the eye such as anterior chamber depth, angle-to-angle width, and sulcus-to-sulcus width. Measurements can be made of pathologic structures such as solid masses and cysts.

Indications for Use

The ArcScan Insight® 100 is indicated for use in patients to measure dimensions of the anterior and posterior chambers of the human eye, and to provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure structures, such as anterior chamber depth, angle-to-angle width, and sulcus-to-sulcus width. Measurements can be made of the cornea and its individual layers including the epithelium, stroma, and surgically induced surfaces. Measurement also may be made of pathological structures such as solid masses or cysts and it is useful in evaluation and/or planning of refractive surgery and evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, glaucoma and hypotony.

Contraindications

Scanning should not be attempted on unrepaired ruptured globes or in other situations where ocular integrity is questionable.

General Warnings

***Warning: Do not** allow the transducer to touch the surface of the cornea. Adjustment of the transducer's distance from the eye should be done carefully by the operator in manual mode while monitoring the distance using the live video from the camera and/or the A-mode image to judge the remaining distance to the patient's eye.*

***Warning**: It is important to use a new, packaged, sterile EyeSeal for each patient. Diseases, such as endophthalmitis, can be transmitted from patient to patient. Discard the used EyeSeal between each patient exam.*
***Warning:** This instrument is intended solely for use by trained professionals in a clinical environment as an ophthalmic diagnostic tool. Operators must read and fully understand the User Manual and operation of both the hardware and software before examining any patients.*
***Warning:** This instrument relies on proper grounding as one of its safety features. To avoid electrical shock, use only the supplied power cord and connect only to mains outlets that contain protective earth.*
***Warning:** Do not position the instrument such that it is difficult to unplug the instrument from the mains outlet.*
***Warning:** Power cords and water lines can be a strangulation hazard. Keep small children away from the cords and lines when in use. When not in use, store cords and water lines as instructed.*
***Warning:** This instrument has not been tested in conjunction with HF surgical (e.g., electrocautery) equipment and should not be used with such equipment.*
***Warning:** This instrument is intended for use by healthcare professionals only and may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ArcScan Insight® 100 or shielding the location.*
***Warning:** Do not modify this equipment without authorization of the manufacturer.*
***Warning:** The use of accessories or cables other than those specified, or supplied by the manufacturer as replacement parts, may result in increased electromagnetic emissions or decreased immunity of the ArcScan Insight® 100 and will void manufacturer's warranty.*
***Warning:** ArcScan Insight® 100 is to be assembled by an ArcScan authorized field service engineer.*

Warning: *The ArcScan Insight® 100 should not be used adjacent to or stacked with other equipment. If adjacent use is necessary, the ArcScan Insight® 100 should be observed to verify normal operation in the configuration in which it will be used.*

Warning: *The ArcScan Insight® 100 should not be used with any electrically powered accessories.*

Warning: *No other equipment can be placed upon the ArcScan Insight® 100 tabletop.*

Warning: *Fire Hazard—Do not use extension cords or surge protectors.*

Warning: *Improper leveling of the device or placement of device on an inclined surface can result in patient and/or operator injury.*

Caution: *For North America, Japan, Denmark, Australia, and New Zealand, to maintain proper grounding use only the supplied power cord, plugged into a "hospital grade" identified receptacle.*

Caution: *Power supply cord must be no longer than 3 meters. Use of a longer cord may increase electromagnetic emissions or reduce immunity.*

Notice: *If after 1-year manufacture warranty expiration customer chooses not to extend annual service contract, all bi-annual periodic maintenance, repairs, updates, and training will be billed to customer on a time/materials/travel expenses basis. Should customer opt to discontinue periodic maintenance altogether, ArcScan, Inc. will require system to be put out of clinical service and deemed unsuitable for patient use due to risks related to lack of required bi-annual periodic maintenance.*

Software License Restrictions

The ArcScan Insight® 100 has been delivered with operating system and application software on the internal hard drive. These applications are licensed, not sold, by ArcScan, Inc. The license entitles use of the ArcScan Insight® 100 software only in association with the ArcScan Insight® 100 hardware.

Insight® 100 Overview

The ArcScan Insight® 100 is designed for functional efficiency and ease of use. The system is comprised of four main components: the scanner, the fluidics

module, the electronics unit, and the software package. These components are described in the following sections.

All operators are expected to undergo training before using the system. Operators are also expected to read and be familiar with the contents of this User Manual, videos, and other training pieces prior to using the system.

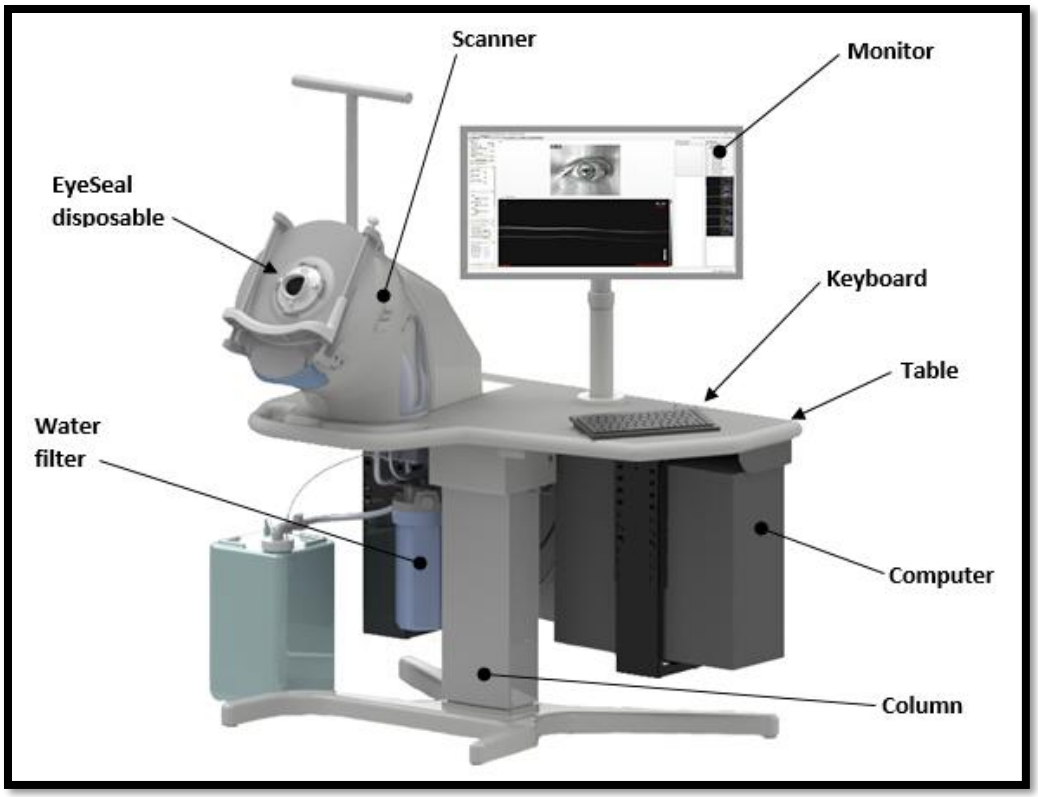


Figure 1: ArcScan Insight® 100 Front View

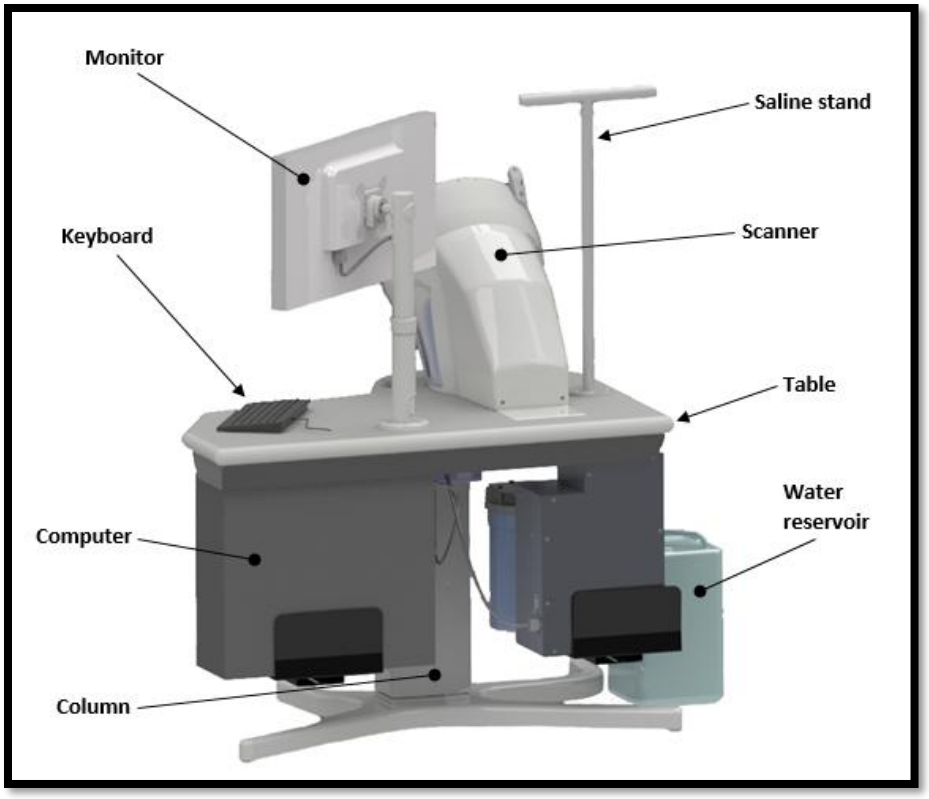


Figure 2: ArcScan Insight® 100 Back View

Instrument Module

The scanner is designed to comfortably position the patient, so the eye is looking through the center of the EyeSeal Disposable while keeping the head still. EyeSeal Disposables are used to separate the distilled water in the instrument from the patient's eye and prevent cross contamination between patients and are changed between each patient exam.

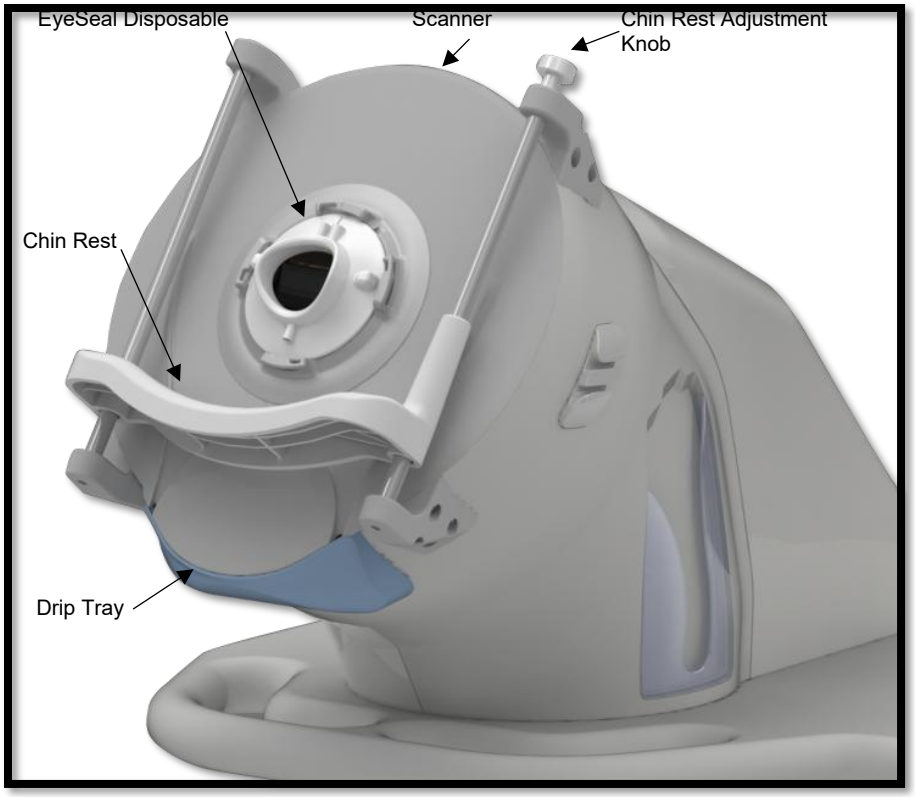


Figure 3: ArcScan Insight® 100 Scanner

The scanner exterior is comprised of the following:

Component	Description
Chin Rest	The adjustable chin rest is intended to give support to the patient's chin to stabilize the patient's head during scanning. The chin rest can be raised to accommodate differences in patients. The chin rest can be raised with the adjustment knob after the patient's eye is situated in the EyeSeal.
EyeSeal Disposable	The EyeSeal Disposable protects the patient's eye to be scanned. An EyeSeal Disposable provides a hygiene barrier between the distilled water in the scanner and the sterile saline solution surrounding the patient's eye. The EyeSeal Disposable is symmetrical for right and left eye scanning. A new EyeSeal Disposable is used with each patient.
Drip Tray	The drip tray is intended to collect any saline that may drip or leak from the EyeSeal Disposable. Empty the tray as needed.

Component	Description
Drain Bag Holder	The EyeSeal drain bag may be placed in the drain bag holder before placing the patient. This holder is located on the side of the scanner and stores the drain bag out of the patient's way.

Inside the scanner, is a liquid chamber, the scan probe, and probe positioning hardware.

Fluidics Module

The fluidics module is comprised of the following:

Component	Description
Reservoir	The fluid container which holds the distilled water necessary for the instrument to function
Fill/Drain Pump	The pump and valve combination for transferring water from the reservoir to the scanner chamber.
Bearing Pump	The high-pressure pump that recirculates water from the scanner through the fluid bearings that provide smooth friction-free motion of the scan probe.
Water Filter	The standard water filter that removes sediment from the scan head fluid to prevent clogging of the fluid bearings.

Electronics Unit

The electronics unit consists of the central column, computer, monitor, keyboard, and mouse. The main power switch for the ArcScan Insight® 100 system is located on the central column. Individual power switches are located on the computer and monitor. The main power switch should be turned on during startup, and then turned off when the system is not in use. The computer and monitor may be left on at the operator's discretion.

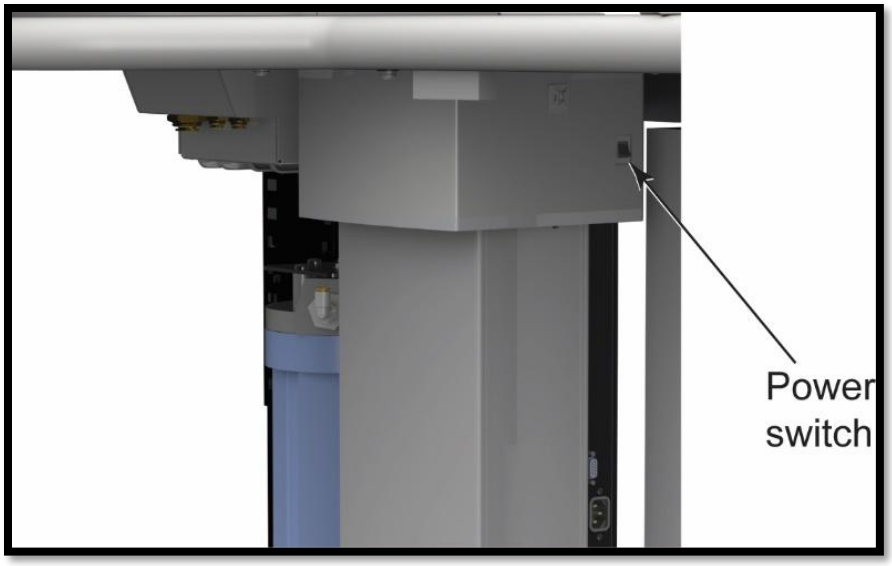


Figure 4: Main Power Switch

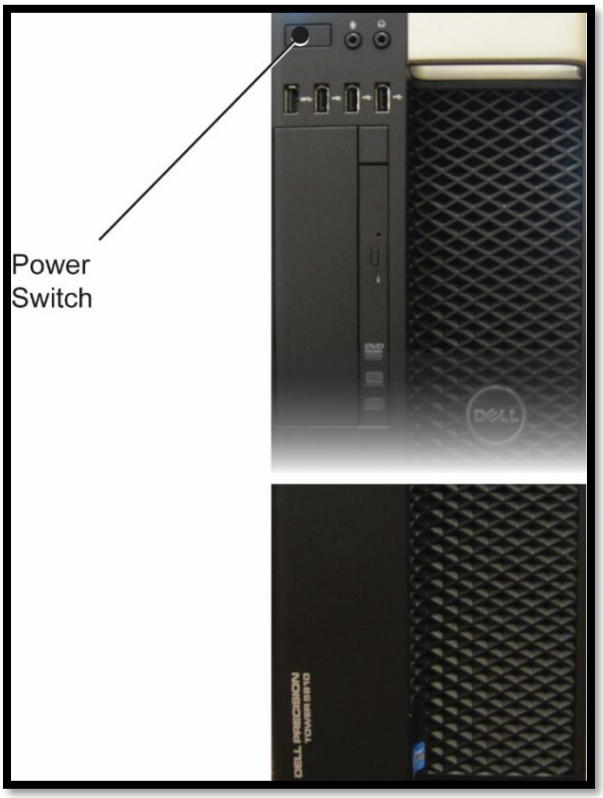


Figure 5: Computer Power Switch

Software Package

ArcScan Insight® 100 software has six main pages, and four plugin pages, accessed through the tabs on the upper left-hand side of the application window. These pages and their descriptions are shown below.

Upon startup, the ArcScan Insight® 100 software opens to the **Patient Page**. This page is used to enter patient demographics or access prior patient data.

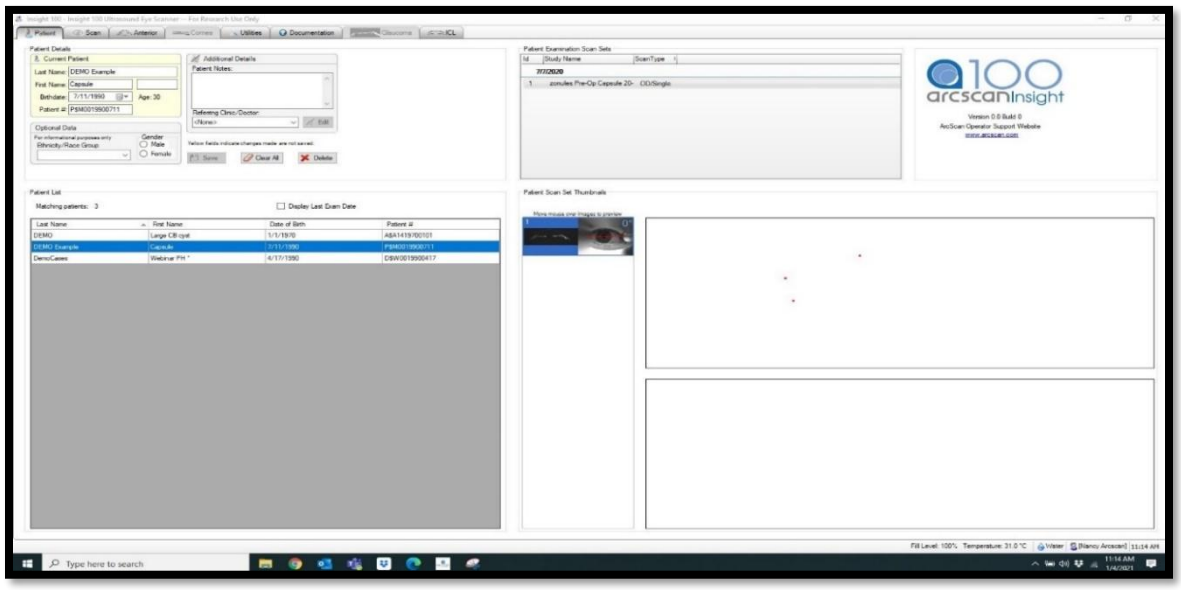


Figure 6**: Patient Page**

The **Scan Page** is used for performing scans on the patient. All existing scans for the selected patient are displayed on this page. New scans can be captured, and rescanned if desired.

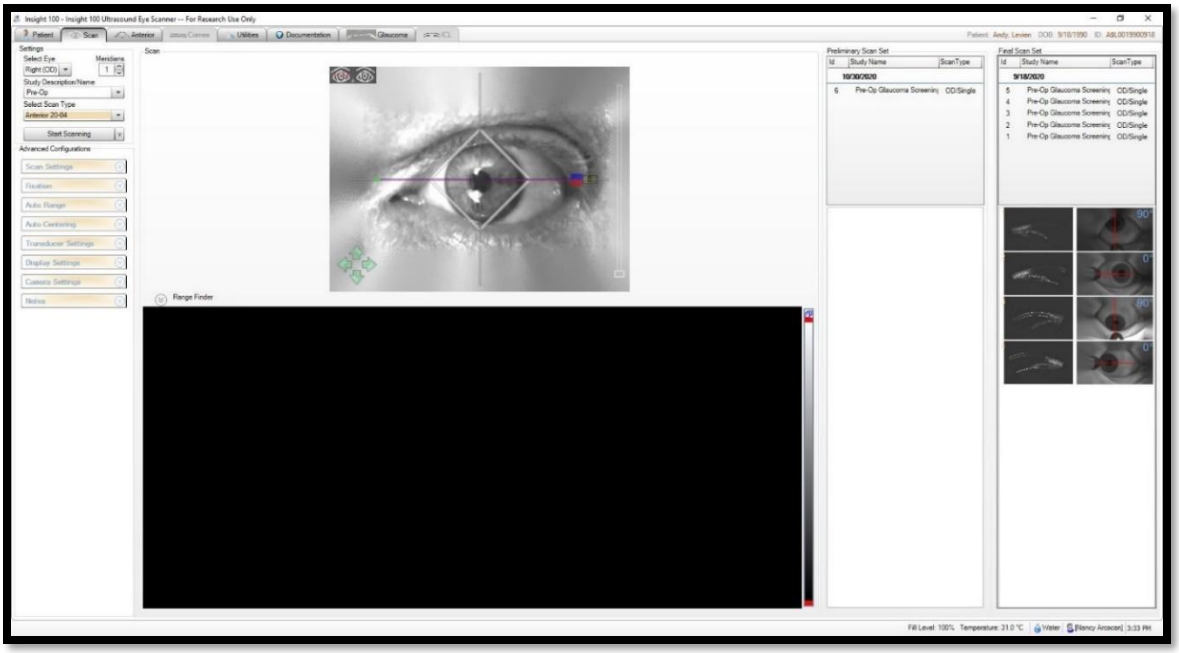


Figure 7: Scan Page

The **Anterior Page** is used for Anterior and Capsule scan review. Measurements may be taken as well as annotating individual scan images.

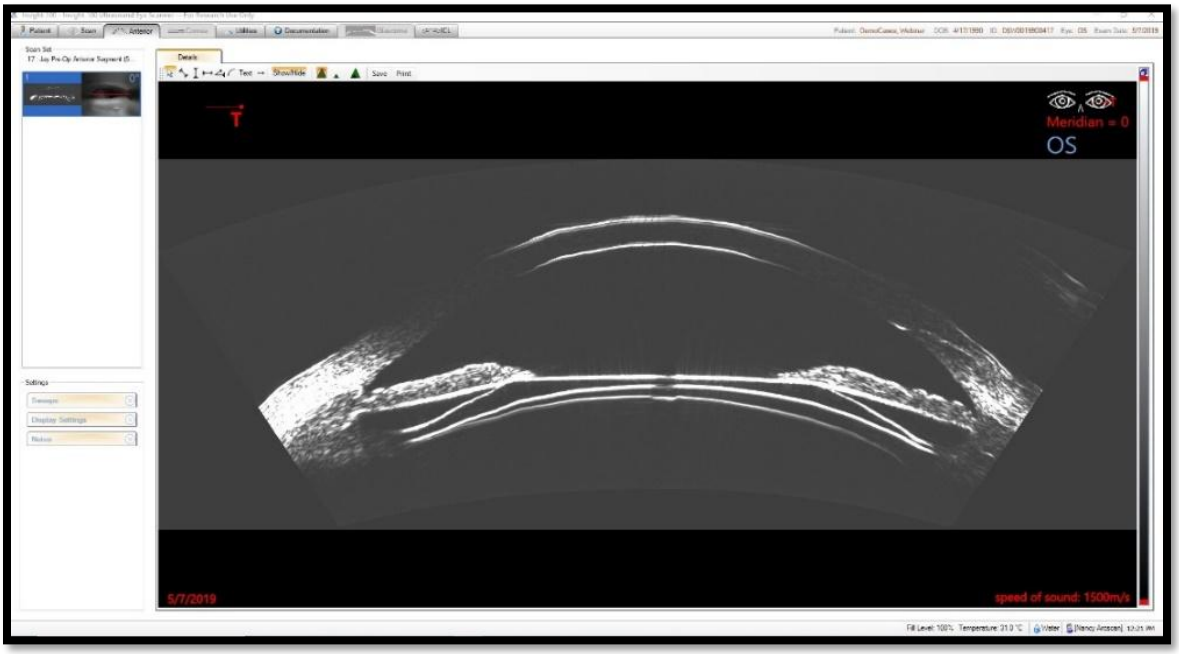


Figure 8: Anterior Page

The **Cornea Page** is used for Cornea scan image review, as well as viewing Keratoconus (when the Keratoconus plugin is installed) and Cornea Map data. Scan images may also be measured and annotated on the Corrected tab.

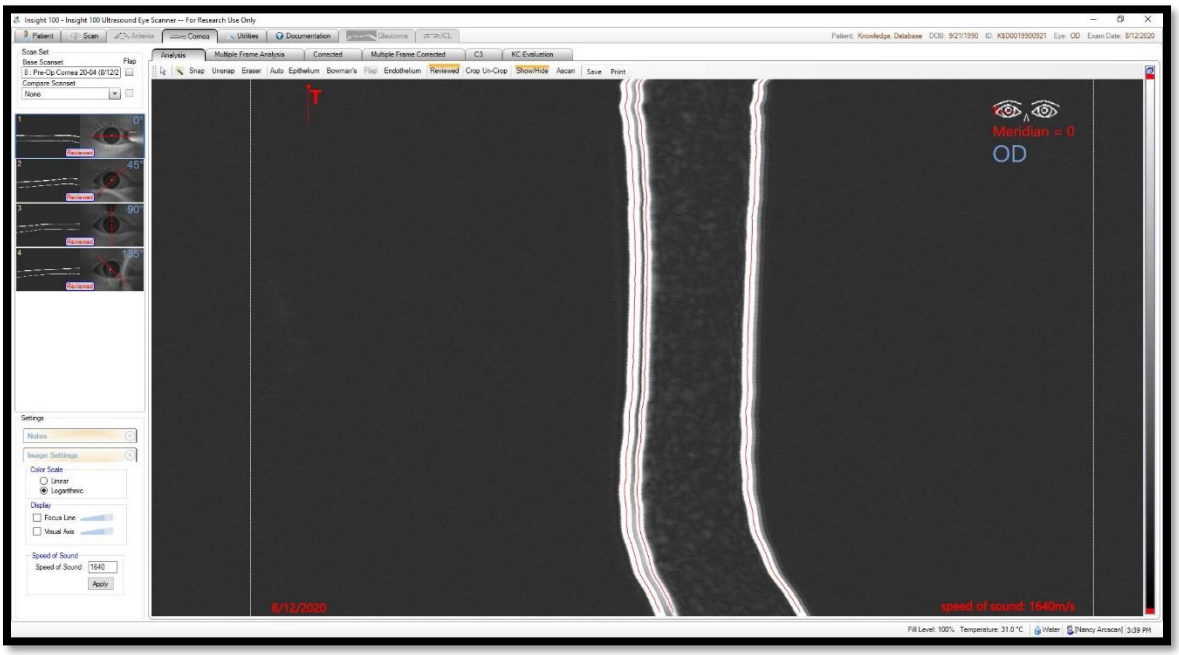


Figure 9: Cornea Page

The Keratoconus Plugin is an addition to the Cornea page, and provides an estimate for a patient's risk of developing keratoconus.

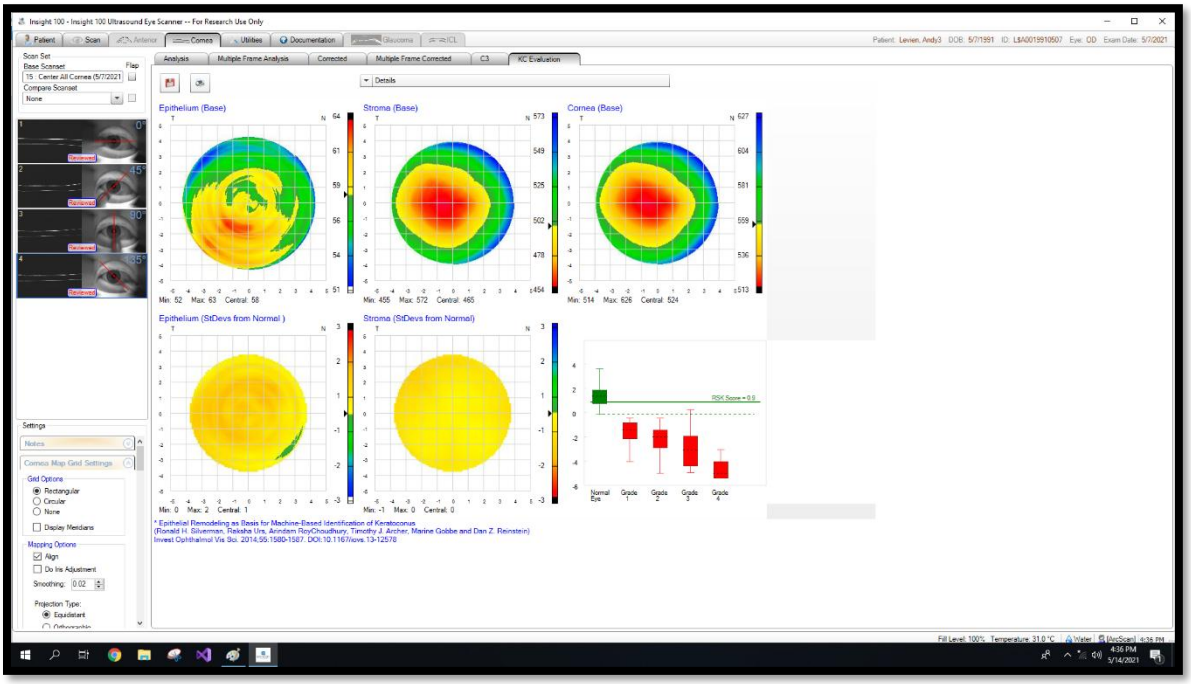


Figure 10: Keratoconus Plugin

The **Utilities Page** provides status information and control of the Camera, Motion, and Ultrasound subsystems.

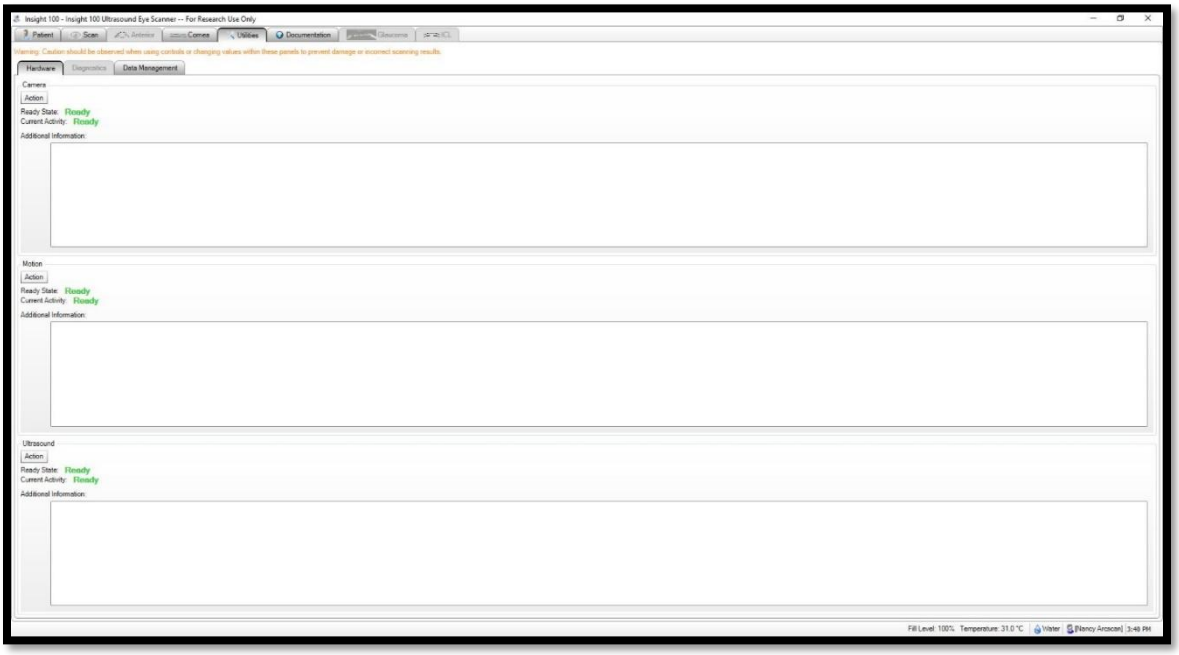


Figure 11: Utilities Page

Documentation Page contains an electronic version of the current User Manual.

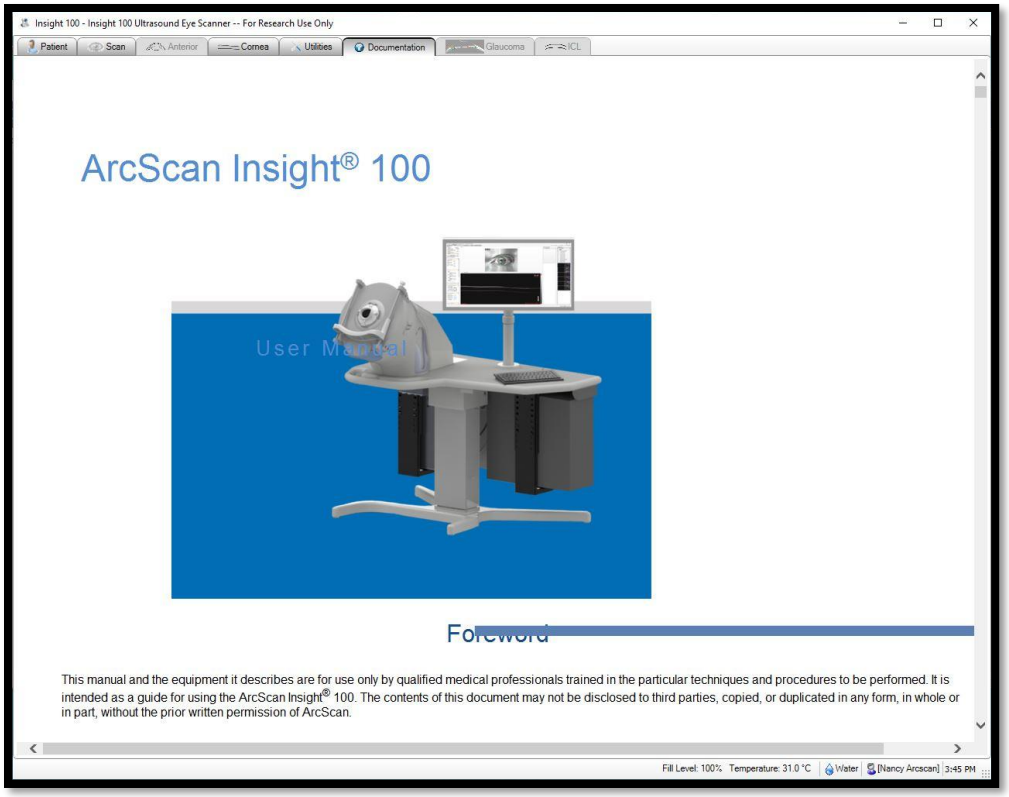


Figure 12: Documentation Page

The **Glaucoma** tab becomes available when the Glaucoma plugin is installed and will access the **Glaucoma Page** when a glaucoma scan set is reviewed**.** The **Glaucoma Page** is used for Glaucoma scan image review, as well as preparing reports for comparing angles. Scan images may also be measured and annotated.

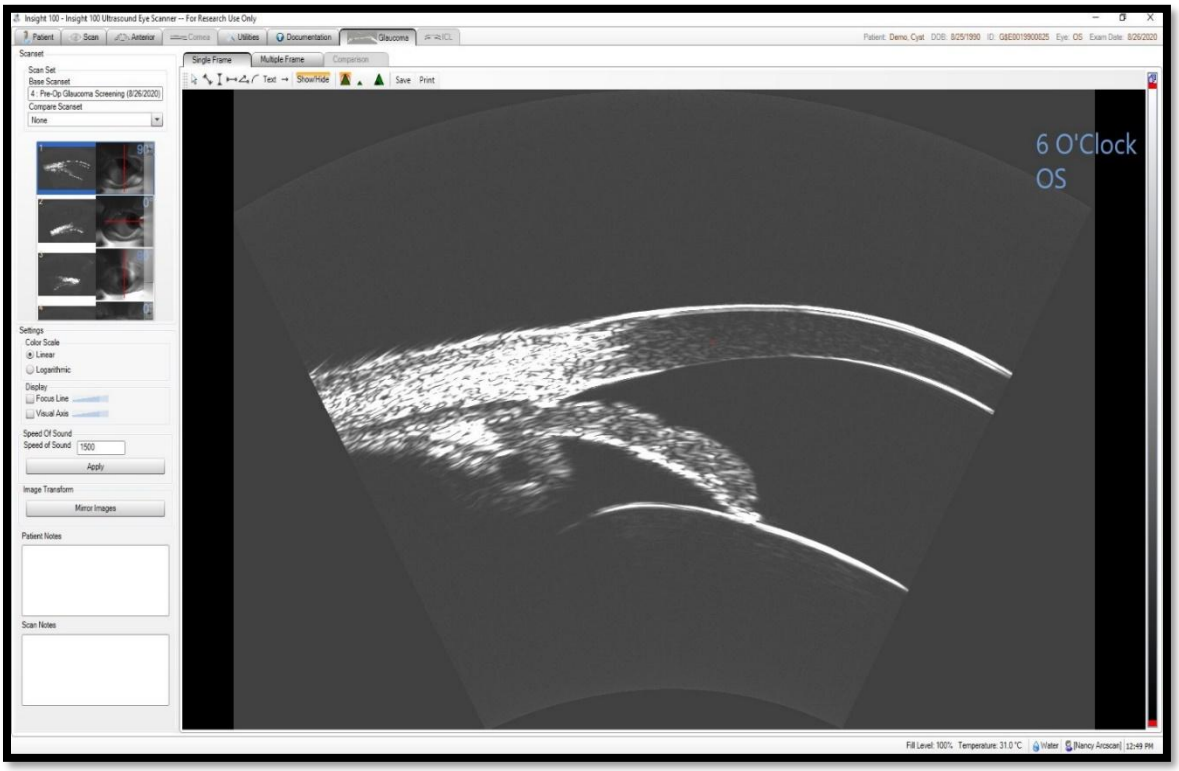


Figure 13: Glaucoma Screening image

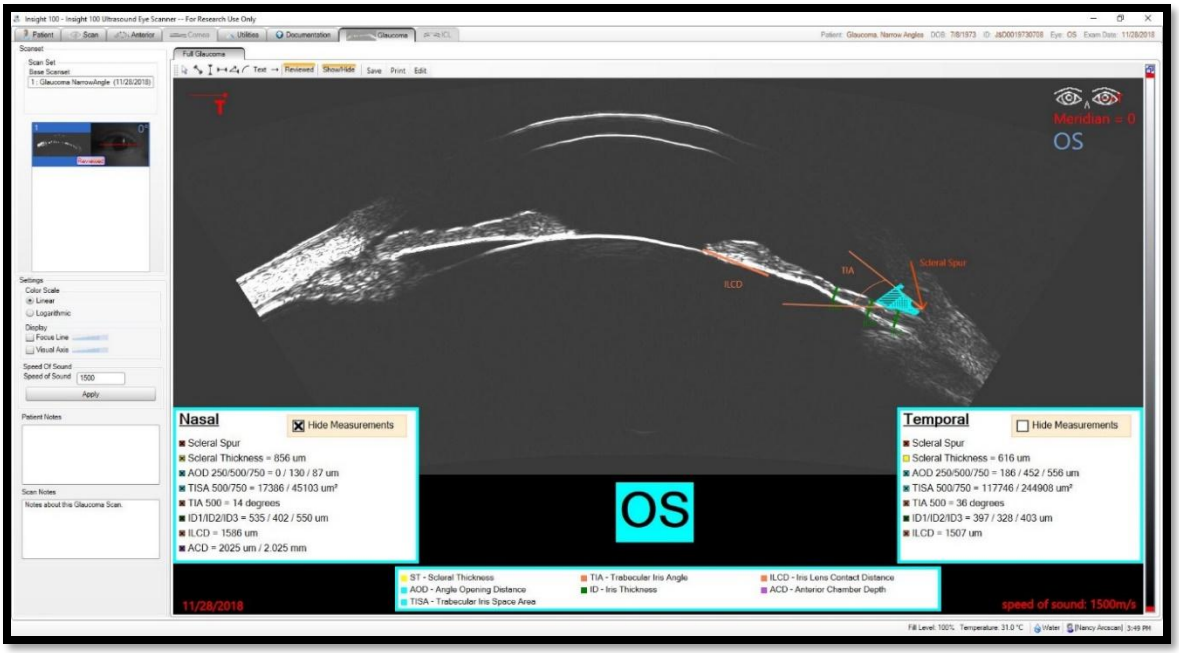
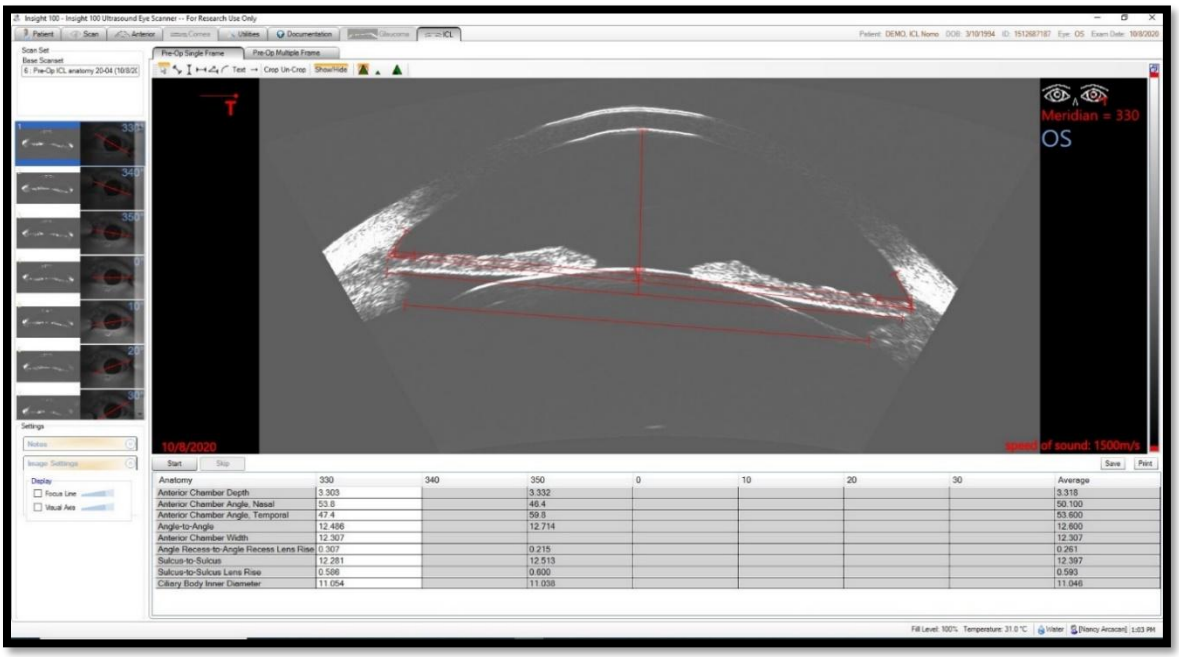


Figure 14: Glaucoma Report image

The **ICL Page** becomes available when the ICL plugin is installed and will produce an ICL sizing chart or a vault map chart depending on whether a pre- or post-op scan set is being reviewed. These tables are populated using the Rapid Caliper Tool.



Anatomy	330	340	350	0	10	20	30	Average
Anterior Chamber Depth	3.303		3.332					3.318
Anterior Chamber Angle, Nasal	53.8		46.4					50.100
Anterior Chamber Angle, Temporal	47.4		59.8					53.600
Angle-to-Angle	12.486		12.714					12.600
Anterior Chamber Width	12.307							12.307
Angle Recess-to-Angle Recess Lens Rise	0.307		0.215					0.261
Sulcus-to-Sulcus	12.281		12.513					12.397
Sulcus-to-Sulcus Lens Rise	0.586		0.600					0.593
Ciliary Body Inner Diameter	11.054		11.038					11.046

Figure 15: ICL Pre-op Anatomy Page

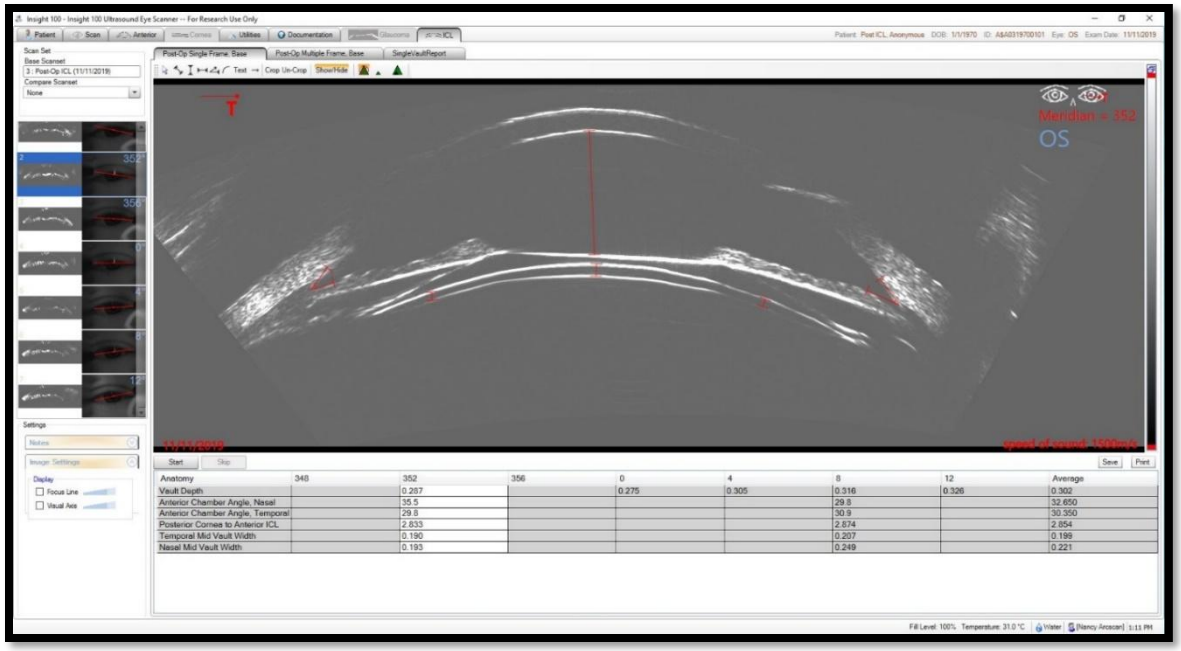


Figure 16: ICL Post-op ICL Vault Page

The DICOM Page becomes available when the DICOM plugin is installed, and the system is linked to a clinic's DICOM server. The DICOM page replaces the functionality of the patient page, as new patients are received from the server. Once a patient, and associated scan request, is selected, scanning is performed normally, and a report can be sent to the DICOM storage server.

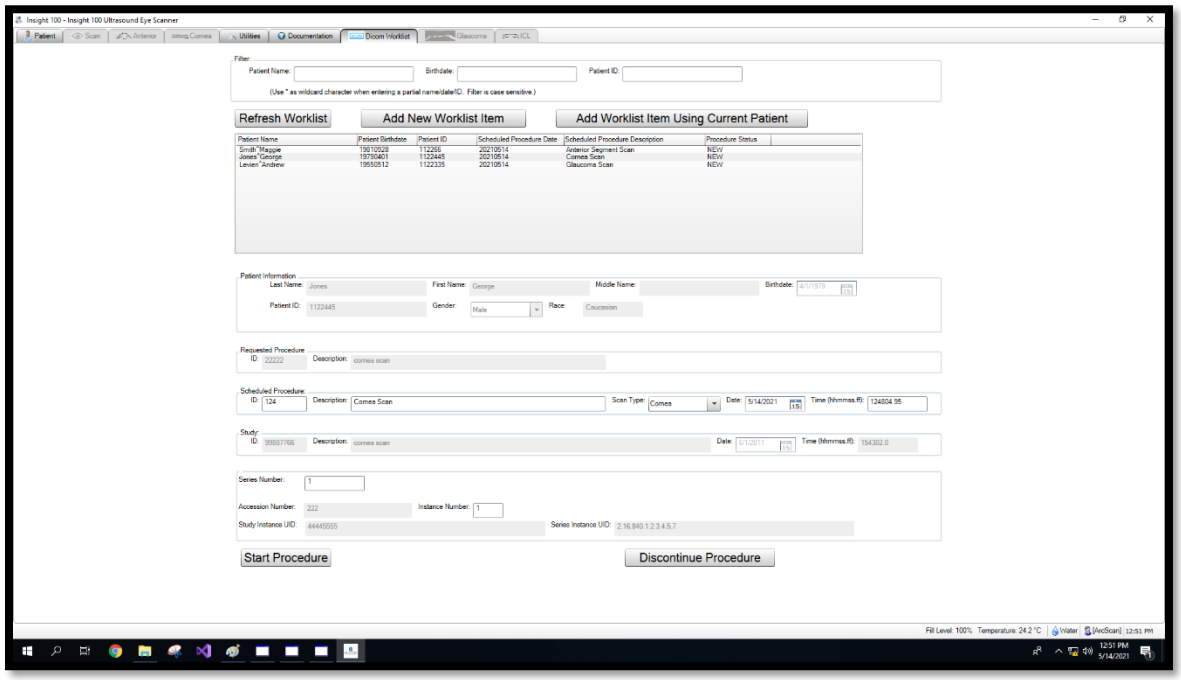


Figure 17: DICOM Page

List of Components

The following components are supplied with the ArcScan Insight® 100 system.

- Fluidics Module and Installation Hardware
- Computer, Mouse, Keyboard, Monitor, Installation Hardware
- Reservoir
- Column
- Table, Table Legs, Protector Plate, Saline Pole, Monitor Mount
- Calibration (marble) Fixture
- Cables and Hoses

List of Accessories

The following accessories are used with the ArcScan Insight® 100 system for scanning and are purchased separately.

Accessories - Scanning
EyeSeal Disposables

List of Supplies

The following supplies are used with the ArcScan Insight® 100 system for scanning and maintenance and should be purchased separately.

Supplies – Used with scanning
0.9% Sodium Chloride (Baxter Item #2B1322Q), Ringer's Lactate USP (Baxter Item #2B2322Q) or equivalent solution, 100 mL or greater. 50ML option also available from Baxter (Baxter item #2B1308).
Saline Administration Set (Baxter Clearlink System Secondary Medication Set 2C7461, or equivalent)
Dilute bleach (5000 ppm ± 10% sodium hypochlorite) cleaning solutions

Chapter 2: Available Scan Types

This chapter includes information about:

- Scan Types and Default Settings
- Available Scan Modifications

Scan Types and Default Settings

The ArcScan Insight® 100 can perform Anterior Segment, Capsule, Cornea, ICL, and Glaucoma Imaging. The following individual scan types are provided in each category:

SCAN TYPE	MERIDIANS	AUTO-RANGE TARGET	MERIDIAN INCREMENTS
Anterior Segment Imaging			
Anterior	1	Capsule	Meridian 0 only
Capsule Imaging			
Capsule	1	Capsule	Meridian 0 only
Cornea Imaging			
Cornea	4	Cornea	45 degrees, 360-degree field
Glaucoma Imaging			
Glaucoma	1	Capsule	Meridian 0 only
Glaucoma Screening	1	Scleral Wall	N/A
Limbus 12 O'Clock	1	Scleral Wall	N/A
Limbus 3 O'Clock	1	Scleral Wall	N/A
Limbus 6 O'Clock	1	Scleral Wall	N/A
Limbus 9 O'Clock	1	Scleral Wall	N/A
ICL Imaging			
ICL Anatomy	7	Capsule	10 degrees; 30 degrees either side of horizontal
ICL Nomogram	7	Capsule	3 degrees; 9 degrees either side of horizontal
ICL Vault	6	Cornea + Offset	30 degrees; 360-degree field

Anterior Segment Imaging

Anterior segment imaging is used for general assessment and measurement of pathology in the anterior segment. The following parameters are used in anterior segment imaging:

- The system automatically sets the ultrasound range to capture 4.5 mm of data in front of the transducer's focal plane and 3 mm of data behind the focal plane. This range sets the height of the resulting B-Scan.

- One meridian is imaged, default setting is horizontal at Meridian 0. If a vertical scan is required, the use of a speculum or tape to keep the eyelid from obstructing the edges of the scan is recommended.

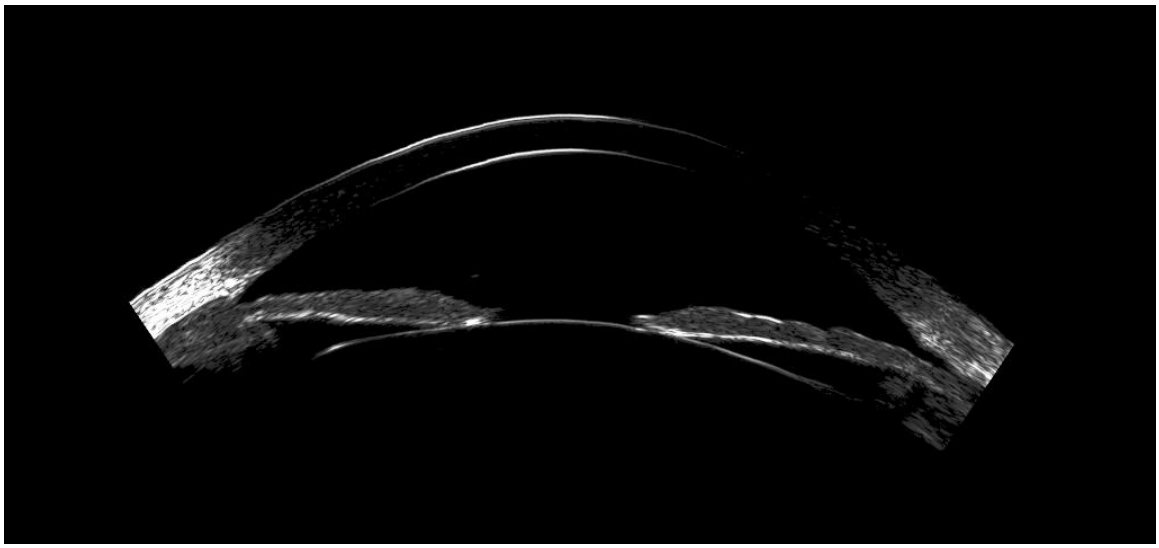


Figure 18: Anterior B-Scan

Capsule Imaging

Capsule imaging is used for assessment of pathology and anatomical measurements such as sulcus to sulcus distance, angle-to-angle distance, anterior chamber depth, and capsule thickness.

The following parameters apply to capsule imaging:

- The system automatically sets the ultrasound range to capture 5 mm of data in front of the transducer's focal plane and 5 mm of data behind the focal plane.

- The system automatically sets the scan geometry to acquire five sweeps. The system sets the scan area to image one horizontal meridian and visualizes the anterior segment from anterior cornea to posterior lens capsule.

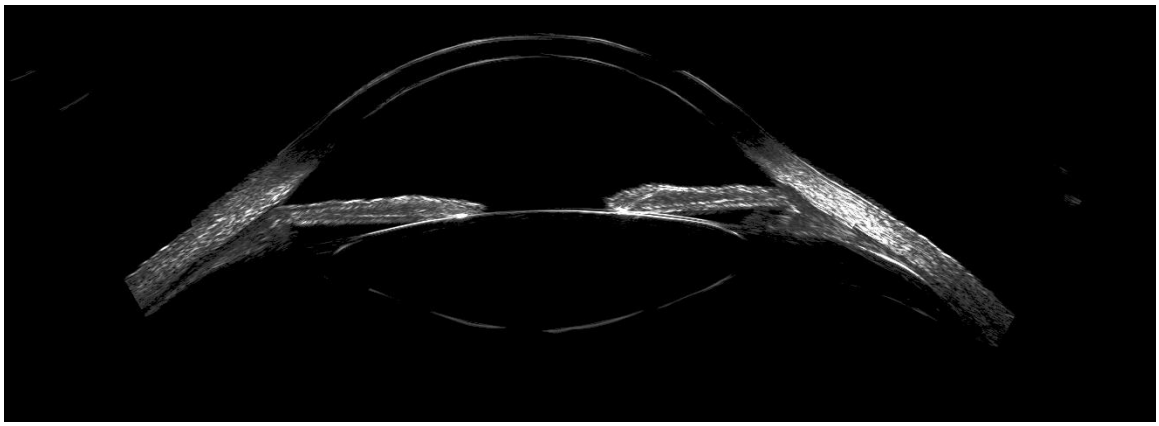


Figure 19: Capsule B-Scan (composite of 5 sweeps)

Cornea Imaging

Corneal imaging is used for pre- and post-Lasik biometry, early detection of Keratoconus, and evaluation of corneal scars.

Note: Corneal imaging requires an arc radius of 8-9 mm to match the cornea's radius of curvature.

The following parameters apply to normal corneal scans:

- The system automatically sets the ultrasound range to capture 2 mm of data in front of the focus line, and 2 mm of data behind the focus line.
- The system sets the scan area to image the entire cornea using four equally spaced meridians at 0, 45, 90 and 135 degrees.

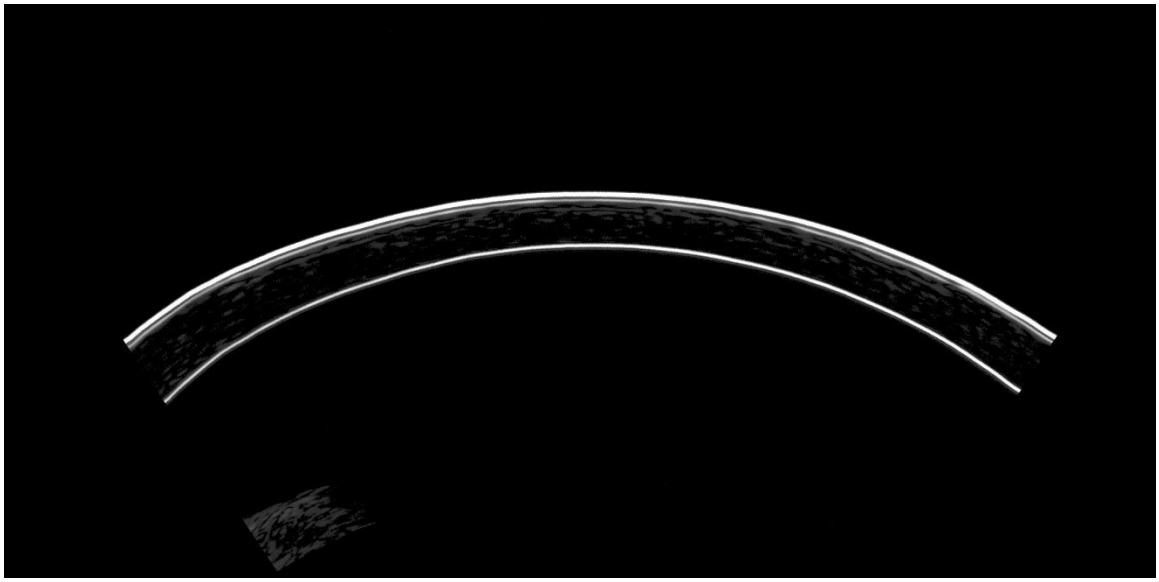


Figure 20: Cornea B-Scan (Geometrically Corrected)

Glaucoma Imaging

Glaucoma Imaging is used for detection and monitoring of Closed-Angle Glaucoma. Several types of Glaucoma scans are available depending on the use case, desired anatomy, and the preference of the operator. All scans provide clear imaging of the angle and surrounding anatomy.

Glaucoma – This scan has many similarities to the anterior scan used above. This scan type may be opened in the Glaucoma plugin, where the angle and other anatomy is automatically detected and measured. Please see the Glaucoma Supplement for more information.

The following parameters apply to Glaucoma Scans:

- The system automatically sets the ultrasound range to capture 4.5 mm of data in front of the transducer's focal plane and 3 mm of data behind the focal plane. This range sets the height of the resulting B-Scan.

- One meridian is imaged, default setting is horizontal at Meridian 0. If a vertical scan is required, the use of a speculum or tape to keep the eyelid from obstructing the edges of the scan is recommended.

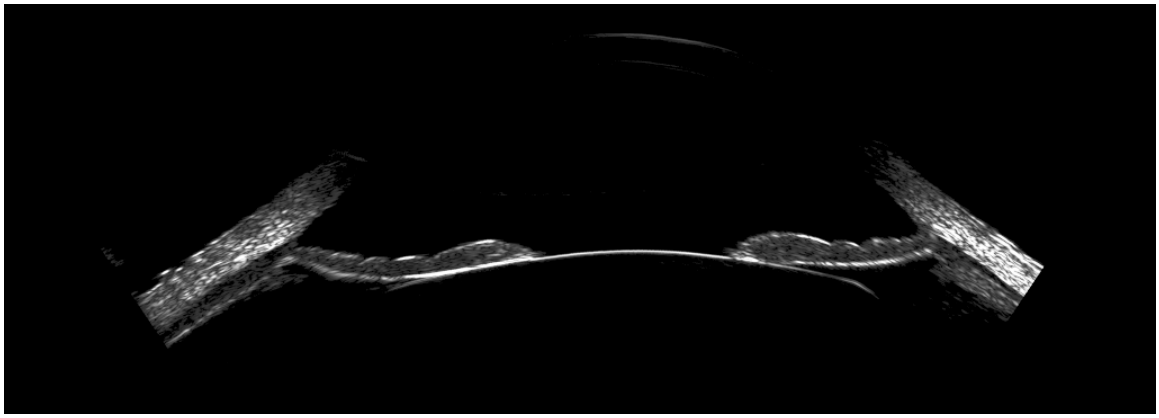


Figure 21: Glaucoma Scan

Limbus – These scans provide an enhanced view of the angle and ciliary process by centering the instrument over the limbus instead of the center of the cornea. There are 4 scans provided which will automatically center the instrument on the 3, 6, 9, or 12 O'Clock limbus positions.

The following parameters apply to Limbus Scans:

- The system automatically sets the ultrasound range to capture 4.5 mm of data in front of the transducer's focal plane and 3 mm of data behind the focal plane. This range sets the height of the resulting B-Scan.

- One meridian is imaged corresponding to the clock position. If a vertical scan is required, the use of a speculum or tape to keep the eyelid from obstructing the edges of the scan is recommended.

- The off-axis fixation light is illuminated for this scan type, requiring the patient to look away from center. This brings the limbus into a position where it can be scanned by the Insight® 100. The fixation light appears in the opposite direction of the limbus clock position being scanned.

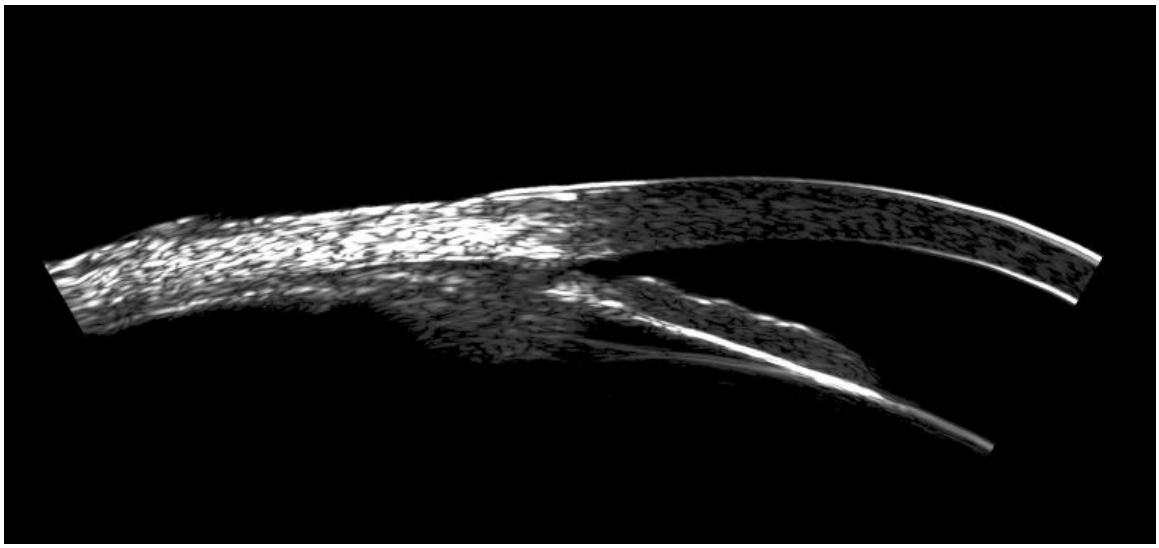


Figure 22: Limbus Scan

Glaucoma Screening – This scan performs all the Limbus scans in sequence and stores the data in a single scan set. All parameters from the individual limbus scans are unchanged.

ICL Imaging

ICL Imaging is used for measuring the anatomy of a patient pre-operatively to determine the best size ICL implant. Post-operative ICL scanning is used to verify the footplates of the ICL implant are in ideal locations, and that the vault is of sufficient size to allow flow of aqueous fluid into the anterior chamber. Two pre-op and one post-op scans are provided to gather this information.

ICL Anatomy (pre-op) – This pre-op scan is used to assess the anatomy in the full range where the ICL implant could be placed.

The following parameters apply to the ICL Anatomy Scan (pre-op):

- The system automatically sets the ultrasound range to capture 4.5 mm of data in front of the transducer's focal plane and 4 mm of data behind the focal plane. This range sets the height of the resulting B-Scan.

- 7 meridians are imaged, all of which are evenly spaced in the range of +/- 30 degrees around horizontal. The patient's eye is usually open enough that tape or a speculum is not required, but it may be necessary for a narrow fissure.

ICL Nomogram (pre-op) – This pre-op scan is used to closely assess the anatomy where the ICL footplates will be placed. The patient's eye is usually

open enough that tape or a speculum is not required, but it may be necessary for a narrow fissure.

The following parameters apply to the ICL Nomogram Scan (pre-op):

- The system automatically sets the ultrasound range to capture 4.5 mm of data in front of the transducer's focal plane and 4 mm of data behind the focal plane. This range sets the height of the resulting B-Scan.
- 7 meridians are imaged, all of which are evenly spaced in the range of +/- 9 degrees around horizontal.

ICL Vault (post-op) – This post-op scan is used to assess the placement of the ICL implant, and the resulting Vault formed between the anterior capsule and posterior ICL surfaces. The patient's eye is usually open enough that tape or a speculum is not required to see the vault at the vertical meridians, but it may be necessary for a narrow fissure.

The following parameters apply to the ICL Vault Scan (post-op):

- The system automatically sets the ultrasound range to capture 3 mm of data in front of the transducer's focal plane and 4 mm of data behind the focal plane. This range sets the height of the resulting B-Scan.
- 6 meridians are imaged, all of which are evenly spaced in the full 360 range.

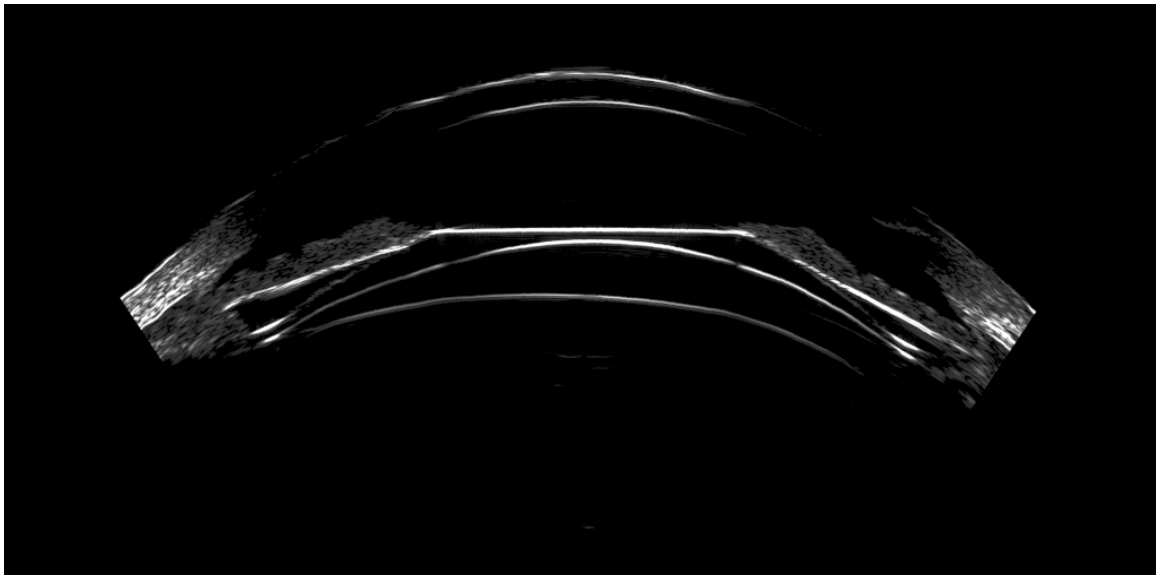


Figure 23: Post-Op ICL Vault Scan

Available Scan Modifications

The number of meridians, and area of scanning, can be changed for each scan type.

Adding Meridians

The number of meridians can be increased for all scan types except for limbus scans. This option is available in the Settings window in the upper left corner of the scan page. Select the desired Eye, Study Description, and Scan Type before making these changes, as the default settings are loaded every time a new scan is selected.

By default, new meridians will be evenly spaced around the eye.

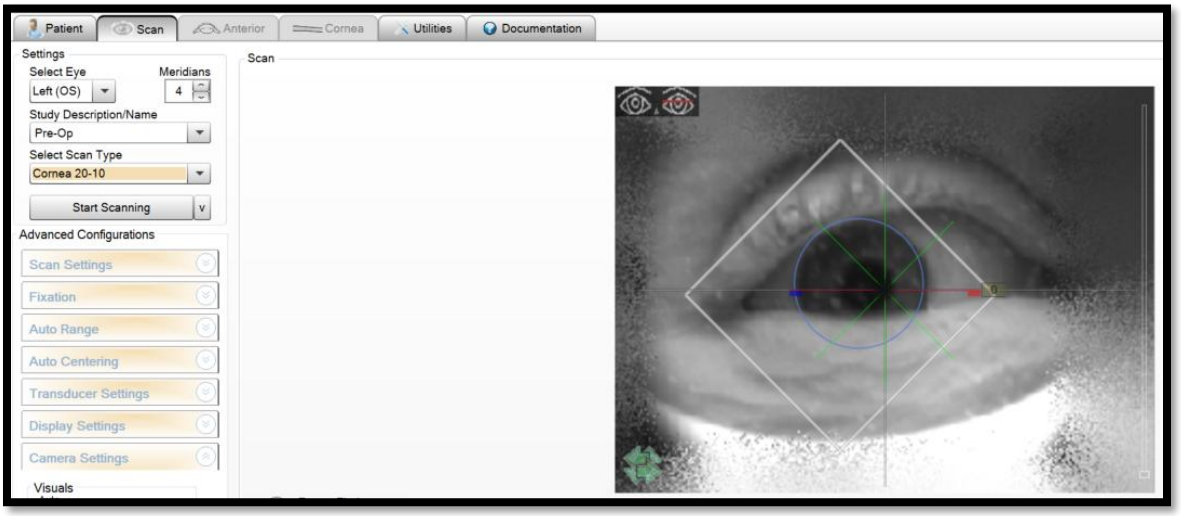


Figure 24: Cornea scan, standard meridians

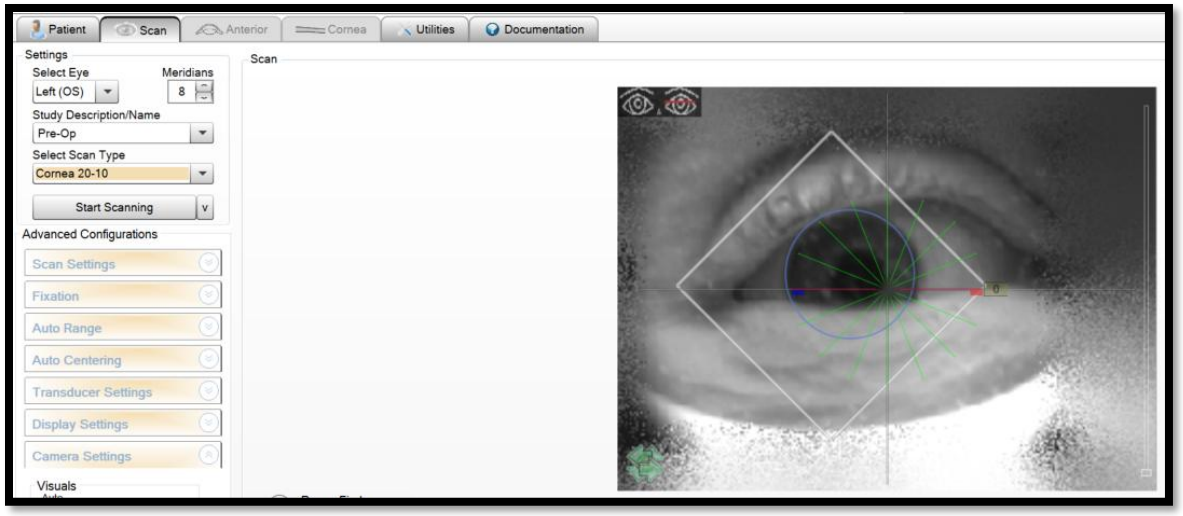


Figure 25: Cornea scan, 8 meridians

Area of Scanning

The area of scanning can be changed for all scan types. To select a specific scan region:

1. Click and drag the red and blue tabs to limit the meridians to the desired scan area.

2. Once narrowed, click and drag the green meridian lines to relocate the limited scan area.

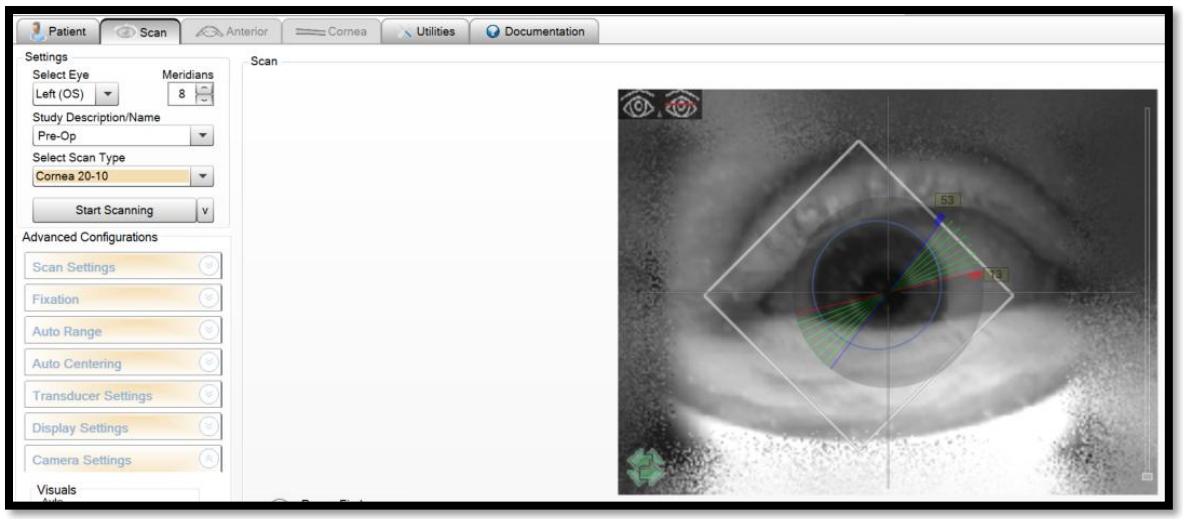


Figure 26: Cornea scan, 8 meridians, narrowed scan area

Other Modifications

The default scans, and meridian modifications, are suitable to address most cases. The ArcScan Insight® 100 has many degrees of freedom, and it is possible to make additional changes. If the available options are not adequate for a specific case, please contact ArcScan's Clinical Applications to discuss specific needs.

Chapter 3: Setup and Scanning Procedure

This chapter includes information about:

- Instrument Setup
- Entering Patient Information
- EyeSeal Placement
- Patient Setup and Scanning
- Resetting the Instrument between Patients
- Instrument Shutdown

Caution: *Read all warnings, cautions, and instructions provided with this instrument before using.*
Caution: *Read the instructions, warnings, and cautions provided with accessories before using. Specific instructions are for accessories not included in this manual.*
Warning: *Do not place or store items, except for the ArcScan instrument module, monitor, keyboard, mouse, and saline stand, weighing more than 4.5 kg (10 pounds) on the table.*

Instrument Set-up

The following procedure must be performed at the start of each day the instrument is to be used:

1. Inspect all cable and tube connections.

Warning: *To prevent injury due to unexpected mechanism motion,* ***DO NOT*** *insert hands into the interior of the scanner unless the power to the system is turned off.*

Notice: Do not *touch the end of the probe as this can damage the transducer.*

2. Ensure the probe is magnetically mounted to the probe holder. If not, reseat the probe.

Figure 27: Probe placement

3. Observe reservoir to ensure the fluid is filled to the upper ridge. Add distilled water to the reservoir, if necessary.

Notice: *Use distilled water only. Use of tap water or other water sources can cause damage to the Instrument and will void product warranty.*

Caution: *Spillage of fluids from the instrument or saline bag can result in a slip hazard that may result in operator or patient injury. If spillage of fluids occurs, dry surfaces immediately.*

Figure 28: Water levels for Filled and Emptied, respectively

4. Turn on the main power switch for the system (located beneath the table on the column).

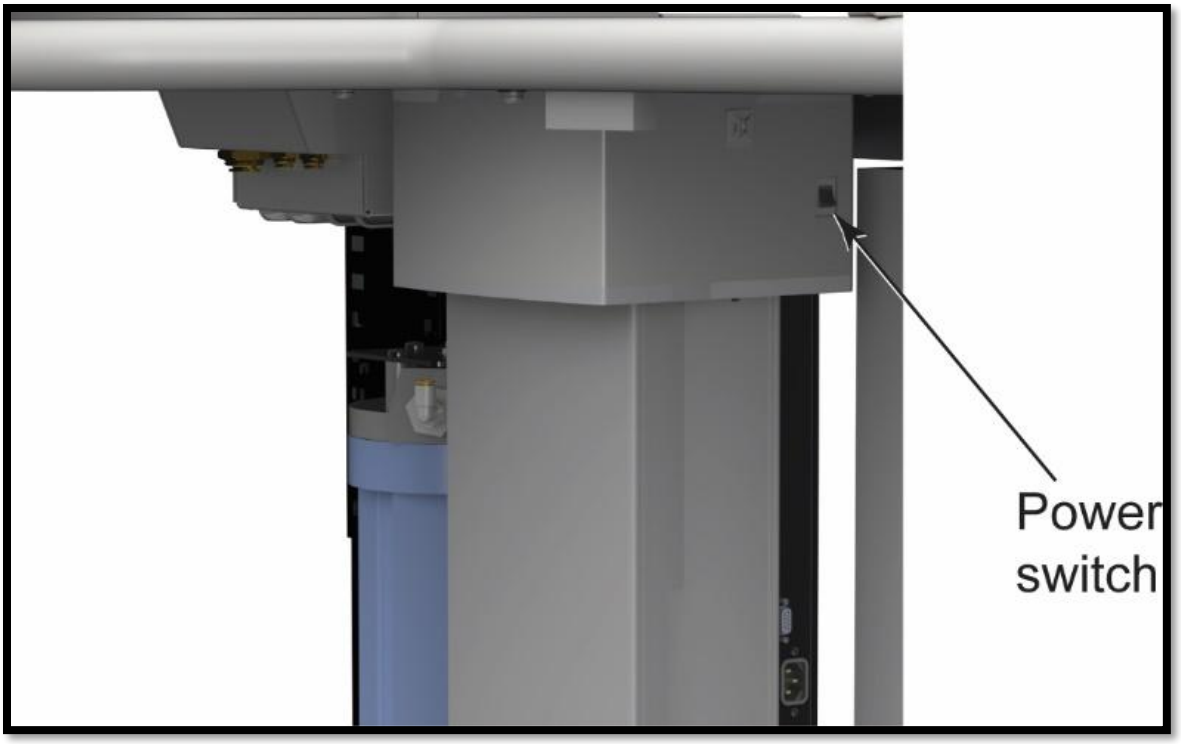


Figure 29: Main Power Switch

5. Turn on both the computer and monitor.

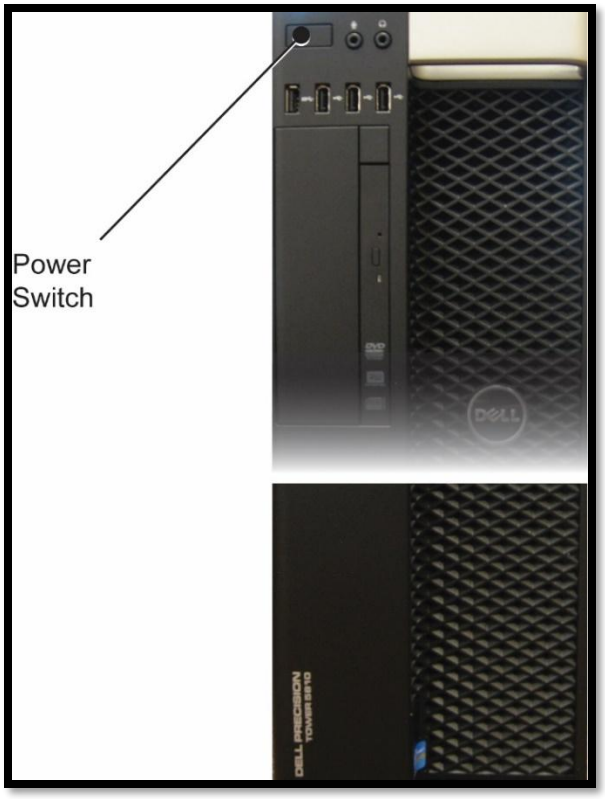


Figure 30: Computer Power Switch

6. Computer will display the Windows user logon. Enter the system password to access desktop.

   Password: **Insight 100**

***Caution: Do not** change the password. This password is used by ArcScan service personnel when performing routine maintenance or service.*

7. Launch the ArcScan Insight® 100 software by clicking on desktop icon.

   a. Initial system check box will appear on the Desktop. When all fields state “Ready” the software will open.

Figure 31: Software Initialization Box

8. Attach a saline bag to the instrument.
    a. Obtain a bag of saline.
    b. Remove and discard any packaging.
    c. Hang the saline bag from the saline pole.
    d. Obtain a saline administration set
    e. Remove and discard any packaging.
    f. Close the clamp on the saline administration set.
    g. Spike the saline bag, using aseptic techniques.
9. Fill the instrument module to half position.
    a. Click on the Water icon (bottom right-hand corner of the screen).
    b. Click the Half button to fill the scanner halfway. The instrument will fill to approximately 50%, and the motors will begin homing.

    Note: If a message appears indicating the instrument is not full enough to scan,

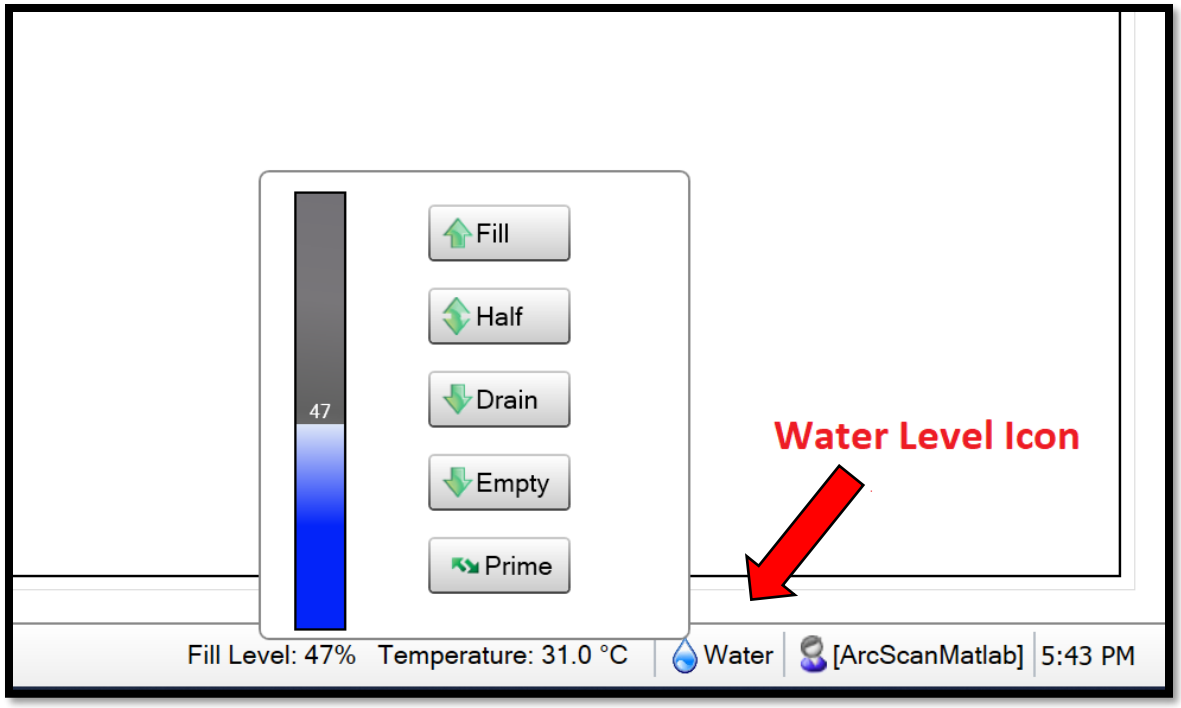


Figure 32: Scan Head filled to half

10. Clean the chin rest, face plate, and hand holds with cleaning solution.

Entering Patient Information

Following initial setup, an existing patient can be selected, or the information can be entered for a new patient. Once a patient is created the information is saved in the database and will appear in the Patient List. The Patient List is an alphabetical list of all patients in the system. This list can be sorted by last name, first name, date of birth, patient #, or exam date. When an existing patient is selected, scan sets saved for the patient will appear under the scan set list. Patient data can be modified by the operator.

Caution: *Failure to follow the steps below can result in patient demographic data being unintentionally modified.*

1. Access the Patient tab in the software (open by default when starting up the software, unless the DICOM plugin is installed).

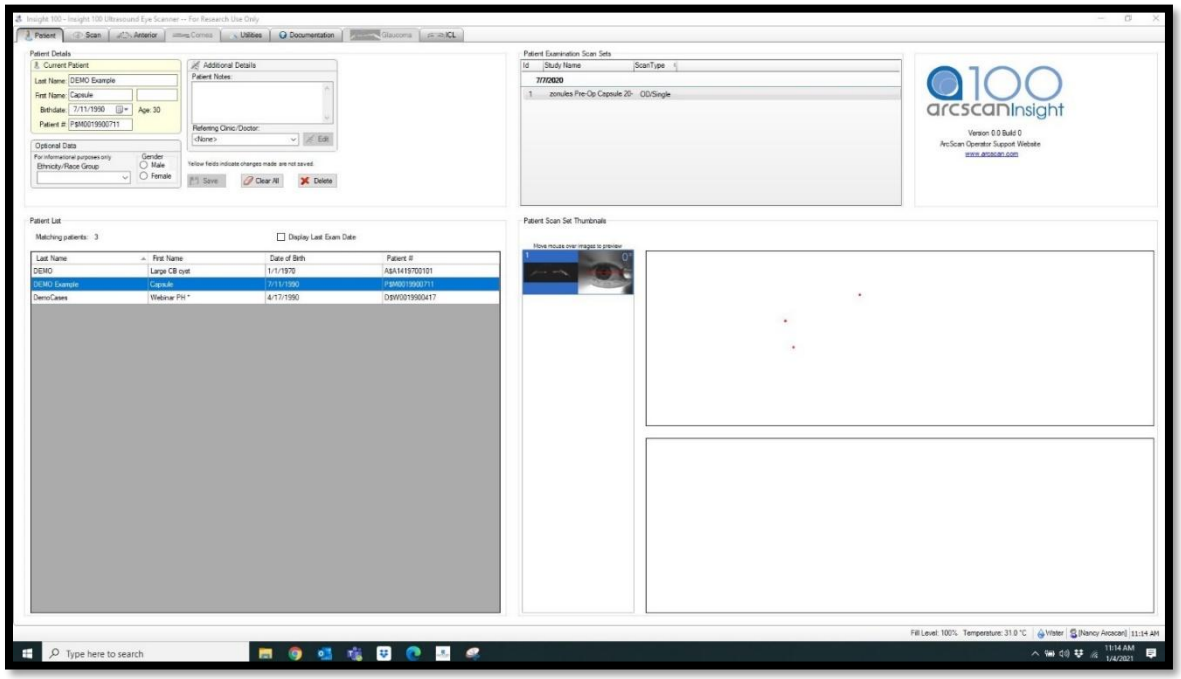


Figure 33: Patient Tab for Data Entry

2. To select an existing Patient:

    a. Click Clear All (below patient demographic fields) to reset the fields to blank.

    b. Locate the patient's name in the Patient List and click on the entry or type the patient's information into the fields.

    Note: Matching patient information will populate the Patient List when information is manually entered. Additional fields may require population if there are multiple entries with the same last name. Be careful not to modify existing patient data when using the search functionality.

3. To modify an existing patient's data:

    a. Select the patient per step 2 above.

    b. Delete the data from the selected field.

    c. Enter new data.

    d. Review yellow highlighted fields for intended changes.

e. Click save

4. To create a new patient:

   a. Click **Clear All** (below patient demographic fields) to reset the fields to blank.

   b. Enter the following details at a minimum:

      - Last name
      - First name
      - Birthdate

   c. Click **Save** to create a new patient entry once desired information is entered.

EyeSeal Placement

After the patient data has been entered attach the EyeSeal Disposable and accessories.

Warning: *The patient or operator should not lean on or use the table as a means of support.*
Notice: *Before examining a patient, ensure that the proper set up procedure (under "Instrument Set-up" has been performed.*
Caution: *Patients wearing contact lenses should remove them prior to any scan as their physical barrier can impact proper structure visualization by ultrasound.*
Caution: *Patients should remove makeup prior to any scan as the makeup may cause irritation to the eye when exposed to saline.*
Warning: Do not *reuse accessories labeled "disposable" or "single use only".*
Notice*: Ensure that there is no leakage of the EyeSeal Disposable. If leakage is noted prior to placing the patient on the EyeSeal disposable, immediately reset the distilled water level to "Half". Attach a new EyeSeal disposable according to the instructions for use.*

Install a new sterile EyeSeal disposable by following the instructions below.

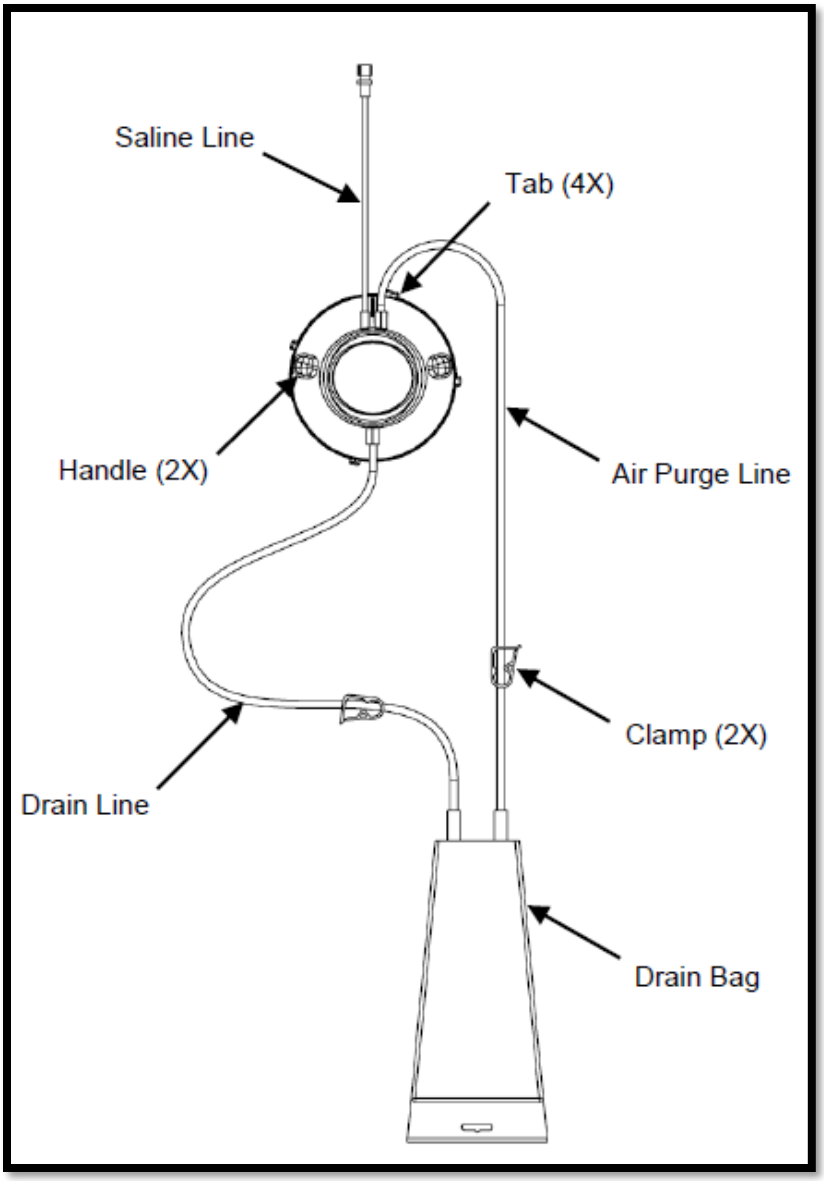


Figure 34: EyeSeal Disposable

11. Remove the EyeSeal Disposable from the sterile packaging.
12. Remove the protective cap and paper tabs from tubing and discard.
13. Locate the four tabs on the perimeter of the EyeSeal. Hold the EyeSeal so the largest tab and two tubes are oriented upward.
14. Align the tabs with the grooves in the receptacle on the ArcScan Insight® 100 instrument.

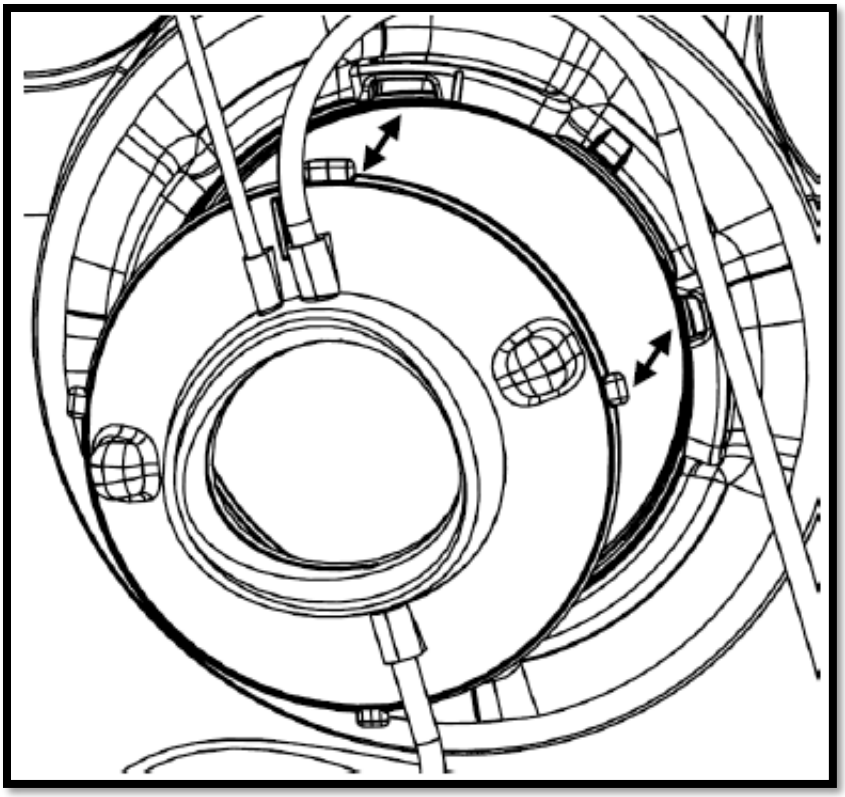


Figure 35: EyeSeal Placement

15. Place the EyeSeal into the receptacle. Insert all tabs into the grooves.
16. Grip the handles located on both sides of the EyeSeal Disposable.

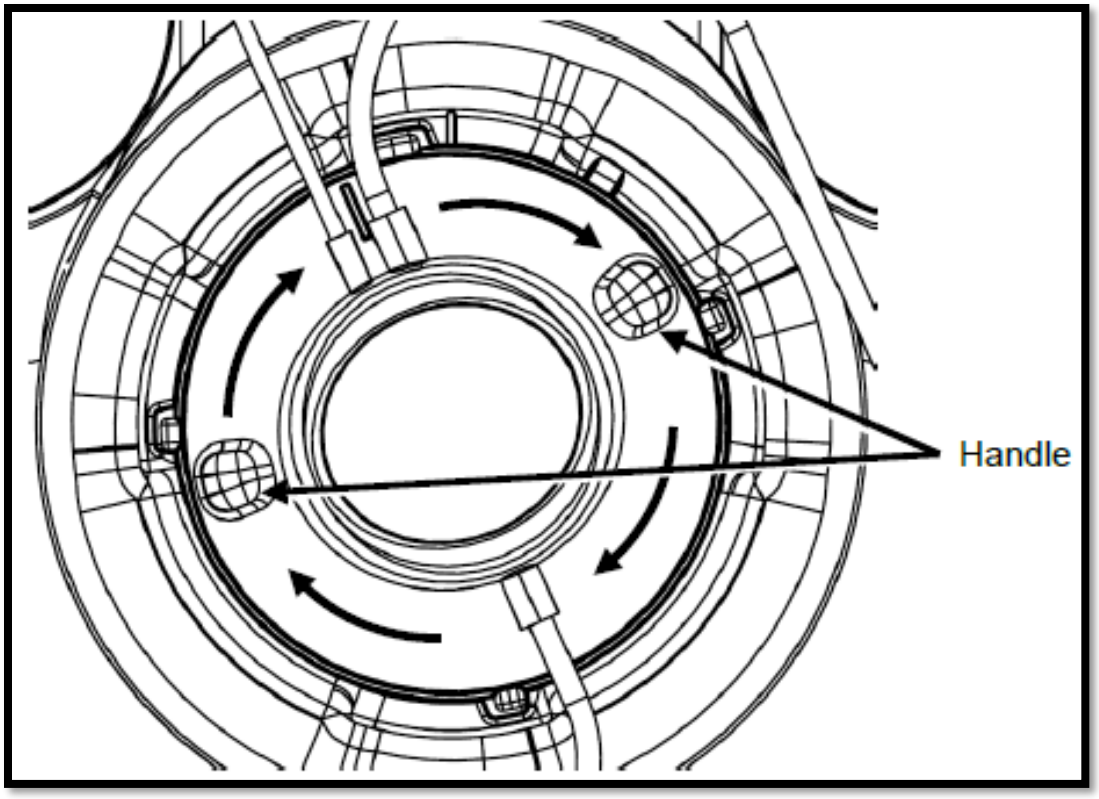


Figure 36: Eyeseal Installation

Note: Do not use the inner goggle ring to turn the EyeSeal.

17. Rotate the EyeSeal Disposable clockwise until the upper and lower ridges are aligned and the EyeSeal is tightened.

18. Click the water button in the lower right corner of the Insight® 100 application.

Figure 37: EyeSeal in place

19. Click Fill. The Scan head will fill, and the water level menu will show approximately 100.

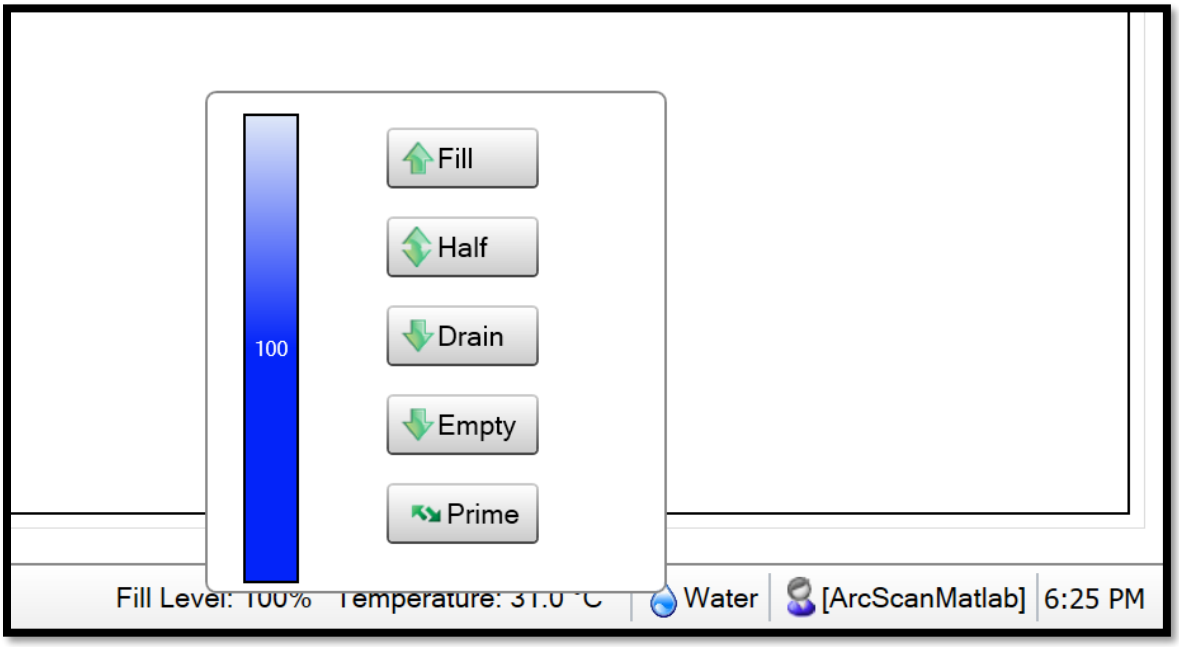


Figure 38: Full Water Level

20. Connect the saline administration set to the EyeSeal Disposable line. Hand-tighten the connection.

21. Close the white clamp on the EyeSeal drain line.

22. Ensure the blue clamp on the air purge line is open.

Patient Setup and Scanning

Once the patient's information is entered into the database, and the EyeSeal Disposable is in place, the patient can be brought in for scanning. A chair or stool without wheels is recommended to prevent the patient from rolling away from the instrument during scanning. The patient should employ good posture, look straight ahead and not lean into the instrument. The patient may hold on to the handles below the chin rest for stability. The EyeSeal should fit as a swim goggle and be situated securely within the orbital rim. The patient will need a few seconds for the eye to adjust to the temperature of the saline. Achieving a watertight seal around the patient's eye requires the careful attention of the operator. The chair and table height may be adjusted to ensure that the top and bottom of the EyeSeal Disposable are both being compressed equally ensuring that the EyeSeal is in contact surrounding the patient's eye.

Not all patients fit on the EyeSeal disposable in the same way, and a few patients will be unable to form a complete seal. In these situations, ArcScan recommends placing a bib or towel to catch any leaking saline, so the patient's clothing does not get wet. It may be helpful to ask patient to cover their other eye, or use a disposable patch, to aid in comfort while one eye is being scanned.

If the patient has an IOL implant, automatic scanning will not work. Please see the Manual Scanning section for instructions on imaging these patients.

Patient Set-up

1. Introduce the patient to the instrument and explain the scanning process.
2. Adjust chin rest to lowest position by using control knob.
3. Instruct the patient to sit up straight and move close to the Insight® 100.
4. Adjust the table high for the patient.
5. Instruct the patient to place the right or left eye against the EyeSeal.
6. Ensure that the EyeSeal is positioned inside the bridge of the nose and below the brow.

Figure 39: Patient Positioning

7. Visually inspect the interface between the patient and EyeSeal Disposable for obvious gaps or areas that may leak.

8. Rotate the knob located on top of the right support rod to raise chinrest to provide comfortable support.

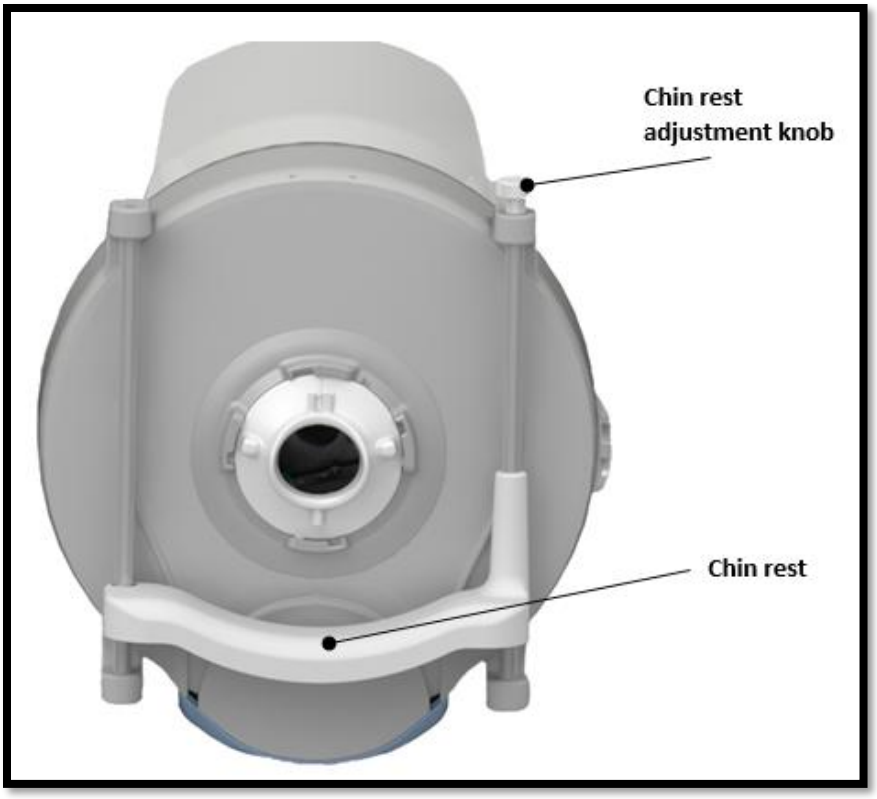


Figure 40: Chin Rest and Adjustment Knob

9. Instruct the patient to look straight ahead.

10. Ensure the patient's eye is roughly centered within the diamond on the video screen.

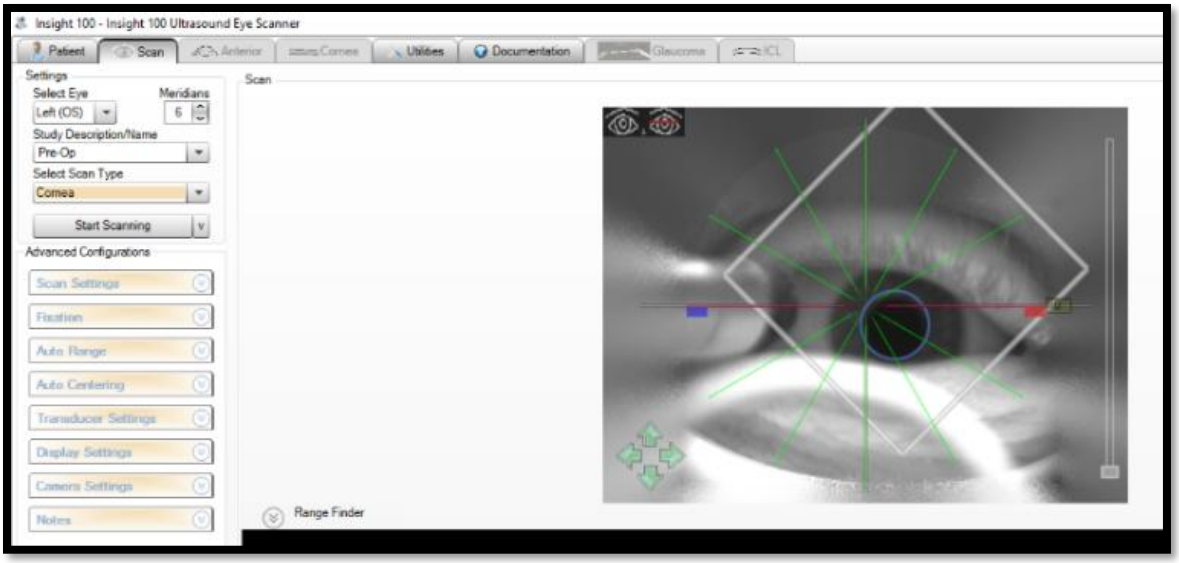


Figure 41: Eye Centered

11. If necessary, reposition patient by having them sit back and return to steps 3.

12. Instruct the patient to stay in place, and not move back off the seal until told to do so after scanning is completed.

13. Instruct the patient to blink normally until scanning begins.

    Note: If the patient's eye lids are taped or open with speculum to enable better imaging, the patient may move the eye around while the saline is being instilled. Advise the patient that the room temperature saline may feel cold, but to allow a few seconds for the eye to acclimate.

14. Fill the EyeSeal Disposable with saline:

    a. Open the clamp on the saline administration set to fill the EyeSeal Disposable with saline.

    b. Observe the fill level on the monitor, until the EyeSeal appears to be full.

    c. Close the clamp on the Administration set when the saline in the air purge line is about one inch above where it exits the EyeSeal Disposable.

    d. Inspect the EyeSeal Disposable and patient interface for any leaks.

    e. If leaks are present, try adjusting the patient's position slightly while remaining in contact with the EyeSeal. If leaks persist, drain the saline from the EyeSeal Disposable by opening the white clamp drain line on the EyeSeal and return to step 3.

15. Allow several seconds for the patient's eye to acclimate to the saline temperature.

Scanning

16. In the upper left corner of the scan page, select eye (OS or OD), pre-op or post-op, and the desired scan type.

    Note: If the motors are still homing, these settings cannot be changed. The Utilities tab will be highlighted yellow while the motors are homing. Wait for motor homing to complete.

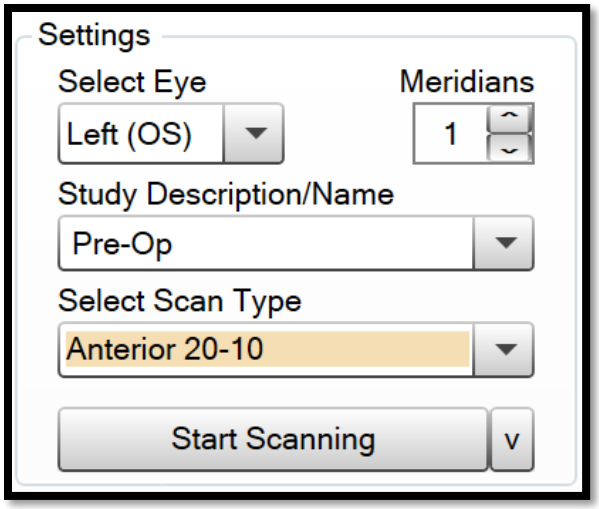


Figure 42: Scan Settings

17. Modify the number of meridians or the scan area if desired per Available Scan Modifications.

18. If bubbles are observed on the patient's eyelashes, instruct patient to blink until they dislodge.

19. Increase brightness or gain of the camera image under the dropdown Advanced Settings/Camera Settings on the left side of the Scan page until the eye can be clearly visualized.

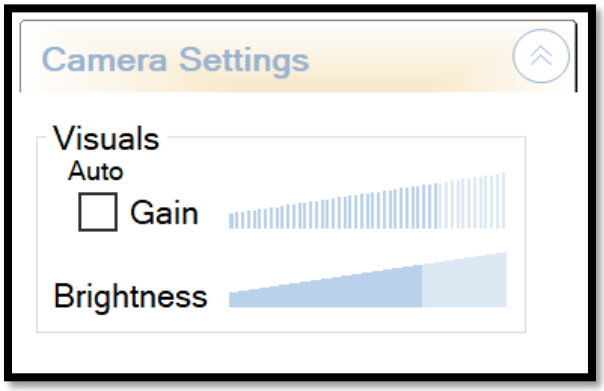


Figure 43: Brightness and Gain settings under Camera Options

20. Double click on the patient's pupil in the camera image to roughly center the instrument.

    Note: The fixation light may not be visible to the patient until the instrument is centered.

21. Observe the pupil/iris tracker in the camera image. The indicator will begin to track the pupil or iris.

Note: If the indicator does not center on the pupil or iris, the scan will not succeed. Adjusting the gain can help the software distinguish the pupil/iris from the sclera.

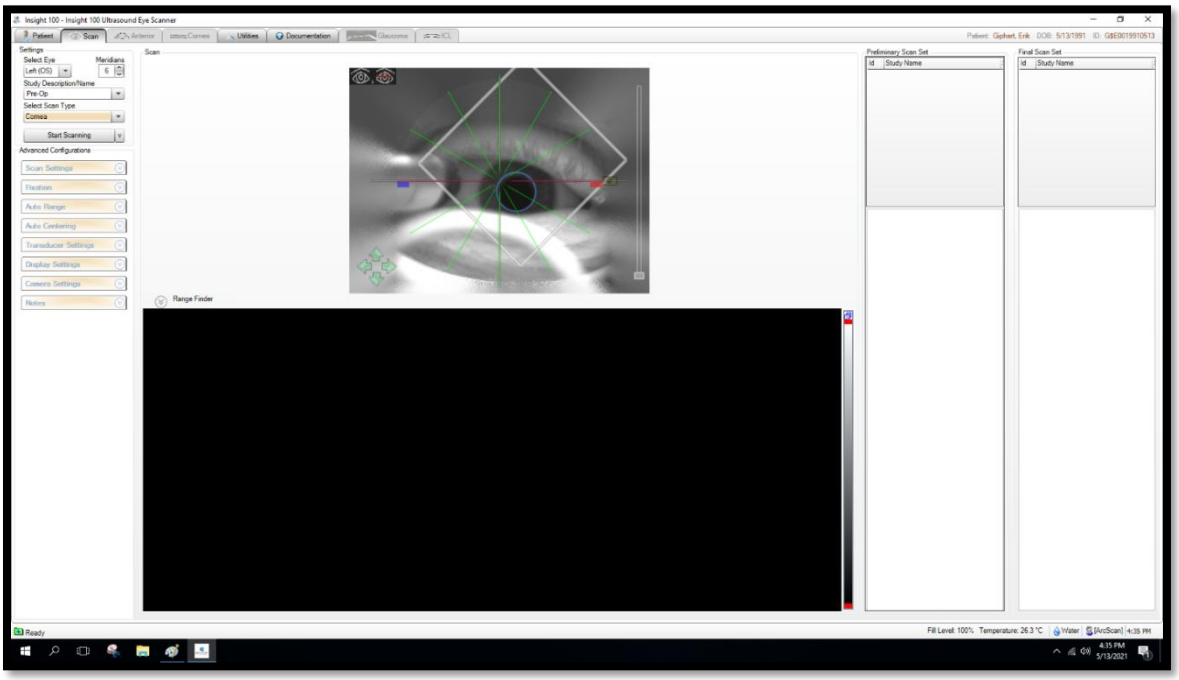


Figure 44: Pupil indicator centered

22. Instruct the patient to fixate on the light, hold still, and not blink.

23. Observe the patient's eye in the camera image. Wait for the pupil/iris indicator to settle in the correct location.

24. Click Scan. The pupil/iris indicator will turn green for the duration of scanning and will resume tracking the pupil/iris once scanning is complete.

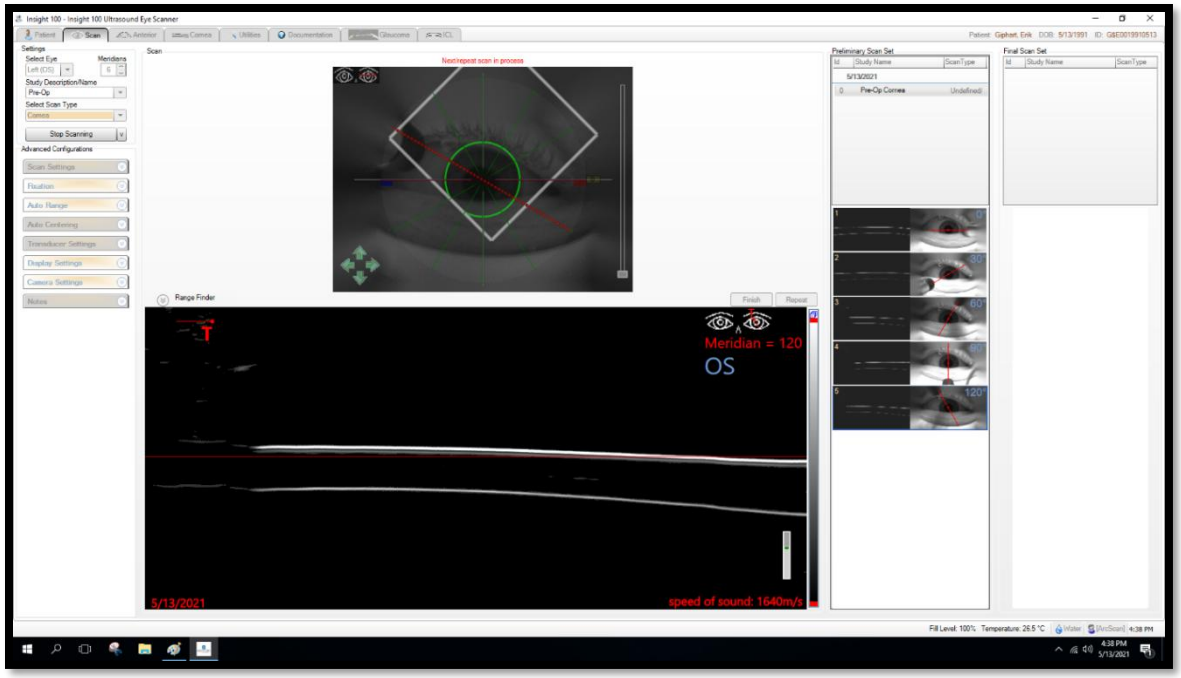


Figure 45: Instrument acquiring Cornea scans

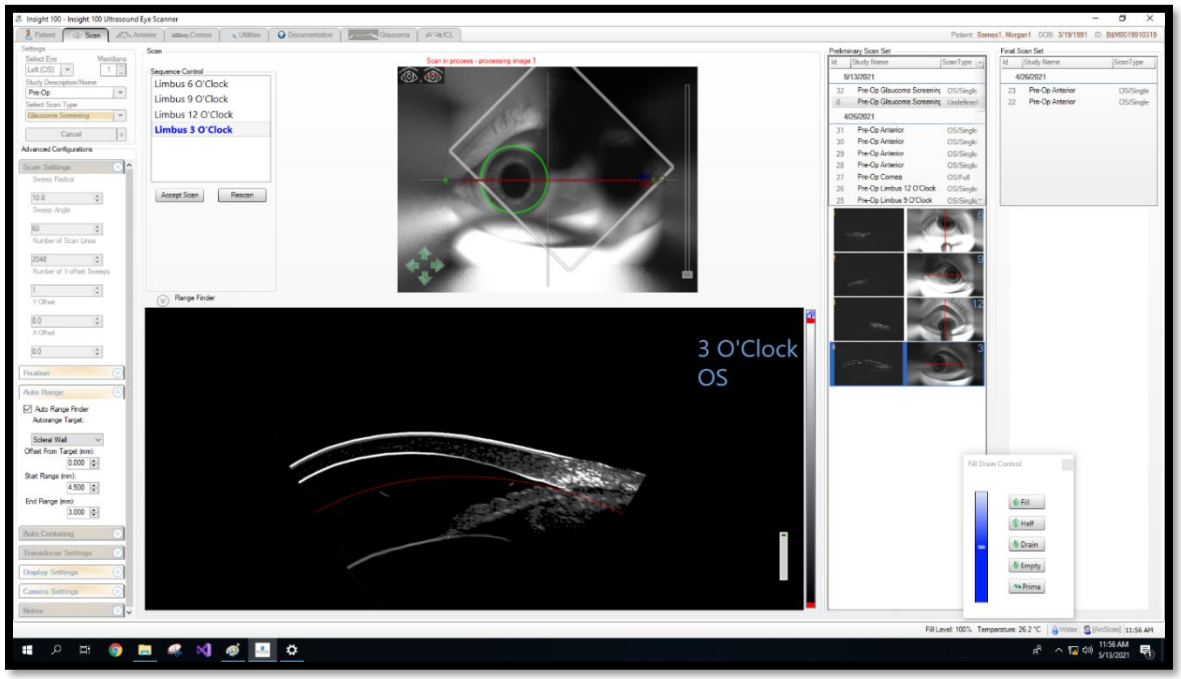


Figure 46: Instrument acquiring 3 O'Clock Limbus scan

Note: If one of the images in a scan does not come out as desired, right click on the thumbnail of the image in the Preliminary Scan set list and click rescan. Rescanning is only available for images that were acquired during the current scan set. New scan sessions are started when the operator changes the selected

eye, the operator selects a new patient, or the operator has not clicked the scan button in the last 10 minutes.

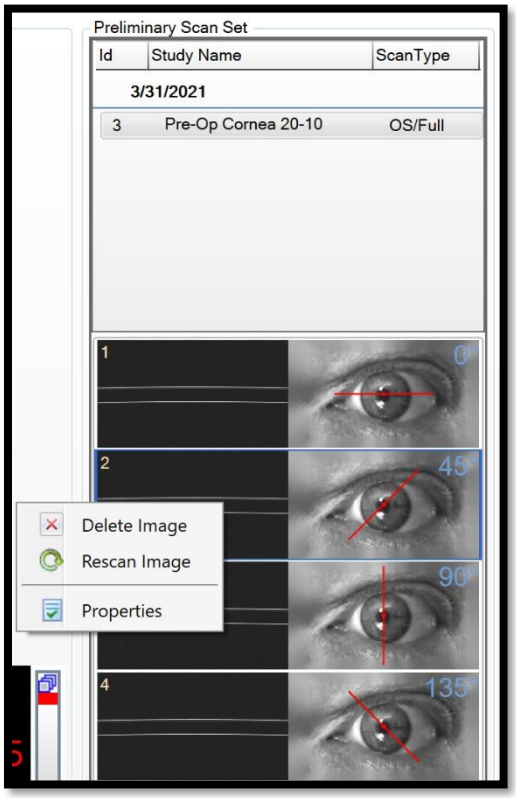


Figure 47: Rescan option

Note: If the patient has a deeper set eye, the instrument may not be able to focus deep enough to reach the capsule surface. This is a physical limitation of the instrument, and the following message will appear. Scanning will still be performed at this depth.

Figure 48: Maximum Z depth message

25. One or more scan types may be completed while the patient is positioned in the EyeSeal Disposable. It is not necessary for the patient to sit back between scans.

26. When scanning is completed, drain the EyeSeal:

    a. Open white clamp drain line of EyeSeal.

    b. Saline will flow out of EyeSeal into drain bag. This can be observed on video monitor.

    c. When saline is drained, patient may sit back.

27. The patient's other eye may be scanned at this time by returning to Patient Set-up step 5.

28. Dismiss the patient once all scans have been captured, and the EyeSeal is drained.

Manual Scanning

If automatic scanning fails, or the pupil/iris indicator is unable to locate the correct anatomy, manual scanning can always be used to scan any patient. Manual scanning involves setting the X, Y, and Z positions of the instrument. Centering sets the X and Y positions, while Range Finding sets the Z position, or depth, of the probe. All resulting scans can be reviewed normally, there is no difference between B-Scans captured using automatic or manual scanning.

1. Set up the patient per Patient Set-up.

2. Set the scan parameters.

   Note: The scan type must be selected prior to setting the manual positions, as the default settings are reloaded every time a new scan type is selected.

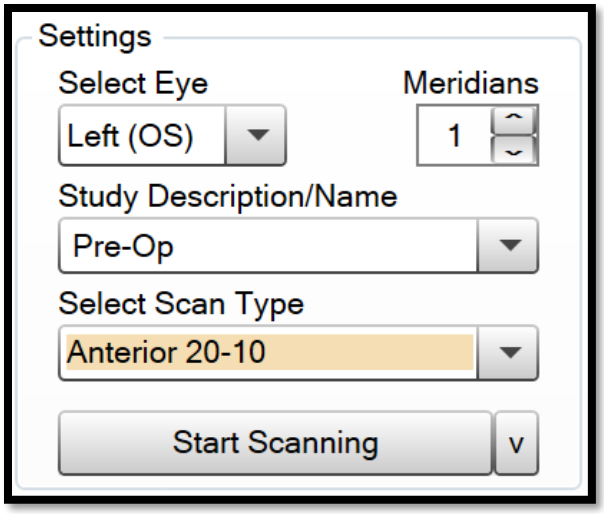


Figure 49: Scan Settings

3. Instruct the patient to look at the fixation light.
4. Double click on the desired anatomy (e.g. Pupil or limbus) to provide an initial centering.
5. Expand the Auto Range dropdown on the Advanced Configuration section and uncheck the “Auto Range Finder” box.

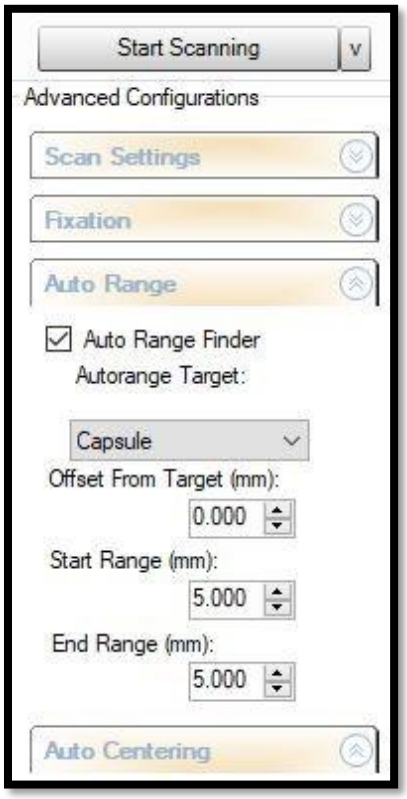


Figure 50: Range Finder Options

6. Expand the Range Finder window (below the camera image).

Figure 51: Range Finder dropdown

The full A-Scan is shown on the left-hand side of the Range Finder Window and only the selected acquisition portion is shown in the rest of the window. Only the area within approximately +/- 5mm is focused enough to generate a clean image. This area is shown in black on the left-hand side of the Range Finder window and can be varied by sliding the yellow indicators. The A-scan in the main window is what is acquired and used in the creation of a B-Scan.

Surfaces appear as horizontal green spikes in the A-Scan. The membrane of the eye seal appears as the top bright reflector. The Cornea appears as two reflections, the capsule surface is one, and the limbus is a collection of many reflections.

By default, the probe sits off to one side between scans. This can be seen on the arc at the top of the Range Finder window.

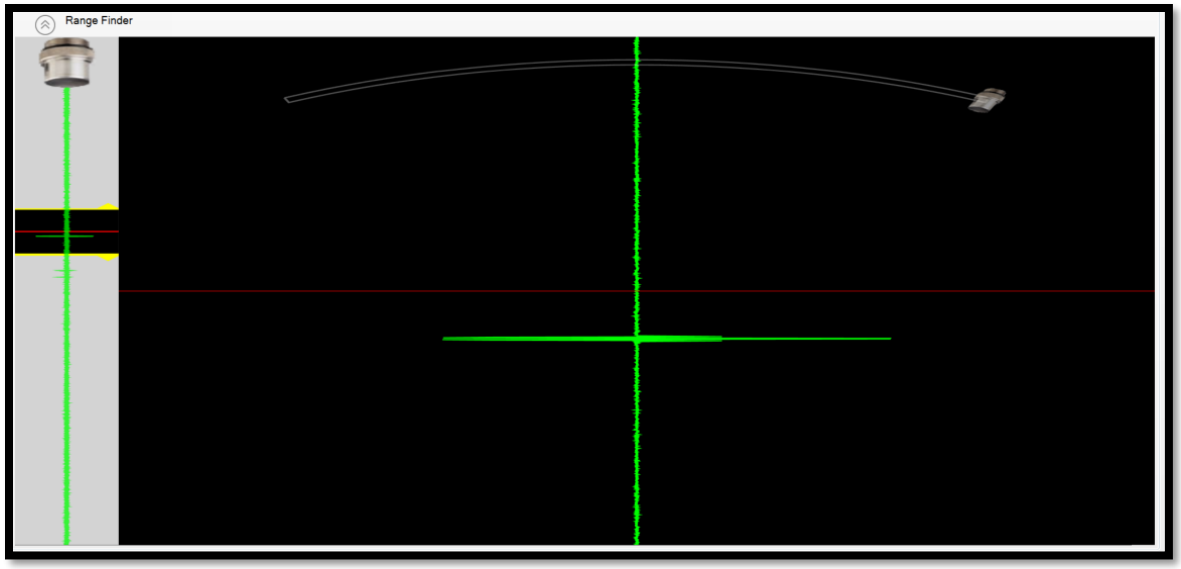


Figure 52: Range Finder window, probe in default position, membrane reflection visible

7. Move the probe closer to the center but offset by about 5-10 degrees so the patient can still see the fixation light.

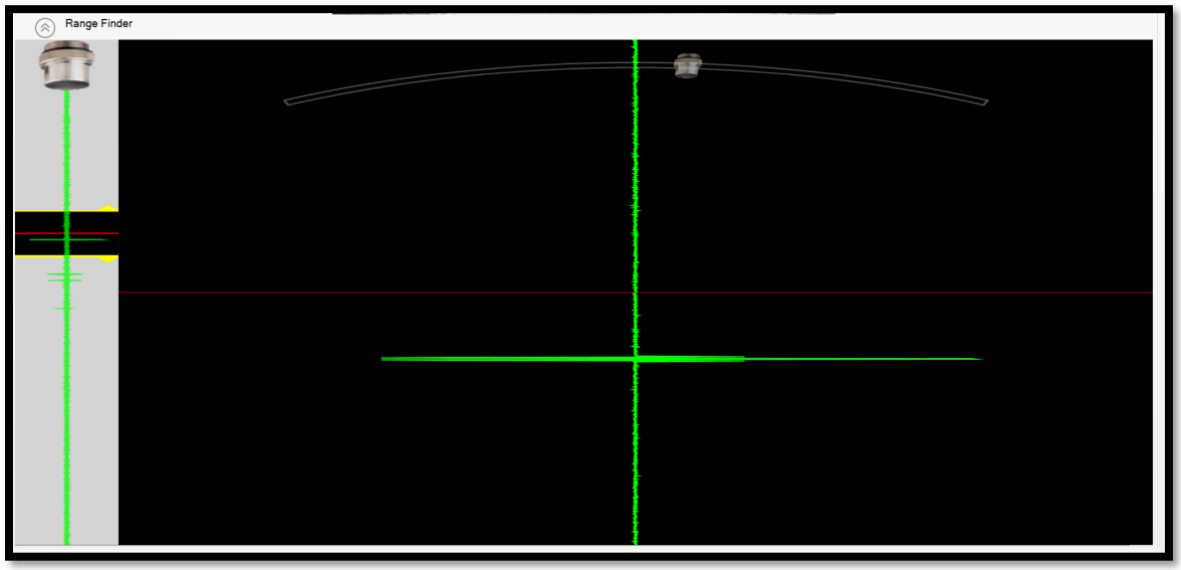


Figure 53: Probe offset 5-10 degrees

Cornea and capsule surfaces are only visible if properly centered. If no surfaces are visible in either the A-Scan or the main Range Finder window the instrument is likely uncentered or the patient is no longer looking at the fixation light. Recenter by following steps 3 and 4.

The red line in the main Range Finder window is the focus depth of the probe. The Cornea, Capsule, or Scleral Wall may be visible in the full A-Scan display, but not in the main Range Finder window.

The probe depth can be set by following one of the options below.

8. If the desired surface is visible, double click on the surface in the main Range Finder window.

9. If the desired surface is not visible, click and drag on the probe icon in the left-hand display to move the probe deeper until the surface is visible in the main Range Finder window.

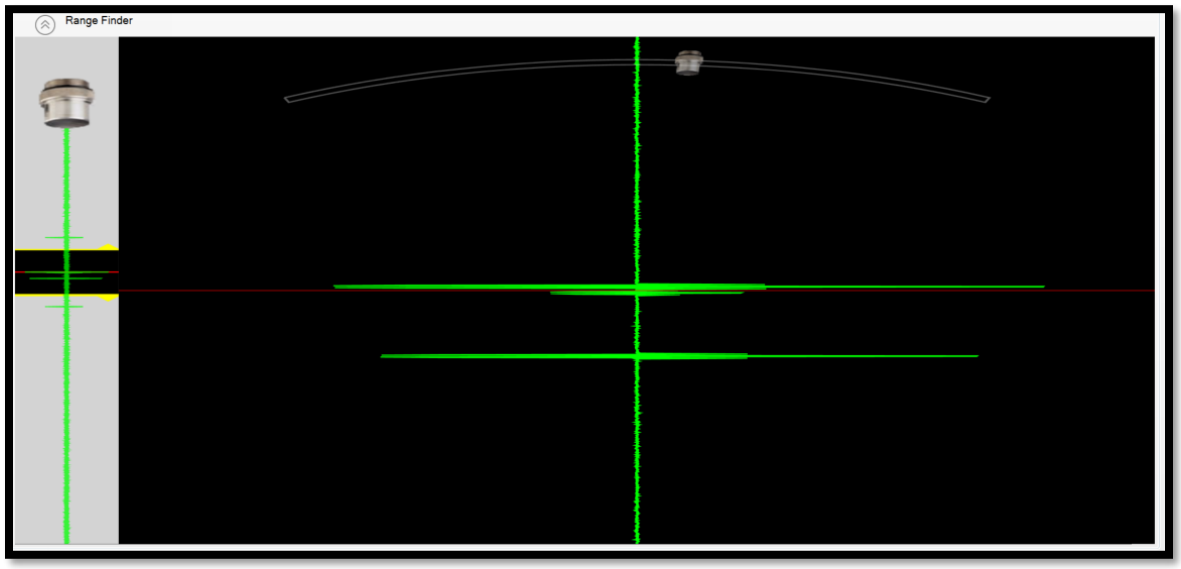


Figure 54: Probe focused on the Epithelium surface of the Cornea

To manually target the anatomy for each scan type, place the red line in the following locations:

10. **Cornea Scans:** Set the red line on top of the epithelium surface, the top surface shown in the display.

11. **Anterior, Pre-Op ICL, Glaucoma, and Capsule Scans:** Set the red line directly on the capsule surface. If the patient has an IOL implant, two reflectors will be visible in place of the one capsule surface. Place the red line on top of the anterior (front) surface.

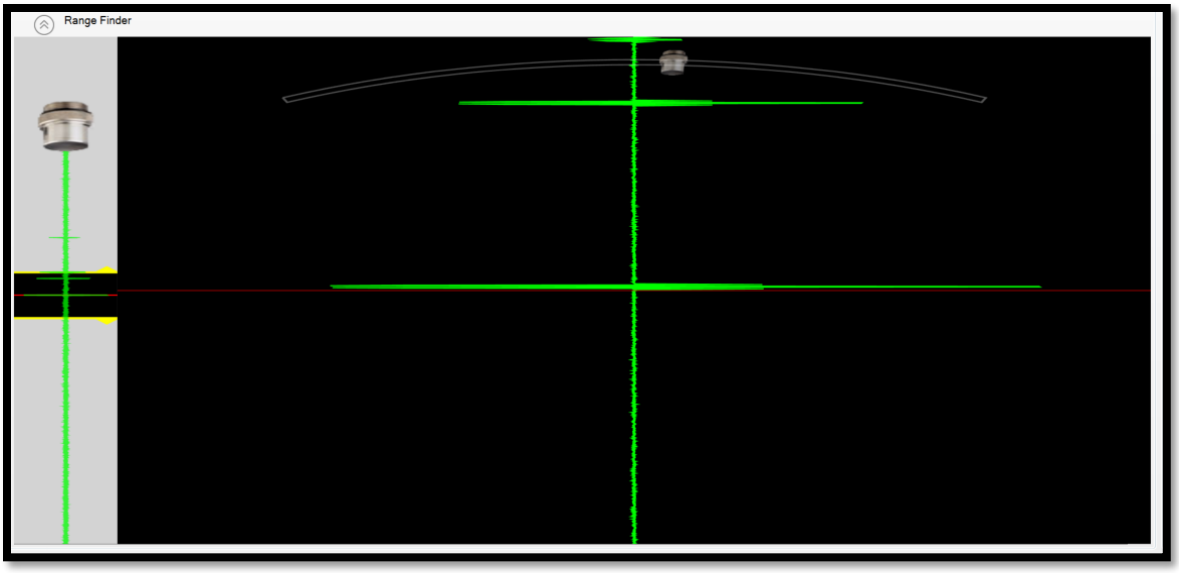


Figure 55: Probe focused on the capsule surface

12. **Post-Op ICL:** Instead of 1 capsule surface, three reflections will be visible from the anterior and posterior ICL surfaces, as well as the anterior capsule. Set the red line on the capsule surface.

13. **Limbus Scans:** None of the usual surfaces are visible, and the scleral wall appears as a group of many reflectors. Place the red line at the top of this group, so all green spikes appear below the line.

    Note: If the following message appears in the upper left corner, the focus line cannot be set any deeper in the patient's eye than it is already. This is a physical limitation of the instrument. The warning can be ignored, and a scan can still be captured at this position.

Figure 56: Z position warning

14. Once the depth is set, instruct the patient to look at the fixation light and open their eye wide.
15. Double click in the camera image to center the instrument.
16. Click Scan.

Resetting the Instrument Between Patients

Follow the procedure below to prepare the instrument for a new patient scan.

1. Set the water level to half.
2. Disconnect the saline administration set from the saline line on the EyeSeal Disposable.
3. Close both clips to prevent used saline from inadvertently draining from the drain bag.
4. Grip the handles located on both sides of the disposable.
5. Rotate the EyeSeal Disposable counterclockwise until it can be removed through recessed areas.
6. Gently pull the EyeSeal Disposable out of the receptacle.
7. Discard the used EyeSeal Disposable according to clinic or hospital policies.
8. Clean all surfaces with cleaning solution.
9. Attach a new sterile EyeSeal Disposable to the instrument and set the water level to Full.
10. Go to Entering Patient Information section.

Instrument Shutdown

If scanning is finished for the day, follow these steps to shut down the instrument.

1. Empty water from unit and remove the EyeSeal Disposable. Leave the scanner open overnight.
2. Toggle the power switch on the instrument column to off.
3. Clean all surfaces with cleaning solution.

Instrument Upkeep

If scanning will not be performed for a period longer than one week, follow these steps at least once per week to exercise the system:

1. Start system as per “Instrument Set-Up" section of this User Manual.
2. Place supplied white marble calibration fixture into EyeSeal Mount and fill instrument by clicking “Fill” on water control console.
3. Allow the instrument to sit in full water state for approximately 5-10 minutes.
4. Empty instrument by clicking “Empty” on water control console.
5. Remove and safely store white marble calibration fixture.
6. Shut down instrument as per “Instrument Shutdown” section of this User Manual.

Note: These steps are not a substitute for bi-annual maintenance provided by ArcScan.

Chapter 4: Image Analysis

Post processing refers to the utilization of scan data for:

- Finalizing Scan sets
- Annotating Scan sets
- Report Generation

Finalizing Scan sets

After each scan, the software automatically converts the ultrasound signals into an image and displays it on the screen.

1. Inspect the scans and select one or more for detailed evaluation.
2. Drag the scans from the Preliminary to the Final Scan Set list on the Scan page.

On the Scan page, the following options are available for **Preliminary** and **Final Scan Sets**:

Rescanning a Scanned Image	The operator may right-click on an image and select **Rescan Image**. Once clicked, the instrument immediately rescans this one image.
Deleting a Scan Set	The operator can delete a scan set by right clicking and selecting the menu item.
Deleting an Image	The operator can delete a single image from the scan set by right clicking on an image and selecting the menu item.
Deleting All Preliminary Scan Sets	The operator can delete all preliminary scans by right-clicking on a preliminary scan set and selecting the **Delete All** preliminary scan set menu item.
Rating Final Scan Sets	The operator can rate a scan set from one to five stars by right clicking on the final scan set and selecting the menu item.
Combining Scan Sets	An image can be dragged from a preliminary scan set to a final scan set, given the scans are of the same type and from the same scan session.
Viewing an Image	Selecting an image allows the operator to view the image. **Note:** This function is not available when the range finder is open. See Advanced instructions.

Annotating Scans and Report Generation

1. Select the patient
2. Select the desired scan to view from the Final Scan Sets box on the scan page by:

a. Double clicking on the desired scan set

b. Single click on the desired scan set and use the tab controls at the top of the application, to access the analysis pages.

3. Use software tools to measure the features of interest on the selected scan images.

   Note: The Anterior and Cornea tabs are available by default, and specialized scans can be viewed in the tabs of respective plugins.

4. The option to generate a PDF report is available on all analysis pages.

5. The following image control options are available when viewing images:

Adjusting Brightness and Contrast	The operator may change the brightness and contrast of the B-scan image by holding the right mouse button and moving the mouse as follows: If evaluating an older scan, right-click the mouse button and select Undo Color Balance. *To decrease brightness*— move to the left *To increase brightness*— move to the right *To decrease contrast*— move up *To increase contrast*— move down
Zooming	Scrolling the mouse wheel in and out will adjust the zoon level. **Note:** Zooming does not work on the **Scan Page**.
Eye Marker ( **)**	The **Eye Marker** allows to operator to quickly identify which eye was scanned. The **Eye Marker** can be moved by right clicking on it and dragging it out of the way.
Display Focus Line	Displays lines marking the focus plane of the transducer.
Color Scale	Allows operator to change between a linear and a logarithmic color scale
Mouse Pointer ( **)**	Allows the operator to select or move points on existing annotations. Annotations have a right-click menu that allows the operator to delete them.

Arbitrary Distance Measurement ( **)**	Allows the operator to measure distance between two arbitrary points.
Vertical Distance Measurement ( **)**	Allows the operator to measure the distance between two points with the same X coordinate.
Horizontal Distance Measurement ( **)**	Allows the operator to measure distance between two points with the same Y coordinate.
Angle Measurement ( **)**	Allows the operator to measure an angle.
Arc Measurement ( **)**	Allows the operator to measure the radius of an arc.
Text Tool	Allows the operator to annotate the image with text.
Pointer	Allows the operator to annotate the image with a pointer.
Show/Hide Button	Allows the operator to hide all annotations.
Save Image Button	Saves a .jpg file image.
Print	Prints the report on a network attached printer (not supplied by ArcScan).

For more detailed post-processing instructions for the different scan types, please refer to appropriate Supplement.

Chapter 5: Data Management

This chapter includes information about:

- Exporting patient data, and exporting anonymized patient data
- Importing patient data
- Backing up patient data

Caution: *If backing up patient data to a clinic server, the device should only be connected to a firewall protected network.*
Notice*: Use caution when sending non-anonymized patient data to another clinic.*
Notice*: If sending patient information of any kind to ArcScan Inc, please use the anonymized options only.*

Exporting patient data

In some cases, it is useful to share data between clinics. Scan set and Patient files can be exported and imported into the Insight® 100 application. To comply with regulations around patient privacy, the Insight® 100 software includes the ability to anonymously export patient data, as well as individual scan sets. When these options are used, all patient demographic data is scrubbed, while the clinical data is unaltered.

To export a scan set, either normally or anonymized, follow these steps:

1. On the Scan page, right click on the scan set to export.
2. Select either “Export Scan set…” or “Export Scan set, Anonymized…”. The anonymized option will scrub patient data.
3. A save file window will appear where a name for the exported file can be chosen, and a folder location selected. The resulting file is a “.Scanset” file.

   Note: Multiple scan sets can be exported by selecting a scan set, holding down the shift key, and selecting a second scan set. This will select a range of scan sets to export, which will be given a standardized name in the export folder.

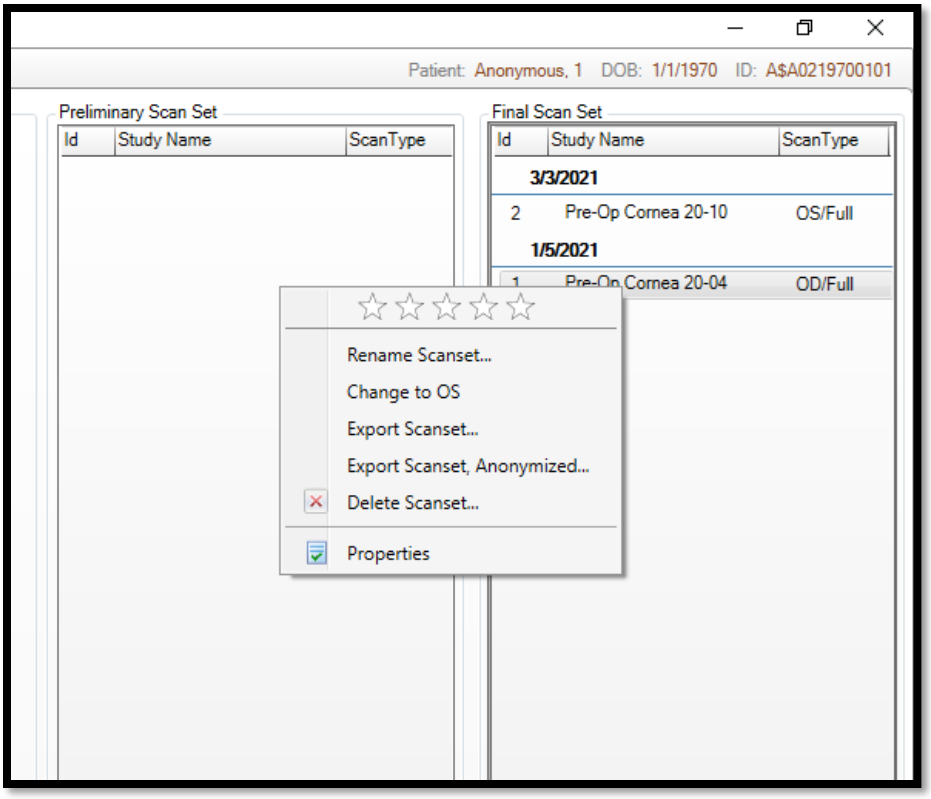


Figure 57: Scan set Export

To export an entire patient file, and all associated scan sets, follow these steps:

1. On the Patient page, select a patient and right click.
2. Select either “Export Selected Patient…” or “Export Selected Patient, Anonymized…”. The anonymized option will scrub patient data.
3. A save file window will appear where a name for the exported file can be chosen, and a folder location selected. The resulting file is a “.Patient” file.

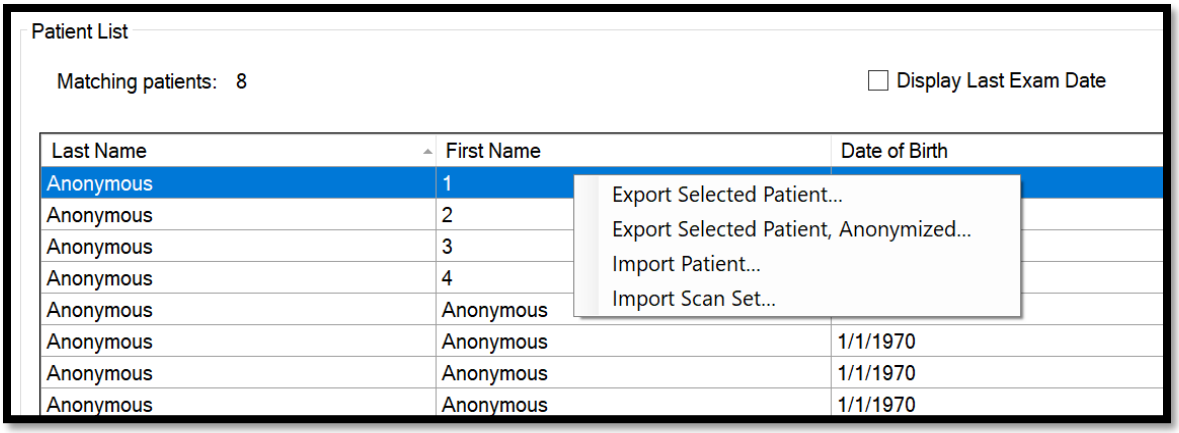


Figure 58: Patient Export Options

Importing patient data

Patient and Scan set files can be imported into the Insight® 100 software. This is used when reviewing patient data from another clinic or backing up patient information. ".Patient" and ".Scanset" files can be imported in the same manner, and anonymized patient information will be loaded using default identifiers.

To import patient data:

1. On the Patient page, right click anywhere in the Patient List. A Patient does not need to be selected.

2. Select "Import Patient…" to import ".Patient" files.

3. Select "Import Scan Set…" to import ".Scanset" files.

A file import window will open, with the option to select Patient or Scan set files. Only one type of file may be selected, depending on the choice made in step 1. Multiple files may be selected and imported at one time.

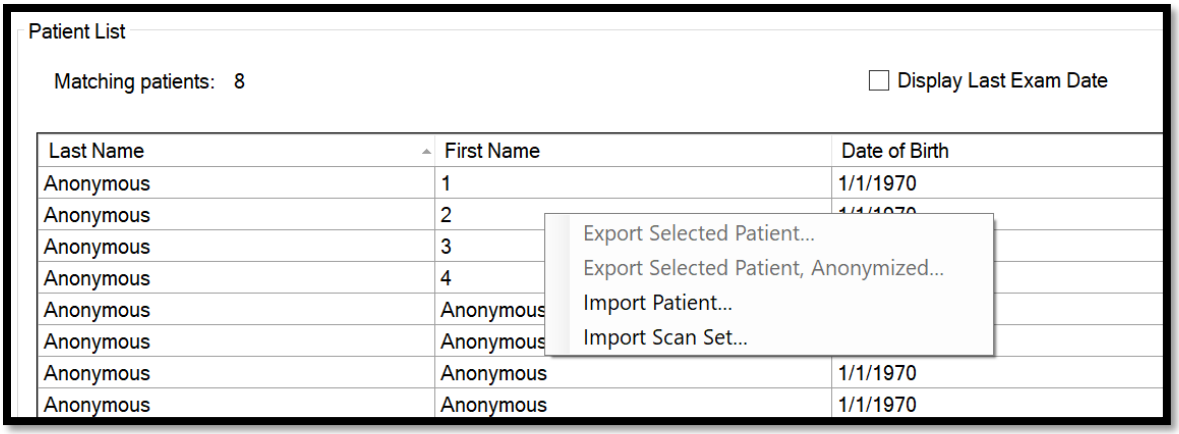


Figure 59: Patient and Scan set import options

4. Patient data will be imported according to the following parameters:

    a. If an entry exists in the database for an imported patient, the user will be prompted that these entries will be merged. This applies to all imported patient files and all duplicate entries. If cancelled, no files will be imported.

    b. Anonymized patient data will always be saved to a new anonymized patient in the database. This will be done for each anonymized patient file selected.

    c. Anonymized patient files will be given an entry with the name “Anonymous, Anonymous”, and the birthday “1/1/1970”. The ID will be incremented for each new anonymized entry in the database.

5. Scan set data will be imported according to the following parameters:

    d. Each scan set file is associated with a patient, unless the scan set is anonymized. The importer will look for a matching patient entry. If a match is found, the scan set will be saved to that entry. It will create a new patient if a match is not found.

    e. For each anonymized scan set file, a new anonymized patient will be created.

Backing up database

To prevent the loss of patient data, the database should be updated at least every 3-6 months, depending on usage. To back up the database, open the Insight® 100 software and navigate to “Utilities/Data Management”.

1. To create a backup of the database, click on Backup Database. A save file window will appear where a name for the exported file can be chosen, and a folder location selected. The resulting file is a ".A3Backup" file.

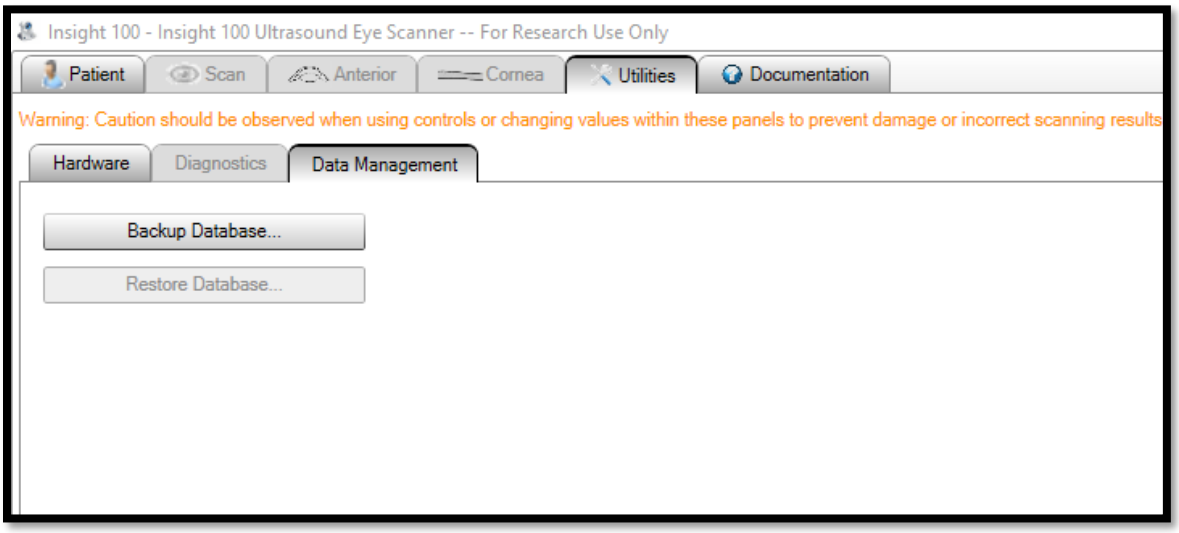


Figure 60: Database Backup

The option to restore the database is unavailable to the standard user. To restore the database, the user must be logged in as a Supervisor.

Note: Restoring the database from a ".A3Backup" file will overwrite the existing database. Export all Patient data which has not been backed up before using this option.

Chapter 6: Troubleshooting

This chapter includes information about:

- Correcting malfunctions
- Responding to error messages
- When to contact ArcScan Service

Symptom	Recommended Action
System fails to power up	Power cables disconnected – Ensure that all four power cables are connected to the ArcScan Insight® 100 and the main power cable is connected to a wall socket, then power up the system. Ensure the module cables are firmly inserted into the power connector on each module. If problem persists, contact ArcScan Service.
Scan chamber will not fill when **Fill** button is pressed	Contact ArcScan Service.
Scan chamber will not drain when **Drain** button is pressed	Contact ArcScan Service.
Bubbles visible in the camera image	Drain instrument fluid to “half”, refill and reattempt scan. If bubbles persist, drain instrument fluid to “half”, then run Prime cycle on water control console. Refill instrument and reattempt scan. If bubbles continue, contact ArcScan Service.
Other artefacts appear in B-Scan	Contact ArcScan Service.
Utilities tab highlighted yellow	Verify the water level is set to Half or Full. If motors do not home automatically, open the Utilities page. On the Hardware sub tab, under ”Motion” click “Action” and select “Home Motors”.
Motor disconnection error during normal operation	Click “Start”, search for “Windows Update” open Update console and install any listed updates. If no updates are listed, click Check for Updates to verify. Restart PC if prompted. **DO NOT POWER DOWN PC VIA POWER BUTTON DURING RESTART SEQUENCE.**

Symptom	Recommended Action
	If problem persists, contact ArcScan Service.
Device unable to connect on software startup	Contact ArcScan Service.
Blue screen, black screen, or Windows will not start up	Restart the computer. If problem persists, contact ArcScan Service.

For any other malfunction, contact ArcScan Service.

Chapter 7: Specifications

This chapter includes information about:

- Power Input Requirements
- Physical Construction
- Ultrasonic Output Specifications
- Scanner Fluid Capacity and Type
- Operating Conditions
- Transport and Storage Conditions
- Resolution, Precision, and Accuracy
- Essential Requirements
- Guidance and Manufacturer's Declaration of Electromagnetic Emissions and Immunity

Power Input Requirements

Model AS100-120: 120 VAC, 50/60 Hz, 8 A, single phase

Model AS100-230: 230 VAC, 50/60 Hz, 4 A, single phase

Physical Construction

Dimensions: 140 cm wide x 92 cm deep x 140 cm high / 55” wide x 36” deep x 55” tall (table and saline stand at lowest position)

Weight: 120 kg / 265 lbs

Table Height Range: 70-90 cm / 27.5-35.5 in

Ultrasonic Output Specifications

Frequency: 20-60 MHz

The Thermal and Mechanical Indices are below 1.0 for all device settings.

Acoustic Output Reporting Table for Track 1

Transducer Model: Blatek AT20573 **Operating Mode:** B-Mode

Application: Ophthalmic, Non-Autoscanning Mode

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			5.72E-02	1.50E-03		1.50E-03		6.35E-04
Index component value				1.50E-03	2.70E-04	1.50E-03	5.19E-04	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.28					
	P	(mW)		1.27E-02		1.27E-02		1.27E-02
	$P_{1\times1}$	(mW)		1.27E-02		1.27E-02		
	z_s	(cm)			1.00			
	z_b	(cm)					1.00	
	z_{MI}	(cm)	1.00					
	$z_{pii,\alpha}$	(cm)	1.00					
	f_{awf}	(MHz)	24.83	24.83		24.83		24.83
Other Information	prr	(Hz)	2.05E+04					
	srr	(Hz)	N/A					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm2)	3.1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm2)	2.19					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm2)	12.17					
	p_r at z_{pii}	(MPa)	0.67					
Operating control conditions	High output							

Note: Per Marketing Clearance of Diagnostic Ultrasound Systems and Transducers Guidance for Industry and Food and Drug Administration Staff Issues June 27, 2019

Scanner Fluid Capacity and Type

Capacity: 9.5 L / 2.5 Gallons

Type: Distilled water

Operating Conditions

Temperature: 18-28 °C / 65-82 °F

Humidity: 10-80% relative humidity, non-condensing

Altitude: ≤3000 m / 9,800 feet

Transport and Storage Conditions

Temperature: 0-45 °C / 32-113 °F

Humidity: < 80% relative humidity, non-condensing

Resolution, Precision, and Accuracy

Based on results obtained and published in Reinstein, et al. J. Refract Surg. 16:414-430, 2000, the following are the expected resolution, precision, and accuracy of the ArcScan Insight® 100.

Axial resolution: 35 µm

Lateral resolution: 65 µm

Single point precision (Standard deviation of successive quasi-instantaneous measurements at same corneal position)

Epithelial thickness: 0.7 µm

Corneal thickness: 0.8 µm

Map precision (Standard deviation of successive measurements of same corneal position in repeated scans in central 4 mm zone)

Epithelial thickness: 0.8 µm

Corneal thickness: 5.5 µm

Accuracy (4%) (Accuracy estimates based on uncertainty of true speed of sound in corneal tissues)

Epithelial thickness: 2 µm

Corneal thickness: 20 µm

ArcScan Insight® 100 Essential Performance

Free from noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect, and which may alter the diagnosis. Free from the display of incorrect numerical values associated with the diagnosis to be performed. [a] Free from the display of incorrect safety-related indications[a]. Free from the production of unintended or excessive ultrasonic output. Free from the production of excessive infrared output.
[a] "Incorrect" in the sense that the displayed value differs from what is calculated (having been altered during the data transfer), or the calculation itself is not correct.

Guidance and manufacturer's declaration electromagnetic emissions and immunity

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in the document. This declaration currently applies to the ArcScan Insight® 100.

Electromagnetic Emissions

The ArcScan Insight® 100 is intended for use in the electromagnetic environment specified below. The customer or user of the ArcScan Insight® 100 should assure that it is used in such an environment

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ArcScan Insight® 100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class A	The ArcScan Insight® 100 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided that the following warning is heeded: WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ArcScan Insight® 100 or shielding its location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The ArcScan Insight® 100 is intended for use in the electromagnetic environment specified below. The customer or operator of the ArcScan Insight® 100 should assure that it is used in such an environment

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T for 0,5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (95% dip in U_T for 5 s)	<5% U_T (>95% dip in U_T for 0,5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (95% dip in U_T for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the ArcScan Insight® 100 requires continued operation during power mains interruptions, it is recommended that the ArcScan Insight® 100 be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to the application of the test level.			

Immunity to RF Wireless Communication Equipment

The ArcScan Insight® 100 is intended for use in the electromagnetic environment specified below. The customer or operator of the ArcScan Insight® 100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ArcScan Insight® 100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,17 \sqrt{P}$

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol.

NOTE 1 – At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3 – All decimals are denoted by a "," in the above table.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ArcScan Insight® 100 is used exceeds the applicable RF compliance level above, the ArcScan Insight® 100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ArcScan Insight® 100.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ArcScan Insight® 100

The ArcScan Insight® 100 is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The customer or the operator of the ArcScan Insight® 100 can help prevent electromagnetic interference by maintaining a minimum distance between

portable and mobile RF communications equipment (transmitters) and the ArcScan Insight® 100 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1,17 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1,17 \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,33 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 – At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Chapter 8: Authorized Service Center

Authorized ArcScan Service Center

ArcScan, Inc.
433 Park Point Drive, Suite 220
Golden, CO 80401
Ph: (720) 773-8550
Email: service@arcscan.com

Warranty

ArcScan, Inc. warrants each product manufactured by ArcScan to be free from defects in material and workmanship under normal use and service for one year from the date of install. ArcScan's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to ArcScan or its distributor within the applicable time period after delivery of the product to the original purchaser, and which examination discloses, to ArcScan's satisfaction, that the product is defective. This warranty does not apply to any product, or part thereof, which has been repaired or altered outside ArcScan's factory in a way so as, in ArcScan's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ARCSCAN.

ArcScan neither assumes nor authorizes any person to assume for it any other liability in connection with the sale or use of any of ArcScan's products.

This Warranty is void if the ArcScan Insight® 100 is not properly maintained.

Glossary

This glossary contains key terms for the ArcScan Insight® 100 eye scanning system.

A

Acoustically reflective surface or interface	A surface or interface that has sufficient acoustic impedance difference across the interface to cause a measurable reflected acoustic signal. A specular surface is typically a very strong acoustically reflective surface.
Animate	Of or relating to animal life as opposed to plant life.
Anterior	Situated at the front part of a structure; anterior is the opposite of posterior.
A-scan	A representation of a rectified, filtered reflected acoustic signal as a function of time, received by an ultrasonic transducer from acoustic pulses originally emitted by the ultrasonic transducer from a known fixed position relative to eye anatomy.
Accommodative lens	An artificial intraocular lens that changes its focal distance in response to contraction of the ciliary body. When successfully implanted, an accommodative lens reverses presbyopia, the inability of the eye to change its focal distance from far to near. Also known as a presbyopic lens.
Accuracy	As used herein means substantially free from measurement error.
Anterior chamber	Comprises the region of the eye from the cornea to the iris.
Anterior segment	Comprises the region of the eye from the cornea to the back of the lens.
Arc scanner	An ultrasound scanning device utilizing a transducer that both sends and receives pulses as it moves along an arcuate guide track, which guide track has a center of curvature whose position can be moved to scan different curved surfaces.

B

B-scan	A processed representation of A-scan data by either/or converting it from a time distance to a brightness scale, using acoustic velocities and dots, which correspond to A-scan amplitudes. The brightness of the echo on the B scan correlates to the amplitude of the A-scan spike.

C

Calculate	The terms ***calculate***, ***compute***, and ***determine***, and variations thereof, as used herein, are used interchangeably and include any type of methodology, process, mathematical operation or technique.
Canthus	The angular junction of the eyelids at either corner of the eye where the upper and lower eyelids meet.
Center of rotation of the eye	There is a point within the eyeball that is fixed when the eye rotates in its orbit. It is considered that the center of rotation of an emmetropic eye (that is, a normal eye with about 20/20 vision) lies on the line of sight of the eye about 13.5 mm behind the anterior pole of the cornea when the line of sight of the eye is perpendicular to both the base line and the frontal plane.
Ciliary body	The circumferential tissue inside the eye composed of the ciliary muscle and ciliary processes. There are three sets of ciliary muscles in the eye, the longitudinal, radial, and circular muscles. They are in the anterior portion of the eye, above and below the lens, attached to the lens by connective tissue called the zonule of Zinn, and are responsible for shaping the lens to focus light on the retina. When the ciliary muscle relaxes, it flattens the lens, generally improving the focus for farther objects. When it contracts, the lens becomes more convex, generally improving the focus for closer objects.
Ciliary sulcus	The groove between the iris and ciliary body. The scleral sulcus is a slight groove at the junction of the sclera and cornea.

Coronal	Of or relating to the frontal plane that passes through the long axis of a body. With respect to the eye or the lens, this would be the equatorial plane of the lens which also approximately passes through the nasal canthus and temporal canthus of the eye.

D

E

EyeSeal	The disposable assembly comprised of a body, which is further comprised of a clamp and a membrane. In use, the device is filled with saline and the seal separates the eye from the distilled water in the instrument module.

F

Fixation	Focusing an eye on an optical target such that the eye's visual axis is in a known spatial relationship with the target.
Fovea	A small depression in the macula lutea of the retina where visual acuity is highest.

G

H

Haptics	Small protrusions extending from the outer diameter of some artificial lenses. These haptics fix the position of the lens to the ciliary body by protruding into the ciliary sulcus.

I

Imaging ultrasound transducer	The device that is responsible for creating the outgoing ultrasound pulse and detecting the reflected ultrasound signal that is used for creating the A-Scans and B-Scans.

Intraocular lens	An artificial lens implanted in the eye. Intraocular lenses can be pseudophakic (replacing natural lens) or phakic (augmenting natural lens).

J

K

L

LASIK	***LASIK*** is a procedure performed on the cornea for correcting refractive errors, such as myopia, hyperopia, and astigmatism. Commonly, an excimer laser selectively removes tissue from the inside of the cornea, after it is exposed, by cutting a thin flap, to reshape the external shape of the cornea.

M

Meridian	As used herein, a ***meridian*** is a 2-dimensional plane section through the approximate center of a 3-dimensional eye and its angle is commonly expressed relative to a horizon defined by the nasal canthus and temporal canthus of the eye.

N

Natural lens	The ***natural lens*** or crystalline lens is a transparent, biconvex structure in the eye that, along with the cornea, refracts light to be focused on the retina. The lens, by changing shape, functions to change the focal distance of the eye so that it can focus on objects at various distances, thus allowing a sharp real image of the object of interest to be formed on the retina. This natural adjustment of the lens is known as accommodation. The lens is located in the anterior segment of the eye behind the iris. The lens is suspended in place by the zonular fibers, which attach to the lens near its equatorial line and connect the lens to the ciliary body. The lens has an ellipsoid, biconvex shape whose size and shape can change due to accommodation and due to growth during aging. The lens is comprised of three main parts: namely the lens capsule, the lens epithelium, and the lens fibers.

O

Ocular	Having to do with the eye or eyeball.
Ophthalmology	The branch of medicine concerned with the study and treatment of disorders and diseases of the eye.
Optical	As used herein, refers to processes that use light rays.
Optical axis of the eye	A straight line which passes through the centers of curvature of the refracting surfaces of an eye (the anterior and posterior surfaces of the cornea and lens).
Optical Coherence Tomography (OCT)	High resolution cross-sectional imaging initially developed for retinal imaging. With anterior segment OCT, the imaging is noncontact, noninvasive, and quick to perform. OCT is optical imaging, as compared to ultrasonography, therefore structures posterior to other structures or opacities cannot be imaged.
Orbit	As used herein, the ***orbit*** of the eye is the cavity or socket of the skull in which the eye and its appendages are situated. Orbit can also refer to the bony socket.
Organ	A group of tissues in a living organism adapted to perform a specific function

P

Pachymetry	Process of measuring the thickness of the cornea with ultrasound or optical methods. Also called corneal pachymetry, this test is performed prior to refractive surgery to determine adequate corneal thickness to avoid ectasia or other corneal complications.
Phakic	An eye containing the natural lens
Phakic Intraocular Lens	***Phakic*** intraocular lenses, or phakic lenses, are lenses made of plastic or silicone that are implanted into the eye to reduce a person's need for glasses or contact lenses. Phakic refers to the fact that the lens is implanted into the eye without removing the eye's natural lens. During phakic lens implantation surgery, a small incision is normally made in the front of the eye. The phakic lens is inserted through the incision and placed just in front of or just behind the iris.
Posterior	Situated at the back part of a structure; further back in position, posterior is the opposite of anterior.
Posterior chamber	Comprises the region of the eye from the posterior iris to the front of the lens and ciliary processes
Posterior segment	Comprises the region of the eye from the anterior hyaloid membrane to the retina and optic nerve head.
Presbyopia	Farsightedness caused by a loss of elasticity of the natural lens of the eye. This occurs as part of the aging process and can be corrected by wearing glasses or implantation of an artificial lens

Purkinje images	Reflection of an object. in the eye of a person. There typically exist four Purkinje images. The first Purkinje image (P1) is the reflection from the outer surface of the cornea. The second Purkinje image (P2) is the reflection from the inner surface of the cornea. The third Purkinje image (P3) is the reflection from the outer (anterior) surface of the lens. The fourth Purkinje image (P4) is the reflection from the inner (posterior) surface of the lens. Unlike the others, P4 is an inverted image. The first and fourth Purkinje images are used by some eye trackers, devices to measure the position of an eye. Purkinje images are named after Czech anatomist Jan Evangelista Purkyně (1787-1869).

Q

R

Refraction	A change of direction that light undergoes when it enters a medium with a different density from the one through which it has been traveling.

S

Saccades	Rapid, intermittent eye movements made as the attention switches from one point to another. Saccades are a part of normal eyesight
Suprachoroidal space	A potential space between the sclera and choroid that traverses the circumference of the posterior segment of the eye.

T

Tissue	A group of cells. that have a similar structure and act together to perform a specific function.

U

Ultrasound	Sound that is above the human ear's upper frequency limit. Ultrasound travels through soft tissues and fluids, but bounces back, or echoes, off denser surfaces. For diagnostic uses, ultrasound is usually between 2 and 18 MHz. For high-resolution acoustic imaging in the eye, the frequency is typically in the range of about 5 to about 80 MHz.
Ultrasonic Bio Microscopy (UBM)	. A technique primarily used for imaging of the anterior segment of the eye. First introduced in the early 1990s by Foster and Pavlin as a way to obtain cross sections of the eye at microscopic resolution
Ultrasound probe	Also called an ultrasound transducer, an assembly comprised of an element (e.g., a piezoelectric material), handpiece or other holder,-that produces sound waves that bounce off body tissues and generates echoes
Ultrasound pulse	A mechanical reverberation of the transducer in a pulse-echo sonographic device after electrical stimulation. Ultrasound waves are produced in pulses. Each pulse is 2-3 cycles of the same frequency. The pulse length is the distance each pulse travels. The pulse repetition frequency is the rate at which the transducer emits the pulses. An ultrasound pulse is further described in "Ultrasonography of the Eye and Orbit", Second Edition, Coleman et al., published by Lippincott Williams & Wilkins, 2006 which is incorporated herein by reference.

V

Vector	Refers to a single acoustic pulse and its multiple reflections from various eye components. An A-scan is a representation of this data whose amplitude is typically rectified. Not sure this is correct
-**VHFU**	**V**ery **H**igh **F**requency **U**ltrasound is when the frequency is higher than 30MHz, which yields improved spatial resolution at the expense of a shallower depth of penetration,
Visual axis of the eye	An imaginary line passing from the midpoint of the visual field to the fovea centralis.

W

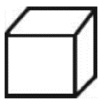
X

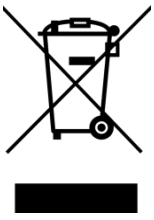
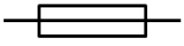
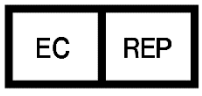
Y

Z

Zonules A series of fibers connecting the ciliary body and lens of the eye, holding the lens in place

Symbols

Symbol	Meaning
	CAUTION: See Instructions for Use
	CAUTION
	Use By
	Single Use ONLY
	Do NOT use if package is damaged - Sterility and product performance may be compromised.
	Do NOT double stack packaging.
Rx ONLY	Federal law restricts this device for sale to or on the order of a physician or licensed practitioner
	Package Quantity
	Catalog Number
	Lot Number
	Serial Number

Symbol	Meaning
	Sterilized using Irradiation
	Date of Manufacture
	Manufacturer
	Temperature limits
	Humidity limits
	Keep dry
	Separate collection for electrical and electronic equipment
	Type B applied part
	Alternating current
	Fuse
	Authorized Representative in the European Community
	CE Mark