arcscan
ULTRASOUND: EVOLVED

User Manual

# ArcScan Insight® 100

**Arcscan, Inc.**
433 Park Point Drive
Golden, CO 80401

# Foreword

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and procedure to be performed. 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.

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

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**Equipment covered in this manual:**
ArcScan Insight® 100

**Manufacturer:**
ArcScan, Inc.
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Golden, CO 80401
USA

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Translations for this manual may be provided upon request.

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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

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***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 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 in Appendix B.*

***Caution:*** *Portable and mobile RF communications equipment can adversely affect the performance of medical electrical equipment.*

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## 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 adults to measure dimensions of components of the human eye. To provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure these tissues and 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 therefore 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

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***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, 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: 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.*

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***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.*

## 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.

## Getting to Know the Instrument

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 before beginning to use the system.

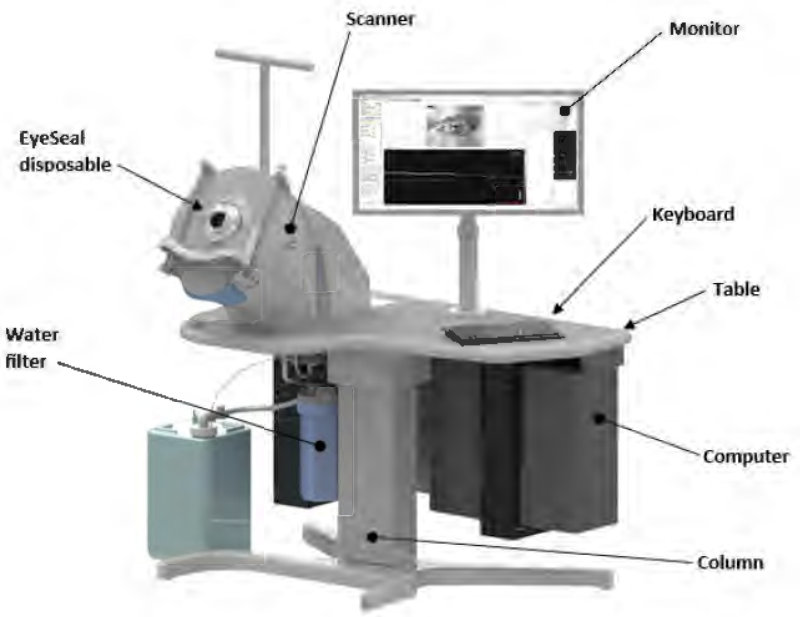


**Figure 1. ArcScan Insight 100 Front View**

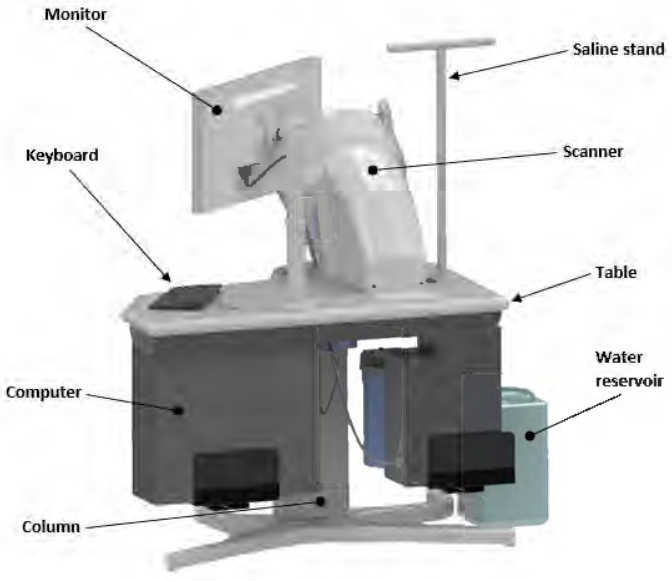


**Figure 2. ArcScan Insight 100 Back View**

## Scanner

The scanner is designed to comfortably position the patient so their eye is looking through the center of the EyeSeal Disposable while keeping their head still. EyeSeal Disposables are used to prevent cross contamination between patients.

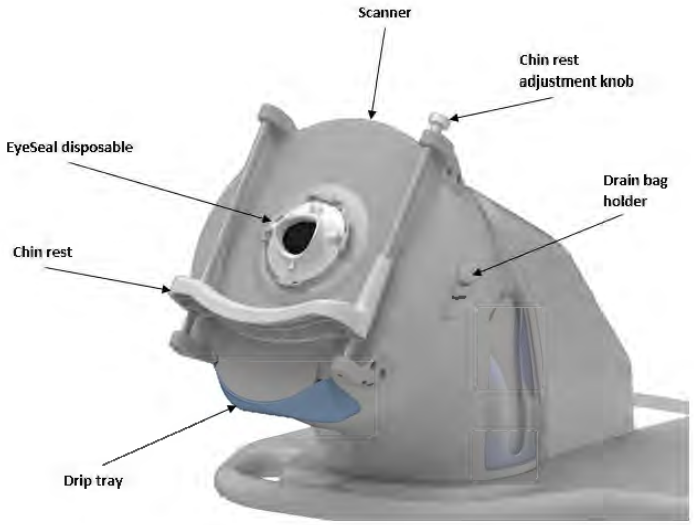


**Figure 3. ArcScan Insight 100 Scanner**

The scanner exterior is comprised of the following:

| Component | Description |
|---|---|
| **Chin rest** | This is intended to give support to the patient's chin to prevent motion during scanning. The chin rest can be moved to accommodate differences in patients. The chin rest can be moved with the adjustment knob. |
| **EyeSeal Disposable** | The EyeSeal Disposable locates the patient's eye that is to be scanned. An EyeSeal Disposable provides a hygiene barrier between the 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 should be used with each patient. |

| | |
|---|---|
| **Drip tray** | The drip tray is intended to collect any residual saline when the patient removes their eye from the EyeSeal Disposable. |
| **Drain bag holder** | The EyeSeal drain bag should 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, there is a liquid chamber, the scan probe, and probe positioning hardware.

## Fluidics Module

The fluidics module is comprised of the following:

| Component | Description |
|---|---|
| **Reservoir** | A fluid container for storing distilled water when the scanner is not in use. |
| **Fill/Drain Pump** | A pump and valve combination for transferring water from the reservoir to the scanner chamber. |
| **Bearing Pump** | A 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** | A standard water filter that removes sediment from the scan head fluid to prevent clogging of the fluid bearings. |

## Electronics Unit

The electronic 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.

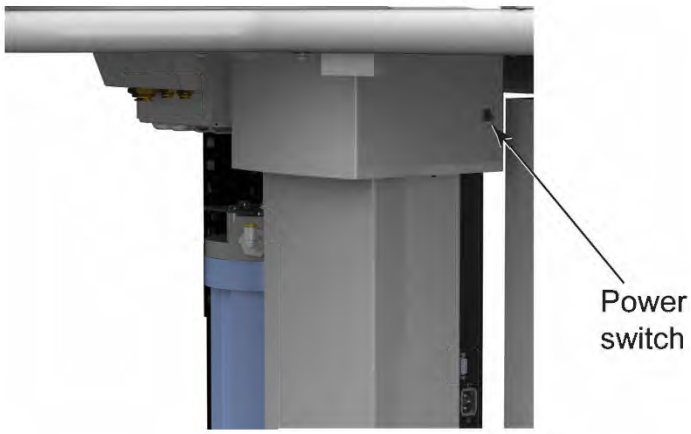


**Figure 4. Main Power Switch**

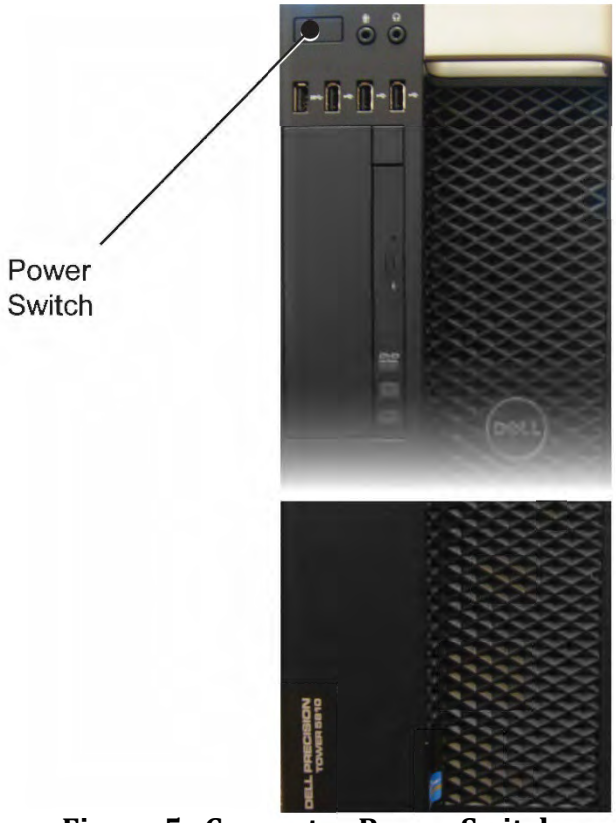


**Figure 5. Computer Power Switch**

## Software Package

ArcScan Insight 100 software has seven main pages, accessed through the tabs on the upper left-hand side of the application window. These seven pages and their components are shown in the following sections.

Upon startup, the ArcScan Insight 100 software opens to the **Patient Page**. This page is used to enter patient information and obtain patient data.

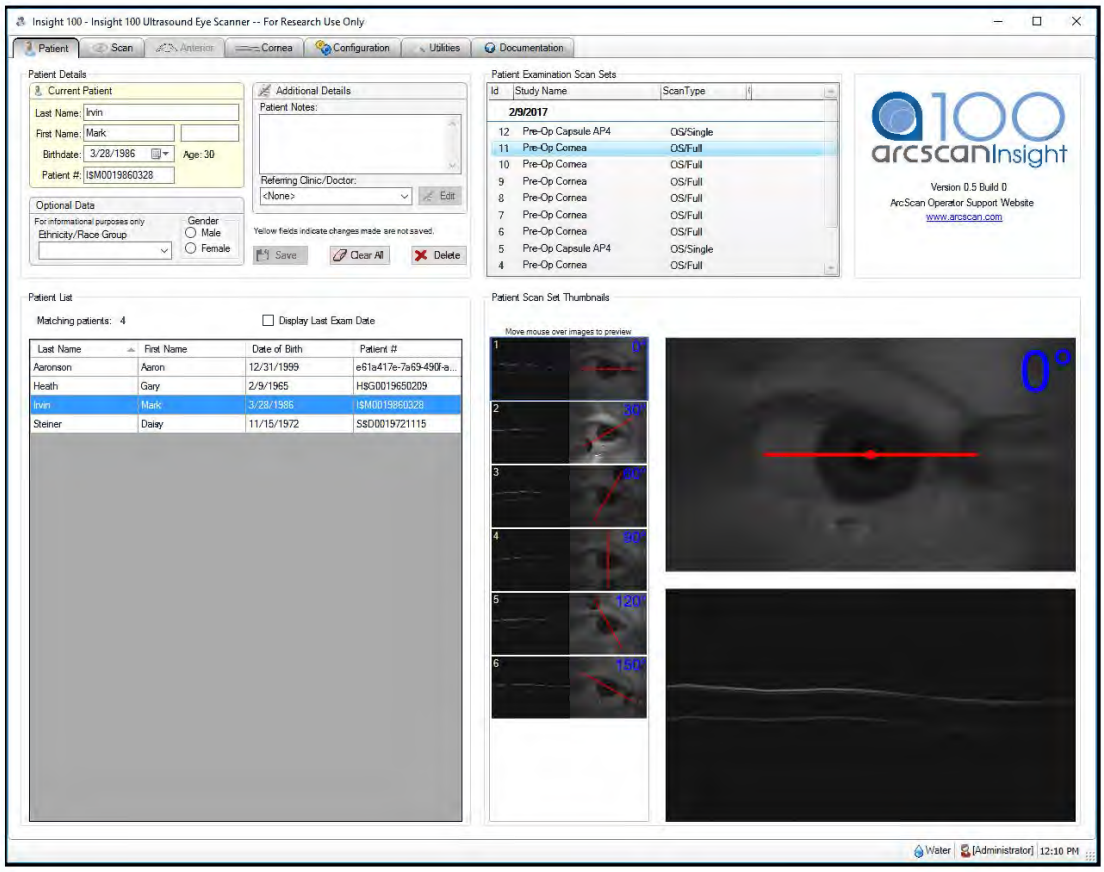


**Figure 6. Patient Page**

Click on the Scan tab to open the **Scan Page**. The **Scan Page** is used to enter settings for and performing scans. Previous patient scans may also be viewed on the **Scan Page** in the Preliminary and Final Scan Set groups.

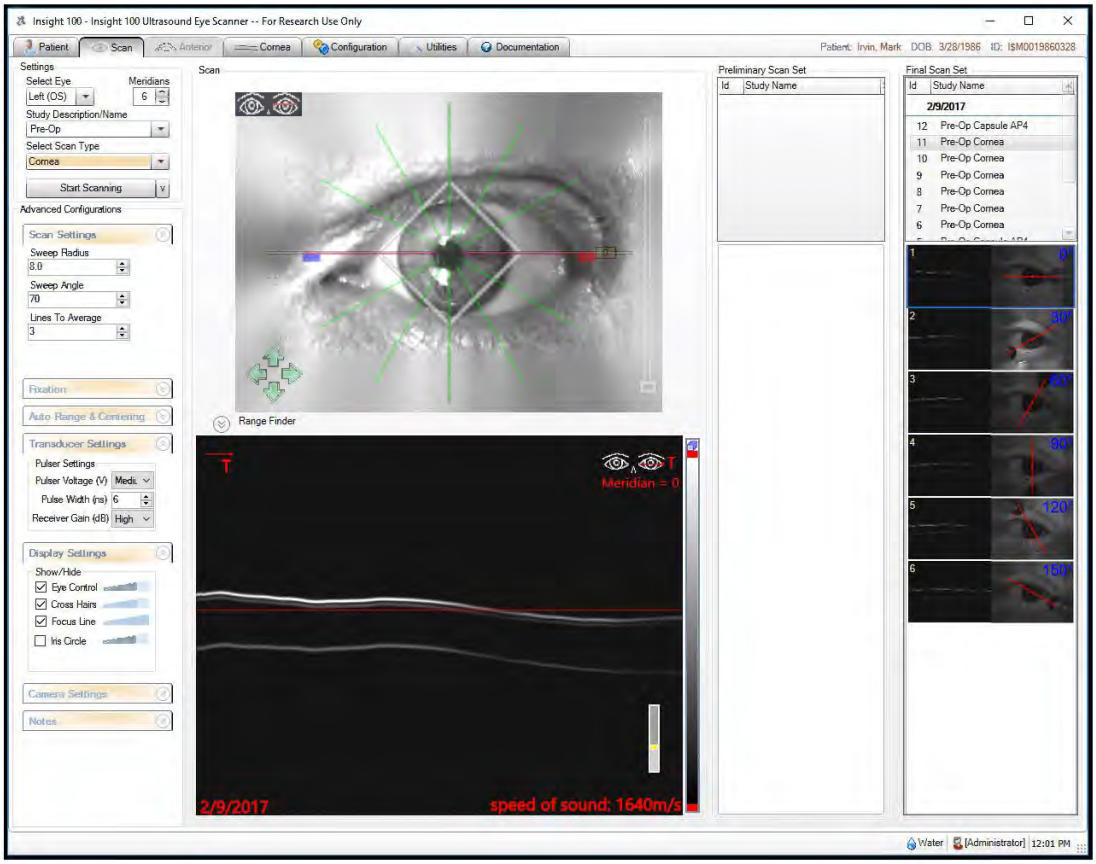


**Figure 7. Scan Page**

Click on the **Anterior** tab to open the **Anterior Page**. The **Anterior Page** is used for Anterior and Capsule scan review. Measurements may be taken as well as annotating individual scan images.

**Note:** The **Anterior Page** is only available when an anterior scan set is selected.


**Figure 8. Anterior Page**

Click on the Cornea tab to open the **Cornea Page**. The **Cornea Page** is used for Cornea scan image review, as well as viewing Keratoconus and Cornea Map data. Scan images may also be measured and annotated on the Corrected tab.

**Note:** The **Cornea Page** is only available when a cornea scan set has been selected

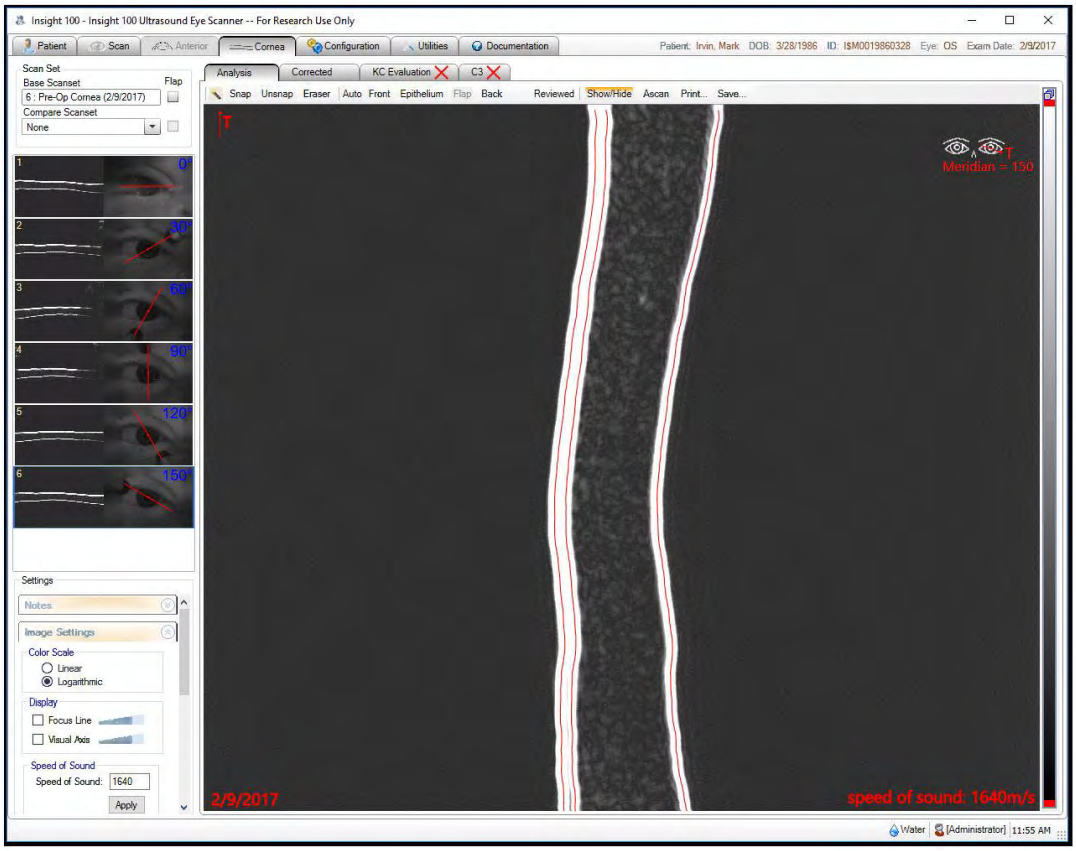


**Figure 9. Cornea Page**

Click on the Configuration tab to open the **Configuration Page**, available to operators with elevated privileges, like Administrators and Service operators. The **Configuration Page** provides operator management and program configuration adjustments.

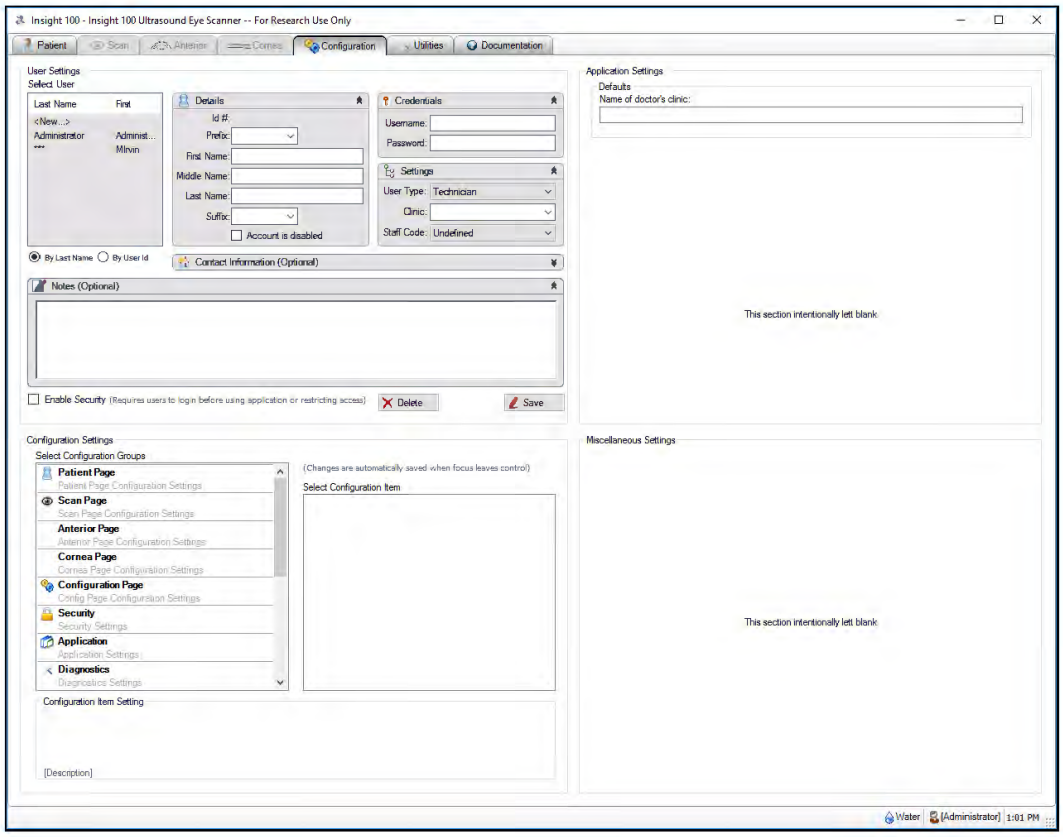


**Figure 10. Configuration Page**

Click on the Utilities tab to open the **Utilities Page**. The **Utilities Page** provides status information and control of the Camera, Motion, and Ultrasound subsystems. Operators with elevated privilege may also use the Data Management and Diagnostic features on this page.

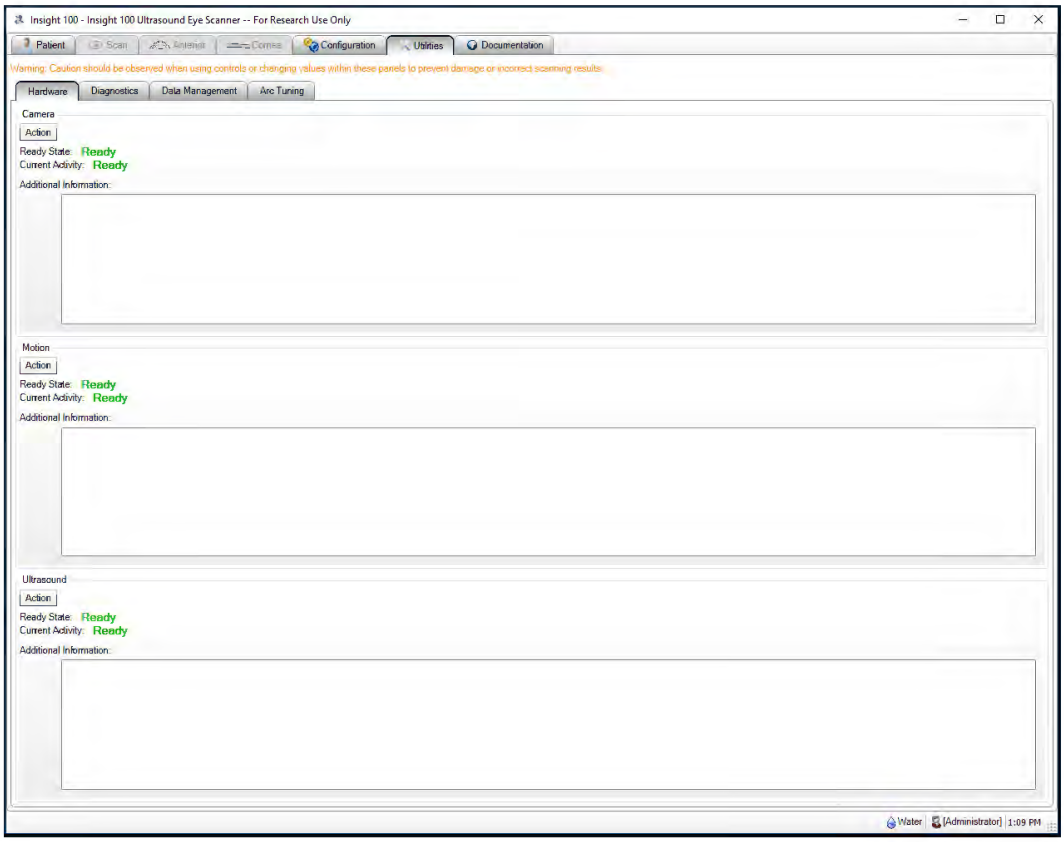


**Figure 11. Utilities Page**

Click on the Documentation tab to open the **Documentation Page**. An electronic version of the User Manual is accessible on this page.

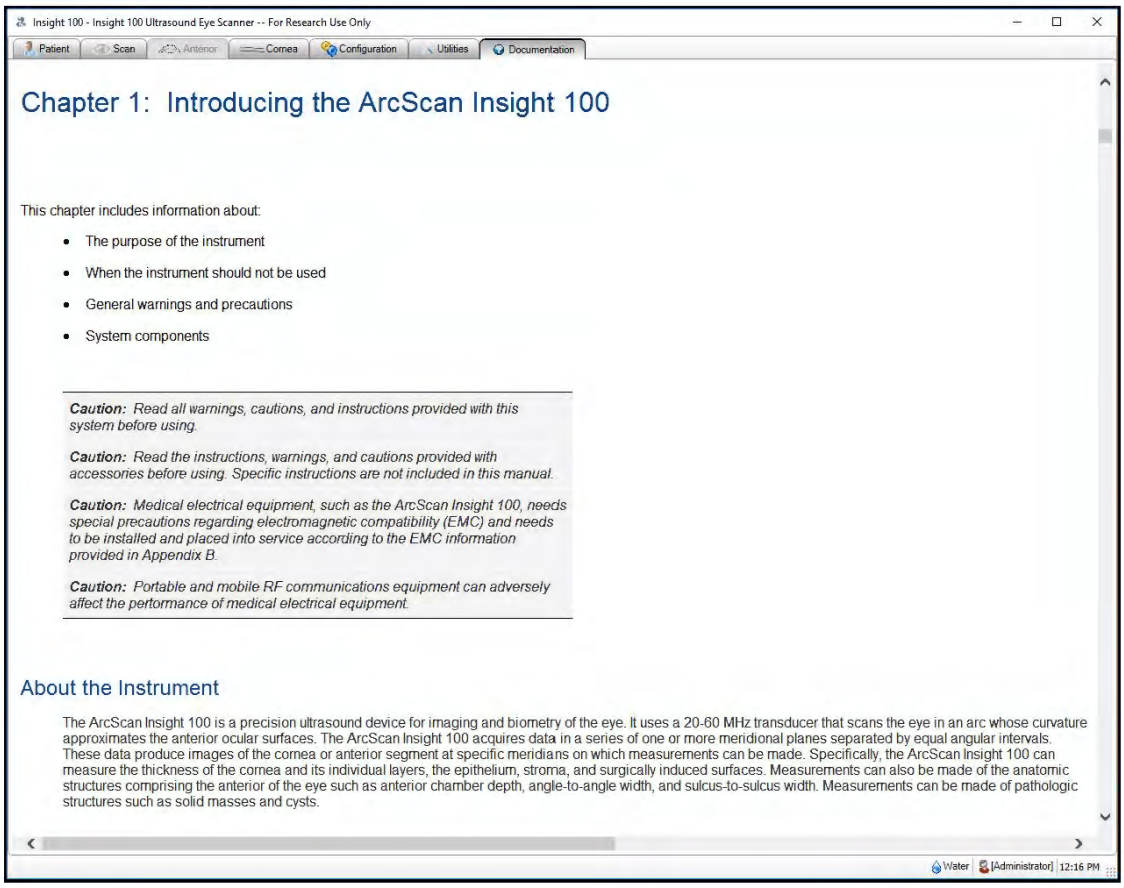


**Figure 12. Documentation Page**

# Chapter 2: Setup

This chapter includes information about:

- The lists of components and accessories
- Connecting to power source

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***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 not included in this manual.*

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# List of Components

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

| Box | Contents |
|---|---|
| 1 | Instrument Module with Chinrest |
| 2 | Fluidics Module and Installation Hardware |
| 3 | Computer, Mouse, Keyboard, Monitor, Installation Hardware |
| 4 | Reservoir |
| 6 | Column |
| 7 | Table, Table Legs, Protector Plate, Saline Pole, Monitor Mount |
| 8 | Calibration Fixture |
| 9 | Cables and Hoses |

# List of Accessories

The following accessories are used with the ArcScan Insight 100 system for scanning and maintenance and should be 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 |
| Saline Administration Set (Baxter Clearlink System Secondary Medication Set 2C7461, or equivalent) |
| **Supplies – User Maintenance** |
| Disinfecting Kit (ArcScan P/N 21346) |
| Water Filter (ArcScan P/N 20896) |
| Fuse (Model AS100-120: 250V, 8 A, time lag, Littelfuse 0218008.MXP or equivalent) |
| Fuse (Model AS100-230: 250V, 4 A, time lag, Littelfuse 0218004.MXP or equivalent) |

## Assembling the System

***Warning:*** *ArcScan Insight 100 is to be assembled by a trained ArcScan technician only.*

***Warning:*** *The ArcScan Insight 100 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked 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.*

## Connecting to Power Source

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

***Caution:*** *Connect the power cord to a wall outlet having the correct voltage. Otherwise product damage may result.*

***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.*

1. Ensure the power cord is plugged into a grounded wall receptacle.
2. Ensure the leveling feet contact the floor to stabilize the device.

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

# Chapter 3: Before Scanning

This chapter includes information about:

- Setting up the instrument
- Entering patient information
- Placing the patient
- Setting up the instrument between patients

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***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 not included in this manual.*

***Warning:*** *Do not place or store materials, with the exception of the ArcScan scanner, monitor, keyboard, mouse and saline stand, weighing more than 4.5 kg (10 pounds) on the table.*

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## Setting Up the Instrument

Each day before scanning, the preparation procedure described below should be followed.

1. Inspect all cable and tube connections.

2. Inspect the transducer for damage or dislodgement. The transducer is magnetically mounted and held in place with a wire tether, but may have become detached during shipment. Ensure transducer is mounted and wire tether secured prior to continuing with scanning.

***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 transducer as this can damage the unit.*

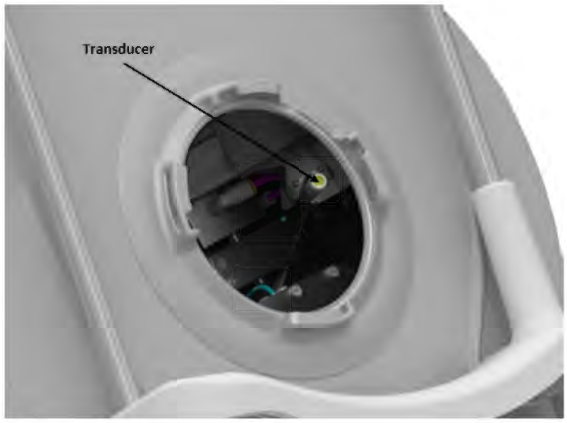


**Figure 13. Transducer**

3. Attach a new EyeSeal Disposable to the scanner as described below (The *EyeSeal Disposable Instruction for Use (IFU)* can be found in Appendix C, which also contains steps on how to attach, fill, drain, and detach an EyeSeal Disposable).

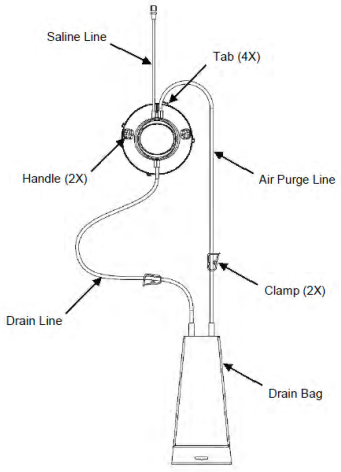


**Figure 14. EyeSeal Disposable**

a. Remove the EyeSeal Disposable from the packaging.

b. Remove the protective cover.

c. Locate the four tabs on the perimeter of the EyeSeal. Hold the EyeSeal so the largest tab faces upward.

d. Align the tabs with the grooves in the receptacle on the ArcScan Insight 100 instrument.

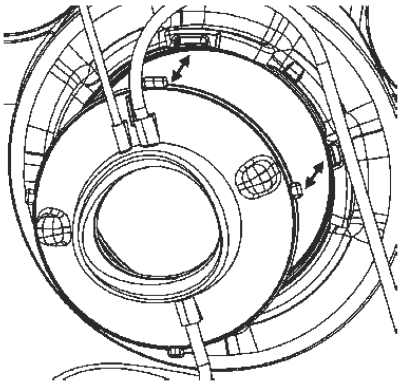

**Figure 15. EyeSeal Insertion**

e. Lower the EyeSeal into the receptacle. Insert all tabs into the grooves.

f. Grip the handles located on both sides of the EyeSeal Disposable.

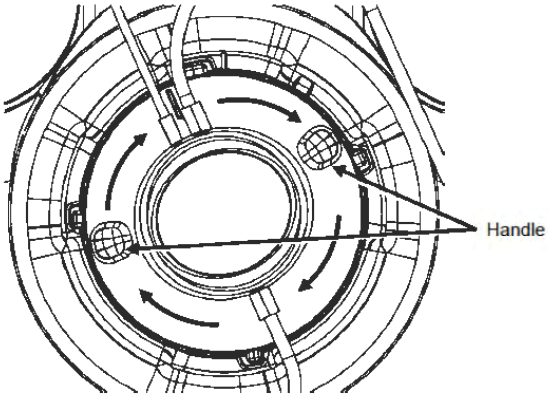


**Figure 16. EyeSeal Tightening**

g. Rotate the EyeSeal Disposable clockwise until the vertical indicators are aligned.

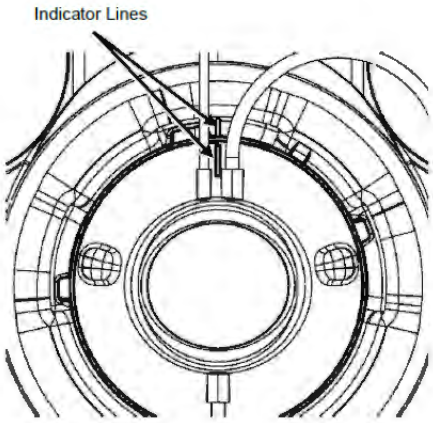


**Figure 17. EyeSeal Installation Check**

h. Place the drain bag into the drain bag holder on the side of the ArcScan Insight 100 instrument.

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

5. Turn on both the computer and monitor. Start up the ArcScan Insight 100 software.

6. Ensure the reservoir is full with distilled water. Click on the **Water** button on the bottom right-hand corner of the screen. Then click the **Fill** button. The scan head will fill with water. However, if the fluid reservoir has already been filled, first select the Prime button. The prime function ensures purging of air from the fluid system and will take several minutes to complete. Once complete scanning can begin.

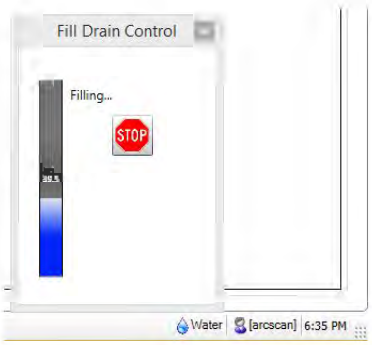


**Figure 18. Filling Scan Head**

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

***Notice:*** *Ensure there is no leakage between the EyeSeal Disposable and the ArcScan Insight 100. If leakage occurs then drain the water and re-attach the disposable according to the instructions for use.*

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

The following graphic will appear when the scan head is full.

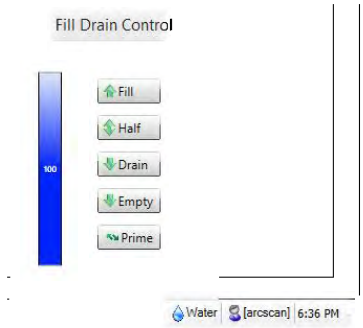


**Figure 19. Full Water Level**

7. Clean the chin rest, face plate, and hand holds with a disinfectant wipe.

8. Finally, on the sub-tab **Device Info** under the **Utilities tab**, enter probe and device information, then **Save**. See **Figure 20** for an example.

   a. Note: since the release of the **ArcScan software Version 0.7 Build 48239 *Aspen Prime***, probe/transducer focal length information is a requirement that needs to be entered for accurate functioning of the device; **it cannot be left blank**! If in doubt about your Instrument's probe/transducer focal length, ask ArcScan.

   b. Additional information about device and probe serial number can also be entered. These are ok to be left blank if unknown, however, ask ArcScan for information.

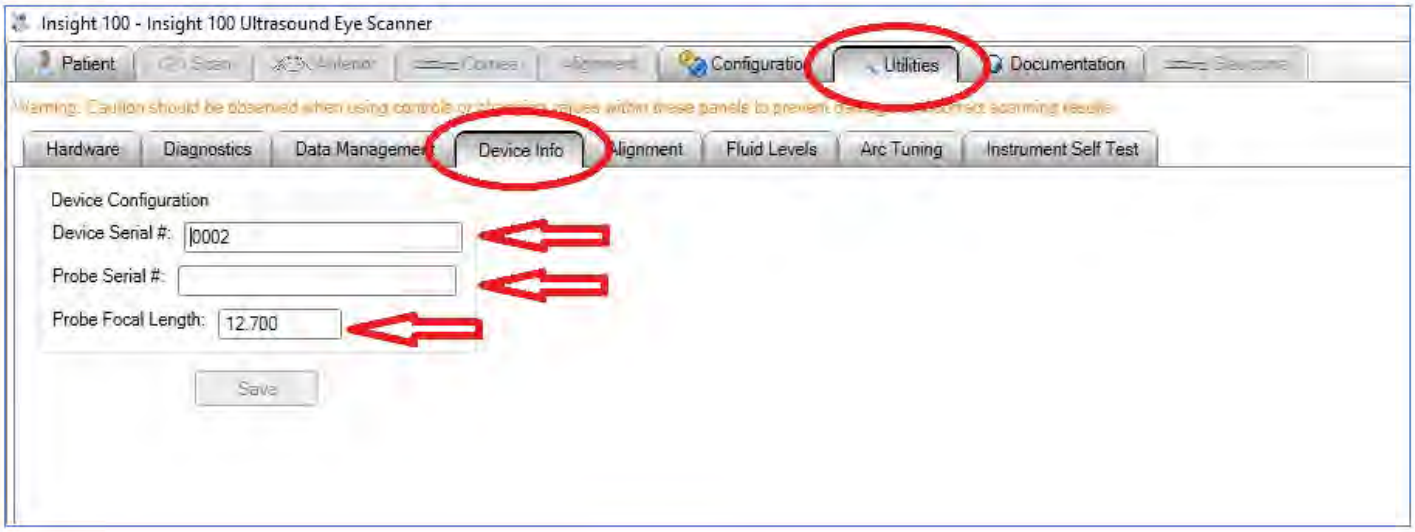


**Figure 20: Device and Probe serial number, as well as Probe Focal length information should entered under Device Info sub-tab. Particularly, Probe focal Length is a requirement for proper functioning of the device. As an example, a 12.7 mm focal length transducer is entered. The "mm" unit is not needed.**

## Entering Patient Information

1. Access the **Patient** tab in the software.

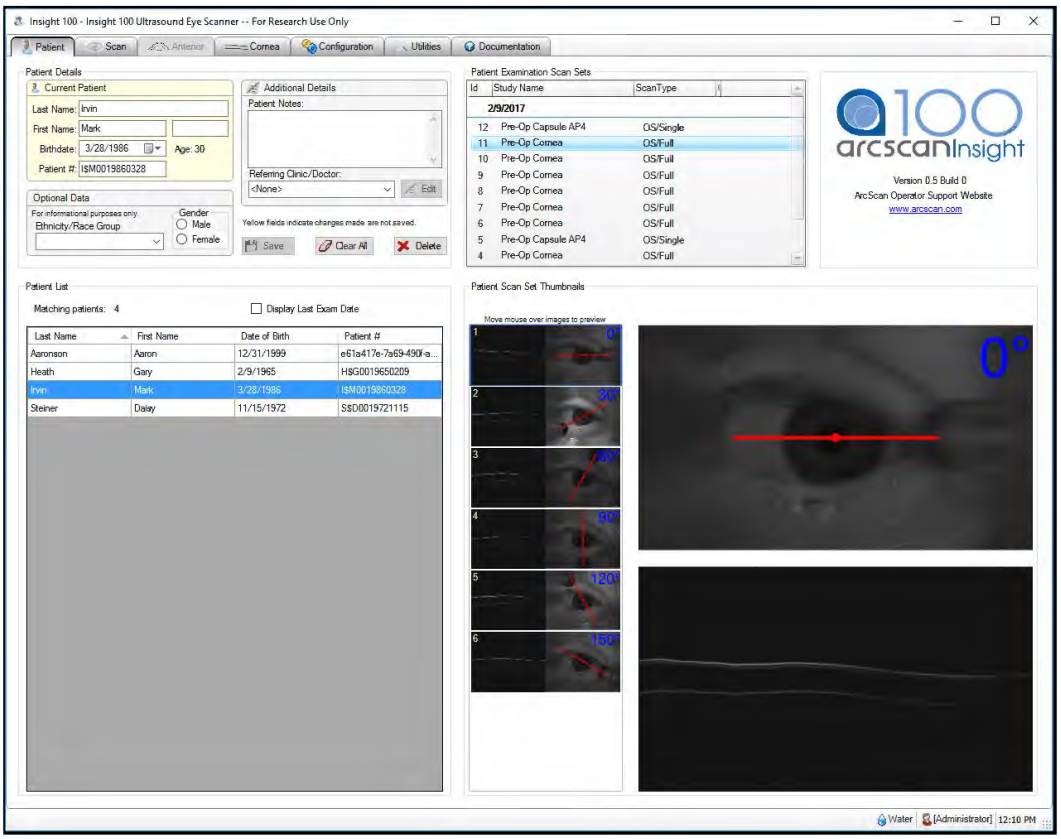


**Figure 21. Patient Entry**

2. *For new patients,* enter patient details including:

   - Last name
   - First name
   - Birthday
   - Ethnicity/Race Group (optional)
   - Gender (optional)

   *For former patients,* locate the patient's name in the Patient List and select the name.

   The patient list is a list of all patients in the system. This list can be sorted by last name, first name, date of birth, patient #, or exam date.

   *To pare down the Patient List,* enter any of the patient's information in the Patient Details box.

**Note:** By pressing the **Clear All** button, all the fields will be reset to blank. All data typed within these fields will be lost, however no data stored in the database will be affected.

3. Additional patient details may be added for new or existing patients including:

    - Patient notes
    - Referring clinic/doctor

4. Click the **Save** button. This saves any information on a patient that has been edited or adds the new patient to the database. Thumbnails of patient scans are displayed on the **Patient Page** in the Patient Scan Set Thumbnails window. Click a thumbnail to view the patient scan.

# Placing the Patient

Begin preparing the patient for the eye scan after patient data has been entered.

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***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 startup procedure (under "Setting Up the Instrument" has been performed.*

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1. Ensure that a new EyeSeal Disposable has been attached to the scanner as instructed in the Setting Up the Instrument section (or refer to the *EyeSeal Disposable IFU* in Appendix C*)*.

2. Attach a saline bag to the EyeSeal Disposable as described below.

    a. Obtain a bag of saline. Remove and discard any packaging. Hang the saline bag from the saline pole.

    b. Obtain a saline administration set. Remove and discard any packaging.

    c. Close the clamp on the saline administration set. Using aseptic technique, spike the saline bag.

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

    e. Clamp the drain line on the EyeSeal Disposable.

    f. Ensure the clamp on the air purge line is open.

3. Show the EyeSeal Disposable to the patient and explain how it will fill with saline.

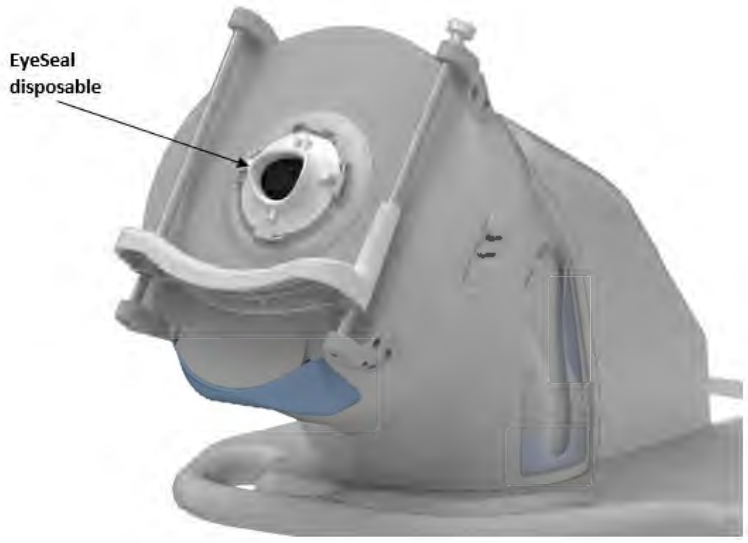


**Figure 22. EyeSeal Disposable**

4. Instruct the patient to remove contact lenses and clean the eyelids and surrounding skin.

5. Instruct the patient to place their eye against the EyeSeal Disposable, making sure the eyeseal is positioned inside the bridge of the nose, not on the bridge of the nose.

6. Visually inspect the interface between the patient and EyeSeal Disposable for obvious gaps or areas that may leak. Have patient open the eye and check to ensure the patient eye is roughly centered in the video image on the scan page. Reposition the patient and/or adjust the instrument height as necessary.

7. Instruct the patient to close their eye to prevent any discomfort when the EyeSeal Disposable fills with saline. Instruct the patient to not remove their eye off the seal until told to do so.

8. Fill the EyeSeal Disposable with saline as described below (or refer to the *EyeSeal Disposable IFU* in Appendix C).

    a. Open the clamp on the saline administration set to fill the EyeSeal Disposable with saline. The fill level can be seen on the camera image.

    **Note:** When full, saline will flow through the air purge line.

    b. Clamp the air purge line on the EyeSeal Disposable.

    c. Close the clamp on the saline administration set to discontinue the flow of saline to the EyeSeal disposable.

9. Visually inspect the interface for leaks. If leaks are present, try adjusting the patient's position. If leaking persists, drain the saline as instructed in the Scanning the Patient section (or refer to the *EyeSeal Disposable IFU* in Appendix C) and repeat steps 5 through 8.

   **Note:** 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 against the forehead and cheek. For example, a tall patient may contact the EyeSeal Disposable first at the forehead, and will not seal adequately at the cheek. See steps 5 and 6 above to ensure sufficient seal with patient's eye and EyeSeal Disposable.

10. Adjust the position of the chinrest to provide comfortable support using the chinrest adjustment knob.

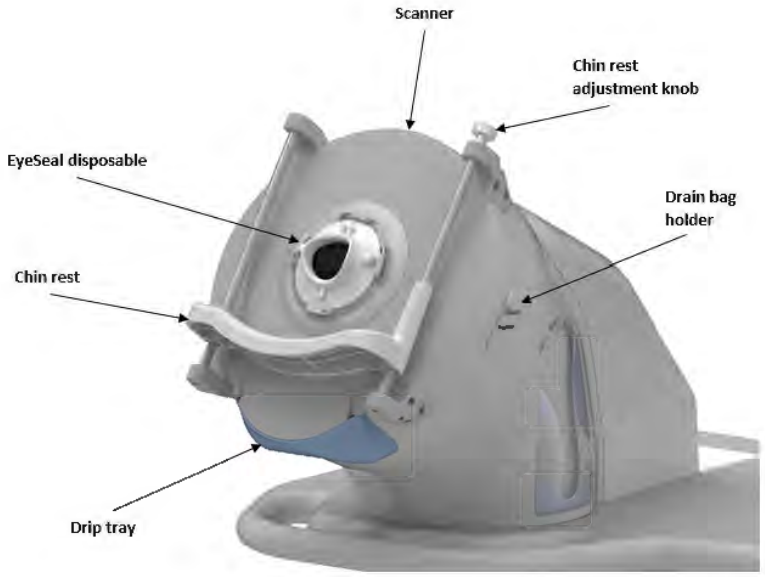


**Figure 23. Scanner**

**Note:** The adjustment knob is located at the top of the right support rod. Rotate the knob to raise or lower the chin rest.

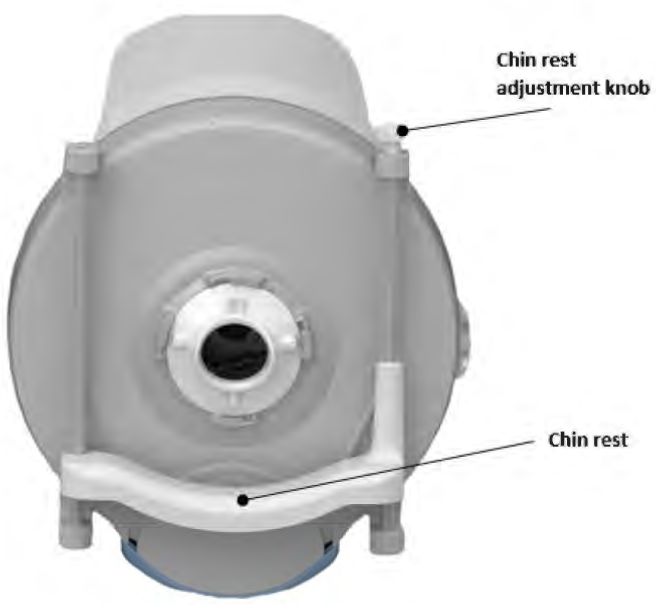


**Figure 24. Chin rest**

11. Allow 20 seconds for the patient's eye to acclimate to the saline temperature prior to the patient opening their eye.

12. Instruct the patient to open their eye and focus on light source. The patient is ready to be scanned.

## Setting Up the Instrument Between Patients

Between patients, follow the procedures below to prepare the instrument for a new patient scan.

1. Click on the **Water** button on the bottom right-hand corner of the screen. Then click the **Half** button. The scan chamber will drain to half full.

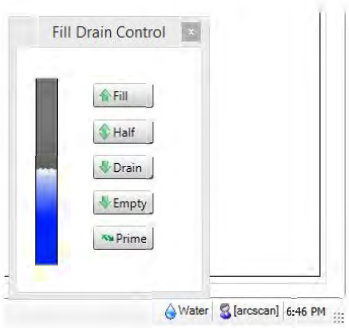


**Figure 25. Half Water Level**

2. When the water level in the scan chamber is below the EyeSeal Disposable remove the used EyeSeal Disposable.

   a. Ensure the scan head has been drained, or the water level is below the EyeSeal Disposable.

   b. Disconnect the saline administration set from the saline line on the EyeSeal Disposable.

   c. Grip the handles located on both sides of the disposable.

   d. Rotate the EyeSeal Disposable counter-clockwise until it cannot rotate further.

   e. Gently pull the EyeSeal Disposable out of the receptacle.

   f. Discard the used EyeSeal Disposable.

3. Clean all surfaces with a disinfectant wipe.

4. Attach a new EyeSeal Disposable to the scanner and refill container as instructed in the “Setting Up the Instrument” section (or refer to the *EyeSeal Disposable IFU* in Appendix C).

5. Enter patient information and place the patient as instructed in the previous sections.

***Note:*** *If scans are completed for the day, drain water from unit and remove eyeseal or calibration fixture and allow to remain open until preparation for next scan or set of scans.*

# Chapter 4: Scan Procedure

This chapter includes information about:

- Scan types
- Scanning the patient
- Adjusting scan settings
- Scanning options

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***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 not included in this manual.*

---

## Types of Scans

The ArcScan Insight 100 performs three different types of scans: anterior segment imaging, capsule AP4 imaging, and cornea imaging. These scan types are described in the following subsections.

### Anterior Segment Imaging and Biometry

Anterior segment imaging is used for:

- Biometry for lens replacement including sulcus to sulcus distance (for posterior chamber IOL) or angle-to-angle distance (for anterior chamber IOL)
- Assessment of pathology

The anterior segment imaging procedure is identical to the procedure used for corneal imaging, except for the radius setting and the location of the focal plane. In anterior segment imaging, the radius is set to 12 mm during setup and the focal plane is set on the ciliary body. Vertical scans may require the use of a speculum to keep the eyelid from obstructing the edges of the scan.

The following parameters apply to anterior segment imaging:

- The system sets the ultrasound range to capture approximately 4 mm of data in front of the transducer's focal plane and 1 mm of data in back of the focal plane.
- The system sets the scan geometry to an arc of default radius of 14 mm.
- The system sets the scan area to image the entire eye using four equally spaced meridians.

## Capsule AP4 Imaging

Capsule imaging is used for:

- Biometry for pre-op and post-op lens replacement including sulcus to sulcus distance, angle-to-angle distance, anterior chamber depth, capsule thickness, anterior capsule curvature, posterior capsule curvature, capsule diameter, and capsule volume
- Assessment of pathology

The following parameters apply to capsule imaging:

- The system sets the ultrasound range to capture approximately 6 mm of data in front of the transducer's focal plane and 2 mm of data in back of the focal plane.
- The system sets the scan geometry to acquire three sweeps:
    - an arc of default radius of 18 mm,
    - a planar scan with the transducer tilted at 25 degrees,
    - a planar scan with the transducer tilted at -25 degrees.
- The system sets the scan area to image the entire eye using four equally spaced meridians.

## Cornea Imaging and Biometry

Corneal imaging is used for:

- Pre-Lasik biometry
- Keratoconus early detection
- Evaluation of corneal scars
- Post-Lasik biometry

**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 sets the ultrasound range to capture approximately 1 mm of data, centered approximately on the transducer's focal plane.
- The system sets the scan geometry to an arc of default radius of 8 mm.
- The system sets the scan area to image the entire cornea using four equally spaced meridians.

The following parameters apply to imaging of pterygium or corneal scars:

- For this procedure, the patient is required to fixate to either side, up, or down. During, a particular area of the cornea may be chosen to image.
- The system sets the ultrasound range to capture approximately 1 mm of data, centered approximately on the transducer's focal plane.
- The system sets the scan geometry to an arc of default radius of 8 mm.
- Specify the start meridian angle, end meridian angle, and number of meridians to scan.

# Scanning the Patient

13. Enter or select a patient on the **Patient** screen, as described in Chapter 3, Finally, on the sub-tab **Device Info** under the **Utilities tab**, enter probe and device information, then **Save**. See **Figure 20** for an example.

    a. Note: since the release of the **ArcScan software Version 0.7 Build 48239 *Aspen Prime***, probe/transducer focal length information is a requirement that needs to be entered for accurate functioning of the device; **it cannot be left blank**! If in doubt about your Instrument's probe/transducer focal length, ask ArcScan.

    b. Additional information about device and probe serial number can also be entered. These are ok to be left blank if unknown, however, ask ArcScan for information.

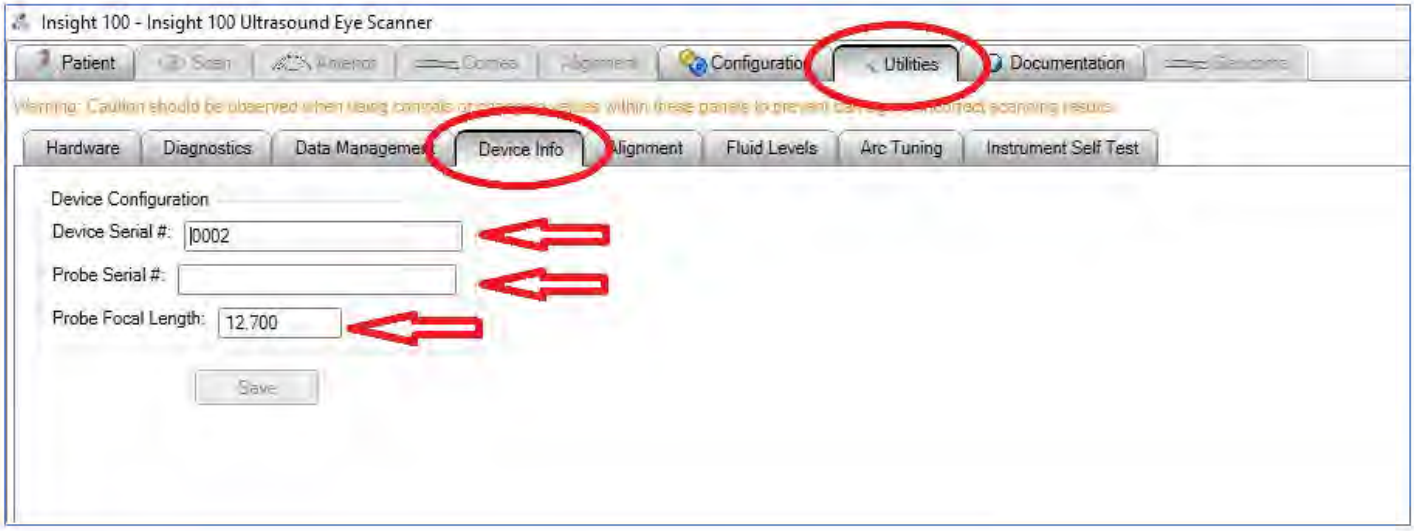


**Figure 20: Device and Probe serial number, as well as Probe Focal length information should entered under Device Info sub-tab. Particularly, Probe focal Length is a requirement for proper functioning of the device. As an example, a 12.7 mm focal length transducer is entered. The "mm" unit is not needed.**

1. Entering Patient Information.

2. Click on the **Scan** tab.

   **Note**: The **Scan** tab is not available unless a patient is selected.

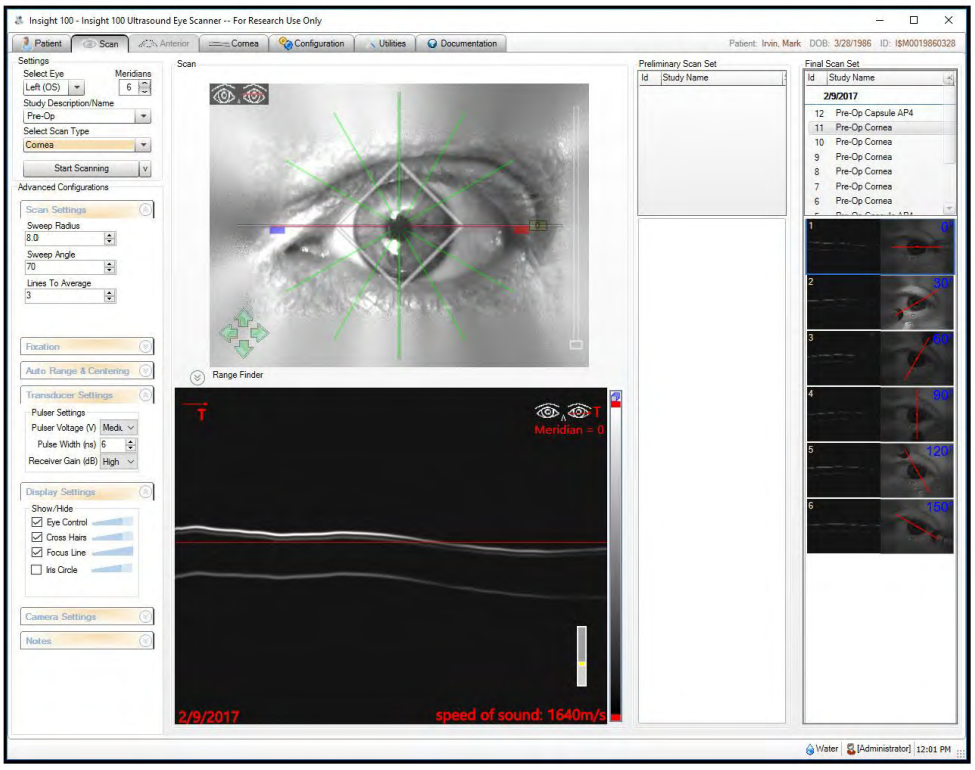


**Figure 26. Scan Page**

3. Enter the general settings for the scan.

| | |
|---|---|
| Select Eye | Select the **Left (OS)** or **Right (OD)** eye.<br>**Note:** The eye can also be selected by clicking the eye marker on the camera image. |
| Meridians | Select the number of meridians that will be contained in the scan set. |
| Study Description | Select **Pre-Op** or **Post-Op**. |
| Scan Type | Select one of the following: |
| | **Anterior Segment**: A single sweep that will be analyzed using the anterior segment tab. |
| | **Capsule APP**: Combines an arc scan with two lateral scans to allow for better images of the back of the lens. |
| | **Cornea**: A single arc sweep that will be used to measure thickness of the cornea. |

4. Enter the advanced configurations for the scan.

For **Anterior Segment** scans:

| | |
|---|---|
| Scan Settings | Choose the **Radius** of a given sweep. |
| | Choose the **Sweep Angle** (the total angle that the arc motor will sweep). |
| Centering | Select one of the following: |
| | **Center None**: No centering scan will be performed without adjusting X or Y. |
| | **Center First Meridian**: The system will try to center first, before the scan is performed. |
| | **Center All Meridians**: The system will try to center before each meridian is scanned. This option is primarily used when patient have difficulty holding still. |
| | Choose the **Mode**: |
| | **Auto** Centering: The system will take two scans and automatically moves X and Y in order to center the image. |
| | **Manual** Centering: The system will continuously scan using short sweeps, allowing the operator to adjust X and Y, before performing the scan. |
| | Choose the **Autocenter Sweep Distance.** |
| Transducer Settings | Choose the **Pulser Voltage (V)**. |
| | Choose the **Pulse Width (ns).** |
| | Choose the **Receiver Gain (dB)**. |
| Display Settings | Show or hide each of the following: |
| | **Eye Control** |
| | **Cross Hairs** |
| | **Focus Line** |
| Camera Settings | Show or hide the Visual **Gain**. This adjusts the camera sensitivity to the light. |
| | Visual **Brightness**. This adjusts the image brightness. |

Refer to the *Anterior Segment Imaging and Biometry* subsection for detailed information about this scan type.

For **Capsule AP4** scans:

| | |
|---|---|
| Scan Settings | **Lateral Range** (the distance, in millimeters, of a lateral sweep). |
| | Choose the **Arc Position** (the position of the arc motor during the lateral sweep).<br>**Note:** On the AP4 scan, the symmetric lateral sweep is a mirror image of the last lateral sweep described in the scan. |
| | Choose the **Radius** of a given Arc sweep. |
| | Choose the **Sweep Angle** (the total angle that the arc motor will sweep). |
| Centering | Select one of the following: |
| | **Center None**: No centering scan will be performed without adjusting X or Y. |
| | **Center First Meridian**: The system will try to center first, before the scan is performed. |
| | **Center All Meridians**: The system will try to center before each meridian is scanned. This option is primarily used when patient have difficulty holding still. |
| | Choose the **Mode**: |
| | **Auto** Centering: The system will take two scans and automatically moves X and Y in order to center the image. |
| | **Manual** Centering: The system will continuously scan using short sweeps, allowing the operator to adjust X and Y, before performing the scan. |
| | Choose the **Autocenter Sweep Distance.** |
| Transducer Settings | Choose the **Pulser Voltage (V)**. |
| | Choose the **Pulse Width (ns).** |
| | Choose the **Receiver Gain (dB)**. |
| Display Settings | Show or hide each of the following: |
| | **Eye Control** |
| | **Cross Hairs** |
| | **Focus Line** |

| | |
|---|---|
| Camera Settings | Show or hide the Visual **Gain**. This adjusts the camera sensitivity to the light. |
| | Choose the Visual **Brightness**. This adjusts the image brightness. |

Refer to the *Capsule Imaging* subsection for detailed information about this scan type.

For **Cornea** scans:

| | |
|---|---|
| Scan Settings | Choose the **AvgLines** of a given Arc sweep. |
| | Choose the **Radius** of a given Arc sweep. |
| | Choose the **Sweep Angle** (the total angle that the arc motor will sweep). |
| Centering | Select one of the following: |
| | **Center None**: No centering scan will be performed without adjusting X or Y. |
| | **Center First Meridian**: The system will try to center first, before the scan is performed. |
| | **Center All Meridians**: The system will try to center before each meridian is scanned. This option is primarily used when patient have difficulty holding still. |
| | Choose the **Mode**: |
| | **Auto** Centering: The system will take two scans and automatically moves X and Y in order to center the image. |
| | **Manual** Centering: The system will continuously scan using short sweeps, allowing the operator to adjust X and Y, before performing the scan. |
| | Choose the **Autocenter Sweep Distance.** |
| Transducer Settings | Choose the **Pulser Voltage (V)**. |
| | Choose the **Pulse Width (ns).** |
| | Choose the **Receiver Gain (dB)**. |

| | |
|---|---|
| Display Settings | Show or hide each of the following: |
| | **Eye Control** |
| | **Cross Hairs** |
| | **Focus Line** |
| Camera Settings | Show or hide the Visual **Gain.** This adjusts the camera sensitivity to the light. |
| | Choose the Visual **Brightness**. This adjusts the image brightness. |

Refer to the *Corneal Imaging and Biometry* subsection for detailed information about this scan type.

5. Using the video image, center the scan head such that the pupil is in the center of the image. Centering the image can be done using any of the following methods:

   - Double-click with the left mouse button to center over the mouse button.
   - Hold the center mouse button down while moving the mouse.
   - Use the arrow keys in the lower left corner of the eye control.

6. Align the bicanthal plane of the patient's eye to the horizontal axes of the video image. This can be done by clicking on the cross hairs on the video image and rotating.

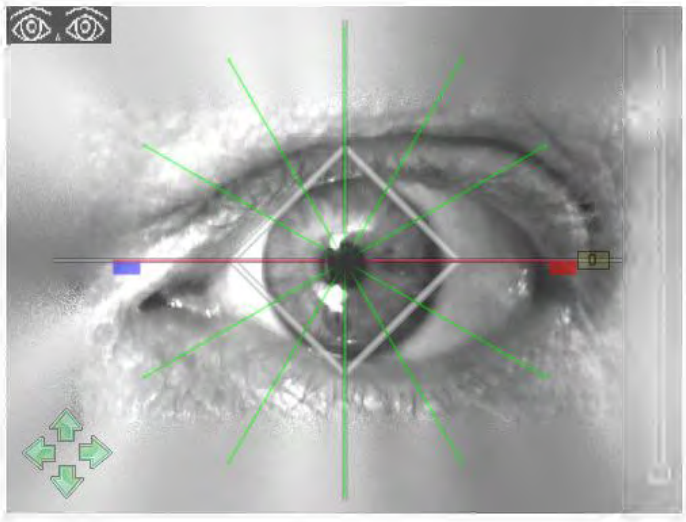

**Figure 27. Camera Image**

7. Use the range finder to position the transducer focal plane on the front of the iris. If using the Auto Range Finder this step may be skipped, as it will set the depth on its own at the start of the scanning process.

    - Click on the yellow lines and drag to adjust the scan depth.
    - Click on the Transducer icon ( ) to the left of the screen to adjust the vertical position up or down.
    - Click on the Transducer icon ( ) to the right of the screen to adjust the horizontal position right or left.
    - The red line notes the patient's focus.

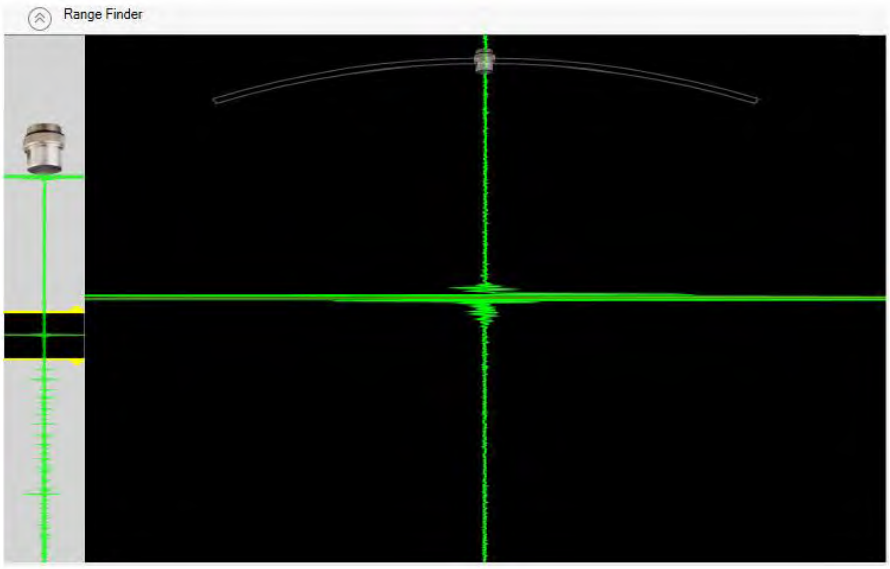


**Figure 28. Range Finder**

8. Perform the scan. Instructions for the various types of scans are provided in the following sections:

    - Full scan set with automatic centering
    - Auto-centering on every meridian
    - No centering
    - Manual centering
    - Continuous scan mode
    - Next/repeat scan mode

9. After a scan, the new scan set is placed in the **Preliminary Scan Set** window (on the **Scan Page**). Use this control to select and view scans.

   A scan set can be acquired from the **Preliminary Scan Set** window to the **Final Scan Set** window. This will allow access to the review tabs.

   Final scans will appear in the **Final Scan Set** window.

   **Note:** To delete or rescan a patient scan, right click on the appropriate thumbnail and select an option from the pull-down list (see below). This option is available by right-clicking on a scan thumbnail in the **Preliminary Scan Set** group.

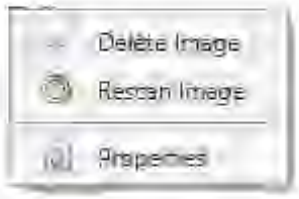


**Figure 29. Rescan and Delete Options**

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**. This will take a new scan using the original scan parameters.<br>**Note:** Rescanning is only available for images that were acquired during the current scan set. New scan sessions are started when the operator selects a new patient, has not clicked the scan button in the last 10 minutes, or the operator changes the selected eye. |
| **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 and image allows the operator to view the image.<br>**Note:** This function is not available when the range finder is open. |

10. 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:<br>*To decrease brightness*— movement to the left<br>*To increase brightness*— movement to the right<br>*To decrease contrast*— movement up<br>*To increase contrast*— movement down |
| **Zooming** | Scrolling the mouse wheel in and out will adjust the zoon level.<br>**Note:** Zooming does not work on the **Scan Page**. |
| **White and Black Point Adjustment** | The control to the right of the images allows the operator to set the minimum black and white points of an image. |
| **Eye Marker (**  **)** | The **Eye Marker** allows the 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. |

11. When scanning has completed, drain the EyeSeal Disposable as described below (or refer to the *EyeSeal Disposable IFU* in Appendix C).

    a. Open the clamp on the air purge line.

    b. Ensure the clamp on the saline administration set is closed.

    c. Open the clamp on the drain line to remove saline from the EyeSeal Disposable.

    **Note:** When air is seen in the drain line the saline has been drained.

12. Instruct the patient to remove their eye from the EyeSeal Disposable.

13. If scanning the patient's other eye, place the patient as instructed in Chapter 3,

14. Placing the Patient and scan the patient as instructed above. The same EyeSeal Disposable may be used to scan the other eye.

# Scanning Options

The following subsections provide instructions on performing various scanning options:

- Full scan set with automatic centering
- Auto-centering on every meridian
- No centering
- Manual centering
- Continuous scan
- Next/repeat scan mode

## Full Scan Set with Automatic Centering (Standard Type of Scan)

This type of scan only does auto centering on the first meridian. Follow these steps to perform the scan:

1. Roughly align the ultrasound axes to the patient's eye by centering the video image of the patient's pupil to crosshairs that are superimposed on the video image.
2. Instruct the patient to open their eye wide.
3. Initiate the scan.
4. The system scans the patient's system and uses the ultrasound data to determine the position of the corneal apex. The system moves the scan head mechanism to align the ultrasound axes with the corneal apex.
5. The system acquires a scan
6. The system moves to the next meridian
7. The system repeats steps 5 and 6 until the scan set is complete.

## Auto-centering on Every Meridian (Variation)

In some cases, it may be desirable to center before every meridian. In this case, select the option to center all meridians.

1. Roughly align the ultrasound axes to the patient's eye by centering the video image of the patient's pupil to crosshairs that are superimposed on the video image.
2. Instruct the patient to open their eye wide.
3. Initiate the scan.
4. The system scans the patient's system and uses the ultrasound data to determine the position of the corneal apex. The system moves the scan head mechanism to align the ultrasound axes with the corneal apex.
5. The system acquires a scan
6. The system moves to the next meridian
7. The system repeats steps 4, 5, and 6 until the scan set is complete.

## No Centering (Variation)

In some cases, it is desirable to scan the patient's eye without the machine automatically centering on the corneal apex. In this case, override the default centering mode to disable centering.

1. Roughly align the ultrasound axes to the patient's eye by centering the video image of the patient's pupil to crosshairs that are superimposed on the video image.
2. Instruct the patient to open their eye wide.
3. Initiate the scan.
4. The system acquires a scan
5. The system moves to the next meridian
6. The system repeats steps 4 and 5 until the scan set is complete.

## Manual Centering (Variation)

Auto centering may not work with all patients due to anatomic variations or the ability of the patient to hold their eye steady. In this case, override the default auto-centering mode and select manual centering.

1. Roughly align the ultrasound axes to the patient's eye by centering the video image of the patient's pupil to crosshairs that are superimposed on the video image.
2. Instruct the patient to open their eye wide.
3. Initiate the scan.
4. The system repeatedly scans the current meridian and displays non-geometrically corrected b-scans. Use the mouse to move the scan head such that the scan is symmetric and as flat as possible.
5. When satisfied that centering is adequate, command the system to acquire a scan.
6. The system acquires a scan
7. The system moves to the next meridian
8. The system repeats steps 6 and 7 until the scan set is complete.

## Continuous Scan (Variation)

When imaging a particular feature of the eye that is small (eg, corneal scar, specific zonular region, implant haptic, etc.) it will be required to fine tune the scanning position to produce the desired image, per the procedure below.

1. Roughly align the ultrasound axes to the patient's eye by centering the video image of the patient's pupil to crosshairs that are superimposed on the video image.
2. Instruct the patient to open their eye wide.
3. Initiate the scan.
4. The system scans the patient's system and uses the ultrasound data to determine the position of the corneal apex. The system moves the scan head mechanism to align the ultrasound axes with the corneal apex.
5. The system continually acquires scans at the current meridian until the software is stopped by the operator. The software keeps the most recent 10 images in a buffer for later review.

6. While scanning, the following actions may be performed:

    - Move the scan head in the XY plane to center the scan.
    - Move the transducer's Z position.
    - Move the beta position.
    - Adjust the scan geometry.

**Note:** In Continuous Mode, the system does not collect the full scan set. However, it does save the last 10 scans that were taken during continuous mode.

## Next/Repeat Scan Mode (Variation)

Patients who have difficulty holding their eye still may require several attempts to get a good quality scan. In this case, it is desirable to step through the scanning process to ensure each scan is good before proceeding to the next.

1. Roughly align the ultrasound axes to the patient's eye by centering the video image of the patient's pupil to crosshairs that are superimposed on the video image.
2. Instruct the patient to open their eye wide.
3. Initiate the scan.
4. The system scans the patient's system and uses the ultrasound data to determine the position of the corneal apex. The system moves the scan head mechanism to align the ultrasound axes with the corneal apex.
5. The system displays the most recently acquired scan prior to moving Beta to the next meridian.
6. The system prompts the operator to either proceed to the next meridian or repeat the scan again.

    - If operator selects **Repeat**, the current scan is discarded and the scan is repeated.
    - If operator selects **Next**, the current scan is saved and the beta position is moved to the next meridian.

7. The system repeats steps 5 and 6 until the scan set is complete.

# Chapter 5: Post Processing

Post processing refers to the utilization of scan data for:

- Calculations
- Measurements
- Report generation

---

***Caution:*** *Read all warnings, cautions, and instructions provided with this instrument before using.*

---

## Objective

The objective of post processing is to present the scan data in a format that presents the desired information to the doctor or technician.

## Procedure

1. After each scan, the software converts ultrasound signal into an image and displays it on the screen.
2. Inspect the scan(s) and select one or more scans for detailed evaluation.
3. Use software tools to measure the features of interest on the selected scan images.
4. After all scans are complete a report is generated from the saved images and measurements.

## Viewing Scans

1. Select the desired scan to view.
2. 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:<br>*To decrease brightness*— movement to the left<br>*To increase brightness*— movement to the right<br>*To decrease contrast*— movement up<br>*To increase contrast*— movement down |
| **Zooming** | Scrolling the mouse wheel in and out will adjust the zoon level.<br>**Note:** Zooming does not work on the **Scan Page**. |

| | |
|---|---|
| **White and Black Point Adjustment** | The control to the right of the images allows the operator to set the minimum black and white points of an image. |
| **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. |

# Post-Processing for Corneal Imaging and Biometry

The following post-processing procedures are performed for corneal imaging and biometry.

1. Click on the **Cornea** tab to open the **Cornea Page**. The **Cornea Page** will open with the **Analysis** tab on the screen.

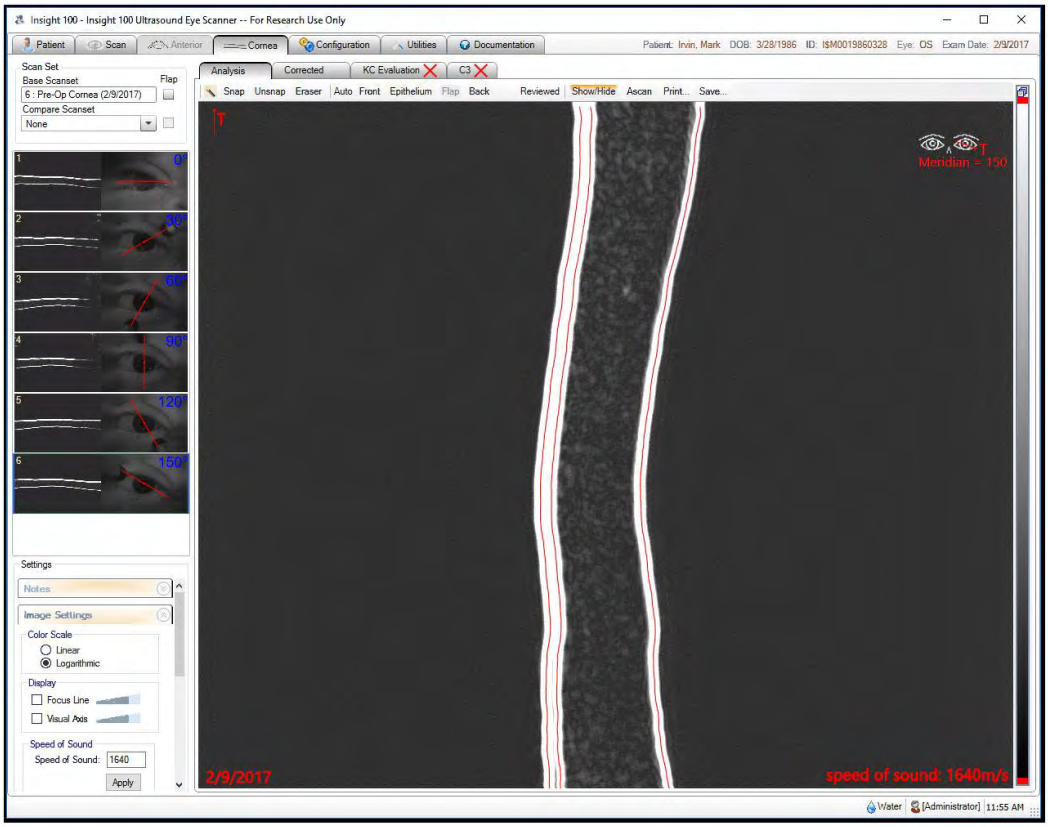


**Figure 30. Cornea Page - Analysis Tab**

2. Select the desired scan set to view on the upper left-hand side of the **Cornea Page**.

The following options are available in the **Analysis** tab:

| | | |
|---|---|---|
| **Tools** | **Snap** | Allows operator to force a system to snap to the largest peak. |
| | **Unsnap** | Allows operator to force an unsnap. |
| | **Magic Wand (  )** | The system automatically chooses to snap or unsnap the point. |
| | **Eraser** | Allows operator to delete the point. |

| | | |
|---|---|---|
| **Surface Selection** | **Auto** | The system will automatically select the closest surface when performing surface edits. |
| | **Front** | Locks all edits to the front. |
| | **Epithelium** | Locks all edits to the epithelium. |
| | **Flap** | Locks all edits to the flap. |
| | **Back** | Locks all edits to the back. |
| **Surface Right-Click Menu** | **Revert Surface** | Will revert the surface to the state it was before it was edited. |
| | **Re-Detect Surface** | Will run the surface to the auto-detection routine again. |
| | **Delete All Surface Points** | Removes all surface points. |
| **Other** | **Show/Hide** | Shows or hides all of the surface points. |
| | **Save Image** | Saves a .jpg file of the image. |
| | **Ascan** | Displays the A-scan that the mouse is currently over. |
| | **Print** | Prints the report. |

3. From the **Cornea Page**, click on the **Corrected** tab.

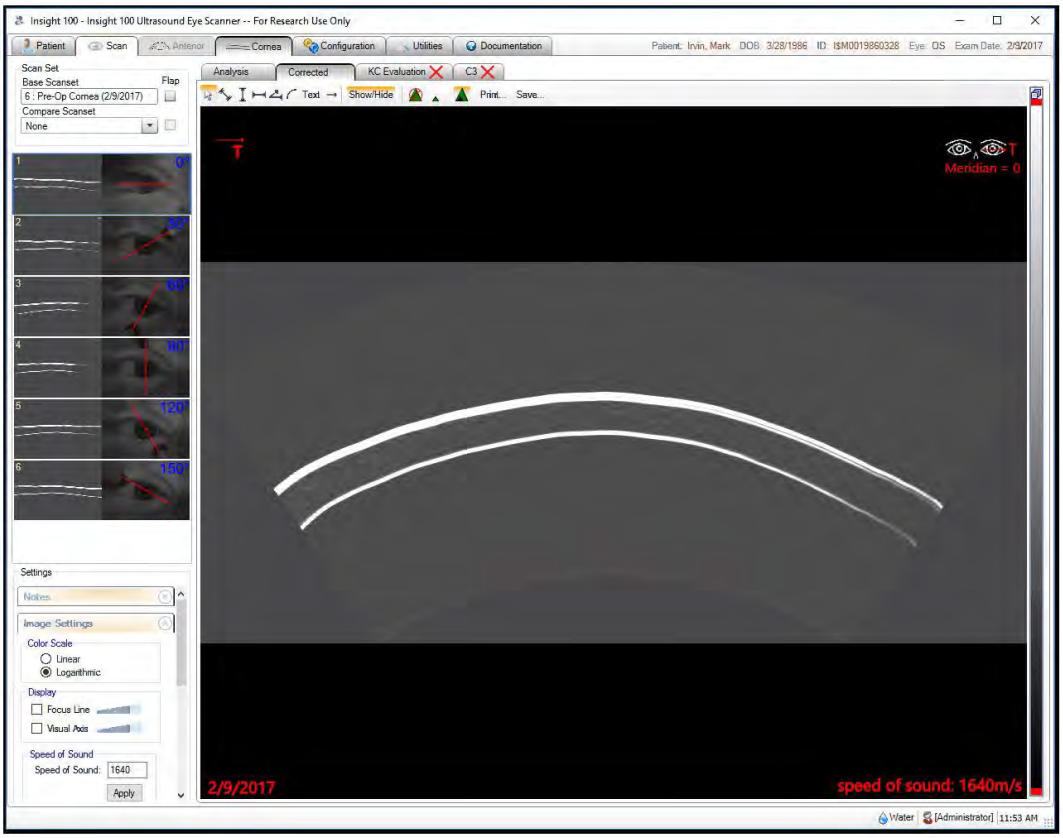


**Figure 31. Cornea Page - Corrected Tab**

The following display settings are available in the **Corrected** tab:

| | |
|---|---|
| **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 |

The following measurement tools are available in the **Corrected** tab:

| | |
|---|---|
| **Mouse Pointer ( )** | Allows the operator to select or move points on existing annotations.<br>Annotations will 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 .jpeg file image. |
| **No Peak Detection Option (**  **)** | Turns off all peak detection when making measurements. |
| **Small Search Radius for Peak Detection Option (**  **)** | Sets the peak detection search radius to a minimal value. |
| **Large Search Radius for Peak Detection Option (**  **)** | Sets the peak detection search radius to a larger value. |
| **Print** | Prints the report. |

4. From the **Cornea Page**, click on the **Thickness Maps** tab.

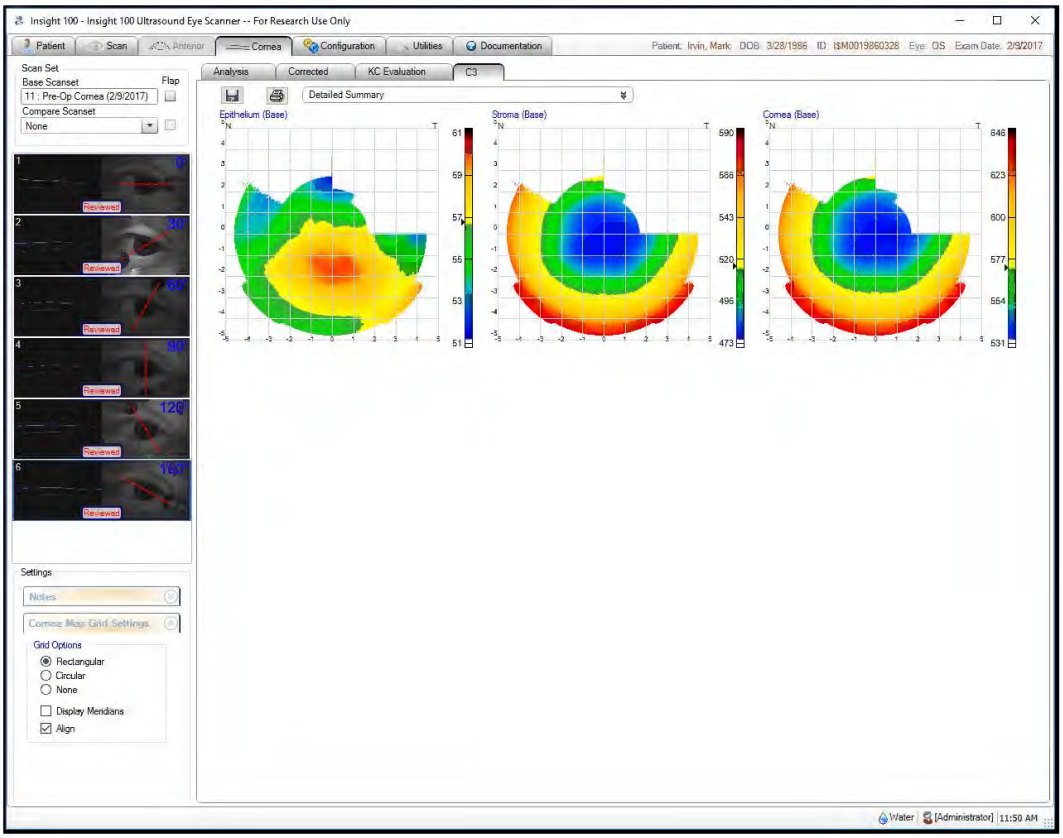


**Figure 32. Cornea Page - Thickness Maps**

The following thickness maps may be available:

| | | |
|---|---|---|
| **Thickness Maps:** | **C3** | Includes thickness maps of the following:<br>Epithelium (base)<br>Stroma (base scan)<br>Cornea (base scan) |
| | **C6** | Includes thickness maps of the following:<br>Epithelium (base)<br>Stroma (base)<br>Cornea (base)<br>Flap (base)<br>Residual Stroma (base) |
| | **C6** *(continued)* | Stroma Component of flap (base) |

| | | |
|---|---|---|
| | **C9** | Includes thickness maps of the following:<br>Epithelium (base)<br>Stroma (base)<br>Cornea (base)<br>Epithelium (compare)<br>Stroma (compare)<br>Cornea (compare)<br>Epithelium (compare – base)<br>Stroma (base – compare)<br>Cornea (compare – base) |
| | **C12** | Includes thickness maps of the following:<br>Epithelium (base)<br>Stroma (base)<br>Cornea (base)<br>Epithelium (compare)<br>Stroma (compare)<br>Cornea (compare)<br>Flap (compare)<br>Epithelium (compare – base)<br>Stroma (base – compare)<br>Full Flap<br>Residual Stroma (compare)<br>Stroma Component of flap (compare) |
| | **C15** | Includes thickness maps of the following:<br>Epithelium (base)<br>Stroma (base)<br>Cornea (base)<br>Flap (base)<br>Stroma Component of flap (base)<br>Residual Stroma (base)<br>Epithelium (compare) |
| | **C15** *(continued)* | Stroma (compare)<br>Cornea (compare) |

| | | |
|---|---|---|
| | | Flap (compare)<br>Stroma Component of flap (compare)<br>Residual Stroma (compare)<br>Epithelium (compare – base)<br>Stroma Component of flap (compare – base)<br>Residual Stroma (compare – base) |
| **Map Options:** | **Grid Options** | A circular or rectangular grid may be added to the map. |
| | **Display Meridians** | Meridian lines may be added to the cornea maps. |
| | **Align** | If surface data is misaligned to the arc motor travel, it will be aligned prior to display. This is done so that surfaces in difference maps may be accurately compared. |
| **Detailed Summary:** | Provides a table that includes the minimum, maximum, and central thickness for the displayed Maps. | |

To compare a patient's scanset to their base scanset, select the desired scan set to compare from the pull-down list on the upper left-hand corner of the **Cornea Page**.

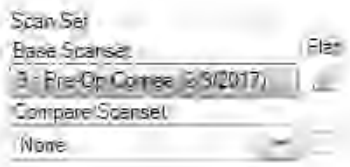


**Figure 33. Scan Set Comparison Selector**

## Post-Processing for Anterior Segment Imaging and Biometry

The following post-processing procedures are performed for anterior segment imaging and biometry.

1. Click on the Anterior tab to open the **Anterior Page**. The **Anterior Page** will open with the **Details** tab on the screen.


**Figure 34. Anterior Page - Details Tab**

2. Select the desired scan set to view on the upper left-hand side of the **Anterior Page**.

The following options are available on the **Details** tab:

| | |
|---|---|
| **Mouse Pointer ( )** | Allows the operator to select or move points on existing annotations.<br>Annotations will 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. |
| **Print Button** | Prints the image displayed including annotations. |
| **Save Image Button** | Saves a .jpeg file image. |
| **No Peak Detection Option ( )** | Turns off all peak detection when making measurements. |
| **Small Search Radius for Peak Detection Option ( )** | Sets the peak detection search radius to a minimal value. |
| **Large Search Radius for Peak Detection Option ( )** | Sets the peak detection search radius to a larger value. |

# Chapter 6: After Scanning

This chapter includes information about:

- Shutting down the instrument
- Storing the system

---

***Caution:*** *Follow the cleaning procedures exactly as described in the instructions. Skipping a cleaning, skipping steps, or using different cleaning agents could lead to damage to the equipment.*

***Caution:*** *Properly dispose of the electronic instrument and disposable accessories according to clinic or hospital policies.*

---

# Shutting Down the Instrument

At the end of each day, follow the procedures below to shut down the system.

1. Drain the scan head. Click on the **Water** button on the bottom right-hand corner of the screen. Then click the **Drain** button. The distilled water will automatically drain from the scan head.

   The scan head is empty when the water level reaches 0%, as shown in the following graphic.

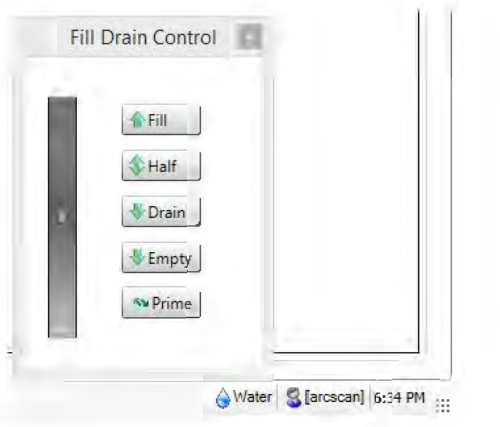


**Figure 35. Empty Water Level**

2. Remove the EyeSeal Disposable from the scanner as described below (or refer to the *EyeSeal Disposable IFU* in Appendix C).

   a. Disconnect the saline administration set from the saline line on the EyeSeal Disposable.

   b. Grip the handles located on both sides of the disposable.

   c. Rotate the EyeSeal Disposable counter-clockwise until it cannot rotate further.

   d. Gently pull the EyeSeal Disposable out of the receptacle.

   e. Discard the used EyeSeal Disposable.

3. Clean all surfaces with a disinfectant wipe.

4. Close the software.

5. Turn off the computer and monitor.

6. Turn off the power button on the electronics unit.

# Storing the System

1. With the instrument and software running, click Empty in the Fluid Drain Control window and click the Stop when the scan head is sufficiently drained. When the Empty operation is finished close the software and power down the instrument.

   ***Note**: As the pump begins to pull in air there will be a gurgling noise coming from inside the scan head, continue draining for 5-10 additional seconds.*

2. Fully drain the reservoir.

   a. Remove the hoses on the reservoir. The small metal fitting can be unscrewed and the fill drain tube can be disconnected at the quick-disconnect fitting.

   b. Unscrew the cap on the reservoir and drain all the fluid.

3. Remove filter housing and filter as described in Chapter 8, Replacing the Water Filter and store open.

4. Allow the unit to dry, then install the calibration fixture on the EyeSeal Disposable holder to prevent dust from entering the scan head.

# Chapter 7: Troubleshooting

This chapter includes information about:

- Correcting malfunctions
- Responding to error messages

| Symptom | Recommended Action |
|---|---|
| System fails to power up | Cable is 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. See the images* below. |
| | Blown fuse – Contact manufacturer. |
| | Bios default – Contact manufacturer. |
| Calibration failure – *Motors Failed to Initialize* error message | The ArcScan Insight 100 instrument module cable is not attached to scan housing – Connect the cable and recalibrate. If the problem persists, contact the manufacturer. |
| | Motors not homing – Check **Advanced troubleshoot 1** |
| | Blown fuse – Contact manufacturer. |
| Calibration failure – *Digitizer Failed to Initialize* error message | Digitizer failure – Contact manufacturer. |
| | Blown fuse – Contact manufacturer. |
| | The ArcScan Insight 100 fluidics cable is disconnected. Reconnect the cable to the |

| Symptom | Recommended Action |
|---|---|
| Scan chamber will not fill when **Fill** button is pressed | fluidics module and restart the device. If the problem persists, contact the manufacturer. |
| | There is no liquid in the reservoir – Fill the reservoir and try again. |
| | Fill hose is pinched. |
| | Electronics failure – Contact manufacturer. |
| Scan chamber will not drain when **Drain** button is pressed | Drain hose is pinched. |
| | Electronics failure – Contact manufacturer. |
| No image appears on the display during scanning | Electronics failure – Contact manufacturer. |
| | Z position is incorrect – Contact manufacturer. |
| Scan image has partial garbled data | Wrong transducer focal length – Check **Advanced troubleshoot 2**<br>Electronics failure – Contact manufacturer. |

For any other malfunction, contact the manufacturer for instructions on how to proceed.

*Module power cables from left to right (cables and receptacles are color coded for ease of installation): Computer (green), Fluidics (white), Instrument (red), Monitor (orange).

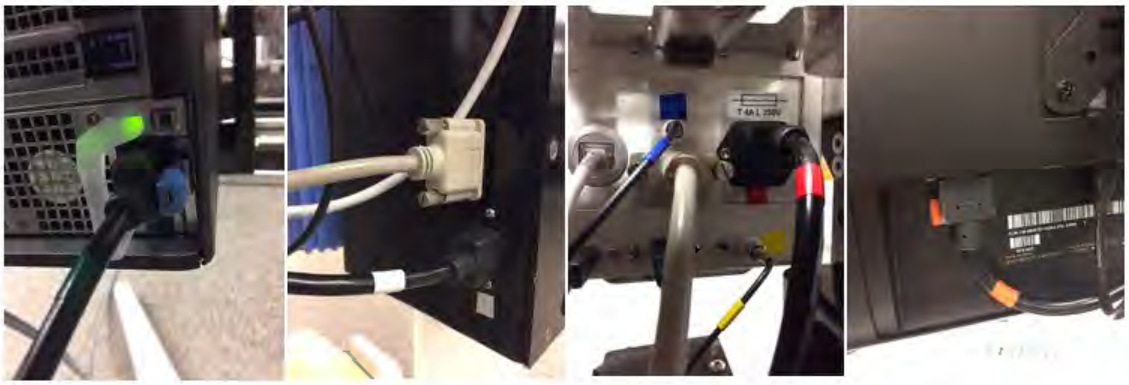

**Figure 36. ArcScan Power Connections**

## Advanced troubleshoot 1

**Issue**

- Motors not homing

**Special Tools Required:**

- ArcScan software in service mode

**Procedure:**

1. Power on the computer of the ArcScan Insight 100, sign into Windows.
2. Turn on the ArcScan Insight 100
    a. Note: the power switch of the ArcScan Insight 100 is located on the central column, underneath the table desk.
3. Launch the ArcScan Insight 100 software
4. On the bottom right-hand corner of the software screen, log in as **Service**. The password is **33arc$$scan76**. See Figure 37 as an example.

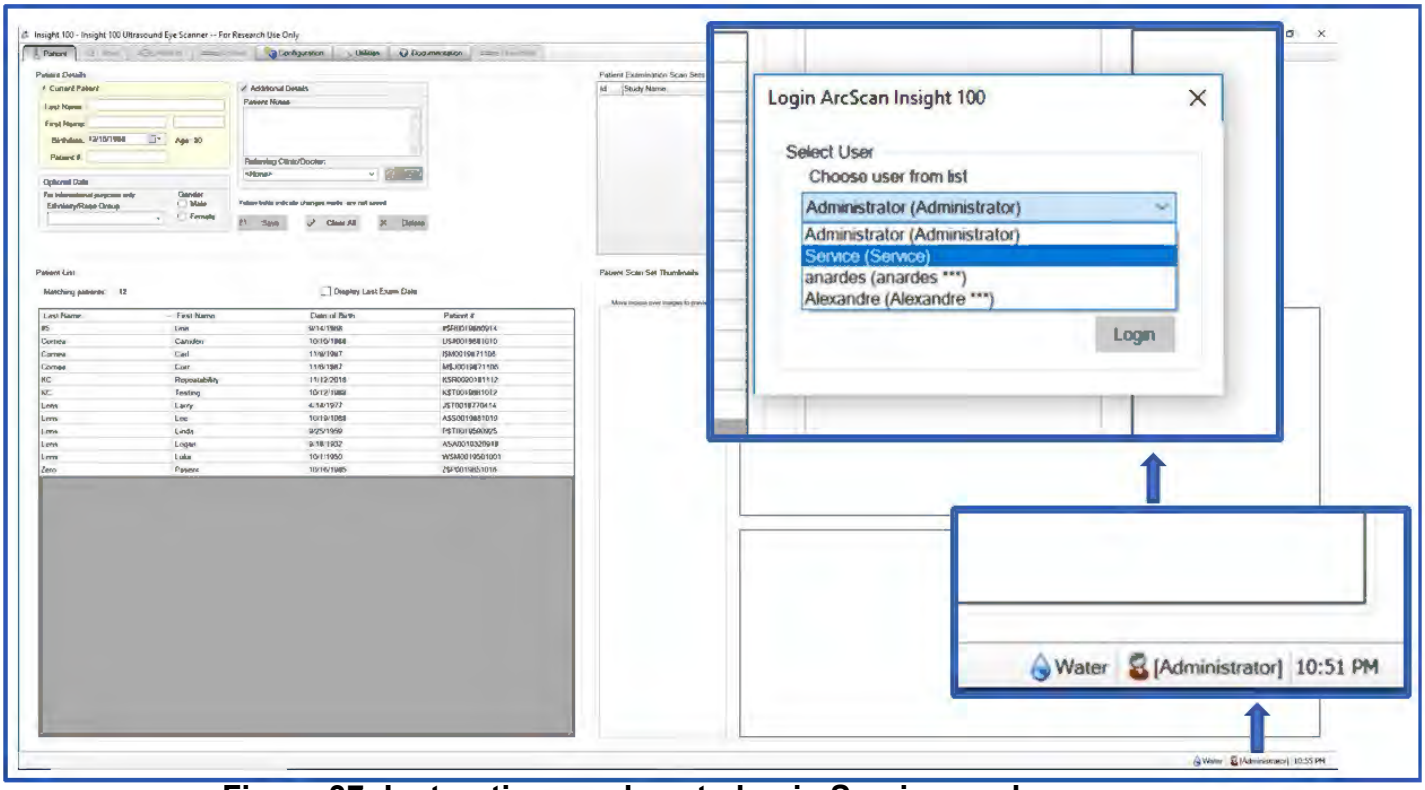


**Figure 37: Instructions on how to log in Service mode**

5. Attach a **marble test fixture** or an **EyeSeal** to the scan head.
6. Ensure the distilled water reservoir is full. Click on the **Water** button on the bottom right-hand corner of the screen. Then click the **Fill** button. The scan head will fill with water.
    a. Note: during filling water, motors will start homing. If the **Utilities** tab turns red, motors will stop homing and system will stop filling water. Click the **Fill** button again to keep the filling water process going.

7. Once the scan head is 100 % filled with water, go to the **Hardware** subtab under **Utilities** tab. Then, on **Motion**, click the **Action** button, then **Reset.** Wait for motors to reset. Then click **Home Motors.** See Figure 38**.**

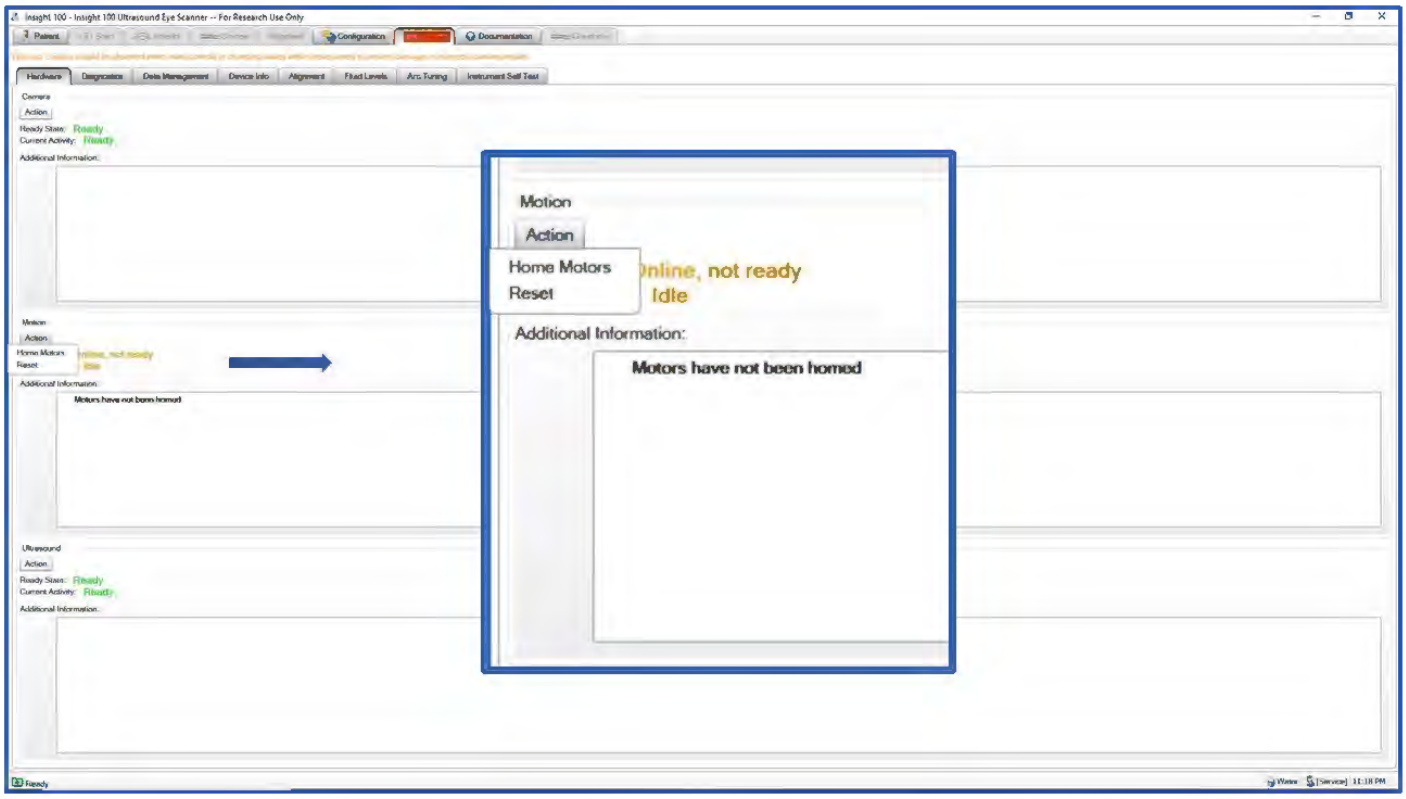


**Figure 38: Home motors command**

8. If Motors still do not home, go to the **Alignment** subtab under the **Utilities** tab and click **Calculate.**
    a. Note: a window will pop up asking to commit to the new values. Click **ok**. Then click **Save** to make the values effective.
9. Go back to the **Hardware** subtab, then click **Home Motors** under the **Action** button. Motors will start moving. When motors are homed, a green **Ready** message will show up.

## Advanced troubleshoot 2

### Issue

- Scan image has partial garbled or distorted data due to incorrect focal length transducer

### Special Tools Required:

- ArcScan software in service mode

### Procedure:

1. Power on the computer of the ArcScan Insight 100, sign into Windows.
2. Turn on the ArcScan Insight 100
    a. Note: the power switch of the ArcScan Insight 100 is located on the central column, underneath the table desk.
3. Launch the ArcScan Insight 100 software
4. On the bottom right-hand corner of the software screen, log in as **Service**. The password is **33arc$$scan76**. See **Figure 37** as an example.
5. Attach a **marble test fixture** or an **EyeSeal** to the scan head.
6. Ensure the distilled water reservoir is full. Click on the **Water** button on the bottom right-hand corner of the screen. Then click the **Fill** button. The scan head will fill with water.
7. Once full of water and motors homed (check **Advanced Troubleshoot 1** for ensuring motors homed), go to **Utilities** tab, then **Device Info** sub-tab. Make sure the correct probe focal length is entered. Save it. See **Figure 39** as an example

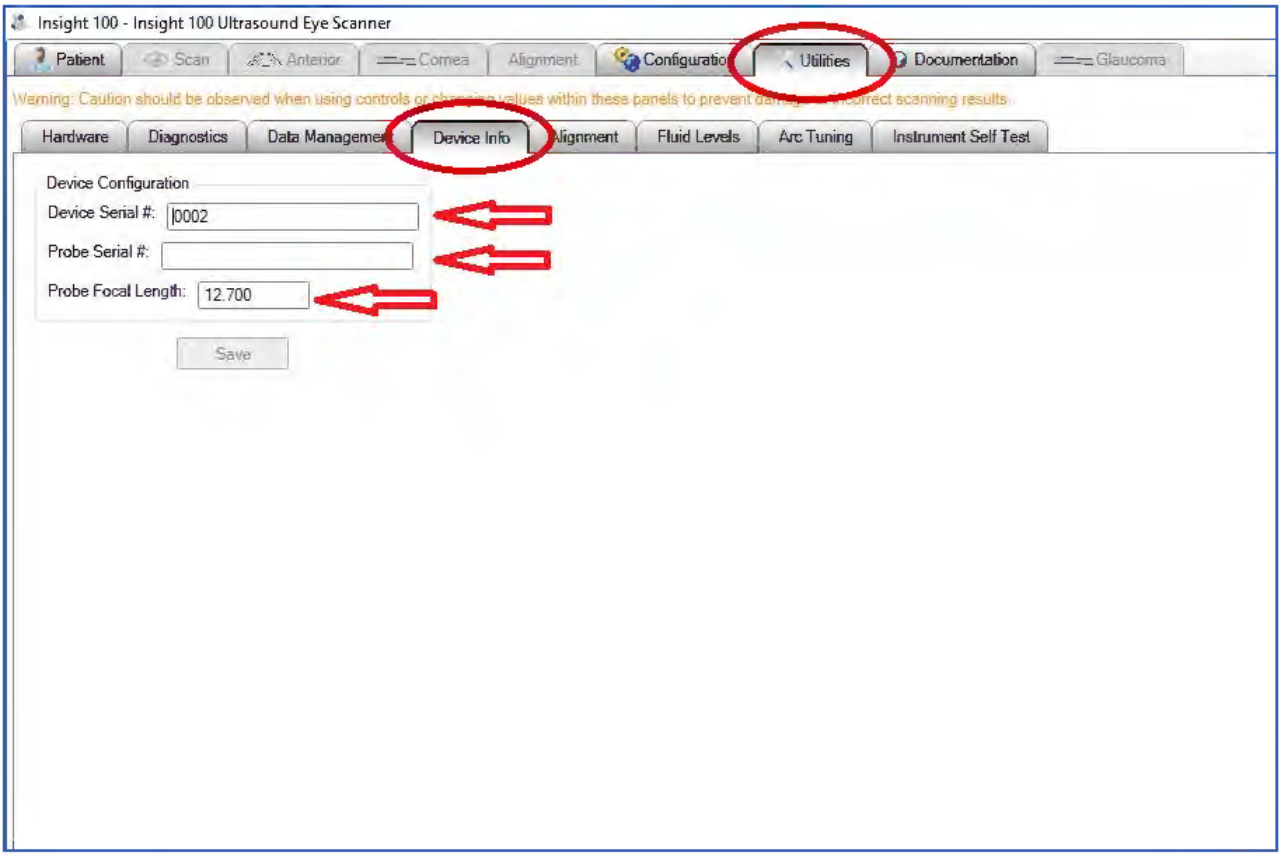


**Figure 39: Device info tab for correct probe focal length data.**

8. Run a scan and compare the image quality this time.

# Chapter 8: Cleaning and Maintenance

This chapter includes information about:

- The manufacturer's responsibility
- General cleaning
- Routine maintenance
- Replacing the fuses
- Replacing the system water
- Cleaning the fluid system
- Replacing the water filter
- Returning the system for service
- Contact information for ArcScan service centers

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***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.*

---

***Caution:*** *Follow the cleaning procedures exactly as described in the instructions. Skipping a cleaning, skipping steps, or using different cleaning agents could damage the equipment*

***Caution:*** *To maintain optimum performance, have the system serviced and calibrated by an authorized service representative on at least a semi-annual basis.*

***Caution:*** *Always replace the filter according to the defined schedule. Failure to replace filter can result in damage to the system.*

***Caution:*** *After each patient, the external surfaces of the ArcScan Insight 100 system must be disinfected.*

***Caution:*** *Avoid allowing cleaning fluids to enter the system.*

***Caution:*** ***Do not*** *reuse accessories labeled "disposable" or "single use only."*

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# Responsibility of the Manufacturer

ArcScan is responsible for the safety, reliability, and performance of the ArcScan Insight 100 system only under the following circumstances:

- Setup and scanning procedures in this manual are followed.
- Installation, service, readjustments, modifications, or repairs of the system are carried out by persons authorized by ArcScan.
- Routine customer maintenance procedures in this manual are followed.
- The ArcScan Insight 100 system is used in accordance with the ArcScan Insight 100User Manual.

# Broad overview of the maintenance frequency

1. The following Table summarizes ArcScan maintenance frequency

| Respon-sibility | Month 1 | Month 2 | Month 3 | Month 4 | Month 5 | Month 6 | Month 7 | Month 8 | Month 9 | Month 10 | Month 11 | Month 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| User | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test | Scan Self Test |
| User | | | Cleaning the Fluid System | | | Cleaning the Fluid System | | | Cleaning the Fluid System | | | Cleaning the Fluid System |
| ArcScan | | | | | | Factory Maintenance | | | | | | Factory Maintenance |

# General Check – Scan Self Test

1. Every month, ArcScan recommends users to run a Scan Self-test and record the results in the maintenance sheet provided. If none maintenance sheet, ask ArcScan for one.

2. The Scan Self Test is performed as follows (see **Figure 41** for visual guidance):

   a. Turn on the computer.

   b. Turn on the ArcScan. Note: the power switch of the ArcScan Insight 100 is located on the central column, underneath the table desk.

   c. Make sure the distilled water reservoir is full of water.

   d. Attach a marble test fixture to the scan head, **Figure 40** (ask ArcScan for a marble test fixture if none).


**Figure 40: Marble test fixture attached to the scan head.**

e. Launch the ArcScan Software

f. Log in **Service** mode (bottom right-hand side corner; password is **33arc$$scan76**), see **Figure 41**.

g. **Fill** water, see **Figure 41**.

h. On the bottom left-hand side corner, make sure system is **Ready**, see **Figure 41**.

i. Go to **Utilities** tab, see **Figure 41**.

j. Go to **Instrument Self Test** sub-tab, see **Figure 41**.

k. On the left-hand side of the screen, press **Scan Self Test** and wait for results, see **Figure 41**.

l. If all four Scan tests are **"true"**, note the results in the maintenance sheet (four digits after the decimal point is good enough), see **Figure 41**. Contact ArcScan if system does not pass one or more tests ("**false**"),

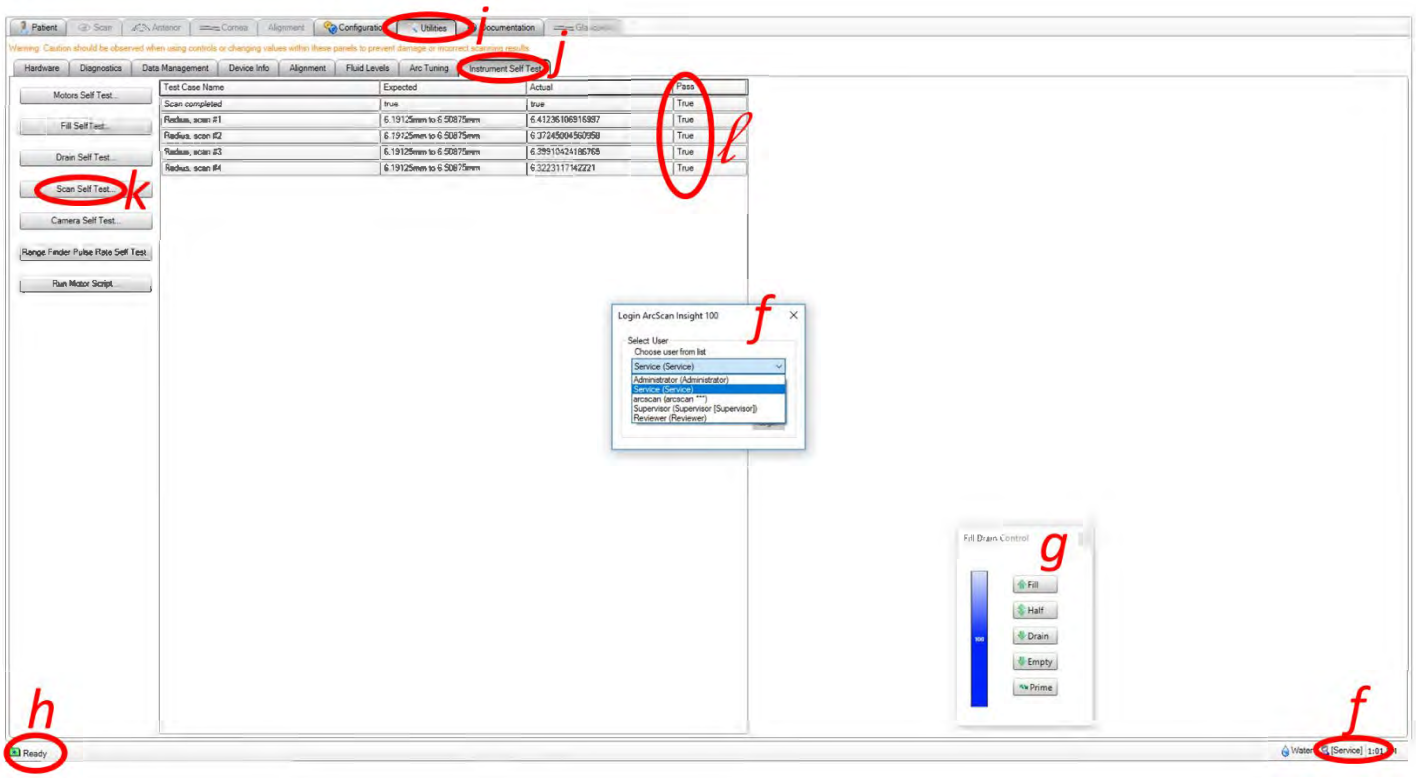



**Figure 41: Scan Self Test**

## General Cleaning

3. After every patient, thoroughly wipe all exposed surfaces of the system with a 1:10 (approximately 5000 ppm) bleach wipe. **Do not** allow cleaning fluids to enter the system.

## Customer Routine Maintenance

***When should the ArcScan Insight 100 system be checked or serviced?***

ArcScan recommends that the system be inspected by either authorized service personnel or personnel trained by ArcScan at least twice a year. This inspection will include any necessary calibration of the system and internal in-line filter replacements.

***When should the power cord be checked or replaced?***

Check the power cord each time the ArcScan Insight 100 system is used, or at the interval recommended by your facility. Replace the power cord if exposed wires, cracks, frayed edges, or a damaged connector are observed.

***When should the filter be replaced?***

The filter must be replaced on a semi-annual basis. Refer to Replacing the Water Filter in this chapter for filter replacement instructions.

## Replacing the System Water

The distilled water in the water reservoir should be replaced once every 2 months during Cleaning the Fluid System.

# Cleaning the Fluid System

The fluid system should be disinfected and water replaced once every three months. Tools and Materials needed:

- Approximately 9 gallons (34 liters) of distilled water;
- ArcScan disinfecting kit;
- EyeSeal (used or new) or marble test fixture;
- Small container: Becker, plastic cup, or something similar.

1. Obtain a disinfecting kit (ArcScan P/N 102-001).


**Figure 42: ArcScan disinfecting kit: disinfecting solution (left), test strips (right) and absorbent pad (bottom).**

2. Locate the water reservoir beneath the instrument table and disconnect the Fill/Drain line from the reservoir. For a push-to-connect fitting, press the orange tab on it as shown in **Figure 43** and pull the tubing. For a screw connector, unscrew the connector and remove the Fill/Drain line from the reservoir.

3. Unscrew the Purge line connector and remove from the reservoir (see **Figure 43**).


**Figure 43: Fill/Drain and Purge Lines.**

4. Discard all distilled water present in the reservoir

5. Add fresh distilled water up to the molded “line” at the bottom of the reservoir (see **Figure 44**) and stir thoroughly then discard the water. Repeat this process if particulates are found on the bottom of the reservoir or floating on/under water. Ensure the reservoir is fully clean.


**Figure 44: Water levels in the reservoir.**

6. Add contents of the one-time use bottle of disinfectant to the reservoir and approximately 2.5 gallons (9.5 liters) of fresh distilled water until water level is at the molded “line” at the top of reservoir (see **Figure 44**)

> ***Caution:  Do not*** *use more disinfectant than directed. Using more disinfectant could damage the equipment, cause foaming during scans, or cause eye irritation if there is leakage between the EyeSeal Disposable and the ArcScan Insight 100.*

7. Re-connect the Fill/Drain line to the attachment on the reservoir lid.

8. Re-connect the Purge line to the attachment on the corner of the reservoir.

9. Attach a marble test calibration fixture or an EyeSeal (used or new) to the scan head (see **Figure 45**).

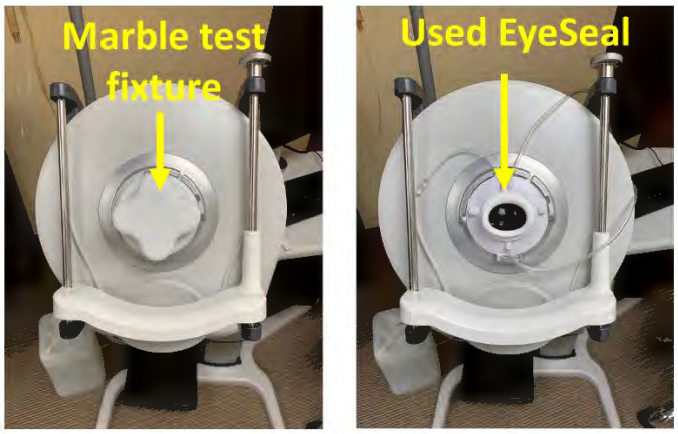



**Figure 45: Scan head with marble test fixture and EyeSeal attached to it.**

10. Click the **Water** button on the bottom right-hand corner of the screen. Fill the instrument using the **Prime** function until it states "Ready" in the bottom left.

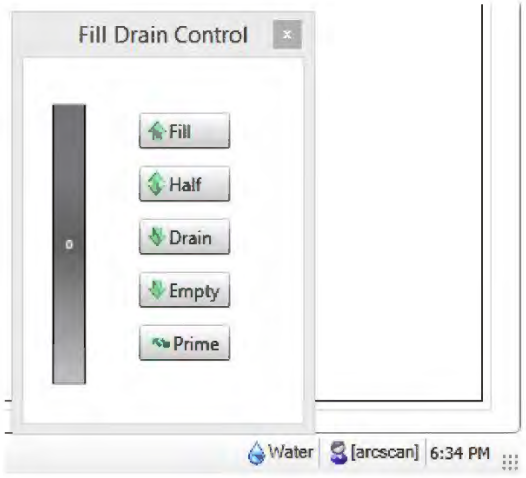



**Figure 46. Prime Button.**

11. Keep checking both top and bottom water levels in the reservoir during Fill/Drain cycles. Levels are at the molded "line" at the top and bottom of reservoir. For optimal performance, make sure water levels are always at the marks as shown in **Figure 44** while filling or draining. **Stop** the cycle in order to add more water if needed.

12. Complete 3 **Drain** and **Fill** cycles. During Drain/Fill cycles. Foam formation might occur (see **Figure 47**). Wipe it up with the absorbent pad that comes with the kit and keep going with fill/drain cycles.

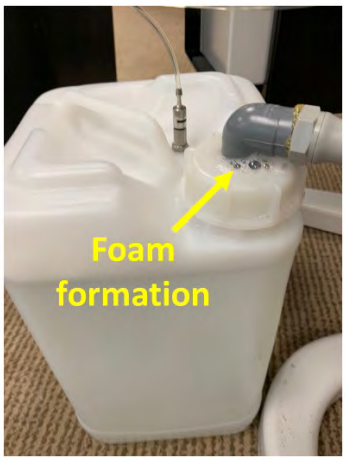



**Figure 47: Foam formation on reservoir.**

13. Leave the system full of distilled water for 5 minutes.

14. Empty the instrument with the **Empty** function.

15. Press the tab on the Fill/Drain line connector or unscrew the connector and remove the Fill line from the reservoir (see **Figure 43**).

16. Unscrew the Purge line connector and remove from the reservoir (see **Figure 43**).

17. Discard the distilled water/disinfectant from the reservoir, then rinse the reservoir with distilled water. Make sure the reservoir is clean and there are no particles sitting on the bottom or floating on the water while rinsing it.

18. Rinse the marble test fixture or the EyeSeal used for carrying on the cleaning process. Use distilled water for rinsing it, then wipe it up with tissue paper or something similar and reattach it to the scan head.

19. Fill the reservoir with fresh distilled water until water level is at the molded “line” at the top of reservoir (see **Figure 44**).

---

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

---

20. Place the reservoir beneath the ArcScan Insight 100.

21. Re-connect the Fill/Drain line to the attachment on the reservoir lid.

22. Re-connect the Purge line to the attachment on the corner of the reservoir.

23. Fill the instrument using the **Prime** function.

24. Complete 3 additional **Drain** and **Fill** cycles.

25. Drain the system as described in Shutting Down the Instrument.

26. Unscrew the reservoir's purge line connector (see **Figure 43**) and take a sample of water into a small container (**Figure 48** shows a Becker, but a cup or anything similar should work) and test it with a test strip. Follow the instructions shown on the vial of the test strips. Contact ArcScan if the cleaning process does not match the 0 ppm color indicator.

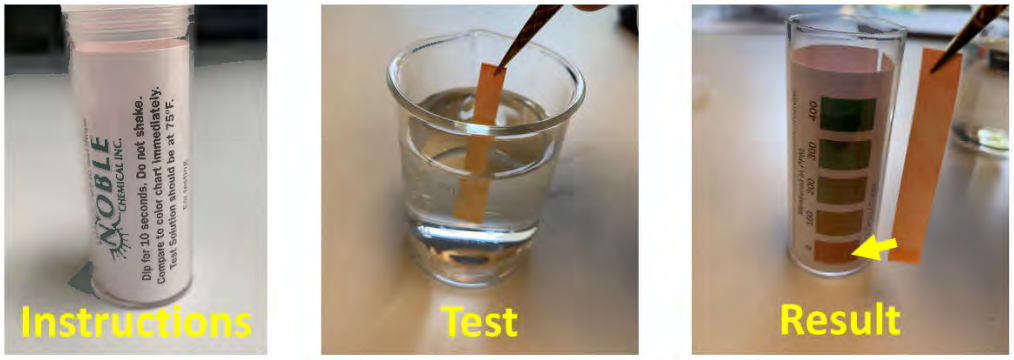



**Figure 48: Test strips.**

27. Top the water level up, if needed. Make sure it lines up with the molded "line" at the top of the reservoir (**Figure 44**).

28. Make sure the cleaning process is recorded in the maintenance sheet. If none, ask ArcScan for one.

# Replacing the Water Filter

The ArcScan Insight 100 has one water filter that should be replaced on a semi-annual basis.

To replace the water filter:

1. Obtain a new filter (ArcScan P/N 20896). Remove and discard any packaging.
2. Locate the clear filter housing beneath the scanner table next to column.
3. Unscrew and lower the filter housing. Remove the used filter from the housing and discard the filter. Note: Use caution as filter housing will be full of water. Dump water prior to removal of filter to avoid fluid spillage.
4. Center the new filter in the housing. Raise the housing under the cap, and screw the housing to the cap.
5. Press the tab on the Fill/Drain line connector and remove the Fill line from the reservoir.
6. Unscrew the Purge line connector and remove from the reservoir.
7. Fill the reservoir with fresh distilled water until water level is at the molded “line” at the top of reservoir.

---

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

---

8. Place the reservoir beneath the ArcScan Insight 100.
9. Re-connect the Fill/Drain line to the attachment on the reservoir lid.
10. Re-connect the Purge line to the attachment on the corner of the reservoir.
11. Fill the instrument using the **Prime** function.
12. Complete 3 additional **Drain** and **Fill** cycles.

## Replacing the Fuses

The ArcScan Insight 100 has two fuses at the main power entry module that may require replacement.

***Warning:*** *Fuse replacement should only be attempted by properly qualified and trained service personnel.*

***Warning:*** *Ensure that the replacement fuses have the same voltage and current ratings and performance characteristics as the fuses that were originally supplied with the system.*

Replacement fuses can be ordered directly from ArcScan.

- Model AS100-120: 250V, 8 A, time lag, Littelfuse 0218008.MXP or equivalent
- Model AS100-230: 250V, 4 A, time lag, Littelfuse 0218004.MXP or equivalent

## Factory maintenance

On a semi-annual basis, ArcScan authorized personnel will perform factory maintenance on site, which will include a thoughtful inspection and calibration of the system, component replacements and upgrades as needed.

# Chapter 9: Specifications

## 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 (table and saline stand at lowest position)

Weight: 120 kg

Table Height Range: 70-90 cm

## Ultrasonic Output Specifications

Frequency: 20-60 MHz

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

## Scanner Fluid Capacity and Type

Capacity: 9.5 L

Type: Distilled water

## Operating Conditions

Temperature: 18-28 °C

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

Altitude: ≤2000 m

## Transport and Storage Conditions

Temperature: 0-45 °C

Humidity: < 80% relative humidity, non-condensing

Anterior segment scan parameters

| Number | Unit | Range | Increment | Accuracy |
|---|---|---|---|---|
| Radius | mm | 10 - 22 | 0.1 | 0.65 |
| Sweep angle | degrees | 45 - 70 | 1 | 0.1 |

Capsule scan parameters

| Number | Unit | Range | Increment | Accuracy |
|---|---|---|---|---|
| Lateral Range | mm | 15 - 28 | 1 | 0.1 |
| Arc position | degrees | -35 - +35 | 1 | 0.5 |
| Radius | mm | 10 - 22 | 0.1 | 0.65 |
| Sweep angle | degrees | 45 - 70 | 1 | 0.1 |

Cornea scan parameters

| Number | Unit | Range | Increment | Accuracy |
|---|---|---|---|---|
| Average lines | lines | 1 - 8 | 1 | NA |
| Radius | mm | 6 - 9 | 0.1 | 0.25 |
| Sweep angle | degrees | 45 - 70 | 1 | 0.1 |

All scans

| Number | Unit | Range | Resolution | Accuracy |
|---|---|---|---|---|
| Meridians | scans | 1 - 10 | 1 | NA |
| Pulse width | ns | 6 - 15 | 1 | 2 |
| Arc center sweep distance | mm | 1 – 30 | 1 | 0.1 |

**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 um
Lateral resolution: 65 um

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

Epithelial thickness: 0.7 um
Corneal thickness: 0.8 um

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

Epithelial thickness: 0.8 um
Corneal thickness: 5.5 um

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

Epithelial thickness: 2 um
Corneal thickness: 20 um

## Acoustic Output Reporting Table for Track 1

**Transducer Model:** Blatek AT20573 **Operating Mode:** B-Mode
**Application:** Ophthalmic, Non-Autoscanning Mode

| Acoustic Output | | | | MI | $I_{SPTA.3}$ (mW/cm$^2$) | $I_{SPPA.3}$ (W/cm$^2$) |
|---|---|---|---|---|---|---|
| **Global Maximum Value** | | | | **0.0226** | **0.347** | **0.614** |
| Associated Acoustic Parameter | pr.3 | | (MPa) | 0.128 | | |
| | $W_0$ | | (mW) | | 2.48E-3 | 2.48E-3 |
| | $F_c$ | | (MHz) | 34.8 | 34.8 | 34.8 |
| | $z_{sp}$ | | (cm) | 0.700 | 0.700 | 0.700 |
| | Beam dimensions | $x_{-6}$ | (cm) | | 0.0462 | 0.0462 |
| | | $y_{-6}$ | (cm) | | 0.0463 | 0.0463 |
| | PD | | (µsec) | 0.0258 | | 0.0258 |
| | PRF | | (Hz) | 2.054E+4 | | 2.054E+4 |
| | EBD | Az. | (cm) | | 0.500 | |
| | | Ele. | (cm) | | 0.500 | |
| Operating Control Conditions | M-Lines: 4096<br>Image Rate: 5 Hz<br>Radius of Scan: 0.6 cm | | | | | |

**Transducer Model:** Blatek AT20573 **Operating Mode:** A-Mode
**Application:** Ophthalmic, Non-Autoscanning Mode

| Acoustic Output | | | | MI | $I_{SPTA.3}$ (mW/cm$^2$) | $I_{SPPA.3}$ (W/cm$^2$) |
|---|---|---|---|---|---|---|
| **Global Maximum Value** | | | | **0.0226** | **8.47E-4** | **0.614** |
| Associated Acoustic Parameter | pr.3 | | (MPa) | 0.128 | | |
| | $W_0$ | | (mW) | | 6.06E-6 | 6.06E-6 |
| | $F_c$ | | (MHz) | 34.8 | 34.8 | 34.8 |
| | $z_{sp}$ | | (cm) | 0.700 | 0.700 | 0.700 |
| | Beam dimensions | $x_{-6}$ | (cm) | | 0.0462 | 0.0462 |
| | | $y_{-6}$ | (cm) | | 0.0463 | 0.0463 |
| | PD | | (µsec) | 0.0258 | | 0.0258 |
| | PRF | | (Hz) | 50 | | 50 |
| | EBD | Az. | (cm) | | 0.500 | |
| | | Ele. | (cm) | | 0.500 | |
| Operating Control Conditions | M-Lines: 4096<br>Image Rate: 5 Hz<br>Radius of Scan: 0.6 cm | | | | | |

## Acoustic Output Reporting Table for Track 1

**Transducer Model:** Blatek AT29839 **Operating Mode:** B-Mode
**Application:** Ophthalmic, Autoscanning Mode

| Acoustic Output | | | | MI | $I_{SPTA.3}$ (mW/cm$^2$) | $I_{SPPA.3}$ (W/cm$^2$) |
|---|---|---|---|---|---|---|
| **Global Maximum Value** | | | | **0.0147** | **4.57E-3** | **0.330** |
| Associated Acoustic Parameter | pr.3 | | (MPa) | 0.079 | | |
| | $W_0$ | | (mW) | | 2.28E-3 | 2.28E-3 |
| | $F_c$ | | (MHz) | 28.8 | 28.8 | 28.8 |
| | $z_{sp}$ | | (cm) | 1.07 | | 1.07 |
| | Beam dimensions | $x_{-6}$ | (cm) | | | 0.0397 |
| | | $y_{-6}$ | (cm) | | | 0.0443 |
| | PD | | (µsec) | 0.028 | | 0.028 |
| | PRF | | (Hz) | 1.23E+4 | | 1.23E+4 |
| | EBD | Az. | (cm) | | 1.68 | |
| | | Ele. | (cm) | | 0.700 | |
| Operating Control Conditions | Cornea setting | | | ✓ | ✓ | ✓ |
| | | | | | | |
| | | | | | | |
| | | | | | | |

# Chapter 10: Authorized Service Center

## Authorized ArcScan Service Center

ArcScan, Inc.
433 Park Point Drive
Golden, CO 80401
Ph: (720) 287-8800

# Appendix A: 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 an eye component. |
| **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 or presby lens. |
| **Accuracy** | As used herein means substantially free from measurement error. |
| **Aligning** | Positioning the acoustic transducer accurately and reproducibly in all three dimensions of space with respect to a feature of the eye component of interest (such as the center of the pupil, center of curvature or boundary of the cornea, lens, retina, etcetera). |
| **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. |
| **Aperture** | Refers to the ultrasonic transducer face which may be planar but is commonly shaped as a concave surface so as to form a focal point at a desired location in front of the transducer face |
| **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. |
| **Arc scanning transducer center of curvature** | Same as the center of curvature of the arc scanning guide. |
| **Auto-centering** | Automatically, typically under computer control, causing centration of the arc scanning transducer with the eye component of interest. |
| **Automatic** | Refers to any process or operation done without material human input when the process or operation is performed. However, a process or operation can be automatic, even though performance of the process or operation uses material or immaterial human input, if the input is received before performance of the process or operation. Human input is deemed to be material if such input influences how the process or operation will be performed. Human input that consents to the performance of the process or operation is not deemed to be “material.” |

# B

| | |
|---|---|
| **B-scan** | A processed representation of A-scan data by either or both of converting it from a time to a distance using acoustic velocities and by using grayscales, which correspond to A-scan amplitudes, to highlight the features along the A-scan time history trace (the latter also referred to as an A-scan vector). |

# 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 more or less fixed relative to the orbit 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.

**Centration**

Substantially aligning the center of curvature of a precision arc scanning transducer in all three dimensions of space with the center of curvature of the eye component of interest (such as the cornea, pupil, lens, retina, etcetera) such that rays from the transducer pass through both centers of curvature. A special case is when both centers of curvature are coincident.

**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 near the front of the eye, above and below the lens. They are 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.

| | |
|---|---|
| **Compute** | 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. |
| **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

| | |
|---|---|
| **Determine** | 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. |

## E

| | |
|---|---|
| **EyeSeal** | As used herein means the eye seal assembly comprised of a body, which is further comprised of a clamp and a membrane; a seal which seals the eye piece to the patient. |

## F

| | |
|---|---|
| **Fiducial** | A reference, marker or datum in the field of view of an imaging device. |
| **Fixation** | Having the patient focus an eye on an optical target such that the eye's optical axis is in a known spatial relationship with the optical target. In fixation, the light source is axially aligned in the arc plane with the light source in the center of the arc so as to obtain maximum signal strength such that moving away from the center of the arc in either direction results in signal strength diminishing equally in either direction away from the center. |
| **Fovea** | A small depression in the macula lutea of the retina where visual acuity is highest. |

# G

| | |
|---|---|
| **Guide** | An apparatus for directing the motion of another apparatus. |

# H

| | |
|---|---|
| **Haptics** | Little protrusions extending from the outer diameter of some types of artificial lenses. These haptics fix the position of the lens to the ciliary body by protruding into the ciliary sulcus. In the case of accommodative lenses, the haptics enable the lens to accommodate in response to the action of the ciliary body. |
| **Home position** | Position of a precision imaging ultrasound transducer during the registration process. |

# 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 that is implanted in the eye to take the place of the natural lens. |

# 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, so as to reshape the external shape of the cornea. |

# M

| | |
|---|---|
| **Means** | The term ***means*** as used herein shall be given its broadest possible interpretation in accordance with 35 U.S.C., Section 112, Paragraph 6. Accordingly, a claim incorporating the term “means” shall cover all structures, materials, or acts set forth herein, and all |

| | |
|---|---|
| | of the equivalents thereof. Further, the structures, materials or acts and the equivalents thereof shall include all those described in the summary of the invention, brief description of the drawings, detailed description, abstract, and claims themselves. |
| **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. |
| **Module** | The term ***module*** as used herein refers to any known or later developed hardware, software, firmware, artificial intelligence, fuzzy logic, or combination of hardware and software that is capable of performing the functionality associated with that element. |

# N

| | |
|---|---|
| **Natural lens** | The ***natural lens*** (also known as the aquula or crystalline lens) is a transparent, biconvex structure in the eye that, along with the cornea, helps to refract 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 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. The lens capsule forms the outermost layer of the lens and the lens fibers form the bulk of the interior of the lens. The cells of the lens epithelium, located between the lens capsule and the outermost layer of lens fibers, are generally found only on the anterior side of the lens. |

# O

| | |
|---|---|
| **Ocular** | Having to do with the eye or eyeball. |
| **Ophthalmology** | The branch of medicine that deals with the eye. |
| **Optical** | As used herein, refers to processes that use light rays. |
| **Optical axis of the eye** | A straight line 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)** | A light based imaging technology that bases itself upon low coherence interferometry. In conventional interferometry with long coherence length (laser interferometry), interference of light occurs over a distance of meters. In OCT, this interference is shortened to a distance of micrometers, due to the use of broadband light sources (sources that can emit light over a broad range of frequencies). Light with broad bandwidths can be generated by using superluminescent diodes (superbright LEDs) or lasers with extremely short pulses (femtosecond lasers). An optical beam is directed at the tissue, and a small portion of this light that reflects from sub-surface features is collected and combined with reflection from a reference beam in a Michelson interferometer. Time domain based OCT systems require a moveable mirror in the reference beam to provide depth for the scanning field. Spectral domain and swept source OCT systems do not require a moveable mirror in the reference beam and instead us a spectrometer (usually diffraction grating) to separate frequency components in the interference signal which are in turn converted to reflectance profile along the beam axis. Application of OCT in this disclosure will emphasize the use of the spectral domain and swept source variants, as the elimination of the moveable mirror of the time domain technique represents an advantageous elimination of considerable mechanical detail in the reference arm. |
| **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. In the adult human, the volume of the orbit is about 30 ml, of which the eye occupies about 6.5 ml. |
| **Organ** | A differentiated structure (as a heart, kidney or eye) consisting of cells and tissues and performing some specific function in an organism. |

# P

| | |
|---|---|
| **Pachymetery** | Technically referred to as Time Domain Reflectometry ultrasound. A pulse of ultrasonic energy is sent toward the cornea and the time spacing of the returning echoes are used to arrive at corneal thickness. Also called corneal pachymetery. |
| **Phakic** | ***Phakic*** intraocular lenses, or phakic lenses, are lenses made of plastic or silicone that are implanted into the eye permanently 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. |
| **Positioner** | The mechanism that positions a scan head relative to a selected part of an eye. In the present disclosure, the positioner can move back and forth along the x, y or z axes and rotate in the β direction about the z-axis. Normally the positioner does not move during a scan, only the scan head moves. In certain operations, such as measuring the thickness of a region, the positioner may move during a scan. |
| **Position tracking sensors** | A set of position sensors whose sole purpose is to monitor the movement of the eye or any other anatomical feature during the imaging scan so as to remove unwanted movement of the feature. |
| **Posterior** | Situated at the back part of a structure; posterior is the opposite of anterior. |

| | |
|---|---|
| **Posterior chamber** | Comprises the region of the eye from the back of the iris to the front of the lens |
| **Posterior segment** | Comprises the region of the eye from the back of the lens to the rear of the eye comprising the retina and optical nerve. |
| **Precise** | As used herein, means sharply defined and repeatable. |
| **Precision** | How close in value successive measurements fall when attempting to repeat the same measurement between two detectable features in the image field. In a normal distribution precision is characterized by the standard deviation of the set of repeated measurements. Precision is very similar to the definition of repeatability. |
| **Precision ultrasonic scanner** | An ultrasound scanning device utilizing a transducer that both sends and receives pulses as it moves along 1) an arcuate guide track, which guide track has a center of curvature whose position can be moved to scan different curved surfaces; 2) a linear guide track; and 3) a combination of linear and arcuate guide tracks which can create a range of centers of curvature whose position can be moved to scan different curved surfaces. |
| **Presbyopia** | Typically caused by a loss of elasticity of the natural lens inside the eye. This occurs as part of the ageing process and, although it cannot be 'cured', it can be corrected by wearing glasses or implanting an artificial lens |
| **Probe** | As used herein, means a measuring or testing device that converts variations in a physical quantity such as pressure or light into an electrical signal and vice versa. An ultrasound transducer holder comprising a transducer element and an OCT probe are examples of probes. |
| **Pulse transit time** | The ***pulse transit time*** across a region of the eye is the time it takes a sound pulse to traverse the region. |
| **Purkinje images** | Reflections of objects from structure of the eye. There are at least four Purkinje images that are |

| | |
|---|---|
| | visible on looking at an eye. 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** ***(continued)*** | Purkinje images are named after Czech anatomist Jan Evangelista Purkyně (1787-1869). |

# R

| | |
|---|---|
| **Refractive** | Anything pertaining to the focusing of light rays by the various components of the eye, principally the cornea and lens. |
| **Registration** | As used herein means aligning. |

# S

| | |
|---|---|
| **Saccades** | Quick, simultaneous rotations of both eyes in the same direction involving a succession of discontinuous individual rotations of the eye orbit in the eye socket. These rapid motions can be on the order of 20 degrees of rotation with a maximum velocity of 200 degrees/sec and are a part of normal eyesight. |
| **Scan head** | The mechanism that comprises the ultrasound transducer, the transducer holder and carriage as well as any guide tracks that allow the transducer to be moved relative to the positioner. Guide tracks may be linear, arcuate or any other appropriate geometry. The guide tracks may be rigid or flexible. Normally, only the scan head is moved during a scan. |
| **Sector scanner** | An ultrasonic scanner that sweeps a sector like a radar. The swept area is pie-shaped with its central point typically located near the face of the ultrasound transducer. |

| | |
|---|---|
| **Specular surface** | A mirror-like surface that reflects either optical or acoustic waves. For example, an ultrasound beam emanating from a transducer will be reflected directly back to that transducer when the beam is aligned perpendicular to a specular surface. |
| **Suprachoroid** | Lies between the choroid and the sclera and is composed of closely packed layers of long pigmented processes derived from each tissue. |
| **Suprachoroidal space** | A potential space providing a pathway for uveoscleral outflow and becomes an actual space in choroidal detachment. The hydrostatic pressure in the suprachoroidal space is an important parameter for understanding intraocular fluid dynamics and the mechanism of choroidal detachment. |

# T

| | |
|---|---|
| **Tissue** | An aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of a plant or an animal and that in animals include connective tissue, epithelium, muscle tissue, and nerve tissue. |
| **Track or guide track** | An apparatus along which another apparatus moves. In an ultrasound scanner or combined ultrasound and optical scanner, a guide track is an apparatus along which one or more ultrasound transducers and/or optical probes moves during a scan. |

# U

| | |
|---|---|
| **Ultrasonic** | Sound that is above the human ear's upper frequency limit. When used for imaging an object like the eye, the sound passes through a liquid medium, and its frequency is many orders of magnitude greater than can be detected by the human ear. For high-resolution acoustic imaging in the eye, the frequency is typically in the approximate range of about 5 to about 80 MHz. |

| | |
|---|---|
| **Ultrasonic Bio Microscopy (UBM)** | An imaging technique using hand-held ultrasound device that can capture anterior segment images using a transducer to emit short acoustic pulses ranging from about 20 to about 80 MHz. This type of ultrasound scanner is also called a sector scanner. The UBM method is capable of making qualitative ultrasound images of the anterior segment of the eye but cannot unambiguously make accurate, precision, comprehensive, measurable images of the cornea, lens or other components of the eye. |
| **Ultrasound probe** | An assembly comprised of a transducer element (eg, a piezoelectric material), a probe body and electrical conduits that carry transmitted and received signals from the transducer element to an A/D converter external to the probe. |
| **Ultrasound pulse** | A group of ultrasound waves centered around a center frequency where the pulse is comprised of at least one wave cycle. For example, the ultrasound pulse is a short burst of one to about ten wavelengths truncated at both ends of the wave train. 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. |
| **VHUF** | **V**ery **H**igh **F**requency **U**ltrasound where the frequency is typically in the approximate range of about 5 to about 80 MHz. |
| **Visual axis of the eye** | The line joining the object of interest and the fovea and which passes through the nodal points of the eye. |

# Z

**Zonules** Tension-able ligaments extending from near the outer diameter of the crystalline lens. The zonules attach the lens to the ciliary body, which allows the lens to accommodate in response to the action of the ciliary muscle.

# Appendix B: Electromagnetic Compatibility

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| 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. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br><br>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<br><br>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:<br><br>**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<br><br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions | Complies | |

| ArcScan Insight 100 Essential Performance |
|---|
| Free from noise on a waveform or artefacts 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.<br><br>Free from the display of incorrect numerical values associated with the diagnosis to be performed. [a]<br><br>Free from the display of incorrect safety-related indications.[a]<br><br>Free from the production of unintended or excessive ultrasonic output.<br><br>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 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)<br><br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±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<br><br>IEC 61000-4-4 | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ±1 kV line to line<br><br>±2 kV line to earth | ±1 kV line to line<br><br>±2 kV line to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5% $U_T$ (>95% dip in $U_T$ for 0,5 cycle)<br><br>40% $U_T$ (60% dip in $U_T$ for 5 cycles)<br><br>70% $U_T$ (30% dip in $U_T$ for 25 cycles)<br><br>< 5% $U_T$ (95% dip in $U_T$ for 5 s) | <5% $U_T$ (>95% dip in $U_T$ for 0,5 cycle)<br><br>40% $U_T$ (60% dip in $U_T$ for 5 cycles)<br><br>70% $U_T$ (30% dip in $U_T$ for 25 cycles)<br><br>< 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<br><br>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 a.c. mains voltage prior to the application of the test level. | | | |

**Guidance and manufacturer's declaration – 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 |
|---|---|---|---|
| | | | 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.<br><br>Recommended separation distance |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | $d = 1,17\ \sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2,5 GHz | 3 V/m | $d = 1,17\ \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2,33\ \sqrt{P}$ 800 MHz to 2,5 GHz<br>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).<br>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].<br>Interference may occur in the vicinity of equipment marked with the following symbol.<br>[TBD INSERT 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.

[a] Field strengths 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**<br>**W** | **Separation distance according to frequency of transmitter**<br>**m** | | |
|---|---|---|---|
| | **150 kHz to 80 MHz**<br>$d = 1{,}17\sqrt{P}$ | **80 MHz to 800 MHz**<br>$d = 1{,}17\sqrt{P}$ | **800 MHz to 2,5 GHz**<br>$d = 2{,}33\sqrt{P}$ |
| 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.

# Appendix C: Warranty

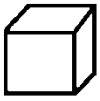
ArcScan, Inc. warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for one year from the date of shipment. ArcScan's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to it or its distributor within the applicable time period shown below 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.

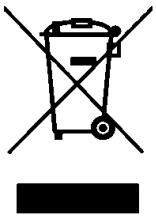
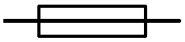
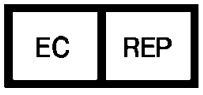
THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ARCSCAN.

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 as described in this User Manual.

# Appendix D: 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 |

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