4SIGHT

◢ ACCUTOME®

4Sight User's Guide

24-8016-US   Rev-K

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

FEDERAL COMMUNICATIONS COMMISSION (FCC)
UNINTENTIONAL EMITTER PER FCC PART 15

This device has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in an office installation.
This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions in the user's guide, may cause harmful interference to radio or television reception. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a different circuit than the receiver is connected to.

Consult Accutome Ultrasound, Inc., or an experienced radio/TV technician for help.
This device complies with Part 15 of the FCC Rules. Operation of this product is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not expressly approved by Accutome, Inc., could void the FCC compliance and negate your authority to operate the product.

The 4Sight is manufactured and trademarked by:
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1 Safety

Safety Issues to Consider When Using the Accutome 4Sight

This instrument has no user-operated controls or settings that affect the acoustic output. The Accutome 4Sight is noninvasive. The ultrasonic probes touch the surface of the anesthetized cornea during the scanning process. Energy in the form of ultrasound is transmitted into the eye. The maximum power allowed to be set by the application software and/or by the user is below the FDA, HEALTH CANADA, and EU maximum power limits.

Indications for Use

The 4Sight is to be used in a medical setting and only by ophthalmic technicians, optometrists, and ophthalmologists who are experienced and trained in ophthalmic ultrasound techniques.

A-Scan Module

This module is used for measuring the axial length, anterior chamber depth, lens thickness, and vitreous chamber depth of the eye. It also is used for calculating the optical power of the IOL (Intraocular Lens) to be implanted during cataract surgery.

B-Scan/UBM Modules

These modules are used for imaging the internal structure of the eye, including the opaque media and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye.

Pachymetry Module

This module is used for measuring the corneal thickness of the eye.

Side Effects

There are no known side effects associated with the use of Accutome 4Sight ultrasound imaging.

Any side effects associated with the use of the 4Sight are related to the topical anesthetic chosen by the physician to anesthetize the eye of the patient. Please consult the warning label of the chosen topical anesthetic for further information.

Contradictions

There are no known contraindications associated with the use of the 4Sight.

WARNING! THE 4SIGHT IS NOT INTENDED FOR FETAL USE!

Symbol Definitions for the 4Sight

Attention! Consult Instruction Manual

No User Serviceable Parts

Do Not Use Near Flammable Gases

Type B Medical Device

USB Connector

Disposal of Product within the EU

Electrical Shock Hazard

The 4Sight has an enclosure rated Degree of Protection of IP32. The enclosure provides protection for objects larger than 2.5 mm and dripping water. The footswitch is rated IPIX. In the event of a spill contacting the unit, disconnect the mains cord and wipe the unit completely dry before returning it to service.

Disposal Requirements

The Accutome 4Sight internal processor contains electronic components. At the end of its useful life, it must be properly disposed of in compliance with local regulations.

Disposal of the Product outside the USA

OUS directives and national regulations currently in force at the time of marketing prohibit the disposal of the 4Sight specified on the delivery note in domestic waste or by municipal waste disposal companies. If the 4Sight or its components are resold, the seller has the duty to notify the buyer that the product must be disposed of in accordance with currently valid national regulations.

Disinfection and Cleaning

Disinfection issues are confined to the Accutome probe that comes in contact with the patient's eye. In order to prevent the transmission of disease, refer to the OSHA and CDC guidelines for proper control of disinfection. These guidelines are frequently updated so be sure to contact OSHA, CDC, or your local disease-control agency for the latest information and disinfection technique.

Accessories such as the extension handle or Goldman Tonometer Adapter that might come in contact with eye fluids should be cleaned with an FDA-cleared high-level disinfectant.

The probe must be cleaned between patients to prevent patient-to-patient transfer of infection. It is the user's responsibility to ensure that the relevant standards are maintained and that the products and procedures are effective and appropriate for ophthalmic applications. The following information is provided for the guidance of users, and specific products are mentioned for illustration only. Accutome does not endorse the use of these or any other product. Products must be used in accordance with the manufacturer's instructions.

Warnings

There are several areas in the use of the above Accutome products that require special attention, as they may pose a safety threat.

DO NOT AUTOCLAVE THE PROBES OR CONNECTORS.

DO NOT IMMERSE THE PROBE'S CABLES OR METAL CONNECTORS. ALLOW TO DRY BEFORE USE.

DO NOT IMMERSE THE PROBE TIPS IN TAP WATER. USE DISTILLED WATER FOR CLEANING AND DISINFECTION.

DO NOT WIPE THE PROBE END OF THE UBM PLUS PROBE; IT MAY RESULT IN DAMAGE TO THE CRYSTAL.

Cleaning Procedure at Point of Use

1. Wear protective gloves when performing the cleaning process.
2. Disconnect the probe from the system.
3. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any particulate matter or body fluids that remain on the probe or cable except for the UBM. Do not touch the crystal, arm or mounting system for the UBM.
4. To remove remaining particulates, rinse with a distilled water–dampened cloth to remove soap residue, and then wipe with a dry cloth. If cleaning the UBM, let the probe air dry after rinsing with distilled water.

Disinfection of the Probes with Alcohol

One recommended disinfection technique is to clean the probe assemblies with 70% isopropyl alcohol.

A 5- to 10-minute exposure is recommended. It is imperative that the alcohol be given time to evaporate before applying a probe to a patient's eye. Do not completely immerse the probe or cable; only the tip of the probe should be placed in the solution.

After cleaning, rinse the end of the probe thoroughly with distilled water to remove all traces of alcohol.

Probe surfaces should be dried with a lint-free cloth.

High-Level Disinfection of the Probe

If high-level disinfection is required by your facility, the probe may be cleaned using an FDA-cleared high-level disinfectant, such as Cidex OPA Activated Dialdehyde Solution.

If your facility is located in the EU, Mikrozid wipes are a compatible method of high-level disinfection for Accutome probes.

Note: Be sure to follow the disinfectant manufacturer's written protocol when using any antibacterial solution, including high-level disinfectants.

Cleaning and Disinfection of Immersion and Sclera Shells

After applying new gloves, soak the shell for 10 minutes in Cidex or 10% bleach solution. Thoroughly rinse the device with sterile water, allowing to air-dry. Do not use heat or gas.

Electrical Hazard and Safety

The 4Sight and all of its attachments, including the power supply, footswitch, probes, keyboard, and mouse, are electrical/electronic devices. Reasonable care should be taken when making electrical connection and handling electrically powered devices. Avoid the use of damaged electrical equipment or frayed electrical cords. If repair or maintenance is being performed on the 4Sight and/ or any attachments, the equipment must be turned off and the power cord disconnected.

The device covers must not be removed except by Accutome qualified personnel. To avoid injury, do not operate the 4Sight without protective covers.

Use only the Accutome-provided power supply, probes, and footswitch.

Be sure the cable and connectors are in good condition. Inspect the probe before each use to ensure that there are no breaks, cracks, or other damage.

WARNING! THE ACCUTOME 4SIGHT IS ONLY TO BE USED WITH THE ACCUTOME-SUPPLIED MEDICAL-GRADE POWER SUPPLY COMPLIANT WITH IEC60601-1. THE POWER SUPPLY MUST BE CONNECTED TO A GROUNDING-TYPE POWER OUTLET FULLY COMPLIANT WITH APPLICABLE CODES FOR MEDICAL FACILITIES.

To avoid interruption of a procedure, the user is responsible for ensuring that all power, probe, and USB connections are secure.

CAUTION: Cardiac Rhythm Disturbances During Perfusion Studies Using Gas Ultrasound Contrast Agents Have Been Observed In The Diagnostic Range Of Mechanical Index (Mi) Values. For Details, See The Specific Package Insert For The Contrast Agent Being Used.

WARNING! BEFORE EACH PATIENT PROCEDURE, INSPECT THE PROBE TO ENSURE THAT THERE ARE NO BREAKS OR CRACKS IN THE OUTSIDE SHELL.

CAUTION: Before starting a patient exam, ensure that the probe type selected and the probe used are the same and appropriate to the desired application.

CAUTION: When using the A-Scan contact method, care should be taken to minimize corneal compression. Corneal compression will result in a shorter axial length measurement and will affect the calculations.

CAUTION: To avoid possible loss of patient data stored in the 4Sight, ensure that the data is backed up on a device external to the 4Sight.

CAUTION: External office equipment such as printers or HDMI monitors that are compliant with IEC 60950-1 should not be utilized when the device is being used on a patient.

When positioning the 4Sight device for use, ensure that the operator has access to the power supply unit.

Isolation from the electrical socket is achieved by disconnecting the power cord from the power supply.

WARNING! CONNECTION OF THE 4SIGHT SYSTEM TO EXTERNAL OFFICE EQUIPMENT VIA SIP/SOP CONNECTION PORT IS STRICTLY PROHIBITED DURING PATIENT CARE. CONNECTION TO SUCH DEVICES MAY LEAD TO ELEVATED LEAKAGE CURRENT FROM CONDUCTIVE ENCLOSURE PARTS ON THE 4SIGHT.

WARNING! ANY EQUIPMENT CONNECTED TO THE 4SIGHT MUST BE COMPLIANT WITH IEC 60950.

WARNING! IF CONNECTION OF THE 4SIGHT SYSTEM TO EXTERNAL OFFICE EQUIPMENT COMPLIANT WITH IEC 60950 VIA THE SIP/SOP PORTS IS REQUIRED, IT IS THE RESPONSIBILITY OF THE HOSPITAL/CLINIC (RESPONSIBLE ORGANIZATION) TO ENSURE THAT THE 4SIGHT SYSTEM CONTINUES TO MEET THE REQUIREMENTS OF IEC 60601-1, 3RD EDITION, WITH RESPECT TO ALLOWABLE LEAKAGE CURRENT REQUIREMENTS. THERE MAY BE ADDITIONAL, UNFORESEEN RISKS THAT DEVELOP DUE TO THE CONNECTION OF SUCH DEVICES. IT IS THE RESPONSIBILITY OF THE HOSPITAL/CLINIC (RESPONSIBLE ORGANIZATION) TO IDENTIFY, ANALYZE, AND REDUCE THESE RISKS.

Avoiding Equipment Damage

The Accutome 4Sight provides no explosion protection from static discharge or arcing components. Do not operate the instrument in the presence of explosive gases such as flammable mixtures of anesthetic and air, or nitrous oxide.

CAUTION: This Device is intended for use in a controlled environment only; it is not intended for outdoor use.

WARNING! OPERATING OR STORING THE DEVICE BEYOND THE ENVIRONMENTAL RANGES IN THE SPECIFICATIONS CHAPTER MAY RESULT IN ERRONEOUS READINGS AND/OR PREMATURE FAILURE OF THE DEVICE.

Avoiding Electromagnetic and Other Interference

Do not use a cellular telephone or other devices not compliant with EMC Class B requirements, as its signals may cause the equipment to malfunction. The effect

of radio signals on medical devices is dependent on various factors and therefore unpredictable. To avoid electromagnetic interference, the device must be installed and operated in accordance with the user's guide and using the components supplied by Accutome.

WARNING! THE USE OF ACCESSORIES, TRANSDUCERS, AND CABLES OTHER THAN THOSE SPECIFIED BY THE MANUFACTURER MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE ACCUTOME 4SIGHT.

WARNING! THE ACCUTOME 4SIGHT SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE ACCUTOME 4SIGHT SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION.

If the PEMS (Programmable Electrical Medical System) is intended to be connected by NETWORK/DATA COUPLING to other equipment that is outside the control of the PEMS MANUFACTURER, the technical description shall:

    a) specify the characteristics of the NETWORK/DATA COUPLING necessary for the PEMS to achieve its INTENDED USE;

    b) list the HAZARDOUS SITUATIONS resulting from a failure of the NETWORK/DATA COUPLING to provide the specified characteristics;

    c) instruct the RESPONSIBLE ORGANIZATION that:

        – connection of the PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS, or THIRD PARTIES;

- the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate, and control these RISKS;
- subsequent changes to the NETWORK/DATA COUPLING could introduce new RISKS and require additional analysis;
- changes to the NETWORK/DATA COUPLING include:
- changes in NETWORK/DATA COUPLING configuration;
- connection of additional items to the NETWORK/DATA COUPLING;
- disconnecting items from the NETWORK/DATA COUPLING;
- update of equipment connected to the NETWORK/DATA COUPLING;
- upgrade of equipment connected to the NETWORK/DATA COUPLING.

ALARA Principle

When using this instrument, the ALARA (As Low As Reasonably Achievable) principle should be followed. This principle is used to reduce unnecessary, potentially hazardous exposure to individuals by keeping doses and test repetition as low as reasonably achievable to achieve the required diagnostic information.

2 Hardware Connections

Introduction

Figure 2.1 - Accutome 4Sight
Note: Your unit may not have all of the attachments shown above.

Common Features

- A single, readily portable, platform for all four possible modules:
    - A-Scan Biometry
    - B-Scan Ultrasonography
    - UBM (Ultrasound Bio-Microscopy)
    - Pachymetry
- New, icon-based user interface
- High-resolution, 12-inch touch screen. For user convenience, buttons/ locations may be selected either by using the mouse or by touching the appropriate screen location.
- Easy EMR (Electronic Medical Record) integration via DICOM (Digital Imaging and Communications in Medicine) compatibility. DICOM is a widely accepted standard for handling, storing, printing, and transmitting information in medical imaging.
- IOL Master connectivity for A-Scan (if connected to applicable IOL Master)
- 4Sight uses the same algorithms that have been proven in field use by thousands of Accutome customers.

- 4Sight has convenient screens for entering and storing information about facilities, physicians, and users. The information is shared across 4Sight functional modules and can be readily selected to be associated with individual patient data.

Application Modules

4Sight, fully configured, provides the following ophthalmologic function modules:

A-Scan Module

A-Scan uses ultrasound to measure the axial length of the eye and calculate parameters for an IOL.

Measurements

The accuracy of the A-Scan module measurement is provided by the following:

- High-resolution, real-time waveform display
- High-speed digitalization acquires more than 4,000 points per waveform
- Continuous display of Axial Length, ACD, Lens Thickness, and Vitreous dimensions
- Audible feedback of contact and capture
- Immersion mode yields improved accuracy; contact mode also supported
- Automatically or manually capture up to five waveforms for each eye
- Adjustable Gain, Velocities, Gates, and Amplitude Thresholds
- Modify all waveform parameters using real-time or frozen waveforms
- Predefined Eye Types and Velocities handle most situations such as phakic, dense cataract, three types of pseudo-phakic, aphakic, silicone oil–filled, and even phakic ICL eyes; all velocities are fully adjustable
- Custom Eye Types and Material Velocities can be created to handle individual preferences, special pathologies, or future trends
- Highly sensitive 10 MHz composite Broadband probe, which features fixation and multiple mounting options

IOL Calculations

The Accutome A-Scan module is also a leader in IOL calculations and provides the following:

- Modern formulas including Hoffer Q, Holladay, SRK/T, SRK II, Binkhorst II, and Haigis
- Compare results of all formulas simultaneously on a single screen for selected lenses
- Instantly calculates emmetropic and targeted ametropic IOL powers for dozens of lenses, viewed four at a time, using the average of selected waveforms, a single waveform, or manually entered data
- Conveniently group lenses by favorite designation such as surgeon, user, type, manufacturer, etc.
- Personalization of IOL Constants is easy and straightforward, encouraging improved patient outcomes
- Maintains individual IOL Constants for each formula and clearly identifies which IOL constant is used with the selected formula
- IOL calculation for post refractive surgery patients

B-Scan/UBM Modules

The B-Scan and UBM Modules provide high-quality ultrasonography imaging and playback, with many additional features that allow multiple methods of viewing, examining, and printing acquired images.

High-Definition Imaging – detailed structure definition of the posterior and anterior segments as well as pathologies.

Video Recording - connect software has the ability to convert your B-Scan/UBM Videos into .MP4 or .AVI. The software can also record during a live scan in .MP4 or .AVI.

State-of-the-Art Probe Design – sharper, more-focused images due to the elimination of signal loss.

Adjustable TGC Curves – adjust the Gain, Time Gain Compensation (TGC) as a default in Setup, live during an exam or on a saved existing exam.

Gamma Settings – adjust the Gamma settings as a default in Setup, live during an exam or on a saved existing exam:
- Log Full Range
- Linear Full Range
- S-Curve Full Range
- Color

Gain Adjustment – adjust the signal gain while scanning or on a saved image to enhance image quality.

Automatic Image Orientation Labeling – set image orientation labels as a default in Setup, live during an exam, or on a saved existing exam.

Image Playback – play live images during scanning or playback saved images.

Diagnostic Measurements – tools useful for measuring sulcus-to-sulcus, anterior chamber depth, positioning of intraocular lenses, filtration angle of the eye, and other features:
- Six lines
- Two areas
- Two angles
- Two arrows

Patient Data Storage and Retrieval – saves all patient exams in a preset designated folder on the device, external hard drive, network location, or user computer, allowing you to play back, archive, and back up any and all patient exams.

Reports and Printouts – allows you to prepare reports containing exam information and snapshots of selected imaging views. You can also print a snapshot at any time during an exam or from a stored exam.

Outstanding Image Quality
- 0.015 mm resolution is among the highest in the medical industry
- Probe design gives sharper, more-focused images due to the elimination of signal loss
- "Smooth Zoom" technology – the only unit with 2x full image zoom without distortion of real-time or captured scan

A-Vector – A-Vector function displays an equivalent A-Scan of the captured B-Scan Plus and UBM images. Looking at the A-Vector, you can get a graphical picture of the echoes received back through the eye from the ultrasonic probe.

Film Loop Viewing Flexibility – familiar icons for positioning within the loop, pause, stop, forward, fast forward, and rewind, as well as the ability to control the speed at which the film loop is played back.

Image Annotation – in addition to probe frequency, maximum depth, and gain, the user may select up to six other parameters to show on/store with the image.
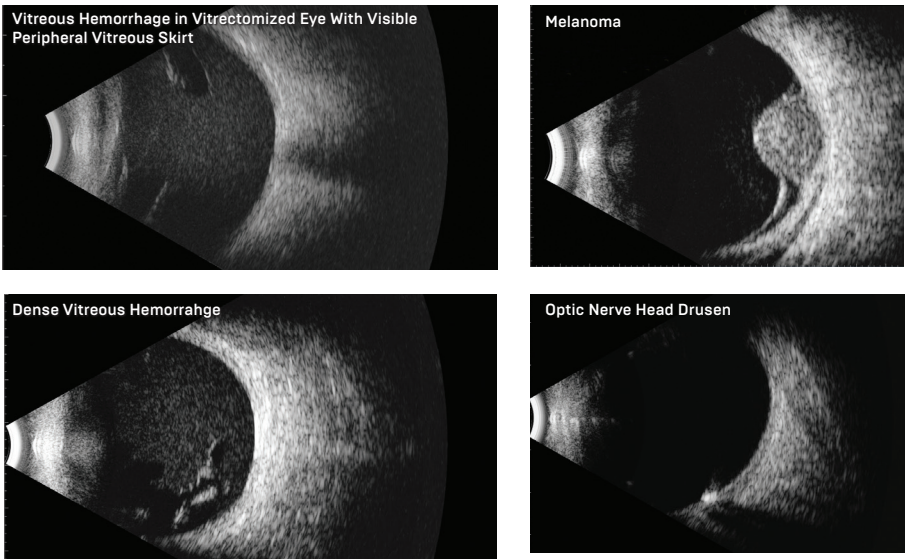
Figure 2.2 - Sample B-Scan Images
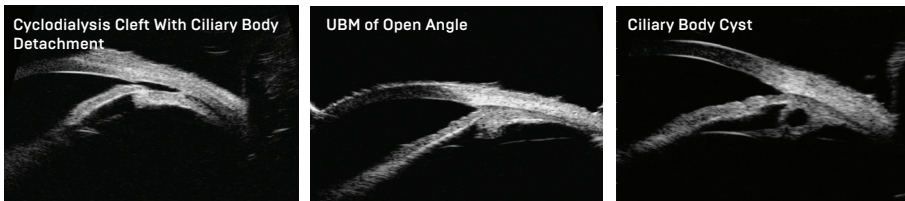
Figure 2.3 - Sample UBM Images

Pachymetry Module

The Pachymetry Module accurately measures corneal thickness and also provides corrected IOP (Intraocular Pressure) based upon the corneal thickness measurements.

Pachymetry Features:

- **Measurements**
  - High-resolution, real-time waveform analysis
  - High-speed signal digitalization
  - Automatic gain control to acquire the optimum signal
  - Highly sensitive 10 MHz composite probe
  - 20 individual signals acquired and analyzed to produce each measurement

- **Smarter Software**
  - Display of measured corneal thickness, entered IOP, and Corrected IOP for all stored measurements
  - Automatically capture and store up to nine measurements for each eye along with the running average of all measurements taken
  - Built-in IOP correction calculator adjusts IOP based upon corneal thickness
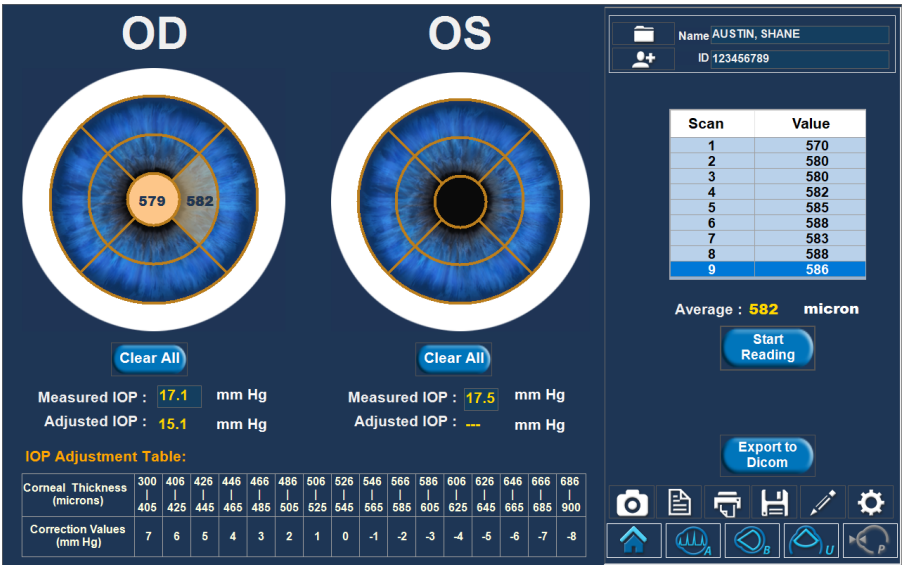
Figure 2.4 - Pachymetry Measurement Screen

Hardware Connections

Figure 2.5 - 4Sight with Attachment Locations

Before turning on power, plug all of the cables into the unit as indicated in figure 2.5 and as by the labels on the sides of the 4Sight. The sequence of plugging in cables is not critical. B-Scan/UBM Probes are able to "Plug and Play". Make sure probes are connected at Home Screen, allowing probe to be ready for use in software. (Note: Plugging the USB connector cables into USB jack locations other than as marked will do no damage, but function may be improper.)

WARNING! DAMAGE AND/OR INCORRECT OPERATION ARE LIKELY TO OCCUR UNLESS ONLY ACCUTOME-SUPPLIED PROBES, POWER SUPPLY, AND FOOTSWITCH ARE UTILIZED.

The user may supply a USB interface mouse and/or keyboard, if desired.

Working clockwise from the bottom left of the unit (front/screen view):
- Power connector (3/16"/4.8mm OD): located at the bottom left and is the main power source for the unit.
- HDMI and RJ__ jacks: lower left, for external data interchange connection.
- USB jacks (3): keyboard, mouse, or external hard drive located at the left side of the unit.
    - Note: External hard drives used with the 4Sight device must not contain a separate power supply as this can lead to elevated leakages.
- Pachymetry Probe (single pin, 3/16"/4.8mm OD): located left, above center.
- B-Scan and UBM Probes: located right center use the USB receptacles.
- A-Scan Probe (4 pin, 1/4"/6.4mm OD): 4-prong jack, next-to-bottom right.
- Footswitch connector (1/8"/3.2mm OD): bottom right.
- Items prohibited during patient interaction:
    - External office equipment such as printers or HDMI monitors that are compliant with IEC 60950-1.
    - Ethernet internet connection.

Figure 2.6 - 4Sight – Rear View

The rear view above shows the probe holders and built-in support stand. The probe holders may be positioned in any of the 10 slots provided for future expansion and personal location preference.

Figure 2.7 - 4Sight Power Module

AC Power Connection: It is required to connect the AC power cord to a grounded AC outlet only. The AC outlet used should be medical grade and surge protected.

Home Screen

Power Up/Down

Power up the unit by pressing the on/off button on the front, bottom left of the unit. The button has an illuminated blue ring when on. To power down the unit after use, simply press the on/off button and the unit will automatically shut down.

Figure 3.1 - Introductory Screen (Splash Screen)

You should see an Introductory "Splash" Screen (see figure 3.1) for a few seconds, followed by the Home Screen.

Overview

Figure 3.2 - 4Sight Home Screen

The Home Screen is designed to be a single repository for patient info recall or entry and also for ease of access to any measurement modality. When in one of the functional application programs (e.g., A-Scan, B-Scan), the user can return directly to the Home Screen by activating the Home Screen Icon.

Home Screen Icon

Patient Info Box (left side of screen)

Application Buttons
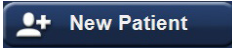
New Patient

New Patient Button - allows the user to enter information about a patient not yet known to the system. Those items marked with an asterisk are mandatory entries.

A-Scan Button
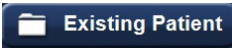
Existing Patient

Existing Patient Button – activation pulls up a list of existing patients.

B-Scan Button

- Exam Folder initially shows the default folder for patient data storage. Use Select to choose another location. Use Reset to return to the default location.

UBM Button

- Find is used to find a specific patient by entering a Last Name, First Name, or MRN (Medical Record Number) as selected via the pull-down menu to the right of the Find box. Entering information in the Find box automatically pulls up and highlights the appropriate patient. It is not case sensitive.

Pachymetry Button

Settings Button

- Selecting a patient record (via double mouse click or double touch) causes return to the Home Screen with the known information automatically entered.

IOLMaster

IOL Master Button - activating this button will open up an exam list of patients measured on the IOL Master and that are ready to be measured with the 4Sight unit using the A-Scan modality.

Information about the patient selected on the IOL Master list will be automatically entered into 4Sight.

DICOM

DICOM Button - activating this button brings up a screen to search for patient information through the DICOM Worklist. This screen brings up information entered in Setup: General/DICOM Servers.
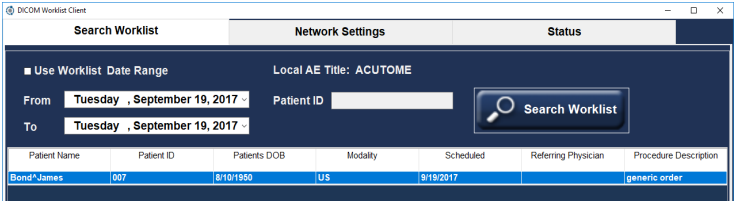
Figure 3.3 - DICOM Worklist

Search Worklist Tab – brings up boxes prompting information to search.

Date Range – the pull-down arrows bring up calendars for convenient selection of dates.

Search Worklist – activating this button retrieves patient options via DICOM in the format at the bottom of the screen. Double-click the patient name in the list to automatically enter the patient information on the Home Screen and return to that screen.

Patient ID –search worklist by patient ID number.

Network Settings Tab – shows the network settings used for the DICOM server and that were entered in the DICOM setup tab in the settings screen.

Status – used to monitor the connection with the DICOM server.

Click on the red X (upper right) to close out the box if the user doesn't want to select any patient from the retrieved list.

Keratometry Readings and IOP Readings
Keratometry Readings and IOP Readings may be entered here or later in A-Scan or Pachymetry screens. These readings correspond directly with the current patient and will be saved with the patient data if entered.

Exam Info Box (right side of screen)
If an existing patient is selected, the appropriate information will be automatically entered in this section. This information corresponds directly with the current patient and will be saved with the patient data, if entered.

Exam ID – automatically assigned by 4Sight.

The Facility, Physician, and Operator selections are made from the options shown via the pull-down tabs in each box. The options can be added to/modified in the Setup Screen.

Facility – the facility at which the readings are taken/the facility responsible for the patient in question.

Physician – the physician responsible for the readings/the physician responsible for the patient in question.

Operator – the person who performed the measurements on the patient in question.

Indication of Scan – a section where users can make notes about the exam and why they feel it is necessary.

B-Scan/UBM Sequences

Create Date/Time – this information is created automatically by the system. It's a date/time stamp for the patient.

Scan Group – system Defaults brings up all of the system options in the Protocol box drop-down list. User Defined brings up only the user-defined protocols in the Protocol box drop-down list.

Protocol – the user may make selections from the drop-down options or add/modify entries in Setup/B-Scan/Sequence.

Description – box elaborates upon the Protocol selected.

The System Default protocols include:
- Free Scan
- Basic Screening - OD only (6 views)
- Basic Screening - OS only (6 views)
- Basic Screening - both eyes (12 views)
- Modified Basic Screening 1 – OD only (6 views)
- Modified Basic Screening 1 – OS only (6 views)
- Modified Basic Screening 1 – both eyes (12 views)
- Modified Basic Screening 2 – OD only (6 views)
- Modified Basic Screening 2 – OS only (6 views)
- Modified Basic Screening 2 – both eyes (12 views)
- Standard Scan – OD only (22 views)
- Standard Scan – OS only (22 views)
- Standard Scan – both eyes (44 views)
- Modified Standard Scan 1 – OD only (22 views)
- Modified Standard Scan 1 – OS only (22 views)
- Modified Standard Scan 1 – both eyes (44 views)

Setup: Facilities/ Physicians/Users

Setup Screen

Select the cogwheel button to bring up the Setup screen.

Figure 4.1 - Setup Screen – Facilities Tab Open

The Setup Section is used to enter information that is used by the Application Modules (e.g., A-Scan, B-Scan, UBM, and Pachymetry) and also for external connections such as DICOM.

Buttons Common to All Setup Screens

Cancel exits Setup to the most recently used application program without saving changes. Selection of Cancel prompts the warning "Exit Setup without saving changes?"

Done saves changes and exits Setup to the most recently used application.

Setup Facilities, Physicians, Users

These screens prompt the entry of information and define the default choices for Facilities, Physicians, and Users to be pulled up and utilized in the Application Modules.

Facility – the facility at which the readings are taken/the facility responsible for the patient in question.

Physician – the physician responsible for the readings/the physician responsible for the patient in question.

Users – the person who performed the measurements on the patient in question.

Available Facilities/Available Physicians/Available Users

If you select one of the existing Available items (top right box), information about that item will show in the detail box on the left of the screen. Make corrections/additions, if appropriate.

New – initiates a new item, which is initially marked "undefined". Enter the appropriate information in the detail box on the left. When the entries are complete, select Save or Done to save and exit back to the Home screen.

Delete – deletes the currently selected item.

Duplicate From Selected – adds another facility with the same location and telephone information. The name and other information should be modified appropriately and saved.

Set Selected as Default – sets the currently selected item as the default to be called up in applications, and marks that item with a check in the Available list.

Save saves all changes up to that point.
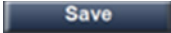
Restore deletes the entries subsequent to the last Save (warning before activation).

Large decorative "5" in left margin

Setup: General

Setup: General – Folder
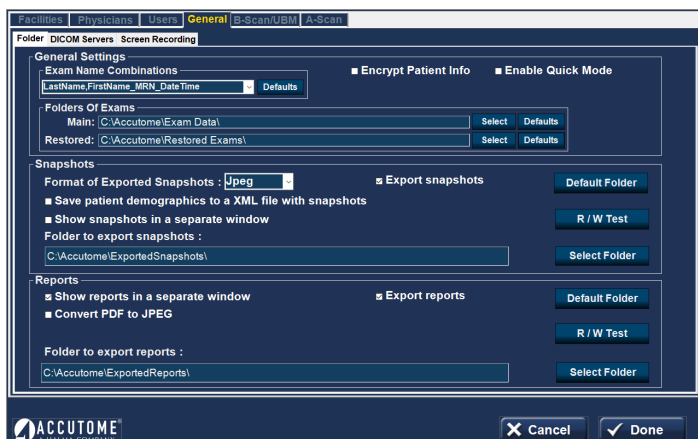
Figure 5.1 - Setup: General - Folder

General Settings Box
Exam Name Combinations
Exam Name Combinations delineates what inputs are required to identify each exam. To use a combination other than the default, select the combination from the drop-down list.

Encrypt Patient Info - selecting this option encrypts patient identification information.

Quick Mode - Quick Mode may be selected if you want to immediately take scans or make measurements prior to entry of the Patient Information and/or Exam Information described below.

If the user selects Quick Mode and Done on the Setup Screen, the Home Screen comes up with Quick Mode highlighted and the Patient and Exam Info grayed out (entry not allowed). The user may then move into one of the Application Modules without entering the Patient or Exam Info. The patient name and/or ID will come up blank on the application screen, but the appropriate information may be entered at a later stage.

However, at the Home Screen, the user may select patient information via one of the "Import From" buttons such as the Existing Patient button. That information is then carried over into the Application Module.

It should be noted that patient information is not saved in Quick Mode unless the user decides to save information by manually clicking the Save icon on any screen or the save scan in the B-Scan/UBM mode. IF PATIENT DATA IS NOT SAVED, IT WILL BE LOST.

Folders of Exams Box
There are two selections of folders: Main and Restored. The Main folder is where you store any new patient exams. The Restored folder is the location designated for restoring patient exams. To change from the default folder, choose the Select button and designate a different location from the options shown or make a new folder.

Functions/Buttons Common to Snapshots and Reports
Export Snapshots/Reports – to select the export of snapshots and/or reports automatically, check next to Export snapshots and/or Export reports near the top line of the respective box area.

Default Folder Button – check this button if you want to export to the default folder.

R/W Test – once the folder location for the export of either Snapshots or Reports has been selected, you may test the read/write capability of this location by activating the appropriate R/W Test button. If the location path is OK, the Message "Successfully write to 'Export Snapshots Folder'" will appear. Click OK. If the path is not found, an error message will appear and you should contact your system administrator.

Select Folder – the Select Folder button brings up possible options for selection of the folder to which to export Snapshots or Reports. Select subfolders to bring up the desired location. The selected folder will be entered in the box under "Folder to export snapshots". The selected snapshots and reports folders may be different folders.

Show snapshots/reports in a separate window – select, if desired. The snapshots/reports appear when the camera or reports icon is selected within one of the application modules.

Functions/Buttons Unique to Snapshots
Format of Exported Snapshots – from the drop-down menu, select the appropriate file format for exported snapshot image files.

Save patient demographics to an .XML file with snapshots – select, if desired.

Functions/Buttons Unique to Reports

Convert .PDF to .JPEG – select, if desired.

Setup: General – DICOM Servers

Figure 5.2 - Setup: General - DICOM Servers

Information of Facility Used in Exporting DICOM SOPs

The appropriate information will be displayed if the DICOM capability has been activated by Accutome. In order to activate DICOM capabilities, please contact your local Accutome representative.

PACS (Picture Archiving and Communication System) Box

Local AE Title – this is the externally known name of an application entity used to identify a DICOM application to other DICOM applications on the network. The AE Title is often set by the device's system administrator.

Remote Servers Box

New Server – a new remote server may be defined by activating the New Server button. The appropriate information is then entered in the Display As, AE Title, IP Address or host name, and Port Number boxes.

Save Server – saves the current server setup after New Server.

Remove Sel. – this is the Remove Selected button which removes the currently selected remote server.

Verify Connection – attempts to verify connection to the selected remote server. A pop-up window will indicate if the connection was successful.

Set Selected as Default – makes the currently selected remote server the default server and marks it with an asterisk on the List of Remote Servers.

DICOM Folder – this box gives the location of the folder currently used to store patient files for DICOM transmission.

Select Folder – brings up accessible locations that might be selected for DICOM file storage.

Default SOPs to Export Box
Check to select the desired items.

DICOM Store Location Box
Selects between a remote server and the DICOM Folder selected on this screen.

Duplicate to Worklist Server – check the box, if appropriate.

Worklist Box
This box allows the use of another DICOM server for patient file storage that may be different from the PACS server.

Local AE Title – this is the externally known name of an application entity used to identify a DICOM application to other DICOM applications on the network. The AE Title is often set by the device's system administrator.

Remote Servers Box
New – a new remote server may be defined by activating the New server button. The appropriate information is then entered in the Display As, AE Title, IP Address or host name, and Port Number boxes.

Remove – removes the currently selected remote server.

WARNING! CONNECTION TO AN EXTERNAL NETWORK IS PROHIBITED DURING PATIENT INTERACTION WHILE USING THE 4SIGHT DEVICE

Setup: General - Screen Recording Tab

Figure 5.3 - Setup: General - Screen Recording

B-Scan/UBM has the ability to convert videos into .MP4 and AVI format.

Recording Area — select what part of the screen the video should record.

Record Whole Screen — video will record the entire screen with the Connect Software options in view.

Record Subsection — video will record only the Scan Window.

Recording Start/Stop Hotkey— F5 is the default Start and Stop of the video recording.

Start Delay — delay the start of the video recording. Allow for a delay to set up probe or scan position on the eye before recording begins. Maximum delay is 30 seconds.

Max Recording Length — set length of video recording (Max length is 5 minutes 300 seconds).

Target FPS by resolution — based on your computer specs, your target Frames per Second for the scans.

Output — Video Save Path-Save location for finished videos (videos can be set as .AVI or MP4).

Recording Log — log of recordings taken with the software.

Installing a Printer

Accutome understands that the need may arise to access the 4Sight operating system in order to install printer drivers or for other IT necessities. In order to access the embedded operating system, please read the statement and instructions below.

Accutome, Inc., and its parent, sister, and affiliate companies and distribution agents around the world (collectively referred to as "Accutome") make no guarantees of any kind with regard to any programs, files, drivers, or any other materials contained on or downloaded from any type of web site, digital storage media, digital storage device, digital server, digital network, or digital intranet. The use of all such software, programs (including but not limited to drivers), files, documents, manuals, instructions, or any other materials (collectively, the "Downloaded Information") will fall under the sole responsibility of the owner/buyer/user/operator of this 4Sight unit. Accutome disclaims all warranties, express or implied, as to downloaded information and as to any Accutome-supplied information in connection with this 4Sight unit, including, without limitation, warranties of accuracy, timeliness, completeness, usefulness, merchantability, suitability for a particular purpose, non-interruption of operations, and noninfringement.

You assume all damages and risks associated with downloading and/or using any downloaded information for the purposes of installing printer drivers and all other software on the 4Sight unit. Accutome shall not be held liable for any damages whatsoever, including, without limitation, damages for destruction, impairment, or improper functioning of your 4Sight unit; computers, systems, servers, Internet machines, and any other hardware and/or software; damages for loss of business or business profits, information, or opportunities; business interruption, loss of data, programs and/or information contained in the information-processing system or elsewhere; and any direct, indirect, consequential, exemplary, or incidental damages incurred as a result of downloading and/or using any downloaded information in any other way. Accutome makes no representations or warranties of any kind concerning the downloaded information, including but not limited to its safety, suitability, lack of viruses or other malware, inaccuracies, typographical errors, and/or any other harmful components thereof. There are inherent dangers in the use of any software, and you are solely responsible for determining whether the downloaded information is compatible with your equipment and other software installed on your equipment, including but not limited to the 4Sight unit, and any other hardware or software, whether connected physically or otherwise. You are also solely responsible for the protection of your equipment and backup of your data, and Accutome will not be liable for any damages you may suffer in connection with using, modifying, or distributing the downloaded information.

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1. Navigate to the 4Sight home screen.
2. Click on the Windows OS button located in the bottom right-hand corner.
3. Type in the 4Sight password — malvern19355 — once the password is entered, you leave the 4Sight software and are at the operating system desktop.
4. Proceed to install your printer driver per the printer manufacturers' directions.
5. When complete, restart the 4Sight software by double-clicking on the 4Sight software icon located on the desktop. This will reopen the software.

Setup: A-Scan

Setup: A-Scan – Options Tab
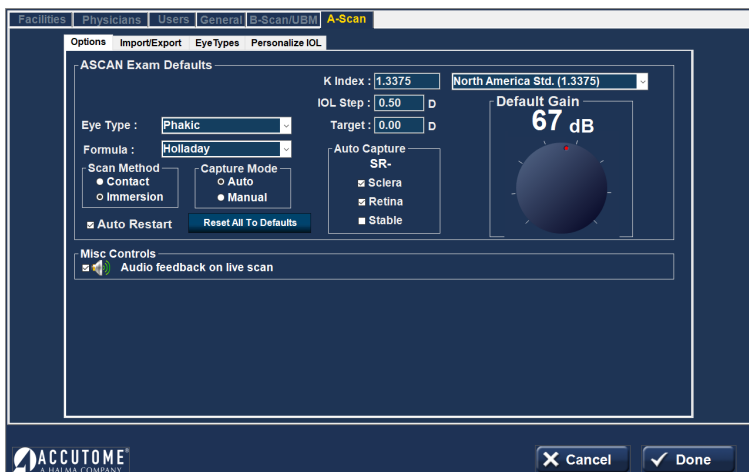
Figure 6.1 - Setup: A-Scan - Options Tab

A-Scan Exam Defaults Box

Eye Type - select the eye type from the drop-down options as described below. The default is Phakic.

- Phakic - Setting for eyes with natural lenses. This will be the setting for most patients
- Silicone Oil Filled - Phakic eye with silicone oil in the vitreous
- Dense Cataract - Using this setting when a dense cataract prevents measurement of lens thickness
- Pseudo PMMA - Patient with Pseudophakic PMMA IOL
- Pseudo Silicone - Patient with Pseudophakic Silicone IOL
- Pseudo Acrylic - Patient with Pseudophakic Acrylic IOL
- Aphakic - Patient with no lens, lens is not measured or assumed
- Phakic + ICL - Phakic eye with ICL implanted

Formula - select the desired formula from the drop-down options:

- HofferQ
- Holladay (default)
- SRKT
- Haigis
- SRK II
- Binkhorst II

The 4Sight A-Scan Module has the latest third and fourth generation IOL calculation program.

Scan Method Box

Scan Method for applying the probe to the cornea:

Contact – the contact method is where the probe is allowed to come in direct contact with the anesthetized cornea.

CAUTION: When using the contact method, care should be taken to minimize corneal compression. Corneal compression will result in a shorter axial length measurement and will affect the calculations.

Immersion (default) – the immersion technique is where a scleral immersion shell is used with immersion fluid to couple the probe to the eye. No contact between the probe and the cornea occurs.

Capture Mode Box

Capture Mode for axial length measurement:

Auto (default) – auto is where the software determines when the minimum criteria is found and automatically locks on the signal.

Manual – the manual mode is where the operator depresses the footswitch when an acceptable pattern is obtained and then the pedal is depressed again to reselect the probe.

Auto Restart

The Auto Restart checkbox controls the default mode of restarting the ultrasound measurements after each successful measurement. When Auto Restart (default mode) is selected, the ultrasound measurements will automatically restart after an auto or manual reading. When Auto Restart is not selected, users have to use the footswitch or "Esc" key to restart the scan.

Note: When in Auto Capture Mode, the instrument will capture when the minimum lock-on criteria are met.

Holding the footswitch down while scanning in the automatic mode will prevent the instrument from capturing automatically until the operator has determined the best measurement is found. Once the best waveform is found, release of the footswitch will allow automatic capture to engage.

The instrument will capture automatically, providing the auto capture conditions set in the options page have been met.

Reset All To Defaults

This button resets all the options within the New Exam box to the default values.

K Index

The refractive index is used to convert the corneal radius of curvature to diopters or millimeters. The refractive index is not the same for all keratometers.

The user should select the default refractive index to match that of the keratometers being used in the office. The drop-down options are:
- North America Standard (1.3375) (default value)
- European Standard (1.3315)
- Custom (between 1.2500-1.500)

IOL Step
To set the IOL Step, left click the IOL Step window and type in the desired diopter value. The default is 0.5 diopter. Most IOL implants are offered in 0.5 diopter steps. Some newer refractive implants are being offered in 0.25 diopter step.

Target
In many instances, the surgeon has developed personal preferences with regard to the targeted post-operative refraction outcome and may want to set it to a default value other than plano. The user may specify the default target refraction that is most commonly used for patients. The target refraction may also be changed on a case-by-case basis when in the IOL calculation screen. The default value is 0.0 diopter.

Auto Capture Box
The user may define the automatic measurement mode by specifying how a measurement is automatically captured. The criteria are:
- Sclera - Automatic capture determined by sclera detection
- Retina - Automatic capture determined by retina detection
- Stable - Automatic capture determined by measurement stability

To configure the Capture Mode, left click on the appropriate feature(s). The default setting is Sclera and Retina.

The Auto Mode setting is displayed in the soft menu on the Measure Screen as Auto (SRS), where SRS means Sclera, Retina, Stable. If the feature is ON, the first letter appears in its place, otherwise a placeholder is displayed.

Sclera, displayed as Auto (S_), must have a distinct sclera echo after the retina, above the threshold.

Retina, displayed as Auto (_R_), must begin at the base line, have no data greater than 10% of the threshold in front of it (for 1.5mm), and be steeply rising.

Stable, displayed as Auto (_S), means the measurement needs to be within a tolerance for a certain amount of time. (±0.0465 mm at 1555 m/sec)

Note: The Stable Auto Mode setting is not recommended for contact method measurements. The measurement variance caused by hand or eye movements may make the stable autolock requirement difficult to achieve.

Default Gain

The gain knob allows the user to adjust the strength of the return signal as it travels through the eye, thereby making the wave patterns higher, compensating for absorption.

The Gain value set on this screen will be the default value for new readings.
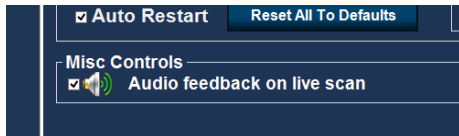
Figure 6.2 - Setup: A-Scan - Misc. Controls

Misc. Controls

Audio feedback on a live scan option can be turned on. When this option is enabled, a pulsating tone is emitted by the system indicating contact with the eye.

This feature may be very helpful when aligning the probe. In some instances, the tone may become a distraction to the patient. When this occurs, it may need to be turned off.

Setup: A-Scan - Import/Export
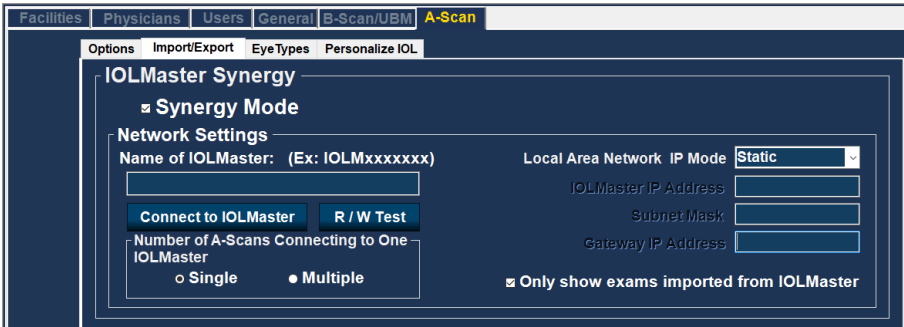
Figure 6.3 - A-Scan Synergy Mode Setup Screen

IOL Master Synergy Box

The Import/Export feature allows you to use the 4Sight as a connection to the IOL Master 500 – called **Synergy Mode**.

To turn on the Synergy Mode, check the box to the left of Synergy Mode.

IOLMaster 500 version 7.7

If you have the IOL Master 500 version 7.7, the data transfer between the two units is via LAN/network. The proper set up and operation is listed step-by-step on page 31.

Setting up the 4Sight Synergy Software for IOLMaster 500 version 7.7:
1. Power on IOL Master.
2. Select the i icon in the top right-hand corner of the IOL Master screen.
3. On the next screen (About IOL Master) find the name of the IOL Master labeled Computer Name (IOLM#######) and write down the name.
4. To exit, click OK.
5. Click on the Settings Icon in the bottom right-hand corner (Wrench Icon).
6. Select the Program tab (Second tab in the settings screen).
7. Insert Accutome software key USB Memory "stick" into the IOL Master.
8. In the Program tab on the IOL Master, select Update.
9. Follow the Install prompts until installation is complete, then click OK to restart the IOL Master. Remove USB Memory "stick" while system reboots.
10. Connect the 4Sight and the IOL Master either by network or switchbox/router.
11. Select the Setup tab on the top center of the A-Scan software.
12. Select the Import/Export tab under the Setup tab.
13. Check the box next to Synergy Mode.
14. Double check the LAN IP Mode is set to Automatic.
15. Enter the Computer Name you found on your IOL Master in the box labeled Name of IOL Master (IOLM#######).
16. Network settings are now active and can be adjusted.
17. After selecting Synergy Mode within the setup screen, choose Network folder under the Method of Data Exchange box.
18. Network settings are now active and can be filled. The Network settings should be filled accordingly:
    a) Number of A-Scans Connecting to One IOL Master 500: If you have more than one IOL Master with Synergy software, you can connect all units to the 4Sight. If multiple connections are done, you will be asked to select the patient name from a pop-up exam list. The patient will not be imported automatically.
    b) Local Area Network IP Mode: This should always be set to automatic.
    c) Only show exams imported from IOLMaster: When selected, the 4Sight will only show exams imported directly from the IOL Master 500, no other exams will be visible. If this box is unchecked, you will be able to see patients imported from the IOL Master 500 as well as other patients that are stored in your exam list. This does not allow any patient to be scanned and exported to the IOL Master 500. ONLY THE EXAM DIRECTLY IMPORTED FROM THE IOL MASTER 500 CAN BE MEASURED AND EXPORTED.
19. Click the Connect to IOLMaster button. You should receive a pop-up window stating the units are successfully connected.
20. Click the Save button on the bottom of the screen, then restart the software.
21. You are now successfully connected to your IOLMaster 500.

IOL Master 500 version 7.5 or older (7.4, 7.3, etc.)

If you have the IOL Master 500 version 7.5 or older with the Sonolink software option from Zeiss installed, the data transfer between the two units happens via USB memory "stick" data storage device. The proper operation is listed below:

1. Select USB Memory "stick" under the Method of Data Exchange portion of the Import/Export screen.
2. Return to the Exams screen by clicking on the Exams tab at the top of the screen.
3. Measure the patient using the IOL Master 500 version 7.5 or older with the Sonolink installed. Once the measurement error appears, complete all other exams before returning to the axial length page of the IOL to schedule the patient for an ultrasound measurement by selecting "Yes" on the pop-up window.
4. Export the patient from the IOL Master 500 to a USB Memory "stick" that is installed to the unit by navigating to the ultrasound waiting room and clicking on the export icon.
5. Remove the USB Memory "stick" from the IOL Master and plug it into a 4Sight USB port.
6. The exam list will be automatically updated with the patient name that you exported from the IOL Master.
7. Double-click the patient name. The software will automatically jump to the measurement page.
8. Measure the patient using your preferred measurement method.
9. Once the measurement is complete, select the "Export to IOLMaster" icon. The software will automatically export the patient data to the USB memory "stick".
10. Return to the Exams page by clicking on the Exams tab. Select the "Eject USB Memory "stick"" icon located at the top of the screen.
11. Remove the USB memory "stick" and plug it back into the IOL Master.
12. Import the patient data by clicking on the import icon on your IOL Master ultrasound page.

Once you have imported patient data back into the IOL Master, you will continue to complete the exam.

Operation of the Accutome 4Sight Software with IOL Master 500 version 7.7

1. Set the Accutome A-Scan software to Network Folder under the Method of Data Exchange under the "Setup" tab.
2. Return to the Exams screen by clicking on the Exams tab at the top of the screen.
3. Measure patient with IOL Master and wait for measurement error.
4. Complete all remaining measurements for both eyes.
5. Schedule patient for ultrasound measurement by returning to the axial length measurement page.
6. Export patient data from the IOL Master.
   a) IOL Master 500 v. 7.5 or older: Patient is scheduled for an ultrasound using the pop-up window. Once patient information is in the ultrasound waiting room, the patient name must be selected and the export icon

must be chosen. The USB memory "stick" must then be removed and plugged into the pc operating the A-Scan software.

   b) IOL Master 500 v. 7.7: As soon as the measurement error is shown, you must finish the other measurements.

    i. Return to the axial length measurement icon and click schedule.

    ii. Click on the people icon. The patient will be exported automatically.

7. Open the 4Sight software and double-click on the patient name that is to be measured.
8. The software will automatically transfer to the measurement screen.
9. Prepare by following the immersion shell/probe setup guidelines.
10. When in auto mode, begin with footswitch pressed.
11. Insert shell into eye and fill shell with BSS past probe tip until waveforms are displayed on screen.
12. Release footswitch when spikes are acceptable and machine will auto capture.
13. Ensure that all waveforms are within 0.1 mm (immersion) and 0.2 mm (contact) and that the spikes are of sufficient amplitude and exhibit proper pattern.
14. You can check scan consistency by tapping the footswitch or pressing the ESC key. To replace a measurement, hold the footswitch or press the Insert key on the PC.
15. When all five measurements are captured, select the Export to IOLMaster icon.

   a) If using an IOL Master 500 v. 7.7, the patient information is exported directly back to the IOL Master where it is imported automatically.

   b) If using an IOL Master 500 v. 7.5 or older, the patient information on the USB memory "stick" must be ejected using the Eject USB Memory "stick" icon on the exams tab.

16. Remove the USB memory "stick" and plug it into the IOL Master.
17. Return to the IOL Master and navigate to the ultrasound screen; the patient should be listed at the bottom of the page with "OK" next to the name.
18. Navigate to the patient list.
19. Select your patient.
20. On the left-hand side of the page, choose the existing measurement.
21. Select Open.
22. Scans can be viewed by clicking on the axial length measurement icon.
23. IOL calculations can now be done for the patient.
24. Be sure to save all information.

Once data is imported back into the IOL Master 500, you may complete all remaining measurements and calculations.

You are able to export the measurements for both eyes for a patient from the IOL Master 500 to the 4Sight in order to speed up measurements. To do so, measure both eyes with the IOL Master 500 before you click on the schedule tab on the IOL Master screen. This will export the measurements for both eyes in one data file to the Accutome 4Sight. If at any point you wish to stop using the 4Sight as the Synergy device, simply turn off the Synergy mode in the setup screen under the Import/Export tab.

Setup: A-Scan - Eye Types

The Accutome 4Sight provides the customer with the ability to create unique eye types that adapt the A-Scan measurement for use with new material being created for ocular surgery.
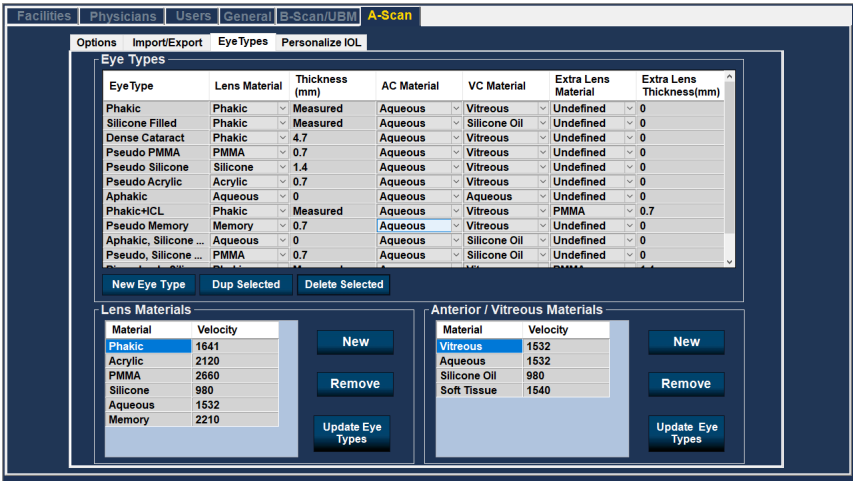
Figure 6.4 - Setup: A-Scan – Eye Types Screen

When in this screen, the user may create new eye types that reflect the changes in ophthalmic materials. Prior to creating a new eye type, the velocities of sound for each material used must be entered.

Adding a New Lens, Anterior Chamber, or Vitreous Chamber Material

Before using a selection from the Lens Material, Anterior Chamber (AC) Material or Vitreous Chamber (VC) Material in the definition of an Eye Type, the material must exist in the respective material table.

Working in the Lens Materials section at the bottom left of the screen, add/modify information, as appropriate. Select the Update Eye Types button when done.

Note: Clicking on the Update Eye Types button only confirms the entries as correct. Done must be selected to save the new entries permanently to memory.

To Add a New Eye Type

Changing eye type and velocity information does not affect the eye type information for current and saved patients. The changes will be in effect the next time the changed eye type is selected or a new patient is started. Current patient eye types that do not match the settings on the eye types screen are indicated with * on the measure and calculate screen.

Open the line for a new eye type by selecting the New Eye Type tab.

Name the new eye type as desired and make selections from the drop-down options and from measured data.

Select Cancel to exit Setup without saving changes, or select Done to save changes and exit Setup.

Setup: A-Scan - Personalize IOL

Personalizing IOL Overview
One of the great features of the Accutome 4Sight is the ability to personalize the lens constants used in calculating lens power. This ability to fine-tune lens constants results in even greater success for patient outcomes.

Note: The Personalize IOL screen does not allow the patient data to be pasted for an eye that has Rx Surg set to Yes. If you attempt to personalize IOLs with post refractive surgery eyes, the following message is shown: "Refractive surgery eyes cannot be used."

Personalizing Lens Constants
IOL constant personalization is a method for removing consistent errors from the entire IOL implant procedure. It is important that as many variables as possible be consistent when personalizing constants for an IOL. These variables include:
- Diagnostic technician
- Diagnostic equipment (A-Scan, Keratometer)
- Surgical technique
- Patient pathology
- IOL manufacturer and model
- IOL calculation formula

For this reason, the Accutome 4Sight tracks personalized constants for each IOL and formula separately.

The process for personalizing lens constants involves entering postoperative results and allowing the 4Sight to recalculate the constants used in the calculation formulas. The instrument tracks all the data entered in the postoperative results and optimizes all the data to determine the new formula constant.

How to Personalize Constants
The process of personalizing IOLs consists of:
- Selecting the IOL group and lenses
- Selecting the saved patient information
- Entering the IOL implant power used in surgery
- Entering the postoperative outcome
- Updating the IOL constant
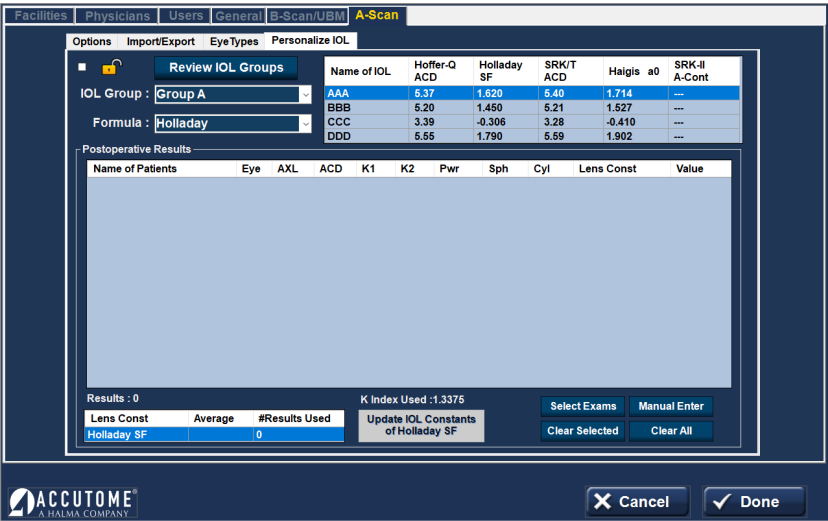
Figure 6.5 - Setup: A-Scan – Personalize IOL Screen

Auto Personalization

1. Unlock the screen (upper left corner).
2. Select the Review IOL Groups button.
3. IOL Group: Select the lens group from the drop-down menu. This will load four possible lenses and the constants in the table to the right.
4. Select the lens to be personalized.
5. Select the Formula to be used.

Figure 6.6 - Setup: A-Scan – Personalize IOL - Review IOL Groups

Note: The 4Sight personalization program allows the user to select any personalization formula. The default value is based on the default formula chosen in the Options tab during the initial setup.

When formulas other than the default formula are used and personalization is required, the alternate formula must be manually selected prior to recalling the saved patient to the personalization table.

It is the responsibility of the user to know the formula used to calculate the initial power of the patient's IOL.

Selecting the Patient Record to be Personalized

1. Select the Select Exams button located on the lower right of the screen.
2. The saved exams page will open. See Saved Exams figure below.
3. Select patient records to be included by left clicking on them. A dark blue highlight indicates the patient record has been selected. More than one patient record may be selected at a time.
4. Click Done at the bottom of the screen to transfer the files to the personalization tables.
5. The postoperative result page will be populated with the stored information.
6. Position the cursor over the Pwr (power chosen) entry and left click to select the entry. Type the power of the implant chosen.
7. Position the cursor over the Sph (postoperative sphere measurement) entry and left click to select the entry. Type in the postoperative sphere.
8. Position the cursor over the Cyl (postoperative cylinder measurement) entry and left click to select the entry. Type in the postoperative cylinder.
9. Left click Done.
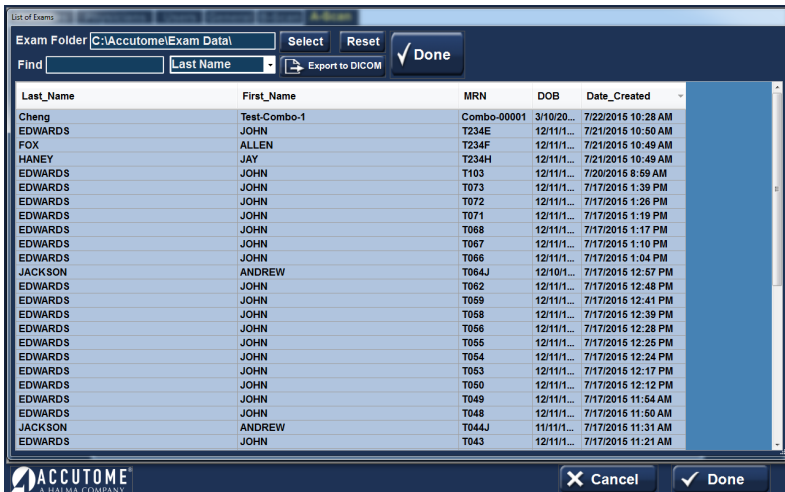
Figure 6.7 - Setup: A-Scan – Personalize IOL – Saved Exam Highlighted

4Sight will automatically calculate the lens constant for the formula selected and save it to memory.

Note: When the Update IOL Constants tab (bottom center) is selected, it will update the existing IOL group table with the personalized lens constants.

Manual Entry of Personalization Information

Many surgeons may want to include information in the personalization of a lens constant when they upgrade from older models of the A-Scan. The Accutome 4Sight has the ability to manually enter previous patient outcome information.

1. Unlock the screen (upper left corner)
2. IOL Group: Select the lens group of interest from the drop-down menu in the IOL Group box. This will load four possible lenses and the constants in the table to the right.
3. Select the lens to be personalized by highlighting one of the rows in the table to the right.
4. Select the Formula to be used.

Note: The Accutome 4Sight personalization program allows the user to select any personalization formula. The default value is based on the default formula chosen in the Options tab during the initial setup.

When formulas other than the default formula are used and personalization is required, the alternate formula must be manually selected prior to recalling the saved patient to the personalization table.

It is the responsibility of the user to know the formula used to calculate the initial power of the patients IOL.

5. Select the Manual Enter button on the screen (lower right). The postoperative result entry table will become active and show an empty table.
6. Position the cursor over the Name of Patient cell and left click. The cell will change shading and allow the patient's name to be entered. Type in the patient's name.
7. Press the tab key or position the mouse over the Eye cell and left click. Type in OD or OS depending on the eye measured.
8. Press the tab key or position the mouse over the AXL cell and left click. Type in AXL (axial length).
9. Press the tab key or position the mouse over the ACD cell and left click. Type in ACD (measured anterior chamber depth).

Note: The ACD measurement, listed as the fourth cell of the postoperative results table is the measured value obtained by the A-Scan. It is not the lens constant. If the value is not known, leave the box empty.

10. Press the tab key or position the mouse over the K1 cell and left click. Type in K1 (keratometry measurement).
11. Press the tab key or position the mouse over the K2 cell and left click. Type in K2 (keratometry measurement).
12. Press the tab key or position the mouse over the Pwr cell and left click. Type in Pwr, the power of the implant chosen by the surgeon.
13. Press the tab key or position the mouse over the Sph cell and left click. Type in Sph (postoperative sphere).

14. Press tab key or position the mouse over the Cyl cell and left click. Type in Cyl (post-operative cylinder).

Once the information has been completely entered, you will see the personalized lens constant in the Value cell.

Once the changes have been made, select the Done button located on the lower right portion of the screen.

Updating IOL Constant

While you enter postoperative results, you will notice the date change in the Average table, located at the bottom of the screen. The Average table displays the count of the postoperative results for the selected calculation formula. The Average table also displays the average IOL constant extracted from the postoperative tables. This constant is based on the formula used to calculate the implant power. Once the user has decided they have obtained and calculated the minimum amount the patient requires, the user may decide to update the existing lens constant with the personalized value.

To do this, click the Update IOL Button.

Deleting Postoperative Results

Normal postoperative results are essential in determining an effective personalized IOL constant. There may be instances when you would like to delete some or all the postoperative results: e.g., a value is very high or low with respect to the average (outlier), entered data is inaccurate.

The Personalize IOL screen provides two methods of deleting postoperative results: you can delete the currently selected result or all postoperative results for the current IOL.

To delete current postoperative result:
1. Select the IOL Group.
2. Select the name of the patient to be deleted.
3. Highlight that patient.
4. Click the Clear Selected button (lower right).

To delete all postoperative results:
1. Select the IOL Group.
2. Click the Clear All button (lower right).

Save and Confirm Configuration Changes

Any time a table is updated, such as when deleting personalization information, the changes must be saved to the configuration file.

Once the changes have been made, left click on the Done button located on the lower right portion of the screen.

Setup: B-Scan/UBM – Options Tab

Figure 7.1 - Setup: B-Scan/UBM Tab Selected

Probe Control Box

Mode - B-Scan – the probe frequency field allows you to select from two frequencies: 12 MHz or 15 MHz. Which frequency you choose for scanning will determine what depth settings you can select. If you choose 12 MHz, the depth options are 30 mm and 60 mm. If you choose 15 MHz, the depth options are 50 mm and 100 mm.

Mode - UBM - The frequency of the Accutome UBM Module is fixed at 48 MHz. On the screen you will see windows that allow change of frequencies. These adjustments are for use with the B-Scan probe only and have no impact upon the operation of the UBM probe.

Video (Cine) Buffer – the Video Buffer is the length of time data is stored for each acquired image. For example, with a setting of 4.5 seconds, the last 4.5 seconds of the scanning time are saved as the scanned image.

The default video buffer is 4.5 seconds. Other video buffer options are:
- 2.25 sec
- 8.5 sec
- 17 sec

Longer video recording length is available up to 5 minutes/300 seconds using B-Scan/UBM recording feature.

Start/Stop Box
Select to start and stop scanning with the Probe Button only, the Footswitch only, or both.

Power – the Power selection allows you to adjust the power level of the signal through the B-Scan or UBM probe. The power level is indicated by a number (a percentage from 0 to 100) located next to the label Power and by the location of the adjustment arrow on the scale. To adjust the power, select the arrow indicator and slide as shown in Figure 7.1 until you reach the appropriate value.

Info on Images Box
The Info on Images selections allow you to choose what information is displayed on patient images and the position of the measured data.

The following fields are available to be shown on any patient image:
- Facility
- Physician
- User
- Patient
- DOB
- Scan Date

To have any of the aforementioned fields display on an image, click in the checkbox to enable the field. The default shows Facility, Physician, User, and Scan Date only.

Position of Measurement Data Box
The Measured Data Position selection determines upon which side of the screen the measured data will appear; the left side is the default. To change the position, select either the left or the right button.

UBM Focal Zone - if selected, dotted lines on the image indicate the area of best image quality (green zone).

Snapshot + Print Box
By selecting the Show Name on Filename whenever you take a snapshot of a patient image, the file name for the image will be stored with the Patient Name (entered when starting an exam) as the first part of the file name.

The Print Format option determines the page layout when printing a patient image; Portrait or Landscape.

Image Controls Box

One of the great features of the B-Scan/UBM Module is the ability to view the actual adjustments to image controls live, while you are changing the settings. As you make image control adjustments, the Small Image Window, located at the bottom right of the screen (see Figure 7.2) displays how the changes will affect image scanning. The image controls on the Setup Options Screen allow you to adjust:

- TGC
- Gamma
- Gain
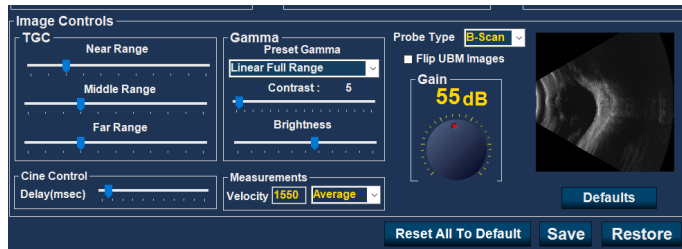
Figure 7.2 - Setup: B-Scan/UBM Tab Selected

TGC

TGC (Time Gain Compensation) – the ability to adjust the signal gain segmentally as distance from the probe increases.

There are three TGC setup options:
- Near - increases the gain for the anterior portion of the eye, near the probe
- Middle - increases the gain for the middle portion of the eye
- Far - increases the gain for the far portion of the eye

Gamma

Preset Gamma – gamma curves are a type of contrast adjustment that favors selectively, the low end, high end, or middle end of the contrast gradient. There is no correct gamma, only the one that best delineates the subject of interest. Select the desired preset gamma setting from the drop-down options:
- Linear Full Range (default setting)
- S-Curve Full Range
- Log Full Range
- Color

Contrast and Brightness – slider controls enable these parameters to be adjusted for the best image.

Probe Type – select B-Scan or UBM, as appropriate.

Caution: Before starting a patient exam, ensure that the probe type selected and the probe used are the same and appropriate to the desired application.

Gain

The default gain is indicated above the thumbwheel. The default gain may be adjusted independently for each of the B-Scan or UBM modes, and remains set at the most recent value selected.

Flip UBM Images (check box) - the box (when in operation and checked) will flip the UBM image. On your current screen you see the Accutome logo on the bottom left hand corner. This indicates or aligns with the marker on the probe. When the "Flip UBM Image" box is checked the logo and indicator will switch to the right-hand side of the screen.

Cine Control Box
Delay (msec) – the speed at which the film loop is played back. The more delay, the slower the speed.

Measurements Box
Velocity – the user may change the velocity of the sound to reflect the density of the tissue being measured. If you select one of the drop-down options: vitreous, aqueous, soft tissue, average, or lens, the velocity for that medium will automatically be entered. To use a different value of velocity, select the velocity field, use backspace to delete the current digits, and type in the new value for the velocity. The new value is set without further action.

Defaults (under the scan image)
Resets the defaults for the "Image Controls" box only.

Reset to All Default
This button resets the entire page.

Setup: B-Scan/UBM - Sequence

Edit Current Sequence Box
Name – enter the name of the newly added sequence under Edit Current Sequence. When you have finished entering the new name, the sequence name in Available Sequences will be renamed to the same new name.

Description – enter a description of the scanning sequence in the description field, if necessary.

How to Define the Sequence Scan
The key components in defining the sequence scan are the eye (OD/OS), scanning method, and probe position for the scan.
To change the first scan of the sequence:
  • Select the first view, or scan, of the new sequence by either clicking in the checkbox (to the left of the view name) or by double-clicking on the scan title (e.g., OD.Scan) in the "Views of Sequence" box as shown in figure 7.4.
The first view of the new sequence can be changed to any eye, scanning method, and position that you want by simply making selections and changing them, if necessary. The selections you can make and edit are listed below.
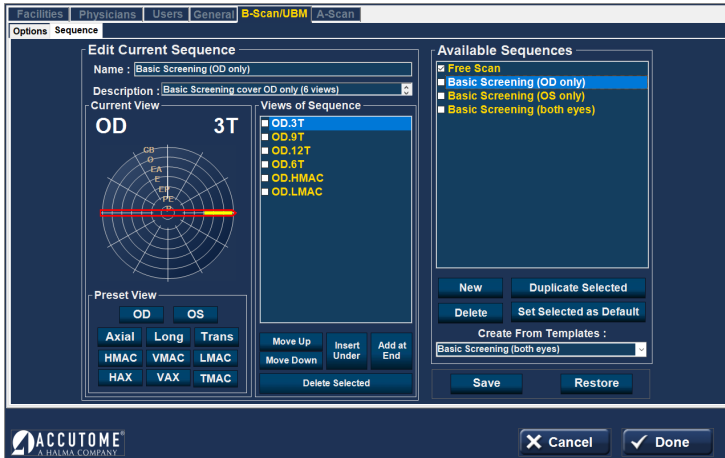
Figure 7.3 - Setup: B-Scan/UBM – Sequence Tab

Current View Box

In the Current View Box:

- Select OD or OS
- Probe Scanning Method

If you would like to change the method of scanning from AX [Axial - the default], select either Long (Longitudinal) or Trans (Transverse).

Select either HAX [Horizontal Axial] or VAX [Vertical Axial] if you want one of those scanning modes.

Probe positioning for a scan is illustrated graphically by a wheel, representing the hours of the clock. There is an indicator with an arrow at one end that indicates the position and that can be dragged to edit the probe position. When you initially select the position wheel to edit the current view, the first scan defaults to the 12AX [Axial] probe position, with 12 being the 12:00 position as shown in figure 7.3.

If you would like to change the probe position for the scan, select the tip of the position indicator and drag the indicator around the position wheel until it is at the appropriate position or hour on the clock.

Note: If you move the probe off of 12:00 for VAX or off 9:00 for HAX, the labeling changes to xxAX where xx is the "time" selected.

If you would like to identify the scan for scanning the macula, select one of the options listed below:

- HMAC-Horizontal Macula
- VMAC-Vertical Macula
- LMAC-Longitudinal Macula
- TMAC-Transverse Macula

Note: OD.Scan, a free scan of the right eye, is the default given to the first scan of any new sequence. If you do not want this as your first scan, edit the scan.

Views of Sequence Box
The Views of Sequence box lists all available scans in the current sequence.

There are several command buttons for manipulating the sequence scans under the views box:
- Move Up - moves the selected scan up in the sequence order
- Move Down - moves the selected scan down in the sequence order
- Insert Under - adds a new scan under the currently selected scan
- Add at End - adds a new scan to the end of the sequence
- Delete Selected - deletes the selected scan from the sequence order

To add another scan to the new sequence:
1. Select the Insert Under button in the Views of Sequence box.
2. The newly added sequence scan will display as Scan as shown in Figure 7.4.
3. Select the appropriate eye button.
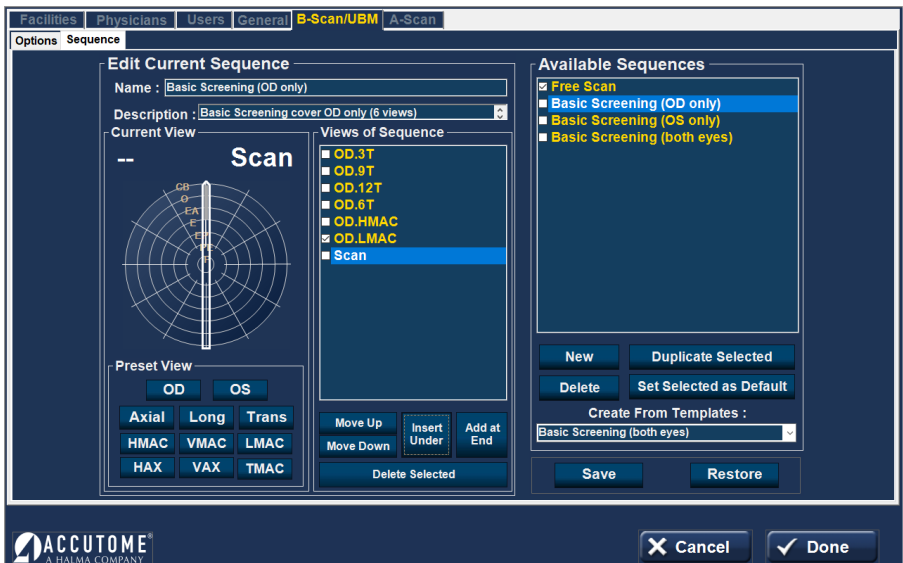
Figure 7.4 - Setup: B-Scan/UBM – Sequence – New Sequence Scan Added

4. Adjust the position for the new sequence scan by dragging the tip of the position indicator. The new scan defaults to AX as the method for probing. If you would like to change the probing method, select either Long or Trans.

5. When you arrive at the appropriate position for the probe in the newly added sequence scan, release the position indicator. The new position will be reflected in the label for the new sequence scan as shown in the figure 7.5. The indicator stopped at 3:00, and the label for the scan was changed from OD.Scan to OD.3AX.

6. Continue to add and define new sequence scans as previously described.

7. Select a specific view in the list and select Delete Selected to delete that view.

8. When the sequence is complete and ready to save, select the Save button at the bottom right of the screen.
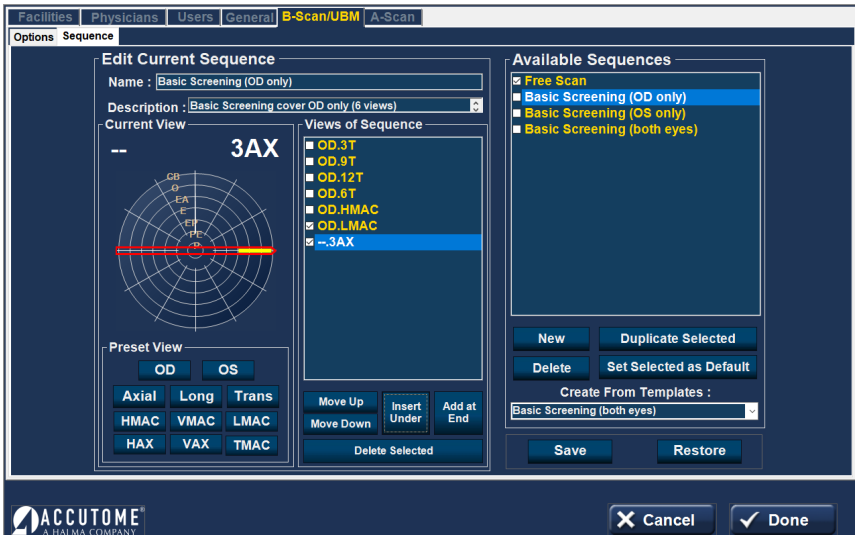
Figure 7.5 - Setup: B-Scan/UBM – Sequence – Change Probe Orientation

Deleting Sequences

Select the sequence you would like to delete from the Available Sequences list and select the Delete button.

Duplicate Sequences from Selected

Select the sequence you would like to duplicate from the Available Sequences and select the Duplicate Selected button.

A copy of the sequence will be displayed in the list of Available Sequences with "(1)" beside the name, as shown in figure 7.5. You may then change any information for the new sequence, as necessary. If you make more than one copy, the number will increase with each copy.

Set Selected Sequence as Default

Select the sequence you would like to become the default from the Available Sequences list, and select the Set Selected as Default button.

The sequence will become the default that appears when you power up the unit.

Create from Templates (lower right of Available Sequences box)

Activating the drop-down button brings up a list of commonly used sequences.

Selecting a sequence on the list copies that sequence into the Available Sequences list and the Views of Sequence list. The sequence may be modified, saved, or renamed as desired.

Save

Select the Save button (screen lower right). A "Set new point of restore?" dialog will launch. If you would like to save all changes and have the current available sequences setup become the data restore point, click "Yes". If you would like to retain the old data restore point, click "No".

Restore

Select the "Restore" button (screen lower right). A "Restore sequences to last saved point?" Select "Yes" to revert to the previously saved sequences information.

8

Application Common Functions

Application Module Common Functions

Screen Snapshot
Selecting this button generates a snapshot of the current screen. Print may be selected to print the snapshot. If Export snapshots was selected in Setup: General, the snapshot is automatically saved in the designated folder.

Print
Selecting this button prints either a screenshot or a report of what is currently on the screen directly to the default printer.

Save
Selecting this button saves all files/scans for the selected patient.

Edit
Selecting this button pulls up a screen where patient and exam information may be edited. When completed, select the Done button to save the information and return to the previous application module screen.

Setup
Exits the application module to the Setup Section – Facilities tab.

Reports
Reports: A-Scan/Pachymetry
Shows report of the scans for the patient currently selected (see sample reports in figure 8.1 and 8.2).

Reports: B-Scan/UBM
Selecting this button brings up a screen showing small versions of all of the snapshots that are stored for the patient selected (see figure 8.3, 8.4 and 8.5).

|
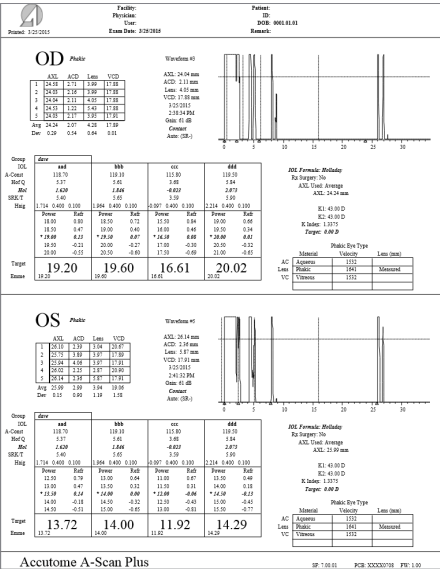
Figure 8.1 - Typical A-Scan Report
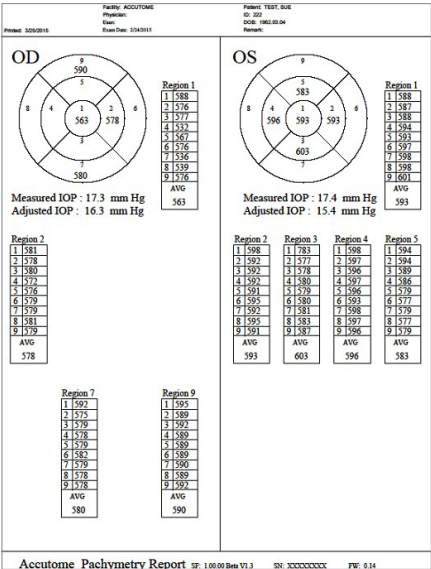
Figure 8.2 - Typical Pachymetry Report
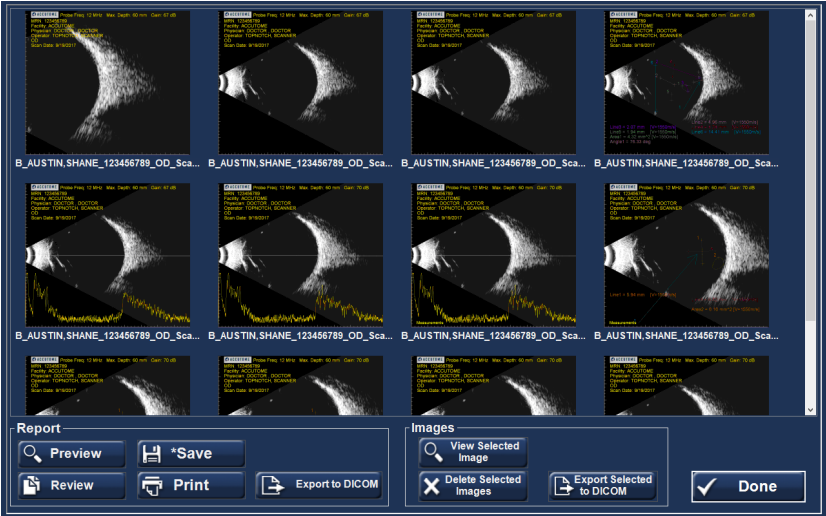
Figure 8.3 - B-Scan Screen after Report Is Selected
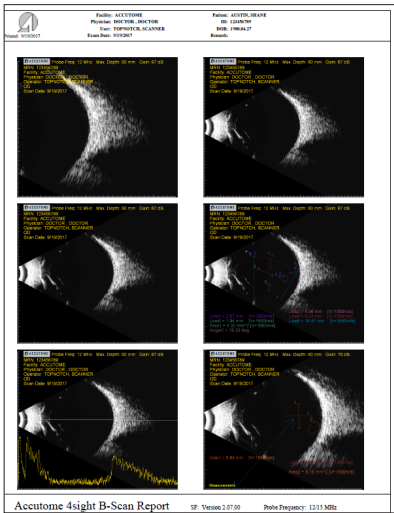
Figure 8.4 - Typical B-Scan Report
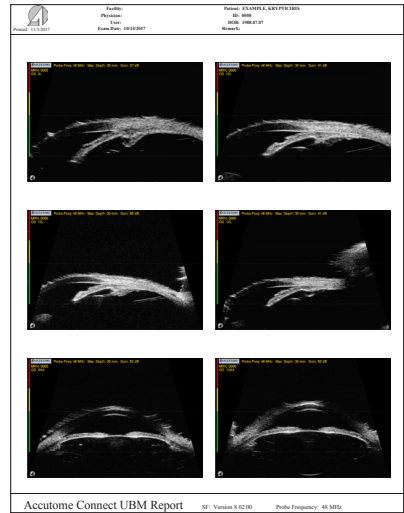
Figure 8.5 - Typical UBM Report

Report Tabs

- Preview brings up the report page as it will look for the screen shot selected.
- Save saves the report in the folder designated in Setup: General.
- Review brings up a listing of all the reports saved for the selected patient.
- Print prints the selected scan.
- Export to DICOM exports the selected report to the DICOM location designated in Setup: General/DICOM Servers.

Image Tabs

- View Selected Image brings up a larger version of the selected snapshot.
- Delete Selected Images deletes the snapshots that have been selected.
- Export Selected to DICOM exports the selected image to the DICOM location designated in Setup: General/DICOM Servers.

9

A-Scan

A-Scan Application Module

A-Scan Probe/Test Block

4Sight must have an Accutome A-Scan probe attached in order to operate the A-Scan function.

The options for probe operation are:

1. With an immersion shell
2. Mounted into a Goldman Tonometer
3. With a probe handle extension
4. Freehand

Figure 9.1 - 4Sight Ultrasonic Probe Kit (PN 24-4001)

A-Scan Probe with Immersion Shell

The immersion mode yields improved accuracy relative to contact methods.

The Accutome A-Scan probe is designed to be used with an Immersion Shell.

Caution: When using an immersion shell, ensure that there is a minimum distance of 5 mm between the bottom of the probe and the bottom of the immersion shell, as shown in figure 9.2.

A-Scan Probe with Goldman Tonometer Adapter

The Goldman Tonometer Adapter is used to properly insert and hold the A-Scan Probe in the Goldman Tonometer apparatus.

Figure 9.2 - A-Scan Probe with Immersion Shell

Figure 9.3 - A-Scan Probe with Goldman Tonometer Adapter

A-Scan Probe with the Probe Handle Extension
The probe handle extension is more comfortable for some users.
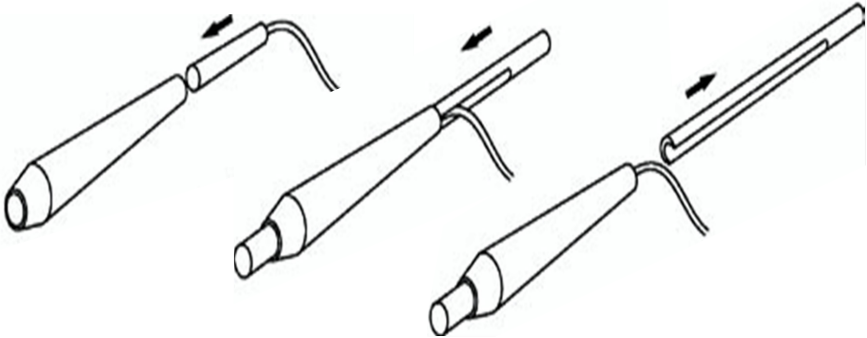
Figure 9.4 - Inserting Probe into Probe Handle Extension

Figure 9.5 - A-Scan Probe with Probe Handle Extension

A-Scan Setup Information – Test Block
The Accutome 4Sight comes with a test block included as an accessory. Refer to figure 9.6. The test block is provided as a convenient way to test the functionality of the instrument and probe.

Note: The test block is not for calibration. The A-Scan probe does not need calibration.

To test the Accutome A-Scan function and the A-Scan Probe:
1. Starting at the A-Scan measurement screen, switch to manual capture (Auto/Manual button at screen bottom) and contact mode (right center).
2. Apply some fluid to the test block, black side.
3. Touch the probe to the flat black surface of the test block.
4. Observe the waveform and AXL measurements on the screen.
5. Depressing the footswitch will capture the waveform and the AXL value displayed.

Figure 9.6 - Using the A-Scan Test Block

A-Scan: Taking Measurements

Preparing a Patient for Examination

Preparing a patient for an A-Scan exam consists of the following steps:

1. Anesthetize the patient's eye with a topical anesthetic such as Proparacaine. Please refer to the manufacturer's instructions for proper use.
2. Clean the probe tip. Refer to Chapter 1, Safety, of this user's guide.

Taking a Patient Measurement
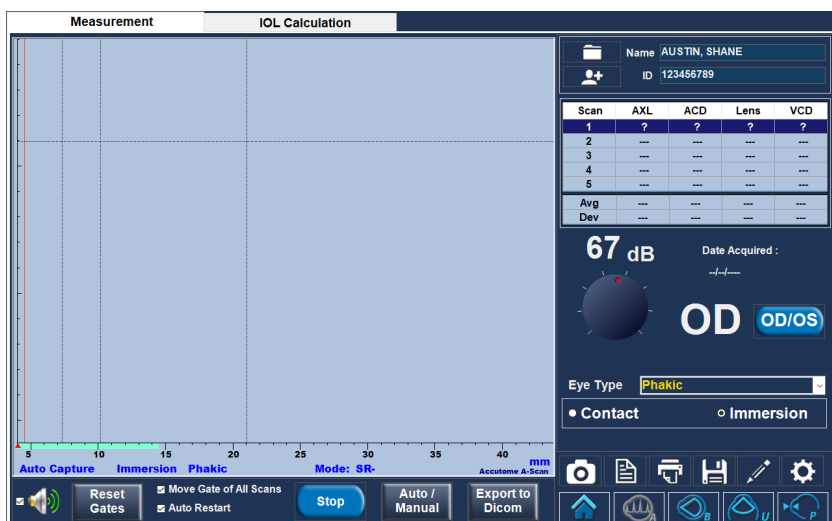
Figure 9.7 - A-Scan Measurement Screen

Patient Name/ID (upper right of screen)

Check that this information is correct. If incorrect, select the edit button, which will automatically bring up the Edit Patient screen. After corrections are made, select the Done button to return to the A-Scan Module. If you are in Quick Mode, you can move ahead without Name/ID information. (see Setup: General Tab - Quick Mode on page 20 for more information.)

OD/OS

Select the appropriate eye with the toggle button.

Gain Knob

The Gain Knob adjusts the height of the waveforms on the screen. The initial setting is the default value from Setup: A-Scan - Default Gain on page 30.
The gain may be changed by:

• Rotating the mouse thumbwheel

- Positioning the cursor over the knob, clicking on the knob, and rotating the knob
- Touching the knob and changing the setting, as desired
- Rotating the physical gain knob in the bottom center of the case

Eye Type
The system defaults to phakic unless set to some other eye type in Setup: A-Scan - Eye Type on page 27.

Contact or Immersion
Ensure that the selection is correct for the scan method employed.

Auto/Manual
- Auto allows the Accutome software to determine when the probe has acquired a measurement and automatically freezes the display when the minimum lock-on criteria are met.
- Manual allows the operator to determine when to capture the waveform. Depressing the footswitch or activating the Stop button (bottom center) freezes the image on the screen. Depressing the footswitch again, or activating Rescan, will reselect the probe to measure.

Note: The user must review the auto measurement for quality.

Stop/Rescan
The rescan/stop button allows you to erase all the scans and start a scan over. It can also freeze the scan when in manual mode.

The **Auto Restart** and **Speaker** options at the bottom of this Measurement Screen are explained in Setup: A-Scan.

A-Scan: Performing IOL Calculations
After you have completed measurements, you can calculate the power of the IOL for the patient. Select the IOL Calculation tab at the top of the A-Scan screen.

Overview
The IOL Calculation Screen shown in figure 9.8 displays the average of the five measurements for the selected eye (if there are five measurements available), and the calculation for the currently selected formula and the four lenses of the current IOL Group.

The 4Sight allows the user to fine-tune the calculation by providing the ability to change the AXL value, the lens, formula, and desired postoperative refraction (the target).

The process for calculating the power of a lens is to select or enter an AXL value, select an IOL Group, select a formula, and enter the K1, K2, and Target Values.

Note: The RX Surg (Postrefractive Corneal Surgery) field should be left at "No". Change the field to "Yes" to calculate IOLs for patients that have had corneal refractive surgery. Refer to the Calculating IOL Power after Corneal Refractive Surgery section on page 55 of this user's guide for instructions on changing the RX Surg field.

Figure 9.8 - A-Scan IOL Calculation Screen

How to Perform a Calculation
OD/OS
Make sure the selection is appropriate.

Select Physician Group
Select the physician lens group from the drop-down menu (upper left). If the desired physician name is not in the drop-down menu, add the information using the Manage Physician Lenses drop-down screen (explained on page 56).

K Index
The default K Index and Eye Type are shown below to the right of the OD/OS button.

AXL
4Sight selects the average of the five measurements and uses that value for the calculation of the implant power. You can also select any one of the individual measurements in the Scan AXL box (lower right) by left-clicking on the desired value. Alternately, you may enter the axial length from a previous measurement directly into the AXL box. The box changes to orange when a number is typed in by the user, indicating that it was manually changed.

ACD values are also shown if the Haigis formula is selected.

K1 and K2

Keratometer information can be entered in mm as well as in diopters. The ranges for the two units are mutually exclusive. Values less than 20 are assumed to be in mm and values 20 or greater are assumed to be in diopters. Units are displayed with all entries. Diopter entries have a keratometer index or refraction associated with them to allow for conversion to mm, as needed by some formulas.

Target

Emmetropia is indicated by a 0.0 target value. For more information, see Setup: A-Scan on page 27.

Rx Surgery

If "Yes" is selected, Kpre and Kpost need to be calculated and entered. See "Determining Corneal Power after Refractive Surgery" on page 57 for more information.

Target

The IOL Calculation Screen will display the emmetropic power of the lens (labeled Target), for each lens, with bold, large, black numbers. These values are the optimal lens and do not necessarily exist in the real world. 4Sight also provides you with the power of the IOL that would achieve emmetropia. The emmetropic power is calculated and displayed (labeled Emme) under the emmetropic power in a smaller font.

Formula

To change formula, select a different formula from the box list.

Compare [Compare button under the boxed list of formula types]

The Formula Compare feature allows the comparison of all formulas for each calculation. When Compare is On, the bottom half of the lens option boxes is re-titled "Compare" and displays the closest matching IOL power that will achieve the target refraction with the expected postoperative refraction as calculated by each formula.

A-Scan: IOL Calculation - Manage Physician Lenses

Select the button at the top center of the IOL Calculation screen to bring up another screen add/modify/delete the defined IOLs for each physician.

Manage Physician Lens Groups

IOLs can be grouped by type, manufacturer, physician, location, patient pathology, or other criteria. IOLs are organized in groups of four. Each group may be given a custom name to distinguish its purpose. Any IOL group may be selected directly from the drop-down menu on the IOL calculations tab. You can set up unlimited IOL groups.

The manage IOL groups screen may also be activated by selecting the Review IOL Groups button in Setup: A-Scan – Personalize IOL tab on page 35.

All current groups are shown on the screen in groups of three vertically. Additional groups of three are seen by moving the horizontal cursor bar at the bottom of the screen.

Figure 9.9 - A-Scan IOL Calculation – Manage Physician Lenses

New – initiates a new group.

Restore – deletes changes since the last save/power down.

Done – closes the screen with an option to save if changes have been made.

Remove Selected Groups – deletes the entire group that has been selected.

Lock Button – selected to unlock or lock an entire Group. When locked, no changes can be made to the group.

Clear – clears all the constants in that row (except the name of the IOL).

Clear All – clears all the constants in that Group.

Entering Lens Constant

For a given lens (row), if you enter any one of the first five constants, 4Sight automatically calculates and fills out the formula cells in each table. Haigis a1 is always 0.4 and Haigis a2 is always 0.1 unless specified by the user as a result of triple optimization.

If you wish to use personalized constants, let the program enter the automatically calculated values first, and then overwrite with personalized constant(s).

Personalized constants should only be used with the formula from which they were derived.

Note: Standard A-Constants come from the lens manufacturer and optimized or updated IOL A-Constants can be manually entered.

When you have completed the table, lock the group.

A-Scan: IOL Calculation – Refractive Surgery
Determining Corneal Power after Refractive Surgery

The K value (corneal power or corneal curvature) for patients that have had corneal refractive surgery (Rx Surg) cannot be determined using common methods. The formulas (methods) available in the Accutome 4Sight to determine the current corneal power for refractive patients (Kpost) are selected via drop-down options in the Kpost Formula box.

Note: If you do not know the patients prerefractive surgery corneal power, you may want to consider using the Haigis formula, which does not require this information.

Post Rx Surg IOL Calculation Steps

The steps to complete a postrefractive surgery IOL Calculation are almost the same as nonrefractive surgery eye calculations, with the addition of selecting a Post K method.

To complete a postrefractive surgery calculation:
1. Set the Rx Surg field to "Yes" (IOL Calculation screen: right center).
2. Select an IOL Group.
3. Select or enter an AXL value.
4. Enter the applicable averaged K1 and K2 readings, Sphere, and Cylinder values.
5. Enter the target value.

The K Post calculation methods are (bottom center):
1. Clinical History method - Calculates Kpost based on Kpre, refraction before and after refractive surgery.
2. Contact Lens method - Calculates Kpost based on refractive surgery with and without a hard contact lens of a known curve and power.
3. Shammas Clinical method - Calculates Kpost by adjusting on manual K reading after refractive surgery using simple formula Kpost=1.14* Kmeasured - 6.8.
4. Entered - This allows the user to calculate the Kpost value in some other manner than listed above and then enter the value accordingly.

Selecting the desired calculation method automatically brings up the appropriate value entry boxes.

The Clinical History method is the default for new patients.

For the refractions entered, the vertex of the refraction is stored and becomes the default for the next patient.

Calculation Results

After all fields have been entered, the Calculate IOL Screen will display the power of the IOL for each lens with large, bold, black numbers. These values are optimal powers for the specified target refraction and do not necessarily exist in the real world.

A list of four IOL powers, and their expected refraction, is displayed for each IOL. Powers are shown in 0.5 D increments (as a default). The highlighted value is the closest to the target power. The default IOL step value may be changed in the A-Scan Setup screen.

The Accutome 4Sight also provides you with a lens value for a zero target (Emmetropia). The zero target values are listed below the optimal IOL powers in small numbers.

B-Scan/UBM

B-Scan/UBM – Probes

Probe

The B-Scan and UBM Application Modules utilize different probes.
The user must select the proper probe in Setup: B-Scan/UBM – Probe Type on page 42.

Figure 10.1 - 4Sight UBM Probe

Figure 10.2 - 4Sight B-Scan Probe

Note: The Accutome UBM probe has been designed to be used with an Anterior Segment Imaging Scleral Shell.

Features Common to B-Scan and UBM Probes

The start/stop button on the probe may be used to start and stop scans. The marker at the end of the Accutome B-Scan and UBM probes indicate the direction of the "slice" being imaged by the probe – see B-Scan/UBM Operation – Using the Probes on page 66.

Figure 10.3 - Anterior Segment Scleral Shells (18mm and 20mm)

Footswitch

The footswitch provided with 4Sight can be used to start and stop scanning. To install, plug the end of the footswitch cable into the jack on the bottom right of the 4Sight unit.

B-Scan/UBM Pre-Scan Setup

Select the B-Scan or UBM button to bring up the desired Application Module. The overall format of the two screens is identical.

Figure 10.4 - Accutome Footswitch
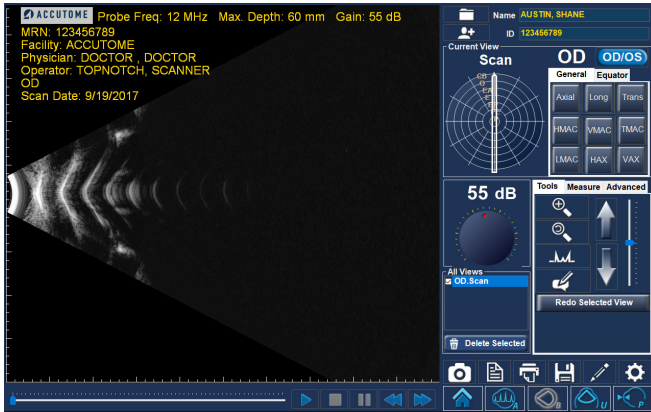
Figure 10.5 - B-Scan Screen Sample
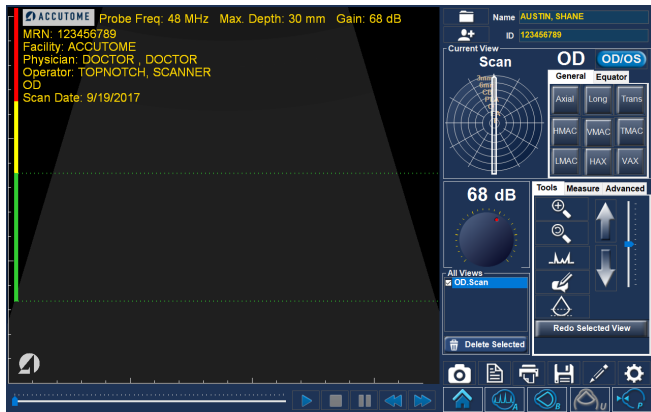
Figure 10.6 - UBM Screen Sample

If you entered a patient name and/or ID on the 4Sight Home Screen, that information will show up in the top right corner of the screen. If you are in Quick Mode, you can move ahead without Name/ID information. (see Home Screen: Quick Mode on page 20 for more information.)

Prior to actual scanning, the imaging control and formatting selections are usually entered in the Setup: B-Scan/UBM section. These selections include:

- Probe Type
- Default Gain
- Probe Controls: Mode, Video buffer length, Start/Stop, Power
- Image Control: TGC, Video delay, Gamma, Contrast, Brightness, medium/ velocity
- Information on Images: facility, physician, user, etc.; measured data position
- Snapshot, Print and Report settings: language, format

The Scan Screen initial settings will default to the settings chosen in Setup: B-Scan/UBM.

If a specific record for a patient was chosen from files for Existing Patient, IOL Master, or DICOM via the Home Screen, the defaults that were used for that patient are also pulled up on the Scan Screen.

The Scan Group and Protocol are defined in the Home Screen.

Prior to scanning you should set the imaging selections to your liking, using the Current View box and the Gain knob.

The Current View area displays the position of the currently active step in the imaging sequence. The Current View box is explained in detail in Setup: B-Scan/UBM– Sequence Tab on page 43.

B-Scan/UBM: Scanning Basics
How to Scan
Before initiating a scan, select the B-Scan or UBM application module and make sure the proper probe is being used. To start and freeze a scan is as simple as pressing the start/stop button on the probe or stepping on the footswitch. Both the probe and the footswitch can be used for start/stop operation if the setup is predefined to use both.

When in quick mode, the Scan button (lower right of scan screens) may also be used to start/stop scans. When selected, scanning is initiated and the button label changes to Stop. Subsequent selection stops scanning and the button label changes back to Scan.

If you are using both the probe and the footswitch for start/stop action, they will each perform the operation that is the opposite of the last operation executed. For example, if you start scanning by stepping on the footswitch and press the trigger button on the probe, the scanning will stop.

Adjusting the Gain
You may decide the signal gain for your new view is too strong or not strong enough. The initial setting is the default value from Settings: B-Scan/UBM on page 41. The gain may be changed by:
- Rotating the mouse wheel
- Positioning the cursor over the screen knob, clicking on the knob, and rotating the knob
- Touching the screen knob and changing the setting, as desired
- Rotating the physical gain knob in the bottom center of the case

Moving the Image
To move the image around on the screen, either touch or left click and hold with the mouse anywhere within the view area. Moving either your finger or the mouse will move the image, as desired.

Positioning Slider (bottom left below the scanned image)
Moving the indicator (with the finger or mouse) moves the displayed section of the image within the scanned loop.

Replay Control Buttons (bottom of screen below scanned image)
The Forward, Pause, Stop, Fast Back, and Fast Forward buttons perform the functions commonly found on audio and video recorders.

Exam Information Displayed above the Scan

At the top of the scan, some or all of the following fields are displayed and will be stored with the scan:

- Probe Frequency
- Maximum Probe Signal Depth (Max. Depth)
- Gain
- Patient
- DOB
- Medical Record Number (MRN)
- Scan Date
- Facility
- Physician
- Operator
- Current View in Image Sequence Protocol

Note: The display of Facility, Physician, User, Patient, DOB, and Scan Date can be turned on or off in Setup: B-Scan/UBM, Options tab, Info on Images box.

Scanning with a Predefined Protocol

The figure 10.8 shows the first step of a scan completed using a scan group protocol. After you complete the first scan and have stopped the probe, you should move the probe to conform to the next scan in the sequence. For example, in Figure 10.7, the first scan is labeled OD.VAX and the second scan is labeled OD.12L. When you finish the first scan, you should move the probe on the patient's eye from the 12:00 axial slice to the 12:00 longitudinal, and then initiate another scan. Figure 10.7 shows a B-Scan; the process is the same for a UBM scan.
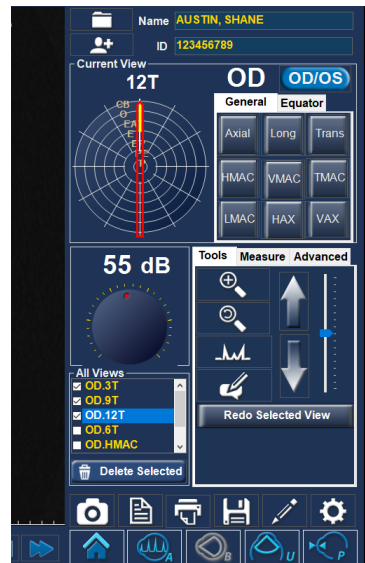
Figure 10.7 - B-Scan Scanning with a Predefined Protocol

Scanning without a Protocol

When you are not following a predefined protocol for scanning, the first scan always defaults to OD Scan. If you are making a free scan of the left eye, you should change the view label for this scan. Figures shown for B-Scan; UBM is analogous.

After you have completed the first scan, the 4Sight will automatically add another scan to the "All Views" list. The label for the second scan will default to OD.Scan(2) (unless the selected eye is changed) as shown in figure 10.9.

Adding and Labeling a New View

To add another view of the patient's eye, simply restart the scan using any of the methods previously described. When you stop scanning, a new view will be listed in the All Views box with the default title OD.Scan(2).

You may want to change the label of the view if the new scan has an intended purpose. For example, if the new scan is intended to capture a transverse view of the eye you want to label the view "transverse".

To change a scan view name:
1. Select the scan by clicking on the scan view name or clicking the checkbox beside scan view name.

Figure 10.8 - New Exam, No Protocol – First Scan Selected (B-Scan sample)
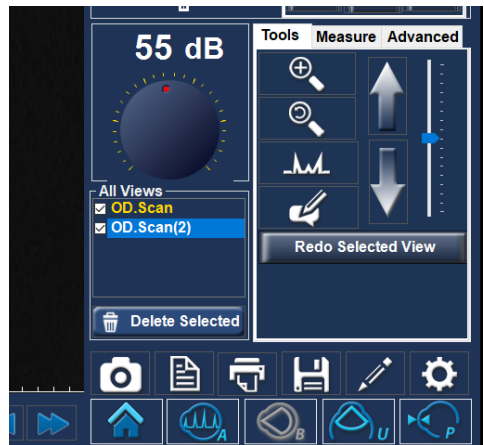
Figure 10.9 - New Exam – First Scan Complete (B-Scan Example)

2. Move to the Current View area of the Exam Screen and select the correct probe position/orientation. Refer to Setup: B-Scan/UBM – Sequence tab on page 43 for an explanation of the meaning and use of the tabs and clockwheel.

B-Scan/UBM: Tools/Measure/Advanced Box

Tools Tab

Zoom

Reset — resets the magnification to 100%

A-Vector — tap the icon to show or hide display of the A-Vector

The A-Vector function displays an equivalent A-Scan of the captured B-Scan or UBM image. Looking at the A-Vector, you can get a graphical picture of the echoes received back through the eye from the ultrasonic probe. See figure below.
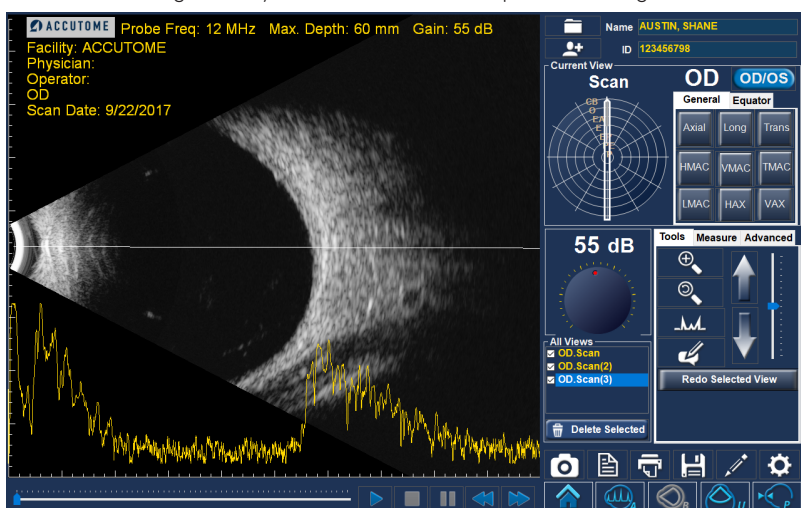
Figure 10.10 - B-Scan with A-Vector Overlay

The echoes are represented as spikes arising from the baseline and indicate the sound beam traveling through the different intraocular tissues. The straight line indicates the angular position of the A-Vector scan.

A-Vector Position – use the large vertical arrows and/or the slider to the right of the buttons to control the angular position of the A-Vector on the scan.

Comments – brings up a box for the addition of user comments, which are stored with the scan.

UBM Focal Zone (only active in UBM Mode) — the dotted lines on the image indicate the area of best image quality (green zone). The red zones indicate close proximity to the eye.

Rescan Selected View Button — allows users to retake the currently selected scan.

Measure Tab

The Measure tab provides the diagnostic feature of making measurements on B-Scan and UBM images. Measurements on a zoomed image yield much finer resolution — as small as 0.1 mm.

Up to six line, two area, and two angle measurements may be simultaneously displayed on, and stored with, an image. In addition, up to two arrows may be generated to point to areas of interest.

The measurements and pointers are generated as follows:
1. Select one of the 12 options in the Measure Tab
2. Using the mouse, right click and hold down while drawing the desired geometric figure

The color-coded measurements will automatically be displayed on the image.

Any measurement may be edited by selecting that item, checking the Edit box, and making the desired changes.

Any item may be deleted by selecting the desired item and clicking the Delete button.

Because the line and area measurements are accurate only to the extent that the soundwave velocity matches the medium, a pull-down box of options is provided for convenient user selection of the most appropriate medium.

Examples of measurements on a B-Scan image are shown in the figure 10.11.
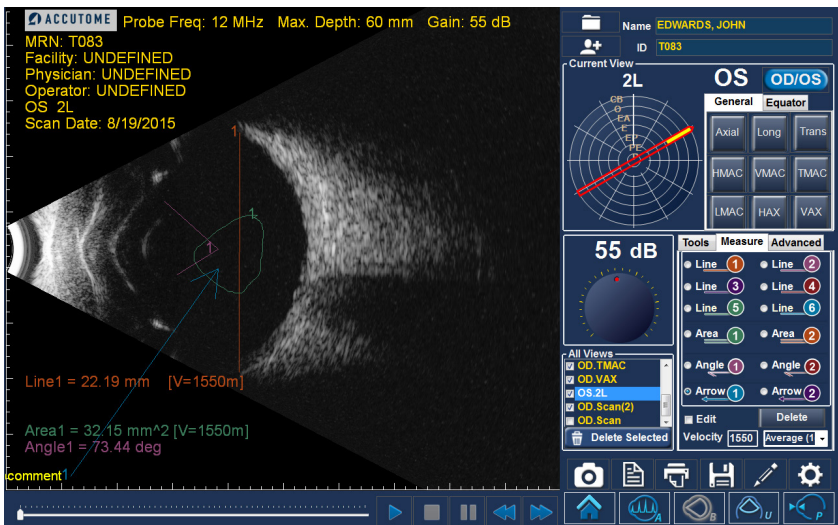
Figure 10.11 - B-Scan Sample Showing Line, Area, Angle, and Arrow Tools

Advanced Tab

Advanced/Recording
Recording Function is located under the Advanced Tab - Recording.

Start — begins the Recording feature based off of your Default Settings within Setup.

Stop — stops recording of video before Max Length times out.

Record Selected View — after Selecting the video within All Views Window, Clicking Record Selected View will convert that view into an .AVI or .MP4.

Start Delay — delay the start of the video recording. Allow for a delay to set up probe or scan position on the eye before recording begins. Maximum delay is 30 seconds.

Max Length — set length of video recording (Max length is 5 minutes 300 seconds).

Recording Area — which part of the screen the video will record (changes can be made in Settings).

Open Recordings Folder — recording folder location for each video made for the patient.
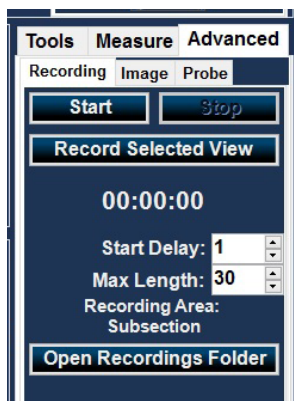
Figure 10.12 - Advanced Recording Tab

Advanced/Image
Gamma Adjustments, Contrast, Brightness, and TGC
Select from the drop-down list of predefined gamma settings and adjust the contrast, brightness, and TGC controls to yield the most instructive view of the area of interest. These parameters are explained in greater detail in Setup: B-Scan/UBM – Image Controls Box on page 42.

Advanced/Probe
Probe Mode, Video buffer length, and probe output Power may be adjusted. See Setup: B-Scan/UBM – Power section on page 41 for more detail.

B-Scan/UBM Operation: Using the Probe
Marker Alignment
The marker at the end of the Accutome B-Scan and UBM probes indicate the direction of the "slice" being imaged by the probe. (The marker is on the same "side" of the probe as the scan start/stop button.)

The user must know where the slice is being directed at all times to produce an accurate scan. In figure 10.12, there are two very different slices with the same probe position; the marker is rotated from a vertical slice position to a horizontal

slice position. The slice positions when defining a probe view are indicated as hours on the face of a clock.

The marker located on the UBM Probe also indicates the orientation of the probe with respect to the image on the monitor. The marker is positioned towards the left side or right – may be changed via Setup: B-Scan/UBM – Image Controls >Flip UBM Images on page 43.

Vertical Slice   Horizontal Slice
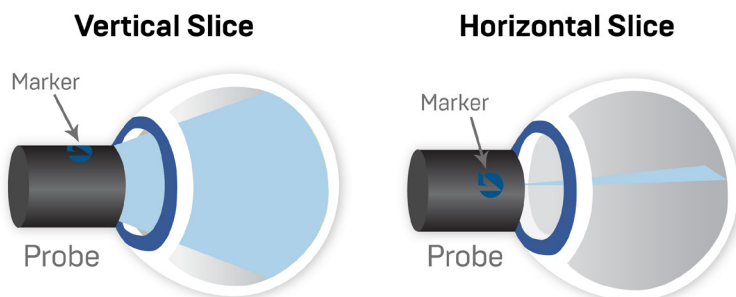
Figure 10.13 - Eye and Probe Marker Alignment

Probe Orientation

One of the great features of the Accutome 4Sight is the ability to use the probe in any position and be able to quickly and easily label the scan view. There are three major positions for holding the probe when you scan. Within these positions, there are slices that correspond to the hours of a clock. A position label consists of the probe position and slice position. The three probe positions are:

- Axial
- Longitudinal
- Transverse

Depending upon the purpose of your scan (e.g., basic scan vs. scanning for a pathology) will determine which probe position you use. When scanning, move the probe around the eye within each of these positions. A brief summary of the three positions follows.

Axial Probe Positions

An Axial scan is a slice through the center of the lens. Axial scans are labeled according to the orientation of the marker, followed by AX. If the scan is performed with the marker aimed superiorly or vertically, the scan can be labeled 12AX. For a horizontal scan, the marker should be aimed nasally and labeled 3AX for the right eye or 9AX for the left eye. For an oblique scan, aim the marker at the oblique clock hour (which will place that meridian at the top of the display screen), while retaining the patient's gaze and the probe face centered on the cornea (i.e., 2:00, 9:30, etc.).

Longitudinal Probe Positions

In a Longitudinal image, the probe can be held at any angle with respect to the patient's limbus.

Longitudinal scans are radial scans encompassing only one clock per slice, from the posterior pole to the anterior periphery. Therefore, the optic nerve shadow (the center of the "clock") will be at the bottom of every longitudinal scan so long as it is aligned properly.

All longitudinal scans should be labeled with an "L" and the clock hour of the meridian being examined (i.e., L10, L3, etc.).

Transverse Probe Positions

Transverse probe positions demonstrate the lateral extent of pathology, encompassing approximately six clock hours in one slice. The patient's gaze is directed toward the area of interest and the probe is placed on the opposite sclera with the marker oriented parallel to the limbus.

In a transverse image, the probe is held at an angle to the optical axis of the eye, not directly over the cornea as in an Axial image, such that the probe crosses or transverses the optical axis.

In the horizontal transverse approach, the marker is aimed nasally so the upper portion of the screen represents the nasal section of the globe (the upper portion of the screen will always be 3:00 in the right eye, or 9:00 in the left eye).

In vertical approaches, the marker is aimed superiorly, so that the upper portion of the screen represents the superior portion of the globe (12:00 in OD or OS). In oblique transverse approaches, the marker is aimed toward the upper portion of the globe so that the upper portion is represented at the top of the screen.

Labeling of transverse scans is done according to the portion of the globe being examined (where the sound beam is being directed), not by the position in which the probe is being held on the globe.

B-Scan and UBM Transverse Scans use different labeling:

B-Scan Transverse Scan Labeling

First, label the portion of the globe being scanned in the center of the display by recording the clock hour that represents the meridian that lies in the center of the screen, followed by the locator that indicates how far out in the periphery you are at the clock hour (i.e., 3P, 3EP, etc.).

The locators are:
- CB - Ciliary Body
- O - Ora Serrata
- EA - Equator Anterior
- E - Equator
- EP - Equator Posterior
- PE - Posterior Equator
- P - Posterior Pole

UBM Transverse Scan Labeling

First label the portion of the globe being scanned in the center of the display by recording the clock hour that represents the meridian that lies in the center of the screen followed by the locator that indicates how far out in the periphery you are at the clock hour i.e. 3-3mm, 3 E etc.

The locators are:
- 3mm-3 mm ring
- 6mm-6 mm ring
- CB-Ciliary Body
- Pla-Pars Plana
- O-Ora Cerata
- EA-Equator Anterior
- E-Equator

11 Pachymetry

Pachymetry Probe/Test Block

Insert the probe connector into the jack on the left (toward the top) of the 4Sight unit (see Hardware Connections section on page 7).

Figure 11.1 - 4Sight Pachymetry Probe

Using the Test Block

The test block is provided with the Pachymetry Module to conveniently test the basic pachymetry operation of the 4Sight and the probe.

To test the 4Sight and probe:
1. Apply some immersion fluid (water or BSS) to the test block.
2. Place the probe on the test block.
3. Access the Start/Stop Reading button to change it to Stop Reading.
4. You should receive measurements in the Buffer/Value matrix box.

Pachymetry: Taking Patient Measurements
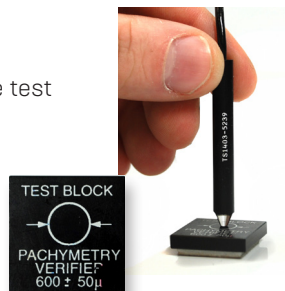
Figure 11.2 - Using the Pachymetry Test Block

To Take Patient Measurements:
1. The patient Name and/or ID will carry over automatically from the Home Screen, if entered there.
2. If you are in Quick Mode, you can move ahead without Name/ID information. (see Home Screen: Quick Mode on page 20 for more information.)
3. Enter the measured IOP (from an external measurement) for one or both eyes, as appropriate.
4. Select the desired segment of OD or OS by activating one of the nine segments of the corneal symbol. The segment selected is indicated by a grayer/lighter shade.
5. Select Clear All to clear all of the measurements for that eye, if appropriate.
6. Select the Start Reading button to the right of the screen
7. Apply the probe to the patient's eye.

WARNING! THE PROBE TIP MUST BE PROPERLY STERILIZED OR DISINFECTED BEFORE TAKING ANY MEASUREMENTS ON A NEW PATIENT.
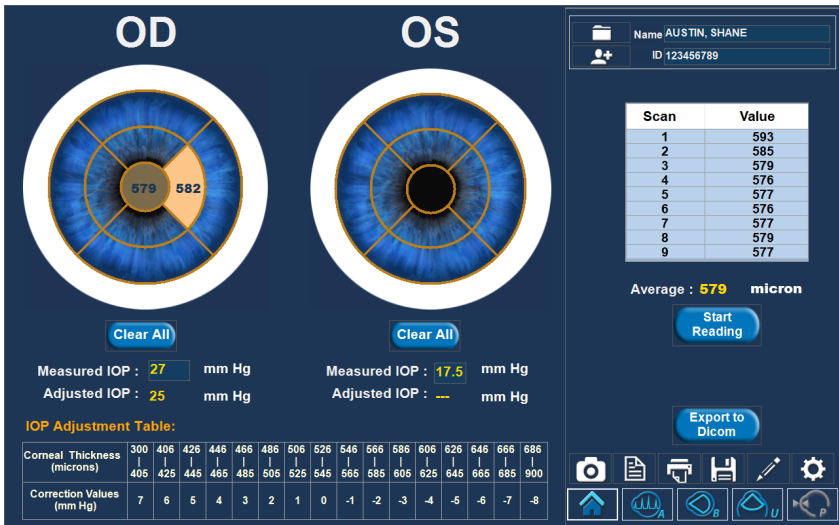
Figure 11.3 - 4Sight Pachymetry Screen

The unit will emit a high-pitched chirp when you have automatically acquired a measurement.

To stop taking readings prior to the completion of all nine readings, either select the Stop Reading button or remove the probe from the patient's eye.

Select another segment and select Start Reading. Repeat until all desired segments have been measured.

Notes
- **The average of the measurements for any given segment is shown within that segment. This average is the number used when calculating the Adjusted IOP.**
- **You can review the measurements taken for any segment by selecting that segment.**

Select the SnapShot, Generate Report, Print, or Save buttons to perform those functions as desired.

The correction values are shown in the IOP Adjustment Table at the bottom of the Pachymetry screen.

12 Maintenance

General Maintenance

Maintenance that should be performed on the Accutome 4Sight consists of activities such as keeping surfaces free of dust and dirt and storing in a dry and cool place so as to not adversely affect electronic parts.

Care must be taken to use only proper lint-free cloths and noncorrosive solvents when cleaning the unit/device.

CAUTION: No abrasives or harsh cleaning solutions should be used while cleaning the 4Sight.

Refer to Safety on page 7 for cleaning and disinfection issues pertaining to the probes.

Safety Inspection

Safety inspections should be done to ensure that the 4Sight remains in perfect operating condition. The device should undergo a monthly safety check involving a visual inspection of the entire system. Inspect the device and its environment specifically against each relevant item in the Safety chapter.

Visual Inspection

A visual inspection should be conducted on a monthly basis on all parts of the 4Sight, including the probe, accessories, and footswitch. Special attention should be paid to the connectors and cords/wires.

Ultrasound Inspection

On a monthly basis, an evaluation of the ultrasonic probes should be conducted using the test block included with the unit.

Calibration

The 4Sight is self-calibrating and therefore requires no adjusting or further calibration by the user.

13 Specifications

Overview
This section provides the physical and operational specifications of the Accutome 4Sight.

Physical Specifications
Table 13.1 below lists the physical specifications of the instrument and associated peripherals.

Table 13.1 - 4Sight Control Unit Physical Specifications

Control Unit (PN 24-8000)	
Dimensions	38.1 cm x 26.1 cm x 8.89 cm (15" x 10 1/4" x 3 1/2")
Weight	3.175 kg (7 lbs)
Input Voltage	100-240Vac, +/-10%, 47-63 Hz
Current	5.6 Amps DC output (80 watts)
Fuses	3.15A, 250V Internal Primary Current Fuse, 6.3A Slo Blo PCB Can Fuse
External I/O Connectors	Power, 18VDC In, HDMI, Network, 3 USB (for mouse and keyboard only), Pach Probe, Footswitch, A-Scan Probe, B-Scan USB, UBM USB
Display	Chimei Innolux G121i1-L01
Size	30.7 cm (12.1")
Resolution	1280 x 800
Power Supply	SL Power MENB1100 100W

Device classification of 4Sight Control Unit: continuous operation.

Table 13.2 - Accutome 4Sight Probe Physical Specifications

A-Scan Probe* (PN 24-8000A)	
Frequency	10 MHz
Dimensions	4.32 cm (1.7") long x 0.63 cm (0.25") diameter
Cable Length	1.5 m (5 ft.)
Accessories	Tonometer adapter, extension handle with installation tool

Pachymeter Probe* (PN 24-8000P)	
Frequency	10.5 MHz, Composite
Dimensions	0.64 cm (0.25") diameter x 4.45 cm (1.75") length
Cable Length	1.52 m (5 ft.)

Table 13.2 - (Continued) Accutome 4Sight Probe Physical Specifications

UBM Probe* (PN 24-8000U)	
Frequency	48Mhz
Dimensions	17.78cm (7.0") long X 3.18 cm (1.25") diameter
Weight	0.170 kg (0.375 lb)
Cable Length	1.83 m (6 ft.)
Interface Connector	USB Type A
B-Scan Probe* (PN 24-8000B)	
Frequency	12 MHz, 15 MHz
Dimensions	17.78 cm (7.0") long x 3.18 cm (1.25") diameter
Weight	0.170 kg (0.375 lb)
Cable Length	1.83 m (6 ft.)
Interface Connector	USB Type A

*Applied parts

Environmental Specifications

Table 13.3 below lists the Accutome 4Sight system operating and storage values for temperature and humidity.

Table 13.3 - Environmental Specifications

Temperature	
Operating	10º—40ºC (50º—104ºF)
Storage	-20º—60ºC (-4º—140ºF)
Relative Humidity	
Operating	20—80% (noncondensing)
Storage	15—90% (noncondensing)
Atmospheric Pressure	
Operating	700—1060 hPa
Storage	500—1060 hPa

Range and Accuracy

Table 13.4 lists the accuracy for each type of measurement. Clinical Accuracy (1s) 0.1 mm, Electronic Resolution (@1550m/s) 0.016 mm.

Table 13.4 - Measurement Clinical Accuracy (1s) Range for A-Scan Function

Measurement	Clinical Accuracy	Range
Axial Length	0.1 mm	0.01 to 63.6 mm@ 1555 m/s
Anterior Chamber Depth	0.1 mm	0.01 to 62.7 mm@ 1532 m/s
Lens Thickness	0.1 mm	0.01 to 67.2 mm@ 1641 m/s
Vitreous	0.1 mm	0.01 to 62.7 mm@ 1532 m/s

Table 13.5 - Range and Accuracy of the B-Scan Plus

B-Scan Plus Setting		Line/Area	Clinical Accuracy	Accuracy Range
Frequency	Depth			
12	30	Line	7.5%	30
12	30	Area	39.5%	30
12	60	Line	3%	60
12	60	Area	22%	60
15	50	Line	3%	50
15	50	Area	20%	50
15	100	Line	7%	50
15	100	Area	14%	50

Table 13.6 - UBM Range and Accuracy

UBM Plus Setting		Line/ Area	Clinical Accuracy	Accuracy Range (mm)
Frequency (MHz)	Depth (mm)			
48	30	Line	<1%	30
48	30	Area	<1%	30
48	30	Angle	<1%	30

Table 13.7 - Measurement Accuracy of the Pachymeter

Measurement Accuracy of the Pachymeter	
Measurement	Corneal Thickness
Clinical Accuracy (1 Sigma)	+/- 5 Micrometers
Electronic Resolution (@1640 m/sec)	+/- 1 Micrometer
Range	300—999 Micrometers

Operating Modes

The table on page 76 summarizes the mode/application possibilities for each system/ transducer combination.

Table 13.8 - Operating Mode(s)

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other[†] (Specify)
Ophthalmic	Ophthalmic	P						P (A-Mode)
Fetal Imaging & Other*	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel								

Clinical Application A B M PED CWD CD Combined (specify), Other (Specify), Ophthalmic X, Fetal Imaging & Other*, Cardiac, Adult, Pediatric, Peripheral Vessel
* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)
† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

Table 13.9 - A-Scan Data Specifications

Stored Data Capacity	
Waveforms/Patient	10
Stored Patients	Unlimited
IOLs	120 total, 30 groups of 4
Post-Operative Results	Unlimited
Waveform Data	
Data Points per waveform	4,096
Max Depth at 1555 m/sec	64 mm
Gain Adjustment Range	30—100db
Eye Type Storage	
Factory Eye Types	8
Custom Eye Types	Unlimited
Factory Aqueous/Vitreous Materials	3
User Aqueous/Vitreous Materials	Unlimited
Factory Lens Materials	4
User Lens Materials	Unlimited
Material Velocity Range	500 to 9,999 m/sec
Assumed Lens Thickness Range	0 to 9.99 m
K Readings Range	20 to 60 D 5 to 19.99 mm
Calculation Field Ranges	
Target Refraction Range	-20 to 20 D
Entered AXL Range	15 to 40 mm
Entered IOL A-Constant Range	110.5 to 122.5
Entered IOL ACD Range	0.10 to 6.50 mm
Entered IOL SF range	-3.5 to 3.5 mm
Entered ACD Range	0.01mm to 9.99 mm
Entered IOl a0 constant range	-0.999 to 9.999
Entered IOLa1 constant range	-0.999 to 9.999
Entered IOL a2 constant range	-0.999 to 9.999
Accutome Clock	
Clock/Calendar valid	Through year 2099

Acoustic Output

Table 13.10 below provides the acoustic output reporting for the following:

Table 13.10 - Acoustic Output Reporting

Transducer Model: Accutome A-Scan
Operating Mode: A mode
Application(s):   Ophthalmic

Acoustic Output		MI	ISPTA.3 (mW/cm2)	ISPPA.3 (W/cm2)
Global Maximum Value		0.18	0.36	7.42
Associated Acoustic Parameter	Pr.3 (MPa)	0.56	---	---
	Wo (mW)	---	0.0265	0.0265
	Fc (MHz)	9.32	9.32	9.32
	Zsp (cm)	0.28	1.54	1.54
	Beam Dimension x-6 (cm)	---	0.19	0.19
	Beam Dimension y-6 (cm)	---	0.182	0.182
	PD (msec)	0.100	---	0.100
	PRF(Hz)	500	---	500
	EBD Az. (cm)	---	0.500	---
	EBD Ele. (cm)	---	0.500	---

Transducer Model: Accutome B-Scan
Operating Mode: B mode
Application(s):   Ophthalmic

Acoustic Output		MI	ISPTA.3 (mW/cm2)	ISPPA.3 (W/cm2)
Global Maximum Value		0.19	0.37	14.87
Associated Acoustic Parameter	Pr.3 (MPa)	0.65	---	---
	Wo (mW)	---	0.22	0.22
	Fc (MHz)	11.30	11.30	11.30
	Zsp (cm)	1.80	1.80	1.80
	Beam Dimension x-6 (cm)	---	0.076	0.076
	Beam Dimension y-6 (cm)	---	0.077	0.077
	PD (msec)	0.200	---	0.200
	PRF(Hz)	3840	---	3840
	EBD Az. (cm)	---	0.600	---
	EBD Ele. (cm)	---	0.600	---

Transducer Model: Accutome UBM
Operating Mode: B Mode
Application(s): Ophthalmic

Acoustic Output			MI	ISPTA.3 (mW/cm2)	ISPPA.3 (W/cm2)
Global Maximum Value			0.0733	0.0157	4.67
Associated Acoustic Parameter	Pr.3 (MPa)		0.33	---	---
	Wo (mW)		---	0.00193	0.00193
	Fc (MHz)		20.28	19.67	19.67
	Zsp (cm)		0.93	1.00	1.00
	Beam Dimension	x-6 (cm)	---	0.0433	0.0433
		y-6 (cm)	---	0.0422	0.0422
	PD (msec)		0.040	---	0.040
	PRF(Hz)		3840	---	3840
	EBD	Az. (cm)	---	1.490	---
		Ele. (cm)	---	0.700	---

Transducer Model: Accutome Pachymeter Probe
Operating Mode: A mode
Application(s): Ophthalmic

Acoustic Output			MI	ISPTA.3 (mW/cm2)	ISPPA.3 (W/cm2)
Global Maximum Value			0.22	0.15	21.55
Associated Acoustic Parameter	Pr.3 (MPa)		0.78	---	---
	Wo (mW)		---	5.11E-04	5.11E-04
	Fc (MHz)		12.89	12.89	12.89
	Zsp (cm)		0.20	0.20	0.20
	Beam Dimension	x-6 (cm)	---	0.067	0.067
		y-6 (cm)	---	0.066	0.066
	PD (msec)		0.070	---	0.070
	PRF(Hz)		100	---	100
	EBD	Az. (cm)	---	0.267	---
		Ele. (cm)	---	0.267	---

The "derated" intensity calculations are based on the measured center frequency of the acoustic signal (fc, MHz) and the distance from the transducer undertest to the hydrophone (z, cm) using the derating factor e-0.069fcz.

Table 13.11 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The 4Sight is intended for use in the electromagnetic environment specified below. The customer or the user of the 4Sight should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11*	Group 1	The 4Sight uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11*	Class A	The 4Sight is suitable for use only in commercial and industrial environments. It is not designed for use in domestic establishments.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 13.12 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The 4Sight is intended for use in the electromagnetic environment specified below. The customer or the user of the 4Sight should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD)	+/- 6kV Contact	+/- 6kV Contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-2	+/- 8kV Air	+/- 8kV Air	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 13.13 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The 4Sight is intended for use in the electromagnetic environment specified below. The customer or the user of the 4Sight should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the 4Sight, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a]should be less than the compliance level in each frequency range. [b]Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[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 4Sight is used exceeds the applicable RF compliance level above, the 4Sight should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 4Sight
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

14 Warranty & Repairs

Accutome, Inc., warrants its new equipment to be free from defects in workmanship or materials. Any product that is proven to be defective will be repaired or replaced, at our discretion, free of charge, up to three years from the date of purchase by the initial user of the equipment from Accutome, Inc., or any of its authorized distributors.

This warranty covers all repairs and servicing of parts that prove defective by manufacture and not by misuse or mishandling. This type of service will be handled by our trained sales force, or, if necessary, in our home office. Shipping charges for returns or repair of nonwarranted items will be the responsibility of the customer. Alteration, repair, or modification of any product that is performed by persons not authorized by Accutome, Inc., will immediately void the warranty.

Product Returns

Follow the instructions given below to return products to Accutome, Inc.

Service and Repair

Before returning instruments for service or repair, contact the Accutome Technical Service Group for a Return Goods Authorization (RGA) number, or contact your local Accutome or Keeler distributor.

Phone Number:	(610) 353-4350
Toll Free:	(800) 523-5620
Fax:	(610) 353-7814

After receiving authorization, print the RGA number on the outside of the package and send the instrument to:

Technical Service Group
Accutome, Inc.
3222 Phoenixville Pike, building 50
Malvern, PA 19355 USA

All Other Returns

Returns for nonservice-related reasons must be authorized by the Accutome Customer Service Department. Please contact Customer Service for an RGA number.

Merchandise returned within 30 days of date of invoice will be credited as follows:

- Full credit for all merchandise returned in reasonable condition.

Nonreturnable Merchandise

Accutome, Inc., will not authorize a return for:

• Merchandise held longer than 30 days.

Training

Accutome can provide training with purchase of the 4Sight device. Please contact Accutome for additional information.

Troubleshooting

Table 14.1 - Troubleshooting Guide

Message	Cause
Error loading configuration file	File may be corrupted. Contact Accutome for assistance.
"Can't find the right type of probe for this exam"	Make sure you are using the correct probe for the modality selected. Recheck USB connection. Contact Accutome if problem persists.
Error deleting snapshots	Make sure snapshot files are not in use by another program or open. Close if open and retry.
Entered value out of range/invalid	Recheck values being entered to make sure they are correct.
Failed to initialize DICOM	There may be an issue with the DICOM connection. Retry connecting the device to the server. If problem persists, contact Accutome support.
Could not locate the folder which contains....	Wrong file path may be specified in setup or folder may have moved. Check to make sure folder is in the right location and make sure file path is correct.
Failed to print to specified printer	There may be an issue with the printer connection. Retry connecting printer to the control unit. Contact Accutome if problem persists.

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