

ACCUTOME® CONNECT™



Accutome Connect User's Guide

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, 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.

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Table of Contents

Chapter 1: Safety	1
Safety Issues to Consider When Using the Accutome Connect Platform	1
Indications for Use	1
A-Scan Module	1
B-Scan/UBM Modules	1
Side Effects	1
Contraindications	1
Symbol Definitions for the Connect Platform	2
Disposal Requirements	2
Disposal of the product within the EU	2
Disinfection and Cleaning	2
Warnings	3
Cleaning Procedure at Point of Use	3
Disinfection of the Probes with Alcohol	3
High-Level Disinfection of the Probe	3
Cleaning and Disinfection of Immersion and Sclera Shells	4
Electrical Hazard and Safety	4
Avoiding Equipment Damage	5
Avoiding Electromagnetic and Other Interference	5
ALARA Principle	6
Chapter 2: Hardware Connections	7
Introduction	7
Common Features	7
Application Modules	8
A-Scan Module	8
B-Scan/UBM Modules	8
Hardware Connections	10
Chapter 3: Home Screen	11
Splash Screen	11
Overview	11
Patient Info Box (left side of screen)	12
Keratometry Readings	13
Exam Info Box (right side of screen)	13
B-Scan/UBM Sequences	14
Chapter 4: Setup: Facilities/Physicians/Users	15
Setup Screen	15
Buttons Common to All Setup Screens	15

Setup Facilities, Physicians, Users	15
Available Facilities/Available Physicians/Available Users	16
Chapter 5: Setup: General	17
Setup: General – Folder	17
General Settings Box	17
Functions/Buttons Common to Snapshots and Reports	18
Functions/Buttons Unique to Snapshots	18
Functions/Buttons Unique to Reports	18
Setup: General – DICOM Servers	19
Information of Facility Used in Exporting DICOM SOPs	19
PACS (Picture Archiving and Communication System) Box	19
Worklist Box	20
Setup: General - Screen Recording Tab	20
Installing a Printer	21
Chapter 6: Setup: A-Scan	22
Setup: A-Scan – Options Tab	22
A-Scan Exam Defaults Box	22
Setup: A-Scan - Import/Export	25
IOL Master Synergy Box	25
Setup: A-Scan - Eye Types	28
Adding a New Lens, Anterior Chamber, or Vitreous Chamber Material	28
To Add a New Eye Type	29
Setup: A-Scan - Personalize IOL	29
Personalizing IOL Overview	29
Updating IOL Constant	33
Chapter 7: Setup: B-Scan/UBM	34
Setup: B-Scan/UBM – Options Tab	34
Probe Control Box	34
Info on Images Box	35
Snapshot + Print Box	35
Image Controls Box	35
Setup: B-Scan/UBM - Sequence	37
Edit Current Sequence Box	37
How to Define the Sequence Scan	37
Deleting Sequences	40
Duplicate Sequences from Selected	40
Set Selected Sequence as Default	40
Create From Templates (lower right of Available Sequences box)	40
Save	41
Restore	41
Chapter 8: Application Common Functions	42
Application Module Common Functions	42
Screen Snapshot	42

Print	42
Save	42
Edit	42
Setup	42
Reports	42

Chapter 9: A-Scan 45

A-Scan Application Module	45
A-Scan Probe/Test Block	45
A-Scan: Taking Measurements	47
Preparing a Patient for Examination	47
Taking a Patient Measurement	47
A-Scan: Performing IOL Calculations	48
Overview	48
How to Perform a Calculation	49
A-Scan: IOL Calculation - Manage Physician Lenses	50
Manage Physician Lens Groups	50
A-Scan: IOL Calculation – Refractive Surgery	51
Determining Corneal Power after Refractive Surgery	51
Post Rx Surg IOL Calculation Steps	52
Calculation Results	52

Chapter 10: B-Scan/UBM 53

B-Scan/UBM – Probes	53
Probe	53
Features Common to B-Scan and UBM Probes	53
Footswitch	53
B-Scan/UBM Pre-Scan Setup	53
B-Scan/UBM: Scanning Basics	55
How to Scan	55
Exam Information Displayed above the Scan	56
Scanning with a Predefined Protocol	56
Scanning without a Protocol	57
Adding and Labeling a New View	57
B-Scan/UBM: Tools/Measure/Advanced Box	58
Tools Tab	58
Measure Tab	59
Advanced Tab	60
B-Scan/UBM Operation: Using the Probe	60
Marker Alignment	60
Probe Orientation	61
B-Scan Transverse Scan Labeling	62
UBM Transverse Scan Labeling	63

Chapter 11: Maintenance 64

General Maintenance	64
Safety Inspection	64

Visual Inspection64

Ultrasound Inspection64

Calibration.....64

Chapter 12: Specifications65

 Overview65

 Physical Specifications65

 Environmental Specifications66

 Range and Accuracy66

 Operating Modes67

 Acoustic Output70

Chapter 13: Warranty & Repairs74

 Product Returns74

 Service and Repair74

 All Other Returns74

 Nonreturnable Merchandise75

 Training75

 Troubleshooting75

List of Figures

Figure 2.1 - Accutome Connect platform	7
Figure 2.2 - Sample B-Scan Images	10
Figure 2.3 - Sample UBM Images	10
Figure 3.1 - Introductory Screen (Splash Screen)	11
Figure 3.2 - Connect Home Screen	11
Figure 3.3 - DICOM Worklist	13
Figure 4.1 - Setup Screen - Facilities Tab Open	15
Figure 5.1 - Setup: General - Folder	17
Figure 5.2 - Setup: General - DICOM Servers	19
Figure 5.3 - Setup: General - Screen Recording	20
Figure 6.1 - Setup: A-Scan - Options Tab	22
Figure 6.2 - Setup: A-Scan - Misc Controls	25
Figure 6.3 - A-Scan Synergy Mode Setup Screen	25
Figure 6.4 - Setup: A-Scan - Eye Types Screen	28
Figure 6.5 - Setup: A-Scan - Personalize IOL Screen	30
Figure 6.6 - Setup: A-Scan - Personalize IOL - Review IOL Groups	30
Figure 6.7 - Setup: A-Scan - Personalize IOL - Saved Exam Highlighted	31
Figure 7.1 - Setup: B-Scan/UBM Tab Selected	34
Figure 7.2 - Setup: B-Scan Image Controls	36
Figure 7.3 - Setup: B-Scan/UBM - Sequence Tab	38
Figure 7.4 - Setup: B-Scan/UBM - Sequence - New Sequence Scan Added	39
Figure 7.5 - Setup: B-Scan/UBM - Sequence - Change Probe Orientation	40
Figure 8.1 - Typical A-Scan Report	43
Figure 8.2 - B-Scan Screen after Report Is Selected	43
Figure 8.3 - Typical B-Scan Report	44
Figure 9.1 - A-Scan Ultrasonic Probe Kit (PN 24-4001)	45
Figure 9.2 - A-Scan Probe with Immersion Shell	45
Figure 9.3 - A-Scan Probe with Goldman Tonometer Adapter	45
Figure 9.4 - Inserting Probe into Probe Handle Extension	46
Figure 9.5 - A-Scan Probe with Probe Handle Extension	46
Figure 9.6 - Using the A-Scan Test Block	46
Figure 9.7 - A-Scan Measurement Screen	47
Figure 9.8 - A-Scan IOL Calculation Screen	49
Figure 9.9 - A-Scan IOL Calculation - Manage Physician Lenses	51
Figure 10.1 - Connect UBM Probe	53
Figure 10.2 - Connect B-Scan Probe	53
Figure 10.3 - Anterior Segment Scleral Shells (18mm and 20mm)	53
Figure 10.4 - Accutome Footswitch	53
Figure 10.5 - B-Scan Screen Sample	54
Figure 10.6 - UBM Screen Sample	54
Figure 10.7 - B-Scan Scanning with a Predefined Protocol	56
Figure 10.8 - New Exam, No Protocol - First Scan Selected (B-Scan sample)	57

Figure 10.9 - New Exam - First Scan Complete (B-Scan Example)	57
Figure 10.10 - B-Scan with A-Vector Overlay	58
Figure 10.11 - B-Scan Sample Showing Line, Area, Angle, and Arrow Tools	59
Figure 10.12 - Advanced Recording Tab	60
Figure 10.13 - Eye and Probe Marker Alignment	6
Table 12.1 - Accutome Connect Probe Physical Specifications	65
Table 12.2 - Environmental Specifications	66
Table 12.3 - Measurement Clinical Accuracy (1s) Range for A-Scan Function	66
Table 12.4 - Range and Accuracy of the B-Scan Plus and UBM Plus	67
Table 12.5 - UBM Range and Accuracy	67
Table 12.6 - Operating Mode(s)	68
Table 12.7 - A-Scan Data Specifications	69
Table 12.8 - Acoustic Output Reporting	70
Table 12.9 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions	72
Table 12.10 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity	72
Table 12.11 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity	73
Table 13.1 - Troubleshooting Guide	75

1

Safety

Safety Issues to Consider When Using the Accutome Connect Platform

The Accutome Connect platform has no user-operated controls or settings that affect the acoustic output. The Accutome Connect platform 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 Connect platform 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, anterior, and posterior pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye.

Side Effects

There are no known side effects associated with the use of Accutome Connect ultrasound imaging devices.

Any side effects associated with the use of the Connect platform are related to the topical anesthetic chosen by the physician to anesthetize the eye of the patient. Please consult the warning labels of the chosen topical anesthetics for further information.

Contraindications

There are no known contraindications associated with the use of the Accutome Connect platform.

WARNING! THE CONNECT PLATFORM AND ASSOCIATED PROBES ARE NOT INTENDED FOR FETAL USE!

Symbol Definitions for the Connect Platform



Attention! Consult
Instruction Manual



No User
Serviceable Parts



Do Not Use Near
Flammable Gases



Type B Medical
Devices



USB Connector



Disposal of Product
within the EU



Electrical Shock
Hazard

Disposal Requirements

The Accutome Connect platform and its accessories contain electronic components. At the end of their useful lives, they must be properly disposed of in compliance with local regulations.

Disposal of the product within the EU

EU directives and national regulations currently in force at the time of marketing prohibit the disposal of the Connect platform and associated probes specified on the delivery note in domestic waste or by municipal waste disposal companies. If the associated probes or 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 probes that come 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 that might come in contact with eye fluids should be cleaned with an FDA-cleared high-level disinfectant.

The Connect probes 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.

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 Accutome Connect platform and probes 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 Connect platform and/or any attachments, the equipment must be turned off and the power cord disconnected.

Use only the Accutome-provided 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 CONNECT PLATFORM AND PROBES ARE ONLY TO BE USED WITH A COMPUTER USING MEDICAL GRADE POWER SUPPLY COMPLIANT with IEC60601-1.

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 PROBES 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 PC, ensure that the data is backed up on a device external to the PC.

CAUTION: The A connector type, Version 1.1 USB ports on the A-scan Plus Control Unit should be used only for low power devices such as the footswitch, a memory "stick", or a mouse.

WARNING! THE PROBE TIP OF THE UBM PLUS IS NEVER TO COME IN CONTACT WITH THE PATIENT'S EYE, AS IT MAY RESULT IN A CORNEAL ABRASION OR SIMILAR TYPE INJURY

Avoiding Equipment Damage

The Accutome Connect platform and associated probes provide 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 CONNECT PLATFORM PROBES OR A-SCAN CONTROL UNIT 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 A 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 CONNECT PLATFORM.

WARNING! THE ACCUTOME CONNECT PLATFORM SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE ACCUTOME CONNECT PLATFORM 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 system, 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 Connect platform

Note: Your unit may not have all of the attachments shown above.

Common Features

- A single, readily portable, platform for three possible modules:
 - A-Scan Biometry
 - B-Scan Ultrasonography
 - UBM (Ultrasound Bio-Microscopy)
- New, icon-based user interface
- For user convenience, buttons/ locations may be selected by using the mouse.
- 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 500)
- The Accutome Connect software uses the same algorithms that have been proven in field use by thousands of Accutome customers.
- The Accutome Connect software has convenient screens for entering and storing information about facilities, physicians, and users. The information is shared across the functional modules and can be readily selected to be associated with individual patient data.

Application Modules

The Connect platform, fully configured, provides the following ophthalmic 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 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 user computer, external hard drive, or network location, 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 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.

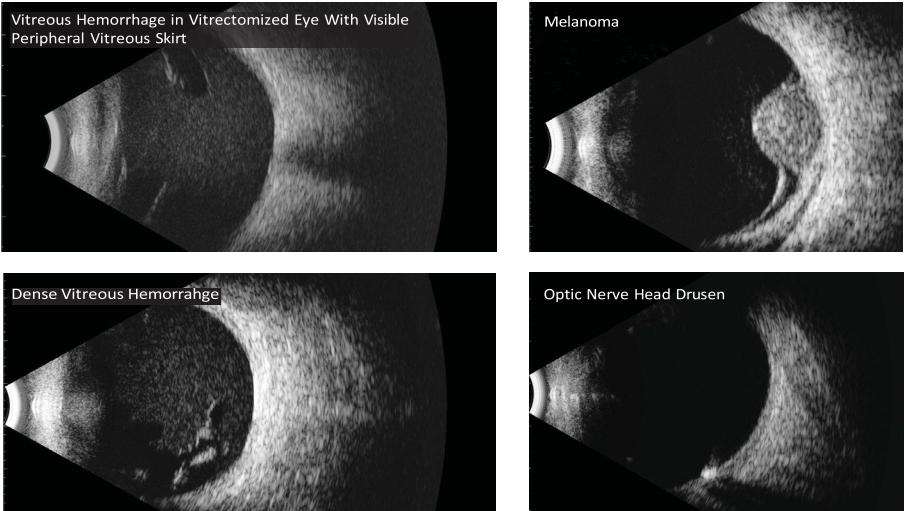


Figure 2.2 - Sample B-Scan Images

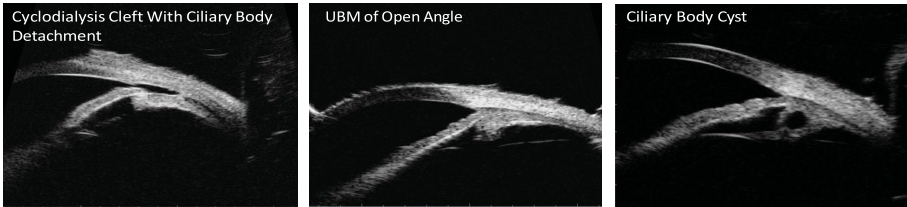


Figure 2.3 - Sample UBM Images

Hardware Connections

Before launching the Connect software, ensure that the Connect probes are plugged into the PC

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

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

3

Home Screen

Splash Screen



Figure 3.1 - Introductory Screen (Splash Screen)

From the Desktop, Launch the Accutome Connect Software by double clicking on the Connect Icon.

Overview

The main interface of the Accutome Connect software. It has a dark blue background with white text and various input fields. The interface is divided into several sections:

- Patient Info:** Includes fields for Last Name, First Name, Medical Record #, Date of Birth (with a calendar icon), Gender, and Age.
- Import From:** Contains buttons for 'New Patient', 'Existing Patient', 'IOLMaster', and 'DICOM'.
- Keratometry Readings:** Divided into OD (Right Eye) and OS (Left Eye) sections, each with input fields for K1 and K2.
- Exam Info:** Includes fields for Exam ID, Facility, Physician, and Operator, each with a dropdown menu.
- Indication of Scan:** A large text area for notes.
- B-Scan / UBM Sequences:** Includes fields for Create Date/Time, Scan Group (with a dropdown), Protocol (with a dropdown), and a Description field.
- Navigation and Settings:** On the right side, there are three large circular icons labeled A, B, and U, and a gear icon for settings.
- Footer:** At the bottom, it displays the Accutome logo (A HALMA COMPANY), the version number 'Accutome Connect Version 8.00.00', the UDI '00897826002284', and an 'Exit' button.

Figure 3.2 - Connect 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)



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.



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

- 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.
- 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 displays and highlights the appropriate patient. It is not case sensitive.
- Selecting a patient record (via double mouse click) causes return to the Home Screen with the known information automatically entered.



IOL Master Button - activating this button will open up an exam list of patients measured with IOL master and exported to the Connect Software. These patients are ready to be measured with the connect software unit using the A-Scan modality.

Information about the patient selected on the IOL Master list will be automatically entered into the Connect software.



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.

Application Buttons



A-Scan Button



B-Scan Button



UBM Button



Settings Button

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.

Patient ID - add patient's ID to limit the search results.

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.

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

Keratometry readings may be entered here or later in A-Scan screen. 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 the Connect software.

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 selected.

Physician - the physician responsible for the readings/the physician responsible for the patient selected.

Operator - the person who performed the measurements on the selected patient.

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 is a date/time stamp for the patient.

Scan Group - System Defaults option displays 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)

4

Setup: Facilities/ Physicians/Users

Setup Screen

Select the cogwheel button to bring up the Setup screen.



The screenshot shows the 'Facilities' tab selected in the top navigation bar. The 'Facility Information' section contains the following fields:

- Name: ACCUTOME INC
- Address: 3222 Phoenixville Pike
- City: Malvern
- Zip: 19355
- State: PA
- Country: US
- Telephone: 800 979-2020

The 'Available Facilities' section on the right lists:

- ACCUTOME INC (selected)
- DAVES EYE

Buttons at the bottom right of the 'Available Facilities' section include: New, Delete, Duplicate from Selected, Set Selected as Default, Save, and Restore. At the bottom of the main window are 'Cancel' and 'Done' buttons. The Accutome logo is visible in the bottom left corner.

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, and UBM) 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 selected patient.

Physician - the physician responsible for the readings/the physician responsible for the selected patient.

Operator - the person who performed the measurements on the selected patient.

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.

A dark blue rectangular button with the word "Save" in white text.

Save - saves all changes up to that point.

A dark blue rectangular button with a white circular arrow icon and the word "Restore" in white text.

Restore - deletes the entries subsequent to the last Save (warning before activation).

5

Setup: General

Setup: General – Folder

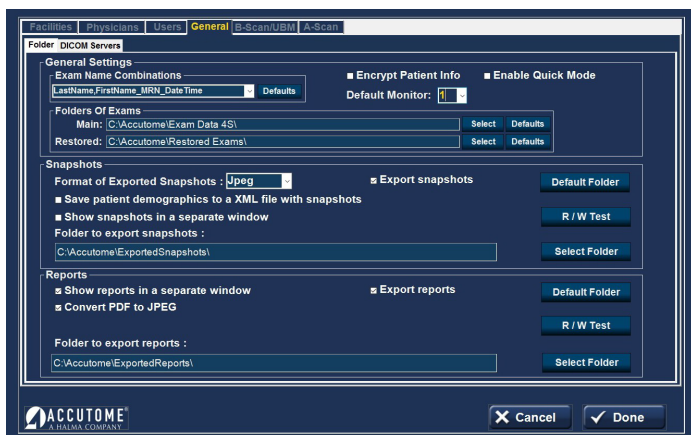


Figure 5.1 - Setup: General - Folder

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 - select from the drop-down box and the next two lines, as appropriate.

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

Functions/Buttons Unique to Reports

Convert .PDF to .JPEG - select, if desired, allows .PDF reports to be converted to .JPEG file type.

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.

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.

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 CONNECT SOFTWARE.

Setup: General - Screen Recording Tab

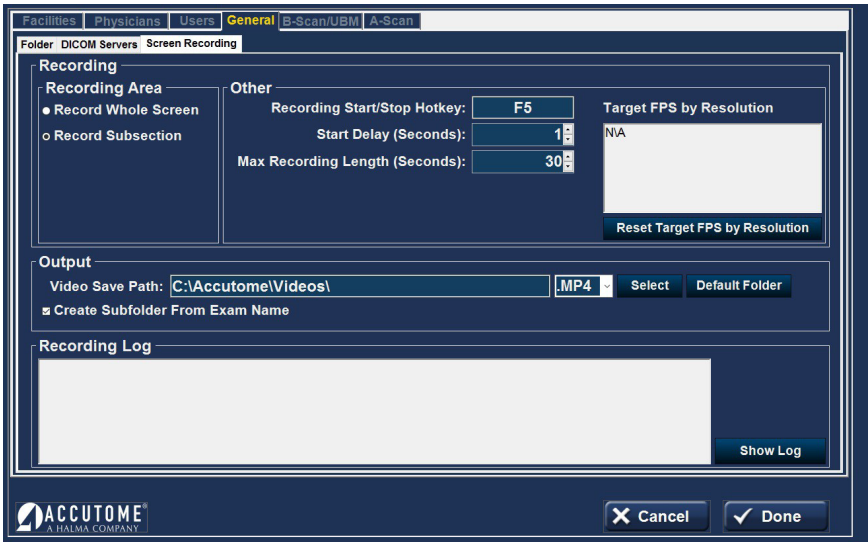


Figure 5.3 - Setup: General - Screen Recording

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

Connect software will use the Defaulted printer set to your computer.

6

Setup: A-Scan

Setup: A-Scan – Options Tab

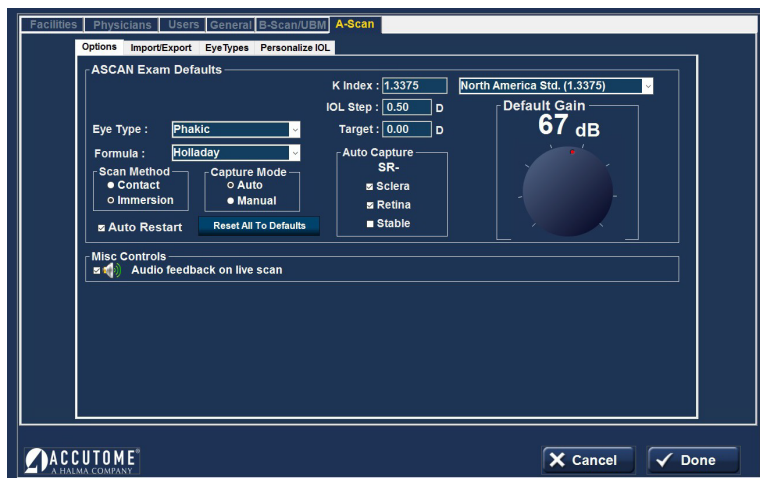


Figure 6.1 - Setup: A-Scan - Options Tab

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 Connect 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 is 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)

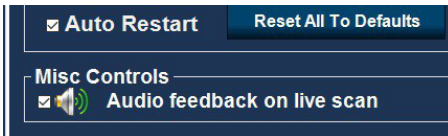
Note: The Stable Auto Mode setting is not recommended for contact method measurements. The measurement variance caused by hand or eye movements may make the stable autolock requirement difficult to achieve.

Default Gain

The gain knob allows the user to adjust the gain value.

The Gain value set on this screen will be the default value for new readings.

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.

Figure 6.2 - Setup: A-Scan - Misc Controls

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

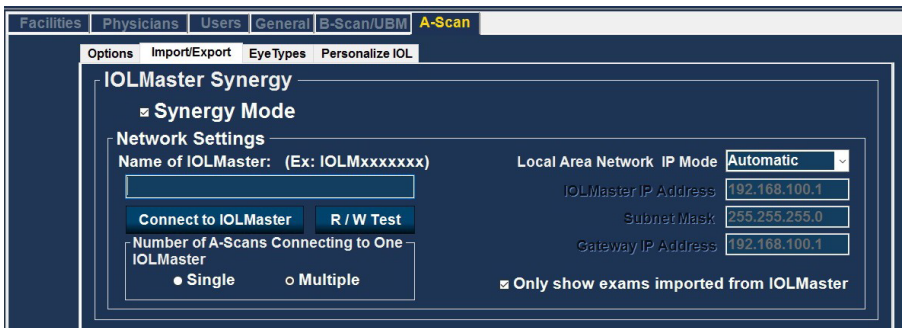


Figure 6.3 - A-Scan Synergy Mode Setup Screen

IOL Master Synergy Box

The Import/Export feature allows you to use the Connect 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.

Method of Data Exchange Box

Select Network Folder to transfer IOL Master 500 7.7 exams.

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 the next page.

Setting up the Connect 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 Connect Software 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 Connect. 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 Connect 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.

Operation of the Accutome Connect 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 Connect 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 autocapture.
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.
16. 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.
17. Navigate to the patient list.
18. Select your patient.
19. On the left-hand side of the page, choose the existing measurement.
20. Select Open.
21. Scans can be viewed by clicking on the axial length measurement icon.
22. IOL calculations can now be done for the patient.
23. 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 Connect 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 Connect. If at any point you wish to stop using the Connect 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 Connect 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.

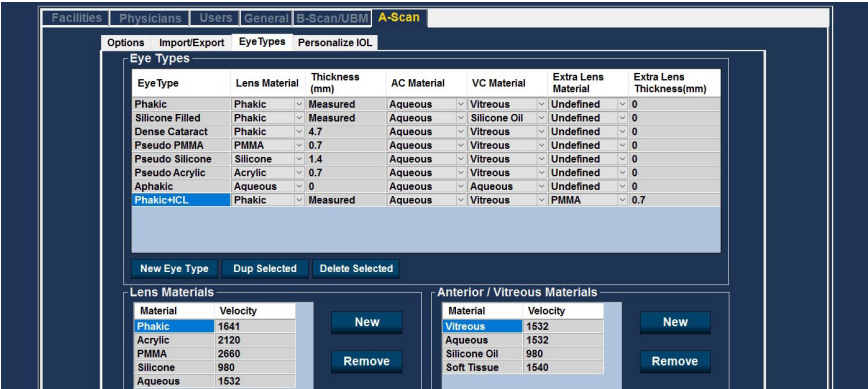


Figure 6.4 - Setup: A-Scan - Eye Types Screen

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 Connect 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 Connect tracks personalized constants for each IOL and formula separately.

The process for personalizing lens constants involves entering postoperative results and allowing the Connect 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.

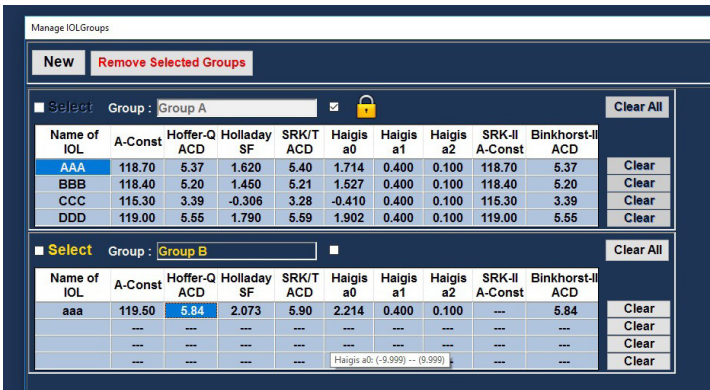


Figure 6.6 - Setup: A-Scan - Personalize IOL - Review IOL Groups

Note: The Connect 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 6.7 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.

Last_Name	First_Name	MRN	DOB	Date_Created
JACKSON	ANDREW	T038J	11/11/1988	16/2017 1:51 PM
ALLEN	FOX	T234F	12/11/1993	16/2017 5:59 PM
HANEY	JAY	T234H	12/11/1982	16/2017 5:56 PM
DOE	JOHN	0123456789KLMN	12/10/1970	16/2017 8:19 AM
EDWARDS	JOHN	T023	12/11/1992	16/2017 10:40 AM
EDWARDS	JOHN	T026	12/11/1992	16/2017 10:57 AM
EDWARDS	JOHN	T035	12/11/1992	16/2017 11:31 AM
EDWARDS	JOHN	T039	12/11/1992	16/2017 1:56 PM
EDWARDS	JOHN	T041	12/11/1992	16/2017 2:30 PM
EDWARDS	JOHN	T041	12/11/1992	16/2017 3:00 PM
EDWARDS	JOHN	T043	12/11/1992	16/2017 3:11 PM
EDWARDS	JOHN	T044	12/11/1992	16/2017 3:20 PM
EDWARDS	JOHN	T048	12/11/1992	16/2017 3:38 PM
EDWARDS	JOHN	T049	12/11/1992	16/2017 3:42 PM
EDWARDS	JOHN	T050	12/11/1992	16/2017 3:48 PM
EDWARDS	JOHN	T053	12/11/1992	16/2017 3:56 PM
EDWARDS	JOHN	T054	12/11/1992	16/2017 5:49 PM
EDWARDS	JOHN	T055	12/11/1992	16/2017 5:52 PM
EDWARDS	JOHN	T056	12/11/1992	16/2017 5:59 PM
EDWARDS	JOHN	T058	12/11/1992	17/2017 9:57 AM
EDWARDS	JOHN	T059	12/11/1992	17/2017 10:01 AM
EDWARDS	JOHN	T062	12/11/1992	17/2017 10:04 AM
EDWARDS	JOHN	T064	12/11/1992	17/2017 10:07 AM
EDWARDS	JOHN	T066	12/11/1992	17/2017 10:12 AM
EDWARDS	JOHN	T067	12/11/1992	17/2017 10:15 AM
EDWARDS	JOHN	T068	12/11/1992	17/2017 10:20 AM
EDWARDS	JOHN	T071	12/11/1992	17/2017 10:23 AM
EDWARDS	JOHN	T072	12/11/1992	17/2017 10:30 AM
EDWARDS	JOHN	T191	19/2017	4:09 PM
EDWARDS	JOHN	T191	19/2017	4:27 PM
EDWARDS	JOHN	T191	19/2017	4:31 PM
EDWARDS	JOHN	T234E	12/11/1992	19/2017 6:00 PM
S	S	S	11/10/2017	11:57 AM
AUSTIN	STEVE	T010A	12/11/1972	16/2017 9:19 AM

Figure 6.7 - Setup: A-Scan - Personalize IOL - Saved Exam Highlighted

The Connect 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 Connect 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 Connect 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 obtained and calculated the minimum number of patients required, the user may 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.

7

Setup: B-Scan/UBM

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.

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

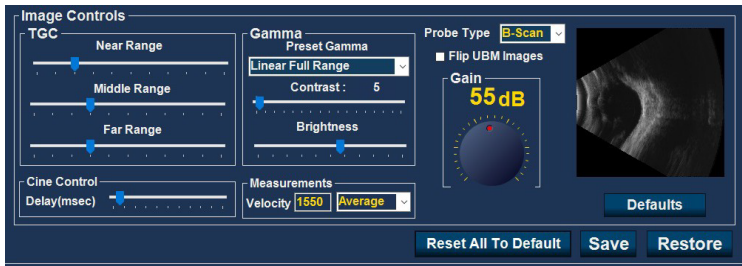


Figure 7.2 - Setup: B-Scan Image Controls

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.

Default Monitor (under Gain Knob)

The Connect software display is the default Monitor "1". If another monitor is plugged into the HDMI jack on the left of the unit, that becomes Monitor "2".

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 7.3.

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.

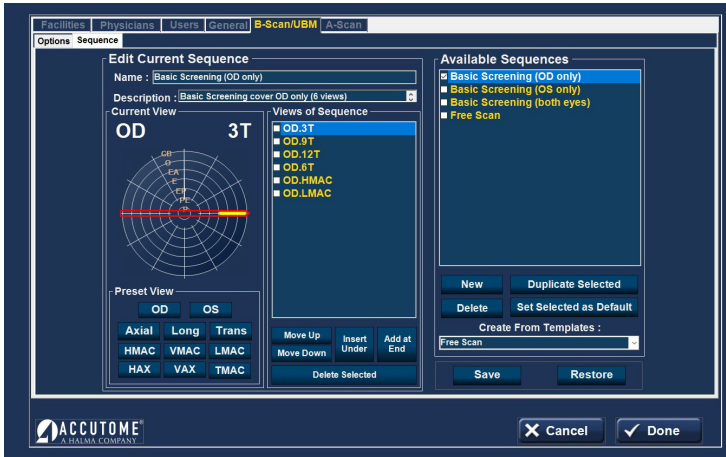


Figure 7.3 - Setup: B-Scan/UBM - Sequence Tab

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 7.4.

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.

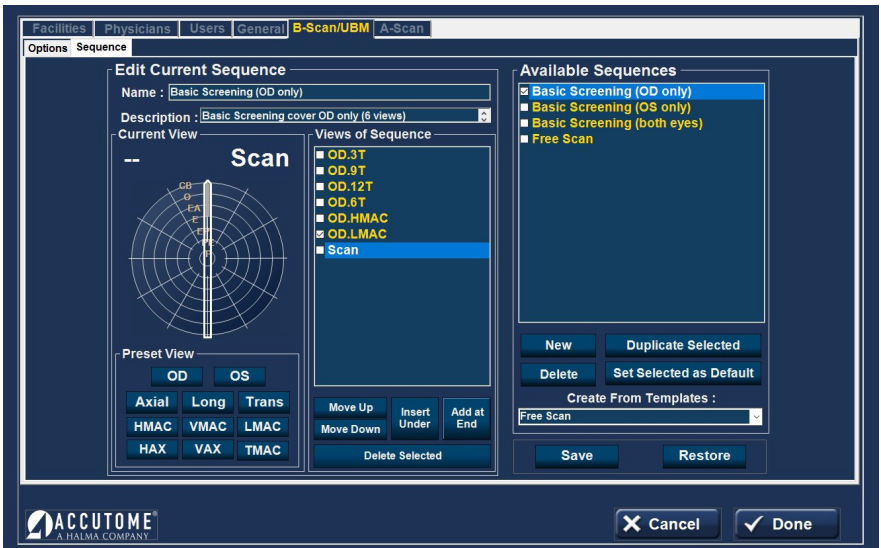


Figure 7.4 - Setup: B-Scan/UBM - Sequence - New Sequence Scan Added

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.

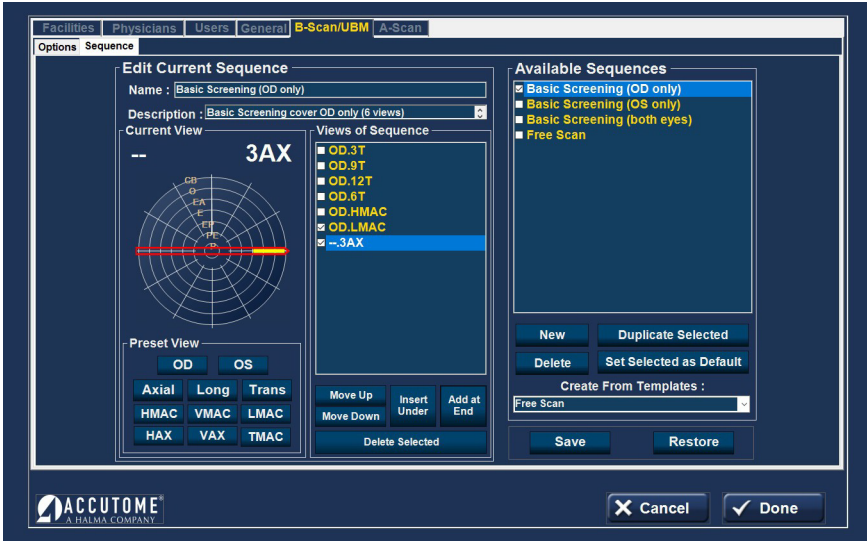


Figure 7.5 - Setup: B-Scan/UBM - Sequence - Change Probe Orientation

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

Shows report of the scans for the patient currently selected (see sample report in figure 8.1).

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 8.2 and 8.3).

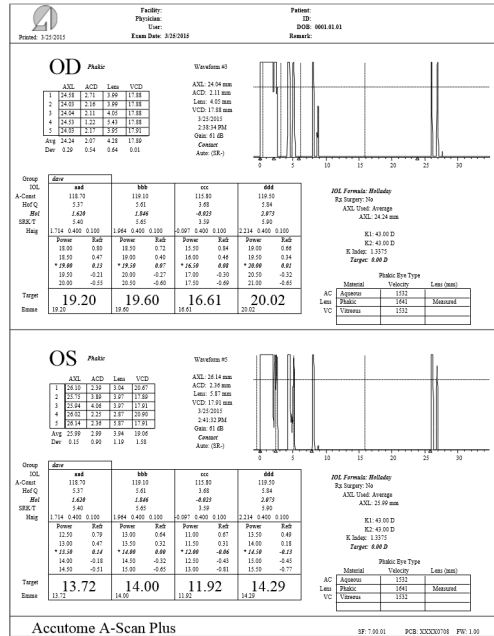


Figure 8.1 - Typical A-Scan Report



Figure 8.2 - B-Scan Screen after Report Is Selected

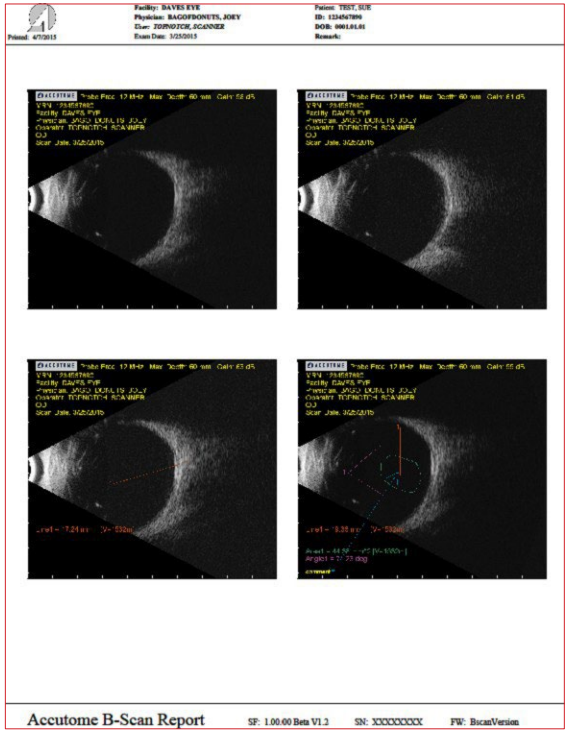


Figure 8.3 - Typical B-Scan Report

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

The Connect 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

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. It is important that the probe does not pass the etched line in the immersion shell.

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 9.1 - A-Scan Ultrasonic Probe Kit (PN 24-4001)



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.

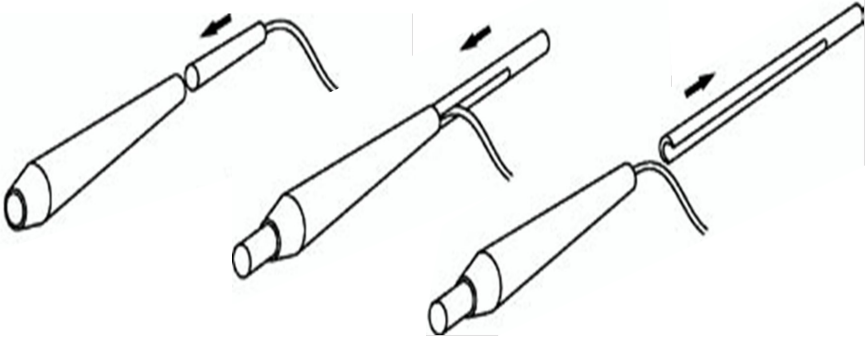


Figure 9.4 - Inserting Probe into Probe Handle Extension



Figure 9.5 - A-Scan Probe with Probe Handle Extension

A-Scan Setup Information – Test Block

The Accutome Connect 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

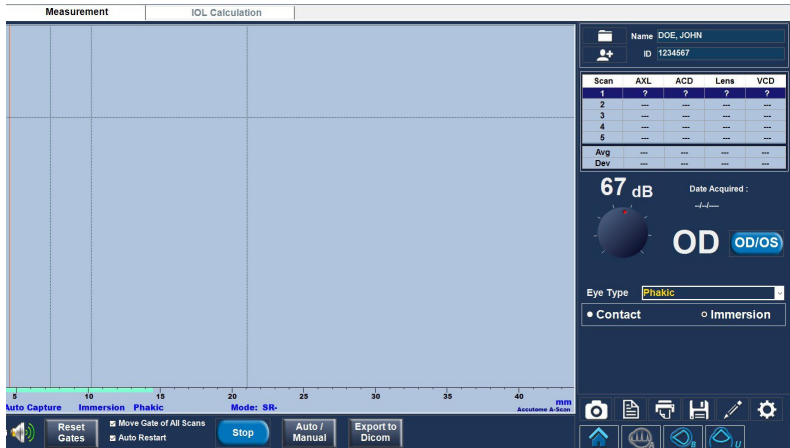


Figure 9.7 - A-Scan Measurement Screen

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 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.

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.

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 Connect 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 for instructions on changing the RX Surg field.

IOL	AAA	BBB	CCC	DDD
A-Const	118.70	118.40	115.30	119.00
Hoffer Q	5.37	5.20	3.39	5.55
Holladay	1.620	1.450	-0.306	1.790
SRK/T	5.40	5.21	3.28	5.59
Haigis	1.714 0.400 0.100	1.527 0.400 0.100	-0.410 0.400 0.100	1.902 0.400 0.100
SRK II	118.70	118.40	115.30	119.00
Binkhorst II	5.37	5.20	3.39	5.55

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 in A-Scan: IOL Calculation - Manage Physician Lenses section).

K Index

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

AXL

The Connect software 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.

Rx Surgery

If “Yes” is selected, Kpre and Kpost need to be calculated and entered. See “Determining Corneal Power after Refractive Surgery” 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. The Connect 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.

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.

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.

Manage IOLGroups

New

Remove Selected Groups

Restore

Done

Select

Group: Group A

Clear All

Name of IOL	A-Const	Hoffer-Q ACD	Holladay SF	SRK/T ACD	Haigis a0	Haigis a1	Haigis a2	SRK-II A-Const	Binkhorst-II ACD	
AAA	118.70	5.37	1.620	5.40	1.714	0.400	0.100	118.70	5.37	Clear
BBB	118.40	5.20	1.450	5.21	1.527	0.400	0.100	118.40	5.20	Clear
CCC	115.30	3.39	-0.306	3.28	-0.410	0.400	0.100	115.30	3.39	Clear
DDD	119.00	5.55	1.790	5.59	1.902	0.400	0.100	119.00	5.55	Clear

Select

Group: Group B

Clear All

Name of IOL	A-Const	Hoffer-Q ACD	Holladay SF	SRK/T ACD	Haigis a0	Haigis a1	Haigis a2	SRK-II A-Const	Binkhorst-II ACD	
aaa	119.50	5.84	2.073	5.90	2.214	0.400	0.100	---	5.84	Clear
										Clear
										Clear
										Clear

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

Entering Lens Constant

For a given lens (row), if you enter any one of the first five constants, the Connect 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.

Note: The Connect software will not automatically generate A-Constants for the SRKII Formula. The User must enter appropriate A-Constant to use SRKII formula in Connect software.

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 Connect 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 $K_{post} = 1.14 * K_{measured} - 6.8$.
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 Connect 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.

10

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.



Figure 10.1 - Connect UBM Probe



Figure 10.2 - Connect 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 section.



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

Footswitch

The footswitch provided with Connect can be used to start and stop scanning. To install, plug the USB cord into any USB port located on the PC, Laptop or Tablet.

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

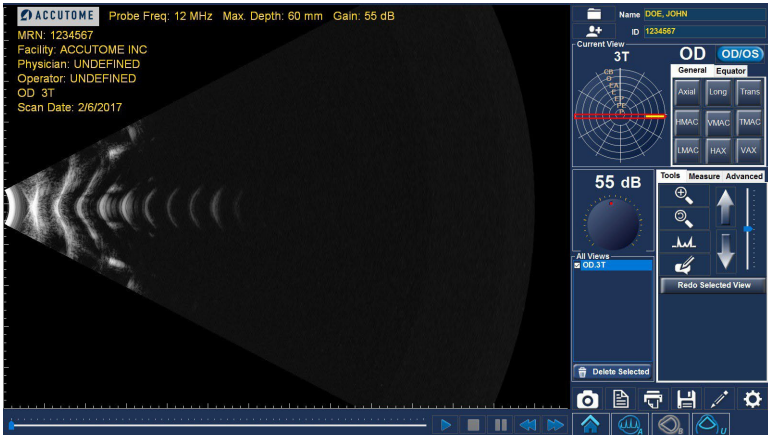


Figure 10.5 - B-Scan Screen Sample

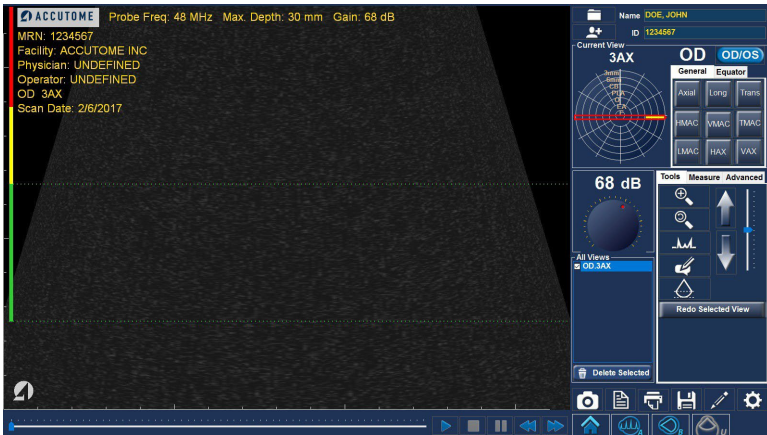


Figure 10.6 - UBM Screen Sample

If you entered a patient name and/or ID on the Connect 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 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.

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. 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
- Rotating the physical gain knob in the bottom center of the case

Moving the Image

To move the image around on the screen, 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 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 10.7 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.3T and the second scan is labeled OD.9T. 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.

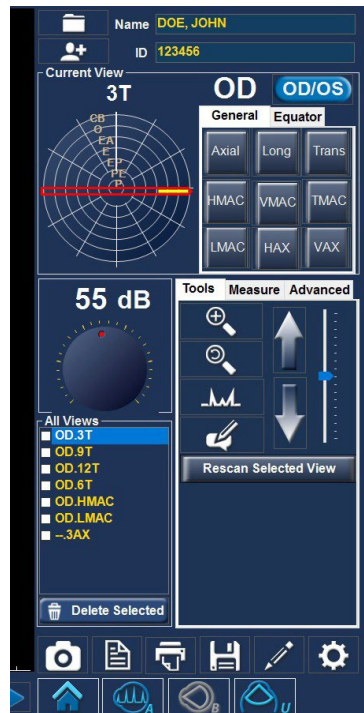


Figure 10.7 - B-Scan Scanning with a Predefined Protocol

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



Figure 10.8 - New Exam, No Protocol - First Scan Selected (B-Scan sample)



Figure 10.9 - New Exam - First Scan Complete (B-Scan Example)

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.

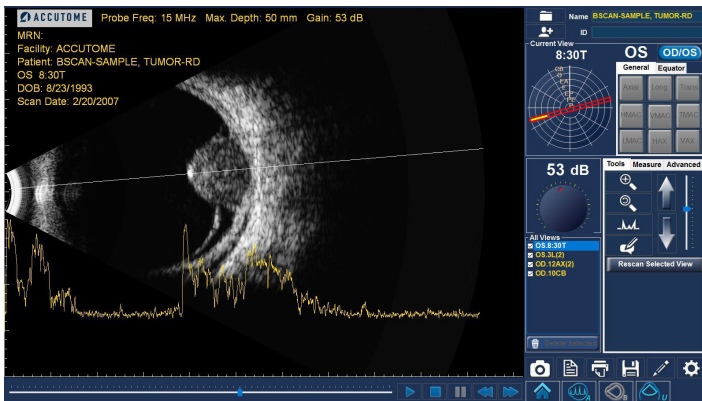


Figure 10.10 - B-Scan with A-Vector Overlay

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.

Rescan Selected View Button- allows user to retake the currently selected 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.

Scan/Stop Button - initiates or stops a scan and may be used as an alternative to the probe ring button or the footswitch (only in Quick Mode).

Save Video Button - saves the scans to the location designated in Setup > General > Folder.

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.

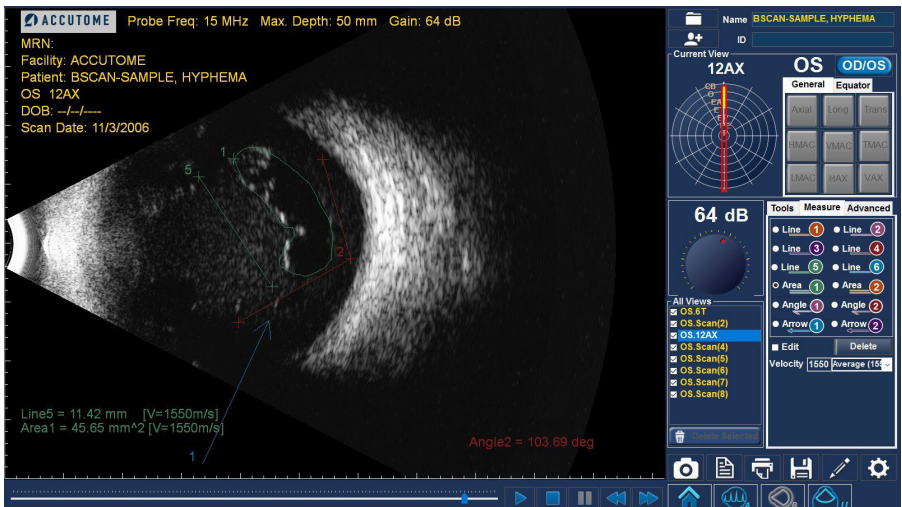


Figure 10.11 - B-Scan Sample Showing Line, Area, Angle, and Arrow Tools

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.

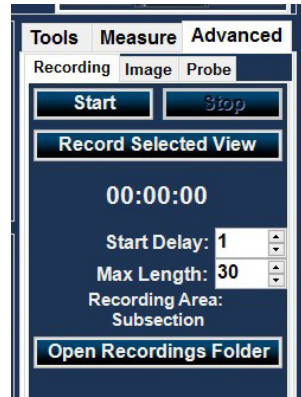


Figure 10.12 - Advanced Recording Tab

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 section.

Advanced/Probe

Probe Mode, Video buffer length, and probe output Power may be adjusted. See Setup: B-Scan/UBM - Power section 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 10.13, 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 section.

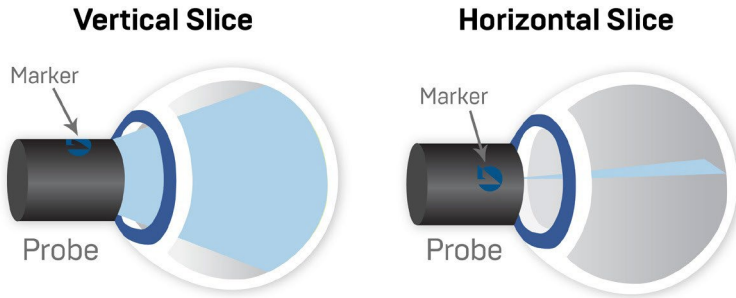


Figure 10.13 - Eye and Probe Marker Alignment

Probe Orientation

One of the great features of the Accutome Connect 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

Maintenance

General Maintenance

Maintenance that should be performed on the Accutome Connect 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 Connect platform.

Refer to the Safety chapter for cleaning and disinfection issues pertaining to the probes.

Safety Inspection

Safety inspections should be done to ensure that the Connect 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 Connect, 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 Connect is self-calibrating and therefore requires no adjusting or further calibration by the user.

12

Specifications

Overview

This section provides the physical and operational specifications of the Accutome Connect platform.

Physical Specifications

Device classification of Connect platform: continuous operation.

Table 12.1 - Accutome Connect Probe Physical Specifications

A-Scan Probe* (Use only Accutome probes)	
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
A-Scan Plus Connect Control Unit* (Use only Accutome probes)	
Dimensions	13.75cm X 9.50cm X 6.40cm (5.4" X 3.7" X 2.5")
Weight	0.43kg (15.1oz)
DC Input	5VDC, 500mA typical via USB cable from PC
External I/O Connectors	
USB Master	USB B Type, R/A
USB Slave	3 USB A Type, R/A, USB 1.1 Compatible
UBM Probe* (Use only Accutome probes)	
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* (Use only Accutome probes)	
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 12.2 below lists the Accutome system operating and storage values for temperature and humidity.

Table 12.2 - Environmental Specifications

Temperature	
Operating	10°–40° C (50°–104° F)
Storage	-20°–60° C (-4°–140° F)
Relative Humidity	
Operating	20–80% (noncondensing)
Storage	15–90% (noncondensing)
Atmospheric Pressure	
Operating	700–1060 hPa
Storage	500–1060 hPa

Range and Accuracy

Table 12.3 lists the accuracy for each type of measurement. Clinical Accuracy (1s) 0.1 mm, Electronic Resolution (@1550m/s) 0.016 mm.

Table 12.3 - 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 12.4 - Range and Accuracy of the B-Scan Plus and UBM 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 12.5 - 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

Operating Modes

Table 12.6 summarizes the mode/application possibilities for each system/transducer combination.

Table 12.6 - 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 12.7 - 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	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
Enteral 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

Table 12.7 - (Continued) A-Scan Data Specifications

Accutome Clock	
Clock/Calendar valid	Through year 2099

Acoustic Output

Table 12.8 below provides the acoustic output reporting for the following:

Table 12.8 - 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			0.148	0.0135	6.76
Associated Acoustic Parameter	Pr.3 (MPa)		0.448	---	---
	Wo (mW)		---	9.98E-4	9.98E-4
	Fc (MHz)		9.16	9.16	9.16
	Zsp (cm)		1.60	1.60	1.60
	Beam Dimension	x-6 (cm)	---	0.175	0.175
		y-6 (cm)	---	0.223	0.223
	PD (msec)		0.100	---	0.100
	PRF(Hz)		20.0	---	20.0
	EBD	Az. (cm)	---	0.500	---
		Ele. (cm)	---	0.500	---

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

Acoustic Output			MI	ISPTA.3 (mW/cm ²)	ISPPA.3 (W/cm ²)
Global Maximum Value			0.202	0.414	23.1
Associated Acoustic Parameter	Pr.3 (MPa)		0.652	---	---
	Wo (mW)		---	0.178	0.178
	Fc (MHz)		10.4	10.4	10.4
	Zsp (cm)		1.60	---	1.60
	Beam Dimension	x-6 (cm)	---	---	0.0790
		y-6 (cm)	---	---	0.0811
	PD (msec)		0.127	---	0.127
	PRF(Hz)		3840	---	3840
	EBD	Az. (cm)	---	0.600	---
		Ele. (cm)	---	0.600	---

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

Acoustic Output			MI	ISPTA.3 (mW/cm ²)	ISPPA.3 (W/cm ²)
Global Maximum Value			0.126	0.150	20.6
Associated Acoustic Parameter	Pr.3 (MPa)		0.528	---	---
	Wo (mW)		---	0.0183	0.0183
	Fc (MHz)		17.6	17.6	17.6
	Zsp (cm)		1.10	---	1.10
	Beam Dimension	x-6 (cm)	---	---	0.0417
		y-6 (cm)	---	---	0.0426
	PD (msec)		0.0550	---	0.0550
	PRF(Hz)		3840	---	3840
	EBD	Az. (cm)	---	1.49	---
		Ele. (cm)	---	0.700	---

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 12.9 - Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

The Accutome Connect is intended for use in the electromagnetic environment specified below. The customer or the user of the Connect should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11*	Group 1	The Connect platform 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 Connect platform 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 12.10 - Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

The Connect is intended for use in the electromagnetic environment specified below. The customer or the user of the Connect 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 12.11 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Connect is intended for use in the electromagnetic environment specified below. The customer or the user of the Connect 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 Connect, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2/P$ $d = 1.2/P$ 80 MHz to 800 MHz $d = 1.2/P$ 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 metres (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 Connect is used exceeds the applicable RF compliance level above, the Connect should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Connect platform.

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

13

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.

Toll Free (In US):	(800) 979-2020
International:	(610) 889-0200
Europe:	+31 (0) 485-350300
Fax:	(610) 889-3233

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
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 Connect platform. Please contact Accutome for additional information.

Troubleshooting

Table 13.1 - 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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