

B-Scan ^{PLUS}



B-Scan Plus 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 B 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 manual, 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 from that to which the receiver is connected.
- 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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1

Introduction

Accutome B-Scan Plus Overview

The Accutome B-Scan Plus provides high quality B-Scan imaging and playback with the ease of plugging into any computer in the world. The Accutome B-Scan Plus also has many additional features that allow multiple methods of viewing, diagnosing and printing acquired images.



Figure 1.1 - Accutome B-Scan Plus Components

Features

The Accutome B-Scan Plus images the internal structure of the eye is designed for easy access to all functions.

The B-Scan provides the following general features:

- Adjustable TGC (Time Gain Compensation) curves
- Gamma Settings (Post Image Processing)
- Automatic Image Orientation Labeling
- A-Vector
- Image Annotation
- Image Movie Playback
- Image Diagnostic Measurements - Distance and Area
- Patient data storage and retrieval
- Patient data reports and printouts

Adjustable TGC Curves

The Accutome B-Scan Plus allows you to adjust the Gain, Time Gain Compensation (TGC) as a default in Setup, live during an exam or on a saved existing exam.

Gamma Settings

The Accutome B-Scan Plus allows you to adjust the Gamma settings as a default in Setup, live during an exam or on a saved existing exam.

Gain Adjustment

The Accutome B-Scan Plus allows you to adjust the signal gain while scanning or on a saved image enhancing image quality.

Automatic Image Orientation Labeling

The Accutome B-Scan Plus allows you to set image orientation labels as a default in Setup, live during an exam or on a saved existing exam.

Image Playback

The Accutome B-Scan Plus allows you to play live images during scanning or to playback saved images.

Measurements

The Accutome B-Scan Plus provides several types of image measurements:

- Point- to-Point
- Distance
- Area

Patient Data Storage and Retrieval

The Accutome B-Scan Plus saves all patient exams in a preset designated folder on the user computer, allowing you to playback, archive and backup any and all patient exams.

Reports and Printouts

The Accutome B-Scan Plus 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.

Components

The components that are standard with each Accutome instrument are:

- B-Scan Ultrasound Probe
- Probe Holder
- Footswitch
- Wireless Mouse
- This User Manual
- CD containing Accutome B-Scan software

All components are packed in a plastic carrying case. The user supplies a PC with Windows XP SP2 as the operating system.

About This Manual

This manual is a guide for technicians and ophthalmologists who are experienced in ultrasonographic biometric techniques.

This manual is organized as follows:

Section 2 - Safety

Summarizes safety precautions, warnings, symbols and terms.

Section 3 - Getting Started

Provides installation instructions, overview of Accutome B-Scan Plus basic operation.

Section 4 - Accutome B-Scan Plus Setup

Provides instructions on how to set up physicians, users, and system operational functions.

Section 5 - Performing Exams

Provides detailed instructions on how to acquire exam images.

Section 6 - Patient Image Analysis

Describes how to review and make comments for an individual patient.

Section 7 - Printing Images and Reports

Provides detailed instructions on how to print patient exam images, create and print or save reports.

Section 8 - Archive

Provides instructions on how to recall patient exams and archive exams to a CD or DVD.

Section 9 - Maintenance

Provides general maintenance instructions.

Section 10 - Specifications

Provides Accutome B-Scan Plus physical and operational specifications

Section 11 - Warranty and Repairs

Describes Accutome B-Scan Plus warranty information and repair procedures.

Having read this manual you will be able to set up the Accutome B-Scan Plus, perform scans, playback, save frames as snapshots, analyze images, print snapshots, create reports and archive patient exams.

2

Safety

Safety Information

The section lists:

- Safety Precautions associated with the Accutome B-Scan Plus
- Safety Precautions of a general nature

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Safety Issues to Consider When Using the Accutome B-Scan Plus

The Accutome B-Scan Plus is non-invasive. The ultrasound probe touches the surface of the anesthetized eye during image acquisition, and energy in the form of ultrasound is transmitted into the eye. The power level of the ultrasound pulses is controllable by the Application Software, and the user has control of this power setting. 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. The Accutome B-Scan Plus Probe must be cleaned and disinfected before use.

Indications for use

This instrument is used for imaging the internal structure of the eye including the opaque media and posterior pathology for the purpose of diagnosing pathological or traumatic conditions in the eye.

WARNING! THE B-SCAN PLUS IS NOT INTENDED FOR FETAL USE!

Disposal Requirements

The B-Scan Plus contains electronic components. At the end of its useful life it must be properly disposed of in compliance with local regulations.

Disposal of the product within the EU

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

Symbol Definitions for the Accutome B-Scan Plus

Statements, graphics and symbols listed on the next page are used on components of the Accutome B-Scan Plus. Descriptions and meanings are listed to the right of the symbols.

Safety Precautions

There are several areas in the use of the Accutome B-Scan Plus that require special

Symbol Definitions for the B-Scan Plus



Attention! Consult Instruction Manual



Type B Medical Device



No User Serviceable Parts



Do Not Use Near Flammable Gasses



Type II Insulation



Disposal of Product within the EU

attention, as they may pose a safety threat.

WARNING! DO NOT AUTOCLAVE!

WARNING! DO NOT IMMERSE THE PROBE TIP IN TAP WATER AS THE FLUORIDE CAN DAMAGE THE CRYSTAL.

Disinfection and Cleaning

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

Accessories such as the extension handle or Goldman Tonometer Adapter which might come in contact with eye fluids should be cleaned with an FDA cleared high level disinfectant. The probe must be cleaned between patients to prevent patient-to-patient transfer of infection. It is the user's responsibility to ensure that

the relevant standards are maintained and that the products and procedures are effective and appropriate for ophthalmic applications. The following information is provided for the guidance of users, and specific products are mentioned for illustration only. Accutome does not endorse the use of these or any other product. Products must be used in accordance with the manufacturer's instructions.

Safety Precautions

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 WIPE THE PROBE END; IT MAY RESULT IN DAMAGE TO THE CRYSTAL.

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

Cleaning Procedure at Point of Use

Clean the probe handle with a damp cloth. Use appropriate products to clean the computer, keyboard and monitor. Cables may be cleaned with a soft cloth and alcohol. The probe holder should be washed with warm water and mild detergent. Probe and Transducer:

The user must use the following procedure to clean the transducer and probe daily: Keep the transducer and probe connected, soak/rinse the transducer and probe end thoroughly with distilled water.

- Inspect all surfaces carefully for debris or build up.
- If there is still debris, soak/rinse the transducer and probe tip end with distilled water again. Repeat until all debris is gone.
- Let the transducer and probe air dry.

Disinfection of the Probes with Alcohol

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

A 5-10 minute exposure is recommended. It is imperative that the alcohol be given to time to evaporate before applying a probe to that 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 the liquid used.

Let transducer and probe air dry.

High- Level Disinfection of the Probe

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

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

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

Electrical Hazard and Safety

The instrument, foot switch and probe of the Accutome B-Scan Plus are electrical/electronic devices. Reasonable care should be taken when making electrical connection and handling electrically powered devices. Avoid use of damaged electrical equipment or frayed electrical cords. If repair or maintenance is being performed, the equipment must be turned off and the power cord disconnected.

WARNING! THE B-SCAN PLUS IS ONLY TO BE USED WITH A COMPUTER USING A MEDICAL

GRADE POWER SUPPLY COMPLIANT WITH IEC60601-1.

Please refer to the manufacturer's instructions regarding its use.

The User is responsible for ensuring that the PC to which the B-Scan Plus system is connected must be of the grounding type in compliance with applicable electrical codes.

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

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

Avoiding Equipment Damage

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

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

Avoiding Electromagnetic and Other Interference

Do not use a cellular telephone and other devices not complying with EMC Class B requirements, as its signals may cause the equipment to malfunction. The effect of radio signals on medical devices is dependent on various factors and therefore unpredictable.

To avoid electromagnetic interference, the device must be installed and put into operation in accordance with the user manual 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 B-SCAN PLUS.

WARNING! THE B-SCAN PLUS SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT AND THAT IF ADJACENT OR STACKED USE IS NECESSARY, THE B-SCAN PLUS SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

3

Getting Started

Assembling the Accutome B-Scan

The B-Scan Plus accurately images intraocular structures of the human eye using ultrasound. The product consists of a B-Scan Plus Ultrasound Probe, a Probe Holder, a footswitch, a wireless mouse, a User Manual, and a CD containing the Accutome software, all packed in a plastic carrying case. The user supplies a PC with Windows XP SP2 as the operating system.

The Accutome B-Scan Plus is designed to be used in multiple environments and is as simple as carrying a notebook computer and probe.

The instrument requires virtually no assembly. You simply need to install the software and plug the probe, the mouse receiver and footswitch into your computer's USB ports and activate the USB ports.

What you need

For a complete Accutome environment you will need the following:

- Windows XP based Personal Computer (PC) - Accutome recommends Dell™ Latitude D820
- Accutome Ultrasonic B-Scan Plus Probe
- Accutome B-Scan Plus software
- 4 USB Port(s)
- Wireless Mouse
- Printer
- Footswitch

PC

The computer used for the Accutome B-Scan Plus should meet the requirements outlined in Table 1.1 below:

Table 1.1 - B-Scan Computer Specifications

PC	Dell™ Latitude D820 with Intel Core™ 2 Duo T7200 (2.00GHz) 4M L2 Cache, 667MHz Dual Core or equivalent with USB ports
Operating System	Genuine Windows® XP Professional, SP2, with media
LCD	15.4 inch Wide Screen WSXGA+ LCD Panel or larger
Memory	2.0GB, DDR2-667 SDRAM, 2 DIMMS
Hard Drive	80GB Hard Drive, 9.5MM, 7200 RPM
Module Bay Devices	8X DVD+/-RW w/Roxio Software™ and Cyberlink Power DVD™, no media
Graphics	256MB NVIDIA® Quadro NVS 110M TurboCache™
Power Supply	Medical Grade Power Supply or Isolation Transformer

***Note:** You will also need a printer connected to the computer to print snapshots or reports.

Probe

The probe provided with the B-Scan Plus is an essential component of the product. No other probes should be used with the instrument.

Printer

The Accutome B-Scan Plus can utilize any PC compatible printer that is connected to the B-Scan Plus computer.

Footswitch

The footswitch can be used to start and stop scan image acquisition.

Installing the Software

The Accutome B-Scan Plus software is shipped on a CD which contains all of the programs you will need to install for proper system operation.

PLEASE READ THROUGH ALL OF THE INSTALLATION INSTRUCTIONS BEFORE INSTALLING ANY SOFTWARE!!

IMPORTANT:

1. DO NOT plug the Accutome Probe into the USB port until all application software and drivers have been installed.
2. Plug the wireless mouse USB adapter (which is found on the underside of the mouse) into a USB port which will not be used for the Accutome Probe
3. Turn your computer to "On".
4. Follow the steps below to install Accutome's B-Scan Plus software to a personal computer.
5. Your computer must have Microsoft Windows XP SP2 and .NET Framework 1.1 installed to operate the Accutome B-Scan Plus properly.

Installation - Phase One

Follow the steps below to check for and, if necessary, install **.NET Framework 1.1** on your computer:

1. Open the Control Panel window by clicking on Start located on the bottom left corner of the window. Click on Control Panel located on the right side of the pop-up menu.
2. In the Control Panel window, click on Add or Remove Programs. The Add or Remove Programs window will appear on the desktop. Scroll down the list to find Microsoft .NET Framework 1.1 in the Currently Installed Programs list. If you CAN NOT find Microsoft .NET Framework 1.1 in the list, proceed to step 3 below. If you DO find Microsoft .NET Framework 1.1 in the list, proceed to install the Accutome B-Scan Plus software found in Installation - Phase Two on page 10. Be sure to close the Add or Remove Programs window and the Control Panel window before you proceed.
3. Install the Microsoft .NET Framework 1.1 program which is included on the Accutome B-Scan Plus installation CD. Install the Microsoft .NET

Framework 1.1 program included on the Accutome B-Scan Plus installation CD. Insert the installation disk into the CDROM drive. The installation process will automatically start, and a window with Preparing to Install ... will open. Click on Cancel to stop the installation process. Open the My Computer window by clicking on Start located on the bottom left corner of the screen. Click on My Computer located on the right side of the popup menu. Right click on the B-Scan Install icon (CDROM drive) and select Open. Double click on the icon dotnetfx.exe. Click Yes when the Microsoft .NET Framework 1.1 Setup window appears. When the License Agreement window appears, click I agree then click Install. Click OK to complete the installation.

4. After finishing installation of the .NET Framework 1.1, double click on the Setup.exe icon on the B-Scan Install window, and go directly to step 2 of Installation - Phase Two on page 10.

Installation - Phase Two

Follow the steps below to install the Accutome B-Scan Plus software.

1. Insert the installation disk into the CDROM drive. The installation process will automatically start and a window with Preparing to Install ... will open. If the installation does not automatically begin, open the My Computer window by clicking on Start located on the bottom left corner of the screen. Double click on the B-Scan Install icon and double click on Setup. It will take several seconds to unpack the installation programs. Advance through the windows by clicking Next.
2. When the window titled Welcome to the InstallShield Wizard for Accutome B-Scan appears, click on Next. Click on I Accept the Terms in the License Agreement when the License Agreement window appears. Click on Next and then Install. Click Finish once installation is complete.
3. Double click on the icon Launch DXSETUP.exe on the computer desktop screen to install Microsoft DirectX 9.0. Click on I Accept Agreement, then Next and then Next again to start installation of Microsoft DirectX 9.0. Click Finish to complete software installation.

Installation - Phase Three

Follow the steps below to set up the Accutome B-Scan Plus probe and USB port(s).

1. Insert the Accutome B-Scan Plus probe into any USB port. Select the port that is most convenient for you to use while taking image scans. The Found New Hardware Wizard window will appear on the desktop. Select No, not this time and click Next.
In the next screen, make sure Install the Software Automatically (Recommended) is selected, then click on Next. The system will find the driver for the probe and the window Hardware Installation will appear. Click Continue Anyway and then Finish.
After the driver has been installed and all windows are closed, the window Found New Hardware Wizard will reappear. You will need to repeat the above two steps one more time to finish the probe driver installation for this USB port.
2. We recommend that you install the Accutome B-Scan Plus probe driver on at least two USB ports in the event one port is already being used by

another device. The Accutome B-Scan Plus probe will not work properly on any USB port on which it has not been installed.

To install the Accutome B-Scan Plus probe on another USB port, repeat section I. Be sure to unplug the probe from the current USB port and insert it into the new USB port to start setup of the new USB port.

3. Unplug the Accutome B-Scan Plus probe from the USB port and eject the installation CD from the CDROM drive. Reboot the computer by clicking on Start, then Shut Down, then Restart, then OK.
4. After the computer restarts, login (if necessary) to your account. Wait until the desktop appears, then plug the probe into any of the USB ports that have been set up. Wait 10 seconds after connecting the Accutome B-Scan Plus probe, then double click the Launch Accutome B-Scan.exe icon on the desktop to start the Accutome B-Scan Plus program. **Please remember that the probe must be plugged into a USB port that has been set up before starting the program.**

Probe

The Accutome B-Scan Plus probe is an integral component of the Accutome B-Scan Plus product. The probe is easily installed by connecting the end of the cable into the B-Scan's computer USB port. The marker at the top of the probe is easily aligned with eye tissues during scanning and the start/stop button makes operation simple. Image scanning can also be started or stopped with the footswitch.

***Note:** You cannot acquire image scans with the Accutome B-Scan Plus product without the Accutome probe.



Figure 3.1 - Accutome B-Scan Plus Probe

Footswitch Setup

The footswitch provided with Accutome B-Scan Plus can be used to start and stop scanning. The footswitch is simple to install; plug the end of the footswitch cable into a USB port on the computer running the Accutome B-Scan Plus.



Figure 3.2 - Accutome B-Scan Plus Footswitch

Basic Operation

The basic operation of the Accutome B-Scan Plus consists of the following steps:

1. Turn on the Accutome B-Scan Plus computer.
2. Start the Accutome program (refer to "Starting Accutome B-Scan Plus Program" below).
3. Start a new exam (refer to "How to Start a New Patient Exam")
4. Enter patient exam information (refer to "How to Start a New Patient Exam" on page 20).
5. Set up the scan
6. Scan the patient eye(s).
7. Make any necessary image adjustments
8. Analyze the image.
9. Print or save the Patient Report.

Starting Accutome B-Scan Plus Program

The Accutome B-Scan program is launched like any other Windows program, either through a shortcut on the desktop or by accessing the "Start > All Programs" menu.

1. If launching the B-Scan Plus software from the desktop, click on the icon displayed below. The B-Scan Plus software will display at the main screen.



Figure 3.3 -
Accutome B-Scan
Plus Desktop
Shortcut

How to Start a New Patient Exam

To start a new Patient exam:

1. On the Accutome Main Screen, click on "New Exam". Refer to Figure 3.4 below.



Figure 3.4 - Main Screen Starting New Exam

Entering Patient Exam Information

After you execute "New Exam" from the Accutome B-Scan Plus main screen the Patient Exam Screen will launch shown in Figure 3.5 on the next page. The pre-filled information fields the setup defaults.

1. When you start a new exam the Accutome B-Scan will launch the Exam Info Screen shown below and will clear all fields.

***Note:**The Patient/Exam Info Screen contains drop down lists that are created during B-Scan setup. Refer to Section 4, Setup for further information.

Figure 3.5 - New Exam Info Screen

2. Enter information in data fields by clicking in each field and typing accordingly. In Figure 3.6 the First Name field has just been completed.

To move from one field to another you may use the Tab Key on your computer keyboard.

3. The Patient Name must be entered to proceed to the next screen. Select the First Name field and enter the Patient First Name.
4. Use the Tab key, or select the Last Name field and enter the Patient Last Name.
5. Continue entering all relevant Patient information.
6. If you wish to select a Facility, select one from the predefined (in B-Scan Setup) Facility drop down list. Position the cursor on the small arrow at the right of the facility field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list. Click the mouse to move through stored facilities. Once you see the facility you want to select, position the mouse cursor over the facility and left click. The selected facility will fill in the facility field.

Figure 3.6 - Entering New Patient Information

Figure 3.7 - Selecting Facility

7. Continue to select Physician and Operator from the drop downs lists located at the right side of the each field.
Position the cursor on the small arrow at the right of the physician and operators fields. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list Click the mouse to select physician and operators. Once you see the Physician and Operator fields, select position the mouse cursor over the Operator field and left click. The selected Physician and Operator field.
8. Select a predefined or undefined Scan Group and Protocol (Sequence) within the group. from the Scan Group and Protocol drop down lists.
Position the cursor on the small arrow at the right of the Scan Group and Protocol fields. Left click to open the drop down lists. Position the mouse over the up/down arrows at the right of the drop down lists. Click the mouse to move through stored Scan Group and Protocols. Once you see the Scan Group and Protocols, to select position the mouse cursor over the Protocol field and left click. The selected Scan Group and Protocol field.
9. Click on the "Start" button, located at the bottom right of the Patient/Exam Info Screen.
10. The Accutome B-Scan Plus will launch the Exam Screen shown below.

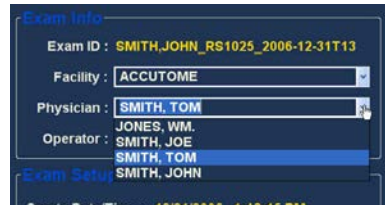


Figure 3.8 - Selecting Physician

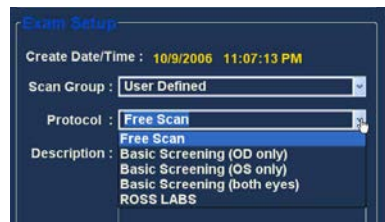


Figure 3.9 - Selecting Scan Group and Protocol



Figure 3.10 - Selecting Scan Group and Protocol

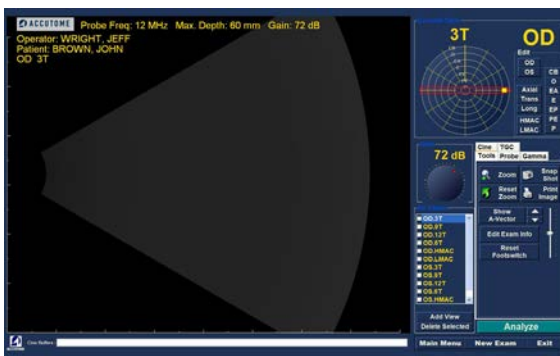


Figure 3.11 - Exam Screen

Operation

After you have entered all the Patient information and prior to scanning you should set the imaging selections to your liking.

The selections you can change are:

- Current View - OD/OS which eye are you measuring, OD or OS? Which orientation is the probe, Axial, Transverse, or Longitudinal
- Probe - available adjustments are range and power
- Cine - available adjustments are Frame Averaging and Frame Render Delay
- TGC - do the System Near, Mid and Far values need adjustment?
- Gamma - Does the Gamma setting need adjustment?

All imaging selections (other than current view) are available in the Tools palette, by selecting the tab. See Figure 3.12 for tools location.

The figures that follow show the imaging tools in their respective tabs; select the tab to display the tools.



Figure 3.12 - Tools Palette and Current View



Figure 3.13 - Probe Tab Active



Figure 3.14 - Cine Tab Active



Figure 3.15 - TGC Tab Active



Figure 3.16 - Gamma Tab Active

Scanning

To capture a patient scan image:

1. Adjust any Probe, Cine, TGC or Gamma settings using the appropriate tab.
2. Click on "Scan" on the Probe tab, or press the start/stop button on the probe, or step on the footswitch to activate the image acquisition film loop.
3. Once the scanning is started the B-Scan Plus computer will store the last "X" seconds of image data (predetermined in Setup, Cine Buffer).
4. When you stop the scanning by either using the trigger switch on the probe, the footswitch, or by clicking "Stop" on the Exam Screen, the Accutome B-Scan Plus will stop the Image Acquisition film loop. To go to the next

view in the sequence you must step on the footswitch or press the start/stop button on the probe. The B-Scan Plus will also create a new view in the sequence if you continue to scan after completing all the defined sequence steps.

***Note: For detailed information on scanning refer to “Performing Exams” on page 89 of this manual.**

How to Print an Exam

After you have acquired and analyzed a patient exam you may want to print a portion of the exam.

To print an image of an scan:

5. With the appropriate Patient exam active, press the “Snapshot ” or “Print Image” button, located to the right side of the image display.
6. The Accutome B-Scan Plus will copy or print the screen. Snapshots are saved as part of the patient exam.
7. You can view and revise all snapshots for printing in an existing exam using the “Reports” tab on the Analyze screen.

***Note:For detailed information on printing and reports refer to “Printing Images and Reports” on page 173 of this manual.**

How to Save Patient Exams

1. The Accutome B-Scan Plus allows you to save patient records at any point during the exam. Whenever you start/stop a scan, using the probe or footswitch, the scan just completed is saved in the patient’s exam folder.
2. There is no need to do anything other than operating the B-Scan Plus to save patient exams. To complete an exam you must leave the screen for the active patient; select “Main Menu”, “New Exam”, “Exit” or “Analyze”. The active patients exam will close and contain all scans made.

4

Setup

Setting Up the B-Scan Plus

The Accutome B-Scan Plus is equipped with personal preference options, and provides the flexibility necessary to customize your instrument. You can not only create new scanning sequences, you can also set many operational defaults.

Setup options include:

- Adding new Users
- Adding Physicians
- Creating Sequences
- Editing Sequences
- Setting New Exam Defaults, including Gamma, TGC, and Information Displayed

How to Access Setup

After you launch the Accutome software the main screen shown in Figure 18 below will be displayed. Select "Setup" and click to launch the Setup window.

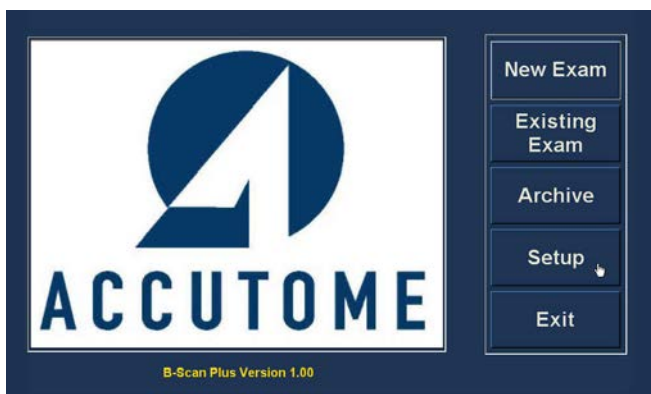


Figure 4.1 – Selecting Setup

Setup Menu Selections

When you select "Setup" the Accutome B-Scan Plus displays the setup window shown below. The window has tabs that correspond to the various setup features. Each tab will display the corresponding screen upon selection. The default tab upon launching setup is "Facilities" as shown in Figure 4.2.

The Setup tabs are as follows:

- Facilities - location to add, edit and delete exam facilities
- User - location to add, edit and delete Accutome B-Scan Plus users
- Sequences - location to add, edit and delete probing sequence protocols

- Options - location to edit application and image control options
- Physicians - location to add, edit and delete physicians associated with the Accutome B-Scan Plus

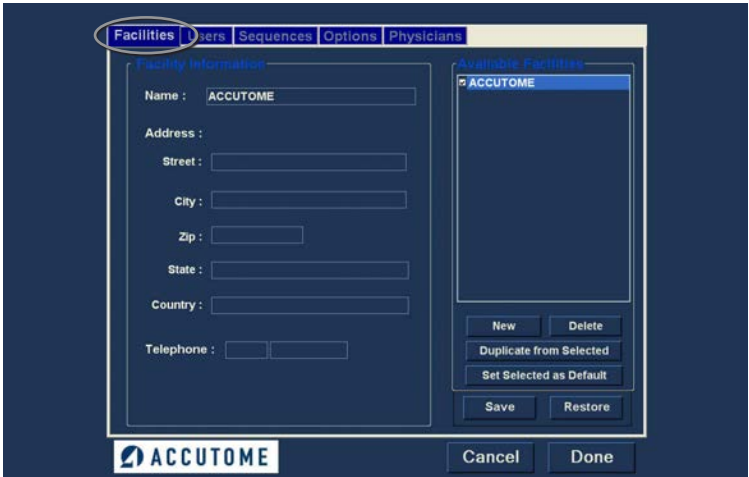


Figure 4.2 - Setup Facilities Tab

Facilities

The Facilities tab (and related screen) is the first tab displayed upon starting Setup. The Accutome B-Scan Plus provides the ability to add facilities where exams will take place. The list of available facilities is displayed at the right of the screen and command buttons related to facility functions are located below the list.

How to Add New Facilities

To add a new facility:

1. In the Facilities screen select "New" as shown in Figure 4.3.



Figure 4.3 - Selecting "New" Facility

2. Activate the Name area under the Facility Information area as shown below.
The available information fields are:
 - Name
 - Address
 - Description

Figure 4.4 - New Facility Information Active

3. After entering all facility data click “Save” to save the information.
4. An “Update Restore Point” dialog will launch. If you would like to save all changes, and have the current facilities setup become the data restore point click “Yes”. If you would like to retain the old data restore point click “No”.

Figure 4.5 - Saving New Facility

Deleting Facilities

To delete a facility:

1. Select the facility you would like to delete from the “Available Facilities” list.
2. Click on “Delete”.
3. The facility will be deleted from the list of Available Facilities.

Duplicate Facilities from Selected

To duplicate a facility’s information:

1. Select the facility you would like to duplicate from the “Available Facilities” list.
2. Click on “Duplicate”.
3. A copy of the facility will be displayed in the list of Available Facilities with “[1]” beside the name. If you make more than one copy the number will

- increment with each copy.
4. You may change any facility information as needed.

Set Selected Facility as Default

To set a facility as the default B-Scan operation:

1. Select the facility you would like to become the default from the “Available Facilities” list.
2. Click on “Set Selected as Default”.
3. The facility will become the default to appear when you power up the Accutome B-Scan Plus.

Save

To save all facility information:

1. Click on “Save”.
2. An “Update Restore Point” dialog will launch. If you would like to save all changes, and have the current facilities setup become the data restore point click “Yes”. If you would like to retain the old data restore point click “No”.



Figure 4.6 - Update Restore Point Dialog

Restore

To restore the previously saved facility information:

1. Click on “Restore”.
2. A “Restore Facilities” dialog will launch. Click “Yes” to revert to the previously saved facilities information.



Figure 4.7 - Restore Facilities Dialog

Users

The Users tab (and related screen) is the second tab from the left in Setup. The Accutome B-Scan Plus provides the ability to add Users to a B-Scan user list.

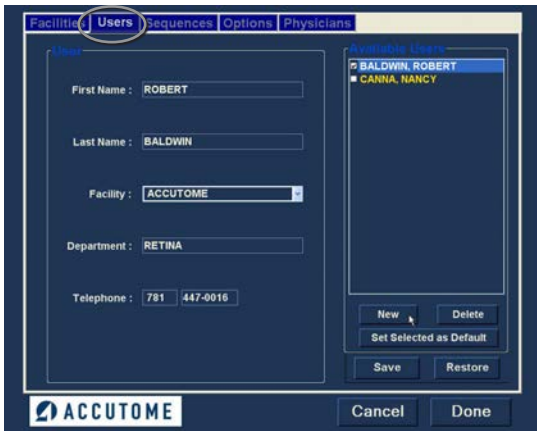


Figure 4.8 - Users Screen

How to Add a New User

To add a new user:

1. In the Users screen select "New" as shown in Figure 4.9.
2. Activate the Name area under the Users Information area as shown below. The available information fields are:
 - First Name
 - Last Name
 - Facility - select entered facility from drop down menu
 - Department
 - Telephone

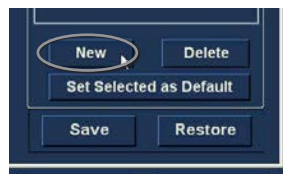


Figure 4.9 - Users Screen, New User

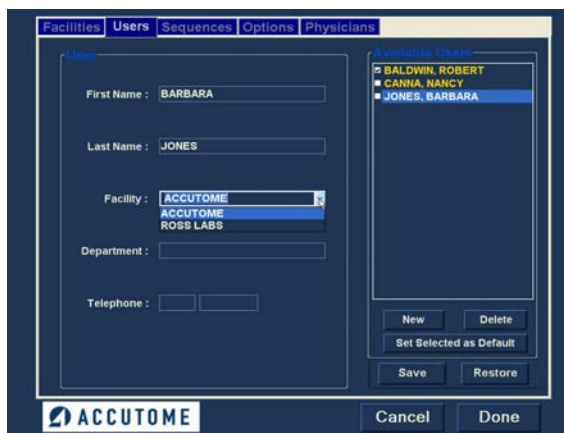


Figure 4.10 - New User Information Active

3. After entering all user data click "Save" to save the information.
4. An "Update Restore Point" dialog will launch. If you would like to save all changes, and have the current users setup become the data restore point click "Yes". If you would like to retain the old data restore point click "No".

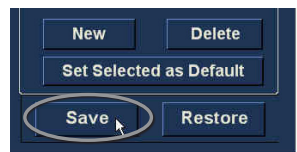


Figure 4.11 - Saving New User

Deleting Users

To delete a user:

1. Select the user you would like to delete from the "Available Users" list.
2. Click on "Delete".
3. The user will be deleted from the list of Available Users.

Set Selected User as Default

To set a user as the default B-Scan operation:

1. Select the user you would like to become the default from the "Available Users" list.

2. Click on "Set Selected as Default".
3. The user will become the default to appear when you power up the Accutome B-Scan Plus.

Save

To save all user information:

1. Click on "Save".
2. An "Update Restore Point" dialog will launch. If you would like to save all changes, and have the current users setup become the data restore point click "Yes". If you would like to retain the old data restore point click "No".



Figure 4.12 - Update Restore Point Dialog

Restore

To restore the previously saved facility information:

1. Click on "Restore".
2. A "Restore Users" dialog will launch. Click "Yes" to revert to the previously saved users information.

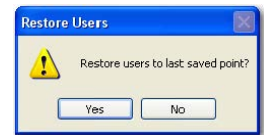


Figure 4.13 - Restore Users Dialog

Sequences

The Sequences tab (and related screen) is the third tab from the left in Setup. The Sequences screen (see Figure 4.14 below) allows you to set up operational protocols for the Accutome B-Scan Plus. A Sequence is the series of predefined scans with labelled views, scan methods and positions that are executed during B-Scan diagnostic imaging. A Sequence is defined by the following:

- Number of scans (or views)
- Eye being scanned -OD/OS during each scan
- Probe scanning method for each scan
- Probe position for each scan

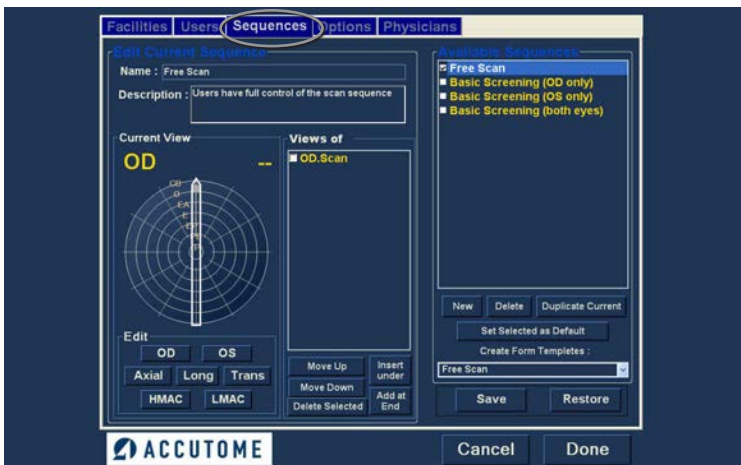


Figure 4.14 - Sequences Screen

How to Create Sequences

The process for creating sequences consists of:

1. Adding a new sequence
2. Adding scans for the sequence
3. Defining each scan

The list of available sequences is displayed at the right of the screen and command buttons related to available sequences are located below the list.

How to Add New Sequences

To add a new sequence:

1. In the Sequences screen select "New" as shown in Figure 4.15.
2. The B-Scan Plus will list the new sequence as "Undefined" in the Available Sequences list.



Figure 4.15 - Adding New Sequence

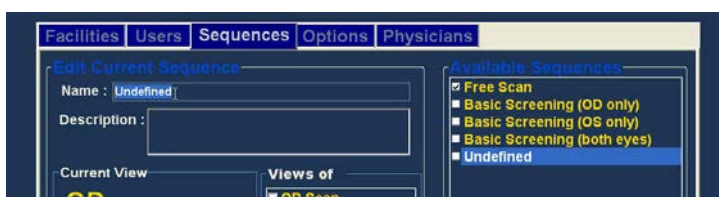


Figure 4.16 - Adding New Sequence

3. In the Name field, located below "Edit Current Sequences" enter the name of the newly added sequence. When you have finished entering the new name the sequence name in "Available Sequences" will be renamed as shown in Figure 33 below. Enter a description of the scanning sequence in the description field if necessary.



Figure 4.17 - Assigning Name to New Sequence

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

1. Select the first view, or scan, of the new sequence by either clicking in the checkbox or double clicking on the scan title [e.g. OD.Scan] as shown in Figure 4.18 below.

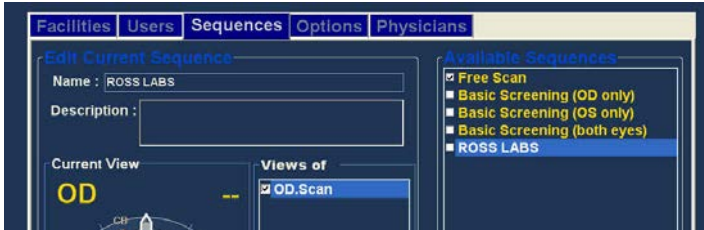


Figure 4.18 - New Sequence - New View Active

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.

Edit Current View Selections

The Accutome B-Scan Plus provides all the tools necessary to change the sequence scan view. Using the Edit Current View selections you can change:

- Eye - OD/OS
- Probe Scanning Method - Axial, Long (Longitudinal) and Trans (Transverse)
- Macula Scan - HMAC (Horizontal Macula), LMAC (Longitudinal Macula)
- Probe Position - Wheel with indicator representing the hours of the clock and position that the probe should be placed on the eye for the active scan. Change position by dragging the indicator.

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.

2. 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 which indicates the position and 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 I2AX [Axial] probe position, with I2 being the 12:00 position as shown in Figure 4.19.
3. If you would like to change the probe position for the scan select the tip of the position indicator and drag the indicator around the position wheel until it is at the appropriate position or hour on the clock.
4. If you would like to change the method of scanning from AX (Axial - the default) select



Figure 4.19 - First Scan Editing View

either or Long (Longitudinal) or Trans (Transverse).

- If you would like to identify the scan for scanning the macula, select either HMAC (Horizontal MACula - used with Axial method) or LMAC (Longitudinal MACula - used with Longitudinal method).

How to Add Another Sequence Scan

The "Views of" panel on the Sequences screen list all available scans in the current sequence. There are several command buttons for manipulating the sequence scans:

- Insert Under - adds a new scan under the currently selected scan
- Add at End - adds a new scan to the end of the sequence
- Move Up - moves the selected scan up in the sequence order
- Move Down - moves the selected scan down in the sequence order
- Delete Selected - deletes the selected scan from the sequence order

To add another scan to the new sequence:

1. Click "Insert Under" as shown in Figure 4.20.
2. The newly added sequence scan will display as "Scan" as shown in Figure 4.21. The "Scan" scan is active, is a free scan view and has no definition.
3. To assign a particular eye for scanning to the sequence scan either OD or OS, click on the appropriate eye. In Figure 4.21 OD is being assigned to the active scan.
4. Adjust the position for the new sequence scan by dragging the tip of the position indicator as shown in Figure 4.22. 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".



Figure 4.20 - Adding a New Sequence Scan



Figure 4.21 - New Sequence Scan (View) Added



Figure 4.22 - Change Probe Orientation

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 Figure 4.23. The indicator stopped at 3:00 AX and the label for the scan was changed from OD.Scan to OD
6. Continue to add and define new sequence scans as previously described. When your sequence is complete and ready to save click on the "Save" button as shown in Figure 4.24.

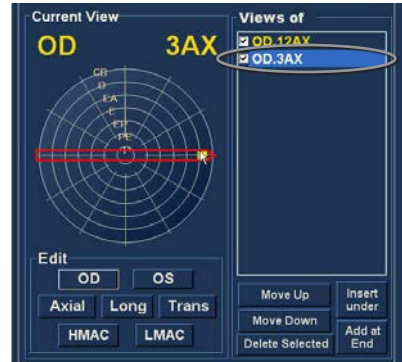


Figure 4.23 - Change Probe Orientation

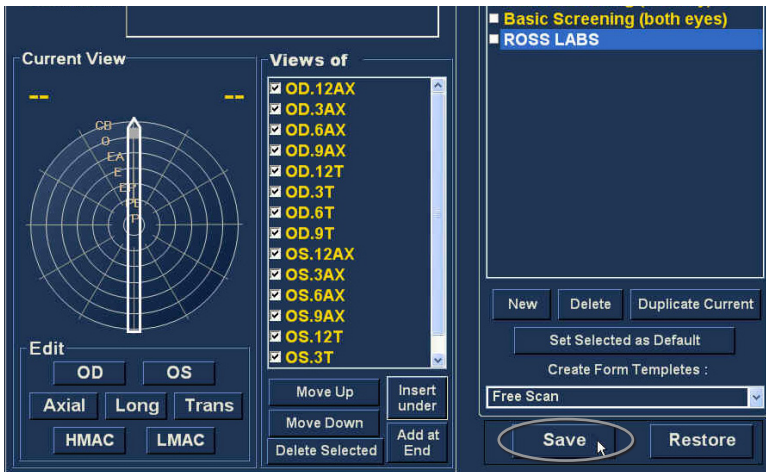


Figure 4.24 - Saving New Sequence

Deleting Sequences

To delete a sequence:

1. Select the sequence you would like to delete from the "Available Sequences" list.
2. Click on "Delete".
3. The sequence will be deleted from the list of Available Sequences.

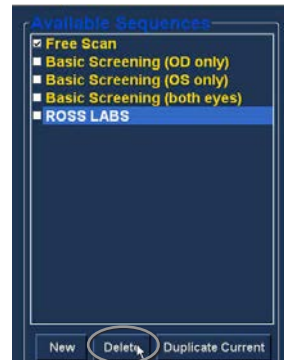


Figure 4.25 - Deleting a Sequence

Duplicate Sequences from Selected

To duplicate a sequence's information:

1. Select the sequence you would like to duplicate from the "Available Sequences" list.
2. Click on "Duplicate".
3. A copy of the sequence will be displayed in the list of Available Sequences with "[1]" beside the name. You may then change any information for the new sequence as necessary. If you make more than one copy, the number will increment with each copy.



Figure 4.26 - Duplicating Current Sequence

Set Selected Sequence as Default

To set a sequence as the default B-Scan Plus operation:

1. Select the sequence you would like to become the default from the "Available Sequences" list.
2. Click on "Set Selected as Default".
3. The sequence will become the default to appear when you power up the Accutome B-Scan Plus.

Save

To save all sequence information:

1. Click on "Save".
2. An "Update Restore Point" 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".



Figure 4.27 - Update Restore Point Dialog

Restore

To restore the previously saved sequence information:

1. Click on "Restore".
2. A "Restore Sequences" dialog will launch. Click "Yes" to revert to the previously saved sequences information.

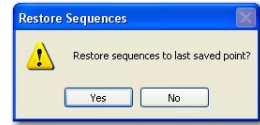


Figure 4.28 - Restore Sequences Dialog

Options

The Options tab (and related screen) is the fourth tab from the left in Setup. The Options screen (see Figure 45 below) allows you to set up optional operational parameters for the Accutome B-Scan Plus application. The options you can set are:

- exam folder
- exam name combination
- probe controls
- Start/Stop controls
- information displayed on images and measurement screen position
- filing and printing options
- Image Controls - TGC, gamma settings and gain



Figure 4.29 - Options Screen

Folders of Exams

There are two selections folders; Main and Restored. The Main folder is the location at which you store any new patient exams. The Restored Exams folder is the location which you designate for restoring patient exams.

Main Folder

The Exam Folder selection allows you to designate the location of the folder in which you would like to store new patient exams.

The default location is: C:\Program Files\Accutome\Exam Data. You can store

patient exams in any computer location you choose. To change from the default location:

1. Click on "Select" as shown in Figure 4.30 below.

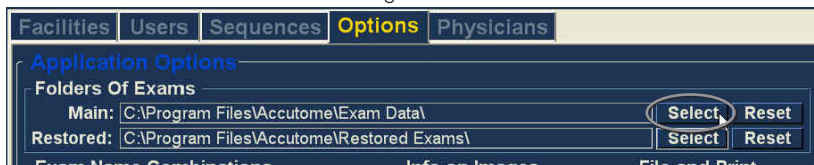


Figure 4.30 - Selecting Main Exam Folder

2. The Accutome B-Scan Plus will launch a Windows browser as shown in Figure 4.31. Using the browser locate the folder for storing exam data.
3. If you would like to restore the default folder for exam data, click on "Reset"

Restored Folder

The Restored selection allows you to designate the exam folder location to which you would like to restore patient exams from backup.

The default location is:

C:\Program Files\Accutome\Restored Exams.

You can store patient records in any computer location you choose. To change from the default location:

1. Click on "Select" as shown in Figure 4.32 below.

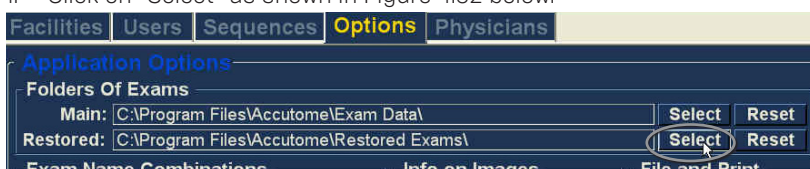


Figure 4.32 - Selecting Restored Exam Folder

2. The Accutome B-Scan Plus will launch a Windows browser as shown in Figure 4.33. Using the browser, locate the folder where you would like to restore exam data.
3. If you would like to restore the default folder for exam data, click on "Reset"

Exam Name Combination

The Exam Name Combination allows you to select how patient information will appear on a patient exam and exam record. There are many combinations of several fields that are available for the Exam Name.



Figure 4.31 - Windows Browser - Locate Exam Folder



Figure 4.33 - Windows Browser - Locate Exam Folder

The fields are as follows:

- LastName - patient's last name
- FirstName - patient's first name
- MRN - medical record number
- DateTime - date and time that exam occurred.

The default Exam Name Combination is: LastName,FirstName_MRN_DateTime

To use a combination other than the default select the combination from the drop down list as shown in Figure 4.34 below.

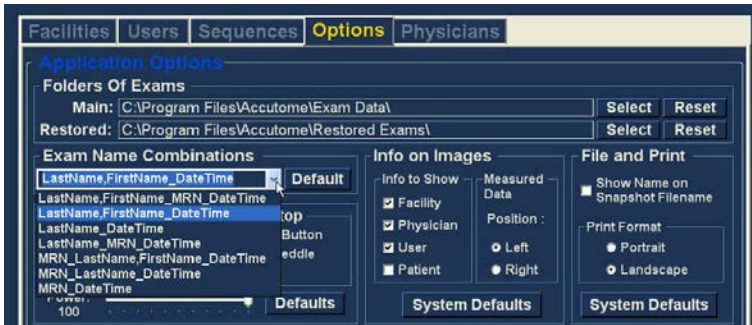


Figure 4.34 - Selecting Exam Name Combination

Probe Control

The Probe Control options allow you to change the default settings of the probe. The options are:

- Frequency
- Depth
- Cine Buffer
- Start/Stop
- Power

Frequency

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 a frequency of 15 MHz the depth options are 50 mm and 100 mm. The default probe settings are 12 MHz and 60 mm.

To change the frequency select the appropriate value from the drop down list located at the right of the frequency field as shown in Figure 4.33.

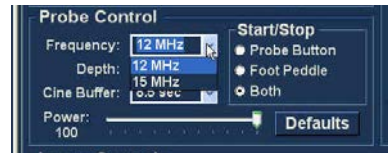


Figure 4.33 - Windows Browser - Locate Exam Folder

Depth

The depth field allows you to change the depth of the probe signal. The depth options are dependent upon the frequency selected:

- 12 MHz - depths are 30 mm and 60 mm
- 15 MHz mm - depths are 50 mm and 100 mm

The default probe settings are 12 MHz at 60 mm. To change the depth select the appropriate value from the drop down list located at the right of the depth field as shown in Figure 4.34.

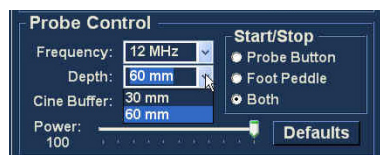


Figure 4.34 - Selecting Probe Depth

Cine Buffer

The Cine Buffer is the length of time data is stored for each acquired image. For example, with a setting of 8.5 seconds, the last 8.5 seconds of the scanning time are saved as the scanned image.

The cine buffer options are:

- 4.5 sec
- 8.5 sec
- 17 sec
- 34 sec

The default cine buffer is 8.5 sec.

To change the cine buffer select the appropriate value from the drop down list located at the right of the Cine Buffer field as shown in Figure 4.35.

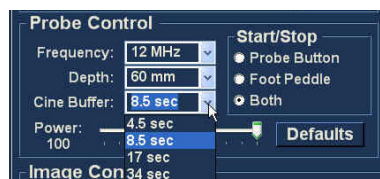


Figure 4.35 - Selecting Probe Cine Buffer

Start/Stop

The Start/Stop selection allows you to choose the method to start/stop the probe. The choices are:

- Probe Button
- Foot Pedal
- Both

To choose a start/stop option simply click the radio button beside the appropriate selection. The default setting is "Both".

Power

The Power selection allows you to adjust the power level of the signal through the B-Scan probe. The power level is indicated by a number [a percentage from 0 to 100] located beneath 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 4.36 until you reach the appropriate value.

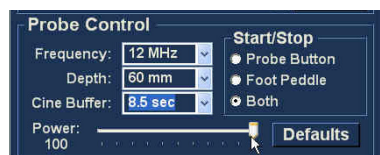


Figure 4.36 - Adjusting the Power Level

System Defaults

When you select "System Defaults" in the Probe Control area, all probe settings will return to the default settings.

Info On Images

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

- Info to Show
- Measured Data Position

Info to Show

The following fields are available to be shown on any patient image:

- Facility
- Physician
- User
- Patient

To have any of the fore mentioned fields display on an image click in the checkbox to enable the field. The default is to show the Facility, Physician and User only.

Measurement Data Position

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 left or right radio button.

File and Print

The File and Print selections allows you to show the name on the medical record snapshot filename and to select a print page format.

Show Name on Snapshot Filename

By selecting the "Show Name on Snapshot 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. To select/deselect this option simply click the checkbox. The default is to show the patient name on the snapshot filename.

Print Format

The Print Format option determines the page layout when printing a patient image; Portrait or Landscape. The default is Landscape. To change print format select either radio button.

Image Controls

One of the great features of the Accutome B-Scan Plus 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 4.37) displays how the changes will affect

image scanning. The image controls on the Setup Options Screen allow you to adjust:

- TGC
- Gamma
- Gain

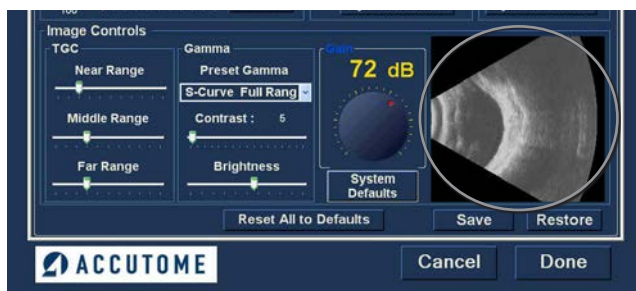


Figure 4.37 - Image Settings Before Adjustment

TGC

TGC [Time Gain Compensation] is the ability to adjust the signal gain segmentally as distance from the probe increases.

There are three TGC setup options:

1. Near - increases the gain for the anterior portion of the eye in the B-Scan image, near the probe
2. Middle - increases the gain for the middle portion of the eye
3. Far - increases the gain for the far portion of the eye

To adjust the TGC image scan presets slide the appropriate setting indicators as shown in Figure 4.37.



Figure 4.38 - TGC Adjustment

Gamma Settings

The Gamma portion of the Image Controls Setup allows you to choose a preset gamma for scanning and to adjust the brightness and contrast for captured images.

Preset Gamma

Adjusting gamma settings make certain parts of the scanned image brighter and others less bright. There are 12 preset gamma settings:

- Linear Full Range
- S-Curve Full Range
- Log Full Range
- Color
- Linear Low Range

The default gamma setting is S-Curve Full Range. To change the gamma preset select the appropriate value from the drop down list located at the right of the depth field as shown in Figure 4.39.

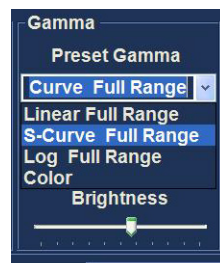


Figure 4.39 - Selecting a Preset Gamma

Contrast

You can adjust the contrast between light and dark areas of the scanned image capture by dragging the slide indicator as shown in Figure 4.40.

Brightness

You can adjust the brightness of the scanned image capture by dragging the slide indicator as shown in Figure 58 below. Figure 4.41 displays the changes made to image controls and their effect on scanning.

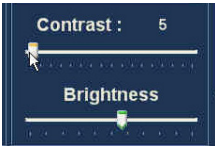


Figure 4.40 – Adjusting Contrast and Brightness

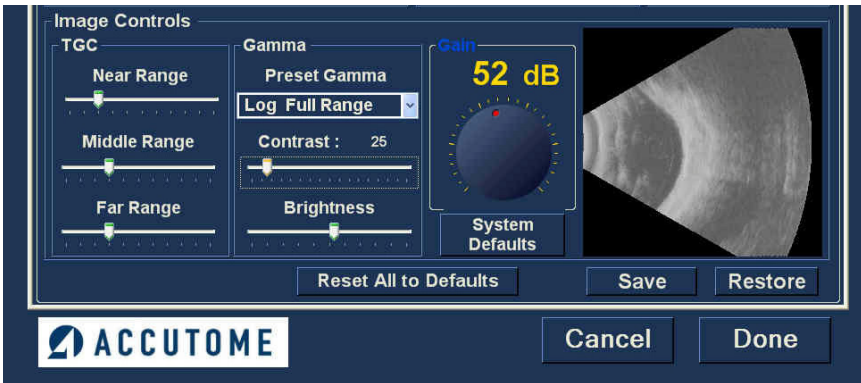


Figure 4.41 – Image Settings After Adjustments

Gain

The gain feature of the Accutome B-Scan Plus allows you to adjust the strength of the signal as it travels through the eye, thereby making the captured image brighter.

Adjusting the Gain

The Accutome B-Scan Plus provides an user-adjustable gain feature. To the left of the Small Image Window there is a knob with a red drag point. Adjustment to the gain is as simple as dragging the knob. As you adjust the gain you can see the difference in the Small Image Window. To adjust the Image Control Gain:

1. Select the red drag point the gain adjustment knob as shown in Figure 4.42.

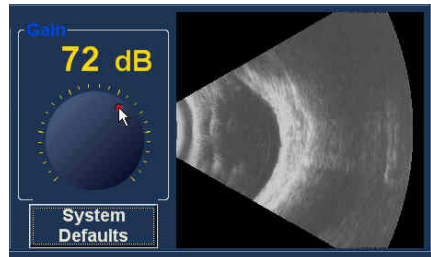


Figure 4.42 – Selecting Gain Adjustment

2. Drag the knob until the dB level (and the image visual) reaches the appropriate level as shown in Figure 4.43.

Image Controls System Defaults

If you would like to restore all adjustments made to the Image Controls to the System Defaults, select "System Defaults" located under the Gain Adjustment knob.

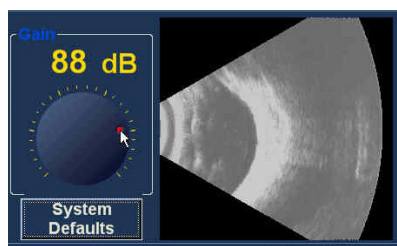


Figure 4.43 - Adjusting Gain

Reset All to Defaults

If you would like to restore all option setting adjustments to the system defaults:

1. Click on "Reset all to Defaults".
2. A "Restore All to System Setting" dialog will launch. If you would like to restore all option settings and not save changes, click "Yes". If you would like to retain the changes made to Option settings click "No".



Figure 4.44 - Restore All to System Defaults

Save

To save all option information:

1. Click on "Save".
2. An "Update Restore Point" dialog will launch. If you would like to save all changes, and have the current options setup become the data restore point click "Yes". If you would like to retain the old data restore point click "No".

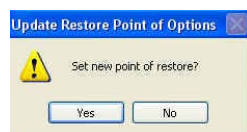


Figure 4.45 - Update Restore Point Dialog

Restore

To restore the previously saved options information:

1. Click on "Restore".
2. A "Restore Options" dialog will launch. Click "Yes" to revert to the previously saved Options information.

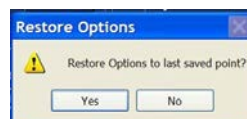


Figure 4.46 - Restore Options Dialog

Exiting Setup

When you want to leave the B-Scan Setup function you must select one of the following:

- Done - Selecting "Done" closes the Setup window and returns you to the main Accutome B-Scan Plus Screen.
- Cancel - Allows you to reject any changes that may have been made in Setup. If you select "Cancel" the dialog box shown in Figure 65 below will launch. Select "OK" if you would like to cancel all changes made and return to the B-Scan Plus main screen.

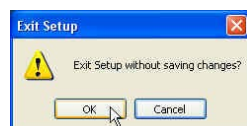


Figure 4.47 - Exiting Setup (Cancel)

Physicians

The Physicians tab (and related screen) is the fifth tab from the left in Setup. The Accutome B-Scan Plus provides the ability to add Physicians to a B-Scan Plus physician list.

How to Add a New Physician

To add a new physician:

1. In the Physicians screen select "New" as shown in Figure 4.48.



Figure 4.48 - Physicians Screen

2. Activate the Name area under the Physicians Information area as shown below. The available information fields are:
 - First Name
 - Last Name
 - Facility - select entered facility from drop down menu
 - Department
 - Telephone



Figure 4.49 - Physician Name Entered

3. After entering all physician data click "Save" to save the information.
4. An "Update Restore Point" dialog will launch. If you would like to save all changes, and have the current physicians setup become the data restore point click "Yes". If you would like to retain the old data restore point click "No".



Figure 4.50 - Saving New Physician

Deleting Physicians

To delete a physician:

1. Select the physician you would like to delete from the "Available Physicians" list.
2. Click on "Delete".
3. The physician will be deleted from the list of Available Physicians.

Set Selected Physician as Default

To set a physician as the default B-Scan Plus operation:

1. Select the physician you would like to become the default from the "Available Physicians" list.
2. Click on "Set Selected as Default".
3. The physician will become the default to appear when you power up the Accutome B-Scan Plus.

Save

To save all physician information:

1. Click on "Save".
2. An "Update Restore Point" dialog will launch. If you would like to save all changes, and have the current physicians setup become the data restore point click "Yes". If you would like to retain the old data restore point click "No".



Figure 4.51 - Update Restore Point Dialog

Restore

To restore the previously saved Physician information:

1. Click on "Restore".
2. A "Restore Physicians" dialog will launch. Click "Yes" to revert to the previously saved Physician information.



Figure 4.52 - Restore Physicians Dialog

5

Performing Exams

Overview

The Accutome B-Scan Plus is very simple to operate, and has advanced features to help you obtain the best possible images.

The Accutome B-Scan Plus creates eye images by sending a signal through the eye from the ultrasonic probe. The signal echoes off the various parts of the eye [cornea, lens, retina] and returns a signal to the probe. The returned signal is translated by the Accutome B-Scan Plus and displayed as the patient image.

The Accutome B-Scan Plus provides many user controls to obtain high quality diagnostic images. These include the probe, TGC and gamma adjustments. This chapter provides you with information to scan, control, and review images.

Exam Steps

The basic steps in performing an exam are:

1. Start a "New Exam" from the main Accutome B-Scan Plus screen.
2. Enter all necessary information on the Initial Exam Screen; i.e. patient, exam and exam setup information.
3. Start the Exam on the Initial Exam Screen.
4. Set up probe if necessary.
5. If using a preset sequence, perform the first scan in the sequence.
6. If not using a preset sequence, perform the first scan and label the scan if necessary.
7. Make any necessary image adjustments while scanning.
8. Add scan views if necessary.
9. Analyze exam or start new exam.

How to Start a New Exam

All Accutome B-Scan Plus functions are easily accessed from the main screen. To start a new exam click on "New Exam" as shown in Figure 5.1.



Figure 5.1 - Starting a New Exam

No Probe Found

If the Accutome B-Scan Plus probe is not connected, not connected properly, or for some other reason is not recognized you will receive the message Figure 72 below. If you exit the program, reinsert the probe, and restart the program, and you still receive the message please contact Accutome Customer Support for help.



Figure 5.2 - No Probe Found Message

Initial Exam Screen

Upon starting a new exam (by selecting "New Exam" from the main Accutome B-Scan Plus Screen) the Accutome B-Scan Plus launches the Initial Exam Screen shown in Figure 5.3 below. On this screen you start a new patient exam by entering Patient data and making appropriate selections for the new patient. The screen is divided into the following areas:

- Patient Info - requires you to enter current patient data
- Probe Info - displays the current probe operational specifications
- Exam Info - displays the Exam ID generated by the Accutome B-Scan Plus and provides selections for facility, physician and operator
- Exam Setup - displays exam creation date and time, and provides selections for the exam to be performed.

The Initial Exam Screen is a software interface with a dark blue background. It is divided into four main sections: "Patient Info" (top left) with fields for First Name, Last Name, Medical Record #, Date of Birth (MM/DD/YY), Gender, and Age; "Probe Info" (bottom left) displaying Frequency (12 / 15 MHz), Default Range (65 / 100 mm), Gain (98 dB), Sweep Angle (60 degree), and Serial Number (000013); "Exam Info" (top right) with dropdown menus for Facility (ACCUTOME), Physician (SMITH, TOM), and Operator (BALDWIN, ROBERT); and "Exam Setup" (bottom right) with fields for Create Date/Time (1/7/2007 3:10:22 PM), Scan Group (User Defined), Protocol (Free Scan), and a Description box containing "Users have full control of the scan sequence". At the bottom, there is an "ACCUTOME" logo and three buttons: "Exit", "Main Menu", and "Start".

Figure 5.3 - Initial Exam Screen

Entering Information on Initial Exam Screen

The Initial Exam Screen is set up like a typical Windows® application and you enter information, move between fields, and select items from drop down lists like using any other software tool.

Entering Data



When you are in a field, such as the First Name, you simply place the cursor in the field and type the appropriate information.

Moving Between Fields

To move from one field to another you can either click in the new field or use the Tab key. The tabbing order of fields on the Initial Exam Screen runs in an intuitive, sequential order.

Selecting Items from a Drop Down List

Many of the fields in the Initial Exam Screen contain a drop down list at the right of the field. To select an item from the drop down list:

1. Select the drop down arrow and scroll through the list
or
2. Use the   arrow keys to scroll through the list
or
3. Type the first letter of the item you wish to select and scroll through the list.

Patient Info

The Patient Info area displays patient information and has fields that require data entry as outlined below.

Required Fields

The only fields that require entry in the Patient Info area are the First Name and Last Name fields. Both these fields are used to create a unique patient exam record.

First Name

The Name fields in the Patient Info area require an entry of a minimum of three alphanumeric characters. There is no need to enter names in both First and Last Name fields; if you choose to enter a first name you do not have to enter a last name.

Last Name

The Name fields in the Patient Info area require an entry of a minimum of three alphanumeric characters. There is no need to enter names in both First and Last Name fields; if you choose to enter a last name you do not have to enter a first name.

Medical Record

Whether the Medical Record Number appears is determined by the Exam Name Combination selected in the Setup, Options tab. If the Medical Record Number is included in the Exam Name Combination, the Medical Record number is entered by the user. The B-Scan then generates an Exam ID based on the specific Exam Name Combination chosen. The medical record field requires an entry of a minimum of five alphanumeric characters.

Date of Birth

The patient’s date of birth is not a required field. If you choose to enter the date it should be in the MM/DD/YY format.



Figure 5.4 - Initial Exam Screen with Patient Name

Gender

The gender field provides a drop down to select either Male (M) or Female (F) as shown in Figure 5.5. Gender is not a required entry. Position the cursor on the small arrow at the right of the gender field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list. Click the mouse to move through gender. Select M or F by positioning the mouse cursor and left clicking.

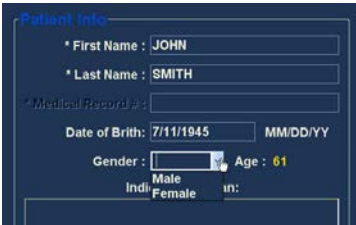


Figure 5.5 - Selecting Gender

Indication of Scan

The Indication of Scan field in the Patient Info area can be edited with any information related to patient’s scan. To add information, click in the field and type.

Probe Info

The Probe Info displayed on the New Exam initial Info Screen is informational only and is determined by the Accutome B-Scan Plus probe setup.

Frequency

The Frequency field indicates the frequency of the signal from the probe through the eye.

Default Range

The Default Range field displays the default depth range displayed on the screen. The range can be adjusted in the B-Scan Setup. (See Chapter 4 of this manual.)

Gain

The Gain field displays the gain of the image signal.

Sweep Angle

The Sweep Angle field displays the angle at which the probe sweeps the eye during imaging.

Serial Number

The Serial Number field displays the serial number of the connected Accutome B-Scan Plus probe.

Exam Info

The Exam Info area displays information related to the current exam and patient.

Exam ID

The B-Scan generates an Exam ID based on this entered Medical Record # number in combination with the date and tracking number.

Facility

In the Facility field you can select the facility for the Patient Exam by selecting the name from the drop down list. Facility names are entered in the B-Scan Setup. (Refer to Chapter 4 of this manual.)

Position the cursor on the small arrow at the right of the facility field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list. Click the mouse to move through stored facilities. Once you see the facility you want to select, position the mouse cursor over the facility and left click. The selected facility will fill in the facility field.

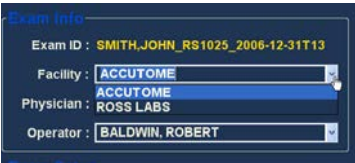


Figure 5.6 - Selecting Facility

Physician

In the Physician field you can select the physician for the Patient Exam by selecting the name from the drop down list. Physician names are entered in the B-Scan Setup. (Refer to Chapter 4 of this manual.)

Position the cursor on the small arrow at the right of the physician field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list. Click the mouse to move through stored physicians. Once you see the physician you want to select, position the mouse cursor over the physician and left click. The selected physician will fill in the physician field.

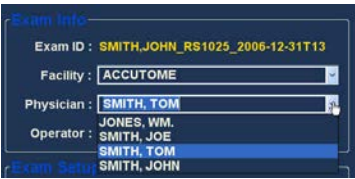


Figure 5.7 - Selecting Physician

Operator

In the Operator field you can select the operator for the Patient Exam by selecting the name from the drop down list. Operator names are entered in the B-Scan Setup on the Users tab. (Refer to Chapter 4 of this manual.) Position the cursor on the small arrow at the right of the operator field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list Click the mouse to move through stored operators. Once you see the operator you want to select, position the mouse cursor over the operator and left click. The selected operator will fill in the operator field.

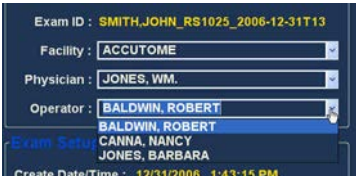


Figure 5.8 - Selecting Operator

Exam Setup

The Exam Setup area displays information relating to the date and time the current exam was created and provides selections for exam scan groups, protocols and a field for describing the selected protocol.

Create Date/Time

The Create Date/Time field displays the time stamp created by the Accutome B-Scan Plus for the time that the current patient exam was started.

Scan Group

The B-Scan Plus provides the ability to set up Imaging Sequence protocols and select the protocols for exams. The setup protocols become User Defined. When you are selecting a Scan Group you have the option to either select User Defined or System Defaults. If you would like to run a customized protocol you must select "User Defined".

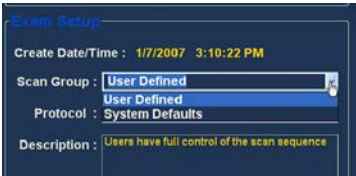


Figure 5.9 - Selecting Scan Group

Protocol

All Sequences protocols created in the B-Scan Plus Setup are listed in the Protocol drop down. If you selected System Defaults as the Scan Group all the system default protocols will be listed. If you selected User Defined as the Scan Group all the customized sequence protocols will be listed. For more information on Sequencing protocols refer to Chapter 4, Setup, of this manual.

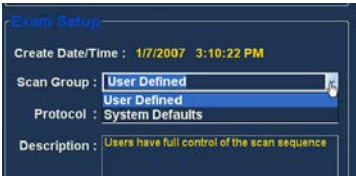


Figure 5.10 - Selecting Scan Protocol

Description

The Description field in the Exam Info area provides a description of the scanning protocol being performed with the Accutome B-Scan Plus.

Start Exam

After you have completed all necessary fields in the Initial Exam Screen and have made the appropriate selections click "Start".



Figure 5.11 - Starting New Exam

Exam Screen Features

Upon start of the exam the Accutome B-Scan Plus launches the Exam Screen. The Exam Screen displays:

- Exam Information
- Current View
- All Views
- Tools Palette with Selectable Tabs for Probe and Scan Controls
- TGC Adjustments
- Gamma Adjustments
- Zoom Controls
- Show A-Vector
- Edit Exam Info
- Analyze
- Cine Buffers Display
- Menu Buttons
- Print and Snap Shot

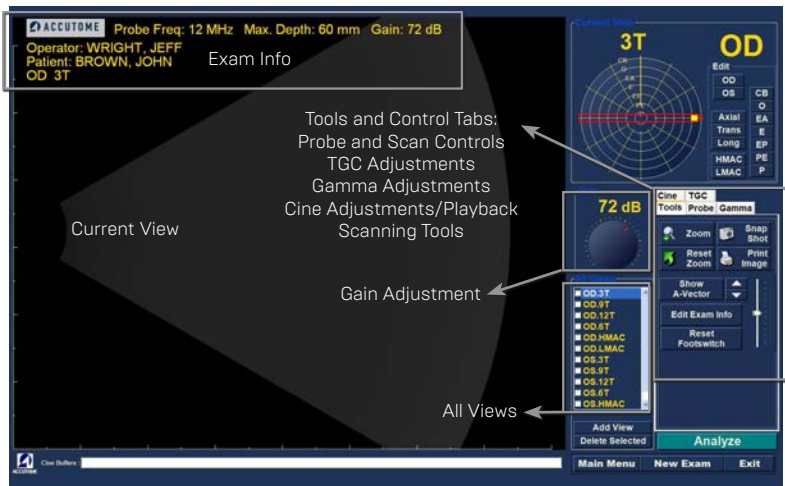


Figure 5.12 - Exam Screen Layout

Exam Information Displayed above Image

Above the Exam Screen's Imaging area, in the top right or left corner there is an area that displays some or all of the following fields:

- Probe Frequency (Prob Freq)
- Maximum Probe Signal Depth (Max. Depth)
- Medical Record Number (MRN)
- Exam Creation Time (Date)
- Facility - Facility display can be turned on or off in B-Scan Plus Setup, Options tab

- Physician - Physician display can be turned on or off in B-Scan Plus Setup, Options tab
- Operator - Operator display can be turned on or off in B-Scan Plus Setup, Options tab
- Current View in Image Sequence Protocol

The information fields displayed and the position of the information on the screen is determined by the Options settings in Setup.

Current View

The Current View area displays the position of the currently active step in the imaging sequence. The position is displayed in both a textual and graphical format. You can also edit the current view in this area. There is also a "View" that allows you to view the image frames for the previous sequence steps.

All Views

The All Views area displays all views in all steps of the current imaging sequence.

Tools Palette

The tools palette contains all the tool for adjusting and controlling scans. In the palette there are tabs for:

- Probe
- TGC
- Gamma
- Cine
- Tools

Probe and Scan Controls

The probe and scan controls shown in Figure 5.13 allow you to adjust the probe settings and start and stop image scans. In this area you can also adjust the probe power level for scanning.

Probe Settings

In the probe settings are you can adjust:

- Frequency - 12 MHz or 15 MHz
- Range - 6 cm or 3 cm for 12 MHz; 10 cm or 5 cm for 15 MHz
- Cine Buffers - 4.5 sec, 8.5 sec, 17 sec, or 34 sec.



Figure 5.13 – Probe and Scan Controls Tab Selected

Scan/Stop and Save Cine

Located below the probe adjustments are the buttons to execute and stop probe scanning. When you are ready to start a sequence step the button will display "Scan". Clicking "Scan" starts the scanning process and the display on the button changes to "Stop". When you are satisfied with image acquired click on "Stop" and "Save" to save the scanning for the active step.

This is another location where you can start and stop scans in addition to the footswitch and the button on the probe.

Adjusting the Power

Above the Scan/Stop and Save buttons there is an adjustable sliding probe power indicator. To increase or decrease the probe power drag the indicator to the right or left.

TGC Adjustments

TGC (Time Gain Compensation) is an adjustment to compensate for the strength of the signal through the eye. The TGC adjustments are:

- Near - adjustment for signal near the probe
- Mid - adjustment for the middle of signal
- Far - adjustment for portion of signal farthest from probe.

TGC is explained in greater detail in Chapter 6, Patient Image Analysis.



Figure 5.14 - TGC Adjustments Tab Selected

Gamma Adjustments

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. The Gamma adjustments allow you to adjust the brightness mapping of the B-Scan image. The adjustments area contains a drop down list of predefined gamma settings, and gamma contrast and brightness controls that can be adjusted by dragging. Gamma is explained in greater detail in Chapter 6, Patient Image Analysis.



Figure 5.15 - Gamma Adjustments Tab Selected

Cine Adjustments/Playback

The cine adjustments allow you to control how an image is captured and displayed. Frame Averaging is used to smooth out an image. A scan takes individual frames and averages up to three frames before displaying the image on the screen. Frame Delay is the speed at which the film loop is played back.

Add View

The Add View function allows you to add new scan views to the scanning sequence. To add a new view to the current scanning sequence:

1. In the All Views area select "Add View"
2. Label the new scan view.
3. In the Current View area select OD or OS for the new step.
4. The newly added scan will be active and display as OD.Scan or OS.Scan.
5. Adjust the new scan settings. Select the probe orientation for the step: Axial, Longitudinal (Long) or Transverse (Trans).
6. Select the view position indicator in the Current View area and drag the indicator tip to the desired position.



Figure 5.16 - Cine Adjustments/Play Tab Selected

Edit Current View

When you select "Edit" in the Current View area the B-Scan Plus allows changes to the currently active scan view label. Edit the label for the view. Make the adjustments to the probe orientation or positions by dragging the position indicator. The changes will be reflected in the new name of the step. For example, if you changed the probing orientation for OD.I2AX to Transverse, the new scan name is "OD.I2T"

Probe Orientation

There are three probe orientations:

- Axial
- Long (Longitudinal)
- Trans (Transverse)

Axial

Axial is the center of the cornea and is used to denote a scan with the probe perpendicular to the cornea.

Longitudinal

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

Transverse

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 tranverses the optical axis.

Edit Exam Info

When you select "Edit Exam Info" the Accutome B-Scan Plus displays a window containing the Patient and Exam info entered in the Initial Exam Screen (refer to "Initial Exam Screen" on page 42). You can edit and save any of the information displayed in this window.

The screenshot shows the 'Edit Exam Information' window. The title bar says 'Edit Exam Information'. The main area has several sections: 'Edit Exam : VITREOUS,BLOOD_2006-11-3T8' at the top. Below it are fields for Facility (ACCUTOME), Name (ACCUTOME), Physician (SMITH, JOE), First Name (JOE), Last Name (SMITH), Operator (BALDWIN, ROBERT), First Name (JEFF), Last Name (WRIGHT), Patient Name (BLOOD), First Name (BLOOD), Last Name (VITREOUS), Date of Birth (MM/DD/YYYY), Gender (Male), and Age. To the right of these fields are two large text areas: 'Indication for Scan : blunt trauma' and 'Diagnosis :'. At the bottom left is the 'ACCUTOME' logo, and at the bottom right are 'Restore', 'Cancel', and 'Done' buttons.

Figure 5.17 - Edit Exam Information Window

Analyze

When you select "Analyze" the Accutome B-Scan Plus launches the Image Analysis Screen where you can play, reverse and forward, take measurements and zoom on selected portions of an image for a highly successful diagnosis. The B-Scan image analysis features are explained in detail in Chapter 6, Patient Image Analysis, of this manual.

Menu Buttons

The three buttons located at the bottom of the Exam Screen; New Exam, Main Menu and Exit perform Accutome B-Scan Plus menu functions.

New Exam

When you click on "New Exam" the Accutome B-Scan Plus will launch the Initial Exam Screen where you can start a new patient exam.

Main Menu

When you click on "Main Menu" the Accutome B-Scan Plus returns you to the top level, main menu.

Exit

When you click "Exit" the Accutome B-Scan Plus program closes.

Probe Usage in Scanning

The Accutome B-Scan Plus provides every feature needed to get high quality, accurate scans. You can place the probe at any angle, on any elevation on the patient eye and always capture a clear image.

How the B-Scan Probe Works

The Accutome B-Scan Plus probe is an ultrasonic probe and sends a sound wave through the eye being scanned. As the sound wave travels through the various eye tissues the sound wave bounces off these tissues and produces an echo of varying amplitude determined by the density of the tissue. The denser the tissue the larger the echo and the greater the signal that is returned. Greater tissue density and a stronger echo show up as a brighter spot in the image.

A-Scan is a thin, parallel sound beam passing through a small point within the eye. The echoes received back as the signal passes through the various eye tissues are represented by spikes arising from a baseline. A-Scan is therefore an Amplitude scan. B-Scan is an oscillating A-Scan passing through a slice of tissue rather than a point and the echoes that are received back represent dots that form an image. The higher the density of tissue that the B-Scan wave hits will be returned as a stronger echo, or brighter dot in the image. B-Scan is therefore a Brightness scan. For example, the retina is a highly dense, smooth surface and when scanned the image returned will be bright as shown in Figure 5.18 on page 50.



Figure 5.18 - B-Scan Example

Probe Operation

The Accutome B-Scan Plus emits an oscillating sound beam that pulses, pauses and pulses again. The pause allows the B-Scan Plus to receive, process and display the returning echo. The pulse-echo is repeated thousands of times per second resulting in a "real-time" display. The sound beam "slices" through a section of intraocular tissue covering approximately sixty degrees.

Marker Alignment

There is a marker at the end of the Accutome B-Scan Plus probe, the Accutome logo, (refer to Figure 2 on page 21 of this manual) that indicates the direction of the "slice" being imaged by the probe. See Figure 89 below for examples of the marker positioning for a vertical and a horizontal slice.

You must know where the slice is being directed at all times to produce an accurate scan. In Figure 5.19 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 a clock.

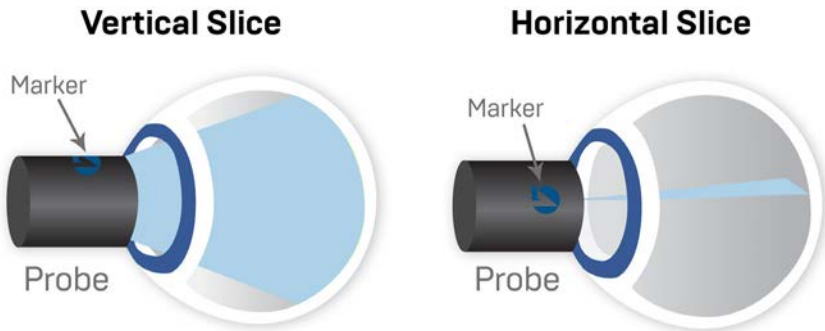


Figure 5.19 - Eye and Probe Marker Alignment

Probe Positions

One of the great features of the Accutome B-Scan Plus 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 you move the probe around the eye within each of these positions. A brief summary of the three positions follows.

Axial Probe Positions

An Axial B-Scan is a slice aligned through the center of the lens with the shadow of the optic nerve centered on the right of the scan.

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 vertical, 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

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 horizontal transverse approaches 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.

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

How to Scan

To start and freeze a scan with Accutome B-Scan Plus 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. (See "Start/Stop" on page 31 of this manual.)

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.

Using the Probe Trigger Button

The probe trigger button toggles between start/stop. When you are scanning and press the button it stops the scan. If you stopped scanning and press the button, the B-Scan Plus will proceed to the next step in your scan sequence, or will add a new scan view.

Using the Footswitch

The Accutome B-Scan Plus footswitch is interchangeable with the probe trigger button. The footswitch toggles between start/stop. To start or stop scanning step on the footswitch.

Once you have completed the first scan the image you have captured will appear in the image area of the screen.

Scanning with a Predefined Protocol

Figure 5.20 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 5.20 the first scan is labeled "OD.12AX" and the second scan is labeled "OD.3AX". When you finish the first scan you should move the probe on the patient's eye from the 12:00 axial slice to the 3:00 axial slice.

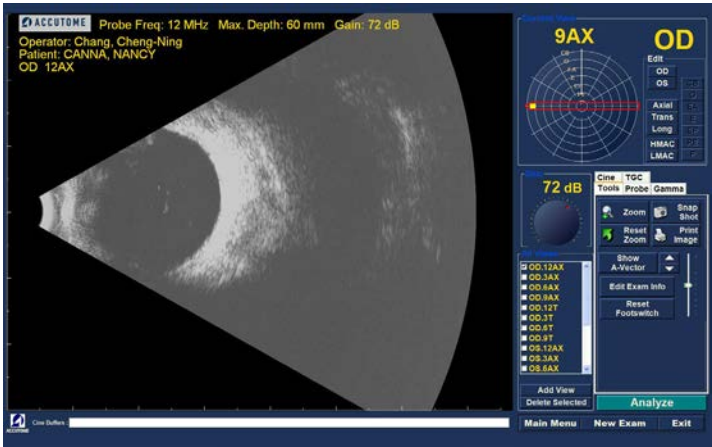


Figure 5.20 - New Exam with Selected Protocol - First Scan Complete

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 right eye you should change the view label for this scan (see "Edit Current View" on page 48).

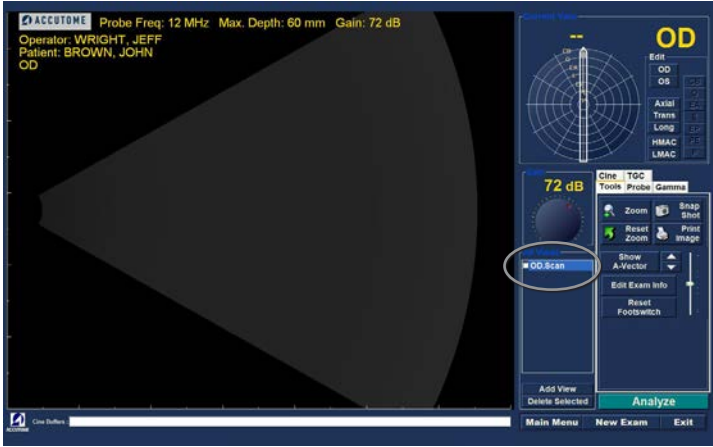


Figure 5.21 - New Exam No Protocol - First Scan Selected

Start and stop the scan using the probe trigger button or the footswitch. Once the first scan is captured as shown in Figure 5.22 below proceed with the second scan.

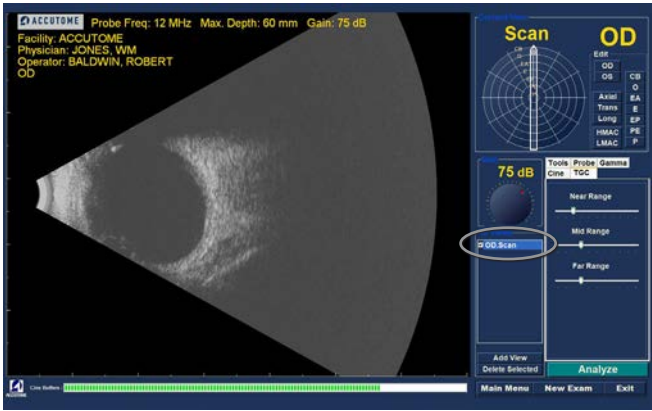


Figure 5.22 - New Exam First Scan Complete

Proceed with the Next Scan

After you have completed the first scan and you press the probe trigger button or step on the footswitch the B-Scan Plus will automatically add another scan to the “All Views” list. The label for the second scan will default to OD.Scan[2].

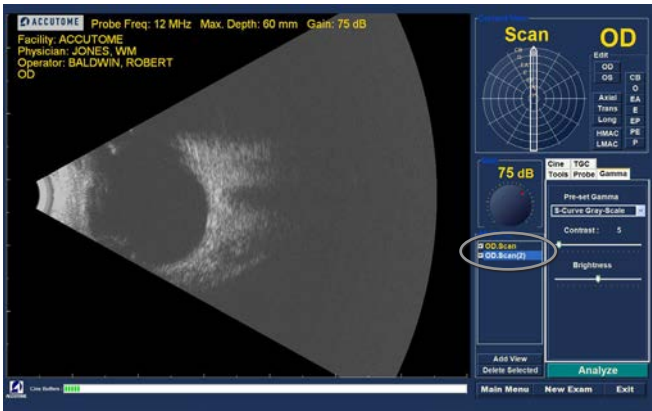


Figure 5.23 - New Exam Second Scan Complete

Adding a View

You may decide during the scanning process that you need to scan another view of the patient’s eye.

To add another view:

1. Click on the “Add View” button as shown in Figure 5.24.

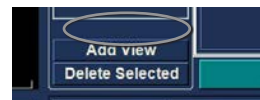


Figure 5.24 - Adding a View

Adjusting the Gain

You may decide the signal gain for your new view is too strong or not strong enough. To adjust the signal gain:

1. Select the red dot in the adjustable gain knob with the mouse cursor.
2. Holding down the left mouse button drag the knob until you reach the gain value you want.
3. If the mouse you are using has a scroll wheel you can move the wheel instead of dragging the knob to reach the gain value.

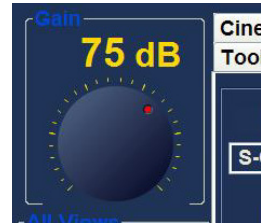


Figure 5.25 - Adjusting Gain

Changing the Scan View

After you have added a new scan to the list of All Views 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:

1. Activate the scan by clicking on the scan view name or clicking the checkbox beside scan view name.
2. Move to the "Edit Current View" area of the Exam Screen and select the correct probe position as shown in Figure 5.26.
3. Change the slice position by dragging the arrow indicator around the clock until you reach the correct slice position.
4. For transverse scans you must also select the appropriate orbit for the new scan. Place the mouse cursor inside the orbit wheel. Click on the correct orbit for the new scan.
5. The edited current view will appear in the list of "All Views" as shown in Figure 5.28.



Figure 5.26 - Changing a View - Probe Position

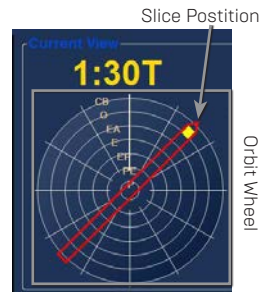


Figure 5.27 - Changing a View - Slice Position and Global Orbit

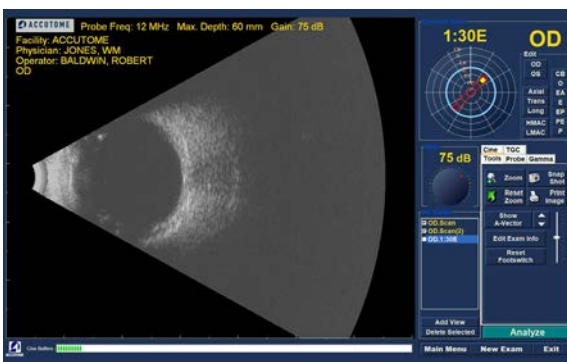


Figure 5.28 - Changing a View - Done

Macula Scans

The macula can be scanned with the Accutome B-Scan Plus in several ways. Two of the ways are a Horizontal (HMAC) and a Longitudinal (LMAC) scan.

Horizontal Macula

The Horizontal Macula scan is accomplished by first aligning a horizontal axial scan and centering the macula by aiming the slice directly above the visual axis, rather than tilting nasally. The marker should be aimed at 3:00 for the right eye (OD) and at 9:00 for the left eye (OS).

Longitudinal Macula

The Longitudinal Macula scan is a scan through the temporal meridian. The marker should be aimed at 9:00 for the right eye (OD) and at 3:00 for the left eye (OS).

Labeling Macula Scans

The Accutome B-Scan Plus makes labeling macula scans as simple as selecting HMAC (Horizontal MACula) or LMAC (Longitudinal MACula) and then selecting either the right eye (OD) or left eye (OS).

When you label a scan view as a macula scan and select either OD or OS, the Accutome B-Scan Plus automatically positions the clock arrow indicator at the right hour.

To label a scan as a macula scan:

1. Select either "HMAC" or "LMAC"

In the example given in Figure 5.29 the scan being labeled is an LMAC scan.

2. The macula scan will appear in the All Views list as the label you assigned to the scan. In Figure 5.30, the new labeled scan is OD.LMAC

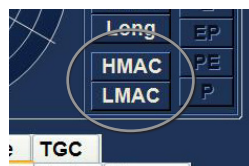


Figure 5.29 - Labeling an LMAC Scan

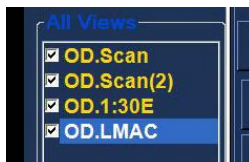


Figure 5.30 - LMAC Scan Labeled

A-Vector

The A-Vector function displays an equivalent A-Scan of the captured B-Scan Plus image. Looking at the A-Vector you can get a graphical picture of the echoes received back through the eye from the ultrasonic probe. The echoes are represented as spikes arising from the baseline and indicate the sound beam travelling through the different intraocular tissues.

To activate the A-Vector:

1. Select "Show A-Vector" from the Tools tab as shown in Figure 5.31.

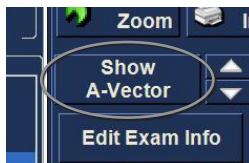


Figure 5.31 - Selecting "Show A-Vector"

- The A-Vector will be displayed under the live image as shown in Figure 5.32 below. To close the A-Vector select "Hide A-Vector".

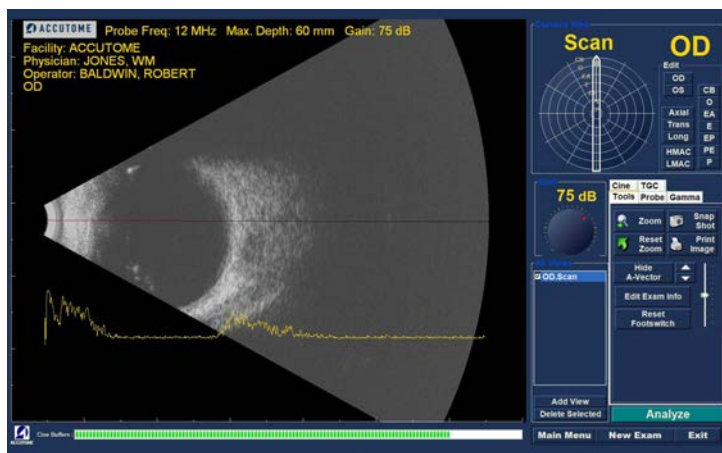


Figure 5.32 - A-Vector Displayed

Completing Patient Exam

After you have completed the patient exam you have several choices to exit the screen.

Main Menu

The Main Menu selection will return to the Accutome B-Scan Plus main screen.

New Exam

The New Exam selection will close the current patient exam and return you to the Initial Patient Exam Screen (see Figure 73 on page 91). Enter new patient information and start a new exam.

Exit

Selecting "Exit" will close the Accutome B-Scan Plus software.

Analyze

Selecting "Analyze" will launch the Analyze Screen with the current patient active. On the Analyze Screen you can make image adjustments, take measurements, and generate snapshot lists and reports. For further information on image analysis refer to "Patient Image Analysis" on page 58 of this manual.

6

Patient Image Analysis

Overview

The Accutome B-Scan Plus provides many features for high quality, personalized, image capture and analysis. You can perform image analysis with Accutome B-Scan Plus during an exam or later, on a saved, existing exam.

Selecting Images for Analysis

There are two methods of selecting an image for analysis:

1. In the New Exam Screen by executing "Analyze" after a patient exam has been scanned.
2. By selecting a saved Existing Exam and displaying it in the Analyze Screen.

How to Select an Existing Exam

To select an existing exam:

1. In the Accutome B-Scan Plus top level, Main Screen select "Existing Exam" as shown in Figure 6.1.
2. The Analyze Screen shown in Figure 6.2 below will display.



Figure 6.1 - Starting Existing Exam

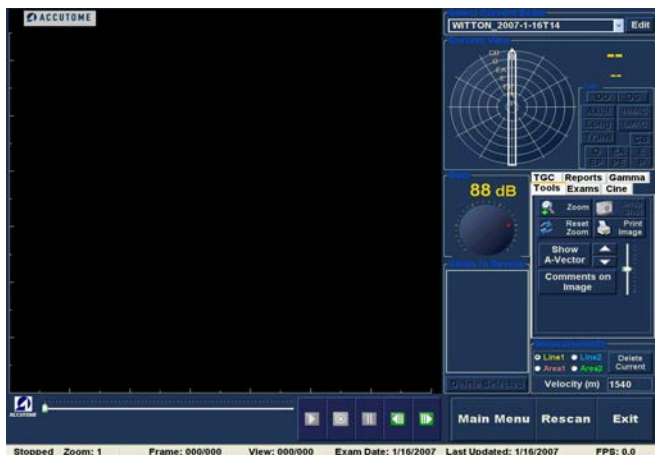


Figure 6.2 - Analyze Screen

Analyze Screen

The Analyze Screen contains many features to enhance image diagnostics

Analyze Screen Features

Upon start of the exam the Accutome B-Scan Plus launches the Analyze Screen.

The Analyze Screen displays:

- Exam Information
- All Exams (drop down list for selecting an existing exam)
- Current View (active display of scan sequence)
- Play Controls (for viewing scan film loops)
- TGC Adjustments
- Tools Palette - including Zoom Controls, A-Vector, Comments, Print Image, Snap Shot
- Gamma Adjustments
- Edit Exam Info

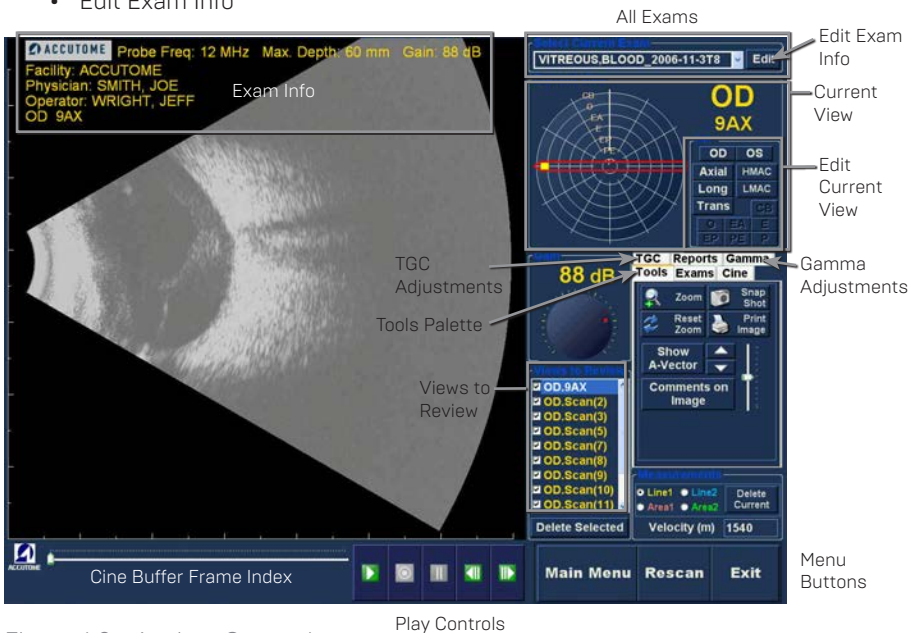


Figure 6.3 - Analyze Screen Layout

Exam Information Displayed above Image

Above the Exam Screen's Imaging area is an area that displays some or all of the following fields:

- Probe Frequency (Prob Freq)
- Maximum Probe Signal Depth (Max. Depth)
- Medical Record Number (MRN)
- Exam Creation Time (Date)
- Facility - Facility display can be turned on or off in B-Scan Plus Setup, Options tab
- Physician - Physician display can be turned on or off in B-Scan Plus Setup,

- Options tab
- Operator - Operator display can be turned on or off in B-Scan Plus Setup, Options tab
- Current View of stored scanned film loops

The default position for exam information fields is at the top left of the screen. The information fields that are displayed and the position on the screen where the fields are displayed can be changed in the setup mode

Current View

The Current View area displays the position of the currently active scan in the scanning sequence. The position is displayed in both a textual and graphical format. You can also edit the current view in this area.

Current View Orbital Locators

When you are examining a captured image the Current View area will display, as you select, on the graphical representation of the image the following orbits:

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

Editing Current View Info

When you click "Edit" in the Current View area the B-Scan Plus changes the currently active imaging sequence step. After you make the adjustments to the probe orientation or positions by dragging the position indicator the changes will be reflected in the new name of the step. For example, you changed the probe orientation for OD.I2AX to Transverse, the new step name is "OD.I2T"

Views to Review

The Views to Review area displays all views in all steps of the current imaging sequence.

Play Controls

The play controls allow you to play, pause, stop, move forward and move back through an image scan.

Zoom Controls

The Zoom Controls allow you to zoom in on the image and then return to the normal size view by clicking "Reset Zoom". Zoom is explained in greater detail in Chapter 6, Patient Image Analysis.

TGC Adjustments

TGC (Time Gain Compensation) is an adjustment to compensate for the strength of the signal through the eye. The TGC adjustments are:

- Near - adjustment for signal near the probe

- Mid - adjustment for the middle of signal
- Far - adjustment for portion of signal farthest from probe.

Gamma Adjustments

The Gamma adjustments allow you to adjust the brightness mapping of the B-Scan image. The adjustments area contains a drop down list of predefined gamma settings and gamma indicators for Contrast and Brightness that can be adjusted by dragging.

Edit Exam Info

When you select “Edit Exam Info” the B-Scan displays a window containing the Patient and Exam info entered in the Initial Exam Screen (refer to “Edit Exam Information Window” on page 144). You can edit and save any of the information displayed in this window.

Menu Buttons

The three buttons located at the bottom of the Exam Screen; Rescan, Main Menu and Exit perform Accutome B-Scan Plus menu functions.

Main Menu

When you click on “Main Menu” the Accutome B-Scan Plus returns you to the top level, main menu.

Rescan

When you click on “Rescan” the Accutome B-Scan Plus will launch the Exam Imaging Screen where you can rescan the patient exam.

Exit

When you click “Exit” the Accutome B-Scan Plus program closes.

Selecting an Existing Exam

The Analyze Screen will display the current patient exam if you entered the Analyze Screen by selecting “Analyze” on the New Exam screen. If you entered the Analyze Screen from the Main Accutome B-Scan Plus Screen you need to select an existing exam from the All Exams drop down list.

1. The “All Exams” drop down list is located at the top, right side of the screen. Select the patient exam for analysis from the list. Position the cursor on the small arrow at the right of the All Exams field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list. Click the mouse to move through stored facilities.

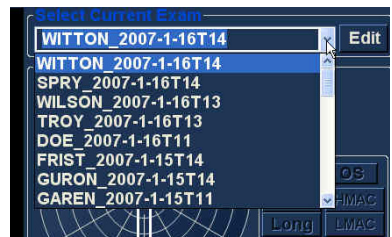


Figure 6.4 - Selecting a Patient Exam

- Position the mouse cursor on the name of the Exam you would like to analyze. The exam will displayed in the screen as shown in Figure 6.5 below.



Figure 6.5 - Existing Exam Displayed

How to Edit Exam Info

To edit the information for the active patient click on "Edit", located at the right of the All Exams field. The "Edit Exam Information" Window shown in Figure 6.6 on page 63 will launch. This window contains all the information entered into the initial patient exam screen. The window contains drop down lists and text fields that can be changed.

Drop Down Lists

The drop down lists in the Edit Exam Information window are all prefilled during setup. The drop down lists are:

- Facility
- Physician
- Operator

To change the fields with drop down lists; position the cursor on the small arrow at the right of each field. Left click to open the drop down list. Position the mouse over the up/down arrows at the right of the drop down list Click the mouse to move through the stored lists. Once you see the item in the drop down list you want to select position the mouse cursor over the item and left click. The selected item will fill in the field.

Text Fields

The text fields in the Edit Exam Information Window that you can change are:

- Facility Name
- Physician First Name
- Physician Last Name
- Operator First Name
- Operator Last Name
- Patient First Name
- Patient Last Name
- Patient First Name
- Patient Date of Birth
- Patient Gender
- Indication for Scan
- Diagnosis

To change any text field:

1. Click the mouse cursor in the field.
2. If there is text to remove drag the mouse and select the text and hit the "Delete" key on the computer keyboard.
3. Place the mouse cursor in the empty text field and type the new text.

Figure 6.6 - Edit Exam Information Window

Restore

If you have made any changes in the Edit Exam Information and would like to restore the information to the previous state click on "Restore". The dialog displayed in Figure II0 below will launch. If you would like to restore the information click "OK", if not click "Cancel"

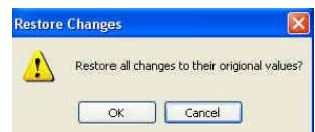


Figure 6.7 - Restore Changes Information Dialog

Cancel

If you would like to cancel the Edit Exam Information activity without saving changes click on "Cancel". The dialog displayed in Figure III below will launch. If you would like to cancel the process click "OK". If you would like to return to the Edit Exam Information window and continue activity, click "Cancel"

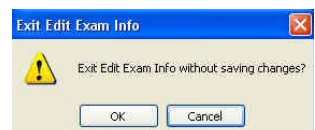


Figure 6.8 - Exit Edit Exam Information Dialog

Done

When you have finished making all edits in the Edit Exam Information window click "Done". The Edit Exam Information window will close and you will return to the Existing Exam Screen.

Exams

In the Tools Palette there is a tab labeled "Exams". The Exams tab allows you to select the Exams folder location. Click on the Exams tab and the Exams folder selections will display as shown in Figure 6.9.

There are two selection on the Exams tab: "Use Main Folder" and "Use Restored Folder". The Restored folder is the folder that has been setup in setup mode for restored exams, or exams that you have loaded from a CD/DVD or restored from a backup on the Local/Net disk. Refer to "Archive and Restore" on page 191 of this manual for more information.

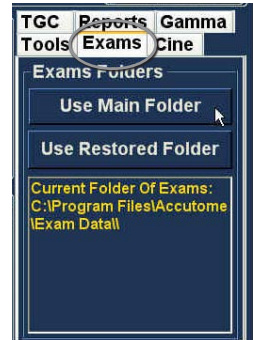


Figure 6.9 - Exams Tab

Playing an Exam

The Accutome B-Scan Plus allows you to view any portion of a scan film loop. At the bottom of the existing exam screen are the image playback controls. They are intuitive and easy to use and similar in appearance to controls on a VCR or DVD remote controller.

The playback controls consist of:

- Play
- Stop (and return to the beginning of the film loop)
- Pause
- Forward one frame at a time or continuously
- Backward one frame at a time or continuously

When you first load a scan film loop the only playback control buttons that are enabled are the play, forward, and backward. To start the scan film loop click on the Play button as shown in Figure 6.10.

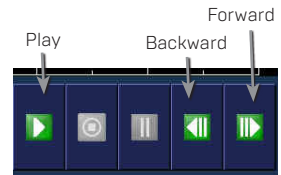


Figure 6.10 - Starting Scan Play

Stopping an Exam

After you have started playing a scan film loop the Stop and Pause buttons become active as shown in Figure 6.11. When you click the Stop button the scan film loop stops and returns to the beginning.

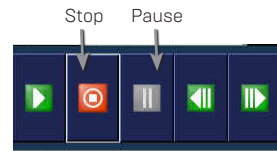


Figure 6.11 - Scan Stopped and Returned to Beginning

Pause

When you click on the Pause button shown in Figure 6.11 the scan film loop will pause and not play in any direction.

Forward

When you click on the Forward button shown in Figure 6.10 the scan film loop will play forward. There are two methods of playing forward: you can move forward one

frame at a time or you can move forward through frames continuously. To play one frame at a time click on the forward button, once and then click again. To play frames forward continuously click on the forward button and hold the left mouse button down. The scan film loop will continue to play forward until you release the left mouse button.

Backward

When you click on the Backward button shown in Figure 6.10 the scan film loop will play backward. There are two methods of playing backward: you can move backward one frame at a time or you can move backward through frames continuously. To play one frame at a time click on the backward button, once and then click again. To play frames backward continuously click on the backward button and hold the left mouse button down. The scan film loop will continue to play backward until you release the left mouse button.

TGC Adjustment

TGC (Time Gain Compensation) feature provides for segmental adjustment throughout the entire range of the probe's sonic echo. For example, the echo nearest to the probe's transducer might be selectively reduced to better distinguish tissue within the anterior segment, while at the same time the echo from the retina and orbit might be selectively amplified in order to achieve a well balanced image having optimum brightness throughout the length of the eye. Alternately, the clinician may use TGC to selectively amplify only the Vitreous echoes or only the Anterior Chamber echoes. This feature provides unparalleled control of image quality and thus diagnostic quality.

The TGC settings can be adjusted to facilitate viewing certain areas of the eye, by increasing the gain for that portion of the signal with a specific TGC setting. There are three adjustable TGC settings:

1. Near - increases the gain for the anterior portion of the eye in the B-Scan Plus image, near the probe
2. Mid - increases the gain for the middle portion of the eye
3. Far - increases the gain for the far portion of the eye

How to Adjust the TGC

The TGC adjustments (see Figure 6.12) on both the Exam and Analyze Screen are easy to use. The adjustments are graphical slide indicators that be dragged to increase and decrease the signal gain for a selected portion of the image.

1. Select the TGC tab from the tools palette.
2. To adjust the gain slide the appropriate setting indicators.

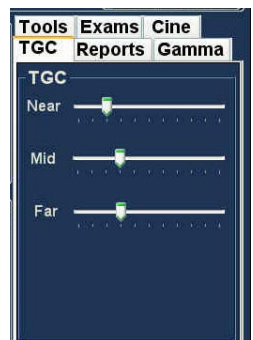


Figure 6.12 - TGC Adjustments Displayed

Image Enhancement Gammas

The Gamma adjustment feature is another great diagnostic feature that allows you to selectively manipulate the ratio between signal [or gain] and image brightness (known as Gamma), resulting in greatly enhanced tissue differentiation. Very subtle tissue differences can be made strikingly different for easy identification of boundaries between tissues of different characteristics. For example, differences between the vitreous and vitreous condensate (floaters), or the differences between the retinal surface and hyaloid membrane can be brought into sharp relief. There are 4 gamma settings and each setting is intended to facilitate viewing different portions of the eye. Gamma can be adjusted in the live Exam Screen or later on an existing image in the Analyze Screen.

The 4 gamma settings are:

- Linear Full Range
- S-Curve Full Range
- Log Full Range
- Color

Linear

The Linear gamma represents a “standard” processing algorithm. Linear describes a greyscale representation of a B-Scan Plus echogram in which the brightness represented on the screen is directly proportional to the strength of the ultrasonic echo. Therefore an ophthalmic structure which reflects the maximum echo would be represented as pure white, while no echo would be represented as pure black; and echoes in between would be represented proportionally as shades of gray, directly proportional to the strength of the ultrasonic echo. Figure 6.13 displays an example of a B-Scan Plus image with a Linear Full Range gamma setting.

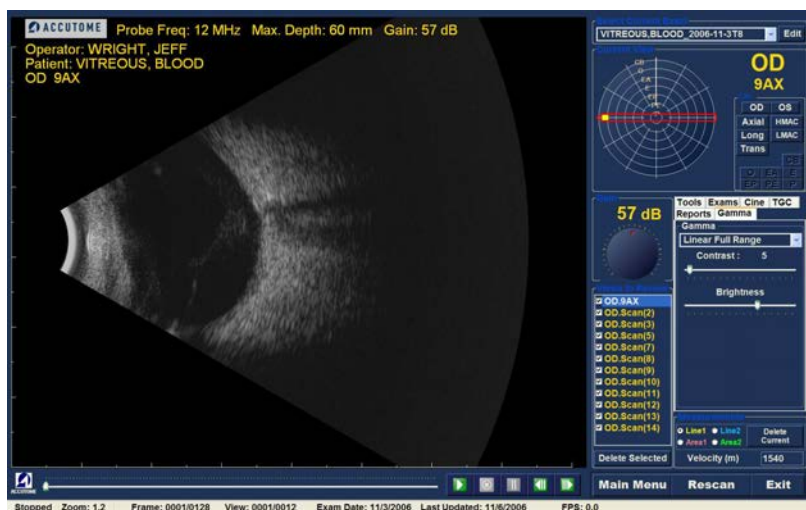


Figure 6.13 - Linear Full Range Gamma Setting

S-Curve

The S-Curve gamma represents a signal to brightness response, which when plotted, would result in a curve resembling the shape of the letter “S”. The brightness response differs from Linear and Log in that the image contains a higher contrast for mid range signals. Figure 6.14 below displays an example of a B-Scan image with a S-Curve Full Range gamma setting.

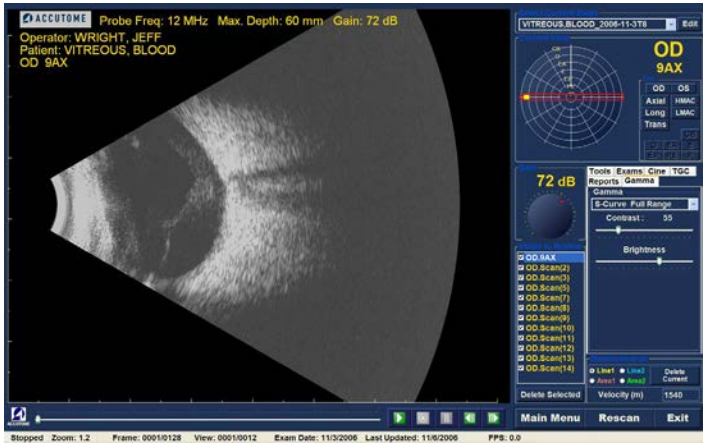


Figure 6.14 – S-Curve Full Range Gamma Setting

Log

The Log gamma settings stands for “Logarithm” and the ultrasound response curve can be represented as conventional logarithmic curve whose brightness response differs from the linear algorithm. The image represented by the Log gamma produces higher contrast for weaker signals. Figure 6.15 below displays an example of a B-Scan image with a Log Full Range gamma setting.

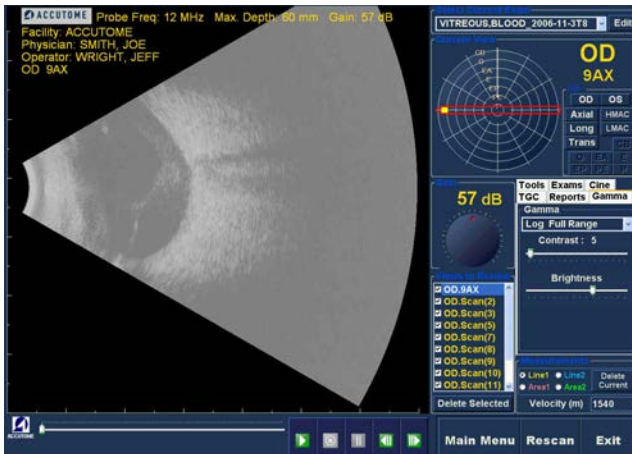


Figure 6.15 – Log Full Range Gamma Setting

Color

The color gamma setting allows you to view the image in color. The color setting can be advantageous in seeing any abnormalities that may not easily be seen in the other greyscale gamma settings.

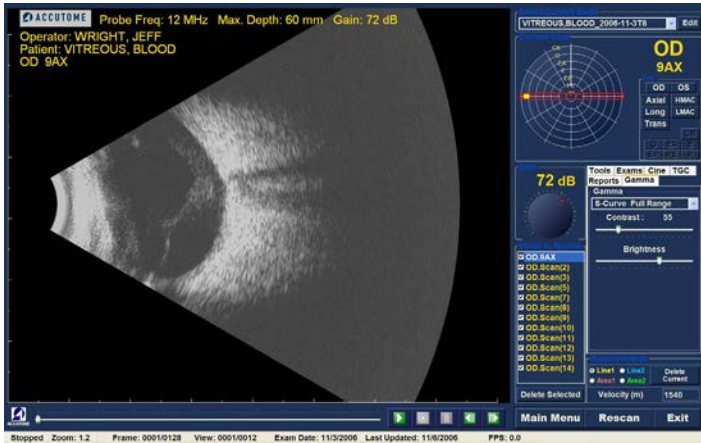


Figure 6.16 - Color Gamma Setting

Changing Gamma Settings

To change the gamma setting you must first select the “Gamma” tab from the tools palette. With the Gamma tab displayed, position the cursor on the small arrow at the right of the gamma field. Left click to open the drop down list as shown in Figure 6.17. Position the mouse over the up/down arrows at the right of the drop down list. Click the mouse to move through gamma list. Once you see the gamma setting you want to select position the mouse cursor over the setting and left click. The selected gamma will adjust the image on the screen.

Once you have selected the new gamma setting you can further adjust the Contrast and Brightness settings by dragging the indicator and viewing the results on the screen. Higher contrast enhances denser tissue; lower contrast enhances lower density tissue such as vitreous membrane.

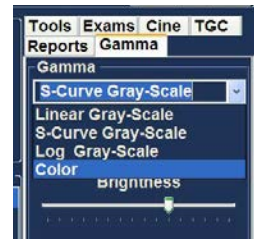


Figure 6.17 - Selecting a New Gamma Setting

How to Use Zoom

To access the Zoom feature click on the “Tools” tab from the Tools palette. The zoom feature allows you to zoom in on a selected patient image. Zoom proportionally expands the image and fills the B-Scan screen. Zoom has preset values that increment by steps of .2 from 1.2 to 8; e.g. 1, 1.2, 1.4, 1.6, 1.8, 2.0 etc., up to 7.99

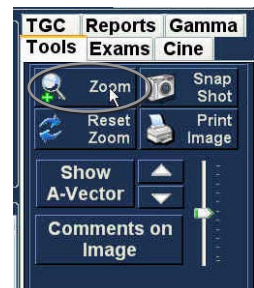


Figure 6.18 - Zoom Selected

To use the Zoom feature:

1. Click the "Zoom" selection.
2. Continue clicking until the image is zoomed at the appropriate level.

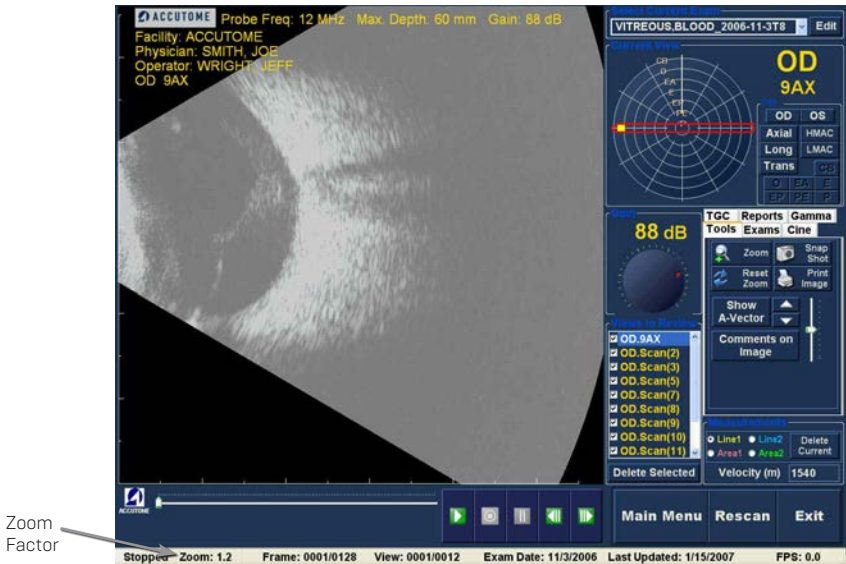


Figure 6.19 – Zoom Changed

Reset Zoom

After you have zoomed in on an image you may want to reset the view back to the default normal view. To reset the zoom value simply click on "Reset Zoom".

How to Move Image

After you have made adjustments to the size of the image you may want to move the image around on the screen to view different portions of the eye. It is simple to move images in the Accutome B-Scan Plus. Place the Windows mouse cursor over any location on the image and notice the cursor become a small cross [small +]. Then hold down the mouse button and the + becomes directional compass. Holding the mouse button down and moving the mouse causes the image to move. The image move icon is shown in Figure 6.20.

1. Move the icon and the image will move in the same direction.



Figure 6.20 – Image Move Icon

How to Take a Measurement on an Existing Image

The Analyze Screen provides the diagnostic feature of making measurements on a B-Scan Plus image. You can measure on a zoomed image; you get much finer resolution of the measurements. Measurements as small as .1 mm can be easily taken. There are four separate measurements you can take:

- Line 1
- Line 2
- Area 1
- Area 2

Measurement Types

The B-Scan Plus provides for two line, or distance measurements and two area measurements. You can display all four measurements on the screen simultaneously.

Taking Distance Measurements

To take a distance measurement:

1. Select either Line 1 or Line 2 in the Measurements area as shown in Figure 6.21.
2. Right click and hold on the image at the starting point of the measurement, and drag the line along the length of the feature you would like to measure.
3. The measurement will be displayed on the screen as shown in Figure 6.22.



Figure 6.21 - Line 1 Measurement Selected

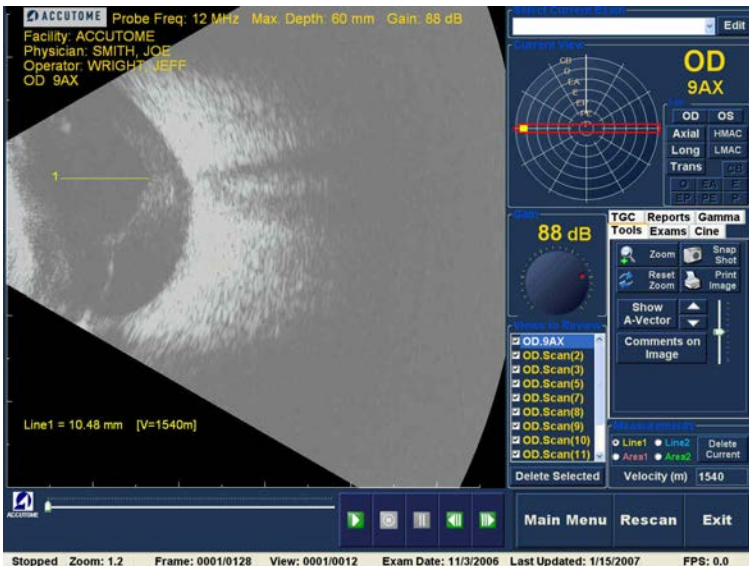


Figure 6.22 - Line 1 Measurement Displayed

Taking Area Measurements

To take an area measurement:

1. Select either Area 1 or Area 2 in the Measurements area as shown in Figure 6.23.
2. Right click on the image and drag the outline of the area on the image you would like to measure.
3. The measurement will be displayed on the screen as shown in Figure 6.24 below.
4. You can change the velocity of the sound to reflect the density of the tissue being measured. Click in the Velocity field. Select the velocity by holding down the left mouse button and dragging the value. Press the keyboard "Delete" key and type in the new value for the velocity.



Figure 6.23 - Area 1 Measurement Selected

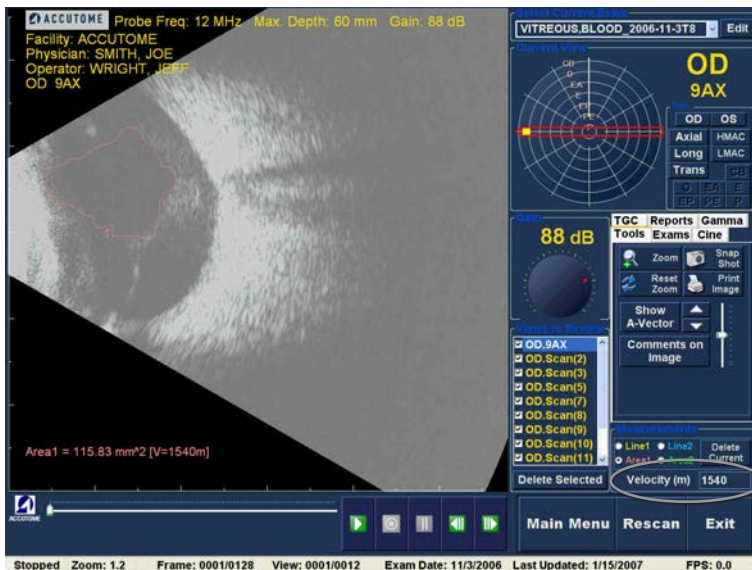


Figure 6.24 - Area 1 Measurement Display

Delete Current

When you click on "Delete Current" the current, active measurement will be deleted from the Analyze Screen.

A-Vector

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

The echoes are represented as spikes arising from the baseline and indicate the sound beam travelling through the different intraocular tissues. The A-Vector function can be useful in diagnosing pathologies with the eye.

To activate the A-Vector:

1. Select "Show A-Vector" as shown in Figure 6.25.
2. The A-Vector will be displayed under the live image as shown in Figure 6.26 below.
3. The position of the A-Vector on the image can be moved by using the buttons or the slide control to the right of the Hide A-Vector button.
4. To close the A-Vector select "Hide A-Vector".



Figure 6.25 - Selecting "Show A-Vector"

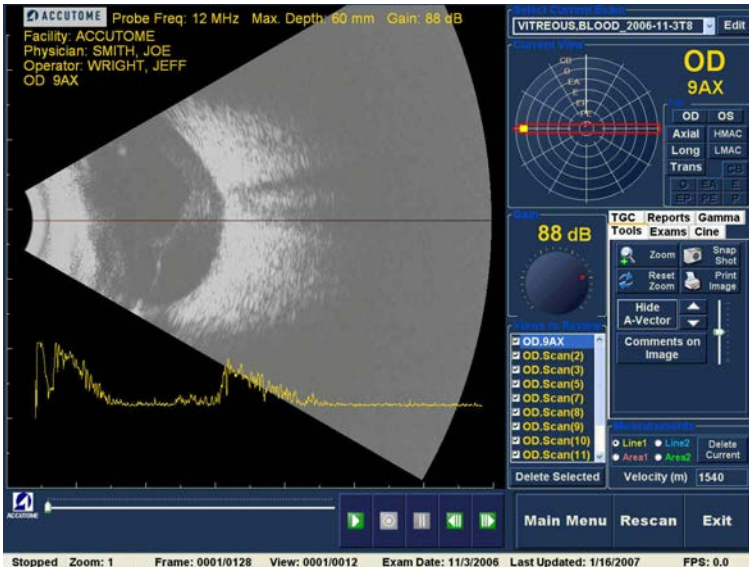


Figure 6.26 - A-Vector Displayed

Comments on Image

The Accutome B-Scan Plus allows you to place comments on an image from a patient exam. The comments feature can be important in providing an accurate image analysis.

To place a comment on an image:

1. In the "Tools" tab of the tools palette, select "Comments on Image" as shown in Figure 6.27.
2. The "Comments on Image" dialog shown in Figure 6.28 will display on the screen.
3. Click in the text field and enter your comments.
4. If you would like to clear the comments that you have typed, click on "Clear".
5. Select "Done" when you are finished.



Figure 6.27 - Selecting "Comments on Image"



Figure 6.28 - Entering Comments

6. The entered comments will appear on the image as shown in Figure 6.29 below.

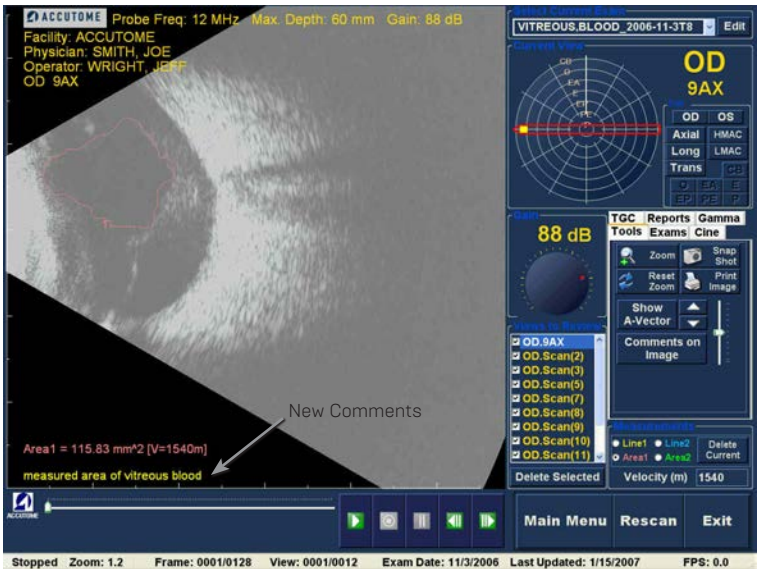


Figure 6.29 - Comments Appearing on Image

7 Printing Images & Reports

Overview

The Accutome B-Scan Plus has every feature you need to capture and print any portion of a patient exam. Not only does the Accutome B-Scan Plus allow you to print to any printer you can also print single snap shots of any elevation of any image, print on plain or thermal paper, select multiple images and print them in a report.

Printing Images

There are three ways to print images:

- Print from a live scan
- Print from an existing patient exam
- Print from a report

When printing from a live scan or an existing patient exam you must first stop the scan at the frame you would like to print.

How to Print an Image

With the Accutome B-Scan Plus you can easily print any frame of any scan by simply selecting the frame, making any necessary image adjustments and clicking the “Print Image” button. You can also select a frame and save the frame as a snapshot.

The steps to print a patient image are:

1. If not printing an active patient scan, select the appropriate patient exam [see “Selecting Patient Exam” below].
2. Select the frame you would like to print [see “Selecting a Frame” below].
3. Print the frame
4. Save or print the report [see “Print or Save Report” on page 187].

Selecting Patient Exam

To select the patient exam:

1. After launching Accutome B-Scan Plus, select “Existing Exam”. The B-Scan Plus Analyze Screen will display with the existing exam drop down list.
2. Scroll through the drop down list until you find the patient for whom you would like to create a report.
3. Once selected, the patient’s exam will appear on the screen.

Note: For more information on selecting existing exams refer to “How to Select an Existing Exam” on page 135 of this manual.

Selecting a Frame

1. In the list of views, click on the elevation you want to watch.

2. Click the play button and hit pause at the appropriate frame.
3. You can also single step through the scans until you display the frame you want to print. Single step through the frames by clicking the forward and back buttons.

Note: For more information on scan playback and selecting frames refer to “Playing an Exam” on page 64.

Adjusting Images

If the frame you would like to print needs enhancement use the tools provided with the Accutome B-Scan Plus.

1. Open the tools palette and make all the necessary adjustments to the image:
 - Zoom and position the image
 - Turn on the A-Vector
 - Add comments
 - Select Print or Snapshot

Note: For more information on adjusting images refer to “Patient Image Analysis” on page 58 of this manual.

Executing Print

To print either a live scan or from an existing exam:

When the frame you have selected is ready for print:

1. Click on the “Print Image” button in the tools palette as shown in Figure 7.1.
2. The frame will be immediately printed to either plain paper printer on plain paper or to thermal paper from a USB video graphic printer.



Note: If you are going to generate a report the images you wish to include in the report must be captured as snapshots.

Figure 7.1 - Printing a Frame

Creating Reports

With the Accutome B-Scan Plus you can create a report for any patient. The report can contain the following:

- Patient Name
- Physician
- Clinician
- Indication for Scan
- Patient snapshot images

All patient information is saved as part of the patient record. Snapshot images of the patient exam are also saved with the patient record every time you save a scan frame as a snapshot.

The steps to create a patient report are:

1. Select the appropriate patient exam (see “Selecting Patient Exam” below).
2. Capture all necessary snapshots if not previously captured (see “Capturing Snapshots” below).
3. Select Reports tool (see “Reports Tool” below).
4. Execute Manage Reports (see “Executing Manage Reports” on page 78).
5. Create a New Report for the active patient (see “Create a New Report” on page 78).
6. Select the snapshots you would like to place in the report (see “Selecting Snapshots” on page 79).
7. Print or save the report (see “Print or Save Report” on page 80).

Selecting Patient Exam

To select the patient exam:

1. After launching Accutome B-Scan Plus, select “Existing Exam”. The B-Scan Plus Analyze Screen will display with the existing exam drop down list.
2. Scroll through the drop down list until you find the patient for whom you would like to create a report.
3. Once selected, the patient’s exam will appear on the screen.

Note: For more information on selecting existing exams refer to “How to Select an Existing Exam” on page 58 of this manual.

Capturing Snapshots

If there are any additional snapshots you would like to add to the patient report:

1. Select the appropriate elevation from the list of scan views.
2. Play the selected patient view.
3. Pause at the frame you would like to make a snapshot.
4. Adjust any of the image settings if necessary.
5. Click “Snap Shot”.
6. The frame will be exported to a file, linked to the patient in either a bit map or jpg format. The file name for the snapshot is determined by the “Exam Name Combination” selected during setup. (Refer to “Exam Name Combination” on page 29). Snapshots can easily be incorporated into an email or pasted into a report.

Reports Tool

When you are ready to create a report select the “Reports” tab from the tools palette as shown in Figure 7.2.

The Reports tools has three function buttons:

- Snapshot List - displays all available snapshots for the active patient
- Manage Reports - launches the manage reports window
- Delete Selected - deletes snapshot(s) selected from the snapshot list.

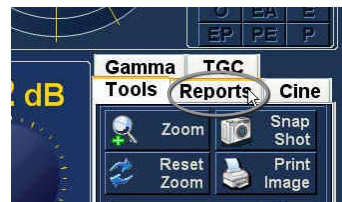


Figure 7.2 - Selecting Reports Tool

Snapshot List

To display all snapshots available for the active patient:

1. Click on "Snapshots List" as shown in Figure 7.3.
2. All snapshots will be displayed in the panel below the reports tool buttons.



Figure 7.3 - Selecting Snapshot List

Deleting Snapshots

If for any reason you don't want to keep one of the patient snapshots the Accutome B-Scan Plus allows you to simply select the snapshot and delete. The snapshot file, in the patient's exam folder will be permanently deleted providing space on the B-Scan computer to store more snapshot files.

To delete a snapshot:

1. Select the snapshot by dragging around it, or clicking on it.
2. You can also select multiple snapshots by dragging around several, or by pressing the "Ctrl" key and clicking each snapshot you'd like to select.
3. When the snapshot(s) you'd like to delete are selected click on "Delete Selected" as shown in Figure 7.4.
4. The Accutome B-Scan Plus will then launch the dialog displayed below. If you would like to permanently delete the snapshot file from the system (from the computer which you are using to operate the B-Scan) select "Yes". If you don't want to delete the snapshot select "No".

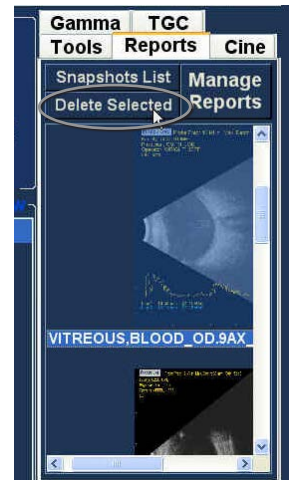


Figure 7.4 - Selecting Snapshot List



Figure 7.5 - Confirming Snapshot Deletion

Executing Manage Reports

When you are satisfied with the list of snapshots to enter in the report click on "Manage Reports" in the Reports tab as shown in Figure 7.6.



Figure 7.6 - Executing Manage Reports

Create a New Report

After you execute "Manage Reports" the Accutome B-Scan Plus launches the Report Form window with the snapshot list at the right as shown in Figure 7.7. The Report Form window also contains function buttons with which you can save additional snapshots to files, delete a selected snapshot, or refresh the image list after making image edits or selections. You will create the actual report in this window.

To start a new report:

1. Click on the "New" button as shown in Figure 7.7. The form for reports will display as shown in Figure 7.8 on page 79.

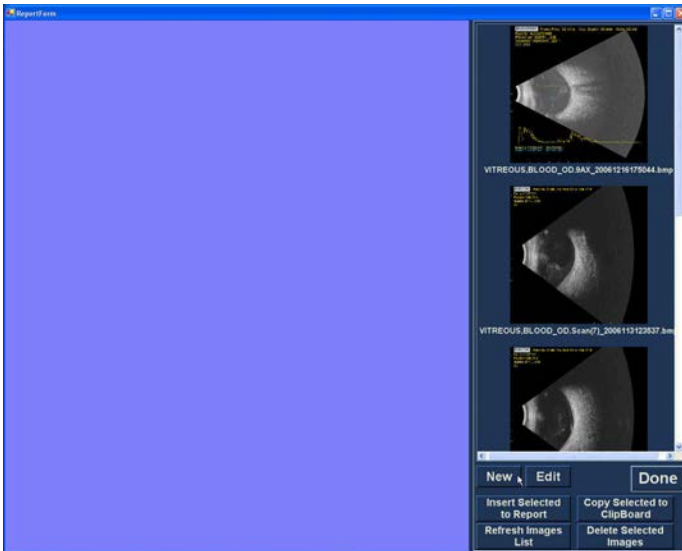


Figure 7.7 - Creating a New Report

Report Form

After you execute "New" in the Manage Reports window the Reports Form will display as shown in Figure 7.8. The Report Form for the selected patient will display all information in all the fields that have been predefined in either the setup or the patient exam (either when creating a new exam file or when editing a patient exam). The Report template displays the following fields:

- Facility
- MRN
- Name
- Physician

- Clinician
- Indication for Scan
- Diagnosis
- Two sign off lines for Clinician and Physician

There is also an area located below the information fields where selected snapshots will be loaded.

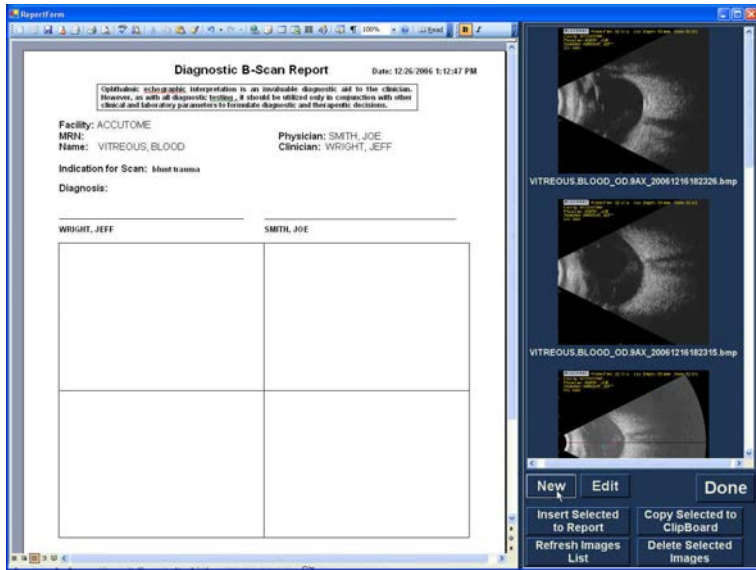


Figure 7.8 - Report Form

Selecting Snapshots

The snapshots are displayed at the right side of the report form. Select the snapshots to be inserted into the report as described below.

1. Left click and hold on the mouse in the blue area near the first snapshot, then drag until you select all snapshots you would like to place in the report as shown in Figure 7.9.
2. You can also select individual snapshots by holding the "Ctrl" key and select each snapshot one at a time.
3. A maximum of four (4) snapshots can be selected at any one time. If you need to insert more than four snapshots, select the first four and insert them, then select up to four more and insert them. Continue selecting and inserting until all snapshots are inserted.

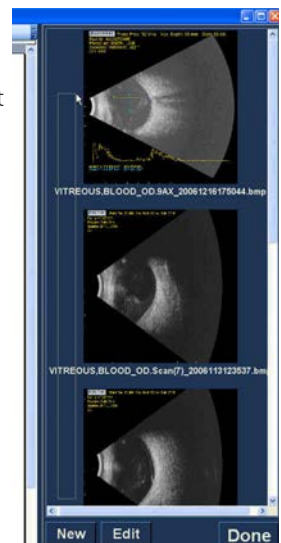


Figure 7.9 - Selecting Snapshots

Inserting Selected Snapshots

After you have selected all the snapshots you would like to include in the report click on "Insert Selected to Report" as shown in Figure 7.10. The report is now ready to print or save.

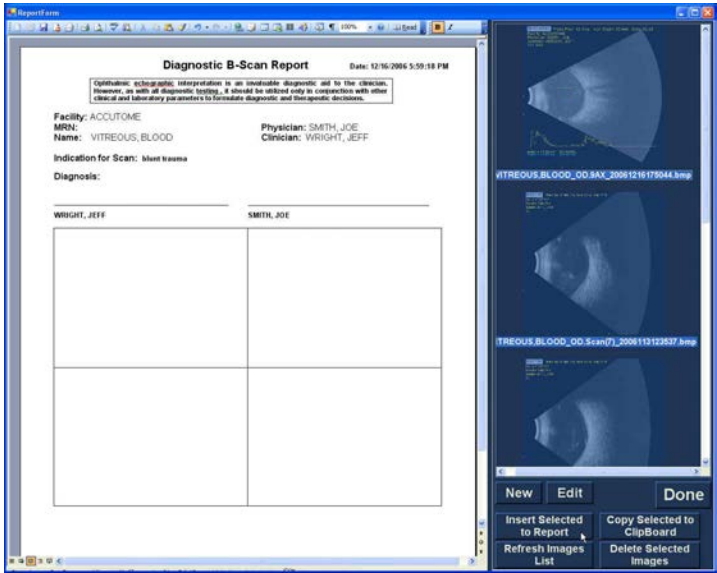


Figure 7.10 - Inserting Selected Snapshots

Alternate Method for Selecting & Inserting Snapshots

1. Left click on the snapshot you want to insert into the report, and click on "Copy Selected to Clipboard".
2. Click on the frame in the report where you want the selected snapshot, and select paste, as shown in Figure 7.11 on, to put the selected snapshot into the selected frame.

Print or Save Report

Once you have completed the report you can print and/or save the report to keep a copy.

To print the report:

1. Click on the Windows printer icon in the Report Form toolbar.
2. The report will print to the printer connected to the Accutome B-Scan Plus computer

To save the report:

1. Click on the Windows save icon as shown in Figure 7.11.



Figure 7.11 - Saving a Patient Report

2. The Accutome B-Scan Plus will launch a Windows browser for you to locate the folder in which to save the patient report.
3. Select the file type you would like to save the report as from the "save as type" drop down list.

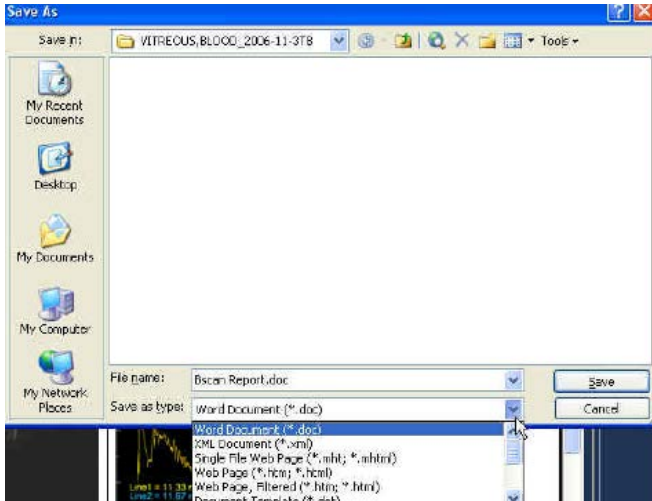


Figure 7.12 - Selecting File Type

4. Enter the name for the report file and click "Save" as shown below.



Figure 7.13 - Saving Report

8

Archive and Restore

Overview

The Accutome B-Scan Plus makes archiving and restoring patient exams and their film loops an easy process. Using the Archive function you can manage all exam file functions; burn exam film loops to a CD/DVD or backup exam film loops on a local or network hard drive. You can also load patient exams from discs, acquire disc information, verify burn or backup and store reports only (not entire patient exam). To access the archive function click on the Archive button in the Accutome B-Scan Plus main window as shown in Figure 8.1 below.



Figure 8.1 - Selecting Archive

Archive Screen

The Accutome B-Scan Plus will launch the Archive screen shown below with two tabs; Backup and Restore. The default is Backup. On this screen you can select multiple patient exams and burn them to a CD or DVD. You can also backup selected exams to a location your computer or network.

The Archive Screen is divided into four major sections:

1. Exams on the System - displays all available exams
2. Exams to Be Archived - after selecting exams for burning to a CD/DVD or for backup they will be displayed in this area
3. Process Information Area - provides live feedback as text for any selected archive activity. When you first start the Archive function this area displays information about the CD/DVD drive and disc.
4. Tool Palettes - contains tools for checking and burning CD/DVDs and tools for archiving (backup) to a local or network hard disk. There are two tabs: CD/DVD Recordable Media and Local/Net Hard Disk

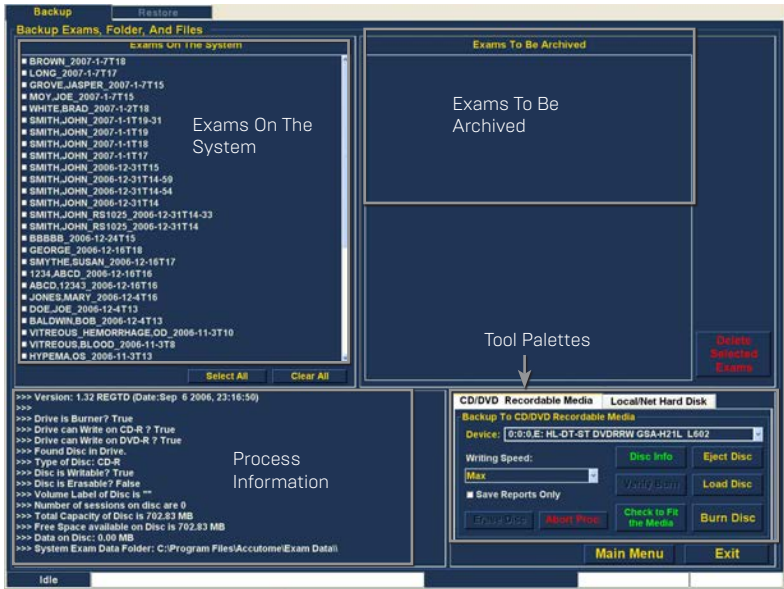


Figure 8.2 - Archive Screen

Archive to CD or DVD

The process to archive patient exams is extremely simply; insert a disc in the CD/DVD drive, select the exams and click burn. The steps to archive patient exams to a CD/DVD are:

1. Insert a CD or DVD into the computer drive.
2. Select the patient exams you would like to archive.
3. Select "Burn Disc" on the CD/DVD Recordable Media tab.

Selecting Patient Exams

When you launch the Archive function the B-Scan Plus displays all exams found on the system at the left side of the screen. You will select the exams to archive from this list. You can select the exams one at a time or select all exams at once.

Selecting Individual Exams

To select exams one at a time:

1. Click in the checkbox beside the exam name as shown in Figure 8.3.
2. You can also click on the name of the exam you would like to select as shown in Figure 8.4.

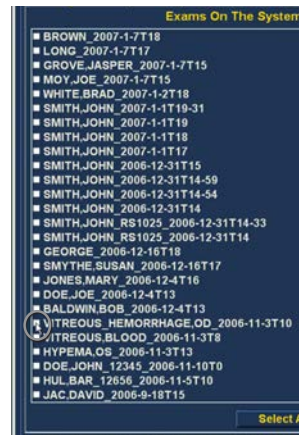


Figure 8.3 - Selecting the First Exam

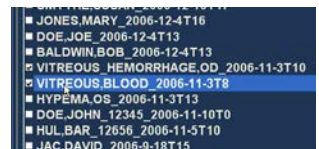


Figure 8.4 - Selecting the Second Exam

Select All

If you would like to archive all exams on the system and don't want to select them individually:

- 1. Click "Select All" as shown in Figure 8.5. All system exams will be displayed in the "Exams To Be Archived" section of the screen as shown in Figure 8.6.



Figure 8.5 - Select All

Clear All

If you don't want to archive all system exams you can individually de-select the exams you don't want to archive by clicking in the checkbox or on the exam name or you can clear all the exams from the list to be archived.

To clear all selected exams from the archive list:

- 1. Click on "Clear All" as shown in Figure 8.7. The "Exams To Be Archived" list will be emptied. You can then individually select the exams if wanted.

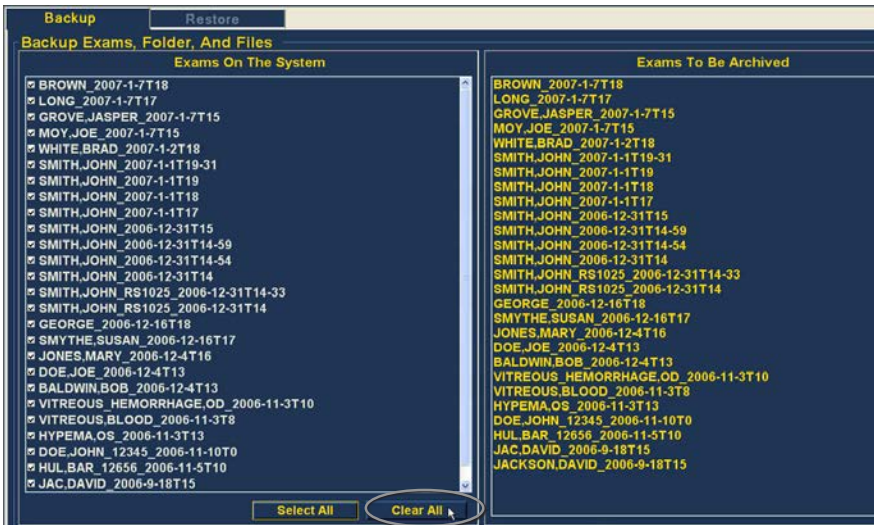


Figure 8.6 - All Exams Displayed - Clear All

Burn Disc

Once you have selected all the exams you would like to burn on the CD/DVD:

- 1. Select "Burn Disc" to execute the burn as shown in Figure 8.7.



Figure 8.7 - Burning the Disc

- While the disc is burning the archive screen will display in the process information area the burning progress as shown in Figure 8.8. Disc burning information includes textual information and burn progress in the status bar at the bottom of the screen.



Figure 8.8 - Disc Burning Progress

Archive to a Local/Net Hard Disk

The Archive function also gives you the option of backing up files to a local or network hard disk. The process like burning a CD/DVD is simple:

- Select the patient exams you would like to backup
- Select the Backup tool.
- Select the Destination Folder
- Select "Backup Exams"

Selecting Patient Exams

When you are backing up patient exams you select them in the same manner as if you were burning a CD/DVD. Refer to "Selecting Patient Exams" on page 83 for instructions.

Selecting the Backup Tool

To activate the backup tools:

- Locate the Local/Net Hard Disk tab in the tools palette.
- Click on the tab as shown in Figure 8.9.



Figure 8.9 - Selecting the Local/Net Hard Disk Tools

Selecting the Destination Folder

After you have selected the exams you would like to back up you need to designate the location at which you would like to store the exams.

- Click on "Select Destination Folder" as shown in Figure 8.10.



Figure 8.10 - Launching Select Destination Folder

Locating Destination Folder

After you execute "Select Destination Folder" the B-Scan Plus will launch a Windows browser shown in Figure 8.11.

1. Using the Windows browser locate the folder in which you would like to backup the patient exams.
2. After you have selected the destination folder the path and name of the folder will appear as shown in Figure 8.12.
3. To complete the backup process click on "Backup Exams" as shown in Figure 8.12.
4. The status bar at the bottom of the Archive Screen will display backup activity, indicating that the backup is in process and how much of the backup has been completed (see Figure 8.13).

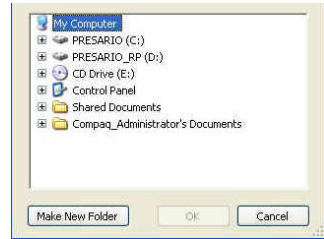


Figure 8.11 - Windows Browser - Locating Destination Folder



Figure 8.12 - Destination Folder Displayed



Figure 8.13 - Backup Activity

Additional Archive Features

The Archive function provides many other additional features that allow you to gather information about disc size and operation, allows you to manage exams, and to load exams from discs.

Delete Selected Exams

After you have archived patient exams you may want to delete them to free up computer disk space. The "Delete Selected Exams" function allows you to permanently remove a patient exam. To delete selected exams:

1. Select the exam(s) you would like to delete (see "Selecting Patient Exams" on page 83).
2. Click on "Delete Selected Exams" as shown in Figure 8.14.
3. The Accutome B-Scan Plus will issue a warning shown in Figure 8.15 about deleting the file. Click on "Yes" if you would like to permanently delete the file. Click "No" or "Cancel" if you would like to terminate the delete process.



Figure 8.14 - Delete Selected Exams

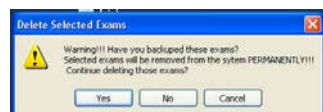


Figure 8.15 - Deleting Exam Warning

Disc Tool Features

There are many features in the CD/DVD Recordable Media tab of the tools palette that are informational and perform disc operations.

Save Reports Only

The "Save Reports Only" function when selected will burn only the reports to the CD/DVD

Erase Disc

The "Erase Disc" function erases all information on the CD/DVD (if it is erasable).

Abort Proc.

The "Abort Proc." function stops whatever disc process is in operation; e.g. you are burning a CD and you would like to stop the burn, select "Abort Proc."

Disc Info

When you select "Disc Info" the Accutome B-Scan Plus displays information about the CD/DVD including disc size, date, the number of sessions, amount of space remaining in the disc, etc. as shown in Figure 8.16.



Figure 8.16 - "Disc Info"

Verify Burn

The "Verify Burn" feature confirms that an executed disc burn actually happened by listing all files burned on the CD/DVD and confirming that the burn process was successful as shown in Figure 8.17.

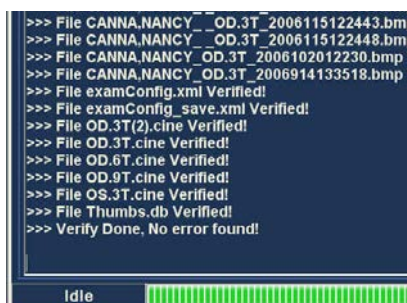


Figure 8.17 - Verify Burn Results

Check to Fit the Media

The "Check to Fit Media" feature checks the amount of disc space required to burn the selected exams and displays both the required and available disc space.

Eject Disc

"Eject Disc" will automatically eject the CD/DVD from the computer drive.

Load Disc

The "Load Disc" feature loads the contents of the disc installed in the CD/DVD drive and launches a Windows browser so that you can select the location for loading the disc.

Local/Net Hard Disk

There are many features in the Local/Net Hard Disk tab of the tools palette that are informational and perform backup operations.

Checking System Free Space

The "Checking System Free Space" feature searches all connected local and net hard disk and displays the amount of disk space available on each.

Space Required

The "Space Required" feature displays the amount of disk space required to backup the selected exams.

If Name Conflict Found

The "If Name Conflict Found" feature allows you select an option if there are duplicate file [exam] names found during your backup.

- Create New - will create a new exam name by adding a number to end of the redundant exam
- Overwrite - will keep the same exam name and overwrite the exam that is currently on the local/net disk.

Check Name Conflict

The "Check Name Conflict" feature will check if there are duplicate names in the selected destination folder and the selected exams that you are going to backup.

Abort Backup

The "Abort Backup" stops the backup process when selected.

Verify

The "Verify" feature allows you to confirm that the selected exams have been backed up into the selected destination folder. When you select this feature you will receive the following message "Exams in the backup are the SAME as the original" if the backup properly executed.

Restore Screen

Not only can you archive patient exams with the Accutome B-Scan Plus but you can also restore them to your computer for analysis and reporting. The Restore screen is represented by a tab on the main Archive screen. To access the Restore screen, click on the "Restore" tab as shown in Figure 8.18.

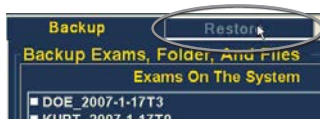


Figure 8.18 - Selecting the Restore Screen

The Accutome B-Scan Plus will launch the Restore screen shown in figure 8.19. On this screen you can select and restore multiple patient exams from a CD or DVD. You can also restore selected exams from a location on your computer or network. The Restore Screen is divided into four major sections:

1. Restore Exams Palette - three tabs when selected display exams selected on backup, exams on destination and exams on system.

2. Exams to Be Restored - after selecting exams for restoring from a DVD/CD or from a local/network hard drive backup they will be displayed in this area.
3. Process Information Area - provides live feedback as text for any selected restore activity. When you first start the Restore function this area displays information about the DVD/CD drive and disc.
4. Tool Palettes - contains tools for locating and loading exams from DVD/CDs and from a local or network hard disk. There are two tabs: DVD/CD Device and Local/Net Hard Disk.



Figure 8.19 – Restore Screen

Restore from DVD or CD

The process to restore patient exams from a DVD/CD is extremely simply; insert a disc in the DVD/CD drive, select the exams and click restore. There may only be one patient exam on a CD or DVD. The steps to restore patient exams to a DVD/CD are:

1. Insert a CD or DVD into the computer drive.
2. Select the patient exam(s) you would like to restore.
3. Select "Restore" on the DVD/CD Device tab.

Selecting Patient Exams

When you launch the Restore function the B-Scan Plus defaults to displaying all exams found on the DVD/CD at the left side of the "Exams on Backup" tab of restore exams palette (top left corner of the screen). You will select the exams to restore from this list. You can select the exams one at a time or select all exams at once.

Note: The folder where the restored exams will be placed is preset on the Options Screen during Accutome B-Scan Plus setup. See “Restored Folder” on page 29 of this manual for more information.

Note: On the DVD/CD Device tab you can also select exams for restoring from a computer folder. See “Selecting the Folder for Restoring Exams” on page 92 for more information.

Selecting Individual Exams

To select exams one at a time:

1. Click in the check box beside the exam name as shown in Figure 8.20.
2. The selected exam will appear in the “Selected Exams To Be Restored” list as shown in Figure 8.21.
3. You can also click on the name of the exam you would like to select as shown in Figure 8.22.

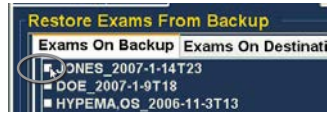


Figure 8.20 - Selecting the First Exam

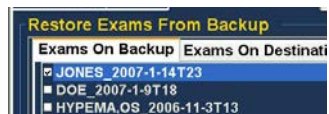


Figure 8.21 - First Exam Selected

Select All

If you would like to restore all exams on the system and don't want to select them individually:

1. Click “Select All” as shown in Figure 8.23. All system exams will be displayed in the “Selected Exams To Be Restored” section of the screen as shown in Figure 8.24.

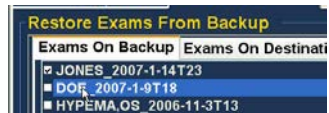


Figure 8.22 - Selecting the Second Exam

Clear All

If you don't want to restore all selected exams you can individually de-select the exams you don't want to restore by clicking in the check box or on the exam name or you can clear all the exams from the list to be restored.

To clear all selected exams from the restore list:

1. Click on “Clear All” as shown in Figure 8.24. The “Selected Exams To Be Restored” list will be emptied. You can then individually select the exams if wanted.

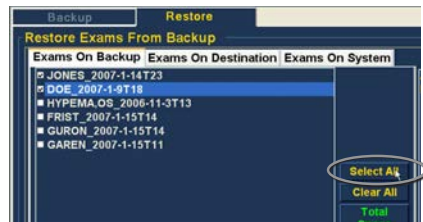


Figure 8.23 - Select All Exams to be Restored

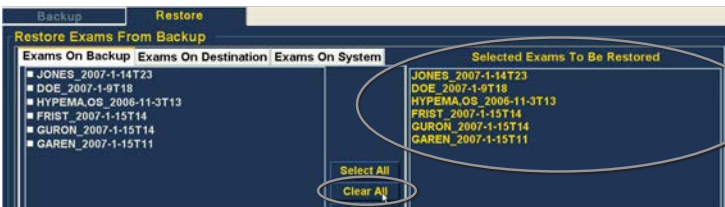


Figure 8.24 - Selected Exams To Be Restored - Clear All

Restore

Once you have selected all the exams you would like to restore from the DVD/CD:

1. Select "Restore" to execute the restoring process as shown in Figure 8.25.
2. While the exams are being restored the restore screen will display in the process information area the restoring progress as shown in Figure 8.26 below. Exam restoring information includes textual information and restore progress in the status bar at the bottom of the screen.



Figure 8.25 - Restoring the Exam from the CD

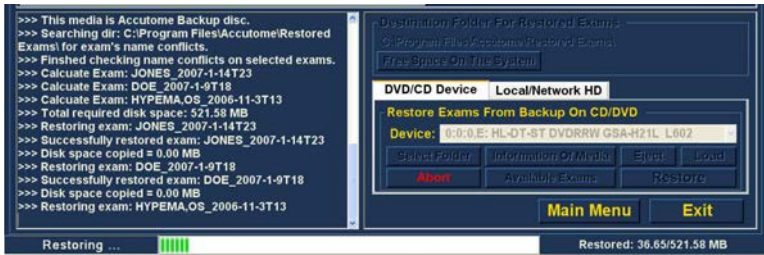


Figure 8.26 - Exam Restoring Progress

Restore Local/Network Hard Disk

The Restore function also gives you the option of restoring files from a local or network hard disk. The process like restoring from a DVD/CD is simple:

1. Select the Local/Network HD tab.
2. Select the folder from which you would like to restore exams.
3. Select the patient exams you would like to restore.
4. Select the Restore tool.

Note: The folder where the restored exams will be placed is preset on the Options Screen during Accutome B-Scan Plus setup. See "Restored Folder" on page 29 of this manual for more information.

Selecting the Local/Network HD Tool

To activate the local/ network hard drive restore tools:

1. Locate the Local/Net HD tab in the tools palette.
2. Click on the tab as shown in Figure 8.27.
3. The Local/Network HD tools will be displayed as shown in Figure 8.28.

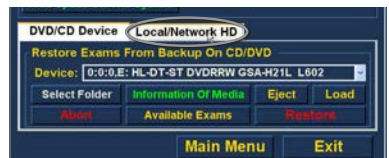


Figure 8.27 - Selecting the Local/ Net Hard Disk Restore Tools



Figure 8.28 - Local/Network HD Restore Tools Active

Selecting the Folder for Restoring Exams

Before you can restore selected exams you need to locate the folder from which they will be restored.

1. Click on "Select Folder" as shown in Figure 8.29.
2. After you execute "Select Folder" the B-Scan Plus will launch a Windows browser shown in Figure 8.30.
3. Browse the local and network drives and folders until you locate the folder from which you would like to restore exams.
4. After you have the selected the restore from folder the path and name of the folder will appear as shown in Figure 181 below. The contents of the folder will also display in the "Exams on Backup" tab.



Figure 8.29 - Launching Select Folder (for Restoration)



Figure 8.30 - Windows Explorer



Figure 8.31 - Locating Source Folder



Figure 8.32 - Source Folder Displayed

Selecting Patient Exams

When you are restoring patient exams you select them in the same manner as if you were burning a DVD/CD. Refer to "Selecting Patient Exams" on page 89 for instructions.

Executing Restore

To complete the restore process:

1. Click on "Restore" as shown in Figure 8.33.
2. The status bar at the bottom of the Restore Screen will display restoring activity, indicating that the exam restoration is in process and how much of the restore has been completed (see Figure 8.34).



Figure 8.33 - Execute Restore Exams on Local/Network HD



Figure 8.34 - Restore Activity

Additional Restore Features

The Restore function provides many other additional features that allow you to gather information about restore size and operation and allows you to manage exams.

Exams on Backup Features

When the "Exams on Backup" tab is active there are many additional features available related to the exams in the backup folder.

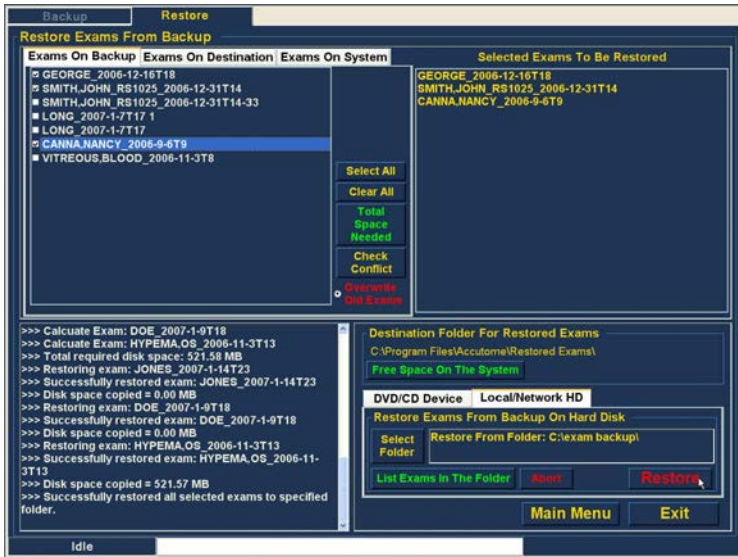


Figure 8.35 - Exams on Backup Tab Active

Select All

When you execute "Select All" all patient exams in the "restore from folder" will be selected for restoration.

Clear All

When you execute "Clear All" all selected exams for restoration will be cleared from the "Selected Exams To Be Restored" list.

Total Space Needed

The "Total Space Needed" feature checks the amount of disk space required to restore the selected exams and displays the required disk space.

Check Conflict

The "Check Conflict" feature will check if there are duplicate names in the Restored Exams folder and the selected exams in the restore from folder.

Overwrite Old Exams

When you activate “Overwrite Old Exams” by clicking the radio button, the restore process will keep the same exam name and overwrite the exam that is currently on the local/net disk.

If you are overwriting an exam in the restore process you will receive a warning message similar to the one shown in Figure 8.36.

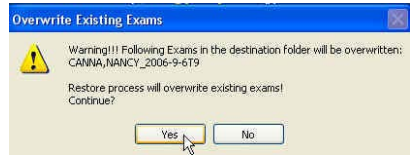


Figure 8.36 - Overwrite Warning

Exams on Destination

The Exams on Destination tab as shown in Figure 8.37 displays the contents of the current Restored exams folder. Additional features allow you to select and delete current restored exams.

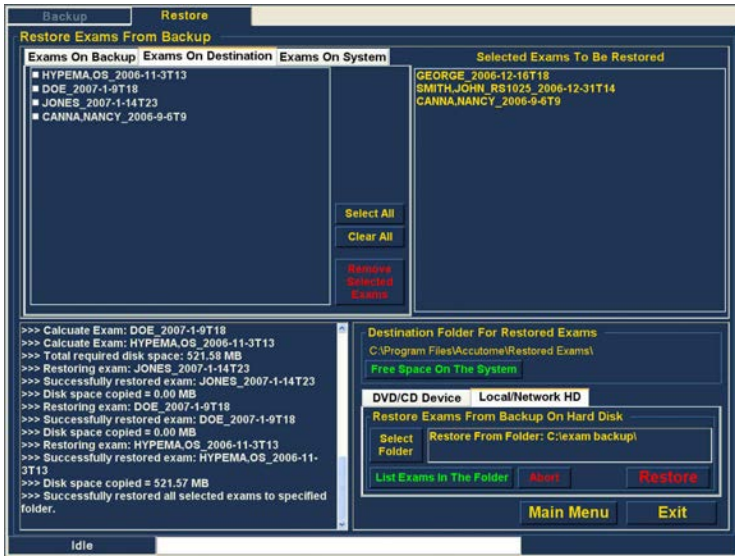


Figure 8.37 - Exams on Destination - Restored Exams Folder

Select All

When you click on “Select All” all the restored exams in the destination folder will be selected.

Clear All

When you click on “Clear All” all the selected restored exams in the destination folder will be de-selected.

Remove Selected Exams

After you have restored patient exams you may want to delete them to free up computer disk space. The “Remove Selected Exams” function allows you

to permanently remove a restored patient exam. To remove selected exams:

1. Select the exam(s) you would like to delete (see "Selecting Patient Exams" on page 89).
2. Click on "Remove Selected Exams" as shown in Figure 8.38.
3. The Accutome B-Scan Plus will issue a warning shown in Figure 8.39 about deleting the file. Click on "Yes" if you would like to permanently delete the file. Click "No" or "Cancel" if you would like to terminate the delete process.



Figure 8.38 - Remove Selected Exams

Exams on System

The "Exams On System" tab when active displays all the exams in the Accutome B-Scan Plus Exam Data folder. The list can be useful in determining which exams need to be restored.

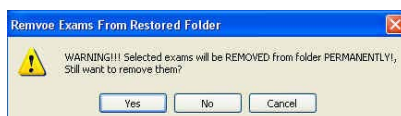


Figure 8.39 - Removing Exam from Restored Folder Warning

DVD/CD Features

There are many features in the DVD/CD Device tab of the tools palette that are informational and perform disc and restore operations.

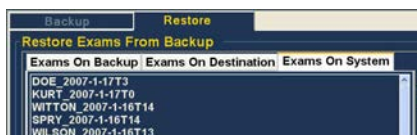


Figure 8.40 - Exams on System - Accutome Exam Data Folder

Free Space On The System

When you execute "Free Space on The System" as shown in Figure 8.41, the Accutome B-Scan Plus will display all available space on all drives.

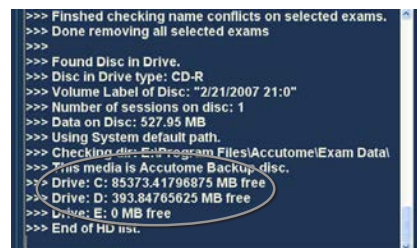


Figure 8.41 - Free Space on The System

Select Folder

The "Select Folder" feature launches a Windows browser and allows you to select the folder from which you would like to restore exams.

Information of Media

When you select "Information of Media" the Accutome B-Scan Plus displays information about the DVD/CD in the device drive, including disc size, date, the number of sessions, amount of space remaining in the disc, etc. as shown in Figure 191 below.

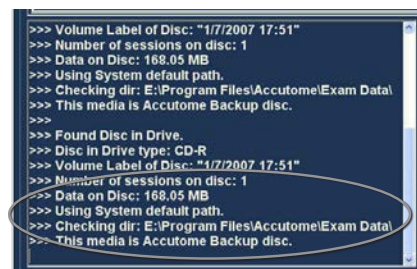


Figure 8.42 - Information of Media

Eject

"Eject" will automatically eject the DVD/CD from the computer drive.

Load

The "Load" feature closes the DVD/CD drive drawer if the computer system has this feature.

Abort

The "Abort" function stops disc process of restoration or loading.

Available Exams

The "Available Exams" function lists all exams that can be restored in the Exams on Backup tab.

Local/Net Hard Disk

There are many features in the Local/Net Hard Disk tab of the tools palette that are informational and perform restore operations.

Select Folder

The "Select Folder" feature launches a Windows browser and allows you to select the folder from which you would like to restore exams.

List Exams in the Folder

The List Exams In The Folder" feature lists all the exams contained in the selected restore folder. Exams are listed in the "Restore Exams from Backup" tab.

Abort

The "Abort" function stops the restoring process when selected.

Main Menu and Exit

The Main Menu and Exit buttons located at the bottom of the Archive and Restore Screens bring you back to the B-Scan Plus main menu and exit the B-Scan Plus program accordingly.

9

Maintenance

General Maintenance

Maintenance that should be performed on the Accutome B-Scan Plus 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 effect electronic parts.

Care must be taken to use only proper non-linting cloths and non-corrosive solvents when cleaning the screen.

CAUTION: NO ABRASIVES OR HARSH CLEANING SOLUTIONS SHOULD BE USED WHILE CLEANING THE ACCUTOME B-SCAN PLUS.

10

Specifications

Overview

This section provides the physical and operational specifications of the Accutome B-Scan Plus.

Physical Specifications

Table 10.1 below lists the physical specifications and associated peripherals.

Table 10.1 - Accutome B-Scan Plus Physical Specifications

Probe (Accutome Part Number 24-6120)	
Frequency	12 MHz, 15 MHz
Dimensions	7.0 inches long X 1.25 inches diameter 17.78 cm long X 3.18 cm diameter
Weight	.375 lb or 0.170 kg
Cable Length	6 feet or 1.83 m
Interface	USB Type A
Footswitch (Accutome Part Number 24-6180)	
Dimensions	4 inches X 3.25 inches X 1.25 inches high 10.16 cm X 8.26 cm X 3.18 cm high
Weight	.337 lb. or .153 kg
Cable Length	6 feet or 1.83 m
Interface Connector	USB Type A
Wireless Mouse (Accutome Part Number 24-6130)	
Dimensions	1.75 inches X 2.25 inches X 1.63 inches 4.45 cm X 5.72 cm X 4.14 cm
Weight	.222 lb. or .101 kg
Interface Connector	USB Type A
Probe Holder (Accutome Part Number 24-6170)	
Dimensions	7.7 Inches X 4.3 Inches X 2.09 Inches High 19.56 cm X 10.92 cm X 5.61 cm
Weight	.75 Lb. or .340 kg

Table 10.1 – Accutome B-Scan Plus Physical Specifications [continued]

Safety and EMI Standards	
IEC 60601-1 Medical Electrical Equipment: General Requirements for Safety	
IEC 60601-1-2 Medical Electrical Equipment: Electromagnetic Compatibility	
IEC 60601-2-37 Medical Electrical Equipment: Particular Requirements for Ultrasound Equipment	

Environmental Specifications

Table 10.2 lists the Accutome B-Scan Plus system operating and storage values for temperature and humidity.

Table 10.2 – Environmental Specifications

Temperature	
Operating	+10° C to +40° C
Storage	-20° C to +60° C
Relative Humidity	
Operating	20% to 80% (non-condensing)
Storage	15% to 90% (non-condensing)
Atmospheric Pressure	
Operating	700 - 1060 hPa
Storage	500 - 1060 hPa

Computer Specifications

Table 10.3 provides the recommended specifications for the computer to be used with the Accutome B-Scan Plus

Table 10.3 – Recommended Computer Specifications

PC	Dell™ Latitude D820 with Intel Core™ 2 Duo T7200 [2.00GHz] 4M L2 Cache, 667MHz Dual Core or equivalent
I/O Ports	Minimum 4 USB 2.0
Operating Systems	Windows® XP Professional, SP2
Display	15.4 inch WSXGA+ LCD or larger
Memory	2.0 GB, DDR2-667 SDRAM
Hard Disk Drive	80 GB Hard Disk Drive, 9.5 MM, 7200 RPM
CD/DVD Drive	8X DVD+/-RW w/Roxio Software™ and Cyberlink Power DVD
Video Controller	256 MB NVIDIA® Quadro NVS 110M TurboCache™
Power Supply	Medical Grade Power Supply or Isolation Transformer

Note: The user must supply the computer. The computer is not provided with the Accutome B-Scan Plus

Operating Modes

The following table summarizes the mode/application possibilities for each system/transducer combination:

Table 10.4 – Operating Mode[s]

Clinical Application	A	B	M	PWD	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.

Storage/Range Specifications

Table 10.5 below lists the data storage and range specifications of the Accutome B-Scan Plus.

Table 10.5 – Data Specifications

Data Storage Capacity	
Patients & Patient Data	Only limited by the computer’s disk storage capacity

Table 10.6 – Range and Accuracy

B-Scan Plus Setting		Line/Area	Clinical Accuracy	Accuracy Range (mm)
Frequency (MHz)	Depth (mm)			
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

Acoustic Output

Table 10.7 below provides the acoustic output reporting for the following:

Transducer Model: OP [S/N 09065836]

Operating Mode: B-Mode

Application(s): Ophthalmic

Table 10.7 - Acoustic Output Reporting Table for Track 1 Non-Autoscanning Mode

Acoustic Output			MI	ISPTA.3 (mW/cm ²)	ISPPA.3 (W/cm ²)
Global Maximum Value			0.199	0.379	21.1
Associated Acoustic Parameter	Pr.3 [MPa]		0.641	---	---
	Wo [mW]		---	0.149	0.149
	Fc [MHz]		10.4	10.4	10.4
	Zsp [cm]		1.50	---	1.50
	Beam Dimension	x-6 [cm]	---	---	0.0765
		y-6 [cm]	---	---	0.0748
	PD [iS]		0.126	---	0.126
	PRF[Hz]		3840	---	3840
	EBD	Az. [cm]	---	0.600	---
		Ele. [cm]	---	0.600	---
Operating Control Conditions	Frame Rate: 15 Hz, 256 Lines/Sector				
	Operating Frequency: 12 MHz				

These values are based on measurements of production units.

EMC Compliance Information

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Table 5.4 - Guidance And Manufacturer’s Declaration - Electromagnetic Emissions


The B-Scan Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the B-Scan Plus should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR II*	Group 1	The B-Scan Plus 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 II*	Class B	The B-Scan Plus is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	N/A	

Table 5.5 - Guidance And Manufacturer’s Declaration - Electromagnetic Immunity

The B-Scan Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the B-Scan Plus 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 5.6 - Guidance And Manufacturer's Declaration - Electromagnetic Immunity

The B-Scan Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the B-Scan Plus 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 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the B-Scan Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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 B-Scan Plus is used exceeds the applicable RF compliance level above, the B-Scan Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the B-Scan Plus

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

Table 5.7 - Recommended Separation Distances Between Portable And Mobile Rf Communications Equipment And The B-Scan Plus

The B-Scan Plus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the B-Scan Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the B-Scan Plus as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.2\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

11

Warranty & Repairs

Warranty

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 one year 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 proved 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 non-warranted 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 result in immediate loss of 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 USA): 1-800-979-2020

Tech Service: 1-610-889-0200

Fax: 1-610-889-3233

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

All Other Returns

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

Merchandise returned within 60 days of date of invoice will be credited as follows:

- Full credit for all merchandise returned in resalable condition

Non-Returnable Merchandise

Accutome Inc. will not authorize a return for:

- Merchandise held longer than 60 days

Replacement Parts

Table 11.1 below lists items that are available from Accutome, Inc. or from your local sales representative. Please be sure to use the Accutome part number for the item when placing an order.

Table 11.1 - Accutome Replacement Parts

Description	Accutome Part No.
Standard Parts	
Probe Kit	24-6120
Foot Switch	24-6180
Mouse	24-6130
Probe Holder	24-6170



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