Volcano CORE Mobile

Volcano CORE Mobile

Precision Guided Therapy System

Operator's Manual

For use with:

Volcano CORE Mobile, Precision Guided Therapy System

400-0100.01

400-0100.07

400-0100.08

Software Version 3.4.X/3.5.X

CE 2797 Complies with the Council Directive 93/42/EEC

Volcano CORE system product meets TUV's safety requirements

Attention: Read Operator's Manual and Instructions For Use prior to using this device. Please contact your local Volcano representative for translated versions.

Do not dispose of this device or its components. Improper disposal may be harmful to the environment and human health. Dispose device per local electronic waste regulations.

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Warranty

NOTICE: Manufacturer's Specifications and Policies Subject to Change. Volcano Corporation reserves the right to make changes in the products described in this manual in order to improve design or performance. Reproduction or distribution of any portion of this manual without the prior written consent of Volcano Corporation is prohibited.

LIMITED WARRANTY

Subject to the conditions and limitations on liability stated herein, Volcano Corporation ("VOLCANO") warrants that the Volcano Precision Guided Therapy System (the "System") as so delivered, shall materially conform to Volcano's then current specifications for the System, for a period of one year from the date of delivery. ANY LIABILITY OF VOLCANO WITH RESPECT TO THE SYSTEM OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO SYSTEM REPAIR, REPLACEMENT OR, IF REPLACEMENT IS INADEQUATE AS A REMEDY OR, IN THE OPINION OF VOLCANO, IMPRACTICAL, TO REFUND OF THE PRICE PAID FOR THE SYSTEM. EXCEPT FOR THE FOREGOING, THE SYSTEM IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF FITNESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. FURTHER, VOLCANO DOES NOT WARRANT, GUARANTEE, OR MAKE ANY REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OF THE SYSTEM OR WRITTEN MATERIALS IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, OR OTHERWISE. Buyer understands that Volcano is not responsible for and will have no liability for any items or any services provided by any persons other than Volcano. Volcano shall have no liability for delays or failures beyond its reasonable control.

Additionally, this warranty does not apply if:

1. The System is operated in other than a manner prescribed by Volcano Corporation in the Operator's Manual, and/or supplements.
2. The System is operated in a manner that is not in conformance with purchase specifications and specifications contained in the Operator's Manual, and/or supplements.
3. The System is not maintained in accordance with procedures in the Operator's Manual, and/or supplements.
4. The System is repaired, altered, or modified in any way by other than Volcano Corporation authorized personnel, or without Volcano Corporation authorization.

Contact Volcano Corporation, Technical Support for instructions and issuance of a Return Material Authorization if claims under this warranty become necessary and if the System or components of the System are to be returned. The System or components will not be accepted for warranty purposes unless the return has been authorized by Volcano Corporation.

System parts or components repaired or replaced under warranty bear the same warranty expiration date as the original equipment, or 90 days, whichever is longer. Consumable parts (data disks, batteries, among others) are warranted only against defects in materials and workmanship. System parts purchased outside the original warranty period are warranted for a period of 90 days, subject to all of the restrictions contained in this Limited Warranty. Use of unauthorized replacement parts may void the warranty. In all cases, Volcano Corporation will be the sole judge as to what constitutes warrantable damage.

Patents and Trademarks

Patents

See Patents (www.philips.com/patents).

Trademarks

Warnings and Precautions

Read and Review Manual before Operation

Carefully read and review the entire Volcano CORE System Operator's Manual before attempting to operate the system.

Volcano Corporation makes no warranty, representation or condition of any kind, expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the misuse of the system or the reuse of the catheter. Volcano Corporation assumes no responsibility or liability for incidental or consequential damages which may result from reuse or misuse of the catheter.

WARNINGS are used to indicate the possibility of severe personal injury. Follow the instruction or procedure correctly to avoid injury to yourself, the patient, or other personnel.

The warnings are identified by the exclamation symbol.

CAUTIONS are used to indicate the possibility of damage to the equipment. Follow the instruction or procedure correctly to avoid damage to the equipment.

For Use only by Trained Medical Personnel

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Only physicians or other persons with adequate medical training in catheter insertion procedures should use the Volcano system. Only those personnel who are familiar with its operation and who have been trained to perform the procedures for which this device is intended should use the system.

System Use Cautions and Warnings

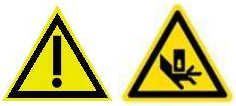
- ***CAUTION:*** For the Volcano CORE system, you can easily roll it by holding the hand grips on either side of the Control Console. Do not exceed a slow walking pace when moving the system to reduce risk of causing the unit to topple which may cause significant damage and/or operator injury.
- ***CAUTION:*** A tipping hazard may occur if the unit is pushed while wheels are immobilized.
- The Volcano system supplies diagnostic information when used in conjunction with the Volcano imaging catheters during ultrasonic imaging of peripheral and coronary vasculature. It is intended to be used as an adjunct to conventional angiographic procedures or interventional therapies such as balloon angioplasty.

- ***CAUTION:*** Although the components are spill-resistant, avoid spilling or dropping any foreign material onto components. It is important to be especially careful with the keyboard, controller, CPU and the monitor.
- The bedside-mounted Volcano system equipment complies with the fluid ingress requirements of IEC60529 (IPX4 for Control Console II and all other bedside peripherals) when configured for normal use. The bedside-mounted Volcano equipment should be located under a sterile drape when configured for normal use.

- **WARNING:** The Volcano system must be properly grounded to avoid electrical shock. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- **WARNING:** To prevent compromising patient isolation, the Volcano system console operator must not simultaneously touch the patient and/or any implanted catheter or guide wire and any part of the Volcano system mobile cart or computer chassis or connector interface.

NOTE: Within the U.S.A., a hospital-grade receptacle *must* be used.



- **WARNING:** Hand crush/pinch potential when positioning device parts.
- ***CAUTION:*** The Volcano system must have the original cord, or installed electrical power in an Volcano integrated system must be used at all times. The Volcano systems are protected against the voltages of defibrillation; still, we recommend that you disconnect the catheter from the patient interface module prior to defibrillation.
- ***CAUTION:*** Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked “hospital only” or “hospital grade.”
- ***CAUTION:*** Do not obstruct access to the main power cord when plugged into wall socket.
- ***CAUTION:*** Do not connect Volcano equipment to non-medical grade or un-grounded power strip, especially when shared with non-medical grade equipment.
- For cardiac catheterization applications, the Volcano system must be connected to the potential equalization system of the hospital room.
- ***CAUTION:*** The Volcano system is a high-gain wide-band patient connected intravascular ultrasound (IVUS) system intended for use during diagnostic or interventional percutaneous coronary or peripheral procedures. As such, the system is susceptible to in-band (5-60MHz) reciprocal interfering signals. Reciprocal interference is non-synchronous to the IVUS system and typically transient in nature. When local intensities are sufficiently high, non-synchronous in-band transient interference will be visible on the IVUS display as random “speckle” like noise, or faint, intermittent radial spokes or rings. This type of electromagnetic interference is an annoyance to the operator but typically does not render the device unusable. Non-transient (modulated continuous wave transmitters) with in-band center frequency carriers can, under high local

intensity levels, “white out” the IVUS image. Under this extreme condition the IVUS system is rendered in-operable. Whenever electromagnetic interference renders the IVUS system inoperable, the appropriate action is to identify the source of the interfering signal and reduce the in-band local intensity levels sufficient to operate the IVUS system.

- ***CAUTION:*** This device is not intended for use in the presence of flammable substances which could cause combustion.
- ***CAUTION:*** The Volcano system should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

- **WARNING:** Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT. See Chapter 18, Technical Specifications for the recommended separation distances between portable and mobile RF communications equipment and the Volcano Model equipment.

- **WARNING:** The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the system as replacement parts for internal components, may result in increased emissions or decreased immunity of the system.

- **WARNING:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1:2005 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1, Clause 16. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1:2000. If in doubt, consult the technical services department or your local representative. In specific, AC Mains powered devices are not recommended unless approved and installed by Volcano Corporation.

- **WARNING:** Changes to IT-networks including network configuration updates, equipment disconnection, equipment update or upgrade, or additional equipment connection to IT-networks could result in previously unidentified risks to patients, operators, or third parties.
- ***CAUTION:*** Non-medical equipment supplied as part of the Volcano Imaging System is intended to be connected to a multiple socket-outlet isolation transformer. If any Volcano or customer-supplied equipment is connected directly to a wall outlet or a multi-socket outlet, this may result in excessive leakage current per IEC 60601-1 and presents a risk of electric shock to the operator and/or patient. The user must verify that the leakage current remains below the IEC 60601-1 limits.

- **WARNING:** Do not connect a multiple socket-outlet or extension cord to the system. This may exceed the safety limits of the system and void the warranty.
- **WARNING:** The Volcano system contains no user-serviceable components. To avoid electric shock, do not remove any panels or covers. In the event of malfunction or system damage, turn the system off, unplug the system from the power receptacle, and contact a qualified service person and Volcano Customer Service.

- **WARNING:** No modification of this equipment is allowed.
- **WARNING**: This instrument is NOT explosion proof. This instrument has been designed and manufactured to minimize the hazard, but the risk, although low, has not been completely eliminated. An explosion risk can exist in sufficiently high atmospheric concentrations of such anesthetics or agents, mixed with air, or with oxygen or with nitrous oxide. The probability of occurrence of the ignition of such anesthetic mixtures depends upon their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures, and the energy of sparking. Sparks can be caused where electrical circuits are opened or closed by the operation of switches, connectors, fuses, or over-current releases and the like.

  Operator action: The operator shall observe care when using this instrument in areas in which flammable anesthetics or flammable agents for disinfection or cleaning are applied. In the event, the atmospheric concentrations of the flammable agents are elevated, the unit should not be powered OFF if running, or should not be powered ON if it is OFF.

PIM Use Cautions and Warnings

- ***CAUTION***: All bedside mounted peripherals should be securely placed to avoid injury to the user or patient.
- ***CAUTION:*** The patient interface module's magnetic strip, which allows it to be attached to various surfaces during use, can damage audiotapes, computer tapes, computer disks, and other magnetically sensitive components. Do not place the PIM near these items.
- ***CAUTION:*** Do not damage the PIM's cable by rolling equipment on it or using excessive force when disconnecting it.
- ***CAUTION:*** If you drop the PIM, you may cause permanent damage to the external packaging and internal electronics. Do not use the system if the outer case of the module appears damaged.
- ***CAUTION:*** The PIM should not be placed below the IV pole where liquids may drip into the catheter connector and cause damage.
- ***CAUTION:*** The PIM cable is susceptible to damage if not stored properly. Never let the PIM cable lay on the floor. Store the PIM cable in a manner where the connector end cannot be damaged by personnel, gurneys or table movements. There must be sufficient slack in the cable when stored on the table to avoid binding during table movements.
- ***CAUTION:*** If the PIM, SpinVision (PIMr), and/or Pimmette are moved while being used with a patient and causes the catheter to be displaced in the body, there is significant risk to the patients' safety. Please ensure that the PIM, SpinVision (PIMr), and/or Pimmette are securely placed at all times.

Catheter and Wire Use Cautions and Warnings

NOTE: See the package insert for a complete description of product usage, warnings, and precautions.

Chapter 1: Overview

Introduction

The Volcano Precision Guided Therapy System provides qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

Intravascular ultrasound (IVUS) utilizes the acoustic impedance of vascular structures to provide cross sectional images from inside the vessel. The IVUS catheter uses a transducer near the distal tip to emit and receive high frequency sound waves.

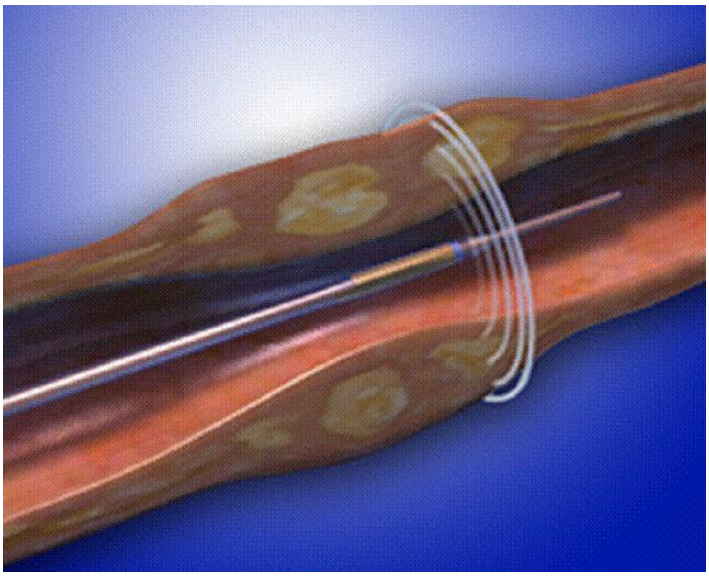


Figure 1: IVUS catheter within vessel

The system is then able to analyze the signal that is received by the transducer to differentiate between vessel structures to produce a 360º cross sectional image.

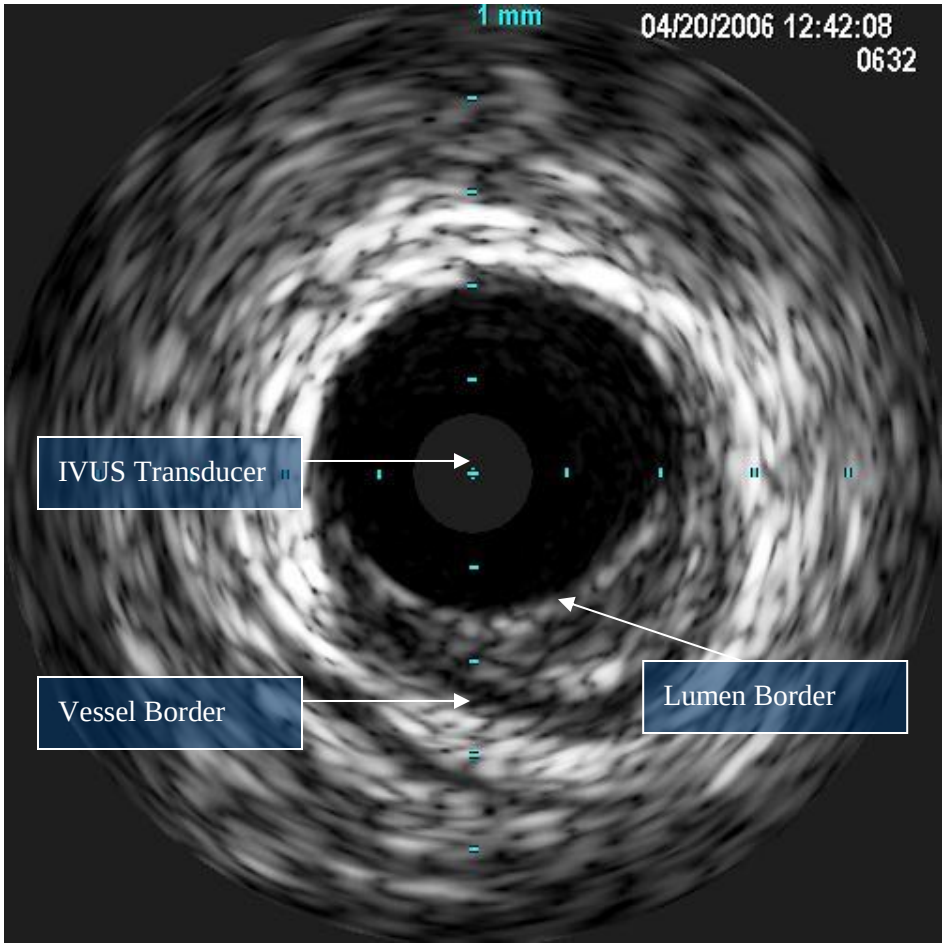


Figure 2: Grayscale IVUS image

These grayscale images can then be enhanced using VH IVUS.

VH analysis provides automatic border detection for the vessel and lumen borders, as well as plaque composition. Plaque is automatically classified into four categories in order to simplify interpretation of the IVUS image:

- FI Fibrous (green)
- FF Fibro-Fatty (light green)
- NC Necrotic Core (red)
- DC Dense Calcium (white)

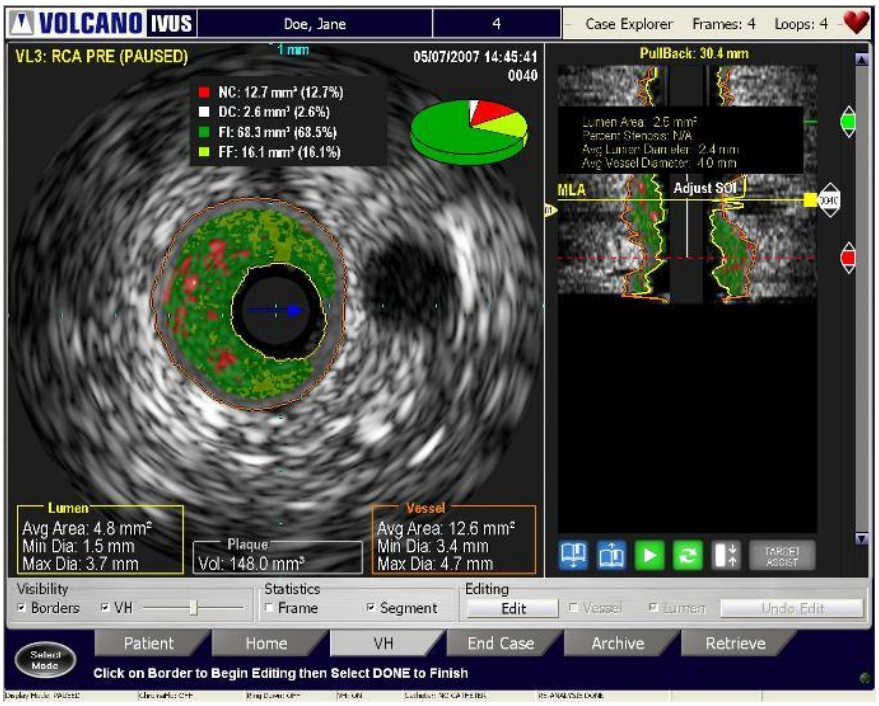


Figure 3: VH display with automatic borders and tissue classification

Alternatively, the ChromaFlo feature can be used to identify the blood flow.

The ChromaFlo feature uses patented technology to provide a visual depiction of blood flow through the vessel. This is accomplished by overlaying a two-dimensional color mapping of relative blood flow velocity onto the grayscale ultrasound image.

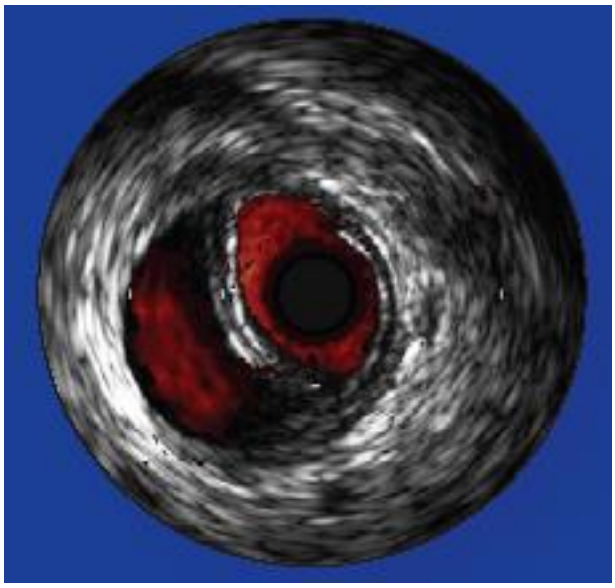


Figure 4: False Lumen in the right iliac identified using ChromaFlo feature

Indications for Use

The Volcano Precision Guided Therapy System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

VH IVUS is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS system is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures. The pullback feature of the SpinVision (PIMr) withdraws the imaging core within the protective sheath for a maximum of 15 cm.

Clinical Applications

The system is used to evaluate vascular morphology and measure blood pressure in the coronary arteries and vessels of the peripheral vasculature.

Contraindications

Use of the Volcano system is contraindicated wherever tissue or organ damage is a reasonable probability.

The catheter is not for fetal use.

Possible Adverse Reactions

The use of the Volcano IVUS imaging catheter—or any percutaneous intravascular catheter—could result in adverse reactions, including, but not limited to:

- Bleeding at the entry puncture site
- Injury to vascular wall
- Thrombosis of the vessel
- Peripheral embolization

NOTE: See the label provided with the imaging catheter for specific indications, contraindications, and possible adverse reactions.

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Chapter 2: System Description

This chapter describes the main components of the Volcano system, as well as the available options.

System Overview

The Volcano system consists of the following main components:

- Monitor
- Control Console (set in Control Pocket)
- Keyboard
- Workstation (Central Processing Unit) [includes inputs/outputs]
- DVD Drive
- Patient Interface Modules (PIMs)
- Printer

Monitor

The 19-inch, high-resolution, flat panel TFT-LCD digital color monitor is provided with the Volcano system. It is a medical grade monitor, and supports 16.7 million colors with a resolution of 1280x1024. The monitor's color temperature, gamma, brightness, and contrast can be adjusted using the menu located on the lower front of the monitor panel.

Monitor Controls

The monitor's controls are located on the lower bezel. The following symbols correspond to the controls:

Figure 5: Monitor Controls

Default Settings

The default settings for the monitor are listed in Table 1 below:

Brightness	54
Contrast	54
Sharpness	8
Color	Full Color
Color Temp	7500

Table 1: Monitor Settings

NOTE: Default settings are manufacturer's suggested settings. Manufacturing default settings can be restored by using the Menu button and going to system reset settings.

Monitor buttons include settings for Brightness, Contrast, Sharpness, and Color. Use the Menu button to adjust Brightness. In Menu mode, use the up arrow button ▲ to adjust Sharpness, Contrast, and Color. In Color mode, use the right arrow button ▶ to adjust Color Temp.

Using DICOM

Another option is DICOM 3.14, standard image settings. To access this in the Menu screen under Gamma, choose PACS. In this mode color temperature, gamma, brightness, backlight brightness and contrast are disabled in favor of the DICOM calibration settings.

CAUTION: Improper adjustment of the monitor may result in image problems.

Control Console

Control of the Volcano system is provided through the control console, shown below.

Figure 6: Control Console

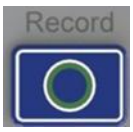
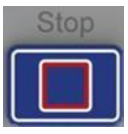
Trackball

The trackball moves the cursor on the monitor to allow function selection. The trackball is also used for selecting annotation locations and making measurements.

Screen Selection Keys

There are several screen selection keys on the Control Console. The following describes the function of each key:

Control Console Key	Description
	**Settings**: Change system settings like date and time; also permits setting and editing default configurations.

Control Console Key	Description
	**Display**: Provide enlarged view for printing or reviewing images.
	**Print**: Print a 4 x 6 inch (10 x 15 cm) photo of the current image on the screen.
	**Ringdown**: Turn Ring Down on or off.
	**Chroma**: Turn the ChromaFlo feature on or off.
	**VH**: Turn VH Display (when present) on or off when VH data is available.
	**Record**: Record a video loop.
	**Stop**: Stop or end recording of a video loop, pause while in live mode, or stop while in Rapid Review.
	**Home/Live**: Press to view the live image.
	**Play (Previous/Next Frame):** Play a recorded video loop (or go to previous or next frame).
	**Save Frame**: Press during Live mode and/or grayscale playback of a recorded loop to save one frame.

Control Console Key	Description
	**Measure**: Initiate autoborder detection.
	**Bookmark**: Press while recording a loop to select specific areas of interest for review later.
	**Scroll**: Press Scroll once, then move track ball up or down to navigate screen. Press again to disable.
	**Select (+) key**: Press to select tabs, areas, or measurement points. It is similar to left-clicking with a mouse.
	**Menu (-) key:** Press to end your selection points. It is similar to right-clicking with a mouse. Additionally, when placing measurements on the Grayscale image, the Menu button will initiate automatic border detection.

The Control Console is connected to a USB port located under the Control Console in the Control Pocket. The Control Console can be removed by squeezing the latch pedal located under the front of the Control Console. Ensure the latch engages the hook when securing the Control Console back into the Control Pocket.

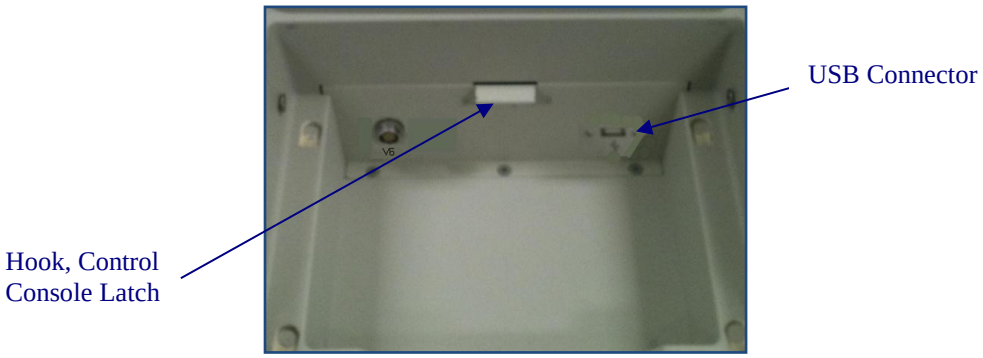


Figure 7: Control Pocket

Alphanumeric Keyboard

A standard alphanumeric keyboard is located under the monitor and next to the control console, and is used for data entry and image annotation.

Joystick Controller Option

The Joystick Controller option for the Volcano system offers convenient sterile field control at the bedside. An available quick-action mount provides easy table mounting and removal.

CAUTION: The Volcano system joystick must be installed on the cath lab bedside.

Figure 8: Joystick

Joystick

The Joystick controls the movement of the cursor within the graphical user interface. The button on top of the joystick is a **Select (+)** key and has the same functionality as the Select hardkey on the control console.

Selection Keys

There are three keys on the joystick: **Select (+), Scroll,** and **Measure**. Use the **Select (+)** key to select options on the screen with the cursor. It is similar to left-clicking with a mouse. Selecting the **Scroll** key allows you to enter scroll mode. In this mode, the user can scroll through a videoloop. Pushing the joystick up scrolls up (distal) in the ILD. Pushing the joystick down scrolls down (proximal) in the ILD. Pressing any button will exit the scroll mode. Pressing the **Measure** key allows the user to generate single frame autoborders. From here the user can edit as needed.

Workstation (Central Processing Unit)

The workstation or CPU (central processing unit) contains the main system electronics as well as the inputs and outputs for all the peripheral devices.

NOTE: The workstation model number and electrical ratings are labeled on the rear panel of the workstation. The workstation model numbers are listed as applicable throughout the manual.

Printer

A color printer is included with your system to provide high quality color printouts for your patient's records. Replacement ink cartridges can be ordered through Volcano or most major office supply stores.

The printer power switch, located on the printer front panel (see below), is dedicated to ON/OFF function of the printer only.

Figure 9: Printer Power Switch

Connector Panel

The Connector Panel is designed to provide a flexible intermediary connection platform for Volcano's multi-modality system. It offers a manageable interface panel for connecting bedside peripherals and patient interface modules. There are flexible mounting schemes to allow adapting the installation to various environments and needs.

Use caution when unplugging a cable from the Connector Panel. See connector types in the table below. Do not unplug by pulling on the cable.

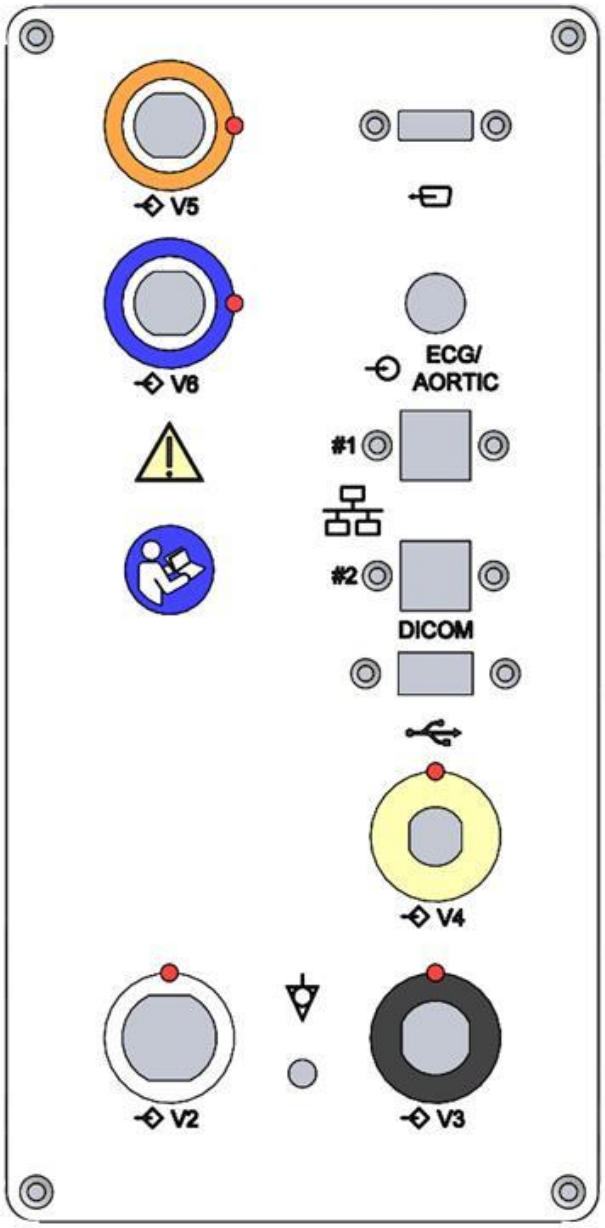


Figure 10: Connector Panel

Connector Panel Connectors	Function	Connect Type
	FM PIM-FFR connection	Push/Pull
	IVUS SA PIM and SpinVision (PIMr)	Twist lock
	CORE FM	Push/Pull
	Display Port	Push/Pull
	USB	Push/Pull
	Network connections (for DICOM and Image Export)	Push and latch/unlatch and pull
	ECG/Aortic input connection	Twist lock
	Connector may be used to accommodate future system upgrades	Push/Pull
	CORE Control Pad (CCP)	Push/Pull

Patient Interface Module

The imaging catheter connects to the patient interface module (also referred to as the PIM), which excites the catheter's transducer elements to transmit ultrasonic energy to the surrounding tissue. The PIM, shown in the figure below, amplifies and processes the resultant echo signals from the transducer, sending them to the console through its connection on the rear panel of the console. Additionally, the PIM provides patient electrical isolation.

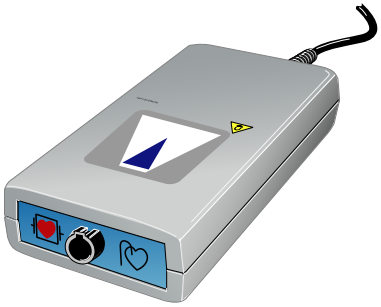


Figure 11: Patient Interface Module

WARNING: The PIM's cable may be damaged if equipment is rolled on it. Do not pull on the cable, place it where there is any traffic, or use extensive force; the strain relief ends may be damaged. Do not use the system if the outer case or wires appear damaged.

Catheters

IVUS imaging catheters are sold separately. Please contact Volcano for more information. The Volcano system is compatible with the following Volcano IVUS catheters:

- Eagle Eye *Platinum*
- Reconnaissance
- Revolution 45MHz
  - Requires Volcano Revolution Option (see below)
- Visions PV .014P
- Visions PV .018
- Visions PV .035
- Pioneer Plus

Available Options

Available options for your Volcano system include:

- **Volcano Revolution**: Includes the rotational patient interface module and pullback device (PIMr) used to drive the Revolution 45MHz rotational catheter.
- **Volcano FFR:** Includes patient interface module specific for Volcano's pressure wires.
- **Volcano CORE-vid:** Scan converter offering composite and svideo outputs.
- **Joystick Controller:** Provides sterile field control for those who prefer a Joystick.
- **Video Switch:** Provides functionality to alternate video input sources to a single monitor
- **Two or Four Channel Video Amplifier:** Provides a source for alternate monitor displays

Please contact your local Volcano representative for more information on these options.

Chapter 3: System Setup

Overview

Your system can be personalized to suit the workflow of your practice. Please work with your local Volcano representative to establish the desired settings. Once set, these settings will be maintained for each use. You can change these settings at any time by following the instructions in this chapter.

Installation

To ensure proper operation and warranty coverage, the Volcano system must be installed and tested by following the Device Installation and Operational Qualification that accompanies each device.

Turning System ON

Connect system power cord to appropriate wall outlet. Turn the system on by using the power button located on the front of the workstation. The monitor displays several messages regarding initialization. If an error occurs during initialization, an information box provides detailed information about the problem to expedite service. Please contact Volcano technical support if an error is encountered.

NOTE 1: The printer, controller, and monitor will receive power once the power cord is connected to the appropriate wall outlet. However, the system will need to be turned on by pressing the main system power button, located on the lower front panel prior to use.

NOTE 2: After the system power button has been pressed, the monitor will cycle through several start-up messages before it is ready for use (approximately two minutes).

Equipotentiality: This symbol on the system rear electrical panel identifies the connector where the hospital room's potential equalization system can be connected during intracardiac applications. The Isolation Transformer ground in the CORE Mobile system is connected to the ground on the Connector Panel through the CPU by an 8AWG green and yellow striped wire. (Equipotentiality cords are available from Volcano Service: PN 804768001 singled ended, PN 804769001 double ended.)

IVUS Software Settings

The system is shipped with default IVUS settings selected and is ready to image. If you wish to change the default settings, press the **Settings** key on the control console. The Settings dialog displays with the following tabs:

- System
- Image
- Acquisition Rate
- Archive
- VH-IVUS
- Measurement
- Security

System Tab

The System tab allows you to do the following:

- Shut Down or Restart the system.
- Select the preferred language of screen and message displays.

NOTE: The Volcano system software displays numeric data in a format appropriate for the chosen display language. For example, in English “12.01 mm” in German “12,01 mm”, in French “12,01 mm” etc. (FFR mode additionally displays Regional Settings.)

- Adjust the date and time. Click the radio button below the Date Format field to select a date format, either M/D/Y, D.M.Y, or Y-M-D. Check **Use 24-Hour Format** to set the date using a 24-hour system.
- Select the default boot-up mode: IVUS or FFR
- Choose to enable (display) all information boxes in which **Do not display again** was selected.

Click **OK** to save your selections or click **Cancel** to disregard selections.

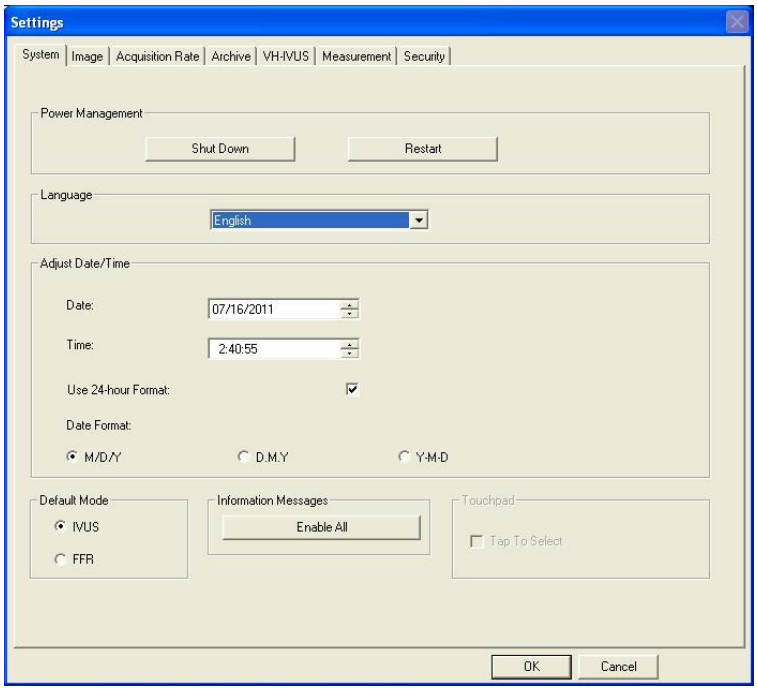


Figure 12: Settings - System Defaults

Image Tab

The Image tab allows you to do the following:

- Select Ringdown Mode: NearVu or Manual
- Check to show (uncheck to hide) measurement graticules on x and y axis
- Select the playback loop size (total number of frames) and loop playback speed (frames/sec) for the Rapid Review feature.

- Check **Compressed ILD On By Default** to view the complete pullback in the ILD view.

Click **OK** to save your selections. Click **Cancel** to disregard selections.

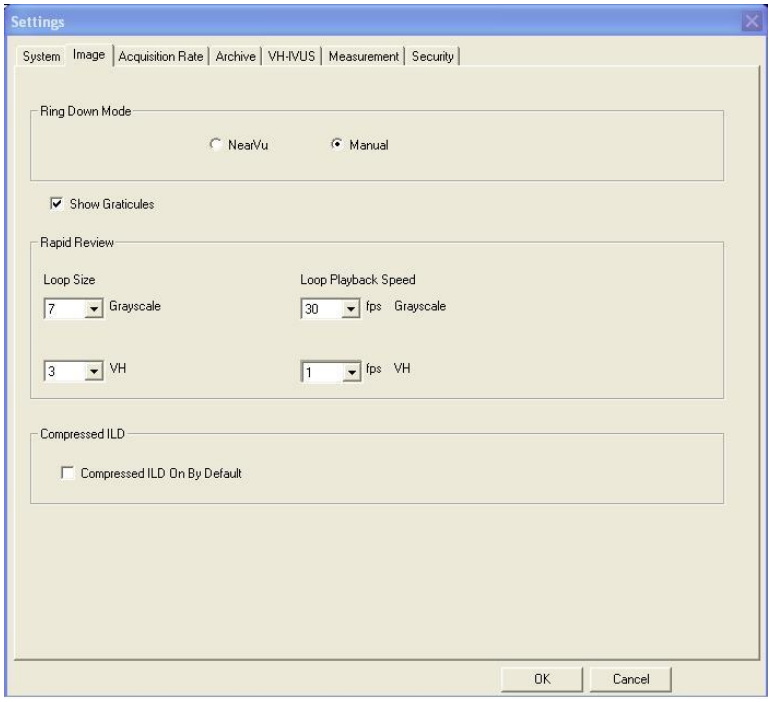


Figure 13: Settings – Image Defaults

Acquisition Rate Tab

The acquisition rate determines how many frames per second are recorded during a pullback and the duration of the video loop at this rate.

Select the **Acquisition Rate/Video Loop Length** and click **OK** to save selections or click **Cancel** to disregard selections.

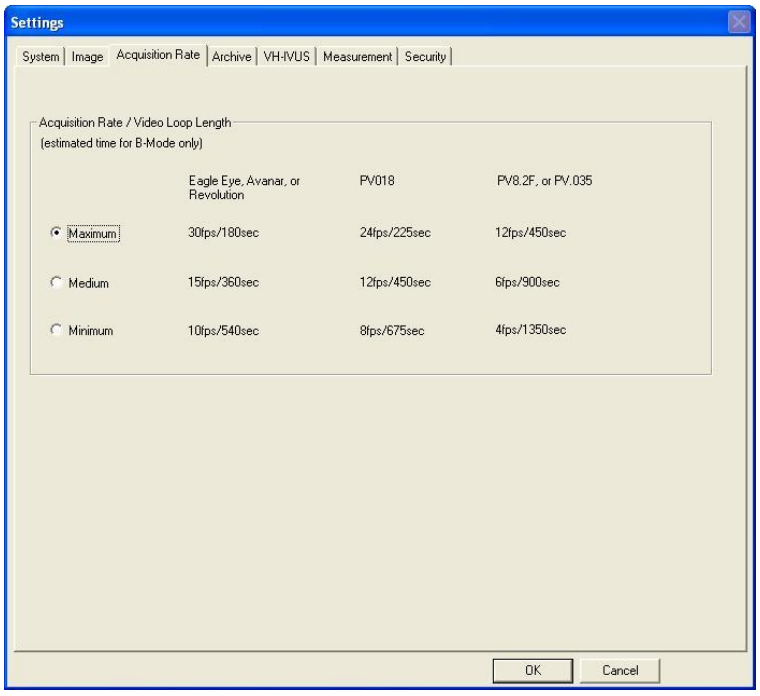


Figure 14: Settings – Acquisition Rate Defaults

Archive Tab

The Archive tab allows you to do the following:

- Select the information you want included with the frames and video loops when cases are archived:
  - Measurements
  - Annotations
  - Graticules
- Configure DICOM (See Appendix C for more information)
- Check **Verify DVD** box if you would like verification to be automatically performed for each archive.
- Check the **Auto Archived Case Deletion** to automatically delete a previously archived case when the 20 case limit on the hard drive is exceeded. Leave the box unchecked if you would prefer to manually delete cases.

Click **OK** to save your selections or click **Cancel** to disregard selections.

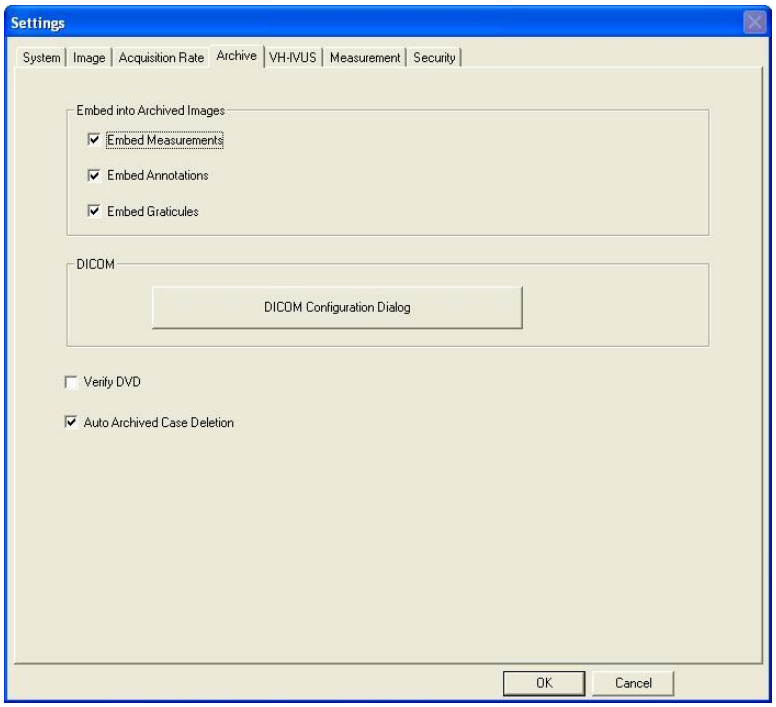


Figure 15: Settings – Archive Defaults

VH-IVUS Tab

The VH-IVUS tab allows you to do the following:

- Click **VH ON By Default** if the VH IVUS images are to be displayed by default when recording video loops, freezing images, and selecting images for review from Case Explorer (only applies to Eagle Eye catheter). VH will display only if VH data is available.
- Adjust the Default Opacity Levels for each tissue type. This allows you to customize the relative prominence of tissue color to be displayed. For example, you may be most interested in necrotic (red) tissue.
- Click **NC/DC Only Mode On** if you want to display only NC and DC. FF and FI will NOT be displayed in this mode. (See NC/DC section.)

Click **OK** to save your selections or click **Cancel** to disregard selections.

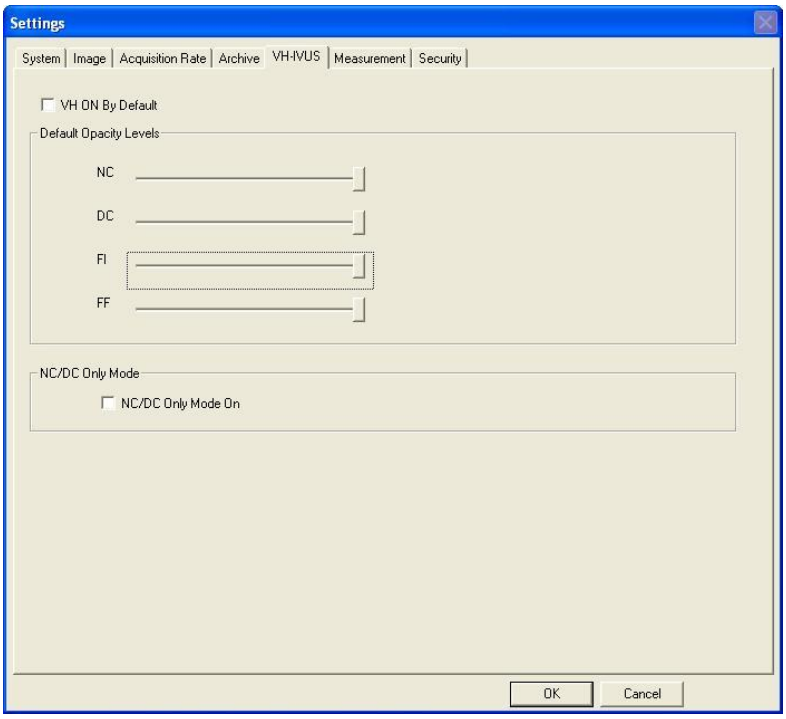


Figure 16: Settings - VH-IVUS Defaults

Measurement Tab

The Measurement tab allows the operator to create and edit measurements and borders.

- Default Measurement Mode: Select the preferred measurement mode to be active once a pullback is completed. The measurement options are **Diameter***, **Draw, or Dots.**
- BorderGuide for Dots: Select whether BorderGuide is turned **On** or **Off***. When creating your border measurements in Dots mode, BorderGuide creates a preview border as you place each of your dots. After you place each dot and move the cursor to place another dot, a preview border is drawn. If the border is correct, press select to lock the dot and border in place. If the border is not correct, continue to move the cursor until the border is correct. When BorderGuide is turned **Off**, no preview border is generated as dots are placed.
- Border Editing Mode: Select whether border measurements are edited by **Dots and Draw***, **Draw Only** or **Dots Only**. In **Draw** edit mode the user can click on the border to draw the border contour. In **Dots** edit mode the user can move the border by clicking in a new location.
- Default Autoborders: Autoborders can be generated on single grayscale frames by pressing the measure key. Select whether you would like the system to draw **Lumen and Vessel***, **Lumen only** , or **Vessel only**.
- Area Measurement Display: Check **Display Minimum and Maximum Diameter Lines** if you would like the diameter lines displayed with each area measurement. Please note: the minimum and maximum values are displayed on the image screen.

*This is the default setting unless otherwise specified

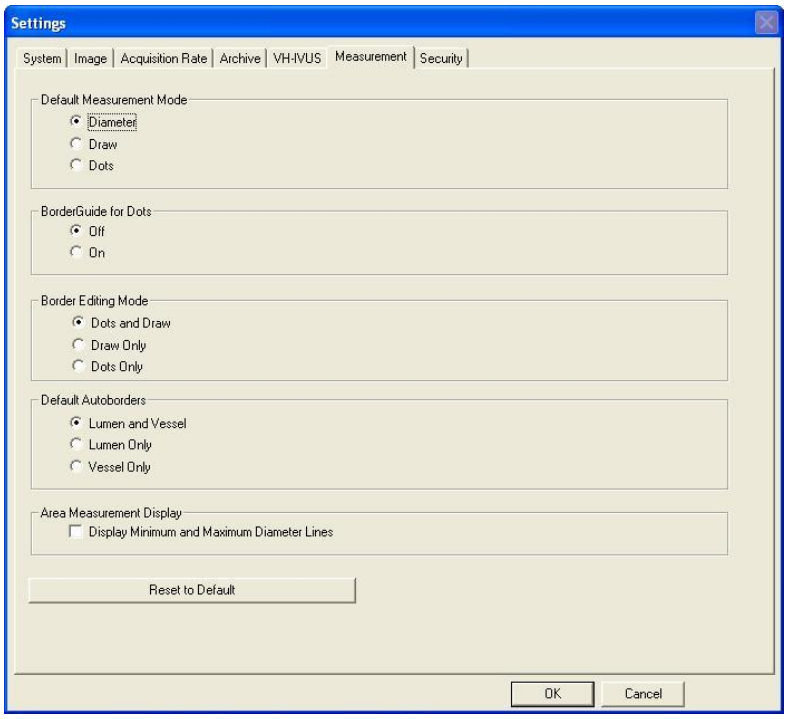


Figure 17: Settings – Measurement Defaults

Security Tab

System access can be restricted by requiring a username and password to operate the system. When security is enabled upon boot-up, you will be prompted to enter your username and password. Once this is done, you will have full access to the system.

It is advised to log off if the system is unattended or if switching users. To Log off, click the **Select Mode** button and then select **Log Off**. To log on, enter username and password.

Upon installation of v3.3.X Software, a site administrator will be assigned to manage system security. Please contact your site administrator or local Volcano representative if you have any questions regarding enabling the Security feature, adding/deleting users, or lost usernames and/or passwords.

If the password is forgotten, please contact the administrator.

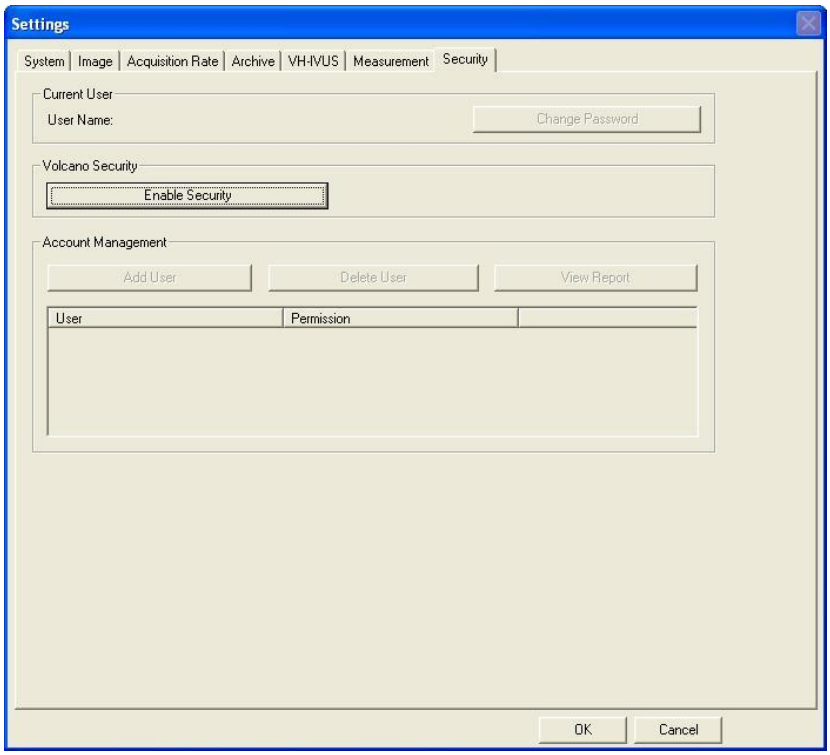


Figure 18: Settings - Security

The site administrator can do the following from the Security Tab:

- Enable or disable the Security feature
  - To enable security the administrator must select **Enable Security** and enter the default username and password. This information should have been provided during installation. If not, please contact your local Volcano Representative.
  - To disable security, the administrator must select **Disable Security** and enter the username and password.
- Add or delete a user:
  - To add a user, select **Add User** in the Account Management section. Specify Account type as user or administrator. Assign a username and password for this user.
  - To delete a user, select the user's name in the Account Management section. Click delete user, then confirm or cancel the action.
- Change administrator username and/or password:
  - You can change your password if you desire by clicking on the **change password** button in the Security tab.
  - Note that the password requires one capital letter
- Access a report showing user activity

- The administrator can also access a report that shows them information on the user and system activity.
- To access the report select **View Report** from the Account Management window.

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Chapter 4: Preparing for a Case

This chapter describes the steps to prepare the system for use. This procedure should be followed prior to each case. Please refer to the previous chapter for system settings.

Overview

The following should be performed in preparation prior to each IVUS case:

- Turn system power on
- Lock the rolling casters
- Ensure that the PIM is attached
- Prepare the catheter
- Connect the catheter to the PIM
- Connect ECG input
- Enter patient information
- Have a DVD-R ready

Ensure System Power is On

Turn the system on by using the power button located on the front of the workstation. The monitor displays several messages regarding initialization. If an error occurs during initialization, an information box provides detailed information about the problem to expedite service. Please contact Volcano technical support if an error is encountered.

NOTE 1: The printer, controller, and monitor will receive power once the power cord is connected to the appropriate wall outlet. However, the system will need to be turned on by pressing the main system power button, located on the lower front panel prior to use.

NOTE 2: After the system power button has been pressed, the monitor will cycle through several start-up messages before it is ready for use (approximately two minutes).

- **Equipotentiality:** This symbol on the system rear electrical panel identifies the connector where the hospital room's potential equalization system can be connected during intracardiac applications. The Isolation Transformer ground in the CORE Mobile system is connected to the ground on the Connector Panel through the CPU by an 8AWG green and yellow striped wire. (Equipotentiality cords are available from Volcano Service: PN 804768001 singled ended, PN 804769001 double ended.)

NOTE: Leave the power on during the case unless there is an emergency.

Connect the PIM

The IVUS catheter connects to the system via the patient interface module (PIM). The PIM is typically left connected to the Connection Panel between cases, but may need to be reconnected if removed after the prior case.

Notification of PIM connection status is provided in the lower right hand corner of the screen. The lit green lamp confirms that a PIM is connected. In this case, the name of the PIM (Phased Array or Rotational) is displayed depending on which PIM is connected.

To connect the PIM:

1 Connect the CPU end of the PIM cable into the PIM connector of the rear CPU panel. Lock it in place using the retaining clips.

2 Connect the patient side of the PIM cable to the rear of the PIM. Orient the marker on the cable connector to align with the indicator on the PIM, and slide the connector in. If you need to remove the cable from the PIM, rotate the collar on the PIM cable connector counterclockwise a quarter turn and then pull back.

CAUTION: Use care when handling the PIM to avoid accidental dropping, especially when a catheter is connected.

NOTE 1: Leave the power on during the case unless there is an emergency.

NOTE 2: If the Volcano logo indicator is not lit, make sure that the system power is on and plugged into a hospital grade grounded outlet. Make sure the fuse switch is turned on (**I** symbol).

NOTE 3: The equipotentiality connector is provided on back panel of mobile chassis and should be connected to the equipotentiality connector at the patient table. (Equipotentiality cords are available from Volcano Service: PN 804768001 singled ended, PN 804769001 double ended.)

Lock the rolling casters

It is important to lock the two casters in the front of the system to prevent movement during the procedure. To lock the casters, press down on the tab with your foot. To unlock the castors, use your foot to lift the tab up.

Prepare the Catheter

The IVUS catheter should be selected based on the needs of the procedure. Proper handling and preparation of the catheter is critical to successful imaging. Prepare the catheter in accordance with the Instructions for Use (IFU) included with each catheter.

CAUTION: Do not re-sterilize a catheter or reuse a catheter.

NOTE: See the catheter label for specific insertion instructions. Consult package insert for full description of warning, precautions, and use instructions.

Connect the Catheter to the PIM

Connect the proximal end of the catheter to the PIM by firmly inserting the connector into the PIM. Verify that the PIM connection is secure by gently pulling on the catheter. Refer to the catheter IFU for directions on use before and during the procedure.

NOTE: Imaging will not start until the catheter is connected to the PIM.

Connect the ECG Input

ECG input must be connected to the Volcano system in order to provide VH analysis (for Eagle Eye catheter). VH IVUS is only available for review if a valid ECG signal was received during acquisition.

To obtain the ECG signal, do the following:

1. Connect the ECG cable to the hemodynamic ECG output
2. Connect the other end of the ECG cable to the rear panel ECG Input connector on the Volcano system rear panel.
3. Verify the signal by observing the blinking red heart icon located in the upper right section of the Volcano system screen.

Enter Patient Information

To enter patient information, press the **Patient** tab on the menu bar. The Patient Information dialog screen displays.

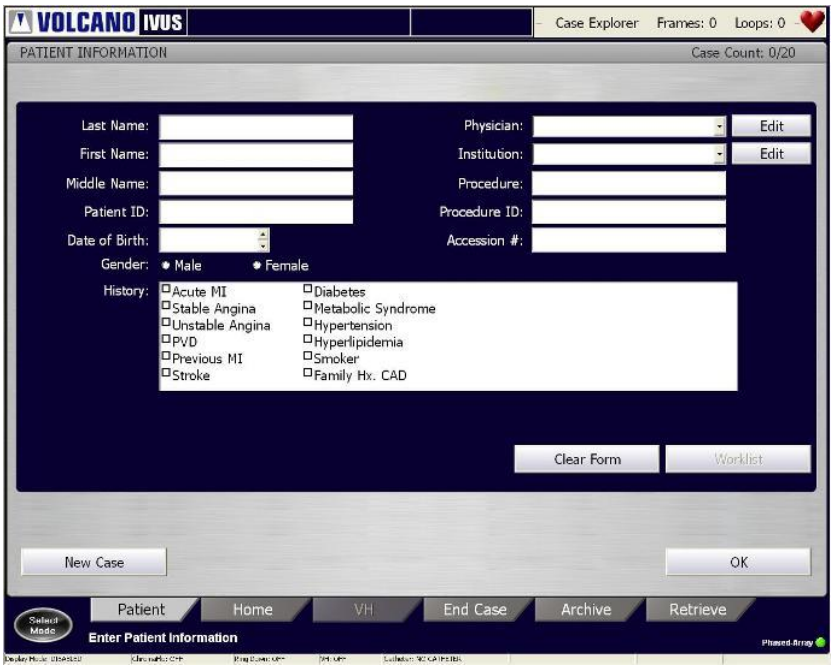


Figure 19: Patient Information Dialog Box

NOTE: The Select Mode button is only available on Volcano system version 3.3 or higher: 400-0100.01, 400-0100.07, and 400-0100.08.

Enter or edit the patient information using the keyboard, or, if the DICOM network worklist is configured in Settings, select the patient from the worklist.

Press the TAB key to move forward from one field to another. To move backward, press the SHIFT + TAB keys simultaneously.

Clear Form will remove all information from the screen.

New Case will remove all information from the screen and deletes any existing image data for the open case. **New Case** should only be used to discard an existing case and start a new case.

Once the patient information is entered correctly, click **OK**. The Home screen is displayed after OK is selected.

Chapter 5: Acquiring IVUS Images

This chapter describes the steps that should be followed for imaging during an IVUS case. Please refer to the previous chapter for instructions on preparing the system and catheter.

Overview

The following should be performed during each IVUS case, prior to recording images:

- Insert the catheter
- Adjust the image (if desired)

Insert the Catheter

The Volcano imaging catheters are designed for placement using standard intra-operative or percutaneous techniques by suitably trained physicians. The frequency and duration of administration is subject to the discretion of the physician and depends upon the procedure and information required.

1 Prepare the patient according to standard catheter lab procedures.

2 Introduce the catheter into the coronary arteries or peripheral vascular system, placing it onto the previously positioned intravascular guide wire.

3 Advance the imaging catheter to the most distal examination site in the coronary or peripheral vasculature.

4 Press the **Home** tab or the **Home (Live)** key on the control console to display the Home screen.

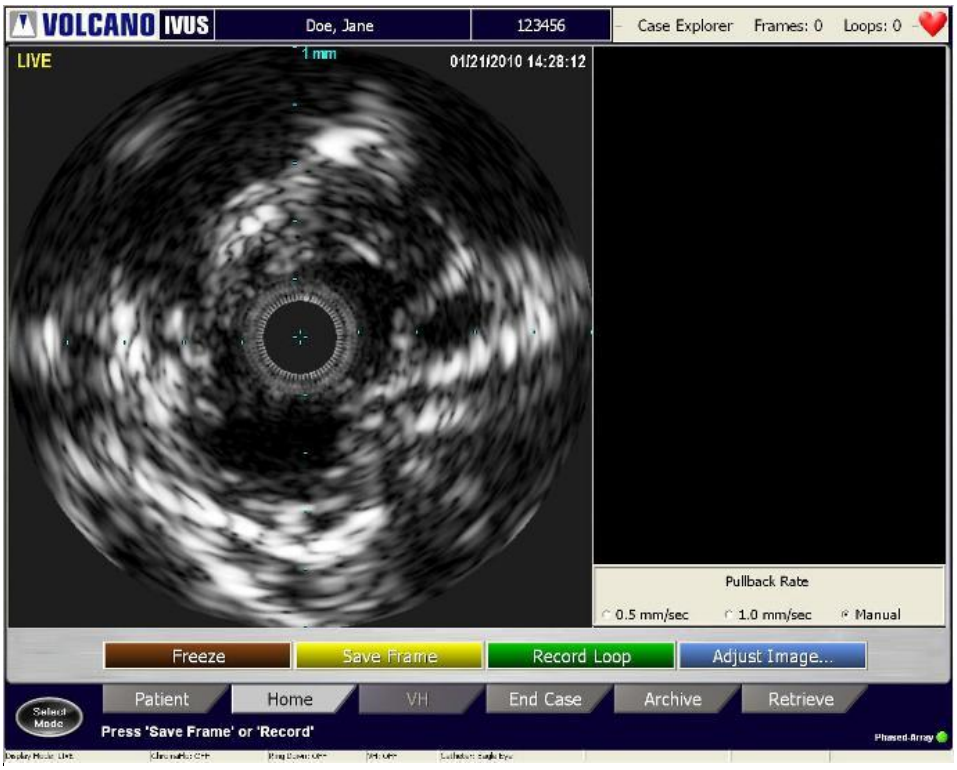


Figure 20: Home Tab Showing Live Imaging

Adjust the Image (if desired)

Your system's image settings will be set to the default values recommended by the manufacturer. These settings can be adjusted based on your preferences. Once set, specific values persist until changed.

To change the settings, press the **Adjust Image** button. The Adjust Image dialog appears at the bottom of the screen.

NOTE: You need to be sure that the image is set up properly before recording because you will not be able to change the values for gain and diameter during the video loop recording process.

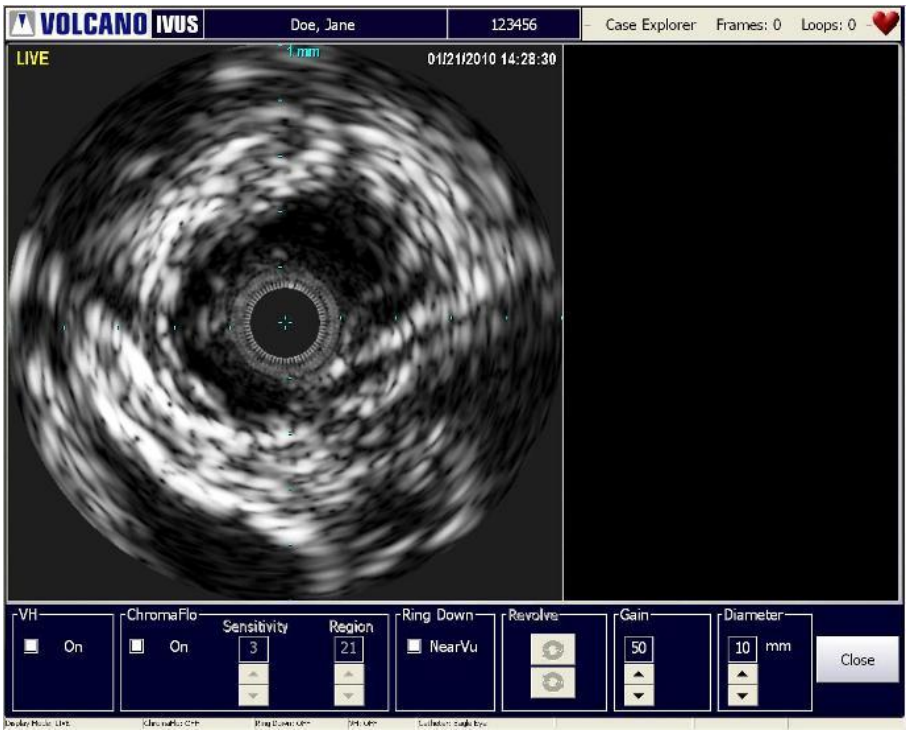


Figure 21: Adjust Live Image Dialog Box

NOTE: The TGC button requires installation of the Revo Option on Volcano system version 3.3 or higher: 400-0100.01, 400-0100.07, and 400-0100.08.

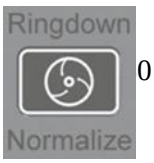
Turning VH IVUS Display On/Off

VH IVUS offers automatic border detection and tissue classification. This feature is available for the Eagle Eye catheter family. When the VH button is selected, it allows VH IVUS to be shown. The default mode for the system catheter is VH Display Off.

Activating ChromaFlo

The ChromaFlo option uses patented technology to provide a visual depiction of blood flow through the vessel. It accomplishes this by overlaying a two-dimensional color mapping of relative blood flow velocity onto the grayscale ultrasound image. Press the **Chroma** key on the control console to activate the ChromaFlo option or open the Adjust Image dialog box and select the **ChromaFlo On** check box. The sensitivity and region can be adjusted using the respective arrow keys. VH is not collected when ChromaFlo is activated.

Ring Reduction (NearVu)



Adaptive Ringdown Reduction - Adaptive NearVu

Adaptive NearVu adaptively corrects for acoustic interference in the image region around the IVUS catheter. It is the default setting for all Eagle Eye Catheters.

NOTE: The operator should ensure there is no tissue or artifact present from guide catheter in the ringdown area before turning on NearVu. Otherwise, a persistent image artifact can remain in the ringdown area.

To perform Adaptive NearVu:

1 Press **Ringdown** key on the control panel or in the Adjust Image screen.

2 Adaptive NearVu is activated and ringdown artifacts are subtracted from tomographic images.

3 Press the **Ringdown** key again to stop the ringdown reduction (if desired).

NOTE: The NearVu option in the Settings dialog box must be checked.

Manual Ringdown Reduction - Manual NearVu

Manual NearVu collects a new, but single, acoustic reference and removes it from tomographic images. This is the only ringdown reduction method available for the PV .018 and PV .35 catheters, and is an optional method for use with Eagle Eye catheters.

To enable Manual NearVu on Eagle Eye catheters, select **Manual** in the Settings dialog box. Press the **Ringdown** key on the control panel to start the ringdown reduction; press the **Ringdown** key again to stop the manual ingdown reduction.

NOTE: Whenever a new catheter is used, or when a catheter is disconnected and reconnected, it is recommended to perform ringdown reduction (automatic NearVu or Manual NearVu).

To perform Manual NearVu:

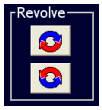
1 Position the catheter coaxially (centrally) in either the aorta or the ostium of the left or right coronary artery, or other large open arterial or venous location, if using the PV catheters..

2 Press the **Ringdown** key on the Control Console.

3 This activates a manual ringdown using a system-derived (fixed) ring down area. Ringdown artifacts are subtracted from tomographic images.

4 Press the **Ringdown** key again to stop Ring Down.

Revolve Tomographic View



Use the revolve feature to rotate the tomographic image to the left or right to determine if there is an arterial branch. This feature is not available with the Eagle Eye Platinum and Pioneer Plus catheters. To rotate the image in a clockwise direction:

1 Using the track ball, move the cursor over the top box with the red and blue rotational arrows and press Select.

2 Press the **Select(+)** key repeatedly to rotate the image in 5 degree increments.

3 Hold the **Select(+)** key down to rotate the image continuously.

4 To rotate the image in a counterclockwise direction, select the bottom box with the red and blue rotational arrows and follow the same steps as above.

Setting Gain

Gain refers to the intensity of the ultrasound echoes. As Gain is increased, the echoes become more intense and the image becomes brighter.

To change the Gain:

1 Open the **Adjust Image** dialog box.

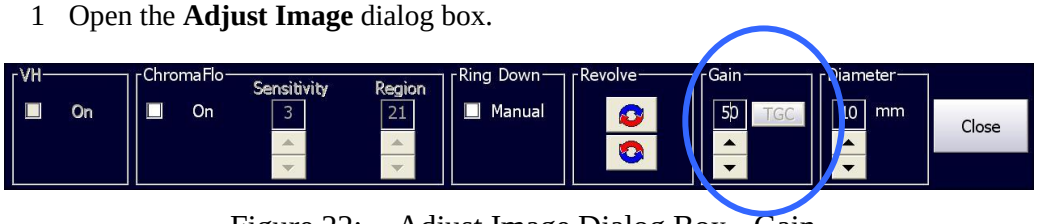


Figure 22: Adjust Image Dialog Box - Gain

2 In the Gain box, use the up and down arrows to increase or decrease the Gain setting. The ultrasound image will become brighter or darker according to the setting.

Catheter Type	Gain Range	Default Gain
Eagle Eye *Platinum*	1-68	50
Reconnaissance	1-68	50
Pioneer Plus	1-68	50
Revolution	1-68	50
Visions PV .014P	1-68	52
Visions PV .018	1-68	52
Visions PV .035	1-68	52

NOTE: The Gain adjustment only applies to the Grayscale collected on the IVUS home tab. The Gain value for Grayscale collected for VH analysis tab is fixed at 50 and cannot be adjusted manually. Gain values that are adjusted for a particular catheter type do not return to default settings at the next occassion when the same catheter type is connected to the system.

Setting Diameter

Diameter is the depth of the field of view to which the ultrasound image data is acquired. The following table defines range of diameter and increments for each catheter.

Catheter Type	Diameter Range	Diameter Step Changes
Eagle Eye *Platinum*	8-20 mm	2
Reconnaissance	8-20 mm	2
Pioneer Plus	8-20 mm	2
Revolution	8-14 mm	2
Visions PV .014P	8-20 mm	2
Visions PV .018	10-24 mm	2
Visions PV .035	20-60 mm	5

To change the diameter:

1 Open the Adjust Image dialog box.

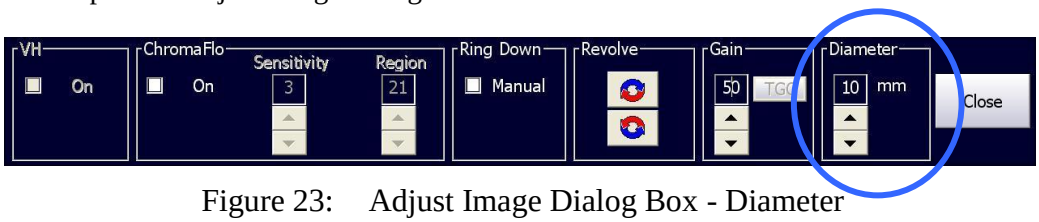


Figure 23: Adjust Image Dialog Box - Diameter

2 In the **Diameter** box, use the up and down arrows to increase or decrease the Diameter setting. The IVUS image diameter will increase or decrease according to the setting.

NOTE: When the catheter is disconnected, the NearVu settings return to the default values. Gain and Diameter settings persist and do not return to their default values.

EXCEPTION: The Eagle Eye and VH Diameters do not return to default 10mm diameter.

Chapter 6: Recording IVUS Images

This chapter describes the methods of recording images. Please refer to the previous chapter for information on inserting the catheter and adjusting the image settings.

Overview

Images can be recorded by either saving a single frame (Save Frame) or recording a video loop of multiple frames.

Recording a Video Loop

Prior to recording, select the intended pullback rate as shown below. Select from manual or automatic pullback rates. Rates of 0.5mm/sec or 1.0mm/sec are available for automatic pullbacks.

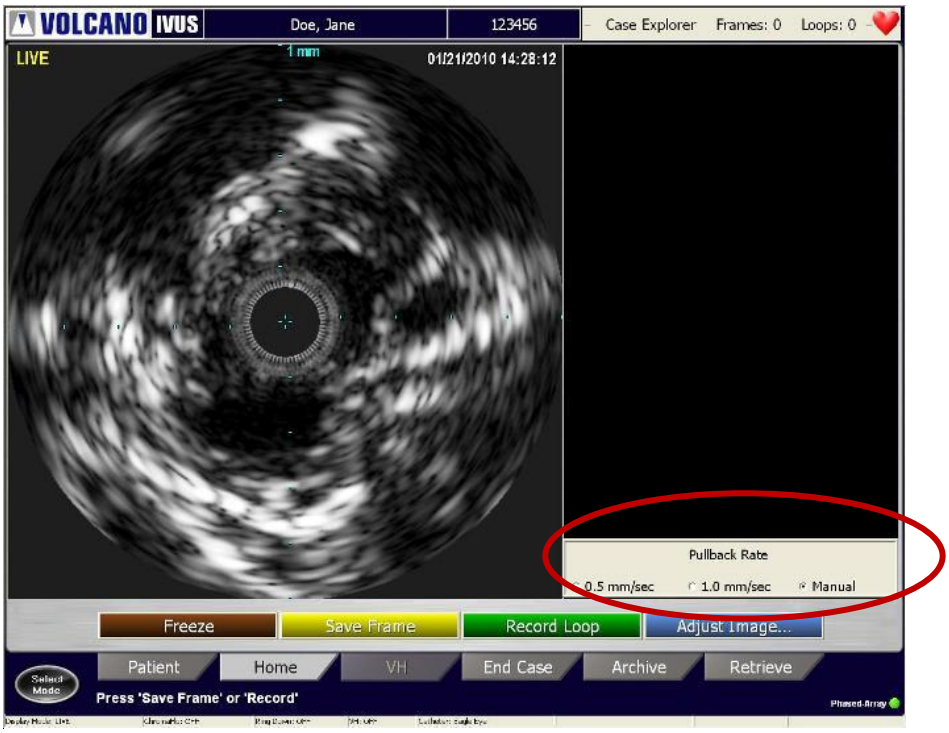


Figure 24: Select the desired pullback rate.

When in LIVE mode, press **Record** on the control console or the green **Record Loop** button to record multiple frames of ultrasound image during a pullback. Capture up to 10 video loops, each with up to 5400 frames. The In-Line Digital (ILD) software display shows a sagittal view of the blood vessel to the right of the tomographic view during the recording. (See In-Line Digital section.)

To record a video loop:

1 Select the correct pullback rate:
- 0.5 mm/sec
- 1.0 mm/sec
- Manual

NOTE: An automatic pullback device should be used to collect data at a steady and precise rate. Length measurements in the ILD are only available when an automatic pullback rate is selected.

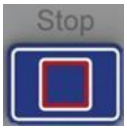
WARNING: Incorrect measurements will be obtained if the Pullback Rate is incorrect.

2 Position the catheter distal to the area to be imaged.

3 Press the **Record Loop** button. Collected data is displayed in the ILD on the right side of the screen.

4 Bookmarks can be set to mark frames of interest. To set a bookmark in the current frame, press the **Bookmark** button on the control console. A white, numbered arrow appears on the left side of the ILD indicating a bookmark set at that frame.

An unlimited number of bookmarks can be stored within a video loop.



5 After the region of interest has been imaged, press the **Stop** button on the console panel or the **Stop** button on the Home screen.

6 Stop the pullback device if one was used.

A new video loop can be recorded by repeating steps 1-6 above. As mentioned previously, a maximum of 10 video loops may be recorded within a single case.

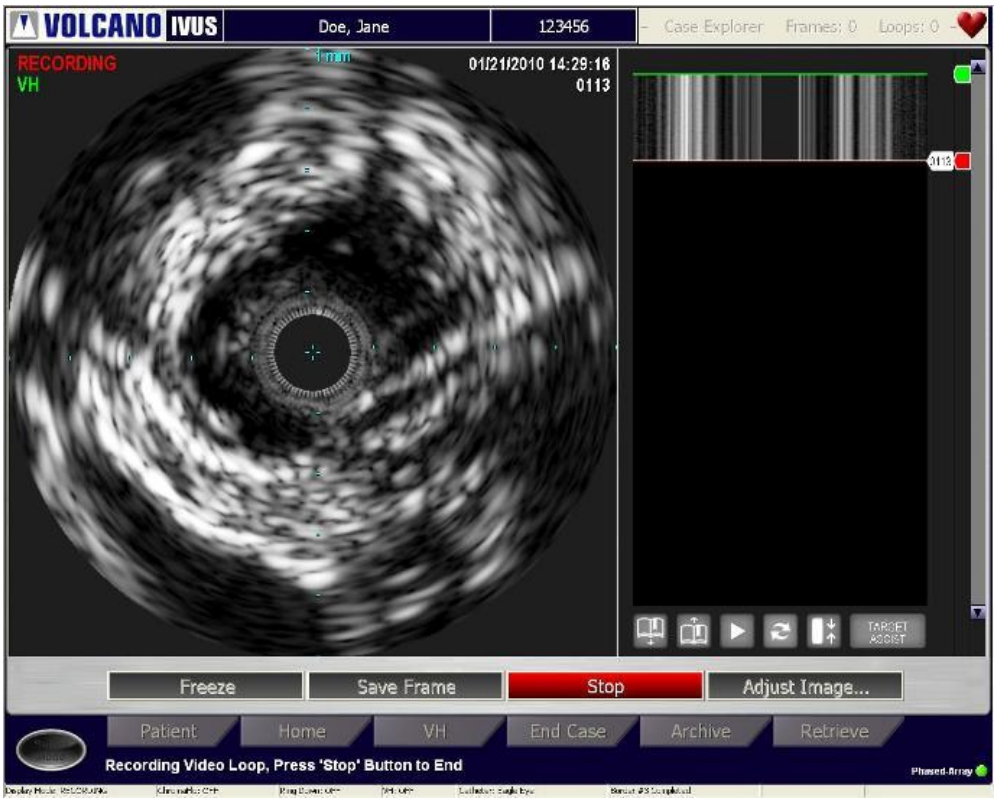


Figure 25: Recording a Video Loop

Saving a Frame

The Volcano system can store up to 99 frame images from a live view or a video loop. Saved frames are labeled automatically and numbered F1, F2, F3, etc.

To save a frame:

1 Press the **Save Frame** button on the control console or on the Home screen in live mode. The current real-time image is stored and labeled , starting with F1. The frame may be viewed in either grayscale or VH mode.

2 Press **Save Frame** again to store another image as F2, and so on. A maximum of 99 frames can be saved.

3 Frames may be saved while a playing a video loop if the VH display is turned off. Only frames that are saved in live mode, while using an Eagle Eye catheter and with an ECG signal present, may display VH.

NOTE 1: Frames can be saved while playing a video loop.

NOTE 2: The saved frame count is displayed at the top of the Case Explorer.

Chapter 7: Reviewing IVUS Images

This chapter describes the process for reviewing IVUS images as well as the tools available for analysis.

Overview

The Case Explorer provides a list of all the video loops and saved frames for the open case. Use this list to select the images that you would like to review. The list displays when the cursor is positioned over the Case Explorer bar located in the upper right hand side of the screen.

Use Case Explorer to display the following:

- Video loops
  - Segment of Interest (SOI)
  - Bookmarks within each video loop
- Saved frames

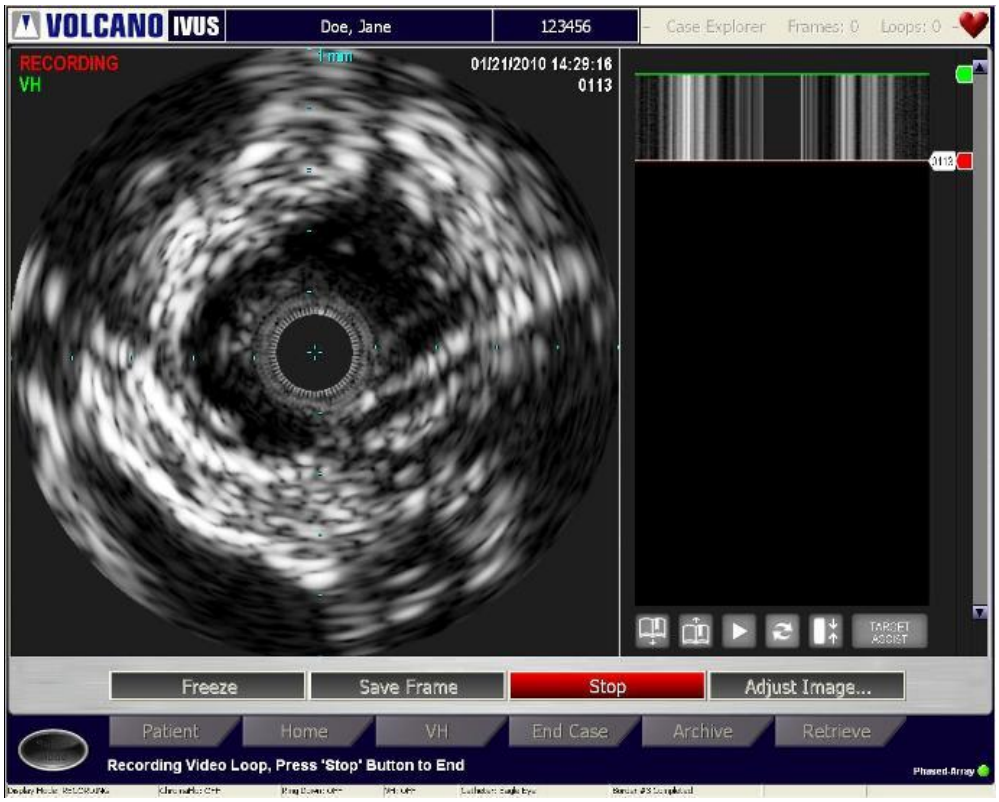


Figure 26: Opening the Case Explorer

Displaying Images

To view an image listed in the Case Explorer, move the cursor over the desired image and press the **Select(+)** key on the control console.

Image Options Menu

Various options associated with images may be accessed by pressing the **Menu(-)** button while the cursor is positioned over the item of interest in the Case Explorer list. This menu provides the following options

- Open: display the image of interest
- Delete: delete the image of interest
- Rename: type in name for the image of interest
- Select Name: select a name from a dropdown list of common names
- Properties: display image properties such as gain, pullback rate, etc.
- Pullback Rate: view or edit the pullback rate for the currently displayed video loop
- Expand: display sub menu items
- Collapse: hide sub menu options
- Cancel: exit from properties menu

Reviewing Saved Frames

To review a Saved Frame:

1 Open the Case Explorer.

2 Move the cursor over the frame to be reviewed and press **Select (**+). The frame displays in the tomographic view. It may be displayed in either VH (only if Eagle Eye image and ECG signal are present) or grayscale.

Make measurements and annotations in saved frames, when viewing them in grayscale mode, which can be found in the Making Measurements and Annotations chapter.

Reviewing Video Loops

To play back a video loop:

1 Open the Case Explorer.

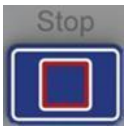
2 Move the cursor over the video loop to be reviewed and press **Select (**+). The video loop will begin playing back.

Play and Stop

Controls to play and stop the video loop are located on the control console and in the lower right hand section of the screen under the ILD.

Figure 27: Review Toolbar, Play

When the video loop is playing, a white frame marker moves downward to represent movement through the frames captured when the loop was recorded. The tomographic image changes to correspond to the location of the frame marker in sagittal view. When the frame marker reaches the end of the video loop, it starts at the first frame and continues until the user stops playback. Use the scroll bar to scroll through the image.



The **Stop** key on the control console or the red button at the bottom of the ILD pauses video loop playback. The **Play** key or green button resumes playback.

Rapid Review Feature

The Rapid Review feature allows you to quickly view a select number of frames proximal and distal to a frame of interest. This feature is used to help identify image elements using nearby frames. The number of frames to be reviewed can be set in the Settings window.

To activate Rapid Review, press the Rapid Review button located between the Play and Stop buttons as shown below. To deactivate Rapid Review, press the same button. The button is green when Rapid Review is not active, and red when is active.

Measurements can be made while in Rapid Review. To make a measurement, simply press the rapid review button and select a measurement option from the submenu underneath the image. To edit a border, click on the border to enter edit mode. The measurement toolbar and editing feature is explained in more detail in Chapter 8.

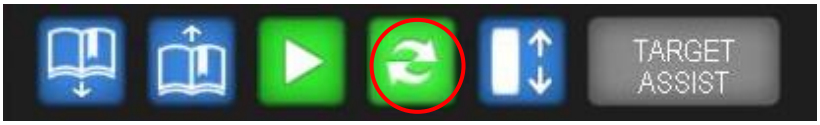


Figure 28: Review Toolbar, Rapid Review

Creating/Reviewing Bookmarks

Bookmarks can be created during playback of a video loop by pressing the **Bookmark** button on the control console or software while the loop is playing. A bookmark will be created for the frame that is currently displayed at the time that the button is pressed.

Bookmarks can be selected for review using the Case Explorer or by using the **Bookmark up/down** arrows located at the bottom of the ILD.

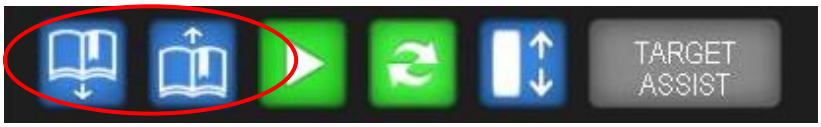


Figure 29: Review Toolbar, Navigate Bookmarks

Full Pulback ILD Display (Compressed ILD)

The ILD view can be compressed so that an entire video loop is seen in the ILD at one time. This can be done by pressing the compressed ILD button or by selecting compressed ILD as the default. This setting can be found in the Settings dialog under the Image tab.

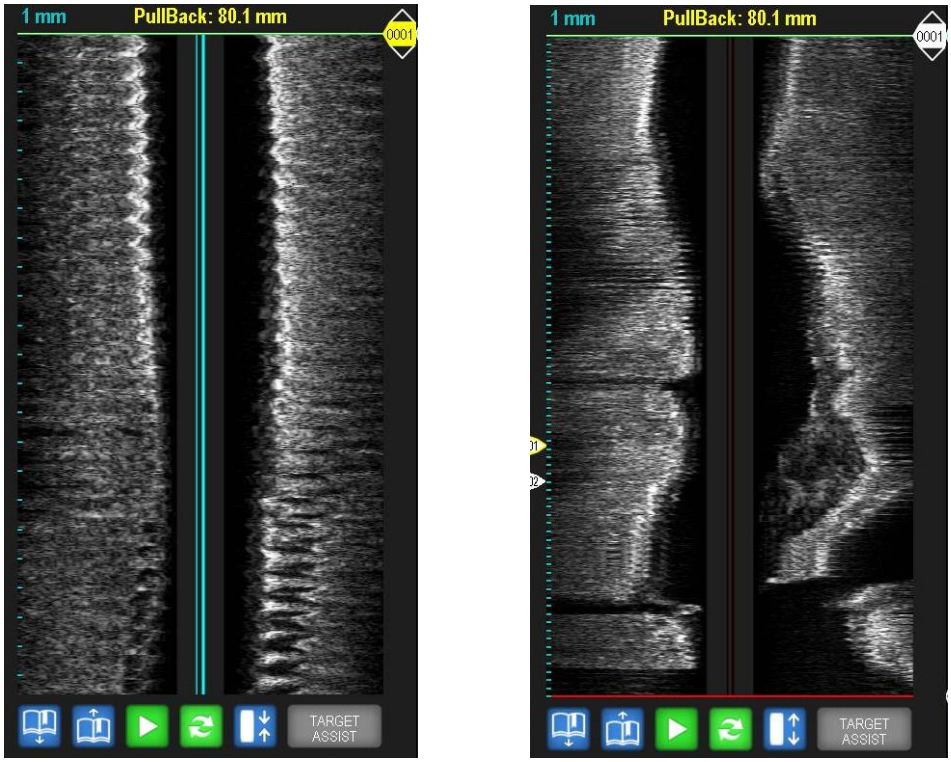


Figure 30: Uncompressed (left) and Compressed (right) ILD view

In-Line Digital (ILD) Display

The In-Line Digital (ILD) displays a sagittal view of the blood vessel that offers additional information for lesion diagnosis, longitudinal measurements, and other diagnostic and treatment options.

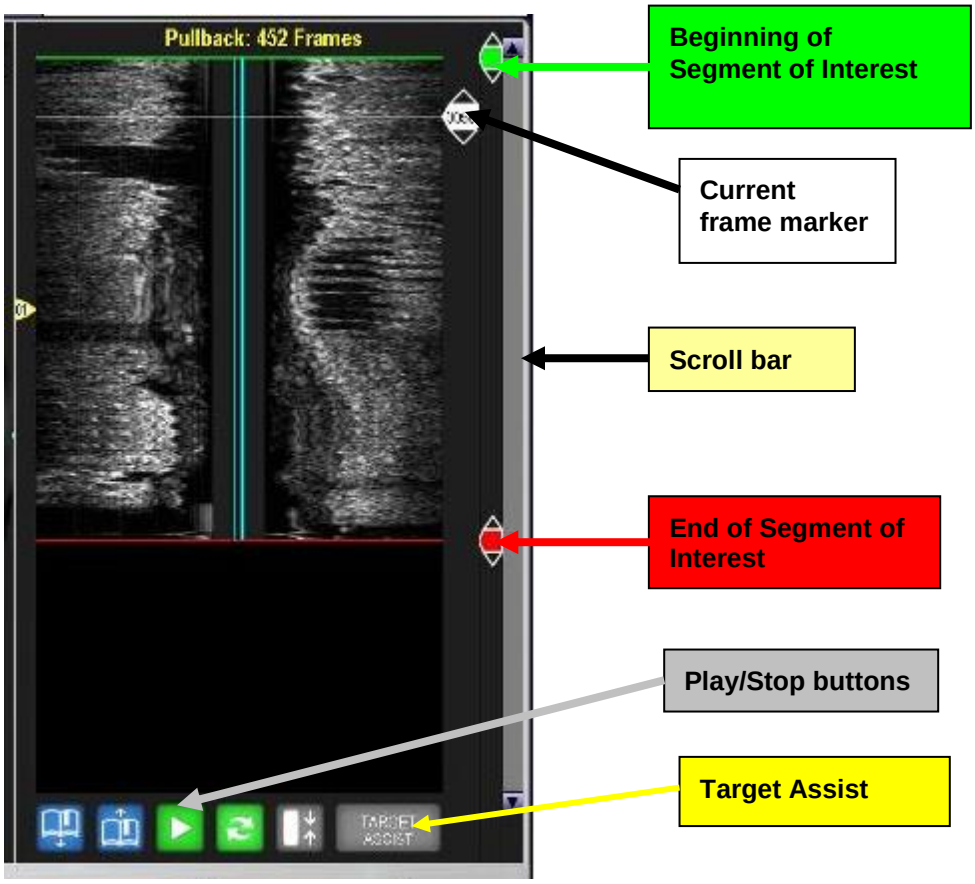


Figure 31: ILD Features

The navigation marker tabs are on the right side of the ILD display:

- White–the current frame marker. The frame number displays in the marker.
- Green–the first frame of the segment of interest
- Red–the last frame of the segment of interest
- Yellow – the target assist marker that displays the Minimum Lumen Area (MLA)

Navigating the ILD

There are three ways to scroll through frames in the ILD:

- Click on the tag of the white marker line and then scroll through video loop. Click once more to release the cursor line. Alternatively, you can click on the up/down arrows on the tag to move one frame at a time.
- Click on the yellow scroll bar and then scroll through video loop. Click once more to release the scroll bar.
- Press the up/down arrow keys on the keyboard.
- Use the **Navigate Bookmarks** to jump to a bookmarked frame in the video loop

NOTE 1: The markers in the ILD are active only when a video loop is paused.

NOTE 2: The scroll bar is active only when the video loop exceeds the viewing area in the ILD.

NOTE 3: There are up to 5400 image frames in a loop. The scroll bar represents a 384-frame section of the video loop; it is sized proportionally to the size of the entire video loop. For example, if all 5400 frames were captured, the scroll bar would be quite small, but if only 600 frames were captured the scroll bar would be larger than half the scroll box.

Creating a Segment of Interest

A segment of interest can be created by moving the proximal (red) and distal (green) markers to define the area of interest. Once set, playback will only occur within the limits of the segment of interest.

To create a segment of interest:

1 Move the cursor over the green (distal) marker. The arrows turn yellow.

2 Click on the tag of the green marker line and then scroll through video loop. Click once more to release the cursor line. Alternatively, you can click on the up/down arrows on the tag to move one frame at a time.

3 Repeat with the red (proximal) marker.

Rotating the ILD

The 360º rotation of the ILD allows for complete vessel visualization. An arrow on the tomographic image corresponds to the angle represented by the straight line arrow cursor in the ILD. The default position of the arrow is at 90 degrees (the 3 o'clock position). See figures below for a graphical representation that describes how the ILD displays the tomographic view.

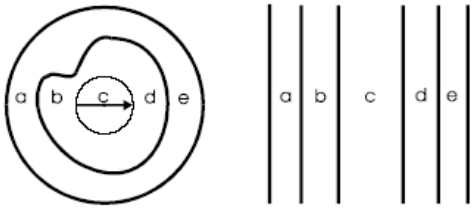


Figure 32: ILD Display of Tomographic View

To rotate the vessel:

1 Mouse over the arrow at the center of the tomographic image until a horizontal blue line spans the image and a half circle with arrows appear in the center.

2 Press the Select key (+) to rotate the arrow in the counterclockwise direction; alternately press the Menu key (-) to rotate the arrow 10 degrees in the clockwise direction.

3 Continue clicking to rotate until the arrow is pointing in the desired direction. Refer to the figure below to see how the ILD corresponds to the tomographic view after the arrow has been rotated.

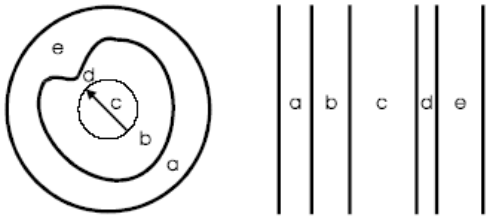


Figure 33: Rotated ILD Display of Tomographic Image

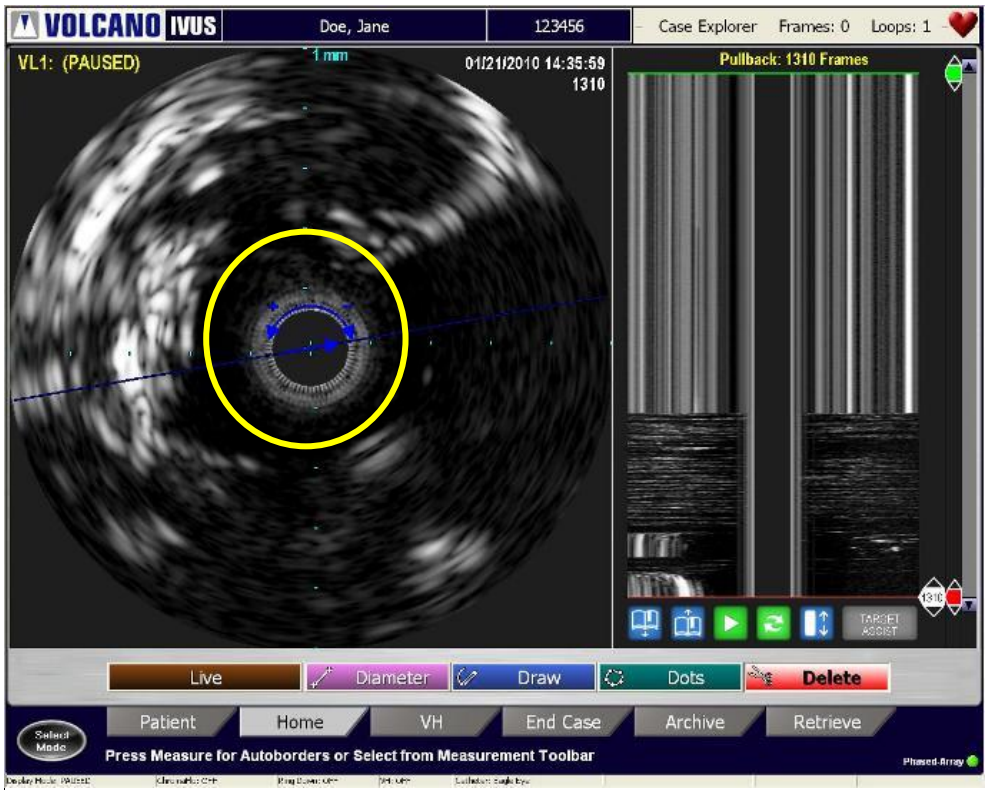


Figure 34: Rotated ILD Display

Display Mode

The display mode can be changed to display a larger tomographic view.

Select the display button on the control console to increase or decrease the size of the tomographic view. This view provides another option for printing an image as a report. The ILD and navigation buttons are not displayed in this view. All of the functions from the control console, such as live, record, bookmark, etc., are available in this view.

Printing

This system uses a high quality digital photo printer for obtaining single copy 4 x 6 inch (10 x 15 cm) photo prints from real time or stored images.

To print:

1 Be sure the paper is loaded.

2 Begin printing the screen by pressing the Print key on the control console.

NOTE 1: An approximate five-second delay occurs between pressing the Print button and printer activation.

NOTE 2: Replacement paper and ink cartridge kits can be ordered through Volcano Corporation or at your local office supply store.

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Chapter 8: Making Measurements and Annotations

This chapter describes the measurement and annotation tools that are available on your system. The measurement tools do not apply to VH frames. See the next chapter for VH measurements.

NOTE: Measurement accuracy is dependent on operator's familiarity with specified measurements and interpretion of ultrasound images.

Making Measurements

The following measurements can be made on any single grayscale (non VH) frame:

- Distance/Diameter
- Area (Dot or Draw)
- Vessel Length (within the ILD)

To Enter Measurement Mode:

1 Navigate to Home screen.

2 Locate the frame of interest, for example:

- Saved Frame
- Frame within a video loop (loop must be stopped)
- Frozen image from Live mode

NOTE 1: To save measurements made on a frame with a video loop or on a frozen image, press **Save Frame** before selecting another tab or control console key, or measurements will be lost.

NOTE 2: Measurements cannot be made on live frames.

Measuring Vessel Diameter

You can make up to four vessel diameter measurements for each frame.

1 Select the **Diameter** button in the Home screen.

2 Using the trackball on the control console, move the cursor to the spot for the first point and press **Select (+)**.

3 Move the cursor to where you want to end the measurement and press Select (+) to anchor it. The diameter line is drawn in color with the number 1 displaying on each end.

4 Repeat for up to 4 diameter lines. Each line will be in a unique color. The diameter measurement, in millimeters (mm), is displayed by number and color at the top left corner of the image.

5 To change a line, press **Select(+)** on the end you wish to move and drag it to the new position. Press **Select(+)** again to anchor it.

6 To delete a line, click the red Delete button. Move the scissors to the line until it is highlighted and press **Select(+)**.

NOTE: There is no undo for deleting a measurement line.

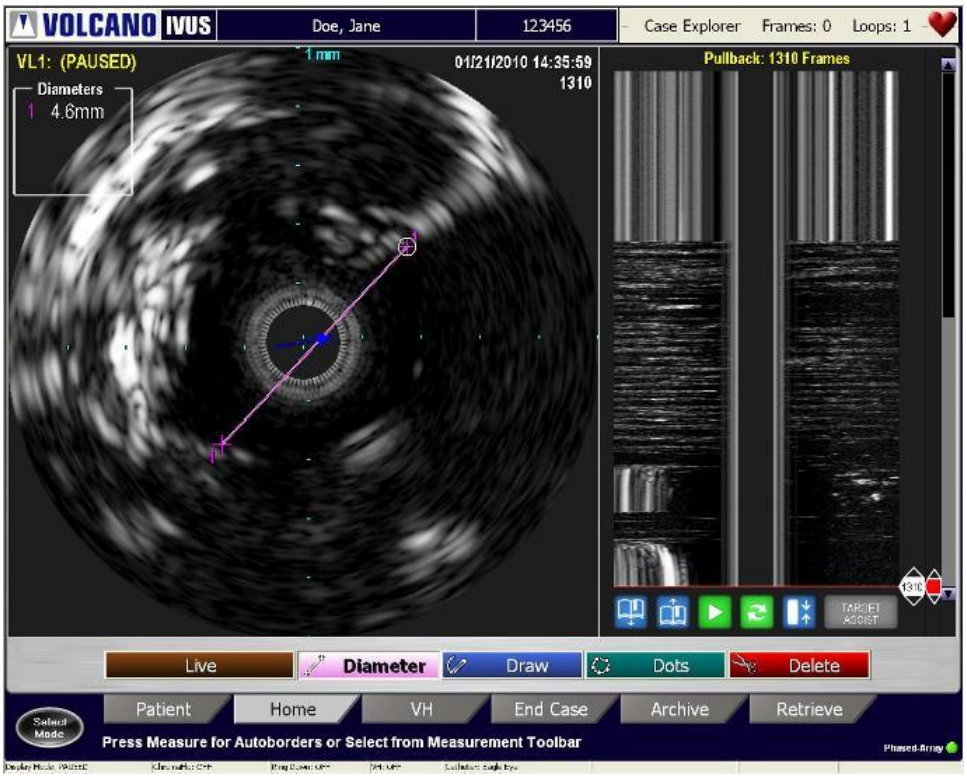

Figure 35: Measuring Vessel Diameter

Measuring Vessel Area

Area measurements can be made by two methods:

1. For automatic border generation, select the Measure button on the Home screen, the **Measure** button or the **Menu(-)** button on the console.

2. For manual border generation, select either the **Draw** or **Dots** button in the Home Tab screen

    i. **Draw**: Press **Select(+)** and use the cursor to trace the border. When you have finished, press **Select(+)** to release the border and click on the **Done** button or double click **Select(+)** button. Do NOT draw past the initial point of the circumference line.

    ii. **Dots**: Place dots along the desired border. You can place 1-32 dots to define your border. When you have finished, click on the **Done** button or double click the **Select(+)** button.

        a. **Borderguide (optional tool):** Turn Borderguide on/off in the Settings dialog on the Measurement tab. Borderguide creates a preview border as you place each of your dots. After you place each dot and move the cursor to place another dot, a preview border is drawn. If the border is correct, press select to lock the dot and border in place. If the border is not correct, continue to move the cursor until the border is correct.

Up to two area measurements can be made for each frame. The area measurements are displayed in boxes in the lower left and right corners of the image. Displayed in each box is the area measurement (mm^2) and the maximum and minimum diameters (mm). The displays are color coded, complementing the corresponding measurements.

The maximum and minimum diameter lines can be shown by checking the **Display Minimum and Maximum Diameter Lines** in the **Settings** dialog under the **Measurement** tab. Please note that the values will always be displayed, but the user can choose whether to show the actual lines.

The difference between the two area measurements will be displayed in the center.

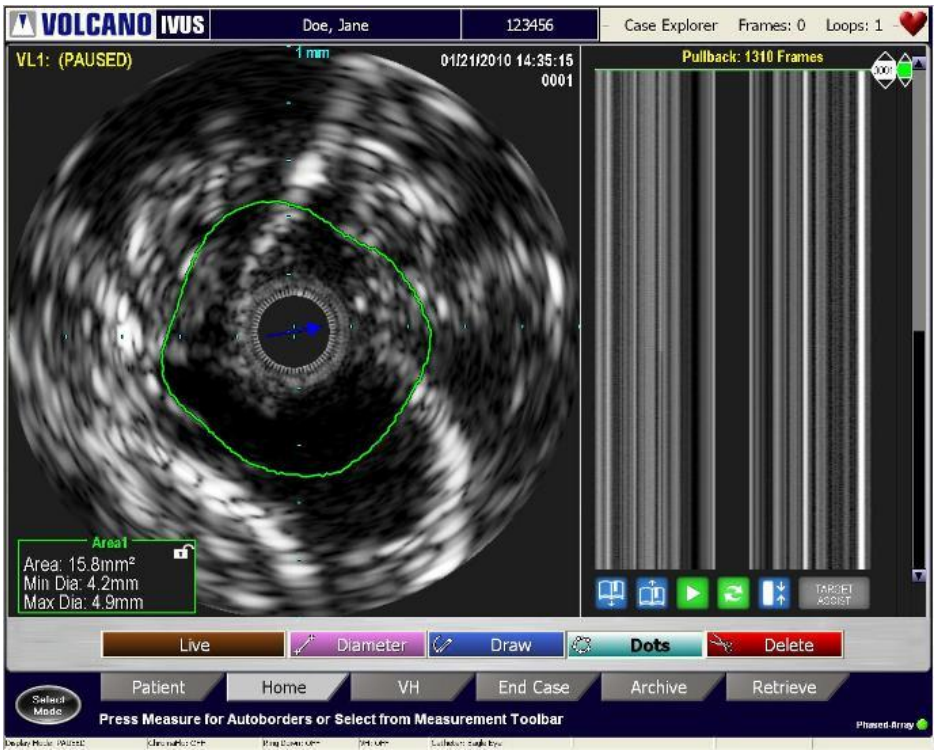

Figure 36: Measuring Vessel Area

To edit the area measurement:

1 Position the cursor over a border and press **Select(+)**. The border becomes a dashed line.

2 There are two ways to edit:

   i. In **Draw** edit mode the user can click on the area measurement line and begin to draw the border contour. To finish click the **Select(+)** button.

   ii. In **Dots** edit mode the user can move the border by clicking in a new location.To end editing, double click the **Select(+)** button or click on the **Done** button.

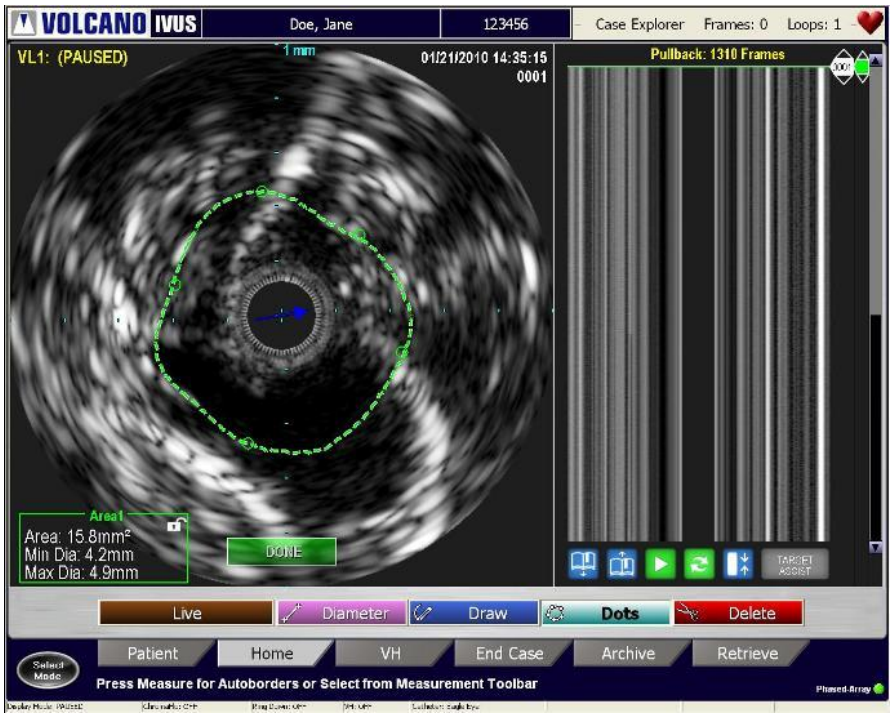

Figure 37: Editing the Vessel Area

To delete area measurement:

1 Select the Delete button in the measurement toolbar.

2 Using the trackball, move the scissors to the area measurement. When the line is highlighted, press **Select(+)**.

NOTE: There is no "undo" for deleting an area measurement.

Measuring Vessel Length

NOTE: Measure vessel length in the ILD only if a non-manual pullback rate has been selected. If the video loop was originally recorded with manual pullback rate, change its pullback rate property by selecting the video loop from Case Explorer. Right-click on the named videoloop and select pullback rate.

You can perform four vessel length measurements in the ILD.

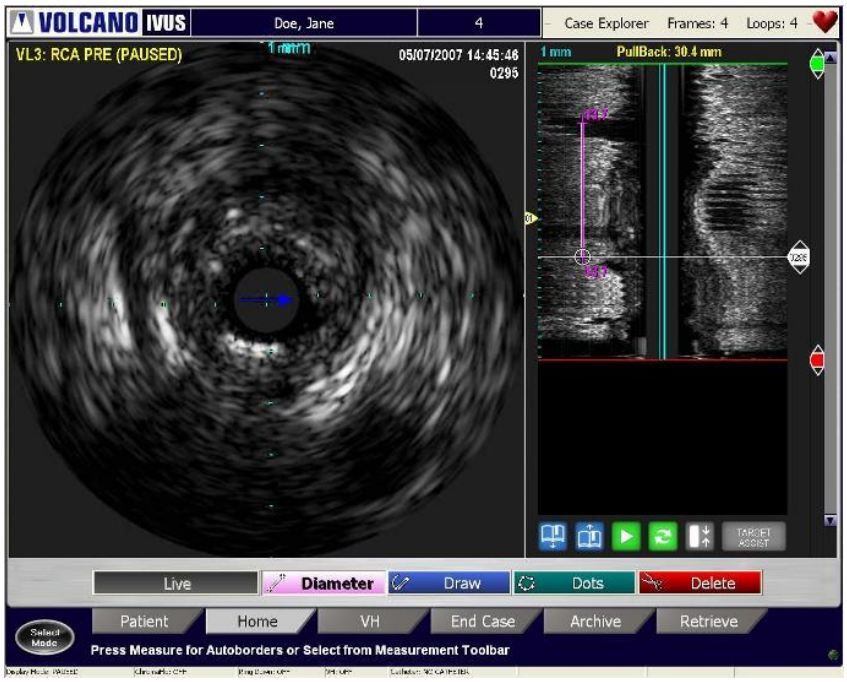

Figure 38: Measuring Vessel Length

To measure the vessel length:

1 Click the **Diameter** button.

2 Using the trackball, move the cursor into the ILD and press **Select(+)** to anchor the first point.

3 Move the cursor to the desired end point and press **Select(+)**again to anchor the line at the second point.

The distance in mm displays at each end of the line.

Annotating Frames

Using the keyboard, you can annotate saved frames and video loops.

1 Select a saved image or video loop to annotate by clicking on its name in the Case Explorer.

2 Using the trackball on the control console, move your cursor to the image area you wish to annotate.

3 Using the retractable keyboard, type the annotation.

4 Press **Select (+) to place it where you want the annotation.**

5 To edit an annotation, move the cursor over the annotation and press **Select(+)**. Edit the annotation and press Select again.

6 To reposition the annotation, press **Select(+)**and drag the annotation to another place on the image. Press Select again.

7 To delete an annotation move the cursor over the annotation, press **Select(+)**, and backspace over it using the keyboard keys. You can also check the **Delete** tab (in Measure mode) and move the scissors to the annotation with the trackball, then press **Select(+)** to delete it.

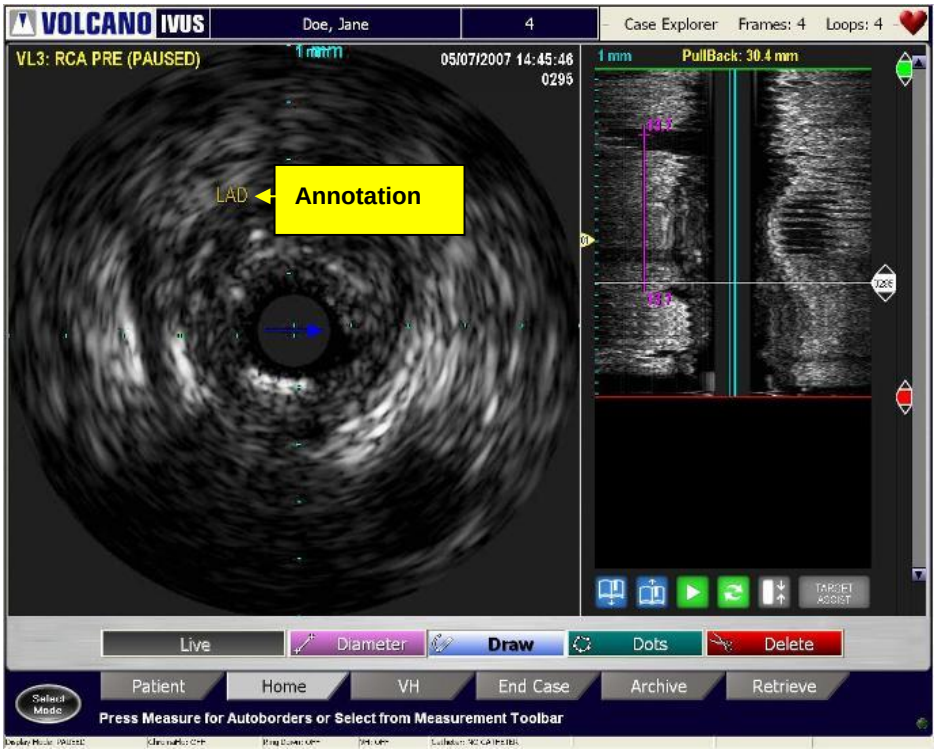

Figure 39: Saved Frame with Annotation

Measuring Percent Difference

This feature provides the ability to compare differences in areas between two grayscale frames. For example, you can compare the percent difference between the minimum lumen area on one frame to a reference lumen area on another frame..

The following formula is used to calculate percent difference:

% Difference = 1 – (Target Lumen Area / Reference Lumen Area)

To calculate percent difference, between frames:

- Navigate to the first frame of interest and make an area measurement.
- To use this measurement as a reference, click on the Area 1 box to lock the measurement.

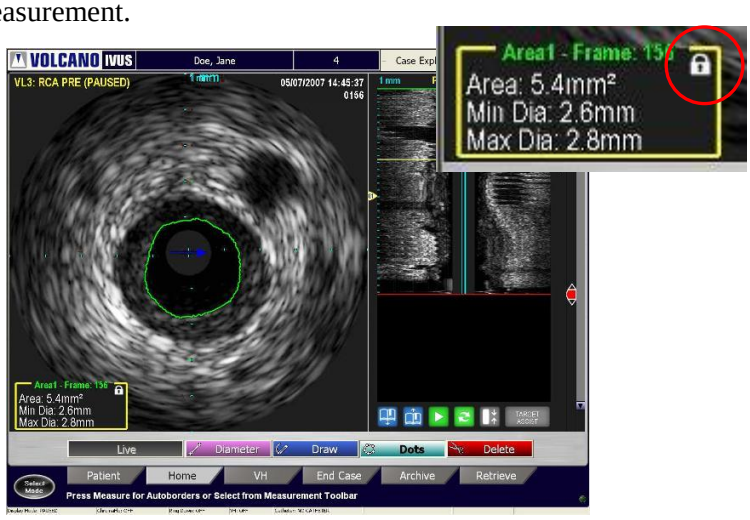

Figure 40: Draw area on 1st frame of interest

- Navigate to the second frame of interest and make an area measurement.
- Note the Difference measurement between the two is displayed.
- Click **Save Frame** to save results.

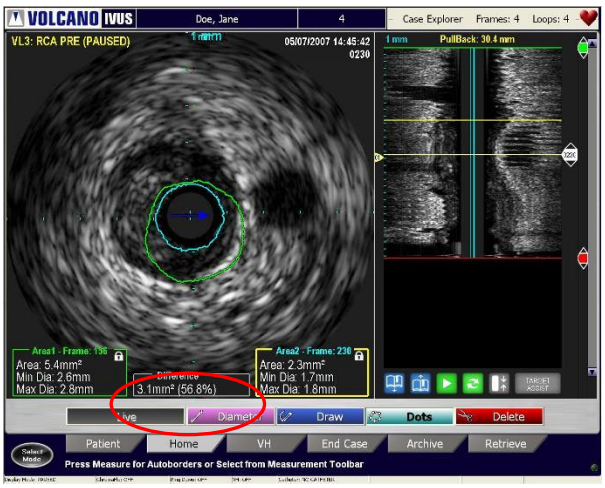

Figure 41: Draw measurement on 2nd frame of interest

To edit a percent difference measurement:

- Move the cursor over the area measurement then press **Select(+)** once it is highlighted.
- Edit as needed.
- Click on the lock icon again to lock in the new measurement.
- The percent difference calculation will now be updated.

To delete a percent difference measurement:

- Select the Delete button in the measurement toolbar
- Move the scissors to the measurement
- Once the border is highlighted, press **Select(+)**

Chapter 9: Using VH IVUS

NOTE: VH IVUS is available on Eagle Eye family of catheters only. Currently, this feature is not available on Visions family of catheters.

Overview

Traditional IVUS has improved the effectiveness of catheter-based coronary therapies. However, it stops short of the ability to characterize and assess lesion composition. The VH IVUS software enhances the current grayscale IVUS diagnostic approach to coronary artery disease by automating the vessel border boundary detection and providing the user with color coded images that more precisely identify what type of plaque is present.

The VH IVUS software is capable of differentiating four tissue types from the radio frequency (RF) data. All elements with the plaque boundaries as defined by the border are identified as one of four tissue types and color-coded:

- FI Fibrous (green)
- FF Fibro-Fatty (light green)
- NC Necrotic Core (red)
- DC Dense Calcium (white)

Implantable devices such as stents, staples, grafts, and leads will appear as one of the four plaque types as well (if located between the lumen and vessel borders).

VH analysis is provided only on ECG gated frames (1frame/cycle). The traditional grayscale IVUS is not gated.

As a pullback occurs, the VH borders are identified on the ILD.

NOTE: A valid ECG signal must be received by the Volcano system during acquisition for VH to be available.

Activating VH Display

Select the VH button on the control console to enable or disable VH display feature. The default setting is **VH off**.

Figure 42: Control Console

Using the VH Screen

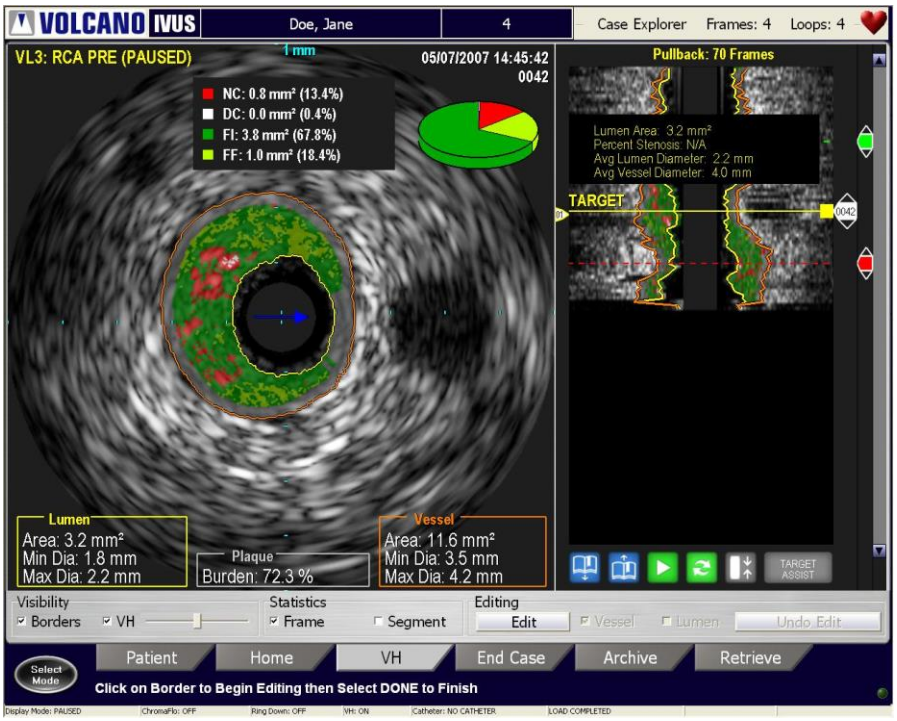

Figure 43: VH Display

The following tasks can be accomplished using the main screen:

- Click the Pie chart to display the tissue composition statistics on the screen
- Click the Visibility box to display the borders and/or VH IVUS
- Click the frame or segment box to display the statistics of your choice
- Move the slider bar to increase or decrease the VH transparency over the gray scale image.
- Select the **Edit** button to edit the borders and select vessel or lumen.

NOTE: Volume and length results are only valid for automated pullbacks.

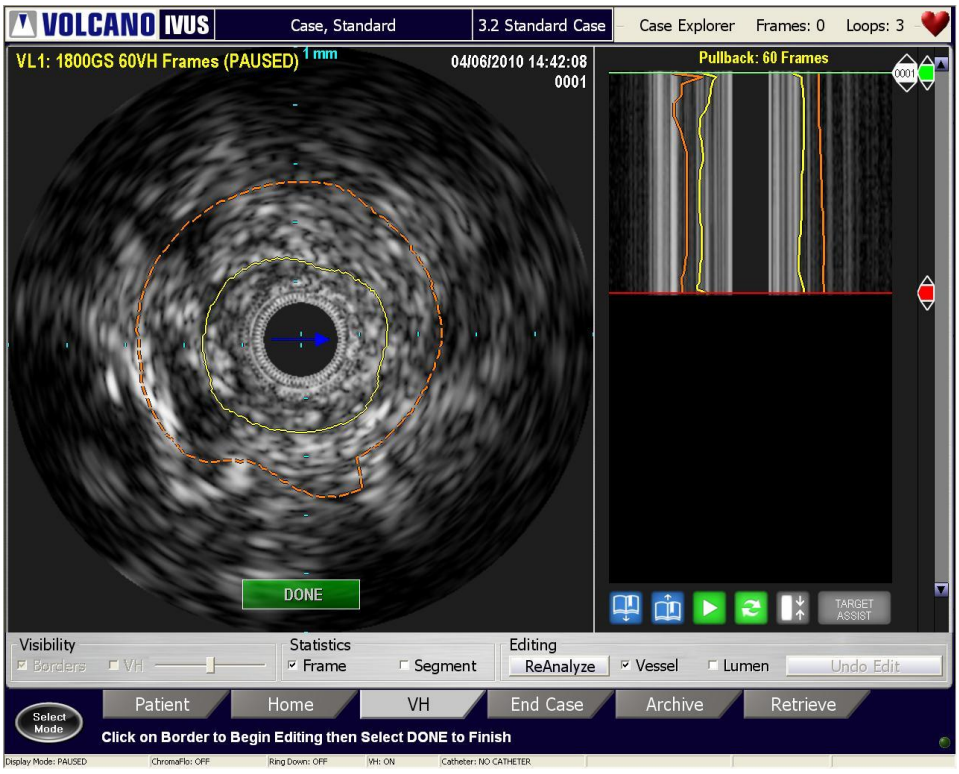

Figure 44: Border Edit Mode – Tomographic View

Border Edit Mode

The borders can be edited by performing any of the following in the tomographic or ILD view:

Tomographic View:

1 Position the cursor over a border and press **Select(+)**. The border becomes a dashed line.

2 There are two ways to edit:

i. In **Draw** edit mode the user can click on the border and begin to draw the border contour. To finish click the **Select(+)** button.

ii. In **Dot** edit mode the user can move the border by clicking in a new location.To end editing, double click the **Select(+)** button or click on the **Done** button

ILD View:

1 Position the cursor over a border and press **Select(+)**. You are now in **Draw** edit mode.

2 To edit the border, move the cursor and trace where the border should be. To end editing, double click the **Select(+)** button or click on the **Done** button.

NOTE 1: Reanalyze button can be selected as an alternative to the **Done** button.

NOTE 2: Edits made in the tomographic view are represented in the ILD view, and vice-versa.

NC/DC Only Mode

NC/DC only mode is an alternative display of the VH data that only displays NC and DC colors. FF and FI are not displayed in this mode. Please note that in this mode, the autoborders will be adjusted so that the inner border is fixed right around the transducer perimeter.

NOTE: It is recommended to consult with your local Volcano representative prior to using this feature.

This mode can be activated in Settings under the VH-IVUS tab. Please note that this mode must be selected prior to acquisition. If an image (saved frame or video loop) is collected in NC/DC mode, it cannot be displayed in full VH mode.

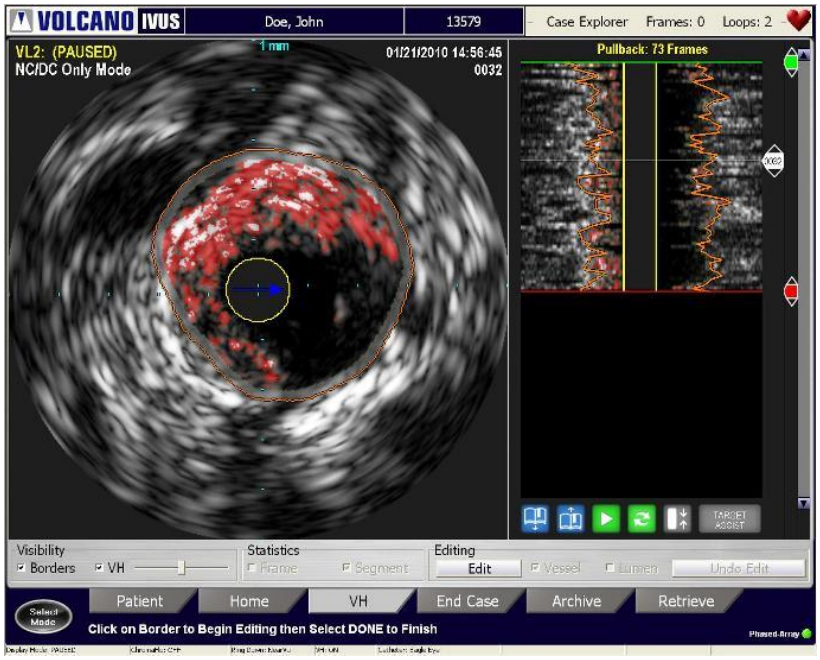

Figure 45: NC/DC Only Mode

Using Target Assist

The Target Assist feature will automatically locate and identify the minimum lumen area (MLA) within the active video loop. To utilize this feature:

1 Adjust the proximal and distal reference lines to define the region of interest. Make sure to exclude the guide catheter.

2 Select the target assist button. The yellow bar will select the smallest Minimum Lumen Area (MLA).

3 Click on the label to display statistics. Move the MLA bar to any frame and the label will change to “Target”.

4 Click on the MLA or Target label for statistics.

5 The proximal and distal frames are used as reference for the percent stenosis calculation. You may adjust the location of these lines if desired.

6 The length of the segment is displayed between the proximal and distal lines.

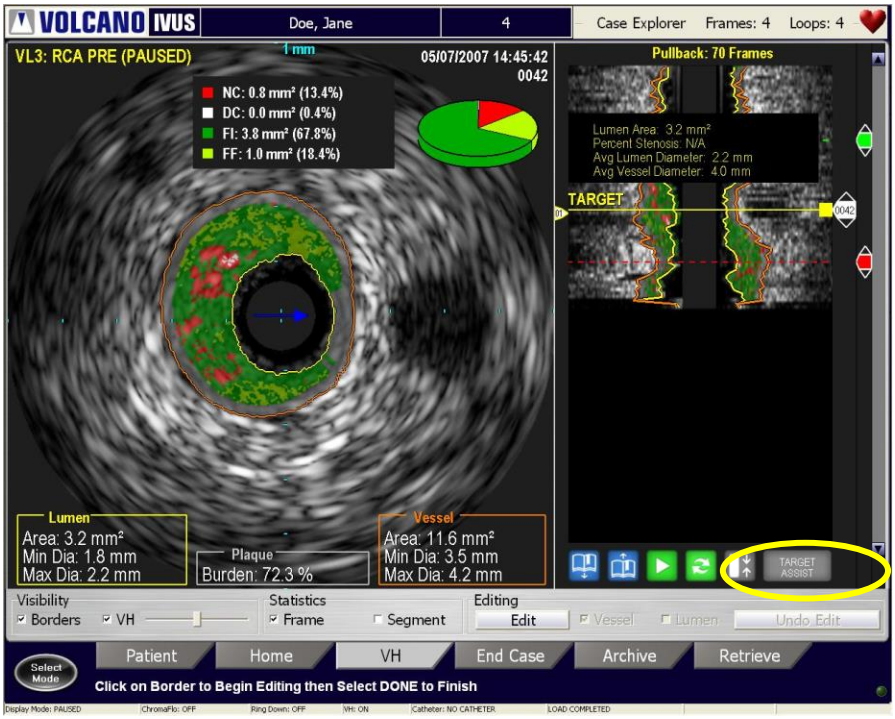

Figure 46: Target Assist Area on the ILD

Chapter 10: Using the ChromaFlo Feature

Overview

The ChromaFlo option uses patented technology to provide a visual depiction of blood flow through the vessel. It accomplishes this by overlaying a two-dimensional color mapping of relative blood flow velocity onto the grayscale ultrasound image. Areas where the blood is moving faster are more yellow: areas where the blood moves more slowly are red. Regions in which there is no or little motion perpendicular to the transducer are presented as clear or non-colored. These regions appear gray in the standard display. When the ChromaFlo feature is activated, the image displays blood flow in the vessel with a red-to-yellow color scale in the image area.

The ChromaFlo processor detects flow of particles (red blood cells) perpendicular to the imaging plane or along the long axis of the catheter. This is unlike conventional Doppler imaging in which the blood must flow toward or away from the transducer. This is possible by utilizing ultra high speed electronics and Volcano's proprietary algorithms.

NOTE 1: Available on Eagle Eye family of catheters, Reconnaissance, Pioneer Plus, and Visions PV .014P and .018 catheters**.**

NOTE 2: The ChromaFlo feature cannot be activated while recording and therefore has to be activated prior to recording.

NOTE 3: In ChromaFlo mode, the frame rate is 12 frames per second.

Activating the ChromaFlo Feature

Press the **Chroma** key on the control console to activate the ChromaFlo option or open the Adjust Image dialog box and select the **ChromaFlo On** check box.

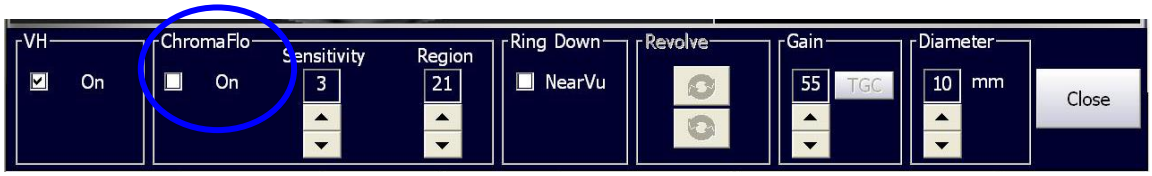

Figure 47: Adjust Image Dialog Box

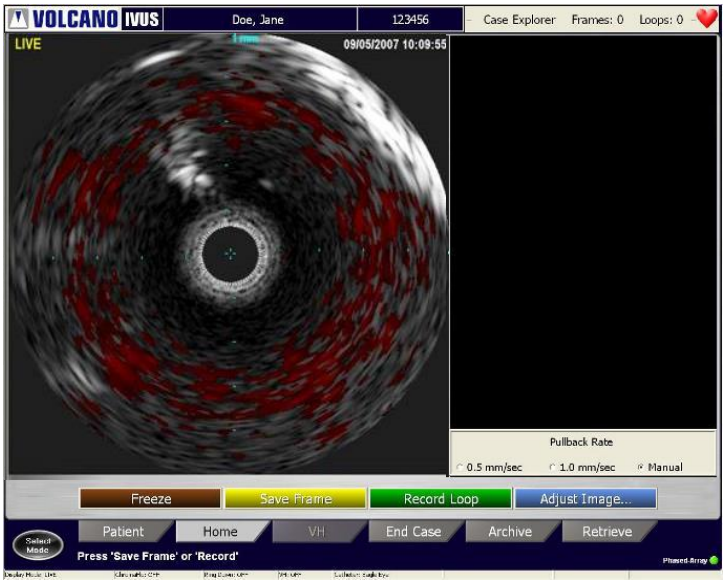

Figure 48: ChromaFlo Image

Controlling the Sensitivity

The Sensitivity setting controls the system's ability to detect and image blood flow color representation in the artery. Areas where the blood is moving faster are more yellow: areas where the blood moves more slowly are red. The sensitivity can be increased to intensify the color of slower moving areas of blood flow, or it can be decreased to diminish the color of faster moving areas of blood flow. Use the up and down arrows located in the Adjust Image screen to adjust the sensitivity value.

Setting the Region of Interest

Setting the Region of Interest restricts the flow detection to a particular area of the ultrasound image. Use the up and down arrows located in the Adjust Image screen to increase or decrease the Region of Interest setting. The Region of Interest circle on the screen image will be adjusted to correspond to your selection.

Value mappings for the Region of Interest range from:

- **Setting 1,** corresponds to an Region of Interest diameter of **3.80 mm**
- **Setting 21,** corresponds to a Region of Interest diameter of **13.96 mm**

Each increment changes the diameter by approximately 0.52 mm with a tolerance of ± 0.03 mm.

Deactivating the ChromaFlo Feature

To deactivate the ChromaFlo feature, press the **Chroma** key on the control console, or open the Adjust Image dialog box and uncheck the **ChromaFlo On** check box.

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Chapter 11: Ending an IVUS Case

Overview

An open case exists after the patient information and/or image data is collected. Once the case is complete, you must end the case before starting a new one. Ending a case is equivalent to saving the case to the system's hard drive. Alternatively, you may choose to delete the case.

NOTE: If power is shut off before ending a case, restart the system. When the system restarts, the End Case screen displays allowing data from the last patient to be confirmed or modified, and the case to be ended.

Ending a Case

To end the current case, do the following:

1 Press the **End Case** tab. The End Case screen displays with the current patient data in the fields.

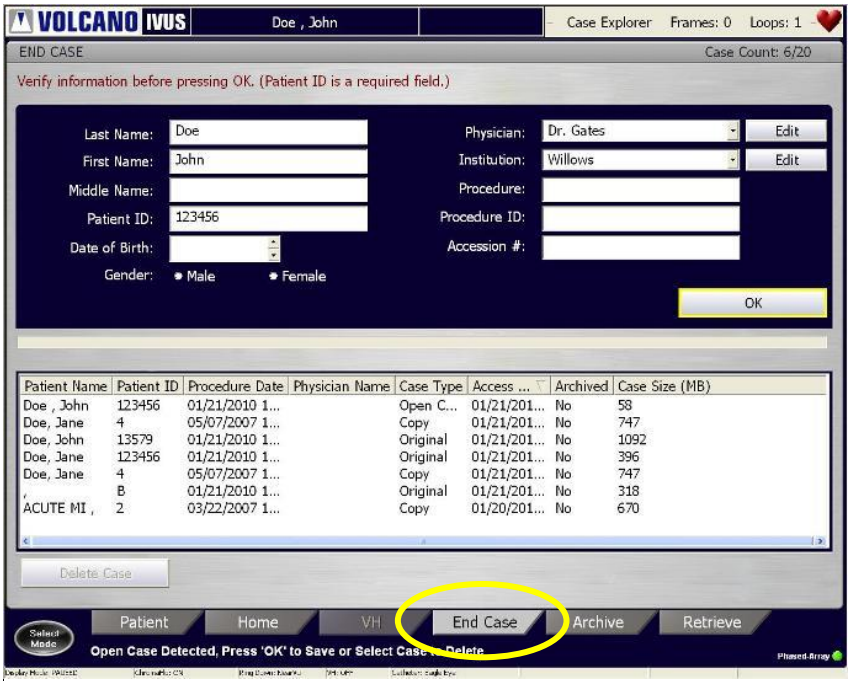

Figure 49: End Case Screen

2 Verify that the patient data is correct or perform edits as needed.

3 Click OK when you are ready to end this case. The case is saved to the hard drive and appears in the list box with Case Type Original.

NOTE 1: All the cases on the hard drive appear in the list box.

NOTE 2: Only 20 cases are allowed on the system's hard drive at one time.

If attempting to end a case when the limit of 20 cases is exceeded on the hard drive, the opened case cannot be saved. Select the Auto Archive Case Deletion in the settings menu to automatically delete the oldest archived case if the 20 case limit has been exceeded.

Deleting a Case

To delete the current case, do the following:

1 Select the case in the list box that you want to delete. The case is highlighted.

2 Press **Delete Case**. A message displays, prompting the user to delete the specific case. The user can click on the **Do not display again** option to prevent this message from redisplaying.

Chapter 12: Archiving an IVUS Case

Overview

A maximum of 20 patient cases can be stored on the system's hard drive. Saving to a hard drive is faster than saving to to a DVD.

However, archiving a case to a DVD allows for viewing or exporting of images or video loops on other PCs.

Patient data is archived in Read-Only format. Archive patient data regularly.

Archiving Options

Cases can be archived using any of the following:

- Recordable DVD-R drive
- DICOM Network Interface Port

WARNING: Do not use CDs for IVUS imaging data. The system will not read legacy DVDs or CDs from Invision. Only use HIGH-QUALITY DVD-Rs (Minimum 8X).

NOTE: FFR data may be stored on DVDs or CDs and used on this system.

What Data is Archived

The data you entered in the Patient screen is archived, as well as the video loops, saved frames and measurements.

CAUTION: A maximum of 20 cases can reside on the system's hard drive. Once this limit is reached, archive and delete a case. To free up more hard disk space, configure the system to delete the oldest archived case. Archive cases to a DVD or network on a regular basis so that you do not exceed the 20 case limit.

Archiving a Case to DVD

When a case is saved to DVD, a DICOM Viewer is automatically installed on the DVD as well. This allows you to view the case on a PC at a later time.

To begin archiving the case:

1 Press the **Archive** tab. The Archive Case screen displays.

2 Select a case by moving the cursor over a case and pressing **Select(+)**.

3 Select the **DVD Media** radio button.

4 Press the **Start Archive** button.

The system first checks to be sure a DVD is in the DVD drive. If no DVD is in place, or if the DVD in place does not have enough storage space, a message box will alert you to that fact. If the DVD contains adequate storage space for the current case, the system will save that case to the DVD in DICOM format. A progress bar on the screen and accompanying messages indicate how much data has been transferred and how much data remains to be transferred.

NOTE: The archived images are stored in DICOM format with Volcano system acting as a File Set Creator (FSC), following the guidelines in the 2004 DICOM 3.0 specification.

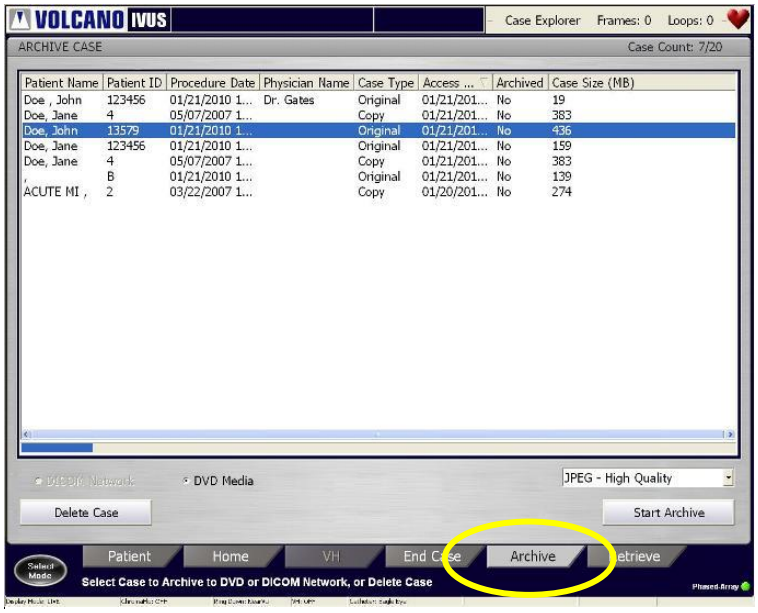

Figure 50: Archiving a Case

The cases displayed in the list box are the cases stored on the system's hard drive. An archived status of **no** indicates they have not been saved to DVD or sent to the DICOM network.

CAUTION: If the system power is turned off while data is being written to the DVD, you could damage the DVD's directory structure. DVD archived cases may be inaccessible by both standard DVD readers and DVD drives, which is the type installed in the Volcano system. Avoid turning off the power during the archiving process, which can take up to several minutes. Should this happen, restart the system and repeat the archive of the desired cases before deleting them.

DVD Use Cautions and Warnings

- The DVD drive may not initialize if there is a DVD-R inserted in the drive when the system is started. If this occurs, a message will appear after the hardware initialization phase: **DVD failed to initialize**. Remove the DVD-R and reboot the system. Allow the system to fully initialize before reinserting the DVD-R.
- You can set the DVD drive to perform a verification pass when data is written. However, the potential exists that a defective DVD-R can be created without your knowledge. After storing a case to a DVD-R, do not delete it from the hard drive before verifying that it was properly archived by first retrieving the case from the DVD-R and then reviewing it.
- To prevent the potential loss of data, always use a new DVD-R when archiving patient cases to the DVD-R.
- Do not share DVD-Rs from other non Volcano systems or computers with the Volcano system; instead keep a separate supply of DVD-Rs just for the system. If you save cases to DVD-Rs that were created on a different system or computer, the potential for data corruption exists.

Archiving Using DICOM

DICOM stands for Digital Imaging and Communications in Medicine. It is an image format for medical images that has been standardized so that images from different types of medical electronic equipment can be shared on a common computer network. The intravascular ultrasound images from your Volcano system can be sent to a network within a hospital or clinic, or to a network of health care providers. Sending images to a remote computer using a standardized format may be able to provide physicians with quicker access to medical information for more rapid diagnoses and treatment decisions.

The DICOM Settings should be set up by either a Volcano Corporation Technical Support representative or the Information Systems manager or network administrator at your facility. For information on configuring the DICOM network, see Appendix C.

You can archive a case to a DICOM Server by clicking the **Archive** tab and selecting the **DICOM Network** radio button.

Printing Images

Color printouts can be generated for the displayed screen by pressing the Print button on the console.

NOTE: Ensure that the printer power is on before printing.

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Chapter 13: Switching Modes

Overview

This chapter describes how to switch between available modalities.

Entering Patient Information

If planning to use more than one mode for a single patient, enter the patient information in the IVUS modality before switching modes.

Switching Modes

You can switch from one modality to another by clicking on the **Select Mode** button shown below. Once selected, a menu of available modes is presented. Click on the modality to be redirected to that modality. If leaving an IVUS open case containing images, the operator is prompted to continue with the current patient. Select **Yes** to continue with the same patient. Select **No** if beginning a case with a new patient.

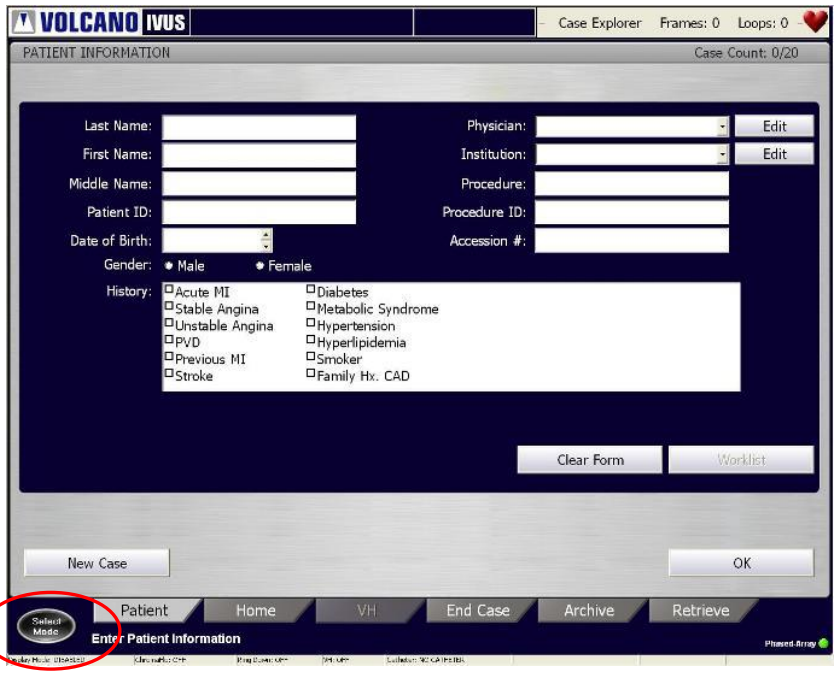

Figure 51: Select Mode Button

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Chapter 14: Retrieving and Deleting an IVUS Case

Overview

This chapter provides the instructions for retrieving a case that has previously been ended to review and/or edit case data. Cases can be retrieved from:

- System Hard Drive
- DVD

NOTE: Cases cannot be retrieved from the DICOM Network.

In addition, instructions are provided for deleting an IVUS case from the hard drive.

Retrieving a Case

To retrieve a case, do the following:

1 Press the **Retrieve** tab to display the RETRIEVE CASE screen.

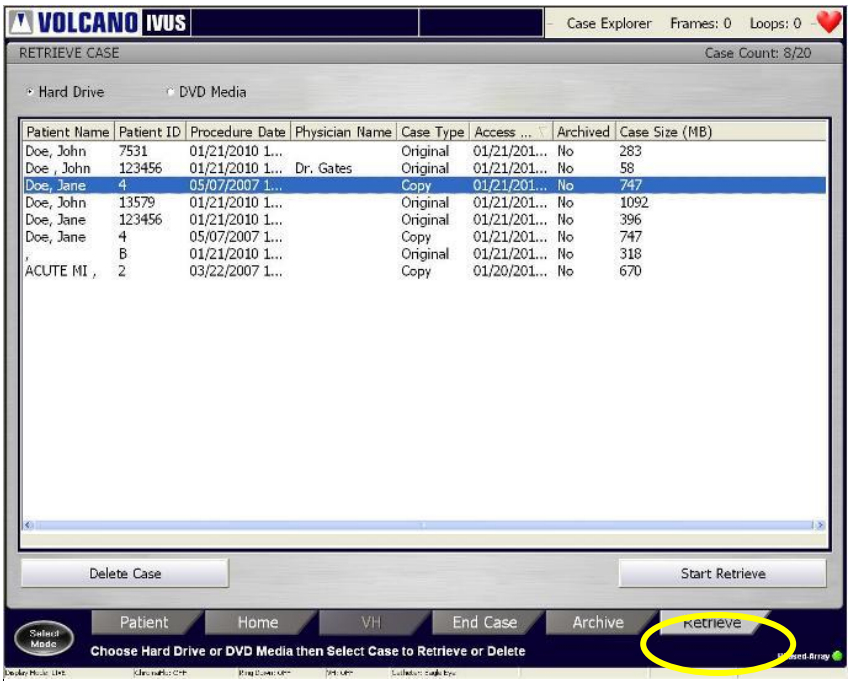

Figure 52: Retrieve Dialog Box

2 Select the **Hard Drive** radio button to display all the cases stored on the hard drive. Select the **DVD Media** radio button if you want to display cases stored on the DVD.

NOTE: Be sure the DVD is in the DVD drive. If it is not in the drive, you will be prompted with a message. Put the DVD in the drive and press **Rescan Media**.

3 Move the cursor over the desired case and press **Select (+)** to select it. The case is highlighted.

4 Press the **Start Retrieve** button to transfer the data from storage to the Volcano system.

A bar on the screen indicates the progress of the data retrieval.

NOTE: You can retrieve only one case at a time.

Deleting a Case

Archive patient cases before deleting them. Otherwise, case data will be lost upon deletion. Patient cases can be deleted from the hard drive, but not from the DVD. To delete a case from the hard drive, first select it from the list, and then click the **Delete Case** button to remove it from the hard drive and the list. If you have more than one case to delete, select all of them before selecting **Delete Case**.

Removing Power from System

1 Turn off system power.
2 Unplug the system at the appliance power inlet (wall socket).
3 Do not block accessibility to the appliance power inlet.

Chapter 15: Image Export Option

NOTE: Image Export is an additional option that can be enabled on compatible Volcano systems. For information on how to enable this functionality, please contact the local Volcano representative.

The two Image Export connectors are located on the rear Connector Panel and use the #1 AUX (auxillary) and #2 DICOM network ports. See Connector Panel section.

The Volcano system is compatible with the Siemens IVUSMap coregistration feature on select systems. The IVUSMap feature provides automated coregistration of the IVUS images to show the corresponding IVUS location in the angiographic roadmap through Volcano's proprietary Image Export function.

The majority of the user interaction and display of IVUSMap resides on the Siemens system. Please reference instructions for use in the IVUSMap section of the Siemens manual.

When this feature is enabled on the Volcano system, registered IVUS images are sent to the Siemens system automatically after acquisition. Two unique behaviors occur on the Volcano system when the Image Export feature is enabled:

1. During an image transfer to the Siemens Artis system after an IVUS pullback, there are some Volcano functions that are not available. This includes reviewing a different IVUS run, recording another run, ending or archiving a case, and switching modalities.

   If the user tries to do any of these actions, the following message appears:

Figure 53: Image Export in Progress Message

2. If transfer of IVUS images is cancelled during the transfer process, the registered IVUS pullback needs to be repeated under X-ray. The user cannot go back and re-send IVUS data for the cancelled pullback after the transfer has been cancelled.

3. The status of the connection for the Image Export feature can be checked as follows using the indicator at the right bottom corner of the screen:

   a. If Image Export is enabled and an active connection is available between the Artis and Volcano system, the right bottom corner of the Status Bar shows "Image Export: ON".

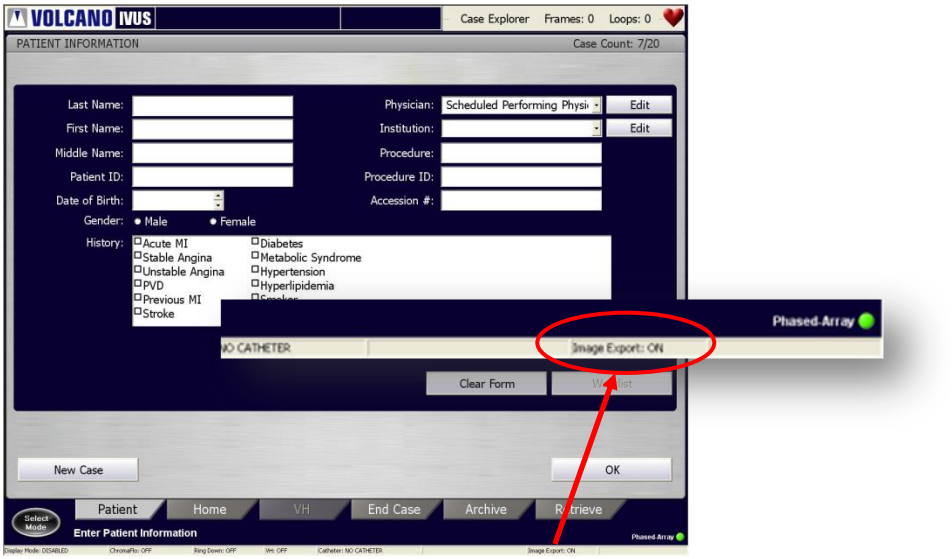

Figure 54: Patient Information – Image Export: ON

   b. If Image Export is enabled but there is *no* active connection between Artis and the Volcano system, the status shows "Image Export: OFF".

Figure 55: Patient Information – Image Export: OFF

   c. If the Image Export feature is not enabled on the system, nothing is displayed on the Status Bar.

Figure 56: 11Image Export Disabled – No Display

Chapter 16: Troubleshooting

Message Alerts

Message	Reason	Resolution
Press F1 to continue	Upon startup the BIOS battery is failing.	Contact your service representative to replace the BIOS battery. Note: Until battery is replaced, current day/date will need to be manually reset each instance of power on.
No Catheter	The patient interface module does not have a catheter plugged in.	Plug in a catheter.
Catheter Failure	The catheter is drawing too much current from the patient interface module.	Replace the catheter.
Dark catheter image <*no message*>	The catheter produces a blank (dark) image in the system.	Replace the catheter. If the condition persists, call Technical Support.
PIM Power Failure	The PIM has detected an undesirable high power condition for the catheter in use. The message disappears approximately two seconds after the catheter has been unplugged from the PIM, or when the high power condition is corrected.	Replace the catheter. If the message persists, call Technical Support.
PIM not Detected	The system is unable to communicate with the PIM unit.	If the message persists, call Technical Support.
No Paper or Ink	Printer is out of paper or ink.	Replenish the paper or ink
PIM Configuration in progress. Please wait.	The hardware must be configured whenever a PIM is changed. This message will disappear once configuration is complete.	Wait for the message to disappear. The wait time of this message is between a few seconds to two or three minutes.
System error detected. Auto-repair in progress, please wait.	When the hardware experiences a failure, the system will try to repair itself by resetting either the VH or IVUS card.	Wait for the message to disappear. If reset fails, the system will shutdown.

An error occurred trying to execute the Health Checker module. Please contact Volcano Technical Support to fix the problem. Click 'Cancel' to shut down the system (RECOMMENDED). Click 'OK' to continue with system start-up.	On startup, the health checker determines the state of the hardware. When cards fail, this message appears.	System should be powered down. The power disconnected from the system for 10 seconds. Then start up system. If startup fails again, call Technical Support.
The current case is still open. Please END the current case before switching to FFR Mode.	The system cannot switch to FFR if there is an open case.	End or delete the open case before switching to FFR.
The Meridian could not stop the VH+ and IVUS boards to switch to FFR Mode.	Failure stopping either the VH+ board or IVUS board while attempting to switch to FFR mode.	End/archive the current IVUS case, shutdown the system. Wait for **1 minute** before powering up again.
The Meridian could not restart the VH+ and IVUS boards back to Meridian Mode.	Failure to start either the VH+ or IVUS board after switching back from FFR to IVUS mode.	Shutdown the system. Wait for **1 minute** before powering up again.
System was shutdown before ending case. Please end or delete the open case.	The system was shutdown prematurely before a case was ended. On startup, the system goes in recover mode and warns the user to end or delete the open case.	End or delete the open case.
Shutting down the system will abort the case archiving.	Pressing the power button while archiving.	Selecting yes will turn off the application.
An error occurred during initialization. Please shut down and then restart the system. Contact Volcano Technical Support if issues persist.	The Health Checker encountered an unrecoverable error on startup.	Shutdown the system. Wait for **1 minute** before powering up again. If the problem persists, call Technical Support.
Error Opening Association: <variable text>.	There is a problem with the worklist network connection.	Check connection to the worklist server

Error starting video loop recording.	The hard drive may be full.	Archive cases, delete them from the hard drive and then try to record video loop again. If the problem persists, call Technical Support.
Error creating a new patient case.	There was a problem synchronizing the Volcano system patient data with GE's Innova system.	Reboot the system and try again. If problem persists, call Technical Support.
Error saving patient case to hard drive.	There is a problem with the hard drive.	Contact Technical Support.
Error retrieving patient case.	There is a problem with the hard drive.	Contact Technical Support.
Retrieve from DVD failed.	There is a problem with the DVD or the DVD drive.	Try retrieving a patient case from another DVD. If that fails, please contact Technical Support. If it works, then the DVD previously used was damaged.
Unable to open <filename>	There is a error opening the DICOM configuration dialog.	Reboot the system and try again. If the problem persists, call Technical Support.
	Missing file.	
Unable to open the file to record the time and date setup.	Missing setup file.	Contact Technical Support.

Unknown Archive Dialog Message	There is a problem with archiving software or DVD or DVD drive.	Try archiving with another DVD, if that does not work, save the patient case, reboot the system and try archiving again. If problem persists, call Technical Support.
Bad Usage	Missing file.	Reboot the system and try again. If problem persists, call Technical Support.
Internal Error		
NeroAPI DLL Not Found		
Missing Valid Nero Serial Number		
Bad Nero Serial Number		
Error obtaining Available Drives		
Missing Drivename		
Error Opening Drive		
Drive Not Found		
Invalid Drive		
Function Not Allowed		
Drive Not Allowed		
Track Not Found		
Unknown File Type		
DAE Failed		
Error Opening File		
Our of Memory		
Error Determining the File Length		
Attempt to Eject Failed		
Bad Import Session Number		
Failed to Create an ISO Track		

File Not Found		
Unknown Error Encountered		
Demo Version of Nero Expired		
Bad Message File		
Please modify the search criteria and query again or increase the maximum number of worklist.	An incorrect query has been entered.	Re-enter the corrected query.
DeepFreeze is in THAWED mode. Please switch DeepFreeze to FROZEN mode to secure the system.	The security protection for the system has not been enabled.	Contact Technical Support.
Failed to turn off DeepFreeze for date/time changes.	The date-time setting could not be applied.	Contact Technical Support.
	Missing setup file.	
Invalid Segment Specified.	Target Assist does not work with VH video loops with only one frame.	Create another VH video loop with more than one frame. Try Target Assist again. If problem persists, call Technical Support.
Unsupported Character Set	The data from the worklist server is in incorrect format.	Contact the hospital network administrator.
Invalid UID		
Type 1 attribute missing or zero length		
Type 2 attribute missing		
MergeCOM-3 Validation Failed		
Error: Invalid DICOM file	The DICOM file on the DVD could not be read most likely due to dirty/damaged DVD	Try cleaning the DVD. Ensure the archived case is a Volcano-system case.
Unable to open config file <filename>	The system cannot archive this case.	Save the patient case, reboot the system and try to archive again. If the problem persists, call Technical Support.

Unable to launch network settings batch file.	A corrupt file has been encountered.	Reboot the system and try again. If the problem persists, call Technical Support.
Unable to launch Dista Config Dialog	A corrupt file has been encountered.	Reboot the system and try again. If the problem persists, call Technical Support.

Potential Imaging Artifacts

The Volcano system software is designed to minimize artifacts and errors. As with any imaging modality, however, some artifacts may occur. Images or features may be presented on the screen which do not directly represent a physical structure or which may cause image defects.

NOTE: Potential imaging artifacts for the Revolution 45MHz Rotational Catheter, please refer to the troubleshooting chapter of the Volcano system Revo Option Operator Manuals (807470-002)

Potential Imaging Artifacts – Adaptive Ringdown Reduction, Adaptive NearVu

Artifact	Cause	Resolution
Image Artifacts appears in area of ringdown Ringdown Reduction, NearVu is activated	Small artifacts may appear for several seconds immediately after toggling Adaptive NearVu RDR on, but NearVu will correct itself gradually	▪ Adaptive NearVu should be turned on just after the imaging catheter exits the guide catheter/sheath, as in the aorta or ostium of coronary artery. ▪ To avoid image artifacts, it is recommended to turn Adaptive NearVu off when imaging catheter is retracted back inside guide catheter/sheath or outside of body. Switch on Adaptive NearVu again when it is re-inserted into artery to quickly clear out artifacts. ▪ It is recommended against toggling Adaptive NearVu from Off to On when catheter is imaging bright areas such as a stent or calcium, otherwise imaging

		artifacts may persist for a sustained period in following images. ▪ If imaging catheter has been placed next to a relatively stationary and bright tissue (e.g. calcified plaque), moving the catheter away afterward may create an artifact that may remain on screen for a short time.
Tissue Artifacts appears in area of ringdown after Adaptive NearVu is activated	Since Adaptive NearVu is based on the assumption that ringdown is relatively stationary compared with the moving tissues, stationary signals in the image are likely to be treated as ringdown and be gradually blanked out over time, within a set radius in the image of the IVUS catheter.	▪ User should be extremely cautious when imaging slow-moving tissues and vessels. It is recommended to keep the imaging catheter constantly moving without being parked next to stationary tissues. ▪ Adaptive NearVu should not be used when imaging stationary phantoms. ▪ To avoid possible tissue blanking and more importantly to prevent restricted blood supply, it is very important to avoid situations where the transducer is barely moving and completely wedged for a prolonged period in a heavily blocked vessel. If catheter is wedged for a long time, an artifact of a darkened concentric circle may appear in and out of image between cardiac cycles.

Potential Imaging Artifacts – Manual Ringdown Reduction, Manual NearVu

Artifact	Cause	Resolution
Stationary crescent-moon-like artifacts in the area of ringdown after Manual NearVu has been activated (especially for PV catheters).	An improper ringdown reference was taken when Manual NearVu was enabled.	Avoid any tissues in the ringdown region when the manual ringdown reduction is toggled. PV catheters only support the manual mode of ringdown reduction, so any poor reference image that was accidentally included will remain as an artifact on the screen until another reference is manually taken.

Potential Imaging Artifacts – the ChromaFlo Feature

- The ChromaFlo option provides a two-dimensional qualitative map of relative blood flow velocities. Due to the qualitative nature, do not use this information

to assess quantitative blood flow or to develop a numeric measure of total cross-sectional blood flow.

- The ChromaFlo option can detect blood velocities in the following range:
  - The lower limit on particle detection is between 4 cm/sec and 7 cm/sec, depending on the intervening attenuation. (The higher limit is obtained with maximum tissue attenuation between the transducer and region of flow.)
  - The upper limit on particle detection is between 107 cm/sec and 110 cm/sec, depending on the intervening attenuation. (The lower limit is obtained with maximum tissue attenuation between the transducer and region of flow.)

Artifact	Cause	Resolution
Flow is not ChromaFlo detected	Velocity sensitivity of the ChromaFlo technique is between 4 cm/sec and 7 cm/ sec, depending on the attenuating tissue between the transducer and the region of flow. The higher velocity number (lower sensitivity) is obtained when detecting flow at depths greater than 8mm. In either situation, flow below this velocity will appear as black.	Carefully identify and compare the lumenal boundary based on grayscale images with those obtained from ChromaFlo images, as well as other modalities such as angiography.
Reduced frame rate	Due to processing speeds in ChromaFlo mode, the overall frame rate of the Volcano system is lowered to approximately 12 frames per second, which represents combined grayscale and color features.	None. Very fast moving structures may appear to move in a more continuous manner during standard, non-ChromaFlo imaging.
Moving tissue coded as color	The ChromaFlo technique uses the changing IQ "speckle" pattern to detect regions of flow. It is possible for tissue motions to generate speckle that is detected as a flow region. The ChromaFlo processor employs a sensitivity control which discriminates between tissue and flow regions based on the magnitude of the grayscale image. For example, a bright reflector, even though it generates an echo which is decoded as flow, is suppressed. A lower level signal is not suppressed. This is based on the clinical findings in which blood	Adjust the region of interest as necessary to prevent tissue from being coded as color.

	signals are usually lower than tissue features. However, slow-moving (<1 cm/sec) acoustically soft tissues, such as plaque and lipids, can give rise to low level signals of the same order as faster moving blood (>4 cm/sec). In these cases, the tissue will be coded as color.	
Dead zone near transducer	Saturation in the analog amplifiers following initial transmit pulse may limit flow readings near the transducer.	Move the catheter to another location.

Potential Imaging Artifacts – Automatic Distance Measurement

Artifact	Cause	Resolution
Automatic Distance Measurement is not proper	The automatic distance measurements may not always correspond to that which a trained operator will select. This algorithm does not replace the operator, but rather assists in identifying starting distance measurements within an area boundary.	Carefully review any automatic distance measurement prior to accepting it. If the distance measurement is not properly placed, the operator should edit the measurement.

Potential Imaging Artifacts - In-Line Digital (ILD)

NOTE 1: Length measurements are not representative of anatomy, since the computer display will always represent the catheter pullback as a linear translation.

NOTE 2: Due to potentially significant inaccuracies, the user should carefully review any computer generated boundary before proceeding with a measurement.

Artifact	Cause	Resolution
Irregular Artery Contours	The imaging transducer at the catheter tip may not always be withdrawn from the artery in a linear manner. Motion of the catheter tip from side to side during a pullback data collection will appear on the sagittal view as if the artery wall is moving towards and away from the transducer axis.	None possible. Carefully review the angiogram to determine the vessel contours. Also, use the outer vessel wall boundary (media to adventitia interface) to evaluate whether luminal irregularities are due to catheter motion or actual lumen variations. (Note that the vessel wall boundary or the media to adventitia interface changes slowly as the catheter is moved axially.)
Catheter slack, same image plane presented along artery length	Due to the mechanical slack which can occur in the pullback system, the beginning of the pullback sequence may contain a series of images in which the image does not change for several frames. This occurs because the pullback device is moving the catheter holder clamp, and the system is collecting data, but the transducer at the tip of the catheter is not moving.	Ensure that there is no excessive slack in the system. Observe the image as the pullback is started. If the image remains unchanged for several images, use the longitudinal editing feature to remove the beginning of the pullback sequence.
Inaccurate pullback rate–Z axis measurement error	Operator entered the wrong pullback rate when questioned by the operating system.	None possible. This relies on the operator correctly entering the data. The pullback speed entered is prominently displayed.

EU Battery Directive, 2006/66/EC Requirements

Instructions for battery removal for disposal when decommissioning the unit:

1. Power down the workstation and unplug the unit.
2. Open the workstation side panel to access the interior of the unit.
3. Remove the coin battery from the motherboard of the workstation.
4. Dispose of battery according to state/local laws.

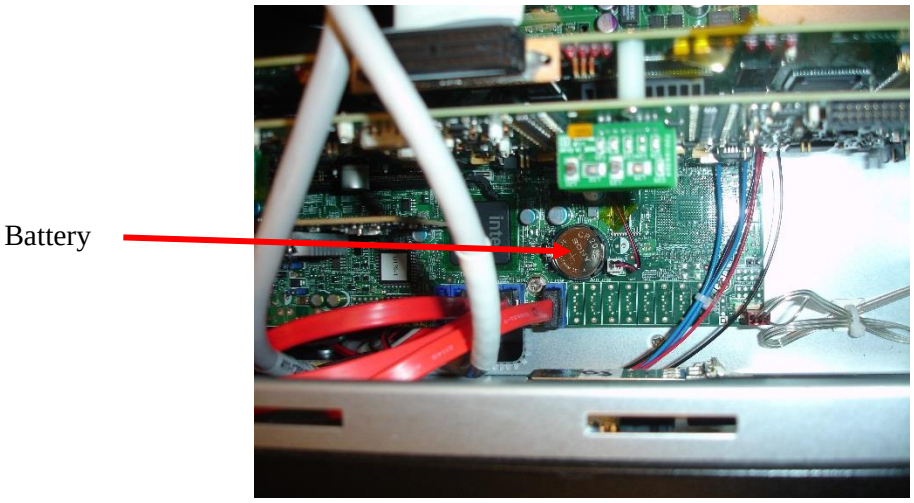

Figure 57: Motherboard Battery

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Chapter 17: Maintenance

Service

The Volcano system contains no user-serviceable components. To avoid electrical shock, do not remove any panels or covers. In the event of malfunction or system damage, turn the system off, unplug the system from the power receptacle, and contact a Volcano-certified service person and/or Volcano Technical Support.

As part of the hospital's maintenance program, routine safety inspections and testing should be conducted annually. Trained hospital technicians should inspect and safety test all isolated connections and the system's power supply.

CAUTION: The Volcano system must be serviced only by Volcano Corporation Service personnel or by Volcano-certified technical representative.

Maintenance Frequency

User-Performed Maintenance	**Frequency**
Archive patient cases	Daily as used
Clean components in patient vicinity	Daily as used
Clean system and monitor	As needed
Clean fan vent and back of PC	Monthly
Clean fan filter	Monthly
PIM cable inspection and placement	Daily as used
Verify cable connections	Monthly
Inspect keyboard slides	Monthly
Inspect and safety test all isolated connections and system power supply	Annually
Volcano-Certified Maintenance	**Frequency**
A comprehensive preventive maintenance procedure performed by Volcano-certified service engineers only	Annually, starting 18 months post-installation

NOTE: As part of the hospital's maintenance program, routine safety inspections and testing should be performed annually. Trained hospital technicians should inspect and safety-test all isolated connections.

Volcano-Certified Maintenance

Volcano-certified maintenance is performed by Volcano-certified service engineers only.

A comprehensive preventive maintenance procedure needs to be done annually, starting approximately 18 months post-installation.

User-Performed Maintenance

Archive Patient Cases

See **Archiving an IVUS Case** chapter.

Cleaning and Disinfecting the Volcano System

- Clean and disinfect the system, patient interface module, and other parts of the equipment as needed with common detergents, liquid chemical germicide, bactericide, and antiviral solutions such as morning mist among others, using warm water and a soft cloth.
- To prevent any patient contamination, always clean and disinfect parts of the equipment which were in patient vicinity with a bactericidal, germicidal and antiviral solution after each procedure. Ensure the solution used is active against HIV virus and hepatitis B virus.
- Do not use solvents to clean any portion of the system.
- Avoid allowing liquids to enter the system openings, especially the keyboard, monitor housing, and patient interface module.
- Remove front panel to clean fan filters as needed or if any dirt and lint accumulates on the back of the PC module.

NOTE: No portion of the system should be immersed in water or other fluids. Never use acetone to clean the bedside peripheral, plastic housings, or patient interface module.

CAUTION: Never spray or otherwise apply any cleaner directly into the openings or seams of the system. Always apply the cleaner to the cloth instead.

- Pay special care to the catheter/cable connections during cleaning to avoid unnecessary bending or breaking.

Monitor Care

Follow the hospital's protocol for the handling of blood and body fluids. Clean the display with a diluted mixture of mild detergent and water. Use a soft towel or swab. Use of certain cleaning agents may cause degradation of the plastic enclosure and labels

of the product. The plastic is composed of acrylonitrile, butadiene, and styrene (ABS). Consult cleanser manufacturer to see if agent is compatible with ABS.

CAUTION: Never spray or otherwise apply any cleaner directly to the touch screen because leakage could cause damage to the system. Always apply the cleaner to the cloth instead.

PC Cooling (Fan/Filter) Maintenance

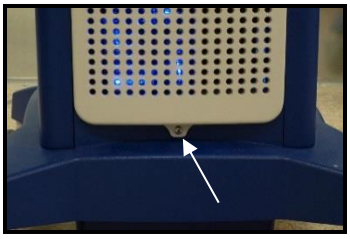
Check workstation PC fans and filter monthly and clean every 18 months to help ensure optimal cooling.

NOTE: The system should be turned off and unplugged from wall outlet before attempting to clean fan filters.

Front and Rear Panel Fans and Filter*

To clean the front filter:

1. Open the front door of the workstation PC by removing the bottom screw of the front chassis cover.

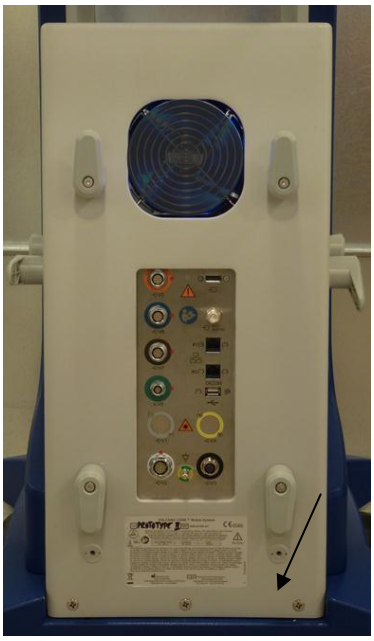


2. Gently lift front cover, before swinging out to disengage tabs.
3. To remove fan filters, slide a flat tool behind the filters (2) to pry them from the case pins.

4. Wash the filters with a mild detergent solution, and allow them to dry thoroughly.
5. If there is dirt accumulated on the front fans, clean with a vacuum.
6. Replace fan covers by aligning the cover holes with case pins, and press covers onto case pins.

To clean the rear panel fan:

1. Open the rear chassis door of the workstation PC by removing the bottom three screws.



2. Gently lift the rear door before swinging out to disengage tabs from the workstation PC, and vacuum the fan.

3. Carefully observe electrostatic discharge (ESD) precautions.

Cable Inspection

- Check placement of PIM cable and connector, and ensure cable is protected from accidental damage
- Inspect cable connections to ensure secure connections

Volcano-Certified Maintenance

Volcano-certified maintenance is performed by Volcano-certified service engineers only.

A comprehensive inspection, operational check, entire system test, and check of any installed options are required.

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Chapter 18: Technical Specifications

Imaging Catheters

Transducer type: Piezoelectric

360° view, multi-element solid state array transducer (except Revolution)

360° view, single-element rotational transducer (Revolution)

Frequency and available imaging diameters are noted in the table below.

Catheter	Frequency	Imaging Diameters (mm)
Eagle Eye Platinum	20 MHz	8, 10, 12, 14, 16, 18, 20
Eagle Eye Platinum ST (Short Tip)	20 MHz	8, 10, 12, 14, 16, 18, 20
Reconnaissance	20 MHz	8, 10, 12, 14, 16, 18, 20
Visions PV .014P	20 MHz	8, 10, 12, 14, 16, 18, 20
Visions PV .018	20 MHz	10, 12, 14, 16, 18, 20, 22, 24
Visions PV .035	10 MHz	20, 25, 30, 35, 40, 45, 50, 55, 60
Revolution	45 MHz	8, 10, 12, 14
Pioneer Plus	20 MHz	8, 10, 12, 14, 16, 18, 20

NOTE 1: Additional information is available in the "Physicians Guide and Instructions for Use" that accompanies each catheter.

NOTE 2: Information about the technical specification for the Revolution catheter, refer to the Volcano System Revo Option Operator's Manual.

Video

System Video Display Format

- Display port and DVI/HDMI/VGA adaptors are available
- 1280 x 1024 pixel resolution
- 60 to 75 Hz refresh

Image

- Live/Still modes
- Variable frame rate
- 360° image
- Multiple depth scaling

Image Sizes

Image Mode	Image Area (in pixels)
Max IVUS	750 x 750
Normal Imaging Mode	500 x 500

CORE Mobile Dimensions and Weights

Volcano System

	Height, in	Width, in	Depth, in	Weight, lb
CORE Mobile Cart	62	22	33	~210

	Height, cm	Width, cm	Depth, cm	Weight, kg
CORE Mobile Cart	157.48	55.88	83.82	~95.25

Power

Volcano Ratings and Fusing

System Input Configurations	Workstation Input	Fusing
100, 120V~ 240V~ 50/60Hz, 1000VA	100-240V~ 50/60Hz	100VAC, 12A 120VAC, 10A 240VAC, 5A

Power Specifications—Input

Maximum Continuous Power	550 watts
Hold-up Time	>40ms @ full load
Over voltage Protection	+15% of set voltage
Overload Protection	Auto Recover
Minimum Loading	None
Cross regulation	<0.5%
Line & Load regulation	<0.5%
Turn on Time	< 2 sec

EMC Compliance

Compliance to the following standards:

- EN61000-4-2 ESD level3
- EN61000-4-3 RF susceptibility 3v/m
- EN61000-4-4 EFT level3
- EN61000-4-5 Surge level3
- EN61000-3-2 Harmonics
- EN61000-3-3 Flicker
- EN61000-4-11 Voltage dips, short interruptions
- EN55011 conducted an radiated emissions

Fusing

The Isolation Transformer is merged with a fuse on each mains leg. The fuse values are dependent on the transformer setting for the available AC mains power from the wall. The transformer uses 5x20mm time delay fuses.

The AC mains input for the workstation power supply and 48VDC power supply are internally fused and are not serviceable parts.

The 48VDC power supply output is protected with a 5A, 5x20mm time delay fuse.

Recording Devices

- Hardcopy Digital Photo printer
- DVD writer

Classifications

Per IEC 60601-1, the Volcano system has these classifications:

Type of Protection against Electric Shock	Class I
Degree of Protection against Electric Shock	Type CF, defibrillation proof
Degree of Protection against the Harmful Ingress of Water	Ordinary
Degree of Safety of Application in the Presence of Anesthetics	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide
Mode of Operation	Continuous Operation

EMC Statement

The Volcano system is medical electrical equipment and needs special precautions regarding EMC and needs to be installed according to EMC information provided in this manual. This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601 and Medical Device Directive 93/42/ EEC as amended by 2007/47/EC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy. And, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or Technical Support technician for help.
- Do not attempt to replace any cables or accessories with non-Volcano approved components as this may affect EMC performance.

Electrical Safety

Type CF Equipment: The heart symbol with the paddles on each side indicates that the patient interface module meets all requirements for International Electrotechnical Commission 60601-1 type CF classification. This device is protected against the voltages of defibrillation, however, it is recommended to disconnect the catheter or pressure wire from the patient interface module prior to defibrillation. If medically possible, remove the catheter from the patient prior to defibrillation.

System has to be installed to IEC 60601-1, including the use of an isolation transformer and potential equalization ⏚ on control console and workstation.

Environmental Conditions

	Temperature, °F	Temperature, °C	Relative Humidity, % non-condensing	Altitude, ft	Altitude, m
Operating	50 to 104	10 to 40	5-80	10,000	3,048
Storage*	-4 to 158	-20 to 70	5-80	—	—
Shipping*	60 to 140	16 to 60	5-80	35,000	10,668

*As per IEC 60601-1, section 7.2.17.

DICOM Image Storage

Saving patient cases to DVD: The archived images are stored in DICOM format with the Volcano system acting as a File Set Creator (FSC), following the guidelines in the 2004 DICOM 3.0 specification.

The DICOM images will be stored using the Ultrasound Application Profile STD-US-SC-MF-DVD, using the UIDs in the following table.

Information Object Definition	SOP CLASS UID	Transfer Syntax UID
DICOMDIR	1.2.840.10008.1.3.10	1.2.840.10008.1.2.1
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50

Sending patient cases to a DICOM server: The Volcano system supports the ultrasound multi-frame image storage SOP Class as an SCU (Service Class User). The SOP Classes supported by the Volcano system are categorized in the following table.

Information Object Definition	SOP CLASS UID	Transfer Syntax UID
Verification	1.2.840.10008.1.1	1.2.840.10008.1.2
Ultrasound Multi-frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50

For more information, see the Volcano system DICOM Conformance Statement located on line at: http://www.volcanocorp.com/

Essential Performance, Catheter Operating Temperatures

The catheters are designed to image under physiologic conditions. Operating Temperature of all solid-state array catheters used with the Volcano system is <55 +/- 0.3 °C in air and <41+/- 0.3 °C under physiologic conditions (37 °C in fluids). Operating Temperature of rotational catheters used with the Volcano system is 1 +/- 0.3 °C above ambient temperature in air and <38 +/- 0.3 °C under physiologic conditions (37 °C in fluids).

Operation of the catheters in air will degrade the life of the catheter, and is not recommended. Should operation of the solid-state array catheters in air occur, this will result in a temperature at the distal end of up to 55 °C, but the catheters thermal load is negligible and the catheters may be safely touched. They will feel slightly warm to the touch under these conditions. Should operation of the rotational catheters in air occur, this will result in a negligible temperature rise at the distal end.

Essential Performance, System

The essential performance of the Volcano system when operating with Volcano catheters is specified below:

- The rotation of the Revolution catheter imaging transducer at the distal tip of the catheter is automatically maintained at a predetermined speed during live imaging operations
- If present, any signal distortion leading to errors of diagnostically relevant parameters is visually evident to the operator
- The ultrasound (acoustic) output and heating of the catheter imaging transducer is maintained within safe levels

- Ultrasound (acoustic) output of the Eagle Eye and PV catheters imaging transducer is active when an active moving image is displayed
- Ultrasound (acoustic) output of the Revolution catheter imaging transducer is active in imaging mode only
- System control of movement of the catheter imaging transducer is limited to the following operator actions:
  - Push and pull motion of the catheter imaging transducer can be initiated through manual manipulation of catheter body by the operator
  - Motorized pullback of the Revolution catheter is manually controlled by the operator. Motorized push motion of Revolution catheter is not possible.
- Changes in Revolution catheter, ultrasound imaging operation from off to on and from on to off occur only when initiated by the operator
- Ultrasound output power settings are automatically maintained at preset and safe levels during imaging operations
- Electrical safety is maintained in all operational modes

Catheter Acoustic Outputs

Ultrasound Exposure Maxima

Ultrasound Exposure/ Acoustic output power is fixed and cannot be adjusted by the operator of this equipment. Ultrasound exposure only when LIVE imaging is enabled. When LIVE imaging is not selected by the operator, no ultrasound exposure occurs.

The Volcano system is in compliance with the Acoustic Output Display Standard and are within FDA limits for Ultrasound equipment.

Eagle Eye *Platinum*

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm^2)[1]	2.93x10^{-3}	7.98x10^{-2}
$I_{SPPA.3}$ (W/cm^2)[1]	7.5x10^{-3}	175.0x10^{-3}
$Pr._3$(MPa)[2]	20.0x10^{-3}	81.5x10^{-3}
PD (µs)[2]	161.0x10^{-3}	125.0x10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)[2]	18.6	17.9
MI[2]	4.5x10^{-3}	1.92x10^{-2}
TI[1]	2.06x10^{-5}	1.56x10^{-4}

1. Uncertainty: +/- 24.5%

2. Uncertainty: +/-12.3%

Reconnaissance PV .018 OTW

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm^2)*	2.93x10^{-3}	7.98x10^{-2}
$I_{SPPA.3}$ (W/cm^2) *	7.5x10^{-3}	175.0x10^{-3}
$P_{r.3}$ (MPa)	20.0x10^{-3}	81.5x10^{-3}
PD (μs)	161.0x10^{-3}	125.0x10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)	18.6	17.9
MI**	4.5x10^{-3}	1.92x10^{-2}
TI**	2.06x10^{-5}	1.56x10^{-4}

* Maximum uncertainty +33.9%/-30.5%

** As estimated in tissue

Pioneer Plus (Catheter manufactured by Medtronic, Inc.)

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm^2)[1]	2.683	20.800
$I_{SPPA.3}$ (W/cm^2)[1]	0.248	1.870
Pr.$_3$(MPa)[2]	137.1x10^{-3}	315.3x10^{-3}
PD (μs)[2]	201.2x10^{-3}	125.0x10^{-3}
PRF (Hz)	53760	88320
Center Freq (MHz)[2]	20	20
MI[2]	3.131x10^{-2}	6.000x10^{-2}
TI[1]	2.781x10^{-4}	5.716x10^{-4}

1. Uncertainty: +33.9% / -30.5%
2. Uncertainty: +17.0% / -15.3%

PV .014P

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm^2)[1]	2.93x10^{-3}	7.98x10^{-2}
$I_{SPPA.3}$ (W/cm^2)[1]	7.5x10^{-3}	175.0x10^{-3}
Pr.$_3$(MPa)[2]	20.0x10^{-3}	81.5x10^{-3}
PD (μs)[2]	161.0x10^{-3}	125.0x10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)[2]	18.6	17.9
MI[2]	4.5x10^{-3}	1.92x10^{-2}
TI[1]	2.06x10^{-5}	1.56x10^{-4}

1. Uncertainty: +/- 24.5%

Uncertainty: +/-12.3%

PV .018

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm^2)[1]	2.087	13.950
$I_{SPPA.3}$ (W/cm^2)[1]	0.2963	1.709
$Pr._3$(MPa)[2]	$132.3x10^{-3}$	$267.7x10^{-3}$
PD (µs)[2]	$168.3x10^{-3}$	$113.8x10^{-3}$
PRF (Hz)	43008	70656
Center Freq (MHz)[2]	20	20
MI[2]	$3.055x10^{-2}$	$5.306x10^{-2}$
TI[1]	$2.698x10^{-4}$	$4.748x10^{-4}$

1. Uncertainty: +33.9% / -30.5%
2. Uncertainty: +17.0% / -15.3%

Visions PV .035F

Acoustic Output Parameter	B-Mode
$I_{SPTA.3}$ (mW/cm^2)[1]	0.0534
$I_{SPPA.3}$ (W/cm^2)[1]	0.0680
$Pr._3$(MPa)[2]	0.0482
PD (µs)[2]	0.333
PRF (Hz)	$2.09x10^4$
Center Freq (MHz)[2]	9.00
MI[2]	0.0162
TI[1]	$6.18x10^{-5}$

1. Uncertainty: +33.9% / -30.5%
2. Uncertainty: +17.0% / -15.3%

Revolution

Acoustic Output Parameter	B-Mode
$I_{SPTA.3}$ (mW/cm^2)[1]	70.778
$I_{SPPA.3}$ (W/cm^2)[1]	95.533
Pr.$_3$(MPa)[2]	1.901
PD (µs)[2]	0.048
PRF (Hz)	15360
Center Freq (MHz)[2]	42.3
MI[2]	0.281
TI[1]	0.010

1. Uncertainty: +/- 29.1%
2. Uncertainty: +/-14.6%

TI: Thermal Index defined as $TI=\frac{W_{01x1}f_c}{210}$

where:

W_{01x1} is the bounded-square output in milliwatts

f_c is the Center Frequency in MHz

MI: Mechanical Index $MI=Pr.3/(f_c^{1/2})$

$I_{SPPA.3:}$ Derated Intensity. Spatial Peak Pulse Average (mW/cm^2)

$I_{SPTA.3:}$ Derated Intensity. Spatial Peak Temporal Average (mW/cm^2)

Pr.3: Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)

$W_{0:}$ Total Power (mW)

PD: Pulse Duration (µs)

PRF: Pulse Repetition Frequency (Hz)

Measurement Accuracy

Measurements obtained with the Volcano system are subject to the following measurement inaccuracies due to variations in tissue speed of sound and display limitations. The measurement precision is limited in both relative and absolute ranges:

Distance Measurement: –4.5%, +7.0% of measured value ± 0.10mm

Area Measurement: –9%, +14% of measured value ± 0.10mm^2

These uncertainties apply to the entire range of measurement achievable with the Volcano system. These are worst case measurement uncertainties and represent situations where the ultrasound signals are entirely within tissue, such as muscle, which has a very different speed of sound than blood. For measurement of luminal boundaries, where the ultrasound only traverses through blood, the inaccuracy is:

Distance Measurement: ± 1% of the measurement ± 0.10mm

Area Measurement: ± 5% of the measurement ± 0.10mm^2

In-Line Digital Measurement Accuracy

- Two distance measurements on the longitudinal display (ILD)
- Maximum Loop Distance (Z axis length) 2700 Frames @ 30 fps & 0.5 mm/sec pull back -> 45 mm
- Accuracy (Trak Back, R-100 Pull Back ± 5%) @ 30 fps & 1.0 mm/sec pull back -> 90 mm
- Accuracy (Trak Back, R-100 Pull Back ± 3%)

Accessories and Replacement Parts

NOTE: The Volcano system is compliant to IEC 60601-1-2 with the following accessories and cabling.

Volcano CORE System		
Part Number	**Description**	**Maximum length/qty**
300004969172 (hardcopy) 300004969262 CD	Volcano CORE Mobile Operator's Manual	N/A
804390001	Large Size (144mm x 100mm), A6 Paper for Sony UP 25MD 4 packs of 50 sheets	N/A
431-0100.01	Small Size (100mm x 90mm), A6 Paper for Sony UP 25MD 3 packs of 80 sheets	N/A
431-2800.01	Keyboard Cover	N/A
421-1202.09	DVI, Display Port Adaptor	N/A
421-1202.10	HDMI, Display Port Adaptor	N/A
421-1202-11	VGA, Display Port Adaptor	N/A
806452009	Detachable PIM cable	5 meters
806395001	VGA interconnect cable	3 meters
804290001	DVI-D interconnect cable	3 meters
806814001	Joystick ground cable	3 meters
804409001	100-240V AC Power cable	3 meters
421-1202.01	220-240V AC Power cable	3 meters
421-2402.02	Fuse, 12A: 100V isolation transformer setting	2 each
421-2402.01	Fuse, 10A: 120V isolation transformer setting	2 each
805642001	Fuse, 5A: 240V isolation transformer setting	2 each

Catheters and Guide Wire

Visions PV .035	88901
Visions PV .018	86700
Visions PV .014P	85900P, 85900PJ
Eagle Eye *Platinum*	85900P, 85900PJ
Reconnaissance	018 OTW, 018 OTWJP
Revolution	89000
SmartWire II (guide wire)	6600, 6600J, 6603, 6603J, 6613, 6613J
PrimeWire (guide wire)	7900, 7900J, 7903, 7903J, 7913, 7913J
PrimeWire PRESTIGE (guide wire)	8185, 8185J, 8300, 8300J
PrimeWire PRESTIGE Plus (guide wire)	9185, 9185J, 9300, 9300J
Verrata (guide wire	10185, 10185J, 10300, 10300J
OmniWire (guide wire)	89185, 89185J

Standards and Regulations

The Volcano System Series of Precision Guided Therapy Systems complies with the requirements of these standards and requirements:

Medical electrical equipment – General requirements for safety

IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012

ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1

IEC 60601-2-37:2007

IEC 60601-2-34:2011

CAN/CSA C22.2 No. 60601-1-14

The Volcano system FFR Option does not comply with Clause 51.102.1 since the guide wire's pressure transducer can drift over extended periods of time. It is important that the guide wire's reading be verified every 10 minutes and normalized to the aortic reading if drift has occurred. The Volcano system FFR Option is not intended for long-term (hours) invasive pressure monitoring but rather is a diagnostic instrument for measuring pressure during catheterization procedures.

Medical electrical equipment – Electromagnetic compatibility

IEC 60601-1-2:2014

SYMBOL: Declaration of Conformity:

We declare that the Volcano system series of Precision Guided Therapy Systems meets the requirements of the Medical Device Directive 2007/42/EC for Electromagnetic Compatibility (EMC) through the use of International Standard IEC/EN 60601-1-2 and complies with the following standards:

Guidance and Manufacturer's declaration – electromagnetic emissions Volcano System Series		
The Volcano System Series of systems is intended for use in the electromagnetic environment specified below. The customer or the user of the Volcano System Series should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment-guidance
RF Emissions CISPR 11	Group 1	Volcano System Family uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	Volcano System Family is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	Not applicable

Guidance and Manufacturer's declaration – electromagnetic immunity Volcano System Series			
The Volcano System Series is intended for use in the electromagnetic environment specified below. The customer or the user of the Volcano System Series should assure that it is used in such an environment. During immunity testing the Volcano system was exercised by placing the system in a simulated imaging mode with normal operation indicated by an active image portrayed on the display. During and after immunity testing the system shall continue to function and accept the commands given by user. It can temporarily lose communication but must return to normal operation without being disconnected.			
Immunity Test	IEC Test Level	Compliance Level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms[c] 3 V/m[c]	WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CORE Mobile system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. 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 Volcano System Family is used exceeds the applicable RF compliance level above, the Volcano System Family should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Volcano System Family. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. (c) Over the frequency range 5 MHz to 150 MHz, image degradation may be encountered but complies with IEC 60601-2-37.

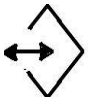
Guidance and manufacturer's declaration – electromagnetic immunity			
The Volcano System Family Image Intensifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Volcano System Family should assure that it is used in such an environment.			
Immunity Test	**IEC Test Level**	**Compliance Level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	±0.5, ±1 kV differential mode ±0.5, ±1, ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Disturbances EN 61000-4-6	Amplitude 3 Vrms 6 Vrms in ISM/Amateur bands Modulation 80%, 1kHz sine wave	Amplitude 3 Vrms 6 Vrms in ISM/Amateur bands Modulation 80%, 1kHz sine wave	Mains power quality should be that of a typical hospital environment. The Range of 5MHz to 50MHz may demand further separation of distance from intentional radiators. The imaging catheters operate in this frequency band, and will be very sensitive to transmissions from intentional, incidental, or accidental radiators.
Voltage dips, short interruptions and voltage variations on power supply input lines	0% U_T; 0.5 Cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	0% U_T; 0.5 Cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Volcano System Family requires continued

IEC 61000-4-11	0% U_T; 1 Cycle 70% U_T; 25/30 Cycles Single Phase: at 0° 0% U_T; 250/300	0% U_T; 1 Cycle 70% U_T; 25/30 Cycles Single Phase: at 0° 0% U_T; 250/300	operation during power mains interruptions, it is recommended that the Volcano System Family be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels typical for commercial or hospital environments.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

RFID Transmitter Specifications		
Frequency/Bandwidth	**Frequency Modulation**	**Radiated Power**
13.56 MHz ± 7 kHz	100%ASK	300mW

Symbols

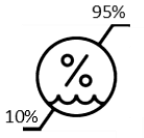
This chapter lists symbols used on the Volcano system and their meanings.

CE 2797	Complies with the Council Directive 93/42/EEC
	Power Off
	Power On
	Warning, Attention, Consult Accompanying Documents
	Power On/Off
	Laser Warning, Attention, Consult Accompaying Documents
	Patient Interface Module (PIM) Connector
	Output Signal
	Equipotentiality
	This device is protected against the voltages of defibrillation
	Input for the catheter connector
	Indicates a strong magnetic field is present

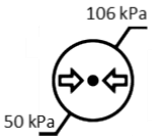
Device or system may pose hazards in magnetic resonance environments.

Attention: observe precautions for handling electrostatic discharge sensitive devices.

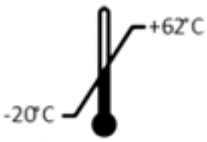
Recycle



Humidity Limitation



Atmospheric Pressure Limitation



Temperature Limitation

Follow Operating Instructions

Follow User Manual

Consult Instructions for Use

Volcano Corporation Logo

Manufacturer

Date of Manufacture

Glossary

Acoustic reference: The collection of an acoustic reference removes the universal minor image imperfections called ringdown artifact, which is caused by catheter noise and offset characteristics.

Diameter: The depth of field to which the ultrasound image data is acquired.

DICOM (Digital Imaging and Communications in Medicine): A format for storing images on DVD and transferring images and patient data over a network. The DICOM standard facilitates the exchange of patient images and data among different pieces and types of medical imaging equipment.

Gain: The intensity of the ultrasound echoes; a higher gain setting results in a brighter image with more intense echoes.

ILD = In-Line Digital: Two-dimensional, 360° rotation, real-time longitudinal view generated by visually "stacking" hundreds of cross-sectional intravascular ultrasound images.

PIM = Patient Interface Module: The imaging catheter connects to the Patient Interface Module which excites the catheter's transducer elements to transmit ultrasonic energy to the surrounding tissue. The PIM amplifies and processes the resultant echo signals from the transducer.

Post-processing: Any operation conducted on a stored ultrasound image. Measurements, annotations, and retrieving and clearing data are examples of post-processing.

Ringdown Artifact: Ringdown artifact is a result of multiple phenomena such as acoustic and RF signal crosstalk between neighboring acoustic elements on synthetic aperture catheters and the innate physical properties of ultrasound crystals and catheter tips. In addition, the operating frequency, temperature, and the size and geometry of the ultrasound elements contribute to the magnitude and appearance of the artifact.

Sensitivity: During ChromaFlo imaging, blood/ luminal flow rates can vary from 4 cm/sec up to 110 cm/sec. The Volcano system is equipped to display, in color, 5 viewable flow ranges. This capability is accessed via the Sensitivity control which is available on the Adjust Image menu. There are 5 selections: Sensitivity 1 for high flow rate vessels and Sensitivity 5 for low flow rate vessels. Typically Sensitivity 3 through 5 will provide the best visualization of coronary vessel flow rates.

For any given sensitivity setting, areas where the relative blood/ luminal flow rates are higher are more yellow; areas where they are slower are more red. By increasing the sensitivity setting to a higher value, one can shift towards yellow the color of slower moving areas of blood flow; by decreasing the sensitivity setting to a lower value, one can shift towards red the color of faster moving areas of blood flow.

Appendix A: VH Measurements

This appendix defines the statistics available using VH IVUS.

Frame Results

Lumen area: cross-sectional area of the lumen for this frame.

Vessel area: cross-sectional area of the vessel for this frame.

Plaque area: cross-sectional area of the plaque for this frame.

plaque plus (+) media complex = plaque area

Vessel minus (-) the lumen area = plaque area

% Plaque Burden: Plaque Area divided by Vessel area.

Composition %: does not include the gray area, for example, Fibrous area % = the fibrous area divided by the sum of all four composition types.

Lumen dia min: smallest (minimum) diameter within this frame.

Lumen dia max: largest (maximum) diameter within this frame.

Lumen dia avg: average diameter within this frame.

Vessel dia min: smallest (minimum) diameter within this frame.

Vessel dia max: largest (maximum) diameter within this frame.

Segment Results

Lumen volume: volume of the lumen within the defined segment.

Vessel volume: volume of the vessel within the defined segment.

Vessel minus (-) Lumen = plaque.

Plaque volume: volume of plaque within the defined segment.

Segment length: length of the defined segment.

Composition %: does not include the gray area.

Lumen dia min: smallest diameter measurement within the defined segment. This measurement occurs at the frame number displayed.

Lumen dia max: largest diameter measurement within the defined segment. This measurement occurs at the frame number displayed.

Min Lumen Area: smallest lumen area within the defined segment. This measurement occurs at the frame number displayed.

Vessel dia min: smallest diameter measurement within the defined segment. This measurement occurs at the frame number displayed.

Vessel dia max: largest diameter measurement within the defined segment. This measurement occurs at the frame number displayed.

Vessel dia avg: average of the diameter averaged across all the frames within the defined segment.

Target Assist

Lumen area: lumen area at the frame number displayed

% Stenosis: % stenosis at the frame number displayed

Avg. Lumen Diameter: average lumen diameter at the frame number displayed

Avg. Vessel Diameter: average vessel diameter at the frame number displayed

Appendix B: Technology Summary

The development and validation of VH IVUS on the Volcano system platform is outlined below.

Methods

The human left anterior descending (LAD) coronary artery was obtained at autopsy. IVUS data from 63 LAD specimens were analyzed with IRB approval from the Cleveland Clinic Foundation, Cleveland, Ohio. The sample space of the study was representative of human beings between the ages of 32 and 79 years, having died of causes not necessarily related to cardiac failure. There were 51 males and 12 females (20 black, 43 white) with a mean age of 55.2 ± 11.6 years. Twenty-three (23) individuals were diabetic, 40 were not diabetic. The study sample was limited to those without prior cardiac percutaneous interventions or surgical revascularizations. Additionally, data was not acquired from alcohol and drug abuse cases. The LAD vessel was harvested, as it most often contains significant disease and is the site of most acute coronary events. Human hearts were procured within 24 hours of death, and IVUS data were acquired in less than 24 hours after excising the LAD vessel. Each artery was dissected from the ostium to the apex, including approximately 40 mm of surrounding fat and myocardial tissue. Inclusion of surrounding tissue ensures the maintenance of proper vessel mechanical support and reduces ultrasound artifacts due to reflections at interfaces. The vessels were then immersed in phosphate buffered saline (PBS) such that no potential reflections from the PBS-air interface were present in the ultrasound data.

The harvested arteries were mounted in a paraffin tray. The ostium was cannulated and side branches were ligated to reduce flow and to maintain physiological perfusion pressure. Constant flow and pressure was ensured with Volcano's SmartMap pressure wire system and a computer-controlled air valve system that pressurized a 20 L PBS tank to 100 mmHg. The PBS was delivered within a physiological temperature range, warmed by a heating coil and measured by a thermistor (P/N WM103C, Sensor Scientific, Fairfield, NJ, USA). This flow system was developed in house, and its usage has been documented and published.[1] The coronary arteries, were imaged within 24 hours of collection using Volcano Eagle Eye Gold™ IVUS transducers with either a standard Volcano In-Vision Gold™ imaging system or a Volcano imaging system.

Accuracy Analysis

Tissue Classification Algorithm Development:

Regions of Interest (ROIs) that represent four basic homogeneous tissue types (i.e., fibrous tissue, fibro-fatty, necrotic core, and dense calcium) were identified on the histology slides, and their location was recorded on the digitized histology images. A total of 290 homogenous ROIs were selected from the 93 lesion sections. See Table 1 for the corresponding distribution of the ROIs by tissue type.

Table 1. The number of regions-of-interest (ROIs) of each tissue type that were used for training the Volcano system Eagle Eye VH algorithm.

Tissue Type	Number of Training ROIs
Fibrous Tissue	114
Fibro-Fatty	25
Necrotic Core	81
Dense Calcium	70

A classification algorithm was trained based on these ROIs that included the plaque type of each ROI and corresponding backscatter spectral properties that were determined from the IVUS data.

VH Algorithm Evaluation:

The algorithm developed above from the set of homogenous ROIs was used to create VH IVUS images for multiple lesion sections. For accuracy analysis, a randomized set of heterogeneous ROIs were identified on the histology slides, and their location was recorded on the digitized histology image. The corresponding regions on the final VH IVUS images were also identified and compared to the digitized histology images. From separate data collection of 51 LADs (94 sections), 889 heterogeneous ROIs were further selected representing the following distribution of tissue types:

Table 2. The number of regions-of-interest (ROIs) of each lesion type that were used for evaluation of the accuracy the Eagle Eye VH algorithm.

Tissue Type	Number of Evaluation ROIs
Fibrous Tissue	471
Fibro-Fatty	130
Necrotic Core	132
Dense Calcium	156

Sensitivity, specificity, and predictive accuracy were calculated using standard formulae.

Results

Table 3 summarizes the sensitivity, specificity, and predictive accuracy results.

Table 3. The predictive accuracy, sensitivity, and specificity of the Volcano system Eagle Eye VH classification tree by tissue type.

Tissue Type	Number of Evaluation Regions	Predictive Accuracy (%)	Sensitivity (%)	Specificity (%)
Fibrous Tissue	471	93.5	95.7	90.9
Fibro-Fatty	130	94.1	72.3	97.9
Necrotic Core	132	95.8	91.7	96.6
Dense Calcium	156	96.7	86.5	98.9

References:

1) Nair, A., M. P. Margolis, et al. (. "Automated coronary plaque characterisation with intravascular ultrasound backscatter: ex vivo validation." EuroIntervention **3**(9): 113-120.

Appendix C: Configuring DICOM

Configuring the DICOM/Network

To configure settings for DICOM and Networking:

1. Press the **Settings** key on the control console. The Settings dialog appears.
2. In the Archive tab area of the Settings dialog box, click the DICOM **Configuration Dialog** button. The DICOM Network Configuration dialog box displays, as shown below.

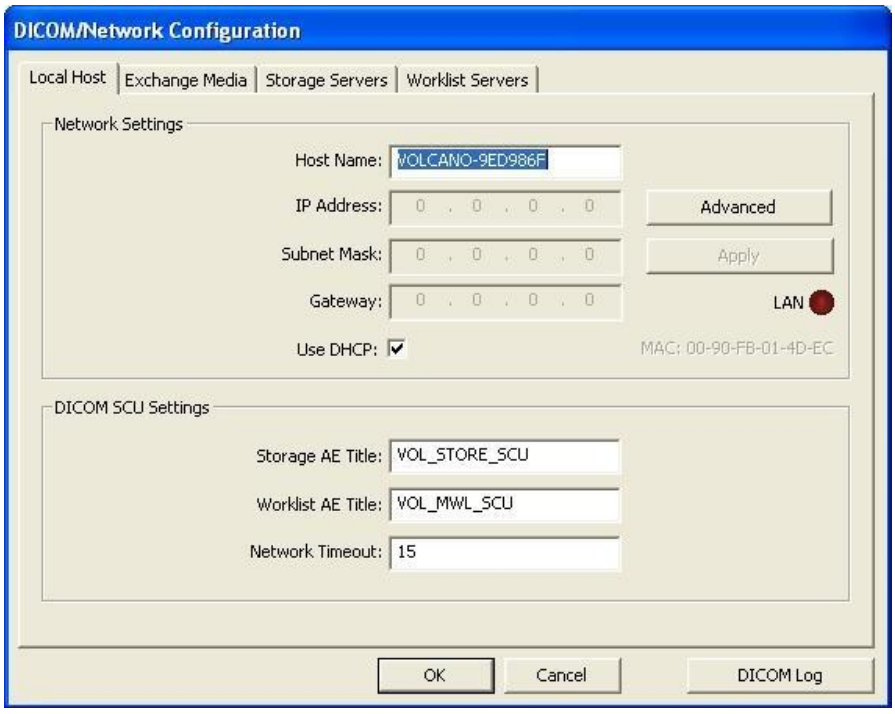


Figure 58: DICOM Settings-Local Host Dialog Box

NOTE: After changing the Local Host settings you need to power down the system for the new settings to take effect. The system powers down, starts up, then powers down and restarts again.

Local Host–Network Settings

- **Host Name:** The factory host name default is "CORE." This field configures the computer host name for the Volcano system.
- **IP Address:** This field is used to configure the network Internet Protocol (IP) address for the system.

- **Subnet Mask:** The Volcano systems use the Subnet mask to determine if communication with the remote host needs to be routed through a gateway. If so, this field configures the Subnet mask for the system's subnetwork.
- **Gateway:** This field is used to configure the gateway IP address for the system.
- **Use DHCP:** Check this box if DHCP (Dynamic Host Configuration Protocol) is used to configure the system's IP address.
- **LAN indicator LED** (green/red): The light indicates whether a connection is connected and host is active. If red, user has the option to click on an Advanced button so user can switch to an active port
- **Appl**y: Select Apply button to apply any setting changes

Local Host–DICOM SCU Settings

- **Storage AE Title:** The Application Entity Title field is used to configure the AE title for the local DICOM Store SCU (Service Class User) application running on the Volcano system. The factory default is VOL_STORE_SCU.
- **Worklist AE Title:** Enter the AE title for the Worklist.
- **Network Timeout:** Used to configure the DICOM Association Response Timer and other network timeouts. This timer is used to terminate the DICOM association (network connection) if communication between systems stops. The factory default is 15.

Exchange Media

- The following compression selections are available for archiving images to DICOM DVD Exchange Media:
  - No compression
  - JPEG High Quality
  - JPEG Medium Quality
  - JPEG High Compression

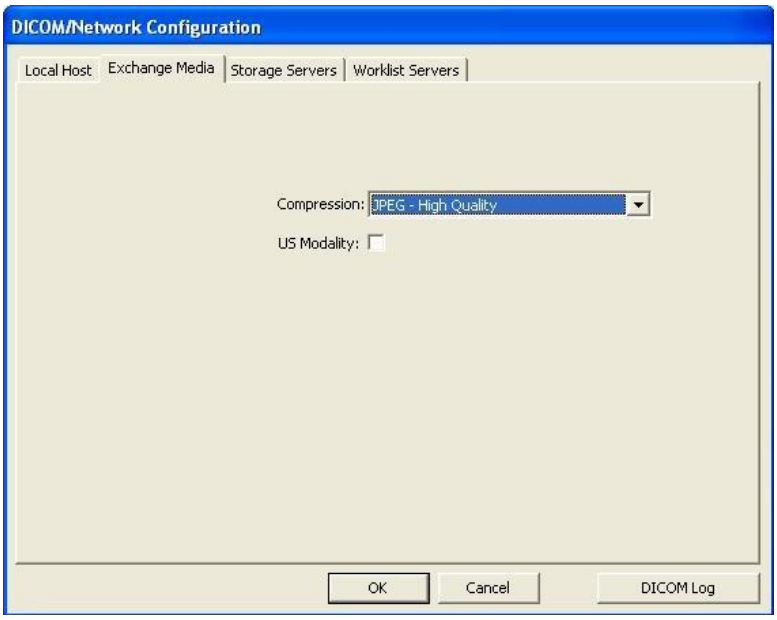


Figure 59: DICOM Settings-Exchange Media Dialog Box

- **US Modality**: When checked, images will be written to DVD using the US (Ultrasound) Modality. When unchecked, images are stored using the IVUS Modality.

Storage Servers

- **Select Server:** Multiple DICOM Store SCP Servers may be configured on the Volcano system. This drop down contains the list of configured servers. The currently selected server will be used for subsequent configuration changes and will also be the server that receives DICOM images from the Volcano system during an Archive to Network operation.
- **New Server**: This field is used to enter the name of a new DICOM Server. This is a user-friendly alias used to identify a remote DICOM Storage Server. Once the name is typed, pressing either the Enter key or selecting the Add button causes the new Server to be created and added to the DICOM Server List. The newly added server becomes the currently selected Server. For example:
  - Cardiology Lab Server
  - Cardiology Lab Backup
  - Radiology PACS
- **Add**: Pressing this button adds a new server to the DICOM Storage Server list. This button is disabled if nothing has been entered in the New Server field.
- **Delete**: Pressing this button deletes the currently selected server from the DICOM server list. The next server in the list becomes the currently selected server.

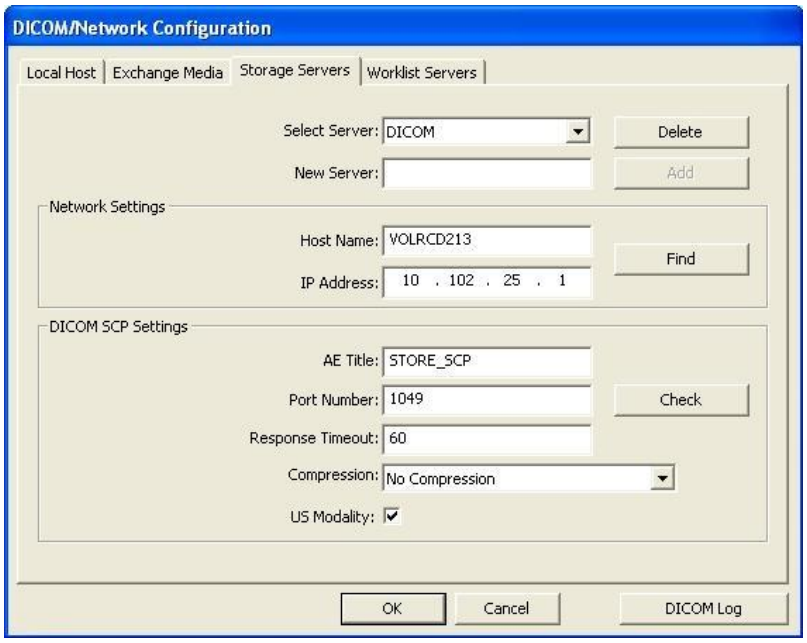


Figure 60: DICOM Settings-Storage Servers Dialog Box

Storage Servers–Network Settings

- **Host Name:** This field contains the host name of the remote computer to which the Volcano system will be sending DICOM images.
- **IP Address:** This field contains the Internet Protocol (IP) address of the system to which the Volcano system will be sending DICOM images.
- **Find:** The Find button performs a Network PING operation to find the configured remote computer. If a remote computer host name is entered and no IP Address is used, the IP Address of the successfully resolved host name is automatically populated in the IP Address field. If both the host name and IP Address are entered, then the IP Address is used for the PING instead of Host Name resolution.

Storage Servers–DICOM SCP Settings

- **AE Title**: This field is used to configure the Application Entity Title field of the remote DICOM Store SCP (Service Class Provider) application to which the Volcano system will be sending images. The factory default is “STORE_SCP”.
- **Port Number**: This field is used to configure the port number to which the remote DICOM Store SCP application will be listening for messages from the Volcano system. The factory default is 104.
- **Response Timeout:** This field is used to configure the amount of time (in seconds) that the system will wait for a response from the remote DICOM Store SCP (Service Class Provider) server after an image has been sent. This timer is used to terminate the DICOM association (network connection) if

communication between systems stops. The range for this value is 10 to 600 seconds. The factory default is 60.

- **Compression:** The following compression selections are available for sending images to the remote DICOM Storage server:
  - No compression
  - JPEG High Quality
  - JPEG Medium Quality
  - JPEG High Compression
- **Check Button:** This button is used to test the connection between the Volcano DICOM SCU and the remote DICOM Storage SCP. The connection is tested using the DICOM C-ECHO service (Verification class).
- **US Modality:** When checked, images will be transferred to remote storage servers using the US Modality. When unchecked, images are transferred using the IVUS Modality.

Worklist Servers Configuration

This section describes the DICOM Configuration Dialog - Worklist Servers Configuration. The following parameters are configurable for the each defined Remote DICOM Modality Worklist SCP Server.

- **Select Server**: Selects the current Server from the Server List for configuration
- **New Server**: Names a New Server. A server name must be entered in this field before it can be added to the Server List.
- **Add**: Adds the New Server to the Server List.
- **Delete**: Removes the current Server from the Server List.

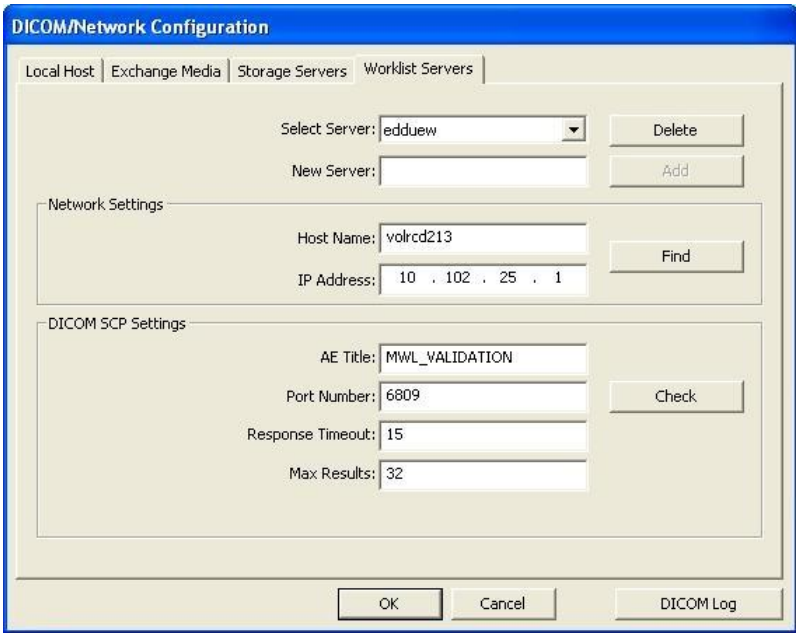


Figure 61: DICOM Settings-Worklist Servers Dialog Box

Worklist Server - Network Settings

The following network parameters are configurable for the each defined Remote DICOM Storage SCP Server

- **Host name**: Computer Host name of the remote device.
- **IP Address**: IP Address of the remote device.
- **Find**: Performs a network PING to determine in the configured device is connected to the network. Find will perform IP address resolution if only the remote host name is entered.