

Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System



Part Number 6746
Revision 3.7



Preface



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- FusionVu™
- Cognitive Assist™
- Exact Imaging™

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Warranty information

The ExactVu micro-ultrasound system and its accessories, when supplied and delivered new, in the original shipping container to the original purchaser, are covered under a one-year warranty that covers damage due to defective materials and workmanship, and/or failure of the equipment to operate in accordance with information in this *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

Version information

System: ExactVu™ High Resolution Micro-Ultrasound System

Software: ExactVu™ Version 3.0

Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System Revision 3.7,
original instructions

DICOM Conformance Statement

The *DICOM Conformance Statement for ExactVu* specifies the capabilities and properties by which ExactVu stores ultrasound studies to a PACS server. The latest version is accessible at the following link:
<https://www.exactimaging.com/dicom-conformance-statement>

End User Licensing Agreement

By accessing and using this system, you agree to be legally bound by the terms and conditions of Exact Imaging's *End User Licensing Agreement*.

Other

HIPAA (the American Health Insurance Portability and Accountability Act of 1996) is a set of U.S. federal standards that ensure the privacy and security of all health-care related data. *ExactVu™ High Resolution Micro-Ultrasound System* is capable of preventing unauthorized access to patient data using password protection.

Table of Contents

Chapter 1 Introduction9

1 Essential Performance9

2 Indication for Use / Intended Use10

3 ExactVu Labeling10

4 Qualification and Training of Operators11

5 ExactVu Configuration11

6 ExactVu System Cart12

6.1 Cart13

6.2 Software20

7 Accessories23

7.1 Transducers23

8 Consumables23

8.1 EV29L Sterile Transrectal Needle Guide for Procedures using the EV29L Transducer23

8.2 EV29L Non-sterile Reusable Transrectal Needle Guide for Procedures using the EV29L Transducer24

8.3 EV29L Sterile Transperineal Needle Guide for Procedures using the EV29L Transducer24

8.4 CIVCO® Disposable Endocavity Needle Guide for Procedures using the EV9C Transducer24

8.5 CIVCO® Non-sterile EV5C Bracket with CIVCO Verza™ Guidance System25

9 Optional Components25

9.1 Thermal Printer25

9.2 Transperineal Stepper25

9.3 Monitor Stand25

10 Lifetime26

Chapter 2 Safety Information27

1 Product Safety and Electrical Testing27

1.1 Certifications27

1.2 Classifications28

1.3 Support for DICOM28

2 Acoustic Output28

2.1 Prudent Use29

2.2 Thermal Index Soft Tissue (TIS) and Mechanical Index (MI)30

3 Transducer Temperature Limits32

4 Symbols Glossary33

4.1 Symbols on the ExactVu System Device Label33

4.2 Symbols on the ExactVu System Package35

4.3 Symbols on the EV29L, EV9C and EV5C Transducer Labels36

4.4 Symbols on the EV29L, EV9C and EV5C Transducer Package37

4.5 Symbols on the EV29L Sterile Transrectal and Transperineal Needle Guide Packaging39

4.6 Symbols on the EV29L Non-sterile Reusable Transrectal Needle Guide Packaging40

5 General Safety Precautions41

5.1 General42

5.2 Mechanical Safety42

5.3 Explosion Hazard43

5.4 Electrical Safety43

5.5 Interference44

5.6 MR (Magnetic Resonance) Safety46

5.7 Bio-safety46

5.8 System50

6 Accuracy of Measurements50

6.1 Accuracy of On-Screen Overlays52

- 7 Operating Specifications.....52
 - 7.1 ExactVu Micro-Ultrasound System and Transducers52
 - 7.2 EV29L Sterile Transrectal and Transperineal Needle Guides53
 - 7.3 EV29L Non-sterile Reusable Transrectal Needle Guide.....53
- Chapter 3 Getting Started with the ExactVu System54**
 - 1 System Setup and Installation54
 - 1.1 Determining Installation Location.....54
 - 1.2 Connecting Components55
 - 1.3 Connecting Power to the ExactVu System55
 - 1.4 Connecting a USB Storage Device56
 - 1.5 Setting up the Control Panel/Monitor Platform57
 - 1.6 Connecting an Optional (Second) Monitor58
 - 1.7 Setting up System Preferences59
 - 2 Getting Started with the ExactVu System69
 - 2.1 Starting the ExactVu System69
 - 2.2 Preparing the Patient69
 - 2.3 Preparing the Transducer70
 - 2.4 Setting up Study Information on the ExactVu System.....71
 - 3 Study Workflow75
 - 3.1 TRUS Imaging and Biopsy Workflows75
 - 3.2 Transperineal Workflow76
 - 3.3 Kidney Imaging and Biopsy Workflows76
 - 3.4 Pelvis / Bladder Imaging Workflow77
 - 3.5 Performing Imaging.....77
 - 3.6 Measuring and Annotating89
 - 3.7 Saving Images.....90
 - 3.8 Determining the Anesthesia Location91
 - 3.9 Administering Anesthesia92
 - 3.10 Performing a Biopsy.....92
 - 3.11 Printing Images92
 - 3.12 Reviewing Saved Images93
 - 3.13 Closing a Study94
 - 3.14 Disconnecting the Transducer96
 - 3.15 Reprocessing the Equipment.....96
 - 3.16 Turning the ExactVu System Off98
- Chapter 4 Patient/Study99**
 - 1 Using DICOM Features99
 - 1.1 Using DICOM Modality Worklist99
 - 2 Using the Patient List Screen.....102
 - 2.1 Selecting Studies.....104
 - 2.2 Reviewing Images105
 - 2.3 Exporting and Archiving Studies106
 - 2.4 Deleting Studies108
 - 2.5 Reviewing ExactVu Data Stored on a USB Storage Device109
 - 2.6 Automatic File Deletion109
- Chapter 5 Using 2D Mode111**
 - 1 Support for Large Prostates111
 - 1.1 Enabling Stitch Sub-mode111
 - 1.2 Canceling Stitch Sub-mode112
 - 2 Support for Transrectal Needle Guidance112
 - 2.1 Biopsy Sub-Mode (enabled only when the EV29L Transducer is Active)112
 - 2.2 Anesthesia Sub-Mode (enabled only when the EV29L Transducer is Active)113

- 2.3 Needle Guide Overlay113
- 2.4 Needle Enhancement (enabled only when the EV29L Transducer is Active)115
- 3 Support for Transperineal Needle Guidance116
 - 3.1 Needle Guide Overlay116
 - 3.2 Performing a Transperineal Procedure121
- 4 Support for Abdominal Needle Guidance121
 - 4.1 Needle Guide Overlay121
- 5 Setting the Angle Value (enabled when the EV29L Transducer is Active)122
- Chapter 6 Using Dual / Transverse Mode124**
 - 1 Dual Mode (enabled when the EV9C or EV5C Transducer is Active)124
 - 1.1 Enabling Dual Mode124
 - 1.2 Canceling Dual Mode125
 - 2 Transverse Mode (enabled when the EV29L Transducer is Active)125
 - 2.1 Enabling Transverse Mode125
 - 2.2 Constructing the Transverse Image126
 - 2.3 Canceling Transverse Mode127
- Chapter 7 Using Color Flow Imaging Modes (Color Doppler Mode and Power Doppler Mode)128**
 - 1 Enabling CFI Modes128
 - 2 Color Box Configuration129
 - 3 CFI Settings130
 - 3.1 Wall Filter131
 - 3.2 Sensitivity131
 - 3.3 Persistence131
 - 3.4 PRF132
 - 3.5 Power Doppler Mode Specific Settings132
- Chapter 8 FusionVu™133**
 - 1 FusionVu (MRI Fusion)134
 - 1.1 FusionVu MRI Workflow134
 - 1.2 FusionVu Alignment138
 - 2 Cognitive Assist (PI-RADS-Based Fusion)141
 - 2.1 Cognitive Assist Workflow141
 - 2.2 Cognitive Assist Alignment (PI-RADS Sectors and Live Micro-Ultrasound)142
 - 3 Common FusionVu Features144
- Chapter 9 Using Measurements145**
 - 1 Creating a Measurement145
 - 1.1 Creating a Distance Measurement146
 - 1.2 Creating an Area Measurement147
 - 1.3 Creating a Volume Measurement149
 - 2 Editing a Measurement153
 - 3 Deleting a Measurement154
 - 4 Canceling a Measurement in Progress155
- Chapter 10 Using Annotations156**
 - 1 Creating an Annotation157
 - 1.1 Creating a Predefined Text Annotation157
 - 1.2 Creating a Custom Text Annotation158
 - 1.3 Creating an Arrow Annotation159
 - 2 Editing an Annotation160
 - 3 Deleting an Annotation160
 - 4 Canceling an Annotation in Progress161
- Chapter 11 PRI-MUS™ Risk Score162**
 - 1 Using the PRI-MUS Risk Score162
 - 2 Validation of the PRI-MUS Protocol163

Chapter 12 Preferences165

- 1 System Information165
 - 1.1 Exporting Log Files166
 - 1.2 Transducer Element Check166
- 2 DICOM Settings168
- 3 Network Settings168
- 4 System Settings.....168
 - 4.1 Clinic Details.....169
 - 4.2 Date and Time170
 - 4.3 EV29L Needle Guide171
 - 4.4 Foot Pedal171
- 5 Security172
- 6 Physicians Setup172
- 7 External Programs.....173
- 8 EULA (End User License Agreement)174

Chapter 13 Caring for and Maintaining the ExactVu System and Transducers175

- 1 Cleaning the Lower Air Filter175
- 2 Cleaning the Left Panel Air Filter176
- 3 Inspecting the Foot Pedal177
- 4 Replacing the Thermal Printer Paper178
- 5 Inspecting the Thermal Printer178
- 6 Inspecting the ExactVu System179
- 7 Inspecting the Transducers179
- 8 Observing Electrostatic Discharge (ESD) Controls.....179

Chapter 14 Service and Support.....181

- 1 Technical Support181
 - 1.1 Service Provided by Exact Imaging181
- 2 Disposal.....181

Appendix A EV29L Transducer Acoustic Output182

Appendix B EV9C Transducer Acoustic Output183

Appendix C EV5C Transducer Acoustic Output184

Appendix D EMC Manufacturer Declarations186

Appendix E Diagnostic Ultrasound Indications for Use Forms190

Appendix F Contact Information194

Chapter 1 Introduction

This *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* provides instructions for the safe and efficient use of the ExactVu™ micro-ultrasound system for clinical urological applications.

Operating up to 29 MHz, the ExactVu™ micro-ultrasound system enables a new level of resolution compared to conventional urological ultrasound systems while maintaining the usual, rapid workflow associated with performing conventional transrectal ultrasound (TRUS) guided prostate biopsies. With the ExactVu system, in addition to systematic biopsies, micro-ultrasound-guided biopsies can be performed, targeted at suspicious regions that are visible to the operator.

ExactVu is to be used by qualified urologists, radiologists, and trained clinicians (referred to as operators in this guide) in a professional, clinical healthcare facility. The platform on which the ExactVu system operates represents the state of the art in high resolution micro-ultrasound technology.

ExactVu provides an option with the ability to overlay data from Magnetic Resonance (MR) with micro-ultrasound images to support PI-RADST™ and MRI image-guided workflows using the *FusionVu™ micro-US/MRI Fusion Application*. The FusionVu feature accommodates both rigid and elastic MRI data registration for prostate imaging.

ExactVu also supports transperineal procedures using a transperineal stepper device, which holds and positions the EV29L transducer and the transperineal needle guides. Typical transperineal procedures include prostate biopsy and image guidance for placing gold fiducial markers and implanting saline or hydrogel perirectal spacers. A software overlay representing the needle guide aids in positioning the biopsy needle.

Operators of the system will be able to benefit from the ExactVu system's usability and system functionality, including:

- The ability to leverage high resolution imaging to target biopsies in the appropriate areas of visibly suspicious regions
- The ability to guide local anesthetic injections prior to a prostate biopsy procedure
- The ability to switch between high resolution transducers (i.e., the EV29L transducer) and conventional transducers (i.e., the EV9C and EV5C transducers) on the same platform without disconnecting either transducer
- The ability to print images using an optional connected thermal printer
- Quick system start-up provides the ability to image immediately in urgent situations

WARNING

EN-W2



Unauthorized modification of this equipment is not permitted and may compromise the safe operation of the equipment.

1 Essential Performance

Essential performance is the system performance necessary to achieve freedom from unacceptable risk. The essential performance of the ExactVu system is:

- The system displays correct numerical values associated with the diagnostic procedure to be performed.
- The system shall be free from the production of unintended or excessive ultrasound output.
- The system does not generate unintended or excessive transducer surface temperature.
- The system shall be free from noise on waveform or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.

CAUTION

EN-C39



Proper care and maintenance of the ExactVu system is required to retain the essential performance of the system. Refer to Chapter 13 for further details.

2 Indication for Use / Intended Use

The ExactVu micro-ultrasound system is intended for use by qualified medical professionals for diagnostic ultrasound imaging or fluid flow analysis of the human body. The indications for use (clinical applications) are:

- Small Organ
- Transrectal
- Abdominal

The system may be used with patients of all ages, but is not designed for pediatric or fetal use. The system is contraindicated for direct cardiac application and for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

WARNING

EN-W6



The use of this equipment is intended for qualified operators only.

Operators should be thoroughly familiar with the safe operation of this equipment and should be knowledgeable in urological ultrasound procedures using transducers in order to reduce discomfort and possible injury to the patient.

Read all Labeling provided with this equipment.

CAUTION

EN-C1



For United States only, federal law restricts this device to sale by or on the order of a physician.

3 ExactVu Labeling

Before using the ExactVu system, please become familiar with the information in this *Operation and Safety Manual* and the proper use of this equipment, as described in the accompanying documents listed below.

Document

Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System (this document)
Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer
Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer
Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer
Service Manual for ExactVu™ High Resolution Micro-Ultrasound System

Table 1: ExactVu Labeling

Other documents that are provided with the ExactVu system include:

- Quick Reference Guide
- PRI-MUST™ Quick Reference Guide
- PRI-MUST™ Quick Reference Poster
- PRI-MUST™ Anterior Quick Reference Guide
- PRI-MUST™ Anterior Quick Reference Poster

WARNING

EN-W1



Failure to follow safety instructions and/or using the equipment for purposes other than those described in *ExactVu Labeling* constitutes improper use.

4 Qualification and Training of Operators

Training on ultrasound imaging techniques and the prostate biopsy procedure is primarily provided through medical fellowship training at academic institutions. Correct use of the ExactVu system relies on this training as well as an understanding of system operation which is provided by the *ExactVu Labeling* and by on-site training by Clinical Applications Specialists. Physician assistants may not have received appropriate fellowship training on transrectal ultrasound or prostate biopsy, and for these operators, oversight by a trained urologist is required. Optional on-site support using the ExactVu system provided by Clinical Applications Specialists is available to ensure correct system operation.

Exact Imaging also provides re-training for existing operators for the current release using online learning modules that demonstrate the changes in this software version.

5 ExactVu Configuration

Configuration for the ExactVu micro-ultrasound system includes the following components:

- ExactVu system cart (including the monitor, touch screen and ExactVu software)
- ExactVu Labeling (refer to Table 1)
- One AC power cable

Exact Imaging catalog references for available configurations are:

- EV-SYS-220: ExactVu™ Micro-Ultrasound Imaging System (220V)

- EV-SYS-120: ExactVu™ Micro-Ultrasound Imaging System (120V)
- EV-SYS-100: ExactVu™ Micro-Ultrasound Imaging System (100V)

Optional accessories (including transducers), consumables and components are listed beginning in section 7 on page 23.

NOTE

EN-N91



Some features described in this guide may not be available with your configuration of ExactVu.

6 ExactVu System Cart

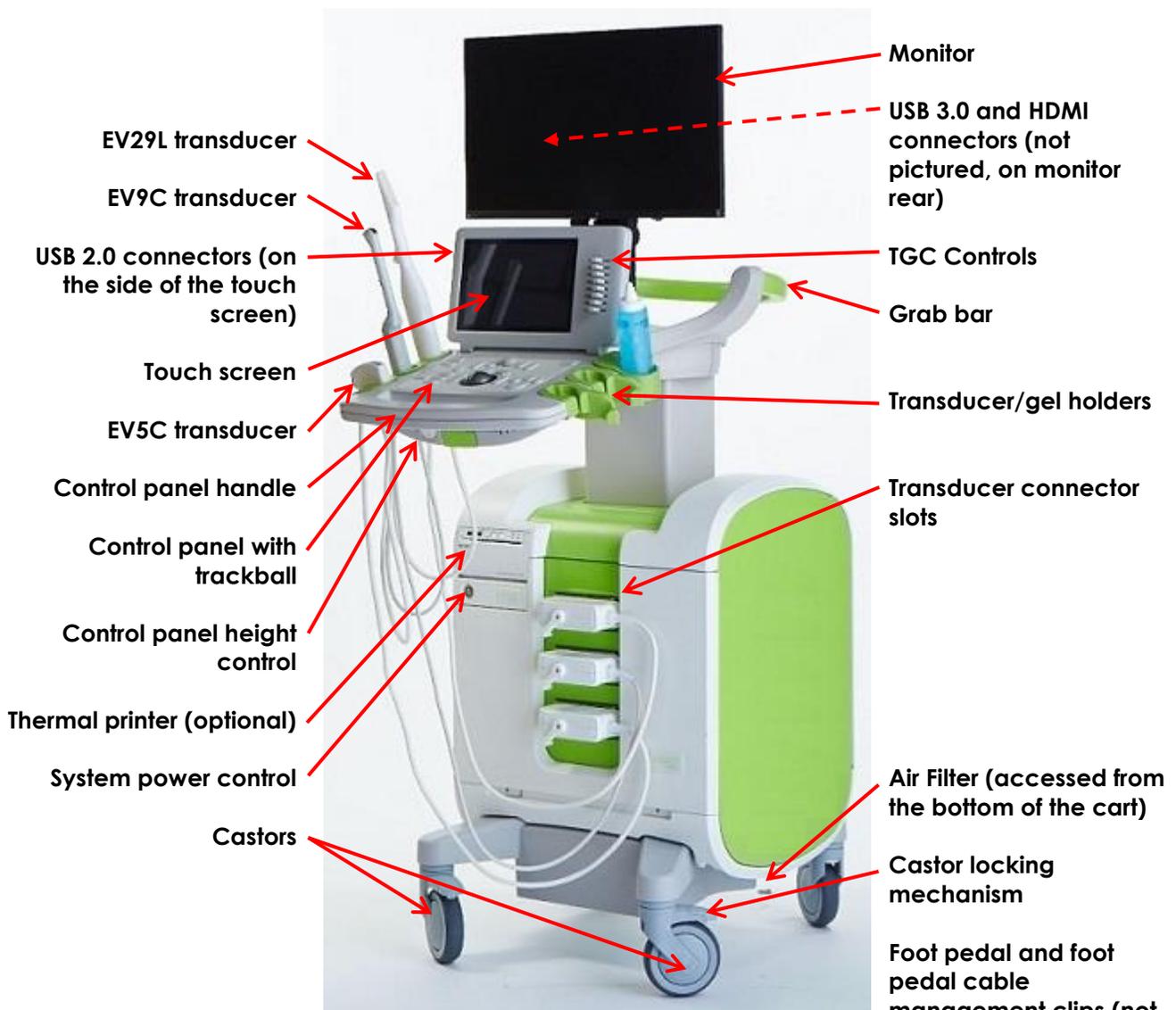


Figure 1: ExactVu High Resolution Micro-Ultrasound System



Only the components listed in this section may be connected to the ExactVu system.

If components other than those specified in this section are connected to the system, the ExactVu software may fail and cause injury to the patient or operator.

6.1 Cart

6.1.1 Control Panel

The ExactVu system's *control panel* contains the main controls for operating the system. It includes a trackball for controlling the cursor, as well as several buttons, switches and a knob for accessing operating modes, patient and study information, saving images and for adjusting imaging settings. The availability of each control is dependent on the ExactVu system's operating state and mode of operation, and is indicated by backlighting.

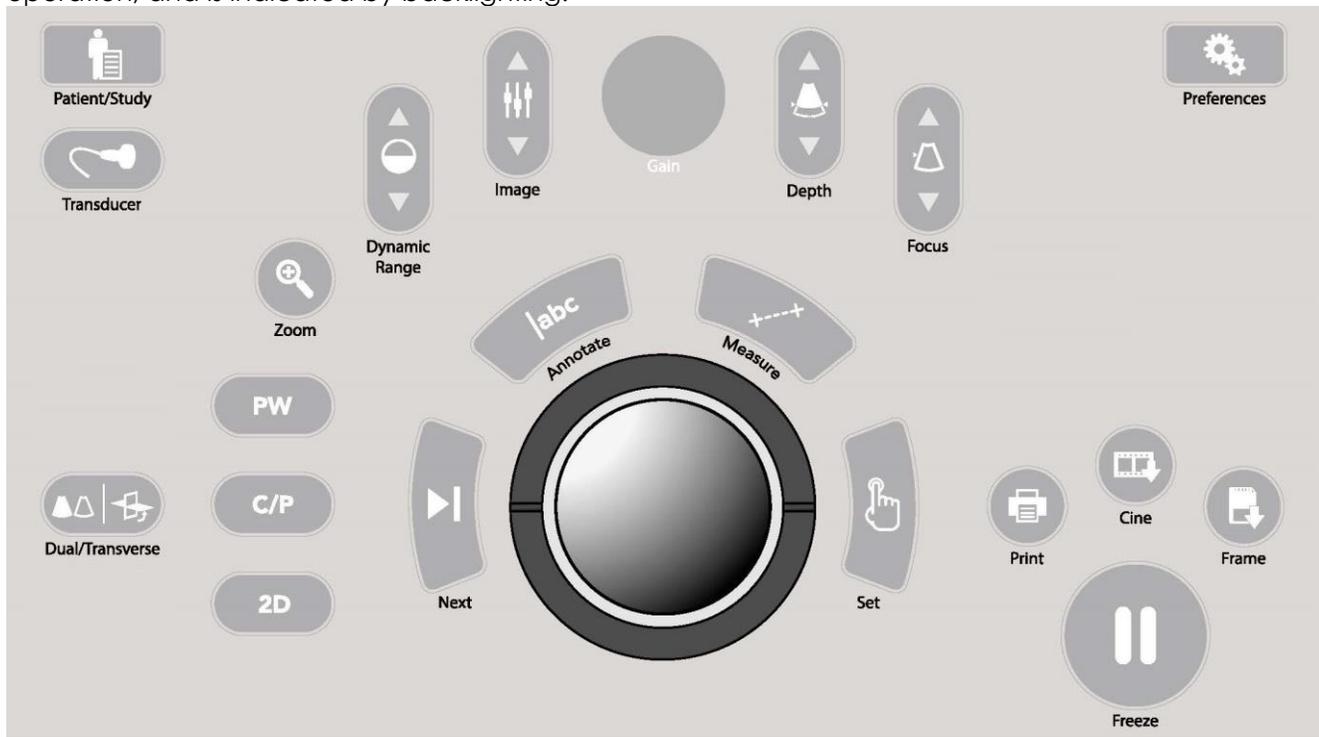
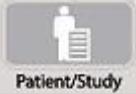


Figure 2: Control Panel Controls

Control	Icon	Function
Patient/Study		Displays the <i>Patient/Study</i> screen
Transducer		Activates the next available transducer

Control	Icon	Function
Dual/Transverse	 Dual/Transverse	<ul style="list-style-type: none"> Begins imaging in <i>Dual Mode</i> when imaging with the EV9C or EV5C transducer Begins imaging in <i>Transverse Mode</i> when imaging with the EV29L transducer, which allows a transverse image to be constructed in real time
2D		Begins imaging in 2D Mode
C/P (Color/Power Doppler)		Functionality is available with the EV5C transducer: <ul style="list-style-type: none"> Begins imaging in Color Doppler Mode from a non-CFI Mode (i.e., Color Doppler Mode or Power Doppler Mode) Toggles between Color Doppler Modes and Power Doppler Mode from within a CFI Mode
PW (Pulsed Wave Doppler)		This functionality is disabled in this version of the ExactVu system
Zoom	 Zoom	This functionality is disabled in this version of the ExactVu system
Dynamic Range	 Dynamic Range	Increases/decreases the contrast between the ultrasound signal and the grayscale mapping
Image	 Image	Cycles through/activates <i>image presets</i> available in the current imaging mode
Gain knob		Increases/decreases the intensity of the active image
Depth	 Depth	Increases/decreases the <i>image depth</i> , up to the maximum for the transducer in use
Focus	 Focus	Increases/decreases the depth of a single <i>focal zone</i>

Control	Icon	Function
Next		Functionality is dependent on the current action: <ul style="list-style-type: none"> • In measurements, toggles the active measurement caliper • In annotations, toggles the active arrow annotation anchor point • In review, toggles play/pause during cine image playback
Annotate		<ul style="list-style-type: none"> • Opens the <i>Annotations</i> touch screen • Initiates/cancels a text annotation
Measure		<ul style="list-style-type: none"> • Pauses imaging and opens the <i>Measurements</i> touch screen • Initiates the default measurement type for the current mode • Cancels a measurement in progress
Set		Functionality is dependent on the current action: <ul style="list-style-type: none"> • When the cursor is active, it acts as a "select" function • In annotations, completes an annotation in progress • In measurements, fixes the position of a line/completes a measurement/initiates the next required line, depending on the state of the measurement • In the Image List Panel, opens the image for a selected thumbnail
Print		Prints the displayed image on the thermal printer (if configured)
Cine		Saves up to 300 retrospective sequential frames as a cine image (not available in all modes or when patient information has not been entered)
Frame		<ul style="list-style-type: none"> • Saves a single frame • In <i>Dual Mode</i> and <i>Transverse Mode</i>, saves the image panes as a single frame
Freeze		Toggles between live/paused imaging
Preferences		Opens the <i>Preferences</i> screen

Table 2: Control Panel Controls

6.1.2 Touch Screen

The ExactVu system's *touch screen* works in conjunction with the *control panel* to operate the system.

The touch screen provides controls on several screens:

- Exam

- Workflow
- Modes
- Measurements
- Annotations

The *touch screen* provides a virtual keyboard for text entry which is automatically activated whenever the operator interacts with functions requiring text entry. It also provides two USB 2.0 connectors.

NOTE

EN-N1



When two or more touch screen control presses are received within 500 ms, the second and subsequent control presses are ignored.

Touch Screen Tab	Control	Function
Exam	Transducer	Provides options to activate a connected transducer while using the imaging screen
	Exam Type	Provides options to select an <i>Exam Type</i> for the selected transducer
	Image Preset	Provides options to enable settings based on the combination of transducer and exam type with the size of the prostate
Workflow	2D	Starts imaging in <i>2D Mode</i>
	Anesthesia	Enables the <i>Anesthesia sub-mode</i> when the EV29L transducer is active and includes a 15° transrectal <i>needle guide overlay</i> , the anesthesia preset and a higher imaging frame rate
	Biopsy	Enables the <i>Biopsy sub-mode</i> when the EV29L transducer is active and includes the transrectal <i>needle guide overlay</i> and the biopsy preset
	Transrectal Needle Guide	Toggles the needle guide overlay ON or OFF. The available needle guide overlays are dependent on the active transducer and needle guide type
	Needle Enhancement	Toggles enhanced visualization of the biopsy needle ON or OFF (available only when using the EV29L transducer in Biopsy sub-mode)
	Transperineal Biopsy Guide	Toggles the <i>Guide overlay</i> ON or OFF (available in Biopsy sub-mode in 2D Mode)
	Transperineal Biopsy Grid	Toggles the <i>Grid overlay</i> ON or OFF (available in Biopsy sub-mode in 2D Mode or Transverse Mode)
Dual	Begins imaging in <i>Dual Mode</i> (enabled when the EV9C or EV5C transducer is active)	

Touch Screen Tab	Control	Function
	Transverse	Begins imaging in <i>Transverse Mode</i> (enabled when the EV29L transducer is active)
	Stitch	Activates the <i>Stitch</i> feature on first press, and then completes and saves the <i>stitched image</i> on the second press and automatically enables <i>Transverse Mode</i> (enabled when the EV29L transducer is active)
	Transverse Position	Adjusts the position of the transverse line indicator in <i>Transverse Mode</i> (enabled when the EV29L transducer is active)
	Angle Reset	Sets the <i>Angle</i> value to 0 degrees (indicating the relative rotation of the EV29L transducer based on its motion sensor position) (enabled when the EV29L transducer is active)
	Patient Right, Patient Left / Mid-Line	FusionVu controls to mark the mid-line and left and right lateral borders of the prostate for aligning micro-ultrasound data with PI-RADS sectors of interest / MR study data
	Overlay	Toggles the display of the MRI or PI-RADS scout image overlay ON or OFF
	Reset	Resets the alignment between PI-RADS sectors or MRI data and the micro-ultrasound image to its pre-alignment state
	New/Close Study	Closes the study, and opens the <i>Patient/Study</i> screen
	Image Enhancement	Toggles the <i>Image Enhancement</i> option ON or OFF
Modes	Orientation (icons)	Provides options to flip an image left or right during imaging with the EV9C and EV5C transducers
	Power slider	Increases/decreases acoustic transmit power between available values 20%, 50% and 100%
	# Focal Zones	Allows selection of 1 or 3 <i>focal zones</i> (not available when using the EV29L transducer in <i>Transverse Mode</i> or <i>Stitch sub-mode</i>)
	Dual	Begins imaging in <i>Dual Mode</i> (enabled when the EV9C or EV5C transducer is active)
	Color	Activates Color Doppler Mode (when the EV5C transducer is active)
	Power	Activates Power Doppler Mode (when the EV5C

Touch Screen Tab	Control	Function
		transducer is active)
	PRF	Provides options based on the image depth to adjust the Pulse Repetition Frequency (PRF), i.e., the range of Doppler velocities (frequencies) that are displayed in the color display map and signal
	Sensitivity	Provides options to adjust the signal-to-noise ratio in order to identify smaller structures in the near field, and larger structures at greater depth
	Wall Filter	Adjusts the level of signals corresponding to low velocity axial motion to be filtered out of the spectral display
	Persistence	Provides persistence options to produce a time-averaged output frame
	PW Doppler and related controls	This functionality is disabled in this version of the ExactVu system
Measurements	Measurement icons	Allows selection of measurement calipers for creating different measurement types: <ul style="list-style-type: none"> • Distance • Area • Volume • Bladder Volume (<i>Pre-void</i> and <i>Post-void</i>, available in Dual Mode when using the EV5C transducer)
		Allows selection of a measurement for editing
	Delete All	Deletes all measurements on the image
	Delete Measurement	Deletes the active measurement
Annotations	Annotation labels	Quick selections: General, Prostate, Abdomen, Pelvis, Kidneys
	Arrow	Draws a line with an arrow
	Select	Activates the annotation created most recently on the image/cycles through annotations on the image
	Delete All	Deletes all annotations on the image
	Delete Annotation	Deletes the active annotation

Table 3: Touch Screen Tabs

6.1.3 Monitor

The ExactVu monitor uses an LED-backlit LCD panel with viewing angles that minimize color shift and

contrast changes when viewing the screen at an angle. The monitor specifications are as follows:

- EIZO FlexScan EV2450 or EIZO FlexScan EV2460 (depending when the ExactVu system was manufactured)
- 23.8-inch (diagonal)
- LED-backlit glossy screen
- 1920 x 1080-pixel resolution
- Two USB 3.0 connectors (enabled in some ExactVu system configurations)
- HDMI input connector

The ExactVu monitor is pre-configured by Exact Imaging for optimal imaging settings. The *HDMI input connector* may be used to connect a second monitor (available in some ExactVu system configurations).

6.1.4 Foot Pedal

This section is applicable to ExactVu system configurations equipped with a foot pedal.

The ExactVu foot pedal is a single-button pedal that may be configured by the operator for saving single frames or cine images. The foot pedal connects to the USB connector at the bottom rear of the ExactVu system cart (refer to Figure 6 on page 55).

The foot pedal specifications are as follows:

- Herga 6226 Foot Switch
- USB Plug-and-Play connection
- Operating voltage does not exceed 42.4V peak AC or 60 V DC



Figure 3: Foot Pedal

6.1.4.1 Foot Pedal Cable Management

The foot pedal cable is secured to the ExactVu system via the clips located at the front, side and rear of the ExactVu system cart.



Figure 4: Foot Pedal Cable Management

The foot pedal cable may be removed from the clips during use or during reprocessing (refer to Chapter 13, section 3 on page 177), and should be reclipped after reprocessing and when moving the ExactVu system cart. When the foot pedal cable is clipped to the ExactVu system cart, ensure there are no loose parts of the cable sitting on the floor.

WARNING
EN-W87



Loose-hanging device cables pose a potential tripping hazard.

Arrange cables so that it is not possible to trip over them, particularly when moving the ExactVu system or monitor stand.

CAUTION
EN-C56



To avoid damaging cables:

- Keep cables off the floor by using transducer holders and foot pedal cable management clips.
 - Do not sharply bend or stretch cables, or allow cables to become knotted.
 - When disconnecting a cable, pull on its connector. Do not pull on the cable itself.
-

6.2 Software

6.2.1 Modes of Operation

The imaging modes available on the ExactVu micro-ultrasound system are dependent on the transducer in use.

When using the EV29L side-fire transducer, 2D Mode imaging is available as the primary form of B-Mode operation. The following forms of B-Mode are also available:

- *Transverse Mode* imaging displays the transverse plane of the prostate using reconstructed 2D Mode data
- *Biopsy sub-mode* supports guidance of biopsy needles to desired areas of the prostate
- *Anesthesia sub-mode* provides higher frame rate imaging and toggles the on-screen anesthesia guide
- *Stitch sub-mode* allows two images to be joined for a larger field of view

When using the EV9C transrectal transducer, the following imaging modes are available:

- 2D Mode, and related sub-mode:

- *Dual Mode* imaging displays two separate side-by-side images in the imaging screen

When using the EV5C abdominal transducer, the following imaging modes are available:

- 2D Mode, and related sub-mode:
 - *Dual Mode* imaging displays two separate side-by-side images in the imaging screen
- *Color Doppler Mode* displays information about the direction and velocity of flow within tissue using different shades of red and blue
- *Power Doppler Mode* displays information about the amount of flow within tissue

6.2.2 Getting Help

The *Preferences > System Information* screen allows the operator to access information including:

- Contact Information for Technical Support
- Configurations for hardware, software, the software dongle
- Message log export options
- Transducer Element Check

6.2.3 System State Messages

The ExactVu software provides information to operators when unusual operating conditions occur that affect the *system state*. The type of condition determines the effect on the ExactVu system state. ExactVu software displays a message to indicate the condition. Messages must be closed by the operator before continuing to use the ExactVu system.

The types of conditions are:

- Critical System Error
- System Error

A *Critical System Error* is a serious error that requires the ExactVu system to be shut down and restarted. It disables all image acquisition functionality, including the supply of acoustic energy output to the transducer. When a *Critical System Error* message is displayed, it informs the operator that the ExactVu system is about to shut down. After 20 seconds, or when the operator closes the *Critical System Error* message, the ExactVu system shuts down automatically.

A *System Error* is a condition that leaves the ExactVu system in an operational state so that images may be saved. After acknowledging a *System Error* message, the operator may close and save the study, and restart the ExactVu system if desired.

NOTE
EN-N10



All error messages provide contact information for Technical Support. For additional contact information, refer to Appendix F.

NOTE

EN-N11



In the event that an unexpected software error occurs, an error message will be displayed.

Condition	Condition Type
Hardware detects the system operating temperature and voltage differs from calculated limits	Critical System Error
Operating conditions determine that TIS and MI differ from calculated values after imaging starts	Critical System Error
Configuration files are inadvertently changed	Critical System Error
Incompatibility between versions for Channel Board FPGA, Beamformer Control Board FPGA, and Beamformer Control Board driver	Critical System Error
Hardware detects the system is operating with temperature and EV29L voltage conditions that exceed expected thresholds when imaging begins (system shuts down after 5 seconds)	Critical System Error
Communication with the ExactVu hardware is lost	System Error
Hardware detects the system is operating in conditions that differ from power supply limits for transmit and image frame rate when imaging begins	System Error
Hardware malfunction	System Error
Non-critical error conditions are detected by the system software	System Error

Table 4: Error Conditions

6.2.4 Information Messages

The ExactVu software provides information to operators after performing an action that is invalid, or that can't be completed (for example, attempting to save patient information when data is missing).

This section provides a list of messages pertaining to safety that may be encountered. If problems arise with the ExactVu system, Exact Imaging will strive to ensure that the system remains operational with minimal downtime. When such problems occur, contact Technical Support using the contact information in Appendix F.

Message
An error has occurred. Save your data and restart the system. Please report this error to Technical Support.
Critical System Error.
The system has encountered a critical error and will shut down. If the system does not shut down automatically, press and hold the power button to complete system shut down.
Contact Technical Support for assistance.
The transducer is not supported by the system.

Table 5: ExactVu Software Information Messages

7 Accessories

7.1 Transducers

Multiple Exact Imaging transducers may be connected to the ExactVu system. The current models are:

- EV29L: 29 MHz High Resolution Side-Fire Transducer (Linear) (Exact Imaging catalog reference: EV-29L)
- EV9C: 9 MHz Transrectal Transducer (Curved) (Exact Imaging catalog reference: EV-9C)
- EV5C: 5 MHz Abdominal Transducer (Curved) (Exact Imaging catalog reference: EV-5C)

The EV29L, EV9C and EV5C transducers meet FDA's Track 3 Requirements, per *Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* and the requirements of IEC 60601-2-37.

Refer to the following manuals for information about the use, accessories and consumables, reprocessing, care and maintenance for ExactVu transducers:

- Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer
- Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer
- Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer

NOTE

EN-N2



The EV29L, EV9C and EV5C transducer models are the only transducers that may be connected to the ExactVu system.

8 Consumables

NOTE

EN-N4



Biopsy and anesthesia needles are not available from Exact Imaging.

NOTE

EN-N5



Operators are responsible for selection of biopsy, anesthesia and other puncture needles, and for adhering to internal clinical procedures regarding checking for and disposing of expired needles.

8.1 EV29L Sterile Transrectal Needle Guide for Procedures using the EV29L Transducer

The *EV29L Sterile Transrectal Needle Guide* is a specially designed transrectal needle guide for use with the EV29L transducer.

This needle guide supports two needles: one for anesthesia delivery and the other for biopsy. Each needle fits into the needle guide at an angle appropriate for its function (15 degrees for anesthesia

delivery and 35 degrees for biopsy). The needle gauge sizes for each function are as follows:

- Anesthesia needle: 22-gauge
- Biopsy needle: 18-gauge

The *EV29L Sterile Transrectal Needle Guide* is intended for single-use only and is provided in sterile packaging. It has a limited shelf life and its package indicates its expiry date.

This needle guide is sterilized using ethylene oxide (also known as EO sterilization), a simple alkaline chemical compound that is commonly used for gaseous sterilization of single-use healthcare products. EO sterilization is a chemical process consisting of four primary variables (gas concentration, humidity, temperature and time) in which ethylene oxide infiltrates packaged medical devices and disrupts the DNA of microorganisms, preventing them from reproducing.

For complete details about the *EV29L Sterile Transrectal Needle Guide*, refer to *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

8.2 EV29L Non-sterile Reusable Transrectal Needle Guide for Procedures using the EV29L Transducer

The *EV29L Non-sterile Reusable Transrectal Needle Guide* provides the means to guide a needle through a stainless-steel needle cannula.

There are two variants available for this needle guide:

- 18 GA EV29L Non-sterile Reusable Transrectal Needle Guide
- 16 GA EV29L Non-sterile Reusable Transrectal Needle Guide

Both variants fit needles into the needle guide at an angle of 35 degrees. Anesthesia needles may also be used with the needle guide.

For complete details about the EV29L non-sterile reusable transrectal needle guide, refer to *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

8.3 EV29L Sterile Transperineal Needle Guide for Procedures using the EV29L Transducer

The *EV29L Sterile Transperineal Needle Guide* provides the means to guide a transperineal needle through a plastic needle guide.

18 GA needles fit into the *EV29L Sterile Transperineal Needle Guide* at an angle of 13 degrees relative to the transducer neck at a distance from the center of the transducer lens of 11 cm. It allows the *needle guide tower* to slide along the *guide plug* to a distance of 8 cm the center of the transducer lens.

For complete details about the EV29L Sterile Transperineal Needle Guide, refer to *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

8.4 CIVCO® Disposable Endocavity Needle Guide for Procedures using the EV9C Transducer

For biopsy procedures using the EV9C transducer, use only the CIVCO® *Disposable Endocavity Needle*

Guide. It is manufactured by CIVCO and may be ordered from your local distributor. For contact information refer to Appendix F.

Exact Imaging recommends using an 18-gauge biopsy needle.

For complete details about the CIVCO® *Disposable Endocavity Needle Guide*, refer to *Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer*.

8.5 CIVCO® Non-sterile EV5C Bracket with CIVCO Verza™ Guidance System

For biopsy procedures using the EV5C transducer, use only the CIVCO® *Non-sterile EV5C Bracket with CIVCO Verza™ Guidance System*. It is manufactured by CIVCO and may be ordered from your local distributor. Refer to Appendix F for contact information.

The needle guide provided by the *Verza Guidance System* supports the following:

- a range of needle gauges: 25g, 22g, 21g, 20g, 18g, 17g, 16g, 15g
- five different positioning angles
- a range of depths from 2 - 15 cm

For complete details about the *Non-sterile EV5C Bracket* and the *Verza Guidance System*, refer to *Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer*.

9 Optional Components

9.1 Thermal Printer

The optional ExactVu thermal printer is an A6 medical grade black and white digital printer manufactured by Sony Corporation. The printer specifications are as follows:

- Sony® UP-D898MD
- Up to 325 dpi and gray levels up to 256 steps
- Image area 320 x 100 mm (12 5/8 x 4 inches)

When the thermal printer is part of the ExactVu system configuration, it is pre-configured by Exact Imaging to print ExactVu images and is shipped with the *Thermal Printer Instructions for Use*.

9.2 Transperineal Stepper

Complete details about supported transperineal steppers and their accessories may be found in the document *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

9.3 Monitor Stand

The ExactVu system is compatible with an optional monitor stand for displaying a second monitor. The monitor stand is manufactured by GCX Mounting Solutions with specifications as follows:

- GCX VHRS Series Variable Height Roll Stand with Hand Knob Actuated Height Control and VESA Mounting Plate, FLP-0001-76
- VESA® FDMI™ 75/100 mm compatible

- 4" / 10.2 cm diameter dual wheel nylon casters (2 locking and 3 non-locking) for easy transition over uneven surfaces
- Gas spring assisted for easy height adjustment
- Hand knob for height adjustment

The GCX VHRS Series Variable Height Roll Stand is sold together with the EIZO FlexScan monitor, power and HDMI cables and assembly instructions together as a kit. Refer to Chapter 3, section 1.6 on page 58 for information about using the monitor stand with a second monitor and adjusting its height.

10 Lifetime

The ExactVu system is designed for a working lifetime of 5 years. The EV29L, EV9C and EV5C transducers are designed for a working lifetime of 5 years, when used with proper care. The working lifetime for Exact Imaging transducers is based on their ability to withstand the effects of cycles of the reprocessing procedure without degrading functionality or compromising safety. Therefore, the lifetime is determined beginning when the transducer is first reprocessed.

Chapter 2 Safety Information

1 Product Safety and Electrical Testing

The ExactVu micro-ultrasound system and its transducers comply with the applicable portions of the standards and regulations indicated in the following sections.

1.1 Certifications

United States

- 510(k) clearance (FDA Track 3 requirements). Track 3 is for diagnostic ultrasound systems that follow the Output Display Standard. Under Track 3, acoustic output is not evaluated on an application-specific basis, but the maximum derated Spatial Peak–Temporal Average Intensity (ISPTA) must be $\leq 720\text{mW/cm}^2$, the maximum Mechanical Index (MI) must be ≤ 1.9 , and the maximum Thermal Index (TI) must be < 6 . The EV29L, EV9C and EV5C transducers meet the requirements for Track 3.
- 47 CFR Part 18 Industrial, Scientific and Medical Equipment (FCC)
- NEMA UD 3-2004 Standard for Real-Time Display of Thermal & Mechanical Acoustic Outputs
- 21 CFR 801 Labeling
- The system is capable of preventing unauthorized access to patient data (HIPAA)

Canada

- Medical Device License
- ICES-001 Industrial, Scientific and Medical Equipment

Europe

- Exact Imaging declares conformity to the essential requirements of the following Council Directives of the European Union, and applies the CE Mark to its products accordingly:
 - REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
 - Council Directive 2006-42-EC (the “Machinery Directive”) to the extent which these requirements are more specific than the essential requirements of the European Medical Device Regulations
 - Council Directive 2011/65/EU of the European Parliament (the “RoHS Directive”)

Standards

- Exact Imaging declares conformity to the following standards:
 - IEC 60601-1 Part 1: General requirements for basic safety and essential performance, edition 3.1
 - IEC 60601-1-2 Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests, edition 4.0
 - IEC 60601-2-18 Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment, edition 3.0

- IEC 60601-2-37 Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, edition 2.1
- ISO 10993-1 Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
- IEC 62304 Medical device software – Software life cycle processes, edition 1.1
- IEC 62366-1:2015/AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices

1.2 Classifications

Radio Frequency

The ExactVu™ High Resolution Micro-Ultrasound System complies with Part 18 of the FCC Rules and Canadian ICES-001, sections 3 - 7.

Emissions

The emissions characteristics of the ExactVu system make it suitable for use in industrial areas and hospitals, as per classification CISPR 11 class A.

Ingress

Protection against ingress is rated at IP20 for the ExactVu system cart (excluding the foot pedal). Protection against ingress for Exact Imaging transducers is IPX7 from the transducer head to halfway along the handle, and IPX0 for the remainder of the handle to the transducer connector. (Refer to the applicable *Care, Cleaning and Use Guide* for the identification of these locations on the transducer.) Protection against ingress for the ExactVu foot pedal is IPX7.

1.3 Support for DICOM

The ExactVu system reads MRI study data in DICOMDIR format, where the study is marked up using a DICOM workstation that supports DICOM GSPS (Grayscale Softcopy Presentation State) for MRI markup.

The ExactVu system uses DICOM Store for export to a PACS server.

The ExactVu system uses DICOM Query Retrieve for retrieval of MRI data from a PACS server. Modality types are limited to MR and GSPS.

The ExactVu system uses DICOM Modality Worklist for querying patient procedures from a PACS server.

The *DICOM Conformance Statement for ExactVu* provides details about the ExactVu system's conformity to the DICOM standard. The latest version is accessible at the following link:

<https://www.exactimaging.com/dicom-conformance-statement>

2 Acoustic Output

It is generally accepted that no harmful physiological effects have been demonstrated at the frequency, intensity, and exposure times used in diagnostic ultrasound examinations. However, the interaction of sound energy with tissue at sufficiently high levels can produce physiological effects of either a mechanical or thermal nature, such as cavitation or tissue damage.

The operator must be aware of the particular conditions that exist during the examination to recognize the potential for physiological effects in the patient and then to take appropriate action to reduce the risk. The recognition of potential harm comes from an understanding of tissue characteristics and a real-time knowledge of acoustic output.

When conditions indicate the potential for harmful physiological effects, Exact Imaging recommends taking prompt action to reduce the risk by changing imaging settings or altering procedural techniques:

- Optimize gain and other image enhancement features before increasing the settings that significantly affect the acoustic output level. Settings affecting acoustic output are described in section 2.2.1.2 on page 31.
- Become sufficiently familiar with Exact Imaging equipment and ExactVu imaging settings to localize anatomy and adjust image quality rapidly, and then freeze the image as soon as the necessary diagnostic information is obtained.
- Follow the ALARA (As Low as Reasonably Achievable) principle, as described in the following section.

2.1 Prudent Use

The operator is encouraged to follow the principle of ALARA (As Low as Reasonably Achievable), i.e., to use the lowest acoustic output necessary to produce clinically acceptable data.

Controls that have no noticeable impact on image quality should be set to minimize the output. Controls that improve the image quality and also increase acoustic output should be set no higher than needed to achieve a diagnostic quality image.

This practice keeps the acoustic output exposure at the minimum level necessary to obtain the diagnostic information.

Examples of practicing prudent use with the ExactVu system include:

- Where the operator wishes to review or compare a lesion identified on the MRI image with the ultrasound image, the operator may *pause* imaging on the ExactVu system using the *Freeze* control to reduce energy delivery when live imaging is not required.
- When performing an abdominal exam, the operator should turn off the display of the *color box* when not in use to prevent unnecessary energy delivery.
- If an image's quality is acceptable, and the exam is expected to take significant time, the operator should navigate to the *Modes* tab and reduce the *transmit* power to the lowest level which maintains good image quality.
- During prostate biopsy, bleeding may occur and the transducer is occasionally used to apply pressure to the rectal wall until the bleeding has stopped. Transmit functionality should be switched off during this period using the *Freeze* control.

WARNING

EN-W7



At all times, the operator must follow the principle of ALARA to minimize the acoustic output and exposure time.

NOTE
EN-N6



Acoustic Output Tables for the EV29L, EV9C and EV5C transducers are provided in Appendix A, Appendix B and Appendix C. The display accuracy for each transducer is also listed.

NOTE
EN-N7



Acoustic energy is emitted only when the ExactVu system is acquiring ultrasound data.

2.2 Thermal Index Soft Tissue (TIS) and Mechanical Index (MI)

The ExactVu system provides a real-time display of the Mechanical Index (MI) and Thermal Index Soft Tissue (TIS) indices as indicators of potential physiological effects, in order to allow the operator to implement the ALARA principle while using the system. Further details are provided in the following sub-sections.

The MI and TIS values are displayed on the *imaging* screen in real-time during imaging, as well as in saved and printed images.

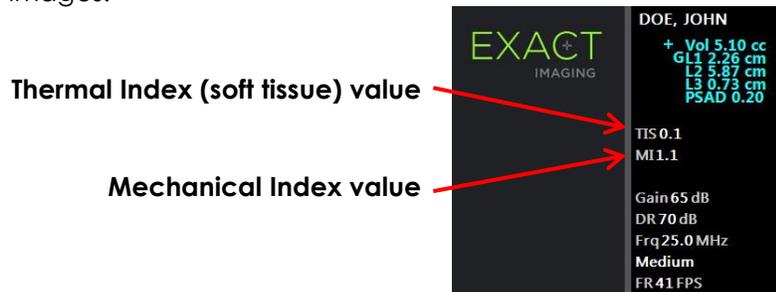


Figure 5: TIS and MI

MI is an indication of an ultrasound beam's ability to cause cavitation-related bioeffects, and is sometimes interpreted more broadly as an indicator for potential mechanical stress or damage to tissue. The Thermal Index (TIS) indicates the highest expected temperature increase in degrees Celsius. It is based on an average level of blood perfusion. Factors that contribute to the uncertainty of the output display include:

- The displayed TIS value may be low where it estimates a temperature rise in poorly perfused tissue.
- The displayed TIS value may be high where it estimates a temperature rise in richly perfused tissue.

The ExactVu software uses data in *acoustic measurement tables* to generate the MI and TIS values for a given set of operating conditions. It also generates values for spatial peak temporal average intensity (I_{SPTA}), though this is not displayed on-screen. These tables contain acoustic measurement data collected for different transmit parameter configurations that are used per mode/sub-mode preset.

The ExactVu software monitors the acoustic output following each setting change and limits the transmit power and image frame rate in order to keep within allowed power limits.

These limits are calculated by the ExactVu software, with failsafe monitoring of output voltage and current levels. Power output measurements were made following *Good Laboratory Practice*.

2.2.1 Mechanical Index (MI)

2.2.1.1 Description of MI

The mechanical index is proportional to an ultrasound beam's peak negative pressure (or peak rarefactional pressure). It is also inversely proportional to the square root of the frequency of the beam. Therefore, higher frequencies have a lower mechanical index.

The MI value is calculated as follows:

$$MI = \frac{PNP}{\sqrt{F_c}}$$

Where:

- PNP is the peak negative pressure of the ultrasound wave (MPa), derated by 0.3 dB cm⁻¹ MHz⁻¹ to account for the difference between in-water and in-tissue acoustic attenuation
- F_c is the center frequency of the ultrasound wave (MHz)

2.2.1.2 Operator Controls Affecting the MI Value

The MI value is dependent on the depth of the focal zone for the transducer combined with its transmit voltage.

The operator is able to change both the position and the number of focal zones. The operator is able to adjust the transmit voltage (using the Power slider on the Modes touch screen) to lower the MI. MI at 100% transmit power meets the specified acoustic output limits.

Refer to Chapter 3, section 3.5.4 on page 83 for further information about *imaging settings*, including using *focal zones* and adjusting the *transmit power*.

2.2.2 Thermal Index Soft Tissue (TIS)

2.2.2.1 Description of TI and TIS

The purpose of the thermal index (TI) is to translate the acoustic output of an ultrasound machine into a quantity that correlates with the risk of causing an adverse effect due to a thermal mechanism. The temperature rise is impacted by how the directed power (i.e., acoustic output) flows through tissue.

Highly focused sources with stationary ultrasound beams focus the power into a smaller volume (i.e., high spatial-average acoustic intensity), resulting in higher temperature increases. Conversely, imaging an ultrasound beam, as is done when obtaining a typical 2D Mode image, spreads the power over a larger volume of tissue.

In addition to dependence on acoustic intensity, the resulting temperature rise also depends on the rate at which the power is converted into heat in the tissue (i.e., tissue absorption, which also increases with frequency), the diffusion of the heat in the tissue (i.e., thermal conductivity), and the rate at which the heat is removed by blood flow in the tissue (i.e., blood perfusion). The acoustic intensity decreases with increasing depth and acoustic pulse center frequency due to the loss of the ultrasound signal from tissue attenuation.

The thermal index model for soft tissue (i.e., Thermal Index Soft Tissue, represented by TIS) assumes a worst-case combination of attenuation and absorption coefficients.

The TIS value is calculated as follows:

$$\text{TIS} = \frac{W_{01}f_{\text{awf}}}{210 \text{ mW MHz}}$$

Where:

- W_{01} is the maximum value of the acoustic output power emitted from any 1-cm length of the radiating aperture in the imaging direction
- f_{awf} is the center frequency (MHz)

2.2.2.2 Operator Controls Affecting the TIS Value

TIS is affected by frame rate, transmit voltage and focal depth.

In *2D Mode*, controls that increase the frame rate, such as selecting one focal zone, may also increase the TIS value.

In *CFI modes* (i.e., *Color Doppler Mode* and *Power Doppler Mode*), controls including *color box size*, *Sensitivity*, and *PRF* (pulse repetition frequency) can affect the *frame rate* and transmit voltage, and therefore TIS.

The *Power* setting impacts the transmit voltage of the ultrasound beam in all modes. The operator may decrease the TIS value by decreasing the *Power* setting on the *Modes touch screen*.

Refer to Chapter 3, section 3.5.4 on page 83 for further information about *imaging settings*, including using *focal zones* and adjusting the *transmit power*.

NOTE
EN-N8



The frame rate, the position of focal depths and the transmit power are dependent on the transducer in use.

3 Transducer Temperature Limits

The ExactVu software is designed to limit the surface temperature of the EV29L, EV9C and EV5C transducers so that it doesn't exceed safe limits. The software does this by limiting the maximum image frame rate and transmit voltage. These parameters are measured during live imaging, and acoustic output stops automatically if they differ from limit values. In addition, the ExactVu software monitors the elapsed continuous imaging time and stops acoustic output automatically if time limits are exceeded.

In accordance with IEC 60601-2-37, at ambient operating temperature ($23\text{ °C} \pm 3\text{ °C}$), measured EV29L, EV9C and EV5C transducer temperatures ensure:

- Transducer surface temperature rise in air $< 27\text{ °C}$
- Transducer surface temperature rise when coupled with tissue $< 6\text{ °C}$

In accordance with IEC 60601-1 and 60601-2-18, at maximum ambient operating temperature (35 °C), measured EV29L and EV9C transducer temperatures ensure:

- Transducer shaft and handle temperature $< 41\text{ °C}$

- Transducer surface temperature < 41 °C

These same specifications are also applicable to EV5C.

The surface temperature rise for ExactVu transducers has been measured in the “worst-case” normal use where imaging settings result in maximum transducer surface temperatures. These temperatures were measured in accordance with IEC 60601-2-37.

CAUTION
EN-C2



If the ExactVu system or transducer overheats, contact Technical Support using the contact information in Appendix F.

Do not continue to use the system/transducer.

WARNING
EN-W8



Do not unfreeze imaging and hold the transducer in mid-air without there being ultrasound gel applied to the transducer's imaging surface. Doing so may cause the temperature on the imaging surface to heat, and possibly cause injury to the patient.

NOTE
EN-N2



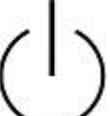
The EV29L, EV9C and EV5C transducer models are the only transducers that may be connected to the ExactVu system.

4 Symbols Glossary

The tables in the following sections contain brief explanations of the safety symbols and other information used to label the ExactVu system, its accessories, and its consumables.

4.1 Symbols on the ExactVu System Device Label

Symbol	Meaning	Symbol Reference
	The unique device identifier ("UDI"); includes a production identifier segment that conveys serial number and manufacturing date	21 CFR 801.20
	Legal manufacturer	ISO 15223-1 symbol 5.1.1
	Country of manufacture, also used in lieu of ISO 15223-1 symbol 5.1.3 to identify the date of manufacture	ISO 15223-1 symbol 5.1.11
	Authorized representative in the European Community	ISO 15223-1 symbol 5.1.2
	The entity importing the medical device into the European Community	ISO 15223-1 symbol 5.1.8
	The entity distributing the medical device into the European Community	ISO 15223-1 symbol 5.1.9

Symbol	Meaning	Symbol Reference
	Manufacturer's catalog number	ISO 15223-1 symbol 5.1.6
	Device serial number	ISO 15223-1 symbol 5.1.7
	Refer to instruction manual	IEC 60601-1 symbol 10 in table D.2
	Consult operating instructions	IEC 60601-1 symbol 11 in table D.1
	Indicates authorization under the FCC Declaration of Conformity procedure	FCC title 47, Part 18.209 b (symbol shown in 47 CFR 15.19 b)
	The safety test symbol is issued for the application of the selected test criteria	Logo for the company that performs electrical safety and EMC test (TUV)
	CE Marking indicates conformity to the European Medical Device Regulations	REGULATION (EU) 2017/745
	When disposing of the equipment, it must be sent to appropriate facilities for recovery and recycling	Annex IX of Directive 2012/19/EU for WEEE
	Voltage / frequency standard: Alternating current	IEC 60601-1 symbol 1 in table D.1
IP20	Specifies the ingress protection level for the ExactVu system (indicates protection against solid objects 12.5 mm and greater in diameter)	IEC 60601-1 symbol 2 in table D.3
	Electricity warning: Disconnect the power supply before servicing the system (symbol appears on the ExactVu system's peripheral panel, located at the bottom rear of the cart)	IEC 60601-1 symbol 2 in table D.2
	Equipotentiality: Potential equalization conductor terminal ("ground pin"), located outside the ExactVu system cart on the IO plate	IEC 60601-1 symbol 8 in table D.1
	System power control (located on the front of the ExactVu system cart)	IEC 60601-1 symbol 29 in table D.1
	Indicates that the equipment contains components that are sensitive to electrostatic discharge (located inside the ExactVu system)	ANSI/ESD S20.20 2014

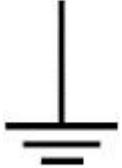
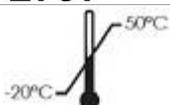
Symbol	Meaning	Symbol Reference
	Earth (ground) (located inside the ExactVu system cart on the master chassis)	IEC 60601-1 symbol 7 in table D.1
	Indicates that the device must be kept away from MRI imaging equipment	Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (FDA Draft Guidance)
	Indicates that the device is a medical device	ISO 15223-1 symbol 5.7.7

Table 6: Symbols on the ExactVu System Device Label

4.2 Symbols on the ExactVu System Package Label and Crate

Symbol	Meaning	Symbol Reference
	Legal manufacturer	ISO 15223-1 symbol 5.1.1
	Country of manufacture	ISO 15223-1 symbol 5.1.11
	Authorized representative in the European Community	ISO 15223-1 symbol 5.1.2
	The entity importing the medical device into the European Community	ISO 15223-1 symbol 5.1.8
	The entity distributing the medical device into the European Community	ISO 15223-1 symbol 5.1.9
	Manufacturer's catalog number	ISO 15223-1 symbol 5.1.6
	Caution: General warning symbol advising operator to consult the accompanying documents for safety-related information	IEC 60601-1 symbol 10 in table D.1
	CE Marking indicates conformity to the European Medical Device Regulations	REGULATION (EU) 2017/745
	Temperature range limitation	ISO 15223-1 symbol 5.3.7

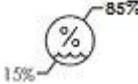
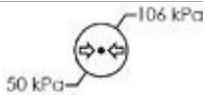
Symbol	Meaning	Symbol Reference
	Humidity range limitation	ISO 15223-1 symbol 5.3.8
	Pressure range limitation	ISO 15223-1 symbol 5.3.9
	Do not use the ExactVu system if its packaging has been damaged	ISO 15223-1 symbol 5.2.8
	Indicates that the device is a medical device	ISO 15223-1 symbol 5.7.7
	Fragile, handle with care	ISO 15223-1 symbol 5.3.1
	Do not stack	ISO 780:2015 symbol 17
	This way up	ISO 780:2015 symbol 13
	Universal recycling symbol	ISO/IEC JTC1/SC2/WG2 N2342 Universal Multiple Octet Coded Character Set

Table 7: Symbols on the ExactVu System Package Label and Crate

4.3 Symbols on the EV29L, EV9C and EV5C Transducer Labels

Symbol	Meaning	Symbol Reference
	Legal manufacturer	ISO 15223-1 symbol 5.1.1
	Manufacturer's catalog number	ISO 15223-1 symbol 5.1.6
	The entity importing the medical device into the European Community	ISO 15223-1 symbol 5.1.8

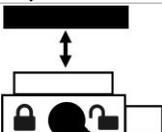
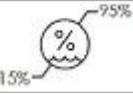
Symbol	Meaning	Symbol Reference
	The entity distributing the medical device into the European Community	ISO 15223-1 symbol 5.1.9
	Device serial number	ISO 15223-1 symbol 5.1.7
	Country of manufacture, also used in lieu of ISO 15223-1 symbol 5.1.3 to identify the date of manufacture	ISO 15223-1 symbol 5.1.11
	Consult operating instructions	IEC 60601-1 symbol 11 in table D.1
	Type BF Applied Part	IEC 60601-1 symbol 20 in table D.1
	When disposing of the equipment, it must be sent to appropriate facilities for recovery and recycling	Annex IX of Directive 2012/19/EU for WEEE
	CE Marking indicates conformity to the European Medical Device Regulations	REGULATION (EU) 2017/745
	The unique device identifier ("UDI"); includes a production identifier segment that conveys serial number and manufacturing date	21 CFR 801.20
	Indicates that the device is a medical device	ISO 15223-1 symbol 5.7.7
	Indicates that the transducer connector cover is securely attached to the transducer	Device-specific label
	Indicates that the transducer connector cover may be removed or attached to the transducer	Device-specific label

Table 8: Symbols on the EV29L, EV9C and EV5C Transducer Labels

4.4 Symbols on the EV29L, EV9C and EV5C Transducer Package

Symbol	Meaning	Symbol Reference
	Legal manufacturer	ISO 15223-1 symbol 5.1.1
	Country of manufacture, also used in lieu of ISO 15223-1 symbol 5.1.3 to identify the date of manufacture	ISO 15223-1 symbol 5.1.11

Symbol	Meaning	Symbol Reference
	Authorized representative in the European Community	ISO 15223-1 symbol 5.1.2
	The entity importing the medical device into the European Community	ISO 15223-1 symbol 5.1.8
	The entity distributing the medical device into the European Community	ISO 15223-1 symbol 5.1.9
	Manufacturer's catalog number	ISO 15223-1 symbol 5.1.6
	Device serial number	ISO 15223-1 symbol 5.1.7
	Consult operating instructions	IEC 60601-1 symbol 11 in table D.1
	CE Marking indicates conformity to the European Medical Device Regulations	REGULATION (EU) 2017/745
	Temperature range limitation	ISO 15223-1 symbol 5.3.7
	Humidity range limitation	ISO 15223-1 symbol 5.3.8
	Pressure range limitation	ISO 15223-1 symbol 5.3.9
	Fragile, handle with care	ISO 15223-1 symbol 5.3.1
	Do not stack	ISO 780:2015 symbol 17
	When disposing of the equipment, it must be sent to appropriate facilities for recovery and recycling	Annex IX of Directive 2012/19/EU for WEEE
	Corrugated recyclables symbol, indicates that the container can and should be recycled	Corrugated Packaging Alliance, CPA White Paper
	The unique device identifier ("UDI"); includes a production identifier segment that conveys serial number and manufacturing date	21 CFR 801.20

Symbol	Meaning	Symbol Reference
	Indicates that the device is a medical device	ISO 15223-1 symbol 5.7.7

Table 9: Symbols on the EV29L, EV9C and EV5C Transducer Package

4.5 Symbols on the EV29L Sterile Transrectal and Transperineal Needle Guide Packaging

NOTE
EN-N9



The EV29L Sterile Transrectal Needle Guide is only compatible with the EV29L transducer.

Symbol	Meaning	Symbol Reference
	Manufacturer's catalog number	ISO 15223-1 symbol 5.1.6
	Batch code	ISO 15223-1 symbol 5.1.5
	Temperature range limitation	ISO 15223-1 symbol 5.3.7
	The needle guide is for single-use only	ISO 15223-1 symbol 5.4.2
	Country of manufacture, also used in lieu of ISO 15223-1 symbol 5.1.3 to identify the date of manufacture	ISO 15223-1 symbol 5.1.11
	Use the needle guide by the indicated date	ISO 15223-1 symbol 5.1.4
	The unique device identifier ("UDI"); includes a production identifier segment that conveys serial number and manufacturing date	21 CFR 801.20
	The needle guide has been sterilized using ethylene oxide	ISO 15223-1 symbol 5.2.3
	Single sterile barrier system with protective packaging inside	ISO 15223-1 symbol 5.2.13
	Do not use the needle guide if its packaging has been damaged	ISO 15223-1 symbol 5.2.8

Symbol	Meaning	Symbol Reference
	Consult operating instructions	IEC 60601-1 symbol 11 in table D.1
	Legal manufacturer	ISO 15223-1 symbol 5.1.1
	Authorized representative in the European Community	ISO 15223-1 symbol 5.1.2
	The entity importing the medical device into the European Community	ISO 15223-1 symbol 5.1.8
	The entity distributing the medical device into the European Community	ISO 15223-1 symbol 5.1.9
	CE Marking indicates conformity to the European Medical Devices Regulations	REGULATION (EU) 2017/745
Rx Only	Indicates that the device is for prescription use only	United States Federal Register Volume 81, Number 115 Rules and Regulations Pages 38911-38931, "Use of Symbols in Labeling"
	Indicates that the device is a medical device	ISO 15223-1 symbol 5.7.7

Table 10: Symbols on the EV29L Sterile Transrectal and Transperineal Needle Guide Packaging

4.6 Symbols on the EV29L Non-sterile Reusable Transrectal Needle Guide Packaging

NOTE
EN-N142


The EV29L Non-sterile Reusable Transrectal Needle Guide is only compatible with the EV29L transducer.

Symbol	Meaning	Symbol Reference
	Manufacturer's catalog number	ISO 15223-1 symbol 5.1.6
	Batch code	ISO 15223-1 symbol 5.1.5
	Country of manufacture, also used in lieu of ISO 15223-1 symbol 5.1.3 to identify the date of manufacture	ISO 15223-1 symbol 5.1.11
	CE Marking indicates conformity to the European Medical Devices Regulations	REGULATION (EU) 2017/745

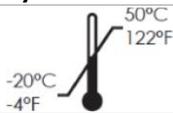
Symbol	Meaning	Symbol Reference
	Temperature range limitation	ISO 15223-1 symbol 5.3.7
Rx Only	Indicates that the device is for prescription use only	United States Federal Register Volume 81, Number 115 Rules and Regulations Pages 38911-38931, "Use of Symbols in Labeling"
	Refer to instruction manual	IEC 60601-1 symbol 10 in table D.2
	Consult operating instructions	IEC 60601-1 symbol 11 in table D.1
	Legal manufacturer	ISO 15223-1 symbol 5.1.1
	The unique device identifier ("UDI"); includes a production identifier segment that conveys serial number and manufacturing date	21 CFR 801.20
	Authorized representative in the European Community	ISO 15223-1 symbol 5.1.2
	The entity importing the medical device into the European Community	ISO 15223-1 symbol 5.1.8
	The entity distributing the medical device into the European Community	ISO 15223-1 symbol 5.1.9
	Indicates that the device is a medical device	ISO 15223-1 symbol 5.7.7

Table 11: Symbols on the EV29L Non-sterile Reusable Transrectal Needle Guide Packaging

5 General Safety Precautions

Warnings, cautions, and notes are used to describe serious and non-serious conditions of the system. The symbols used to describe these safety conditions are:

WARNING



Messages with this heading indicate serious adverse reactions, potential safety hazards, and limitations in use imposed by a condition. The warning will identify steps that should be taken if the incident occurs.

CAUTION



Messages with this heading indicate information regarding any special care to be exercised by the operator and/or patient for the safe and effective use of the device and to prevent damage. All caution statements should be followed to ensure data and system integrity.

NOTE



Messages with this heading provide additional information that will increase the operator's understanding of the operation of the system.

5.1 General

WARNING

EN-W9



If the ExactVu system malfunctions, fails to respond, if the image is severely distorted or degraded, or you suspect the system is not functioning correctly in any way:

- Remove all transducers from contact with the patient
 - Turn off the ExactVu system
 - Unplug the ExactVu system from its power source
 - Contact Technical Support using the contact information in Appendix F
-

WARNING

EN-W10



Service activities must be performed by qualified Technical Support technicians only.

Opening the ExactVu system cart will void the terms of the warranty.

Only those maintenance activities specified in Chapter 10 should be performed by ExactVu operators.

WARNING

EN-W88



In the event of a serious incident involving the use of ExactVu or any Exact Imaging medical device, contact Technical Support using the contact information in Appendix F as well as the authority governing medical device regulation in the locale.

A serious incident is an incident that directly or indirectly led or may have led to any of the following:

- The death of a patient, user or other person
 - The temporary or permanent serious deterioration of a patient's, user's or other person's state of health
 - A serious public health threat
-

5.2 Mechanical Safety

WARNING

EN-W43



To prevent injury and equipment damage, use caution when moving the ExactVu system or accessories such as the monitor stand, especially when rolling the system over an uneven surface.

To prevent injury and equipment damage, use caution when adjusting movable parts of the ExactVu system.

WARNING
EN-W44



Ensure there are no obstructions near the control panel/monitor platform when adjusting its height or rotation.

If you observe unexpected behavior or noise in the performance of the control panel and/or monitor platform when adjusting its height or rotation, unplug the ExactVu system and contact Technical Support using the contact information in Appendix F.

WARNING
EN-W13



Do not lean or sit on the control panel or any other part of the ExactVu system. This could cause the system to become unstable and cause injury to the operator or patient.

5.3 Explosion Hazard

WARNING
EN-W42



The equipment is not designed to be used in potentially explosive environments. Do not operate the ExactVu system in the presence of flammable liquids or gases.

5.4 Electrical Safety

A potential equalization conductor terminal ("ground pin") is located on the IO plate. This is for use by qualified personnel only. Additional information is available in IEC 60601-1 section 8.6.7

WARNING
EN-W26



All equipment must be connected to a grounded AC power supply (or wall outlet) that meets EN/IEC/NEC requirements or applicable local regulations. The examination room's grounding system should be checked regularly by either a qualified electrician or other safety personnel.

CAUTION
EN-C3



Only use cables that have been specified by Exact Imaging as part of ExactVu or as being compatible with the ExactVu system.

If compatible replacement cables are required, contact Technical Support using the contact information in Appendix F.

WARNING
EN-W89



Extension cords and multiple-socket outlets must not be connected to the ExactVu system. The use of extension cords or multiple-socket outlets could result in improper operation of the ExactVu system.

WARNING
EN-W12



Inspect transducers often for cracks or openings in the transducer housing and connector, for scratches, and for holes in and around the acoustic lens or other damage that could allow liquid entry.

If the transducer housing or connector shows any cracking or sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix F.

Inspect the transducer cable for damage.

CAUTION
EN-C4



Do not spray or drip any liquid onto the ExactVu system's control panel, as this could affect reliable operation.

5.5 Interference

Installation procedures are to be performed by qualified Technical Support personnel only.

5.5.1 Electromagnetic Compatibility (EMC) Interference

Medical electrical equipment requires special precautions regarding EMC (electromagnetic compatibility). The following warnings and cautions must be observed when the ExactVu system is installed and put into service. If images are distorted, it may be necessary to position the ExactVu system further away from sources of electromagnetic interference or to install magnetic shielding.

WARNING
EN-W14



EMC noise can affect the quality of ultrasound images, which may lead to incorrect image interpretation. If the image is distorted, it may be necessary to position the ExactVu system further away from sources of electromagnetic interference.

WARNING
EN-W15



The use of accessories, transducers and cables other than those specified or provided by Exact Imaging could result in increased electromagnetic emissions or decreased electromagnetic immunity of the equipment and result in improper operation.

WARNING
EN-W17



Do not activate ExactVu transducers outside the patient's body if it would not comply with electromagnetic compliance requirements. It may cause harmful interference with other nearby equipment.

CAUTION
EN-C7



The ExactVu system may cause electromagnetic interference to nearby equipment. If necessary, reorient or relocate the equipment, or shield its location.

WARNING

EN-W16



Do not stack the ExactVu system with other equipment because it could result in improper operation.

5.5.2 Radio Frequency (RF) Interference

Portable and mobile RF (radio frequency) communication equipment could affect the ExactVu system, but the system will remain safe and meet its essential performance requirements.

The ExactVu system intentionally receives RF electromagnetic energy for the purpose of its operation. Its transducers are very sensitive to frequencies within their signal frequency range (0.15 MHz to 160 MHz). Therefore, it is possible for RF equipment operating in this frequency range to affect the ultrasound image. However, if disturbances occur, they appear as white lines or white haze in the ultrasound image and cannot be confused with physiological signals.

The ExactVu system complies with limits in Part 18 of the FCC Rules and for CISPR 11 Class A (as outlined in IEC 60601-1-2, edition 4.0). These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The ExactVu system generates, uses, and can radiate radio frequency energy. If the ExactVu system is not installed and used in accordance with this *Operation and Safety Manual*, it may cause harmful interference to radio communications.

Operation of this equipment in a residential area may cause harmful interference, in which case the operator will be required to correct the interference (for example, by reorienting or relocating the ExactVu system or by increasing the distance between the interfering equipment and the ExactVu system).

WARNING

EN-W18



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used in close proximity to any part of the ExactVu system, including cables specified by Exact Imaging. Otherwise, degradation of the performance of the equipment could result.

CAUTION

EN-C8



The ExactVu system may cause radio interference to nearby equipment. If necessary, reorient or relocate the equipment, or shield its location.

5.5.3 Electrical Noise

WARNING

EN-W19



Electrical noise from nearby devices (such as electrosurgical devices or devices that can transmit electrical noise to the AC line) may cause degradation of the ultrasound images.

5.6 MR (Magnetic Resonance) Safety

WARNING

EN-W83



The ExactVu system is MR Unsafe. It represents a projectile hazard. Keep it outside the MRI scanner room.

5.7 Bio-safety

5.7.1 General Bio-safety

WARNING

EN-W20



To avoid cross-contamination, follow all internal clinical procedures for infection control for personnel and equipment.

WARNING

EN-W21



Failure to properly clean transducers and applicable accessories carries a risk of infection to patients, due to residual microbial contamination.

WARNING

EN-W35



To prevent possible infection or contamination, the transducer must be reprocessed following the complete procedure in the applicable *Care, Cleaning and Use Guide* for the transducer prior to using it in another procedure.

Always use a sterile sheath or endocavity balloon during the procedure.

5.7.2 TRUS Bio-safety

WARNING

EN-W40



Reprocess transrectal transducers as soon as possible after use to prevent biological materials from drying on them.

CAUTION

EN-C60



The Exact Imaging transducers and the EV29L Reusable Transrectal Needle Guide are not designed and validated to withstand a reprocessing method that uses an automated reprocessor, with the exception of those identified on the Material Compatibility List.

WARNING

EN-W22



Before putting a reprocessed transducer into the transducer holder on the ExactVu system cart, ensure the holder is clean to avoid the risk of cross-contamination.

WARNING
EN-W83

Do not use any needle guide if it appears to be damaged.

If a needle guide shows any sign of damage, contact Technical Support using the contact information in Appendix F.

5.7.3 Transperineal Bio-safety

WARNING
EN-W63

To prevent possible infection or contamination, the transperineal stepper must be reprocessed following the complete procedure referenced in *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer* before its first use and prior to using it in another procedure.

WARNING
EN-W59

Some components of the transperineal stepper must be disinfected or sterilized before first use.

Refer to the manufacturer's instructions for the transperineal stepper to determine whether it must be disinfected or sterilized before its first use.

WARNING
EN-W58

Refer to the manufacturer's instructions for the transperineal stepper to determine which of its components must be disinfected or sterilized before and after each use.

WARNING
EN-W60

Do not store a reprocessed transducer on the transperineal stepper unless the stepper has been reprocessed following the procedure referenced in *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

WARNING
EN-W64

After checking the vertical height of the transperineal stepper, the reprocessing procedure referenced in *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer* must be performed prior to using the stepper in a procedure.

The transperineal *needle guide overlays* are intended to assist the operator to visualize the approximate needle path. However, the actual needle movement may deviate from the overlays. Always monitor the relative positions of the biopsy needle and the tissue target during the procedure.

WARNING
EN-W57

For transperineal procedures, ensure there is alignment between the position on the needle guide overlay and the needle entrance position on the physical EV29L sterile transperineal needle guide or template grid.

The use of a small preset may prevent visualization of needles inserted through the deepest needle entrances (i.e., the highest numbered needle entrances). If the needle is not visible, changing the image depth may help to ensure the needle is displayed.

WARNING
EN-W65

Never reuse the EV29L sterile transperineal needle guide or a single-use template grid. Re-use of a single-use device carries a risk of infection to patients, due to residual microbial contamination.

After procedures using the EV29L sterile transperineal needle guide or a single-use template grid, discard the device according to internal clinical procedures for safe disposal.

WARNING
EN-W66

After checking the needle path alignment for the transperineal stepper, the cleaning, disinfection and sterilization procedure referenced in *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer* must be performed prior to using the stepper in a procedure.

5.7.4 Kidney, Bladder and Pelvis Bio-safety**WARNING**
EN-W77

The EV5C is not intended for direct use on the heart.

5.7.5 Precautions Concerning Biopsy Procedures**WARNING**
EN-W31

The use of damaged transducers can result in injury or increased risk of infection. Inspect transducers often for sharp, pointed, or rough surface damage that could cause injury to the patient or increased risk of infection.

WARNING
EN-W80

The use of damaged transducers may cause the reprocessing procedure in the applicable *Care, Cleaning and Use Guide* for the transducer to be ineffective.

If the transducer shows any sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix F.

WARNING
EN-W29

If air bubbles or wrinkles occur near the point where the needle exits the needle guide, the sheath may be punctured by the needle during biopsy and may increase the risk of infection.

If the sheath is punctured by the needle, discard it and re-prepare the transducer as described in the applicable *Care, Cleaning and Use Guide* for the transducer.

WARNING
EN-W33

Do not freeze the image during a biopsy procedure. The image must be live to provide real-time biopsy guidance and to avoid a positioning error.

WARNING

EN-W51



Do not proceed with a biopsy procedure if the ultrasound image is seriously degraded or compromised.

WARNING

EN-W34



The needle guide overlay is intended to assist the operator to visualize the approximate needle path. However, the actual needle movement may deviate from the needle guide overlay. Always monitor the relative positions of the biopsy needle and the tissue target during the procedure.

WARNING

EN-W47



Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some patients.

Exact Imaging recommends using a latex-free sheath for patients identified as latex-sensitive or talc-sensitive.

Be prepared to treat allergic reactions promptly.

WARNING

EN-W28



Always wear gloves when handling sterile items.

WARNING

EN-W72



Do not use the EV29L reusable transrectal needle guide to perform a biopsy for a patient diagnosed with variant Creutzfeldt-Jakob disease (vCJD).

For transrectal procedures, use only the single-use needle guide, or alternatively, follow a transperineal protocol to perform the biopsy for a patient with this disease.

5.7.6 Precautions Concerning Consumables

WARNING

EN-W56



Never reuse the single-use endocavity balloon. Re-use of a single-use device carries a risk of infection to patients, due to residual microbial contamination.

After use, discard the endocavity balloon according to internal clinical procedures for safe disposal.

WARNING

EN-W49



To ensure optimal performance of the ExactVu™ High Resolution Micro-Ultrasound system, use only the accessories and consumables listed in this document and other ExactVu instructions for use listed in Table 1 on page 11.

WARNING

EN-W4



Do not use a single-use needle guide or any component of a needle guide package or kit if its packaging indicates its expiry date has passed.

Operators are responsible for adhering to internal clinical procedures regarding checking for and disposing of expired consumables.

WARNING
EN-W5



Do not use the *EV29L Sterile Transrectal Needle Guide*, any component of the *CIVCO® Disposable Endocavity Needle Guide Kit* or any component of the *CIVCO® Verza Guidance System* if the packaging appears to be compromised.

Discard the component and its packaging according to internal clinical procedures for safe disposal.

5.8 System

5.8.1 System

CAUTION
EN-C9



Exact Imaging recommends a virus check be performed prior to connecting a USB storage device to the ExactVu system to ensure it is virus-free. Exact Imaging does not take responsibility for computer viruses from USB storage devices that may infect the ExactVu computer.

CAUTION
EN-C52



Exact Imaging recommends the use of an encrypted USB device for archiving and exporting studies.

5.8.2 Network

WARNING
EN-W23



If the ExactVu system is connected to a network that has not been isolated, there is a risk of electric shock in the event of a power surge.

Exact Imaging recommends the use of a network isolator when connecting the ExactVu system to a network.

CAUTION
EN-C10



When the ExactVu system is connected to a clinic's network, Exact Imaging does not take responsibility for computer viruses from the network that may infect the system's computer.

6 Accuracy of Measurements

This section provides the accuracies for measurements made using the ExactVu system, with the specific values described in Table 12. All errors are based on linear measurements. Calculations such as area and volume that combine multiple line segment measurements will have compounded errors.

Meas. Type	Degree of Accuracy	Effective Range	Effective Range	Degree of Accuracy	Effective Range
	EV29L and EV9C	EV29L	EV9C	EV5C	EV5C
Distance	± Maximum of (6% or 0.08 cm)	0 – 5.0 cm	0 – 8 cm	± Maximum of (6% or 0.16 cm)	0 – 18 cm

Meas. Type	Degree of Accuracy	Effective Range	Effective Range	Degree of Accuracy	Effective Range
	EV29L and EV9C	EV29L	EV9C	EV5C	EV5C
Area	± Maximum of (8% or 0.21 cm ²)	0 – 18 cm ²	0 – 69 cm ²	± Maximum of (8% or 0.88 cm ²)	0 – 336 cm ²
Volume	± Maximum of (15% or 0.43 cc)	0 – 60 cc	0 - 500 cc	± Maximum of (15% or 3.60 cc)	0 – 5594 cc

The stated accuracy applies to area measurements created using orthogonal line segments. An area measurement is most accurate when its constituent line segments are orthogonal.

The stated accuracy applies to volume measurements created using orthogonal line segments and assuming the prostate is well represented by a 3-dimensional ellipsoid. Every degree away from orthogonality introduces inaccuracy due to violation of the assumption that the area being measured is an ellipse with major and minor axes along the measurement lines.

A volume measurement is most accurate when its constituent line segments are orthogonal.

The accuracy of the calculated PSA Density value (denoted on the imaging screen as *PSAD*) depends on both the accuracy of the PSA value used as well as the accuracy of the volume measurement.

The accuracy of the alignment function in *FusionVu* features depends on the variability of the motion sensor in the EV29L transducer (angle accuracy ± 5 degrees). Refer to Chapter 8 for information about *FusionVu*.

Table 12: ExactVu Measurement Accuracy

A variety of sources of error were considered in the determination of the measurement accuracy reported in Table 12. These include:

- Limitation of spatial resolution, transducer resolution, and display resolution (depending on the transducer type)
- Rounding of reported values, in that values are rounded for display to include 2 decimal places
- Motion sensor variability in transverse image construction (angle accuracy ± 5 degrees) (applies to the EV29L transducer only)
- Transducer array geometric tolerance affecting lateral measurements

For real time tissue imaging, other errors that may contribute to the reported accuracy of the measurements are:

- Variability in the sound velocity in tissue, based on an assumption of “ideal” prostate tissue. The ExactVu system uses an average sound velocity of 1560 m/s, though the sound velocity in the prostate may vary up to 2-3%
- Refraction occurring at tissue boundaries

When making clinical measurements with ultrasound, human errors may arise. These may be caused by:

- Inaccurate positioning of measurement calipers on a structure in the image
- Non-orthogonality of line segments in area and volume measurements

Another error contributing to the area and volume accuracy derives from algorithm error:

- The use of the standard assumption that the measured structure approximates an ellipse in

area measurements and an ellipsoid in volume measurements, which may result in decreased measurement accuracy for structures that deviate from this approximation

6.1 Accuracy of On-Screen Overlays

The operator should be aware of the effect of deflection of the needle when performing biopsy procedures.

Transperineal needle guide overlay

The accuracy of EV29L Transperineal Needle Guide when used with the with EV29L transducer and an 18 GA needle compared to the transperineal *needle guide overlay* (refer to Chapter 5, section 3.1 on page 116) is ± 1 mm when the *needle guide tower* is positioned closest to the transducer lens and it is ± 1.5 mm when the *needle guide tower* is positioned at its furthest distance from the transducer lens.

Transrectal needle guide overlay

The accuracy of the EV29L Sterile Transrectal Needle Guide when used with the with EV29L transducer and an 18 GA biopsy needle or a 22 GA anesthesia needle compared to the available transrectal *needle guide overlays* (refer to Chapter 5, section 2.3.1 on page 113) is ± 1 mm when measured at the center of the image width.

The accuracy of both the 18 GA and 16 GA variants of the EV29L Non-sterile Reusable Transrectal Needle Guide when used with the with EV29L transducer and the corresponding needle compared to the transrectal *needle guide overlay* (refer to Chapter 5, section 2.3.1 on page 113) is ± 1 mm when measured at the center of the image width.

7 Operating Specifications

7.1 ExactVu Micro-Ultrasound System and Transducers

Operating Environment	Details
Electrical ExactVu system and ExactVu transducers	North America
	<ul style="list-style-type: none"> • 110-120 VAC • 50/60 Hz • 600 VA Max Power Draw
	Europe
	<ul style="list-style-type: none"> • 220-240 VAC • 50/60 Hz • 600 VA Max Power Draw
	Japan
	<ul style="list-style-type: none"> • 100 VAC • 50/60 Hz • 600 VA Max Power Draw
	Electrical components of the ExactVu system are attached to an isolation transformer through a series of IEC power connectors. The isolation transformer protects the ExactVu system and the operator against electric shock and power surges and is located inside the ExactVu system cart.

Environmental (Operating) ExactVu system and ExactVu transducers	<p>Temperature</p> <ul style="list-style-type: none"> • 10 °C to 35 °C (50 °F to 104 °F) <p>Humidity</p> <ul style="list-style-type: none"> • 15% to 80% non-condensing <p>Atmospheric Pressure (at altitudes less than 2000 m)</p> <ul style="list-style-type: none"> • 80 kPa to 106 kPa
Environmental (Storage) ExactVu system and ExactVu transducers	<p>Temperature</p> <ul style="list-style-type: none"> • -20 °C to 50 °C (-4 °F to 122 °F) <p>Relative Humidity</p> <ul style="list-style-type: none"> • 15% to 95% non-condensing <p>Atmospheric Pressure</p> <ul style="list-style-type: none"> • 50 kPa to 106 kPa
Environmental (Transportation) ExactVu system	<p>Temperature</p> <ul style="list-style-type: none"> • -20 °C to 50 °C (-4 °F to 122 °F) <p>Relative Humidity</p> <ul style="list-style-type: none"> • 15% to 85% non-condensing <p>Atmospheric Pressure</p> <ul style="list-style-type: none"> • 50 kPa to 106 kPa
Environmental (Transportation) ExactVu transducers	<p>Temperature</p> <ul style="list-style-type: none"> • -20 °C to 50 °C (-4 °F to 122 °F) <p>Relative Humidity</p> <ul style="list-style-type: none"> • 15% to 95% non-condensing <p>Atmospheric Pressure</p> <ul style="list-style-type: none"> • 50 kPa to 106 kPa

Table 13: ExactVu System and Transducer Operating and Storage Environment

7.2 EV29L Sterile Transrectal and Transperineal Needle Guides

Operating Environment	Details
Environmental (Operating and Storage)	<p>Temperature</p> <ul style="list-style-type: none"> • 11 °C to 29 °C (52 °F to 85 °F)

Table 14: ExactVu Sterile Transrectal and Transperineal Needle Guide Operating and Storage Environment

7.3 EV29L Non-sterile Reusable Transrectal Needle Guide

Operating Environment	Details
Environmental (Operating and Storage)	<p>Temperature</p> <ul style="list-style-type: none"> • -20 °C to 50 °C (-4 °F to 122 °F)

Table 15: ExactVu EV29L Non-sterile Reusable Transrectal Needle Guide Operating and Storage Environment

Chapter 3 Getting Started with the ExactVu System

1 System Setup and Installation

Prior to using the ExactVu system, there are several preparatory activities to ensure that the system will provide a high-quality experience, both in terms of optimizing the images it produces, and in the ease of system use.

1.1 Determining Installation Location

Install the ExactVu system in the examination room so that it is situated beside the examination table. Operators can stand or sit to operate the ExactVu system. The emissions characteristics of the ExactVu system make it suitable for use in industrial areas and hospitals, as per classification *CISPR 11 class A*. The ExactVu system must be installed in an environment that meets the operating specifications in Chapter 2, section 7.1 on page 52.

WARNING
EN-W26



All equipment must only be connected to a grounded AC power supply (or wall outlet) that meets EN/IEC/NEC requirements or applicable local regulations. The examination room's grounding system should be checked regularly by either a qualified electrician or other safety personnel.

Use the *grab bar* at the rear of the ExactVu system cart or the *control panel handle* when moving the ExactVu system (refer to Figure 1).

To move the ExactVu system:

1. If applicable, disconnect the power cable from the wall outlet.
2. Check that the ExactVu transducers are secure in the *transducer holders* (if they are not stored elsewhere).
3. Unlock the *castors*.
4. Push the ExactVu system using the *grab bar* or *control panel handle*.

CAUTION
EN-C11



Use caution when moving the ExactVu system around corners. Ensure there is sufficient distance between walls and all parts of the ExactVu system.

5. When the ExactVu system is in its desired location, lock the *castors*.

CAUTION
EN-C12



Do not use the *grab bar* to lift the ExactVu system. It is not designed to bear the weight of the system.

WARNING
EN-W25



To prevent injury or damage to the ExactVu system or accessories such as the monitor stand, ensure that all *castors* are locked whenever the ExactVu system and monitor stand are not being moved.

1.2 Connecting Components

On-site assembly is performed by Technical Support technicians during installation of the ExactVu system. There are no components that need to be connected by operators, other than transducers (refer to section 2.3.1 on page 70) and USB storage devices (refer to section 1.4 on page 56).

1.3 Connecting Power to the ExactVu System

The ExactVu system is equipped with an AC power cable with the appropriate plug for a wall outlet, and lock buttons that securely connect the power cable to the ExactVu system.

WARNING

EN-W89



Extension cords and multiple-socket outlets must not be connected to the ExactVu system. The use of extension cords or multiple-socket outlets could result in improper operation of the ExactVu system.

To connect power to the ExactVu system:

1. Ensure the *main power switch* (i.e., the rocker switch on the bottom rear panel shown in Figure 6) in the *OFF* position and the *system power control* is unlit.
2. Connect the AC power cable into the ExactVu system power cable receptacle (beside the *main power switch*) (refer to Figure 6).

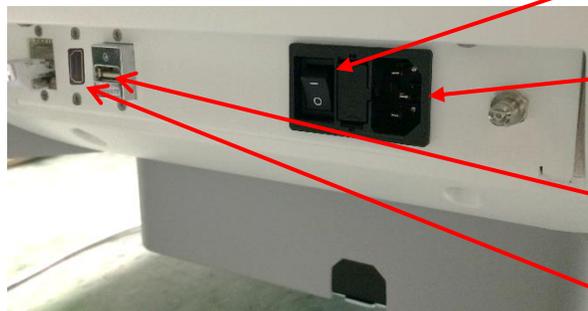


Figure 6: ExactVu System Power

Main power switch (in the OFF position)

ExactVu system power cable receptacle

USB connector for foot pedal

Second monitor output (HDMI) connector

3. Connect the plug end of the AC power cable to the wall outlet.
4. Switch the *main power switch* to the *ON* position.

To disconnect power from the ExactVu system:

1. Switch the *main power switch* to the *OFF* position.
The *system power control* on the front of the ExactVu system is unlit.
2. Unplug the AC power cable from the wall outlet.

CAUTION

EN-C3



Only use cables that have been specified by Exact Imaging as part of ExactVu or as being compatible with the ExactVu system.

If compatible replacement cables are required, contact Technical Support using the contact information in Appendix F.

1.4 Connecting a USB Storage Device

A USB storage device may be connected to the ExactVu system using any of the following:

- the connectors on the side of the touch screen
- the connectors on the rear of the monitor (available in some ExactVu system configurations)

If the *FusionVu* option is configured on the ExactVu system, a DVD drive may also be connected to a USB connector for importing MR (magnetic resonance) study data (refer to Chapter 8).

To connect a USB storage device to the ExactVu system:

- Connect the USB storage device to one of the USB connectors on the left side of the touch screen (refer to Figure 7) or on the rear of the monitor (refer to Figure 8).

The ExactVu system detects the USB storage device, and makes it available for study export and message log export operations.



Figure 7: USB Connectors on the Left Side of the Touch Screen

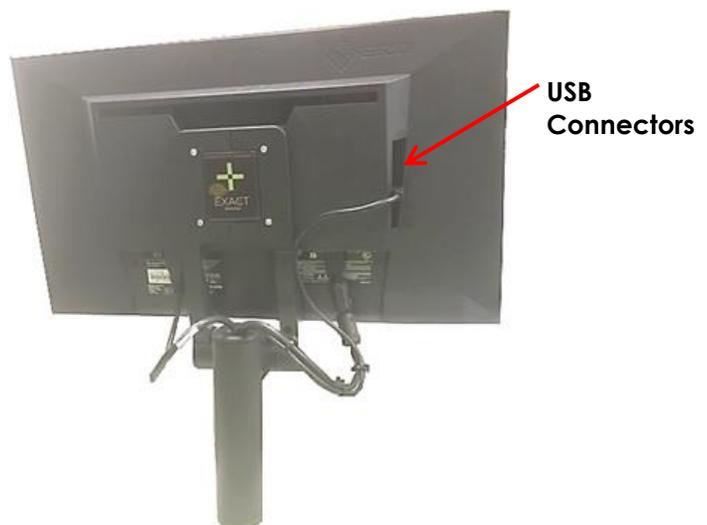


Figure 8: USB Connectors on the Rear of the Monitor (available in some ExactVu system configurations)

CAUTION
EN-C42



Exact Imaging recommends that USB storage devices be formatted to the FAT32 file system, using a format that supports large USB drives and storage of files greater in size than 4 GB (such as exFAT by Microsoft).

CAUTION
EN-C9



Exact Imaging recommends a virus check be performed prior to connecting a USB storage device to the ExactVu system to ensure it is virus-free. Exact Imaging does not take responsibility for computer viruses from USB storage devices that may infect the ExactVu computer.

NOTE
EN-N51



At the bottom rear of the ExactVu system cart there is an additional USB connector to which a USB storage device may be connected. Multiple USB storage devices are not supported for export operations.

1.5 Setting up the Control Panel/Monitor Platform

To optimize comfort when using the ExactVu system, the operator may adjust the height of the platform that supports the control panel and monitor (refer to Figure 9 and Figure 10).

Some ExactVu systems may not support the horizontal rotation of the control panel/monitor platform.

To raise the control panel/monitor platform height:

- Press the up arrow on the *control panel height control* indicated in Figure 9.

To lower the control panel/monitor platform height:

- Press the down arrow on the *control panel height control*.



Figure 9: Control Panel/Monitor Height



Figure 10: Control Panel/Monitor Height

WARNING
EN-W44



To prevent injury and equipment damage, use caution when adjusting movable parts of the ExactVu system, specifically the control panel/monitor platform.

Ensure there are no obstructions near the control panel/monitor platform when adjusting its height or rotation.

If you observe unexpected behavior or noise in the performance of the control panel and/or monitor platform when adjusting its height or rotation, unplug the ExactVu system and contact Technical Support using the contact information in Appendix F.

To rotate the control panel/monitor platform horizontally (applicable only if your ExactVu system is equipped):

1. Pull the *control panel swivel handle* out from the cart.

2. Rotate the control panel/monitor platform to the desired position and release the control panel swivel handle.

The control panel/monitor platform may be rotated to the left or right up to 15°.

NOTE
EN-N119



The operator may adjust the height and rotation of the platform that supports the control panel and monitor even when the ExactVu system is powered off.

1.6 Connecting an Optional (Second) Monitor

Some ExactVu systems may not be equipped with an HDMI connector. This section is applicable only to ExactVu systems that have an HDMI connector.

The bottom rear of the ExactVu system cart provides a second monitor output (HDMI) connector that may be used to connect a second monitor.

To connect a second monitor to the ExactVu system:

1. Insert the HDMI cable into the second monitor output connector at the bottom rear of the ExactVu system cart (refer to Figure 11).
2. Connect the other end of the HDMI cable into the HDMI input connector on the second monitor.
3. Power on the second monitor and set its input to indicate HDMI mode (or similar setting).

Both the ExactVu monitor and the second monitor show the same output from the ExactVu system.



Second monitor output (HDMI) Connector

Figure 11: Second monitor output (HDMI) Connector

CAUTION
EN-C55



Exact Imaging recommends connecting only monitors configured with 1920 x 1080-pixel resolution to the ExactVu system, and using an HDMI certified cable with a maximum length of 16'4" (5 meters).

WARNING
EN-W86



Use only the monitor(s) identified in Chapter 1, section 6.1.3 for clinical applications and image quality assessment.

Other monitors connected to the ExactVu system via its HDMI connection are only to be used for duplicating the screen display and are not to be used for clinical purposes.

The second monitor may be mounted on the optional accessory, *GCX VHRS Series Variable Height Roll Stand*. Refer to Chapter 1, section 9.3 on page 25 for the manufacturer's specifications. To assemble the monitor stand and connect the second monitor to it, refer to the assembly instructions and the manufacturer's information provided with the monitor stand kit, observing all warnings and cautions.

After the monitor stand has been assembled, the height and tilt orientation of a connected monitor may be adjusted.

To adjust the height and tilt orientation of a second monitor connected to the GCX VHRS Series Variable Height Roll Stand:

1. Disconnect the HDMI cable and C-13 power cable from the second monitor if it was already in use and connected to a power outlet.
2. Ensure the monitor is secured to the mounting plate.
3. Use the provided hex key to loosen the two tilt tension screws and tilt the monitor to the desired orientation. Use caution when performing this action because the monitor can be damaged by quick and sudden movements.
4. Turn the variable height adjustment knob slowly to adjust the height of the stand. Use caution when doing this because the stand may rise quickly if the height adjustment knob is loosened too quickly.
5. After the monitor is positioned at the desired height and tilt orientation, re-connect the HDMI cable and the C-13 power cable to the monitor.
6. Adjust the cable management clips as necessary to ensure the wires are secured to the post of the monitor stand.

WARNING

EN-W25



To prevent injury or damage to the ExactVu system or accessories such as the monitor stand, ensure that all castors are locked whenever the ExactVu system and monitor stand are not being moved.

WARNING

EN-W43



To prevent injury and equipment damage, use caution when moving the ExactVu system or accessories such as the monitor stand, especially when rolling the system over an uneven surface.

WARNING

EN-W87



Loose-hanging device cables pose a potential tripping hazard.

Arrange cables so that it is not possible to trip over them, particularly when moving the ExactVu system or monitor stand.

1.7 Setting up System Preferences

Chapter 12 provides detailed information about how to set up *system preferences*, such as the system date and time, and clinic information as well as to review details of the end user license agreement.

This section discusses setup of preferences for *system security* and network configuration (including PACS and DICOM) only.

1.7.1 System Security

The ExactVu system provides an optional system security feature that requires the operator to enter a security password to access secured features, which are features that display patient data.

The following are secured features in the ExactVu system:

- Patient/Study screen
- Preferences > Security screen

NOTE
EN-N13



For HIPAA compliance, the system security feature is recommended.

To toggle system security:

1. Press **Preferences** on the control panel.
2. Select the *Security* screen.
The *Security* screen is displayed.
3. Select **ON** or **OFF** next to *Enable Security*.
System security toggles on or off as selected.
4. Select **Save**.
The changes made are saved.

When system security is enabled (i.e., toggled on), a security password is required to access secured features if the operator hasn't accessed a secure feature within the security timeout specified. System security allows operators to meet HIPAA obligations when using the ExactVu system.

To set a Security Password and Security Timeout:

1. Enable system security.
2. Type a Security Password:
 - The security password must be 4 to 16 characters in length
 - If no security password is specified, the default security password 1234 is used
3. Select a Security Timeout from the Security Timeout dropdown:
 - Options are 15, 30 or 60 minutes
4. Select one of the following:
 - Select **Save** to save changes made in all *Preferences* tabs. A security password is required to access secured features.
 - Select **Close** to close *Preferences* without saving changes. The ExactVu system returns to the screen it displayed prior to *Preferences*.



Figure 12: System Security Password and Timeout

NOTE
EN-N14



The factory default security password is 1234. If system security is toggled on without entering a new security password, the security password 1234 must be entered in order to use secured features.

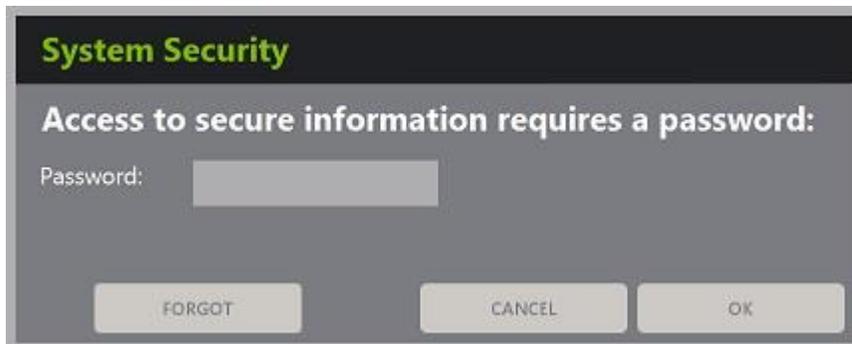
1.7.1.1 Using the Security Password

When the system security option is enabled, a System Security dialog is displayed when the operator

attempts to access secured features.

To access secured features using the Security Password:

1. Without having previously entered the Security Password, attempt to access a *secured feature*.
The *System Security* dialog is displayed.



2. Type the *Security Password*.

NOTE
EN-N15



Security password characters are hidden.

3. Press **OK**.

The *System Security* dialog closes, and the secured feature being accessed is displayed.

All *secured features* in the ExactVu system are accessible for the duration of the security timeout specified in the *Security* screen in *Preferences*.

The ExactVu system returns to a state of requiring the security password to be entered when no *secured feature* has been accessed for a period longer than the duration of the security timeout.

NOTE
EN-N16



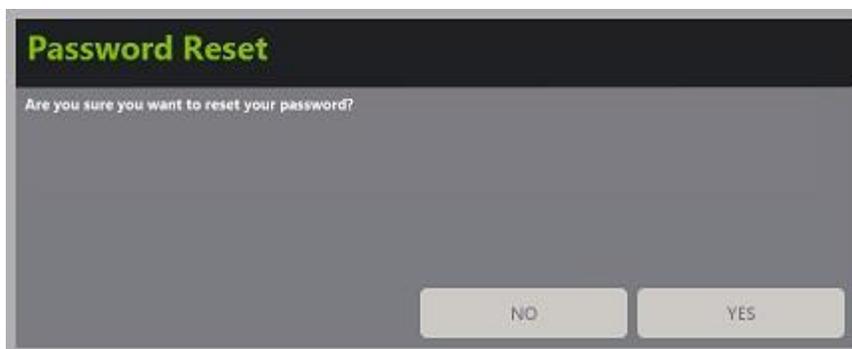
If an incorrect *Security Password* is used, the operator is prompted to re-enter the security password. If an incorrect security password is entered three consecutive times, the *System Security* dialog closes and the previous screen is displayed.

1.7.1.2 Resetting the Security Password

If the security password is forgotten, the procedure to reset the security password requires the assistance of Technical Support.

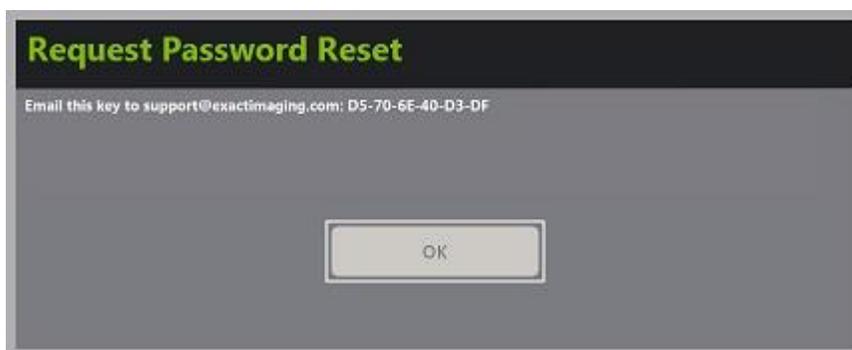
To reset a forgotten security password:

1. Shut down and restart the ExactVu system.
2. When the ExactVu system restarts, press **Patient/Study** on the control panel.
The *System Security* dialog is displayed.
3. Select **Forgot**.
The *Password Reset* dialog is displayed.



4. Select **Yes**.

The *Request Password Reset dialog* is displayed, providing a reset key in the form xx-xx-xx-xx-xx-xx, where each character is case-sensitive. Copy the reset key.



5. Contact Technical Support using the contact information in Appendix F and provide the reset key. Indicate that a reset password is required.
6. When Exact Imaging provides a reset password, press **Patient/Study** on the control panel. The *Patient/Study* screen opens.
7. Enter the reset password provided by the Exact Imaging technician.
8. Change the password to one that is easily remembered using the procedure in section 1.7.1 on page 59.

1.7.2 DICOM and Network Connection

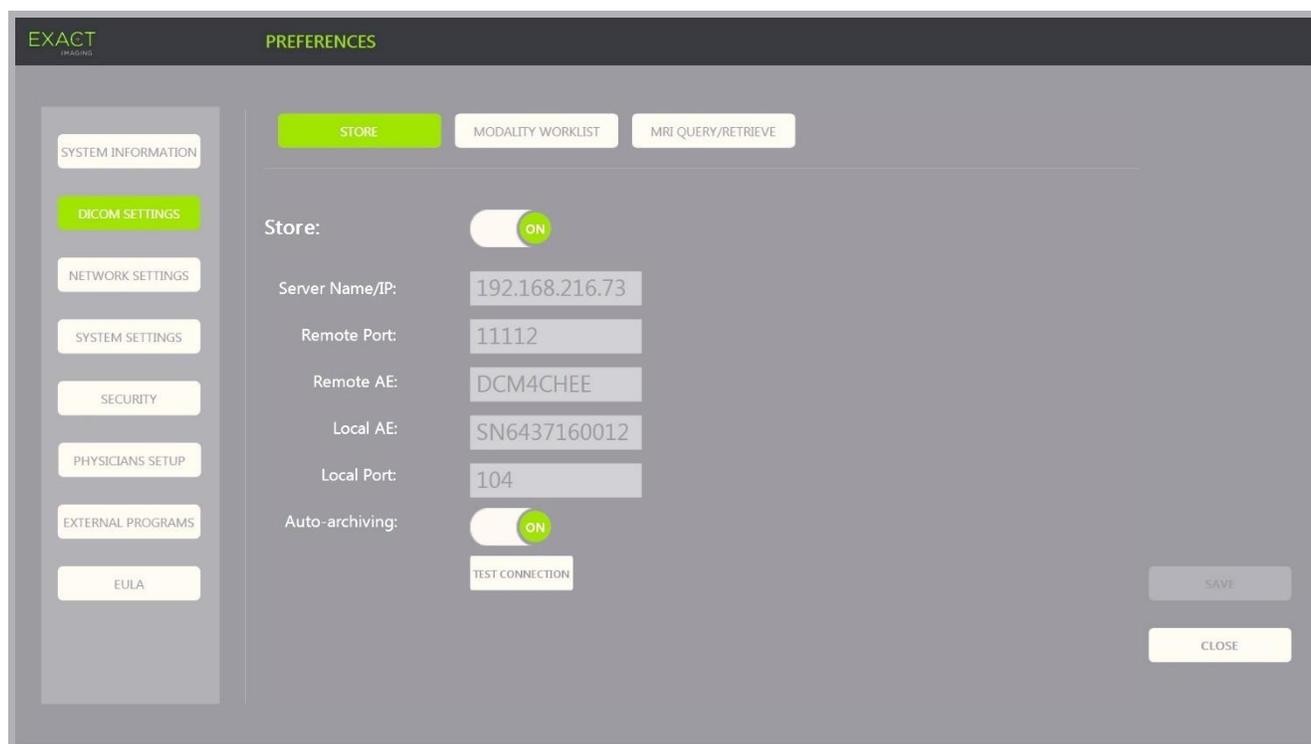
NOTE
EN-N150



Exact Imaging recommends that network configuration be performed by IT professionals. Values used in *Preferences > DICOM Settings* and in *Preferences > Network Settings* must be assigned by the clinic's IT department prior to performing this configuration.

1.7.2.1 Configuring DICOM Settings

Configuration of DICOM and PACS (Picture Archiving and Communication System) server settings for DICOM Store, Modality Worklist and MRI Query/Retrieve is performed in the *Preferences > DICOM Settings* screen.

To specify DICOM Store configuration settings:**Figure 13: DICOM Store Settings Configuration**

1. Press **Preferences** on the control panel.
Preferences > System Information is displayed.
2. Select **DICOM Settings**.
The *DICOM Settings* screen is displayed displaying the following options across the top:
 - Store
 - Modality Worklist
 - MRI Query/Retrieve
3. Configure *DICOM Store* as follows:
 - Select the **Store** control
 - Specify the *Server Name/IP*
 - Specify the *Remote Port* (default is 104)
 - Specify the *Remote AE* (Application Entity)
 - Specify the *Local AE*
4. Toggle *Auto-archiving* for completed studies ON or OFF:
 - To configure the system so that studies with *PACS Status* set to *Pending* are archived to the configured PACS server as a background process, toggle *Auto-archiving* to **ON**.
 - To configure the system to require that studies be exported manually to a PACS server, toggle *Auto-archiving* to **OFF**.

5. Toggle *DICOM Store* ON or OFF:

- Toggle the *DICOM Store* option to **ON** to enable export to a PACS server
- Toggle the *DICOM Store* option to **OFF** to disable export to a PACS server

When *DICOM Store* is *ON*, the *PACS Status* is automatically set to *Pending* when the study is closed, provided at least one image is saved in the study and *Auto-archiving* is toggled **ON**.

6. Test the connection to the PACS server:

- With *Store* toggled *ON*, press **Test Connection**.

A *DICOM C-Echo* connection test is performed, and the results of the test are displayed.

If errors are displayed check the *DICOM* settings. Make any corrections and repeat the test.

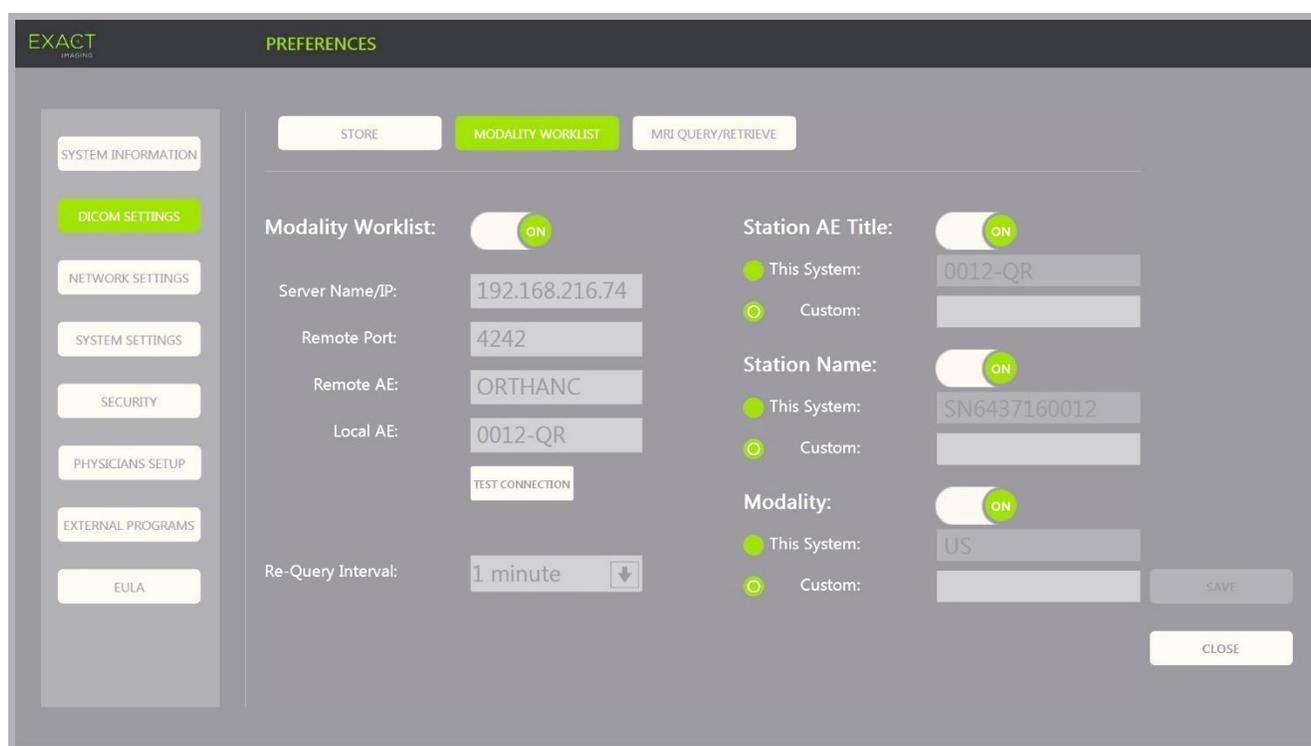
To specify Modality Worklist configuration settings:

Figure 14: DICOM Modality Worklist Settings Configuration

1. Specify *DICOM Modality Worklist* settings:

- Select the **Modality Worklist** control from the *DICOM Settings* screen
- Specify the *Server Name/IP*
- Specify the *Remote Port*
- Specify the *Remote AE*
- Specify the *Local AE*

2. Test the connection to the Modality Worklist server:

- With *Modality Worklist* toggled *ON*, press **Test Connection**.

A test is performed to confirm the connection between the specified server and Local AE. The results of the test are displayed.

If errors are displayed check the DICOM settings. Make any corrections and repeat the test.

3. Select a *Re-query Interval* configuration option from the dropdown. The default option is *No re-query*.
4. Specify values for at least one *Query Attributes Configuration Parameter* and toggle it to **ON**:
 - Station AE Title
 - Station Name
 - Modality
5. Toggle *DICOM Modality Worklist* ON or OFF:
 - Toggle the *Modality Worklist* option to **ON** to enable querying patient procedures from a PACS server
 - Toggle the *Modality Worklist* option to **OFF** to disable querying patient procedures from a PACS server

NOTE
EN-N180



The Modality Worklist feature is disabled if the *Server Name/IP* is not provided in *Preferences > DICOM Settings*.

To specify MRI Query / Retrieve configuration settings:

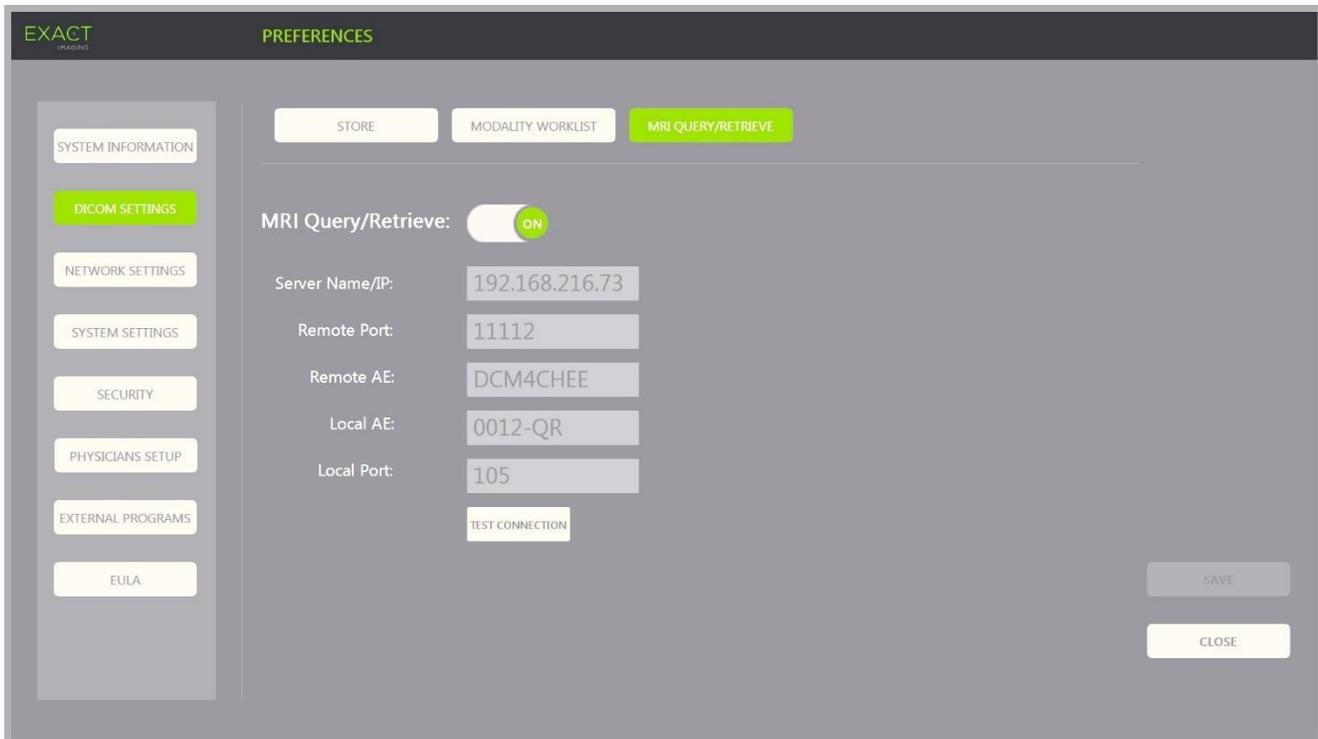


Figure 15: DICOM MRI Query/Retrieve Settings Configuration

1. Specify *DICOM MRI Query/Retrieve* settings:

- Select the **MRI Query/Retrieve** control from the *DICOM Settings* screen
 - Specify the *Server Name/IP*
 - Specify the *Remote Port* (default is 104)
 - Specify the *Remote AE*
 - Specify the *Local AE*
 - Specify the *Local Port* (default is 105)
2. Toggle *DICOM MRI Query/Retrieve* ON or OFF:
- Toggle the *MRI Query/Retrieve* option to **ON** to enable retrieval of images from the remote DICOM server
 - Toggle the *MRI Query/Retrieve* option to **OFF** to disable retrieval of images from the remote DICOM server
3. Test the connection to the PACS server:
- With *MRI Query/Retrieve* toggled ON, press **Test Connection**.
A *DICOM C-Echo* connection test is performed, and the results of the test are displayed.
If errors are displayed check the DICOM settings. Make any corrections and repeat the test.

To save changes to any DICOM Configuration:

- Select **Save**.

The operator is prompted to confirm new settings if changes were made. Pressing **Yes** saves the changes.

1.7.2.2 Configuring Network Settings

Configuration of network settings is performed in the *Preferences > Network Settings* screen.

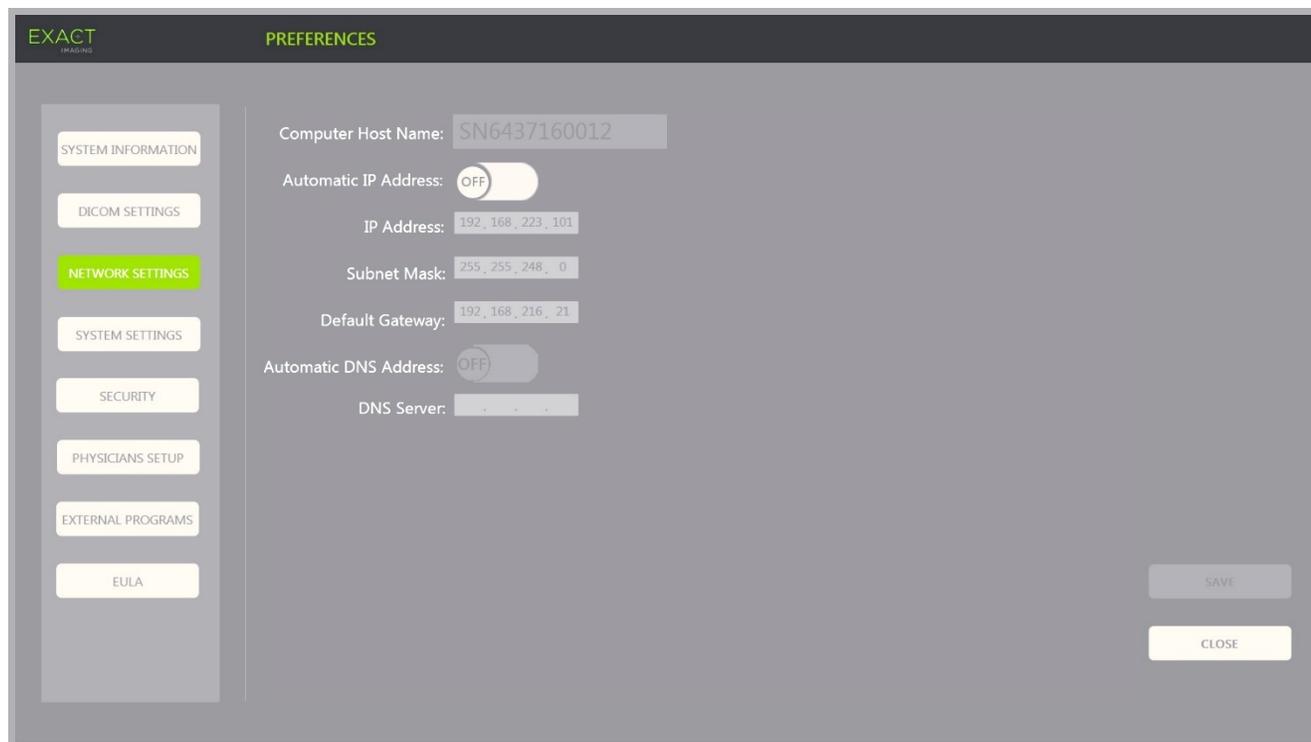


Figure 16: Network Settings on Preferences > Network Settings

To specify network configuration settings:

1. Press **Preferences** on the control panel.
Preferences > System Information is displayed.
2. Select **Network Settings**.
The *Network Settings* screen is displayed.
The *Computer Host Name* for the ExactVu computer is configured by Exact Imaging.

NOTE EN-N17



The *Computer Host Name* identifies the ExactVu system on a network.

3. To obtain an IP address using Dynamic Host Configuration Protocol (DHCP), toggle *Automatic IP Address* to **ON**.
Automatic IP Address toggles **ON** and the IP address is automatically obtained using DHCP.
4. To specify a static *IP Address*, toggle *Automatic IP Address* to **OFF**. Enter the values assigned by the clinic's IT department below:
 - Type the *IP Address* for the ExactVu network connection using the touch screen's keyboard.
 - Type the *Subnet Mask* for the ExactVu network connection using the touch screen's keyboard.
 - Type the *Default Gateway* for the ExactVu network connection using the touch screen's keyboard.

NOTE

EN-N19



The ExactVu system may be configured to automatically obtain the IP address using DHCP or to specify a static IP address, but not both.

NOTE

EN-N149



If the ExactVu system is connected to a network that supports DHCP, it may be necessary to disconnect the network cable and restart the ExactVu system prior to specifying a static IP Address, to prevent the DHCP client from overriding the IP address.

After the static IP Address has been specified, re-connect the network cable and restart the ExactVu system.

5. Configure the DNS Server:

- To obtain DNS server settings automatically through DHCP, toggle *Automatic DNS Address* to **ON**.

Automatic DNS Address toggles ON and DNS server settings are automatically obtained using DHCP.

- To configure a *DNS Address* manually, toggle *Automatic DNS Address* to **OFF**. Type the address for the preferred *DNS Server* using the touch screen's keyboard.

NOTE

EN-N20



The ExactVu system may be configured to automatically obtain DNS server settings using DHCP or to specify a DNS server. It is not permitted to use both methods.

6. Select **Save.**

The operator is prompted to confirm new settings if changes were made. Pressing **Yes** saves the changes.

The ExactVu system restarts whenever network settings are modified.

When the ExactVu system restarts, it automatically joins the network with the settings specified.

1.7.2.3 Network Requirements

Exact Imaging recommends that network settings be configured and provided only by qualified on-site information technology (IT) personnel.

Specifications for networks to which the ExactVu system may be connected include:

- The network must be a standard Ethernet based network with cables using RJ-45 connectors and conforming to CAT5e or CAT6 specifications, and supporting speeds of 10, 100 and 1000 Mbps and preferably using a gigabit switch.
- Network communications must be based on TCP (transmission control protocol) and IPv4 (Internet Protocol version 4). (IPv6 is not supported).
- A DHCP server is recommended (though configuration with a static IP address is possible).
- Exact Imaging recommends using a *wired* network connection for exporting ExactVu studies to a PACS server. A wireless network should not be used with the ExactVu system.

It is the responsibility of on-site IT personnel to use caution when connecting USB storage devices:

- Exact Imaging recommends scanning any USB storage device with an up-to-date virus scanning tool prior to connecting it to the ExactVu system, such as those available from Symantec, McAfee, Kaspersky Lab and others.
- The ExactVu system does not have installed virus scanning software.

It is the responsibility of on-site IT personnel to maintain the network and identify, analyze, evaluate and control new risks caused by a change in the network configuration. Possible changes to the network configuration include:

- Connection and disconnection of additional items to the network, including USB storage devices
- Update and/or upgrade of equipment connected to the network, including USB storage devices
- Software installed on the network, including from USB storage devices

2 Getting Started with the ExactVu System

The ExactVu system is designed to optimize the workflow of a standard TRUS (transrectal ultrasound) procedure. It is designed based on the assumption that its operators will wish to begin imaging as quickly as possible. Once the ExactVu system is turned on and it initializes, it may be used for imaging immediately.

2.1 Starting the ExactVu System

To turn on the ExactVu system:

1. Switch the *main power switch* to the ON position.
2. Press and briefly hold the *system power control* on the front of the ExactVu system cart.
The ExactVu system powers on.

When the ExactVu system starts, several things happen automatically:

- If the ExactVu system was previously configured, it automatically joins the network with the parameters specified in the *Preferences > Network Settings* screen. A network firewall is activated on startup to prevent unauthorized network messages and to allow only essential system and DICOM protocol messages.
- The transducer connected to the topmost *transducer connector slot* becomes active.
- The imaging screen opens in 2D Mode.
 - The default exam type for the active transducer is selected, with the corresponding default *image preset* values for that exam type loaded.
 - The header of the imaging screen displays "Patient Name Not Entered" to indicate that information pertaining to the patient and study has not been entered.

Patient and study information may be specified at any time and must be specified before images (including any measurements or annotations) can be saved or printed. Refer to section 2.4.1 on page 71 for details about how to enter patient and study information.

2.2 Preparing the Patient

Prepare patients for the procedure as per internal clinical protocols for prostate biopsy.

2.3 Preparing the Transducer

Refer to the following guides for information about preparing the selected transducer for procedures:

- For the EV29L transducer, refer to the *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*
- For the EV9C transducer, refer to the *Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer*
- For the EV5C transducer, refer to the *Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer*

2.3.1 Connecting the Transducer to the ExactVu System

NOTE
EN-N12



Connect the transducer to the ExactVu system according to internal clinical protocols for biopsy.

This procedure assumes the transducer will be connected to the ExactVu system after it has been prepared for the procedure in which it will be used.

To connect the transducer to the ExactVu system:

1. On the transducer connector, turn the *lock knob* to its *unlocked* position (refer to the unlocked icon in Figure 18).
2. Line up the *locking pin* (refer to Figure 19) on the transducer connector with the *lock notch* on the *transducer connector slot* on the ExactVu system (refer to Figure 20) so that the transducer connector is oriented as indicated in Figure 21.
3. Push in the connector and then turn the *lock knob* to the *locked* position (refer to Figure 21).

When the ExactVu system is powered on, the *Transducer Element Check* is automatically executed when a transducer is



Figure 17: Transducer Locked Icon



Figure 18: Transducer Unlocked Icon

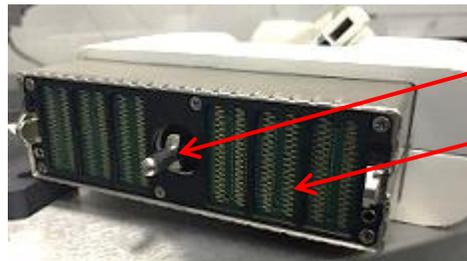


Figure 19: Locking Pin

Locking pin

Contact pads



Figure 20: Lock Notch on the Transducer Connector Slot

Lock notch



Figure 21: Transducer Connector Orientation

Transducer connector lock knob (in the locked position)

connected. Refer to Chapter 12, section 1.2 on page 166.

2.4 Setting up Study Information on the ExactVu System

2.4.1 Using the Patient/Study Screen

Patient and study information is entered using the *Patient/Study* screen which contains data entry fields for the patient, as well as controls to select a transducer, exam type and image preset for the study.

Patient and study information may be entered manually, or may be retrieved using *Modality Worklist*, a DICOM workflow service that makes patient demographic information available from a connected Radiology Information System.

If the *FusionVu* option is configured on the ExactVu system, the *Patient/Study* screen also provides access to import MR (magnetic resonance) study data from a connected USB storage device or DVD, from a network folder or from a connected PACS server (refer to Chapter 8).

Each study consists of one or more *exam types*, and contains images obtained for a specific combination of transducer and exam type.

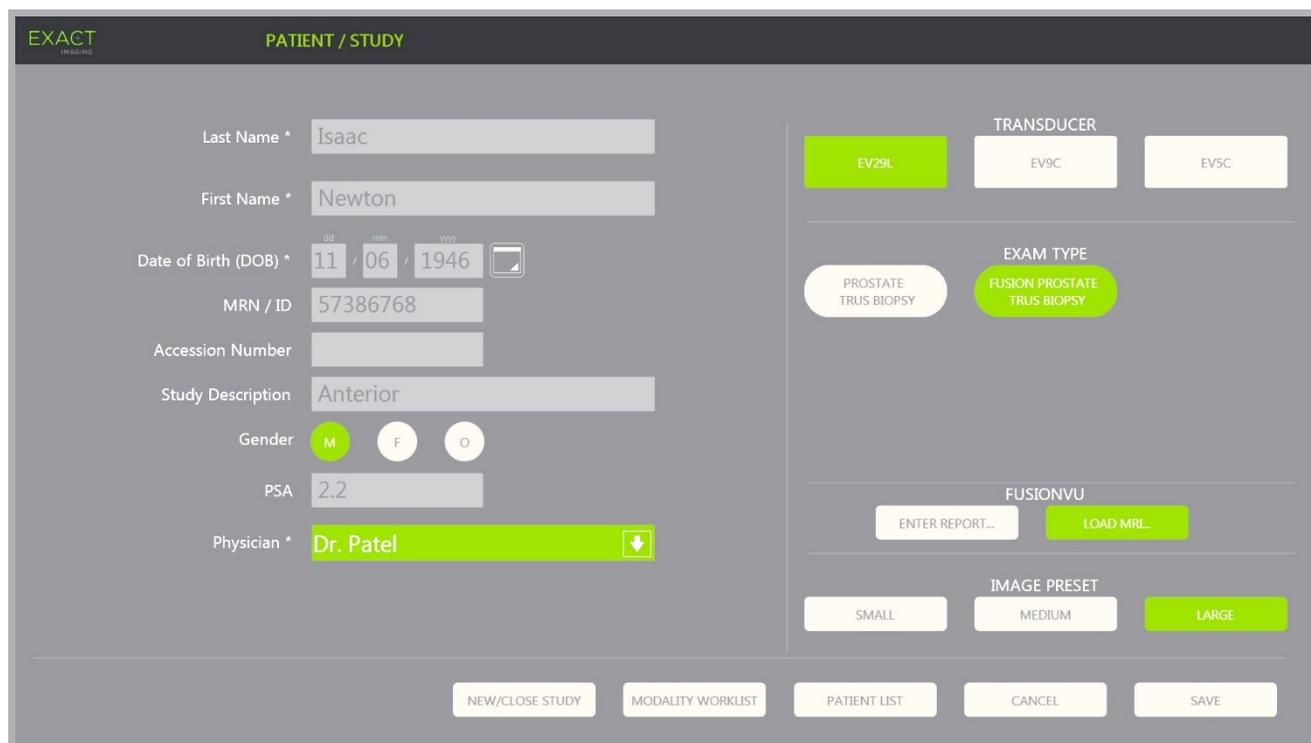


Figure 22: Patient/Study Screen

NOTE

EN-N21



If system security is enabled on the ExactVu system, and secured features have not been accessed for a period longer than the duration of the security timeout, the System Security dialog appears and requires a security password to be entered before the Patient/Study opens.

To manually enter information for a new study:

1. Press **Patient/Study** on the control panel.
The *Patient/Study* screen is displayed.
2. Enter the following information:
 - Last Name (required)
 - First Name (required)
 - Date of Birth (required)
 - MRN (Medical Record Number)/ID Number
 - Accession number
 - Study Description
 - Gender
 - Physician (required)
 - Select a Physician from the dropdown
 - If the desired physician's name is not available in the list, select *Other*, or add the physician's name to the list by following the procedure described in Chapter 12, section 6 on page 172
 - Exam-specific attribute (such as *PSA* (prostate-specific antigen))

Information about using DICOM Modality Worklist to search for patient records is described in Chapter 4, section 1.1 on page 99.

NOTE

EN-N23



A *PSA* value is required for calculating the *PSA* Density for volume measurements.

To cancel a new study:

1. From the *Patient/Study* screen, move the trackball to *Cancel* and press **Set**.
A confirmation indicating whether there are unsaved changes is displayed.
2. Select **Yes** to continue without saving changes. Otherwise, select **No**.
After selecting to continue, the *Patient/Study* screen refreshes for entry of information for a new study.

NOTE

EN-N111



If imaging is initiated when there are unsaved changes on the *Patient/Study* screen, a confirmation prompt is displayed.

2.4.2 Selecting the Transducer, Exam Type and Image Preset

Studies are performed using ExactVu transducers, which may be concurrently connected to the ExactVu system in three available transducer ports. Each of the EV29L, EV9C and EV5C transducers are associated with imaging settings and image presets specific to the exam types for which they will be used.

The *image preset* settings for each transducer/exam type combination have been optimized on the ExactVu system to give the best balance between producing low acoustic output and sufficient power to view features on the structure being imaged as quickly as possible.

The default imaging settings for all transducers are intended to ensure the lowest acoustic output during imaging, and are displayed on the imaging screen when a transducer, exam type and image preset are selected.

Selection of transducers, exam type and image preset are made from the *Patient/Study* screen or from the *Exam touch* screen (refer to Figure 23). Only connected transducers are available. Use the trackball or Return key on the touch screen's keyboard to navigate through the fields.

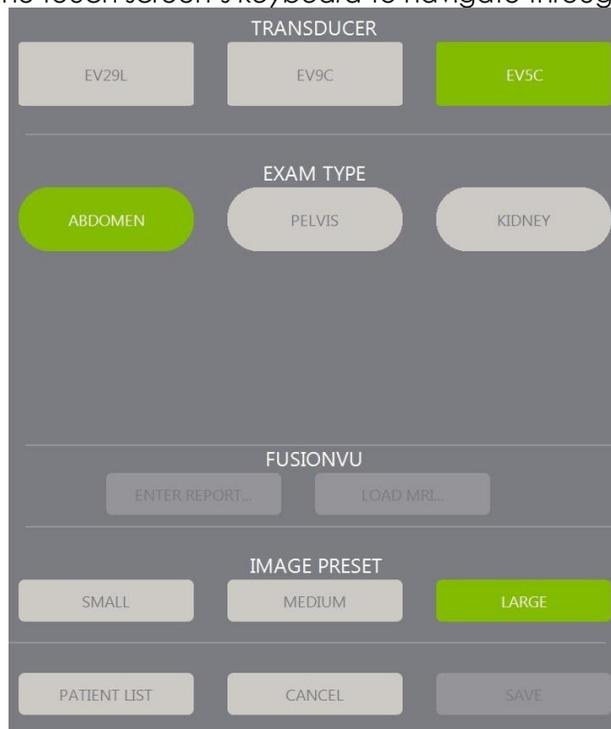


Figure 23: Transducer, Exam Type, Image Preset Selection

To select a transducer:

- Press **EV29L**, **EV9C** or **EV5C**.

The available *exam types* for the selected transducer are displayed.

Transducer Name	General Description	Broadband Frequency	ExactVu Exam Types	Supported Imaging Modes
-----------------	---------------------	---------------------	--------------------	-------------------------

EV29L	29 MHz High Resolution Side-Fire Transducer (Linear)	29 MHz	Prostate TRUS Biopsy (default) Fusion Prostate TRUS Biopsy (default only if MRI study is loaded)	2D Mode Anesthesia sub-mode Biopsy sub-mode Transverse Mode Stitch sub-mode
EV9C	9 MHz Transrectal Transducer (Curved)	8.5 MHz	Prostate TRUS Biopsy	2D Mode Dual Mode
EV5C	5 MHz Abdominal Transducer (Curved)	5 MHz	Abdomen Kidney Pelvis (default)	2D Mode Dual Mode Color Doppler Mode Power Doppler Mode

Table 16: ExactVu Transducers and Exam Types

WARNING

EN-W27



Always use the correct transducer for the intended exam type.

NOTE

EN-N2



The EV29L, EV9C and EV5C transducer models are the only transducers that may be connected to the ExactVu system.

To select an exam type:

- Select one of the available exam types for the selected transducer.

If the *Fusion Prostate TRUS Biopsy* exam type is selected, an MRI study must be loaded from the *Patient/Study* screen in order to access FusionVu features. (Refer to Chapter 8 section 1.1 on page 134 for further details.)

Each transducer has a set of *image presets*, specific to the exam type. Available image presets are based on prostate size:

- Small
- Medium
- Large

The default image preset for all exam types for the EV29L transducer is *Large*. An additional *XLarge* image preset may be selected when imaging with the EV29L transducer (refer to section 3.5.2 on page 82 for further details). The default image preset for all exam types for the EV9C transducer is *Large*. The default image preset for all exam types for the EV5C transducer is *Medium*.

To select an image preset for a study:

- Select one of the available image presets for the selected transducer.

NOTE

EN-N25



Presets may be changed during imaging. Refer to section 3.5.2 on page 82 for further details.

To save the patient and study information:

- Select **Save**.

All information entered is saved in a new study.

The imaging screen opens, ready to image in *2D Mode*.

The *Transducer Element Check* is automatically executed on the selected transducer. Refer to Chapter 12, section 1.2 on page 166.

The *Workflow* touch screen opens.

Images may be saved.

NOTE

EN-N26



For the Prostate and Pelvic exam types, if PSA has not been entered, a message is displayed to notify the operator that PSA Density will not be calculated for volume measurements.

Patient and study information may be edited for the active study using the *Patient/Study* screen. Data fields for the patient, as well transducer and exam type may be edited using the same fields that were used to specify this information when the study was created.

To edit patient and study information:

1. Press **Patient/Study** on the control panel.

The *Patient/Study* screen opens, displaying information for the current study.

2. Edit any desired fields.

3. Select **Save**.

All information entered is saved.

The imaging screen opens, ready to image.

The *Modes* touch screen opens.

To cancel changes made on the Patient/Study screen:

1. Select **Cancel**.

A confirmation is displayed.

2. Select **Yes**.

Changes are not saved. The *Patient/Study* screen closes and the imaging screen is displayed.

3 Study Workflow

After saving Patient/Study information, all transducers and exam types default to 2D Mode imaging.

3.1 TRUS Imaging and Biopsy Workflows

The general workflow for performing TRUS (transrectal ultrasound) studies using the ExactVu system is as follows:

- Image the prostate to determine pathology
- Document any lesions (optional)

- Measure the volume of prostate
 - Use *Stitch sub-mode* for large prostates
- Save images of interest
- Determine the anesthesia location and optimize the image
- Administer anesthesia using the *needle guide overlay*
- Perform biopsy (optional) using the *needle guide overlay*
- Save and close the study

3.2 Transperineal Workflow

The general workflow for performing transperineal studies using the ExactVu system is as follows:

- Image the prostate
- Optimize the image
- For transperineal biopsy procedures:
 - Image the prostate to determine pathology (document any lesions (optional))
 - Measure the volume of the prostate (use *Stitch sub-mode* for large prostates)
 - Save and annotate images (optional)
 - Enable the display of the *Transperineal Guide* or *Transperineal Grid* overlay (depending on the physical configuration for the procedure)
 - Perform biopsy
 - Save and close the study
- For image guidance of gold fiducial implantation procedures:
 - Image the prostate to determine pathology
 - Enable the display of the *Transperineal Guide* or *Transperineal Grid* overlay
 - Place fiducial markers in the required locations
 - Save and annotate images (optional)
 - Save the study (optional) and close it
- For image guidance of perirectal spacer placement procedures:
 - Image the prostate to determine pathology
 - Place fiducial markers in the required locations, if needed
 - Inject saline or hydrogel into the required locations
 - Save and annotate images (optional)
 - Save the study (optional) and close it

3.3 Kidney Imaging and Biopsy Workflows

The general workflow for performing Kidney imaging and biopsy studies using the ExactVu system is as follows:

- Image the kidney to optimize the image and assess anatomy
- Measure the kidney
- Measure the volume
- Interrogate the kidney to determine pathology
- Document any abnormalities
- Use CFI Modes to assess flow within abnormalities
- Image the abdominal aorta to identify the renal arteries
- Use CFI Modes to:
 - Differentiate kidney vessels
 - Assess including renal artery and vein and arcuate arteries in the cortex
- Enable the *needle guide overlay* (optional)
- Administer anesthesia
- Perform targeted biopsy
- Save and close the study

3.4 Pelvis / Bladder Imaging Workflow

- Image the pre-void bladder and/or prostate to optimize the image and assess anatomy
- Measure the volume of the pre-void bladder and/or prostate
- Interrogate the bladder and/or prostate to determine pathology
- Document any abnormalities
- Use CFI Modes to:
 - Assess flow within urethral jets
 - Assess flow within abnormalities
- Perform volume measurement on post-void bladder
- Save and close the study

3.5 Performing Imaging

During imaging, the following information is displayed on the imaging screen:

- Study information:
 - Patient name, date of birth and MRN (Medical Record Number)/ID
 - The exam type, study date and time, the clinic name, accession number, the transducer and imaging mode
- Acoustic output energy indices:
 - Thermal Index Soft Tissue (TIS)
 - Mechanical Index (MI)
- Imaging state:

- *Live* indicates imaging is active
- *Frozen* indicates imaging is paused
- *Review* indicates a previously saved image is displayed
- *Frame* or *Cine* indicates the type of image in review. *Cine* also indicates the frame currently displayed
- Study status:
 - *Active* indicates new images may be acquired and saved as part of the current study
 - *Closed* indicates the displayed image was acquired in a study that has been closed, and new images may not be acquired or added to the study
 - The status of background processes for archiving studies to a PACS server is also displayed in this area, and may indicate the following:
 - *Off* - Auto-archiving is disabled in *Preferences*.
 - *Running* - Auto-archiving is in progress
 - *Paused* - Auto-archiving is paused
 - *Idle* - Queued studies are archived, and the background process is waiting for the next study to be closed
 - *Error* - connection problem or other PACS error
- The current imaging mode
- Transducer:
 - When a transducer is connected and activated, the *active transducer* is displayed
 - When no transducer is connected, "No transducer" is displayed
 - When no transducer is connected and a *review* image is displayed, the name of the transducer used to acquire the image is displayed
- Imaging settings as indicated in Figure 24

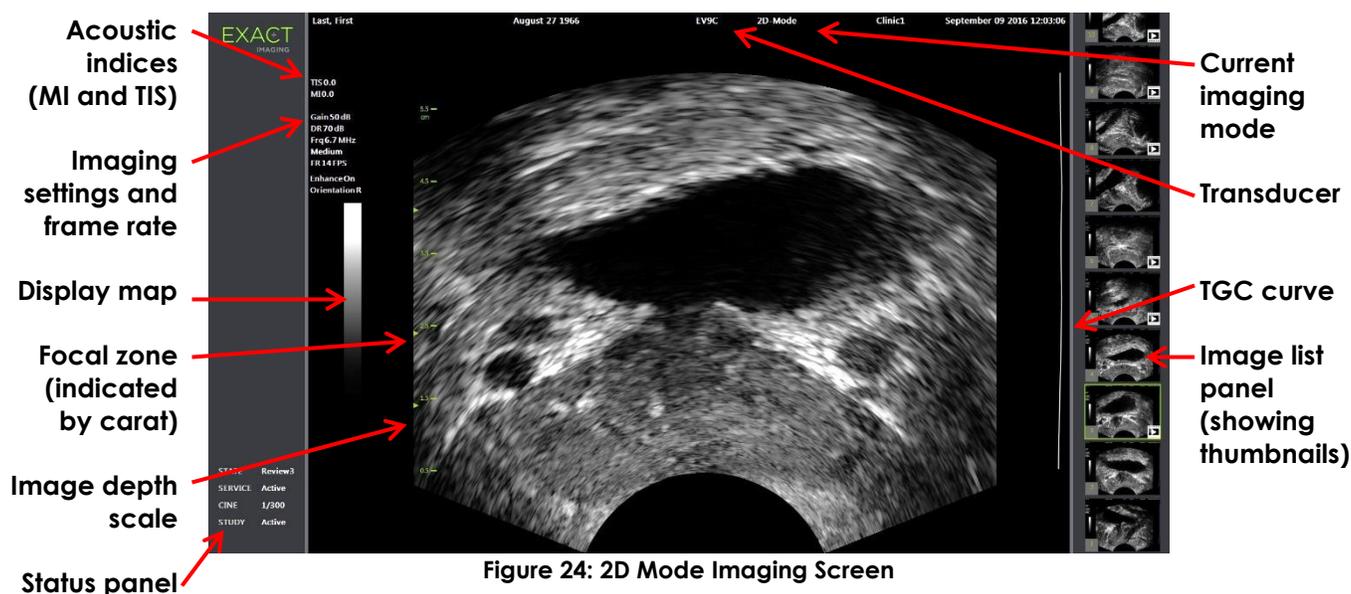


Figure 24: 2D Mode Imaging Screen

Additional mode-specific imaging settings are displayed in the applicable modes. Imaging settings may be adjusted during imaging to alter the image appearance.

To pause imaging:

- Press **Freeze** on the *control panel* while imaging.
Imaging stops.
The status panel shows *Frozen*.

To restart imaging:

- Press **Freeze** on the *control panel* while imaging is paused.
Imaging starts. The status panel shows *Live*.

Single frames and cine images (i.e., multiple sequential frames) may be saved during imaging. Refer to section 3.7 on page 90 for details.

NOTE

EN-N28



If the operator opens the Patient/Study or Preferences screen or presses *Measure* during imaging, imaging is paused.

WARNING

EN-W9



If the ExactVu system malfunctions, fails to respond, if the image is severely distorted or degraded, or you suspect the system is not functioning correctly in any way:

- Remove all transducers from contact with the patient
 - Turn off the ExactVu system
 - Unplug the ExactVu system from its power source
 - Contact Technical Support using the contact information in Appendix F
-

3.5.1 Imaging Modes and Mode Switching

Available imaging modes are determined by the transducer in use and are listed in Chapter 1, section 6.2.1 on page 20.

With the EV29L transducer, operators may also use *FusionVu* for PI-RADST™ and MRI image-guided workflows in the following modes and sub-modes:

- 2D Mode
- Anesthesia sub-mode
- Biopsy sub-mode

Full details of *FusionVu* features are provided in Chapter 8.

Operators may switch to a new imaging mode using the *touch screen* or using the *control panel*. When imaging in a new mode, unless switching from Anesthesia sub-mode, the new mode retains the values from the previous imaging mode for the following settings:

- Dynamic Range
- Image depth
- Focal zone number and position

When imaging in a new mode other than Biopsy sub-mode and Anesthesia sub-mode, the new mode

also retains the values for the following settings:

- Gain

With the EV5C transducer, when switching between Color Doppler Mode and Power Doppler Mode, the new mode retains the values from the previous imaging mode for the following settings:

- Color box position and size
- Wall filter
- Sensitivity
- Persistence
- PRF

Other imaging settings that are retained when switching to a new imaging mode are dependent on the transducer in use, the selected *image preset* and on the new imaging mode. When imaging settings are not retained, default values for imaging settings for the new mode are used.

CAUTION

EN-C16



After changing to a new imaging mode, ensure that live imaging as described below is observed.

To switch modes using the EV29L transducer:

1. For 2D imaging:
 - Press **2D** on the *Workflow* touch screen, OR
 - Press **2D** on the *control panel*

2D Mode imaging begins.

2. From the *Workflow* touch screen, press **Anesthesia**.

Imaging begins in *Anesthesia sub-mode*.

When imaging with the EV29L transducer, switching to *Anesthesia sub-mode* disables *Needle Enhancement* and provides a higher imaging frame rate. The *anesthesia needle guide overlay* is enabled automatically.

3. From the *Workflow* touch screen, press **Biopsy**.

Imaging begins in *Biopsy sub-mode*, using the *Small* image preset and imaging settings that optimize visualization for biopsy. The 35° *transrectal needle guide overlay* is enabled automatically.

When using the EV29L transducer, *Needle Enhancement* may be toggled *ON* and *OFF*.

4. From the *Workflow* touch screen, press **Stitch**.

Imaging begins in the *Stitch sub-mode*. The *Stitch* feature is activated which allows two images to be combined together for measurement of large prostates.

NOTE

EN-N29



Stitch sub-mode is enabled only when the EV29L transducer is active. For further details, refer to Chapter 5, section 1 on page 111.

5. For *Transverse Mode* imaging:

- Press **Transverse** on the *Workflow* touch screen, OR
- Press **Dual/Transverse** on the control panel

Imaging begins in *Transverse Mode*, which allows a transverse image to be constructed in real time. *Transverse Mode* is used to obtain sagittal and transverse views for volume measurements.

NOTE

EN-N30



Transverse Mode is a variation of Dual Mode, and is enabled only when the EV29L transducer is active.

To switch modes using the EV9C transducer:

1. For 2D imaging, press **2D** on the *control panel*.
2D Mode imaging begins.
2. For Dual Mode imaging:
 - Press **Dual** on the *Workflow* or *Modes* touch screen, OR
 - Press **Dual/Transverse** on the *control panel*

Imaging begins in *Dual Mode*, which displays two separate images in the imaging screen. *Dual Mode* is used to collect sagittal and transverse views for volume measurements. *Dual Mode* uses the preset 2D Mode imaging settings.

To switch modes using the EV5C transducer:

1. For 2D imaging:
 - Press **2D** on the *Workflow* touch screen, OR
 - Press **2D** on the *control panel*

2D Mode imaging begins.

The *Modes* touch screen is displayed.
2. For Dual Mode imaging:
 - Press **Dual** on the *Workflow* or *Modes* touch screen, OR
 - Press **Dual/Transverse** on the *control panel*

Imaging begins in *Dual Mode*, which displays two separate images in the imaging screen. *Dual Mode* is used to collect sagittal and transverse views for volume measurements. *Dual Mode* uses the preset 2D Mode imaging settings.

3. For Color Doppler imaging:
 - Press **Color** on the *Modes* touch screen, OR
 - Press **C/P** on the *control panel*

Imaging begins in *Color Doppler Mode*. (From a CFI Mode, pressing C/P toggles between Color Doppler Mode and Power Doppler Mode.)

4. For Power Doppler imaging:
 - Press **Power** on the *Modes* touch screen, OR

- Press **C/P** on the *control panel*

Imaging begins in *Power Doppler Mode*. (From a CFI Mode, pressing C/P toggles between Color Doppler Mode and Power Doppler Mode.)

3.5.2 Image Presets

Image presets may be changed during imaging using the control panel.

To use the *control panel* to change the image preset during imaging:

- Press **Image** on the *control panel*.
The name of the next available *image preset* is highlighted to the left of the image.
After a brief pause, the highlighted *image preset* is activated.

To use the *Exam touch screen* to change the image preset during imaging:

1. While imaging, press the **Exam** on the touch screen.
The *Exam touch screen* is displayed.
2. Select an available *image preset*.
Imaging begins in 2D Mode using the settings for the selected *image preset*.

NOTE

EN-N115



It is not possible to change presets while imaging in *Transverse Mode* or in *Anesthesia sub-mode* with the EV29L transducer.

NOTE

EN-N177



The *XLarge* image preset cannot be selected from the Patient/Study screen. *XLarge* can only be selected during imaging with the EV29L transducer by pressing *Image* on the control panel.

3.5.3 Image Orientation

The *Modes touch screen* indicates the orientation of a live image on the imaging screen for the EV9C and EV5C transducers.

During imaging with the EV9C or EV5C transducer, the operator may switch the orientation of images in *2D Mode*, *Dual Mode* and *CFI Modes*.

To modify the orientation of a live image:

- From the *Modes touch screen*, press either *Orientation icon*.
The orientation of the image flips along the vertical axis (i.e., in the left-right direction).
In *Dual Mode*, only the live image flips.
The green *Orientation icon* indicates the current orientation of the image.



It is not possible to modify the orientation of an image when imaging with the EV29L transducer. It is not possible to modify the orientation for a frozen image or a review image.

3.5.4 Imaging Settings

During imaging, the information in the header of the imaging screen is displayed in green text. While paused, the information is displayed in white text. The imaging settings displayed during imaging are summarized in the following sections. These are:

- *Gain* is indicated in the upper area to the left of the image (denoted as Gain with units dB).
 - *2D Gain* is displayed when imaging in 2D Mode
 - *CFI Gain* is also displayed when imaging in Color Doppler Mode or Power Doppler Mode (denoted as *C Gain*)
- *Dynamic Range* is indicated in the upper area to the left of the image
 - denoted as *PD DR* with units dB when imaging in Power Doppler Mode
 - denoted as *DR* with units dB when imaging in any other mode
- *Frequency* is indicated in the upper area to the left of the image (denoted Frq with units MHz). The frequency is dependent on other imaging settings and cannot be set by the operator.
- *Frame rate* is indicated in the upper area to the left of the image (denoted FR with units FPS (i.e., frames per second)). The frame rate is dependent on other imaging settings and cannot be set by the operator.
- *Display map* is indicated by the grayscale bar to the left of the image. The display map is pre-set and cannot be set by the operator.
- *Angle* is indicated in the left panel and provides the rotation detected in the EV29L transducer. It is available when the EV29L transducer is activated.
- *TGC (time gain compensation) curve* is indicated by a curved line to the right of the image, indicating the relative gain of the image at the different tissue depths to correspond with the position set for each TGC slider.
- *Focal zone* number and depth(s) is indicated by one or more focal zone indicators displayed on the depth scale.
- *Image depth* is indicated by the depth scale, which may be displayed to the left or right of the image, depending on the imaging mode.
- In Color Doppler Mode and Power Doppler Mode, the *color box position* and *color box size* are indicated by the outline of the color box.

This section discusses settings that are adjustable in all imaging modes. Imaging settings that are specific to an imaging mode are discussed in Chapter 5, Chapter 6 and Chapter 7.

For most imaging settings, if the value is adjusted during imaging, its value is highlighted briefly on the imaging screen to identify the updated value.

NOTE
EN-N107

Imaging settings may only be adjusted during imaging.

3.5.4.1 Dynamic Range

The Dynamic Range control adjusts the mapping of the ultrasound signal to the grayscale for the displayed image, i.e., the contrast in the displayed image. The control allows adjustments over a range of 20 dB to 100 dB, with the default for all exam types set to 65 dB. In *Power Doppler Mode*, this control also adjusts the color map dynamic range used by the color box.

To adjust the Dynamic Range:

1. Press the upper arrow on the **Dynamic Range** control on the *control panel*.

The contrast between the ultrasound signal and the grayscale mapping increases.

In *Power Doppler Mode*, this also increases the contrast in the color map for the *color box*.

2. Press the lower arrow on the **Dynamic Range** control on the *control panel*.

The contrast between the ultrasound signal and the grayscale mapping decreases.

In *Power Doppler Mode*, this also decreases the contrast in the color map for the *color box*.



Figure 25: Dynamic Range Control

3.5.4.2 2D Mode Gain

In 2D Mode, the Gain knob adjusts the intensity of the displayed 2D image by amplifying the reflected signal in post processing, where the intensity is applied to the image based on the Gain setting. The control allows adjustments over a range of 0 dB to 120 dB. Default values are dependent on the selected exam type, with default 70 dB for exam types available for the EV29L transducer, 56 dB for exam types available for the EV9C transducer, and 50 dB for exam types available for the EV5C transducer.

In a CFI Mode, the Gain knob adjusts the intensity within the color box but does not impact the 2D Mode Gain.

To adjust the 2D Mode Gain:

- During imaging, turn the **Gain** knob to the right to increase the *2D Mode Gain* or left to decrease the *2D Mode Gain*.

Increasing the *2D Mode Gain* increases the intensity of the 2D Mode image. Decreasing the *2D Mode Gain* decreases the intensity of the displayed image.

To adjust the Gain in a CFI Mode:

- During imaging, turn the **Gain** knob to the right to increase the gain in the color box or left to decrease the gain in the color box.

Increasing the *Gain* increases the intensity in the color box. Decreasing the *Gain* decreases the intensity in the color box.

3.5.4.3 Image Depth

Adjustments made to the image depth control the depth of the far field of the image.

The scale units and maximum image depth are dependent on the transducer in use. For the EV29L transducer, the units are millimeters (mm) rounded to the nearest 10 mm and the maximum image depth is 60 mm. For the EV9C transducer, the units are centimeters (cm) rounded to the nearest 1 cm and the maximum image depth is 8 cm. For the EV5C transducer, the units are centimeters (cm) rounded to the nearest 1 cm and the maximum image depth is 18 cm.

For the EV9C and EV5C transducers, the size of the displayed image scales based on the image depth. The adjustment size is dependent on the transducer.

The function of the arrows on the *Depth* control corresponds to the orientation of the image in that the image depth changes in the direction indicated by the arrow.

NOTE
EN-N108



Image depth may not be adjusted in Transverse Mode or Stitch sub-mode.

To adjust the image depth:

1. Press the upper arrow on the **Depth** control on the *control panel*.

For the EV29L or EV9C transducer, the image depth increases until the maximum for the active transducer is reached. For the EV5C transducer, the image depth decreases until the minimum is reached.

The image depth is adjusted consistently with the direction of indicated by the arrow on the control.

2. Press the lower arrow on the **Depth** control on the *control panel*.

For the EV29L or EV9C transducer, the image depth decreases until the minimum for the active transducer is reached. For the EV5C transducer, the image depth increases until the maximum is reached.



Figure 26: Image Depth Control

3.5.4.4 Focal Zones

ExactVu operators are able to adjust both the number of focal zones and the depth of the focal zone(s), in order to place the focus of the ultrasound image at a desired position.

The operator is able to select one or three focal zones in all modes, with the following exceptions:

- When using the EV29L transducer, the operator is able to select one or three focal zones in all modes other than Transverse Mode and Stitch sub-mode. Transverse Mode and Stitch sub-mode use the number of focal zones in use when either mode is initiated; however, the number cannot be changed while in the mode.
- When using CFI Modes, only one focal zone is available, and it must always be within the color box. If the color box is moved or resized so that the focal zone position is outside the color box, the focal zone is automatically reset to a position nearest to the middle of the color box. The

exception to this occurs when the bottom of the color box lies above the position of the first focal zone (i.e., above 31 mm). For details about adjusting the position and size of the color box, refer to Chapter 7, section 2, on page 129.

When more than one focal zone is active, ultrasound beams are focused at different depths in the tissue. This improves the focus in several zones, however results in a lower frame rate.

NOTE

EN-N85



To improve the spatial resolution, the ExactVu system is capable of automatically adjusting the line density based on the transducer and imaging mode.

To select the number of focal zones:

1. Open the *Modes* touch screen.
2. Under # *Focal Zones*, press the left or right arrow to display the desired number of focal zones.

The selected number of *focal zones* is displayed and activated.

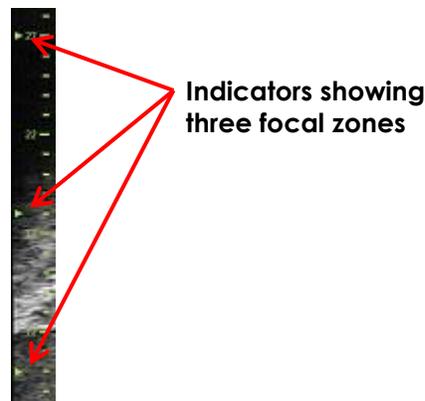


Figure 27: Focal Zone Indicator

Adjustments to the depth of a single focal zone or a group of focal zones of fixed spacing can be made. Adjustments made to the focal zone depth establish the resolution in the focal zone(s).

The function of the arrows on the *Focus* control corresponds to the orientation of the image in that the focal zone depth changes in the direction indicated by the arrow.

To adjust the depth of the focal zone(s):

1. With one or more focal zones displayed, press the upper arrow on the **Focus** control on the *control panel*.

For the EV29L or EV9C transducer, the *focal zone (or focal zones)* moves deeper in the image. For the EV5C transducer, the *focal zone* moves less deep in the image.

2. Press the lower arrow on the **Focus** control on the *control panel*.

For the EV29L or EV9C transducer, the *focal zone (or focal zones)* moves less deep in the image. For the EV5C transducer, the *focal zone* moves deeper in the image.



Figure 28: Focus Control

NOTE

EN-N109



The depth and number of focal zones may not be adjusted in Transverse Mode or Stitch sub-mode.

3.5.4.5 Time Gain Compensation (“TGC”)

The ExactVu system is able to apply variable amplification to echoes from different depths in the tissue using Time Gain Compensation ("TGC"). TGC compensates for minor attenuation and scattering of the ultrasound beam as it returns through more deeply situated tissue.

Each slider adjusts the return signal across a specific depth band. The topmost slider adjusts the return signal across the top 1/8th of the image. The bottom slider adjusts the return signal across the bottom 1/8th of the image.

The relative gain of the image at the different tissue depths is illustrated with a smooth TGC curve is displayed to represent the grayscale intensity at the position of each slider. The TGC controls do not affect the color gain setting in CFI Modes.

To adjust the TGC:

1. During imaging, slide a *TGC slider* to the right.

The return signal for that depth band boosts, and the image data in the horizontal band corresponding to the slider brightens.

The *TGC curve* adjusts to show a shape that reflects the slider position.

2. During imaging, slide a *TGC slider* to the left.

The return signal for that depth band attenuates, and the image data in the horizontal band corresponding to the slider darkens.

The *TGC curve* adjusts to show a shape that reflects the slider position.



Figure 29: TGC Sliders

Adjustments made to the *TGC sliders* affect the display of a live image only. Changes made to the TGC slider positions while the system is paused or with a review image displayed do not affect the displayed image.

3.5.4.6 Transmit Power

Default settings for transducer/exam type combinations have been optimized to give the best balance between producing low acoustic output and providing sufficient power to view features on the structure being imaged as quickly as possible; however, sometimes it is necessary to change imaging settings such as transmit power to increase or decrease the intensity of the displayed image.

To adjust the Transmit Power:

1. Open the *Modes* touch screen.
2. Under *Power (dB)*, press the left or right arrow button to move the *Power slider* between available values 20%, 50% and 100%.

The *transmit power* increases or decreases to reflect the current slider position. An increase to the transmit power results in a corresponding transmit voltage used to produce ultrasound beams. The appearance of the image's intensity increases as the transmit power value increases and decreases as the transmit power value decreases.

WARNING

EN-W7



At all times, the operator must follow the principle of ALARA to minimize the acoustic output and exposure time.

3.5.4.7 Image Enhancement

Operators are able to enable an image processing tool to enhance the appearance of ultrasound images using the *Image Enhancement* option on the *Workflow* touch screen. This feature is turned *ON* by default when a new Patient/Study is created.

To enable Context Vision imaging processing:

1. Open the *Workflow* touch screen.
2. If *Image Enhancement* is toggled *OFF*, select **OFF**.

The *Image Enhancement* feature toggles *ON*. The appearance of the image is adjusted to reduce its graininess and increase its smoothness.

The *Image Enhancement* feature retains its *ON/OFF* state until a new patient is created.

NOTE

EN-N160



Image Enhancement affects the grayscale image only. It does not affect the color map in Color Doppler Mode and Power Doppler Mode.

NOTE

EN-N161



The *Image Enhancement* toggle is not available in Transverse Mode or Stitch Mode.

3.5.5 Changing the Active Transducer

The active transducer and preset may be changed during a study. It is important to note that changing transducers updates all settings to use the default values for the default exam type for the newly selected transducer. When changing transducers during a study or when changing the *Exam Type*, a new *series* is created in the study.

To change transducers from the Patient/Study screen:

1. Press **Patient/Study** on the *control panel*.

The *Patient/Study* screen opens.

2. Select **EV29L**, **EV9C** or **EV5C**.

The available *exam types* for the selected transducer are displayed, with the default *exam type* selected.

3. If desired, change the *Exam Type*.
4. If desired, change the *Image Preset*.

5. Select **Save**.

Changing the transducer updates the imaging settings to their default values for the selected

transducer, *Exam Type* and *Image Preset*.

The *Transducer Element Check* is automatically executed on the selected transducer. Refer to Chapter 12, section 1.2 on page 166.

6. Press **Freeze** on the *control panel* to begin imaging.

Imaging begins in 2D Mode.

Changing transducers while imaging may be done one of two ways:

- Using the *Transducer* control on the control panel
- Using the *Exam* touch screen

To change transducers via the control panel during imaging:

1. Press **Transducer** on the *control panel*.

The header of the imaging screen highlights the name of the next available transducer, i.e., the transducer connected to the next available slot.

2. Press **Transducer** again to cycle through available transducers.

The *Transducer Element Check* is automatically executed on the selected transducer. Refer to Chapter 12, section 1.2 on page 166.

3. Press **Freeze** on the *control panel* while imaging is paused.

Imaging begins in 2D Mode using the settings for the default *Image Preset* and *Exam Type* for the transducer.

To change transducers via the Exam touch screen while imaging:

1. Press **Exam** on the *touch screen*.

2. Select **EV29L**, **EV9C** or **EV5C**.

The available *Exam Types* for the selected transducer are displayed, with the default *Exam Type* selected.

The *Transducer Element Check* is automatically executed on the selected transducer. Refer to Chapter 12, section 1.2 on page 166.

3. If desired, change the *Exam Type*.

4. If desired, change the *Image Preset*.

Changing the transducer also updates the default *Image Preset* to *Large* and updates the corresponding imaging settings to their default values.

5. Press **Freeze** on the *control panel*.

Imaging begins in 2D Mode using the settings for the default *Image Preset* and *Exam Type* for the transducer.

3.6 Measuring and Annotating

Typically, a biopsy protocol includes:

- Measuring the prostate volume using sagittal and transverse images
- Measuring and documenting any suspicious lesions

Anatomical structures may be labeled prior to performing the biopsy. *Annotations* are text labels used

to label anatomical structures on the image. Up to eight annotations may be added to an image.

Complete details about using ExactVu measurements and annotations are in Chapter 9 and Chapter 10, respectively.

3.7 Saving Images

Single frames and cine images (i.e., multiple sequential frames) may be saved with a study using controls on the control panel or the foot pedal. Images may be saved during imaging or while paused. Saved images may be reviewed when the study is active (i.e., not closed) or after it has been closed.

CAUTION

EN-C48



For studies saved in software versions earlier than 1.0.3, changes made to images will not be saved.

To save a single frame:

- When an image of interest is displayed, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.

An audible chime indicates a successful save.

- In *2D Mode* and sub-modes, a single frame is saved in *PNG* format.
- In *Dual Mode* and *Transverse Mode*, the image panes are saved as a single frame in *PNG* format.

A thumbnail is displayed for the saved image in the *Image List Panel*, which displays thumbnails for all images saved in the current study (refer to Figure 24 on page 78). The thumbnail indicates whether the image is a frame or a cine image, and indicates any overlays saved with the image (i.e., measurements, annotations and *needle guide overlays*).

NOTE

EN-N86



A single frame may be saved individually or from a cine image.

To save a cine image:

- When a cine image of interest is displayed, press **Cine** on the *control panel*, or, if the foot pedal is configured to save cine images, press the foot pedal.

An audible chime indicates a successful save.

- In *2D Mode* and most sub-modes, the set of frames comprising up to 300 of the most recently acquired frames are saved together with the study as a cine image.
- When the EV29L transducer is active in *Biopsy sub-mode* or when the *transperineal needle guide overlay* is enabled, the set of frames is comprised of up to 60 of the most recently acquired frames.
- For the EV9C and EV5C transducers, the memory buffer contains a maximum of 60 frames at any time.
- In *Dual Mode*, *Transverse Mode* and *Stitch sub-mode*, the *Cine* control is disabled.

A thumbnail is displayed for the saved image in the *Image List Panel*, which displays thumbnails for all images saved in the current study. The thumbnail indicates whether the image is a frame or a cine image, with an arrow for cine images, and includes any overlays saved with the image (i.e., measurements, annotations and needle guide overlays).

NOTE

EN-N113



If a cine image is open in *review*, attempting to save it has no effect. Only single frames may be saved in *review*.

During imaging, the most recently acquired frames are temporarily stored in a *memory buffer* that is continuously being overwritten during imaging.

When imaging is paused, unsaved frames remain in the buffer until imaging resumes, at which point the buffer resumes being overwritten continuously, and unsaved frames become unavailable.

Other actions cause unsaved frames to become unavailable. These are:

- Initiating a measurement or annotation when imaging is paused. This action clears the buffer, so that the current frame is the only available frame, even if the measurement is subsequently canceled.
- Opening a saved cine image or frame by selecting a thumbnail image.
- Changing imaging settings or selecting a new image preset

CAUTION

EN-C34



Exact Imaging recommends saving frames and cine images of interest prior to performing an action that causes the memory buffer (as well as any measurements and annotations) to be overwritten.

Saved single frames and cine images contain information about the patient and study. The information is visible on a saved image. The information includes:

- Patient name, date of birth and MRN (Medical Record Number)/ID
- The exam type, the date and time on which the image was saved, the clinic name, accession number, the imaging mode and transducer in use when the image was acquired
- Image overlays (including *needle guide overlay*, *Needle Enhancement*, measurements and annotations)
- Imaging settings (such as frequency, TGC curve, MI and TIS, etc.)
- CFI Mode settings (if applicable), including PRF, Filter, Sensitivity, Persis, C Gain, PD DR, Color Box and Color Map
- Transducer position and orientation information, including *Angle* (if available)

3.8 Determining the Anesthesia Location

Perform an imaging sweep of the prostate according to internal clinical protocols.

Include imaging the gland from mid-line of the prostate (i.e., the urethra) to the lateral border of the prostate on the left side, and repeat this motion for the right side.

This allows the entire peripheral zone to be imaged and all sextants to be reviewed in order to identify

any suspicious regions and/or lesions.

3.9 Administering Anesthesia

After locating the anesthesia site prior to biopsy, administer the anesthesia, and discard the anesthesia needle in accordance with internal clinical procedures.

To visualize the administration of anesthesia when using the EV29L transducer:

- Select **Anesthesia** on the *Workflow* touch screen.

Anesthesia sub-mode is enabled, and the 15° *transrectal needle guide overlay* is enabled. This *needle guide overlay* may be toggled on and off.

Anesthesia sub-mode enables a higher frame rate compared to other 2D sub-modes.

Further details about *Anesthesia sub-mode*, including using the 15° *transrectal needle guide overlay* and additional instructions for procedures using the *EV29L non-sterile reusable transrectal needle guide* are provided in Chapter 5, section 2.3 on page 113.

3.10 Performing a Biopsy

Perform the biopsy procedure according to internal clinical protocols for prostate biopsy. Observe all cautions and warnings related to performing prostate biopsy and concerning consumables in Chapter 2.

To use the ExactVu system when performing a transrectal biopsy using the EV29L transducer:

- Select **Biopsy** on the *Workflow* touch screen.

Biopsy sub-mode is enabled, and the 35° *transrectal needle guide overlay* is enabled. This *needle guide overlay* may be toggled on and off using the *Workflow* touch screen.

For the EV29L transducer, *Needle Enhancement* may be toggled *ON* and *OFF* using the *Workflow* touch screen.

Further details about *Biopsy sub-mode*, including using the *needle guide overlays* and *Needle Enhancement* are provided in Chapter 5, section 2.1 on page 112.

To use the ExactVu system when performing a transperineal biopsy using the EV29L transducer:

When using the EV29L transducer to perform a transperineal biopsy, transperineal overlays may be enabled using the *Workflow* touch screen. Details about how to use the overlays to perform transperineal biopsies using the ExactVu system are provided in Chapter 5, section 3 on page 116.

To use the ExactVu system when performing a biopsy using the EV9C or EV5C transducer:

When using the EV9C or EV5C transducers, *needle guide overlays* may be enabled using the *Workflow* touch screen. Details about available *needle guide overlays* are provided in Chapter 5, section 2.3 on page 113.

After the biopsy procedure, discard the biopsy needle in accordance with internal clinical procedures.

3.11 Printing Images

Displayed images may be printed using the thermal printer (if configured).

To print a displayed image:

1. If necessary, press the **ON** button on the thermal printer.
2. Open the image to print.
3. Press **Print** on the *control panel*.

The displayed image is printed on the thermal printer.

3.12 Reviewing Saved Images

Cine images and frames that have been saved with the study may be reviewed during the study or after the study has been closed. *Review* images may be measured and annotated as well. Thumbnails for cine images and frames that have been saved with the current study are displayed in the *Image List Panel*. Images in the *Image List Panel* are listed according to the time at which they were saved with the most recently saved image at the top.

NOTE

EN-N113



If a cine image is open in *review*, attempting to save it has no effect. Only single frames may be saved in *review*.

NOTE

EN-N178



Measurements and annotations cannot be made on images in *review* if the study was loaded from an external source such as a USB storage device.

To review saved images:

1. Pause imaging.
2. Press **Set** to access thumbnail selection.
3. Select the thumbnail for the image to be viewed and press **Set** on the *control panel*.

The image is displayed in the imaging screen.

When a cine image or frame is displayed for review, the image's status is displayed as *Review* in the *status panel* with an appended number that indicates the sequential position of the image in the *Image List Panel*. The following information about the image is displayed:

- Patient name, date of birth and MRN (Medical Record Number)/ID
- The exam type, the date and time on which the image was saved, the clinic name, accession number, imaging mode and transducer in use when the image was acquired
- Image overlays (including *needle guide overlay*, *Needle Enhancement*, measurements and annotations)
- Imaging settings (such as frequency, TGC curve, MI and TIS, etc.)
- CFI Mode settings (if applicable), including PRF, Filter, Sensitivity, Persis, C Gain, PD DR, Color Box and Color Map
- Transducer position and orientation information, including *Angle* (if available)

When cine image is in displayed for review, the following controls are available to view a specific frame or to play the image:

- The *Frame Position indicator* in the *Status panel* shows the current frame displayed in the cine

image. For example, "1/300" indicates that frame 1 of a 300-frame cine image is displayed.

- The trackball allows the operator to scroll through the cine frames by rolling it right or left to move forward or backward through frames. Small trackball motions result in frame-by-frame scrolling, and progressively larger motions result in larger frame adjustments.

To playback/pause a cine image:

1. While paused, press **Next** on the *control panel*.

Cine image playback begins. During playback, the *frame position indicator* updates to show the position of the displayed frame.

2. While playing back a cine image, press **Next** on the *control panel*.

Cine image playback pauses.

To review other images in the Image Panel List:

1. While cine image playback is paused, press **Set** on the *control panel*.
2. Roll the trackball up or down.

Upward trackball motion scrolls through thumbnails for saved images towards the top of those listed in the *Image List Panel*. Downward trackball motion scrolls through saved images towards the bottom of those listed in the *Image List Panel*.

The current thumbnail is highlighted to indicate that it may be selected.

3. When the desired thumbnail is displayed in the trackball's scrolling sequence, press **Set** on the *control panel* to select it.

The image corresponding to the thumbnail is displayed in the imaging screen.

The trackball focus changes so that it may be used to scroll through frames of a displayed cine image.

NOTE

EN-N45



Some controls are not available when an image is displayed for review.

It is not possible to access Dual Mode or Transverse Mode when an image is displayed for review. Dual Mode and Transverse Mode are only available when a live or paused image is displayed on the imaging screen.

NOTE

EN-N154



When a Transverse Mode image is displayed for review, it includes the paused sagittal and the transverse fan images. The scout image does not appear.

If the study is active (i.e., not closed) and additional images are required to complete the study, resume imaging.

NOTE

EN-N49



When reviewing a closed study, it is not possible to acquire new images for the study. A new study must be created in order to acquire new images.

3.13 Closing a Study

When a study is complete and all required images have been acquired and saved, the study may be closed. When a study is closed, it is not possible to modify information in the *Patient/Study* screen,

though it may be viewed.

To close a study:

1. Open the *Workflow* touch screen.
2. Press **New/Close Study**.
If there are unsaved changes, a confirmation is displayed.
3. Select **Yes** to continue without saving changes. Otherwise, select **No**.

After selecting to continue:

- The study closes. The saved images, measurements, and annotations are saved with the study, and may be reviewed after the study has been closed.
- The imaging screen clears the data from the closed study.
- The *Patient/Study* screen is displayed so new patient information may be entered for a new study.
- If the *DICOM Store* and *Auto-archiving* options are enabled in *Preferences > DICOM Settings* (refer to Chapter 3, section 1.7.2.1 on page 62), the study is marked *Pending* for being archived to a PACS server.

After a TRUS procedure, dispose of consumables as follows:

1. Unclip the needle guide and:
 - Discard single-use sterile transrectal needle guides and sterile transperineal needle guides according to internal clinical procedures for safe disposal, OR
 - Prepare reusable transrectal needle guides for reprocessing according to *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*
2. Remove the sheath from the transducer and discard it according to internal clinical procedures for safe disposal.
3. Discard gloves used during the procedure according to internal clinical procedures for safe disposal.

3.14 Disconnecting the Transducer

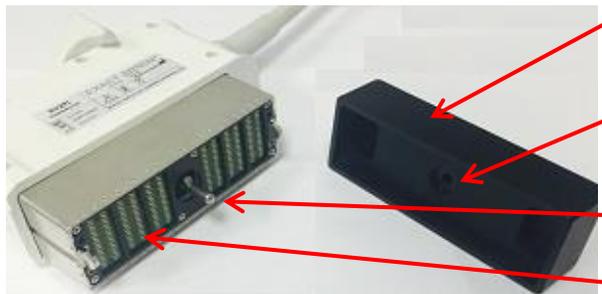
To disconnect the transducer from the ExactVu system:

1. On the connected transducer connector, turn the lock knob to its unlocked position.
2. Grip the connector firmly and pull it out of the transducer connector slot.
3. Line up the locking pin on the transducer connector with the notch on the transducer connector cover.
4. Attach the transducer connector cover to the connector (to protect the contact pads).
5. If your transducer has a *lockable transducer connector cover*, turn the lock knob on the transducer connector to its *locked* position (refer to Figure 21).



Transducer connector lock knob (in the unlocked position)

Figure 30: Unlocked Transducer Connector Lock Knob



Transducer connector cover
Notch
Locking pin
Contact pads

Figure 31: Transducer Connector Cover



Lockable transducer connector cover (i.e., a large-sized cover)

Figure 32: Lockable Transducer Connector Cover

CAUTION
EN-C23



Do not transport or clean the transducer without securely attaching the transducer connector cover. Do not allow debris or moisture to come in contact with the contact pads on the connector. Failure to use the transducer connector cover can cause damage to the transducer.

3.15 Reprocessing the Equipment

ExactVu operators have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. It is the responsibility of the operator to verify and maintain the effectiveness of the infection control procedures in use. Adequate reprocessing is necessary to prevent disease transmission.

3.15.1 Transducers and Related Accessories

Refer to the following manuals for information about the use, accessories and consumables, reprocessing, care and maintenance for ExactVu transducers:

- Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer
- Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer
 - The *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer* also provides instructions for reprocessing the *EV29L Non-sterile Reusable Transrectal Needle Guide*.
- Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer

3.15.2 Surface Cleaning for the ExactVu System

Surface cleaning is required for *non-critical devices*, defined by *Centers for Disease Control and Prevention* as "a reusable medical device that comes in contact with unbroken skin and does not penetrate it".

Cleaning *non-critical devices* is performed using a disinfecting cleaner. This procedure is applicable to surface cleaning the ExactVu system, which is to be performed after every procedure.

To surface clean the ExactVu system:

1. Ensure the system is free from any foreign material that may impede the cleaning process.
2. Wipe all exterior surfaces with one or more low-alcohol surface disinfecting wipes. Pay particular attention to:
 - Transducer holders (transducer holders can be removed for further cleaning if required)
 - Touch screen
 - Control panel
 - TGC sliders
3. Discard used cleaning materials as per internal clinical procedures for safe disposal.

NOTE

EN-N72



Dispose of cleaning materials and consumables according to internal clinical procedures for safe disposal.

4. Inspect the ExactVu system for signs of deterioration due to the effects of cleaning:
 - Unsmooth movement of the trackball
 - Controls not depressing on the control panel
 - Noticeable discoloration of parts of the ExactVu system cart

3.15.3 Foot Pedal

Clean the foot pedal after each use or as needed to avoid the build-up of hazardous bacteria and dirt.

To clean the foot pedal:

1. Use a cloth with a general-purpose detergent to wipe the foot pedal to remove dust, dirt and organic matter.
2. Disinfect the foot pedal using either:

- isopropyl alcohol wipes (70%)
- immersion in a disinfectant solution, prepared and used according to the manufacturer's instructions for the selected disinfectant

NOTE
EN-N176

Chlorine-based disinfectants may lead to deterioration of this device.

3. After disinfecting the foot pedal, rinse the foot pedal thoroughly under running water and allow water to drain by holding the foot pedal by the cable and allowing liquid to drain away.
4. Wipe residual moisture from the foot pedal enclosure.
5. Carefully hand-dry the foot pedal using a non-shredding absorbent cloth, an industrial hot air dryer or by placing it into a drying cabinet.

3.15.4 Transperineal Stepper

Refer to the *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer* for references to instructions for cleaning, disinfecting and sterilizing the transperineal stepper.

3.16 Turning the ExactVu System Off

To turn off the ExactVu system:

- Press the system power control on the front of the ExactVu system cart.

The ExactVu system saves and closes the active study, including any cine images and frames that were saved with the study, and powers off the ExactVu system.

Chapter 4 Patient/Study

1 Using DICOM Features

The ExactVu system provides two mechanisms for retrieving DICOM data from a PACS server:

- DICOM Modality Worklist
- MRI Query/Retrieve

These features are described in the following sub-sections.

1.1 Using DICOM Modality Worklist

To access DICOM Modality Worklist:

1. From the *Patient/Study* screen, select **Modality Worklist**.
A prompt to close the current study is displayed.
2. Close the current study.

The *Modality Worklist* screen opens, displaying the following two tabs:

- Modality Worklist Search
- Patient Search

The touch screen displays the virtual keyboard for the duration in which the Modality Worklist screen is open.

1.1.1 Modality Worklist Search

The Modality Worklist Search screen is used to specify query details for executing Modality Worklist queries and to display query results in the *Modality Worklist* table.

Modality Worklist queries are executed by querying the Modality Worklist server at the interval specified in *Preferences > DICOM Settings* (refer to Chapter 3, section 1.7.2.1 on page 62). The *Modality Worklist table* is populated at the selected interval as well as each time it is opened. During execution of the query a search progress message is displayed.

1.1.1.1 Modality Worklist Table

The *Modality Worklist table* displays a list of studies that reflect the result of the most recent query using the query parameters currently in place. Listed studies may be selected for use with the ExactVu system. It contains the following columns, and may be sorted by the columns indicated:

- Exam Date
- Exam Time
- Patient Name
- MRN
- Accession Number
- Patient Date of Birth

- Study Description
- Physician
- Gender
- Station
- Procedure ID
- AE Title
- Modality



To sort studies in the Modality Worklist table:

1. Select a column heading available for sorting the list.
 The *Modality Worklist* table sorts to correspond to the column selected for sorting. An arrow in the heading name indicates the sort order.
2. Select the heading again to switch the sort order of the column between ascending order and descending order.
 The *Modality Worklist* table re-sorts to correspond to the column selected for sorting. An arrow in the heading name indicates the sort order.

To select and load a study:

1. Using the trackball, position the cursor over the *Select* checkbox for the desired study and press **Set**.
 The *Select* checkbox is checked for the selected study.
 The *Load* control becomes enabled.
2. Select **Load**.
 The *Modality Worklist* screen closes, and the *Patient/Study* screen opens. The *Patient/Study* screen populates fields using details from the selected study for the following fields:
 - Patient First and Last Name
 - Patient Date of Birth

- MRN
- Accession Number
- Study Description
- Physician

If these fields were already manually entered by the operator, they are overwritten by the details from the study selected from the *Modality Worklist table* and made read-only, except for the Physician field, which may be edited before saving the information.

1.1.1.2 Executing Modality Worklist Queries

The Modality Worklist Search screen contains information about the query result shown in the *Modality Worklist table*:

- Current Time: indicates the current time in HH:MM:SS format and is updated every minute
- Last Data Acquired At: indicates the time of the most recent query in HH:MM format and is updated every 10 seconds.

There are also controls to perform the following two functions:

- Refresh: performs the following actions using either default query parameters or operator-specified query parameters:
 - Populate the *Modality Worklist table* from the most recent query
 - Update the *Last Data Acquired At* value



If the No re-query option is selected in the *Preferences > DICOM Settings* screen for configuring *Modality Worklist*, the "Refresh" button is not displayed. Refer to Chapter 3, section 1.7.2.1 on page 62 for more information.

- Query from PACS: performs the following actions using either default query parameters or operator-specified query parameters:
 - Perform a DICOM query to update the query results
 - Populate the *Modality Worklist table* from the updated query results
 - Update the *Last Data Acquired At* value
- Query Parameters: provides access for the operator to specify query parameters or to reset any operator-specified query parameters already configured in *Preferences > DICOM Settings*. Operator-specified query parameters are retained until the ExactVu system is restarted.

1.1.2 Patient Search

The *Patient Search* screen allows the operator to specify demographic and procedure data to perform the Modality Worklist query. It contains options for the following:

- Modality Worklist table
- Search Definition
- Query and Study Load controls

The *Modality Worklist table*, *Query from PACS* and *Load* controls on the *Patient Search* screen are the

same as those on the *Modality Worklist* screen.

1.1.2.1 Search Definition

The Search Definition contains the following fields against which the operator may perform a search:

- Last Name
- MRN
- Modality
- Accession number
- Procedure ID
- Physician

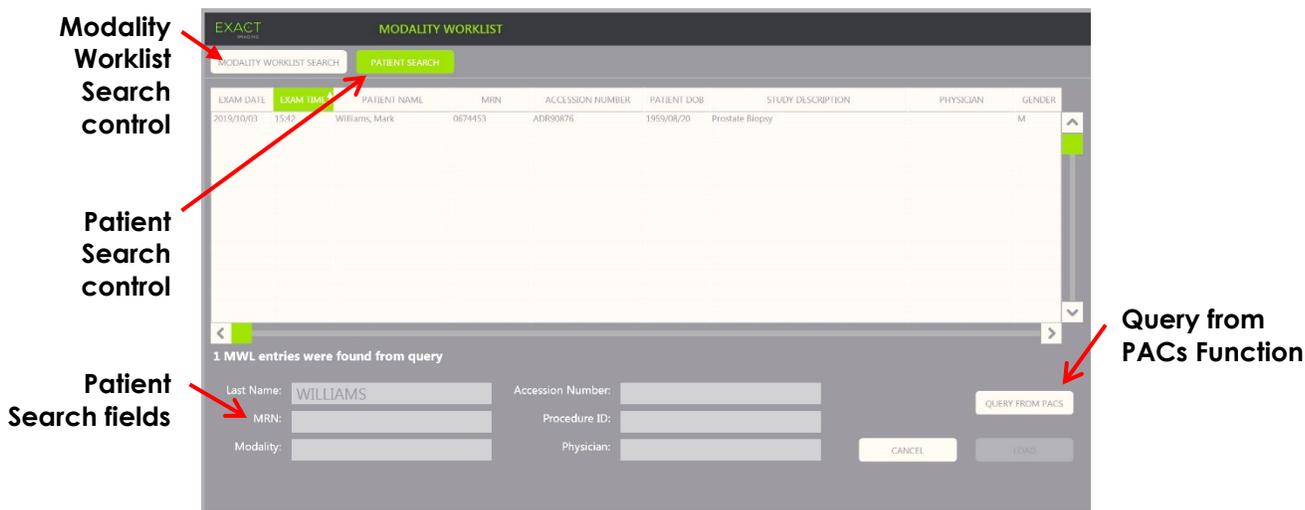


Figure 34: Modality Worklist Patient Search Screen

2 Using the Patient List Screen

The *Patient List* screen provides a way for operators to review images from studies performed previously (i.e., *closed studies*). It provides access to the studies stored on the ExactVu system or on a connected USB storage device.

When a study is selected in the *Patient List*, the *Patient List* screen provides controls to access images saved in each study, as well as to controls for exporting studies, and studying new patients. It also indicates the number of patients in the list.

The *Patient List* screen is accessed from the *Patient/Study* screen. Opening the *Patient List* screen closes the active study.

To access the Patient List screen:

1. From the *Patient/Study* screen, select **Patient List**.
If a study is active, a *Close Study confirmation* indicating whether there are unsaved changes is displayed.
2. Select **Yes** to continue without saving changes. Otherwise, select **No**.

After selecting to continue:

- The *Patient List* screen opens, displaying the *Patient List* in which studies stored on ExactVu are displayed in a sortable list. By default, the list is sorted alphabetically by last name, with the topmost patient highlighted.
- A vertical scroll bar allows the operator to scroll through studies stored on ExactVu. A search function allows the operator to search for a specific study using the patient's last name.

The Patient List contains the following columns, and may be sorted by the columns indicated:

- Row selection indicator
- Patient Name (column is sortable by the patient's last name)
- Date of Birth
- Patient ID/MRN
- Gender
- Accession Number (sortable column)
- Exam Type
 - The Exam Type column identifies information to reflect image presets used when images are saved. This column is empty for studies with no saved images.
- Study Date (sortable column)
- Status (sortable column), includes icons to indicate:
 - Mark for Deletion: The icons in this column indicate one of the following statuses: Marked, Unmarked. For a study that has not been exported or marked for deletion, no icon is displayed. For information about exporting studies, refer to Chapter 4, section 2.3 on page 106.
 - PACS Status: The icons in this column indicate one of the following statuses: Pending, Sending, Stored, Failed. If no attempt has been made to export a study to a PACS server, no icon is displayed.
 - Study size (i.e., number of frames and cine images)

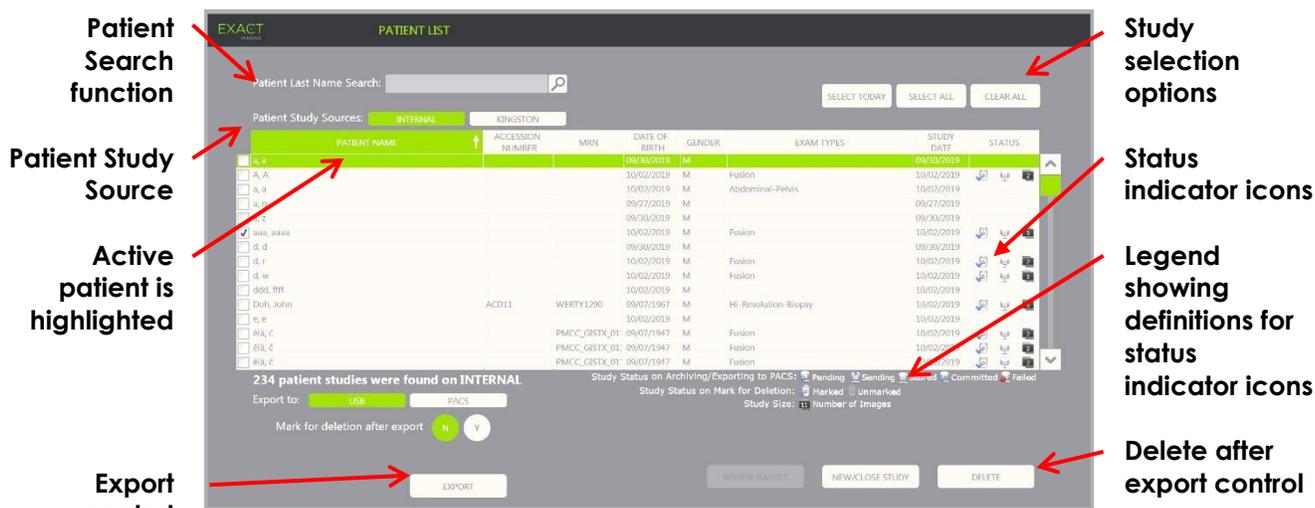


Figure 35: Patient List Screen

To search for a study in the Patient List:

1. Select the **Patient Last Name Search** field.
2. Type the patient's last name and select the search icon or press the *Return* key on the touch screen's keyboard.

The *Patient List* scrolls to display the first study for which the patient's last name matches or partially matches the search criteria entered. The list of studies is sortable as indicated previously.

Patient Study Source is used to select a source for patient studies. *Internal* identifies that studies on the ExactVu system's hard drive are displayed. When a USB storage device or a DVD drive is connected to the ExactVu system, the volume label for the hard drive on the connected device is displayed as an option next to *Internal*. Studies from the selected *Patient Study Source* may be reviewed as described in section 2.2 on page 105.

To specify a Patient Study Source:

- Select one of the options next to *Patient Study Source*.

The *Patient List* displays studies stored on the connected USB storage device.

To sort studies in the Patient List:

1. Select a column heading available for sorting the list.

The *Patient List* sorts to correspond to the column selected for sorting. An arrow in the heading name indicates the sort order.

2. Select the heading again to switch the sort order of the column between ascending order and descending order.

The *Patient List* re-sorts to correspond to the column selected for sorting. An arrow in the heading name indicates the sort order.

To begin a new study:

- From the *Patient List* screen select **New/Close Study**.

The *Patient/Study* screen is displayed so new patient information may be entered for a new study.

2.1 Selecting Studies

The *Patient List* includes controls for selecting a single study or multiple studies for further action, including:

- Reviewing images (images may be reviewed from one study at a time)
- Exporting studies to a USB storage device or to a PACS server
- Deleting studies

To select one or more specific single studies:

- Using the trackball, position the cursor over the *Select* checkbox for the desired study and press **Set**.

The *Select* checkbox is checked for each selected study.

The *Export* and *Delete* controls become enabled.

To select a group of studies:

- Using the trackball, position the cursor over one of the following options and press **Set**:
 - Select Today: selects all studies saved on the ExactVu system with the current day as the Study Date
 - Select All: selects all studies saved on the ExactVu system

The *Select* checkbox is checked for each selected study.

The *Export* and *Delete* controls become enabled.

To deselect selected studies:

- Using the trackball, position the cursor over the *Clear All* button press **Set**
All studies become deselected.

NOTE
EN-N127

The Review Images, Export and Delete controls are disabled if no studies are selected.

2.2 Reviewing Images

Images from an active study may be reviewed as described in Chapter 3, section 3.12 on page 93. Images from closed studies may be reviewed for patient follow-up, printing and to make additional measurements and annotations.

To display an image in a closed study:

1. From the *Patient List*, select a single study to be reviewed.
2. Select **Review Images**.

The first image in the study opens in the imaging screen. Information displayed with the image includes information from the time it was saved, such as the date and time, patient name and date of birth, as well as information about the image, including the imaging mode, transducer, and overlays (such as needle guide overlay, measurements and annotations).

The study's status is displayed as *Closed* in the *status panel* of the imaging screen.

Thumbnails for cine images and frames that have been saved with the study being reviewed are displayed in the *Image List Panel*, and may be viewed as described in Chapter 3, section 3.12 on page 93.

Changes to single frames may be saved for images in a study in *Review* using the *Frame* control. It is not possible to save changes to cine images (i.e., multiple sequential frames) when a study is in *Review*.

Details about measuring and annotating are described in Chapter 9 and Chapter 10.

NOTE
EN-N48

Some features that are available for live and paused images are not available when an image from a closed study is displayed. These are:

- Dual Mode / Transverse Mode
 - Live imaging
 - Modify patient and study information
 - Save a cine image
-

NOTE

EN-N49



When reviewing a *closed* study, it is not possible to acquire new images for the study. A new study must be created in order to acquire new images.

2.3 Exporting and Archiving Studies

Studies may be exported, in order to create a copy that may be reviewed at a later date, or to create a backup copy of data prior to deleting the study from the ExactVu system. Studies may also be archived on a PACS server.

When exporting studies, the data can be saved to either:

- A connected USB storage device, where the study will be exported in the ExactVu system's data format. Refer to Chapter 3, section 1.4 on page 56 for details about recommended formatting for USB storage devices and connecting a USB storage device to the ExactVu system. It is not possible to export studies to a connected CD or DVD drive.

CAUTION

EN-C52



Exact Imaging recommends the use of an encrypted USB device for archiving and exporting studies.

- A PACS server, as configured in *Preferences > DICOM Settings*, where the study will be exported in DICOM format. When a study is exported to a PACS server, it uses both standard and private DICOM tags to retain image data, needle guide overlays, measurements, annotations, imaging settings etc., for future review on a DICOM workstation.

NOTE

EN-N132



Single frames and cine images exported to a PACS server are displayed on DICOM viewers in compressed multi-frame format.

NOTE

EN-N121



When a connected USB device is the selected *Patient Study Source*, controls for selecting, exporting and deleting studies are disabled. Refer to Chapter 4, section 1 on page 99 for details about selecting the *Patient Study Source*.

The operator is able to mark a study for future automatic deletion after exporting it to USB. Studies are automatically deleted only when disk space available for new studies becomes limited. The operator may also manually delete a study. Studies that are archived to a PACS server are automatically marked for future automatic deletion.

NOTE

EN-N78



If a study that was previously exported is modified, its *Study Status on Mark for Deletion* state is updated. If the study is later exported to a USB storage device, it is exported to a new file.

2.3.1 Manual Export Processes

To manually export studies (and mark studies for deletion after they are exported):

1. Connect a USB storage device to the ExactVu system, formatted as recommended in Chapter 3, section 1.4 on page 56.
2. In the *Patient List* choose one of the options for selecting studies:
 - Manually select studies
 - Select **Select Today**
 - Select **Select All**
3. Select an *Export to* option:
 - If *USB* is selected:
 - Select **Y** next to *Mark for deletion after export* to automatically mark studies for deletion after they are exported.
 - Alternatively select **N** next to *Mark for deletion after export*. Studies can be manually marked for deletion individually after they are successfully exported using the icon in the *Status* column.
 - If *PACS* is selected, studies are automatically marked for deletion after they are successfully archived to a PACS server.
 - If the studies selected to be archived to a PACS server are already archived, a confirmation prompt is displayed. If the operator chooses to archive them again, the status for those studies changes to *Pending*.
4. Select **Export**.

A message is displayed to indicate that studies are being exported.

Studies are archived to a PACS server in chronological order based on the study date, such that the oldest studies are archived first.

A typical TRUS workflow normally includes approximately three frames, two 300-frame cine images (when using the EV29L transducer) and twenty 60-frame cine images being saved for the study.

NOTE
EN-N146



A typical kidney, pelvis or bladder workflow normally includes approximately twelve frames, and twelve 60-frame cine images being saved for the study.

It may take several minutes for a study that follows this workflow to be exported to a USB device or to be archived to a PACS server. Exact Imaging recommends exporting studies when the ExactVu system is not required for other procedures. When exporting to a USB storage device, Exact Imaging recommends using the USB connectors located on the rear of the monitor (if enabled).

5. Press **OK** to acknowledge the export completion status message.

The *Status* column indicates the studies that were successfully exported with either a *Marked* icon indicating *Marked for Deletion* or with a PACS Status of *Stored*.

For studies exported to a USB storage device, the studies specified are copied to the folder, *ExactData*, on the USB storage device.

For a study successfully archived to a PACS server, *Status* column displays the *Stored* icon as

well as the *Marked* icon, indicating that the study is marked for deletion.

For an unsuccessful archive to a PACS server:

- Another attempt is made ten minutes after the unsuccessful first attempt to archive the study.
- Where the process fails due to a network or PACS server error, three attempts are made to archive the study. Following this, no further attempts are made until the ExactVu system is restarted. In this situation, the PACS status is displayed as *Error* in the *status panel* of the imaging screen.
- Where the process fails due to a study-related error, no further attempts are made, and the *Status* column displays the *Failed* icon.
- Where attempts to export studies to a PACS server continue to be unsuccessful, contact Technical Support using the contact information in Appendix F.

6. Refer to section 2.6 on page 109 for information about automatic deletion.

To cancel an export in progress:

- When the export of studies to a USB storage device is in progress, press **Cancel** on the export progress dialog.

The export operation stops.

A message indicates the number of studies that were and were not exported.

To deselect the Marked for Deletion icon:

- Using the trackball, position the cursor over the *Marked* icon for the study in the *Status* column of the *Patient List* and press **Set**.

The *Unmarked* icon is displayed indicating that the study will not be deleted automatically.

2.4 Deleting Studies

Studies may be manually deleted in order to make disk space available for creating new studies on the ExactVu system.

To delete studies from the ExactVu system:

1. In the *Patient List* choose one of the options for selecting studies:
 - Manually select studies
 - Select **Select Today**
 - Select **Select All**

2. Select **Delete**.

A delete confirmation message is displayed.

3. Select **OK** to acknowledge the delete confirmation.

The selected study or studies are deleted from the ExactVu system.

Studies may also be marked for automatic deletion as part of the study export process. For information about automatic study deletion, refer to section 2.6 on page 109.

NOTE
EN-N133

Studies may only be marked for automatic deletion from the ExactVu system if they are successfully exported to a USB storage device or archived to a PACS server.

2.5 Reviewing ExactVu Data Stored on a USB Storage Device

Images from studies exported to a USB storage device may be reviewed. When an operator measures and annotates images from studies on a USB storage device, the images are resaved on the USB storage device.

Refer to Chapter 3, section 1.4 on page 56 for details about recommended formatting for USB storage devices and connecting a USB storage device to the ExactVu system.

To review images from studies on a USB storage device:

1. Connect a USB storage device to the ExactVu system that contains studies created using ExactVu.
2. From *Patient/Study*, select **Patient List**.

The *Patient List* screen is displayed.

The *Patient Study Source* options include the volume label for the connected USB storage device.

3. From the *Patient List* screen, select the option representing the connected USB storage device.

The *Patient List* updates to list the ExactVu studies on the connected USB storage device, and studies stored on the ExactVu system are not displayed.

For ExactVu studies stored on a USB storage device, the procedure to search for studies and review images is the same as the procedure for studies stored on the ExactVu system. It is not possible to export or delete studies on a USB storage device, or to mark them for deletion.

To review patients saved on the ExactVu system:

- From the *Patient List* screen, select **Internal** next to *Patient Study Source*.

The *Patient List* screen updates to display information for the first alphabetical patient study saved on the ExactVu system.

2.6 Automatic File Deletion

When the ExactVu system is started it determines the available disk space.

When the available disk space is checked and is less than the *Disk Space Auto Delete Threshold* (20% of total disk space), the ExactVu system automatically deletes studies that are *Marked for Deletion* in order to ensure space is available for new studies. It also automatically deletes message logs when the total disk space used by message logs exceeds 10 GB.

If the available disk space is less than the *Disk Space Warning Threshold*, an on-screen message indicates that soon it will be impossible to save patient and image data.

Furthermore, the ExactVu system prevents study data and message logs from being saved if available disk space is less than the *Disk Full Threshold* (7% of total disk space).

Automatic deletion workflow:

1. When the available disk space is checked, it is compared with the *Disk Space Auto Delete Threshold*.
2. If the available disk space is less than the *Disk Space Auto Delete Threshold*, the ExactVu system automatically deletes message logs and studies that are *Marked for Deletion*. The oldest studies are deleted in a batch, where the batch size is between 1-5% of disk space. The oldest message logs are deleted in a batch, where the batch size is up to 2 GB.
3. Study deletion continues until available disk space is more than the *Disk Space Stop Auto Delete Threshold* (50% of total disk space).
4. If disk space is less than the *Disk Full Threshold* after the automatic deletion process is performed, a message is displayed to inform the operator that further saving of study data is disabled.

After exporting and deleting sufficient additional studies, a message is displayed to inform the operator that study data is enabled.

NOTE

EN-N79



When a study (or message log file) is deleted from the ExactVu system, it may only be reviewed from a copy exported to a USB storage device or exported to PACS.

Disk management workflow during imaging:

1. During imaging, the available storage space is compared with the *Disk Space Warning Threshold*.
2. If the remaining available disk space is less than the *Disk Space Warning Threshold*, the status panel displays the remaining disk space percentage as follows:
 - A yellow display indicates that the available disk space is less than the *Disk Space Warning Threshold*, and the operator is able to continue saving study data
 - A red display indicates that the available disk space is less than the *Disk Full Threshold*, and the operator is not able to continue saving study data

Chapter 5 Using 2D Mode

Chapter 3, section 3.5.4 on page 83 provides a description of imaging settings that are used to control the acquisition and display of images for all imaging modes, including dynamic range, gain, image depth, focal zones, TGC, and transmit power.

This chapter describes features that are specific to 2D Mode.

1 Support for Large Prostates

Stitch is a sub-mode of 2D Mode that allows two images to be combined together during live imaging in order to extend the field of view.

NOTE
EN-N52



Stitch sub-mode is enabled only when the EV29L transducer is active.

1.1 Enabling Stitch Sub-mode

Stitch sub-mode may be enabled using a control on the Workflow touch screen.

Typically, the apical part of the prostate is visualized first. *Stitch* displays this view statically on the screen, to be used as a guide while the operator aligns the live basal portion of the prostate to the static image.

To use *Stitch*:

1. Image the prostate to display the apical view.
2. From the *Workflow* touch screen, press **Stitch**.

The apical view is frozen and displayed on the right-hand pane on the imaging screen.

3. Obtain the basal view of the prostate and align the live image to the image displaying the apical view.
4. Press **Stitch**.

A single image is formed by combining the two views, and the *Stitch* image is saved as a single frame.

Stitch sub-mode toggles off, and *Transverse Mode* is initiated.

Images saved in *Stitch sub-mode* may be measured and annotated. Measurements up to 6.5 cm may be made on imaged saved in *Stitch sub-mode*.

NOTE
EN-N53



During imaging in *Stitch sub-mode*, it is not possible to change imaging settings.

2.2 Anesthesia Sub-Mode (enabled only when the EV29L Transducer is Active)

To enable Anesthesia sub-mode:

1. Press **Workflow** on the *touch screen*.

The *Workflow touch screen* is displayed.

2. Press **Anesthesia**.

Anesthesia sub-mode is enabled, and the 15° *transrectal needle guide overlay* is enabled. This *needle guide overlay* may be toggled *ON* and *OFF* when viewing live or frozen images.

When using the EV29L transducer, *Anesthesia* sub-mode enables a higher imaging frame rate compared to other 2D sub-modes and enables the *needle guide overlay* automatically.

2.3 Needle Guide Overlay

The *needle guide overlay* is displayed on the imaging screen, to aid in identifying the expected path of the anesthesia or biopsy needle. The *needle guide overlay* tracks a needle inserted in the physical *needle guide* on the imaging screen.

Needle guide overlays are available in *2D Mode*, *Biopsy* sub-mode, *Anesthesia* sub-mode and *CFI Modes*. The available *needle guide overlays* are dependent on the active transducer and *needle guide* type.

Needle guide overlays may be selected from the *Workflow touch screen*.

2.3.1 Using the Needle Guide Overlay with the EV29L Transducer

When the EV29L transducer is active, the *needle guide overlays* are available in *Biopsy* sub-mode and *Anesthesia* sub-mode.

The display of the *needle guide overlay* is toggled *ON* and *OFF* from the *Workflow touch screen*. Only one *needle guide overlay* may be displayed at a time.

For procedures that use the EV29L sterile transrectal needle guide:

- Use the setting in *Preferences* (refer to Chapter 12, section 4.3 on page 171) to select the EV29L sterile transrectal needle guide.

Two *needle guide overlays* are available on the *Workflow touch screen* (green for biopsy guidance and white for anesthesia guidance), to correspond to the two needles supported by the *EV29L sterile transrectal needle guide*.

The angle and color for each *needle guide overlay* corresponds to the needle entrances on the *EV29L sterile transrectal needle guide* in which each supported needle fits.

For anesthesia delivery using *Anesthesia sub-mode*, the recommended *needle guide overlay* is at 15 degrees and is white.

For biopsy procedures using *Biopsy sub-mode*, the only available *needle guide overlay* is at 35 degrees and is green.

WARNING
EN-W53

For the single-use EV29L sterile transrectal needle guide, the anesthesia needle can be inserted into both needle entrances in the needle guide.

When using the needle guide overlay during anesthesia administration with the EV29L transducer, the operator must ensure that the *needle guide overlay* displayed on screen corresponds to the *needle entrance* in which the anesthesia needle is inserted in the physical needle guide.

If the anesthesia needle is inserted in the *biopsy needle entrance*, the operator must use the needle guide overlay in order for the overlay to track the path of the needle in the displayed image.

For procedures that use the EV29L non-sterile reusable transrectal needle guide:

Needles fit into the EV29L reusable transrectal needle guide at an angle of 35 degrees. Anesthesia needles may be used with this needle guide; however, the 35° needle guide overlay is recommended.

- Use the setting in *Preferences* (refer to Chapter 12, section 4.3 on page 171) to select the EV29L reusable transrectal needle guide.

One *needle guide overlay* is available on the *Workflow* touch screen to correspond to the single needle angle supported by the EV29L reusable transrectal needle guide.

To manually select the 35° transrectal needle guide overlay from Anesthesia sub-mode:

- If the EV29L reusable transrectal needle guide preference has not been set, in *Anesthesia sub-mode*, with the 15° transrectal needle guide overlay toggled on, press **35** on the *Workflow* touch screen.

The 35° transrectal needle guide overlay toggles on and is appropriate for use with EV29L reusable transrectal needle guide.

Refer to section 3.1 on page 116 for information about *needle guide overlays* for use in transperineal procedures.

2.3.2 Using the Needle Guide Overlay with the EV9C Transducer

When the EV9C transducer is active, the needle guide overlay is available only in 2D Mode.

To toggle the display of the needle guide overlay when using the EV9C transducer:

1. From the *Workflow* touch screen, while imaging in 2D Mode and with the *needle guide overlay* toggled OFF, press **ON**.

The *needle guide overlay* toggles ON over the image.

Only one *needle guide overlay* is available for the EV9C transducer, and it is used for both anesthesia and biopsy.

2. From the *Workflow* touch screen, with the *needle guide overlay* toggled ON, press **OFF**.

The *needle guide overlay* toggles OFF.

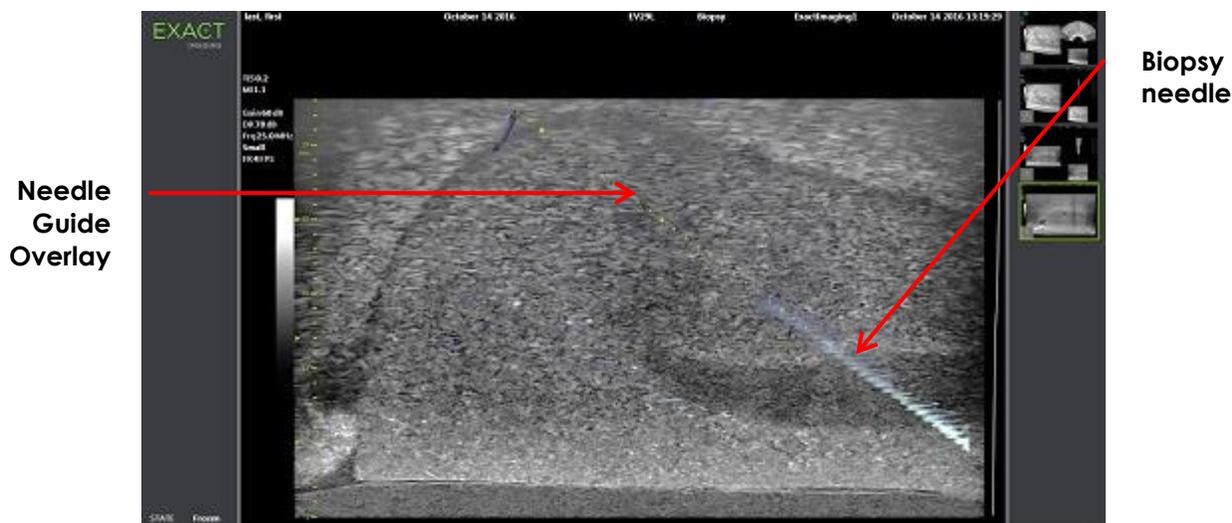


Figure 38: Needle Enhancement

3 Support for Transperineal Needle Guidance

The ExactVu system offers several features to support guidance for transperineal procedures, with needle guidance provided using either the *EV29L sterile transperineal needle guide* or the template grid.

3.1 Needle Guide Overlay

Transperineal *needle guide overlays* are available to be displayed on the imaging screen when imaging in Biopsy sub-mode and Transverse Mode (depending on the overlay), to aid in identifying the expected path of the inserted needle.

Transperineal *needle guide overlays* may be selected from the *Workflow* touch screen and may be enabled only when the EV29L transducer is active. Two transperineal *needle guide overlays* are available, depending on the physical needle guide in use. Only one transperineal *needle guide overlay* may be displayed at a time.

The *needle guide overlay* tracks on the imaging screen a needle inserted in the physical EV29L sterile transperineal needle guide or transperineal grid.

Saved single frames and cine images include transperineal *needle guide overlays* when saved with the image.

WARNING
EN-W57

The *transperineal needle guide overlays* are intended to assist the operator to visualize the approximate needle path; however, the actual needle movement may deviate from the *overlays*. Always monitor the relative positions of the biopsy needle and the tissue target during the procedure.

For transperineal procedures, ensure there is alignment between the position on the needle guide overlay and the needle entrance position on the physical EV29L sterile transperineal needle guide or template grid.

The use of a small preset may prevent visualization of needles inserted through the deepest needle entrances (i.e., the highest numbered needle entrances). If the needle is not visible, changing the image depth may help to ensure the needle is displayed.

NOTE
EN-N168

Needle Enhancement is not available when using *transperineal needle guide overlays*.

NOTE
EN-N138

Transperineal needle guide overlays may be used when using *FusionVu* in *Biopsy sub-mode*.

3.1.1 Using the Transperineal Guide Needle Guide Overlay

The *Transperineal Guide overlay* is a needle guide overlay to provide onscreen needle guidance by indicating which needle entrance position on the physical *EV29L sterile transperineal needle guide* aligns with the position of the prostate. The *Transperineal Guide overlay* is available in *Biopsy sub-mode* only.

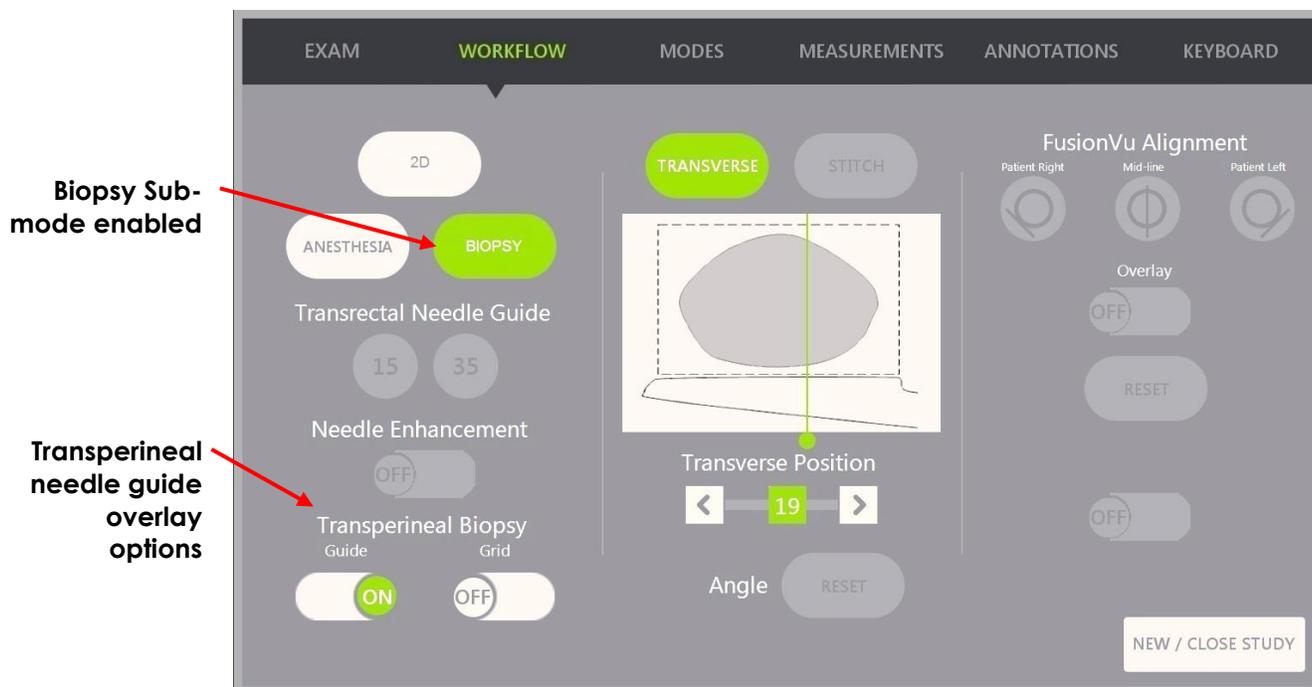


Figure 39: Workflow Touch Screen

To toggle the Transperineal Guide overlay in Biopsy Sub-mode:

- Below Transperineal Biopsy, press **ON** or **OFF** next to *Guide* on the *Workflow* touch screen while imaging in Biopsy sub-mode.

The *Transperineal Guide* overlay toggles *ON* or *OFF*.

When the *Transperineal Guide* is toggled *ON*, the image displays an onscreen overlay for the *transperineal needle guide* that shows the expected needle trajectory through it.

To align the Transperineal Guide overlay with the needle:

- Align the marking on the needle with the marking on the entrance of the EV29L sterile transperineal needle guide.

The tip of the needle aligns with the number for the corresponding marking on the physical EV29L sterile transperineal needle guide and the label of the *Transperineal Guide* overlay line on the right side of the image.

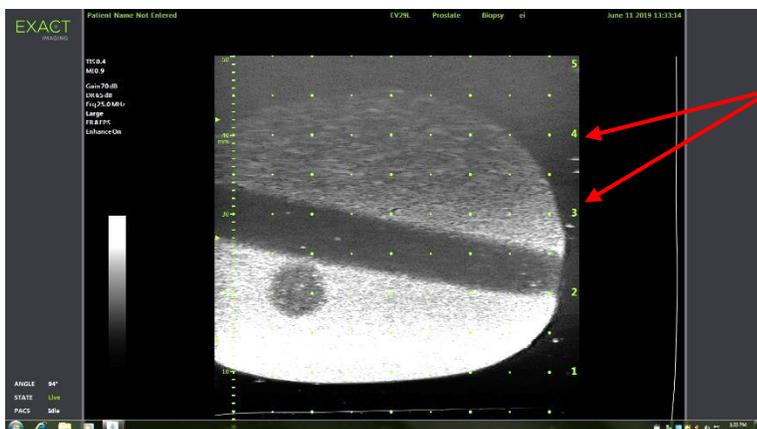


Figure 40: Transperineal Guide Overlay Enabled

Transperineal Guide overlay labels

Needle entrance markings

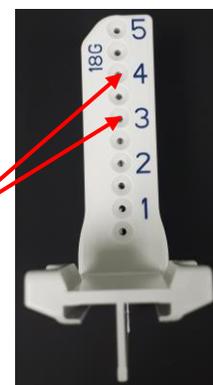


Figure 41: EV29L Sterile Transperineal Needle Guide

3.1.2 Using the Transperineal Grid Needle Guide Overlay

The *Transperineal Grid* is a needle guide overlay displayed on the micro-ultrasound image to provide onscreen needle guidance by indicating which *template grid* positions align with the position of the prostate. The *Transperineal Grid* is available in *Biopsy sub-mode* or in *Transverse Mode*.

When the *Transperineal Grid* is enabled, it is not possible to access *Anesthesia sub-mode* or *Stitch mode*, or the overlays available in those sub-modes.

To toggle the Transperineal Grid in Biopsy sub-mode:

- Below Transperineal Biopsy, press **ON** or **OFF** next to *Grid* on the *Workflow* touch screen while imaging in *Biopsy sub-mode*.

The *Transperineal Grid* toggles *ON* or *OFF*.

In the sagittal view, when the *Transperineal Grid* is toggled *ON* and aligned with the center column of the *template grid*, the image displays an onscreen overlay for the *template grid* that shows the expected needle trajectory through it. When the transducer is rotated, and no longer aligned with the center column of the *template grid* (marked "D"), the needles may no longer continue being in alignment with the grid lines.

NOTE
EN-N123



The needle in the center column of the *template grid* (marked "D") corresponds to correct height and trajectory of the onscreen lines. Needles in columns other than the center column show the expected needle trajectory only.



Figure 42: Transperineal Grid Enabled

To toggle the Transperineal Grid in Transverse Mode:

1. Begin imaging in 2D Mode in order to access Transverse Mode. Then switch to Transverse Mode.
2. Next to *Transperineal Grid*, press **ON** or **OFF** on the *Workflow* touch screen while imaging in Transverse Mode.

The *Transperineal Grid* toggles *ON* or *OFF*.

When the *Transperineal Grid* is toggled *ON*, it displays marks identifying the grid and column indicators of the *template grid* and may be used to map the procedure by indicating the grid positions to sample.

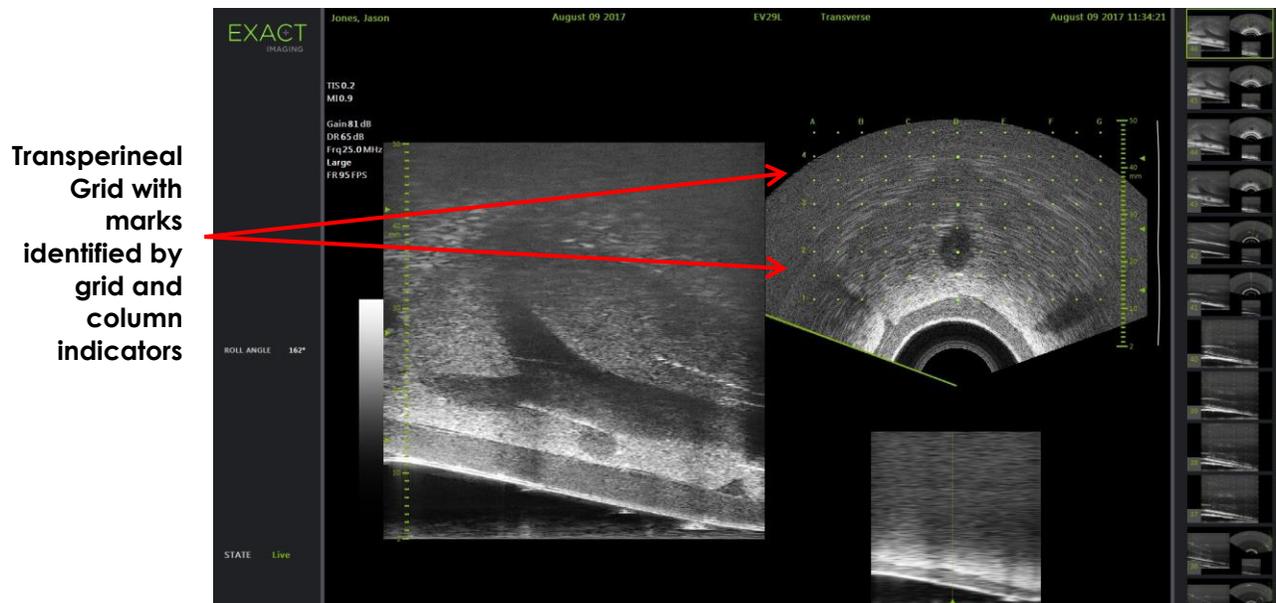


Figure 43: Transverse Mode with Transperineal Grid Enabled

NOTE
EN-N124

When viewing the prostate in the transverse view, ensure the prostate is vertically aligned with the *template grid* and is contained within its borders.

3.2 Performing a Transperineal Procedure

Perform the transperineal procedure according to internal clinical protocols. Observe all cautions and warnings related to performing transrectal and transperineal procedures using the ExactVu system.

For transperineal procedures, always point the bevel of the needle (i.e., the sharpest point) away from the transducer.

WARNING
EN-W82

If the needle is pointed toward the transducer and is inserted through the shallower needle entrances (i.e., the lowest numbered needle entrances) of the EV29L sterile transperineal needle guide, it is possible for the needle to injure the patient's rectum as well as to scratch or cause other damage to the transducer lens.

When using the shallower needle entrances take extra caution to track the full path of the needle to ensure any needle deflection is away from the rectum as well as from the transducer lens.

4 Support for Abdominal Needle Guidance

The ExactVu system offers several features to support guidance for transperineal procedures, with needle guidance provided using either the *EV29L sterile transperineal needle guide* or the *template grid*.

4.1 Needle Guide Overlay

Abdominal needle guide overlays may be selected from the *Workflow* touch screen. When the EV5C transducer is active, the needle guide overlay is available only in *2D Mode* or the *CFI Modes*.

To use the needle guide overlay with the EV5C transducer:

When the EV5C transducer is active the operator is able to choose from five *abdominal needle guide overlay* options, to correspond to those supported by the CIVCO® Verza™ needle guide for use with the EV5C transducer (refer to Chapter 1, section 8.5 on page 25).

Each available position for the *abdominal needle guide overlay* reflects its point of intersection with the midline of the transducer, as follows:

- Position 1: 50.4° at 0.759" (1.93 cm) depth
- Position 2: 38.4° at 1.421" (3.61 cm) depth
- Position 3: 28.4° at 2.317" (5.88 cm) depth (default position)
- Position 4: 19.4° at 3.828" (9.72 cm) depth
- Position 5: 13.4° at 5.906" (15.00 cm) depth

The display of the *abdominal needle guide overlay* position is selected from the *Workflow* touch screen. Only one *needle guide overlay* position may be displayed at a time.

To toggle the display of the needle guide overlay when using the EV5C transducer:

1. When imaging in 2D Mode or either of the CFI Modes, enable the *Workflow* touch screen, and with the *needle guide overlay* toggled *OFF*, press **ON**.
2. Press the left or right arrows under *Position* until the number matches the selected *Angle Indicator* on the physical needle guide.
The *needle guide overlay* toggles *ON* over the image at the selected position.
3. To toggle *OFF* the needle guide overlay, press **OFF** on the *Workflow* touch screen.

4.1.1 Needle Guide Overlay Markings

The abdominal *needle guide overlays* display dots that correspond with needle markings at each of 5 mm, 10 mm and 50 mm spacing. These markings allow the operator to plan the depth for needle penetration.

To align the needle guide overlay with the needle:

- Align the marking on the needle with the marking on the entrance of the needle guide.
The tip of the needle aligns with the corresponding dot on the *needle guide overlay*.

5 Setting the Angle Value (enabled when the EV29L Transducer is Active)

The EV29L transducer has a *motion sensor* that allows an *Angle* value to be indicated on the imaging screen based on its rotational position relative to a zero-degree position.

When a new study is created, the default *Angle* value is set to 90 degrees when the transducer lens is facing upwards (i.e., to correspond to a left lateral decubitus position for the patient). Rotating the transducer in a counter-clockwise direction increases the *Angle* value up to 180 degrees. Rotating the transducer in a clockwise direction decreases the *Angle* value down to -180 degrees.

The operator is able to set a desired zero-degree position in *2D Mode* and in *Transverse Mode* using a control on the *Workflow* touch screen.

To set the zero-degree position for the Angle value while imaging with the EV29L transducer:

1. While imaging with the EV29L transducer in *2D Mode* or *Transverse Mode*, observe the *Angle* value in the status area of the imaging screen.

The value is displayed in white text.

Rotating the transducer in a counter-clockwise direction increases the *Angle* value, and rotating the transducer in a clockwise direction decreases the *Angle* value.

2. Rotate the transducer so that the transducer lens is facing towards the desired zero position.
3. From the *Workflow* touch screen, press **Reset** next to *Angle*.

The *Angle* value displayed on the imaging screen changes to show 0 degrees and changes to be displayed in yellow text, to indicate that the *Reset* feature has been applied.

The updated zero-degree position is retained for the remainder of the study.

NOTE
EN-N169



It is important to remember that when the Angle value is displayed in yellow text, it indicates that the Reset feature was applied one or more times during the study.

Chapter 6 Using Dual / Transverse Mode

The ExactVu system provides the capability to split the *imaging screen* vertically to display side-by-side images. This allows volume measurements to be made using images from two planes.

When imaging with the EV9C or EV5C transducer, split screen imaging is available in as *Dual Mode*. When imaging with the EV29L transducer, split screen imaging uses *Transverse Mode*.

Dual Mode and *Transverse Mode* are only available when a live or paused 2D Mode image is displayed in the imaging screen. Neither *Dual Mode* nor *Transverse Mode* is available when an image is displayed for review.

Dual Mode and *Transverse Mode* images may be saved, measured and annotated, similar to images in other modes.

1 Dual Mode (enabled when the EV9C or EV5C Transducer is Active)

When Dual Mode is enabled, the screen splits to display the frozen 2D Mode image in the left pane, and live imaging continues in the right pane. As in 2D Mode, the image displayed using the EV9C transducer is either in the sagittal view or transverse view, depending on how the inserted transducer is positioned. For the EV5C transducer, the view is determined by the physical position of the transducer relative to the patient.

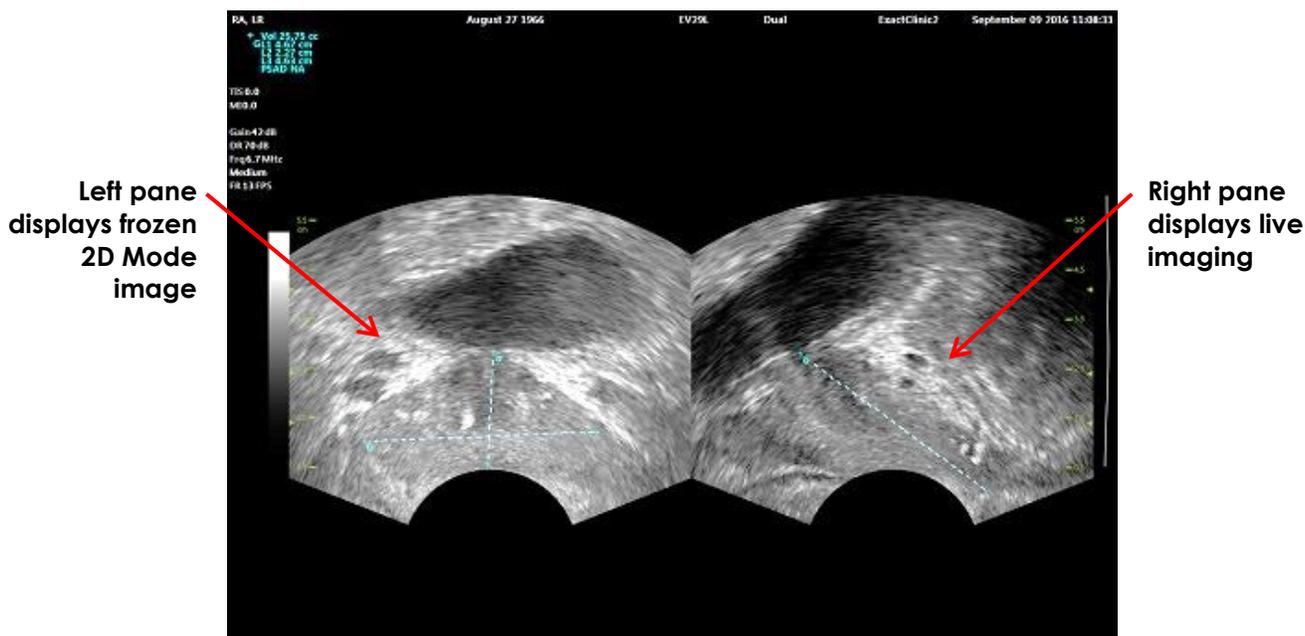


Figure 44: Dual Mode Imaging Screen

1.1 Enabling Dual Mode

To enable Dual Mode:

- From 2D Mode:
 - Press **Dual** on the *Workflow* or *Modes* touch screen, OR

- Press **Dual/Transverse** on the *control panel*

The screen splits into a left and right pane.

The current image is paused and displayed in the left pane. Any image previously displayed in the left pane is discarded.

Live imaging continues in the right pane.

When imaging in *Dual Mode*, all imaging controls are applied to the active pane (i.e., the right pane).

Chapter 3, section 3.5.4 on page 83 provides a description of imaging settings that are used to control the acquisition and display of images for all imaging modes, including dynamic range, gain, image depth, focal zones and transmit power.

NOTE
EN-N59



When imaging with the EV9C transducer, a transverse view may be obtained by rotating the transducer.

1.2 Canceling Dual Mode

To cancel Dual Mode:

- When imaging in *Dual Mode*, switch to another imaging mode.

2 Transverse Mode (enabled when the EV29L Transducer is Active)

Imaging in *Transverse Mode* allows the operator to display two orthogonal images in side-by-side image panes. Typically, a sagittal view is displayed in the left-hand pane while obtaining a transverse view in the right-hand pane. In *Transverse Mode*, the transverse plane of the prostate is displayed one line at a time using reconstructed 2D Mode data to create a Transverse Mode image.

2.1 Enabling Transverse Mode

To enable Transverse Mode:

- From any imaging mode other than *Biopsy* sub-mode or *Anesthesia* sub-mode, press **Dual/Transverse** on the control panel or press **Transverse** on the *Workflow* touch screen.

The *Transverse Mode* imaging screen opens.

The screen splits into a left and right pane.

The current image (i.e., the sagittal view) is paused and displayed in the left pane. If the operator is already using *Transverse Mode*, the previously displayed image is retained.

The right pane enables a *transverse image* to be constructed.

The right pane also displays a low-resolution live scout window, to help orient the transverse plane in reference to the standard sagittal image.

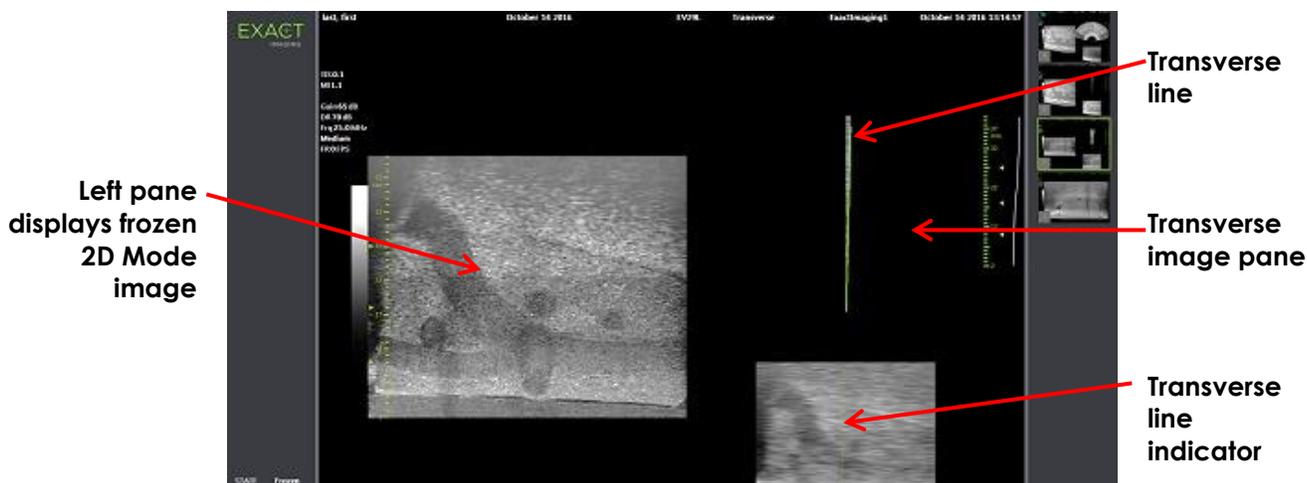


Figure 45: Transverse Mode Before Transverse Image Construction

2.2 Constructing the Transverse Image

In Transverse Mode, the transverse image is constructed in real-time using 2D line acquisition, i.e., the image is constructed one line at a time.

The transverse image is constructed by rotating the EV29L transducer around the mid-line of the prostate. This center position is recommended so that the prostate is centered in the transverse image and to optimize the volume measurement workflow. A fan-shaped transverse image is created as the transducer is rotated and may include up to 160 degrees of rotation.

To construct the transverse image:

1. With the transducer positioned at the mid-line of the prostate, rotate the transducer slowly and carefully, such that it takes approximately 5 seconds to rotate it 160 degrees. Do not introduce extra motion during rotation and image construction, or the image may be distorted.

In the *transverse image pane*, a fan-shaped transverse image is drawn one line at a time in real-time to follow the rotation of the transducer.

The green *transverse line* follows the rotational path as the fan is constructed.

The detected *Angle* value is displayed on the imaging screen in increments of one degree and is accurate within 5 degrees. The angle is measured in a clockwise direction from the nominal prostate mid-line when the patient is in the left lateral decubitus position.

2. If image is visibly distorted, repeat the rotation to overwrite the image. If necessary, press **Dual/Transverse** on the *control panel* to reinitialize and re-center the *Transverse Mode* fan.
3. If the desired image is still not displayed, adjust the *transverse line position* (refer to the procedure below) and repeat step 1.



If the rotation of the transducer is irregular or too quick, the matching sector of the fan may be distorted and may not be displayed.

Do not make measurements on a distorted image.

NOTE
EN-N126



The edges of the fan are removed to reduce the width of the image.

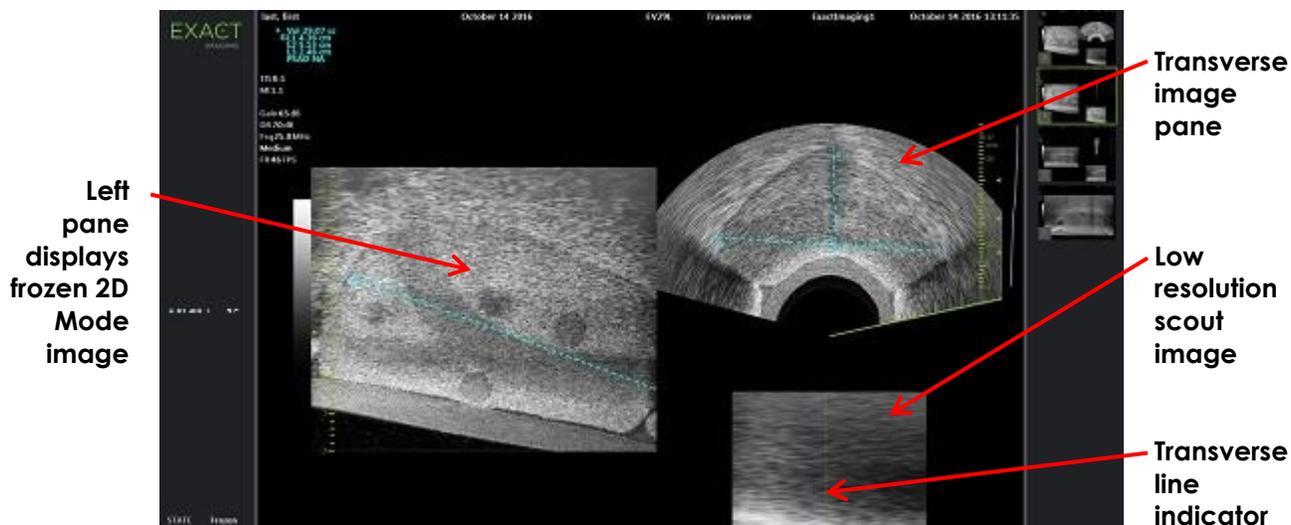


Figure 46: Transverse Mode After Transverse Image Construction

To adjust the transverse line position:

1. Under the *Transverse Position* slider on the *Workflow* touch screen, press the left or right arrow to move the slider left or right.
2. Use the *Freeze* control on the *control panel* to toggle imaging off and then on.

As the slider position moves left or right, the transverse line moves left or right correspondingly in both the transverse line indicator and in the live scout image in the right pane of the imaging screen.

When imaging in *Transverse Mode*, adjustments to all imaging settings are applied to the active pane (i.e., the right pane).

Chapter 3, section 3.5.4 on page 83 provides a description of imaging settings that are used to control the acquisition and display of images for all imaging modes, including dynamic range, gain, image depth, focal zones, TGC and transmit power.

2.3 Canceling Transverse Mode

To cancel Transverse Mode:

- When imaging in *Transverse Mode*, switch to another imaging mode.
Transverse Mode is canceled, and imaging resumes in the mode in use prior to selecting *Transverse Mode*.

Chapter 7 Using Color Flow Imaging Modes (Color Doppler Mode and Power Doppler Mode)

Color flow imaging is a form of Doppler imaging, in which fluid flow velocities are mapped over the 2D image using color. ExactVu provides two color flow imaging modes ("CFI Modes"):

- Color Doppler Mode
- Power Doppler Mode

Both Color Doppler Mode and Power Doppler Mode use a configurable *color box*. The color box is a fan-shaped area of a CFI Mode image in which velocity data for the image is displayed and is overlaid on the 2D Mode image.

In Color Doppler Mode, the flow velocity is indicated by the color displayed in the color box. A blue color indicates flow away from the transducer and red indicates flow towards the transducer. In Power Doppler Mode, the flow magnitude is indicated by the color displayed in the color box.

CFI Modes are available only when using the EV5C transducer. References made in this chapter to CFI Modes apply to both Color Doppler Mode and Power Doppler Mode.

1 Enabling CFI Modes

CFI Modes can be enabled using either the control panel or the touch screen. The controls for selecting a CFI Mode toggle between CFI Modes, depending on the mode in use when the control is accessed.

To enable a CFI Mode using the control panel:

- From a non-CFI Mode, press **C/P** on the *control panel*, or
Color Doppler Mode opens in the imaging screen, and imaging begins.
The *Modes* touch screen opens.
The color box is in a *color box position configuration* state, which means its position can be adjusted as described in section 2 on page 129.
- From either CFI Mode, press **C/P** on the *control panel*
The Imaging Screen toggles to the other of the CFI Modes, and imaging begins.
The *Modes* touch screen opens.
The color box retains its state, position and size from the previous CFI mode. Acquisition parameters are also retained when switching between CFI Modes.

To enable a CFI Mode using the touch screen:

- From the *Modes* touch screen, press **Color**, or
- From the *Modes* touch screen, press **Power**
The selected mode opens in the Imaging Screen, and imaging begins.
When switching from a non-CFI mode, the color box is in a *color box position configuration* state.
When switching from a CFI mode, the color box retains its state, position and size from the previous CFI mode. Acquisition parameters are also retained when switching between CFI

Modes.

When toggling between live imaging and pausing:

- When imaging in a CFI mode is paused, the color box is not configurable
- When imaging restarts in a CFI mode, the color box retains its previous position and size

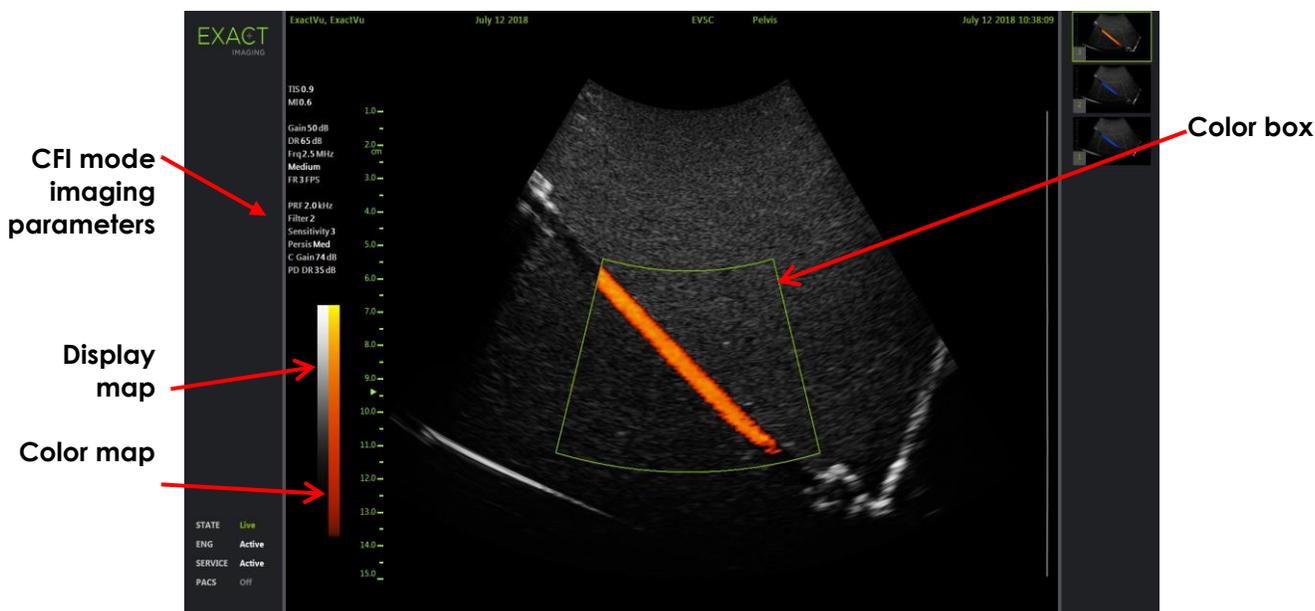


Figure 47: Power Doppler Mode Imaging Screen

In CFI modes, a vertical color bar is displayed in the imaging screen to reflect the color display map. In Color Doppler mode, this scale is displayed in cm/s. No numerical scale is used in Power Doppler Mode.

In addition to the imaging settings displayed while imaging in 2D Mode, values for several CFI mode-specific imaging settings are displayed. These are:

- Wall Filter is denoted as *Filter* and displays its numeric value
- Sensitivity is denoted as *Sensitivity* and displays its numeric value
- Persistence is denoted as *Persis*
- CFI Gain is denoted as *C Gain* with units dB
- Dynamic Range is denoted as *PD DR* with units dB

2 Color Box Configuration

When the color box is displayed, its *size* and *position* may be configured. When the color box size is in a configurable state, its outline is dashed, to indicate that trackball changes will change it. When the color box *position* is in a configurable state, its outline is solid.

If the color box position and/or size are configured during imaging, the configuration is saved when imaging is paused, and color box configuration becomes inactive.

For a new exam type, the default color box position is centered within the 2D image.

To toggle between configuring the color box size and color box position:

1. With the color box displayed in a CFI mode, press **Next** on the control panel.
Color box position configuration toggles to color box size configuration.
2. Press **Next** again.
Color box size configuration toggles to color box position configuration.
Subsequent presses of *Next* toggles between *color box position configuration* and *color box size configuration*.

To configure the color box position:

- With *color box position configuration* active, roll the trackball in any direction.
The angular position of the color box moves to follow the movement of the trackball.
The portion of the image within color box updates after a short delay of approximately one second.
The color box remains within the displayed image width and depth.

NOTE

EN-N155



It is not possible to adjust any color box setting such that the color box lies outside the displayed image width and depth.

To configure the color box size:

1. With *color box size configuration* active, roll the trackball up or down.
Rolling the trackball up decreases the height of the color box. Rolling the trackball down increases the height of the color box.
The portion of the image within color box updates after a short delay of approximately one second.
2. Roll the trackball right or left.
Rolling the trackball right increases the width (i.e., the angle of the fan arc) of the color box. Rolling the trackball left decreases the width of the color box.
The portion of the image within color box updates after a short delay of approximately one second.

NOTE

EN-N152



It is not possible to adjust the color box width below the minimum or above the maximum size allowed for the transducer. For the EV5C transducer, the color box width range is 20-60 degrees.

3 CFI Settings

Chapter 3, section 3.5.4 on page 83 provides a description of imaging settings that are used to control the acquisition and display of images for all imaging modes, including dynamic range, gain, image depth, focal zones, TGC, and transmit power.

This section describes features that are specific to *Color Doppler Mode* and *Power Doppler Mode*.

3.1 Wall Filter

In CFI Modes, the operator is able to adjust the *Wall Filter*.

The received signal used to process the displayed Color mode velocity and magnitude information is composed of many frequency components arising from different sources moving at different velocities. Tissue motion, for example, is caused by the patient moving or breathing and usually results in low frequency signals that can obscure the vessels of interest.

In order to suppress these low frequency signals, the *Wall Filter* feature may be used to remove frequencies below a set value.

To set the Wall Filter frequency:

1. Open the *Modes* touch screen.
2. Under *Wall Filter*, use the left or right arrow to select available values.

Selecting a lower value decreases the frequency value below which the signal does not contribute to the color flow image. Selecting a higher value increases the frequency value below which the signal does not contribute to the color flow image.

NOTE

EN-N156



Set the Wall Filter value low enough to retain the display of flow and high enough to suppress artifacts arising from tissue motion.

3.2 Sensitivity

In CFI Modes, the operator is able to adjust the *Sensitivity*.

The *Sensitivity* setting affects the signal to noise ratio of the signal from which the CFI mode velocity or power information is derived. Increasing the *Sensitivity* results in a lower frame rate.

To set the Sensitivity:

1. Open the *Modes* touch screen.
2. Under *Sensitivity*, use the left or right arrow to select available values.

Moving the slider increases or decreases the *Sensitivity* value to reflect the slider position.

Selecting a lower value decreases the *Sensitivity* value. Selecting a higher value increases the *Sensitivity* value.

3.3 Persistence

In CFI Modes, the operator is able to adjust the *Persistence*.

Persistence processing results in a time-averaged output frame, by combining information from the previous frames of CFI mode data with the most recent frame of CFI mode data.

The *Persistence* setting provides options for using few or many averaged frames to produce the output frame and may also be turned off.

To set the Persistence:

1. Open the *Modes* touch screen.
2. Under *Persistence*, use the left or right arrow to select available values.

Each frame displayed during imaging is calculated using the *Persistence* setting indicated.

A *Low* setting corresponds to a smaller number of combined frames and may provide better temporal resolution of flow. A *High* setting corresponds to a larger number of combined frames and may result in blurring in the image due to tissue movement.

When *Persistence* is *Off*, acquired images are not time-averaged with previously acquired data.

3.4 PRF

In CFI Modes, the operator is able to adjust the Pulse Repetition Frequency ("PRF").

Adjusting the PRF adjusts the range of velocities shown in the color display map. Increasing the PRF increases the range of velocities displayed, however this also reduces the ability to distinguish velocity differences within the range shown.

Decreasing the PRF decreases the displayed velocity range and provides the ability to visualize velocity differences (within the range) in more detail. In order to visualize vessels with slow flow, it is best to decrease the PRF. When imaging vessels with higher velocities, it is usually best to increase the PRF.

To adjust the PRF:

1. Open the *Modes* touch screen.
2. Under *PRF*, use the left or right arrow to select available values.

Selecting a lower value decreases the PRF and is reflected in the velocity range in the color map. Selecting a higher value increases the PRF.

3.5 Power Doppler Mode Specific Settings

3.5.1 Dynamic Range

In *Power Doppler Mode*, the *Dynamic Range* control on the control panel adjusts the dynamic range used by the color box.

To adjust the Dynamic Range:

1. Press the upper arrow on the **Dynamic Range** control on the *control panel*.
For the color box, this increases the contrast in the color map for the *color box*.
2. Press the lower arrow on the **Dynamic Range** control on the *control panel*.
In *Power Doppler Mode*, this decreases the contrast in the color map for the *color box*.

Chapter 8 FusionVu™

The *FusionVu™ micro-US/MRI fusion application* is an option that complements ExactVu's capabilities for prostate imaging and biopsy by allowing operators to incorporate MRI images or reports to supplement micro-ultrasound-guided biopsies. Not all ExactVu systems are configured with this option.

While the ExactVu operator is normally able to identify and target suspicious areas using the *PRI-MUS™ protocol* (refer to Chapter 11), *FusionVu* allows data from imported MR images to be overlaid on ExactVu images during live imaging to display areas marked by the radiologist. Using the *Cognitive Assist™* feature, it also provides operators with the option to use radiological reports from MRI studies for comparison with micro-ultrasound images.

When importing MRI study data, the ExactVu system locates and retrieves standard DICOM tags and image data from the GSPS (Grayscale Softcopy Presentation State) markup for use with the *FusionVu* features. These include the following:

- *Presentation State region of interest markers*, i.e., circle and ellipse tags to mark lesions and other regions of interest
- *Presentation State alignment marker* for aligning the prostate mid-line (i.e., the urethra) on the micro-ultrasound image with the MRI study data

For information about GSPS markup using the Weasis Medical Viewer, refer to the document *Use Guide for Weasis Medical Viewer with the ExactVu Micro-Ultrasound System* from Exact Imaging.

When a study containing an imported MRI study is exported to a PACS server, it uses both standard and private DICOM tags to retain image data, needle guide overlays, measurements, annotations, imaging settings etc., for future review on a DICOM workstation.

The ExactVu system provides the following two *FusionVu* features:

- *FusionVu micro-ultrasound/MRI Fusion*: the micro-ultrasound image is aligned with imported MRI study data, and the *imaging screen* overlays a small, square-shaped MRI *scout image* on the micro-ultrasound image
- *Cognitive Assist (using PI-RADS Reports)*: the micro-ultrasound image is aligned with sectors of interest using a radiology report based on PI-RADS v2 reporting diagrams

NOTE

EN-N139



Only one *FusionVu* feature may be used at a time.

FusionVu features are available only when using the EV29L transducer in the following modes:

- 2D Mode
- Anesthesia sub-mode
- Biopsy sub-mode

NOTE

EN-N138



Transperineal *needle guide overlays* may be used when using *FusionVu* in Biopsy sub-mode.

FusionVu features are available when the EV29L transducer is activated, the *Fusion Prostate TRUS*

Biopsy exam type is selected and a connected USB storage device or PACS server contains MRI study data. FusionVu features may be accessed from the *Patient/Study* screen or from the *Exam* touch screen.

To access FusionVu features from the Patient/Study screen or Exam touch screen:

- From the *Patient/Study* screen and with the EV29L transducer and the *Fusion Prostate TRUS* Biopsy exam type selected:
 - For FusionVu/MRI, select **Load MRI....**
MRI Fusion initiates and the *MRI Study Load* screen opens.
The *MRI Study Load* screen provides a list of MRI studies that are available to be loaded from a connected USB storage device, network location or PACS server.
 - For Cognitive Assist, select **Enter Report....**
PI-RADS Fusion initiates and the *PI-RADS Region Selection* screen opens.

NOTE
EN-N135



The ExactVu system supports MRI study data written on a DICOM workstation that supports DICOM GSPS (Grayscale Softcopy Presentation State) for MRI markup. The ExactVu system locates and retrieves standard DICOM tags and image data from the GSPS markup.

NOTE
EN-N163



The FusionVu features require the mid-line slice in the MRI study data to have been marked (i.e., a single *Presentation State alignment marker* in the GSPS markup) for aligning the MRI or the PI-RADS report to the micro-ultrasound image.

A *Presentation State alignment marker* is the line drawn most recently that is between 20 mm and 150 mm long and consists of a polyline DICOM tag in the sagittal series.

NOTE
EN-N164



The FusionVu features require *lesion markers* and other regions of interest to have been marked using *Presentation State region of interest* tags in the GSPS markup.

FusionVu recognizes *lesion markers* that are either circles or ellipses and created in an axial, coronal or sagittal MRI series in the same coordinate system as the series in which *Presentation State alignment marker* was marked.

1 FusionVu (MRI Fusion)

1.1 FusionVu MRI Workflow

The FusionVu feature accommodates both rigid and elastic MRI data registration for prostate imaging.

The difference between rigid and elastic registration is that elastic registration accounts for local deformations between the MRI study data and the micro-ultrasound image. These deformations may be caused by the transducer, the time lapsed between the MRI exam and the micro-ultrasound exam and in the image scale differences between the two modalities.

In rigid registration, MRI information is overlaid on the micro-ultrasound image, where each image set is limited to rotational and translational transformations. The shape and local deformation may differ between MRI and TRUS, and because of this, the difference may impact location of the overlaid

regions of interest and targeting success. The operator may account for any misalignment by manually adjusting probe depth and/or pressure during targeting, or by using elastic registration. In elastic registration, images are modified by deforming one of the image volumes to match the other.

In FusionVu, rigid registration is achieved by aligning the prostate mid-line in both modalities using the alignment line annotation in the loaded MRI study. Elastic registration is achieved by aligning the mid-line as well as the lateral edges of the prostate on the micro-ultrasound with those in the MRI image.

The FusionVu MRI workflow consists of the following activities:

- Using the *MRI Study Load* screen, select and load an MRI study from the connected USB storage device, from a connected PACS server, or from a network location (where configured by Technical Support personnel).
 - An MRI study must be loaded in order to use the FusionVu features. If the operator cancels the *MRI Study Load* screen without loading an MRI study, the exam type automatically changes to *Prostate TRUS Biopsy*.
- Image the prostate, optimize the image and align the micro-ultrasound image with the MRI study data with the prostate mid-line (i.e., the urethra), and for optional elastic MRI registration, align the lateral borders of the prostate on the left and/or right sides in the micro-ultrasound image with those in the MRI scout image as required
- Image the prostate to determine pathology, with guidance from the MRI scout image
- Document any lesions (optional)
- Measure the volume of prostate
 - Use *Stitch sub-mode* for large prostates
- Image the prostate to determine the anesthesia location
- Administer anesthesia
- Re-image the prostate to determine pathology, with guidance from the MRI scout image
- Perform targeted biopsies
- Perform systematic biopsies
- Save and close the study

1.1.1 MRI Study Load Screen

The *MRI Study Load* screen provides controls to search for and load MRI studies available on a connected USB storage device, PACS server or network. It also provides a *Check* function to determine whether an MRI study will load successfully prior to loading it. This feature is provided as a convenience for the operator to evaluate the study for Presentation State markers required to load the study in FusionVu.

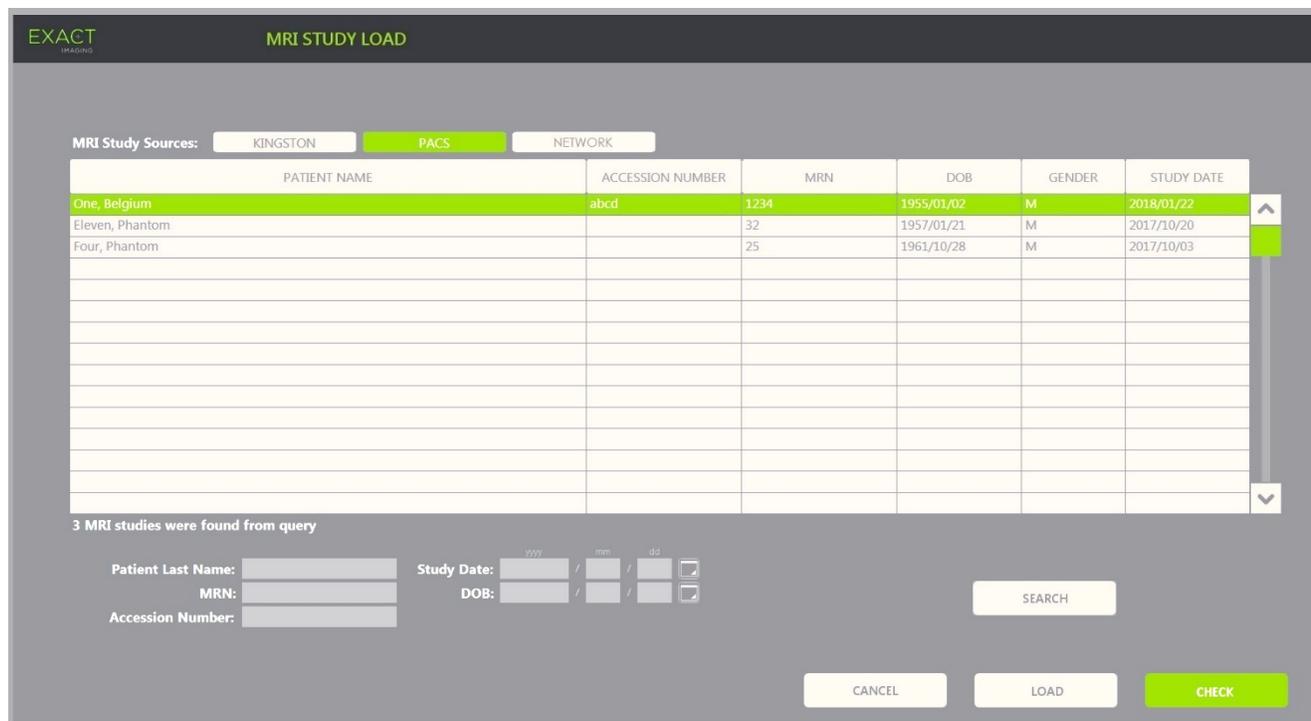


Figure 48: MRI Study Load Screen

To search for an MRI study from a connected USB storage device, a connected PACS server, or a network location and start a FusionVu study:

1. Ensure that the EV29L transducer is active, and the current study uses the *Fusion Prostate TRUS Biopsy* exam type.
2. From the *MRI Study Load* screen, select the *MRI Study Source*, i.e., a connected USB storage device, a connected PACS server, or a network location configured by Technical Support personnel.

The *MRI Study Load* screen displays MRI studies stored on the selected source.

3. For MRI studies stored on a connected PACS server, query a desired study using DICOM MRI Query/Retrieve as follows:
 - Entering search criteria using the fields *Last Name*, *Study Date*, *Date of Birth*, *MRN*, and/or *Accession number*. The *Last Name* query is not case-sensitive and returns records based on a partial match. The other search fields are case-sensitive and do not return results for partial matches.
 - Press **Search**.

The Patient List displays patient records on the connected PACS server that match the search criteria specified.

4. Select the study that corresponds to the current procedure, or another study of interest.

(Optional) To check whether selected MRI study will load in FusionVu:

- With a study selected, select **Check**.

The Check feature evaluates the MRI study for the existence of the following:

- A sagittal series MRI image with a mid-line annotation in the range 20 mm – 150 mm

- Presentation State region of interest markers that are:
 - circle or ellipses created in an axial, coronal or sagittal MRI series
 - created in the same coordinate system as the series in which Presentation State alignment marker was marked

The output of the check feature is a message indicating whether the MRI may be loaded in FusionVu and the number of valid and invalid markers (indicated as "ROIs", i.e., regions of interest).

To load a selected MRI study:

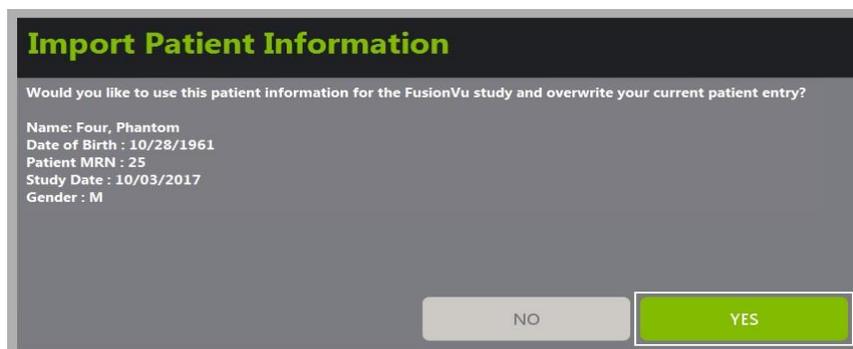
1. Select **Load**.

If the details on the *Patient/Study* screen were previously populated by selecting a study using the *Modality Worklist table*, the data in the study selected from the *MRI Study Load* screen is compared with the data in the *Patient/Study* screen as follows:

- If the data in each is the same, details from the selected study selected from *MRI Study Load* screen populate the *Patient/Study* screen.
- If the data in each is not the same, the operator is prompted to either:
 - load the MRI image study and retain the patient data previously populated from the *Modality Worklist* record
 - cancel loading the MRI study

If the details on the *Patient/Study* screen were entered by the operator, the data in the study selected from the *MRI Study Load* screen is compared with the data in the *Patient/Study* screen as follows:

- If the data in each is the same, details from the selected study selected from *MRI Study Load* screen populate the *Patient/Study* screen.
- If the data in each is not the same, the operator is prompted to either:
 - import the indicated patient information from the MRI study and overwrite the fields on the *Patient/Study* screen. (If this option is selected, note that *Accession number* and *Study Description* are not updated using information read from the MRI study.)
 - cancel loading the MRI study



2. Respond to the prompt.

If the option to proceed with loading the MRI study is selected, the MRI study loads and the fields on the *Patient/Study* screen are updated (where applicable).

3. Select any other options for the study and select **Save**.

The information, including the MRI study information, is saved in a new study.

The imaging screen opens, ready to image in *2D Mode*.

The *Workflow* touch screen opens.

If an MRI study cannot be loaded, a message is displayed that identifies aspects of the GSPS markup required for FusionVu that are not available in the study.

NOTE

EN-N137



A message is displayed if data for the selected MRI study is missing, corrupted or cannot be read when loading an MRI study.

NOTE

EN-N165



A message is displayed if lesion markers in the MRI study being loaded were tagged during GSPS markup in a different coordinate system as the series in which the *Presentation State alignment marker* was marked.

NOTE

EN-N179



If a valid GSPS marker is far enough away from the *Presentation State alignment marker*, it may not appear in the scout window.

1.2 FusionVu Alignment

FusionVu uses the *FusionVu Alignment* function to locate the mid-line slice in the sagittal series of the loaded MRI study using the *Presentation State alignment marker* in the GSPS markup. It also locates *lesion markers* (i.e., circle or ellipsoid *Presentation State region of interest markers*) in the loaded MRI study. Controls for aligning the MRI study data are on the *Workflow* touch screen.

NOTE

EN-N164



The FusionVu features require *lesion markers* and other regions of interest to have been marked using *Presentation State region of interest* tags in the GSPS markup.

FusionVu recognizes *lesion markers* that are either circles or ellipses and created in an axial, coronal or sagittal MRI series in the same coordinate system as the series in which *Presentation State alignment marker* was marked.

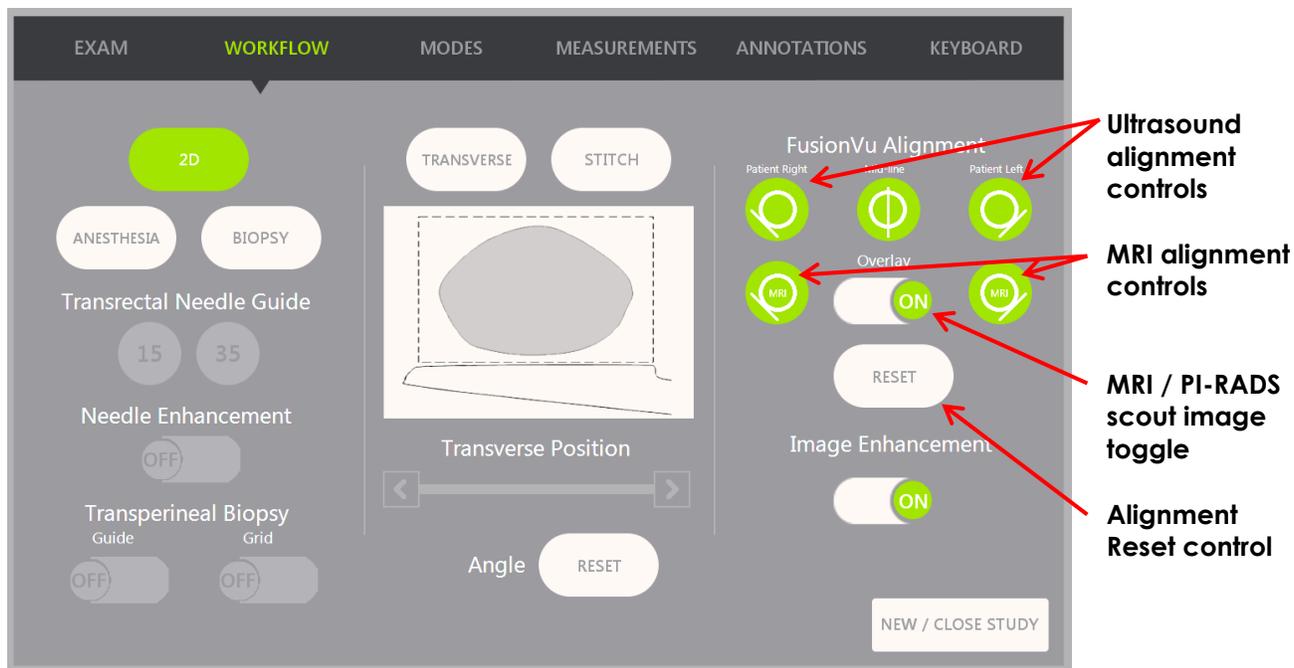


Figure 49: Workflow Touch Screen

To align the micro-ultrasound image with the MRI study data:

NOTE
EN-N140

The *Alignment* feature is enabled on the *Workflow touch screen* only for supported FusionVu modes and sub-modes.

1. Open the *Workflow touch screen*.
2. Rotate the EV29L transducer so that the urethra (i.e., the mid-line of the prostate) is displayed in the micro-ultrasound image.
3. Press the **Mid-line** *FusionVu Alignment* option for rigid MRI registration.

The mid-line of the prostate in the micro-ultrasound image is aligned with the mid-line alignment marker (i.e., the *Presentation State alignment marker* in the GSPS markup) in the MRI data. A *Presentation State alignment marker* must be between 20 mm and 150 mm long and must consist of a polyline DICOM tag in the sagittal series. If more than one *Presentation State alignment marker* is tagged in the series, FusionVu uses the most recently tagged for alignment with the mid-line of the prostate.

A small, square-shaped *MRI scout image* is displayed on the micro-ultrasound image, which may be toggled *ON* and *OFF*. The MRI scout image tracks the rotation of the EV29L transducer by increments of one degree in real-time. *Lesion markers* (i.e., *Presentation State region of interest markers*) that were marked up in the MRI study appear in red and are circular in shape.

NOTE
EN-N141

The MRI scout image is displayed only if the mid-line slice in the MRI study data has been aligned with the mid-line of the prostate on the micro-ultrasound image.

Markers become enabled on the *Workflow touch screen* that allow the operator to align the

left and right lateral borders of the prostate in both the ultrasound image and the MRI scout image for elastic MRI registration.

Pressing the Mid-line button also resets the zero-degree position of the EV29L transducer as described in Chapter 5, section 5 such that the *Angle* value indicated on the imaging screen reflects its rotational position relative to the zero-degree position.

4. (Optional) Align the left and/or right lateral borders of the prostate for elastic MRI registration using the *FusionVu Alignment* options:
 - Rotate the EV29L transducer until the lateral border of the prostate on the right side is displayed in the micro-ultrasound image. Press **Patient Right**.
 - Rotate the EV29L transducer until the lateral border of the prostate on the right side is displayed in the MRI scout image. Press **MRI Right**.
 - Rotate the EV29L transducer until the lateral border of the prostate on the left side is displayed in the micro-ultrasound image. Press **Patient Left**.
 - Rotate the EV29L transducer until the lateral border of the prostate on the left side is displayed in the MRI scout image. Press **MRI Left**.

When a pair of edges is set on either the left side or right side or both, the elastic alignment correction is applied to the display of the ultrasound image to improve its alignment with the MRI image.

If a pair of left edges or right edges has not been set, rigid MRI registration based on alignment of the mid-line continues to be used.

5. Continue imaging as per internal clinical procedures.

As the EV29L transducer rotates, lesion markers in the MRI scout image align with suspicious tissue in the micro-ultrasound image.

WARNING
EN-W73



Real-time updates of the MRI scout image reflect rotation of the transducer only. They do not reflect lateral movements of the transducer after the alignment is performed.

Moving the transducer laterally in or out of the rectum after aligning the MRI scout image with the micro-ultrasound image may prevent a targeted biopsy from being taken from the correct location.

WARNING
EN-W71



The MRI scout image is intended to assist the operator to visualize the MRI target for biopsy. The actual alignment between the MRI scout image and the micro-ultrasound image is dependent on the accuracy of the motion sensor on the EV29L transducer.

Always check the relative alignment between lesion markers on the MRI scout image and the live micro-ultrasound image. Reset the alignment when required.

NOTE
EN-N145



Do not measure the MRI scout image. The MRI scout image is not displayed at the same scale as the micro-ultrasound image. Measurements made on the MRI scout image will be incorrect.

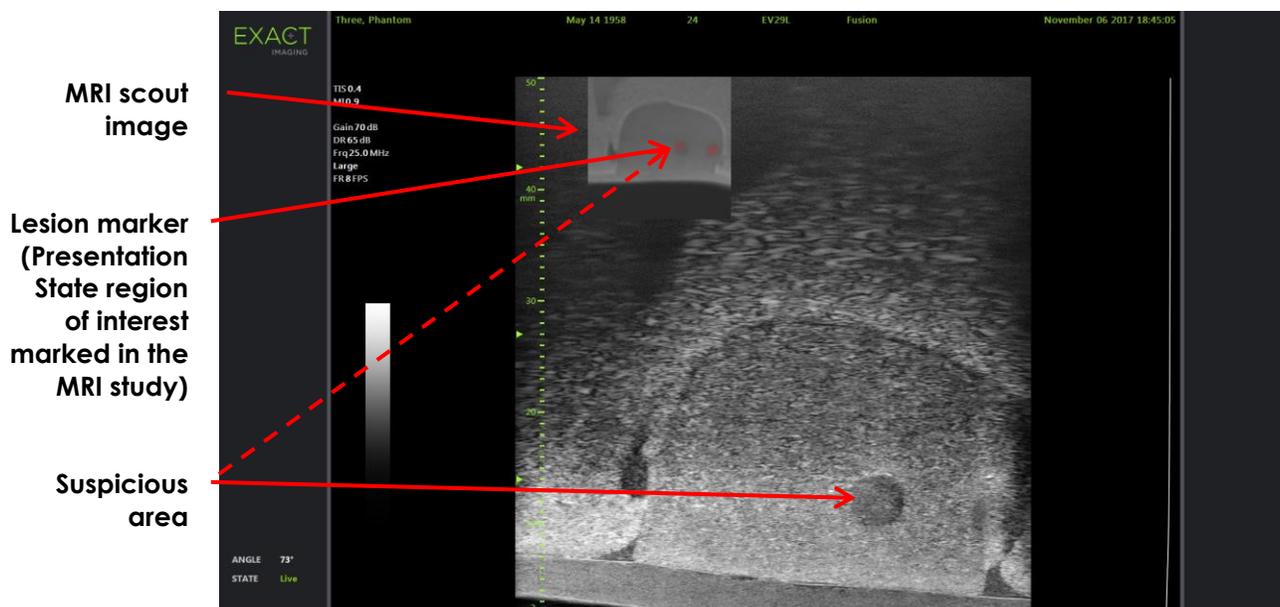


Figure 50: FusionVu MRI Scout Image in 2D Mode

To toggle the display of the MRI scout image:

- Select the **ON/OFF** toggle next to *Overlay*.
In the imaging screen, the MRI scout image toggles on and off.

2 Cognitive Assist (PI-RADS-Based Fusion)

2.1 Cognitive Assist Workflow

The Cognitive Assist workflow consists of the following activities:

- On the *PI-RADS Region Selection* screen, use the PI-RADS report to identify and select the prostate sectors that are noted in the PI-RADS report
- Image the prostate, optimize the image and align the micro-ultrasound image with the prostate mid-line (i.e., the urethra) and its lateral borders on the left and right sides
- Image the prostate to determine pathology, with guidance from the PI-RADS scout image
- Document any lesions (optional)
- Measure the volume of prostate
 - Use *Stitch sub-mode* for large prostates
- Image the prostate to determine the anesthesia location
- Administer anesthesia
- Image the prostate to determine pathology, with guidance from the PI-RADS scout image
- Perform targeted biopsies
- Perform systematic biopsies
- Save and close the study

The *PI-RADS Region Selection* screen provides PI-RADS v2 reporting diagrams on which the operator is able to indicate *sectors of interest*.

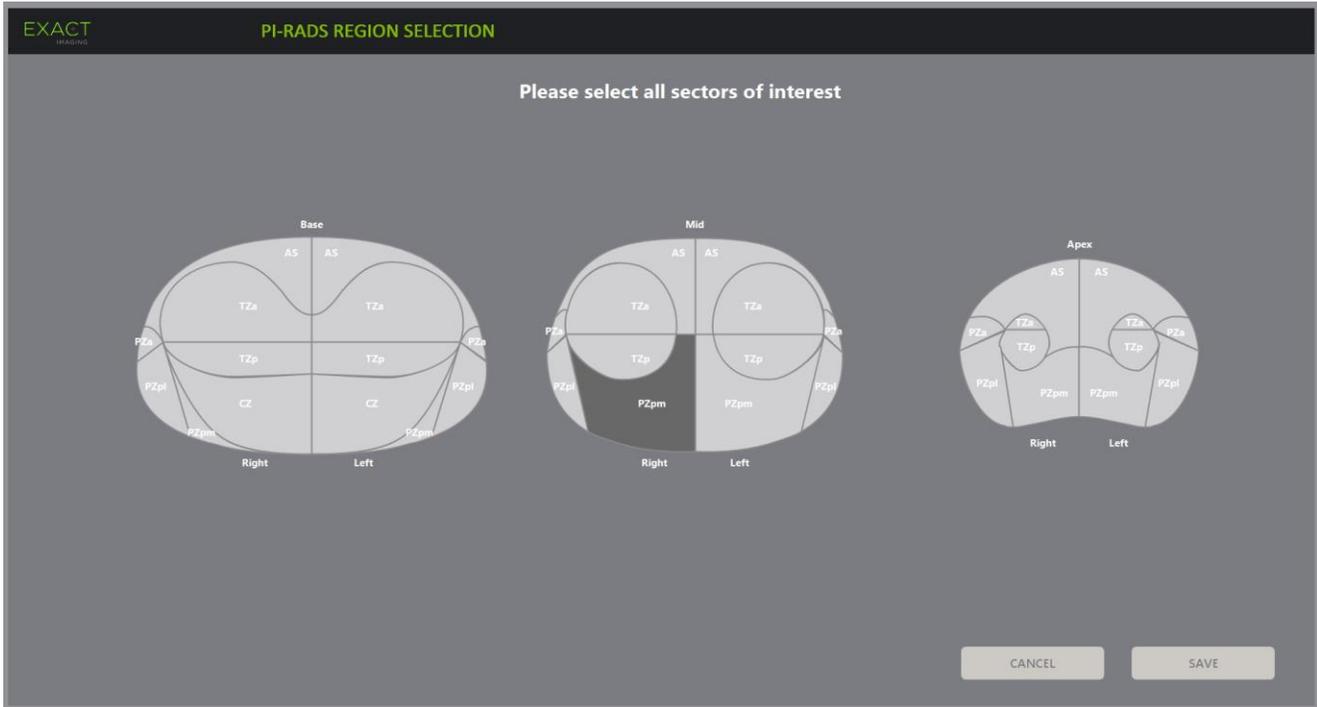


Figure 51: PI-RADS Region Selection

To select PI-RADS sectors of interest and start a Cognitive Assist study:

1. Referring to the PI-RADS report, use the trackball to position the cursor over a *sector of interest*.
2. Press **Set** on the *control panel*.
The *sector of interest* is selected.
3. Repeat step 1 and step 2 until all *sectors of interest* in the PI-RADS report are selected in each region of the prostate.
4. Press **Save** to continue, or press **Cancel** to return to the *Patient/Study* screen.
If *Save* is pressed, the *sectors of interest* are saved, and the *Patient/Study* screen is displayed.
5. Select any other options for the study and select **Save**.
The information including the *sectors of interest* is saved in a new study.
The imaging screen opens, ready to image in 2D Mode.
The *Workflow* touch screen opens.

2.2 Cognitive Assist Alignment (PI-RADS Sectors and Live Micro-Ultrasound)

The operator uses the *FusionVu Alignment* function to identify the mid-line of the prostate (i.e., the urethra) and its lateral borders on the left and right sides. The ExactVu system uses these markers to create a PI-RADS scout image that displays the selected *sectors of interest*. *FusionVu Alignment* controls are on the *Workflow* touch screen.

To align the micro-ultrasound image with PI-RADS sectors of interest:

1. Open the *Workflow* touch screen.

2. Align the PI-RADS data with the prostate boundaries using the *FusionVu Alignment* options:
 - Rotate the EV29L transducer so that the urethra (i.e., the mid-line of the prostate) is displayed in the micro-ultrasound image. Press **Mid-line**.
 - Rotate the EV29L transducer until the lateral border of the prostate on the right side is displayed. Press **Patient Right**.
 - Rotate the EV29L transducer until the lateral border of the prostate on the left side is displayed. Press **Patient Left**.

A small PI-RADS scout image is displayed on the micro-ultrasound image and represents the prostate based on the operator-specified left and right lateral borders and the mid-line of the prostate. It indicates the sectors of interest identified by the operator on the *PI-RADS Region Selection* screen.

NOTE

EN-N144



The PI-RADS scout image is displayed only if the mid-line of the prostate (i.e., the urethra) and the left and right boundaries have been aligned on the *Workflow* touch screen.

The status panel displays PI-RADS v2 reporting diagrams indicating the sectors of interest selected by the operator on the *PI-RADS Region Selection* screen. Each contains a PI-RADS *region indicator*, indicated by a red arrow.

Pressing the Mid-line button also resets the zero-degree position of the EV29L transducer as described in Chapter 5, section 5 such that the *Angle* value indicated on the imaging screen reflects its rotational position relative to the zero-degree position.

3. Continue imaging as per internal clinical procedures.

When the EV29L transducer is rotated during imaging, the PI-RADS *scout image* and PI-RADS *region indicators* are updated to track the rotation of the EV29L transducer, and the displayed *Angle* value updates in real-time (refer to Figure 52).

NOTE

EN-N145



Do not measure the PI-RADS scout image. The PI-RADS scout image is not displayed at the same scale as the micro-ultrasound image. Measurements made on the PI-RADS scout image will be incorrect.

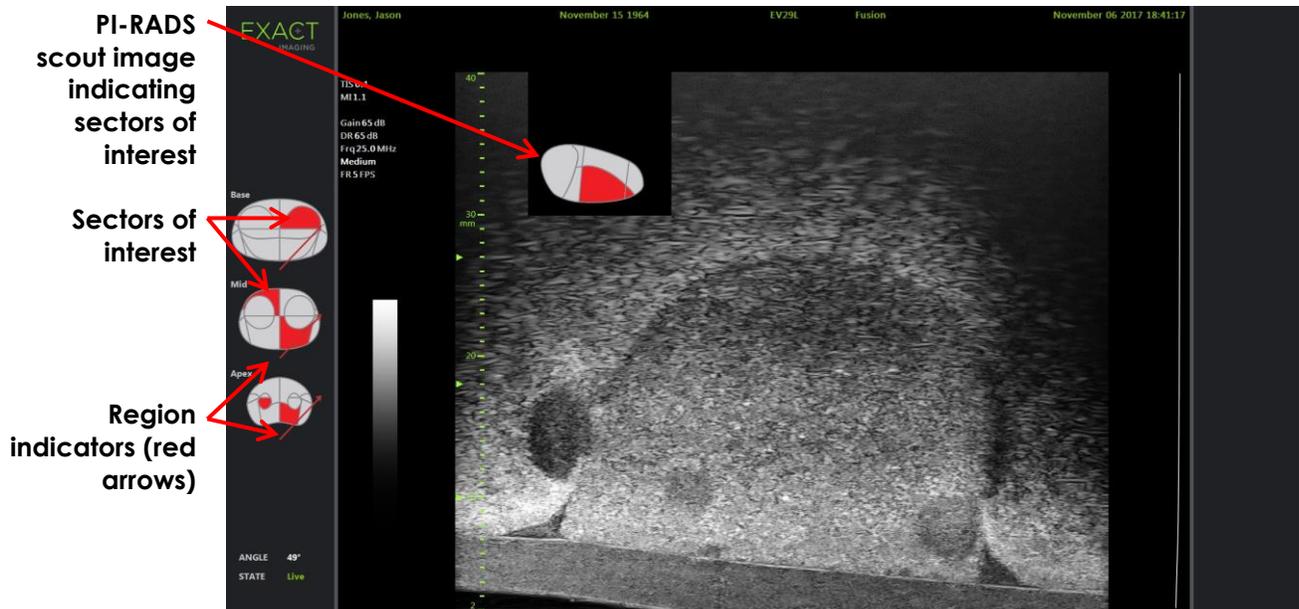


Figure 52: Cognitive Assist PI-RADS Scout Image and Region Indicators in 2D Mode

NOTE
EN-N131



If no PI-RADS sectors of interest were identified in the PI-RADS Region Selection screen, the PI-RADS scout image and PI-RADS region indicators are not displayed in the status panel.

3 Common FusionVu Features

The operator is able to toggle the display of the MRI scout image and PI-RADS scout image ON or OFF using the *Workflow touch screen*.

To toggle the MRI or PI-RADS scout image ON or OFF:

- On the *Workflow touch screen* toggle the *Overlay* option to **ON** to enable the display of the applicable scout image
- On the *Workflow touch screen*, toggle the *Overlay* option to **OFF** to disable the display of the applicable scout image

Occasionally the micro-ultrasound image and the PI-RADS or MRI scout image may appear to be losing their alignment with one another. The operator is able to reset the alignment using the *Workflow touch screen*.

To reset the MRI and PI-RADS alignment:

- On the *Workflow touch screen* press **Reset**.
The PI-RADS and MRI study data alignment resets to its default state of not having been set. The scout image is removed from the imaging screen, and if applicable, the PI-RADS region indicators are removed.
The *FusionVu Alignment* options on the *Workflow touch screen* indicate that they may be set.

Chapter 9 Using Measurements

The ExactVu system provides several measurement types that can be used to measure various aspects of anatomical structures.

These are:

- Distance (displayed in cm): up to 4 can be made on a single frame
- Area (displayed in cm²): up to 2 can be made on a single frame
- Volume (displayed in cc)
 - Up to 3 volume measurements can be made on a single Dual Mode or Transverse Mode frame
 - For the *Pelvis* exam type, a pre-void or post-void volume measurements can also be made

Distance and area measurements may be applied to an image in any mode when imaging is paused or when an image is displayed for review. If a measurement is made on a cine image, it is only applied to the single frame on which it is created. Volume measurements require Dual Mode or Transverse Mode in order to create the sagittal and transverse plane images that capture length, width and height.

NOTE

EN-N178



Measurements and annotations cannot be made on images in *review* if the study was loaded from an external source such as a USB storage device.

1 Creating a Measurement

Measurements are made on an image using the Measurements touch screen. The Measurements touch screen contains icons for each measurement type to be selected and placed on an image. For each measurement type, there is a selection of caliper options.

Measured values are displayed in the header of the imaging screen. Each is displayed showing the type and an identifying number, to distinguish it from others of the same measurement type. Measured values are displayed to two decimals. The *Residual Volume* value is displayed with one decimal.

To open the Measurements touch screen:

- Press **Measure** on the control panel.

The *Measurements* touch screen opens.

The default *measurement type* for the current mode is initiated. This is:

- *Volume* for Dual Mode and Transverse Mode
- *Distance* for any other mode



The button state of the caliper icon on the Measurements touch screen indicates the type of measurement in progress.

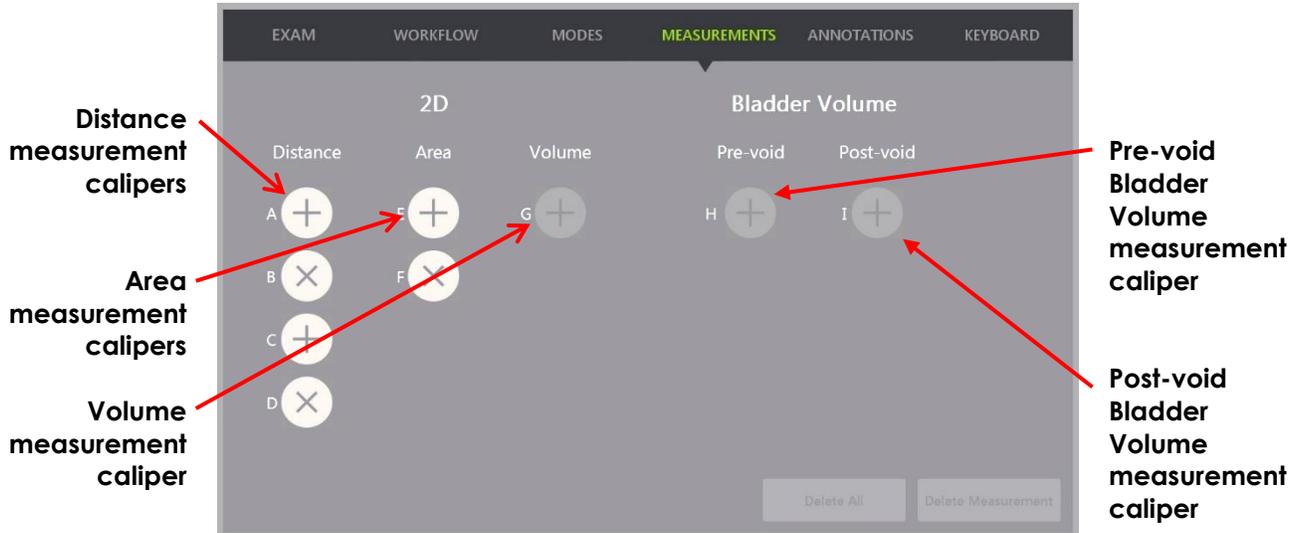


Figure 53: Measurements Touch Screen

1.1 Creating a Distance Measurement

A distance measurement is the line joining two calipers.

Measurement calipers are placed using the trackball along with **Next** and **Set**.

To create a Distance measurement and save the image:

1. On the *Measurements* touch screen, press one of the icons for the *Distance* measurement caliper.

The first caliper of the measurement is active, and its movement is controlled by the trackball.

2. Using the trackball, position the caliper at the desired location.
3. Press **Next** on the *control panel*.

The first caliper position is fixed, and the second caliper of the same *Distance* measurement becomes active.

The distance between the calipers is displayed in the header of the *imaging* screen and updates in real-time as the caliper moves.

4. Using the trackball, position the second caliper at the desired location.
5. Press **Set** on the *control panel*.

The second caliper position is fixed, and the *Distance* measurement is complete.

The caliper icon used for the measurement is no longer available on the *Measurements* touch screen to be used to create a new measurement.

The measured value is displayed in the header of the *imaging* screen.

- To save the image, press **Frame** on the control panel, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved with the study and includes the distance measurement. If the image had been opened as a review image, another copy of the image is saved that includes the distance measurement.

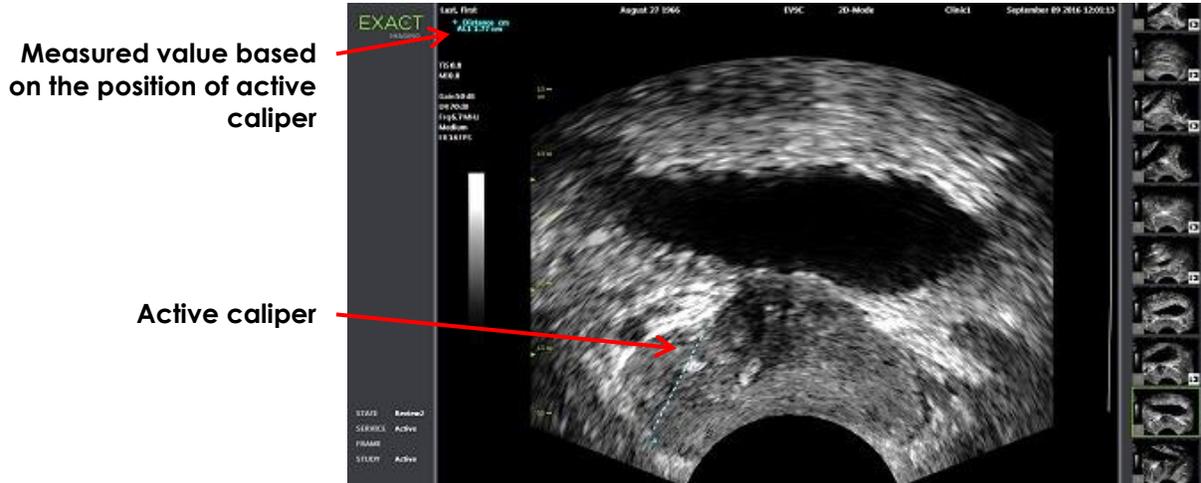


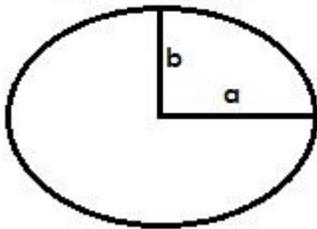
Figure 54: Distance Measurement

1.2 Creating an Area Measurement

An area measurement is an ellipsoid created by two intersecting line segments, where typically length and height are measured.

The area measurement is calculated using a standard ellipsoid area formula:

$$A = \pi a b$$



Where:

- a and b are ½ the lengths of the two line segments (regardless of the order in which they are measured)

For modes that show multiple images (i.e., Dual Mode and Transverse Mode), both calipers for each line segment must be placed on the same pane.

CAUTION

EN-C20



The two line segments should be orthogonal for maximum measurement accuracy.

To create an Area measurement and save the image:

1. On the *Measurements* touch screen, press one of the icons for the desired Area measurement calipers.

The first caliper of the *first line segment* is active, and its movement is controlled by the trackball.

2. Using the trackball, position the caliper at the desired location.

3. Press **Next** on the control panel.

The first caliper position is fixed, and the second caliper becomes active.

The distance between the calipers is displayed in the header of the *imaging screen* and updates in real-time as the caliper moves.

4. Using the trackball, position the second caliper at the desired location.

5. Press **Set** on the *control panel*.

The second caliper position is fixed, and completes the *first line segment* for the Area measurement.

The *second line segment* initiates.

6. Using the trackball, position the first caliper at the desired location.

7. Press **Next** on the *control panel*.

The first caliper position is fixed, and the second caliper becomes active.

The distance between the calipers is displayed in the header of the *imaging screen* and updates in real-time as the caliper moves.

8. Using the trackball, position the caliper at the desired location.

9. Press **Set** on the *control panel*.

The second caliper position is fixed, and completes both the *second line segment* and the Area measurement.

The caliper icon used for the measurement is no longer available to be used to create a new measurement.

The measured value is displayed in the header of the *imaging screen* along with the values of the constituent measurements.

10. To save the image, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved and includes the area measurement. If the image had been opened as a *review image*, another copy of the image is saved that includes the area measurement(s).

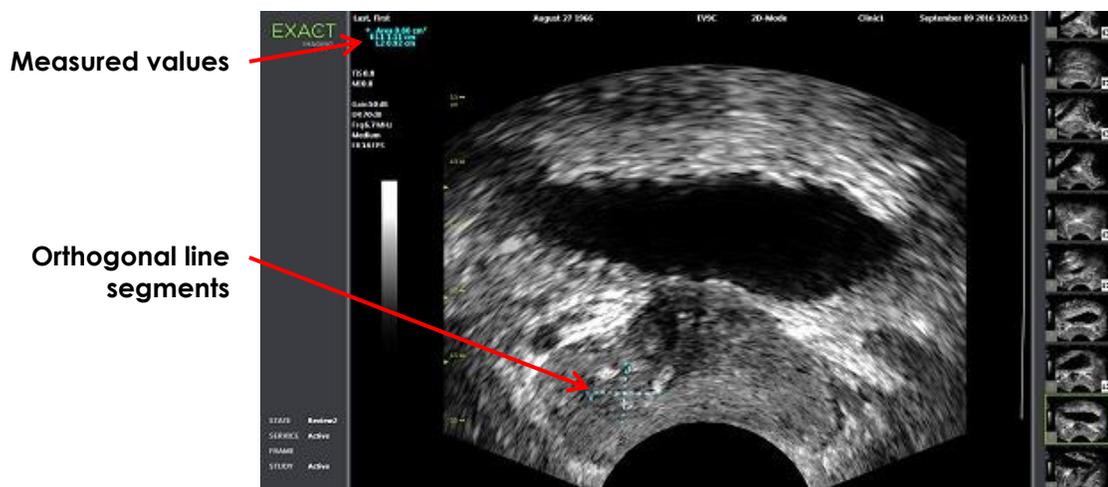


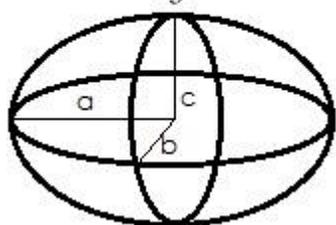
Figure 55: Area Measurement

1.3 Creating a Volume Measurement

The ExactVu system provides the option to create a volume measurement, using measurements taken on transverse and sagittal images in Dual Mode or Transverse Mode. This measurement consists of three line segments, which are typically measured as the transverse view height and width, and the sagittal view length (though all line segments may be measured in any view). Both calipers of each line segment must be placed on the same pane.

A volume measurement is calculated from three linear measurements of length, width and height made on sagittal and transverse images obtained in *Dual Mode* or *Transverse Mode*. It is calculated using a standard ellipsoid volume formula:

$$V = \frac{4}{3} \pi abc$$



Where:

- a, b and c are ½ the lengths of the line segments (regardless of the order in which they are measured)

CAUTION
EN-C20



The two line segments should be orthogonal for maximum measurement accuracy.

To create the required images on which to make volume measurements:

1. Obtain a sagittal image and press **Dual/Transverse** on the control panel.

The sagittal image will be saved to the left of the imaging screen. Live imaging continues on the right.

2. Obtain a transverse image:

- When using the EV9C transducer, the transverse image is obtained by rotating the transducer 90°.
- When using the EV29L transducer, the transverse image is obtained by rotating the transducer to obtain a complete sweep of the prostate gland.
 - The scout image (a smaller version of the 2D image) can be used as a guide during transverse image construction.
 - Smooth rotation motion is required to obtain a representative transverse image. Rotate slowly, and do not introduce extra motion during image construction.
 - If the image is visibly distorted, repeat the rotation to overwrite the image.

The *imaging screen* displays side-by-side sagittal and transverse images.

CAUTION
 EN-C18


If the rotation of the transducer is irregular or too quick, the matching sector of the fan may be distorted and may not be displayed.

Do not make measurements on a distorted image.

To create a volume measurement and save the image:

1. With side-by-side sagittal and transverse images displayed on the imaging screen, either:
 - Press **Measure** on the *control panel*, OR
 - On the *Measurements* touch screen, press the **Volume** measurement

A line segment appears with two end calipers.

2. Use the trackball to position the first caliper at the desired location in either pane.
3. Press **Next** on the *control panel*.
The first caliper position is fixed, and the second caliper becomes active in the same pane.
4. Using the trackball, position the second caliper at the desired location.
5. Press **Set** on the *control panel*.

The second caliper position is fixed, and completes the *first line segment* for the volume measurement.

The *second line segment* initiates on the transverse image, with its first caliper active.

NOTE
 EN-N90


The sagittal length and transverse height and width are measured on the sagittal image.

6. Using the trackball, position the first caliper at the desired location in either pane.
7. Press **Next** on the *control panel*.
The first caliper position is fixed, and the second caliper becomes active in the same pane.
8. Using the trackball, position the second caliper at the desired location.
9. Press **Set** on the *control panel*.

The second caliper position is fixed, and completes the *second line segment* for the volume measurement.

The *third line segment* initiates in the transverse image pane.

10. Using the trackball, position the first caliper at the desired location in either pane.

11. Press **Next** on the *control panel*.

The first caliper position is fixed, and the second caliper becomes active in the same pane.

12. Using the trackball, position the second caliper at the desired location.

13. Press **Set** on the *control panel*.

The second caliper position is fixed and completes the *third line segment*. The volume measurement is complete.

The measured value is displayed in the header of the *imaging screen* along with the values of the constituent measurements. PSA Density (PSAD) is displayed if PSA was entered when the patient/study was created.

The caliper icon for the volume measurement indicates it is in use for an existing measurement.

14. To save the image, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved and includes the volume measurement.

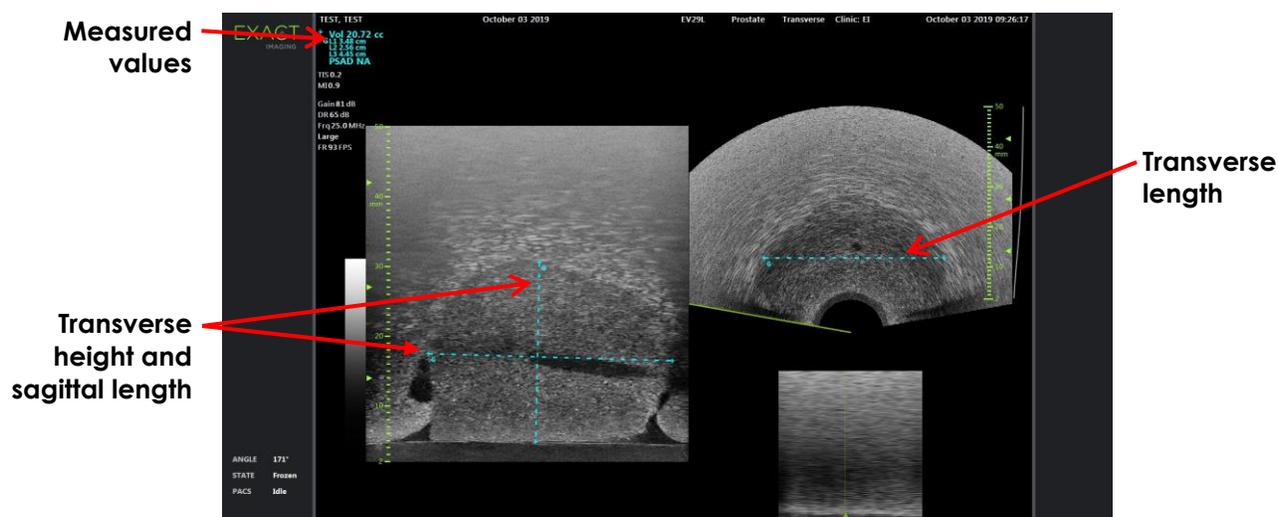


Figure 56: Volume Measurement (Transverse Mode)

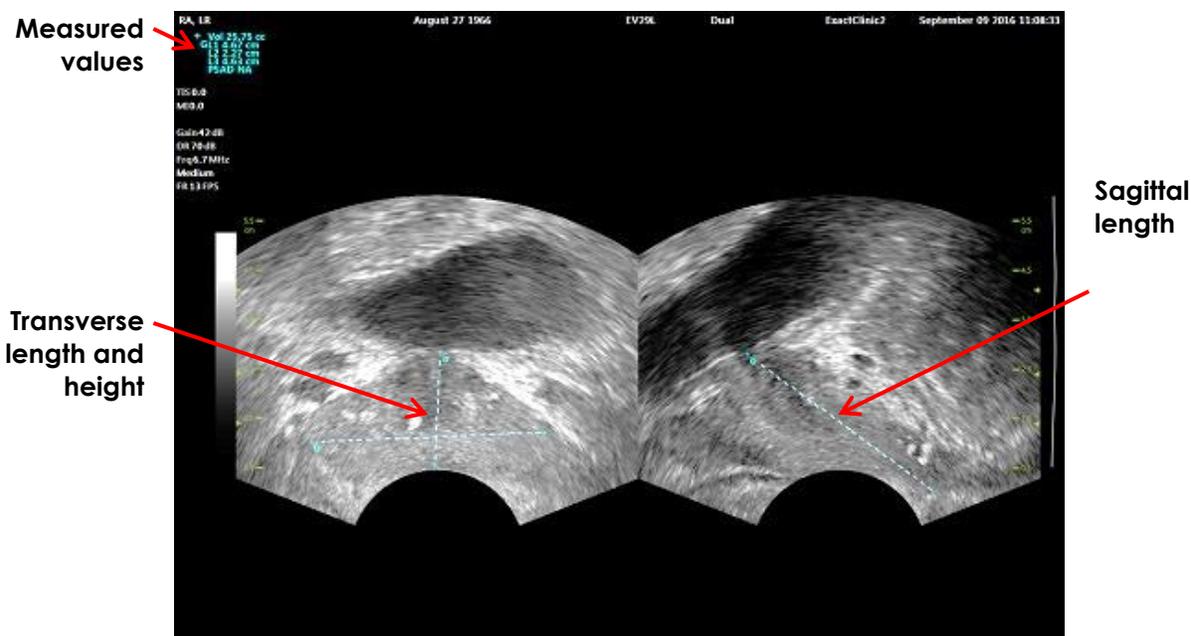


Figure 57: Volume Measurement (Dual Mode)

1.3.1 PSA Density

The ExactVu software will automatically calculate the PSA density (PSAD) value when a volume measurement is taken, using the PSA value entered on the Patient/Study screen.

PSAD is displayed in the header of the imaging screen with the other measured values.

NOTE
EN-N63



“N/A” appears for PSAD if no PSA value was entered in the Patient/Study screen. If the PSA value or volume is changed, calculated PSAD values are updated accordingly. Calculated PSAD values do not change for saved frames.

1.3.2 Pre-void and Post-void Volume Measurements

For the *Pelvis* exam type, two volume measurements are available for Dual Mode images:

- Pre-void Bladder
- Post-void Bladder

To create Pre-void and Post-void bladder volume measurements:

1. With a Dual Mode image displayed, press the icon for the *Pre-void* bladder volume measurement from the *Measurements* touch screen.
2. Place all calipers for the measurement as described in section 1.3 on page 149 and press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.

When the measurement is completed and the image is saved, the measured value for the bladder volume is displayed in the header of the imaging screen along with the values of the constituent measurements.

The *Post-void* bladder volume measurement icon is enabled.

3. On the *Measurements* touch screen, press the *Post-void* bladder volume measurement icon.
4. Place all calipers for the measurement as described in section 1.3 on page 149.

When the measurement is completed, the measured value for the volume is displayed in the header of the imaging screen along with the values of the constituent measurements.

When both the *Pre-void* and *Post-void* bladder volumes are measured, the *Residual Volume* is calculated and displayed as a percentage in the header of the image on which the post-void bladder volume was measured. The label for the *Residual Volume* calculation is displayed as *Resid*.



Figure 58: Residual Volume Calculation

Neither the *Pre-void* nor the *Post-void* bladder volume measurement is enabled.

5. To save the image, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved and includes the bladder volume measurement.

NOTE

EN-N157



One set of bladder volume measurements can be made each time the Pelvis exam type is used.

NOTE

EN-N166



If the measured *Post-void* bladder volume is greater than the measured *Pre-void* bladder volume, the *Residual Volume* is displayed as "N/A".

2 Editing a Measurement

Measurements on an image may be edited by selecting a measurement to edit from the *Measurements* touch screen, and then moving the calipers as required.

To edit a measurement and save the image:

1. With the image to be edited displayed, press the caliper icon for the measurement to be edited on the *Measurements* touch screen.
The selected measurement becomes active, and indicates which caliper and which line (if applicable) are active.
2. If the desired caliper is active, use the trackball to position the caliper at the desired location.
3. Press **Next** on the *control panel*.
4. To toggle the active caliper in the active line, press **Next** on the control panel.
The active caliper for the active line toggles to the other caliper.

5. To switch the active line to the next available line, press **Set** on the control panel.
The next available line becomes the active line.
6. Position all desired calipers.
The distance between the calipers for the active line is displayed in the header of the imaging screen, and updates in real-time as the caliper moves.
7. When all calipers are positioned correctly, press **Set** on the *control panel* to complete the measurement edit.
The measured value is displayed in the header of the imaging screen along with the values of the constituent measurements.
The caliper icon for the measurement indicates that is used for an existing measurement.
8. To save the image, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.
The image is saved and includes the edited measurement. If the image had been opened as a *review image*, another copy of the image is saved that includes the edited measurement(s).

CAUTION

EN-C48



For studies saved in software versions earlier than 1.0.3, changes made to images will not be saved.

3 Deleting a Measurement

Measurements may be deleted using the *Measurements* touch screen.

To delete a measurement:

1. Press the caliper icon for the measurement to be deleted.
The *Delete Measurement* button is enabled.
2. Press **Delete Measurement**.
The measurement is removed from the image.
The caliper icon for the deleted measurement is available for a new measurement.
3. To save the image, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.
The image is saved and the saved image does not include the deleted measurement.

To delete all measurements:

1. On the *Measurements* touch screen, press **Delete All**.
All measurements are removed from the image.
The caliper icons for the deleted measurements are available for a new measurement.
2. To save the image, press **Frame** on the *control panel*, or, if the foot pedal is configured to save frames, press the foot pedal.
The image is saved and the saved image does not include any measurements.

4 Canceling a Measurement in Progress

When a measurement is in progress, several actions cancel the measurement, including:

- Start imaging
- Change screens
- Change modes
- Press the caliper for an existing measurement or for another measurement type
- Press Measure

Chapter 10 Using Annotations

Annotations are text labels used to label anatomical structures on the image.

Annotations are created using the *Annotations* touch screen. The Annotations touch screen contains icons for views, annotation labels and predefined annotations, based on applicable views and structures and the exam type.

Annotations may be applied to an image during imaging, when imaging is paused or when the image is displayed for review. An annotation may be applied to a cine image during imaging, to a frame, or to a single frame of a cine image. When a cine image is displayed for review, an annotation is applied only to the single frame on which it is created. Up to eight annotations may be added to an image.

NOTE

EN-N178



Measurements and annotations cannot be made on images in review if the study was loaded from an external source such as a USB storage device.

A *live annotation* (i.e., an annotation created during imaging) is displayed on the frames of the memory buffer that are acquired after the annotation is created. The position of a live annotation remains the same relative to the image depth scale when the operator changes the depth.

A *live annotation* remains on the image unless one of the following actions occurs:

- The annotation is deleted
- A new study is started

Live annotations are not present on images in review. They are also not present in the following imaging modes:

- Transverse Mode
- Stitch sub-mode

When live annotations are present, and the operator begins imaging in *Dual Mode*, the live annotations appear in left pane only (i.e., the static pane). They are not applied to the live image.

The ExactVu system supports the following types of annotations:

- Predefined text
- Custom text
- Arrow

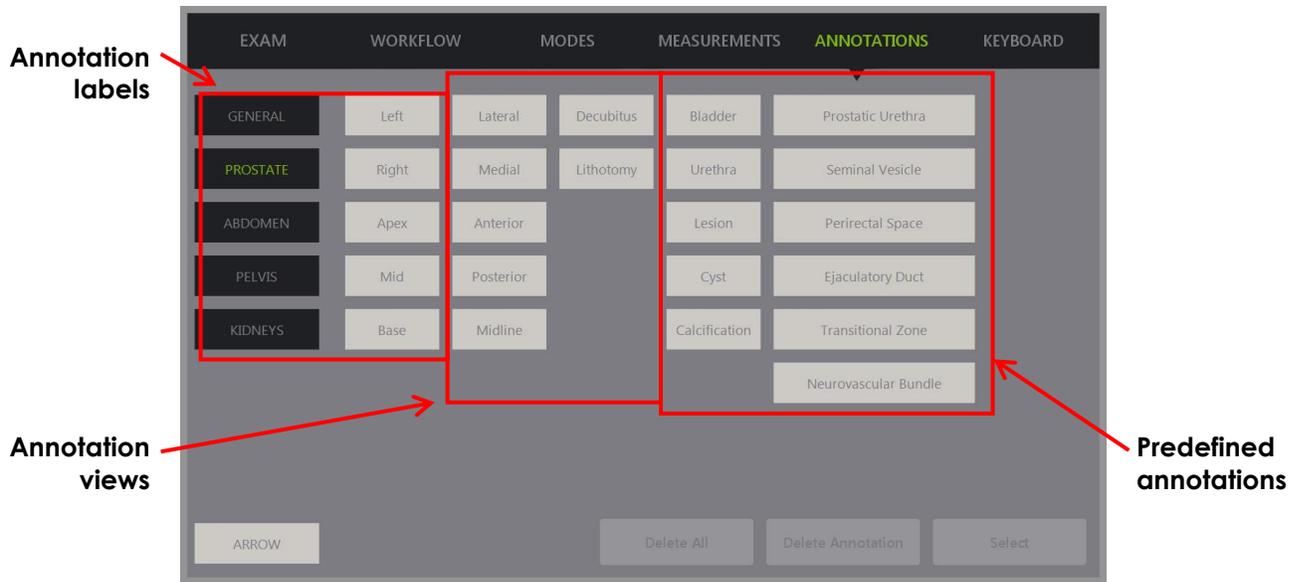


Figure 59: Annotations Touch Screen

1 Creating an Annotation

To create an Annotation:

- Press **Annotate** on the control panel or press **Annotation** on the *touch screen*.

The *Annotations* screen opens on the touch screen, and a text annotation is initiated. Its position is based on the transducer in use and may be changed:

- For the EV29L transducer, it is initiated in the top left corner of the imaging area
- For the EV9C transducer, it is initiated in the bottom center of the imaging area in all modes except *Dual Mode*, in which it is initiated in the middle of the right pane
- For the EV5C transducer, it is initiated in the top center of the imaging area in all modes except *Dual Mode*, in which it is initiated in the middle of the right pane

The operator may proceed to create a text annotation, a predefined annotation, or an arrow annotation.



If a cine image is open in review, attempting to save it has no effect. Only single frames may be saved in review.

1.1 Creating a Predefined Text Annotation

Creating a predefined text annotation consists of two steps:

- Positioning the text annotation
- Selecting the annotation

To create a predefined text annotation:

1. With the text box active, use the trackball to position the annotation at the desired location.
2. From the *Annotations* touch screen, touch an *annotation view* and/or any other desired *annotation label* for the annotation.
3. Touch the desired *predefined annotation*.

The annotation consists of the selected labels in the order in which each was touched.

NOTE
EN-N122

The ExactVu system prevents the selection of labels if the active annotation can fit no annotation labels or predefined annotations on the imaging screen beyond those already selected.

4. Press **Set** on the *control panel*.

The annotation is complete.

If the annotation is placed during imaging, imaging continues and the live annotation remains on the image. In this case, the live annotation is set when the operator pauses imaging.

To save the image:

- Press **Frame** on the control panel to save a single frame, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved with the study, and includes the annotation. If the image had been opened as a review image, another copy of the image is saved that includes the annotation.

To save a cine image with a static annotation:

- When imaging is paused, create an annotation and press **Cine**, or, if the foot pedal is configured to save cine images, press the foot pedal.

A cine image is saved with the study, and includes the static annotation on each frame.



Figure 60: Predefined Annotation

1.2 Creating a Custom Text Annotation

Creating a custom text annotation consists of two steps:

- Positioning the annotation

- Typing the text

To create a custom text annotation:

1. With the text box active, use the trackball to position the annotation at the desired location.
2. Press **Keyboard** on the touch screen.
The touch screen's keyboard is displayed.
3. Type the annotation text.
The text appears in the text box.
4. Press **Set** on the *control panel*.
The annotation is complete.

If the annotation is placed during imaging, imaging continues and the annotation remains on the image. In this case, the live annotation is set when the operator pauses imaging.

To save the image:

- Press **Frame** on the control panel to save a single frame, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved with the study, and includes the annotation. If the image had been opened as a review image, another copy of the image is saved that includes the annotation.

1.3 Creating an Arrow Annotation

An arrow annotation is a line with an arrow, and no text. Creating an arrow annotation consists of positioning the *anchor point* (i.e., the end) for the line and the *anchor point* for the arrow.

To create an arrow annotation:

1. From the *Annotations* screen, press **Arrow**.
An arrow annotation is displayed, with one of its anchor points active.
2. Use the trackball to position the active anchor point at the desired location.
3. Press **Next** on the *control panel*.
The anchor point for the line is fixed, and the anchor point for the arrow becomes active.
4. Use the trackball to position anchor point for the arrow.
5. Press **Next** on the *control panel* to switch to the other anchor point if further adjustment is required.
6. Press **Set** on the *control panel* to complete the annotation.
The annotation is complete.

If the annotation is placed during imaging, imaging continues and the annotation remains on the image. In this case, the live annotation is set when the operator pauses imaging.

To save the image:

- Press **Frame** on the *control panel* to save a single frame, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved with the study, and includes the annotation. If the image had

been opened as a review image, another copy of the image is saved that includes the annotation.

2 Editing an Annotation

The position of an annotation may be edited by selecting the annotation from the Annotations touch screen, and then moving the annotation or anchor point (for arrow annotations) as required.

NOTE
EN-N87



It is not possible to edit the annotation text.

To edit an annotation:

1. With the annotation to be edited displayed on the image, press **Select** on the *Annotations* touch screen.
The annotation created most recently becomes active.
The active anchor point is indicated by its color.
2. If the active annotation to be edited is not active, press **Select** until the desired annotation becomes active.
3. When the desired annotation is active, use the trackball to position it at the desired location.
4. Press **Set** on the *control panel* to complete the annotation or press **Next** to switch to the other anchor point (if editing an arrow annotation).
5. When the annotation is at the desired position, press **Set** on the *control panel*.
The edit is complete.

To save the edit:

- Press **Frame** on the *control panel* to save a single frame, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved with the study, and includes the edit to the annotation. If the image had been opened as a *review image*, another copy of the image is saved that includes the edit to the annotation.

NOTE
EN-N113



If a cine image is open in review, attempting to save it has no effect. Only single frames may be saved in review.

NOTE
EN-N159



A *live annotation* is not visible on an image opened in review.

3 Deleting an Annotation

Annotations may be deleted using the Annotations touch screen.

To delete an annotation:

1. With the annotation to be deleted displayed on the image, press **Select** on the *Annotations* touch screen.

The annotation created most recently becomes active.

2. If the annotation to be deleted is not active, press **Select** until the desired annotation is active.
3. If the annotation to be deleted is active, press **Delete Annotation**.

The active annotation is deleted.

To delete all annotations:

- On the *Annotations* touch screen, press **Delete All**.

All annotations on the image are deleted.

To save the image:

- Press **Frame** on the *control panel* to save a single frame, or, if the foot pedal is configured to save frames, press the foot pedal.

A single-frame image is saved with the study, and the saved image does not include the deleted annotation(s). If the image had been opened as a *review image*, another copy of the image is saved that does not include the deleted annotation(s).

- When the imaging state is frozen, pressing **Cine** on the *control panel* also saves a single frame that does not include the deleted annotation.

NOTE

EN-N113



If a cine image is open in *review*, attempting to save it has no effect. Only single frames may be saved in *review*.

4 Canceling an Annotation in Progress

When an annotation is being created or edited, several actions cancel the annotation, including:

- Start imaging
- Change screens
- Change modes
- Select a different annotation type
- Press *Annotate* on the *control panel*

Chapter 11 PRI-MUS™ Risk Score

The PRI-MUS™ Risk Score (prostate risk identification using micro-ultrasound) is an evidence-based protocol for identifying features of the prostate using micro-ultrasound imaging (for example, when imaging using the EV29L transducer) to help direct and target biopsies.

1 Using the PRI-MUS Risk Score

In studying cine images of biopsies performed during the *Multi-Center Trial of High-resolution Transrectal Ultrasound Versus Standard Low-resolution Transrectal Ultrasound for the Identification of Clinically Significant Prostate Cancer*¹, distinct ultrasound appearances were observed.

During the *Multi-Center Trial*, Ghai et. al². reviewed cine images of 400 biopsies, and correlated the distinct appearances with the diagnosis on histology of biopsy core samples with malignant prostate cancer, with Gleason Score greater than 7. Using this information, the PRI-MUS™ (prostate risk identification using micro-ultrasound) protocol and risk scale was developed.

The ultrasound appearances translate to a *PRI-MUS Risk Score*, which is associated with increasing risk of cancer. Table 17 describes the findings related to each *PRI-MUS Risk Score*.

PRI-MUS Risk Score	Cancer Risk	Findings
1	Very low	Some regular ducts, "Swiss cheese" with no other heterogeneity or bright echoes
2	Some	Hyperechoic with or without ductal patches
3	Indeterminate	Mild heterogeneity or bright echoes in hyperechoic tissue
4	Significant	Heterogeneous cauliflower/smudgy/mottled appearance or bright echoes (possible comedonecrosis)
5	Very high	Irregular shadowing (originating in prostate, not prostate border) or mixed echo lesions, or irregular prostate and/or peripheral zone border

Table 17: PRI-MUS Risk Score

Figure 61 depicts the distinct ultrasound appearances that were observed during the *Multi-Center Trial*, and relates them to each *PRI-MUS Risk Score*.

¹ ClinicalTrials.gov NCT02079025

² Ghai S, Eure G, Fradet V, Hyndman ME, McGrath T, Wodlinger B and Pavlovich CP, Assessing Cancer Risk on Novel 29 MHz Micro-Ultrasound Images of the Prostate: Creation of the Micro-Ultrasound Protocol for Prostate Risk Identification, J Urol. 2016 Aug;196(2):562-9.

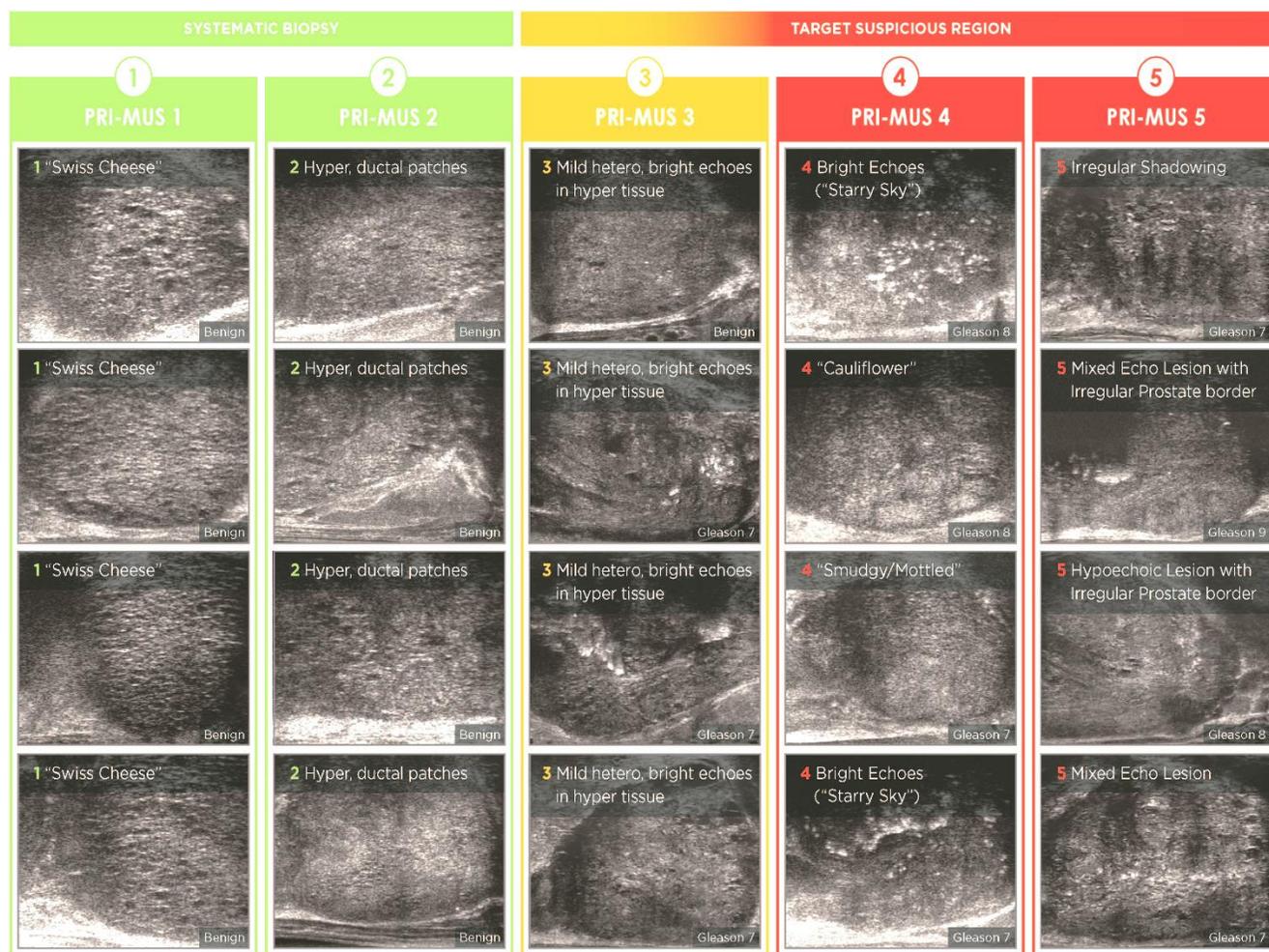


Figure 61: Ultrasound Features used in PRI-MUS Protocol Correlated with PRI-MUS Scores

2 Validation of the PRI-MUS Protocol

Following the *Multi-Center Trial*, validation was performed in an independent pathology blinded set of 100 subsequent cines images, evaluated by five investigators.

An overall statistically significant, linearly increasing trend was found. Each increase in risk score demonstrated a 10.1% increase (95% CI 9.3-10.8) in the probability of clinically significant cancer². The risk score also increased with Gleason sum and cancer length with a slope of 0.15 (95% CI 0.09-0.21) and 0.58 (95% CI 0.43-0.73), respectively. Sensitivity and specificity were 80% and 37%, respectively, and the mean ± SD ROC AUC was 60% ± 2%. The protocol was more accurate for detecting high grade disease (Gleason sum greater than 7) with a peak AUC of 74% (mean 66%).

In summary, in each of five PRI-MUS Risk Scores, each ultrasound appearance is linearly correlated with the probability of cancer such that tissue with a higher *PRI-MUS Risk Score* should be found to be malignant on biopsy more often than tissue with a lower *PRI-MUS Risk Score* (refer to Figure 62).

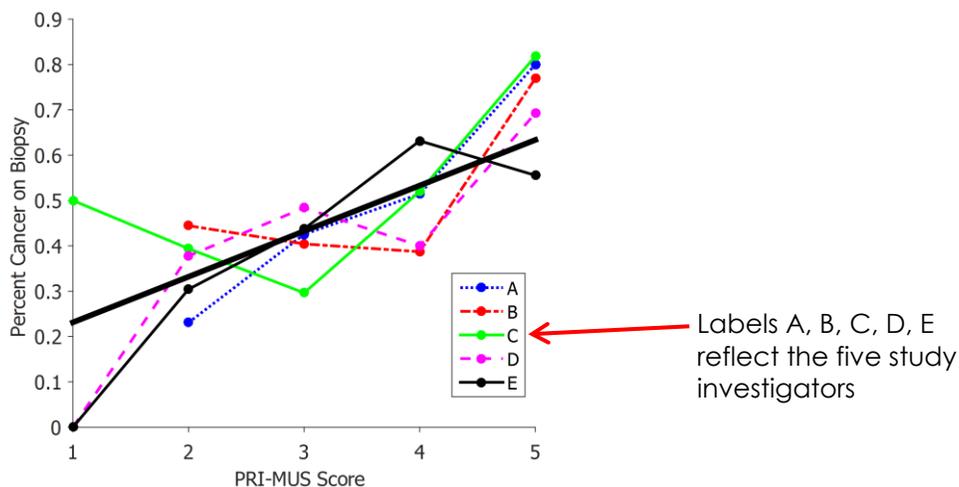


Figure 62: Linear Correlation of PRI-MUS Score with Malignant Cancer on Core Biopsy²

The results in Table 18 demonstrate a positive correlation with five ultrasound appearances.

Feature	Number of Malignant Samples / Number of Cine Images	Risk Ratio (90% CI)
Some regular ducts, "Swiss cheese"	1/7	0.28 (0.05-1.72)
Hyperechoic with or without ductal patches	14/50	0.49 (0.31-0.78)
Mild heterogeneity	24/42	1.19 (0.87-1.62)
Bright echoes in hyperechoic tissue	4/10	0.79 (0.37-1.71)
Heterogeneous cauliflower/smudgy/mottled appearance	22/32	1.48 (1.11-1.97)
Bright echoes	18/30	1.24 (0.89-1.73)
Irregular peripheral zone border	1/1	2.01 (1.75-2.31)
Mixed echo lesions	2/2	2.02 (1.76-2.33)
Irregular shadowing	11/12	1.94 (1.54-2.43)

Table 18: RR of Ultrasound Features on Blinded Analysis of 100 Biopsy Samples Proven Benign and 100 Biopsy Sample Proven Malignant Cine Images²

Chapter 12 Preferences

The Preferences window provides a series of screens that display information about the configuration of the ExactVu system, and provide controls to modify system preferences.

ExactVu Preferences contains the following screens:

- System Information (provides access to ExactVu configuration information, message log export options and the *Transducer Element Check*)
- DICOM Settings (provides configuration for PACS Store and DICOM MRI Query/Retrieve and Modality Worklist)
- Network Settings (provides information about the ExactVu computer and network connection)
- System Settings (clinic information, language preference, system date and time and configuration for needle guides and foot pedal)
- Security (provides settings for patient data access controls)
- Physicians Setup (allows a list of physicians to be stored that can be selected from the Patient/Study screen)
- External Programs (provides access to available programs that can be launched outside the ExactVu software application)
- EULA (end user license agreement)

To access Preferences:

- Press **Preferences** on the control panel.
The *Preferences > System Information* screen is displayed.

To save Preferences:

- Select **Save** on the current *Preferences* screen.
Changes made on any *Preferences* screen are saved.

To close Preferences without saving changes:

- Press **Close** on the current *Preferences* screen.
Preferences closes and no changes are saved. Imaging may be resumed in the current imaging mode.

1 System Information

The *Preferences > System Information* screen displays a variety of information, including:

- ExactVu configuration and copyright information, including software and hardware component versions
- ExactVu activation information, indicating the software features that are activated in the current configuration
- Contact information for Technical Support (refer to Appendix F for additional contact information)
- *Message log* export options

- *Transducer Element Check*, for assessing the integrity of transducer elements when the transducer is activated

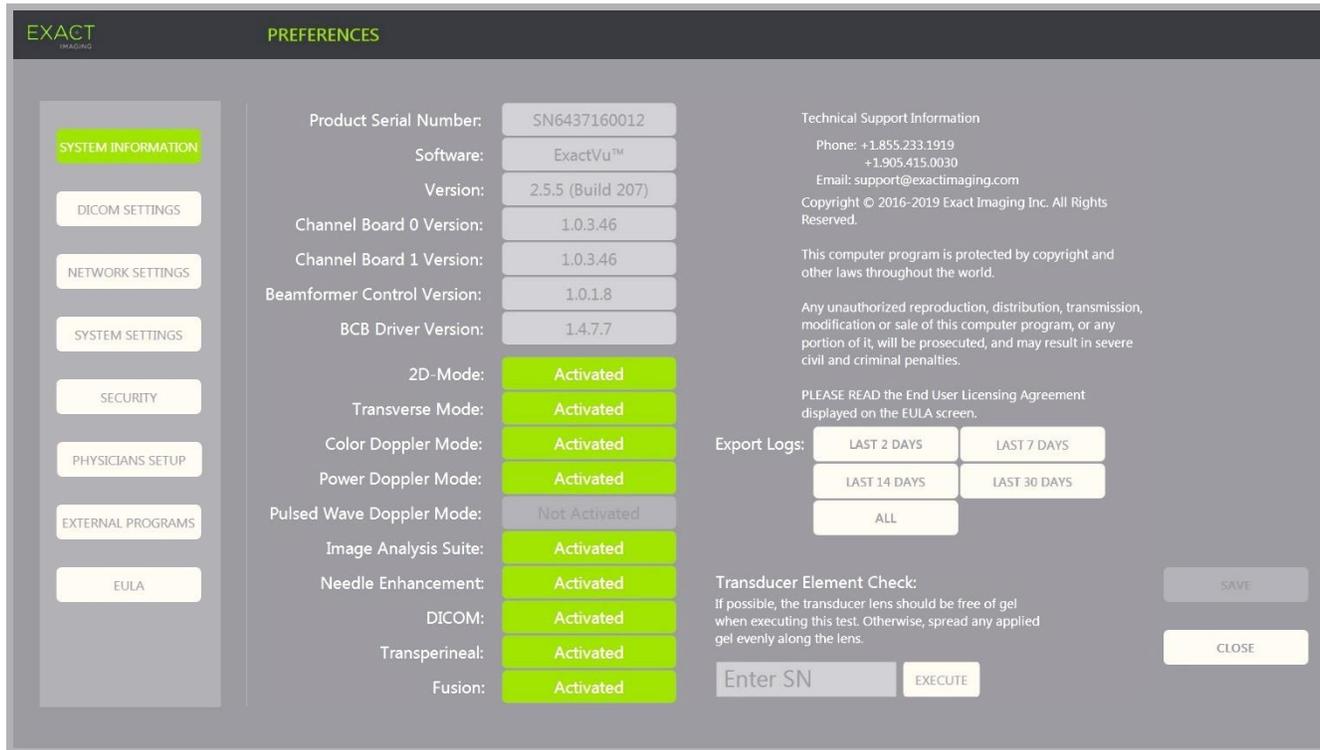


Figure 63: Preferences > System Information

1.1 Exporting Log Files

The ExactVu system tracks the status of hardware and software events that occur during operation and saves them in a *message log* file. Log files are created when the ExactVu system is turned on and are used by Technical Support technicians to diagnose problem conditions. The *Preferences > System Information* screen provides an option to select log files to export, so that they can be sent to Technical Support technicians.

Log files may be exported to a USB storage device. Refer to Chapter 3, section 1.4 on page 56 for details about recommended formatting for USB storage devices and connecting a USB storage device to the ExactVu system.

To export log files:

1. Connect a USB storage device to the ExactVu system, formatted as recommended in Chapter 3, section 1.4 on page 56.
2. Next to *Export Logs*, select the desired time range for message log files to export.

An *Export progress* status is displayed.

When the export is complete, the progress dialog closes, and the selected range of message log files is copied to the folder, *ExactData*, on the USB storage device.

1.2 Transducer Element Check

The purpose of transducer element testing is to assess the integrity of transducer elements before the

transducer is used for imaging.

The *Transducer Element Check* is executed as follows:

- When the operator manually selects to execute it from the *Preferences > System Information* screen
- When the operator connects any transducer, the *Transducer Element Check* is automatically performed on the connected transducer
- When the operator selects to activate any transducer from the *control panel*, from the *touch screen* or from the *Patient/Study* screen, the *Transducer Element Check* is automatically performed on the activated transducer
- When the ExactVu system starts and one or more transducer is connected, the *Transducer Element Check* is automatically performed on the transducer connected to the top-most *transducer connector slot*

Exact Imaging recommends executing the *Transducer Element Check* whenever unexpected behavior is observed.

CAUTION

EN-C51



If possible, the transducer lens should be free of gel when executing this test. Otherwise, spread any applied gel evenly along the lens.

To execute the Transducer Element Check from the Preferences > System Information screen:

1. Below *Transducer Element Check*, type the serial number of the connected transducer being checked. The serial number is located on the label on the *transducer connector housing* next to the symbol **SN**.
2. Press **Execute**.

The *Transducer Element Check* process is executed and results are reported in an on-screen message.

The results presented indicate the number of non-active elements, as well as an indication of whether the results are acceptable. A limited number of non-active elements is acceptable.

When the results are acceptable, the on-screen message closes and the ExactVu system may be used for imaging.

When the results are not acceptable, the location of the non-active elements are indicated by vertical yellow lines on the imaging screen (refer to Figure 64). In this case, a message is displayed to re-execute the *Transducer Element Check* process.

Prior to re-executing the test check the transducer lens for gel. The lens should either be free of gel or any applied gel should be spread evenly along the lens.

If results continue not to be acceptable, contact Technical Support using the contact information in Appendix F.

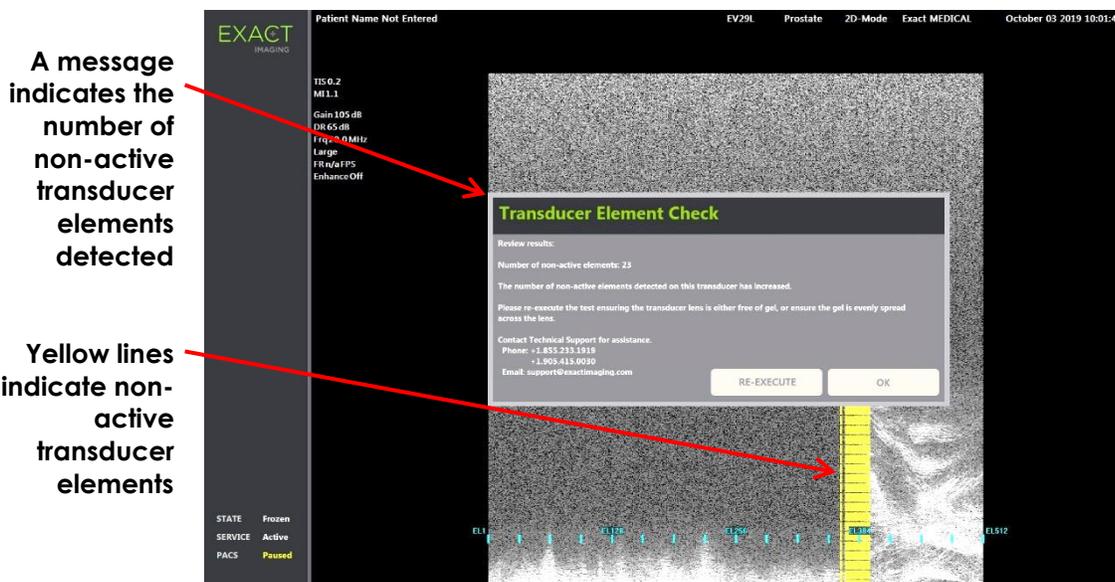


Figure 64: Transducer Element Check, Non-Active Elements

The *Transducer Element Check* may be performed at any time.

2 DICOM Settings

Details for how to configure DICOM settings for the ExactVu system are provided in Chapter 3, section 1.7.2.1 on page 62.

3 Network Settings

Details for how to configure network settings for the ExactVu system are provided in Chapter 3, section 1.7.2.2 on page 66.

4 System Settings

The *Preferences > System Settings* screen provides several configurable settings related to the ExactVu software, including:

- Clinic name and Clinic ID
- Language preference
- Date and time settings
- EV29L Needle Guide preference
- Foot Pedal preference

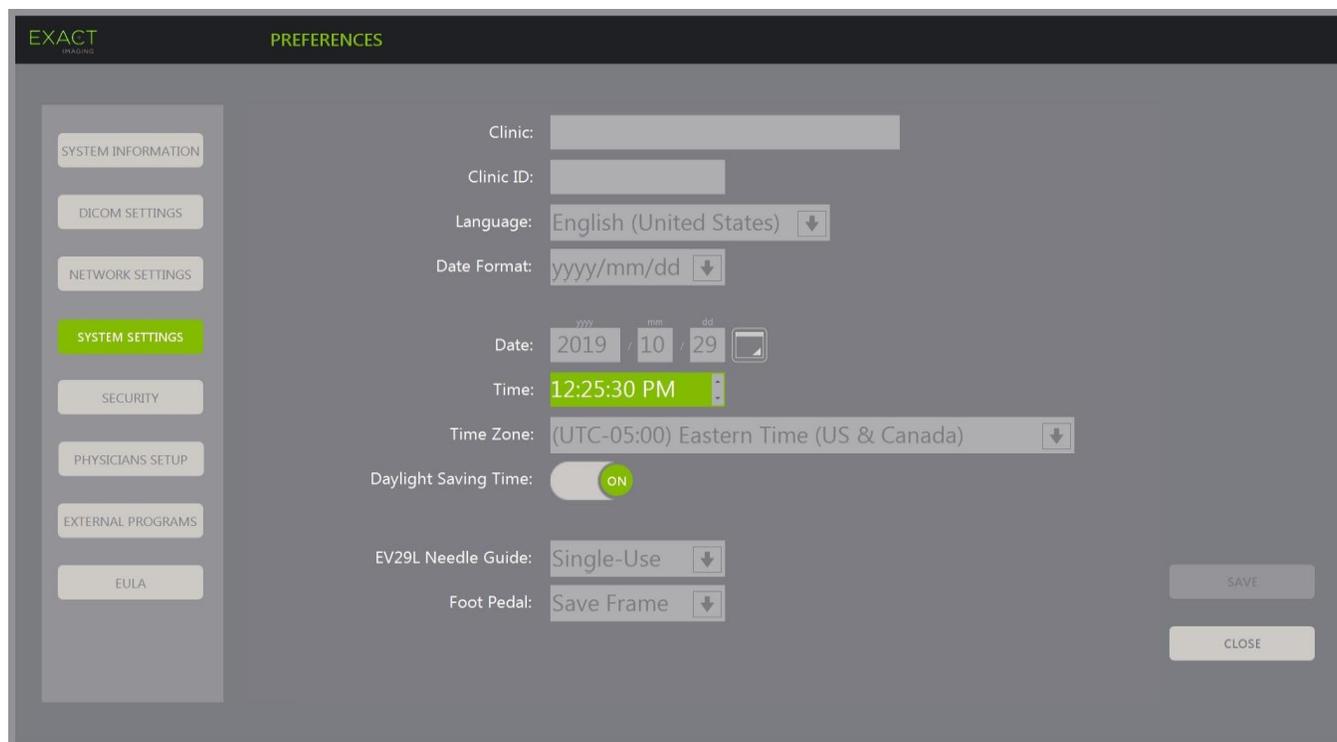


Figure 65: Preferences > System Settings

4.1 Clinic Details

To enter details about the clinic:

1. Select the *Clinic* field and type the name of the clinic using the touch screen's keyboard.
2. Select the *Clinic ID* field and type the name of the clinic using the touch screen's keyboard.
3. Select **Save** if no further Preferences updates are being made.

To specify the language preference:

1. Select the dropdown arrow next to *Language*.
A list of language options is displayed. The default language is set to English.
2. Scroll to the desired language and press **Set** on the control panel.
3. Select **Save** if no further Preferences updates are being made.
The selected language is set as ExactVu's *system language*.

The ExactVu software uses the selected *system language* as follows:

- A language-specific virtual keyboard is displayed on the touch screen
- Software messages that pertain to safety and to display are displayed in the selected language
- Operator-specified Patient/Study information is displayed on the imaging screen using the characters from the virtual keyboard for the selected language
- Details about the patient and procedure are loaded from scheduled Modality Worklist procedures and displayed in the selected language on the Patient/Study screen

- Details about the ExactVu study that are exported to a USB storage device or to a PACS server are exported using the characters from the virtual keyboard for the selected language

To set the Date Format:

1. Next to *Date Format* select one of the available options:
 - mm/dd/yyyy
 - dd/mm/yyyy
 - yyyy/mm/dd

The date format setting is applied to the display of all dates in the ExactVu system.

2. Select **Save** if no further Preferences updates are being made.

4.2 Date and Time

To set the system date:

1. Next to the *Date* field, enter the current date, or select the calendar icon.
The *calendar control* is displayed.

2. Select the current month and date.

3. Press **Set** on the *control panel*.

The selected date is assigned as ExactVu's system date, and the calendar control closes.

4. Select **Save** if no further Preferences updates are being made.

To set the system time:

1. Next to the *Time* field, select the value for the current hour by scrolling the up or down arrow.
2. Press **Set** on the *control panel*.

3. Repeat step 1 and step 2 to assign minute and second values.

The selected hour, minute and second values are assigned as ExactVu's system time.

4. Select **Save** if no further Preferences updates are being made.

To set the system time zone:

1. Select the dropdown arrow to the right of the *Time Zone* field.

A list of time zones is displayed. The factory default setting is (GMT-05:00) Eastern Time.

2. Scroll the list to the current time zone.

3. Press **Set** on the *control panel*.

The selected time zone is set as ExactVu's system time zone.

4. Select **Save** if no further Preferences updates are being made.

To toggle the Daylight Savings Time preference:

1. Select *OFF* next to *Daylight Savings Time*.

The ExactVu system's setting to automatically adjust for daylight savings toggles on. The factory default setting is for Daylight Savings Time to be on.

2. Select *ON* next to *Daylight Savings Time*.

The ExactVu system's setting to automatically adjust for daylight savings toggles off.

3. Select **Save** if no further Preferences updates are being made.

NOTE

EN-N64



If there are unsaved changes to any date or time setting, a confirmation is displayed when closing Preferences.

NOTE

EN-N183



The ExactVu system uses the Windows operating system for time synchronization.

4.3 EV29L Needle Guide

Chapter 1, section 8 describes the needle guides that are compatible with the EV29L transducer. The *EV29L Non-sterile Reusable Transrectal Needle Guide* supports a single needle entrance angle of 35 degrees, and the *EV29L Sterile Transrectal Needle Guide* supports two needle entrances angled at 35 degrees and 15 degrees.

The operator is able to indicate a preference for either of these two needle guides, which limits the availability of the *needle guide overlay* selection on the *Workflow* touch screen to those that correspond to the needle entrances available on the physical needle guide. (Refer to Chapter 5, section 2.3.1 on page 113 for information about *needle guide overlays*.)

To toggle the preference for the EV29L Sterile Transrectal Needle Guide:

1. Select **Single-Use** next to *EV29L Needle Guide*.
2. Select **Save** if no further Preferences updates are being made.

The *Single-Use* setting enables both the 35-degree *needle guide overlay* and 15-degree *needle guide overlay* on the *Workflow touch screen*.

To toggle the preference for the EV29L Non-sterile Reusable Transrectal Needle Guide:

1. Select **Reusable** next to *EV29L Needle Guide*.
2. Select **Save** if no further Preferences updates are being made.

The *Reusable* setting enables only the 35-degree *needle guide overlay* on the *Workflow touch screen*.

4.4 Foot Pedal

This section is applicable to ExactVu systems equipped with a foot pedal.

The operator is able to set a preference for the foot pedal function to save either single frames or cine images.

To set the preference for the foot pedal to save a single frame:

1. Select **Save Frame** next to *Foot Pedal*.
2. Select **Save** if no further Preferences updates are being made.

The foot pedal saves a single frame when pressed. This preference is retained until it is

changed by the operator.

To set the preference for the foot pedal to save a cine image:

1. Select **Save Cine** next to *Foot Pedal*.
2. Select **Save** if no further Preferences updates are being made.

The foot pedal saves a cine image when pressed. This preference is retained until it is changed by the operator.

5 Security

Details for how to configure system security on the ExactVu system are provided in Chapter 3, section 1.7.1 on page 59.

NOTE

EN-N21



If *system security* is enabled on the ExactVu system, and secured features have not been accessed for a period longer than the duration of the security timeout, the *System Security* dialog appears and requires a security password to be entered before the *Security* screen opens.

6 Physicians Setup

The *Preferences > Physicians Setup* screen provides a means of creating and storing a list of physicians that can be selected from the Patient/Study screen.

To add a name to the Physician List:

1. Select **Add Name**.
The edit field below the button becomes enabled.
2. Type the name of the physician and select **Save Name**.

The physician is added to the *Physician List*.

The physicians in the list may be viewed by selecting the dropdown arrow and may be selected from the Patient/Study screen.

To delete a name from the Physician List:

1. Select the *Physician List* dropdown, and select one of the listed physicians.
2. Select **Delete Name**.

The physician is removed from the *Physician List*.

Changes made on the Physicians Setup screen do not require the Save button to be pressed.

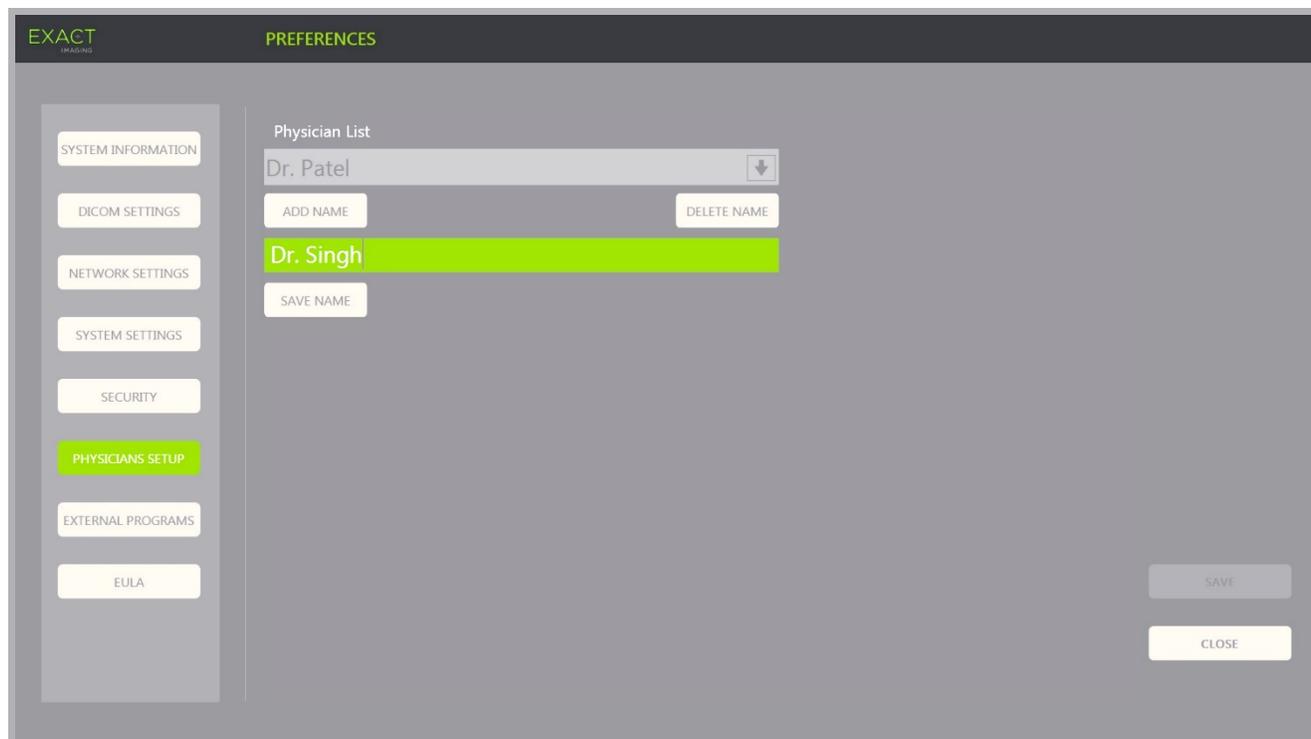


Figure 66: Preferences > Physicians Setup

7 External Programs

The *Preferences > External Programs* screen provides access to available programs that can be selected from a specially configured USB storage device or from those installed on the ExactVu system (if available).

To launch a program from the External Program List:

1. When programs are available on the ExactVu system or with a USB storage device containing available programs connected to the ExactVu system, select **Preferences > External Programs**.
The External Programs screen is displayed with a list of executable programs in the External Program List. When no programs are available, the External Program List dropdown displays a message, "No valid programs are available."
2. Select an available program from the *External Program List* dropdown.
The selected program launches and runs separately from the ExactVu system software.
3. When finished with the program, Exact Imaging recommends restarting the ExactVu system prior to using it for imaging procedures. To do this, press the system power control on the front of the ExactVu system cart.

Changes made on the External Programs screen do not require the Save button to be pressed.

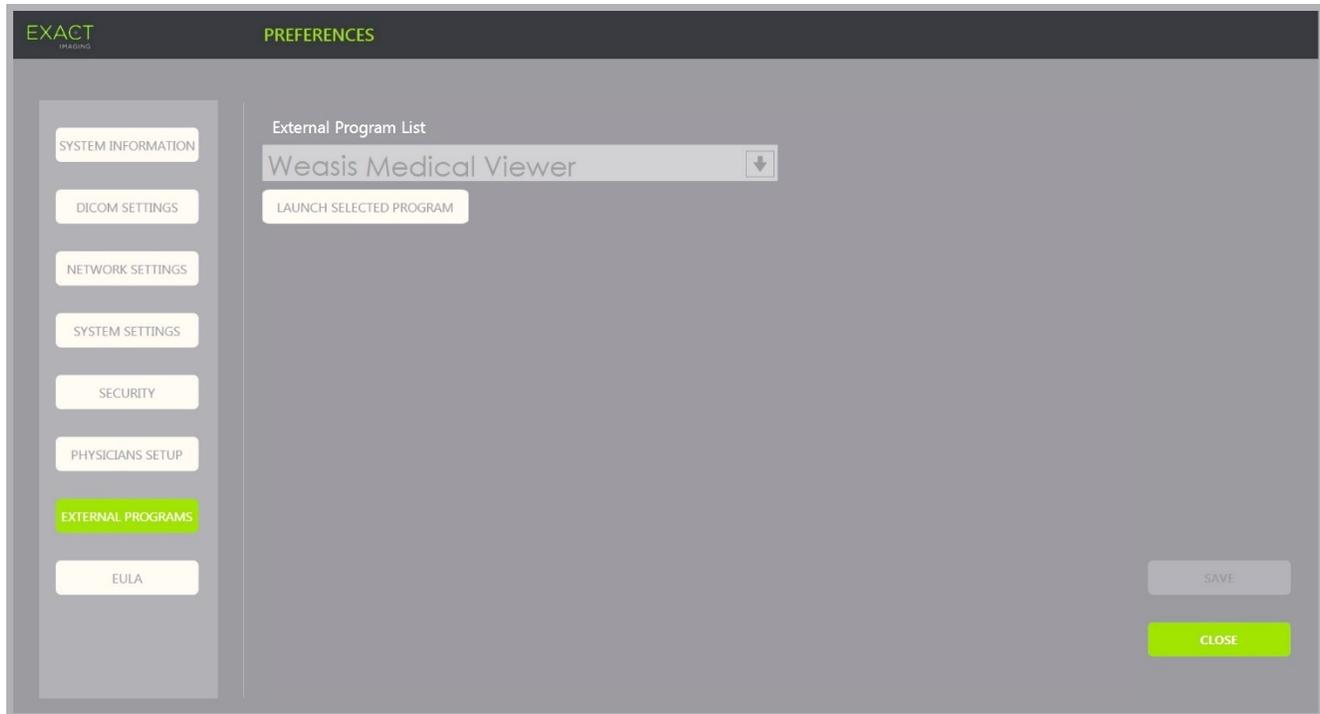


Figure 67: Preferences > External Programs

8 EULA (End User License Agreement)

The *Preferences > EULA* screen provides information related to the EULA, including obligations of operators of the ExactVu system.

Chapter 13 Caring for and Maintaining the ExactVu System and Transducers

The ExactVu system must be checked regularly to maintain a high level of safety and performance.

Some maintenance activities are performed by ExactVu operators. These include:

- Cleaning the lower air filter
- Cleaning the left panel air filter
- Reprocessing and inspecting the foot pedal
- Replacing thermal printer paper
- Inspecting the thermal printer
- Inspecting the ExactVu system
- Inspecting the ExactVu transducers
- Observing Electrostatic Discharge (ESD) Controls

WARNING

EN-W37



No parts of the ExactVu system may be serviced or have maintenance performed while in use with a patient.

CAUTION

EN-C35



When maintenance or service procedures include instructions to wear a wrist strap connected to the ground pin, the ground pin must also be connected directly to ground, and the system power must be turned off.

1 Cleaning the Lower Air Filter

The ExactVu system includes an air filter, located on the bottom of the ExactVu system cart on the right side.

Exact Imaging recommends cleaning the lower air filter every six months.

If an air filter has been torn, it must be replaced. Contact Technical Support using the contact information in Appendix F to order a replacement air filter.

Required tools:

- #1 Phillips screw driver

To clean the lower air filter:

1. Loosen the *captive screw* indicated in Figure 68.
2. Pull the *air filter cover* away from the panel.
3. Using the #1 Phillips screw driver, loosen the 5 screws that secure the *filter plate* cover indicated in Figure 69.
4. Remove the 5 screws and their washers.
5. Remove the *air filter*, and wash it with water and mild detergent.
6. Completely dry the *air filter*.
7. Place the *air filter* in its compartment.
8. Place the plate over the filter.
9. Using the #1 Phillips screw driver, tighten the 5 screws and washers to secure the *filter plate*.
10. Replace the *air filter* compartment on the bottom right side of the ExactVu system



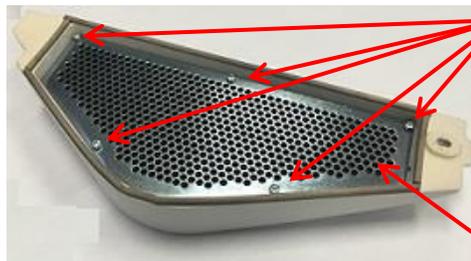
Captive screw for air filter access

Figure 68: Bottom Right Side of the ExactVu System Cart



Air filter cover

Figure 69: Lower Air Filter Access



5 screws

Air Filter Plate

Figure 70: Air Filter Plate



Air Filter

Figure 71: Air Filter

2 Cleaning the Left Panel Air Filter

The ExactVu system includes an air filter for the computer unit fan, located in the vented portion of the left side panel.

Exact Imaging recommends cleaning the air filter every six months. If an air filter has been torn, it must be replaced.

Required tools:

- #2 Phillips screw driver

To clean the air filter:

1. Using the #2 Phillips screw driver, remove the screw that secures the *filter cover* from the left side of the ExactVu system cart (i.e., the computer side), indicated in Figure 72.
2. Remove the *filter cover*.
3. Remove the air filter, and wash it with water and mild detergent.
4. Completely dry the air filter.
5. Replace the air filter in the left side panel.
6. Place the *filter cover* over the filter.
7. Using the #2 Phillips screw driver, replace the screw to secure the *filter cover*.



Figure 72: Inside View of Left Side Panel

3 Inspecting the Foot Pedal

This section is applicable to ExactVu systems equipped with a foot pedal.

Perform a visual inspection of the foot pedal on a weekly basis:

What to look for	Where to look
Cuts or abrasions	Entire length of the cable (light scuffing is acceptable)
Outer covering of the cable appears stretched, strained or pinched	Where the cable enters the foot pedal enclosure
Colored insulation of internal wires is showing	Where the cable enters the foot pedal enclosure
Excessive damage that could present a hazard or prevent proper operation	The foot pedal enclosure

Table 19: Foot Pedal Visual Inspection

If you observe any damage or defects, contact Technical Support using the contact information in Appendix F.



Loose-hanging device cables pose a potential tripping hazard. Arrange cables so that it is not possible to trip over them, particularly when moving the ExactVu system or monitor stand.

To avoid damaging cables:

CAUTION
EN-C56



- Keep cables off the floor by using transducer holders and foot pedal cable management clips.
- Do not sharply bend or stretch cables, or allow cables to become knotted.
- When disconnecting a cable, pull on its connector. Do not pull on the cable itself.

4 Replacing the Thermal Printer Paper

To replace thermal printer paper in the thermal printer (if configured):

1. Ensure that the ExactVu system is powered on.

This automatically turns the thermal printer power ON.

2. Press the *OPEN* button to open the door panel (refer to Figure 73).

The *door panel* opens.

3. Insert the paper by following the *instructions for replacing the thermal paper roll* displayed on the inside of the door panel,

4. Make note of the instruction to load the paper with the printing side (heat sensitive side) facing up. (Printing is not possible if the paper is reversed.)

5. Close the *door panel* by pushing it closed.



Figure 73: Printer Control Panel

OPEN button

Power ON/OFF button



Figure 74: Open Printer Door Panel

Instructions for replacing thermal paper roll

Door panel

5 Inspecting the Thermal Printer

Printed ExactVu images may occasionally display unexpected artifacts that do not appear when the same images are viewed on the ExactVu monitor. When this occurs, refer to the troubleshooting instructions in the *Thermal Printer Instructions for Use for Sony® UP-D898MD* provided by Exact Imaging.

NOTE
EN-N66



Refer to the Instructions for Use for UP-D898MD for additional help with troubleshooting, or refer to the Sony Corporation website.

6 Inspecting the ExactVu System

Perform a visual inspection of the following ExactVu parts on a monthly basis:

What to look for	Where to look
Any mechanical defects	Connectors on all cables
Cuts or abrasions	Entire length of electrical and power cables
Loose or missing hardware	<ul style="list-style-type: none"> Control panel handle or grab bar Transducer connectors on the ExactVu system cart Monitor connection to the ExactVu system cart
Mechanical damage or improper operation	Control panel
Mechanical damage or improper operation	Touch screen
Proper locking and unlocking operation	Castors

Table 20: ExactVu Visual Inspection

If you observe any damage or defects, contact Technical Support using the contact information in Appendix F.

7 Inspecting the Transducers

Refer to the following guides for instructions about how to inspect ExactVu transducers and when to perform the inspection:

- *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*
- *Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer*
- *Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer*

If you observe unexpected behavior in the performance of an ExactVu transducer, contact Technical Support using the contact information in Appendix F.

8 Observing Electrostatic Discharge (ESD) Controls

Electronic components and assemblies can be permanently damaged or destroyed when near or in contact with electrostatically charged objects, unless they are properly protected against electrostatic discharge (ESD).

Servicing activities are to be performed in accordance with precautionary procedures for ESD controls. When servicing ESD-sensitive equipment in the field, the following should be observed wherever possible:

- Perform all service procedures in a static-protected environment. Always use techniques and equipment designed to protect personnel and equipment from electrostatic discharge.
- Remove or insert static-sensitive components and assemblies only with ExactVu system power turned off, the power cable disconnected, and the ExactVu system connected to ground via the *ground pin*.
- Remove static-sensitive components and assemblies from their static-shielding bags only at static-safe workstations, and only when wearing a grounded wrist strap (with a resistor of at

least 0.8-1.5 Mohm resistance), with its ground cord connected to the ground pin at the bottom rear of the ExactVu system cart (refer to Figure 75), or an equivalent ground source.

- Insert and seal static-sensitive components and assemblies into their original static-shielding bags before removing them from static-protected areas.
- Always test the wrist strap and ground cord before removing components and assemblies from their protective bags and before beginning any disassembly or assembly procedures.



Figure 75: Ground Pin

WARNING
EN-W2



Unauthorized modification of this equipment is not permitted and may compromise the safe operation of the equipment.

WARNING
EN-W52



Disconnect the ExactVu system power cable before servicing any internal components.

Do not touch the pin of a connector marked by the ESD symbol.

Do not make a connection to a connector marked by the ESD symbol unless ESD precautionary procedures are used.

CAUTION
EN-C28



The ExactVu system contains components that are sensitive to electrostatic discharge (ESD). Proper static procedures, protection, and equipment must be used when handling this equipment.

Always use correct ESD procedures. Failure to use ESD procedures will cause damage to these components.

CAUTION
EN-C35



When maintenance or service procedures include instructions to wear a wrist strap connected to the *ground pin*, the ground pin must also be connected directly to ground, and the *system power* must be turned off.

Chapter 14 Service and Support

1 Technical Support

If problems arise with the ExactVu system, Exact Imaging will strive to ensure that the system remains operational with minimal downtime. When such problems occur, contact Technical Support using the contact information in Appendix F.

NOTE
EN-N65



Contact information for Technical Support is provided in *Preferences > System Information*.

1.1 Service Provided by Exact Imaging

The ExactVu system is designed with software tools that allow Technical Support technicians and engineers to make adjustments, diagnose problems and install software updates.

Some parts of the ExactVu system are maintained by Technical Support technicians according to a service schedule for system maintenance while the system is covered under the manufacturer's warranty period. Service records are maintained for all installed ExactVu systems.

Occasionally the ExactVu system does not function as expected. If problems arise with the ExactVu system or it does not perform as expected, Technical Support technicians may be required to assist in resolving those problems.

Problems may be resolved remotely by telephone or during an on-site visit by Technical Support technicians (when required).

Extended Warranty programs are available to ensure service and support coverage for ExactVu systems is provided beyond the original manufacturer's warranty period. Contact Technical Support using the contact information in Appendix F for more information on *Extended Warranty* programs.

2 Disposal

When the ExactVu system reaches the end of its working life, it must be sent to appropriate facilities for recovery and recycling. When transducers reach the end of their working life, national rules for discarding/recycling the relevant material in each individual country must be followed.

The EV29L, EV9C and EV5C transducers are designed for a working lifetime of 5 years, when used with proper care. The ExactVu system is designed for a working lifetime of 5 years.

For consumables such as needle guides, sheaths, gloves and needles, follow internal clinical procedures for safe disposal.

If further information is required regarding disposal of the ExactVu system and its accessories, contact Technical Support using the contact information in Appendix F.

Appendix A EV29L Transducer Acoustic Output

Operational Mode: 2D Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.12	(a)		(b)		(b)
Index component value			-	-	-	-	-
Acoustic parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	4.06	-	-	-	-	-
	P (mW)	-	-		-		-
	P_{IXI} (mW)	-	-		-		-
	Z_s (cm)	-	-	-	-	-	-
	Z_b (cm)	-	-	-	-	-	-
	Z_{MI} (cm)	0.89	-	-	-	-	-
	$Z_{pii,\alpha}$ (cm)	0.95	-	-	-	-	-
	f_{awf} (MHz)	13.15	-		-		-
Other information	P_{rr} (Hz)	25600	-	-	-	-	-
	S_{rr} (Hz)	25	-	-	-	-	-
	N_{pps}	1	-	-	-	-	-
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$ (W/cm ²)	549	-	-	-	-	-
	$I_{sp\alpha,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$ (mW/cm ²)	8	-	-	-	-	-
	$I_{sp\alpha}$ at Z_{pii} or Z_{sii} (mW/cm ²)	20	-	-	-	-	-
	p_r at Z_{pii} (MPa)	5.38	-	-	-	-	-
Operating control conditions	Focal Depth (mm)	10	-	-	-	-	-

(a) TIS is lower than 1.0; therefore, it is not reported.

(b) Application of this transducer is only for transrectal prostate imaging where bone is not exposed to the ultrasound beam.

Display Accuracy for EV29L Transducer Acoustic Output

- For MI: +24% and -33%
- For TIS: +48% and -78%

Appendix B EV9C Transducer Acoustic Output

Operational Mode: 2D Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.32	(a)		(b)		(b)
Index component value			-	-	-	-	-
Acoustic parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	2.95	-	-	-	-	-
	P (mW)	-	-		-		-
	P_{IXI} (mW)	-	-		-		-
	Z_s (cm)	-	-	-	-	-	-
	Z_b (cm)	-	-	-	-	-	-
	Z_{MI} (cm)	1.98	-	-	-	-	-
	$Z_{p_{ii},\alpha}$ (cm)	2.15	-	-	-	-	-
	f_{awf} (MHz)	5.02	-		-		-
Other information	P_{rr} (Hz)	6400	-	-	-	-	-
	S_{rr} (Hz)	25	-	-	-	-	-
	N_{pps}	1	-	-	-	-	-
	$I_{p_{\alpha,\alpha}}$ at $Z_{p_{ii},\alpha}$ (W/cm ²)	369	-	-	-	-	-
	$I_{s_{p_{\alpha,\alpha}}}$ at $Z_{p_{ii},\alpha}$ or $Z_{s_{ii},\alpha}$ (mW/cm ²)	9	-	-	-	-	-
	$I_{s_{p_{\alpha,\alpha}}}$ at $Z_{p_{ii}}$ or $Z_{s_{ii}}$ (mW/cm ²)	19	-	-	-	-	-
	p_r at $Z_{p_{ii}}$ (MPa)	3.83	-	-	-	-	-
Operating control conditions	Focal depth (mm)	24	-	-	-	-	-

(a) TIS is lower than 1.0; therefore, it is not reported.

(b) Application of this transducer is only for trans-rectal prostate imaging where bone is not exposed to the ultrasound beam.

Display Accuracy for EV9C Transducer Acoustic Output

- For MI: +28% and -42%
- For TIS: +56% and -84%

Appendix C EV5C Transducer Acoustic Output

Operational Mode: 2D Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		1.04	(a)		(a)		(b)
Index component value		-	-	-	(b)	-	-
Acoustic parameters	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.85	-	-	-	-	-
	P (mW)	-	-		-		-
	P_{IXI} (mW)	-	-		-		-
	Z_s (cm)	-	-	-	-	-	-
	Z_b (cm)	-	-	-	-	-	-
	Z_{MI} (cm)	2.16	-	-	-	-	-
	$Z_{p_{ii},\alpha}$ (cm)	2.53	-	-	-	-	-
	f_{awf} (MHz)	3.20	-		-		-
Other information	P_{rr} (Hz)	3200	-	-	-	-	-
	S_{rr} (Hz)	25	-	-	-	-	-
	N_{pps}	1	-	-	-	-	-
	$I_{p_{\alpha,\alpha}}$ at $Z_{p_{ii},\alpha}$ (W/cm ²)	117.8	-	-	-	-	-
	$I_{sp_{t\alpha,\alpha}}$ at $Z_{p_{ii},\alpha}$ or $Z_{s_{ii},\alpha}$ (mW/cm ²)	3.08	-	-	-	-	-
	$I_{sp_{t\alpha}}$ at $Z_{p_{ii}}$ or $Z_{s_{ii}}$ (mW/cm ²)	5.09	-	-	-	-	-
Operating control conditions	p_r at $Z_{p_{ii}}$ (MPa)	2.19	-	-	-	-	-
	Focal depth (mm)	31	-	-	-	-	-

(a) TIS is lower than 1.0; therefore, it is not reported.

(b) Application of this transducer is only for abdominal imaging in urological applications and is not designed for pediatric or fetal use.

Display Accuracy for EV5C Transducer Acoustic Output

- For MI: +28% and -27%
- For TIS: +56% and -54%

Operational Mode: Color Doppler Mode/Power Doppler Mode

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.91	1.00		1.00		(c)
Index component value		-	1.00	1.00	(c)	1.00	-
Acoustic parameter s	$p_{r,\alpha}$ at Z_{MI} (MPa)	1.43	-	-	-	-	-
	P (mW)	-	495.24		495.24		-
	$P_{1 \times 1}$ (mW)	-	85.97		85.97		-
	Z_s (cm)	-	-	N/A	-	-	-
	Z_b (cm)	-	-	-	-	N/A	-
	Z_{MI} (cm)	1.86	-	-	-	-	-
	$Z_{pii,\alpha}$ (cm)	1.95	-	-	-	-	-
	f_{awt} (MHz)	2.48	2.48-3.22		2.48-3.22		-
Other information	P_{rr} (Hz)	7000	-	-	-	-	-
	S_{rr} (Hz)	16.39	-	-	-	-	-
	N_{pps}	1/16 ^a	-	-	-	-	-
	$I_{p,\alpha}$ at $Z_{pii,\alpha}$ (W/cm ²)	79.29	-	-	-	-	-
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ or $Z_{sii,\alpha}$ (mW/cm ²)	42.84 ^b	-	-	-	-	-
	I_{spta} at Z_{pii} or Z_{sii} (mW/cm ²)	73.50 ^b	-	-	-	-	-
	p_r at Z_{pii} (MPa)	1.50	-	-	-	-	-
Operating control conditions	Preset Name	Small	Large				
	FZ (Focal Zone-mm)	31	149				
	Depth (mm)	90	180				
	Number of Ensembles (Ne)--sensitivity	16	16				
	PRF (kHz)	7	2				
	Box angle (deg)	20	20				

(a) $N_{pps} = 1$ for B-Mode component, 16 for CFI (color) component

(b) I_{spta} values reported for combined mode (i.e., B-Mode + CFI Mode)

(c) Application of this transducer is only for abdominal imaging in urological applications and is not designed for pediatric or fetal use.

Display Accuracy for EV5C Transducer Acoustic Output

- For MI: +28% and -27%
- For TIS: +56% and -54%

Appendix D EMC Manufacturer Declarations

Manufacturer’s Declaration – Electromagnetic Emissions

The ExactVu system is intended for use in the electromagnetic environment specified below. The operator of the ExactVu system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The ExactVu system 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	The ExactVu system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the warnings and cautions in Chapter 2, section 5 on page 41 are observed.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 21: Electromagnetic Emissions Declaration

Manufacturer’s Declaration – Electromagnetic Immunity

The ExactVu system is intended for use in the electromagnetic environment specified below. The operator of the ExactVu system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Electrostatic Discharge (ESD)	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 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%.
IEC 61000-4-2			
Electrical Fast Transient/Burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4			
Surge	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5			
Voltage dips, short interruptions and voltage variations on power supply input lines	<0% U _T (>100% dip in U _T) for 0.5 cycle 0% U _T (100% dip in U _T) for 1 cycle	<0% U _T (>100% dip in U _T) for 0.5 cycle 0% U _T (100% dip in U _T) for 1 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the ExactVu system requires continued operation during power mains interruptions, it is recommended that the ExactVu system be powered from an uninterruptible power supply or a battery.
IEC 61000-4-11	70% U _T (30% dip in U _T) for 25 cycles 0% U _T (100% dip in U _T) for 5 s	70% U _T (30% dip in U _T) for 25 cycles 0% U _T (100% dip in U _T) for 5 s	
Power Frequency Magnetic Field (50/60 Hz)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			

U_T is the AC mains voltage prior to application of the test level.

Table 22: Electromagnetic Immunity Declaration

Manufacturer’s Declaration – Recommended Separation Distances

The ExactVu system is intended for use in the electromagnetic environment specified below. The operator of the ExactVu system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ExactVu system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
	6 Vrms ISM bands inside 150 kHz to 80 MHz	6 Vrms ISM bands inside 150 kHz to 80 MHz	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b .
	RF communication equipment inside 80 MHz to 6 GHz	RF communication equipment inside 80 MHz to 6 GHz	

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 ExactVu system is used exceeds the applicable RF compliance level above, the ExactVu system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ExactVu system.

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

Table 23: Recommended Separation Distances

Manufacturer’s Declaration – Recommended Separation Distances Between Portable and Mobile Equipment and the ExactVu system

The ExactVu system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The operator of the ExactVu system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment transmitters) and the ExactVu system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 24: Recommended Separation Distances Between Portable and Mobile Equipment and the ExactVu system

Appendix E Diagnostic Ultrasound Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form – ExactVu™ High Resolution Micro-Ultrasound System

System	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer	N/A						
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
	Mode of Operation						
Clinical Application	B (2D Mode)	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic							
Fetal							
Abdominal	P				P (3)		P (2)
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P						P, 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P						P, 1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							
Dermatology							

N= new indication; P= previously cleared ; E= added under this appendix

Additional Comments:

1. Includes imaging to assist in the placement of needles for prostate biopsy procedures.
2. Includes imaging to assist in the placement of needles for kidney biopsy procedures.
3. ExactVu supports simultaneous color flow imaging with B-Mode.

Diagnostic Ultrasound Indications for Use Form – Ultrasound Indications for Use Form – EV29L™ High Resolution Transrectal Side-fire Transducer

System	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer	EV29L						
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
	Mode of Operation						
Clinical Application	B (2D Mode)	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P						P, 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P						P, 1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							
Dermatology							

N= new indication; P= previously cleared ; E= added under this appendix

Additional Comments:

1. Includes imaging to assist in the placement of needles for prostate biopsy procedures.

Diagnostic Ultrasound Indications for Use Form – EV9C™ Transrectal End-fire Transducer

System	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer	EV9C						
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
	Mode of Operation						
Clinical Application	B (2D Mode)	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)	P						P, 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal	P						P, 1
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							
Dermatology							

N= new indication; P= previously cleared ; E= added under this appendix

Additional Comments:

1. Includes imaging to assist in the placement of needles for prostate biopsy procedures.

Diagnostic Ultrasound Indications for Use Form – EV5C™ Abdominal Transducer

System	ExactVu™ High Resolution Micro-Ultrasound System						
Transducer	EV5C						
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
	Mode of Operation						
Clinical Application	B (2D Mode)	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic							
Fetal							
Abdominal	P				P (2)		P (1)
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (prostate)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							
Dermatology							

N= new indication; P= previously cleared ; E= added under this appendix

Additional Comments:

1. Includes imaging to assist in the placement of needles for kidney biopsy procedures.
2. ExactVu supports simultaneous color flow imaging with B-Mode.

Appendix F Contact Information

For Technical Support

Region	Phone number	Email address
All regions except North America – contact EDAP TMS	+33(0)472 153 150	ccc@edap-tms.com
North America (US, CA, MX) – contact EDAP USA	+1 (512) 852-9685	service@edap-usa.com

For ordering consumables and other accessories and parts

Region	Phone number	Email address
France (FR), Belgium (BE) - contact EDAP TMS	+33(0)472 153 150	order@edap-tms.com
Germany (DE), Austria (AT), Switzerland (CH) - contact EDAP TMS GmbH	+49 461 80 72 590	order@edap-tms.de
North America (US, CA, MX) - contact EDAP USA	+1 (512) 832-7956	order@edap-usa.com
All other regions - contact EDAP TMS	+33(0)472 153 150	order@edap-tms.com