

Service Manual

for ExactVu™ High Resolution Micro-Ultrasound System



Part Number 7007
Revision 2.6



Preface



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Version information

System: ExactVu™ High Resolution Micro-Ultrasound System

Software: Applicable for ExactVu™ Versions 2.5.5, 2.6.0, 2.8.x, 2.9.x, 3.0.x

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>

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Chapter 1 Introduction

This *Service Manual for ExactVu™ High Resolution Micro-Ultrasound System* provides instructions intended to be used by personnel trained by Exact Imaging to install, service, test and maintain the ExactVu ultrasound imaging system. It is applicable to ExactVu systems with **ExactVu 2.5** hardware, **ExactVu 2.6** hardware, or **ExactVu 2.9** hardware. ExactVu 2.9 hardware is similar to ExactVu 2.6 hardware with two exceptions:

1. ExactVu 2.9 hardware does not require a separate HDMI splitter
2. ExactVu 2.9 hardware has an updated computer that runs Windows 10 IoT

Software version 3.0 is compatible with all hardware versions.

For ExactVu 2.6 and ExactVu 2.9 hardware systems, the serial number of the channel boards and beamformer control board are stored on the flash memory of the board and reported in the Message Log.

The different revision numbers for the channel board and beamformer control board are listed in Table 1.

Component	ExactVu 2.6 HW/2.9 HW part number and revision	ExactVu 2.5 HW part number and revision
Channel Board ("CB")	PN 6005 Rev 5.1 (FPGA: 1.0. 4.x)	PN 6005 Rev 4.0 (FPGA: 1.0. 3.x)
Beamformer Control Board ("BCB")	PN 6006 Rev 3.1 (FPGA: 1.0. 2.x)	PN 6006 Rev 1.1 (FPGA: 1.0. 1.x)
Card cage	PN 6110 Rev 1.3	PN 6110 Rev 1.1, 1.2

**Table 1:
Hardware Part
Revisions for
Between
ExactVu 2.6
HW/2.9 HW and
ExactVu 2.5
HWNOTE
EN-N175**

Regarding compatibility, the correct FPGA version indicated in Table 1 must be used when configuring the channel board and beamformer control board in the ExactVu 2.5 or ExactVu 2.6/2.9 version of the hardware.



The instructions in this manual make reference to information that may be found in the other ExactVu manuals and guides. Before servicing the equipment, please ensure you have access to these documents.

Document

Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System
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 (this document)

Table 2: 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
- Release Notes for Customers

Exact Imaging catalog references for configurations of the ExactVu micro-ultrasound system 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)

Problems reported by ExactVu operators may be resolved remotely by email, by telephone support, local Technical Support trained by Exact Imaging, or by means of an on-site visit by Technical Support personnel when necessary.

Instructions for these procedures are provided in this *Service Manual for ExactVu™ High Resolution Micro-Ultrasound System*. Where necessary, additional circuit diagrams, component part lists, descriptions, and other instructions that will assist Technical Support personnel in repairing components of the ExactVu system will be made available.

1 ExactVu System Overview

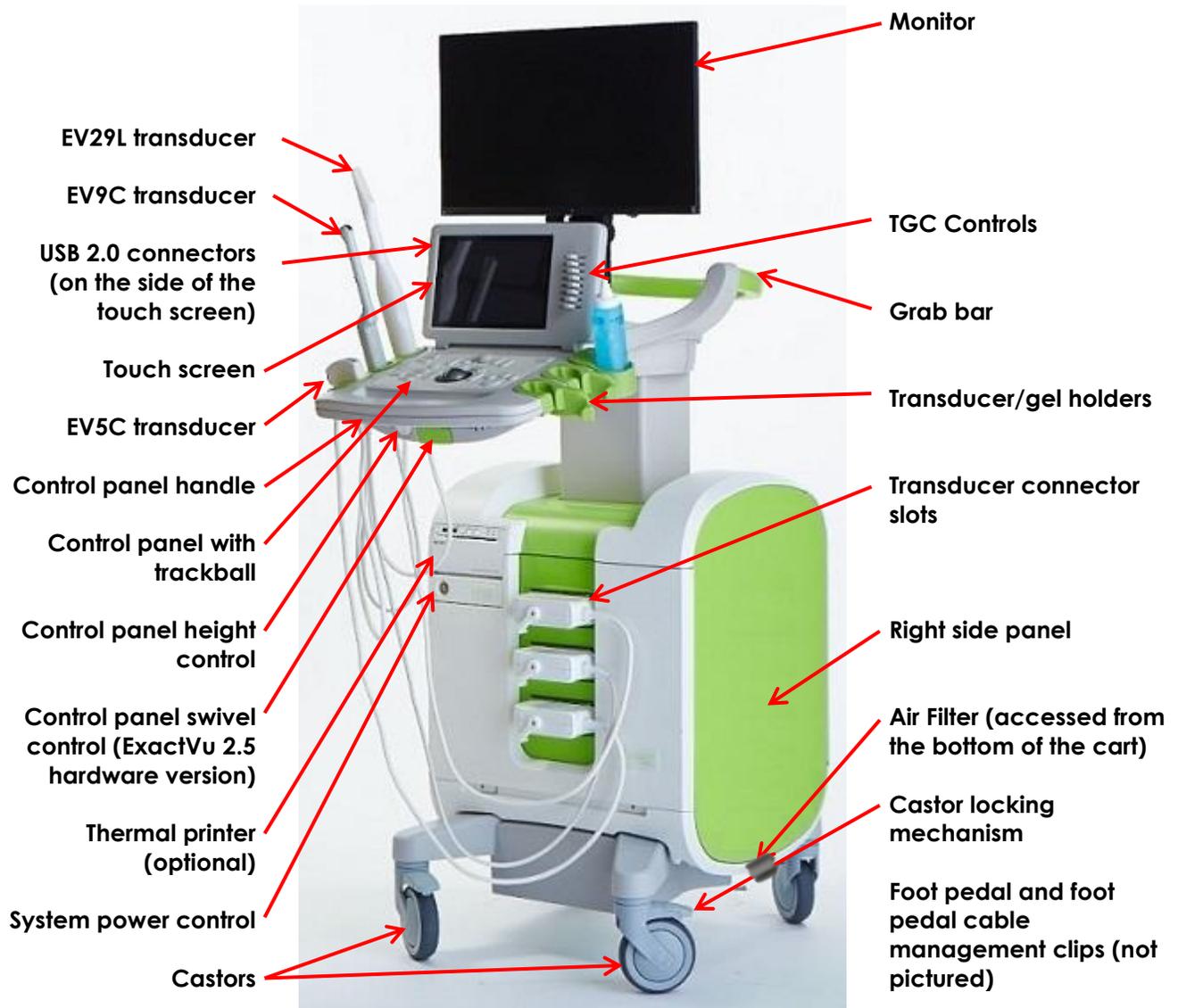


Figure 1: ExactVu™ High Resolution Micro-Ultrasound System: Front View

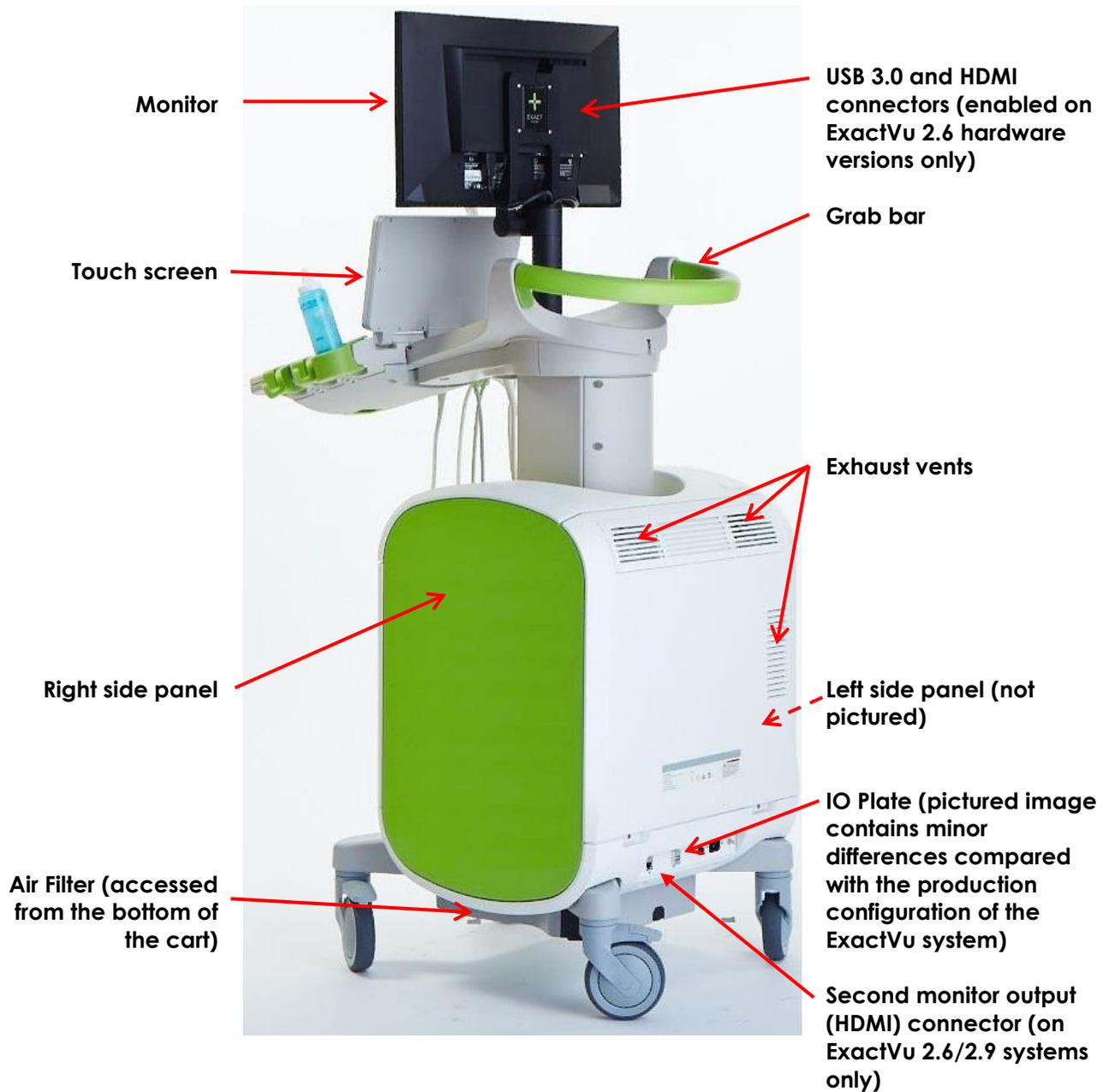


Figure 2: ExactVu™ High Resolution Micro-Ultrasound System: Rear View

WARNING
EN-W3



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.

The ExactVu micro-ultrasound system consists of the following sub-assemblies:

- ExactVu System Cart
- Control Panel and Touch Screen

- ExactVu Software
- Channel Board (x2)
- Beamformer Control Board
- Transducer Switch Board
- Computer Unit
- Power Box (contains the power supply unit and isolation transformer)
- System Cabling
- EV29L Transducer
- EV9C Transducer
- EV5C Transducer
- Transducer Connector
- Foot Pedal

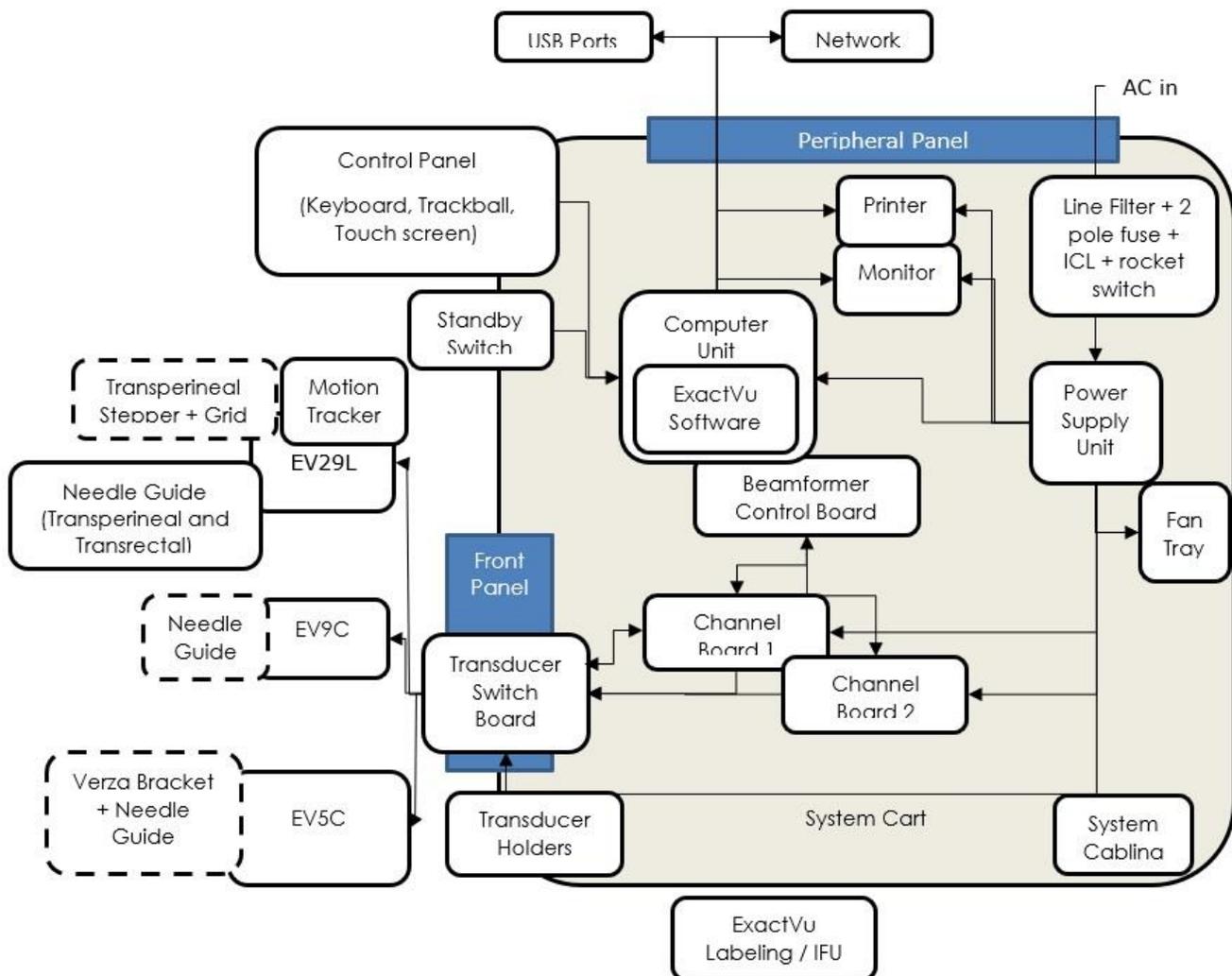


Figure 3: ExactVu Major Architecture Components – ExactVu System Hardware Version 2.5

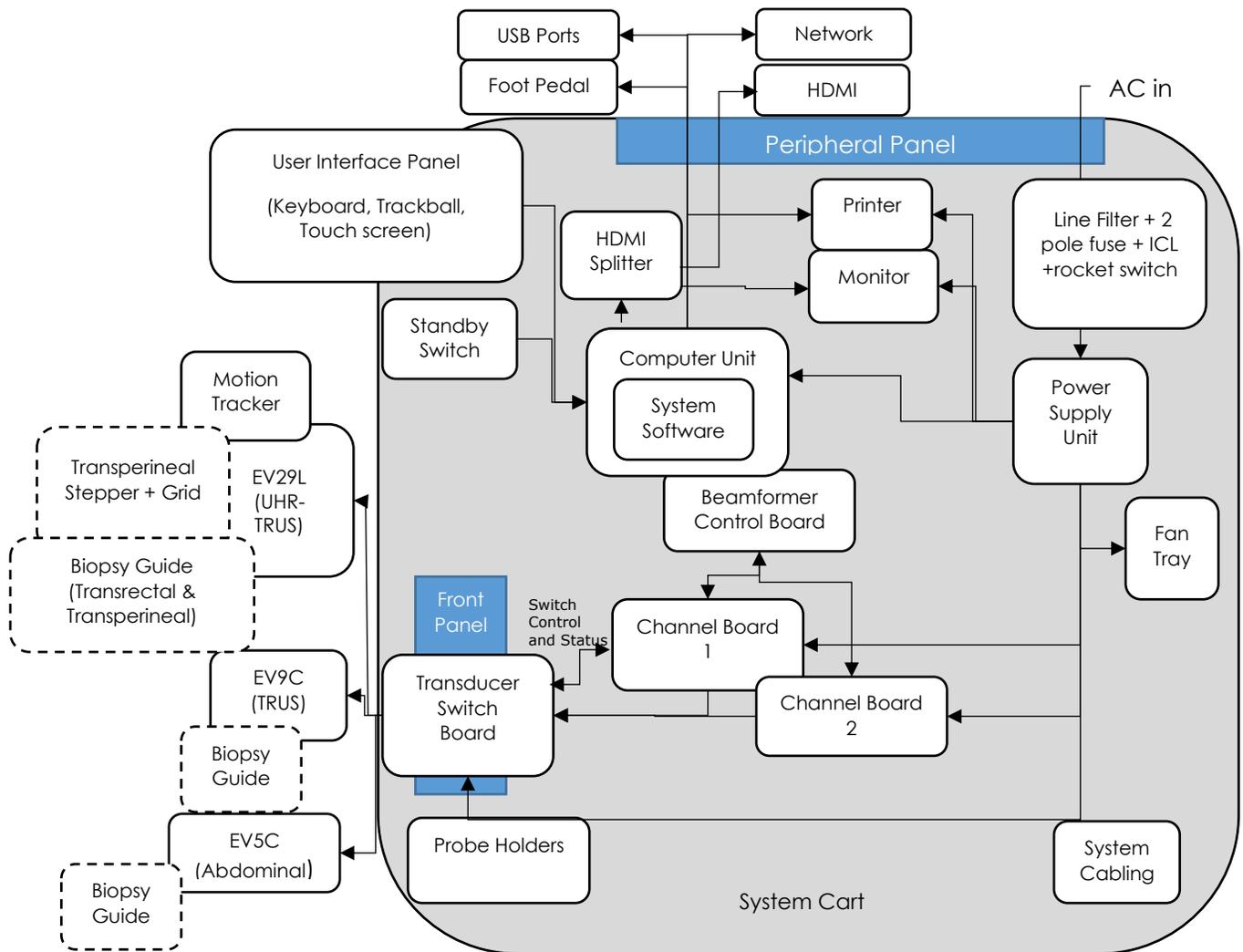


Figure 4: ExactVu Major Architecture Components – ExactVu System Hardware Version 2.6/2.9

These sub-assemblies are described in the following sections.

1.1 ExactVu System Cart

The ExactVu system cart houses the electronics, computer unit, power box, and system cabling. The user interface includes a control panel with a trackball, a touch screen and a monitor.

The front panel of the cart has three connectors for array-based transducers. The cart has a system of cooling fans, air guides, and air vents to control the heat of the various electronics.

1.1.1 System Cart Specifications

The ExactVu system cart specifications are as follows:

- Width: 61 cm (24")
- Height: 153 cm (60.2") (includes the monitor)

- Depth: 92 cm (36.2")
- Weight: 122.5 kg (270 lb.) (includes the thermal printer)

1.1.2 Control Panel Assembly

The control panel assembly includes the *control panel*, the *touch screen*, and the *control panel handle*.

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 ExactVu's operating state and mode of operation, and is indicated by backlighting.

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

It also provides a virtual keyboard for text entry which is automatically activated whenever the operator interacts with functions requiring text entry.

NOTE

EN-N1



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

1.1.3 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

The ExactVu monitor is pre-configured by Exact Imaging for optimal imaging settings.

1.1.4 Cooling System

The ExactVu system cart includes a system of cooling fans, air guides, and air vents to control the temperature of the various electronics.

Filtered ambient air is provided by cooling fans that support an ambient operating temperature range of +10 °C to +35 °C.

1.2 ExactVu Software

1.2.1 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* supports guidance of anesthesia delivery to the appropriate nerve block sites for the prostate
- *Stitch sub-mode* aids in the measurement of a large prostate

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

- *2D Mode*, and related sub-modes:
 - *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

1.2.2 Getting Help

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

- Contact Information for Technical Support
- Configurations for ExactVu hardware, software, software dongle
- Message log *export* options
- Transducer Element Check (available in software versions ExactVu 2.5.5 and newer)

1.3 Channel Board

There are two identical channel boards installed in the card cage. The channel boards contain sensitive transmit and receive electronics.

The channel boards in ExactVu System Version 2.6/2.9 system provide version and serial number by means of nonvolatile memory (EEPROM). They provide increased ESD protection; however, protection against electrostatic discharge (ESD) is required when handling the channel boards.

1.4 Beamformer Control Board

The beamformer control board (BCB) is contained within the computer unit. It allows communication between the computer unit and the channel boards.

The BCB in ExactVu System Version 2.6/2.9 system provides version and serial number by means of nonvolatile memory (EEPROM).

1.5 Transducer Switch Board

The transducer switch board has connectors for up to three transducers to be connected to the system.

1.6 Computer Unit

The *computer unit* is an industrial Intel architecture processor running 64-bit Microsoft Windows 7 (ExactVu 2.5/2.6) or IoT 2019 LTSC High End (ExactVu 2.9).

1.7 Power Box

The power box is housed in a separate shielded enclosure within the system. It contains the DC power supply unit and the isolation transformer. The isolation transformer isolates the power supply unit from the system power supply.

1.8 System Cabling

The ExactVu system cabling consists of:

- AC cables that provide power to various components of the ExactVu system, for example, the computer unit, monitor, fan tray, etc.
- Instrument electronics cables that provide power and allow data transfer between components such as the channel boards and the beamformer control board
- Data cables, for example, the printer cable, the video extension cable, etc.

The supplied AC cables meet the requirements of IEC 60601-1 for separation and leakage currents. A complete list of ExactVu cables is provided in Appendix B.

1.9 Transducers

NOTE

EN-N2



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

1.9.1 EV29L Transducer

The EV29L transducer (Exact Imaging Catalog Reference EV-29L) is a 22.5 MHz, 512-element linear array, side-firing transducer. To support this transducer, an Element Mux Board is embedded within the transducer handle in order to select the active aperture. This transducer also includes a motion sensor that is used to determine its position during Transverse Mode imaging.

The EV29L transducer meets FDA's *Track 3 Requirements*, per *Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*.

1.9.2 EV9C Transducer

The EV9C transducer (Exact Imaging Catalog Reference EV-9C) is intended for use on larger prostates that extend beyond the maximum depth or field of view of the EV29L transducer. It is a 6.5 MHz, 128-element curved linear array, end-firing transducer.

The EV9C transducer meets FDA's *Track 3 Requirements*, per *Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*.

1.9.3 EV5C Transducer

The EV5C transducer (Exact Imaging Catalog Reference EV-5C) is intended for abdomen imaging and kidney biopsy. It is a 3.5 MHz, 128-element curved linear array, end-firing transducer.

The EV5C transducer meets FDA's *Track 3 Requirements*, per *Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*.

1.10 Transducer Connector

The transducer connector sub-assembly is designed by Exact Imaging and provides the connection to the ExactVu system cart. It includes the housing, boards and connector required for the termination of the transducer cable. The transducer connector is compatible with a DLP408 ITT connector and is properly shielded to suppress RF interference.

The transducer connector includes a DLP408 ITT connector, connector enclosures, 4x tuner boards (specific to each transducer), 2x control board (for the EV29L transducer), and a plug board.

1.11 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 5).

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 5: Foot Pedal

1.11.1 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 6: Foot Pedal Cable Management

The foot pedal cable may be removed from the clips during use or during reprocessing (refer to *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*), 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.

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

The *EV29L Sterile Transrectal Needle Guide* (Exact Imaging catalog reference EV-29L-TRK-24) is a specially designed needle guide for use with the EV29L transducer.

The 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.

These needle guides are 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*.

1.13 EV29L Non-Sterile Reusable Transrectal Needle Guide

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 (Exact Imaging catalog reference EV-BIOGR)
- 16 GA EV29L Non-Sterile Reusable Transrectal Needle Guide (Exact Imaging catalog reference EV-BIOG-R16)

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*.

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

The *EV29L Sterile Transperineal Needle Guide* (Exact Imaging catalog reference EV-29L-TPK-24) 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*.

1.15 CIVCO® Disposable Endocavity Needle Guide for Procedures Using the EV9C Transducer

For biopsy procedures using the EV9C transducer, only use the *CIVCO® Disposable Endocavity Needle Guide*. It is manufactured by CIVCO and may be ordered from your local distributor. Refer to Appendix D for contact information.

Exact Imaging recommends using an 18-gauge biopsy needle.

This needle guide is depicted and described fully in *Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer*.

1.16 CIVCO® Verza Guidance System for Procedures Using the EV5C Transducer

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 D for contact information.

This needle guide is 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*.

2 Optional Components and Accessories

2.1 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*.

2.2 Transperineal Stepper

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

2.3 Monitor Stand (ExactVu 2.6/2.9 Hardware Versions Only)

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
- 5 lockable 4" / 10.2 cm diameter dual wheel nylon casters 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 2, section 3.7 on page 29 for information about using the monitor stand with a second monitor and adjusting its height.

Chapter 2 System Installation

System installation procedures are to be performed by qualified Technical Support personnel.

Operators and other clinical personnel with questions regarding these installation procedures may contact Technical Support using the contact information in Appendix D.

Observe all cautions and warnings in this chapter.

WARNING
EN-W2



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

WARNING
EN-W50



To prevent injury or damage to the ExactVu system, ensure that a minimum of two personnel is available to unpack the shipping crate.

1 Inspecting the ExactVu System Packaging for Shipping Damage

Perform a visual inspection to confirm that system packaging doesn't indicate shipping damage. (Further inspection and operational tests are performed when the ExactVu system is out of its system packaging and in its installation location.)

To inspect the ExactVu system for signs of shipping damage:

1. Inspect the vial on each of the two Shockwatch 25G indicators.
 - If either is red, it indicates the shipping crate experienced a large impact or drop during shipping.
2. Inspect the tamper-evident security tape covering the cardboard box inside the shipping crate (containing system peripherals).
 - If any part of it is torn or the lines are misaligned, it indicates the cardboard box has been opened since it was initially packaged.
3. Inspect both tilt indicators on the shipping crate.
 - Determine whether the maximum allowed tilt angle has been exceeded.

WARNING
EN-W45



If signs of shipping damage are detected on the ExactVu system, the transducers or any Exact Imaging equipment, do not use the affected equipment.

2 Unpacking the ExactVu System Packaging

The following tools are necessary to unpack, assemble and install the ExactVu system:

- Long-handed slotted screwdriver (size 5 or 6)

- 4 mm hex driver (ball head)
- Side cutter
- Hex L-Key, 3mm, ball-ended, at least 5 1/8" long

2.1 Opening the ExactVu Shipping Crate

Required Tools:

- Long-handed slotted screwdriver (size 5 or 6)

To open the ExactVu shipping crate:

1. Ensure there is sufficient clearance surrounding the shipping crate to open it. There should be a minimum of 3 meters on all sides.
2. Identify the correct side of the shipping crate from which to unload the ExactVu system by referring to the markings on the panels.
3. Insert the slotted screwdriver into either slot on a clamp (refer to Figure 7) and apply pressure to expand the lip of the clamp.
4. Pry the clamp away from the crate panel (refer to Figure 8).
The clamp is now unsecured and can be removed from the crate.
5. Repeat step 3 and step 4 for all clamps securing the top, all sides of the crate, and the bottom of the crate.
6. From the top of the crate, lower the front panel on the unloading side of the crate to the floor, so that it becomes a ramp.

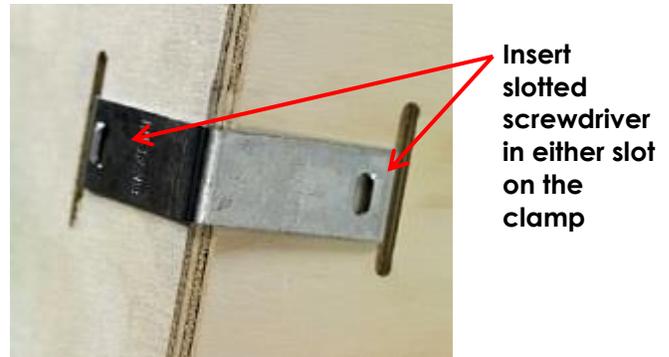


Figure 7: Slots in Clamp



Figure 8: Clamps Securing Crate Panel

7. Lower the opposite panel and remove it.
8. Lower the side panel of the crate as far as required so that the protective foam around the monitor will not contact any part of the ExactVu system when it is moved off the base of the shipping crate.

WARNING

EN-W54



To prevent injury, apply pressure slowly and carefully when prying the crate clamps away from the crate walls.

CAUTION

EN-C40



Do not step on the panels of the crate, other than the ramp panel.

2.2 Removing the ExactVu System from its System Packaging

The ExactVu system packaging contains the following components:

- ExactVu system cart (including the monitor, touch screen and ExactVu software)
- Labeling:
 - ExactVu Labeling (refer to Table 2 on page 6)
 - Thermal Printer Instructions for Use (printed manual) (included if the optional thermal printer is configured)
 - Quick Reference Guide
 - PRI-MUST™ Quick Reference Guide (quantity 5)
 - PRI-MUST™ Quick Reference Poster
 - PRI-MUST™ Anterior Quick Reference Guide (quantity 5)
 - PRI-MUST™ Anterior Quick Reference Poster
 - Release Notes for Customers
- One AC power cable
- Up to three transducers
- Foot Pedal

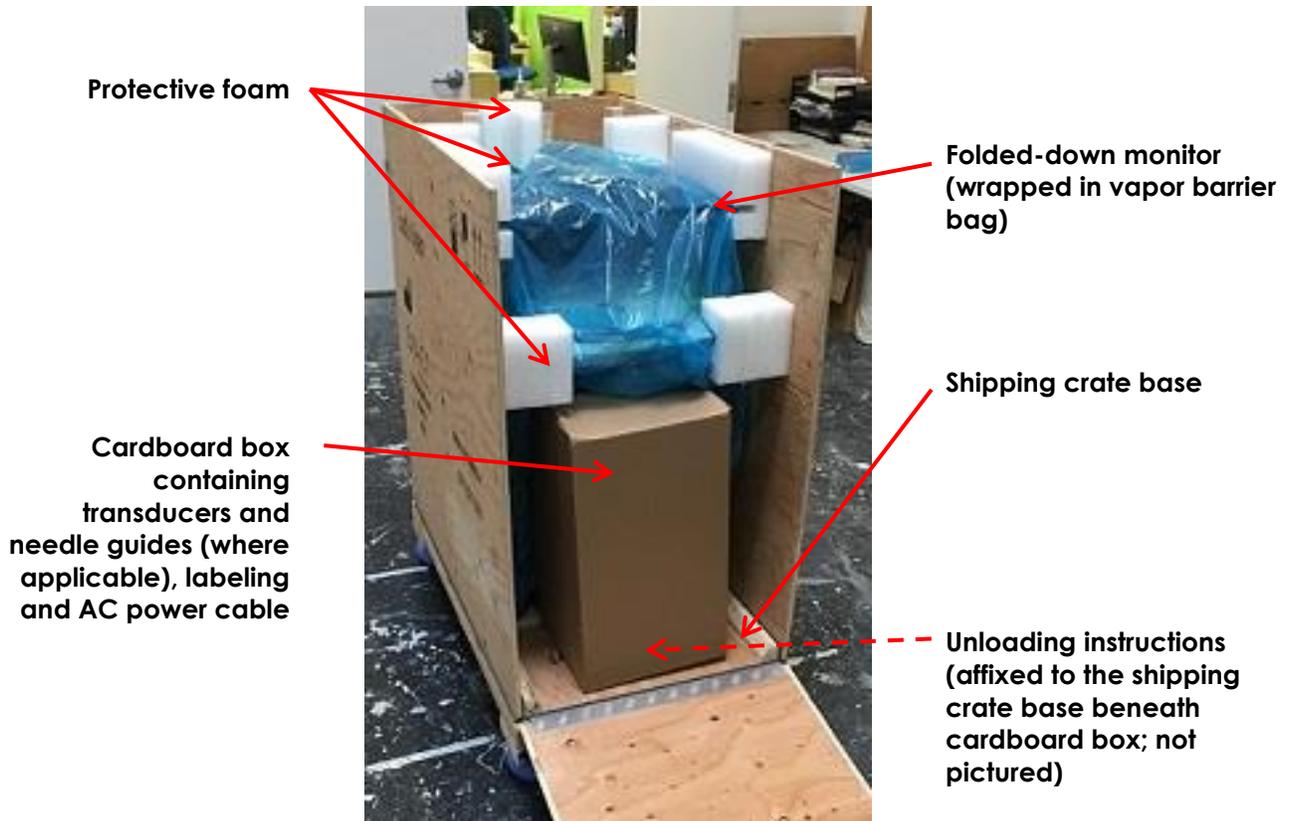


Figure 9: ExactVu System Inside the System Packaging

To remove the ExactVu system and its components from the ExactVu system packaging:

1. Remove the cardboard box from the shipping crate. Check the tamper-evident tape for any indication of tampering with the cardboard box.
2. Remove and discard the vapor barrier bag wrapped around the ExactVu system.
3. Remove the protective foam from the ramp. (All other protective foam is attached to the shipping crate and is not removed).



Figure 10: Ramp with Inserted Protective Foam



Figure 11: Ramp with Protective Foam Removed

4. Remove the cardboard box from the shipping crate.



Exact Imaging recommends that transducers, sterile needle guides and the foot pedal are left in their packaging until the ExactVu system is moved to its installation location.

5. On the *unload side* of the ExactVu system:

- Rotate the pin counter-clockwise until it comes out of the base fixture and put it aside.
- Remove the plywood and wood block and put them aside.

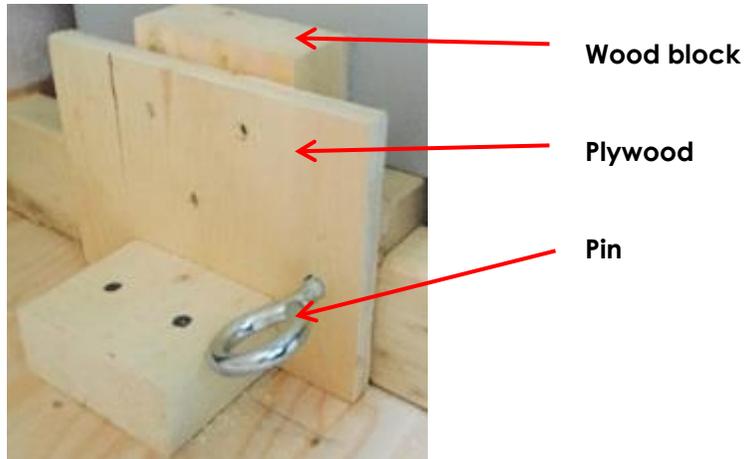


Figure 12: Shipping Crate Base Fixture

6. Unlock the castors, and roll the ExactVu system off the *shipping crate base* in the direction indicated by the *unloading instructions* affixed to the shipping crate base.
7. Assemble and inspect the ExactVu system prior to moving it to its installation location. Refer to section 3 on page 25 for precautions to take when moving the ExactVu system.

2.3 Assembling the ExactVu System Components

Assemble components such that the ExactVu system can be moved to its installation location.

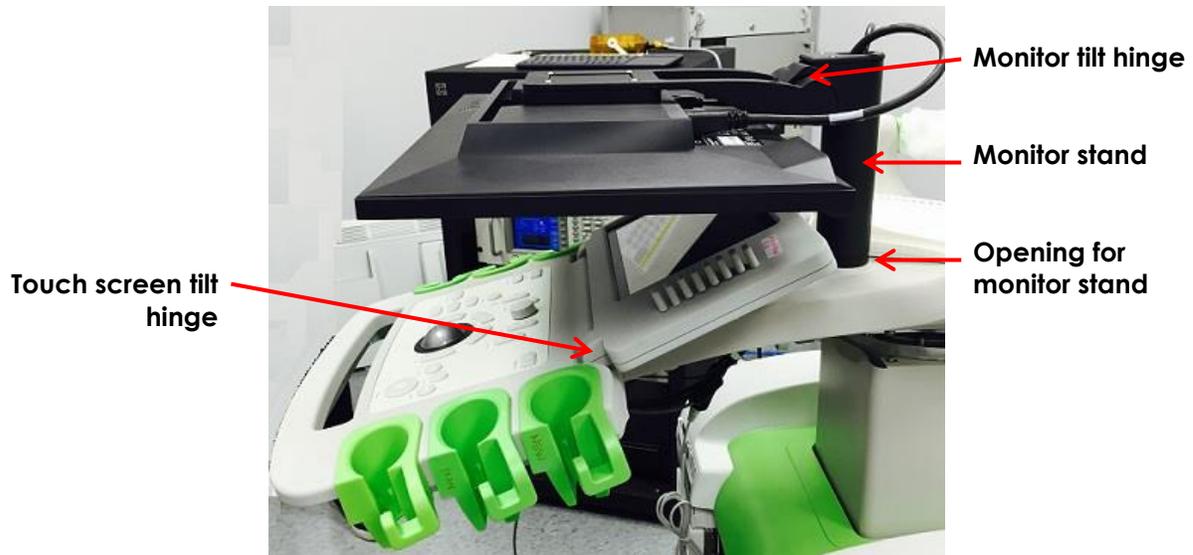


Figure 13: Monitor and Touch Screen in Folded Position

To rotate the monitor to its upright position:

- With both hands on the sides of the monitor, firmly push the monitor into an upright position so that it rotates on its hinge until it reaches a desired tilt angle.

To rotate the touch screen to its upright position:

- With both hands on the sides of the touch screen, gently push the touch screen into an upright position until it reaches a desired tilt angle.

2.4 Inspecting the ExactVu System

Perform a visual inspection that the ExactVu system was not damaged during transportation. (Operational inspection and tests are performed when the ExactVu system is in its installation location.)

Any damage must be reported on the *Customer Acceptance Form* and by contacting Technical Support using the contact information in Appendix D.

2.5 Discarding the ExactVu System Packaging

The ExactVu system packaging is constructed of materials that are recyclable in North American and European countries.

The ExactVu system packaging is to be discarded in accordance with internal clinical procedures.

The transducer packaging may be kept for use in storing transducers.

3 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 Appendix A.

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-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.

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.

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.

WARNING

EN-W84



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

3.1 Moving the ExactVu System

The ExactVu system should be moved using the *grab bar* at the rear of the cart or the *control panel handle*. (Refer to Figure 1).

To move the ExactVu system:

1. Check that the *castors* are unlocked.
2. Check that the ExactVu transducers are secure in the *transducer holders* (if they are not stored elsewhere).
3. 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.

4. 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.

3.2 Unlocking the Deck (ExactVu 2.5 Hardware Versions Only)

The ExactVu system has a mechanical safety locking mechanism to prevent movement of the *upper deck* during shipping. Prior to shipping, a hidden 3 mm hex screw is fastened, and is located at the rear of the upper deck assembly (refer to Figure 14).

Required Tools:

- Hex L-Key, 3mm, ball-ended, at least 5 1/8" long

To release the mechanical safety lock:

1. Locate the circular opening at the rear of the upper deck assembly.
2. Insert a 3 mm 5 1/8" long hex L-key into the opening and find the hidden 3 mm hex screw.
3. Unfasten the screw by turning six full turns counter-clockwise.
4. Verify that the lock has been released by pulling the *control panel swivel handle* and rotate the upper deck.

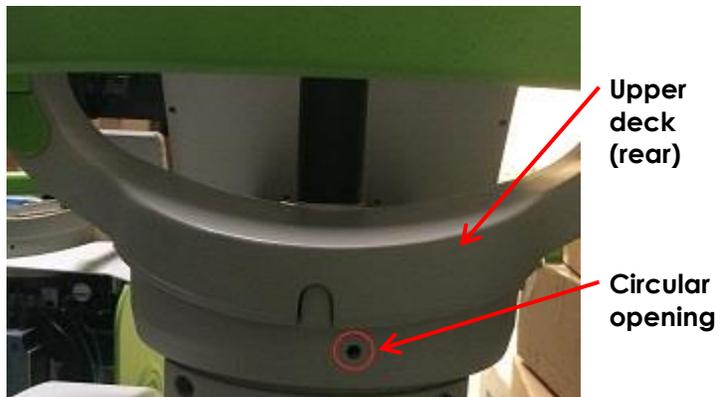


Figure 14: Mechanical Safety Lock on Rear Upper Deck

3.3 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 and USB storage devices as required. Refer to Chapter 3, section 1 on page 61 for information about recommended formatting for USB storage devices and connecting a USB storage device to the ExactVu system.

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 D.

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.

3.4 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 15) is 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 15).
3. Connect the plug end of the AC power cable to the wall outlet.
4. Switch the *main power switch* to the **ON** position.

**ExactVu system power cable receptacle****Main power switch (in the OFF position)****Figure 15: ExactVu System Power****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 D.

3.5 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 *Transducer Element Check* is automatically executed (available in software version ExactVu 2.5.5 and newer).
- The imaging screen opens in 2D B-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 area 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 can be saved or printed.

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

3.7 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 16 and Figure 17).

To raise the control panel/monitor platform height:

- Press the *up arrow* on the *control panel height control* indicated in Figure 17.

To lower the control panel/monitor platform height:

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

To rotate the control panel/monitor platform horizontally (ExactVu 2.5 hardware versions only):

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°.



Figure 16: Control Panel/Monitor Height



Figure 17: Control Panel/Monitor Height and Rotation (Rotation is available for ExactVu 2.5 hardware versions only)

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 D.

NOTE
EN-N119



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

3.8 Connecting an (Optional) Second Monitor (ExactVu 2.6/2.9 hardware versions only)

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 18).
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. For information about configuring display settings, refer to Chapter 3, section 7.1.3 on page 88.



Figure 18: 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 section 1.1.3 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 2.3 on page 18 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-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.

3.9 Unpacking and Connecting the Foot Pedal

1. Remove the foot pedal from its packaging
2. Connect the foot pedal to the USB port at the back of the system.
3. Clip the foot pedal cord into the clips on the back, side and front of the system as shown in Figure 19.



Figure 19: Foot pedal cable clips

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.
-

3.10 Unpacking and Connecting the Transducers

3.10.1 Unpacking Transducers from the System Packaging

Required Tools:

- None

To unpack transducers from the system packaging:

1. Remove the transducer from its packaging.
2. Securely place the transducer in a *transducer holder* on the ExactVu system cart.
3. Exact Imaging recommends that the transducer packaging is kept for storage and/or transportation of the transducers.

3.10.2 Inspecting the Transducers

Perform a visual inspection that the transducers were not damaged during transportation. (Operational inspection and tests are performed when the ExactVu system is in its installation location.)

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

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.

Inspect the transducer cable for damage.

WARNING
EN-W45

If signs of shipping damage are detected on the ExactVu system, the transducers or any Exact Imaging equipment, do not use the affected equipment.

3.10.3 Connecting the Transducer to the ExactVu System

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 21).
2. Line up the locking pin (refer to Figure 22) on the transducer connector with the lock notch on the transducer connector slot on the ExactVu system (refer to Figure 23) so that the transducer connector is oriented as indicated in Figure 24.
3. Push in the connector and then turn the *lock knob* to the *locked* position (refer to Figure 24).
4. When the ExactVu system is powered on, the *Transducer Element Check* is automatically executed when a transducer is connected (in software versions 2.5.5 and newer).



Figure 20: Transducer Locked Icon



Figure 21: Transducer Unlocked Icon

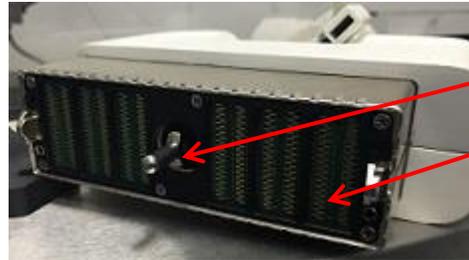


Figure 22: Locking Pin

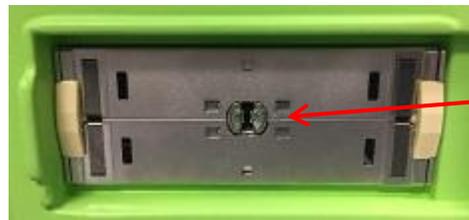


Figure 23: Lock Notch on the Transducer Connector Slot



Figure 24: Transducer Connector Orientation

3.10.4 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 24).



Figure 25: Unlocked Transducer Connector Lock Knob

Transducer connector lock knob (in the unlocked position)

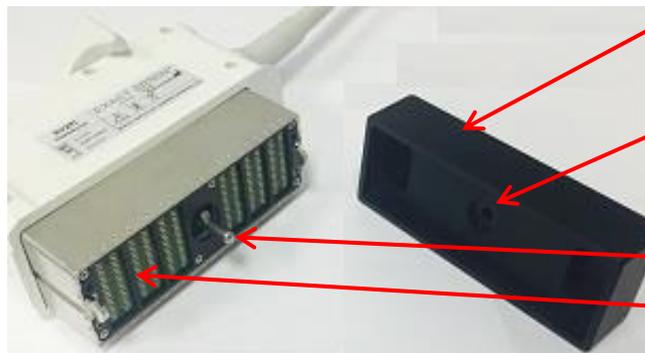


Figure 26: Transducer Connector Cover

Transducer connector cover
Notch
Locking pin
Contact pads



Figure 27: Lockable Transducer Connector Cover

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

4 Inspecting the ExactVu System

Refer to the inspection procedures in Chapter 5, section 1.2.1 on page 171 for instructions about how to inspect the ExactVu system, and perform each procedure indicated as required next to the heading *After a new ExactVu installation*.

5 Testing the ExactVu System

After completing a new installation of the ExactVu system, test all components as described in Chapter 4 to ensure proper function of the ExactVu system.

When all components have been tested, complete the *Installation* section(s) of the *Customer Acceptance Form*.

6 ExactVu Software

6.1 Error Management and 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 study if desired.

NOTE

EN-N10



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

All system error and warning levels generate an entry in the *message log*, which may be used by Technical Support technicians to diagnose and troubleshoot problems. The *message log* can only be accessed by Technical Support technicians.

The types of events that trigger error conditions include:

Condition	Condition Type
System diagnostic result from the hardware indicates the temperature of the system electronics exceeds safe 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
Communication with the ExactVu hardware is lost	System Error
Hardware detects the system is operating outside of the power supply limits	System Error

Condition	Condition Type
Hardware malfunction	System Error
Non-critical error conditions are detected by the system software	System Error

Table 3: Error Conditions

NOTE
EN-N11

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

6.2 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*) (*Transducer Element Check* is available in software versions ExactVu 2.5.5 and newer)
- DICOM Settings (provides configuration for PACS Store, DICOM MRI Query/Retrieve and Modality Worklist)
- Network Settings (provides information about the ExactVu computer and network configuration)
- 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.

6.2.1 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 installation
- Contact information for Technical Support (for additional contact information, refer to Appendix D)
- *Message log* export options
- *Transducer Element Check*, for assessing the integrity of transducer elements when the transducer is activated (*Transducer Element Check* is available in software versions ExactVu 2.5.5 and newer)

6.2.1.1 Export 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. Message log files may be copied to a USB storage device from the *Preferences > System Information* screen or from the *Message Log Viewer* application itself. Refer to Chapter 3, section 3.3 on page 73 for details on how to export message log files.

6.2.1.2 Transducer Element Check (available in software versions ExactVu 2.5.5 and newer)

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.



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 28). 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 D.

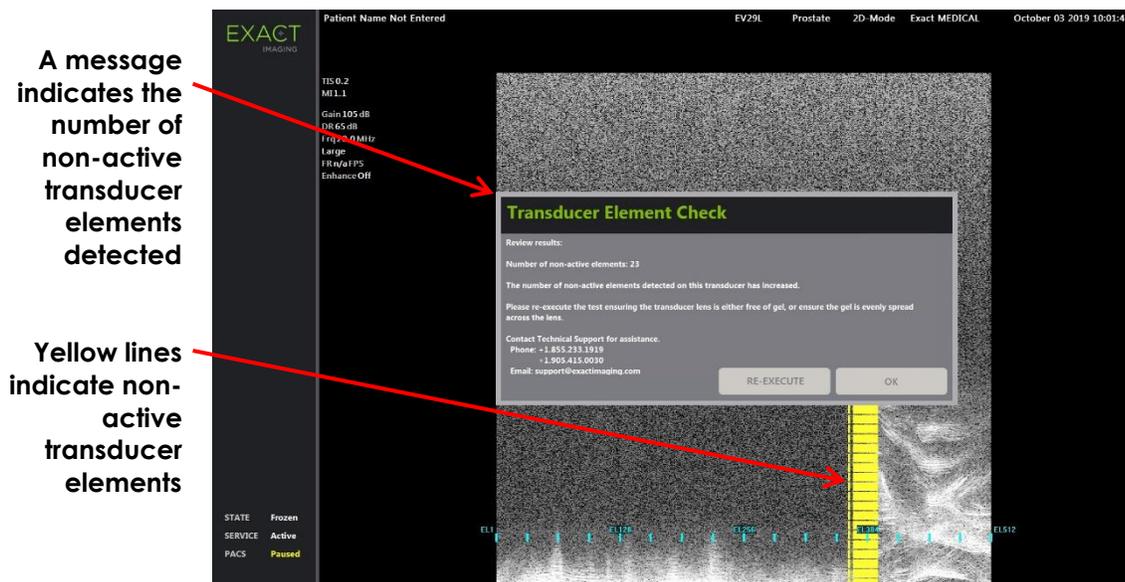


Figure 28: Transducer Element Check, Non-Active Elements

The *Transducer Element Check* may be performed at any time.

6.2.2 DICOM Settings

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.

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:

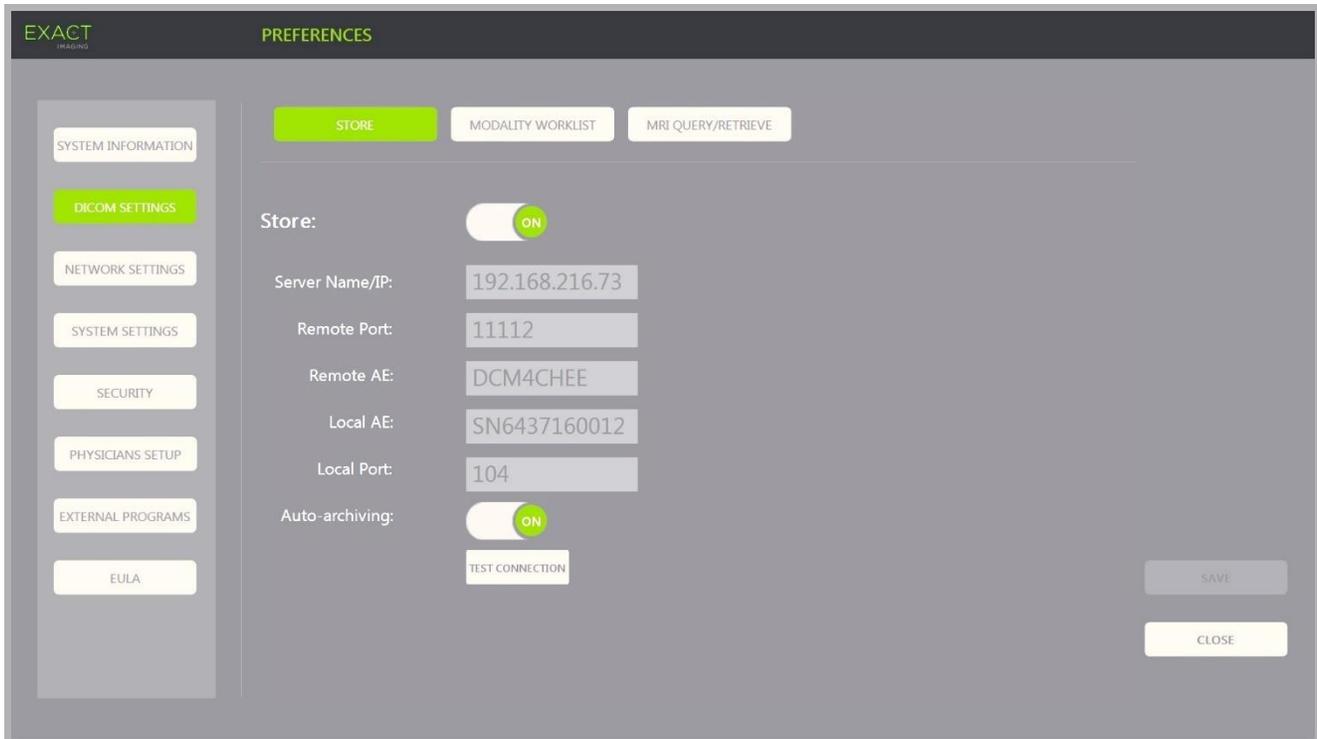


Figure 29: DICOM Store Settings Configuration

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.

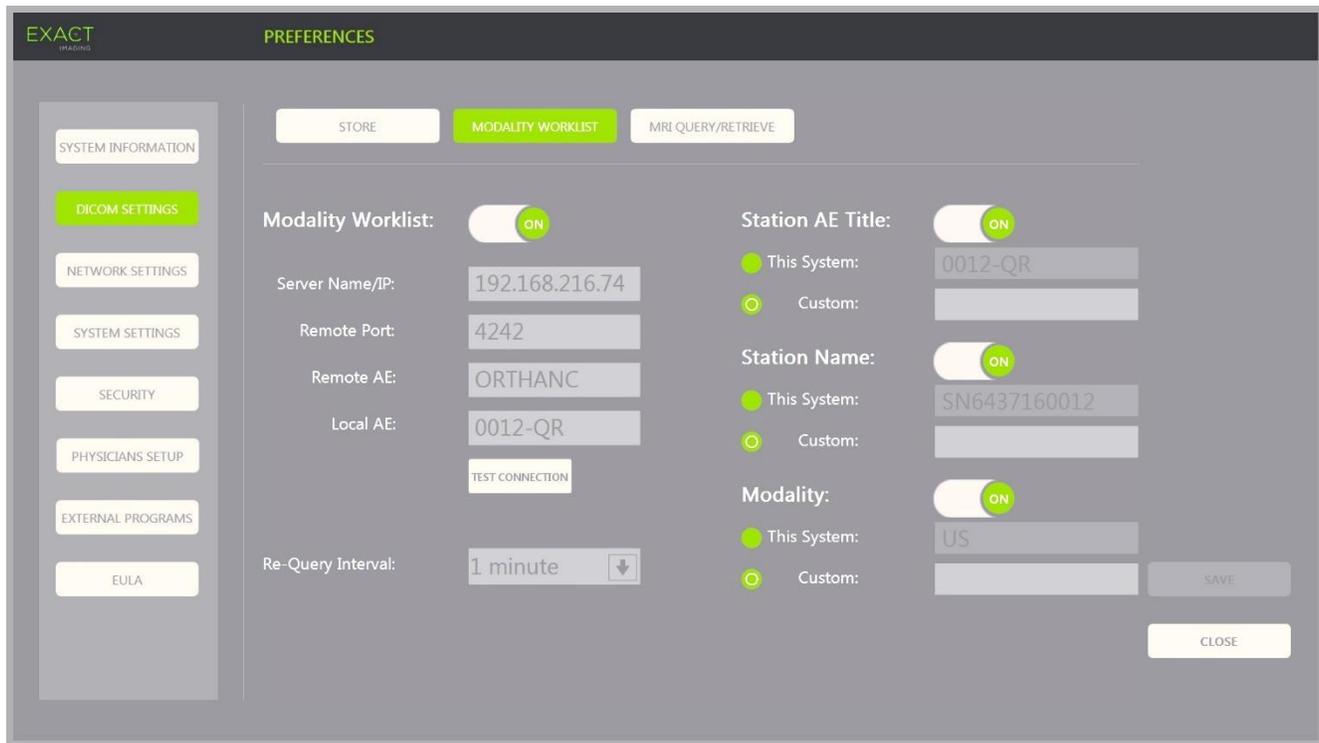
6.2.2.1 Configuring Auto-archiving PACS Settings

When *Auto-archiving* is toggled **ON**, the ExactVu system queues studies to be archived to the configured PACS server as a background process, such that archiving occurs without affecting the performance of functions such as imaging.

The background process is set to handle unsuccessful attempts to archive studies to a PACS server using the following default settings:

- After an unsuccessful attempt to archive a study, a second attempt is made one minute after the first attempt.
- 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 PACS status is displayed as *Failed* in the *status panel* of the imaging screen.

These default settings may be configured in Engineering Mode. Refer to Chapter 3, section 2.2 on page 62 for details about using Engineering Mode.

To specify Modality Worklist configuration settings:**Figure 30: 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:

The screenshot shows the 'EXACT IMAGING PREFERENCES' window. On the left is a sidebar with menu items: SYSTEM INFORMATION, DICOM SETTINGS (highlighted in green), NETWORK SETTINGS, SYSTEM SETTINGS, SECURITY, PHYSICIANS SETUP, EXTERNAL PROGRAMS, and EULA. The main area has three tabs: STORE, MODALITY WORKLIST, and MRI QUERY/RETRIEVE (highlighted in green). Under the 'MRI QUERY/RETRIEVE' tab, there is a toggle switch for 'MRI Query/Retrieve' which is currently turned ON. Below the toggle are five input fields: 'Server Name/IP' (192.168.216.73), 'Remote Port' (11112), 'Remote AE' (DCM4CHEE), 'Local AE' (0012-QR), and 'Local Port' (105). A 'TEST CONNECTION' button is located below the 'Local Port' field. At the bottom right of the window are 'SAVE' and 'CLOSE' buttons.

Figure 31: DICOM MRI Query/Retrieve Settings Configuration6. 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)

7. 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

8. 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.

6.2.3 Network Settings

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

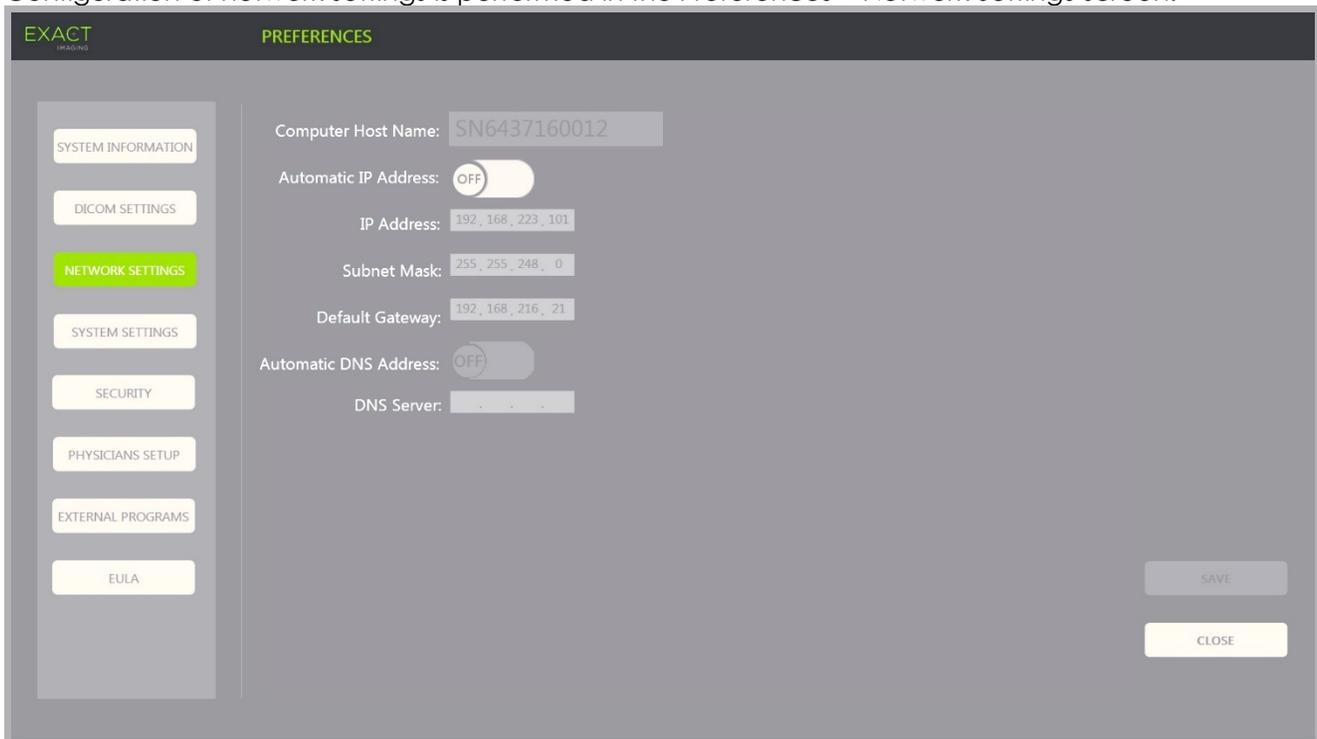


Figure 32: Network Settings on Preferences > Network Settings

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:
 - 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.

6.2.3.1 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 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.

6.2.3.2 Network Safety

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

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



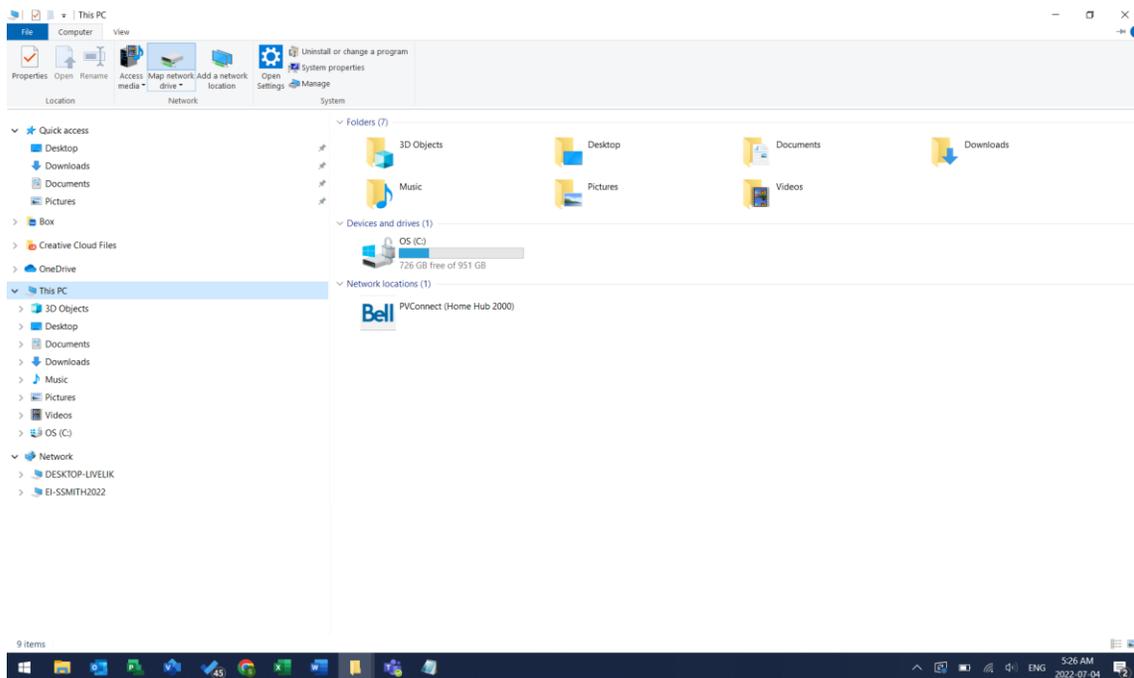
When the ExactVu system is connected to a clinic's network, Exact Imaging does not take responsibility for computer viruses from the network that may infect the system's computer.

6.2.3.3 Mapped Network Folder for MRI Studies

Technical Support personnel are able to map a network drive containing MRI study data so that it may be accessed when loading MRI studies for use with the FusionVu application.

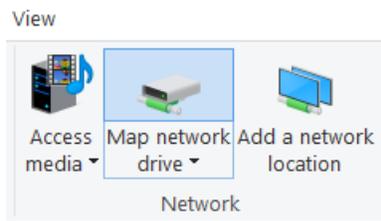
To map a network drive:

1. Determine the network folder location where MRI study data is stored, or create the folder and copy the MRI study data into it.
2. Ensure that on-site IT personnel have granted local network access to both the ExactVu system and the network location storing the MRI study data.
3. Press **CTRL+ALT+SHIFT+R** hotkey combination.
4. Open *File Explorer* and select *This PC*.



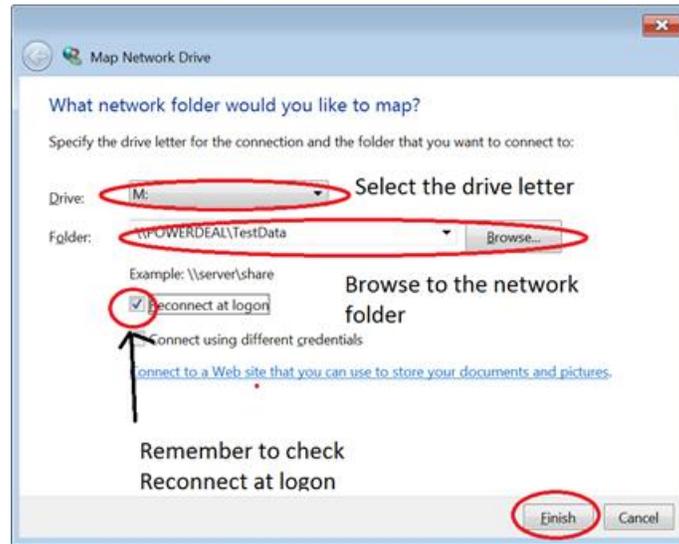
5. Map the network folder to a network drive of the ExactVu system as follows:

- From *File Explorer*, select **Computer**.
- Select **Map network drive**.

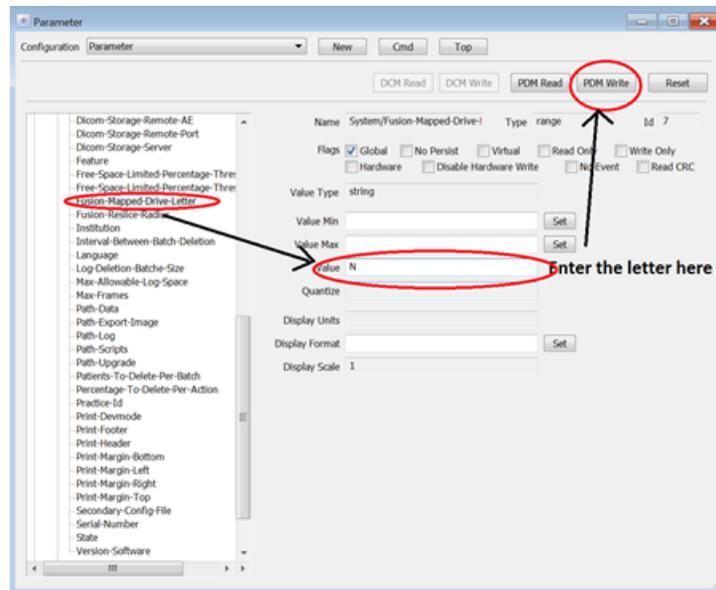


- From the *Map network drive* dialog:
- Select the Drive letter to use for the network folder.
- Browse to the network drive Folder and select the folder. Do not select the option to allow *Network Discovery and File Sharing*.

- Select **Reconnect at logon**.
- Select **Finish**.

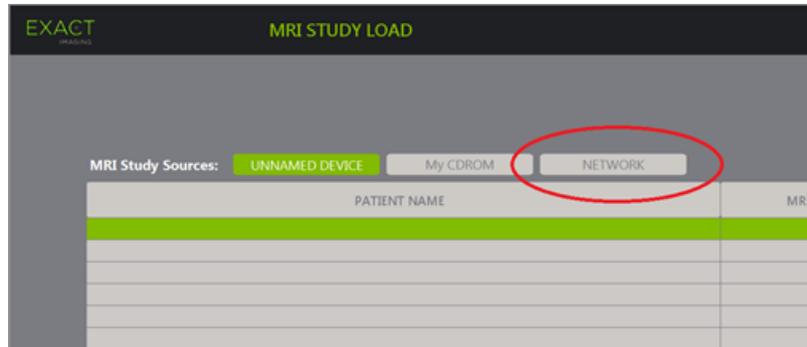


6. Open another instance of File Explorer and verify that the mapped drive has been created.
7. Press **CTRL+ALT+E** hotkey combination to open *Engineering Mode*.
8. Navigate the tree structure to select the Preferences/Public/System/Fusion-Mapped-Drive-Letter parameter.
9. Type the drive letter and select **PDM Write**.



10. Close *Engineering Mode* and restart the ExactVu system.
11. Connect an EV29L transducer and open the *Patient/Study* screen.
12. Select **Load MRI**.

When the network drive has been mapped, the *MRI Study Load* screen displays a *NETWORK* button.



By selecting the *NETWORK* button, the operator may select MRI studies from the mapped network location using the same method by which studies are selected from a USB storage device.

NOTE
EN-N182



The ExactVu system must be able to access the network using its login credentials.

The ExactVu system and the computer with the DICOM MRI study data must be connected to the network when the ExactVu system is started to resume the connection to the mapped drive.

6.2.4 System Settings

The *Preferences > System Settings* screen provides several configurable settings related to the ExactVu software, including:

- Clinic name and ID
- Language preference
- Date and time settings
- EV29L Needle Guide preference
- Foot Pedal preference

6.2.4.1 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 *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.

6.2.4.2 Language

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

6.2.4.3 Date and Time

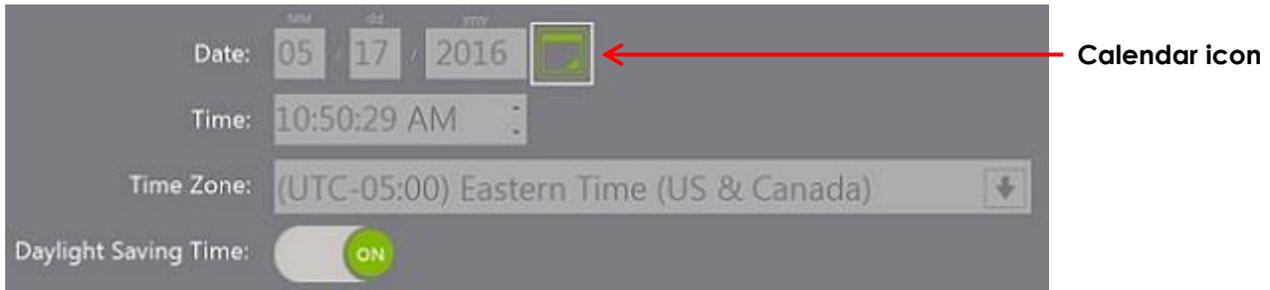


Figure 33: Date and Time Settings on Preferences > System Settings

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.

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 and minute 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.

6.2.4.4 EV29L Needle Guide

Chapter 1, section 1.13 on page 17 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.

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*.

6.2.4.5 Foot Pedal

The operator is able to set a preference for the foot pedal function to save either single frames or cine images. The factory default is for the foot pedal to save single frames.

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.

NOTE
EN-N174



The hotkey combination **CTRL+ALT+X** performs the same function as the foot pedal as configured in *Preferences > System Settings*.

6.2.4.6 Default Study Description

It is possible for a customer to require a specific value to be used for the default *Study Description* when creating a new *Patient/Study*.

When required, this value may be set by Technical Support personnel using Engineering Mode. Refer to Chapter 3, section 2.2 on page 62 for details about using Engineering Mode.

To specify a default Study Description:

1. Press **CTRL+ALT+E** hotkey combination to enable *Engineering Mode*.
If a connected software dongle is not configured for Service Mode, a password prompt is displayed.
2. If prompted for a password, type **wa1nut** and select **OK**.

Engineering Mode is enabled, and the *Engineering Mode Tool* is displayed.

3. Navigate to the parameter *Preferences\Public\System\Default-Study-Description*.
4. Type the *Study Description* value required by the customer.
5. Select **PDM Write**.

The new value is assigned to the selected parameter.

6.2.5 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.

System security is normally configured as part of the installation of a new ExactVu system. *System security* allows operators to meet HIPAA obligations when using the ExactVu system.

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.

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.

NOTE

EN-N95



When *Service Mode* is enabled on the software dongle, *system security* authentication prompts are not displayed, even when *system security* is enabled on 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 34: 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*.

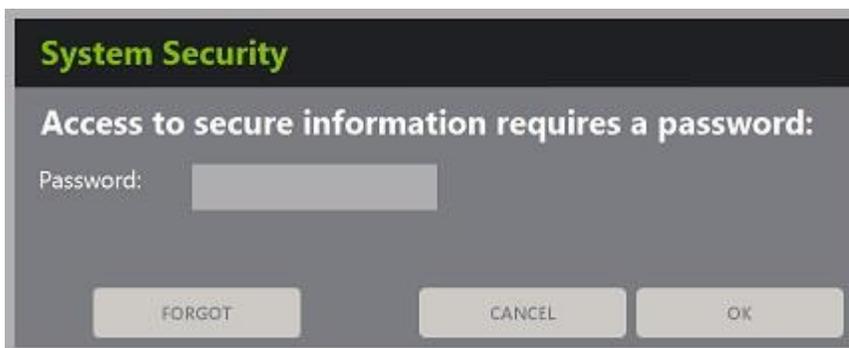
6.2.5.1 Using the Security Password

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.

**Figure 35: System Security Dialog**

2. Type the security password.

NOTE

EN-N15



Security password characters are hidden.

3. Select **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.

NOTE

EN-N95



When *Service Mode* is enabled on the software dongle, system security authentication prompts are not displayed, even when *system security* is enabled on the ExactVu system.

6.2.5.2 Resetting the Security Password

If the System 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.

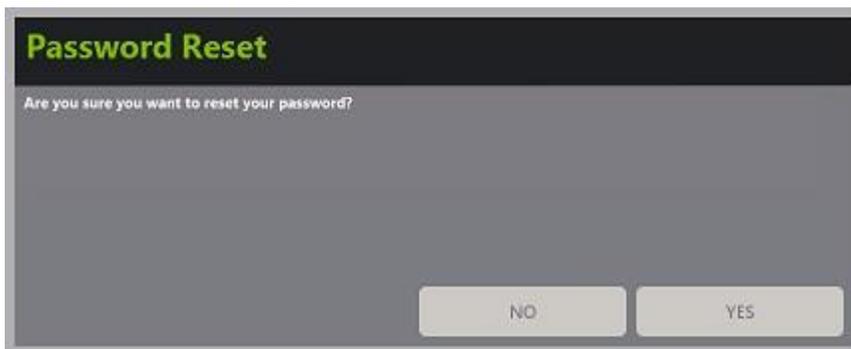


Figure 36: Password Reset Dialog

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 D and provide the *reset key*. Indicate that a *reset password* is required.

Technical Support will use the *reset key* to create a *reset password* using the *Software Password Reset Application (PN 6629)*.

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 Chapter 2, section 6.2.5.2 on page 55.

6.2.6 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.

6.2.7 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.

6.2.8 EULA (End User License Agreement)

The *Preferences > EULA* screen provides information related to the EULA, including obligations of operators of the ExactVu system.

6.3 Software Dongle

The ExactVu system uses a software dongle to control access to the ExactVu software as well as to specific features. The software dongle is a USB device that connects to the computer unit.

The ExactVu software is inoperable when the software dongle is not connected.

NOTE

EN-N101



The *Preferences > System Information* screen provides information about activated and non-activated features.

The *License Programming Tool* is used to configure the settings for a specific software dongle. The ExactVu software dongle can be configured to enable and disable specific features. It is also capable of enabling a *trial period* that allows the ExactVu system to be used during a specified period of time. It can similarly be configured to enable a trial period for specific features. These details are indicated in the ExactVu system on the *Preferences > System Information* screen.

The *License Programming Tool* is only available to Technical Support personnel. For more information or assistance, contact Technical Support using the contact information in Appendix D.

6.4 Power Management

The ExactVu software uses a *power management scheme* to ensure that the acoustic ultrasound energy transmitted by the EV29L, EV9C and EV5C transducers does not exceed safe limits. This is achieved by calculating limits for transmit current and voltage as a function of the operating conditions, including settings specified by the operator and internal settings. Values used in these calculations are part of the *scan format file* for each transducer.

Scan format files provide information about permissible and default values for transducer settings listed in Table 4 (refer to page 64). The scan format files are found with the ExactVu software program files and are:

- For EV29L: SF-IMX-512.xml
- For EV9C: Vermon-CLA6.5-1373.xml
- For EV5C: Vermon-CLA3.5.xml

The ExactVu software communicates the calculated limits to the hardware each time the operating conditions change, which includes:

- When imaging begins
- When settings are changed
- When a new transducer is used
- When a new exam type is used

The hardware compares the limits to the actual operating values to determine if the ExactVu system is operating outside normal parameters.



If the scan format file is not available (i.e., because it was either deleted or renamed), the ExactVu system prevents the associated transducer from being activated.

6.4.1 Hardware/Software Communication

The ExactVu software monitors communication with the system hardware at one-second intervals and causes an error if the communication channel becomes faulty or inactive. If the ExactVu software detects communication with the hardware has been lost, the error is a *System Error*.

The ExactVu system also uses a hardware *watchdog timer* that monitors communication with the ExactVu software, where the ExactVu software pulses the FPGA at one-second intervals. If the watchdog timer detects that communication with the ExactVu software is lost, the FPGA disables acoustic power output.

6.4.2 Power Monitoring

In addition to monitoring communication, the ExactVu software performs verification of all electrical and acoustic power limits to guard against fault conditions. The ExactVu software monitors the power monitor bus on the BCB to obtain power supply currents and voltages every 1.0 s.

The maximum voltage for the transducer is specified in the scan format file and limits the maximum voltage that can be set in the hardware.



A redundancy check of power format files power tables is built into the ExactVu software to prevent their usage in the event they are corrupted or inadvertently changed.

Corrupted power tables prevent the ExactVu system from being used without intervention by Technical Support.

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

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

For FDA Track 3 transducers, these limits are:

- Global derated $I_{SPTA} \leq 720 \text{ mW/cm}^2$ AND
- Either: global maximum MI ≤ 1.9 OR global maximum I_{SPPA} should be $\leq 190 \text{ W/cm}^2$.

NOTE
EN-N105

Settings that are not identified in the power tables (i.e., they lie outside the valid range for the setting) are not allowed.

6.4.3 Mechanical Index and Thermal Index

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 (As Low As Reasonably Achievable) principle while using the system. Full details are provided in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

6.4.4 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 $< 41\text{ °C}$

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 D.

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.

6.5 ExactVu System Sound Setting

In the event that Technical Support personnel are required to modify the ExactVu system's sound volume settings, the following procedure provides a method for this.

1. Press **CTRL+ALT+SHIFT+R** hotkey combination.
2. Open *Control Panel* from the taskbar.
3. Select **Sounds**.
4. Select **Speakers**.
Speakers Properties opens.
5. Select the **Levels** tab from the *Properties* dialog.
6. Adjust the *Audio Output* levels to desired level (the default is 50).

Chapter 3 Service the ExactVu System

1 Connecting a USB Storage Device

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

- the connectors on the side of the touch screen
- the connectors on the rear of the monitor (for ExactVu 2.6/2.9 hardware versions)

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

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 37) or on the rear of the monitor (refer to Figure 38).

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



Figure 37: USB Connectors on the Left Side of the Touch Screen



Figure 38: USB Connectors on the Rear of the Monitor (ExactVu 2.6/2.9 hardware versions)

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 a USB connector to which a USB storage device may be connected. Multiple USB storage devices are not supported for export operations.

2 Diagnosing the ExactVu System

2.1 Using Service Mode for System Diagnosis

Service Mode is a software feature that is intended to aid Technical Support personnel in diagnosing and servicing the ExactVu system and its accessories. It provides access to additional touch screen controls, as well as access to additional features that are unavailable to ExactVu operators, such as installing ExactVu software, viewing the Message Log, and accessing Windows.

Access to *Service Mode* is a configurable option on the software dongle. The ExactVu system is able to run with two connected software dongles. When a software dongle configured for *Service Mode* is connected, it supersedes the configuration of a *product software dongle*.

To enable Service Mode:

1. Obtain a software dongle configured to include the *Service Mode* option. (Refer to Chapter 2, section 6.3 on page 57.)
2. With the ExactVu system powered off, connect the software dongle to the ExactVu system.
3. Turn on the ExactVu system.

Service Mode is enabled.

Service Active is indicated in the image status panel.

NOTE
EN-N134

After connecting a new or reprogrammed software dongle to the ExactVu system, the ExactVu system must be restarted.

In this version of the ExactVu system, the functions available in *Service Mode* are:

- Access to the file system (via **CTRL+ALT+SHIFT+R** hotkey combination)
- Access to ExactVu system diagnostics functionality (via *Engineering Mode*)

2.2 Using Engineering Mode for Low Level System Control

Engineering Mode is a software state that is intended to aid Technical Support personnel in low level control of the ExactVu system and to aid in diagnosing problems. When enabled, *Engineering Mode* opens a standalone software tool that is used to program specific values to ExactVu hardware and software. It also provides access to the operating system settings.

Engineering Mode capabilities are typically used for testing purposes, and may be used by Technical Support personnel to diagnose problems in the ExactVu system's components and transducers that are returned to Exact Imaging for repair.

Engineering Mode is unlikely to be used in the field during servicing, and as such, the full range of its capabilities is not documented in this *Service Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

To enable *Engineering Mode*:

1. Enable *Service Mode* as described above.
 - Restart the ExactVu system if a new software dongle was connected in order to enable *Service Mode*.
2. Press **CTRL+ALT+E** hotkey combination.

If a connected software dongle is not configured for *Service Mode*, a password prompt is displayed.
3. If prompted for a password, type **wa1nut** and select **OK**.

Engineering Mode is enabled, and the *Engineering Mode Tool* is displayed.

Eng Active is indicated in the image status panel.

Access to operating system settings is available.

When *Engineering Mode* is enabled, the ExactVu system's *power management* can be toggled *ON* and *OFF*. *General power management* functionality is described in Chapter 2, section 6.4 on page 57. Details of *power management* parameters are described in section 2.2.1.2 on page 64. In order to re-engage normal *power management* functionality, and to reset imaging settings and hardware values to default settings, the ExactVu system must be shut down and restarted.

2.2.1 *Engineering Mode Tool*

The *Engineering Mode Tool* provides direct access to and control of imaging settings, as well tools to measure the resolution and intensity of the DB contour, *single line mode* for acoustic measurement, the ability to write and execute scripts, and a depth indicator tool.

Scripts in both *.vts* format and accessed using the Automated Software Test Tool are supported.

2.2.1.1 *Parameter Configuration*

The *Parameter* configuration for the *Engineering Mode Tool* provides direct access to and control of imaging settings, including B-Mode settings such as delay (depth offset), line density, beam steering, and many others (refer to Figure 39). Transducer default values specified in *scan format* files may also be modified using the *Parameter* configuration functionality of *Engineering Mode*.

Imaging settings are editable using the *Parameter Configuration*, where specific values can be read as well as assigned to any setting.

To read the current value for a selected parameter:

1. Select the parameter of interest.
 - To facilitate searching for the parameter of interest, check applicable *Flags*.
2. Select **PDM Read**.

The current value for the selected parameter is displayed.

To specify a value for a selected parameter:

1. Select the parameter of interest.
 - To facilitate searching for the parameter of interest, check applicable *Flags*.
2. Select the *Value* field.
3. Type the value to assign to the parameter.
4. Select **PDM Write**.

The new value is assigned to the selected parameter.



Imaging must be paused prior to updating a parameter in *Engineering Mode* in order for the update to be applied successfully.

2.2.1.2 Power Management Configuration

The *Engineering Mode Tool* can be used to toggle *power management ON* and *OFF* using the *DoPowerManagement* parameter and by following the procedure described in section 2.2.1.1. The *DoPowerManagement* parameter is toggled *ON* by default.

When power management is toggled *OFF*, operators are able to access and control the 2D Mode and CFI Modes parameters listed in Table 4.

2D Mode Parameters	CFI Modes Parameters
<ul style="list-style-type: none"> • V1 supply • V2 supply • Beam steering • Delay (Depth offset) • Element enable (RX) • Fan angle • Rx/f_# • TX/f_# • Frame rate • Image enhancement (ON/OFF) • Line density • Multi-line factor • Pulse width pos • Pulse width neg • Pulse ground • Speed of sound in tissue • Timeout • Wave cycle (Tx # cycle) (extra cycle) • Width (vs the center line) • Frequency domain BPF parameters (as function of Tx zone) • Gain profile parameters (as function of Tx zone) 	<ul style="list-style-type: none"> • V1 supply (B-Mode lines) • V2 supply (CFI lines) • 2-D spatial filter (CFI image processing) • Box angle • Rx/f# • TX/f# • B-Mode write priority • Doppler Speed of Sound • # of ensemble • Noise threshold profile • Pulse width pos • Pulse width neg • Pulse ground • Wave cycle (Tx # cycle) (extra cycle) • CFI digital Tx focal depth dependent gain settings

Table 4: Accessible Parameters when Power Management is Powered Off

2.2.1.3 GOPView™ PlusView Enhancement

The ExactVu software incorporates *GOPView™ PlusView*, a set of third-party libraries that enhances ultrasound images. This enhancement may be tuned using the *Engineering Mode Tool*, and may also be turned on/off. Operators are able to turn the feature *ON* or *OFF* using the *Workflow* touch screen. The enhancement is on by default.

To turn the GOPView™ PlusView enhancement off:

1. Using *Engineering Mode*, navigate the tree structure to select the *BMode/Public/BModeSoft/Image-Enhancement* parameter.
2. Remove the check from the *State* checkbox.
3. Select **PDM Write**.

The GOPView™ PlusView image enhancement is turned off.

To turn the GOPView™ PlusView enhancement on:

1. Using *Engineering Mode*, navigate the tree structure to select the *BMode/Public/BModeSoft/Image-Enhancement* parameter.
2. Check the *State* checkbox.
3. Select **PDM Write**.

The GOPView™ PlusView image enhancement is turned on.

Tuning the GOPView™ PlusView enhancement settings is specific to the nature of the issue being diagnosed and is performed under the direction of Technical Support personnel.

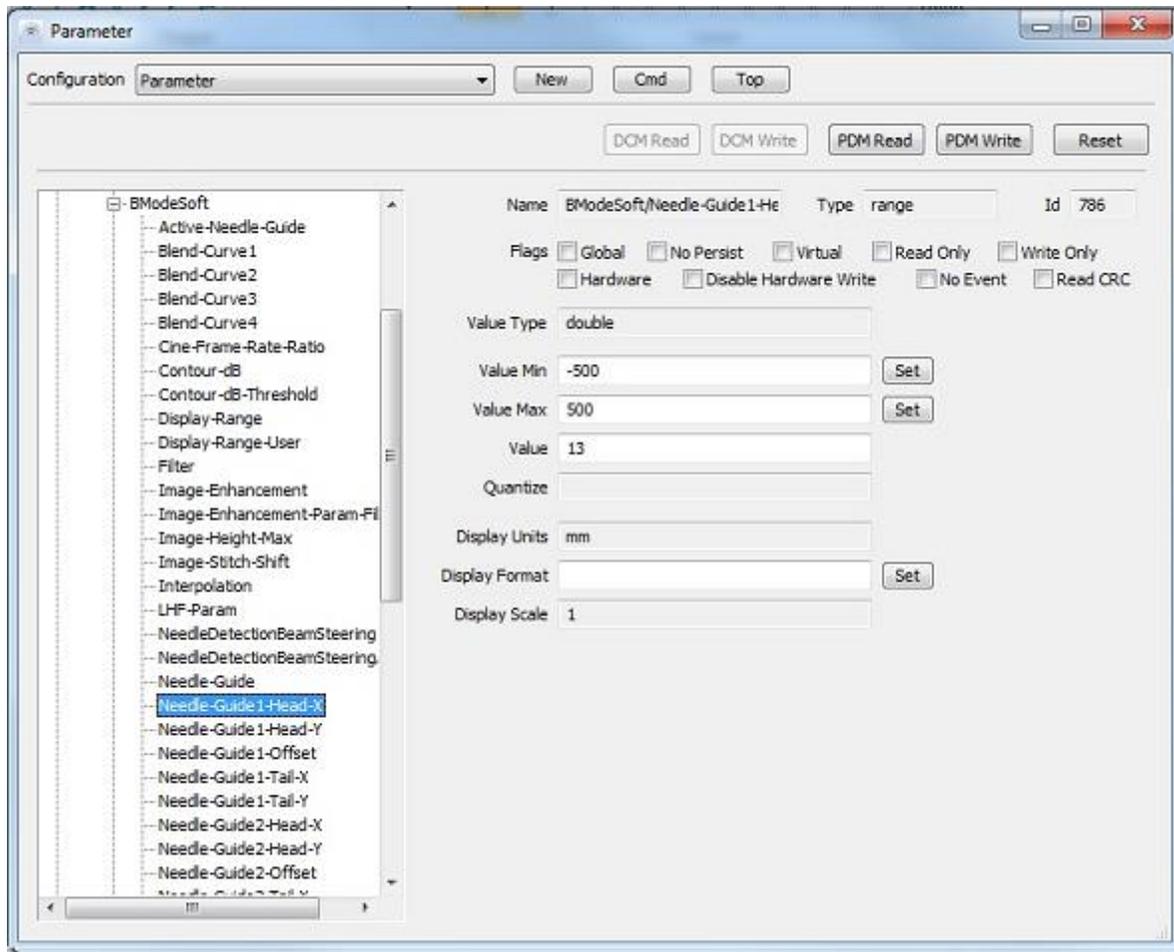


Figure 39: Engineering Mode Parameter Configuration

2.2.1.4 PACS Background Archiving

ExactVu operators are able to configure settings for background archiving processes for archiving studies to a PACS server.

The operator may configure the following settings:

- The time delay after which the background process re-attempts to send a study to the PACS server after the background archiving process fails to send it. (The default setting is 1 minute, i.e., 60000 ms.)
- The number of attempts the background progress makes to send a study to the PACS server following a failure to send due to a network / server error. (The default setting is 3 retries.)

To configure the time delay for the background process to re-attempt a study archive:

1. Using *Engineering Mode*, navigate the tree structure to select the *Preferences/Public/System/Dicom-Storage-Interval-Failure-Retry* parameter.
2. Type the desired retry delay in milliseconds.
3. Select **PDM Write**.

The time delay for the background process to re-attempt a study archive is set to the new value.

To configure the number of retry attempts for the background process to archive a study:

1. Using *Engineering Mode*, navigate the tree structure to select the *Preferences/Public/System/Dicom-Storage-Times-Failure-Retry* parameter.
2. Type the desired number of attempts.
3. Select **PDM Write**.

The number of times the background process re-attempts a study archive following a network failure is set to the new value.

2.2.1.5 DICOM Specific Character Set for DICOM Store

When a DICOM Specific Character Set (0008,0005) is associated with an MRI study or Modality Worklist procedure that is loaded to create an ExactVu study, that character set is used when archiving the study to a PACS server.

If no Specific Character Set is associated with a query for a MRI study or Modality Worklist procedure that is loaded on the ExactVu system, ExactVu operators are able to configure a default Specific Character Set to use when archiving.

To specify a default Specific Character Set for DICOM Store:

1. Using *Engineering Mode*, navigate the tree structure to select the *Preferences/Public/System/Dicom-Storage-Patient-Level-Char-Set* parameter.
2. Type the desired *Specific Character Set*.
3. Select **PDM Write**.
4. Restart the ExactVu system.

The Specific Character Set that will be used by ExactVu system as a default for DICOM Store is set to the new value.

If no default value is specified, the ExactVu system archives studies to PACS using Specific Character Set *ISO_IR 192*.

2.2.1.6 DICOM Query

The system shall provide the Engineering parameter "Preferences/System/Dicom-Query-Configurable-Modalities-In-Study" to pass to DICOM Query(C-FIND) parameters as the Modalities in Study (0008,0061) attribute.

The DICOM Query(C-FIND) setting is configurable. The default value of the parameter is an empty string, which constrains the query to *MR*. To remove this constraint the value can be set to an asterisk (*).

To configure DICOM Query (C-FIND) settings:

1. Using *Engineering Mode*, navigate the tree structure to select the *Preferences/System/Dicom-Query-Configurable-Modalities-In-Study* parameter.
2. Type the desired the Modalities in Study (0008,0061) attribute.
3. Select **PDM Write**.

The Modalities in Study (0008,0061) attribute is set to the new value.

WARNING

EN-W46



After completing service activities using *Engineering Mode*, the system must be restarted to take the system out of *Engineering Mode*.

2.2.2 Using Zoom

The ExactVu system provides the capability of zooming in on an image during imaging. Zoom is available for any transducer in 2D Mode (including sub-modes and FusionVu workflows). If zoom is toggled on during imaging, the zoom configuration is retained when imaging is paused.

The Zoom feature works using a *zoom box*. After positioning the zoom box over the part of the image to be zoomed, the area within the zoom box is magnified using a control on the *control panel*.

NOTE

EN-N120



Zoom is available for access by Technical Support personnel only, via *Engineering Mode* and hotkey combination.

To toggle zoom on:

1. With Zoom inactive, press **Keyboard** on the *touch screen* while imaging in 2D Mode or its sub-modes.
2. Select **CTRL+ALT+G**.

Zoom is activated.

A *zoom box* is displayed in the center of the image.

The *status panel* indicates that Zoom is Active.

Zoom box configuration is active, whereby the *zoom box position* and *zoom box size* are ready to be set.



Figure 40: 2D Mode Imaging Screen

When the *zoom box* is displayed, both its position and size may be configured. Its outline is dashed, to indicate that *trackball movements* will change it.

To toggle between configuring the zoom box position and the zoom box size:

1. With the zoom box displayed, press **Next** on the control panel.
Zoom box position configuration switches to zoom box size configuration.
2. Press **Next** again.
Repeatedly pressing **Next** toggles between zoom box position configuration and zoom box size configuration.

To configure the zoom box position:

- With zoom box position configuration active, roll the trackball in any direction.
The zoom box moves to follow the movement of the trackball.

To configure the zoom box size:

1. With zoom box size configuration active, roll the trackball up or to the right.
The zoom box size increases.
2. Roll the trackball down or to the left.
The zoom box size decreases.

After the zoom box size and position are configured, perform the zoom.

To zoom the image:

- With zoom box size and position configured, press **Set** on the control panel.
The area in the zoom box is enlarged to cover the entire imaging area.
The zoom box is no longer visible.
Zoom box position configuration and zoom box size configuration become inactive.

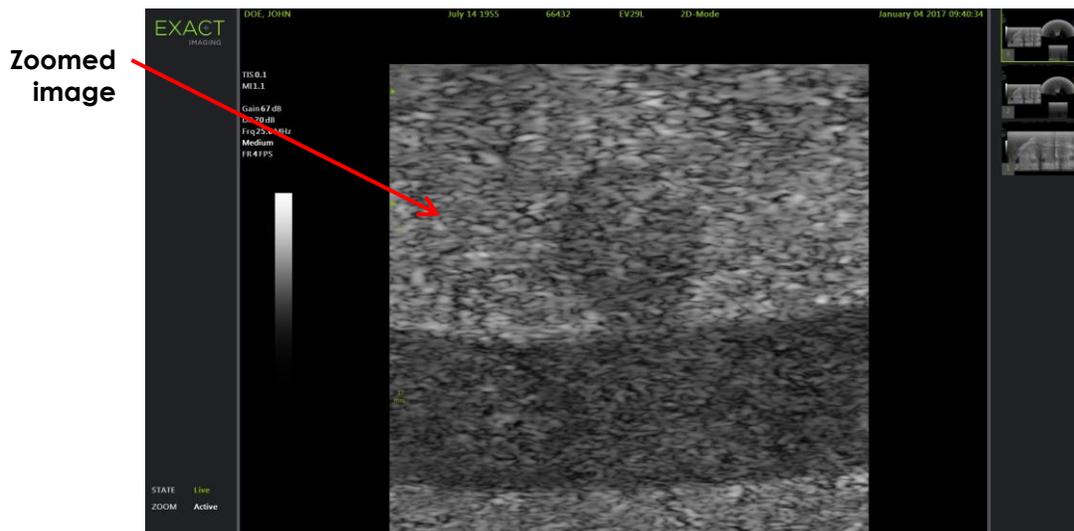


Figure 41: Zoomed 2D Mode

Zoomed frames may be saved the same way non-zoomed images can, and may be measured and annotated.

To toggle zoom off:

1. With Zoom active, press **Keyboard** on the touch screen.

2. Select **CTRL+ALT+G**.

Repeatedly typing **CTRL+ALT+G** toggles zoom on/off.

When Zoom is toggled off, the imaging screen displays the full-sized image.

When viewing a zoomed image, several actions automatically toggle zoom off. These are:

- Switch to Transverse Mode and other modes
- Open Patient/Study
- Open Preferences
- Changing a transducer, exam type or preset

NOTE

EN-N93



It is not possible to zoom an image that is open for review. Zoom is only available when a live or paused image is displayed on the imaging screen, and only in 2D Mode.

NOTE

EN-N58



Zoom is only available in 2D Mode.

3 Analyzing the Message Log

The ExactVu system keeps a *message log* that records information about all events that happen during operation, including operator interactions with the ExactVu system and error conditions. The *Message Log Viewer* is a standalone application that remains open while service personnel interact with the ExactVu system.

Four types of message log files are created and saved, to capture information about how the operator interacts with the ExactVu system. These are

- Main message log: This log is denoted *ExactVuLog*, and captures events logged during the operation of the ExactVu system.
- Control panel message log: This log is denoted *TechboardLog*, and captures events related to the operator's interaction with the *control panel* and *touch screen*.
- DICOM message log: This log is denoted *DicomMsgLog*, and captures events related to communication between the ExactVu system and the PACS server and any read/write/query activity that pertains to DICOM. It is updated only if there is DICOM-related activity.
- Transducer Element Check log: This log records the result of the Transducer Element Check after each execution. (*Transducer Element Check* is available in software versions ExactVu 2.5.5 and newer.)

3.1 Message Log Contents

The following events automatically create entries in the applicable message log(s):

- System errors and warnings
- Power management adjustments that override settings specified by the operator

- Engineering parameters including the following:
 - hardware frame rate
 - estimated frame rate
 - number of active elements per focal zone
 - acoustic output details
 - FPGA versions of channel board, beamformer control board (BCB) and BCB driver version and hardware/software compatibility status
 - Transducer Element Check results
 - Channel board and BCB hardware serial number and board revision
- The MAC address and IP address of the software host system
- DICOM Store, Modality Worklist and MRI Query/Retrieve settings
- Information about GSPS (Grayscale Softcopy Presentation State) markup in loaded MRI studies for use with the *FusionVu* features
- External Programs activity
- Any interaction the operator has with the control panel or foot pedal (excluding the virtual keyboard on the *touch screen*)
- Transducer Element Check after each time a transducer is selected (*Transducer Element Check* is available in software versions ExactVu 2.5.5 and newer)

Each ExactVu application instance creates a new empty *message log* file. Messages in the *message log* have the following properties:

- Each message is timestamped
- Each message has a *level* that identifies the message type and relates to the type of action resulted in the message being created (i.e., error, warning, information, etc.).
- Each message shows the details of the action or event that generated the message

If messages are added to the message log such that its file size reaches the maximum allowed, the ExactVu system stops adding new messages to the log. The maximum allowed message log file size may be configured in Engineering Mode. Refer to Chapter 3, section 2.2 on page 62 for information about Engineering Mode.

3.2 Using the Message Log

When troubleshooting a problem, it is useful to be able to reproduce the scenario that caused the problem. By filtering the *message log* on a particular type of message, it may aid in determining what was happening with the ExactVu system immediately prior to when the problem occurred. For example, it may be useful to filter the message log by operator interactions with the ExactVu system.

To launch the Message Log:

- Press **CTRL+ALT+L** on the *touch screen*.

The *Message Log Viewer* launches, displaying messages sorted in reverse chronological order.

NOTE

EN-N98



It is possible to use the ExactVu system while the *Message Log Viewer* application is open.

To toggle the sort order of the message log:

1. In the *Message Log Viewer*, select the **View** menu.
A context menu containing view options is displayed.
2. From the *View* menu, select **Reverse Time Order**.

The *message log* re-sorts the timestamp column each time the *Reverse Time Order* option is selected.

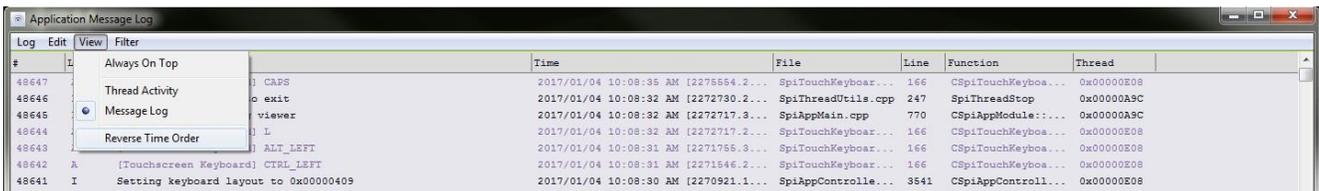


Figure 42: Message Log Viewer View Menu

To filter messages in the message log:

1. Select the dropdown next to the *Filter* menu.
A context menu displaying a list of levels (i.e., message types) is displayed.
2. Select the desired message level.
The messages are filtered by the selected level.
3. For advanced filtering, select **Advanced Filter**.

The *Advanced Filter* dialog is displayed, and allows the selection of multiple filters, and searching by text.

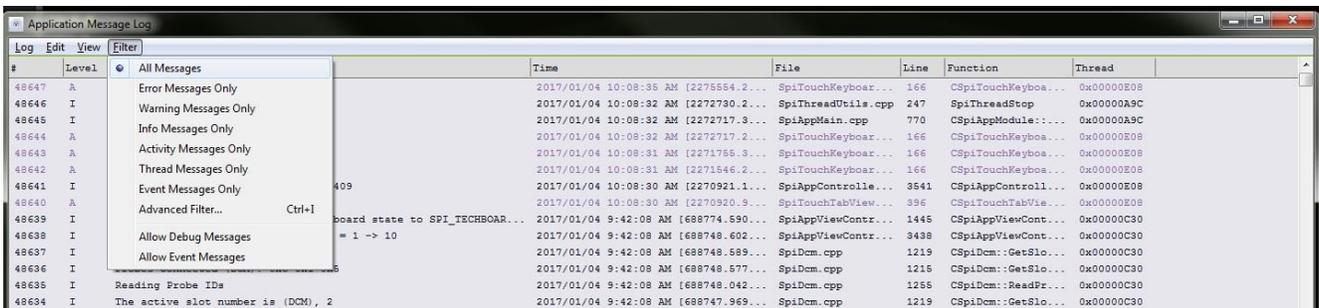


Figure 43: Filter Menu

Messages can be filtered further, using options in the *View* menu. For example, by enabling *Event Trace*, messages of various levels may be viewed in a way that distinguishes them from others, and may aid in determining a set of repeatable actions that lead to an undesired event.

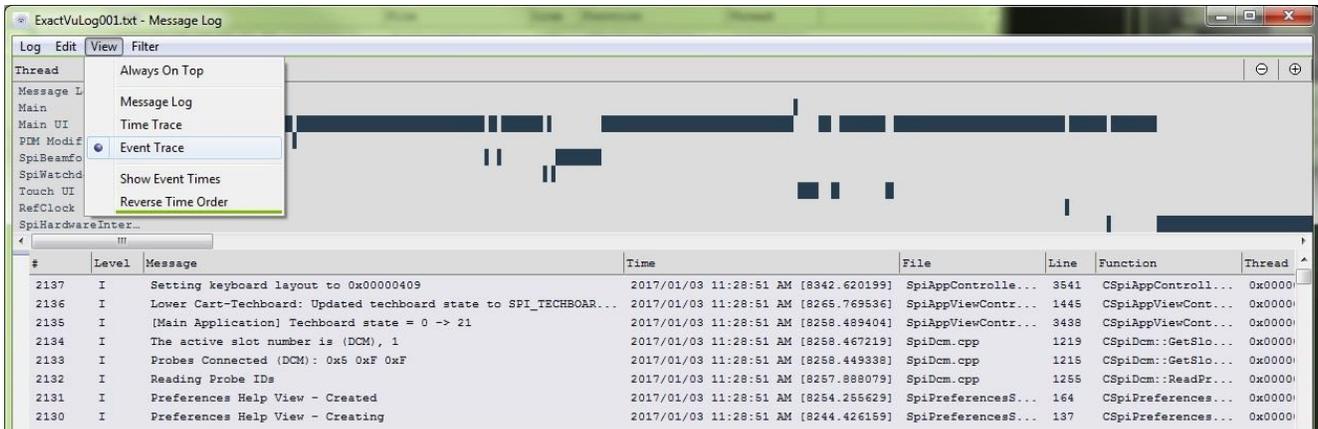


Figure 44: Event Trace

Several events cause a timestamped copy of the *message log* to be saved. These include:

- The operator shuts down the ExactVu system
- A critical system condition occurs

NOTE

EN-N99



When a copy of the *message log* is saved due to an unhandled exception in the ExactVu software, a timestamped *application dump file* is saved with it.

3.3 Exporting Saved Message Logs

Message log files may be exported from the ExactVu system to a USB storage device for internal use by Technical Support personnel. There are two ways to do this:

- Exporting a specific message log
- Exporting all log files during a time range

To export a specific message log:

1. Connect a USB storage device to the ExactVu system, formatted as recommended in section 1 on page 61.
2. From the Log menu in the *Message Log Viewer* application, select **Manage Archives**.

A list of saved message log files is displayed.

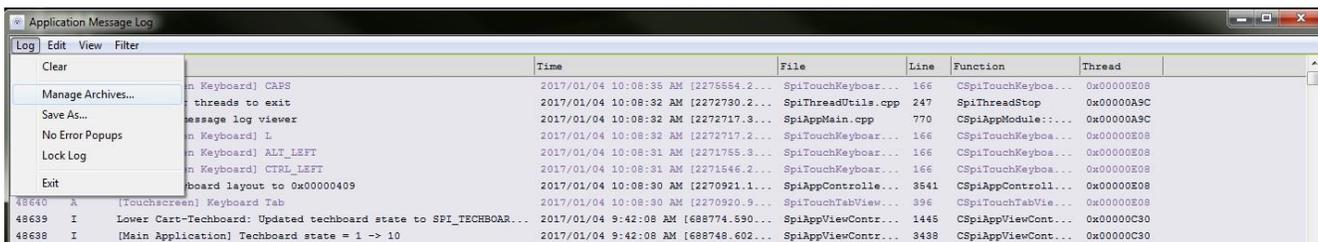


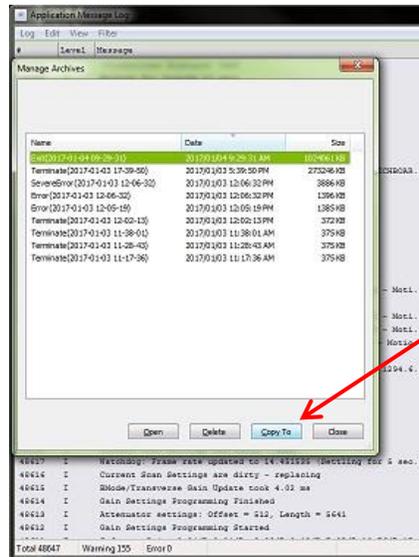
Figure 45: Filter Menu

3. Select the message log file or files to export.
4. Select **Copy To**.

A *Browse for Folder* dialog is displayed.

5. Navigate to the desired folder and select **OK**.

The selected message log file(s) are copied to the selected folder on the USB storage device. The corresponding error and terminate logs are copied with the message log files (if each exists).



Copy To

Figure 46: Copy To Option

To export all log files saved during a time range:

1. Connect a USB storage device to the ExactVu system, formatted as recommended in section 1 on page 61.
2. Open *Preferences > System Information*.
3. 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.

3.4 Disk Space Management and Automatic File Deletion

Disk space check is checked against the *Disk Space Warning Threshold* (15% of disk space) when the following actions are performed:

- At system startup
- When saving an image
- When closing a study

If the available disk space is less than the *Disk Space Auto Delete Threshold* (20% of disk space), the ExactVu system automatically deletes studies that are *Marked for Deletion* in order to ensure space is available for new studies. Automatic study deletion does not interrupt system functions, though it is not possible to access the Patient List during auto deletion.

Automatic study deletion workflow:

- The oldest studies are deleted in a batch, where the batch size is between 1-5% of disk space.
- Automatic deletion continues until available storage space is more than the *Disk Space Stop Auto Delete Threshold* (50% of disk space).
- If the available disk space is less than *Disk Space Warning Threshold* (15% of disk space) but more than 7%, the system prompts the user with an on-screen message indicating that soon it will be impossible to save patient and image data.
- After deleting all studies marked for deletion, if the remaining available storage space is less than the *Disk Full Threshold* (7% of disk space), the system prompts the user with an on-screen message indicating that study data and message logs are prevented from being saved until sufficient disk space is available.
- Message logs are also automatically deleted when the total disk space used by message logs exceeds 10 GB. The oldest message logs are deleted in a batch, where the batch size is up to 2 GB.

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

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.

4 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 Exact Imaging procedures for ESD controls. 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.

When servicing ESD-sensitive equipment 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.
- Unless indicated otherwise, perform all service procedures with the *main power switch* in the *OFF* position and the power cable disconnected from the ExactVu system (refer to Figure 47).
- Remove or insert static-sensitive components and assemblies only with the 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 47), or an equivalent grounding source.



Figure 47: Ground Pin

- Insert and seal static-sensitive components and assemblies into their original static-shielding bags before removing them from static-protected areas.
- Always test your wrist strap and ground cord before removing components and assemblies from their protective bags and before beginning any disassembly or assembly procedures.

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.

5 Opening the ExactVu System Cart

Prior to opening the ExactVu system cart for on-site or off-site service activities, disconnect all transducers from the ExactVu system. To access system components for service and repair, remove the required panels. The front or rear panel must be removed before a side panel may be removed. To access components located at the front of the cart, the front insert panel must be removed after the front panel is removed.

This section also includes instructions for opening panels for the power button plate and either the

printer or printer panel cover.

5.1 Front or Rear Panel

Required Tools:

- # 1 Phillips screwdriver

To remove the front or rear panel from the ExactVu system cart:

1. Using a # 1 Phillips screwdriver, rotate the two screws at the bottom of the ExactVu system cart $\frac{1}{4}$ turn counter-clockwise (refer to Figure 48).
2. Pull the bottom of the panel away from the ExactVu system cart, so that the panel is tilted towards you.
3. Carefully pull the panel downwards and away from the ExactVu system cart.
4. Place the panel on the floor or flat surface, or lean it securely against a wall.



Figure 48: Bottom Front of the ExactVu System Cart

Remove two screws (screws are in the same position on the front and rear of the cart)

5.2 Front Insert Panel

Required Tools:

- 3 mm hex driver

To remove the front insert panel from the front of the ExactVu system cart:

1. Using a 3 mm hex driver, remove the four screws securing the front insert panel (refer to Figure 49).
2. Pull the bottom of the panel away from the ExactVu system cart, so that the bottom is tilted towards you.
3. Carefully pull the front insert panel downwards and away from the *top panel*.
4. Place the panel on the floor or flat surface, or lean it securely against a wall.

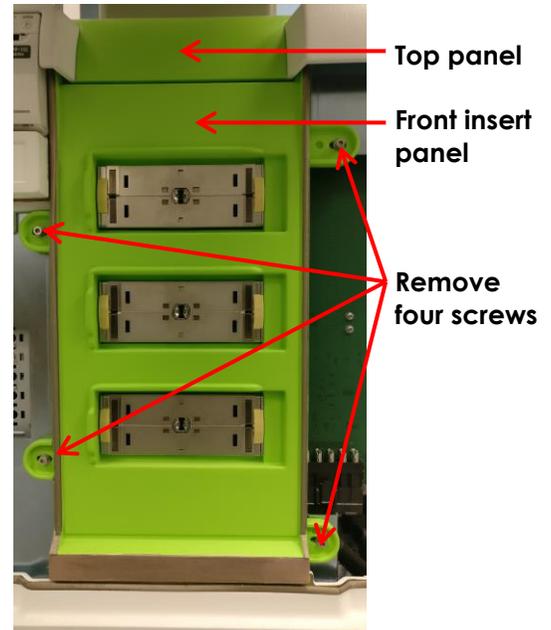


Figure 49: Front Insert Panel

5.3 Left or Right Side Panel

To remove a side panel from the ExactVu system cart:

1. Place both hands on the side panel, with one hand on the inside of the ExactVu system cart, and one outside.
2. Firmly press the side panel away from ExactVu system cart.
The side panel *pops out*.
3. Place the panel on the floor or flat surface, or lean it securely against a wall.

NOTE

EN-N96



Do not remove the side panels from the ExactVu system cart before removing the front and/or back panel.

5.4 Power Button Plate

Required Tools:

- 3 mm hex driver

To remove the power button plate:

1. Switch the main power switch for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.
3. Remove the front panel as described in section 5.1 on page 77.
4. Remove the three screws, washers and lock washers from the *power button plate* (refer to Figure 50).

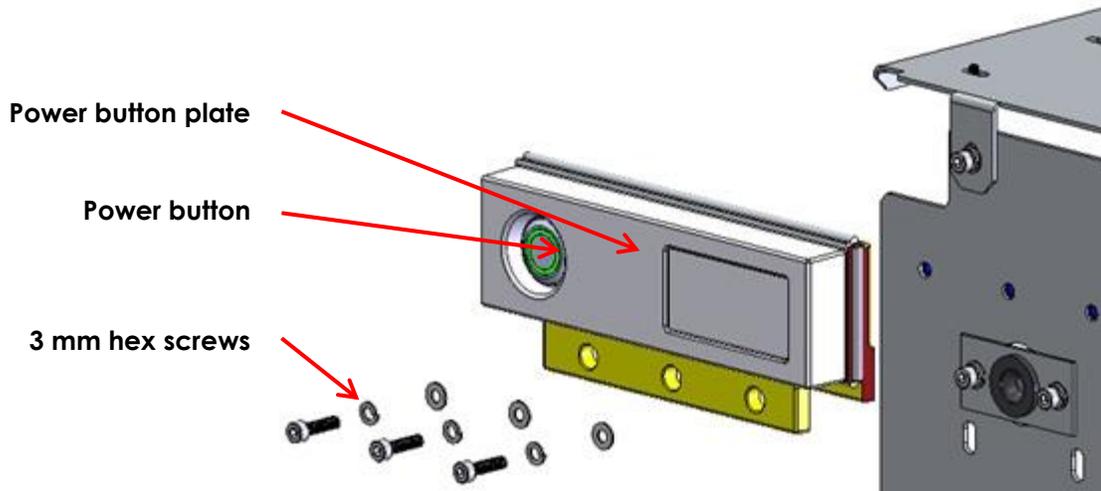


Figure 50: Power Button Plate

5. Rotate the metal ring at the back of the *power button plate* counter-clockwise (refer to Figure 51). Detach the *power button* by removing the metal ring.

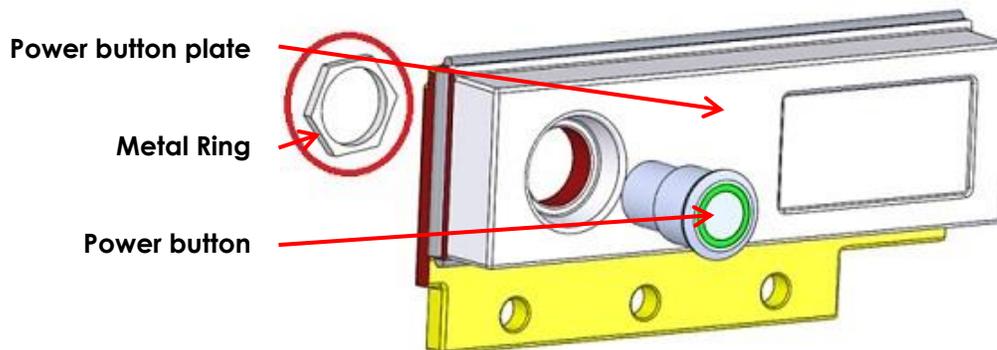


Figure 51: Metal Ring at the Back of the Power Button Plate

6. Service the *power button plate*.
7. Replace the serviced *power button plate* or install a new *power button plate*.

To install the power button plate:

1. Attach the power button to the *power button plate*.
2. Tighten three hex screws with washers and lock washers between the *power button plate* and the chassis.
3. Close the front panel as described in section 6.2 on page 81.
4. Document the appropriate records about the service performed for the *power button plate*.

5.5 Printer Panel Cover

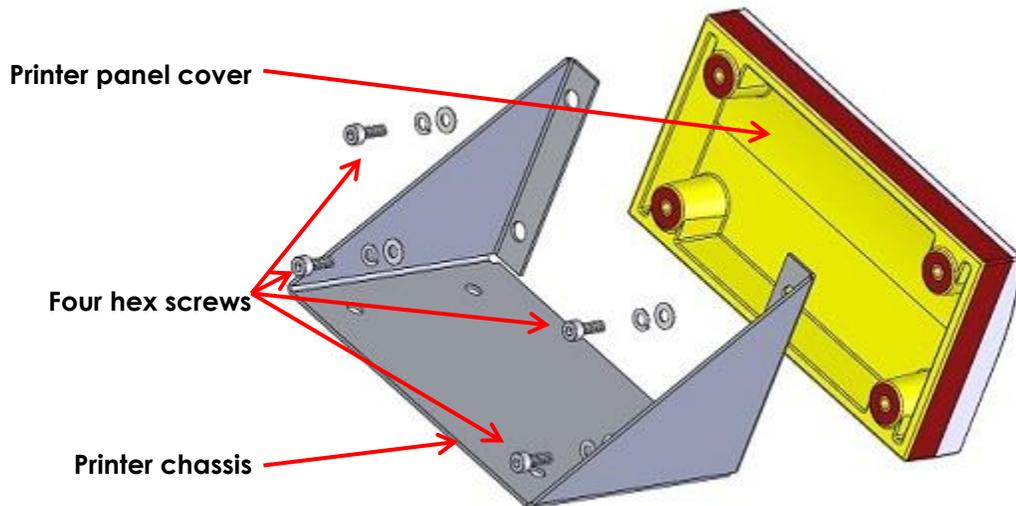
This section is applicable if the thermal printer is not part of the ExactVu system configuration. For this configuration, a *printer panel cover* is connected to the printer chassis to form part of the front panel of the ExactVu system cart.

Required Tools:

- 3 mm hex driver

To remove the printer panel cover:

1. Switch the main power switch for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.
3. Remove the front panel as described in section 5.1 on page 77.
4. Remove the left panel as described in section 5.3 on page 78.
5. Remove the four screws securing the *printer panel cover* to the printer chassis (refer to Figure 52).

**Figure 52: Printer Panel Cover**

6. Service the *printer panel cover*.
7. Replace the serviced *printer panel cover* or install a new *printer panel cover*.

To install the printer panel cover:

1. Tighten four hex screws with washers and lock washers to secure the *printer panel cover* to the chassis.
2. Replace the left panel as described in section 6.3 on page 81.
3. Replace the front panel as described in section 6.2 on page 81.
4. Document the appropriate records about the service performed for the *printer panel cover*.

6 Closing the ExactVu System Cart

After service is complete, and the USB software dongle and all cables have been reconnected, replace the panels on the ExactVu system cart. Each panel has four *snap-lock studs* that align and snap into four *snap-lock grommets* when the panel is attached to the ExactVu system cart (refer to Figure 54 and Figure 55).

To properly secure the front panel, replace it and the front insert panel before replacing the side

panels.

6.1 Front Insert Panel

Required Tools:

- 3 mm hex driver

To replace the front insert panel on the front of ExactVu system cart:

1. Hold the front insert panel to the chassis so that the four hex screw holes are aligned with the screw holes on the chassis.
2. Using a 3 mm hex driver, tighten the four screws at the bottom of the front insert panel to secure it to the ExactVu system cart.

The front insert panel is securely in place.

6.2 Front or Rear Panel

Required Tools:

- # 1 Phillips screwdriver

To replace the front or rear panel from the ExactVu system cart:

1. Lift the panel to the front or the back of the ExactVu system cart (as appropriate) such that:
 - The panel is just below the frame of the cart, with the bottom of the panel tilted away from the cart
 - The *snap-lock studs* are horizontally aligned with the *snap-lock grommets* on the frame of the cart



Figure 53: Screws Securing Front and Rear Panels

2. Press the panel upwards into place, such that the snap-lock studs snap into the snap-lock grommets.

The side panel snaps securely into place.

3. Using a # 1 Phillips screwdriver, tighten the two screws at the bottom of the panel to secure it to the ExactVu system cart (refer to Figure 53).

CAUTION

EN-C30



Do not replace the rear panel on the ExactVu system cart unless both side panels have been replaced.

6.3 Left or Right Side Panel

Replace the front panel prior to replacing the side panels.



Figure 54: Snap-lock Stud

Snap-lock stud (four in each panel and front insert panel)

Snap-lock grommet on each side of the cart and for connecting front insert panel

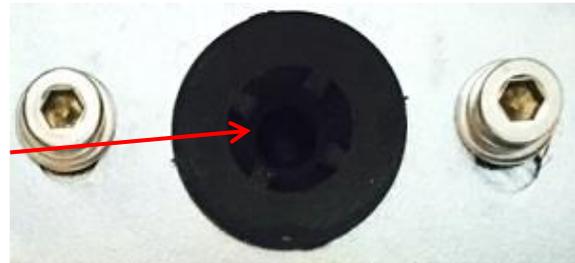


Figure 55: Snap-lock Grommet

To replace a side panel on the ExactVu system cart:

1. Lift the side panel to the side of the ExactVu system cart, such that:
 - The panel is just below the frame of the cart, with the bottom of the panel tilted away from the cart
 - The *snap-lock studs* are horizontally aligned with the *snap-lock grommets* on the frame of the cart
2. Press the side panel upwards into place, such that the *snap-lock studs* snap into the *snap-lock grommets*.

The side panel snaps securely into place.

CAUTION

EN-C29



The side panel that includes the air filter must be replaced on the left side of the ExactVu system cart, so that it is beside the computer unit.

7 On-Site Servicing

On-site servicing for the ExactVu system cart consists of assessing issues with the major components housed by the cart, including the monitor, control panel, thermal printer, speakers and computer unit, resetting the position references for the lift column, and assessing the channel boards and beamformer control board.

Service for components of the power box, the transducer switch board, replacement of the lift column, and service for other parts of the ExactVu system are presented in other sections in this chapter.

The following tools are necessary to perform on-site repair tasks for the ExactVu system:

- Long-handed slotted screwdriver (size 5 or 6)
- 2.5 mm, 3 mm, 4 mm, 5 mm and 6 mm hex drivers
- 4 mm hex driver (ball head)
- 7 mm, 10 mm nut driver
- # 1 Phillips screwdriver
- # 2 Phillips screwdriver

- Side cutter
- Cable ties (2.5x100 mm and 2.5x200 mm)
- Cable tie mounts
- ESD wrist strap and cord
- ESD static mat

WARNING

EN-W10



Service activities must be provided by qualified Technical Support personnel only.

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

Only those maintenance activities specified in Chapter 5, section 2 on page 182 should be performed by ExactVu operators.

7.1 On-Site Servicing for the ExactVu System Cart

The parts of the ExactVu system cart that may be serviced at a customer site are presented in this section.

Some parts of the ExactVu system cart cannot be serviced at a customer site due to the testing requirements that follow servicing procedures. Servicing for those parts is described in section 8.1 on page 125.

7.1.1 Servicing the Monitor

7.1.1.1 Overview

For all ExactVu system hardware versions, the *monitor* is attached to the *monitor support arm* using a *monitor adapter* (refer to Figure 57). The *monitor* can be removed from the *monitor adapter* without removing any panels.

The monitor cabling for ExactVu 2.5 and ExactVu 2.9 hardware versions is different from that for ExactVu 2.6 hardware versions. The rear panel must be removed if it is necessary to disconnect the monitor power cable from the power supply unit or to disconnect the display port cable from the computer unit (for ExactVu 2.5 and ExactVu 2.9 hardware versions).

Figure 56 and Figure 57 show images of the EIZO 2450 monitor. For ExactVu systems configured with the EIZO 2460 monitor, there are minor differences to the locations for the monitor adaptor and cable connections; however, there are no functional differences. For ExactVu 2.5 and ExactVu 2.9 hardware versions, the location for the display port cable (PN 6030) is slightly inconvenient to install but is not pinched or constricted.

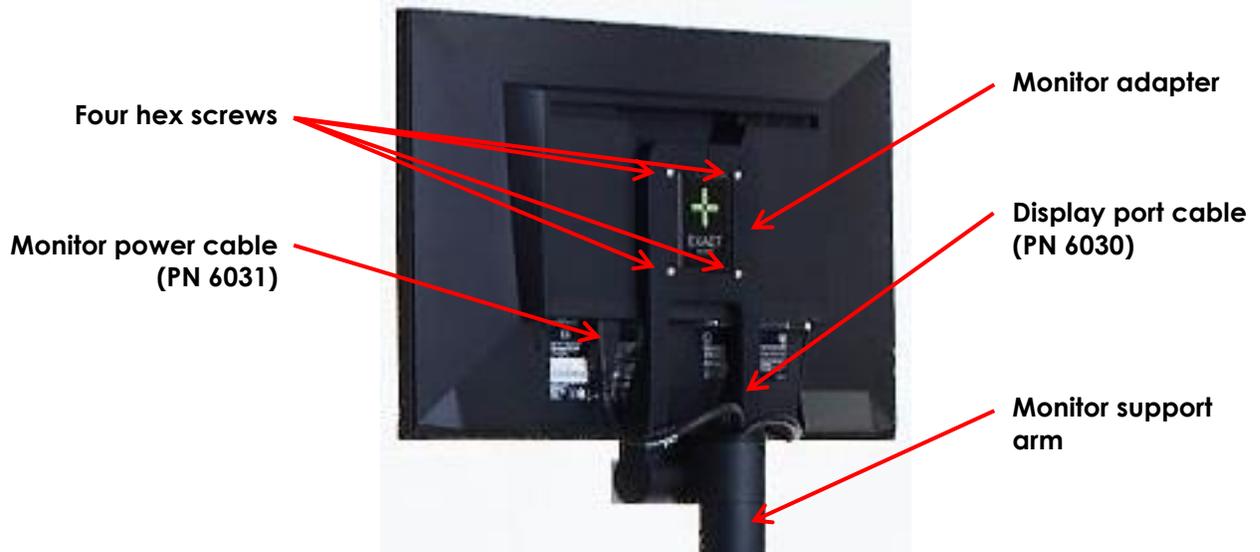


Figure 56: Monitor Adapter and Support Arm – Connections for ExactVu 2.5 and ExactVu 2.9 Hardware Versions

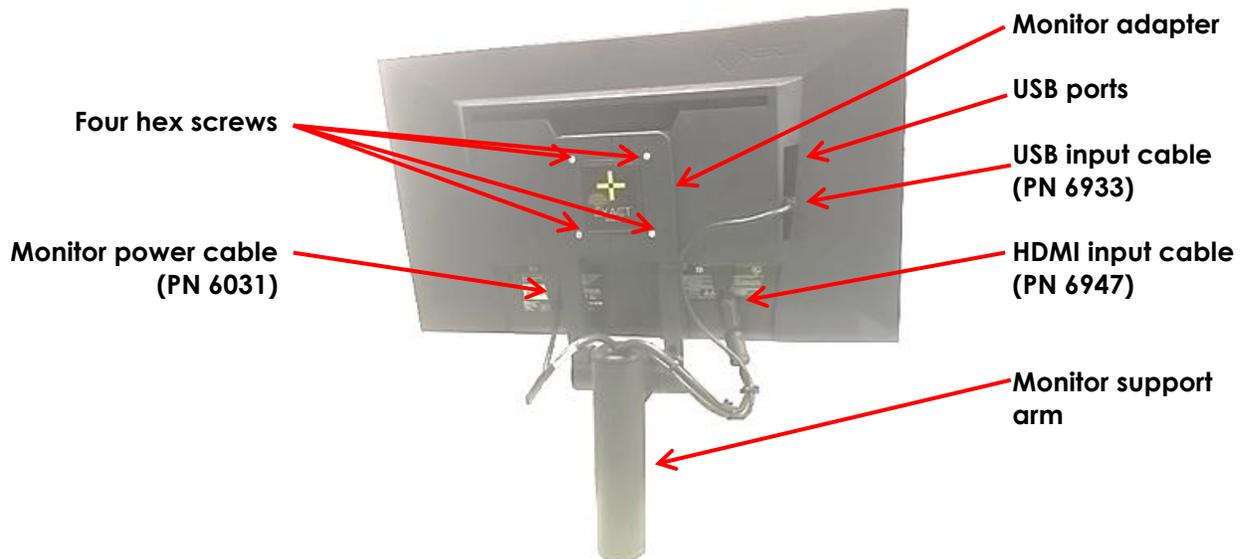


Figure 57: Monitor Adapter and Support Arm – Connections for ExactVu 2.6 Hardware Versions

7.1.1.2 Performing Service

Required Tools:

- 2.5 mm hex driver

To remove the monitor from the monitor adapter:

1. Disconnect the *monitor power cable* (PN 6031) from the monitor.

2. Depending on the hardware version disconnect the following cables:
 - For ExactVu 2.5 and ExactVu 2.9 hardware versions:
 - Disconnect the *display port cable* (PN 6030) from the monitor.
 - For ExactVu 2.6 hardware versions:
 - Disconnect the *USB Input cable* (PN 6933) and *HDMI Input cable* (PN 6947) from the monitor.
3. While holding the monitor, use the 2.5 mm hex driver, remove four hex screws securing the *monitor* to the *monitor adapter*.

CAUTION

EN-C33



While removing the hex screws from the monitor adapter, hold the monitor securely so that it doesn't drop.

4. Lift the *monitor* away from the *monitor adapter*.
5. Service the *monitor*.
6. Replace the serviced monitor or insert a new monitor.

To install the monitor:

1. Carefully hold the *monitor* to the *monitor adapter* such that the four hex screw holes on the adapter are aligned with the screw holes in the monitor.
2. While holding the monitor, use the 2.5 mm hex driver to tighten the four screws.
3. Depending on the hardware version connect the following cables:
 - For ExactVu 2.5 and ExactVu 2.9 hardware versions:
 - Connect the *display port cable* (PN 6030) to the monitor.
 - For ExactVu 2.6 hardware versions:
 - Connect the *USB Input cable* (PN 6933) and *HDMI Input cable* (PN 6947) to the monitor.
4. Connect the monitor power cable (PN 6031) to the monitor.
5. Document the appropriate records about the monitor service performed.
6. Test the monitor as described in Chapter 4, section 1.1.2 on page 142.

7.1.2 Servicing the Monitor Support Arm

7.1.2.1 Overview

The *monitor support arm* supports the *monitor adapter* and is connected to the deck.

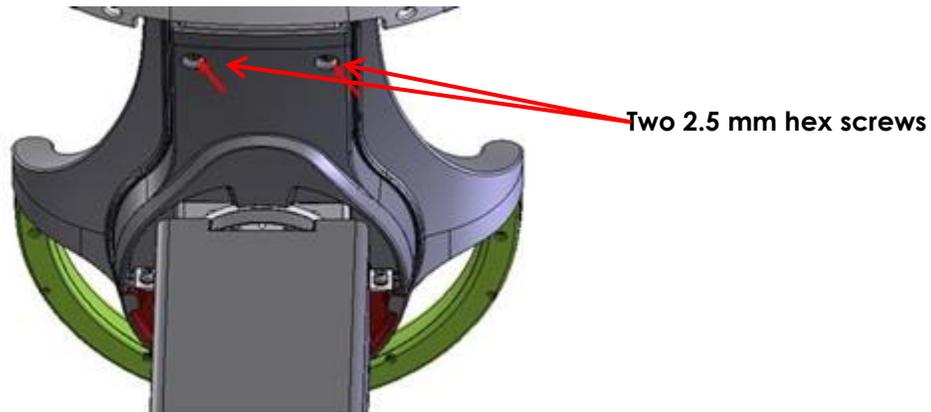
7.1.2.2 Performing Service

Required Tools:

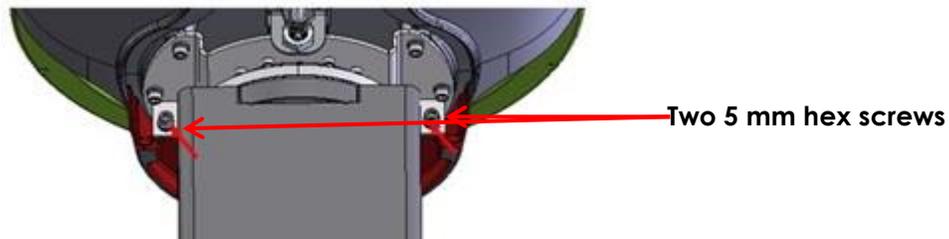
- 2.5 mm, 3 mm and 5 mm hex driver

To remove the monitor support arm from the deck:

1. Set the *lift column* to the middle position.
2. Switch the main power switch for the ExactVu system to the **OFF** position.
3. Unplug the ExactVu system's power cable from the wall outlet.
4. Using the 2.5 mm hex driver, remove the two hex screws at the front column and remove the *deck front panel* (refer to Figure 58).

**Figure 58: Deck Front Panel, Front Column View**

5. Using the 5 mm hex driver, remove the two hex screws at the front column and remove the *deck rear panel* (refer to Figure 59).

**Figure 59: Deck Rear Panel, Front Column View**

6. Depending on the hardware version, disconnect the following cables:
 - For ExactVu 2.5 and ExactVu 2.9 versions:
 - Disconnect the *monitor power cable* (PN 6031) from the top of the power box and disconnect the *display port cable* (PN 6030).
 - For ExactVu 2.6 versions:
 - Disconnect the *monitor power cable* (PN 6031), *USB Input cable* (PN 6933) and *HDMI Input cable* (PN 6947) from the monitor.
7. If necessary, remove the *monitor* from the *monitor adapter* as described in section 7.1.1 on page 83.
8. Using the 3 mm hex driver, loosen the hex screw at the rear of the deck (refer to Figure 60). Once loosened, pull the *monitor support arm* upwards. Feed the monitor cables out of the arm.

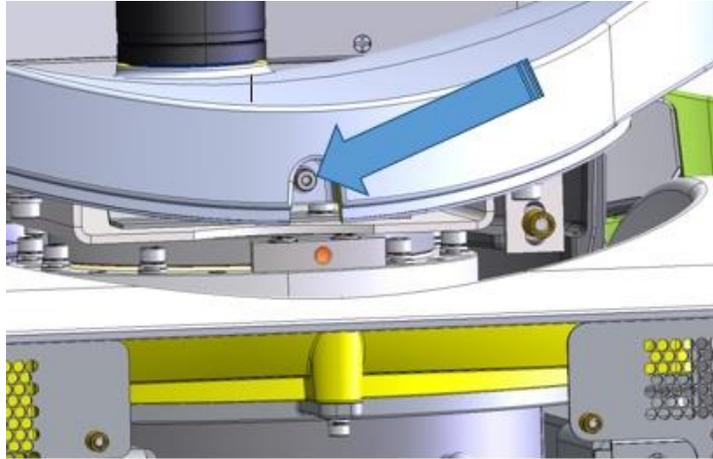


Figure 60: Deck Rear View

9. Service the *monitor support arm*.
10. Replace the serviced *monitor support arm* or insert a new *monitor support arm*.

To install the monitor support arm in the deck:

1. Depending on the hardware version, feed the following cables into the *monitor support arm*.
 - For ExactVu 2.5 and ExactVu 2.9 versions:
 - Feed the *monitor power cable* (PN 6031) and *display port cable* (PN 6030) into the *monitor support arm*.
 - For ExactVu 2.6 versions:
 - Feed the following cables *monitor power cable* (PN 6031), the USB Input cable (PN 6933) and the HDMI Input cable (PN 6947) into the *monitor support arm*.
2. Insert the *monitor support arm* into the slot on the deck.
3. Lock the arm by fastening the screw at the rear of the deck (refer to Figure 60).
4. If necessary, attach the *monitor* to the *monitor adapter* as described in section 7.1.1 on page 83.
5. Depending on the hardware version, connect the following cables:
 - For ExactVu 2.5 and ExactVu 2.9 hardware versions:
 - Connect the *monitor power cable* (PN 6031) and the display port cable (PN 6030) to the monitor.
 - For ExactVu 2.6 hardware versions:
 - Connect the *monitor power cable* (PN 6031), the USB Input cable (PN 6933) and the HDMI Input cable (PN 6947) to the monitor.
6. Install the deck rear panel and deck front panel.
7. Document the appropriate records about the service performed for the monitor support arm.
8. Test the monitor as described in Chapter 4, section 1.1 on page 142.

7.1.3 Servicing the Primary Display Settings

7.1.3.1 Overview

The display settings can be reset in the event that the default display settings are lost, and the display normally seen on the touch screen appears on the main monitor and vice versa. This may occur when an additional monitor is connected.

7.1.3.2 Performing Service to Reset the Primary Display Settings

Required Tools:

- None

To reset the primary display settings:

1. Press **CTRL+ALT+SHIFT+R** hotkey combination and navigate to the Windows desktop.
2. If monitor commands need to be unlocked:
 - Obtain a USB storage device containing the latest revision of the *Monitor Configuration Scripts* from Exact Imaging and connect it to the ExactVu system.
 - Copy the Monitor Configuration Scripts to C:\ServiceFiles\.
 - Connect a USB 3.1 Type A Male to B SuperSpeed Cable from the USB slot on the IO plate to the monitor.
 - Execute *AllLockOff.bat* from the *Monitor Configuration Scripts* directory.
3. Press **Next** and select *Screen resolution*.
4. Select the EIZO monitor as the main display monitor.
5. Position the secondary monitor (i.e., the control panel touch screen) to the top-right of the main display monitor so that the top of the secondary monitor aligns with the main display monitor.



Figure 61: Main and Secondary Display Monitor

6. Press the physical monitor buttons located at the bottom-right section of the monitor.
7. Select **Menu** and choose *Preferences* and *Monitor Reset*. Press **OK** to confirm.
8. Select **Mode** and choose *DICOM*.
9. Select **Menu** and choose *Preferences*. Turn **OFF** the following settings:
 - Power Save
 - ECO Timer (available on the EIZO 2450 only)
 - Power Indicator
10. Turn off the EIZO monitor.
11. Hold the left-most button and press the power button until the EIZO monitor turns on.

12. Apply the following settings and then select **Apply**:

- Set *Auto Input Detection* to *OFF*
- Set *On-Screen Logo* to *OFF*
- Set *Key Lock* to *ON* (EIZO 2450) or *ALL* (EIZO 2460)

13. Lock the monitor commands as follows:

- Obtain a USB storage device containing the latest revision of the *Monitor Configuration Scripts* from Exact Imaging and connect it to the ExactVu system.
- Copy the *Monitor Configuration Scripts* to C:\ServiceFiles\.
- Connect a USB 3.1 Type A Male to B SuperSpeed Cable from the USB slot on the *IO plate* to the monitor.
- Run *AllLockOn.bat* from the *Monitor Configuration Scripts* folder. (This script works the same way on both the EIZO 2450 and EIZO 2460.)

14. Verify that all the buttons on the monitor are locked.



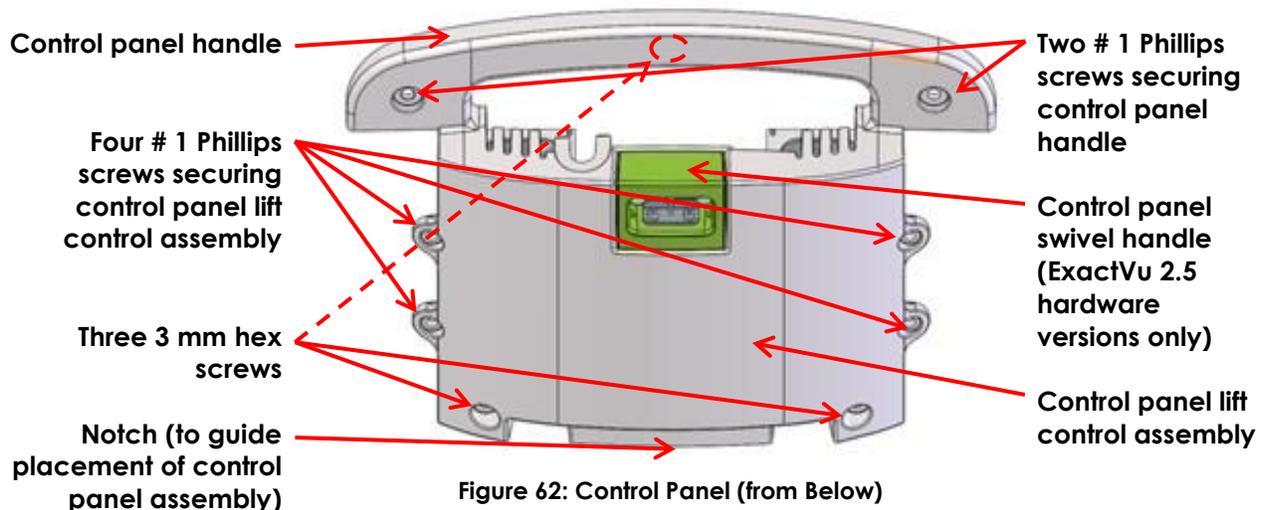
After the all the buttons are locked (including the power button), when any of the keys on the monitor are pressed, a *Locked* message is displayed briefly. This does not affect imaging.

15. Perform the monitor calibration procedure that appears in section 1.1.5 on page 144.

7.1.4 Servicing the Control Panel Assembly

7.1.4.1 Overview

The control panel assembly is located at the front of the ExactVu system cart. The hardware that secures it to the ExactVu system cart is accessed from below the control panel assembly.



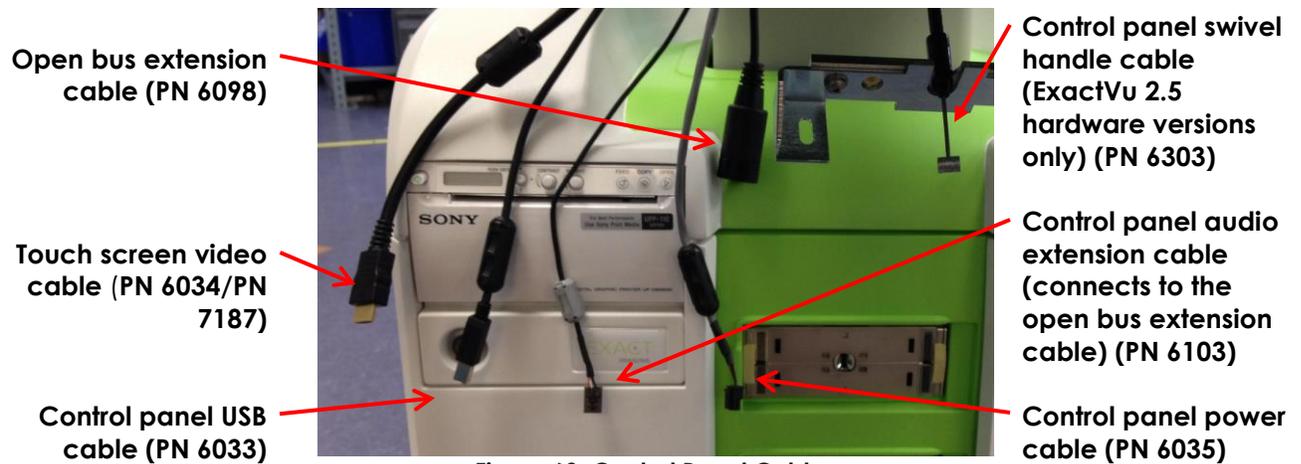


Figure 63: Control Panel Cables

7.1.4.2 Performing Service

Required Tools:

- # 1 Phillips screwdriver
- 3 mm hex driver
- ESD wrist strap

To remove the control panel assembly:

1. Switch the main power switch for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.
3. If necessary, remove each *transducer/gel holder* from the control panel by pressing it upwards from the bottom.
4. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
5. While holding the *control panel lift control* assembly, use a # 1 Phillips screwdriver, remove the four screws securing the *control panel lift control* assembly and the two screws securing the *control panel handle*.
6. Continue holding the *control panel lift control* assembly and use a 3 mm hex driver, remove the three remaining screws securing the *control panel handle*.

CAUTION

EN-C32



While removing the hardware securing the *control panel lift control* assembly, hold it securely from below so that it doesn't drop.

7. Disconnect the cables connected to the control panel assembly (refer to Figure 63).
8. Disconnect the *control panel swivel handle cable* from the lower control panel assembly (ExactVu 2.5 hardware versions only).
9. Lift the control panel assembly from the ExactVu system cart.
10. Service the control panel assembly.

11. Replace the serviced control panel assembly or insert a new control panel assembly.

To insert the control panel assembly:

1. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
2. Carefully place the control panel assembly onto the frame of the ExactVu system cart, such that the notch in the control panel assembly fits securely on the corresponding ridge on the ExactVu system cart.
3. Press the control panel assembly firmly into its correct position.
The control panel assembly does not wobble when it is securely positioned.
4. Connect the following cables:
 - Connect the *control panel swivel handle cable* (PN 6303) to the groove in the *control panel swivel handle* (ExactVu 2.5 hardware versions only)
 - Connect the *control panel power cable* (PN 6035)
 - Connect the *touch screen video cable* (PN 6034 in ExactVu 2.5/2.6 hardware versions, PN 7187 in ExactVu 2.9 hardware version)
 - Connect the *control panel USB cable* (PN 6033)
 - Connect the *open bus extension cable* (PN 6098)
5. Connect the *audio extension cable* (PN 6103) to the *open bus extension cable*.
6. Using a # 1 Phillips screwdriver, replace and tighten two 5 mm screws, each with a 5 mm washer and lock washer to secure the *control panel handle*.
7. Using a 3 mm hex driver, replace and tighten four 3 mm screws, each with a 3 mm washer and lock washer to secure the *control panel lift control assembly*.
8. Connect the ExactVu system's power cable to the wall outlet.
9. Switch the main power switch for the ExactVu system to the **ON** position.
10. Document the appropriate records about the control panel assembly service performed.
11. Test the control panel assembly as described in Chapter 4, section 1.1.2 on page 142.

7.1.5 Servicing the Thermal Printer

7.1.5.1 Overview

If configured, the thermal printer is located at the front of the ExactVu system cart. It is accessed by removing the front and left side panels. To remove and replace the thermal printer, the computer unit must also be removed from the ExactVu system cart.

The scope of thermal printer service performed by Technical Support personnel is limited to diagnosing, reconnecting cables, reseating the paper roll, etc.

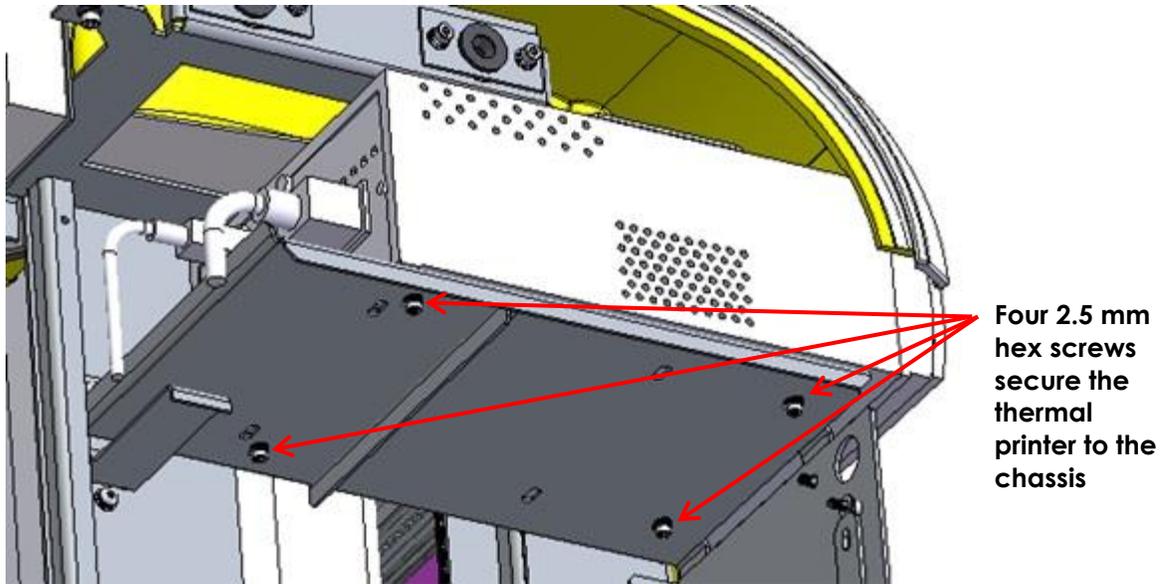


Figure 64: Thermal Printer from the Right Side View

7.1.5.2 Performing Service

Required Tools:

- 2.5 mm hex driver

To remove the thermal printer (if configured):

1. Prepare a static bag or mat for holding the thermal printer after it is removed from the system cart.
2. Switch the main power switch for the ExactVu system to the **OFF** position.
3. Unplug the ExactVu system's power cable from the wall outlet.
4. Remove the left panel and the front panel.
 - It is not necessary to remove the front insert panel.
5. Remove the ExactVu computer unit using the instructions in section 7.7 on page 109.
6. Disconnect the power cable connecting the thermal printer to the power supply unit (PN 6101).
7. Disconnect the USB cable between the thermal printer and the computer unit (PN 6102).
8. Use the 2.5 mm hex driver, remove four 2.5 mm hex screws, washers and lock washers securing the printer to the chassis.
9. Slide the printer forward through the front panel and pull it out from the chassis.
10. Place the thermal printer inside the static bag or on the static mat.
11. Service the thermal printer.
12. Replace the serviced thermal printer or insert a new thermal printer.

To insert a thermal printer:

1. From the right side of the ExactVu system cart, place the thermal printer on the chassis, and

slide it towards the front of the cart so that the four screw holes on the chassis are aligned with the screw holes on the bottom of the printer.

- Using a 2.5 mm hex driver, replace and tighten four 2.5 mm screws, each with a 2.5 mm washer and lock washer.

Replace and tighten all mounting screws

- Connect the following cables:
 - printer USB cable (PN 6102)
 - printer power cable (PN 6101)
- Replace the ExactVu computer unit using the instructions in section 7.7 on page 109.
- If no further components are to be serviced, replace the side and front panel.
- Connect the ExactVu system's power cable to the wall outlet.
- Switch the main power switch for the ExactVu system to the **ON** position.
- Document the appropriate records about the thermal printer service performed.
- Test the thermal printer as described in Chapter 4, section 1.6 on page 146.

7.1.6 Servicing the Speakers

7.1.6.1 Overview

The speakers are located within the control panel, and are accessed by removing the lower part of the control panel.

7.1.6.2 Performing Service

Required Tools:

- Phillips #1 screwdriver
- 3 mm and 5 mm hex driver

To remove the speakers from the control panel:

- Set the *lift column* to the highest position.
- Switch the *main power switch* for the ExactVu system to the **OFF** position.
- Unplug the ExactVu system's power cable from the wall outlet.
- From the *lower control panel*, remove the two types of screws at the lower side of the control panel to access the control panel PCB assembly (refer to Figure 65).

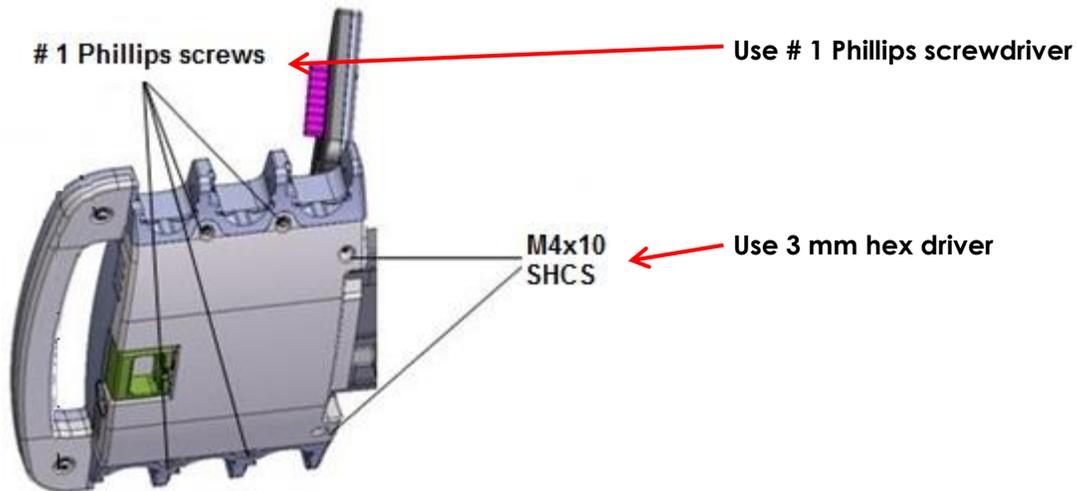


Figure 65: Lower Side of Control Panel

5. Disconnect the speaker cables from the control panel PCB assembly (refer to Figure 66).

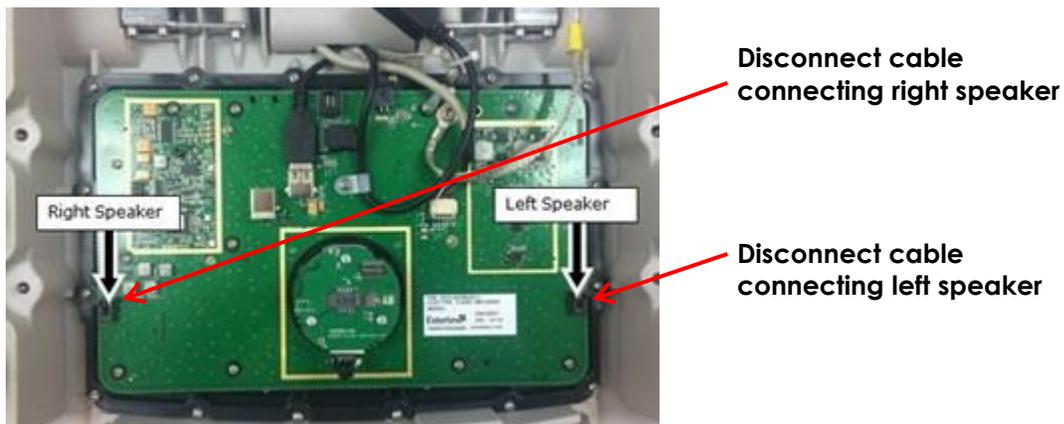


Figure 66: Control Panel PCB Assembly

6. Remove the hex screws, washers and lock washers at the speaker assemblies (refer to Figure 67).

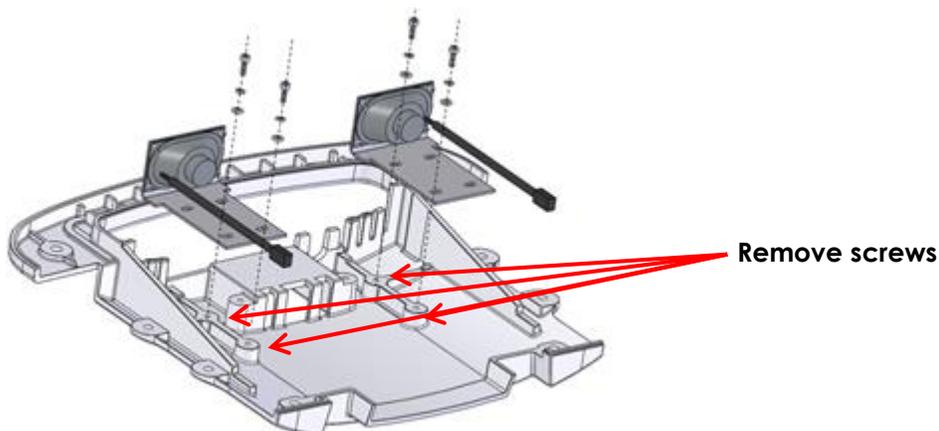


Figure 67: Lower Side of Control Panel

7. Service the speakers.
8. Replace the serviced speaker assembly or insert a new speaker assembly.

To insert the speakers in the control panel:

1. Place the speaker assembly on the control panel so that the four screw holes on the chassis are aligned with the screw holes on the control panel.
2. Replace and tighten four screws, each with a washer and lock washer.
3. Connect the speaker cables to the control panel PCB assembly.
4. Replace the cover of the lower side of the control panel. Replace and tighten all screws to secure the cover.
5. If no further components are to be serviced, connect the ExactVu system's power cable to the wall outlet.
6. Document the appropriate records about the service performed for the speakers.
7. Test the speakers as described in Chapter 4, section 3.1.6 on page 153.

7.1.7 Servicing the Fuses

7.1.7.1 Overview

The fuses are located in a fuse holder, located at the lower rear of the ExactVu system cart, between the *power cable receptacle* and the *main power switch*.

Blown fuses may be triggered by other component failures which are investigated and serviced according to Exact Imaging internal procedures.

7.1.7.2 Performing Service

Required Tools:

- 2 mm slotted screwdriver

To replace blown fuses in the ExactVu system:

1. Switch the *main power switch* for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.
3. Use a 2 mm or equivalent slotted screwdriver to:
 - Lower the upper clip to eject the upper part of the *fuse holder*
 - Lift the lower clip to eject the *fuse holder* (refer to Figure 68)

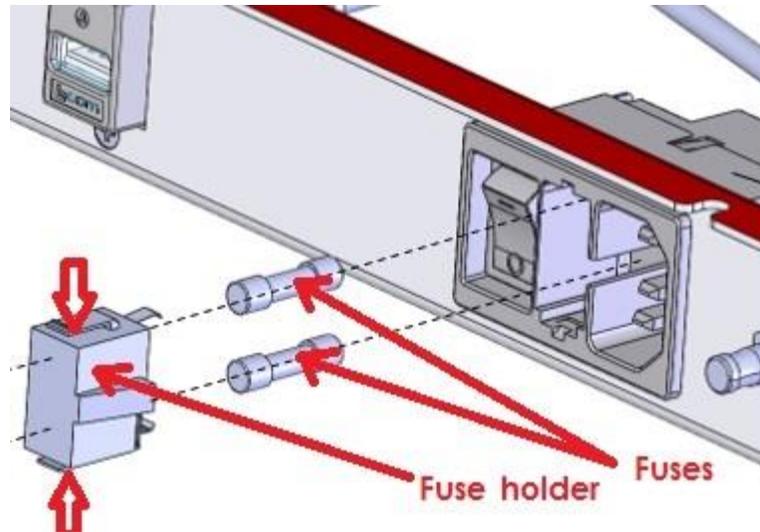


Figure 68: Fuses and Fuse Holder

4. Insert new fuses appropriate for the system configuration into the *fuse holder*.
5. Insert the *fuse holder* with fuses into its slot.
6. Document the appropriate records about the service performed for the fuses.
7. Test the fuses as described in Chapter 4, section 1.10 on page 149.

7.1.8 Servicing the Cooling System: DC Fan # 1 and DC Fan # 2

The cart has a system of cooling fans, air guides, and air vents to control the heat of the various electronics. DC fan # 1 and DC fan # 2 are attached to the top panel and are serviced as described in this section.

DC fan # 3 is located on top of the card cage and is attached to the top of it. These are serviced off-site as described in section 8.2.2 on page 126. Cooling fans 4 and 5 are internal card cage fans, are not serviced separately from the card cage.

7.1.8.1 Overview

Prior to servicing any cooling fan, disconnect power from the ExactVu system.

To disconnect power from the ExactVu system:

1. Switch the main power switch for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.

CAUTION

EN-C31



When servicing any cooling fan, the fan must be placed correctly and carefully within the enclosure so that regulatory and noise requirements are met.

7.1.8.2 Performing Service to DC Fan # 1

Required Tools:

- Long-handled 3 mm hex driver

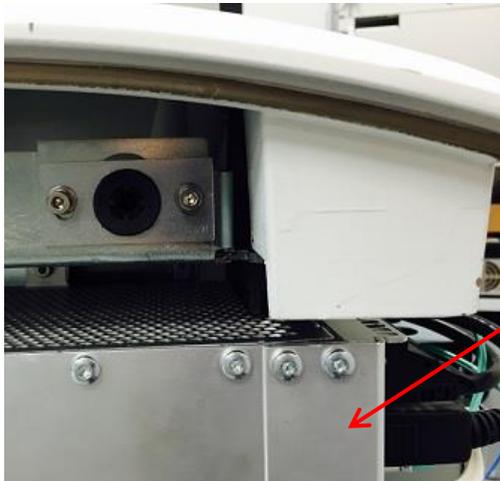


Figure 69: Cooling Fan 1 Right Side View

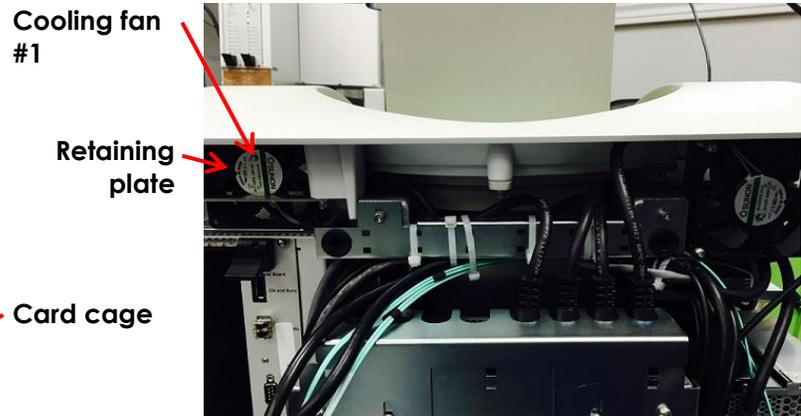


Figure 70: Cooling Fan 1 Rear View

To remove DC fan # 1:

1. Remove the front panel, the front insert panel, the rear panel and the right side panel from the ExactVu system cart.
2. Remove the card cage as described in section 8.3 on page 127.
3. Disconnect the power cable for the fan.
4. Using the long-handled 3 mm hex driver, remove the two hex screws, washers and lock washers securing the fan, accessing them from towards the rear of the ExactVu system cart (refer to Figure 69).
5. Carefully pull out the fan (including the bracket) towards the right side of the ExactVu system cart and place it on a flat surface.
6. Remove the two hex screws to remove the fan from the bracket.
7. Service the fan.
8. Replace the serviced fan or insert a new fan.

To insert DC fan # 1:

1. Attach the fan to the bracket using two 3 mm hex screws.
2. Slide the bracket onto the guide rail so that it aligns with the mounting hold on the top panel.
3. Using the long-handled 3 mm hex driver, replace and tighten the two screws, washers and lock washers to secure the bracket to the top panel.
4. Connect one of the connectors from power cable PN 6497.
5. Replace the card cage as described in section 8.3 on page 127.
6. If no further components are to be serviced, replace the right side panel the rear panel.
7. Connect the ExactVu system's power cable to the wall outlet.

8. Switch the main power switch for the ExactVu system to the **ON** position.
9. Document the appropriate records about the fan service performed.
10. Test the fan as described in Chapter 4, section 1.7.2 on page 148.

7.1.8.3 Performing Service to DC Fan # 2

Required Tools:

- Long-handled 3 mm hex driver

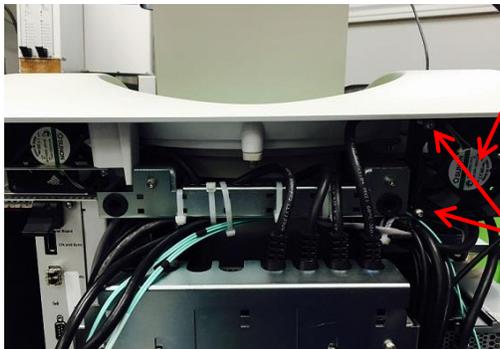


Figure 71: Cooling Fan 2 Rear View

Cooling fan 2

Remove four screws (two not pictured)

Power cable bundle

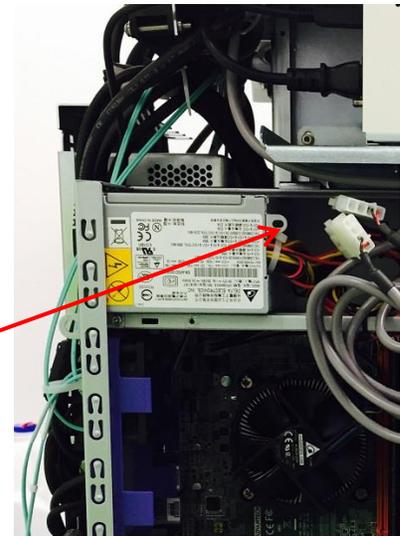


Figure 72: Cooling Fan 2 Left Side View

To remove DC fan # 2:

1. Remove the rear panel and the left side panel from the ExactVu system cart.
2. Disconnect the power cable bundle for the fan (refer to Figure 72).
3. Use the 3 mm hex driver to remove the four screws, washers and lock washers securing the fan to the fan bracket.
4. Carefully pull out the fan towards the rear of the ExactVu system cart and place it on a flat surface.
5. Service the fan.
6. Replace the serviced fan or insert a new fan.

To insert DC fan # 2:

1. Carefully slide the fan into position above the computer unit.
2. Using the 3 mm hex driver, replace and tighten the four screws located at the back of the ExactVu system cart.
3. Connect the power cable for the fan (PN 6497).
4. If no further components are to be serviced, replace the left side panel the rear panel.
5. Connect the ExactVu system's power cable to the wall outlet.
6. Switch the main power switch for the ExactVu system to the **ON** position.

7. Document the appropriate records about the fan service performed.
8. Test the fan as described in Chapter 4, section 1.7.2 on page 148.

7.1.9 Servicing the Panels of the ExactVu System Cart

7.1.9.1 Overview

Prior to servicing the panels, disconnect all transducers from the ExactVu system. To service the panels, they must be removed from the ExactVu system cart. The front or rear panel must be removed before a side panel may be removed. The front insert panel may only be removed after the front panel is removed.

7.1.9.2 Performing Service

To service the panels:

1. Remove the applicable panel(s) as described in section 5 on page 76.
2. Service the applicable panel(s).
3. Replace the applicable panel(s) as described in section 5.4 on page 78.
4. Document the appropriate records about the service performed for the panel(s).
5. Test the panel(s) as described in Chapter 4, section 1.11 on page 150.

7.1.10 Resetting the Position References for the Lift Column Control Box

7.1.10.1 Overview

If the lift column stops earlier than its expected limit when driving up, it may be caused by the lift column's position references being out of synch with normal values. It may be corrected by re-synching the lift column position references in the lift column control box. Re-synching is required, even when a new column control box is installed.

If the lift column is unresponsive or if a beeping sound occurs when pressing the button, it may be caused by a position feedback error.

7.1.10.2 Performing Service

To re-synch the position references in the lift column control box with the lift column:

1. Drive the lift column down fully.
The lift column's position references become known to the lift column control box.
2. Drive the lift column up fully.
The lift column should travel upwards to reach its upper limit. Its travel should not stop early.

To correct the position feedback error when the lift column control box is unresponsive:

1. Press and hold both the up and down buttons at the same time for 6 seconds.
The lift column emits a beep pattern.
2. Drive the lift column down fully to the bottom point of travel.

3. The lift column should operate normally. If it doesn't, perform step 1 and step 2 one or two more times.
4. When the lift column is operating normally, test the lift column as described in Chapter 4, section 1.5 on page 146.

If the lift column continues to be unresponsive or does not complete its full drive following these procedures, off-site servicing is required for the lift column.

7.2 Servicing the HDMI Splitter (ExactVu 2.6 Hardware Versions only)

7.2.1 Overview

The HDMI Splitter located on top of the computer, behind the printer and can be reached after removal of the rear panel of the system.

7.2.2 Performing Service

Required Tools:

- Phillips #1 screwdriver

To remove the HDMI Splitter:

1. Remove the rear panel from the ExactVu system cart.
2. Disconnect cables from HDMI Splitter (refer to Figure 73)
 - HDMI Splitter power cable (PN 6969)
 - Display Port to HDMI adapter cable (PN 6932)
 - HDMI Mount with Cable (PN 6900 or 7186)
 - Main monitor video, HDMI cable (PN 6947)

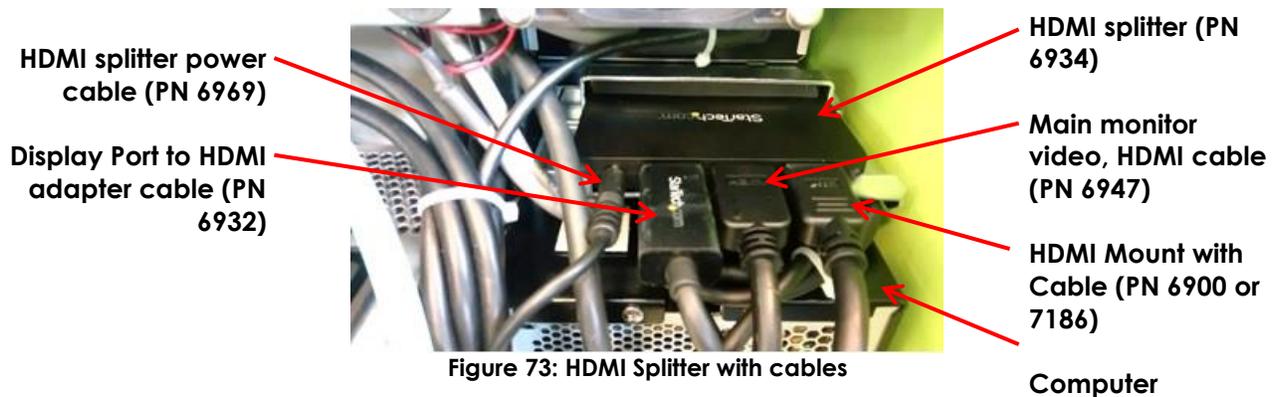


Figure 73: HDMI Splitter with cables

3. Lift the HDMI Splitter as shown on Figure 74 and remove it from the system.

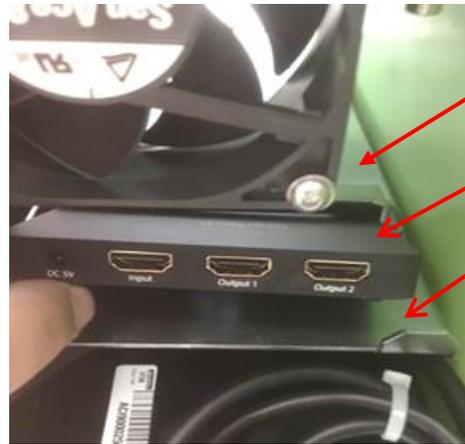


Figure 74: Removing HDMI Splitter

HDMI splitter clamp
(PN 6926)

HDMI splitter (PN 6934)

HDMI splitter mount
(PN 6907), front
support

To insert the new HDMI Splitter:

1. Place (push in) the HDMI Splitter under Splitter Clamp (PN 6926). HDMI splitter should fit tightly under the clamp and behind Splitter Mount front support (PN 6907) (refer to Figure 74).
2. Connect the following cables to the HDMI Splitter (refer to Figure 73)
 - HDMI Splitter power cable (PN 6969)
 - Display Port to HDMI adapter cable (PN 6932)
 - HDMI Mount with Cable (PN 6900 or 7186)
 - Main monitor video, HDMI cable (PN 6947)
3. Be sure that the Display Port to HDMI adapter cable (PN 6932) is routed as shown in Figure 75.

CAUTION

EN-C57



Improper routing of the Display Port to HDMI adapter cable (PN 6932) may lead to EMC issues.

4. Twist the cable as shown in Figure 76, tie it and put it under the Splitter. Install a cable tie mount on right side of computer and attach the Display Port to HDMI adapter cable (PN 6932) to the cable tie as shown in Figure 75.



Figure 75: Routing Display Port to HDMI Adapter Cable



Figure 76: Display Port to HDMI Adapter Cable

5. Test the second monitor output as described in Chapter 4, Section 1.8 on page 148.

7.3 Servicing the Second Monitor Output (ExactVu 2.6/2.9 Hardware Versions only)

7.3.1 Overview

The second monitor output located on the IO Plate at the bottom rear of the ExactVu system cart. The IO plate must be removed from the cart to perform service to the second monitor output.

7.3.2 Performing Service

Required Tools:

- 2.5mm hex driver
- #4-40 Nut Driver
- #1 Philips screwdriver

To remove the I/O plate and service the second monitor output:

1. Using a 2.5 mm hex driver, remove the screws securing the *I/O Plate assembly*.



Figure 77: Screws Securing IO Plate Assembly

2. Remove the two screws securing the *HDMI Mount with Cable* to the *I/O plate* as shown in Figure 79.



Figure 78: HDMI Mount with Cable

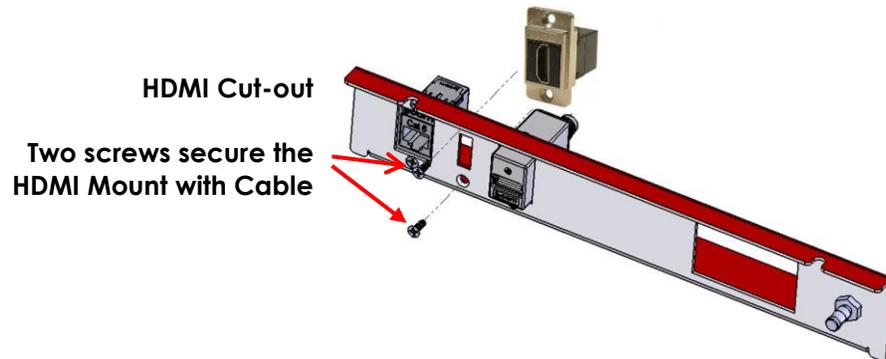


Figure 79: HDMI Cut-out on I/O Plate

3. Remove the HDMI Mount with Cable assembly from the system.
4. Service the HDMI Mount with Cable assembly.
5. Replace the serviced HDMI Mount with Cable assembly or insert a new HDMI Mount with Cable assembly.

To insert the new second monitor output:

1. Align the *HDMI Mount with Cable* assembly to the HDMI cut-out on the I/O Plate with the “L-com” label pointing up.
2. Using the Phillips # 1 screwdriver, replace the screws securing the HDMI Mount with Cable assembly to the I/O plate.
3. Using a 2.5 mm hex driver, replace the screws securing the *I/O Plate assembly* to the system.
4. Test the second monitor output as described in Chapter 4, Section 1.8 on page 148.

7.4 Servicing the Foot Pedal (if equipped)

7.4.1 Overview

The foot pedal is connected to the USB port on I/O panel at rear of the system cart.

7.4.2 Performing Service

To change the foot pedal:

1. Switch the main power switch on the bottom rear of the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.

3. Disconnect the foot pedal from USB port.
4. Connect the new foot pedal.
5. Test the foot pedal as described in Chapter 4, Section 1.9 on page 149.

7.5 Servicing the Channel Boards

7.5.1 Overview

The channel boards are held in the *card cage* and are accessed by removing the rear panel.

The two channel boards fit into two designated card cage slots, with channel board 1 on the right, and channel board 2 on the left (when viewing the channel boards from the back of the ExactVu system cart.)

For ExactVu 2.6/2.9 hardware versions, the serial numbers of the channel boards are stored on the flash memory (i.e., EEPROM) of each board and reported in the message log.

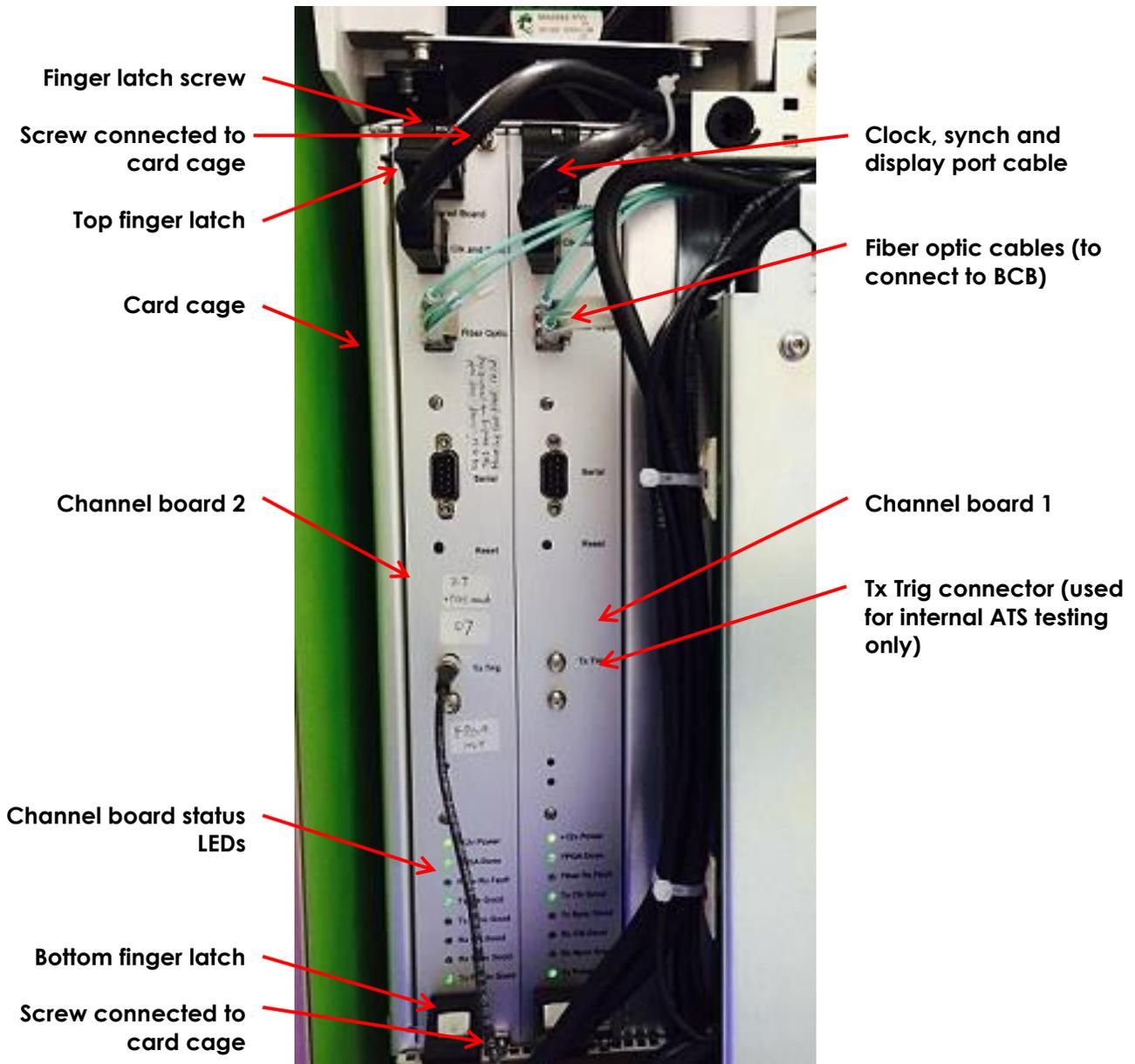


Figure 80: Channel Boards

7.5.2 Performing Service

Required Tools:

- Phillips #1 screwdriver
- ESD wrist strap
- static bag or static mat



Regarding compatibility, the correct FPGA version indicated in Table 1 on page 6 must be used when configuring the channel board and beamformer control board in the ExactVu 2.5 or ExactVu 2.6/2.9 version of the hardware.

To remove the channel board:

1. Prepare a static bag or mat for holding the channel board after it is removed from the card cage.
2. Switch the main power switch for the ExactVu system to the **OFF** position.
3. Unplug the ExactVu system's power cable from the wall outlet.
4. Remove the rear panel of the ExactVu system cart.
5. Label each *fiber optic cables* (PN 6046) and the *clock, synch and display port cable* (PN 6048) (to facilitate reconnecting them to their original connection) and then disconnect each cable.
6. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
7. Use a Phillips # 1 screwdriver to remove the screws securing the top finger latch and the bottom finger latch.
8. Use a Phillips # 1 screwdriver to remove the top and bottom screws securing the channel board to the card cage.
9. Press the top finger latch up and the bottom finger latch down. Carefully pull out the channel board along the guide rail and remove it from the cage.
10. Place the channel board inside the static bag or on the static mat.
11. Service the channel board.
12. Replace the serviced channel board or insert a new channel board.

To insert a channel board:

1. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
2. Hold the top finger latch of the channel board up and the bottom finger latch down.
3. Carefully slide the channel board onto the guide rail, and push it all the way in so that it is inserted in the connector on the *backplane assembly*. (Note that the backplane is also called *transducer switch board* in this manual.)
4. Release the top and bottom finger latches.
The top and bottom finger latches are in their locked position.
5. Using the Phillips # 1 screwdriver, replace the screws securing the channel board to the card cage.
6. Using the Phillips # 1 screwdriver, replace the screws for the top and bottom finger latch.
7. Connect the following cables:
 - Two *fiber optic cables* (PN 6046)
 - Two *clock, synch and display port cables* (PN 6048)

8. If no further components are to be serviced, replace the rear panel.
9. Connect the ExactVu system's power cable to the wall outlet.
10. Switch the main power switch for the ExactVu system to the **ON** position.
11. Document the appropriate records about the channel board service performed.
12. Test the channel board as described in Chapter 4, section 1.6.2 on page 147.

7.6 Servicing the Beamformer Control Board

7.6.1 Overview

The beamformer control board (BCB) is located on the left side of the ExactVu system cart, and is contained in the computer unit sub-assembly. It is accessed by removing the left side panel as well as the side panel of the computer unit.

For ExactVu 2.6/2.9 hardware versions, the serial number of the beamformer control board is stored on the flash memory (i.e., EEPROM) of the board and reported in the software log.



Figure 81: BCB Press Plate

Press plate

Beamformer
control board
(BCB)



Figure 82: Beamformer Control Board (BCB)

7.6.2 Performing Service

Required Tools:

- Phillips #2 screwdriver
- 2.5 mm hex driver
- ESD wrist strap
- static bag or static mat

To remove the BCB:

1. Prepare a static bag or mat for holding the BCB after it is removed.
2. Switch the main power switch for the ExactVu system to the **OFF** position.
3. Unplug the ExactVu system's power cable from the wall outlet.
4. Remove the left side panel from the ExactVu system cart.
5. Label the following cables from the back of the BCB (to facilitate reconnecting them to their original connection) and then disconnect each cable.
 - Two fiber optic cables (PN 6046)
 - Two clock, synch and display port cables (PN 6048)

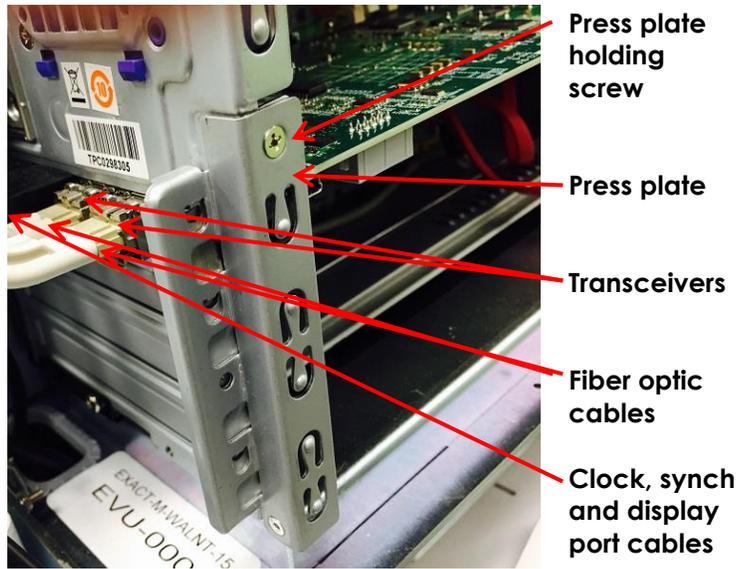


Figure 83: BCB Press Plate

6. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
7. Flip the latch on each fiber optic transceiver to its *UP* position and pull out the transceiver (refer to Figure 84).

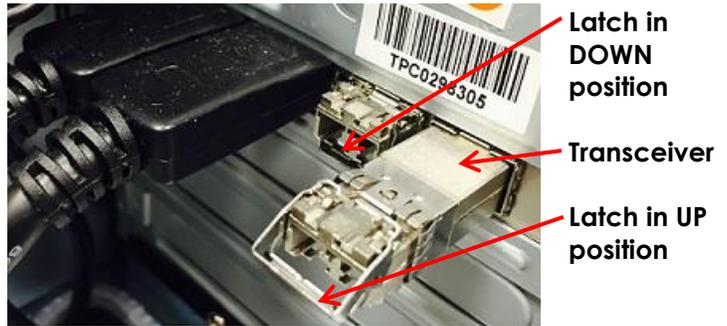


Figure 84: Fiber Optic Transceiver

8. Place the fiber optic transceivers in the static bag or on the static mat.
9. Use the Phillips # 2 screwdriver to remove the press plate holding screw (refer to Figure 83).
10. Pull the top of the press plate away from the BCB (the bottom stays connected).
11. For ExactVu 2.5 hardware versions, using the 2.5 mm hex driver, remove the two screws, washers and lock washers securing the right side of the BCB to the computer unit (refer to Figure 85).

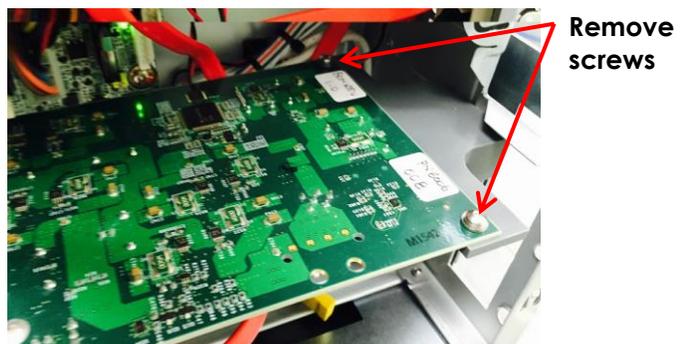


Figure 85: Screws holding BCB

12. Carefully pull out the BCB along the guide rail and remove it from the cage.
13. Place the BCB inside the static bag or on the static mat.
14. Service the BCB.
15. Replace the serviced BCB or insert a new BCB.

To insert a BCB:

1. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
2. Carefully slide the BCB onto the guide rail, and push it all the way in.
3. For ExactVu 2.5 hardware versions, using the 2.5 mm hex driver, replace and tighten two 2.5 mm hex screws, 2.5 mm washers and lock washers securing the BCB to the computer unit.
4. Flip up the press plate and secure it using the Phillips # 2 screwdriver to replace and tighten the press plate holding screw.
5. Carefully push each fiber optic *transceiver* into its slot, and flip the latch to its *DOWN position*.
6. Connect the following cables:
 - Two fiber optic cables (PN 6046)
 - Two clock, synch and display port cables (PN 6048)
7. If no further components are to be serviced, replace the left side panel.
8. Connect the ExactVu system's power cable to the wall outlet.
9. Switch the main power switch for the ExactVu system to the **ON** position.
10. Document the appropriate records about the BCB service performed.
11. Test the BCB as described in Chapter 4, section 4 on page 154.

7.7 Servicing the Computer Unit

7.7.1 Overview

The computer unit is located on the left side of the ExactVu system cart. Connectors are located at the back of the ExactVu system cart. It is accessed by removing the rear and left side panels.

In some cases, the computer unit must be removed from the ExactVu system cart in order to service another component. This includes:

- Thermal printer
- Lift column

There are differences in cables connected the computer unit between ExactVu 2.5, ExactVu 2.6 and ExactVu 2.9 hardware versions.

7.7.1.1 ExactVu 2.5 Computer Unit Cabling

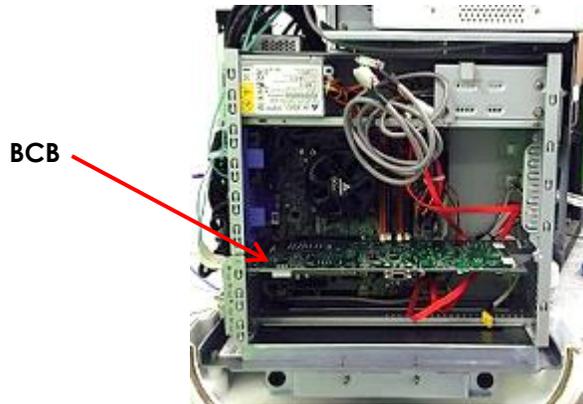


Figure 86: ExactVu Computer Unit Side View for ExactVu 2.5 Hardware Versions



Figure 87: ExactVu Computer Unit Rear View for ExactVu 2.5 Hardware Versions

Computer unit power cable

Display port cable

Touch screen video cable

Software dongle

Printer USB cable (if configured)

Control panel USB cable

USB extension cable

Ethernet extension cable

Control panel audio cable

Fiber optic cables

Clock, synch and display port cables

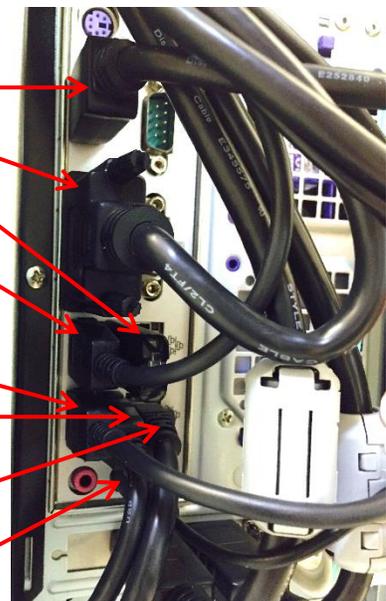
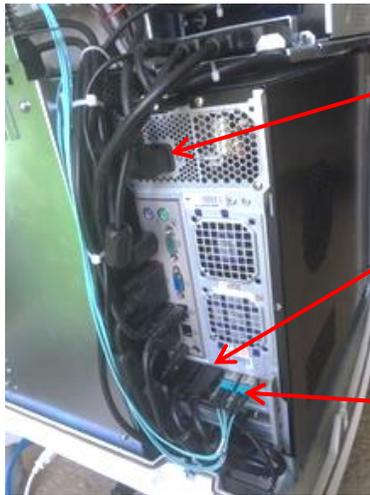


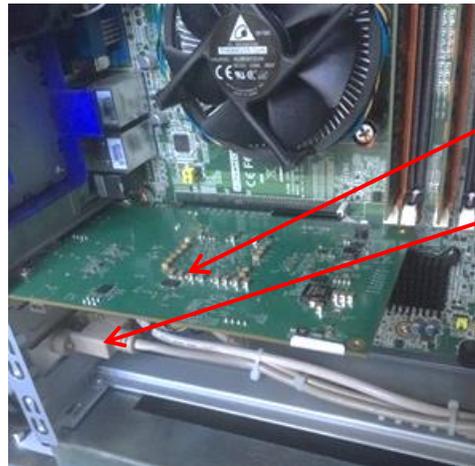
Figure 88: ExactVu Computer Unit Cable Connections for ExactVu 2.5 Hardware Versions

7.7.1.2 ExactVu 2.6 Computer Unit Cabling



- Power input
- Ethernet cable
- Clock, synch and display port cables (PN 6048)
- Fiber optic cables

Figure 89: Computer Unit Rear View for ExactVu 2.6 Hardware Versions



- BCB
- USB back plate (PN 6899)

Figure 90: Computer Unit Side View for ExactVu 2.6 Hardware Versions

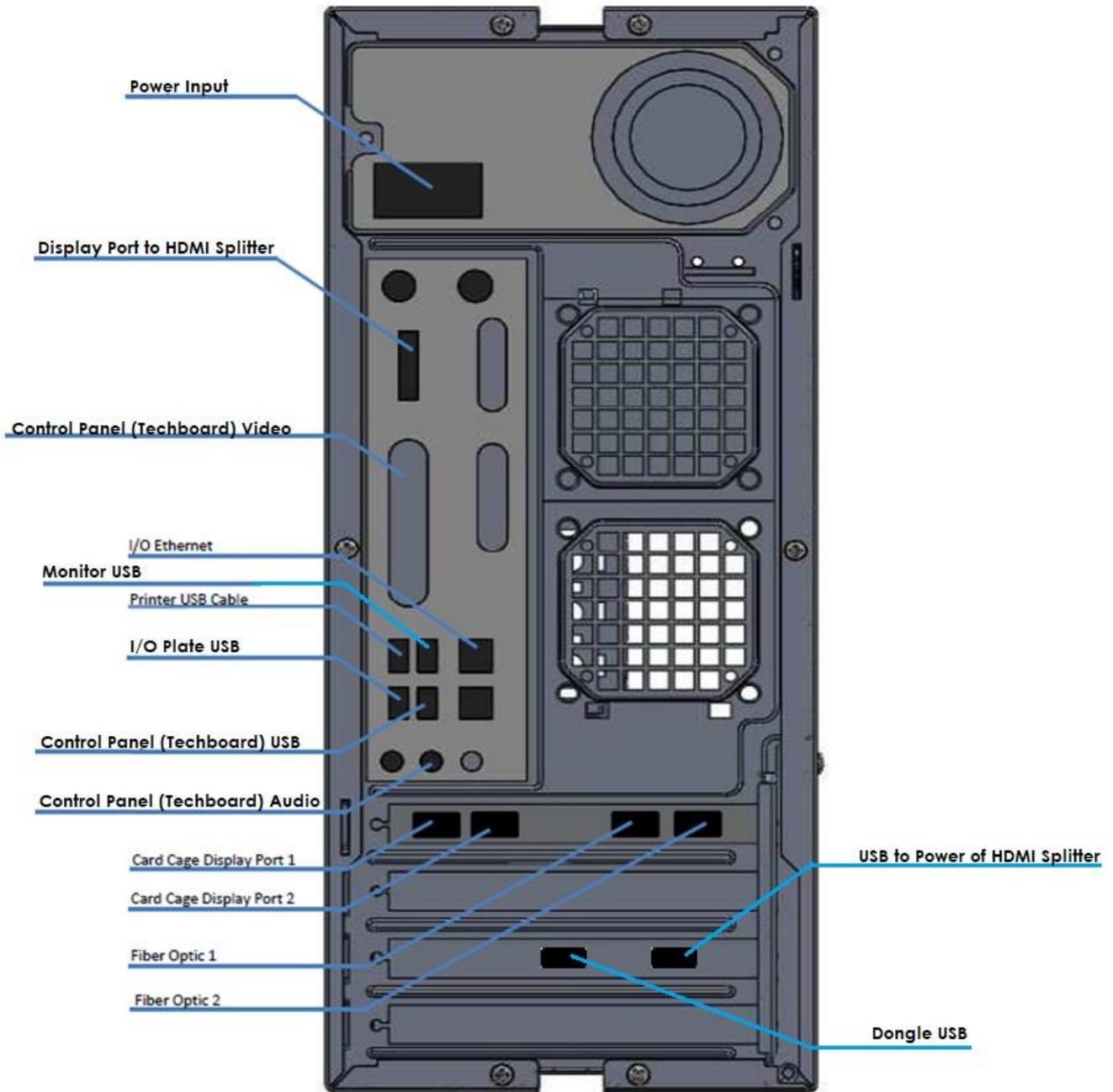


Figure 91: Computer Rear View and Cabling for ExactVu 2.6 Hardware Versions

7.7.1.3 ExactVu 2.9 Computer Unit Cabling

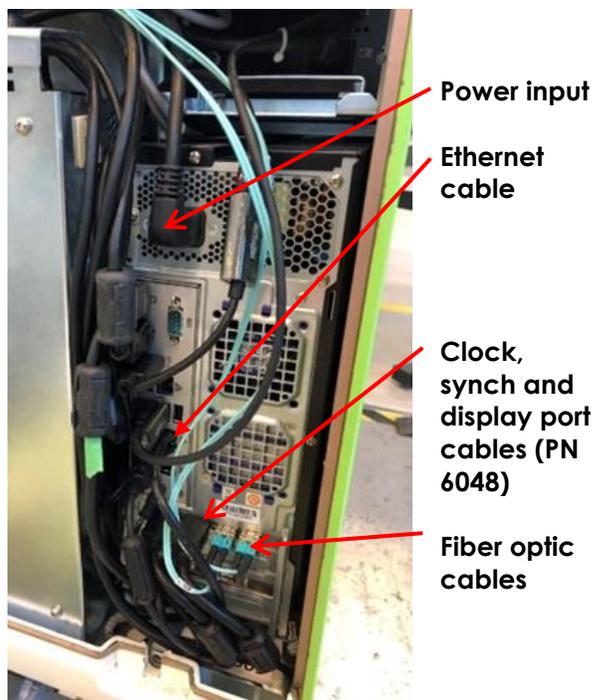


Figure 92: Computer Unit Rear View for ExactVu 2.9 Hardware Versions

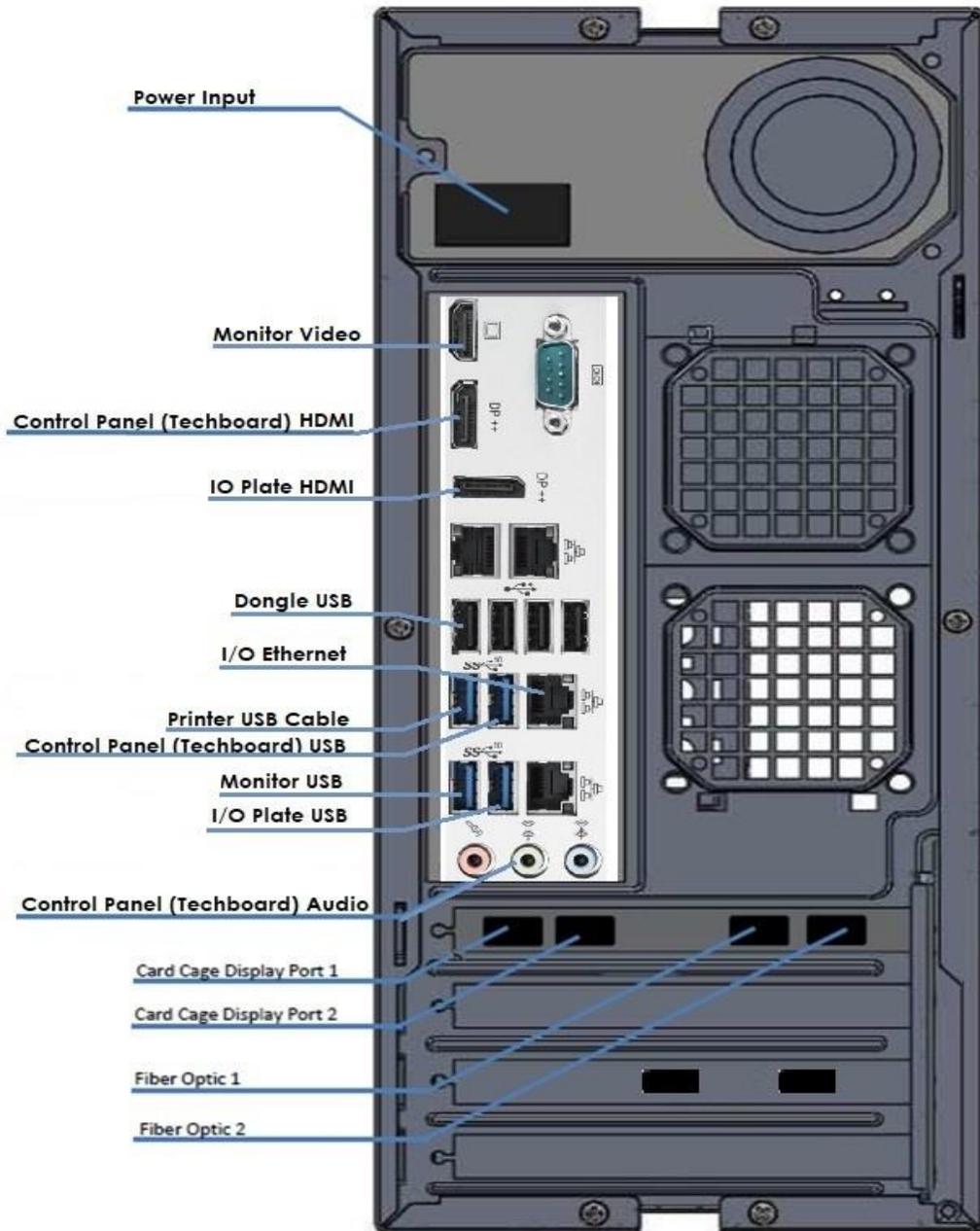


Figure 93: Computer Rear View and Cabling for ExactVu 2.9 Hardware Versions

7.7.2 Performing Service

Required Tools:

- 3 mm hex driver
- ESD wrist strap

To remove the computer unit (if required):

1. If required, export studies stored on an ExactVu system prior to removing the computer unit for service.
2. Prepare a static mat for holding the computer unit after it is removed from the chassis.
3. Switch the main power switch for the ExactVu system to the **OFF** position.
4. Unplug the ExactVu system's power cable from the wall outlet.
5. Disconnect the following cables from the back of the computer unit:
 - All hardware versions:
 - Computer unit power cable (PN 6037)
 - Touch screen video cable (PN 6034)
 - Software dongle (PN 6436)
 - Printer USB cable (PN 6102) (if the printer is part of the ExactVu system configuration)
 - Control panel USB cable (PN 6033)
 - I/O USB extension cable (PN 6036)
 - Ethernet extension cable (PN 6107)
 - Control panel audio cable (PN 6103)
 - ExactVu 2.5 and ExactVu 2.9 hardware versions only:
 - Display port cable (PN 6030)
 - ExactVu 2.9 hardware versions only:
 - Display port to HDMI adapter (PN 7191) and Touch screen video cable (PN 7187) (remove together as a cable assembly)
 - ExactVu 2.6 hardware versions only:
 - Display port to HDMI adapter cable (PN 6932)
 - HDMI Splitter power cable (PN 6969)
 - Monitor USB 3.0 Cable (PN 6933)
6. Label the following cables at the back of the BCB (to facilitate reconnecting them to their original connection) and then disconnect each:
 - Two *fiber optic cables* (PN 6046)
 - Two *clock, synch and display port cables* (PN 6048)
7. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.

8. Use a 3 mm hex driver to loosen the *computer unit mounting bracket* on the chassis (refer to Figure 94).

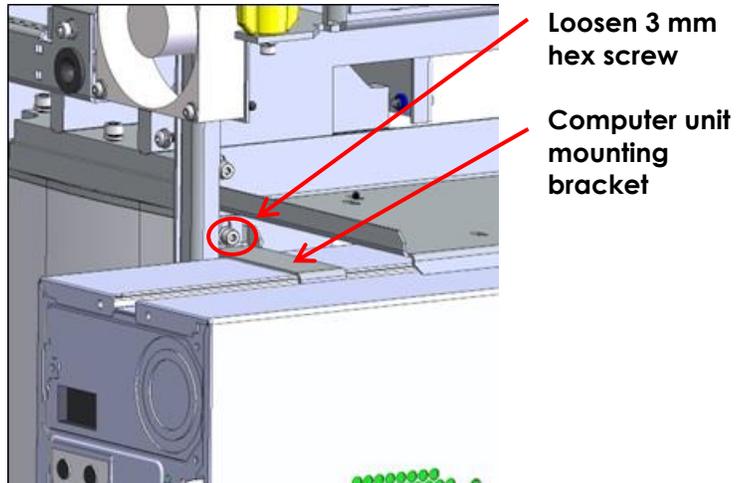


Figure 94: Computer Unit Mounting Bracket

9. Use a 3 mm hex driver to remove two hex screws, washers and lock washers located on the front of the chassis below the upper *snap-lock grommets*.
10. Carefully slide the computer unit along the guide rail towards the back of the ExactVu system cart.
11. Remove the computer unit from the guide rail.
12. Place the computer unit on the static mat.
13. Service the computer unit.
14. Replace the serviced computer unit or insert a new computer unit in the ExactVu system cart.

To insert a computer unit:

1. Put on an ESD wrist strap and connect the clip on the long end of the ESD cord to the ground pin at the bottom rear of the ExactVu system cart or to an equivalent grounding source.
2. From the back of the ExactVu system cart, place the computer unit, facing forwards, on the chassis at the back of the ExactVu system cart.
3. Using a 3 mm hex driver, adjust the screw holding securing the *computer unit mounting bracket* on the chassis so that it grips the middle rail of the computer tightly (refer to Figure 94).
4. Carefully slide the computer unit along the guide rail until it reaches the front of the chassis.
5. Using a 3 mm hex driver, replace two 3 mm hex screws, each with a 3 mm washer and lock washer to the front of the chassis below the upper *snap-lock grommets*.
6. Connect the following cables at the back of the computer unit:
 - All hardware versions:
 - Computer unit power cable (PN 6037)
 - Touch screen video cable (PN 6034)
 - Software dongle (PN 6436)
 - Printer USB cable (PN 6102) (if the printer is part of the ExactVu system configuration)
 - Control panel USB cable (PN 6033)

- I/O USB extension cable (PN 6036)
 - Ethernet extension cable (PN 6107)
 - Control panel audio cable (PN 6103)
 - ExactVu 2.5 and ExactVu 2.9 hardware versions only:
 - Display port cable (PN 6030)
 - ExactVu 2.9 hardware versions only:
 - Display port to HDMI adapter (PN 7191) (together as a cable assembly with the Touch screen video cable (PN 7187))
 - ExactVu 2.6 hardware versions only:
 - Display port to HDMI adapter cable (PN 6932)
 - HDMI Splitter power cable (PN 6969)
 - Monitor USB 3.0 Cable (PN 6933)
7. Apply Ferrites on the cables connecting to computer (close to the computer side) using the Ferrite mapping indicated:
 - PN 6194 Ferrite, 5mm, applied to Control panel USB cable (PN 6033)
 - PN 6191 Ferrite, 3-5mm, applied to Control panel audio cable (PN 6103)
 - PN 7190 Ferrite, 9mm, applied to HDMI Mount w/Cable (PN 7186)
 8. If the ferrite is too loose on HDMI cables, secure it by applying the cable ties on both ends of the ferrite.
 9. If no further components are to be serviced, replace the side panel.
 10. Connect the ExactVu system's power cable to the wall outlet.
 11. Switch the main power switch for the ExactVu system to the **ON** position.
 12. Document the appropriate records about the computer unit service performed.
 13. Test the computer unit as described in Chapter 4, section 3 on page 152.

7.8 Servicing the ExactVu Software

Updates to ExactVu software resolve problems, provide user interface improvements and introduce new features. Updates to ExactVu software are backwards compatible with all data saved in previous ExactVu software versions. Neither data nor software configurations is lost during a software upgrade.

Refer to the latest revision of the upgrade and downgrade *AP & ATP* procedure to install and uninstall upgrades and downgrades of specific ExactVu software versions.

7.9 Servicing the Transducer and Transducer Connector

Technical Support personnel will assess and document issues related to transducers and transducer connectors. Transducers that are damaged or not performing to specification must be returned to Exact Imaging for further service or rework. To assess issues related to the transducer and transducer connector refer to Chapter 4, section 8 on page 158, and perform all parts of the procedure.

7.10 Servicing the System Cabling

The system cables are used to provide power to specific components of the ExactVu system, and to provide data transfer or communication between other components. With the exception of the main AC power cable and foot pedal cable, all system cabling is located inside the ExactVu system cart.

The computer unit cables are collected in a harness at the back of the computer unit.

There are minor differences in the system cabling between each ExactVu hardware version. A complete list of the ExactVu system cables for all hardware versions on-site is provided in Appendix B. Most cables in the ExactVu system must be serviced off-site by Technical Support personnel. Those that may be serviced at a customer site are listed separately.

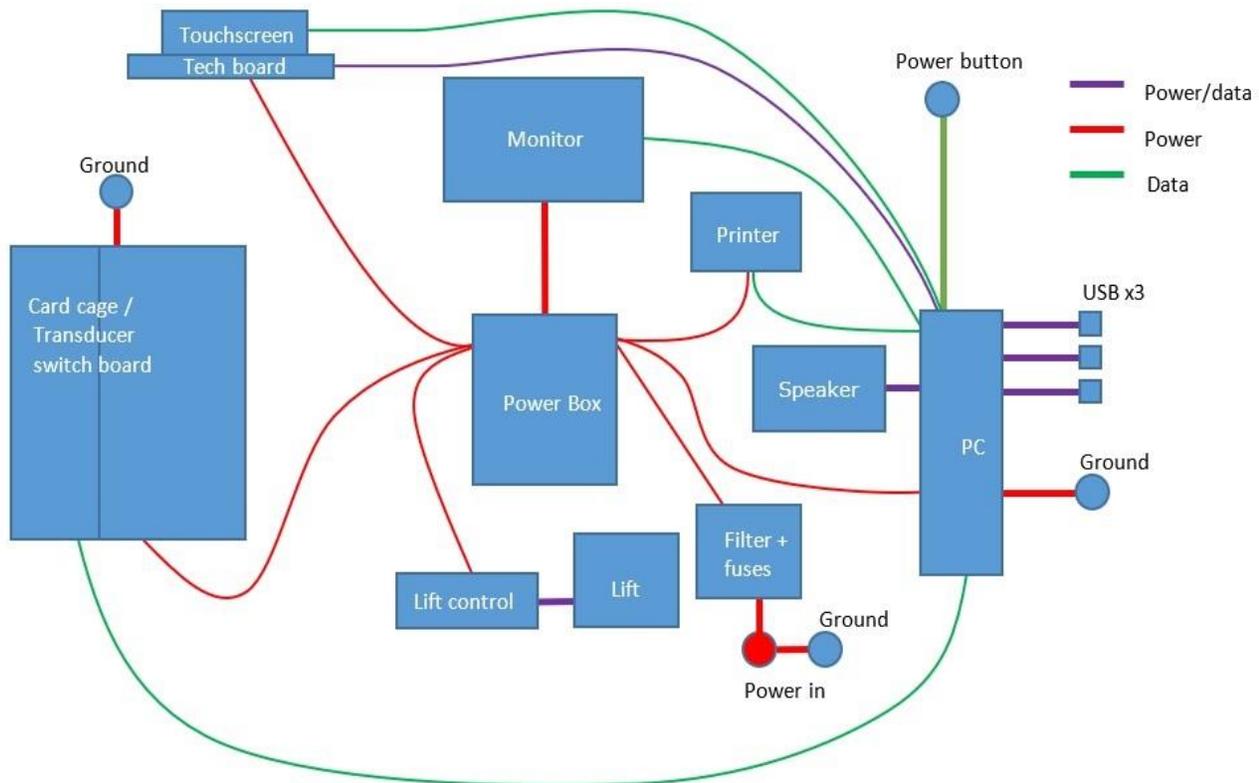


Figure 95: System Cabling for ExactVu 2.5 Hardware Versions

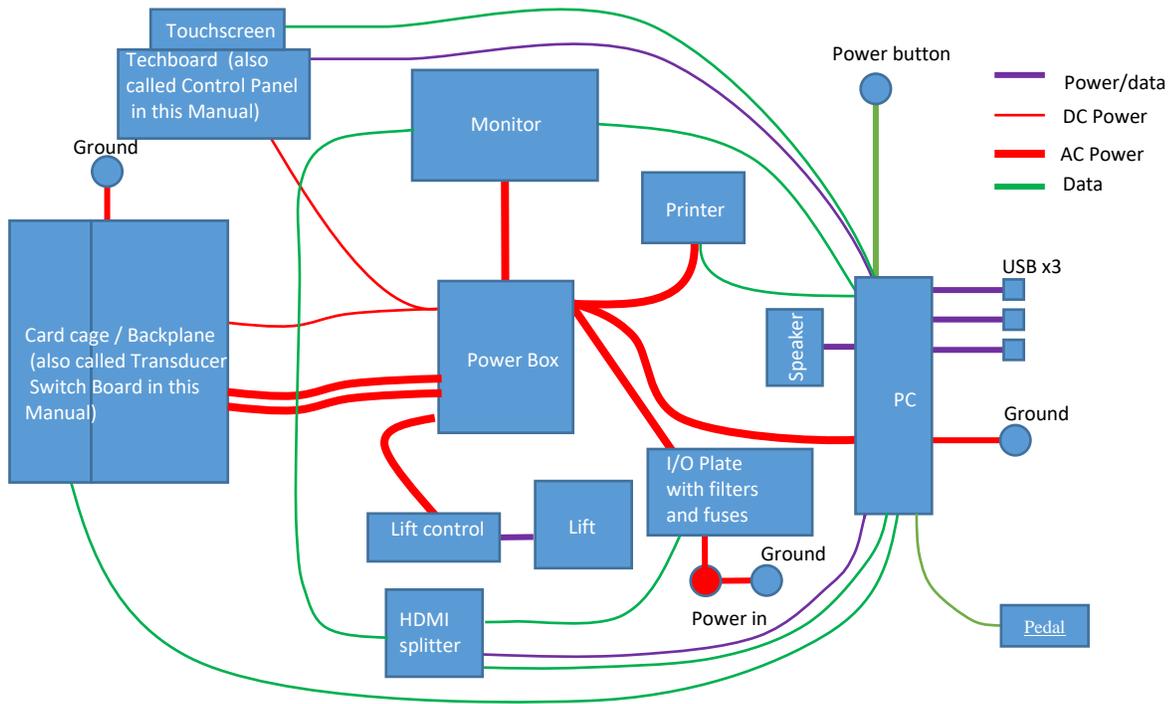


Figure 96: System Cabling for ExactVu 2.6 Hardware Versions

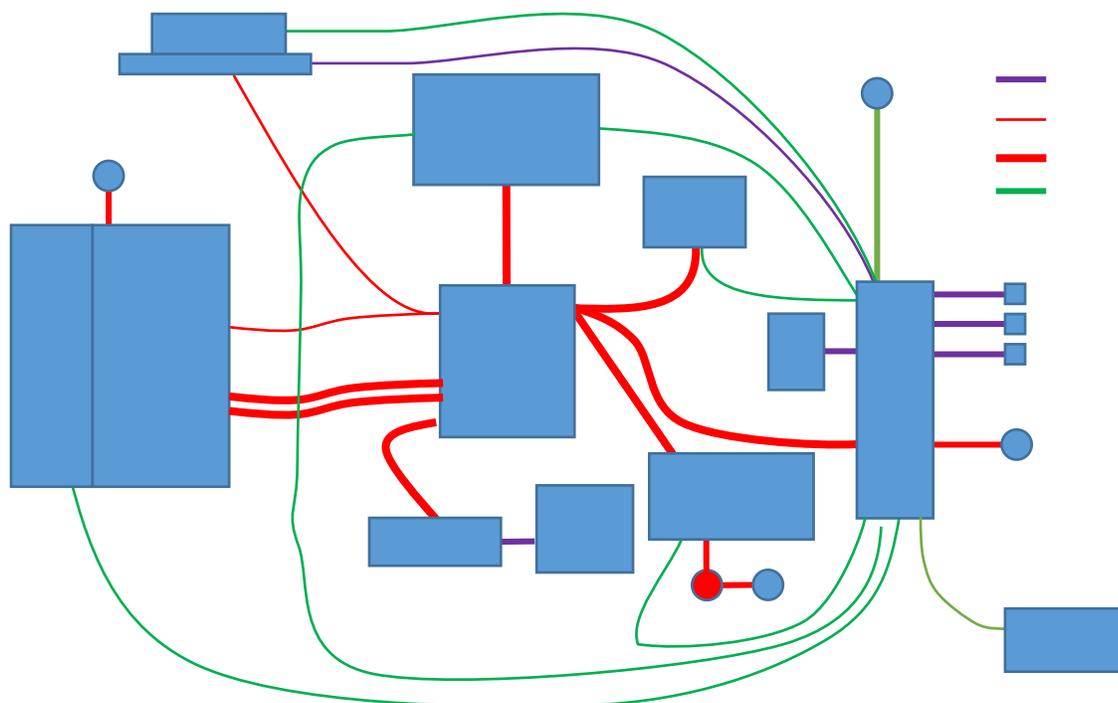


Figure 97: System Cabling for ExactVu 2.9 Hardware Versions

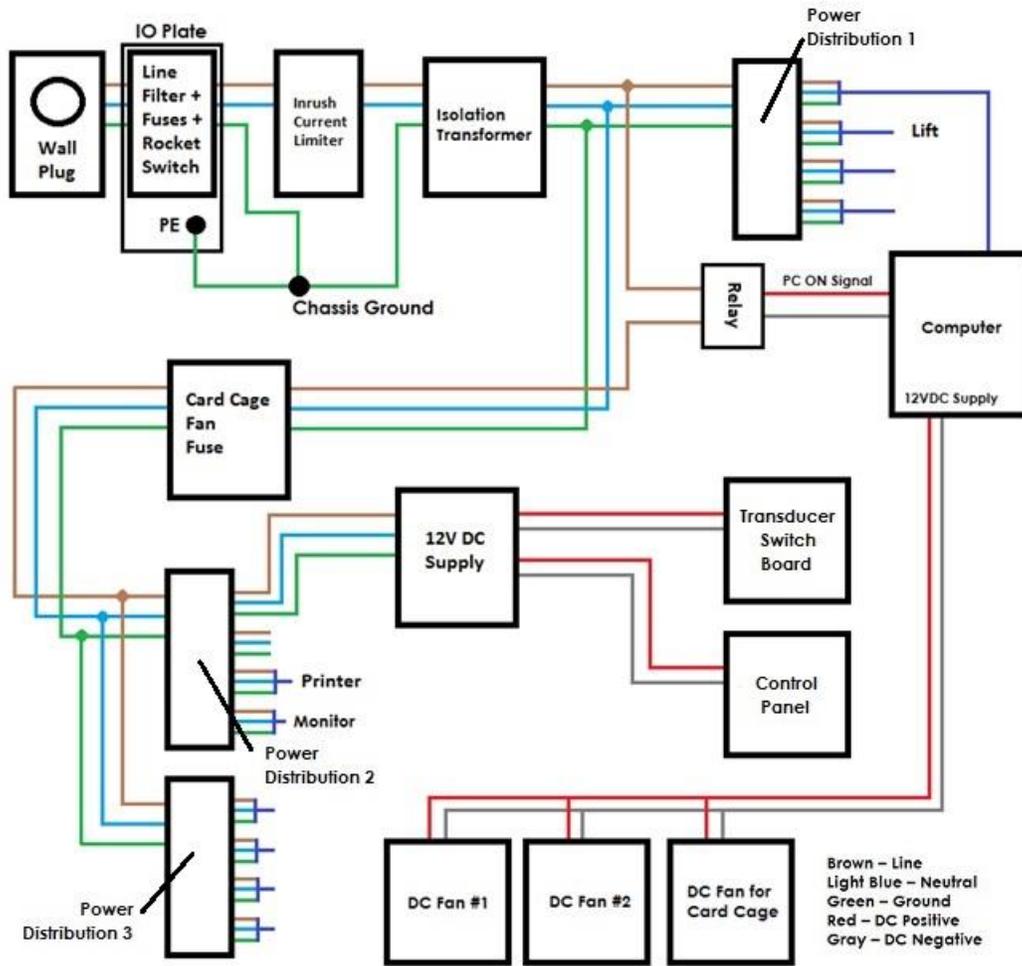


Figure 98: ExactVu Power Cabling for ExactVu 2.5 Hardware Versions

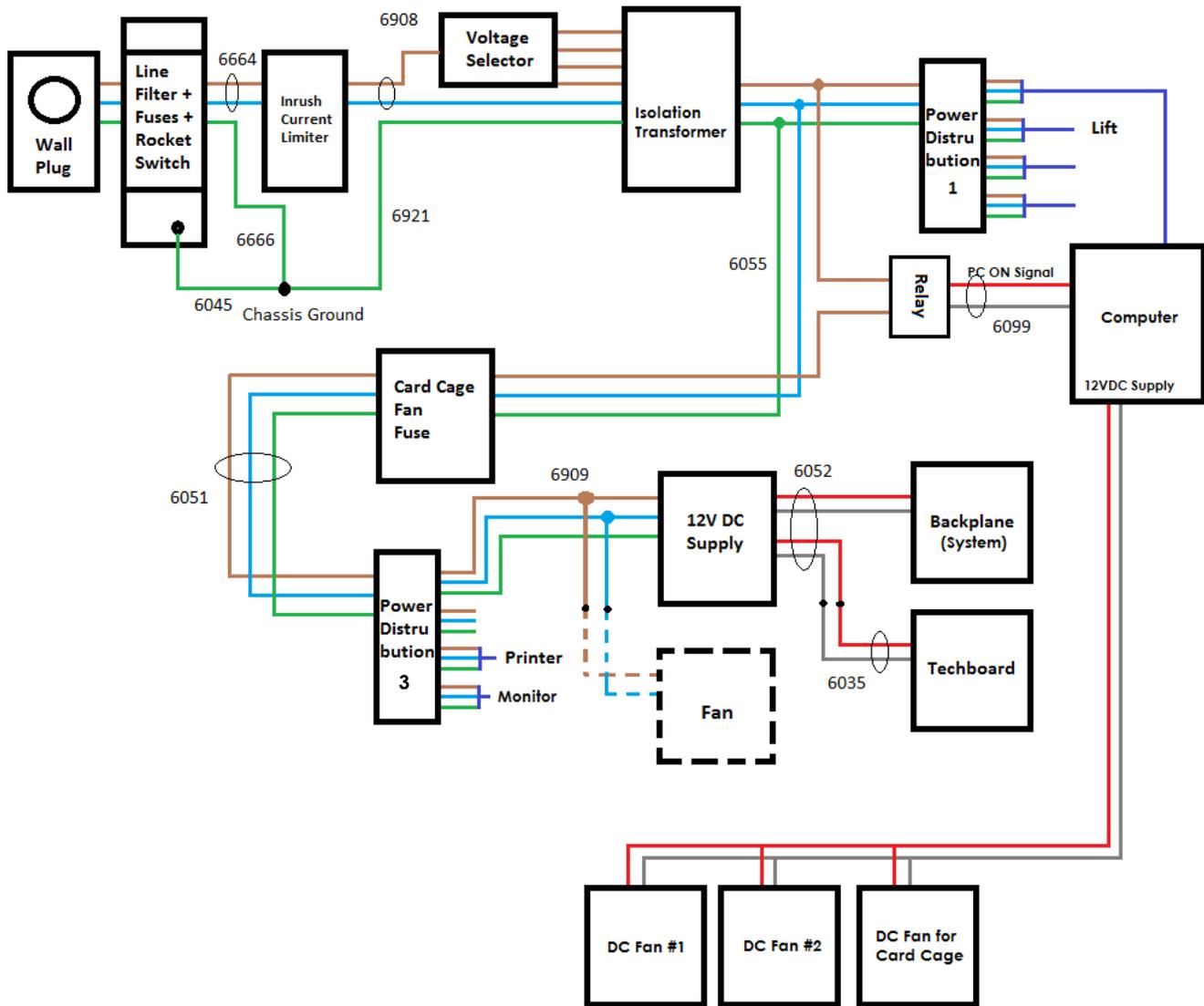


Figure 99: ExactVu Power Cabling for ExactVu 2.6 and ExactVu 2.9 Hardware Versions

To service the ExactVu system cabling:

1. Identify the cable requiring service.
2. Replace the cable requiring service with a new cable.
3. Return the affected cable to Exact Imaging for service, rework or disposal.

To disconnect cables:

- Grip the connector for the cable, and firmly pull the cable away from the component to which it is connected.

To connect cables:

- After servicing or to replace a system cable, grip the connector for the cable and firmly push the cable into the appropriate connector.

- Manage the cables using cable ties (PN 6333) and a cable tie mount (PN 6334). Ensure that the empty USB slot behind the computer is not blocked by cables. Cables shouldn't interfere with the panels when panels are closed.



Figure 100: Sample Use of Cable Ties



Figure 101: Sample Use of Cable Ties

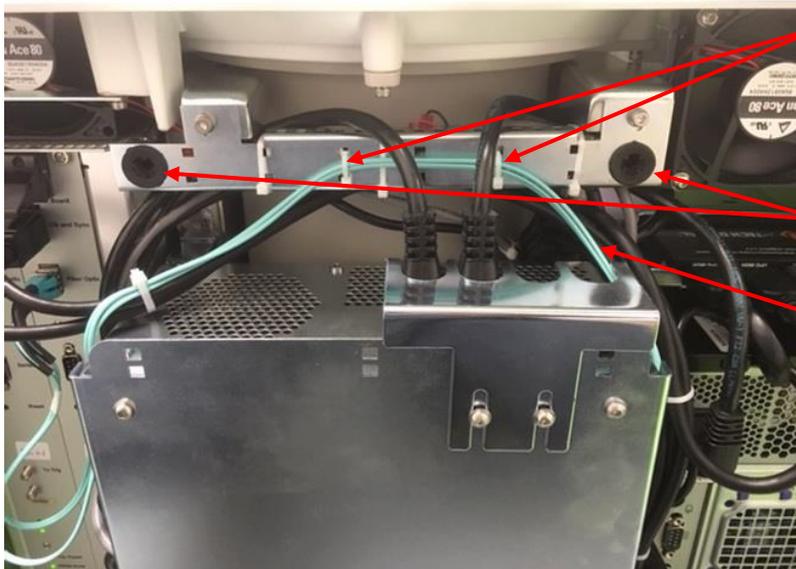


Figure 102: Sample Use of Cable Ties

Use cable ties to fix fiber optic cables, and ensure they are loose enough to not damage the cables

Snap lock grommet

Fiber optic cable

CAUTION
EN-C49



Ensure that fiber optic cables do not cross any *snap lock grommet*.

8 Off-Site Servicing

Service for components of the card cage, parts of the cooling system, the system electronics, replacement for the control column box, and servicing other parts of the ExactVu system are not performed at the customer site, due to the testing requirements that follow servicing procedures.

The following tools are necessary to perform off-site repair tasks for the ExactVu system:

- Long-handed slotted screwdriver (size 5 or 6)
- 2.5 mm, 3 mm, 4 mm, 5 mm and 6 mm hex drivers
- 4 mm hex driver (ball head)
- 7 mm, 10 mm nut driver
- # 1 Phillips screwdriver
- # 2 Phillips screwdriver
- Side cutter
- Cable ties (2.5x100 mm and 2.5x200 mm)
- Cable tie mounts
- ESD wrist strap and cord
- ESD static mat

WARNING
EN-W10



Service activities must be provided by qualified Technical Support personnel only.

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

Only those maintenance activities specified in Chapter 5, section 2 on page 182 should be performed by ExactVu operators.

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.

8.1 Returning Components to Exact Imaging

Where it is necessary to return a component or the ExactVu system to Exact Imaging, it must be packed and labeled correctly.

To package a component for returning to Exact Imaging:

1. Where applicable, follow the complete reprocessing procedure for the component being returned as indicated in the *ExactVu Operation and Safety Manual*, or in the applicable *Care, Cleaning and Use Guide* for the transducer or transperineal stepper.
2. Package any ESD-sensitive components in ESD-protective bags.
3. Package the component in the appropriate shipping container or storage case for shipping and seal it with packing tape.
4. Contact Technical Support using the contact information in Appendix D to obtain an RMA (Return Material Authorization) number. The RMA number must appear on the shipping label.
5. Send the component to Exact Imaging or as directed by the Technical Support technician.

8.2 Off-Site Servicing for the ExactVu System Cart

The parts of the ExactVu system cart that may not be serviced at a customer site are presented in this section.

The parts of the ExactVu system cart that may be serviced on-site are found in section 7.1 on page 83.

8.2.1 Replacing the Lift Column

The lift column is the innermost component in the ExactVu system cart. It is accessed by removing all panels and many components surrounding it. Refer to *Assembly Procedure for ExactVu Lift Column Sub-Assembly (PN 6220)* for information about installing the lift column in the ExactVu system cart.

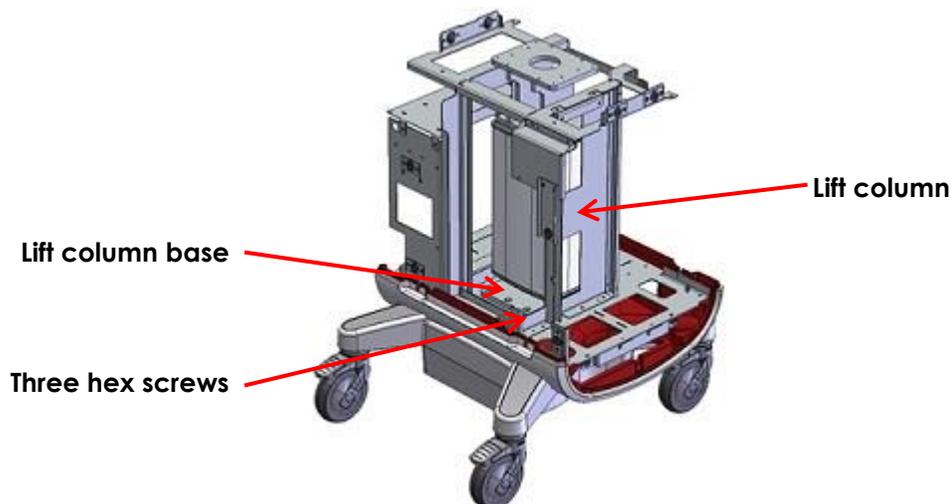


Figure 103: Lift Column

After installing a new lift column, reset the position references as described in Chapter 3, section 7.1.10 on page 99.

8.2.2 Servicing the Cooling System: DC Fan # 3

The cart has a system of cooling fans, air guides, and air vents to control the heat of the various electronics. Servicing for DC fan # 3 is described in this section.

DC fan # 1 and DC fan # 2 are attached to the top panel. These are serviced at the customer site, as described in section 7.1.8 on page 96.

8.2.2.1 Overview

DC fan # 3 is located on top of the card cage and is attached to the top of it. In order to remove DC fan # 3, the entire card cage must be removed from the ExactVu system cart, and the channel boards need to be removed from the card cage. As such, cooling fan 3 is accessed by removing the front panel, the front insert panel, the rear panel and the right side panel.

Prior to servicing any cooling fan, disconnect power from the ExactVu system.

To disconnect power from the ExactVu system:

1. Switch the main power switch for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.

CAUTION
EN-C31



When servicing any cooling fan, the fan must be placed correctly and carefully within the enclosure so that regulatory and noise requirements are met.

8.2.2.2 Performing Service to DC Fan # 3

Required Tools:

- 3 mm hex driver



Figure 104: Cooling Fan 3 Right Side View

Screw position 4 holes from right edge, 29 holes from the bottom edge (as pictured)

Power cable bundle

Cooling fan 3

Screw position (4 holes from left edge, 4 holes from bottom edge)

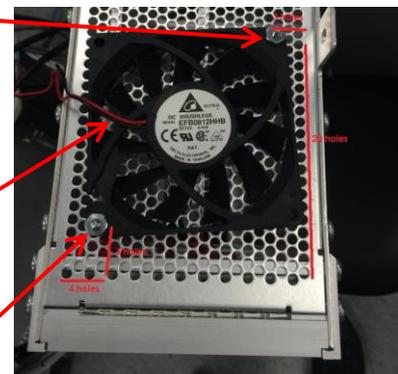


Figure 105: Cooling Fan 3 Top View

To remove DC fan # 3:

1. Remove the front panel, the front insert panel, the rear panel and the right side panel from the ExactVu system cart.
2. Remove the card cage from the ExactVu system cart as described in section 8.3 on page

127.

3. Remove both channel boards from the card cage as described in section 7.2 on page 100.
4. Disconnect the power cable for the fan.
5. Use the 3 mm hex driver to remove the two screws, washers and lock washers securing the fan to the top of the card cage.
6. Pull the fan from the top of the card cage and place it on a flat surface.
7. Return the affected fan to Exact Imaging for service, rework or disposal.
8. Insert a new fan above the card cage.

To insert DC fan # 3:

1. Carefully place the fan in position on top of the card cage over the holes described in Figure 105.
2. Use the 3 mm hex driver to replace and tighten two screws, washers and lock washers to the top of the card cage.
3. Connect the power cable for the fan.
4. Replace both channel boards from the card cage as described in section 7.2 on page 100.
5. Replace the card cage in the ExactVu system cart as described in section 8.3 on page 127.
6. If no further components are to be serviced, replace the front panel, the front insert panel, the rear panel and right side panel the rear panel.
7. Connect the ExactVu system's power cable to the wall outlet.
8. Switch the main power switch for the ExactVu system to the **ON** position.
9. Document the appropriate records about the fan service performed.
10. Test the fan as described in Chapter 4, section 1.7.2 on page 148.

8.3 Servicing the Card Cage

8.3.1 Overview

The card cage assembly includes the *card cage fans* and the *transducer switch board* as well as the card cage itself. If the card cage requires servicing, the entire card cage is serviced, and the card cage returned to a customer will include the *card cage fans* and the *transducer switch board* already installed.

8.3.2 Performing Service to the Card Cage

Required Tools:

- Long-handled 3 mm hex driver

To remove the card cage:**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.

1. Switch the main power switch for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.
3. Remove the front panel, the front insert panel, the rear panel and the right side panel from the ExactVu system cart.
4. Label the cable locations for the two AC power connectors (to facilitate reconnecting them to their original connection) and then disconnect each.
5. Disconnect the 12V DC power connector:

- Push down on the *power connector latch* (refer to Figure 106)
- Pull the *12V DC power connector* downwards and away from the transducer switch board.

6. Disconnect the *clock, synch and display port cable* (PN 6048) and *fiber optic cable* (PN 6046) from

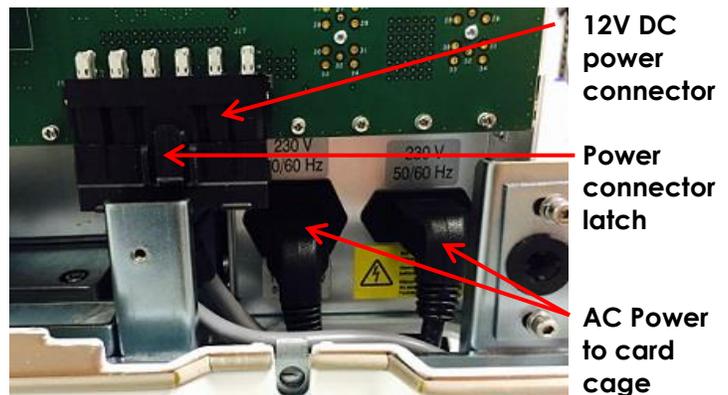


Figure 106: Front Insert Panel

- both channel boards.
7. Use the long-handled 3 mm hex driver to remove the screw securing the top of the card cage (refer to Figure 107).
 8. Use the 3 mm hex driver to remove two screws securing the bottom of the card cage (refer to Figure 107).
 9. Pull and rotate the end of the card cage nearest the front of the ExactVu system cart towards you.
 10. Pull the card cage away from the ExactVu system cart.
 11. Return the affected card cage to Exact Imaging for service, rework or disposal.
 12. Insert a new card cage in the ExactVu system cart.

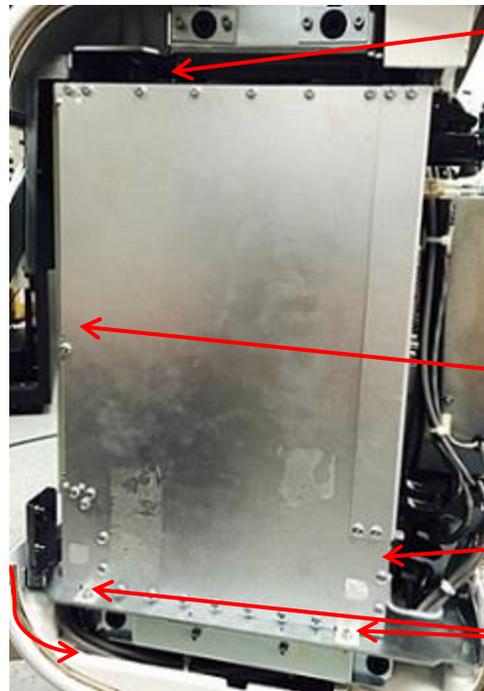


Figure 107: Card Cage

- 3 mm hex screw (remove using long-handled hex driver)
- Remove card cage by pulling this side first and rotating the card cage
- Rear of card cage
- 3 mm hex screws on front and rear mounting brackets

To replace the card cage:

1. Lift the right side of the card cage onto the chassis such that the hex screw hole on the rear mounting bracket side of the card cage is aligned with the screw hole on the chassis.
2. Rotate the front of the card cage so that both mounting brackets are centered between the notches on the chassis.
3. Use the 3 mm hex driver to tighten two screws securing the bottom of the card cage (refer to Figure 107).
4. Use the long-handled 3 mm hex driver to tighten the screw securing the top of the card cage (refer to Figure 107).
5. Connect the clock, synch and display port cable (PN 6048) and fiber optic cable (PN 6046) to each channel board.
6. Push the 12V DC power connector upwards onto the transducer switch board.
7. Pull up on the power connector latch.
8. Connect the two AC power connectors.
9. If no further components are to be serviced, replace the right side panel, front insert panel, front panel and rear panel.



Figure 108: Card Cage (from the Right Side View of the ExactVu System)

- Alignment notches (on each side of each mounting bracket)
- Rear of card cage

10. Connect the ExactVu system's power cable to the wall outlet.
11. Switch the main power switch for the ExactVu system to the **ON** position.
12. Document the appropriate records about the service performed.
13. Test the card cage as described in Chapter 4, section 9 on page 160.

8.3.3 Realigning the Card Cage

The ExactVu card cage may shift over time causing imperfect alignment of the transducer connector with the front panel. This may lead to transducer performance degradation such as erroneous reporting of non-active elements, poor Transverse Mode imaging performance or transducer recognition failure.

Realignment of the card cage is required if the gap between the connector and the front panel is uneven. This can be determined by a visual inspection.

To perform a visual inspection of the card cage alignment:

1. Check the gap between the front insert panel and the metal connector on both sides of the connector.
2. Repeat for all three connector slots.

If the gap on the left and right side are uneven, the card cage needs to be adjusted.

If the gap is even on both sides, no adjustment is required.



To realign the card cage:

1. Follow step 1 through step 8 in section 8.3.2.
2. Adjust the card cage position so that the gap between the front insert panel and the metal connector is even on both sides for all three connector slots.
3. Use the 3 mm hex driver to tighten two screws securing the bottom of the card cage. Use the long-handled 3 mm hex driver to tighten the screw securing the top of the card cage. Tighten the screws gradually and monitor the card cage positioning during tightening to ensure it remains in position.
4. Document the appropriate records about the service performed.

8.4 Servicing the Power Box

8.4.1 Overview

For ExactVu 2.6/2.9 HW versions, the power box contains the power supply unit, the isolation transformer, the *inrush current limiter (ICL)* and power distribution blocks. For ExactVu 2.5 HW versions, the ICL is located in the wheel base, and the power box contains an additional power distribution block (*power distribution block 2*).

The power box is located at the back of the ExactVu system cart. It is accessed by removing the rear panel. The power supply unit is located above the isolation transformer. Neither the power supply unit nor the isolation transformer is serviced as a separate part.

CAUTION

EN-C43



Always verify the voltages from the output of both the isolation transformer and the 12V DC power supply prior to powering the ExactVu system on. Refer to Chapter 4, section 6 on page 155.

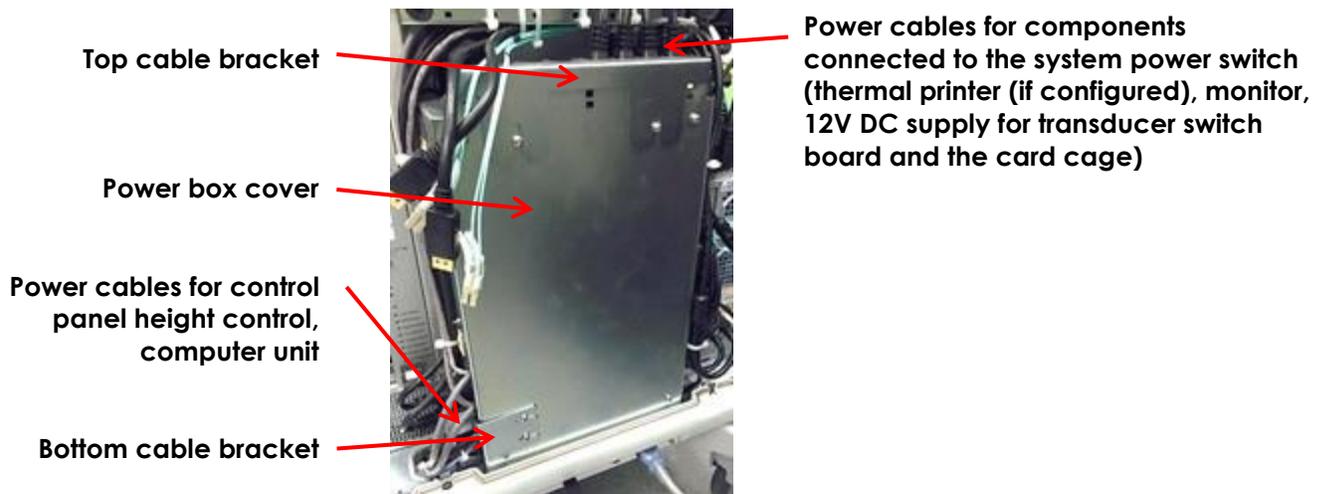


Figure 109: Power Box

8.4.2 Performing Service to the Power Box

Instructions performing service to the power box are provided separately for ExactVu 2.5 hardware versions and ExactVu 2.6/2.9 hardware versions.

8.4.2.1 Performing Service to the Power Box (ExactVu 2.5 Hardware Versions)

For ExactVu 2.6/2.9 hardware versions, refer to section 8.4.2.2.

Required Tools:

- 2.5 mm and 3 mm hex driver

To remove the power box from the ExactVu system:

1. Switch the *main power switch* for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.

3. Remove the rear panel of the ExactVu system cart as described in section 5.1 on page 77.
4. Using a 2.5 mm hex driver, remove the hex screws securing the cable brackets from the power box (refer to Figure 119).

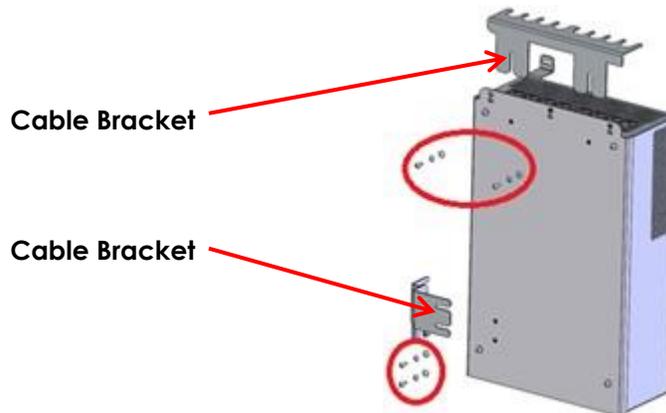


Figure 110: Cable Brackets securing the Power Box Cover

5. Disconnect all the cables connected to power distribution block 1, power distribution block 2 and power distribution block 3 (refer to Figure 111).

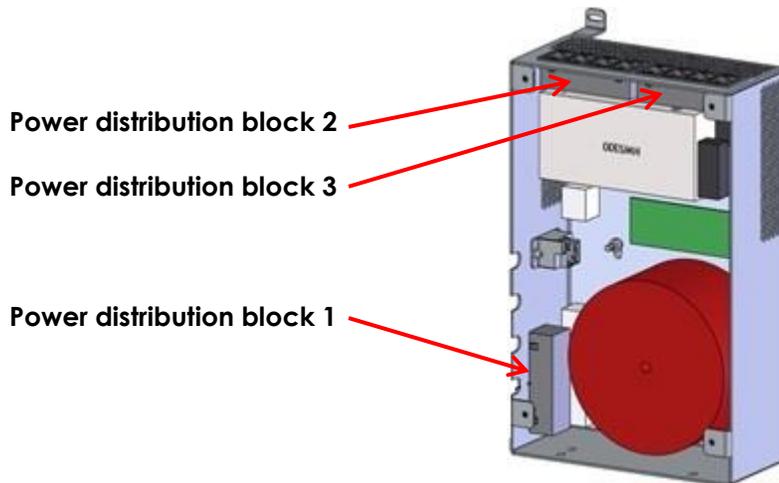


Figure 111: Power Box showing Power Distribution Blocks (internal view pictured for clarity)

6. Using a 2.5 mm hex driver, remove the four screws, washers and lock washers securing the power box cover.

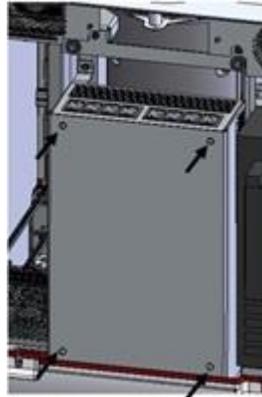


Figure 112: Power Box Cover

7. Disconnect the *relay power wires* (positive and negative) from the relay.

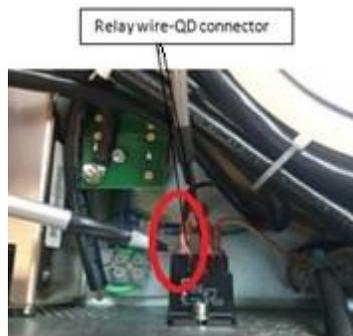


Figure 113: Relay Power Wires

8. Using a 3 mm hex driver, remove three screws attached to the power box as shown in Figure 114 and Figure 115.

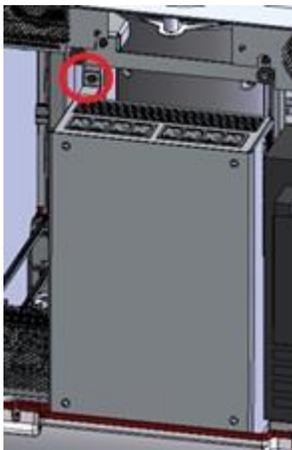


Figure 114: Upper Power Box Screw

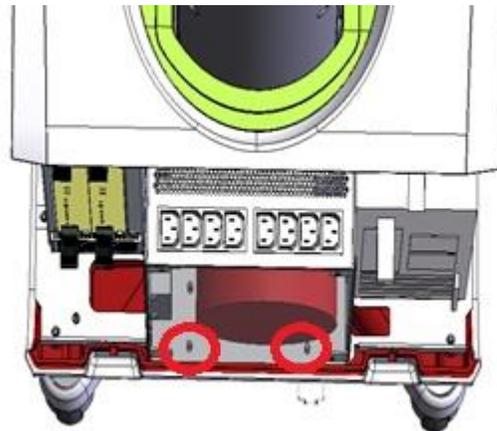


Figure 115: Lower Power Box Screws

9. Disconnect the following cables from the 12V DC power supply. (If necessary, take out the DC power supply.):

- *Control panel power cable* (PN 6035)
- *Transducer switch board power cable* (PN 6052)

10. Disconnect the QD connectors at the transformer input (line and neutral wires from the inrush current limiter (ICL)).
11. Using a 2.5 mm hex driver, remove the screws securing the *IO Plate assembly*.



Figure 116: Screws Securing IO Plate Assembly

12. Remove the line filter cable by disconnecting the ground wire from the power filter. Cut any cable tie if necessary.



Figure 117: Line Filter Cable Wires

13. Pull out the line filter cable from the opening as shown in Figure 118.

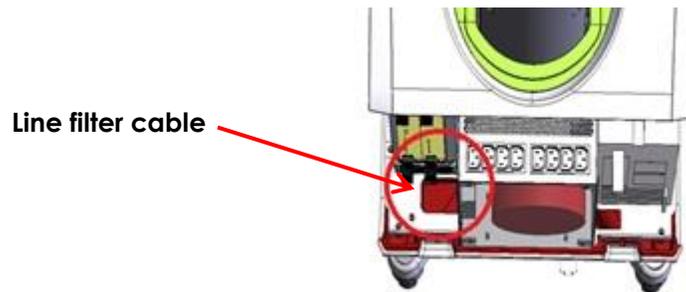


Figure 118: Line Filter Cable

14. Remove the power box from the ExactVu system.
15. Return the affected power box to Exact Imaging for service, rework or disposal.
16. Insert a new power box in the ExactVu system cart.

To replace the power box in the ExactVu system cart:

1. Place the power box in position on the ExactVu chassis.
2. Connect the *line filter cable* at the opening shown in Figure 118.
3. Connect the ground wire to the *line filter cable* in accordance with the latest revision of the *Assembly Procedure for ExactVu Main Assemblies (PN 6060)* from Exact Imaging.
4. Using a 2.5 mm hex driver, replace the hex screws to secure the *IO Plate* to the power box.
5. Connect the following cables to the 12V DC power supply. Refer to the latest revision of the *Assembly Procedure for ExactVu Power Supply Box Sub-Assembly (PN 6062)* from Exact Imaging:

- Control panel power cable (PN 6035)
 - Transducer switch board power cable (PN 6052)
6. Connect the QD connectors (line and neutral wires) from the ICL at the transformer input.
 7. Using a 3 mm hex driver, replace one screw at the top of the power box as shown in Figure 114 and two screws at the bottom of the power box as shown in Figure 115 to secure the power box in place in the ExactVu system cart.
 8. Connect the *relay power wires* (positive and negative) from the relay in accordance with the latest revision of the *Assembly Procedure for ExactVu Power Supply Box Sub-Assembly (PN 6062)* from Exact Imaging (refer to Figure 113).
 9. Using the 2.5 mm hex driver, replace and tighten four 2.5 mm hex screws, each with a 2.5 mm washer and lock washer to secure the power box cover to the power box.
 10. If no further components require service that requires the power cables to be disconnected, connect the following cables to power distribution block 2 and power distribution block 3:
 - Thermal printer power cable (PN 6101) (only if the printer is part of the ExactVu system configuration)
 - Monitor power cable (PN 6031)
 - 12V DC supply for transducer switch board and the card cage (PN 6050)
 11. Using the 2.5 mm hex driver, replace the two cable brackets to secure each to the power box cover (refer to Figure 119).
 12. Connect the following cables to power block 1 (refer to Figure 120):
 - Control panel height control (PN 6106)
 - Computer unit (PN 6037)
 13. Neaten cables:
 - Ensure cables are not loose. Use cable ties to fix them in position.
 - Feed tied cables into the cable grommets, keeping just enough cable length inside of the power box.
 14. If no further components are to be serviced, replace the rear panel of the ExactVu system cart.
 15. Connect the ExactVu system's power cable to the wall outlet.
 16. Switch the main power switch for the ExactVu system to the **ON** position.
 17. Document the appropriate records about the power box service performed.

8.4.2.2 Performing Service to the Power Box (ExactVu 2.6/2.9 Hardware Versions)

For ExactVu 2.5 hardware version, refer to section 8.4.2.1.

Required Tools:

- 2.5 mm and 3 mm hex driver

To remove the power box from the ExactVu system:

1. Switch the *main power switch* for the ExactVu system to the **OFF** position.
2. Unplug the ExactVu system's power cable from the wall outlet.

3. Remove the rear panel of the ExactVu system cart as described in section 5.1 on page 77.
4. Using a 2.5 mm hex driver, remove the hex screws securing the cable brackets from the power box (refer to Figure 119).

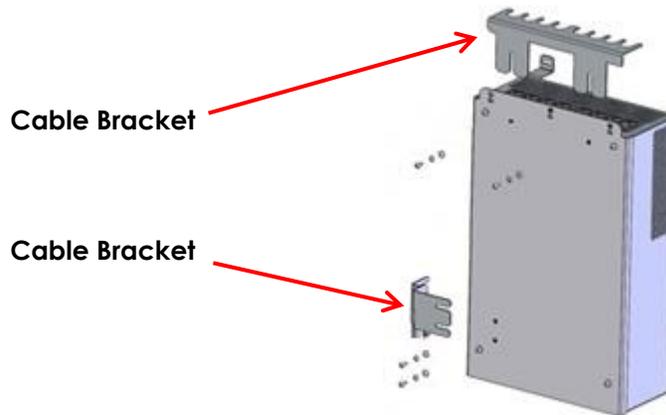


Figure 119: Cable Brackets securing the Power Box Cover

5. Disconnect all the cables connected to power distribution block 1 and power distribution block 3 (refer to Figure 120).

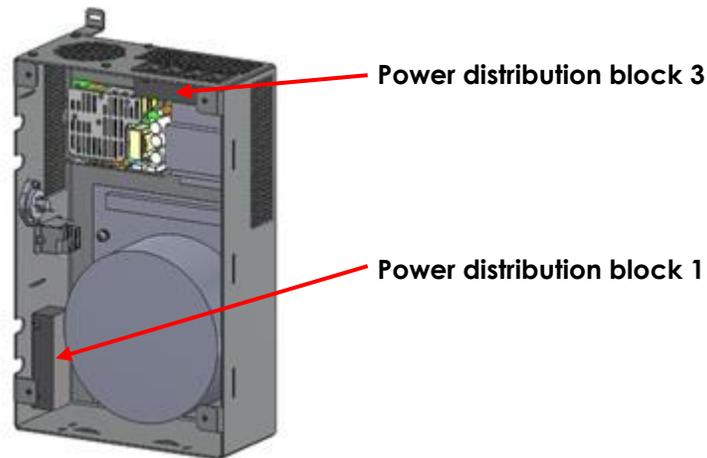


Figure 120: Power Box showing Power Distribution Blocks (internal view pictured for clarity)

6. Using a 2.5 mm hex driver, remove the four screws, washers and lock washers securing the power box cover (Figure 121).

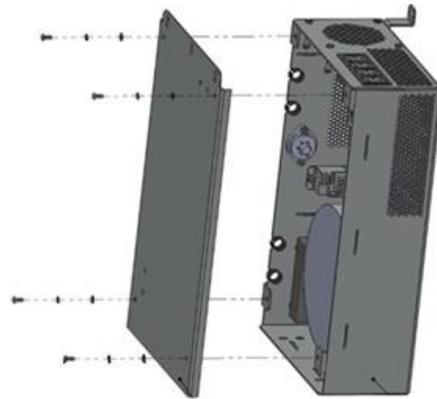


Figure 121: Power Box Cover removal

7. Disconnect the *relay control wire* from the relay.
8. Disconnect the following cables from DC power supply and transformer. (If necessary, take out the DC power supply and Power distribution block 1):
 - Transducer switch board power cable (Backplane power cable PN 6052)
 - Power module 1 power cable (PN 6055)

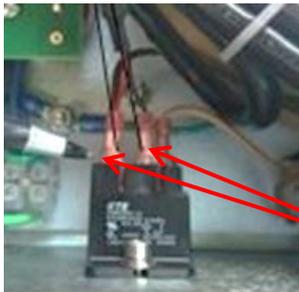
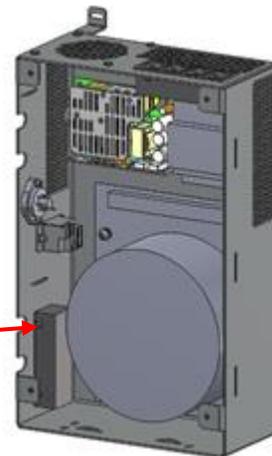


Figure 122: Relay Control Wires

Relay control wire QD Connector (PN 6099)



9. Using a 2.5 mm hex driver, remove the screws securing the *I/O Plate assembly*.

Four screws

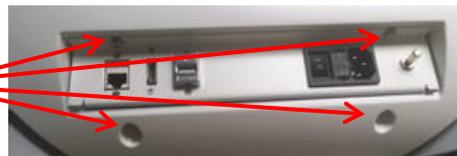


Figure 123: Screws Securing IO Plate Assembly

10. Remove the Power filter to ICL cable (PN 6664) by disconnecting wires from the power filter. Cut any cable tie if necessary.
11. Pull out the *power filter to ICL cable* (PN 6664) from the opening as shown in Figure 125.

Disconnect line, ground
and neutral wires

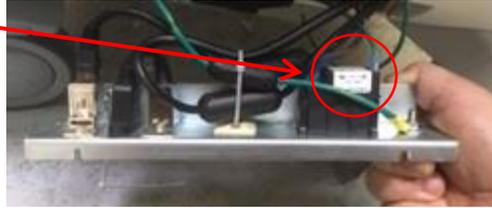


Figure 124: Line Filter Cable Wires



Power filter to ICL cable
(PN 6664)

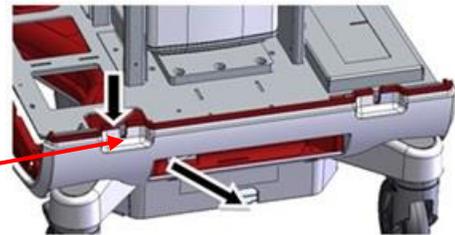


Figure 125: Line Filter Cable

- Using a 3 mm hex driver, remove three screws attached to the power box as shown in Figure 126 and Figure 127.
- Remove the power box from the ExactVu system.



Figure 126: Upper Power Box Screw

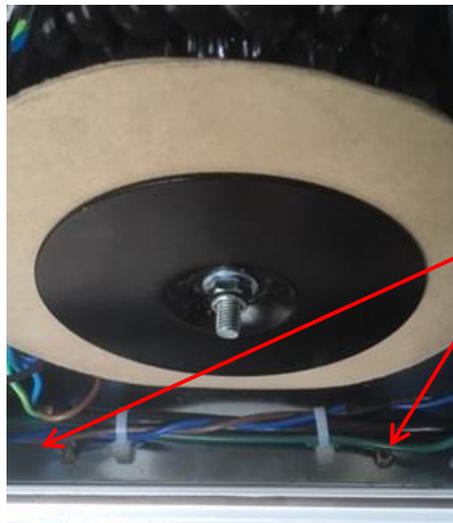


Figure 127: Lower Power Box Screws

- Return the affected power box to Exact Imaging for service, rework or disposal.

15. Insert a new power box in the ExactVu system cart.

To replace the power box in the ExactVu system cart:

1. Place the power box in position on the ExactVu chassis.
2. Route the Power filter to ICL cable (PN 6664) at the opening shown in Figure 125.
3. Connect the Power filter to ICL cable to the filter in accordance with the latest revision of the *Assembly Procedure for ExactVu Main Assemblies (PN 6060)* from Exact Imaging.
4. Using a 2.5 mm hex driver, place the hex screws to secure the *I/O Plate* to the cart (refer to Figure 123).
5. Connect the following cables to the 12V DC power supply and transformer. Refer to the latest revision of the *Assembly Procedure for ExactVu Power Supply Box Sub-Assembly (PN 6062)* from Exact Imaging:
 - Transducer switch board power cable (PN 6052)
 - Power module 1 power cable (PN 6055)
6. Using a 3 mm hex driver, replace one screw at the top of the power box as shown in Figure 126 and two screws at the bottom of the power box as shown in Figure 127 to secure the power box in place in the ExactVu system cart.
7. Connect the *Relay control wire (PN 6099)* coming from the computer to the relay in accordance with the latest revision of the *Assembly Procedure for ExactVu Power Supply Box Sub-Assembly (PN 6062)* from Exact Imaging.
8. Apply proper cable management before attaching the power box cover. Use cable ties (PN 6333) and cable tie mounts (PN 6334) to manage all internal cables and wires. Be sure there are no floating or wiggling wires or cables inside the power box.
9. Using the 2.5 mm hex driver, place and tighten four 2.5 mm hex screws, each with a 2.5 mm washer and lock washer to secure the power box cover to the power box (refer to Figure 121).
10. If no further components require service that requires the power cables to be disconnected, connect the following cables to power distribution and power distribution block 3:
 - Thermal printer power cable (PN 6101) (only if the printer is part of the ExactVu system configuration)
 - Monitor power cable (PN 6031)
11. Connect the following cables to power block 1:
 - Control panel height control (PN 6106)
 - Computer unit (PN 6037)
12. Neaten cables:
 - Ensure cables are not loose. Use cable ties to fix them in position.
 - Feed tied cables into the cable grommets, keeping just enough cable length inside of the power box.
13. Using the 2.5 mm hex driver, place and fix two cable brackets to the power box cover (refer to Figure 119).
14. If no further components are to be serviced, replace the rear panel of the ExactVu system cart.
15. Connect the ExactVu system's power cable to the wall outlet.

16. Switch the main power switch for the ExactVu system to the **ON** position.
17. Document the appropriate records about the power box service performed.

8.5 Servicing the IO Plate

IO plates that are damaged or not performing to specification will be assessed by Technical Support personnel and serviced off-site.

8.6 Servicing the Wheel Base

For circumstances in which the wheel base, the top panel, bottom panel or deck is not performing to specification, the component will be assessed by Technical Support personnel and serviced off-site.

8.7 Servicing the Transducer and Transducer Connector

Technical Support personnel will assess and document issues related to transducers and transducer connectors. Transducers that are damaged or not performing to specification must be returned to Exact Imaging for further service or rework. To assess issues related to the transducer and transducer connector refer to Chapter 4, section 8 on page 158, and perform all parts of the procedure.

If Exact Imaging has recommended adjusting the transducer connector locking screw, perform the procedure in the following sub-section.

8.7.1 Overview

The screw securing the locking arm on the transducer connector housing may loosen over time causing a loose connection of the transducer connector with the ExactVu connector port. This may lead to transducer performance degradation, such as increased detection of non-active elements or transducer recognition failure.

8.7.2 Performing an Adjustment to the Transducer Connector Locking Screw

Required Tools:

- 3 mm hex driver

To remove the power box from the ExactVu system:

1. Using a 3mm hex driver, tighten the locking arm screw in quarter-turn increments.



Be careful not to overtighten the transducer connector locking screw. Overtightening may damage the screw or connector, and cause the transducer to become inoperable.

2. Re-test the connection after each adjustment until there is no movement between the transducer connector and transducer connector slot on the ExactVu system when wiggling the connector.
3. Test the transducer as follows:
 - Connect the transducer to the ExactVu system, fully engage the lock and start scanning.

- Assess the connection by gently wiggling the connector housing and monitoring the imaging screen while imaging.
 - The transducer connector should sit snugly in the port without any movement between the transducer and the port.
 - Perform the Transducer Element Check described in Chapter 2, section 6.2.1.2 on page 38 while gently pushing the connector up, down, left and right.
4. Repeat the test for all three transducer slots.
 5. Document the appropriate records about the transducer service performed.

8.8 Servicing the ICL (Inrush Current Limiter) (ExactVu 2.5 HW versions only)

For ExactVu 2.6/2.9 HW versions, the ICL is located in the power box. (Refer to section 8.4.2.2 on page 135 for instructions for servicing the power box.)

8.8.1 Overview

The Inrush Current Limiter is located inside the wheel base in the same area as the lift controller.

8.8.2 Performing Service to the ICL

To replace the ICL:

1. Place a support with dimensions 8" x 6.5" x 3.5" at the bottom of the system.
2. Unscrew the bottom plate on the wheel base, slowly remove the support and lay the plate on the ground.
3. Disconnect the power cables from the ICL. Note which cable connects to each terminal.
4. Use a screwdriver to unlock the ICL from the *Din rail*.
5. Place the new ICL on the *Din rail*. Make sure it has a piece of protective foam on one side.
6. Reconnect all the power cables. Apply a cable tie and secure both cables at the cable tie mount.
7. Use the support box and screw the bottom plate back on the wheel base.
8. Connect the AC power cable to the wall outlet.
9. Switch the *main power switch* for the ExactVu system to the ON position.
10. Test the power box as described in Chapter 4, section 6 on page 155.
11. Document the appropriate records about the ICL replacement performed.

Chapter 4 Testing the ExactVu System

This chapter contains tests to perform on specific components of the ExactVu system.

These tests are applicable:

- following the installation of an ExactVu system
- after servicing or replacing specific components of the ExactVu system
- during scheduled maintenance

Refer to the latest revision of *ATP (Assembly Test Procedure) for Servicing the ExactVu System* for details of the tests indicated in this chapter.

1 Testing the System Cart

1.1 Testing the Monitor and Monitor Support Arm

Required Tools:

- X-Rite i1 DisplayPro colorimeter

1.1.1 Monitor Functionality Check

To test the monitor:

1. Turn on the ExactVu system.
The monitor should turn on and all monitor buttons should be disabled.
The ExactVu screen should show the expected image.
2. Press all monitor buttons.
Pressing any monitor button should have no effect.

1.1.2 Safety Test

- Perform the safety test for leakage that appears in Chapter 4, section 11 on page 170.

1.1.3 Monitor Support Arm Mechanical Test

1. Pull the monitor support arm upward slightly and verify that it is locked into the deck.
2. Rotate the monitor support arm 90 degrees to the left and then 90 degrees to the right and verify it is free from any obstruction.
3. Verify the monitor can be bent 90 degrees forward without stretching the cables.

1.1.4 Monitor Quality Assurance Check

There are two procedures depending on the monitor's date of manufacture. The Manufactured Date can be found on the back of the monitor:

- For monitors manufactured 2018-12 or later, follow section 1.1.4.1

- For monitors manufactured 2018-11 or earlier, follow section 1.1.4.2

1.1.4.1 Monitor Quality Assurance Check for Monitors Manufactured 2018-12 or Later

1. Open the *RadiCS calibration software*.
 - If the software is not already installed, install it from the *Production Tools Master (PN 6205)*.
 - Run the *EIZO_RadiCS installer*, use the default settings for the installation and select **Install**.
2. Plug the *EIZO UX2 Sensor* into an available USB slot.
3. From the *Home screen*, select **Acceptance Test**.

The EIZO monitor is selected and the UX2 Sensor is available.
4. Verify that the Acceptance Test is *Basic QC Secondary*. Click **Proceed**.
5. Make sure the cover is removed on the sensor and place the sensor in the center of the monitor. Make sure that the room is not too bright and the sensor is flush against the screen. It may be helpful to tilt the monitor to keep the sensor in place. Click **Proceed** and follow any on-screen instructions.
6. Check that the Acceptance Test has "Passed". Specific results may be reviewed by clicking the *Result*.
 - If the test Fails, run the Monitor Calibration procedure in section 1.1.5 on page 144.
7. Place the cover on the UX2 Sensor and disconnect from the system.
8. Close the *RadiCS calibration software*.

1.1.4.2 Monitor Quality Assurance Check for Monitors Manufactured 2018-11 or Earlier

1. Connect an *X-Rite i1 DisplayPro colorimeter* in one of the USB connectors on the ExactVu system.
2. Open **i1Profiler** software from the Desktop.
3. From the *Workflow Selector* view, under *Display*, select **Quality**.
4. Change/verify the following settings:
 - *Current Display Profile*: ExactVuDICOM.icm
 - *Patch Set Type*: Standard
 - *Industry Standard Targets*: X-Rite ColorChecker Classic
5. From the *Display Profiling Workflow*, select **Measurement**.
6. Select **Start Measurement**.
7. Rotate the lens to face the monitor direction. Tilt the monitor backwards, then place and align the colorimeter at the center of the screen. (Note: make sure the surface of the colorimeter sits on the screen. Any misalignment will give incorrect measurements.)
8. Select **OK** when the colorimeter is placed.
9. Select the **Next** arrow key and wait for the measurement to complete.
10. From the *Display Profiling Workflow*, select **QA Report**.

11. Verify that the result passed. If the result fails, run the Monitor Calibration procedure described in the following section.

1.1.5 Monitor Calibration

1. Refer to the latest revision of ATP (*Assembly Test Procedure*) for Servicing the ExactVu System and perform the *Monitor Calibration* tests provided for the *OS Settings Verification*.
2. Refer to the latest revision of ATP (*Assembly Test Procedure*) for Servicing the ExactVu System and perform the *Monitor Calibration* tests provided for the *ExactVu Computer*.

1.2 Testing the Control Panel Assembly

1.2.1 Control Panel Functionality Check

To test the control panel functionality:

1. Turn on the ExactVu system.
The *touch* screen should turn on and display the expected touch screen image.
2. Verify the touch screen's touch capability works by pressing one of its tabs.
3. Press a control panel control that is inactive (such as pressing the *Measure* control during imaging).
An audible sound should chime from both the left and right speakers.
4. Press **CTRL+ALT+SHIFT+R** hotkey combination.
5. Insert a USB storage device in one of the connectors on the touch screen.
6. The ExactVu system should detect the USB storage device.
7. For ExactVu 2.5 HW versions and earlier:
 - Pull the control panel swivel handle out from the cart.
 - Rotate the control panel/monitor platform to the desired position.
 - Release the control panel swivel handle.

The control panel/monitor platform is fixed in its current position.

1.2.2 Control Panel Verification and Calibration

8. For ExactVu 2.5 or ExactVu 2.6 hardware versions using Windows 7, open Windows Control Panel and navigate to *Tablet PC Settings*. For ExactVu 2.9 hardware versions using Windows 10, type **Calibrate** in the *Windows search bar* and select **Calibrate the screen for pen or touch input**.
9. Under the *Display* tab, select **Configure**.
10. Select **Setup**.
11. Press the **return** key and double-tap the *touch* screen. (Pressing *return* selects the correct touch screen.)
12. Obtain a USB storage device containing the latest revision of the *ExactImaging_Test_App* application from Exact Imaging and connect it to the ExactVu system.

13. Run the *ExactImaging_Test_App* shortcut from the production files folder.
14. Under the *Startup* tab, navigate to *Version Information*, and press **Get**. Read the firmware version.
15. Select **Upper Panel** under the USB Communication window.
16. Select the *Slidepots* tab and adjust each TGC slider left and right until both green squares are on.



Figure 128: Control Panel Verification Slidepots Tab

17. Select **Lower Panel** under the USB Communication window.
18. Select the *Encoders* tab and rotate the *Gain* knob clockwise and counter-clockwise until both green arrows are on.



Figure 129: Control Panel Verification Encoders Tab

19. Select the *Pushbuttons* tab and press all control panel buttons individually until all the green buttons are on, with the exception of the *Gain* knob, and the *Set* and *Next* buttons.



Figure 130: Control Panel Verification Pushbuttons Tab

20. Select the *LEDs* tab and press **Control LEDs**.
21. Set the Blue LED to *High* and the White LED to *Off*. Verify all LEDs are ON and blue color.
22. Set the Blue LED to *Off* and the White LED to *High*. Verify all LEDs are ON and white color.
23. Select the *Touchscreen* tab and select *9 Point Cal*. Press **Run Windows Calibration**.
24. Follow the instructions displayed and save the calibration data.
25. Select the *LCD test* tab and press **Gradient**.
26. Verify that the image on the display is the same as the image shown.

27. Exit the *ExactImaging_Test_App* application.

1.2.3 Control Panel and Software Communication

1. Restart the ExactVu System.
2. Create a patient and toggle imaging on and off.
3. Verify that the control panel corresponds with the ExactVu software.

1.3 Testing the USB Slots

1. Press **CTRL+ALT+SHIFT+R** hotkey combination.
2. Plug a USB storage device into an empty USB slot.
The operating system should detect the USB storage device.
3. Repeat the test for each USB slot (including 2 USB slots on the monitor for ExactVu 2.6/2.9 hardware versions).

1.4 Testing the Ethernet Connection

- Provide an internet connection to the ExactVu system by plugging in a connected Ethernet cable.
The operating system should detect the connection.

1.5 Testing the Lift Column

1. Check that no loose cables will be pulled while the lift column is moving up or down.
2. Press the *UP* button from Linak medical button, and drive the column all the way up.
The lift column should reach its highest position.
3. Press the *DOWN* button, and drive the column all the way down.
The lift column should reach its lowest position.
4. Repeat step 1 through step 3 five times.

1.6 Testing the Thermal Printer

Perform the tests in this section only if the thermal printer is part of the ExactVu system configuration.

1.6.1 Printer Functionality Test

To test the thermal printer:

1. Turn on the ExactVu system.
The printer should turn on.
2. Press the printer **POWER** button a few times.
The printer should turn off/on with each button press.
3. Briefly press and hold the **FEED** button on the printer.
The printer paper should feed from the printer output slot.



Figure 131: Printer Control Panel

1.6.2 Printer Settings

1. Press **CTRL+ALT+SHIFT+R** hotkey combination.
2. Open *Windows Control Panel*.
3. Navigate to *Devices and Printers*.
The printer *Sony UP-D898MD/X898MD* should be listed.
4. Right-click the printer and select **Printing Preferences**.
5. Verify the following settings:
 - Paper size: 1920 x 1280
 - Scaling: 100%
 - Interpolation Method: Bilinear
 - Orientation: Landscape
6. Set the *Contrast* and *Brightness* by turning the respective knobs:
 - Contrast: -12
 - Brightness: 0
7. Right-click the printer and select **Printer Properties**.
8. Select **Print a Test Page** and close the window.

1.6.3 Printer and Software Communication

1. Restart the ExactVu system.
2. When the ExactVu software launches, insert any available transducer.
3. Begin imaging.
4. Adjust the Gain to 70-80 dB.
5. Press **Print** on the *control panel*.

6. The printed image should match the image displayed on the screen.

1.6.4 Safety Test

- Perform the safety test for leakage that appears in section 11 on page 170.

1.7 Testing the Cooling System

1.7.1 General Cooling System Test

To test the cooling system:

1. With no transducers connected to the ExactVu system, press the *system power control* on the front of the ExactVu cart.
All AC and DC fans installed in the ExactVu system should turn on.
All fans have the correct orientation and airflow direction.
2. Press **CTRL+ALT+0** hotkey combination.
Three simulated transducers are available as follows:
 - EV29L in transducer connector slot 1 (i.e., the top-most slot)
 - EV9C in slot 2
 - EV5C in slot 3
3. Activate one of the simulated transducers and begin imaging in *simulation mode*.
4. Run the activated simulated transducer for 30 minutes.
No errors related to the cooling system should occur.

1.7.2 Card Cage DC Fan Test

- Perform the card cage tests that appear in section 9 on page 160.

1.8 Testing the Second Monitor Output (ExactVu 2.6/2.9 Hardware Versions only)

1. Power on the system.
2. Turn on the computer by pressing the power button.
3. Insert the HDMI cable into the second monitor output connector at the I/O plate (refer to Figure 132), and the other end of the cable into the HDMI input connector on the second monitor.
4. Power on the second monitor and set the input to HDMI mode. Verify that both screens are ON and showing the same output.
5. Image a prostate phantom using EV29L transducer, meanwhile, disconnect and connect the second monitor, and verify the image on the main monitor is not affected.



Figure 132: View of I/O panel at the back of the system

1.9 Foot Pedal Test (if equipped)

1. Connect the foot pedal cable to the USB connector on the system's back panel (if not already connected).
2. Press **Preferences** on the control panel and navigate to the *System Settings* tab.
3. Ensure that the foot pedal preference is set to *Save Frame*.
4. Open the imaging screen and press the foot pedal twice and ensure that a frame was saved.
5. Press the foot pedal and hold it down to ensure that no more than one frame is saved.
6. Ensure that the foot pedal cable management clips are all present, and the cord can be clipped through all of them (refer to Figure 133).

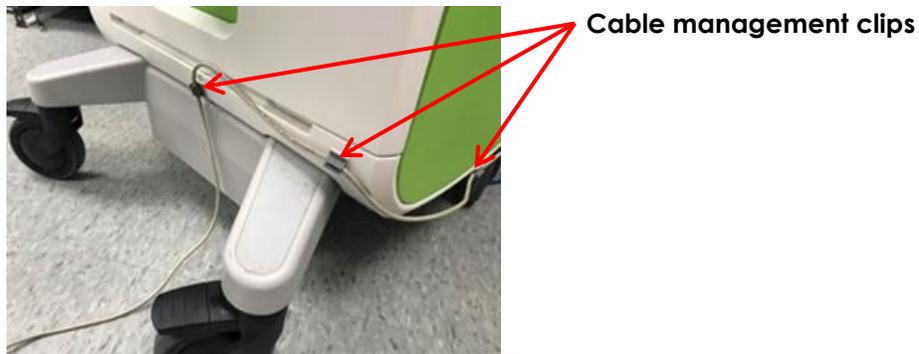


Figure 133: Foot Pedal Cable Management

NOTE

EN-N174



The hotkey combination *CTRL+ALT+X* performs the same function as the foot pedal as configured in *Preferences > System Settings*.

1.10 Testing the Fuses

1.10.1 Fuses Functionality Check

1. Turn on the ExactVu system.
2. Verify that the ExactVu system is functional after operating for few minutes.

1.10.2 Safety Test

- Perform the safety test for leakage that appears in section 11 on page 170.

1.11 Testing the Panels of the ExactVu System Cart

1.11.1 Panels Mechanical Test

1. Verify that all panels of the ExactVu system cart are aligned.
2. Verify that it is not possible to insert fingers into the gaps between adjacent and that the gaps look reasonably close together.
3. Using a force gauge tool with a hook, apply a pull test on each corner of the panels.
Each panel must hold a pulling force at 20 Nm for 10 seconds.

2 Testing the Channel Board

NOTE

EN-N114



Complete servicing activities for both the beamformer control board and the channel board(s) before performing this test.

2.1 Hardware Communication Test

To test the channel board:

- Turn on the ExactVu system.
No errors related to the channel board should occur.

To test communication between the channel boards and the BCB:

1. Check the status of the LEDs on the channel boards and BCB:
 - Check the LEDs on the BCB. Both should be *ON*. If they are not, it may indicate incorrect wiring of the fiber optic cables.



Figure 134: LEDs on the Beamformer Control Board

- Check the *Fiber Rx Fault* LEDs on the channel boards. Both should be *OFF*.



Figure 135: Fiber Rx Fault LEDs on the Channel Boards

- Check the *Tx Clk Good* LED and the *Rx Clk Good* LED on the channel boards. Both should be ON.

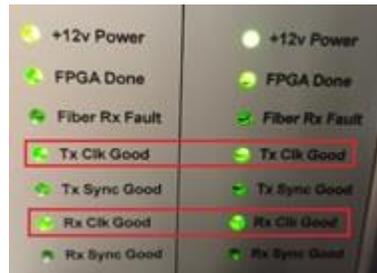


Figure 136: Clk Good LEDs on the Channel Boards

2. Press **CTRL+ALT+SHIFT+R** hotkey combination.
Any system error that indicates incorrect wiring may be ignored.
3. Open a Windows command prompt.
4. Type "C:" and press **return**.
5. Type "cd ExactImaging\ServiceFiles\System Driver and UFCtool" and press **return**.
6. Type "UFC_tool.exe" and press **return**.
7. Type "connect" and press **return**.
8. Type "read 1 20008" and press **return**. Verify the returned buffer is "0x00000001".
If the value returned is "0x00000002", swap the fiber optic cables on the channel boards and repeat this step.
9. Type "read 2 20008" and press **return**. Verify the returned buffer is "0x00000002".
10. Type "read 0 24" and press **return**. Record the BCB major version number.
11. Type "read 0 20" and press **return**. Record the BCB minor version and build version numbers.
12. Type "read 1 20000" and press **return**. Record the CB 1 version number.
13. Type "read 2 20000" and press **return**. Record the CB 2 version number.
14. Type "disconnect" press **return**.
15. Close the Windows command prompt.

2.2 General Imaging Test

1. Perform the general imaging test that appears in section 10 on page 160.

2. Repeat for each of transducer slot 1, transducer slot 2 and transducer slot 3.

2.3 Safety Test

- Perform the safety test for leakage that appears in section 11 on page 170.

3 Testing the Computer Unit

To test the computer unit:

1. Press **CTRL+ALT+SHIFT+R** hotkey combination.
2. Open the Windows desktop.
3. Perform the tests in all sub-sections of the *Component Sanity Check* in the latest revision of *ATP (Assembly Test Procedure) for Servicing the ExactVu System* from Exact Imaging.

3.1 Operating System Settings Verification

3.1.1 Monitor Setup

- Perform the procedure provided in Chapter 3, section 7.1.3.2 on page 88.

3.1.2 Computer Name

1. Open *Windows Control Panel*.
Windows Control Panel is displayed.
2. Navigate to *System and Security*.
Select **System**.
3. Verify the *Computer Name* and *Computer Description* is the Serial Number of the ExactVu Main Assemblies System.

3.1.3 D: Drive and System Folders

1. In Windows, verify that the *D: drive* is initialized.
2. Navigate to the *D: drive* and review the folders.
The *SpiLog* and *SpiData* folders should be present.

3.1.4 ContextVision License

1. Open a Windows command prompt.
2. Type "cd C:\ServiceFiles\ContextVision" and press **return**.
3. Type "cvietest64 -C 0" and press **return**.
The license status should be OK.

3.1.5 Control Panel Calibration

1. Open *Windows Control Panel*.

Windows Control Panel is displayed.

2. Navigate to *Tablet PC Settings*.
3. Under the *Display* tab, select **Configure**.
4. Select **Setup**.
5. Press the **return** key and double-tap the *touch* screen. (Pressing *return* selects the correct touch screen.)
6. Under *Display options*, select **Display device on: HDMI** for the *Display*.
7. Select **Calibrate**.



Figure 137: Control Panel Calibration

8. Follow the instructions on the screen to calibrate the *touch* screen.

3.1.6 Speakers

3.1.6.1 Functionality and Operating System Settings Check

1. Open *Windows Control Panel*.
Windows Control Panel is displayed.
2. Select **Hardware and Sounds** and then select **Sound**.
3. Verify the speakers are set as default devices.
Verify that the speaker volume is set to 50%.
4. Right-click the speakers and select **Test**.
Both the left and right speakers should play a sound.

3.1.6.2 Speaker and Software Communication

1. Restart the ExactVu System
2. Press a *control panel* control that is inactive (such as pressing the *Measure* control during imaging).
An audible sound should chime from both the left and right speakers.

3.2 Hardware Communication Test

- Perform the communication test between the channel boards and BCB that appears in section 2.1 on page 150.

3.3 General Imaging Test

1. Perform the *general imaging test* that appears in section 10 on page 160.

- Repeat for each of transducer slot 1, transducer slot 2 and transducer slot 3.

3.4 Safety Test

- Perform the safety test for leakage only if the computer unit has been replaced. The test appears in section 11 on page 170.

4 Testing the Beamformer Control Board



Complete servicing activities for both the beamformer control board and the channel board(s) before performing this test.

To test the BCB:

- Perform the communication test between the channel boards and BCB that appears in section 2.1 on page 150.
- Perform the *general imaging test* that appears in section 10 on page 160.

5 Testing the ExactVu Software Dongle

To test the ExactVu software dongle:

- Turn on the ExactVu system and begin imaging using a transducer.
No errors related to the ExactVu software should occur.
- Press **Preferences** on the *control panel*.
- Under the *System Information* tab, review the software features that are activated, and verify that they match the configuration on the software dongle.

2D-Mode:	Activated
Transverse Mode:	Activated
Color Doppler Mode:	Activated
Power Doppler Mode:	Activated
Pulsed Wave Doppler Mode:	Not Activated
Image Analysis Suite:	Activated
Needle Enhancement:	Activated
DICOM:	Activated
Transperineal:	Activated
Fusion:	Activated

Figure 138: Activation Configuration

4. Begin imaging in *2D Mode*.
Imaging in *2D Mode* begins.
5. Repeat step 4 for other activated modes.
Imaging in each activated mode begins.

6 Testing the Power Box

Required Tools:

- Digital multimeter, with AC voltage measurement mode set to 250V AC or higher

CAUTION
EN-C43



Always verify the voltages from the output of both the isolation transformer and the 12V DC power supply prior to powering the ExactVu system on.

WARNING
EN-W55



Ensure the transformer is configured to the local voltage configuration. If the voltage is overly transformed, there is a risk of a fire and the isolation transformer may be damaged.

CAUTION
EN-C44



Use caution when measuring the high voltage AC terminals in order to avoid a short circuit between line and neutral, or positive and negative terminals.

6.1 Input Power Supply

1. Disconnect all the cables connected to power distribution block 1 and power distribution block 3 (refer to Figure 120).
2. Disconnect the following cables connecting the power box to the card cage:
 - *Card cage power cable* (PN 6050)
 - *Power distribution block 3 power cable* (PN 6051)



Figure 139: Card Cage and Distribution Block 3 Power Cables

- Computer unit power cable (PN 6037)
- Control panel height control power cable (PN 6106)



Figure 140: Computer Unit and Control Panel Height Control Power Cables

3. Connect the AC power cable between the wall outlet and the *IO plate* at the back of the system to power the isolation transformer.
4. Measure the AC voltage on power distribution block 1 (refer to Figure 120) in the following probe termination locations:
 - Line (positive)
 - Neutral (negative)

The AC voltage should be in the range of 220V - 260V AC.

6.2 12V DC Power Supply

1. Disconnect the power from the ExactVu system.
2. Disconnect the following cables:
 - Transducer switch board power cable (PN 6052)



Figure 141: Transducer Switch Board Power

- Control panel power cable (PN 6035)



Figure 142: Control Panel Power

3. Connect the *computer unit power cable* (PN 6037) to power distribution block 1.
4. Connect the following cables to the card cage:
 - *Card cage power cable* (PN 6050)
 - *Power distribution block 3 power cable* (PN 6051)



Figure 143: Card Cage Power Cable Connections

5. Connect the other end of the *power distribution block 3 power cable* (PN 6051) to power distribution block 3.
6. Connect the power cable between the wall socket and the I/O plate at the back of the system.
7. Turn on the ExactVu system.
8. Set the digital multimeter to DC voltage measurement mode. Measure the voltage across the positive and negative terminal of the following cables:
 - *Transducer switch board power cable* (PN 6052): White is positive and black is

negative

- Control panel power cable (PN 6035): red is positive and black is negative

The DC voltage should be in the range of 11.4 – 12.6 V DC.

9. After verifying all voltages, disconnect the power from the ExactVu system.
10. Re-connect all the cables to their original state.

7 Testing the System Cabling

To test the system cabling, perform a visual inspection on cables as follows:

What to look for	Where to look
Cracking or gap opening (there should be none)	Both ends of the cable connector
Cracking, gap opening or exposed wires (there should be none)	Entire length of cable

Table 5: System Cabling Visual Inspection

8 Testing the Transducer and Transducer Connector

To assess issues related to the transducer and transducer connector:

1. Perform a visual inspection to determine if mechanical damage contributes to the issue. This involves the following steps:
 - Inspect the transducer (lens, handle, cable, connector housing, cable joints, connector pins) to be free of damage and dirt.
 - Inspect transducers 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.
 - Check that the black connector pin cover is present.
2. Document all findings from the visual inspection.
3. If there is no safety risk suspected in using any of the EV29L transducer, the EV9C transducer, or the EV5C transducer, connect the transducers to the ExactVu system.
4. Check the *needle path verification* for each transducer. The instructions for checking the alignment are found in:
 - 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
5. Document all findings from checking the *needle path verification*.
6. Activate the EV29L transducer.
 - Use gel and the tissue mimicking phantom to begin imaging in 2D Mode.
 - Evaluate the image for any artifact.
 - Move the transducer over the tissue mimicking phantom and look for any stationary vertical/horizontal shadow.

- Press **Dual/Transverse** on the *control panel* and start imaging. The Transverse Mode image and 2D Mode image on the right side of the screen should update as the transducer is rotated.
 - Select *Anesthesia sub-mode*. The *needle guide overlay* should be displayed on the live 2D Mode image.
 - Select *Biopsy sub-mode*. The *needle guide overlay* should be displayed on the live 2D Mode image.
7. Activate the EV9C transducer.
- Use gel and the tissue mimicking phantom to start imaging in 2D Mode.
 - Evaluate the image for any artifact.
 - Move the transducer over the tissue mimicking phantom and look for any stationary vertical/horizontal shadow.
 - Toggle the *needle guide overlay ON/OFF*. When toggled *ON*, the *needle guide overlay* should be displayed on the live 2D Mode image.
 - Press **Dual/Transverse** on the *control panel* and begin imaging. The Dual Mode image should show a paused image in the left pane and a live image in the right pane.
8. Activate the EV5C transducer.
- Use gel and the tissue mimicking phantom to start imaging in 2D Mode.
 - Evaluate the image for any artifact.
 - Move the transducer over the tissue mimicking phantom and look for any stationary vertical/horizontal shadow.
 - Toggle the *needle guide overlay ON/OFF*. When toggled *ON*, the *needle guide overlay* should be displayed on the live 2D Mode image.
 - Press **C/P** on the *control panel* and begin imaging. The color box should be displayed on the live image.
 - Press **Dual/Transverse** on the *control panel* and begin imaging. The Dual Mode image should show a paused image in the left pane and a live image in the right pane.
 - No artifact should be noticeable vertically (at the near field) or horizontally. (If there is a gel or tissue mimicking phantom effect, it disappears when the transducer is moved). Focal zone boundaries might be noticed on the image
9. After imaging, clean the transducers and the tissue mimicking phantom with low-alcohol surface disinfecting wipes (*Kimwipes* are recommended).
10. Document all findings from the testing.
11. Perform the *Transducer Element Check* described in section 1.3.2. (For software versions earlier than ExactVu 2.5.5, if the *Transducer Element Check* is not available, perform the *Transducer Sensitivity Test* described in section 1.3.2.4).
12. If a transducer is not performing as expected, return the affected transducer to Exact Imaging.

9 Testing the Card Cage

Testing the card cage includes a check that the transducer switch board is performing as expected.

9.1 Mechanical Check

1. Collect available transducers and/or “fake” transducer plugs.
2. Insert a transducer or transducer plug and insert into transducer slot 1.
3. Lock the transducer plug.
4. Unplug the transducer plug and verify that the receptacle on the transducer switch board can return to a closed position.

If it is not possible, re-align the card cage with the front insert panel.

5. Repeat step 1 through step 4 for transducer slots 2 and 3.

9.2 Hardware Communication Test

- Perform the communication test between the channel boards and BCB that appears in section 2.1 on page 150.

9.3 General Imaging Test

1. Perform the general imaging test that appears in section 10 on page 160.
2. Repeat for each of transducer slot 1, transducer slot 2 and transducer slot 3.

9.4 Safety Test

- Perform the safety test for leakage that appears in section 11 on page 170.

10 General Imaging Test

Perform the tests in the following sections for each transducer provided to the operator.

10.1 General Imaging with EV29L

WARNING
EN-W35



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

Always use a sterile transducer sheath during a transrectal procedure.

10.1.1 Imaging with a Tissue Mimicking Phantom

1. Connect the EV29L transducer to the ExactVu system.
2. Place the EV29L transducer against the tissue mimicking phantom coupled with gel.
3. Begin imaging in 2D Mode using the Large *image preset*.

4. Check that the image looks similar to the image shown in Figure 144 after adjusting settings as follows:
 - Vary the *Gain* from 62 dB to 66 dB.
 - Set the TGC sliders in a curved pattern similar to “)” at the center of the slider, in order to merge focal zone boundaries as seen in Figure 144. (Since the tissue is attenuative, there will not be much visibility past 17 mm).
 - The *Dynamic Range* can vary between 60 dB to 70 dB.



Figure 144: 2D Mode with the EV29L Transducer and Tissue Mimicking Phantom

5. Move the EV29L transducer back and forth and monitor the image.
6. No artifact should be noticeable vertically (at the near field) or horizontally. (If there is a gel or tissue mimicking phantom effect, it will disappear when the transducer is moved). Focal zone boundaries might be noticed on the image.
7. Press **Freeze** on the *control panel*.
8. Press **Annotate** on the *control panel*.
9. Press **Keyboard** on the *touch screen*.
10. Type the serial number of the transducer as an annotation at the top-left side of the image.
11. Press **Dual/Transverse** on the *control panel*.
Transverse Mode is enabled.
12. Rotate the EV29L transducer along its main axis.
A transverse image is obtained.
13. Without rotating the EV29L transducer, view the green bar on the transverse image.
The green bar on the transverse image does not move.
14. If there are no other transducers to test, remove the gel from the tissue phantom with paper towel, clean it with damp paper towel, and store it properly in the container. Make sure the container is sealed properly.
15. Remove gel from the transducers with *Kimwipes* and thoroughly clean the residual gel using additional damp *Kimwipes*.

10.1.2 Phantom Imaging with the EV29L Transducer

The purpose of this test is to check the depth of penetration and noise of the system with EV29L on each *transducer connector slot* after installation.

If it is the transducer is used in the field or is customer property, use a sheath for this test. Repeat the test for all EV29L transducers at the customer site.

To perform phantom imaging with the EV29L transducer:

1. Connect the EV29L transducer to *transducer connector slot 3*.
2. Create a new Patient/Study using *Last Name* "noise", and *First Name* [transducer serial number] (i.e., "6089xxxxx").
3. Apply gel to the transducer and cover it with a sheath as appropriate.
4. Insert the transducer into the prostate phantom (use either the CIRS (PN 6914) or Yezitronix (PN 6911) phantom).
5. If the image is paused, press **Freeze** to begin imaging. Image for 10-20 seconds.
6. Verify that the information in the header of the imaging screen is correct and that there are no system errors while imaging.
7. While imaging, increase and decrease the **Gain**.
Verify that the image brightens and darkens as the *Gain* is increased and decreased.
8. Move the **TGC sliders** left and right.
9. Assess the TGC behavior.
Different depths on the image should brighten and darken as each slider is moved.
10. Cycle through each mode and sub-mode, and ensure imaging works as expected in each.
11. Go to the midline plane (i.e., the urethra is displayed in the image).
12. Begin imaging in *2D Mode* using the *Large image preset*.
13. Make sure there is no bubble on the image and contact is ok between the transducer and phantom.
14. Image in *Transverse Mode* and check the motion sensor behavior by comparing with the movement of the *transverse line* in the *Transverse image pane*.
15. Go back to *2D Mode* using the *Large image preset*.
16. Adjust TGC to be "J" shape.
17. Set the *2D Gain* to 76 dB.
18. Assess the depth of penetration.
The phantom should be visible at 40 mm or above as shown in Figure 145 and Figure 146.
19. Assess the noise pattern on the image in the far field.

The far field noise may look blurry and moving but it should not have any noticeable pattern such as tilted lines, rain of white noise, fan shape noise from top to bottom.

Figure 145 and Figure 146 show acceptable reference images. Additional references for Noise Evaluation are available in the latest revision of *AP and ATP for EV SYS Conf - EV 2.5* from Exact Imaging. Using that reference, select the folder that corresponds the currently select

image preset and the phantom in use.

Large image preset

**Blurry moving noise
marked in the far
field**

**Depth of
penetration is 40
mm or above**

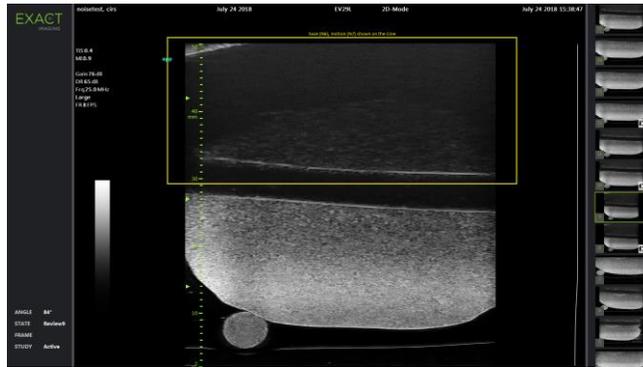


Figure 145: CIRS Phantom Reference Image

Large image preset

**Blurry moving noise
marked in the far
field**

**Depth of
penetration is 40
mm or above**

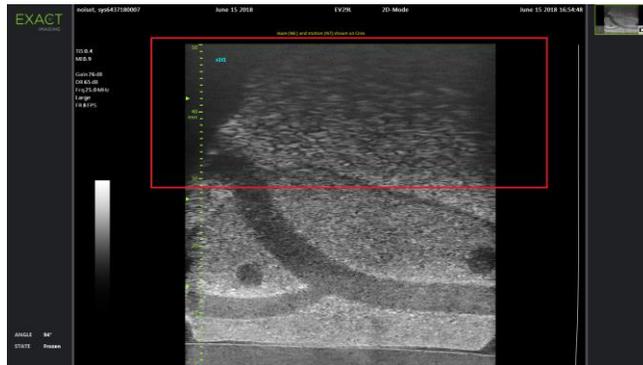


Figure 146: Yezitronix Phantom Reference Image

20. Save one *cine image* and one *frame*.
21. Begin imaging in 2D Mode using the *Medium image preset*.
22. Set the 2D Gain to 74 dB.
23. Assess the noise in the image by following step 5 through step 20.
 - It is only necessary to save the cine image and frame if the image is not acceptable.
24. Begin imaging in 2D Mode using the *Small image preset*.
25. Set the 2D Gain to 72 dB.
26. Assess the noise in the image by following step 5 through step 20.
 - It is only necessary to save the cine image and frame if the image is not acceptable.
27. Connect the EV29L transducer to *transducer connector slot 2* and repeat step 11 through step
 - It is not necessary to save the cine image and frame if the images are comparable to the images obtained using **slot 3**.
28. Connect the EV29L transducer to *transducer connector slot 1* and repeat step 11 through step
 - It is not necessary to save the cine image and frame if the images are comparable to the images obtained using **slot 3**.

29. After completing the tests:

- If available: Review noise in images from the current study and compare with previous studies to assess whether noise in current images is similar to that in previous studies.
- Export the study to the hard drive or to a connected storage device.
- Delete the study from the ExactVu system
- To prevent possible infection or contamination, reprocess the transducer following the complete procedure in *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

30. Package and store the phantom properly.

10.2 General Imaging with EV9C

WARNING

EN-W35



To prevent possible infection or contamination, the transducer must be reprocessed following the complete procedure in *Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer* prior to using it in another procedure.

Always use a sterile transducer sheath during a transrectal procedure.

1. Connect the EV9C transducer to the ExactVu system using **slot 3**.
2. Create a new Patient/Study using *Last Name* "noise", and *First Name* [transducer serial number] (i.e., "6087xxxxx")
3. Place the EV9C transducer against the tissue mimicking phantom (PN 6462) coupled with gel.
4. Begin imaging in *2D Mode* using the *Medium image preset*.
5. Check that the image looks similar to the image shown in Figure 147 after adjusting settings as follows:
 - Vary the *Gain* from 62 dB to 67 dB.
 - Set the *TGC* sliders so that they are all in the middle or are in a curved pattern similar to "J" at the center of the slider, in order to merge focal zones.

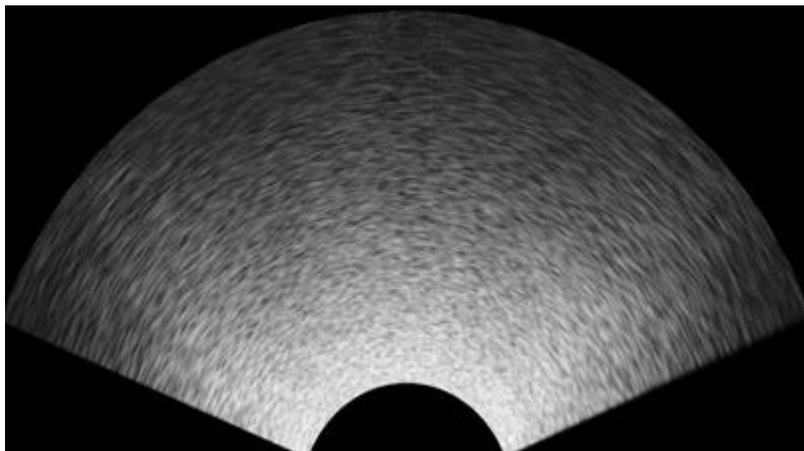


Figure 147: 2D Mode with the EV9C Transducer and Tissue Mimicking Phantom

6. Make some measurements and annotations.

7. Move the EV9C transducer back and forth and monitor the image.
No artifact should be noticeable vertically (at the near field) or horizontally. (If there is a gel or tissue mimicking phantom effect, it will disappear when the transducer is moved). Focal zone boundaries might be noticed on the image.
8. Evaluate the noise on the image. There should be no “snowy” dotted patterns or tilted lines on the image.
9. Save some cine images and frames.
10. Press **Freeze** on the *control panel*.
11. Press **Annotate** on the *control panel*.
12. Press **Keyboard** on the *touch screen*.
13. Type the serial number of the transducer as an annotation at the top-left side of the image.
14. Press **Dual/Transverse** on the *control panel*.
Dual Mode is enabled.
15. Obtain a *Dual Mode* image.
16. After completing the tests:
 - Review noise images from this study and previous ones to assess whether the noise is similar to previous studies
 - Export the study to the hard drive or to a connected storage device
 - Delete the study from the ExactVu system
17. If there are no other transducers to test, remove the gel from the tissue phantom with paper towel, clean it with damp paper towel, and store it properly in its container. Ensure the container is sealed properly.
18. Remove gel from the transducers with *Kimwipes* and thoroughly clean the residual gel using additional damp *Kimwipes*.

10.3 General Imaging with EV5C

WARNING

EN-W35



To prevent possible infection or contamination, the transducer must be reprocessed following the complete procedure in *Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer* prior to using it in another procedure.

10.3.1 Imaging with a Tissue Mimicking Phantom

1. Connect the EV5C transducer to the ExactVu system using **slot 3**.
2. Create a new Patient/Study using *Last Name* “noise”, and *First Name* [transducer serial number] (i.e., “6088xxxxx”).
3. Place the EV5C transducer against the tissue mimicking phantom (PN 6462) coupled with gel.
4. Begin imaging in *2D Mode* using the *Medium image preset*.
5. Check that the image looks similar to the image shown in Figure 148 after adjusting settings as follows:

- Vary the *Gain* from 62 dB to 67 dB.
- Set the TGC sliders so that they are all in the middle or are in a curved pattern similar to “J” at the center of the slider, in order to merge focal zones.

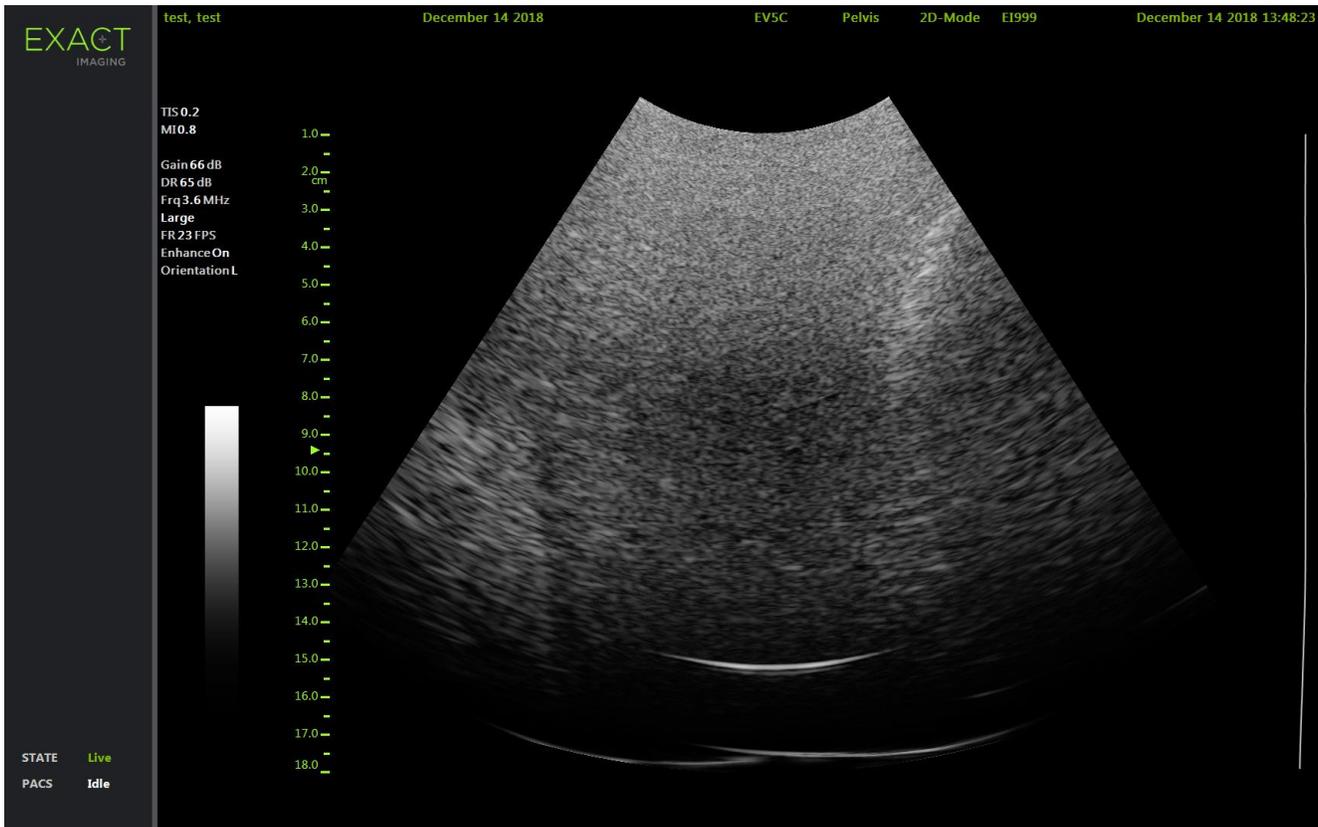


Figure 148: 2D Mode with the EV5C Transducer and Tissue Mimicking Phantom

6. Move the EV5C transducer back and forth and monitor the image.
No artifact should be noticeable vertically (at the near field) or horizontally. (If there is a gel or tissue mimicking phantom effect, it will disappear when the transducer is moved). Focal zone boundaries might be noticed on the image.
7. Evaluate the noise on the image. There should be no “snowy” dotted patterns or tilted lines on the image.
8. Save some cine images and frames.
9. Press **Freeze** on the *control panel*.
10. Press **Annotate** on the *control panel*.
11. Press **Keyboard** on the *touch screen*.
12. Type the serial number of the transducer as an annotation at the top-left side of the image.
13. Press **Frame** on the *control panel* to save a frame.
14. Press Print on the *control panel*. Write the transducer serial number on the printed image.
15. Press **Dual/Transverse** on the *control panel*.
Dual Mode is enabled.

16. Obtain a *Dual Mode* image.
17. After completing the tests:
 - Review noise images from this study and previous ones to assess whether the noise is similar to previous studies
 - Export the study to the hard drive or to a connected storage device
 - Delete the study from the ExactVu system
18. If there are no other transducers to test, remove the gel from the tissue phantom with paper towel, clean it with damp paper towel, and store it properly in its container. Ensure the container is sealed properly.
19. Remove gel from the transducers with *Kimwipes* and thoroughly clean the residual gel using additional damp *Kimwipes*.

10.3.2 Imaging in CFI Modes

To test imaging in CFI modes:

1. Press **2D** on the *control panel*.
2. Set the *2D Gain* to 60 dB.
3. Select the **Small image preset**
4. Press **C/P** on the *control panel*.
5. Press **Next** on the *control panel* to enable color box size configuration.
6. Use the trackball to resize the *color box* to the maximum height and width. Press **Next** to set the color box size.
7. Use the *Gain knob* to set the *C Gain* to 75 dB.
8. Set the TGC sliders to the middle.
9. Keep the EV5C on the transducer holder facing the ceiling. **Do not** apply gel.
10. Move the palm of your hand up and down slowly over the top of the EV5C, about an inch from the surface of the EV5C transducer and observe the CFI image.



Move the palm of your hand up and down over EV5C Transducer

Figure 149: Move Palm of Hand over EV5C Transducer

It should show a blue color as your hand moves away from the transducer and an orange/red color as your hand moves toward the transducer as shown in Figure 150 and Figure 151.

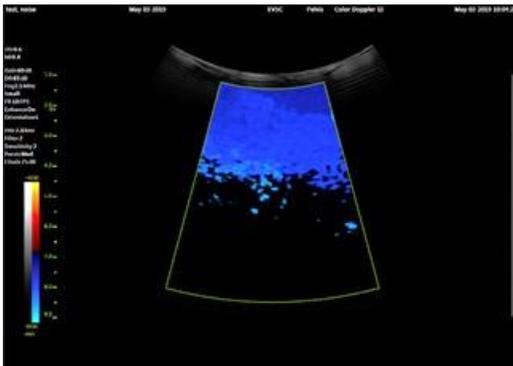


Figure 150: Color Flow as Hand is Moved Away EV5C

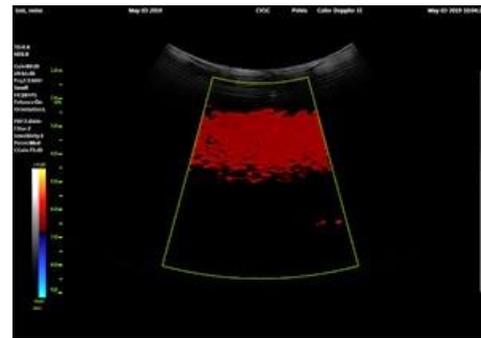


Figure 151: Color Flow as Hand is Moved Toward EV5C

11. Apply ultrasound gel to the EV5C transducer and image the tissue mimicking phantom (PN 6462).
 - Hold the transducer very still during imaging.
 - Any small movements may cause wall motion doppler shifts.
12. Press **2D** on the control panel. Scan the phantom with the following settings:
 - Enable the Large *image preset*
 - Set the *2D Gain* between 62 to 67 dB
 - Center the *TGC sliders* (i.e., so that they are in the middle)
 - Position the *depth* of the focal zone to 94 mm
13. Press **C/P** on the control panel.
14. Inspect the 2D image in CFI mode.

The 2D image in the *CFI mode* should look equivalent to the image in *2D Mode*.

15. Enable the following CFI mode settings:

- Set the *Sensitivity* to 3
- Set the *Persistence* to *Med*
- Set the *Wall Filter* to 2
- Set the *PRF* to 2 kHz
- Position the *depth* of the focal zone to 94 mm
- Set the *C Gain* at 70 dB

16. In CFI mode, ensure the 2D image in the background is equivalent to the corresponding image in 2D Mode. There should be no additional noise, gain differences or artifacts.

17. Hold the transducer very still on the phantom and inspect for any CFI noise in Color Doppler Mode and Power Doppler Mode especially at the bright reflectors, e.g., the wall of the phantom, where phase noise may appear even when the transducer is held very still. The pass criteria for this test are:

- The phase noise (represented by color dots) that appear on the bright reflector should be indicated by fewer than 5 dots.
- The presence of grids lines occasionally appears in Power Doppler Mode and are acceptable.
- An artifact occasionally appears at the left edge of the color box in Color Doppler Mode and Power Doppler Mode and is acceptable.
- The presence of a left edge artifact when the PRF is set to 5.5 kHz or higher is acceptable.
- Changing PRF should not introduce additional noise.

18. Press **Frame** on the *control panel* to save a frame.

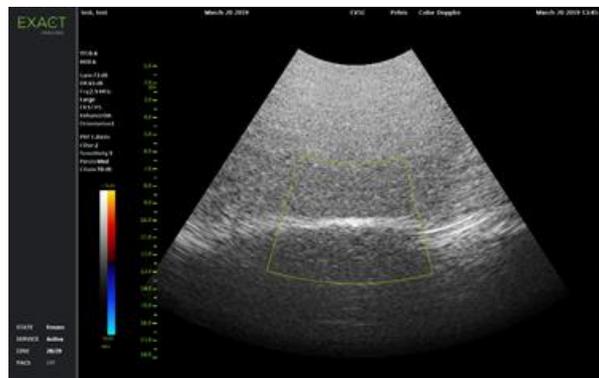


Figure 152: CFI mode with EV5C Transducer and Tissue Mimicking Phantom

19. Clean and store the tissue mimicking phantom as follows:

- Remove the gel from the phantom with paper towel
- Clean the phantom with damp paper towel
- Store the phantom properly in its container, and seal it

11 General Safety Test: Leakage

Before performing the tests in these sub-sections, ensure all the panels on the ExactVu system cart are closed, the ExactVu system is powered off and the *main power switch* (i.e., the rocker IO) is ON.

Run the following tests in the following sections with an *electrical safety analyzer*.

11.1 Chassis Ground Resistance Test

Required Tools:

- Phillips #2 screwdriver

To perform the chassis ground resistance test:

1. Connect a ground test lead to the equipotential pin at the *IO plate*.
2. Switch the control knob on the *electrical safety analyzer* to *Ground-Wire Resistance Test*.
3. Plug the power cord from the ExactVu system into the *electrical safety analyzer's* test receptacle.
4. Record the resistance.

11.2 Ground and Chassis Leakage Current

Required Tools:

- Phillips #2 screwdriver

To test the ground and chassis leakage current:

1. Connect ground test lead to the equipotential pin at the *IO plate*.
2. Switch the control knob on the *electrical safety analyzer* to *Earth Leakage Current Test*.
3. Set the *Outlet switch* in the *Normal* position and the *Neutral switch* to *Closed*.
4. Turn on the ExactVu system.
5. Record the Ground Leakage Current (uA).
6. Turn off the ExactVu system. Change the *Outlet switch* to *reverse*, and turn on the ExactVu system.
7. Record the Ground Leakage Current (uA).
8. Turn off the system, Change the *Neutral switch* to *Open* and the *Outlet switch* to *Normal*.
9. Record the Ground Leakage Current (uA).
10. Change the control knob on the *electrical safety analyzer* to "Enclosure Leakage Current Test" and repeat step 3 through step 9.

Where the *chassis leakage current test* is also required, perform the following additional steps:

1. Turn off the system. Change the *Neutral switch* to *Closed*, the *Outlet switch* to *Normal*, the *Ground switch* to *Open* and turn on the system.
2. Record the Ground/Chassis Leakage Current (uA).
3. Turn off the system.

Chapter 5 Maintaining the ExactVu System

1 Maintenance Performed by Exact Imaging Service Personnel

1.1 Maintenance Schedule

Scheduled maintenance is planned to ensure that ExactVu system components and accessories perform as expected through their operating lifetime. Manufacturing records are kept to track the history of servicing and maintenance performed.

Exact Imaging will provide a service contract as an offering and this *Service Manual for ExactVu™ High Resolution Micro-Ultrasound System* that describes recommended operational checks, tests, and inspections. The *Service Manual for ExactVu™ High Resolution Micro-Ultrasound System* is available as a special-order option.

Table 6 shows the recommended maintenance schedule for the activities performed by Technical Support personnel that are described in this chapter.

Maintenance Activity	Recommended Schedule
Inspecting the Monitor	Annually
Inspecting the Control Panel	Annually
Inspecting the Lift Column	Annually

Table 6: ExactVu Maintenance Schedule

1.2 Inspecting the ExactVu System

1.2.1 Inspecting the ExactVu System Cart

1.2.1.1 Inspecting the Monitor

When to perform this inspection	Yes/No
After a new ExactVu system installation	Yes
During scheduled maintenance	Yes
When investigating an operator complaint or non-conforming product report	Yes

Inspection procedure:

- Visual inspection
- Test the monitor as described in Chapter 4, section 1.1 on page 142
- Document results

1.2.1.2 Inspecting the Control Panel

When to perform this inspection	Yes/No
After a new ExactVu installation	Yes
During scheduled maintenance	Yes

When investigating an operator complaint or non-conforming product report Yes

Inspection procedure:

- Visual inspection
- Test the control panel assembly as described in Chapter 4, section 1.2 on page 144
- Document results

1.2.1.3 Inspecting the Thermal Printer

This section is applicable only if the thermal printer is part of the ExactVu system configuration.

When to perform this inspection	Yes/No
After a new ExactVu system installation	Yes
During scheduled maintenance	No
When investigating an operator complaint or non-conforming product report	Yes

Inspection procedure:

- Visual inspection
- Test the thermal printer as described Chapter 4, section 1.6 on page 146
- Document results

1.2.1.4 Inspecting the Lift Column

When to perform this inspection	Yes/No
After a new ExactVu system installation	Yes
During scheduled maintenance	Yes
When investigating an operator complaint or non-conforming product report	Yes

Inspection procedure:

- The procedure for inspecting the lift column consists of the following:
 - Drive the column fully and listen for unusual noise
 - If signs of damage, wear or unusual noise are observed, determine whether service or replacement is required
- Test and re-synch the lift column as described in Chapter 3, section 7.1.10 on page 99.
- Document results

1.3 System and Transducer Unit Tests

1. Clean and disinfect the on-site system and transducer before use.
2. Inspect the transducer (lens, handle, cable, connector housing, strain relief, pins) to be free of damage and dirt. Check that the *transducer connector cover* is present.

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.

Inspect the transducer cable for damage.

1.3.1 Testing the System Channels

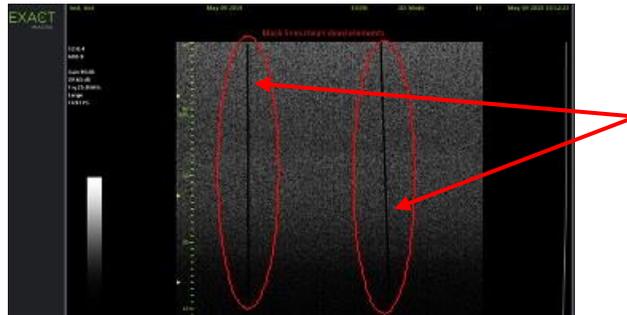
This section is intended to test the channels of the system to ensure they have not been degraded. For ExactVu software version 2.5.5 or higher, follow the procedure in section 1.3.2.1, section 1.3.2.2 or section 1.3.2.3.

For ExactVu software versions 2.5.3 and earlier:

1. Disconnect the transducer.
 2. Press **Ctrl+Alt+0** to simulate imaging with the EV29L transducer.
 3. Increase the Gain setting to visualize the image as needed. Ensure there are no artifacts (i.e., tilted lines) in the far field or near field.
 4. Follow the procedure in the appropriate subsection for the transducer being tested based on the installed ExactVu version.
- For ExactVu 2.0 versions:
 - enable the following settings:
 - Image Preset: **Small**
 - Number of focal zones: **1**
 - TGC sliders: slide each slider all the way to the right (i.e., their maximum)
 - Press **CTRL+ALT+E** hotkey combination to open Engineering Mode
 - From the Configuration dropdown, select **Scripts**
 - Ensure that the file path shows /ExactVu/Version-2.0.x/Scripts/
 - Select *Transducer-Sens-Param-set.vts* and select **Run**
 - Press **Scan/Freeze** two times to stop and start imaging
 - For ExactVu 2.5 or ExactVu 2.5.3 software versions:
 - Enable the following settings:
 - Image Preset: **Small**
 - Number of focal zones: **1**
 - TGC sliders: slide each slider all the way to the right (i.e., their maximum)
 - Press **CTRL+ALT+E** hotkey combination to open Engineering Mode
 - From the Configuration dropdown, select **Scripts**
 - Ensure that the file path shows /ExactVu/Version-2.5.x/Scripts/
 - Select *Mfctr-sens- test-v25.vts*, change "ApplySoftwareGain" from 0 to 1 and then

select **Run**

- Press **Scan/Freeze** two times to stop and start imaging
5. Begin imaging and evaluate the image. Verify that the image has no black lines on it, such as those illustrated in Figure 153.
 6. Press **Frame** on the control panel to save a frame.



Black lines indicating
dead elements in
the transducer

Figure 153: Example Image Indicating Dead Elements
in the Transducer

1.3.2 Testing the Transducer Elements

The section is intended to test the transducer elements to ensure none has degraded.

1.3.2.1 EV29L Transducer Elements Test

1. Restart the ExactVu system.
2. Connect the EV29L transducer to **slot 1**
3. Press **Preferences**, enter **SN** of the transducer, and press **Execute** to perform the Transducer Element Check. (For software versions earlier than ExactVu 2.5.5, if the Transducer Element Check is not available, perform the *Transducer Sensitivity Test* described in section 1.3.2.4).

A message is displayed showing the results.

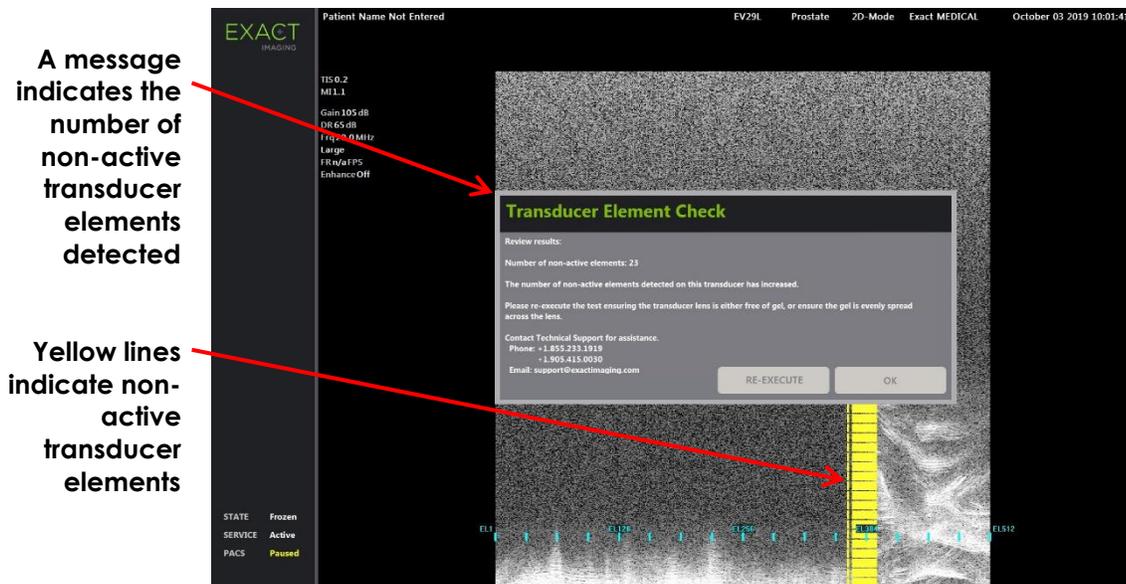


Figure 154: Transducer Element Check, Non-Active Elements

4. Compare the number of dead elements found by this test with the number of dead elements recorded in the DHR record for the transducer. For this test to pass, the criteria are:
 - Fewer than 7 dead elements in total, where:
 - Fewer than 5 dead elements in total are at both array ends (i.e., the sum of elements 1-8 and elements 506-512)
 - Fewer than 5 dead elements in the middle of the array (Elements 9-505)
 - Fewer than 4 dead elements per aperture
5. If it is difficult to determine whether there are dead elements and how many there are, store a frame in .png format, and forward it to Technical Support using the contact information in Appendix D to analyze.
6. If the number of dead elements is different than DHR while the above criteria is passed, record the detail in the applicable Assembly Test Form.

1.3.2.2 EV9C Transducer Elements Test

1. Disconnect other transducers and connect EV9C to **slot 1**.
2. Repeat the steps in section 1.3.2.1 to perform the *Transducer Element Check*. (For software versions earlier than ExactVu 2.5.5, if the Transducer Element Check is not available, perform the *Transducer Sensitivity Test* described in section 1.3.2.4).
3. For this test to pass, the criteria are:
 - Fewer than 3 dead elements total
4. If it is difficult to determine whether there are dead elements and how many there are, store a frame in .png format, and forward it to Technical Support using the contact information in Appendix D to analyze.
5. If the number of dead elements is different than DHR while the above criteria is passed, record the detail in the applicable Assembly Test Form.

1.3.2.3 EV5C Transducer Elements Test

1. Disconnect other transducers and connect EV5C to **slot 1**.
2. Repeat the steps in section 1.3.2.1 to perform the *Transducer Element Check*. (For software versions earlier than ExactVu 2.5.5, if the Transducer Element Check is not available, perform the *Transducer Sensitivity Test* described in section 1.3.2.4).
3. For this test to pass, the criteria are:
 - Fewer than 3 dead elements total
4. If it is difficult to determine whether there are dead elements and how many there are, store a frame in .png format, and forward it to Technical Support using the contact information in Appendix D to analyze.
5. If the number of dead elements is different than DHR while the above criteria is passed, record the detail in the applicable Assembly Test Form.

1.3.2.4 Transducer Sensitivity Test

This section describes transducer sensitivity tests for ExactVu systems with a software version that does not include the *Transducer Element Check* described in the previous subsections.

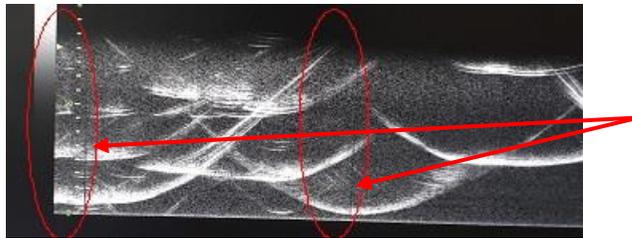
EV29L Transducer Elements Test

1. Restart the ExactVu system.
2. Connect the EV29L transducer to **slot 1** and enable the following settings:
 - Image Preset: **Small**
 - Number of focal zones: **1**
 - TGC sliders: slide each slider all the way to the right (i.e., their maximum)
 - Either apply gel (refer to Figure 155) or perform the test in water
3. Run the *Transducer sensitivity script* based on the installed ExactVu version:
 - For ExactVu 2.0 versions:
 - Press **CTRL+ALT+E** hotkey combination to open Engineering Mode
 - From the Configuration dropdown, select **Scripts**
 - Ensure that the file path shows /ExactVu/Version-2.0.x/Scripts/
 - Select *Transducer-Sens-Param-set.vts* and select **Run**
 - Press **Scan/Freeze** two times to stop and start imaging
 - For ExactVu 2.5 versions:
 - Press **CTRL+ALT+E** hotkey combination to open Engineering Mode
 - From the Configuration dropdown, select **Scripts**
 - Ensure that the file path shows /ExactVu/Version-2.5.x/Scripts/
 - Select *Mfctr-sens- test-v25.vts*, change "ApplySoftwareGain" from 0 to 1 and then select **Run**
 - Press **Scan/Freeze** two times to stop and start imaging

- Increase 2D Gain to visualize the image.



Figure 155: Gel Applied to EV29L Transducer



Black lines indicating
dead elements in
the transducer

**Figure 156: Example Image Indicating Dead Elements
in the EV29L Transducer**

- Begin imaging and increase the 2D Gain if necessary. Evaluate the image. If the system is free of black lines, such as those shown in Figure 156, there are no dead elements.
- Press Frame on the control panel to save a frame
- Compare the number of dead elements found by this test with the number of dead elements recorded in the DHR record for the transducer. For this test to pass, the criteria are:
 - Less than 7 dead elements in total, where:
 - Fewer than 5 dead elements in total at both array ends (i.e., sum of elements 1-8 and elements 506-512)
 - Fewer than 5 dead elements in the middle of the array (Elements 9-505)
 - Fewer than 4 dead elements per aperture

If it is difficult to determine whether there are dead elements and how many there are, store a frame in .png format, and forward it to Exact Imaging's Engineering team to analyze.

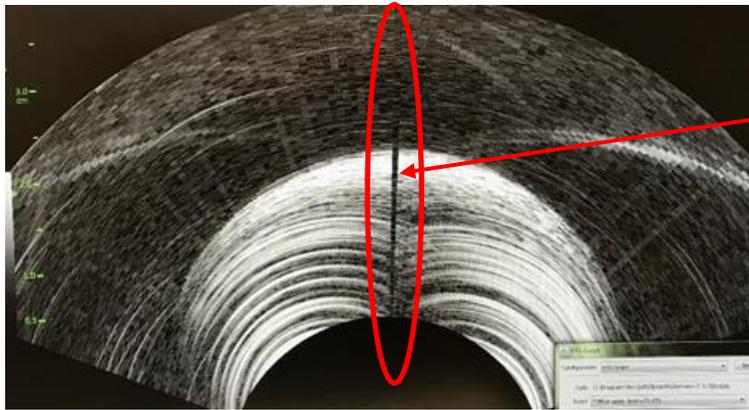
If the number of dead elements is different than DHR while the above criteria is passed, record the detail in the applicable Assembly Test Form.

EV9C Transducer Elements Test

- Disconnect other transducers and connect EV9C to **slot 1**.
- Repeat the steps in this section for the *EV29L Transducer Elements Test*.
- For this test to pass, the criteria are:
 - Less than 3 dead elements in total

If it is difficult to determine whether there are dead elements and how many there are, store a frame in .png format, and forward it to Exact Imaging's Engineering team to analyze.

If the number of dead elements is different than DHR while the above criteria is passed, record the detail in the applicable Assembly Test Form.



Black line indicating dead elements in the transducer

Figure 157: Example Image Indicating Dead Elements in the EV9C Transducer

EV5C Transducer Elements Test

1. Disconnect other transducers and connect EV5C to **slot 1**.
2. Repeat the steps in this section for the *EV29L Transducer Elements Test*.
3. For this test to pass, the criteria are:
 - Less than 3 dead elements in total

If it is difficult to determine whether there are dead elements and how many there are, store a frame in .png format, and forward it to Exact Imaging's Engineering team to analyze.

If the number of dead elements is different than DHR while the above criteria is passed, record the detail in the applicable Assembly Test Form.

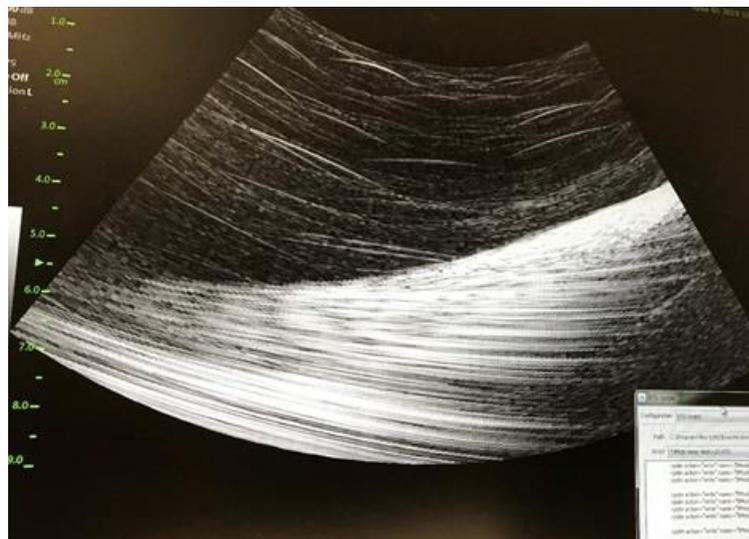


Figure 158: Example Image Indicating No Dead Elements in the EV5C Transducer

1.3.3 Image Quality Testing using On-site Transducers

Perform the appropriate *General Imaging Test* in section 10.1, section 10.2 or section 10.3, beginning on page 160, depending on the available transducer(s) on-site.

1.3.4 Testing the EV29L Transducer Cable

This section is intended to test the transducer cable to make sure it does not affect the performance of EV29L transducer and image quality.

1. Review the number of dead elements from the DHR record for the transducer.
2. If not already performed, run the *Transducer Element Check* as instructed in section 1.3.2 and record the number of dead elements found by this test. Save a frame.
3. While imaging, move the transducer cable around to determine whether the number of dead elements changes.
4. Restart the ExactVu system.
5. Begin imaging in 2D Mode.
6. While holding the transducer horizontally with the lens pointed up, switch from 2D Mode to Transverse Mode.



7. Perform a full transverse sweep as follows:
 - rotate the transducer 90 degrees left
 - then rotate the transducer back to center
 - then rotate the transducer 90 degrees right
 - then rotate the transducer back to center

Observe the behavior of the transverse line while imaging (pay attention to erratic motion of the transverse line).



8. Rotate the transducer 360 degrees to the right so that the lens returns to pointing upwards.

9. Rotate the transducer 360 degrees to the left to fully untwist the transducer cable.
10. Repeat steps 8 and 9 two more times (refer to Figure 159).



Figure 159: Rotate 360 Degrees to the Right and Return (Three Times)

11. Re-initialize Transverse Mode by pressing the **Transverse** button.
12. Repeat Step 7.
13. Rotate the transducer 360 degrees to the Left (Returning to lens pointing up position).
14. Rotate the transducer 360 degrees to the Right to untwist the transducer.
15. Repeat steps 13 and 14 two more times (refer to Figure 160).



Figure 160: Rotate 360 Degrees to the Left and Return (Three Times)

16. Press **Transverse** to re-initialize Transverse Mode.
17. Repeat Step 7.
18. Perform the *Transducer Element Check* described in section 1.3.2. (For software versions earlier than ExactVu 2.5.5, if the *Transducer Element Check* is not available, perform the *Transducer Sensitivity Test* described in section 1.3.2.4).
19. Repeat Step 1 through Step 5. If there is a change in the number of dead elements compared to the observed result in Step 2, flag the transducer for further investigation. Save a frame.

1.3.5 Further inspection on-site

1. If there are EV29L non-sterile reusable transrectal needle guides at the customer's site, perform a visual inspection for damage.

What to look for	Where to look
There should be no cracking	Plastic enclosure
Prongs and locking channel are not damaged or broken	Plastic enclosure
Snug fit in the plastic enclosure	Needle cannula
Ease of attaching the plastic enclosure to the EV29L transducer	

Table 7: EV29L Reusable Transrectal Needle Guide Inspection

For further maintenance instructions for the EV29L Reusable Transrectal Needle Guide, refer to the *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*.

2. If there is a transperineal stepper on the site, inspect it for any damage and test its functionality according to section 2.1 on page 182. Record any damage or improper functionality observed.
3. Check that the site is handling and storing the transducers properly and the reprocessing setup protects the sensitive areas of the transducer as shown in Figure 161. Record any issues and inform Exact Imaging if re-training is required.

CAUTION
EN-C50



Proper handling conditions during reprocessing means:

- the transducer lens is protected
 - the transducer cable is not twisted
 - the transducer connector cover is securely attached to the transducer connector
-

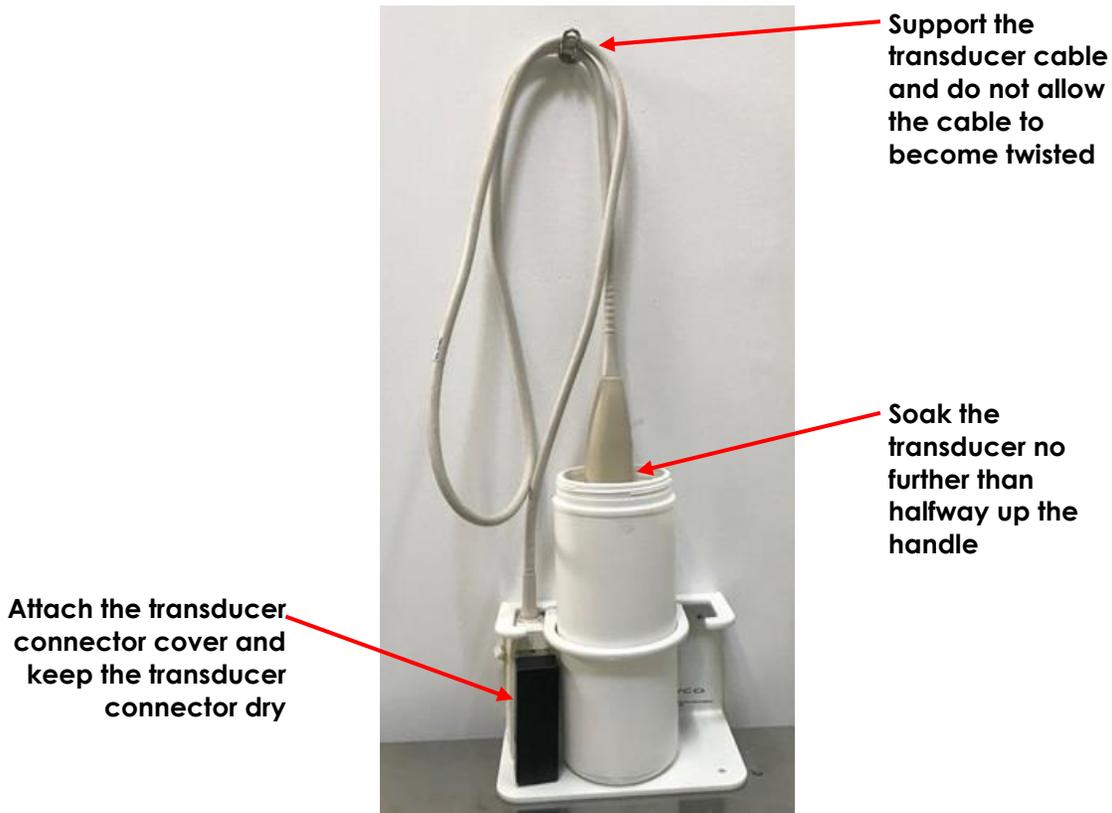


Figure 161: Correct Reprocessing Setup

1.4 Recording Maintenance Activities

Maintenance activities performed by Technical Support personnel must be recorded and filed according to internal Exact Imaging procedures.

2 Maintenance Performed by Operators

Several maintenance and inspection activities are performed by ExactVu operators, and are also part of scheduled maintenance performed by Technical Support personnel. These activities are fully described in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* and include:

- Cleaning the lower air filter
- Cleaning the left panel air filter
- Inspecting the foot pedal
- Replacing thermal printer paper
- Inspecting the thermal printer
- Surface cleaning the ExactVu system
- Inspecting the ExactVu system
- Inspecting the ExactVu transducers
- Checking the transperineal stepper. This procedure is provided in the following section.

2.1 Checking the Transperineal Stepper

In order to maintain the expected performance of the *D&K Technologies Universal Stepper* in transperineal procedures, Exact Imaging recommends performing two tests for the transperineal stepper annually, when improper alignment (due to needle misalignment with the *Transperineal Grid overlay*) is suspected or when the transperineal stepper is disassembled.

The procedures are:

- Check the template grid holder vertical height
- Check the needle path alignment

2.1.1 Checking the Template Grid Holder Height

To verify the template grid holder height:

1. Perform a visual inspection to check if the template grid holder is set to the height corresponding to the 8th pin (refer to Figure 162), and centered (refer to Figure 163)
2. If adjustment is needed, proceed to step 3, otherwise proceed to section 2.1.2, and perform the *needle path alignment check*
3. Refer to the manufacturer's instructions for information about making basic adjustments to the stepper.
4. Using the appropriate hex driver, loosen the screws securing the *template grid holder*.
5. Shift the *template grid holder* upwards until it is set to the height corresponding to the 8th pin (refer to Figure 162).
6. Adjust the horizontal position of the *template grid holder* until it is centered between the arms of the *template grid holder* (refer to Figure 163).

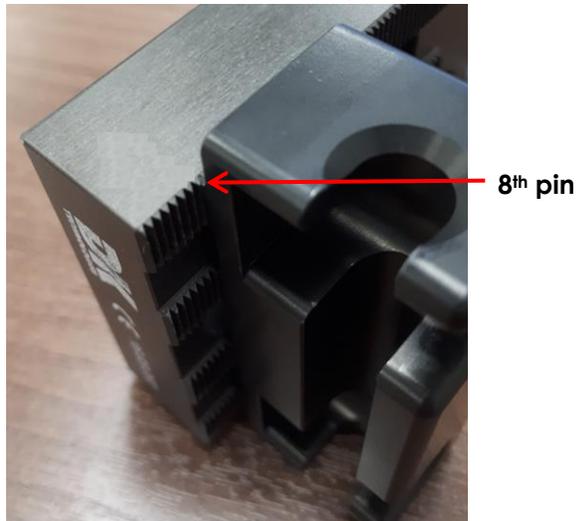


Figure 162: Template Grid Holder at 8th Pin Position



Figure 163: Centered Template Grid Holder



After checking the vertical height of the template grid holder, 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.

2.1.2 Checking the Needle Path Alignment

The procedure to check the needle path alignment consists of the following actions:

- Verifying in the sagittal view that the template grid holder is set to the correct vertical height and is centered correctly
- Verifying in the transverse view that the template grid holder is set to the correct vertical height and is centered correctly

To check the needle path alignment for the transperineal stepper:

1. After performing the template grid holder height check described in section 2.1.1, clamp the transducer into the *transducer cradle*.
2. Create a water bath as follows:
 - Fill a 33 cm x 19 cm (13" x 7.5") container with distilled water
 - If required, a piece of rubber or similar material that is the same width as the container may be placed at the front of the container (to secure the needle tip)

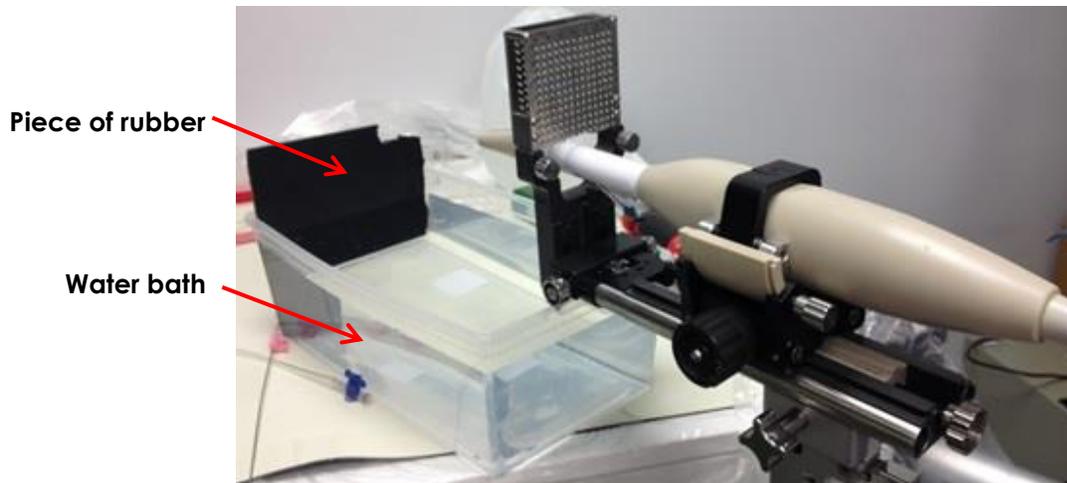


Figure 164: Water Bath Configuration

3. Advance the transducer along the *tracking stepper rail* to the point shown in Figure 165.

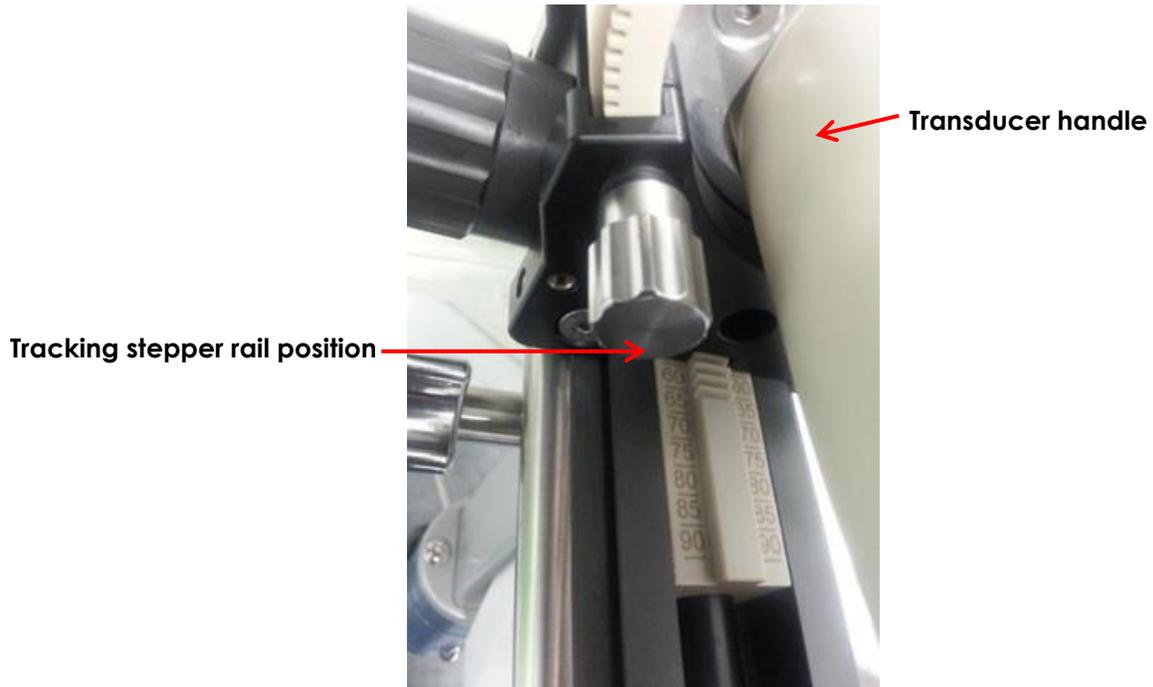


Figure 165: Tracking Stepper Rail Position

4. Tilt the transducer and place it in the water bath as shown in Figure 166.



Figure 166: Transducer and Transperineal Stepper in Water Bath

5. Begin imaging in 2D Mode and observe the *Roll Angle* in the status panel. Adjust the tilt of the transducer as required until the *Roll Angle* is in the range 87 – 93 degrees.

To check the vertical height of the transperineal stepper in 2D Mode:

1. Set up a test patient using the *Medium image preset*.
2. In 2D Mode, enable the *Transperineal Grid* (refer to *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*).
3. Rotate the transducer in the transducer receptacle such that it sits in the *zero notch*.
4. Advance a needle through location D3 on the *template grid*. (If required, secure the tip of the needle in the piece of rubber for increased measurement accuracy.)

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.

5. Using the *Distance* measurement tool, measure the distance between the center of the needle (i.e., the bright area in the image) and the center of the *Transperineal Grid* needle guides representing the expected trajectory for the needle in the D3 location.

A measurement of 0.3 cm or less is an acceptable result.

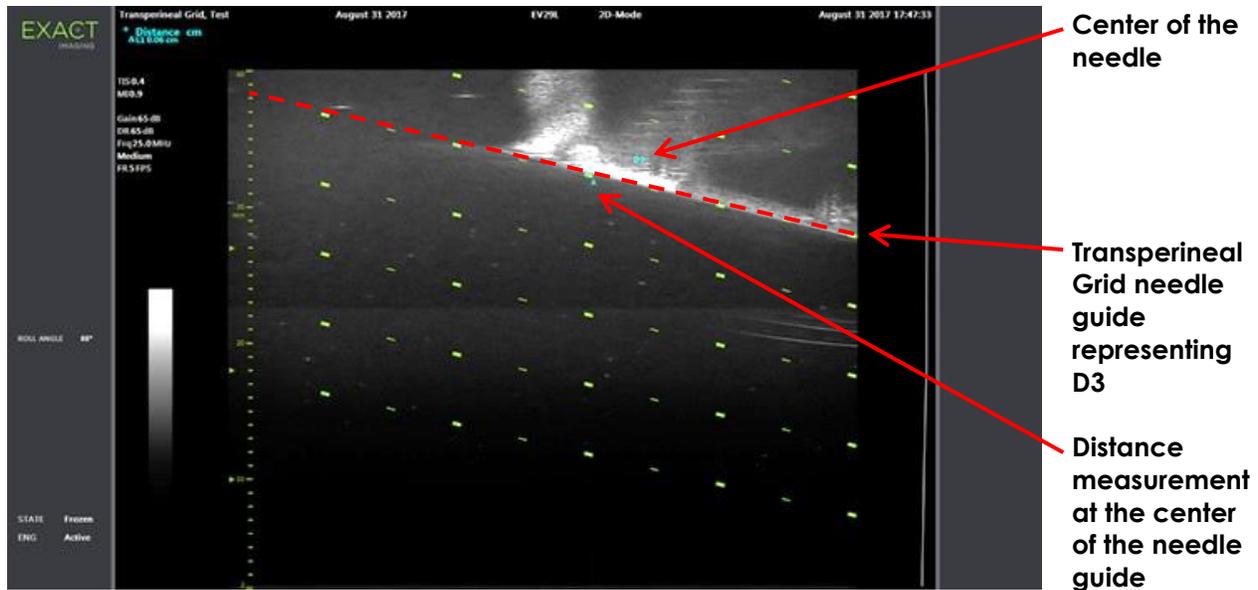


Figure 167: Measured Distance Between Transperineal Grid and Needle

6. Repeat step 1 through step 5 using the *Large image preset*.
A measurement of 0.15 cm or less is an acceptable result.
7. Repeat step 1 through step 5 using the *Large image preset* and location D4 on the *template grid*.
A measurement of 0.15 cm or less is an acceptable result.

To check the vertical height of the transperineal stepper in Transverse Mode:

1. Set up a test patient using the *Medium image preset*.
2. In 2D Mode, enable the *Transperineal Grid*.
3. Rotate the transducer in the transducer receptacle such that it sits in the *zero notch*.
4. Advance needles through locations e2 and b2 on the *template grid*. (If required secure the tip of the needle in the piece of rubber for increased measurement accuracy.)
5. Press **Dual/Transverse** on the *control panel*.
6. Construct a transverse image for the needle in the e2 location as follows:
 - Rotate the transducer to the expected location of the needle (i.e., on or near the e2 location on the image).
 - Gently hold the cradle only with one hand and rotate slowly.
 - Observe the needle in the image as the transverse image is constructed from right to left. (Due to motion sensor accuracy, it may be necessary to construct the image several times to get the required image.)
7. Using the *Distance* measurement tool, measure the distance between the e2 location on the *Transperineal Grid* and the brightest spot in the needle image.
A measurement of 0.3 cm or less is an acceptable result.



Figure 168: Measured Distance Between Transperineal Grid and Needle in Location e2

8. Construct a transverse image for the needle in the b2 location as follows:

- Rotate the transducer to the expected location of the needle (i.e., on or near the b2 location on the image).
- Gently hold the cradle only with one hand and rotate slowly.
- Observe the needle in the image as the transverse image is constructed from left to right. (Due to motion sensor accuracy, it may be necessary to construct the image several times to get the required image.)

9. Using the *Distance* measurement tool, measure the distance between the b2 location on the *Transperineal Grid* and the brightest spot in the needle image.

A measurement of 0.3 cm or less is an acceptable result.

If the measured values are outside an acceptable range, contact Technical Support using the contact information in Appendix D.

WARNING
EN-W66



After checking the needle path alignment of 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.

Appendix A Operating Specifications

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
Environmental (Operating) ExactVu system and ExactVu transducers	Electrical components of the ExactVu micro-ultrasound system are attached to an <i>isolation transformer</i> 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 <i>system cart</i> . Temperature <ul style="list-style-type: none"> • 10 °C to 35 °C (50 °F to 104 °F) Humidity <ul style="list-style-type: none"> • 15% to 80% non-condensing Atmospheric Pressure (at altitudes less than 2000 m) <ul style="list-style-type: none"> • 80 kPa to 106 kPa
Environmental (Storage) ExactVu system and ExactVu transducers	Temperature <ul style="list-style-type: none"> • -20 °C to 50 °C (-4 °F to 122 °F) Relative Humidity <ul style="list-style-type: none"> • 15% to 95% non-condensing Atmospheric Pressure <ul style="list-style-type: none"> • 50 kPa to 106 kPa
Environmental (Transportation) ExactVu system	Temperature <ul style="list-style-type: none"> • -20 °C to 50 °C (-4 °F to 122 °F) Relative Humidity <ul style="list-style-type: none"> • 15% to 85% non-condensing Atmospheric Pressure <ul style="list-style-type: none"> • 50 kPa to 106 kPa

Operating Environment	Details
Environmental (Transportation)	Temperature <ul style="list-style-type: none"> -20 °C to 50 °C (-4 °F to 122 °F)
ExactVu transducers	Relative Humidity <ul style="list-style-type: none"> 15% to 95% non-condensing
	Atmospheric Pressure <ul style="list-style-type: none"> 50 kPa to 106 kPa

Table 8: ExactVu and Transducer Operating and Storage Environment

EV29L Sterile Transrectal Needle Guide

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

Table 9: EV29L Sterile Transrectal Needle Guide Operating and Storage Environment

EV29L Non-Sterile Reusable Transrectal Needle Guide

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

Table 10: EV29L Non-Sterile Reusable Transrectal Needle Guide Operating and Storage Environment

Appendix B System Cabling

Cables that may be serviced at a customer site

Part Number	Description (Cables common to all hardware versions)
6032	Cable, Techboard audio
6036	Cable, IO Plate USB port
6038	Cable, Power button, 2 headers to bare wire cable
6039	Cable, Power cord (North America)
6040	Cable, Power cord (Europe)
6046	Cable, CB to BCB connection, Fiber optic cable #1 & #2
6048	Cable, CB to BCB connection, Display port cable #1 & #2
6058	Cable, Power Button LED
6101	Cable, Printer Power Cable (if the thermal printer is part of the ExactVu system configuration)
6102	Cable, Printer USB Cable (if the thermal printer is part of the ExactVu system configuration)
6104	Cable, DPH Medical Actuation Button Cable
6107	Cable, Ethernet extension cable
6108	Cable, Power cord (United Kingdom)
6202	SATA STR to R/A cable
6496	Cable, DC Fan Extension Cable
6873	Cable, Power cord (Switzerland)
6875	Cable, Power cord (Israel)
7194	Cable, Power cord (Brazil)
7156	Cable, Second Monitor Video, Ultra HDMI Cable, 16 ft
7157	Cable, Second Monitor Power Cord, North America, 15 ft
7158	Cable, Second Monitor Power Cord, Europe, 15 ft
7160	Cable, Second monitor Video, HDMI cable, 20 ft
7162	Cable, Second Monitor Power Cord, United Kingdom, 15 ft
7163	Cable, Second Monitor Power Cord, United Kingdom, 20 ft
7164	Cable, Second Monitor Power Cord, Switzerland, 16 ft
7204	Cable, Second Monitor Power Cord, Israel, 15 ft
7205	Cable, Second Monitor Power Cord, Brazil, 14 ft 9 in

Table 11: System Cabling that may be Serviced On-Site

Part Number	Description (Cables only in ExactVu 2.5 hardware versions)
6675	Voltage selector with cables

Table 12: System Cabling that may be Serviced On-Site – ExactVu 2.5 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.6 hardware versions)
6969	HDMI Splitter power cable
6932	Display Port to HDMI adapter cable

Table 13: System Cabling that may be Serviced On-Site – ExactVu 2.6 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.6 and ExactVu 2.9 hardware versions)
6908	Voltage selector with cable

Table 14: System Cabling that may be Serviced On-Site – ExactVu 2.6 and ExactVu 2.9 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.9 hardware versions)
7191	Display port to HDMI adapter

Table 15: System Cabling that may be Serviced On-Site – ExactVu 2.9 Hardware Versions

Cables that must be serviced off-site

Part Number	Description (Cables common to all hardware versions)
6031	Cable, Main monitor power
6033	Cable, Techboard USB
6034	Cable, Techboard video (PN 7187 in ExactVu 2.9 hardware version)
6035	Cable, Techboard power
6037	Cable, Computer power
6045	Cable, Power socket to ground lug cable
6051	Cable, Power module 3 power
6052	Cable, Backplane power
6055	Cable, Power module 1 power
6097	Cable, OpenBus RJ45 to RJ45 Linak Control Box Cable
6098	Cable, OpenBus extension cable
6099	Cable, Wire - Relay Control
6100	Cable, Wire - Deck Ground Lug to Column Ground Lug
6103	Cable, Techboard audio extension cable
6105	Cable, Linak Modular extension cable 6W
6106	Cable, Linak control box IEC power cord
6497	Cable, DC Fan Power Cable
6664	Cable, Power filter to ICL, no ground
6666	Cable, Ground, Power Filter to Transformer

Table 16: System Cabling that must be Serviced Off-Site

Part Number	Description (Cables only in ExactVu 2.5 hardware versions)
6042	Cable, Transformer Input, No ground
6050	Cable, Card cage power
6056	Cable, Power module 2 power
6057	Cable, DC supply power
6059	Cable, Relay power
6667	Cable, ICL to Transformer

Table 17: System Cabling that must be Serviced Off-Site – ExactVu 2.5 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.5 and ExactVu 2.9 hardware versions)
6030	Cable, Main monitor video, display port cable

Table 18: System Cabling that must be Serviced Off-Site – ExactVu 2.5 and ExactVu 2.9 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.6 hardware versions)
6900	HDMI Mount with Cable (to I/O Plate)
6947	Cable, Main monitor video, HDMI cable

Table 19: System Cabling that must be Serviced Off-Site – ExactVu 2.6 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.6 and ExactVu 2.9 hardware versions)
6909	Power Distribution Module to 12V DC Supply, with Attachment for Fan
6933	Monitor USB 3.0 Cable

Table 20: System Cabling that must be Serviced Off-Site – ExactVu 2.6 and ExactVu 2.9 Hardware Versions

Part Number	Description (Cables only in ExactVu 2.9 hardware versions)
7186	HDMI Mount with Cable (to I/O Plate)

Table 21: System Cabling that must be Serviced Off-Site – ExactVu 2.9 Hardware Versions

Appendix C Measurement of Transducer Leakage Current

The tests outlined in this appendix are performed during the manufacture of the ExactVu system. They are provided as a reference for field tests that may be performed if damage or deterioration to an Exact Imaging transducer is suspected.

Exact Imaging recommends discontinuing the use of a transducer when damage or deterioration is suspected, and to instead contact Technical Support using the contact information in Appendix D.

1 Required Tools and Equipment

1.1 Tools and Test Equipment

Test Equipment	Model/Part Number
Fluke Safety Analyzer	ESA609
Table Top Safety Test Tank	T02600-01
Conductive fluid	Calibration solution WD-00653-16 (Oakton spec, 84µS) or equivalent or 0.9% NaCl using distilled water (i.e., 90 grams of table salt in 1 L of distilled water).
Kimwipe	KimTech Science Brand
Exact Imaging transducer	EV29L, EV9C and EV5C



All test equipment must have up to date calibration.

Record the serial number or asset number on the test form found in section 4 on page 198.

1.2 Safety

ESD clothing and equipment are not required while performing this procedure.



Check if there is a sign of the water leakage before each use of the *Safety Test Tank*.

If there is water leakage around the *Safety Test Tank* at any time before or during the test, stop and turn off the ExactVu system immediately.



High voltages are used in leakage tests. To prevent electrical shock or other injury, do not touch any part of the *Safety Test Tank* while the test is being conducted.



High voltage is applied to the output terminal. Always ensure the *Safety Analyzer* is disconnected from the wall main outlet when connecting and disconnecting it to the *Safety Test Tank*.

2 Test Procedure

CAUTION
EN-C58

Consult with Technical Support before executing these tests to ensure any person performing these tests is properly trained. Improper test setup can cause damage to Exact Imaging transducers.

2.1 Test Setup and Preparation

ExactVu system must be turned on approximately 30 minutes prior to use to allow for proper equipment warm-up time.

2.1.1 Safety Test Tank

- Fill the Safety Test Tank with conductive fluid with no transducer in the tank.
- Add or remove conductive fluid as required as shown in Figure 169.



Figure 169: Safety Test Tank Setup

2.1.2 Setup for the Safety Analyzer

The ESA609 Safety Analyzer setup is shown in Figure 170.

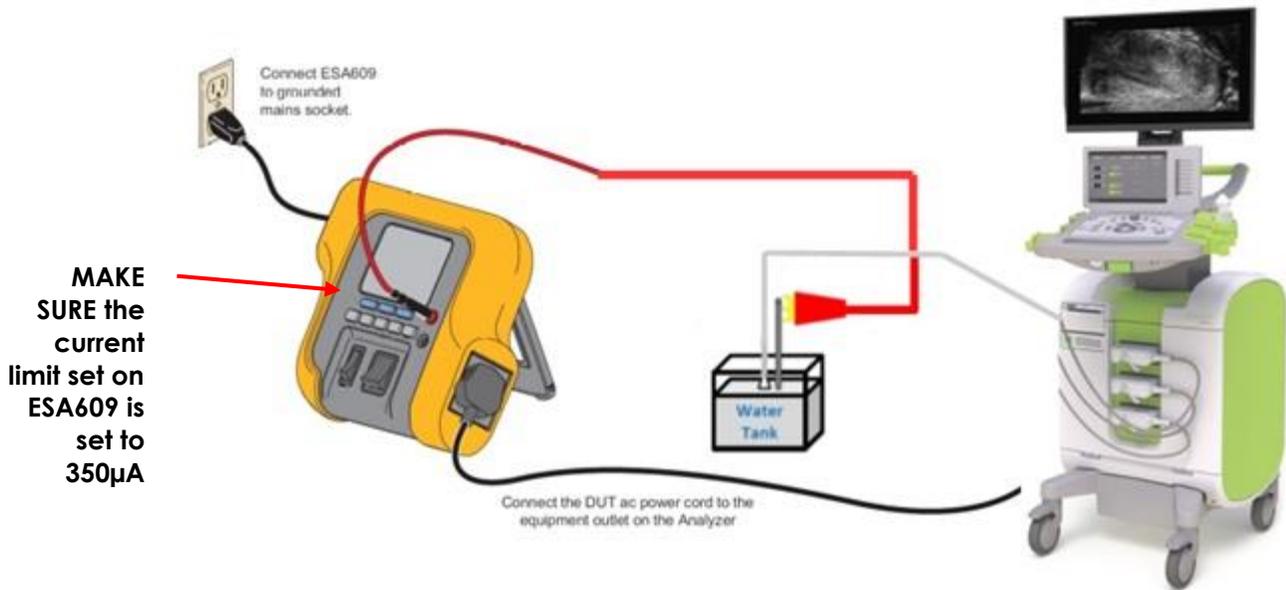


Figure 170: Test Setup for Leakage Testing

To set-up the Safety Analyzer:

1. Turn Polarity to OFF. Turn Neutral to OPEN.
2. Set the current limit on the ESA609 to 350 μ A.
3. Connect the ExactVu system to the ESA609.
4. Connect the ESA609 red lead to the Safety Test Tank as shown in Figure 171.



Figure 171: Connect Safety Analyzer to Safety Test Tank

5. Connect the ESA609 into the power outlet.
6. On the Safety Analyzer, select IEC62353.
7. Press the μ A button.
8. Ensure the display shows Direct Equipment Current as shown in Figure 172.



Figure 172: Safety Analyzer Display

2.2 Electrical Safety Tests

Two electrical safety tests are required according to IEC 62343. These are:

- Transducer soaking
- Leakage test

2.2.1 Transducer Soaking

- Immerse the transducer up to the soak level (approximately half-way up the handle) as shown in Figure 173.



Figure 173: EV9C Transducer Immersed to its Soak Level

CAUTION
EN-C25

Do not immerse the EV29L, EV9C or EV5C transducer beyond its soak level.

2.2.2 Leakage Test

1. Check the lower left corner of the display and ensure it indicates *Earth:Closed*. If it is not, press **F1**.
2. Set the following:
 - *Outlet switch set to normal*
 - *Neutral switch set to Closed*
3. Turn on the ExactVu system. Record the *leakage current*. Turn off the ExactVu system.
4. Set the following:
 - *Outlet switch set to reverse*
5. Turn on the ExactVu system. Record the *leakage current*. Turn off the ExactVu system.
6. Set the following:
 - *Outlet switch set to normal*
 - *Ground set to Open*
7. Turn on the ExactVu system. Record the *leakage current*. Turn off the ExactVu system.
8. Set the following:
 - *Outlet switch set to reverse*
9. Turn on the ExactVu system. Record the *leakage current*. Turn off the ExactVu system.
10. Set the following:
 - *Outlet switch set to normal*
 - *Neutral switch set to Open*
 - *Ground set to closed*
11. Record the *leakage current*.
12. Set the following:
 - *Outlet switch set to reverse*
13. Record the *leakage current*.

3 Shutting down

1. Disconnect the *Safety Analyzer* from the wall outlet.
2. Remove the transducer from the test setup.
3. Rinse the transducer with distilled water.
4. Dry the transducer housing with paper towel.

5. Dry the transducer lens with a Kimwipe.
6. Disconnect the S2 HV red lead.
7. Remove the metal rod from the *Safety Test Tank*.
8. Rinse the rod with distilled water.
9. Store the metal rod in a dry place.
10. Cover the *Safety Test Tank*.

WARNING
EN-W35



To prevent possible infection or contamination, the transducer must be reprocessed following the complete procedure in *Care, Cleaning and Use Guide for EV29L™ High Resolution Side-Fire Transducer*, the *Care, Cleaning and Use Guide for EV9C™ Transrectal Transducer* or the *Care, Cleaning and Use Guide for EV5C™ Abdominal Transducer* prior to using it in another procedure.

Always use a sterile transducer sheath during a transrectal procedure.

4 Safety Test Result

Complete all details in the tables shown in each section below.

4.1 Test Execution Summary

Test Date:

Tester (print & sign):

Part S/N:

4.2 Test Equipment Used

Test Equipment	Model	Part Number	Serial Number
Electrical Safety Analyzer:	Fluke	ESA609	
Table Top Safety Test Tank:		T02600-01	
Kimtech Kimwipes:	KimTech Science Brand	06666A	N/A
Conductive fluid:	Calibration solution WD-00653-16 (Oakton spec, 84µS) or 0.9% NaCl dissipated in distilled water (90 grams of table salt in 1 L of distilled water).		N/A
Transducer 1:			
Transducer 2:			
Transducer 3:			

4.3 Test Results

Test #	Test	Pass Criteria		Leakage Current	Pass/ Fail	Comments
		Minimum	Maximum			
	Leakage Current (Normal, Neutral closed, GND closed)	0 μ A	100 μ A			
	Leakage Current (Reversed, Neutral closed, GND closed)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral closed, GND open)	0 μ A	500 μ A			
	Leakage Current (Reversed, Neutral closed, GND open)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral Open, GND closed)	0 μ A	500 μ A			
	Leakage Current (Reversed, Neutral Open, GND closed)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral closed, GND closed)	0 μ A	100 μ A			
	Leakage Current (Reversed, Neutral closed, GND closed)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral closed, GND open)	0 μ A	500 μ A			
	Leakage Current (Reversed, Neutral closed, GND open)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral Open, GND closed)	0 μ A	500 μ A			
	Leakage Current (Reversed, Neutral Open, GND closed)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral closed, GND closed)	0 μ A	100 μ A			
	Leakage Current (Reversed, Neutral closed, GND closed)	0 μ A	500 μ A			
	Leakage Current (Normal, Neutral closed, GND open)	0 μ A	500 μ A			

Leakage Current (Reversed, Neutral closed, GND open)	0μA	500μA
Leakage Current (Normal, Neutral Open, GND closed)	0μA	500μA
Leakage Current (Reversed, Neutral Open, GND closed)	0μA	500μA

Appendix D 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