

Release Notes for Customers

ExactVuTM High Resolution Micro-Ultrasound System



Part Number 6658 Revision 3.1



Preface



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Trademarks

Exact Imaging trademarks:

- ExactVuTM
- FusionVu™
- Exact Imaging™

Version information

System: ExactVu[™] High Resolution Micro-Ultrasound System

Software: ExactVu™ Version 3.1

Release Notes for Customers (PN 6658) Rev 3.1, original instructions

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1 Introduction

1.1 General

This Release Notes for Customers ExactVuTM High Resolution Micro-Ultrasound System document introduces the new features that are part of software version 3.1 of the ExactVu High Resolution Micro-Ultrasound System. It also identifies issues known to exist in the ExactVu system that may impact the ExactVu system during use. Where available, this document lists suggested workaround(s) for each issue.

It is important to use this Release Notes for Customers in conjunction with the Operation and Safety Manual for ExactVuTM High Resolution Micro-Ultrasound System. All warning and cautions are in chapter 2 of the Operation and Safety Manual provided with the ExactVu system.

If the ExactVu system malfunctions, fails to respond, if the image is severely distorted or degraded, or you suspect the system is not functioning correctly in any way contact Technical Support using the contact information for your region at https://www.exactimaging.com/contact-us.

1.2 New Features in ExactVu Software Version 3.1

ExactVu software version 3.1 releases two features applicable to the general workflow for performing transrectal and transperineal biopsy procedures EV29L transducer:

- Identifying targets (EV29L only)
- Create a study report (EV29L only)

Other feature changes in this software version pertain to:

- EV29L transducer angles
- DICOM Configuration
- Pre-void and Post-void Bladder Volume Measurement
- ExactVu study export formats

These features are described in the following sections.

2 Changes to the Touch Screen

2.1 Workflow

Option	Explanation
Angle Reset -> Mid- Line	In ExactVu 3.1 software, in addition to existing functionality to mark the mid-line and left and right lateral borders of the prostate, the Mid-Line control also sets the Angle value to 0°, indicating the relative rotation of the EV29L transducer based on its motion sensor position (refer to section 3.1).

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Option	Explanation
Target control	In 2D Mode, appears with a bullseye graphic, and adds a target angle to the Target List and saves a frame (refer to section 4.1).
(enabled when the EV29L transducer is active in 2D Mode or Biopsy Mode and a Mid-Line has been	
set)	In Biopsy Mode, appears with a needle gun graphic. The Target control saves a cine image, and links it to a selected target angle (refer to section 4.2).
Change/Done	This control allows the operator to switch between automatically linking biopsy targets to stored cine images based on the transducer angle and manually selecting target angles to link to stored cines (refer to section 5).

2.2 Report (new)

Option	Explanation
Target List	Allows a cine image of a biopsy to be linked to the corresponding target (this is the same as the Target List on the Workflow touch screen)
Volume measurement and alignment controls	Indicates whether the Mid-line, Left and Right frames have been identified, and whether measurements have been made, and allows them to be set if needed
Needle depth positioning controls	Allows the operator to mark the needle's insertion depth and position (enabled only if volume measurements have been made)

Refer to section 5 for details.

3 EV29L Transducer Angles

3.1 Zeroing the EV29L Transducer

	Previous ExactVu software versions	ExactVu software version 3.1
EV29L angle display	Indicated the angle of rotation of the EV29L transducer	Whenever the transducer orientation is more than 20 degrees away from the zero-axis in the pitch and yaw directions, the following information is displayed:
		 The roll angle value is displayed in red text
		 The status area displays "Off Axis"

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	Previous ExactVu software versions	ExactVu software version 3.1
Setting the 0- degree EV29L angle	Reset control on the Workflow touch screen sets the 0-degree position for the EV29L Angle value	FusionVu Mid-Line control sets the 0-degree position for the EV29L Angle and also sets a 0-degree position in the pitch and yaw directions (in addition to its function to align the mid-line of the ultrasound image with a loaded MRI study)

To set the zero-degree position for the Angle value while imaging with the EV29L transducer:

- 1. Rotate the transducer so that the transducer lens is facing towards the desired zero position.
- 2. From the Workflow touch screen, press Mid-Line.

The Angle value displayed on the imaging screen changes to show 0 degrees and changes from white text to yellow text.

The updated zero-degree position is retained for the remainder of the study or until the Mid-Line control is pressed again.

4 Marking Targets for Biopsy (EV29L transducer only)

4.1 Identifying Targets

While imaging with the EV29L transducer in 2D Mode, a Target control is displayed as a bullseye graphic on the Workflow touch screen, used to identify anatomy of interest to consider for biopsy.

The Target control adds a target to a list of sequentially numbered targets in both the status panel and on the touch screen, showing the angle when the Target control was pressed.

The Target List displays five targets at a time, and is sorted by angle value. The Target List can be scrolled when more than five targets are identified. While rotating the EV29L transducer, if the angle is within 5 degrees of a target, the target is highlighted in the Target List. If multiple targets are within range, they will all be highlighted, with a line between the closest targets to indicate the relative position of the transducer to nearby targets.

To identify biopsy targets using the Target control while imaging in 2D Mode:

- 1. Identify the Mid-Line as described in section 3.1.
- 2. While performing an imaging sweep of the prostate, press **Target** on the touch screen.

A target angle is added to the on-screen Target List and on the Workflow touch screen, and a frame is saved.

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Figure 1: Target List in Biopsy Mode

NOTE EN-N190

Targets are identified using the transducer angle relative to the Mid-line. If the Mid-line is changed after targets are identified, the relative angles of existing targets will not change.



In 2D Mode, saving a frame using the *Frame* control or foot pedal does not affect the Target List.

4.2 Linking Targets to Cine Images

If the operator identifies targets of interest while imaging with the EV29L transducer in 2D Mode, they may automatically link cine images stored during biopsy with targets in the Target List. Alternatively, cine images stored during biopsy may be manually linked to target angles.

When one or more biopsy cines has been linked to a target angle, the Target List shall display a checkmark beside the target and a count of the number of cine images linked to the target.

To automatically link a cine image with a single highlighted Biopsy Target:

- In Biopsy Mode, rotate the EV29L transducer to a target of interest.
 If the transducer angle is within ±5° of an angle in the Target List the angle is highlighted.
- 2. Press Target on the touch screen.

A cine image is stored and linked to the highlighted target. The Target List indicates the number of cine images saved at that location.



If multiple targets are highlighted when taking a biopsy at a location of interest, and the operator presses *Target* on the touch screen, a cine image is stored but is not linked to any of the highlighted targets.

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To select a target to link with one or more cine images:

- 1. Tap a target from the Target List on the touch screen.
- 2. Rotate the transducer to the target and press Target on the touch screen.

A cine image is stored and is linked to the highlighted target.

If the operator presses Target again at the same location, an additional cine image is stored and linked to the highlighted target.

The Target List displays the total number of cine images stored at that location.

To identify systematic biopsies:

- 1. Tap **Systematic** on the touch screen.
- 2. Rotate the transducer to the desired angle and press Target on the touch screen.

A cine image is stored and is identified as a Systematic biopsy.

The Target List displays the total number of Systematic biopsy cine images.



Figure 2: Target List in Biopsy Mode



In Biopsy Mode, the Cine control and foot pedal (when configured to save cine images) behave the same way the Target control on the Workflow touch screen behaves.

4.3 Thumbnail for Linked Images

As in previous ExactVu software versions, thumbnails for all images saved in the current study are displayed for saved images in the *Image List Panel*. In ExactVu software version 3.1, the thumbnail for a cine image stored in Biopsy Mode also indicates whether it is linked to any targets listed in the Target List.

Thumbnails that are linked to targets display details within their thumbnail as follows:

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- Lower left corner: the thumbnail number
- Lower right corner: a play icon to identify the thumbnail as a cine image (where applicable)
- Top left corner: the target number and needle (if present) for frames and cine images linked to a target, or "Syst", as applicable
- Top right corner: the angle of the needle for Systematic frames and cine (if identified)

5 Reporting (EV29L transducer only)

The ExactVu system provides options to create reports for studies with images stored using the EV29L transducer. The report is a .pdf file that documents prostate measurements, images of targets, and an optional 3D diagram showing where biopsy samples were taken.

NOTE



The ExactVu Report feature is compatible only with patient studies created in software version 3.1 or later.

The ExactVu report contains the following information:

- Clinic Name
- Patient details, including patient name, date of birth and MRN (Medical Record Number)
- Exam details, including study description, accession number, PSA and PSA density (if available, performing physician, biopsy date)
- Prostate volume measurements: If volume measurement was saved in Transverse Mode, it is
 used in the report; otherwise, the operator may create a Prostate length and height
 measurement from the Report tab
- Image data for each target, including the image captured when the Target control was selected, the number of associated biopsies and space to manually record pathology results
- Data for systematic biopsies, with space to manually record information such as location in the prostate from which the sample was taken and pathology
- Information about other cine images saved in Biopsy Mode
- A diagram showing the angle of the biopsy needles from which biopsy samples were taken (if enabled [refer to section 5.5])

5.1 Report Options

When the operator selects to close the study, a prompt appears with the option to create a report, create a new patient study or cancel.

To create a report:

- 1. Complete a study and press New/Close Study.
- 2. When prompted, select **Reporting** from the prompt.

The Report tab is displayed on the touch screen with configurable options to be displayed in the report:

- Modify links or create new links between cine images and target angles
- Mark the Right edge, Mid-line and Left edges of the prostate

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- Specify the prostate length and height (if a volume measurement was not created during the study)
- Specify needle positions in cine images saved in Biopsy mode

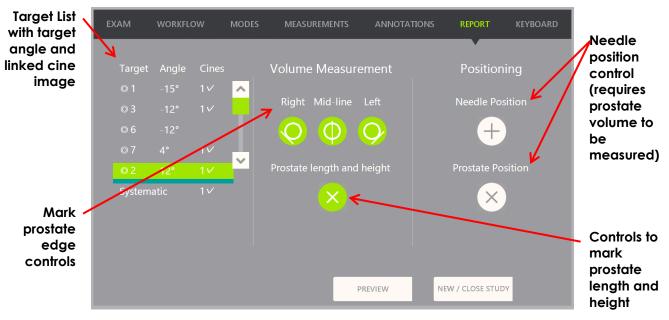


Figure 3: Report touch screen

- 3. Configure options for the report as described in the following subsections.
- 4. Preview the report as described in section 5.2 or close the study as described in section 5.3.

5.1.1 Modify links or create new links to targets

Prior to displaying a report, the operator may make changes to the cine images stored in the study and the targets with which they were linked. The operator may also link a frame or a cine image saved in 2D Mode to a biopsy target.

These changes can only be made during the live study.

To create or modify a link between a target and a cine image:

- 1. Select the thumbnail for the image to link to a target in the Target List.
- 2. Tap **Change** from the Workflow touch screen.
- 3. Select the target in the Target List.
- 4. Tap Done.

A checkmark is placed beside the target and the thumbnail is updated to show the linked target number.

A count of biopsy cine images for the target is shown next to the checkmark.

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5.1.2 Mark the prostate boundaries

The mid-line and lateral boundaries of the prostate are required to be identified in order to include biopsy needle locations in the 3D Diagram in the report. If the operator didn't identify them during imaging, they may be identified when setting up a report.

To mark the mid-line and lateral boundaries of the prostate:

- 1. Select the thumbnail for a suitable cine image.
- 2. Set the mid-line and lateral boundaries on the Report touch screen as follows:
 - Scroll to the frame showing the mid-line and tap **Mid-Line**.
 - Scroll to the frame showing the lateral border of the prostate on the right side and press Right.
 - Scroll to the frame showing the lateral border of the prostate on the left side and press Left.

5.1.3 Specify the prostate length and height

The prostate volume is required to be identified in order to include biopsy needle locations in the 3D Diagram in the report. If the operator didn't take a volume measurement in Transverse Mode during the study, the prostate length and height may be identified when setting up a report.

To specify the prostate length and height:

- 1. Select the thumbnail for a suitable cine image.
- 2. From the Report touch screen, tap **Prostate length and height**.

A caliper is displayed on the image. Either the prostate length or prostate height may be set first.

- 3. Using the trackball, position the caliper at the desired location.
- 4. Press **Next** on the control panel.
- 5. Using the trackball, position the second caliper at the desired location.
- 6. Press **Set** on the control panel.

The first measurement is complete, and caliper to create the second measurement is displayed on the image.

7. Position both calipers and complete the measurement.

5.1.4 Specify the needle position

For each Biopsy mode cine image, the operator may position a line overlay to align the biopsy needle's insertion depth and the prostate position. Both must be identified for a biopsy track to be displayed on the 3D diagram on the report. Either the needle insertion depth or prostate position may be set first.

To position the biopsy needle in a cine image saved in Biopsy Mode:

- 1. Select the thumbnail for the cine image, and scroll to the applicable frame.
- 2. From the Report touch screen, tap **Needle Position**.

A caliper is displayed on the image.

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- 3. Using the trackball, position the caliper at the desired location.
- 4. Press **Next** on the control panel.
- 5. Using the trackball, position the second caliper at the desired location.
- 6. Press **Set** on the control panel.

The needle position is complete, and vertical line with a cross hair is displayed on the image to set the prostate position.

- 7. Using the trackball, position the crosshair desired location and press **Set** on the control panel.
 - The biopsy needle positioning is complete, and the biopsy needle track will be displayed for this cine image in the 3D diagram in the report (if enabled).
- 8. Repeat for all desired cine images.



The mid-line and left and right lateral borders of the prostate must be identified before the Prostate Position and Needle Position controls are enabled.

Both the Prostate Position and Needle Position are required for a biopsy track to be displayed on the 3D Diagram.

5.2 Viewing Reports

After setting up report options on the Report touch screen, the operator may view the report before closing the study.

To view the report:

- 1. From the Report touch screen, tap **Preview**.
 - The first page of the report is displayed on the screen.
 - The controls on the touch screen update to show Previous Page, Next Page and Done.
- 2. Tap the **Previous Page** and **Next Page** controls to scroll through the pages of the report.
- 3. Tap **Done** to close the view of the report.

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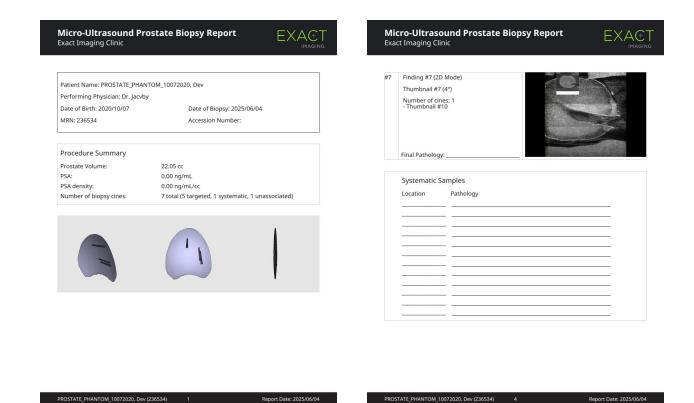


Figure 4: Sample Report page 1

Figure 5: Sample Report last page

5.3 Closing the study

After the operator specifies options to include in the report as described in section 5.1, they may close the study.

When closing the study, the report is saved with the study in .pdf format. The report may be viewed or exported from the Patient List after closing the study, as described in section 5.4.

5.4 Accessing Reports from the Patient List

The Patient List includes controls for ExactVu reports, including:

- Creating reports (available for studies with saved images from the EV29L transducer)
- Exporting reports (available when a USB storage device is connected to the ExactVu system)

It also includes in the Status column an icon that indicates whether or not a study contains a report.

To create a report for a study:

- 1. Using the trackball, select the desired study (with saved EV29L images) for which to create the report.
- 2. Position the cursor over the Review Images control and press Set.
- 3. The Report touch screen opens and the operator is able to configure report options as described in section 5.1.

The operator may view the report or close the study.

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After closing the study, the Patient List displays a status icon to indicate that a report has been created for the study.

To export reports for selected studies:

- 1. Connect a USB storage device to one of the USB connectors on the left side of the touch screen or on the rear of the monitor.
- 2. Using the trackball, select one or more studies that have a report.
 - Studies for which a report has already been created display a Report icon.
- 3. Position the cursor over the Export Reports control and press **Set**.

The reports for the selected studies are exported to the USB storage device.

NOTE EN-N186



It is not possible to export ExactVu reports to a PACS server.

NOTE EN-N187



It is not possible to view reports on the ExactVu system after the study is closed. Reports can only be viewed by exporting them from the ExactVu system to a USB storage device, and then reviewing them using a .pdf viewer.

To view an ExactVu report:

- 1. Connect a USB storage device onto which ExactVu reports have been exported to a device that has a .pdf viewer installed.
- 2. Open Windows Explorer and navigate to the folder containing the reports.
- 3. Open the desired report in the .pdf viewer.

5.5 Reporting Preferences

The Preferences > Reporting screen provides configurable options related to generating reports, including:

- Paper Size (Letter or A4)
- ON/OFF toggle to include/exclude a 3D diagram of biopsy samples

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Figure 6: Preferences > Reporting

To specify a paper size preference:

- 1. Next to Paper Size select one of the available options:
 - Letter
 - A4

The selected paper size is used to format ExactVu reports.

2. Select **Save** if no further Preferences updates are being made.

To toggle the 3D diagram of biopsy samples in the report:

- 1. Select **ON** or **OFF** next to Include 3D Diagram.
 - When *Include 3D Diagram* is toggled *ON*, reports will include a 3D Diagram of the prostate, with angled lines positioned to represent biopsy needles.
- 2. Select **Save** if no further Preferences updates are being made.

6 DICOM Configuration Changes

ExactVu software version 3.1 allows a specific Character Set and Transfer Syntax to be set during configuration of DICOM and PACS settings for the ExactVu system's Store, Modality Worklist and MRI Query/Retrieve features. Configuration of DICOM and PACS settings is performed in the Preferences > DICOM SETTINGS screen for each DICOM option.

Exact Imaging recommends that this configuration be performed by IT professionals, using values assigned by the clinic's IT department.

The following Character Sets may be configured:

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- ISO_IR 192 UTF-8 (default)
- ISO IR 100 Latin No. 1
- ISO IR 101 Latin No. 2
- ISO_IR 6 ASCII

The following Transfer Syntax options may be configured:

- JPEG 2000 Lossless (default)
- Explicit VR Little Endian ISO_IR 192 UTF-8 (default)

NOTE EN-N184

Only ASCII characters are permitted in DICOM, Network and Security configuration fields.



If there is no Character Set that both ExactVu and the PACS server support, then a substitute character is used for the DICOM operation.

When receiving an MWL procedure or MRI study from a PACS server, if there is no Transfer Syntax that both ExactVu and the PACS server support, the operator is notified that the DICOM operation cannot be performed.

7 Pre-void and Post-void Bladder Measurements (EV5C transducer only)

	Previous ExactVu software versions	ExactVu software version 3.1
Pre-void and Post-void Bladder Measurements	Available for Pelvis exam type only	Available for any EV5C exam type

8 ExactVu Study Export Formats

In earlier ExactVu software versions, operators were able to export studies to a connected USB storage device in "ExactVu study format". ExactVu software version 3.1 adds the option to export a study to a connected USB storage device in DICOM format. When a study is exported in DICOM format, it uses both standard and private DICOM tags to retain image data, needle guide overlays, measurements, annotations, imaging settings etc., for future review on a DICOM workstation.



Single frames and cine images exported in DICOM format are displayed on DICOM viewers according to the Transfer Syntax configured in *Preferences > DICOM Settings*.

To manually export a study in DICOM format to a connected USB storage device:

- 1. Connect a USB storage device to the ExactVu system.
- 2. In the Patient List choose one of the options for selecting studies:
 - Manually select studies
 - Select **Select Today**

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• Select Select All

3. Select USB DICOM.

4. Select Export.

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

During export, the ExactVu system uses the Transfer Syntax configured in Preferences > DICOM SETTINGS > STORE.

5. Press **OK** to acknowledge the export completion status message.

For studies exported to a USB storage device, the studies specified are copied to the folder, ExactData, on the USB storage device.

If a study being exported to a USB storage device, all reports stored with the study are exported with the study.

9 FusionVu

Two FusionVu changes are introduced in ExactVu software version 3.1:

	Previous ExactVu software versions	ExactVu software version 3.1
Mid-line annotation for loaded MRI	Used the most recently marked DICOM polyline annotation between 20 mm and 150 mm in the sagittal series	Uses the longest DICOM polyline annotation between 20 mm and 150 mm in the sagittal series
Lesion markers from the MRI mark-up	Lesion markers are displayed as red circles	Lesion markers can be configured to use a different color if required by contacting Technical Support using the contact information for your region at https://www.exactimaging.com/contact-us

10 System Errors and Warnings

10.1 General

The ExactVu system internally logs a wide variety of messages relating to operating and error conditions. The following message types may be observed:

Message Type	Workarounds
System Error	Continue imaging and monitor the ExactVu system. If there are further problems, restart the
(Many System Errors are isolated problems, and do not affect operation.)	ExactVu system.
Critical System Error	The ExactVu system shuts down when the operator selects the OK button on the message, or after 20 seconds.

Table 1: ExactVu System Error Types

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11 Known Use Issues

11.1 Issues Related to Patient Data

Issue Details	Workarounds
Dragging the scroll control in the Patient List responds very slowly, and there is no indication (such as an hourglass) that the system is processing the action.	None. The system ultimately responds correctly.

Table 2: Issues Related to Patient Data

11.2 Issues Related to General Imaging (2D Mode)

Issue Details	Workarounds
Stitch image shows a minor misalignment at the	None.
bottom of the image after changing the image	This effect is observed at the bottom of the
preset.	image only.

Table 3: Issues Related to General Imaging (2D Mode)

11.3 Issues Related to Assigning Targets

Workarounds
Select the thumbnail for the desired cine
Navigate to the Report tab
From the Target List, and choose the desired
target to reassign.

Table 4: Issues Related to Assigning Targets

11.4 Issues Related to Reporting

Issue Details	Workarounds
If the operator doesn't align the prostate during imaging, the 3D model and needle placement that appear in the report may be inaccurate compared to aligning the prostate during the study.	Perform alignment during the study (per the usual workflow).
Measurement, Needle Position and Prostate Position placements performed during Report configuration are saved, but are not visible on the cine when loaded from Patient list.	Icons in the thumbnails indicate the cines that have had a needle placed. Needles can be seen in the 3D model when viewing the report. If in doubt, place a new needle in the cine. (This replaces the previous needle.)
The ExactVu 3.1 Patient List may allow a report to be created for study data created in software versions earlier than ExactVu 3.1; however, it is not possible to identify targets in those studies.	Only use the Reporting features on new studies created in software version ExactVu 3.1.

Table 5: Issues Related to Reporting

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11.5 Issues Related to CFI Modes (Color Doppler / Power Doppler)

Issue Details	Workarounds
An artifact with the appearance of grid lines occasionally appears in Power Doppler Mode.	Exact Imaging recommends adjusting the Gain setting and adjusting the imaging plane to prevent bright reflectors in the plane that may cause in the artifact.
An artifact occasionally appears at the left edge of the color box in Color Doppler Mode and Power Doppler Mode. The artifact is very obvious to the operator and the direction of the artifact is not in the same direction of the vessel.	Sample vessels such that they are centered in the color box rather than on the edges.

Table 6: Issues Related to CFI Modes (Color Doppler / Power Doppler)

11.6 Issues Related to Measurements and Annotations

Issue Details	Workarounds
When the maximum number of measurements (seven) are displayed on a single image, and include both Pre-void and Post-void bladder volume measurement, only the pre-void measurement is displayed on the imaging screen. The Post-void and Residual volume values are not displayed.	A typical workflow uses four measurements. This is a minor inconvenience.
Measurements are not saved on images unless the Operator saves the frame after adding the measurement.	None. This is as designed.

Table 7: Issues Related to Measurements and Annotations

11.7 Issues Related to Transverse Mode (EV29L Transducer) and Dual Mode (EV9C and EV5C Transducers)

Issue Details	Workarounds
Transverse position changes will alter the	None.
geometry/accuracy of the Transperineal grid	The transverse position is not adjusted in a
positioning.	typical workflow as the default position provides
	better image acquisition.

Table 8: Issues Related to Transverse Mode and Dual Mode

11.8 Issues Related to FusionVu

Issue Details	Workarounds
Intermittently and rarely, MRI data can be very	Restart the ExactVu system and load the MRI
slow to load due to an operating system error.	study again.

Table 9: Issues Related to FusionVu

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11.9 Issues Related to DICOM / PACS

Issue Details	Workarounds
Changing the time zone setting on the system causes the study time to change on closed studies when the studies are archived to PACS.	None. Changing the time zone setting is not part of the regular workflow.
Archiving a typical workflow study to PACS can be slow depending on the network connection and the amount of data.	Archive studies at the end of the day or when the system is not in use.
Studies in the Patient List that show the Failed icon (indicating that they failed to be sent to PACS) are unexpectedly being re-sent to PACS automatically.	Export applicable studies to USB and provide to the PACS Administrator directly for upload.
Plugging in / unplugging a connected USB device while querying / loading an MRI study from PACS can cause an error.	While querying or loading an MRI study from PACS, don't touch a connected USB device until the query or load is complete.

Table 10: Issues Related to DICOM / PACS

11.10 Issues Related to Connecting Additional Monitors

Issue Details	Workarounds
After connecting a generic additional monitor to the HDMI connector on the ExactVu system, the ExactVu touch screen and both monitors displayed a message "waiting for the primary monitor" and the system may not be used. This does not happen when connecting the EIZO 2450 or 2460 monitor recommended by Exact Imaging.	Use the EIZO 2450 or 2460 monitor recommended by Exact Imaging when additional monitors are required to use the ExactVu system.

Table 11: Issues Related to Connecting Additional Monitors

11.11 Issues Related to System Support

Issue Details	Workarounds
If the operator exports logs from the Preferences	Either:
> System Information screen, it doesn't include	 Press Ctrl+Alt+L, and export the current log
the log from the current instance of the ExactVu	from the Message Log
system. This means a log needed for	 Restart the ExactVu system and from
troubleshooting is unavailable unless a	Preferences > System Information, select
subsequent log export is performed.	export "Last 2 Days"

Table 12: Issues Related to System Support

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