EXACT IMAGING

Release Notes for Customers

ExactVu™ High Resolution Micro-Ultrasound System

Part Number 6658
Revision 2.9

CE 2797

Preface

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Trademarks
Exact Imaging trademarks:

- ExactVu™
- FusionVu™
- Exact Imaging™

Version information
System: ExactVu™ High Resolution Micro-Ultrasound System

1 Introduction

This *Release Notes for Customers ExactVu™ High Resolution Micro-Ultrasound System* document introduces the new features that are part of this release of the ExactVu High Resolution Micro-Ultrasound System. It also identifies issues known to exist in the ExactVu system with software version 3.0 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 ExactVu™ High Resolution Micro-Ultrasound System*.

2 New Features and Devices in this Version

This version of the ExactVu system (software version 3.0) provides the release of the feature described in the following section. This release is supported by Exact Imaging's exclusive distributor, EDAP TMS. EDAP's contact information is provided in Appendix A.

2.1 Elastic Fusion

ExactVu version 3.0 introduces the elastic MRI data registration to the FusionVu feature.

Previous versions of ExactVu software used rigid registration, and this is still available in ExactVu 3.0. Rigid registration is achieved by aligning the prostate mid-line in both modalities using the alignment line annotation in the loaded MRI study. Elastic registration is achieved by aligning the mid-line as well as the lateral edges of the prostate on the micro-ultrasound with those in the MRI image.

The difference between rigid and elastic registration is that elastic registration accounts for local deformations between the MRI study data and the micro-ultrasound image. These deformations may be caused by the transducer, the time lapsed between the MRI exam and the micro-ultrasound exam and in the image scale differences between the two modalities.

3 System Errors and Warnings

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 *Many System Errors are isolated problems, and do not affect operation.*	Continue imaging and monitor the ExactVu system. If there are further problems, restart the 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

4 Known Use Issues

4.1 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.
Occasionally, a critical system error occurs after sorting the Patient List on the [Status] column.	Restart the system.

Table 2: Issues Related to Patient Data

4.2 Issues Related to General Imaging (2D Mode)

Issue Details	Workarounds
Focal zone carats disappear when scrolling through the buffer.	This happens only with a cine image buffer. To workaround the issue, save a cine or a frame.
Stitch image shows a minor misalignment at the bottom of the image after changing the image preset.	None. This effect is observed at the bottom of the image only.
The operator occasionally needs to press the [Freeze] button twice from the Patient/Study screen to activate live imaging.	Press the [Freeze] button a second time if it does not respond to the first press.

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

4.3 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 4: Issues Related to CFI Modes (Color Doppler / Power Doppler)

4.4 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	A typical workflow uses four measurements. This is a minor inconvenience.

Issue Details	Workarounds
screen. The Post-void and Residual volume values are not displayed.	

Table 5: Issues Related to Measurements and Annotations

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

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

Table 6: Issues Related to Transverse Mode and Dual Mode

4.6 Issues Related to FusionVu

Issue Details	Workarounds
Loading MRI data from CD/DVD or from a USB storage device takes more time than expected.	None. This is a minor inconvenience. The operator is informed that the drive is currently being read.

Table 7: Issues Related to FusionVu

4.7 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.
If the ExactVu system is configured with Auto-Archive toggled OFF, the PACS Store server does not receive all studies selected to be exported manually if the system is used during archiving.	Do not use the system for imaging during a user-initiated export to PACS. Check that studies that are manually exported to PACS are available on the storage server, and re-export if necessary.

Table 8: Issues Related to DICOM / PACS

4.8 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	Use the EIZO 2450 or 2460 monitor recommended by Exact Imaging when additional monitors are required to use the

Issue Details	Workarounds
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.	ExactVu system.

Table 9: Issues Related to Connecting Additional Monitors

Appendix A 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