**Assembly Test Form for Image Quality Test for ExactVu System**

# Test Execution Summary

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| **Test Date:** | 10/07/2023 |
| **Tester (print & sign):** | Jorge F. + Denis C. |
| **ExactVu System S/N:** | 6127 220011 |

# Test Equipment Used

| **Test Equipment** | **Model** | **Part Number** | **Serial Number** |
| --- | --- | --- | --- |
| ExactVu EV29L Transducer | EV29L | 6089 | 220037 |
| ExactVu EV9C Transducer (if applicable) | EV9C | 6087 |  |
| ExactVu EV5C Transducer (if applicable) | EV5C | 6088 |  |
| Prostate tissue phantom | Yezitronix: Bi-plane S-BP-3.1  Or CIRS: 53L prostate phantom with 47 mL prostate | 6914 or 6911 | VIOMERSE |
| General tissue phantom | Gammex | 6462 | N/A |

***Notes:***

* All test equipment shall have up-to-date calibration as per QSP 7.6 Control of Monitoring and Measurement Devices.
* Observe all ESD rules as per SOP Electrostatic Discharge Controls. Check wrist strap before starting.

# Test Results

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| **Test** | **Pass Criteria** | **Pass/Fail** | **Comments** |
| **5.1.1** | **EV29L Transducer** | | |
|  |  |  |
| Step 2) Transducer is connected to system slot 3 and recognized. | **P** |  |
| Step 3) Patient information entered. Record Patient information. | **P** |  |
| Step 4-6) System is able to scan without errors and behaves correctly. | **P** |  |
| Step 7) The transverse mode is works correctly. | **P** |  |
| Step 8) Noise patterns and image are acceptable   * Depth of penetration >40mm * Noise patterns in far field are acceptable. Some blurriness and movement but no tilted lines and bright dots * No image sparkle observed * Cines and frames are saved with correct annotations. | **P** |  |
| Step 9-10) Noise evaluation repeated in slots 1 and 2 with no issues. | **P** |  |
| Step 12) Close study (if applicable) | **P** |  |
| Step 13) Saved images match noise in previous studies | **P** |  |
| Step 14) Saved images copied to hard drive | **P** |  |
| **5.1.2** | **EV9C Transducer (if applicable)** | | |
| Step 1) Transducer recognized in slot 3 | **NA** |  |
| Step 2) Patient information entered (if applicable) | **NA** |  |
| Step 3-5) System is able to scan without errors and behaves correctly | **NA** |  |
| Step 5) Noise patterns and image are acceptable   * No artifacts in the near field * No tilted lines or bright dots * Cines and frames are saved | **NA** |  |
| Step 7) Close study (if applicable) | **NA** |  |
| Step 8) Saved images copied to hard drive | **NA** |  |
| **5.1.3** | **EV5C Transducer (if applicable)** | | |
| Step 1) Transducer recognized in slot 3 | **NA** |  |
| Step 2) Patient information entered (if applicable) | **NA** |  |
| Step 3-5) System is able to scan without errors and behaves correctly | **NA** |  |
| Step 6) Noise patterns and image are acceptable   * No artifacts in the near field * No tilted lines or bright dots * Cines and frames are saved | **NA** |  |
| **5.2** | **EV5C Transducer CFI Imaging (if applicable)** | | |
| Step 2) Image set to small Preset and 2D gain to 60dB | **NA** |  |
| Step 3) Color mode initiated | **NA** |  |
| Step 4-5) Color box set to maximum height and width | **NA** |  |
| Step 6) Color gain set to 75dB | **NA** |  |
| Step 7) TGC set to middle | **NA** |  |
| Step 9) Image shows blue as hand moves away and shows orange as hand move toward transducer. | **NA** |  |
| Step 11) No artifact or noise pattern is noticed on the 2D image when imaging the phantom. | **NA** |  |
| Step 13) Settings updated. Color gain set to 70dB | **NA** |  |
| Step 14) 2D image in CFI mode does not introduce additional noise and artifacts. Image looks equivalent to the image in 2D mode | **NA** |  |
| Step 15) No obvious CFI noise or artifacts noticed in color doppler mode or in power doppler | **NA** |  |
| Step 16) Close Study | **NA** |  |
| Step 17) Saved images copied to hard drive | **NA** |  |

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Additional comments:

**Revision History**

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| **Date** | **Author** | **Revision** | **Description of Change** |
| 18 Sept 2019 | V. Kouznetsov | 1.2 | Initial revision ATF for Image Quality Testing for ExactVu System for ExactVu system Rev 1.1  Additional changes in EV2.5.5- clarity on the PN in the tool section and minor step updated to match with ATP Rev 1.2 |