



# Assembly Test Form for Preventative Maintenance of ExactVu System (PN 6127, 6437, 7060)

## 1 Test Execution Summary

Test Date:	11/07/2023
Tester Name:	Jorge F + Denise C
ExactVu System S/N:	6127 220011

## 2 Test Equipment Used

Test Equipment	Model	Part Number	Serial Number
EV9C Transducer (from the customer)	Exact Imaging	6087	
EV29L Transducer (from the customer)	Exact Imaging	6089	220037
EV5C Transducer (from the customer)	Exact Imaging	6088	
Tissue Phantom General (PN 6462)	Exact Imaging	6462	
Electrical Safety Analyzer	ESA 612		SAV 1162 (1706/11/25)
Colorimeter (for monitors DOM 2018-12 or later)	RadiCS	UX2 Sensor	SAV 1567 m.c 2249716
Colorimeter (for monitors DOM 2018-11 or earlier)	X-Rite	I1 displaypro	NA
Digital Multimeter			

### Notes:

- All test equipment shall have up-to-date calibration in accordance with ISO 13485:2016 requirements.
- Carefully observe proper Electrostatic Discharge Controls using grounding cord and wrist strap where applicable. Test grounding cord and wrist strap before using.

### 2.1 Wrist Strap Verification

Test #	Pass Criteria	Pass/Fail	Comments
4.1	Wrist Strap resistance is within 0.8 to 1.2 mega ohms	P	
4.2	Grounding cord resistance is less than 25 Ohms	P	

### 3 Test Results

Test number corresponds to Assembly Test Procedure number.

#### 3.1 Sanitize System

Test #	Pass Criteria	Pass/ Fail	Comments
5.1.1	Monitors and visible surfaces cleaned	P	

#### 3.2 ExactVu Computer

Test #	Pass Criteria	Pass/ Fail	Comments
5.2.1	System powered up	P	
	Power LED lit up	P	
5.2.2.1	Monitor turned on and showed a proper image	P	
5.2.2.2	Touchscreen turned on and showed a proper image	P	
	Touch Capability is working	P	
	Left and Right speakers are functional	P	
5.2.2.3	All USB slots are functional	P	
5.2.2.4	Verified Ethernet Connection	P	
5.2.2.5	Verify Lift Column	P	
5.2.2.6	Obtain Software Version (Record in comments)	P	2.9.0 (Build 57)
	Obtain Channel Board 1 and 2 FPGA Version (Record in comments)	P	1.0.4.47
	Obtain BCB FPGA Version (Record in comments)	P	1.0.2.11
	Obtain BCB Driver Version (Record in comments)	P	1.4.7.7
	Verified Date and Time	P	
5.2.2.7	Verify Context Vision License	P	

#### 3.3 ExactVu Monitor Calibration

Test #	Pass Criteria	Pass/ Fail	Comments
5.3	Execute the ATP for Monitor Calibration – Service and attach the corresponding ATF for Monitor Calibration – Service	P	

### 3.4 Control Panel Calibration and Service

Test #	Pass Criteria	Pass/ Fail	Comments
5.4.1	Trackball cleaned	P	
5.4.2	Touchscreen configured in Windows Settings	P	
	Techboard version obtained (Indicate at comments)	P	
	All TGC controls are responding	P	
	Gain Knob is responding	P	
	All the buttons are responding	P	
	Blue and white LEDs backlit are working	P	
	Touchscreen calibrated	P	
	LCD is working with no dead pixel or dark spots	P	

### 3.5 Filter Pads

Test #	Pass Criteria	Pass/ Fail	Comments
5.5.1	Filter pads cleaned and reinstalled	P	

### 3.6 Thermal Printer

Test #	Pass Criteria	Pass/ Fail	Comments
5.6.1	Printer powers on	P	
5.6.2	Verified printer settings	P	
5.6.3	Printed test image is OK	P	

### 3.7 DC Fan #1, #2 and Card Cage

Test #	Pass Criteria	Pass/ Fail	Comments
5.7.1	DC Fan#1 is functional (if applicable)	P	
	DC Fan#2 is functional (if applicable)	P	
5.8.1	Card Cage DC Fan is functional	P	

### 3.8 Castors / Wheels

Test #	Pass Criteria	Pass/ Fail	Comments
5.9	Castors / wheels roll smoothly	P	

Test #	Pass Criteria	Pass/ Fail	Comments
	Castors / wheels have functional brakes	P	

### 3.9 Card Cage Alignment

Test #	Pass Criteria	Pass/ Fail	Comments
5.10	Card cage gap is even on both sides of connector slots	P	Adjustment required? (check one): Y: <input type="checkbox"/> N: <input checked="" type="checkbox"/>

### 3.10 Foot Pedal (Hardware V2.6 and above only)

Test #	Pass Criteria	Pass/ Fail	Comments
5.11	Foot pedal cable connected to I/O Plate USB port	NA	
	Inspect, clean and route foot pedal cable through cable management clips	NA	
	Review foot pedal setting and note in comments	NA	
	Test patient created	NA	
	Imaging initiated and foot pedal pressed resulting in a cine or frame being saved	NA	

### 3.11 HDMI Port (Hardware V2.6 and above only)

Test #	Pass Criteria	Pass/ Fail	Comments
5.12	System is turned off	P	
	HDMI cable disconnected from main monitor	P	
	External HDMI cable $\leq$ 16.4 feet connected to HDMI output port on I/O plate and main monitor	P	
	System powered on	P	
	Main monitor displays main screen as normal	P	

**3.12 DK Stepper (Hardware V2.6 and above only)**

Test #	Pass Criteria	Pass/ Fail	Comments
5.13	Device inspected for damage and wear. No major issues detected.	NA	
	Stepper successfully mounted to a bed or table	NA	
	Stepper moves smoothly in all axis	NA	
	Stepper freezes in position when lever is released	NA	
	EV29L successfully clamped in probe cradle / receptacle	NA	
	EV29L is held firmly in place and does not move more than 1mm	NA	

**3.13 Safety Test**

Test #	Pass Criteria	Pass/ Fail	Comments
5.14	Execute the ATP / ATF for Electrical Safety Test of ExactVu System and attach the corresponding ATF to these results.	P	

**3.14 Transducer Inspection and Functional test**

Test #	Pass Criteria	Pass/ Fail	Comments
5.15	Execute ATP for Preventative Maintenance for ExactVu Transducer and attach the corresponding ATF to these results. <b>Note:</b> ATP for Image Quality for ExactVu system is performed as part of this test. Attach relevant ATF.	P	

**4 Service Confirmation**

Comments:

Date Performed:	11/07/2023	Service Performed By: (Print and Sign)	Serge Fernandez + Denis Chabot
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### Revision History

Date	Author	Revision	Description of Change
9 Oct 2019	K. Dunn	1.0	Initial revision based on Service Manual for ExactVu system (PN 6156) Rev 1.8.
10 Aug 2020	K. Dunn	1.1	Sections 3.9, 3.10 and 3.11 added for Foot Pedal, HDMI port and DK Stepper respectively.
29 Sep 2020	J Wen	1.2	Updated Sect 2 equipment list and Sect 3.3 Monitor Calibration for using RadiCS sensor
11 Mar 2021	R. Daling	1.3	Added grounding cord test Updated Notes section Added section for card cage alignment
15 Jun 2021	J Wen	1.4	Minor update to monitor calibration test 5.3.1.2 to accommodate EV2460 monitor (ECR-0150)
25 Jun 2021	J Wen	1.5	Update PNs in title and header to reflect top level system PNs 6127, 6437, 7060
24 May 2023	K Dunn	1.6	Updated section 3.3 ExactVu Monitor Calibration to point to a child ATP document.