Avante | Health Solutions

ULTRASOUND PREVENTIVE MAINTENANCE

Use this document to have a better understanding of what needs to be done during a preventive maintenance, standards for pass/fail and submission for accreditation. You can also use the attached Ultrasound Certification Report to document and develop your own maintenance program that supersedes the OEM recommendation. Avante Health Solutions recommends performing preventive maintenance every 6 months. This schedule will increase the lifespan of your system and will ensure the safety of your patients and operators. You will also see the benefit of regular maintenance in your budget and bottom line.

INTRODUCTION

- When possible introduce yourself to the user
- Inquire as to the current functionality of the equipment
- Inquire as to the current Network configuration
- Ask if there are any items that need to be addressed during the PM.

  - Software updates
  - Options
  - Peripherals
  - Backups

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SYSTEM

MONITOR
- Inspect the monitor for obvious signs of damage and wear
- Inspect the monitor arm/mechanism; insure that it can support the monitor in a fixed location. Make sure the arm/mechanism can be secured via locking mechanism
- Inspect the screen for missing pixels, burn-in
- Verify operation of brightness/contrast controls
- Verify focus of the monitor

CONTROL PANEL
- Inspect the entire control panel for obvious signs of damage/wear
- Closely inspect all keys, buttons, knobs, LEDs for and slide pots for functionality and missing cosmetic pieces
- Inspect touch screens/LEDs for missing pixels, focus and proper touch calibration
- Inspect trackball for proper operation (up, down, left, right)
- Inspect QWERTY keyboard for function of all keys
- Inspect down-lighting assembly for proper illumination
- Inspect control panel arm/mechanism

COSMETIC PANELS
- Inspect all cosmetic panels/covers for obvious damage wear
- Closely inspect all panels for missing screws

AC PLUG/CORD
- Inspect the electrical cord/plug for obvious damage/wear

CASTERS/BRAKES
- Inspect all casters for obvious damage/wear
- Inspect each caster for proper operation
- Inspect brake assembly for proper operation
- Make sure brake assembly can securely hold the system in place

TRANSDUCER

PROBE CONNECTOR:
- Bent, Broken, or Missing Pins
- Missing Housing Screws
- Gaps in the Housing
- Broken/Missing Locking Knob

CABLE:
- Cut or Torn
- Stains
- Separation of the cable and strain reliefs
- Exposed wires

STRAIN RELIEF:
- Separation between the probe and the cable
- Missing Strain Relief
- Cut or Torn

PROBE HOUSING:
- Gaps in the Seals
- Plastic Cracked or Broken
- Discoloration

ACOUSTIC LENS:
- Cuts / Chips
- Gaps in the Seals
- Discoloration
- Delamination

Any damage to the transducer that would allow fluid to infiltrate the transducers internal components is an AUTOMATIC FAILURE. The transducer should be removed immediately from service.

SYSTEM DIAGNOSTICS

- Run diagnostics before performing any maintenance or disassembly
- Diagnostics reside in setup/utility menus
- Perform on-board user level diagnostics to verify system hardware and software
- Note any and all failures
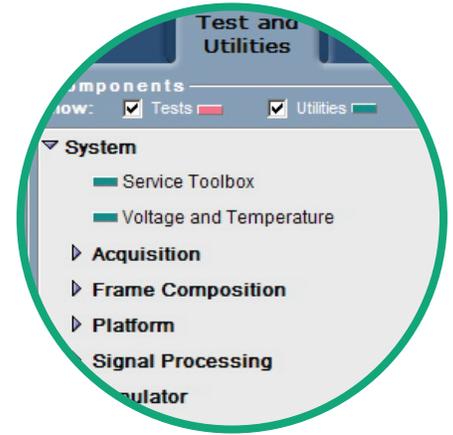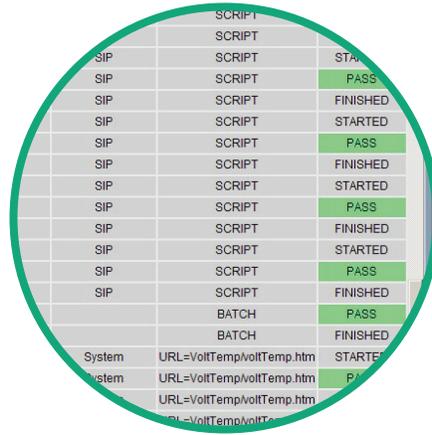
SYSTEM CLEANING

Use a gentle cleaning agent (SonoWipes or warm water & mild soap) and wipe down all surfaces of the equipment to include:

- Monitor/LCDs
- Control Panel
- Handles
- Cosmetic Panels
- Transducers

SYSTEM DISASSEMBLY

- Shut down equipment & unplug
- Remove all filters and clean; clean with a vacuum or warm water
- Remove cosmetic panels
- Remove card cage shields
- Remove circuit boards from card cage (use ESD safe mat or bags)
- Use ESD safe vacuum to clean the card cage and assemblies
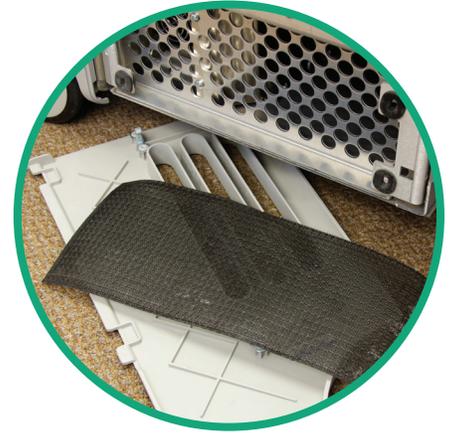
SYSTEM REASSEMBLY

- Reinstall all circuit boards in to the card cage
- Replace the card cage shields
- Replace cosmetic panels
- Reinstall all air filters once cleaning is complete

- *Power up the system and note any boot-up failures*
- *Select New Patient & Enter "Test" Patient Demographics*
- *Select a transducer*
- *Select a <u>factory default</u> preset according to probe type*
- *Acquire/Save an image in each mode of operation*

NOTE:
Use Imaging Phantom
and Human Anatomy

2D MODE

(Use 2D Gain Control and TGC Controls)
- Acquire an even gray-scale image both vertically and horizontally
- Look for signs of weak or dead elements within the scan field
- Once the image is acquired, select a set of targets to perform measurements with and freeze the image
- Select calipers and measure both horizontal and vertical targets. (Horizontal Expected Distance =2.00cm, Vertical Expected Distance =1.00cm)

IMAGE UNIFORMITY CHECKS

- Average brightness at the edge of the scan field is the same as in the middle
- No signs of shadowing vertically or horizontally in the scan-field
- No brightness transitions between focal zones

PENETRATION

- What is the maximum depth you are able to successfully visualize the ecographic pattern on the phantom

TRANSDUCER FAILURE CRITERIA

- No more than 2 dead elements within the scan field
- No more than 4 weak elements within the scan field
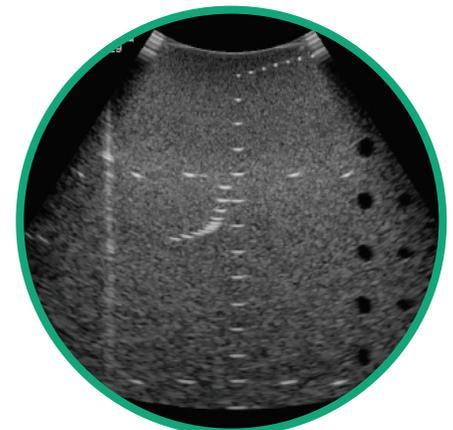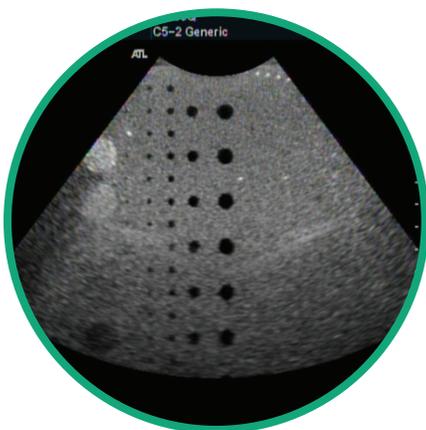
M-MODE

(Use 2D/M-MODE Gain Control and TGCs)
- Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
- Select a target on the phantom within the scan field
- Engage the M-MODE sample line and adjust to the selected target
- Ensure the scrolling graphics display is working properly
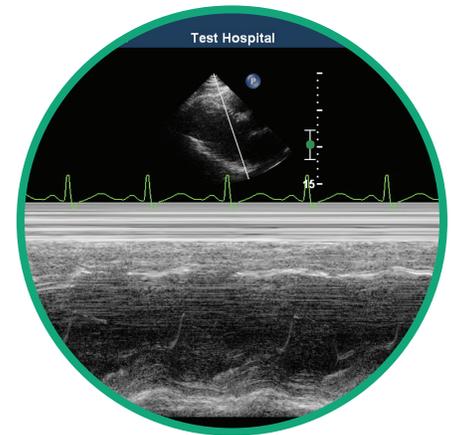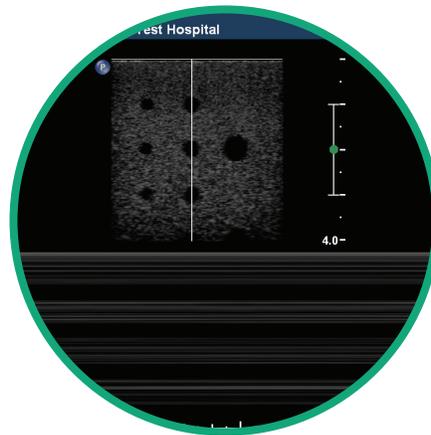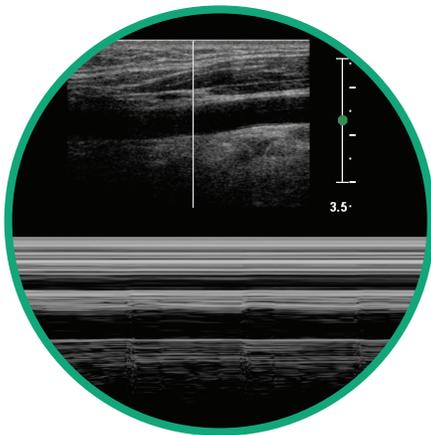
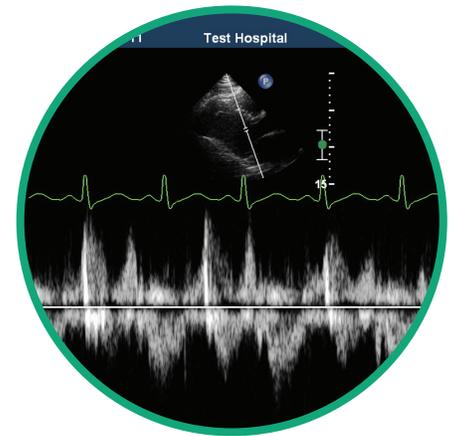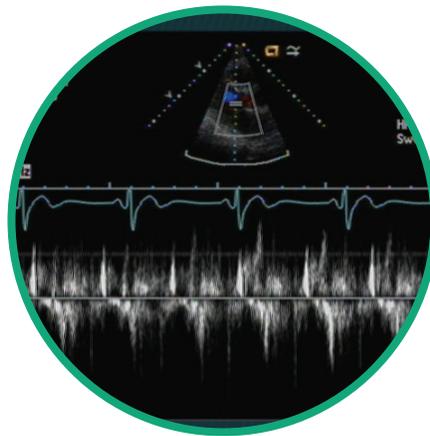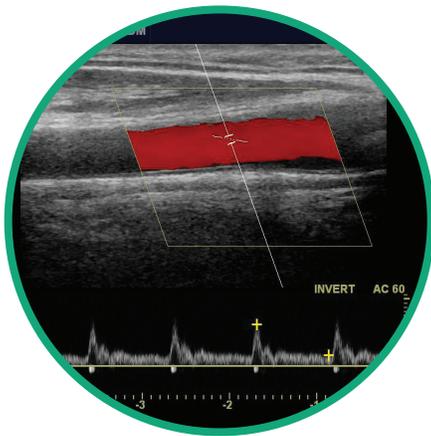## COLOR DOPPLER

(Use 2D Gain, Doppler Gain and TGCs)
- Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
- Acquire an anatomical image based on the transducer and preset selected
- Engage the Color Doppler function
- Adjust the ROI (Region of Interest) using the trackball
- Select an area with measurable blood-flow
- Adjust the Color Doppler Gain, Doppler Scale and Baseline to show proper blood-flow in the selected area
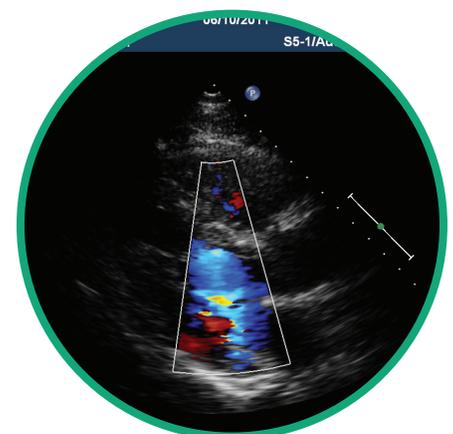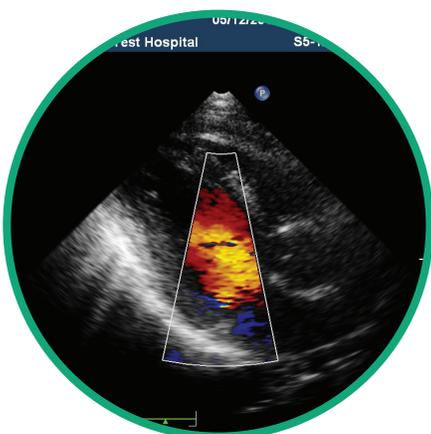
SPECTRAL DOPPLER

(Pulsed & Continuous Wave)
- Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
- Acquire an anatomical image based on the transducer and preset selected
- Engage PW or CW function (CW is only available for Cardiac functions)
- Select an area with measurable blood-flow
- Adjust the Gate or Sample Line using the trackball
- Adjust the Doppler Gain, Doppler Scale and baseline to display the correct spectral waveform for the area of interest

3D/4D

- Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
- Acquire an anatomical image based on the transducer and preset selected
- Engage the 3D function
- Adjust the ROI (Region of Interest) using the trackball
- Freeze the image or engage 3D/4D rendering
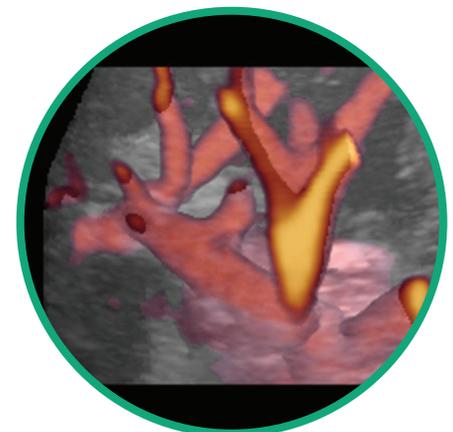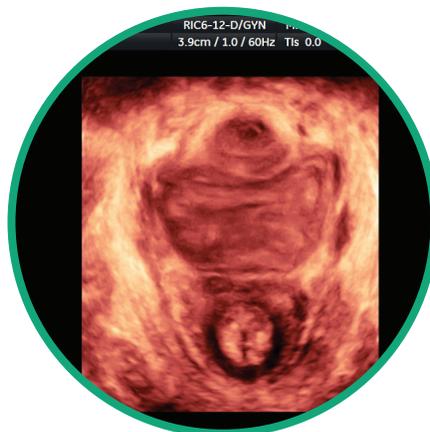
MEDIA

• Select the "Test" patient from the Patient Archive/Hard Drive
• Designate Storage Location: CD/DVD/USB
• Send patient file to specified storage location
• Verify successful write to removable media

DICOM NETWORKING

• Select the "Test" patient from the Patient Archive/Hard Drive
• Designate DICOM Server destination
• Send "Test" patient file to DICOM Server
• Verify successful transmission either by successful send message
  on the machine or physical verification on the server

CERTIFICATION REPORT
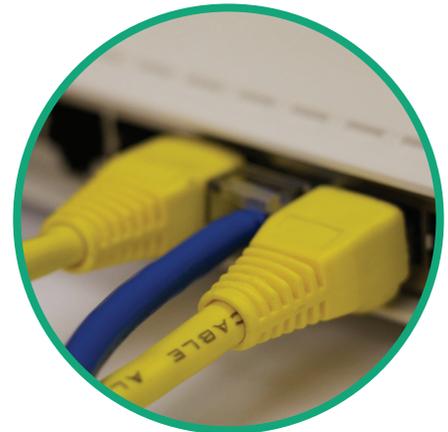
Avante Health Solutions **Ultrasound Certification Report**

Customer Information:
Site Name
Department
Contact
Address
Phone
E-mail Address
WorkOrder #

(1)

Engineer
Date

Equipment Information:
System Type
Manufacturer
System Serial#
Software Version
Build/Cart Version

(2)

Create System/Preset Backup
Document all Board & SW PN's
System Leakage Evaluation
Measured   µA
ECG Leakage Evaluation
Measured   µA

(6)

Equipment Evaluation:

	Pass	Fail	Cleaned	Comments
Chassis/Panels	☐	☐	☐	
Casters/Brakes	☐	☐	☐	
AC Plug	☐	☐	☐	
Fans/Air Filters	☐	☐	☐	
Monitor/LCD's	☐	☐	☐	
Control Panel/UI	☐	☐	☐	
CD/DVD	☐	☐		
DICOM Ping/Verify	☐	☐		
2D Scan	☐	☐		
Color Doppler Scan	☐	☐		
PW/CW Scan	☐	☐		
3D/4D Scan	☐	☐		
On-Board Diagnostics	☐	☐		

(3)

Transducer Information

Model	Part Number	Serial Number	Pass	Fail	Cleaned	Comments

(4)

Peripheral Information

Model	Type	Serial Number	Pass	Fail	Comments

(5)

Transducer Evaluation

Model# P4-2   Type CA-Curved Array   Serial Number 10000000

Parameter	Pass	Fail	Cleaned	Comments
Connector/Pins	✔	☐	☑	
Scanhead/Casing	☑	☐	☑	
Lens/Membrane	☑	☐	☑	
Array/Elements	☑	☐	☑	
Cable/Wiring	☑	☐	☑	
Penetration	40	cm		

Parameters	Measured	Expected	Acceptance +/- 10%	Pass	Fail
Distance (Horizontal)	2.01 cm	2.00		☑	☐
Distance (Vertical)	1.02 cm	1.00		☑	☐

With system sensitivity set up for visualizing echogenicity as deeply as possible, what is the maxium depth you are able to successfully visialize the ecographic pattern on the phantom?

Image Uniformity		Pass	Fail
The average brightness at the edge of the scan area is the same as in the middle		☑	☐
There are no signs of shadowing vertically or radially in image area		☑	☐
There are no brightness transitions between focal zones		☑	☐

(7)

Transducer Evaluation

Model# C5-2   Type CA-Curved Array   Serial Number 3000000

Parameter	Pass	Fail	Cleaned	Comments
Connector/Pins	✔	☐	☑	
Scanhead/Casing	☑	☐	☑	
Lens/Membrane	☑	☐	☑	
Array/Elements	☑	☐	☑	
Cable/Wiring	☑	☐	☑	
Penetration	55	cm		

Parameters	Measured	Expected	Acceptance +/- 10%	Pass	Fail
Distance (Horizontal)	1.98 cm	2.00		☑	☐
Distance (Vertical)	.99 cm	1.00		☑	☐

With system sensitivity set up for visualizing echogenicity as deeply as possible, what is the maxium depth you are able to successfully visialize the ecographic pattern on the phantom?

Image Uniformity		Pass	Fail
The average brightness at the edge of the scan area is the same as in the middle		☑	☐
There are no signs of shadowing vertically or radially in image area		☑	☐
There are no brightness transitions between focal zones		☑	☐

Comments
Additional comments added in this section

1. CUSTOMER INFORMATION
Site Name:
Department:
Contact:
Address:
Phone:
Fax:
E-mail:
WorkOrder Number:

2. EQUIPMENT INFORMATION
System Type:
System Manufacturer
System Serial Number
Software Level/Version
Build/Cart Level:

3. EQUIPMENT EVALUATION
Chassis/Panels
Look for obvious signs of damage and or missing cosmetic panels
Look for damage to the chassis/frame and or missing screws
Caster/Brakes
Check to insure that all casters roll freely in the unlocked position
Check the integrity of the rubber wheels, make sure the wheel is intact and secure
Check to ensure that the casters hold the system in place when the brake is applied

AC Plug
Check to make sure the AC plug is seated and secured to the system
Check the cable for any signs of damage or wear
Fans/Air Filters
Ensure that all air filters have been cleaned
Ensure that all air filters are present
Make sure that all system fans are operational
Monitor/LCD
Inspect the monitor for signs of damage and wear
Inspect the monitor arm/mechanism; ensure that it can support the monitor in a fixed location
Make sure the arm/mechanism can be secured via locking mechanism
Inspect the screen for missing pixels and burn-in
Verify operation of brightness/contrast controls
Verify focus of the monitor
Control Panel
Inspect the entire control panel for signs of damage and wear
Closely inspect all keys, buttons, knob, LEDs and slide pots for functionality and missing cosmetic pieces
Inspect touch screens, LEDs, LCDs for missing pixels, focus and proper touch calibration
Inspect trackball for proper operation (up, down, left, right)
Inspect QWERTY keyboard for function of all keys
Inspect down-lighting assembly for proper illumination
Inspect control panel arm/mechanism

CD/DVD
Verify operation of removable media device by storing digital images to the device and review
DICOM Ping/Verify
Ping the DICOM storage device to verify connectivity
Verify DICOM operation by sending DICOM packet to the storage server
2D Scan
Verify 2D mode of operation based on Diagnostic Imaging section
Color Doppler
Verify Color Doppler mode of operation based on Diagnostic Imaging section
PW/CW Scan
Verify Spectral Doppler mode of operation based on Diagnostic Imaging section
3D/4D Scan
Verify 3D/4D mode of operation based on Diagnostic Imaging section
On-Board Diagnostics
Perform user level system diagnostics

4. TRANSDUCER INFORMATION
Model –This is the model as designated on the transducer
Part Number- This is the actual part number for reorder or replacement
Select Pass or Fail in reference to physical and diagnostic condition of the transducer.
Once the probe has been cleaned, check the Cleaned box
Serial Number-Each probe has a unique serial number and should be documented as such
For any Fail items, make notes in the comments field
Measurements
Select 2 different types of probes to perform the selected measurements.
Enter the probe model number
Enter the probe serial number
Perform measurements in accordance with Imaging Mode 2D section, input the measurements for both horizontal and vertical parameters. (Tolerance +/-10%)
Select Pass if measurements meet the tolerance allowance, select Fail if the tolerance is exceeded

5. PERIPHERAL INFORMATION
Model-The is the model as designated on the peripheral device
Type: VCR/DVR/BW Printer/ Color Printer
Serial Number-Each peripheral device has a unique serial number and should be documented as such
Select Pass or Fail
For any Fail items, make notes in the comment field

6. SYSTEM ADMINISTRATION

Create System/Preset Backup
Create a backup on removable media to be stored off-site or secure location
Backup should consist of all systems settings to include:
 •Software Version
 •User Settings
 •Network Settings
 •Custom Presets
 •Options

Document all Board and Software Part Numbers
Create a hard copy or digital copy of all software and hardware part numbers. Generally accessible under user service menus.

Leakage Evaluation
System
Verify Chassis/Enclosure Leakage with the use of leakage tester. (SA-2010S / Dale 601)
Chassis/Enclosure Leakage Limit = 0.3mA
ECG
Verify ECG/Patient Lead Leakage with the use of a leakage tester. (SA2010S / Dale 601)
ECG/Patient Lead Leakage Limit = 0.01mA

7. TRANSDUCER EVALUATION
Model-This is the model as designated on the transducer
Type
 •CA-Curved Array
 •LA-Linear Array
 •PA-Phased Array
 •TEE-Transesphogeal Echo Transducer
Serial Number- Each transducer has a unique serial number and should be documented as such
Parameter
Pass/Fail based on Visual Inspection - Transducers
Once the transducer has been cleaned, check the Cleaned box
For any Fail items, make notes in the comment field
Penetration
What is the maximum depth you are able to successfully visualize the Ecographic pattern on the phantom, record.
Image Uniformity
Average brightness at the edge of the scan field is the same as in the middle
No signs of shadowing vertically or horizontally in the scan field
No brightness transitions between focal zones
Comments
Freeform comments field for any notes or suggestions
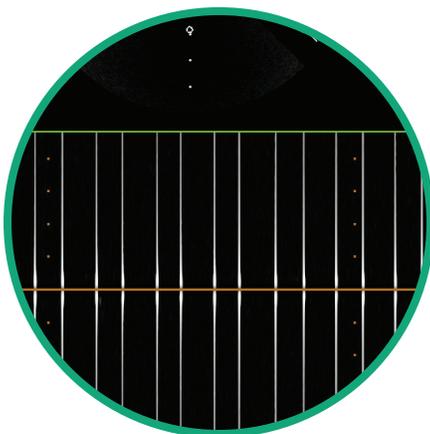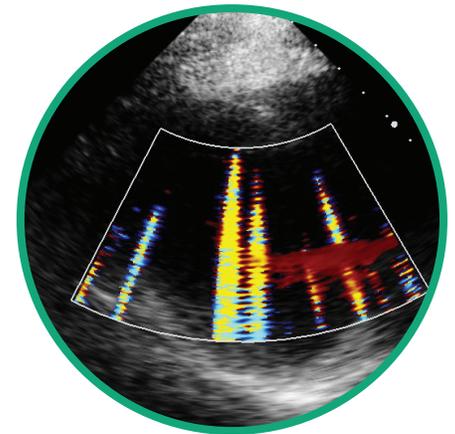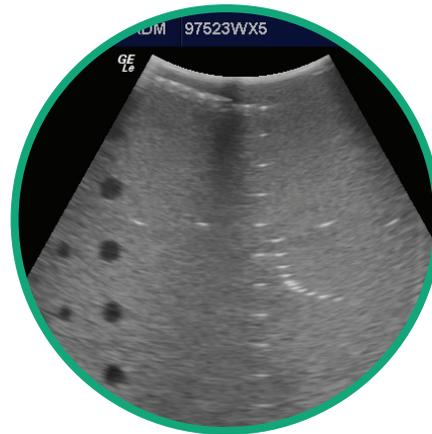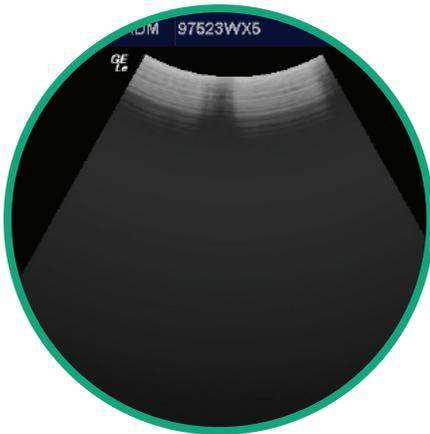
TRANSDUCERS

- IMAGE
  - 2 or more dead elements within the scan field
  - 4 or more weak elements within the scan field
  - Excessive Color Noise (Noise present at minimal gain)
  - Excessive PW/CW Doppler Noise (Noise present at minimal gain)
  - Inability to perform 3D/4D scan

- COSMETIC
  - Any damage that would allow liquid to infiltrate the transducer's internal components.

LEAKAGE TESTING

TRANSDUCERS

TEE Transducer (Type CF) MUST BE PERFORMED BEFORE EACH USE
> 0.01mA (10 microamperes) under Normal Conditions
> 0.05mA (50 microamperes) under Single Fault Conditions

GENERAL Transducer (Type BF)
> 0.1mA (100 microamperes) under Normal Conditions
> 0.5mA (500 microamperes) under Single Fault Conditions

TEE TESTING PROCEDURE

We recommend the BC Biomedical Group ULT-2020 Ultrasound Transducer Leakage Tester. The ULT-2020 is simple to use, with OEM specific adapters that ensure the transducer is connected properly, one button bath test and transducer leakage test and the ability to print reports directly from the device. Easy to read pass/fail test message eliminating confusion about leakage limits.

1. Saline Bath should consist of 27g salt per 3 liters of water.

2. Once the ULT-2020 is powered up and passed it's power up self test, the unit is ready for testing.

3. Connect the dual connectivity probe to the Chassis port of the ULT-2020 and attach it to the test basin.

4. Press the Select Button and use the Up & Down buttons to select the OEM, then use the Up & Down buttons to select the transducer model.

5. Connect the OEM probe adapter to the External port of the ULT-2020 and plug in the transducer for testing.

6. Press the Bath Test button. If the Bath test passes, proceed to the next step. If the Bath test fails, discontinue the test.

7. Insert the probe into the test basin, at least 50cm.

8. Press the Full Test button. If the Full test passes, proceed to the next step. If the Full Test fails, the transducer should be retested and removed from service after a second failure.

9. Remove the transducer from the basin and wipe off any excess water.

10. Record or Print the test results for record keeping.

REFERENCES

1. Centers for Medicare & Medicaid Services; Center for Clinical Standards and Quality & Certification Group. Ref: S&C: 14-07-Hospital
http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGen-Info/Downloads/Survey-and-Cert-Letter-14-07.pdf

2. American College of Radiology: Ultrasound Accreditation Program Requirements: Quality Control; Preventative Maintenance
http://www.acr.org/~/media/ACR/Documents/Accreditation/US/Requirements.pdf