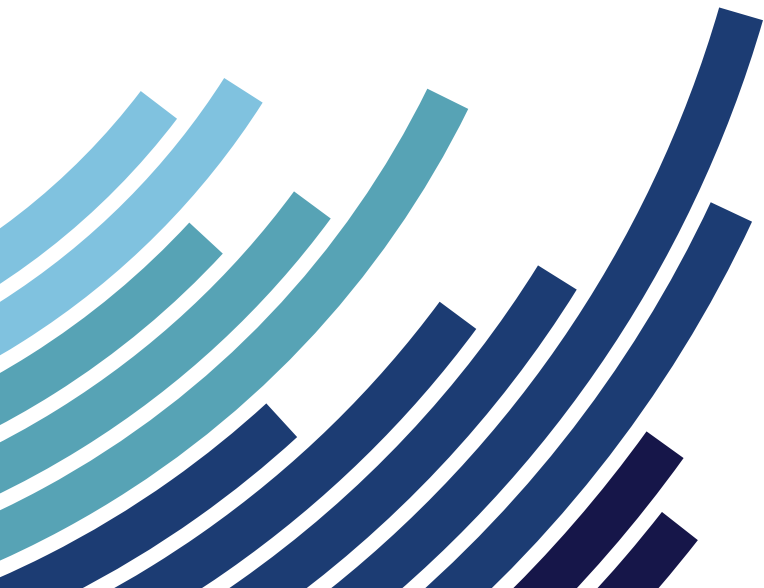




Performing ultrasound probe
quality assurance assessments:

A How-to Guide



SEE **BEYOND**

A comprehensive quality assurance program has the potential to directly contribute to better patient outcomes.

Regular testing provides a mechanism to monitor probe performance and correct as needed. The end result is a continuous quality improvement program that ensures optimal diagnostic outcomes.

As vital as it is to perform regular testing, there is no one standardized process or criteria for effectively field-testing ultrasound probes in the industry.

Innovatus Imaging has designed a guide to assist technicians with understanding industry standard testing criteria for assessing probe performance. The guide presents background information on probe design, detailed testing methods, root cause analysis and troubleshooting techniques.

WHAT YOU'LL LEARN

- Key terminology
- Overview of the components and technologies used in modern probes
- Common quality assurance tests from the most popular accreditation boards including:
 - American College of Radiology (ACR)
 - American Institute of Ultrasound in Medicine (AIUM)
- Best practices and ground rules for performing image quality testing
- Common testing methods, pass/fail criteria and techniques for troubleshooting image quality problems
- How to assess probe performance in the field
- How to acquire and assemble the quality control data required for accreditation

Contents

Industry Standards 2

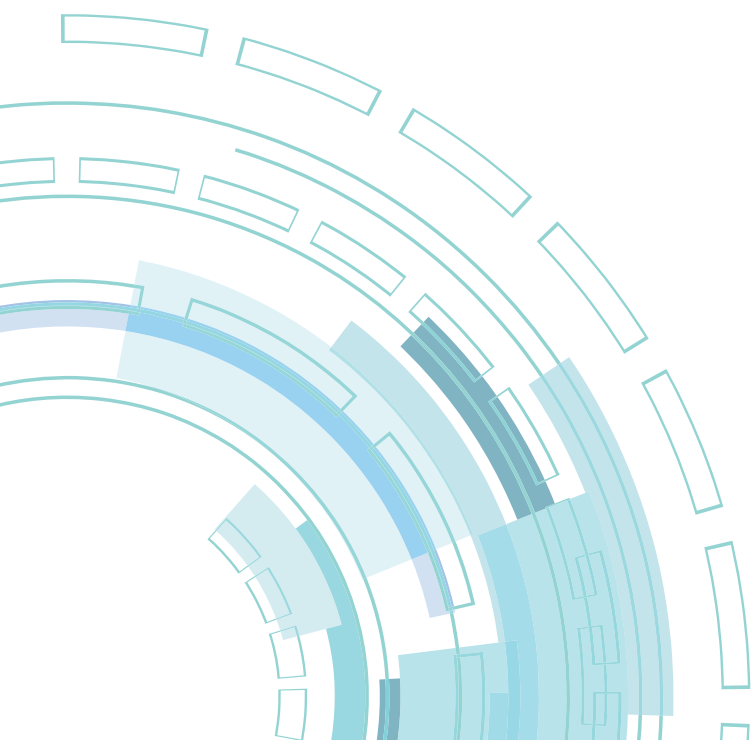
Key Terminology 3

Best Practices 5

Common Testing Methods

- Image Uniformity 7
- Maximum Depth of Penetration and Functional Resolution . . 10
- Geometric Accuracy 13
- Spatial Resolution 15
- Contrast Resolution 17
- Cable Noise Test 19
- Electro-Mechanical Functionality 21

Documentation Template 22



Industry Standards

With more than 300 diagnostic ultrasound probe models on the market, determining which criteria and methods are best for testing image quality can be confusing.

The physical and technical design of one probe can greatly vary from one model to the next. Without a firm knowledge base, consistent methodology and well-defined pass/fail criteria, test results can be highly variable and inconsistent.

Standards established by several accreditation boards offer a framework for testing and solid criteria for assessing the performance of devices used within diagnostic ultrasound.

THE TWO PRIMARY ACCREDITATION BOARDS

- American College of Radiology (ACR)
- American Institute of Ultrasound in Medicine (AIUM)

COMMON REQUIREMENTS FOR ACCREDITATION

- Case study submissions
- Personnel education and continued training
- Document storage and record-keeping
- Policies and procedures to safeguard patients, ultrasound personnel and equipment

COMMON FUNCTIONAL TESTS FOR ACCREDITATION

- Image uniformity
- Maximum depth of penetration
- Geometric accuracy
- Spatial accuracy
- Contrast resolution

Tests for cable noise and electro-mechanical functionality are not addressed by these boards, but offer a more comprehensive performance assessment.

To help close the industry's standardization gap, Innovatus Imaging has established a set of guidelines that will help you perform consistent ultrasound probe quality assurance assessments. The goals are to build technical confidence and to minimize variability so that clinicians can trust the tools that they rely upon the most to provide the most accurate diagnosis possible.

Key Terminology

Each component within the probe plays a vital role in the overall performance of the device.

It's critical to understand the purposes and the functions associated with basic probe construction prior to presenting best practices for assessing performance.

A failure in one area of the probe may affect the performance of or the results provided by another.

ACOUSTIC STACK ELEMENTS

Lens

- Mechanical focus of ultrasound beam
- Model-specific materials and dimensioning
- Electrical insulation
- Fluid barrier
- Single or multilayer materials, must be ISO 10993 compliant

Matching layer(s)

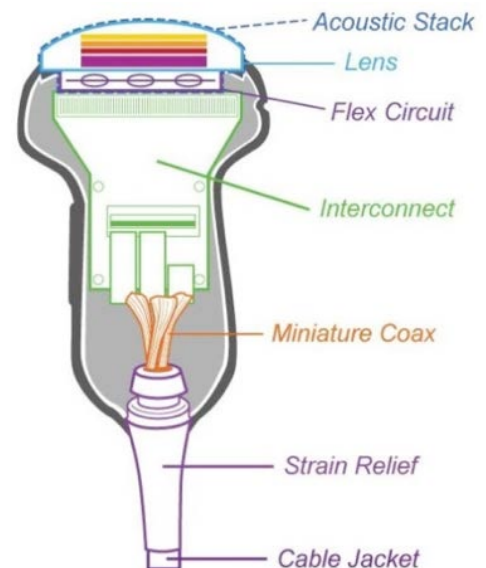
- Maximizes transmission of energy from acoustic array to tissue by reducing reflection and increases spectrum of frequencies (bandwidth) emitted by probe
- Commonly consists of one to seven different layers based on probe model
- Generally $\frac{1}{4}$ wavelength of the array's center frequency in thickness

Acoustic Array

- Converts electrical energy to mechanical energy (pressure wave) and vice versa
- Consists of several to thousands of individual elements

Backing material

- Dampens crystal vibrations to reduce pulse duration, which increases axial resolution



OTHER PROBE ELEMENTS

Flex circuit

- Flexible circuit board that connects the interconnect board to the individual elements

Interconnect/Scanhead electronics

- Bridge between individual coaxial cables and flex circuit
- May include multiplexing circuitry, as well as beamforming circuitry

Shielding

- Reduces the effects of electromagnetic interference
- Typically surrounds the array, the backing material and scanhead electronics

Miniature coax

- Bridge between the connector electronics and the scanhead electronics
- Internal signal wire enclosed within a braided shield
- Typically less than the diameter of a hair
- Model-specific length, impedance and capacitance

Main cable

- Contains several to hundreds of individual coaxial wires
- Model specific shielding to minimize the effects of electromagnetic interference

Strain relief

- Reduces stress on main and coaxial cables

Cable jacket

- Protects main probe cable



Best Practices

Quality assurance testing on probes is a key contributor to improving the accuracy of patient diagnoses, treatment plans and ultimately patient outcomes.

Routine – and consistent – testing is vital to ensuring that devices are performing at a level very similar to that when they were purchased.

By following these best practices, you'll be able to feel confident in equipment quality. The following can be considered a baseline for beginning the QA process.

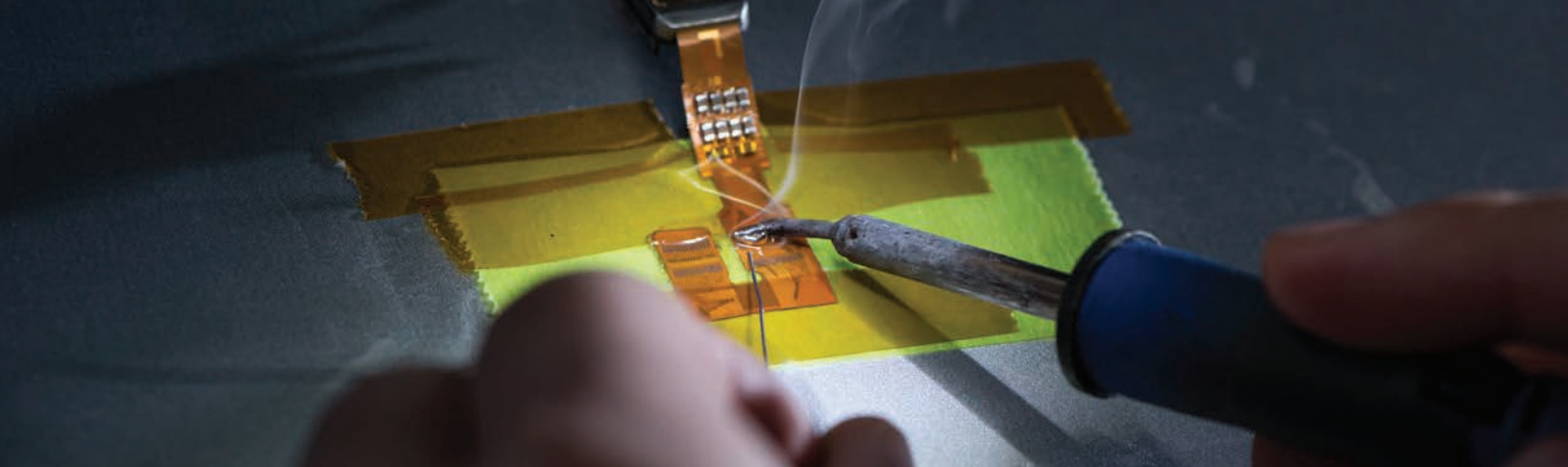
System and environment

- Ensure a quality equipment ground.
- Clean the scanner's probe ports.
- Disconnect all probes except the one being tested.
- Disconnect the network cable from the rear of the scanner.
- Adjust room lighting to typical scanning room intensity.
- Display brightness and contrast:
 - Use the system grayscale bar to adjust brightness so the darkest shade of gray is barely visible.
 - Assure that the grayscale bars are graduated or stepped.
 - Contrast is adjusted for "white whites" but not blooming.
 - Confirm any recommendations or adjustments with the sonographer.

Testing devices

- Specialized high-tech testing devices are not needed to assess probe performance in the clinical setting.
- A tissue-mimicking phantom MUST be used to properly assess image quality.
 - The same model and type of phantom should be used between each assessment.
 - Suppliers include Gammex and ATS.
 - Measurements should remain consistent between like systems and a single probe or a single system and like probe models over the lifespan of the devices.
 - Do not attempt to assess image quality viewing a patient scan.
 - Echogenicity or the ability to bounce an echo varies greatly from person to person.





Consistency between testing is key

- Tests should be conducted always using identical system settings and presets.

Example: Every Philips C5-1 should be tested using the same preset.

Suggested presets

Linear probes	Vascular preset
Curved probes	Abdominal preset
Endo-cavity	OB present
Sector	Cardiac preset

- The number of focal points should be minimal, only one to two.
- Turn off all options such as harmonic imaging, spatial compounding and image smoothing (these options may mask probe and scanner deficiencies). OEMS have brand specific names for these options, some of which are noted below:

Brand specifications

Philips	THI, SonoCT and xRes
Siemens	THI, MultiHz and SieClear
GE	Octave, Crossbeam and CHI

- Periodic inspections should occur at original equipment manufacturer recommended intervals, if not more often. (Accreditation boards recommend at least annually.)

Acceptance testing should be performed when:

- Equipment is new and is being installed
- Equipment has been in storage and is being returned to service
- Image-related assemblies, including probes, have been repaired or replaced

Visual inspections should be conducted by sonographers daily

- By addressing minor physical deficiencies, prior to them progressing to a point where they impact image quality, long-term service costs can be minimized.
- Inspect components for the following concerns:

Lens	Holes, cuts, missing sealant, bulges, air bubbles, worn corners, separation in materials
Housing	Cracks, separation, missing sealant, sharp edges
Strain reliefs	Separation from housing, cuts, holes, excessive stiffness
Cable	Cuts, holes, exposed wiring, roll-over damage, excessive stiffness
Connector	Deformations, cracks, missing/malfunctioning hardware
Pin-bank	Bent pins, corrosion, burn marks, excessive dust/debris

How to Perform Field-based Probe Testing

The following are instructions on how to conduct common functional tests required for accreditation.

Image Uniformity

Common names

Element testing, channel testing

Purpose

To perform element-to-element or channel-to-channel comparison

Region of interest

The entire width of image

Scanner settings

Frequency	Highest possible
Depth	3-6 cm of depth
Focus	Single focal point located in the very near field
Gain	Adjust overall gain and TGC so that mid-range gray level exists over the entire image

Recommended testing method

- 1 Adjust the depth to 3-6 cm (*this is probe dependent*)
- 2 Adjust the number of focal points to one (*or the focal zone to the smallest possible size*)
- 3 Adjust the focal zone to the top-most position of the image
- 4 Adjust the TGCs so that the background is as uniform as possible and is shaded in the middle-range of the grayscale
- 5 Slowly move the probe back and forth along the phantom's surface and monitor the image on the display for any vertical non-uniformity (*weak elements – minor dropout – will be easier to visualize when the probe is in motion*)

Visual criteria

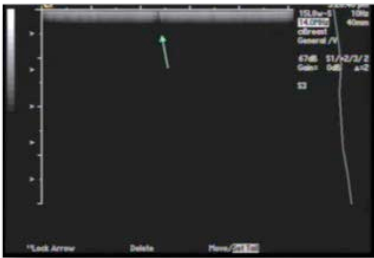
Use the following information to determine next steps for service:

Fine shadow on a single channel: Minor flaw

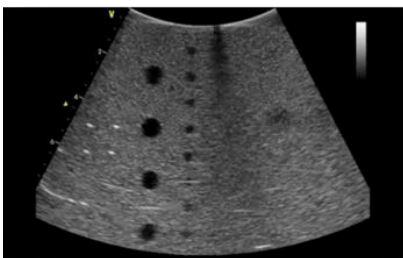
Multiple fine shadows or wide shadow on multiple channels or elements: Major flaw

Ranking and action levels

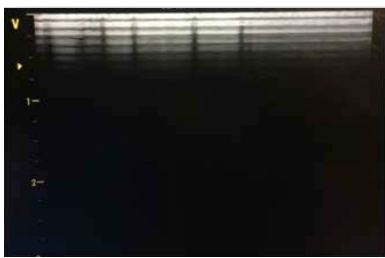
Ranking	Visual Criteria	Potential Impact	Action
1	No flaws are present	Operating as expected	No action required
2	One or two minor flaws are present	Considered operational and can be used for scanning	Inspect occasionally for possible additional deterioration over time
3	Three or more minor flaws are present	Borderline based upon location	Replace as soon as convenient
4	Major flaws are present	Unacceptable for clinical use	Remove from service immediately



Minor



Major



Major

Potential root causes for the artifact

Probe	Root cause/Troubleshooting
Acoustic lens	Lens delamination: wide shadowing
Acoustic array	A single or multiple missing or weak elements may show small artifacts
Cable/wiring harness	Test for intermittencies
Pins/connector	Inspect regularly: clean dust from pinned connectors, clean pin-less connector interfaces

System	Root cause/Troubleshooting
Connector board	Inspect regularly: Examine for damaged pins. Clean dust from scanner ports. Test the probe on multiple ports.
Front-end board	Test the probe on another scanner to rule-out a probe/ connector issue.



Maximum Depth of Penetration and Functional Resolution

Common names

Maximum visualization, relative penetration or functional resolution

Purpose

To provide an indication of overall sensitivity of a scanner/probe to detect weak signals

Regions of interest

Fiber targets	Maximum depth
Anechoic targets	Functional resolution

Scanner settings

You must use same preset for each individual probe model and same model phantom.

Frequency	Typical for the probe model
Depth	Probe dependent
Focus	Adjusted to meet needs

Maximum Depth of Penetration

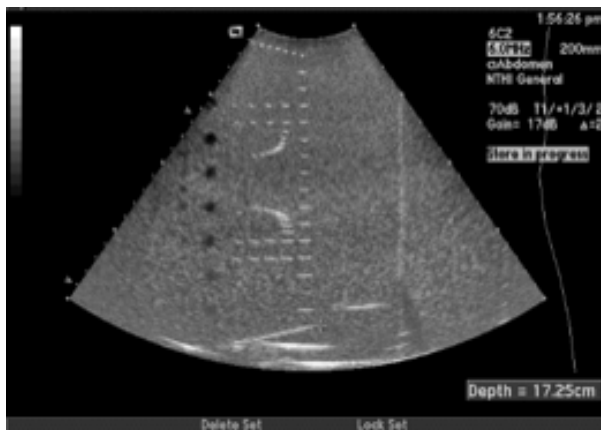
The maximum distance between the top of the image and the deepest vertical target that can be visualized

Recommended testing method

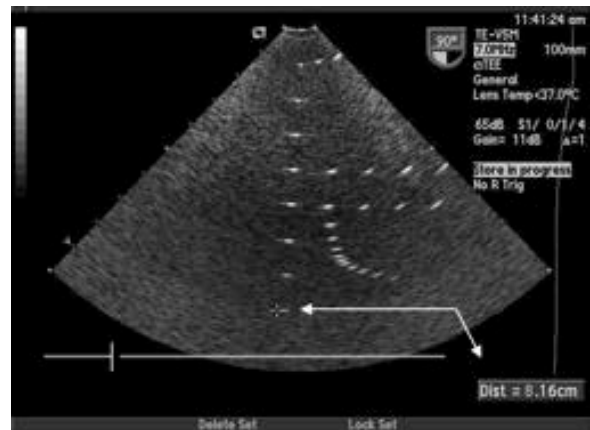
- 1 Position the probe over the vertical group of line targets until a clear image is obtained
- 2 Adjust the depth to a point no deeper than needed to display as many vertical targets as possible
 - This will be different for each make and model of probe
 - Adjust the focal zone to match the depth of the deepest visible target
- 3 Utilize cursors to measure the distance between the top of the phantom and the deepest target that can be clearly imaged
 - This distance should remain consistent over the life of the probe



Examples



17 cm penetration



8 cm penetration

Functional Resolution

The maximum distance between the top of the image and the deepest and smallest anechoic target that can be visualized.

Recommended testing method

- 1 Position the probe over the anechoic target structures until a clear image is obtained
 - The actual depth will depend on the specific make and model of the probe
- 2 Adjust the focal zone to match the depth of the smallest anechoic target that is clearly visible
- 3 Examine the image and determine the depth of the smallest anechoic target that is clearly visible
 - This distance should remain consistent over the life of the probe

Examples



2 mm target at 5 cm

Ranking and action levels

- A 5% decrease in maximum depth of penetration (from the first measurement) is cause of concern
- A 10% decrease is cause for corrective action to the probe or scanner

Potential root causes for change

Probe	Root cause
Acoustic lens	Lens thickness: improper repair
	Fluid/gel infiltration
	Damage to matching layers
Acoustic array	Arrays can degrade over time (>8-10 years)

System	Root cause/Troubleshooting
System	Inconsistent preset
	Display settings

Environmental	Root cause/Troubleshooting
Environmental	Ambient lighting

Geometric Accuracy

Common names

Measurement accuracy

Purpose

To verify both horizontal and vertical accuracy

Region of interest

Respective target groups

Scanner settings

Frequency	<i>Typical for the probe model</i>
Depth	<i>Probe dependent</i>
Focus	<i>Single focal point located in the center of the area to be measured</i>

Vertical measurement

- ① Position the probe above the column of reflector targets in the center of the image
- ② Choose two targets separated by a distance that is consistent with the type of probe
- ③ Place cursors in the middle of each target
- ④ Measurements should remain consistent between like systems and a single probe or a single system and like probe models over the life span of the devices



Horizontal measurement

- 1 Choose two targets that are separated by a distance of at least half of the image width
- 2 Place cursors in the middle of each target
- 3 Verify that the target distance is within 2% or 2mm (*whichever is greater*)



Potential root causes for inaccuracies

Probe	Root cause/Troubleshooting
Acoustic lens	Lens thickness, lens material: improper repair
	Compare measurements between multiple probes of the same model
System	Root cause/Troubleshooting
System	Gross inaccuracies may indicate a major system issue
	Compare measurements between multiple systems of the same model

Spatial Resolution

Common names

Axial/lateral resolution

Purpose

To verify the minimum distance at which two targets can be individually visualized

Region of interest

Resolution targets

Scanner settings

Frequency

Typical for the probe model

Depth

Phantom dependent

Focus

Single focal point located in the center of the area to be measured

Lateral resolution (X)

- Ability to distinguish between two objects that lie on a line perpendicular to ultrasound beam
- Varies with depth and focal point(s)

Axial resolution (Y)

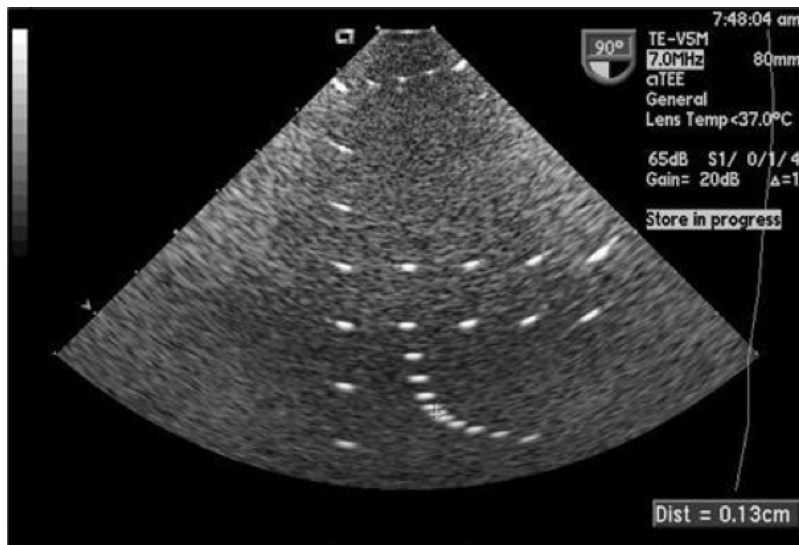
- Ability to distinguish between two objects that lie on a line parallel to ultrasound beam
- Does not vary with depth

Elevational resolution (Z)

- Ability to distinguish between two objects perpendicular to scan plane (*slice thickness*)
- Varies with depth

Recommended testing method

- ① Position the probe over the axial-lateral resolution group
- ② Adjust the focal zone to the center (*or just above the center of the targets*)
- ③ Examine the image and determine the distance at which the targets are clearly displayed as separate target points
 - The distance should remain consistent over the life of the probe



Potential root causes for changes

Probe	Root cause/Troubleshooting
Acoustic lens	Lens delamination
	Lens thickness, lens material: improper repair
	Compare measurements between multiple probes of the same model

System	Root cause/Troubleshooting
System	Improper focal point location
	Gross inaccuracies may indicate a major system issue
	Compare measurements between multiple systems of the same model

Contrast Resolution

Common names

Gray scale, gray scale resolution

Purpose

To provide an indication of the system's and the probe's ability to distinguish between objects of similar and varying densities

Region of interest

Gray scale targets

Scanner settings

Frequency	<i>Typical for the probe model</i>
Depth	<i>Dependent upon phantom model</i>
Focus	<i>Positioned at or right-above targets</i>
Gain	<i>Adjust overall gain and TGC so that mid-range gray level exists over the entire image</i>

Recommended testing method

- 1 Position the probe over the gray scale target group until a clear image is obtained
- 2 Adjust the focal zone to the center or just above the center of the target
- 3 Examine the image
- 4 All shades of gray should be clearly visualized (background and targets).
 - The targets should appear circular in shape and vary in the degree of brightness ranging from low to high levels of contrast



Probe	Root cause/Troubleshooting
Acoustic lens	Lens thickness: improper repair
	Fluid/gel infiltration
	Damage to matching layers
	Compare results between multiple probes of the same model
Acoustic array	Arrays can degrade over time (>8-10 years)

System	Root cause/Troubleshooting
System	Inconsistent preset
	Display settings

Environmental	Root cause/Troubleshooting
Environmental	Ambient lighting

Cable Noise Test

Purpose

To identify intermittencies and breakdowns in signal wiring in the cable harness

Region of interest

Entire width of image

Scanner settings

Frequency	Typical for the probe model
Depth	6-8 cm
Cardiac probes	CW Doppler mode
Non-cardiac probes	Color Doppler mode

Recommended testing method: cardiac probes

- 1 Assure that the lens is clean and dry
- 2 Enable CW Mode or Color Doppler Mode
- 3 Adjust the volume and/or Doppler Gain to an acceptable level
- 4 Use the trackball to move the cursor line slightly left or right of center
 - Avoid a straight vertical line
- 5 Flex each strain relief looking and listening for unacceptable noise
- 6 Move the cursor line to several other locations and evaluate the noise level
- 7 If cable has roll-over damage, flex/stress the damaged region

Recommended testing method: non-cardiac

- 1 Assure that the lens is clean and dry
- 2 Enable color Doppler mode
- 3 Size and position the color box to span the entire width of the image
- 4 Depth of color box should span less than 5 cm
- 5 Adjust the color gain so that there is only very minor speckling in the image
- 6 Flex each strain relief looking for streaks of flashing color
- 7 If cable has roll-over damage, flex/stress the damaged region



Potential root causes for artifact

Probe	Root cause/Troubleshooting
Wiring harness	Intermittent wiring: Heavy static sounds in CW mode, streaks of flashing color in color mode
	Major wiring damage: intermittent dropout in the 2D imaging

Electro-mechanical Functionality

Purpose

To identify electro-mechanical failures in 3D/4D volumetric probes

Region of interest

Probe only

- Internal electro-mechanics
- Motor
- Sensor

Scanner settings

Mode 3D/4D

Recommended testing method

- ① Visually inspect the dome for abrasions and signs of impact
- ② Enable continuous 3D/4D acquisition
- ③ Apply slight pressure to dome
- ④ An error message should not be displayed
 - Stress strain reliefs and any area on the cable that shows evidence of roll-over damage or pinching.

Potential root cause of failure

Probe	Root cause/Troubleshooting
Probe	Impact to dome: internal electro-mechanical damage
	Motor failure
	Sensor failure

Documentation Template

Currently, there is no standardized form within the industry for assessing system or probe performance. Below is an example of a form which can be created using Microsoft Excel. The Innovatus Imaging team can help to customize a form to meet your needs.

Field Evaluation Form											
Ultrasound Transducer QC and Acoustic Performance Evaluation					Probe Manufacturer: _____						
					Probe Model Number: _____						
					Probe Serial Number: _____						
					U.S. System I.D.: _____						
					Preset: _____						
Visual Inspection											
Lens	<input type="checkbox"/>	Cut/Hole	<input type="checkbox"/>	Worn	<input type="checkbox"/>	Open Seals	<input type="checkbox"/>	Other	<input type="checkbox"/>	Fail	Pass
Array Housing	<input type="checkbox"/>	Cracked	<input type="checkbox"/>	Stained	<input type="checkbox"/>	Open Seals	<input type="checkbox"/>	Other	<input type="checkbox"/>		
Bend Relief	<input type="checkbox"/>	Cut/Hole	<input type="checkbox"/>	Separated	<input type="checkbox"/>	Worn	<input type="checkbox"/>	Other	<input type="checkbox"/>		
Cable	<input type="checkbox"/>	Cut/Hole	<input type="checkbox"/>	Stained	<input type="checkbox"/>		<input type="checkbox"/>	Other	<input type="checkbox"/>		
Strain Relief	<input type="checkbox"/>	Cut/Hole	<input type="checkbox"/>	Separated	<input type="checkbox"/>		<input type="checkbox"/>	Other	<input type="checkbox"/>		
Connector	<input type="checkbox"/>	Cracked	<input type="checkbox"/>	Paint Chipped	<input type="checkbox"/>	Locking Knob	<input type="checkbox"/>	Other	<input type="checkbox"/>		
Pins	<input type="checkbox"/>	Bent	<input type="checkbox"/>	Burned	<input type="checkbox"/>	Broken/Missing	<input type="checkbox"/>	Other	<input type="checkbox"/>		
Comments											
Phantom/Scan Testing											
Image Uniformity	Acceptable _____		Unacceptable _____								
Gray Scale	Acceptable _____		Unacceptable _____								
Maximum Penetration	_____ mm										
Ax/Lat Resolution	_____ mm										
Functional Resolution	_____ mm anechoic target @ _____ cm of depth										
CW/PW/Color Noise	Acceptable _____		Unacceptable _____								
Comments											
Scan Acceptable _____										Fail	Pass
										<input type="checkbox"/>	<input type="checkbox"/>

Performing ultrasound probe
quality assurance assessments:

A How-to Guide



INNOVATUS IMAGING
575 Epsilon Drive • Pittsburgh, PA 15238
www.innovatusimaging.com

CUSTOMER CARE/ORDERS
1-844-687-5100
customercare@innovatusimaging.com