

Model 570
Multipurpose - Endoscopic
Phantom

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Introduction

Tissue-mimicking phantoms are used to evaluate the performance of diagnostic ultrasound imaging systems. The phantoms mimic the acoustic properties of human tissue and provide target structures within the simulated environment. They are essential to detect the performance changes that occur through normal aging and deterioration of system components. Routine equipment performance monitoring can reduce the number of repeat examinations, the duration of examinations, and maintenance time. Phantoms are employed in the areas of; Clinical Quality Assurance, Preventative Maintenance Programs, Field Service Testing, Research and Development, Manufacturing, Teaching and Sales & Marketing.

Sound Velocity of Rubber based TM Material

The sound velocity of most diagnostic imaging systems is calibrated to 1,540 meters per second (mps), the assumed average velocity of sound through human soft tissue. The rubber-based tissue-mimicking material used in the Model 570 has a sound velocity of 1450 m/s when measured at room temperature (22-24°C). The line targets and anechoic target structures have been physically positioned to compensate for the differences in the speed of sound, assuring accuracy of measurements.

Effect of Temperature

The acoustic properties of all biologic and non-biologic materials are affected by temperature variations. Most diagnostic imaging systems and tissue-mimicking phantoms are calibrated at room temperature, commonly referred to as 23°C. ATS has affixed a thermometer strip to the outside surface of the phantom housing, room temperature is reflected on the strip, not the interior of the phantom. Therefore, if a rubber-based phantom is exposed to extreme temperatures for several hours, it will take the equivalent amount of time to reach room

temperature once again. Leaving the phantom in your car overnight during a typical New England winter, while the phantom will not be damaged, you will need to wait approximately 24 hours for it to reach room temperature.

Tissue Mimicking Materials

ATS offers a choice between our standard hydrogel-based (water) or rubber-based tissue-mimicking material. As with most things in life, the choice between rubber-based or Hydrogel TM material is a trade off of benefits. We have provided a listing of the features and benefits of both material.

Features	Hydrogel TM Material	Rubber-Base TM Material
Speed of Sound 1540 mps	Yes	No Comment: Line targets & target structures have been physically moved to compensate for the difference in the assumed average speed of sound of soft tissue of 1540 mps and the speed of sound of the phantom. As the attenuation increases so does the speed of sound in the rubber. Attenuation of 0.5 dB/cm/MHz = 1450 mps (measured at 3.5 MHz and 23°C)
Rate of Desiccation	.00005 gm/day/sq. cm	Not affected
Warranty	One-year	Lifetime (estimated to be 10 years)
Estimated Usable life	2-3 years	Greater than 10 years
Consistency of the measurements with time	Changes begin to occur as desiccation progresses, this depends on the climate, storage conditions and the care taken of the phantom.	No change throughout the usable life have been noted to date.
Exposure to temperatures above 49°C or below 0°C	Phantom will be will severely damaged or destroyed	Allow the phantom time to reaches room temperature before using
Accidental Dropping causing cracks in the housing	Damage is usually beyond repair, requiring replacement	Repairable

Baseline Values

The baseline represents the instrument's peak performance. Ideally, the baseline values are established immediately following the installation and acceptance of a new imaging system. If this is not possible, immediately after preventive maintenance and servicing by a qualified service engineer.

Scan the Model 570 Multipurpose Endoscopic phantom, while adjusting the controls to produce the best possible image. If the bottom of the phantom is visualized, adjust the depth of penetration until only the lower targets are visualized without artifacts produced from the work surface. One should take care to avoid over emphasizing a particular area of the image. Make the display monitor's brightness and contrast settings and the room lighting conditions reflect a clinical environment.

When an acceptable image has been obtained with a particular scanner-transducer pair, the system settings must be accurately documented on the quality assurance record. The settings that should be included; dynamic range, gray scale level, power level, gain level, and time gain compensation (TGC).

Remember, the accuracy or the baseline values obtained and recorded are extremely important. These values will become the basis for all future performance testing. Some systems have the ability to save the baseline values.

When recalled the system is automatically setup to reflect the programmed baseline values, thereby reducing the potential for errors.

General Guidelines for Setting Up the Phantom for Scanning

1. Place the phantom on a clean, flat surface with scan surface positioned for use.
2. Apply an adequate amount of low viscosity gel or water to the scan surface. If water is used, fill the scanning well slowly to avoid introduction of air bubbles.
3. Set-up the imaging system-transducer pair in accordance with the established baseline values. Record these settings on the quality assurance record.

Phantom Re-certification

Re-certification of an ATS rubber-base phantom can be performed at any time in accordance with an individual institution's quality assurance procedure. ATS produces a test block of TM material for every rubber-based phantom sold. The test block is used to measure the acoustic properties of the phantom as part of the products final quality assurance procedure. The test block is retained at the company for future reference and testing during the re-certification process.

Procedure for phantom re-certification is simple. The phantom is returned to our facility with all shipping charges paid by the customer. We perform the following steps:

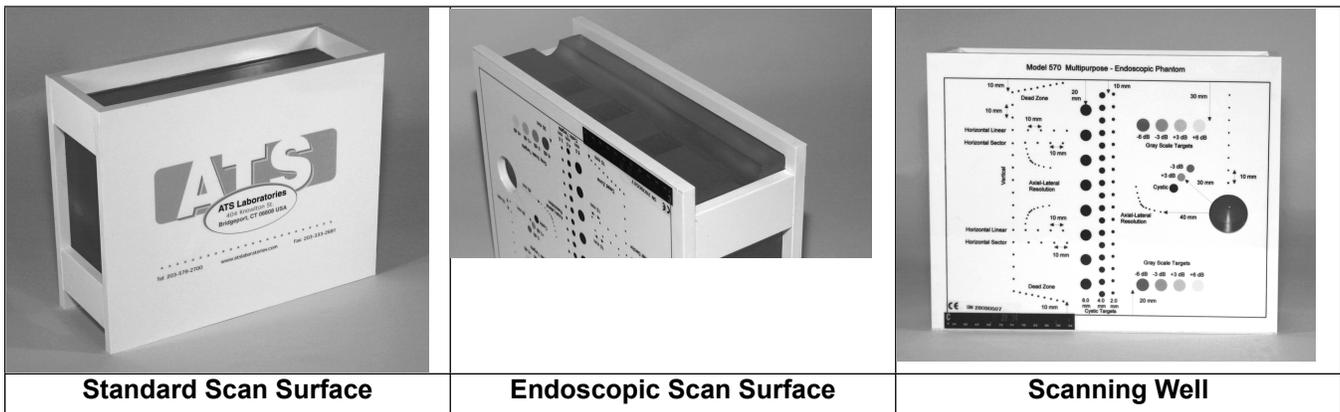
1. Upon arrival, the phantom is inspected for physical damage.
2. The test block is retrieved from the storage library and the acoustic properties are measured.
3. The phantom is then scanned repeating all of the original tests.
4. Results are then compared with the original results on file.
5. A new Quality Assurance certification document similar to the one originally received when the phantom was purchased will be issued. The phantom is then returned to our customer.

Product Description

The Model 570 Multipurpose & Endoscopic phantom is an easy, comprehensive means of evaluating imaging systems with an operating frequency range of 2.25 to 7.5 MHz. The phantom is designed with a combination of monofilament line targets for distance measurements and tissue mimicking target structures of varying sizes and contrasts. Due to the acoustic similarity of the background material and the target structures, artifacts caused by distortion, shadowing and enhancement have been eliminated. Four gray scale targets ranging in contrast from +6 to -3 dB are provided to evaluate the system's displayed dynamic range and gray scale processing performance.

The Model 570 offers a new and improved scan surface design to easily accommodate linear, sector, endoscopic probes and mechanical sector probes such as used for rectal scanning.

Scan Surfaces



Specifications

General		Tissue Mimicking Material	
Overall Dimensions	270 x 215 x 96 cm	Type	Urethane rubber
Housing Material	PVC	Freezing Point	< -40°C
Scan Surfaces	2	Melting Point	> 100°C
Scan Wells	1	Attenuation Coefficient	0.5 dB/cm/MHz ± 5.0%
Weight	4.55 Kg (10 lb)	Speed of Sound	1450 m/s ±1.0% at 23°

Line Targets					
Material Diameter	Monofilament Nylon .12 mm		Dead Zone Groups	A1	A2
			Lateral Displacement	5 mm	5 mm
			Interval Spacing	1 mm	1 mm
			Scan Surface Depth	2-10 mm	2-10 mm
			Standard Endoscopic		
Vertical Groups	B1	B2	Horizontal Linear Groups	C1	C2
Number of Targets	17	8	Number of Targets	5	5
Interval Spacing	10 mm	10 mm	Interval Spacing	10 mm	10 mm
Depth	10-160 mm	10-80 mm	Scan Surface Depth	40 mm	40 mm
			Standard Endoscopic		

Axial-Lateral Resolution Groups	E1	E2	E3	Horizontal Sector Groups	D1	D2
Number of Targets	Standard	Endo- scopic	Scan Well	Number of Targets	5	5
Interval Spacing	6			Interval Spacing	10 mm	10 mm
	5, 4, 3, 2, 1 mm			Scan Surface Depth	50 mm	50 mm
				Standard Endoscopic		
Scan Surface Depth	40 mm	60 mm	40 mm			

Anechoic Target Structures	F1	F2	Gray Scale Target Structures	G1	G2	G3
Type	Non-echogenic, cylindrical		Type	Standard	Endo- scopic	Scan Well
Size	8, 4, 2 mm	6 mm	Diameters	10 mm	10 mm	6 mm
Number of Targets	27	1	Scan Surface Depth	30 mm	20 mm	30 mm
Depth	10 – 170 mm	30 mm	Number of Targets	4	4	2
Interval Spacing	10 & 20 mm	NA	Contrast relative to background material (dB)	+6, +3, -3, -6		+3, -3

*Nominal dimensions

DEAD ZONE (A1 & A2)

Description and Reason For Testing

The dead zone is the distance from the front face of the transducer to the first identifiable echo at the phantom/patient interface. The dead zone occurs because an imaging system cannot send and receive data at the same time. Therefore, no clinical data can be collected in this region. However if artifacts are noted within the dead zone, they may indicate fluctuations in the input power to the system. The depth of the dead zone depends upon the frequency and performance of the transducer and the pulsing/receiving section of the system.

Testing Procedure

1. Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.
2. This group is composed of 9 line targets. The first target is positioned 2 mm below the scan surface. Subsequent targets are spaced 1 mm apart, to a depth of 10 mm.
3. Using the electronic calipers, measure the distance between the first target imaged and the echo produced by the scan surface. The resulting value will be the depth of the dead zone.
4. Document the depth measurement on the quality assurance record.

Results

The system's dead zone should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

VERTICAL MEASUREMENT CALIBRATION (B1 & B2)

Description and Reason For Testing

Vertical distance measurements are obtained along the axis of the sound beam. Accurate representation of the size, depth and volume of a structure is a critical factor in a proper diagnosis. Most imaging systems use depth markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained using the timing markers and/or electronic calipers. The resulting measurement is then compared to the known distance between the line targets in the phantom. The accuracy of vertical distance measurements depends on the integrity of the timing circuitry of the imaging system.

Testing Procedure

1. Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display.
2. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets.
3. Document the measurement obtained on the quality assurance record.

Results

The system's vertical distances measurements should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

HORIZONTAL MEASUREMENT CALIBRATION

Linear Horizontal Group (C1 & C2)

Sector Horizontal Group (D1 & D2)

Description and Reason For Testing

Horizontal distance measurements are obtained perpendicular to the axis of the sound beam. Proper diagnosis depends on the accurate representation of the size and volume of a structure being examined. Most imaging systems use distance markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained. The resulting measurement is then compared to the known distance in the phantom. The accuracy of the horizontal distance measurements depends on the integrity of the transducer scanning assembly, the output intensity and the resolution of the imaging system.

Testing Procedure

Note: The Model 570 General & Small Parts phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Due to the geometry and variety of sector scan transducers a separate set of horizontal line targets are provided to evaluate lateral resolution. Please refer to the specification page for the location of these groups.

1. Position the transducer over the horizontal group of line targets until a clear image is obtained. Freeze the image.
2. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets displayed.
3. Note: Some sector scanners have distance markers on the outside edges of the sector image with no other indicators available. Hand-held calipers must be used for distance measurements within the image on the monitor.
4. Document all of the measurements on the quality assurance record.

Results

The system's horizontal distance measurements should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

AXIAL – LATERAL RESOLUTION ARRAYS (E1, E2 & E3)

Description and Reason For Testing

Resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately along the axis of the beam, whereas lateral resolution defines the system's ability to image objects separately that lie perpendicular to the axis of the sound beam. If a system has poor resolution capabilities, small structures lying close to each other will appear as one image, causing improper interpretation of the ultrasound findings. Axial Resolution depends on the transducer's center frequency, damping characteristics and pulse length. Generally, the higher the frequency the better the system's axial resolution. Lateral Resolution depends on the beam width, focusing characteristics of the transducer, number of displayed scan lines and the system's sensitivity and gain settings.

Testing Procedure

The locations in the phantom are referenced from the first axial target.

The line targets are spaced at 5.0, 4.0, 3.0, 2.0, 1.0 mm intervals both axially and laterally. The last point of the axial array target group is also the first target point in the lateral array group.

1. Position the transducer over the axial-lateral resolution group of line targets on the phantom until a clear image is obtained. Freeze this image.
2. Examine the image to determine if all of the line targets within the group are clearly displayed as separate target points. Record the closest spaced target points which can be imaged (refer to specification drawing). Obtain a hard copy of the display.
3. Document all observations made on the quality assurance record.

Results

The system's ability to resolve the array targets at given depths should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

FOCAL ZONE (B1 & B2)

Description and Reason For Testing

The focal zone is the region surrounding the focal point in which the intensity and the lateral resolution is the greatest. Clinically, structures examined within the focal zone will provide the best diagnostic information obtainable. The focal zone can be affected by changes in the pulsing/receiving section of the imaging system or damage to the transducer.

Testing Procedure

1. Position the transducer over the vertical group of line targets on the phantom, until a clear image is obtained. A line rather than a dot is produced on the display. The length of the line is indicative of the width of the beam. Therefore, targets inside the focal zone form a shorter line than those outside of the focal zone. Adjustments

in the gain settings will change the length of the line targets displayed. Freeze the display and obtain a hard copy.

2. For a variable focused transducer, scans with several different focal zone settings should be performed. Dynamically focused transducers may not display changes in the width of the line targets. However a change in the intensity can be observed upon adjustment of the transmitting focus of the transducer.
3. Using the hard copy, draw a line connecting the ends of the echoes received from the line targets (both sides), the line should form a smooth curve. This will illustrate the shape of the sound beam. Now locate the narrowest portion, this is the focal zone. Measure the width of the beam and the depth at this point.
4. Document the depth of the focal zone and the measurement of the focal width on the quality assurance record.

Results

The system's focal zone should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

SENSITIVITY (MAXIMUM DEPTH OF PENETRATION) (F1)

Description and Reason For Testing

The ability of an imaging system to detect and display weak echoes from small objects located at specified depths (penetration) is referred to as sensitivity. Clinically, weak reflecting echoes are commonly produced from internal structures of organs. Definition of these structures can be extremely important in the interpretation of the ultrasound findings. Sensitivity can be affected by the pulser/receiver section of the system, the degree of focusing of the transducer, attenuation of the medium, depth and shape (geometry) of the reflecting object, and electromagnetic interference from the local surroundings. A system's maximum depth is limited by output power, TGC, gain, transducer frequency, focal depth, number of scan lines and electrical noise.

Testing Procedure

1. Position the transducer over the 8 mm group of anechoic targets.
2. Freeze image and obtain a hard copy.
3. Examine the image to determine the last or deepest target structure displayed. Using the electronic calipers or the timing markers measure the depth of this target.
4. This test should also be performed with output levels set at the highest and lowest settings. This enables any changes in output to be more easily detected.
5. Document the depth measurement on the quality assurance record.

Results

The system's depth of penetration should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Functional Resolution and Image Uniformity (F1)

Description and Reason For Testing

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of the non-echogenic target structures within the TM matrix of the test phantom. The targets should appear circular with sharp clearly defined edges, indicating an abrupt transition from the echogenic to the non-echogenic region. The targets are anechoic and should be free of any internal echoes or fill-in.

Bright artifacts may be observed at the top and bottom of the targets, these are normal specular reflections and do not present a problem. However, observable shade of gray within the anechoic target, usually is indicative of internal system noise and/or the presence of side lobes. Should the targets appear flattened, a geometric distortion problem should be considered. In practice, the data obtained will give a direct indication of the smallest diameter target the system is capable of resolving at a given depth. The functional resolution capabilities of a system can be affected by side lobes in the transducer beam, electrical noise, and problems in the imaging processing hardware.

These artifacts can be the result of transducer malfunction, poor electrical contacts, failure in the image processing and/or system's software, and poor acoustic coupling between the transducer/patient interface causing the introduction of reverberations artifacts. Generally, horizontal bands are often caused by circuitry and focusing problems while vertical bands indicate a damaged transducer element.

Testing Procedure

1. Position the transducer over the anechoic target structures until a clear image is obtained.
2. Freeze image and obtain a hard copy.
3. Examine the image to determine the first and last target in each size group displayed. Record the range of depths visualized for each group. Due to the configuration of the sound beam small targets in the near field may not be imaged.
4. Scan this region to determine if there are any areas of non-uniformity. If the initial image demonstrates non-uniformity or artifacts of this type, repeat the scan at a different location using the same phantom to rule out a defect in a particular region of the phantom. If the artifacts are still present, note the gain settings, gray scale level and focal setting and document with a photograph. Repeat the scan using a different gain and focal setting.
5. Document all findings on the quality assurance record.

Results

The system's functional resolution and image uniformity should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, or major areas of image non-uniformity are observed, corrective action should be considered.

GRAY SCALE & DISPLAYED DYNAMIC RANGE

Description and Reason For Testing

Gray scale or gray scale processing uses the amplitude of the echoes received to vary the degree of brightness of the displayed image. The adjustment of the echo signal required to go from a just noticeable (lowest gray scale level) echo to the maximum echo brightness is referred to as the displayed dynamic range. Clinically, gray scale processing and displayed dynamic range allow echoes of varying degrees of amplitude to be displayed in the same image.

Test Procedure

1. Position the transducer over the gray scale target group until a clear image is obtained.
2. Freeze image and obtain a hard copy.
3. Examine the image. The targets should appear circular in shape, with clear sharp edges and vary in the degree of brightness ranging from low to high levels of contrast. The presence or absence of any shadowing behind the structures should be noted.
4. All findings should be documented on the quality assurance record.

Results

This target group varies in echogenicity and provides a good indication of the performance of the gray scale processing and displayed dynamic range. The system's gray scale processing should remain consistent from week to week when using the same instrument settings and Model 570 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

General References:

Michell M. Goodsitt, Paul Carson; "Real-Time B-mode Ultrasound Quality Control Test Procedures, Report of AAPM Ultrasound Task Group No. 1," Medical Physics, 25 (8) August 1998

W. N. McDicken, PhD, "Diagnostic Ultrasonics, Principles and Use of Instruments," John Wiley & Sons, 1976.

Sandra L. Hagen-Ansert; "Textbook of Diagnostic Ultrasonography," Mosby, 1989.

CARE OF RUBBER-BASED PHANTOMS

For best results the phantom should be kept clean at all times. In particular a build-up of dried coupling gel on the scan surface should be avoided. The phantom may be cleaned with mild hand soap and warm water. Particularly stubborn stains and dirt may be removed with a mild household cleaner. The use of petroleum solvents should be avoided since they may adversely react with the rubber-based material.

WARRANTY

Statement of Warranty

ATS Laboratories, Incorporated warrants this rubber-based phantom for its lifetime from the date of delivery to the purchaser, that the Phantom is free from functional defects in materials and workmanship. The lifetime of this phantom is estimated to be between 7 to 10 years from the date of manufacturing. If ATS Laboratories, Incorporated, deems the phantom to be defective, at its sole option, the Phantom will be repaired or replaced free of charge, in a reasonable amount of time.

ATS shall not be otherwise liable for any damages, including but not limited to incidental damages, consequential damages, or special damages.

There are no express or implied warranties which extend beyond the warranties as stated below.

Conditions of Warranty

1. The defect must be reported and the Phantom returned within the warranty period.
2. The Phantom must be packaged properly to avoid damage during shipping.
3. All transportation charges will be paid by the purchaser.

Invalidation of Warranty

1. If the phantom has been altered or repaired other than by ATS Laboratories, Incorporated.
2. If the phantom has been subject to abuse, misuse, negligence or accident.
3. If the purchaser has exposed the Phantom to petroleum solvents.

Ultrasound Performance Testing Record

Facility: _____ Department: _____

Technician / Sonographer: _____

System Identification

System Manufacturer: _____ Model: _____ S/N: _____

Transducer Type: _____ Model #: _____ S/N: _____

ATS Phantom Model: _____ S/N: _____

Date _____

Routine Testing

Baseline

Initial Setup

Software Upgrade

New Phantom

New Transducer

General Inspection	Pass	Fail		Pass	Fail
Power Cord (cracks, plugs, discoloration)			Transducer (Cable, housing, plug, transducer face)		
Dust Filters (clean & dust free)			Scanner console (free of damage)		
Controls (Clean, broken knobs & switches)			Wheels (rotate freely, locks hold properly)		
Display (clean, free scratches, Brightness/contrast controls)			Comments		

System Settings					
Power	dB	Gain	dB	Dynamic Range	dB
Pre-Processing		Post-Processing		Programed Presets	
Transmit Focus	cm	Image Magnification		Room Temperature:	

Geometric Accuracy Testing	Phantom Distance	Baseline Measured	Distance Measured	Error/Change
Vertical Distance Measurements				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm
Horizontal Distance Measurements				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm
Dead Zone (Ring-down ramp)				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm

Spatial Resolution	Phantom Distance	Baseline Measured	Distance Measured	Error/Change
Axial Resolution				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm
Lateral Resolution				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm

Focal Zone & Sensitivity	System's Mfg. Specification	Baseline Depth	Measured Depth	Error/Change
Focal Zone				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm
Sensitivity				
Electronic Calipers	mm	mm	mm	mm
Display Devices used for interpretation	mm	mm	mm	mm

Functional Resolution	Range of Depths Displayed		Target Shape		Target Edges		Change Yes/No
	Baseline	Display**	Baseline	Display**	Baseline	Display**	
Target Sizes (mm)							
1.0	mm	mm					
2.0	mm	mm					
3.0	mm	mm					
4.0	mm	mm					
6.0	mm	mm					
8.0	mm	mm					
10.0	mm	mm					
**Display Devices used for interpretation							

Image Uniformity - Display Devices used for interpretation	__ No Artifact Detected __ Artifact Detected			
Image Uniformity Artifact Detected	Gain Settings	Gray Scale Level	Focal Setting	Change Yes/No
First Scan System Settings				
Repeat Scan at a different region in the phantom and at different gain and focal distance settings.				
If artifact persists, further investigation and/or corrective action is recommended.				

Gray Scale - Displayed Dynamic Range							**Display Devices used for interpretation
Targets (dB)	Range of Contrast		Target Shape - Circular		Target Edges - Clear/Sharp		Change Yes/No
	Baseline Yes/No	Display** Yes/No	Baseline Yes/No	Display** Yes/No	Baseline Yes/No	Display** Yes/No	
+15	mm	mm					
+6	mm	mm					
+3	mm	mm					
-3	mm	mm					
-6	mm	mm					
-15	mm	mm					

Summary of Results:
Signature: