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Ultrasound Imaging Phantoms

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Model 551

Small Parts Phantom Instructions Manual

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Made in USA

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INTRODUCTION

Quality assurance tissue-mimicking phantoms are used to evaluate the accuracy and performance of ultrasound imaging systems. The phantoms mimic the acoustic properties of human tissue and provide test 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.

This phantom is constructed of a new rubber-based tissue-mimicking material developed by ATS Laboratories. This material extends the useful life of the phantom by avoiding problems due to melting, freezing, dehydration and breakage from dropping which are common with hydrogel (water-based) phantoms. By eliminating these problems, the durability, quality and reliability of this product is guaranteed for ten years.

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. To ensure measurement accuracy ATS incorporates a thermometer strip affixed to the outside surface of the phantom housing.

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 has a sound velocity of 1450 mps at 0.5db/cm/Mhz at room temperature (23°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.

PRODUCT DESCRIPTION

The Small Parts tissue-mimicking phantom allows the Sonographer to monitor the performance of an imaging system using frequencies ranging from approximately 7.5 to 15 MHz.

The Model 551 is constructed of a rubber-base tissue mimicking material. A scanning well is molded into the body of the phantom to permit the use of water or a low viscosity acoustic coupling agent. The phantom is packaged in a carrying case providing added protection during transporting and storage.

TESTS PERFORMED

- Dead zone
- Vertical Measurement Calibration
- Horizontal Measurement Calibration
- Focal Zone
- Sensitivity
- Axial Resolution
- Lateral Resolution
- Functional Resolution & Image Uniformity
- Definition and Fill-In
- Gray Scale & Displayed Dynamic Range

SPECIFICATIONS

GENERAL

Overall dimensions28 x 11 x 11 cm*
Weight3.1 Kg*
Housing Material WallPVC
Surfaces Scan1
Surfaces Size25 cm x 8 cm*

LINE TARGETS

Material Monofilament
nylon Diameter 0.08mm

DEAD ZONE GROUP

Lateral Displacement 5.0 mm
Interval Spacing 1.0 mm
Depth 1.0 - 4.0 mm

VERTICAL GROUP

Number of targets 10
Interval Spacing .5 cm
Depth .5 to 5.0 cm

GRAY SCALE TARGET STRUCTURES

Type Echogenic, cylindrical
Number of targets 6
Diameter 6
Interval Spacing 1 cm (center-to-center)
Depth 2.0 cm
Contrast relative to background material (dB) -15, -6, -3, +3, +6, +15

*Nominal dimensions

TISSUE MIMICKING MATERIAL

Type Urethane rubber
Freezing Point < -40°C
Melting Point >100°C
Attenuation 0.5dB/cm/Mhz 10%
Speed of Sound 1450 mps ± 1%@ 23°C

HORIZONTAL GROUP

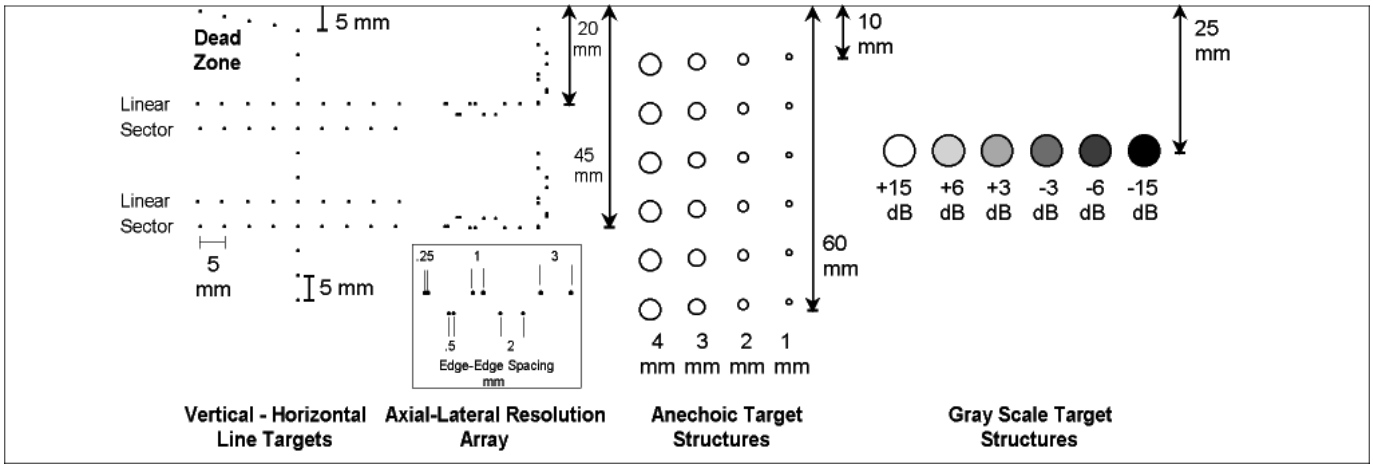
Number of Groups 2
Interval Spacing .5 cm
Depths
Linear Array 2.0 & 4.0 cm
Sector/Convex Array 2.5 & 4.5 cm

AXIAL-LATERAL RESOLUTION GROUP

Number of Groups 2
Target sets per depth 10
Depths 2.0 cm
4.5 cm
Spacing (edge-to-edge) 0.25, 0.5, 1, 2, 3 mm

ANECHOIC TARGET STRUCTURES

Type: Non-echogenic cylindrical
Target groups 4
Targets in each group 6
Diameters 1, 2, 3, 4 mm
Interval spacing 1 cm center to center
Depth 1 to 6 cm



DEAD ZONE

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 5 line targets. The first target is positioned 1 mm below the scan surface. Subsequent targets are spaced 1 mm apart, to a depth of 5 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 551 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

Description and Reason For Testing

Vertical measurements are distance measurements obtained along the axis of the sound beam. The 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 is dependent upon the integrity of the timing circuitry of the imaging system.

Testing Procedure

1. Place the phantom on a clean, flat surface with the scanning 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" small parts or superficial scanning. If the bottom of the phantom is seen, adjust the gain settings until the image goes entirely black. Record these settings on the quality assurance record. These setting should be used for subsequent testing.

4. Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display.

5. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets.

6. Document the measurement obtained on the quality assurance record.

Results

If a discrepancy occurs which is greater than 1.0 mm, corrective action should be considered by the individual Ultrasound Department.

HORIZONTAL MEASUREMENT CALIBRATION

Description and Reason For Testing

Horizontal measurements are distance measurements obtained perpendicular to the axis of the sound beam. Proper diagnosis is dependent upon 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 is dependent upon the integrity of the transducer, the output intensity and the resolution of the imaging system.

Testing Procedure

Note The Model 551 contains two groups of horizontal line targets. For testing a linear array transducer use the first and third rows of targets. For testing a sector or convex array transducer, used the second and forth. Please refer to the target diagram for clarification.

1. Place the phantom on a clean, flat surface with the scanning 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" small parts or superficial scanning. If the bottom of the phantom is seen, adjust the gain settings until the image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4. Position the transducer over the horizontal group of line targets, until a clear image is obtained. Freeze the image.

5. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets displayed.

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.

6. Document the all measurements on the quality assurance record.

Results

If a discrepancy occurs which is greater than 2.0 mm, corrective action should be considered by the individual Ultrasound Department.

AXIAL AND LATERAL RESOLUTION

Description and Reason For Testing

Resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately. 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.

Resolution along the axis of the sound beam is referred to as Axial Resolution. Axial Resolution is affected by the pulsing section of the imaging system and the condition of the transducer.

Resolution perpendicular to the axis of the sound beam is termed Lateral Resolution. Lateral Resolution is dependent upon the beam width, increased beam width will reduce the Lateral Resolution.

Testing Procedure

The Model 551 contains three axial-lateral resolution arrays at two given depths.

1. Place the phantom on a clean, flat surface with the scanning 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" small parts or superficial scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4. Position the transducer over the first axial-lateral resolution group located at a depth of 2.0 cm, until a clear image is obtained. Freeze this image.

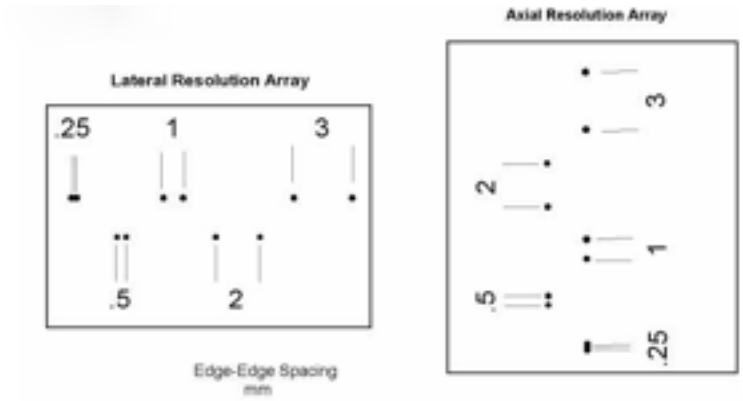
5. Examine the image to determine if all of the line targets within the group are clearly displayed as separate target points. Record the closest spaced target points which can be imaged. Obtain a hard copy of the display.

6. Document all observations made on the quality assurance record.

7. Repeat the above procedure for the remaining depth.

Results

The system's ability to resolve the array targets at all three depths should remain consistent from week to week when using the same instrument settings and the Model 551 phantom. Compare the test results obtained with a baseline or previous test. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.



FOCAL ZONE

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. Place the phantom on a clean, flat surface with the scanning 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" small parts or superficial scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4. Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display and obtain a hard copy.

5. NOTE 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.

6. 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.

7. 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.

8. Document the depth of the focal zone and the measurement of the focal width on the quality assurance record.

Results

The location of the focal zone should agree with the manufacturer's specifications and should not change with time. This applies to both fixed and dynamically focused systems. If changes occur corrective action should be considered.

SENSITIVITY

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.

Testing Procedure

1. Place the phantom on a clean, flat surface with the scanning 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" small parts or superficial scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4. Note In addition to the above, 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. Position the transducer over the 4.0 mm group of anechoic targets.

6. Freeze image and obtain a hard copy.

7. 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.

8. Document the depth measurement on the quality assurance record.

Results

The depth of penetration should not shift by more than 1.0 cm, when using this phantom at same instrument settings and transducer. If a discrepancy occurs corrective action should be considered by the individual Ultrasound Department.

Functional Resolution and Image Uniformity

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

Position the transducer over the anechoic target structures until a clear image is obtained.

Freeze image and obtain a hard copy.

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.

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.

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 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. Place the phantom on a clean, flat surface with the 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" small part or superficial scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4. Position the transducer over the gray scale target group until a clear image is obtained.

5. Freeze image and obtain a hard copy.

6. 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.

7. 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 test should be compared with a baseline test using the same instrument settings, to determine if any change in the characteristics of the target group has occurred with time. If changes are noted, they should be investigated.

CARE 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 warm water using a lint free cloth. 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.

Statement of Warranty

ATS Laboratories, Incorporated warrants this rubber-based phantom for it's 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 5 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

Date _____
__ Routine Testing
__ Baseline
__ Initial Setup
__ Software Upgrade
__ New Phantom
__ New Transducer

Facility: _____ Department: _____

Technician / Sonographer: _____

System Identification

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

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

ATS Phantom Model: _____ S/N: _____

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
Target Sizes (mm)	Baseline	Display**	Baseline	Display**	Baseline	Display**	
1.0	mm	mm					
2.0	mm	mm					
30	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			
	Range of Contrast		Target Shape - Circular		Target Edges - Clear/Sharp		Change Yes/No
Targets (dB)	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: