MODEL 540
RECTAL SCAN PHANTOM

DISCONTINUED

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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 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 three years.

Most diagnostic imaging systems are calibrated for a sound velocity of 1,540 meters per second (mps), which is the assumed average velocity of sound through human soft tissue. The rubber-based tissue-mimicking material has a sound velocity of 1450 and 1473 mps at 0.5db/cm/Mhz and 0.7db/cm/Mhz respectively at room temperature (23°C).

The anechoic target structures have been physically positioned to compensate for the differences in the speed of sound, assuring accuracy of measurements. In those cases, in which the physical positioning of the targets has not been "positioned-compensated," a simple measurement conversion calculation has been provided. This calculation should be used when indicated in the test procedure.

PRODUCT DESCRIPTION

The Model #540 is designed to evaluate the performance of an imaging system's end-fired or bi-planar transrectal rotary probes. The phantom has an internal scanning cavity to permit the insertion of a rotary probe into the body of the phantom. The diameter of the scanning cavity is 3.5 cm (other sizes can be ordered upon request) at the top. The cavity is tapered to prevent artifacts due to reverberation. This feature permits a 360° image to be displayed.

The gray scale and anechoic target structures are positioned radially from the center of the scanning cavity. The center of the first anechoic target in each row is located 1.0 cm from the edge of the scanning wall. Subsequent targets are spaced 1.0 cm center to center, except for the 8.0 mm targets, which are spaced at 2.0 cm intervals. The center of the scanning cavity is eccentric to the center of the phantom, as a result there are different numbers of targets in each row.

TESTS PERFORMED

- Focal Zone
- Sensitivity
- Functional Resolution
- Definition and Fill-in
- Gray Scale
- Displayed Dynamic Range

SPECIFICATIONS

GENERAL

Overall Diameter:	18.2 cm*
Height:	8.4 cm*
Weight:	1.6 Kg*
Housing Material:	Polyethylene
Scanning Well:	1
Scan Well Diameter:	3.5 cm (Tapered)*

TISSUE MIMICKING MATERIAL

Type:	Urethane Rubber
Freezing Point:	< -40° C
Melting Point:	> 100° C
Attenuation Coefficient**:	0.5 db/cm/Mhz (measured at 3.5 MHz)
Speed of Sound:	1450 m/s at 23°C

ANECHOIC TARGET STRUCTURES

Type:	Non-echogenic, cylindrical
Target Groups:	5
Depth:	1.0 to 8.0 cm

Target Diameter	Number of Targets	Interval Spacing
2.0 mm	6	1.0 cm
3.0 mm	7	1.0 cm
4.0 mm	7	1.0 cm
6.0 mm	7	1.0 cm
8.0 mm	4	2.0 cm

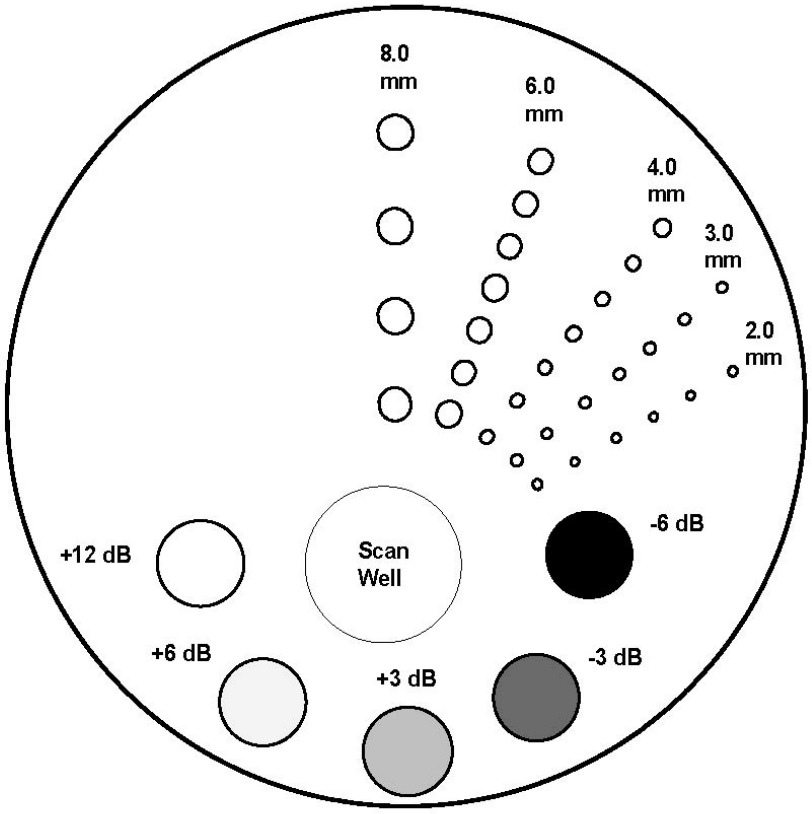
GRAY SCALE TARGET STRUCTURES

Type:	Echogenic, cylindrical
Number of Targets:	5
Diameter:	20.0 mm
Depth:	2.0 cm center to center ± 0.1 mm

Contrast relative to background material: +12 to -6 db

*Nominal dimensions

Target Diagram



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.

Test Procedure

1. Place the phantom on a clean, flat surface with the internal scanning well positioned for use.

2. Fill the scanning well slowly with water to avoid introducing air bubbles.

3. Insert the transducer into the scanning well.

4. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" liver scanning. If the bottom of the phantom is seen, adjust the gain settings until the image fades and goes entirely black at the bottom of the display. Record these

settings on the quality assurance record. These setting should be used for subsequent testing.

5. Move the transducer slightly until the smallest anechoic group of targets is clearly displayed. Freeze the display and obtain a hard copy.

6. Examine the group of targets displayed, to determine which target is the most clearly displayed as compared to the adjacent targets. This target represents the focal zone. Using the electronic calipers, obtain a depth measurement of this target. You will note, the targets above and below this point become progressively fuzzier the further the target is positioned from the focal zone.

7. Document the depth of the focal zone 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. The changeable focal zones should be verified for proper operation of the multi-focal zone button. If changes occur corrective action should be considered.

SENSITIVITY (MAXIMUM DEPTH OF PENETRATION)

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.

Test Procedure

1. Place the phantom on a clean, flat surface with the internal scanning well positioned for use.

2. Fill the scanning well slowly with water to avoid introducing air bubbles.

3. Insert the transducer into the scanning well.

4. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" liver scanning. If the bottom of the phantom is seen, adjust the gain settings until the image fades and goes entirely black at the bottom of the display. Record these settings on the quality assurance record. These setting should be used for subsequent testing.

5. Note: The test should also be performed with the output set at extreme high and low values, in addition to the values given above. This enables any changes in output to be more easily detected.

6. Move the transducer slightly until the smallest group of anechoic targets are clearly displayed.

7. Freeze image and obtain a hard copy.

8. 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.

9. 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 the same phantom, instrument settings and transducer. If a discrepancy occurs corrective action should be considered by the individual Ultrasound Department.

FUNCTIONAL RESOLUTION, DEFINITION AND FILL-IN

Description and Reason For Testing

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of an anechoic structure with the test phantom. In practice, the data obtained will give a direct indication of the minimum size structure the system is capable of resolving at a given depth.

Definition and Fill-in describes the ability of an imaging system to detect and display the shape and echogenic characteristics of a structure. Clinically, a correct diagnosis is dependent upon an imaging system's ability to differentiate between a cystic or solid structure versus echo patterns originating from the surrounding normal tissue.

Test Procedure

1. Place the phantom on a clean, flat surface with the internal scanning well positioned for use.

2. Fill the scanning well slowly with water to avoid introducing air bubbles.

3. Insert the transducer into the scanning well.

4. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" liver scanning. If the bottom of the phantom is seen, adjust the gain settings until the image fades and goes entirely black at the bottom of the display. Record these settings on the quality assurance record. These setting should be used for subsequent testing.

5. Move the transducer slightly until the anechoic circular targets are clearly imaged.

6. Freeze image and obtain a hard copy.

7. 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.

8. All findings should be documented on the quality assurance record.

Results

The targets should appear circular with sharp clearly defined edges, indicating an abrupt transition from the echogenic to the anechoic region. The targets are anechoic and should be free of any internal echoes or fill-in. However, the presence of internal system noise may manifest itself by producing an observable shade of gray within the target area.

The specific values determined, while significant in their own right, are somewhat less important than stability over time. Performing this test on a routine basis at the same instrument settings should produce the same results. Any changes should be investigated.

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 internal scanning well positioned for use.

2. Fill the scanning well slowly with water to avoid introducing air bubbles.

3. Insert the transducer into the scanning well.

4. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" liver scanning. If the bottom of the phantom is seen, adjust the gain settings until the image fades and goes entirely black at the bottom of the display. Record these settings on the quality assurance record. These setting should be used for subsequent testing.

5. Move the transducer slightly until the gray scale target group is clearly imaged.

6. Freeze image and obtain a hard copy.

7. 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.

8. All findings should be documented on the quality assurance record.

Results

This target group varies in echogencity 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 setting, to determine if any change in the characteristics of the target group has occurred with time. If changes are noted, they should be investigated.

STATEMENT OF WARRANTY

ATS Laboratories, Incorporated warrants that for the duration of the warranty period, its products are free from functional defects in materials and workmanship. If ATS Laboratories, Incorporated, deems the product to be defective, at our sole option, we will repair or replace the product, free of charge in a reasonable amount of time.

Warranty Period:

The warranty period begins on the date the product is delivered to the purchaser.

Rubber-Based Phantoms	Lifetime defined as between 7-10 years
Instrumentation Model 700	3 Months

Conditions of Warranty

1. The defect must be reported and the Product returned to ATS Laboratories, Incorporated within the warranty period.

2. The Product 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 product has been altered or repaired other than by ATS Laboratories, Incorporated.

2. If the product has been subject to abuse, misuse, negligence or accident such as;
   a. If the purchaser has exposed the Rubber-Based Phantom to petroleum solvents.

   b. The Doppler Flow Phantoms have been exposed to pressures in excess of 15 PSI or 1.05 Kg/cm^2.

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 above.

WARNING: THIS PRODUCT IS NOT DESIGNED NOR INTENDED FOR MEDICAL USE IN TREATMENT OF PATIENTS AND, ACCORDINGLY, HAS NOT RECEIVED FDA APPROVAL AS A DEVICE FOR MEDICAL USES.