MODEL 560H
3D CALIBRATION
PHANTOM

September 2010

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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 three 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 Model 560 rubber-based, tissue-mimicking (TM) phantom is designed to fulfill the basic testing and spatial measurements calibration requirements of a Quality Assurance Program.

The phantom is designed with a combination of monofilament line targets, six tissue mimicking cylindrical targets of varying sizes, and a three-dimensional egg (ellipsoid) test object. The monofilament line targets have a diameter of 0.12 mm, to optimize the displayed image at frequencies ranging from 2.25 to 7.5 MHz. Four groups of line targets are provided to evaluate the vertical and horizontal calibration measurements, axial-lateral resolution and the dead zone.

TESTS PERFORMED

- Dead Zone or Transducer Ring-Down
- Vertical Measurement Calibration
- Horizontal Measurement Calibration
- Focal Zone
- Sensitivity
- Axial & Lateral Resolution
- Functional Resolution, Definition and Fill-In
- 2D and 3D Spatial Measurement Calibration

SPECIFICATIONS

GENERAL

Overall Dimensions:	23.4 x 20.5 x 9.5 cm*
Weight:	3.1Kg*
Housing Material	PVC
Scan Surfaces:	4
Scan Surface Dimensions:	17 x 8 cm*
	19 x 8 cm*

TISSUE MIMICKING MATERIAL

Type:	Urethane rubber
Freezing Point:	< -40°C
Melting Point:	> 100°C
Attenuation Coefficient:	0.5 dB/cm/MHz ± 10.0%
Speed of Sound:	1450 mps ±1.0% at 23°

LINE TARGETS

Material:	Monofilament Nylon
Diameter:	0.12 mm

Vertical Group:

Number of Targets:	17
Interval Spacing:	1 cm
Depth:	1 - 18 cm

Horizontal Group:

Number of Targets:	10
Number of Groups:	2
Interval Spacing:	2 cm
Depth:	5 cm from Scanning Surface #1 5 cm from Scanning Surface #3

Dead Zone Group:

Number of Targets:	9
Lateral Displacement:	5 mm
Interval Spacing:	1 mm
Depth:	2 - 10 mm

Axial-Lateral Resolution Group:

Number of Targets:	6
Lateral Displacement:	1.0 mm
Interval Spacing:	5, 4, 3, 2, 1 mm
Axial Depths:	5.5 & 12.5 cm
Lateral Depths:	5.5 & 14 cm

ANECHOIC TARGET STRUCTURES

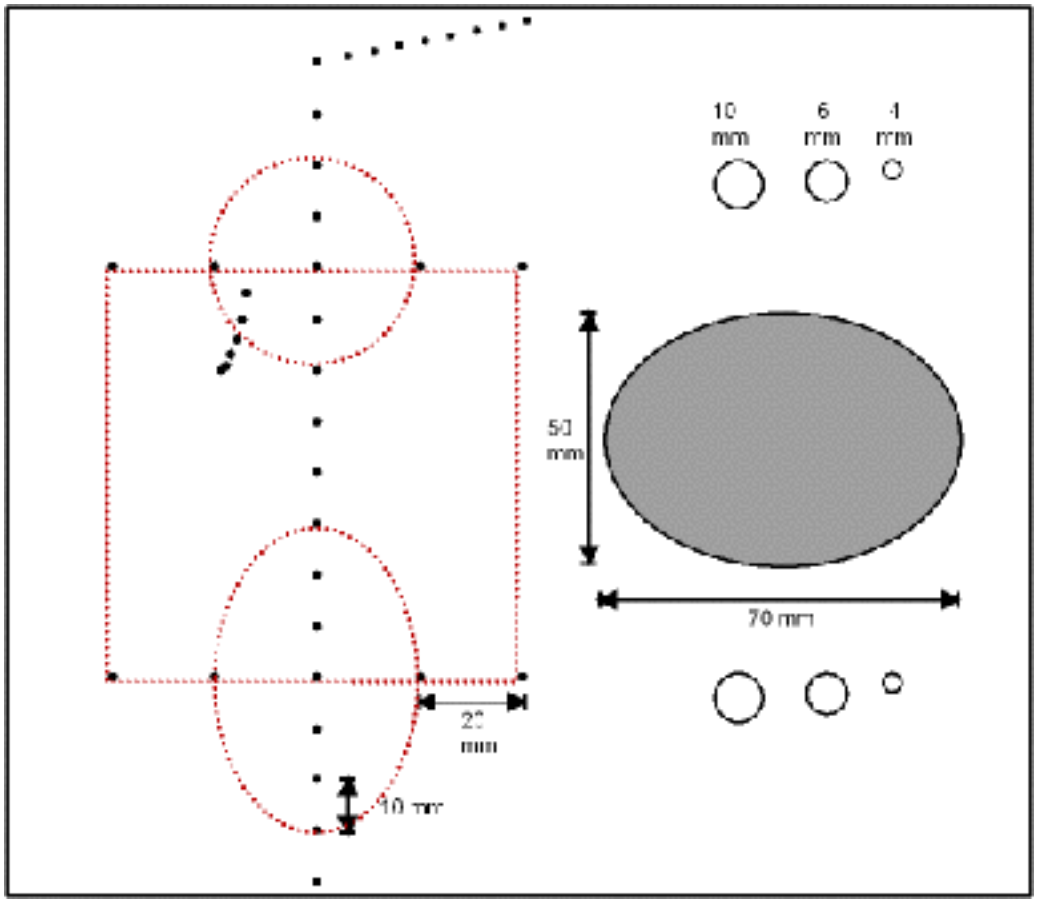
Type:	Non-echogenic, cylindrical
Number of Targets:	6
Diameters:	4, 8, 10 mm
Interval Spacing	1.0 cm
Depth:	3, 5, 12, 15 cm

3D EGG TEST OBJECT

Type:	Echogenic 3D ellipsoid
Major axis:	7.0 cm
Minor axis:	5.0 cm
Volume:	91.6 cm^3

WARRANTY: **10** Years

*Nominal dimensions



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. In the region of the dead zone no clinical data can be collected. The dead zone occurs because an imaging system cannot send and receive data at the same time. 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. Place the phantom on a clean, flat surface with scanning surface #1 positioned for use.

2. Apply an adequate amount of low viscosity gel to the scan surface.

3. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" liver scanning. If the bottom of the phantom is visualized, 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. Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.

5. 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.

6. 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.

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

Results

If the depth of the dead zone is greater than 10.0 mm, corrective action should be considered by the individual Ultrasound Department.

VERTICAL MEASUREMENT CALIBRATION

Description and Reason For Testing

Vertical distance measurements are obtained along the axis of the sound beam. Proper diagnosis is dependent upon accurate representation of the size, depth and volume of structures being examined. Most imaging systems use depth markers and/or electronic calipers to obtain these measurements. The vertical line targets are scanned and a distance measurement obtained. 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 scanning surface #1 positioned for use.

2. Apply an adequate amount of low viscosity gel to the scan surface.
3. 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 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

Vertical Spacing: 1.0 cm center to center ± 0.1 mm

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 distance measurements are 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 560 phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Linear array scanning systems should use #1 scanning surfaces. Sector scanning systems should use #3 scanning surfaces.

1. Place the phantom on a clean, flat surface.

2. Apply an adequate amount of low viscosity gel to the scan surface.

3. 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 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 all of the measurements on the quality assurance record.

Results

Interval Spacing:	2 cm ± 1 mm
Depths:	5 cm ±.1 mm (Scan surface #1)
	5 cm ±.1 mm (Scan surface #3)

If a discrepancy occurs which is greater than 2 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

In the Model 560, scan surface #1 and #3 are used to evaluate axial resolution at depths of 5.5 and 12.5 cm. To evaluate lateral resolution, scan surfaces #2 and #4 are sued, at depths of 5.5 and 14 cm.

The interval spacing of the line targets are 5, 4, 3, 3, and 1 mm. Each target is spaced 1 mm laterally to avoid over shadowing of the adjacent targets.

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

2. Apply an adequate amount of low viscosity gel to the scan surface.

3. 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 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 axial resolution group of line targets on the phantom 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 (refer to specification drawing). Obtain a hard copy of the display.

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

7. Position the phantom with scan surface #3 ready for use. Repeat steps 2-5.

8. Repeat steps 1-6 for scan surfaces #2 and #4 to obtain measurements of the lateral resolution.

Results

The system's ability to resolve the array targets at all four depths should remain consistent from week to week when using the same instrument settings and the Model 560 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 #1 scanning surface positioned for use.

2. Apply an adequate amount of low viscosity gel to the scan surface.

3. 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 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 on the phantom, until a clear image is obtained. Freeze the display and obtain a hard copy.

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.

5. 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.

6. 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.
7. 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 (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.

Testing Procedure

The Model 560 is provided with two sets of anechoic target structures, at two depths from scan surface #1. The ability to use all four scanning surfaces allows measurements to be obtained at 6 depths.

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

2. Apply an adequate amount of low viscosity gel to the scan surface.

3. 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 image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

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.

4. Position the transducer over the two 10 mm anechoic targets. This surface provides measurements at depths of 2.5 and 12.5 cm.

5. Freeze image and obtain a hard copy.

6. Repeat steps 1-5 for the remaining scan surfaces, to provide measurements at remaining scanning depths.

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

Testing Procedure

The Model 560 is provided with two sets of anechoic target structures, at two depths from scan surface #1. The ability to use all four scanning surfaces allows measurements to be obtained at 6 depths.

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

2. Apply an adequate amount of low viscosity gel to the scan surface.

3. 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 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 anechoic circular target group on the phantom, until a clear image is obtained.

5. Freeze image and obtain a hard copy.

6. Repeat steps 1-5 with the remaining 3 scan surfaces.

7. Examine the images obtained to determine the smallest target visualized at the shortest and longest depths. 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.

2D/3D CALIBRATION

Descripton and Reason For Testing

Ultrasound imaging systems may detect differences in echogenicity of tissue structures and determine the dimensions of those structures based on user or automated boundary detection.
Spatial measurement data collected will give an indication of the accuracy the system is capable of.

Testing Procedure

Using the 2D shapes shown in the target diagram on page 4, areas and perimeters may be determined by connecting lines between the filament targets. Linear measurements are taken from an image which is on a plane perpendicular to the line targets. For ultrasound systems which have only linear interpolation between points defining a curve, circular or ellipsoid shapes should not be used. Utilize rectangles or triangles instead. In ultrasound systems which utilize a circle or ellipse measurement algorithm, its accuracy may be tested by defining 3 points to make a circle or 4 points to make an ellipse as shown. The following formulae are useful:

	Rectangle	**Circle**	**Ellipse**
Area	**A = ab**	**$A = \pi r^2$**	**$A = \pi\ (ab)/4$**
Perimeter	**P = 2(a+b)**	**$P = \pi d$**	**$P = \pi\ ((a^2 + b^2)/2)^{0.5}$**

For example, the target diagram shows a circle with a radius of 2.0 cm. Its computed area is 12.57cm^2**.** Its perimeter is 12.57cm (the identical value for the perimeter and area is a coincidence). These computed values may be compared with those calculated from the ultrasound system's algorithm.

Determination of volume or surface area may be accomplished using the line targets or the 3D egg test object. If using line targets, the volume or surface area corresponds to a cylindrical rod, rectangular bar, or prism outlined by the 2D geometrical shape normal to the notional rod or bar.

To calculate a surface area or volume, an image is taken at a particular scan plane. Using the calipers, the dimensions of the 2d shape are taken and area determined based on the system's algorithms. Next, perform a 3D scan of the line targets with the scan planes parallel to each other and the scan direction perpendicular to the axes of the line targets. The distance between the first scan plane and the last multiplied by the 2D area will give the 3D volume. This system calculated value may then be compared to the actual volumes calculated from the rod lengths and the areas coincident with the 2D shape utilized.

A volume measurement of the 3D egg test object may be accomplished by measuring the linear dimensions of the two major axes. Position the transducer so that the scan plane coincides with the maximum cross-sectional area along the length of the object. That is dimension a. Re-position the transducer to measure the maximum circular cross-section, dimension b. Multiple measurements should be made and averaged. The volume of an ellipse with circular cross sections is given by:

$$V = (4/3)\ \pi\ (a/2)\ (b/2)^2$$

The Model 560 3D egg test object has nominal dimensions of 7.0 cm (major axis = a) and 5.0 cm (minor axis = b). The calculated volume is 91.6 cm^3. Note that these nominal dimensions may need to be adjusted by a factor of 0.967 to account for distance measurement errors caused by the urethane tissue mimicking material. The correction applies to all axes when using a sector scanning probe and to just vertical dimension when scanning with a linear probe.

1. Place the phantom on a clean, flat surface with scanning surface #1 positioned for use.
2. Apply an adequate amount of low viscosity gel the scan surface.
3. 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 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 line target target group or 3D egg test object in the phantom, until a clear image is obtained.

5. Freeze image and obtain a hard copy.

6. Measure the appropriate 2D dimensions

7. Perform a 3D scan.

8. Compare computed and system algorithm spatial measurements

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

Results

Spatial measurements are compared with known areas and volumes and compared with the system manufacturer's specifications. Computed values, when compared to baseline measurements should not vary over time.

CARE RUBBER-BASED PHANTOMS

For best results the phantom should be kept clean at all times and stored at room temperature. 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.

WARRANTY

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. Warranty 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.