MODEL 504
Resolution/Penetration
Phantom

DISCONTINUED

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 water-based (Hydrogel) tissue-mimicking material. Care should be taken to avoid exposing this product to environmental temperatures above 49°C and below 0°C.

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 hydrogel-based tissue-mimicking material has a sound velocity of 1540 at room temperature (23°C), to ensure overall accuracy of the measurements obtained.

PRODUCT DESCRIPTION

The Model 504 Resolution/Penetration tissue-mimicking (TM) phantom is designed to evaluate the performance of diagnostic ultrasound imaging systems. This model fullfills the basic testing requirements of a Quality Assurance Program.

The phantom is contained in a protective housing to provide strength and permanence. Built-in scanning wells are provided to permit the use of coupling gels or water as the coupling medium. The phantom is packaged in a sturdy carrying case for ease of transporting and to facilitate storage.

The Model 504 contains anechoic, cylindrical target groups of varying sizes. The target groups are positioned in-line vertically, to permit an entire target group to be displayed in one view. Due to the acoustic similarity of the background material and the anechoic targets, artifacts caused by distortion, shadowing or enhancement of the target structures has been eliminated.

TESTS PERFORMED

- Focal Zone
- Sensitivity
- Functional Resolution
- Definition and Fill-in

SPECIFICATIONS

GENERAL

Overall dimensions:	20.3 x 23.3 x 9.5 cm*
Weight:	3.1 Kg*
Housing Material:	Acrylic
Wall Thickness:	1.0 cm*
Scanning Surfaces:	1
Scan Surface Dimensions:	16.5 x 5.5 cm

TISSUE MIMICKING MATERIAL

Type:	Hydrogel
Freezing Point:	0° C
Melting Point:	49° C
Attenuation Coefficient:	0.5 dB/cm/MHz (measured at 3.5 MHz)
Speed of Sound:	1540 m/s at 23°C .00005 gm/day/sq. cm
Desiccation Rate:	

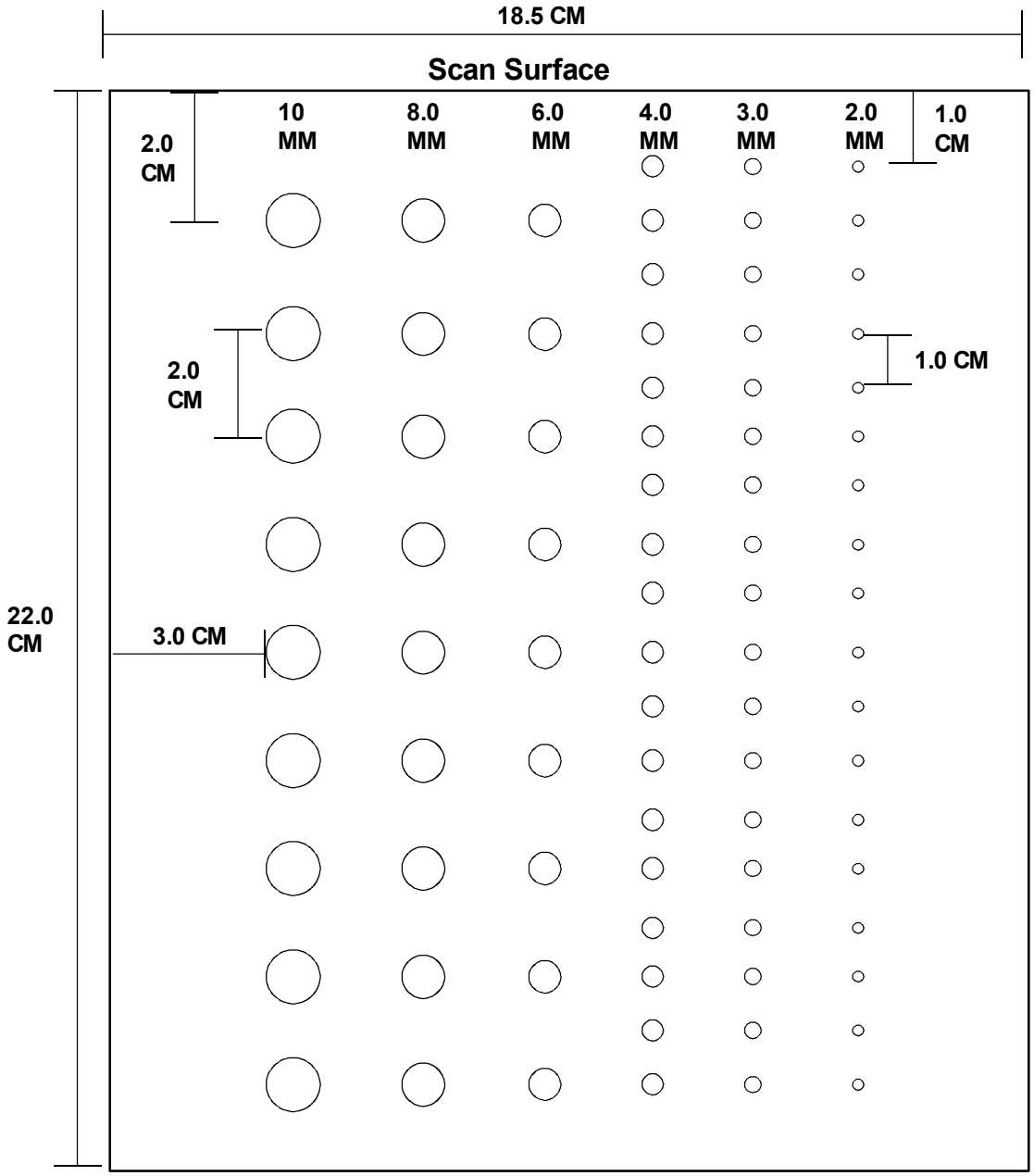
TARGET STRUCTURES

Type:	Anechoic, cylindrical targets
Number of Targets:	81
Target Groups:	6

	Groups 2-4	Groups 6-10
Number of targets:	54	27
Targets per group:	18	9
Diameters (center to center):	2,3,4 mm±5%	6,8,10 mm ±5%
Vertical spacing:	1.0 cm ±0.1mm	2.0 cm ±0.1 mm
Depth:	1-18 cm	2-18 cm

*Nominal dimensions
**Other attenuations available upon request

MODEL 504
RESOLUTION/PENETRATION PHANTOM



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" 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 smallest anechoic group of targets which can be displayed on the phantom, until a clear image is obtained. Freeze the display and obtain a hard copy.

5. Examine the group of targets displayed, to determine which target is the most clearly displayed as compared to the adjacent targets. This target is 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.

6. 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. 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

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" 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 smallest group of anechoic targets which can be clearly displayed on the phantom.

5. Freeze image and obtain a hard copy.

6. Examine the image, note how the echoes will begin to fade as the depth is increased. The maximum depth of penetration will be at the last echo which can be displayed in the target group. Using the electronic calipers, measure the depth of this target.

7. 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 these phantoms at same instrument settings and transducer. If a discrepancy occurs which is

greater than 1.0 cm, some authors suggest corrective action should be taken. However, this decision should be made 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

1. Place the phantom on a clean, flat surface with scanning surface the 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" 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. Examine the image to determine the smallest target size and maximum depth displayed. The targets should appear circular in sharp with clearly defined edges, indicating the 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. Measure the depth of the smallest target which can be displayed, due to the configuration of the sound beam, targets in the near field may not be imaged.

7. 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.

CARE AND HANDLING OF HYDROGEL-BASED PHANTOMS

The phantom should not be exposed to environmental temperatures of less than 0° Centigrade (32° F) or greater than 49° Centigrade (120° F). Freezing temperatures may cause permanent damage to both the contents and the plastic case. Exposure to elevated may cause melting of the contents.

For best results the phantom should be kept clean at all times. In particular, a build-up of dried coupling gel on the scan window 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 oxygenated solvents, such as alcohols, ketones or ammonia should be avoided since they may cause crazing (the formation of multiple fine cracks) at the surface of the acrylic plastic.

WARRANTY

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:	Three Years
Hydrogel (Water-Based) Phantoms:	One Year
Instrumentation:	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;

Rubber-Based Phantoms:

a. If the purchaser has exposed the phantom to petroleum.

Hydrogel-Based Phantoms:

a. If the phantom had been exposed to environmental temperatures of less than 0° Centigrade (32° F) or greater than 49° Centigrade (120° F).
b. If the purchaser has exposed the phantom to oxygenated solvents such as alcohols, ketones or ammonia.

NOTE: This warranty does not apply to the Doppler Flow Pumping Systems or related components.

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.