

Model UC-551M
Instructions Manual

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INTRODUCTION

The instructions in this manual are specific to the use of the ATS model UC-551M ABUS PHANTOM for small parts with the GE Invenia ABUS system.

Quality assurance tissue-mimicking (TM) 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 rubber-based tissue mimicking material has sound velocity of 1450 m/sec and attenuation of 0.5dB/cm/MHz at room temperature (23°C). The corresponding rubber phantom setting of the Invenia system must be used to assure accuracy of measurements. This setting is different than the imaging setting used for patient exams. Ensure that the setting is restored to "Normal" after all testing has been completed.

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 UC-551M is constructed of a rubber-base tissue mimicking material. The scan surface has a 17.5 inch radius of curvature to conform to Invenia ABUS scan head. The phantom is packaged in a carrying case providing added protection during transporting and storage.

TESTS PERFORMED

- Vertical Measurement Calibration
- Horizontal Measurement Calibration
- Axial Resolution
- Lateral Resolution
- Sensitivity
- Functional Resolution
- Image Uniformity
- Gray Scale
- Displayed Dynamic Range

SPECIFICATIONS

GENERAL

Overall dimensions	28.5 x 12 x 10.6 cm*
Weight	3.6 Kg*
Housing Material Wall	PVC
Surfaces Scan Surfaces Size	1 26.7 cm x 10 cm* Curved, radius of 44.50 cm (17.5")

LINE TARGETS

Material	Monofilament nylon
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VERTICAL GROUP

Number of targets	12
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

TISSUE MIMICKING MATERIAL

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

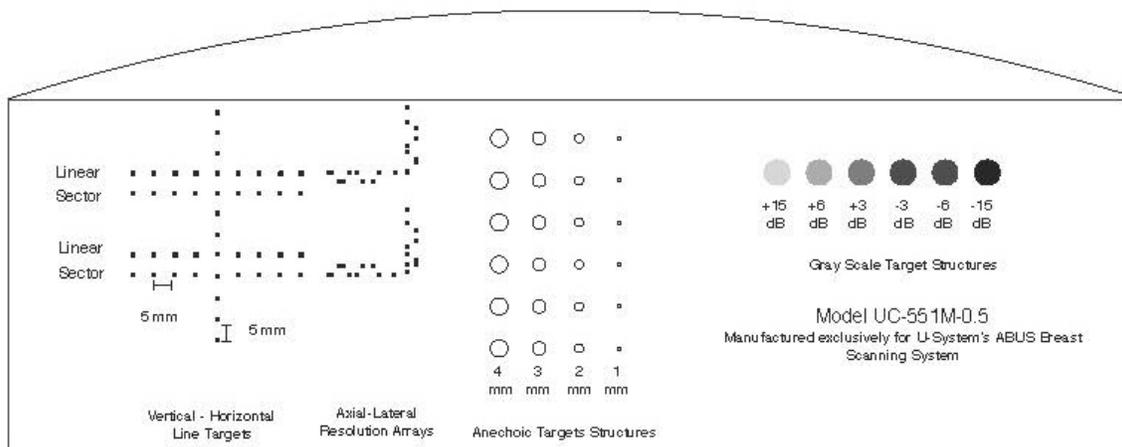
AXIAL-LATERAL RESOLUTION GROUP

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

*Nominal dimensions



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 are critical factors in a proper diagnosis. Invenia ABUS Workstation/ABUS Review Software uses electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained using the 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. In order to image the Model UC-551M ABUS PHANTOM there is a special imaging setting that must be selected. You must be logged in as Admin to access this setting. From the home screen follow the button sequence Config (gears icon) -> System -> Rubber phantom to enable the setting.
3. Apply an adequate amount of ultrasound lotion to the scan surface.
4. Make sure the instrument settings (output, etc.) are set at the factory default values. In particular verify that the output is set at 100%. Record these settings on the quality assurance record. These setting should be used for subsequent testing.
5. Position the transducer over the vertical group of line targets until a clear image is obtained. Perform a scan. After the scan is complete set the nipple marker anywhere on the image. Close the exam to send the images to the workstation.
6. At the workstation using the electronic calipers measure the greatest distance that can be clearly imaged between line targets.
6. Document the measurement obtained on the quality assurance record.
7. Repeat the above procedure for all three display depth settings.

Results

If a discrepancy occurs which is greater than 1.0 mm, check that the rubber phantom setting has been selected, otherwise corrective action should be considered.

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. Invenia ABUS Workstation/ABUS Review Software uses 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 UC-551M ABUS PHANTOM contains two groups of horizontal line targets. For testing a linear or concave 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. In order to image the Model UC-551M ABUS PHANTOM there is a special imaging setting that must be selected. You must be logged in as Admin to access this setting. From the home screen follow the button sequence Config (gears icon) -> System -> Rubber phantom to enable the setting.
3. Apply an adequate amount of ultrasound lotion to the scan surface.
4. Make sure the instrument settings (output, etc.) are set at the factory default values. In particular verify that the output is set at 100%. Position the transducer over the horizontal group of line targets, until a clear image is obtained. Perform a scan. After the scan is complete set the nipple marker anywhere on the image. Close the exam to send the images to the workstation.
5. At the workstation, using the electronic calipers measure the greatest distance that can be clearly imaged between line targets displayed.
6. Document all measurements on the quality assurance record.
7. Repeat the above procedure for all three display depth settings.

Results

If a discrepancy occurs which is greater than 2.0 mm, check that the rubber phantom setting has been selected, otherwise corrective action should be considered by the individual Ultrasound Department.

AXIAL AND LATERAL RESOLUTION

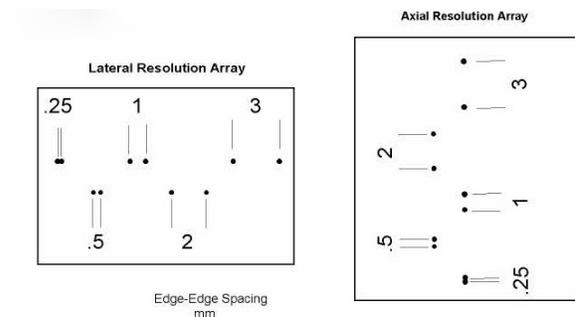
Description and Reason for Testing

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 structure, 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 UC-551M ABUS PHANTOM contains two 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. In order to image the Model UC-551M ABUS PHANTOM there is a special imaging setting that must be selected. You must be logged in as Admin to access this setting. From the home screen follow the button sequence Config (gears) -> System -> Rubber phantom to enable the setting.
3. Apply an adequate amount of ultrasound lotion.
4. Make sure the instrument settings (output, etc.) are set at the factory default values. In particular verify that the output is set at 100%. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
5. Position the transducer over the first axial-lateral resolution group until a clear image is obtained.
6. 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.



7. Document all observations made on the quality assurance record.
8. Repeat the above procedure for all three display depth settings.

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 UC-551M ABUS 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, check that the rubber phantom setting has been selected; otherwise 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. In order to image the Model UC-551M ABUS PHANTOM there is a special imaging setting that must be selected. You must be logged in as Admin to access this setting. From the home screen follow the button sequence Config (gears) -> System -> Rubber phantom to enable the setting.
3. Apply an adequate amount of ultrasound lotion.
4. Make sure the instrument settings (output, etc.) are set at the factory default values. In particular verify that the output is set at 100%. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
5. Position the transducer over the 4.0 mm group of anechoic targets.
6. Examine the image to determine the last or deepest target structure displayed. Using the electronic calipers measure the depth of this target.
7. Document the depth measurement on the quality assurance record.
8. Repeat the above procedure for all three display depth settings.

Results

The depth of penetration should not shift by more than 1.0 cm, when using this phantom at the same instrument settings and transducer. If a discrepancy occurs, check that the rubber phantom setting has been selected; otherwise 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 tissue mimicking 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 beam 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 image 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. Place the phantom on a clean, flat surface with the scanning surface positioned for use.
2. In order to image the Model UC-551M ABUS PHANTOM there is a special imaging setting that must be selected. You must be logged in as Admin to access this setting. From the home screen follow the button sequence Config (gears) -> System -> Rubber phantom to enable the setting.
3. Apply an adequate amount of ultrasound lotion.
4. Position the transducer over the anechoic target structures until a clear image is obtained.
5. Examine the image to determine the first and last target in each size group displayed. Record the range of depths visualized for each group.
6. Document all findings on the quality assurance record.
7. Repeat the above procedure for all three display depth settings.

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, check that the rubber phantom setting has been selected; otherwise corrective action should be considered.

GRAY SCALE AND 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. In order to image the Model UC-551M ABUS PHANTOM there is a special imaging setting that must be selected. You must be logged in as Admin to access this setting. From the home screen follow the button sequence Config (gears) -> System -> Rubber phantom to enable the setting.
3. Apply an adequate amount of ultrasound lotion.
4. Make sure the instrument settings (output, etc.) are set at the factory default values. In particular verify that the output is set at 100%. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
5. Position the transducer over the gray scale target group until a clear image is obtained.
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. All findings should be documented on the quality assurance record.
7. Repeat the above procedure for all three display depth settings.

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, check that the rubber phantom setting has been selected; otherwise the changes 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 ultrasound lotion or 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 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 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.

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