

Advantage 2.0 Ultrasound Tissue Mimicking Phantom User Manual

Acertara Acoustic Laboratories 1950 Lefthand Creek Lane Longmont, CO, 80501 USA www.acertaralabs.com

TABLE OF CONTENTS

ntroduction		
Sound Velocity of Rubber based TM Material	2	
Effect of Temperature	2	
Setting Up the Phantom for Scanning	2	
Phantom Certification	2	
Product Description	3	
Targets and regions of interest	3	
Specifications	5	
Dead Zone (A)	5	
Vertical Measurement Calibration (B)	5	
Horizontal Measurement Calibration	6	
Axial – Lateral Resolution Arrays (D)	6	
Gray Scale & Displayed Dynamic Range (E)	7	
Focal Zone (C1 & C2)	Error! Bookmark not defined.	
Depth Of Penetration (throughout)	7	
Functional Resolution and Image Uniformity (throughout)	Error! Bookmark not defined.	
General References:	8	
Care Of Rubber-Based Phantoms	8	
Warranty	10	

Introduction

Tissue-mimicking phantoms (TMP) are used to evaluate the general imaging performance characteristics of diagnostic ultrasound imaging systems. The TMPs mimic the average acoustic properties of human soft tissue and provide spatial and geometric target structures within the simulated environment. TMPs are useful in detecting general image performance changes that occur through normal aging and deterioration of ultrasound system components and transducers (also known as probes and scanheads). Routine equipment performance monitoring (as part of an overall Evidence Based Quality Assurance ultrasound program) with TMPs can help in the reduction of the number of repeat examinations, the duration of examinations, and maintenance time. TMPs are employed in the areas of; Clinical Quality Assurance, Preventive Maintenance Programs, Field Service Testing, Research and Development, Manufacturing, Teaching, and Sales & Marketing.

Sound Velocity of Rubber based TM Material

The sound velocity of most diagnostic imaging systems is calibrated to 1540 m/s, the assumed average velocity of sound through human soft tissue. The rubber-based tissue-mimicking material used in the Advantage Ultrasound Phantom has a sound velocity of 1476±5 m/s when measured at room temperature (22-24°C). The line targets and anechoic target structures located within the phantom have been physically positioned to compensate for the differences in the speed of sound, assuring accuracy of measurements.

Effect of Temperature

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, 23°C. It is important to allow the tissue mimicking material to reach a steady state room temperature before use if the phantom has been transported or stored in an environment at a different temperature. A uniform offset from 23°C will have only a small effect on the image quality. A temperature gradient, however (e.g., a colder core and warmer sides as the phantom warms up from storage), will cause major distortions to the images.

Setting Up the Phantom for Scanning

Place the phantom on a clean, flat surface with scan surface positioned for use.

Apply an adequate amount of low viscosity acoustic gel or water to the scan surface. If water is used, fill the scanning well slowly to avoid introduction of air bubbles.

In general, the ultrasound system controls should be set to a minimal level to insure there is no "masking" of subtle problem due to processing algorithms within the ultrasound system. Therefore, it is suggested that a single focus is used and positioned to the appropriate depth for any given frequency transducer under test. Also, any special image processing features such as spatial compounding be turned off during phantom scanning. Further use an appropriate amount of acoustic power and overall gain settings to ensure that the signals from the phantom are not saturated. Consult the ultrasound system operator's manual for acoustic power ranges and settings for specific transducers.

Phantom Certification

The Advantage Ultrasound Phantom is shipped with a certification of acoustic performance.

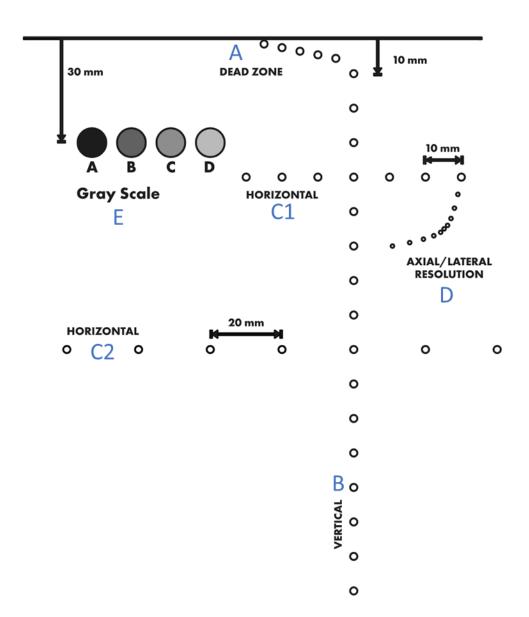
The Advantage Ultrasound Phantom can be re-certified by Acertara Acoustic Labs: call (303) 834-8413 or email sales@acertaralabs.com.

Product Description

The Advantage Ultrasound Phantom provides an easy, comprehensive means of evaluating imaging systems with an operating frequency range of 2 to 15 MHz. The phantom is designed with a combination of monofilament line targets for distance measurements and tissue mimicking target structures of varying sizes and contrasts. Due to the acoustic similarity of the background material and the target structures, artifacts caused by distortion, shadowing and enhancement have been eliminated. Four gray scale targets are included to evaluate system contrast.

Targets and regions of interest

Label	Purpose					
A	Dead zone and ring down evaluation					
В	Focal zone evaluation and vertical measurement calibration; penetration depth quantification					
C	Horizontal measurement calibration					
D	Axial and lateral resolution quantification					
Е	Contrast evaluation					



Specifications

Form factor		Tissue Mimicking Material	
Overall Dimensions	162 x 200 x 94 mm	Туре	Urethane rubber
Housing Material	Aluminum and plastic	Attenuation Coefficient	0.6±0.15 dB/cm/MHz from 2 to 10 MHz
Weight	2.4 kg	Speed of Sound	1476±5 m/s at 23°C

Target group					
Dead zone	Α	Lateral displacement interval	5 mm		
		Vertical displacement interval	1 mm		
Vertical group	В	Number of targets	16		
		Vertical interval	10 mm		
Horizontal group	C1	Number of targets	7		
		Horizontal interval	10 mm		
	C2	Number of targets	7		
		Horizontal interval	20 mm		
Resolution group D		Lateral intervals (from bottom left)	5 mm, 4 mm, 3 mm, 2 mm, 1 mm		
		Vertical intervals (from top right)	5 mm, 4 mm, 3 mm, 2 mm, 1 mm		
Contrast group E		Number of contrast targets	4		
		Diameter	8 mm		

Dead Zone (A)

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. 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

Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.

This group is composed of 5 line targets spaced 1 mm apart (in depth).

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.

Vertical Measurement Calibration (B)

Description and Reason For Testing

Vertical distance measurements are obtained along the axis of the sound beam. 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 depends on the integrity of the timing circuitry of the imaging system. Consult the ultrasound system's operator's manual to get the variation percentage for the electronic calipers.

Testing Procedure

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

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

Horizontal Measurement Calibration

Linear Horizontal Group (C1 & C2)

Description and Reason For Testing

Horizontal distance measurements are obtained perpendicular to the axis of the sound beam. 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 depends on the integrity of the transducer scanning assembly, the output intensity and the resolution of the imaging system. Consult the ultrasound system's operator; smanual to get the variation percentage for the electronic calipers.

Testing Procedure

Note: The Optimal Ultrasound Phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Due to the geometry and variety of sector scan transducers, a separate set of horizontal line targets are provided to evaluate lateral resolution. Please refer to the specification page for the location of these groups.

- 1. Position the transducer over the horizontal group of line targets until a clear image is obtained. Freeze the image.
- 2. 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.

Axial – Lateral Resolution Arrays (D)

Description and Reason For Testing

Axial resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately along the axis of the beam, whereas lateral resolution defines the system's ability to image objects separately that lie perpendicular to the axis of the sound beam. If a system has poor spatial resolution capabilities, small structures lying close to each other will appear as one image. Axial resolution depends on the transducer's center frequency, damping characteristics, and pulse length. Generally, the higher the transducer's frequency the better the system's axial resolution. Lateral resolution depends on the beam width, focusing characteristics of the transducer, number of displayed scan lines, and the system's sensitivity and gain settings.

Testing Procedure

The locations in the phantom are referenced from the first axial target.

The line targets are spaced at 5.0, 4.0, 3.0, 2.0, 1.0 mm intervals both axially and laterally. The last point of the axial array target group is also the first target point in the lateral array group.

- 1. Position the transducer over the axial-lateral resolution group of line targets on the phantom until a clear image is obtained. Freeze this image.
- 2. Examine the image to determine if all 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).

Gray Scale & Displayed Dynamic Range (E)

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. Position the transducer over the gray scale target group until a clear image is obtained.
- 2. Freeze image.
- 3. 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. (As with imaging cysts, the material beyond the low contrast target should appear hyperechoic; conversely, the material beyond the high contrast target should appear hypoechoic.

Depth Of Penetration (throughout)

Description and Reason For Testing

An imaging system's ability to detect and display weak echoes from small objects located at specified depths (penetration), is referred to as sensitivity. 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. A system's maximum useful depth is limited by acoustic output power, TGC, gain, transducer frequency, focal depth, number of scan lines, and electrical noise.

Testing Procedure

- 1. Position the transducer over one of the ends of the phantom so that there are not major target groups in the center of the image.
- 2. Freeze image on one half of a split-screen acquisition.
- 3. On the other half of a split-screen acquisition, obtain an image with the transducer held in the air.
- 4. Using electronic calipers, measure the distance to where the background material is indistinguishable from the signal in air at the same depth.

This test should also be performed with acoustic output power levels set at the highest and lowest settings. This enables any changes in acoustic output to be more easily seen.

General References:

Michell M. Goodsitt, Paul Carson; "Real-Time B-mode Ultrasound Quality Control Test Procedures, Report of AAPM Ultrasound Task Group No. 1," Medical Physics, 25 (8) August 1998

W. N. McDicken, PhD, "Diagnostic Ultrasonics, Principles and Use of Instruments," John Wiley & Sons, 1976.

Sandra L. Hagen-Ansert; "Textbook of Diagnostic Ultrasonography," Mosby, 1989.

Beate Weigang, G. Wayne Moore, et al; "The Methods and Effects of Transducer Degradation on Image Quality and the Clinical Efficiacy of Diagnostic Ultrasound", Journal of Diagnostic Medical Sonography, 19:3-13 January/February 2003

Raymond L. Powis and G. Wayne Moore; "The Silent Revolution: Catching Up with the Contemporary Composite Transducer", Journal of Diagnostic Medical Sonography, Volume 20 Number 6 pp. 395-407 November/December 2004

G. Wayne Moore, Amanda Gessert and Mark Schafer; "The Need for Evidence-Based Quality Assurance in the Modern Ultrasound Clinical Laboratory", Journal of the British Medical Ultrasound Society, Volume 13 Number 3 pp. 158-162

Care Of Rubber-Based Phantoms

The Advantage Ultrasound 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 mild soap and warm water. 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.

Suggested Probe Inspection Routine

Inspecting The Transducer (Probe)

- Cracks on the handle
- Cracks on the nose piece
- Cuts or gouges on the lens material
- Swelling of the lens material
- Condition of the bend relief(s)
- Cracks or other signs of damage to the connector
- Bent or damaged pins in the probe connector
- If using a "pin-less" connector (e.g., Siemens/Acuson Sequoia probes) inspect the surface of the connector to insure it is clean
- Integrity and flexibility of the cable
- Bite marks on the bending rubber (TEE probes)

What Can Hurt a Transducer?

- Gels that have perfume or other molecular changing substances
- Electro-static discharge on or around the lens of the probe, or the pins on the probe connector
- Rapid deceleration trauma (dropping the probe), or other blunt force trauma
- Using the wrong sterilizing agents, or using the correct ones in the wrong manner

- Improper storage
- Not freezing the image before removing or connecting a probe to the system
- Improper or insufficient cleaning, or cleaning with wrong substance (e.g. alcohol-based wipes on the lens tends to dry the lens and make it detach from the probe)
- Not using bite guards when performing a TEE examination

What Preventative Measures Can I take?

- Inspect the probe on a daily basis use a magnifying glass to inspect the lens
- Follow the recommendations for use and cleaning in the probe manual
- Have the probe tested on a six-month basis, or if a problem is suspected
- Keep transducer cables off the floor
- Use the system probe holders when probe is not in use

What Else Should I Be Doing?

- Electrical leakage testing as recommended by the Original Equipment Manufacturer
- Involve your hospital Biomedical Engineer in regularly testing the probe elements
- Establish with your Biomedical Engineering Department a comprehensive ultrasound QA program that includes not only the probes, but the ultrasound system as well
- If you suspect a probe is compromised in some manner, don't use it until it is tested.

Warranty

Statement of Warranty

Acertara Acoustic Labs warrants the Advantage Ultrasound Phantom for 5 years from the date of delivery to the purchaser. Acertara Acoustic Labs warrants that the Advantage Ultrasound Phantom is free from functional defects in materials and workmanship. If Acertara Acoustic Labs 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.

Acertara Acoustic Labs 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 Advantage Ultrasound Phantom returned within the warranty period.
- 2. The Advantage Ultrasound Phantom must be packaged adequately to avoid damage during shipping.
- 3. All transportation charges will be paid by the purchaser.

Invalidation of Warranty

If the phantom has been altered or repaired other than by Acertara Acoustic Labs.

If the phantom has been subject to abuse, misuse, negligence or accident, including improper storage and transportation

If the purchaser has exposed the phantom to petroleum solvents.

For additional Acertara Acoustic Labs test products, see www.acertaralabs.com.





Acertara Acoustic Laboratories
1950 Lefthand Creek Lane
Longmont, Colorado 80501 USA
www.acertaralabs.com
sales@acertaralabs.com
303 834 8413

NO PART OF THIS DOCUMENT MAY BE RE-CREATED OR COPIED IN ANY FORM WITHOUT WRITTEN PERMISSION FROM ACERTARA ACOUSTIC LABORATORIES