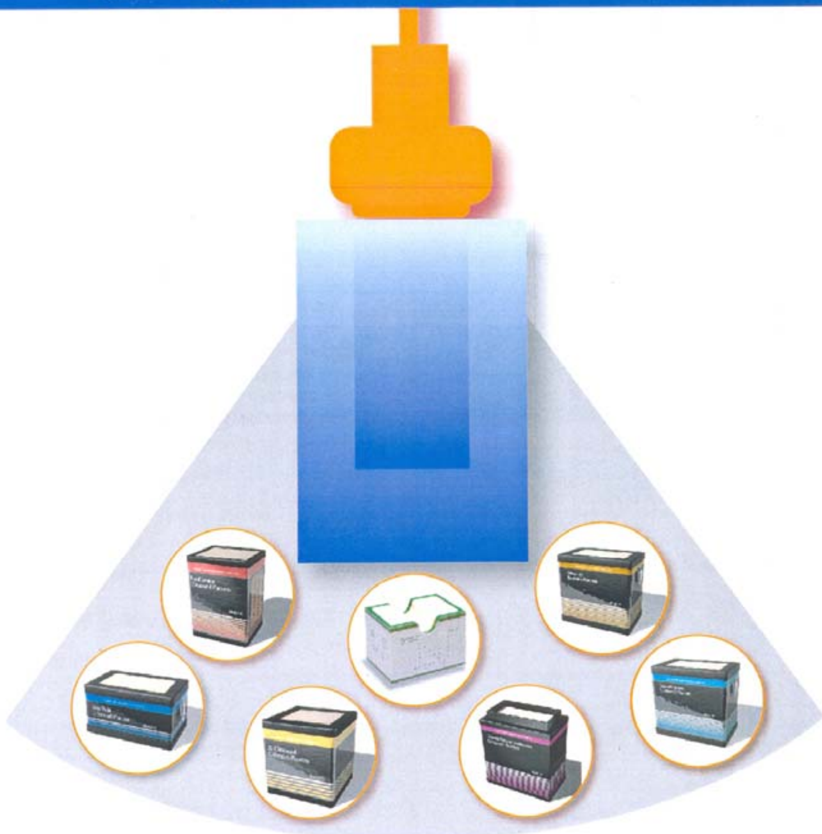
Tissue Equivalent

Ultrasound Quality Assurance Phantoms



User's Guide

MODEL 40 50 54

CIRS
Tissue Simulation Technology

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(800) 617-1177 • (757) 855-2765
FAX (757) 857-0523 • www.cirsinc.com

March 01

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I. INTRODUCTION

Congratulations! You hold in your hands the most reliable Quality Assurance Phantom available. We take special care to ensure that each and every ultrasound phantom meets the highest possible standards. Each phantom is subjected to rigorous testing both during manufacture and upon completion. This series of ultrasound phantoms, unlike any human subject or random scannable material, offers a reliable medium which contains specific, known test objects for repeatable qualitative assessment of ultrasound scanners over time.

II. DESCRIPTION OF THE PHANTOM

This phantom is constructed from a patented, solid elastic material called Zerdine™. Zerdine, unlike other phantom materials on the market, is not affected by changes in temperature. It can be subjected to boiling or freezing conditions without sustaining significant damage. Zerdine is also more elastic than other materials and allows more pressure to be applied to the scanning surface without subsequent damage to the material. At normal or room temperatures, Zerdine will accurately simulate the ultrasound characteristics found in human liver tissue. Specific proprietary fabrication procedures enable close control over the homogeneity of Zerdine and the reliability of its acoustic characteristics from batch to batch. The speed of sound in Zerdine can be adjusted between 1430 and 1650 meters per second. The acoustic attenuation can be adjusted between 0.05 dB/cm/MHz and 1.50 dB/cm/MHz. The relation between the acoustic attenuation, A, and the acoustic frequency, F, is of the form $A = A_o F^n$ with values of the power coefficient, n, in the range of 0.8 to 1.10, indicating the proportional increase of the acoustic attenuation with frequency. Backscatter characteristics can be adjusted through the addition of predetermined amounts of calibrated scatter material. Zerdine can be molded into very intricate shapes, and the material can be cured in layers allowing the production of "multi-tissue" phantoms. Zerdine, like most other phantom materials, will desiccate if unprotected; thus, all phantoms must be stored properly. If stored in the case and bag provided when not in use, your phantom should last many years.

All resolution targets are made from monofilament nylon wire with a diameter of 0.1mm. These wires have a positional accuracy of 0.13 mm. All phantoms are encased in a rugged, shatter-proof container with a thin film membrane and water dam to facilitate scanning. Each phantom comes packaged in a foam lined air tight carrying case to minimize desiccation and damage. All phantoms include an attached certification sheet indicating the exact speed of sound and attenuation for that phantom.

Also included on the certification sheet is the phantoms weight, in grams, at time of certification; this should be noted upon receipt and closely monitored over time to ensure stability and the absence of desiccation. **Please read the following sections of this manual carefully before embarking on your QA program, and do not hesitate to call our technical service number if you have any questions.**

III. ESTABLISHING A BASE LINE WITH YOUR NEW PHANTOM

The first step before scanning any phantom should be to refer to the user's manual of your ultrasound scanner and note the stated accuracies of the system's general imaging measurements. These stated accuracies may greatly influence the conclusions made when evaluating the phantom. For example, if the measurement accuracy for your system is 10% for distances up to 2.0 cm, the scanner may detect 2.0 cm as being anywhere from 1.8 cm to 2.2 cm.

Using the correct instrument settings is imperative to the proper evaluation of the ultrasound system and the phantom; both of which must be evaluated but **not** simultaneously. **To evaluate the integrity of the phantom**, each target or target group must be evaluated individually using the probe and system settings that will make the targets as visible and distortion free as possible. The following are general steps for imaging all targets during phantom assessment.

- Set focus to have multiple focal zones. This will maximize the area of the image which is focused, thus increasing the resolution of the targets.
- Set the number of scan lines to the maximum value. This decreases the real-time response but increases the resolution.
- Maximize the dynamic range.
- Maximize the enhancement.
- For wire targets, decrease the gain so only targets are visible, not the background echo pattern.
- Use the highest frequency probe possible to reach the region of interest. This will increase the resolution and minimize any errors due to resolution loss.
- Use a linear probe whenever possible. If a convex probe is used, center the target within the scan plane in order to minimize degradation and distortion introduced on the outer edges of the probe.
- When assessing the positional accuracy of the wire targets, only measure the distance between adjacent wires rather than across several targets at once.
- When assessing vertical distance measurements, **DO NOT** press on the membrane. Pressure on the membrane (as in humans) causes the wires to become temporarily displaced. Vertical distance measurements will then be wrong.
- Some wires will appear as lines rather than dots. Always take measurements from the center of one wire to the center of the next. Errors may be introduced otherwise.
- Adjust the depth range of the system to achieve the largest possible view of the target.

Your new ultrasound phantom has been thoroughly evaluated before it was shipped and meets all of our specifications. Therefore, it is not absolutely necessary to evaluate the accuracy of the phantom before establishing the base line performance levels on your scanner. A certification sheet is provided with each phantom. All measurements on the certification sheet as well as the target positions are traceable to NIST. Standard test methods are employed in assessing speed, attenuation and contrast. CIRS has an in-house test facility to make measurements on each and every gel batch.

To establish baseline performance levels on your ultrasound system refer to section IV. Once the baseline measurements have been recorded, along with specific instrument settings refer to them when future measurements are made to ensure that no change has occurred. Variance from your baseline measurements indicate a possible change in your scanner. If you have any problems, please do not hesitate to contact CIRS technical service.

Important Note: Always be sure you are scanning the phantom when the phantom is at room temperature. A phantom just received may be colder or hotter than room temperature depending on where it was stored during shipping. Temperature affects the speed of sound and ultimately perceived measurements. The phantom should be stored at room temperature for at least 24 hours before use to ensure its core temperature is correct.

IV. ROUTINE QUALITY CONTROL MEASUREMENTS

A. Uniformity

Uniformity is defined as the ability of the machine to display echoes of the same magnitude and depth with equal brightness on the display. This is a good test to ensure all crystals within the transducer are functioning.

Testing Procedure

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer on the scanning membrane.

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. <u>Record these settings for use on subsequent testing</u>.

4. Align the probe so that the targets are maximized.

5. Freeze the image and obtain a hard copy.

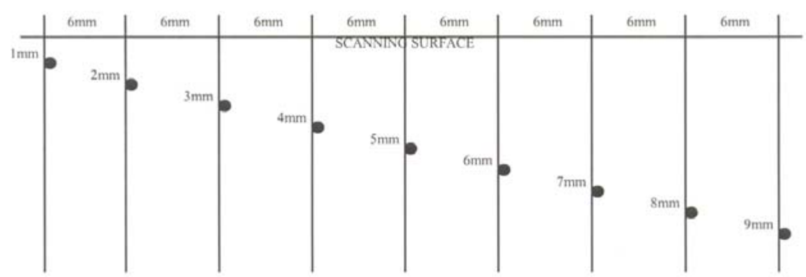
6. Observe the general appearance of phantom. Note if all regions at the same depth are displayed with the same intensity across the width of the image.

8. Record your observations on a data sheet.

B. Near Field Resolution (available in Model 40, 50, and 54)

The near field resolution target assesses the distance from the front face of the transducer to the closest identifiable echo. This region, where no useful information is obtained, is commonly referred to as the "dead zone" or "ring-down distance". The dead-zone occurs because the ultrasound system cannot send and receive data simultaneously. It is instrument dependent and is diminished as frequency is increased. A change in your system's dead-zone is indicative of a problem with the transducer, the pulsing system or both.

The near field target consists of parallel, 0.1 mm diameter nylon wires horizontally spaced 6 mm apart from center to center (Figure 1). Vertical distance from the center of each wire to the top edge of the scanning surface ranges from 9 mm down to 1 mm in 1 mm increments. In the Model 54 the distance ranges from 6 mm to 1 mm in 1 mm increments.



Wire Diameter - .1mm **Positional accuracy ± 0.25 mm**

Figure 1 - Near Field Target

Testing Procedure

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the near field resolution target and perpendicular to the wires. (The wires should appear as dots, not lines).

3. Adjust the instrument settings (gain, TGC, output, etc.) to maximize resolution in the near field. Record these settings for use on subsequent testing.

4. Freeze the image while the near field targets are clearly displayed.

5. Count how many wires of the near field target you can see. Subtracting this number from the total number of targets gives you the dead zone measurement.

Ex: total # of targets in group = 9
# of targets actually seen = 7
dead zone distance = 9 - 7 = 2 mm

For technical assistance call 1-800-617-1177

An alternative methods uses the electronic calipers to measure the distance between the transducer face and the closest wire target to be resolved from the reverberation. If the first target to be resolved is at 4 mm, then the dead zone distance is "something less than 4mm".

6. Record this distance on a record sheet and compare with baseline measurements.

C. Vertical Plane Target Group (available in Model 40, 50 and 54)

ATTENTION

To register accurate vertical distance measurements, *APPLY NO PRESSURE TO THE MEMBRANE!* We strongly encourage the user to scan the phantom with the water well filled with water or coupling gel so the transducer does not make direct contact with the membrane. As with a patient, even the slightest amount of pressure on the membrane will cause incorrect distances to be measured.

The vertical plane target is useful for many different measurements. This target group assesses the depth of penetration, beam profile, lateral response width, vertical distance calibration, and focal zone of an imaging system. The target group consists of a group of 0.1 mm diameter parallel wires positioned 2 cm apart, 1 cm apart in the Model 50, down the center of the phantom in a vertical plane. Refer to the target layout attached to your phantom.

Depth of Penetration

Depth of penetration, also called maximum depth of visualization or sensitivity, is the greatest distance in a phantom for which echo signals due to the scatterers within the tissue-mimicking background material can be detected on the display. The depth of penetration is determined by the frequency of the transducer, the attenuation of the medium being imaged and the system settings.

Testing Procedure

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the vertical plane targets and perpendicular to the wires. (The wires should appear as dots, not lines).

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that all the vertical targets are displayed at their maximum intensity level.

5. While actively scanning, look to see where the scatterers within the background material disappear. Be careful not to confuse electronic noise with the background scatterers. Electronic noise will move; scatterers will remain stationary.

6. Freeze the image

7. With electronic calipers measure the distance between the scanning surface and the last identifiable echo due to scattering. Note: The wires may be visible even though the scatterers are not. Remember to measure the distance to the scatterers not the last visible wire.

8. Record this distance on a record sheet and compare with baseline depth.

Beam Profile, Focal Zone, and Lateral Response Width

The beam profile is the shape of the ultrasound beam. A typical beam profile is shown in the Figure 2 below. The narrowest region within the beam profile is the focal point. The region surrounding the focal point with an intensity within 3 dB of maximum is the focal zone. The best images are obtained while within the focal zone. The vertical plane targets are useful for determining the beam profile and the focal zone of a system.

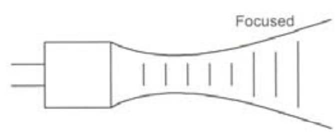


Figure 2 - Typical Beam Profile

Testing procedures

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the vertical plane targets and perpendicular to the wires. (The wires should appear as dots, not lines).

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that all the vertical targets are displayed at their maximum intensity level.

5. Freeze the image and obtain a hard copy.

6. Some of the targets will appear as short lines rather than dots on the frozen image.

7. Measure the length of the targets. These measurements are the lateral response width of the system at the different depths and setup. The minimum length indicates the focal point.

8. If a smooth curve is drawn to connect the edges of the targets, the beam profile is easily discernible.

9. If using a variable focused transducer, repeat the above procedure for several different focal zones (those settings most commonly used are recommended).

10. Record the focal point on a data sheet and save the hard copy image.

Vertical Distance Calibration

Vertical distance is defined as the distance along the axis of the beam. Distances are used to measure areas, volumes, depths and sizes of objects. Accurate measurements are therefore necessary to ensure proper diagnosis. The vertical plane target allows one to assess the accuracy of vertical measurements.

Testing Procedures

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the vertical plane targets and perpendicular to the wires. (The wires should appear as dots, not lines). Do not apply excessive pressure as this may temporarily compress the target and skew the measurements.

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that all the vertical targets are displayed at their maximum intensity level.

5. Freeze the image and obtain a hard copy.

6. Using electronic calipers measure the distances between two wires at various depths or align the echoes to the display markers for comparison.

7. Record these measurements.

8. Compare the measured values with the recorded baseline distances.

D. Horizontal Plane Targets (available in Model 40 and 54)

This target group is used to determine the accuracy of measurements made perpendicular to the beam axis and is critical for the same reasons as vertical distance measurements above. The horizontal plane target consists of a group of seven (7), 0.1 mm parallel wires positioned 2 cm apart in a horizontal plane at mid-depth in the phantom. Refer to target diagram attached to your phantom.

1. Fill the water trough with tap water.

2. Position the transducer above the vertical plane targets and perpendicular to the wires. (The wires should appear as dots, not lines). **Do not apply any pressure** as this may temporarily compress the target and skew the measurements.

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that all the horizontal targets are displayed at their maximum intensity level.

5. Freeze the image and obtain a hard copy.

6. Using electronic calipers, measure the distances between two wires along the horizontal plane.

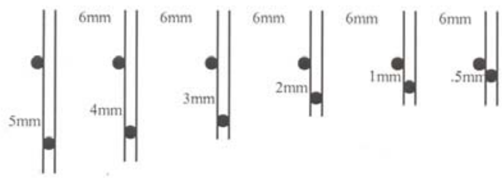
7. Record these measurements.

8. Compare the measured values with the known distances between the targets.

E. Axial Resolution Target (available in Model 40, 50, and 54)

The axial resolution target consists of six pairs of parallel, 0.1 mm diameter wires horizontally spaced 6 mm apart from center to center. The lower wire in each pair is horizontally offset from the upper wire by 1mm to further reduce any acoustic shadowing effects. The vertical distance between each pair of wires is 5, 4, 3, 2, 1, and 0.5 mm from center to center. This target is designed to accurately assess axial resolution capabilities at a depth of 3 cm in the Models 40 and 54 and at 2 cm in the Model 50.

Axial resolution is defined as the ability of an ultrasound system to resolve objects in close proximity along the axis of the beam. In other words, how close can two objects be along the axis of the beam and still be detected as two distinct objects? Axial resolution is proportional to the length of the system's transmitted ultrasonic pulse or pulse length.



Wire Diameter .1 mm **Positional Accuracy ± 0.25 mm**

Figure 3 - Axial Resolution Target

Testing Procedures

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the axial resolution targets and perpendicular to the wires. (The wires should appear as dots, not lines).

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that all the targets are displayed at their maximum intensity level.

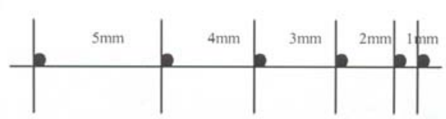
5. Freeze the image and obtain a hard copy.

6. Examine the image to determine the last pair of wires to be distinguished as two separate entities. If the last pair of wires to be resolved are separated by a distance of 1mm then record the axial resolution as being "in between 0.5 mm and 1.0 mm".

F. Lateral Resolution Target (available in the Model 40 and 50)

This target is positioned at depths of 3 cm and 10 cm in the Model 40 and 1.5 cm in the Model 50. Five parallel wires are horizontally spaced precisely at distances of 5, 4, 3, 2, and 1 mm from center to center. This target is designed to accurately assess the lateral resolution of the imaging system.

Lateral resolution is similar to axial resolution except it is concerned with the resolution perpendicular to the beam axis. Lateral resolution will improve with a narrowing of the beam width. Therefore, within the focal zone, the lateral resolution will be at its best.



Wire Diameter .1 mm **Positional Accuracy ± 0.25 mm**

Figure 4 - Lateral Resolution Target

Testing Procedures

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the lateral resolution targets and perpendicular to the wires. (The wires should appear as dots, not lines).

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that all the targets are displayed at their maximum intensity level.

5. Freeze the image and obtain a hard copy.

6. Examine the image to determine the distance between the last two wires as to be resolved as two distinct objects.

7. Record this distance as the lateral resolution.

G. Low Scatter Masses (available in Model 40, 50, and 54)

Machines have a tendency to represent low-contrast structures smaller than they actually are and with irregular rather than smooth borders, this is referred to as fill-in. It is desirous for these effects to be minimal.

In the Model 40, a diagonal row of cylinders having scatter which is -15 dB with respect to the background material is provided in the phantom to test a machine's ability to image cyst-like structures of varying size and depth in two different backgrounds. Cylinder diameters range from 8 mm to 2 mm at depths of 8 cm to 2 cm respectively. The Model 54 has only an 8 mm mass at a depth of 4 cm. Refer to the target diagram attached to your phantom. The Model 50 has three groups of these cylinders with diameters of 3.0, 2.0, and 1.0 mm and arranged in a random pattern at a designated position in the phantom (Figure 5). All these low scatter masses are useful in determining the ultrasonic system's capability of distinguishing low scatter targets. The accuracy of the machine's representation of the masses (proper size and shape) may also be determined using this target group.

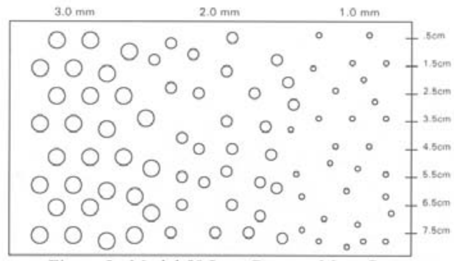


Figure 5 - Model 50 Low Contrast Mass Group

Testing Procedures

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the cyst of interest and perpendicular to the wires (parallel to the wires in Model 50). You should be imaging the circular cross section of the cylinders.

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that the target is maximized.

5. Freeze the image and obtain a hard copy.

6. Observe the general appearance of each cystic structure. Note if there is fill in and if you are able to see each of the masses.

7. A more detailed analysis can be performed by measuring the width and height of each mass.

8. Record your observations and measurements on a data sheet. For the Model 50, record the smallest size masses visible and the depth at which each size mass is no longer able to be seen.

H. High Scatter Masses (available in the Model 40 and 54)

In the Model 40, a diagonal row of cylinders having scatter which is +15 dB with respect to the background material is provided in the phantom to test a machine's ability to image solid tumors of varying size and depth. Cylinder diameters range from 8 mm to 2 mm at depths of 8 cm to 2 cm respectively. The Model 54 has only an 8 mm mass at a depth of 4 cm. These masses are useful in determining the ultrasonic system's capability of distinguishing high scatter targets. The accuracy of the machine's representation of the masses (proper size and shape) may also be determined using this target group. Refer to target diagram attached to your phantom.

Testing Procedures

1. Apply coupling gel to the scanning membrane or fill the water trough with tap water.

2. Position the transducer above the tumor of interest and perpendicular to the wires. (The tumor should appear as a circular region).

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" liver technique. Record these settings for use on subsequent testing.

4. Align the probe so that the target is maximized.

5. Freeze the image and obtain a hard copy.

6. Observe the general appearance of each tumor. Note if you are able to see each of the masses.

7. A more detailed analysis can be performed by measuring the width and height of each mass.

8. Record your observations and measurements on a data sheet.

I. Area Measurements

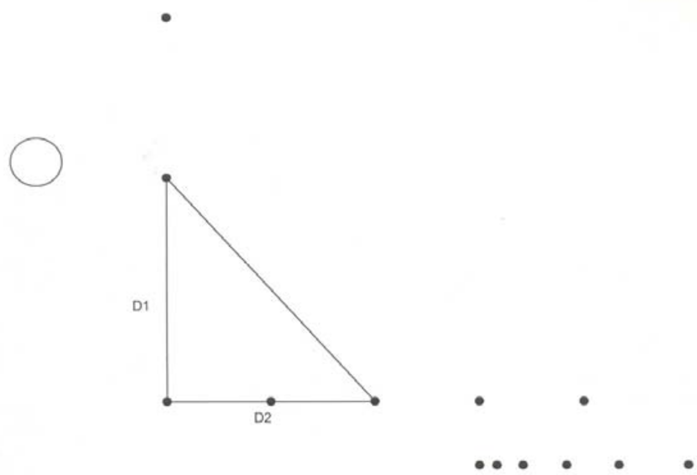
Any phantom with wire targets separated by known distances may be used to compute the area of an imaginery region of interest. The easiest way to do this is to pick wire targets as corner points for your region of interest. Any shape may be used as long as you know the formula for the area of that shape. One example would be to form a triangular region from one vertical target, one horizontal target, and one target in both the horizontal and vertical group.

1. Measure the distance between the targets in the vertical group. Record as D1.
2. Measure the distance between the two targets in the horizontal group. Record as D2.
3. To compute the area use the following formula.

$$Area = 0.5 \times D1 \times D2$$

4. Compare this with the known area by substituting the actual distances between the targets for D1 and D2. Useful formula:

Area of a circle = ¶r^2 (r = radius of circle)
Area of a rectangle = length X height
Area of any shaped triangle = s(s-a)(s-b)(s-c) where s = ½(a+b+c), where a, b, & c are the lengths of each side



J. Analysis

It is recommended that all these measurements be performed at the most frequently used imaging arrangements. The importance of these tests is not so much from a one time analysis as it is to make sure the system performance remains constant over an extended period of time. All these measurements may also be used to compare the performance of various setups of the same machine or to compare different machines with one another in a quantitative manner.

Note: Time-gain properties and sector scanner errors can be evaluated using the vertical plane target in accordance with suggested AIUM techniques. For targets with minimum scattering, lower gain levels can be used; however, higher gain settings enable evaluation at more clinical type settings. When evaluating any machine, settings should be recorded and remain consistent over time. For further instruction on measuring performance refer to Standard Methods for Measuring Performance of Pulse-Echo Ultrasound Imaging Equipment, AIUM Standards Committee, July 1990.

V. STORAGE INSTRUCTIONS

1. When all testing is complete, remove excess coupling material, close the air-tight ziplock bag, and replace the protective carrying case cover.

2. Zerdine will desiccate over time if the phantom is not stored properly. If there is a noticeable change in the phantom or the case and/or membrane are damaged, the phantom should be returned immediately for repair or replacement.

IN THE EVENT OF DAMAGE TO MEMBRANE OR ABS BOX, FOLLOW THESE INSTRUCTIONS TO AVOID IRREVERSIBLE DAMAGE TO PHANTOM:

1. Immediately seal phantom in ziplock bag.
2. Contact technical service at 800-617-1177 for further instructions.

VI. Recertification/Calibration of Phantom:

1. Each phantom is certified with traceability to NIST. The certification sheet provides the weight of the phantom. As with all water-based gels, desiccation could occur. Experience has shown that a 5 to 8% weight loss can be tolerated before the phantom acoustical properties degrade. Should the phantom, its membrane or case be damaged, it would need to be returned for recertification.

2. Services are available for recertification of phantoms. Should you require this for your in-house quality system contact Customer Service for a quotation.

LIMITED WARRANTY

This Ultrasound product and its accessories, except as *noted below, are warranted by the manufacturer against defects in material and workmanship for a period of two years from the date of original shipment. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid. This warranty is extendable in two years increments subject to inspection and successful recertification by the manufacturer. The first recertification inspection is provided at no cost by the manufacturer. Ensuing recertifications will be provided on a time and materials basis. This warranty recognizes the realities of water based polymer gels, the capability of achieving long life of ultrasound phantoms through proper care, and the varied use conditions to which such phantoms can be subjected.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer's option.

This warranty does not apply if the product, as determined by the manufacturer, is defective because of normal wear, accident, misuse, or modification.

NON-WARRANTY SERVICE

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with the repair or replacement.

REPAIR SERVICE / RECERTIFICATION SERVICE: Return the product, prepaid to:

COMPUTERIZED IMAGING REFERENCE SYSTEMS, INC.
2428 Almeda Avenue, Suite 212, Norfolk, Virginia, 23513
(757) 855-2765 Fax (757) 857-0523

IMPORTANT: To expedite your repair, please supply the following: (1) Complete detailed description of problem, (2) Purchase date, (3) Name of vendor, (4) Order number. Also indicate which, if any, accessory items are included in the return.

Q2\gen\instructions\gels\405054.doc

ULTRASOUND QUALITY ASSURANCE RECORD

Location: ______________ **Unit:** ____________ **Probe:** ___________ **QC Phantom SN:** ____________

Machine Settings:

Depth of Field (FOV) _______________ **cm** **Gain:** _________________ **Power:** ______________

Focal Zone(s) _________ **cm** _________ **cm** _________ **cm** _________ **cm** ________ **cm** _________

Preprocessing ______________________ **Postprocessing** _____________ **Dynamic Range** ___________

Other: ____

TEST	BASELINE	TEST RESULTS REMARKS	VARIANCE
Uniformity			
Near Field			
Depth of Penetration			
Focal Point			
Vertical Distance			
Horizontal			
Distance Axial Resolution			
Lateral Resolution			
Low Scatter			
High Scatter			

Order replacement forms from:
CIRS, 2428 Almeda Avenue, Suite 212, Norfolk, VA 23513
800 617-1177 * 757 855-2765 or Fax 757 857-0523

One Sheet per System Setup

For technical assistance call 1-800-617-1177

WORKSHEET INSTRUCTIONS

TEST	EXAMPLE TEST RESULTS	COMMENTS (see specific section in manual for detailed instructions)
Uniformity	Consistent Intensity	Record if all regions at same depth are displayed with same intensity.
Near Field	Can range from	Record depth of 1st echo from wire seen
Depth of Penetration	<1 mm to <9 mm ~16 cm at 3.5 mHz	Record depth of last visible scatters
Focal Point	0.1 mm	Record minimum length of target
Vertical Distance	2.0 cm at all depths	Record distance between targets at different depths
Horizontal	2.0 cm	Record distances between targets
Distance Axial Resolution	0.5 mm is best	Record smallest distance seen between wires
Lateral Resolution	1 mm is best	Record distance between last two resolvable objects
Low Scatter	all visible, no distortion	Note masses which can be seen and measurement of diameter
High Scatter	all visible, no distortion	Note masses which can be seen and measurement of diameter

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Near Field	Can range from	Record depth of 1st echo from wire seen
Depth of Penetration	<1 mm to <9 mm ~16 cm at 3.5 mHz	Record depth of last visible scatters
Focal Point	0.1 mm	Record minimum length of target
Vertical Distance	2.0 cm at all depths	Record distance between targets at different depths
Horizontal	2.0 cm	Record distances between targets
Distance Axial Resolution	0.5 mm is best	Record smallest distance seen between wires
Lateral Response Width	1 mm at 3 cm	Record length of vertical target group wires at various depths
Low Scatter	all visible, no distortion	Note masses which can be seen and measurement of diameter
High Scatter	all visible, no distortion	Note masses which can be seen and measurement of diameter
Order replacement forms from: CIRS, 2428 Almeda Avenue, Suite 212, Norfolk, VA 23513 800 617-1177 * 757 855-2765 or Fax 757 857-0523		One Sheet per System Setup

ULTRASOUND QUALITY ASSURANCE RECORD

Location: ______________ Unit: ____________ Probe: ___________ QC Phantom SN: ____________

Machine Settings:

Depth of Field (FOV) _______________ cm Gain: _______________ Power: __________

Focal Zone(s) _________ cm _________ cm _________ cm _________ cm ________ cm

Preprocessing _______________ Postprocessing _______________ Dynamic Range ________

Other: ____

TEST	BASELINE REMARKS	TEST RESULTS	VARIANCE	
Uniformity				
Near Field				
Depth of Penetration				
Focal Point				
Vertical Distance				
Horizontal				
Distance Axial Resolution				
Lateral Response Width				
Low Scatter				
High Scatter				

Order replacement forms from:

CIRS, 2428 Almeda Avenue, Suite 212, Norfolk, VA 23513 — One Sheet per System Setup
800 617-1177 * 757 855-2765 or Fax 757 857-0523

For technical assistance call 1-800-617-1177

General Purpose Multi-Tissue Ultrasound Phantom

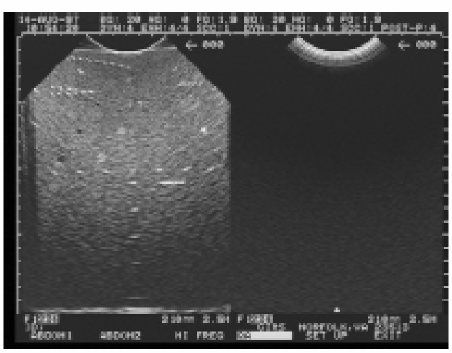
The standard for ultrasound quality assurance
Two Phantoms in one case

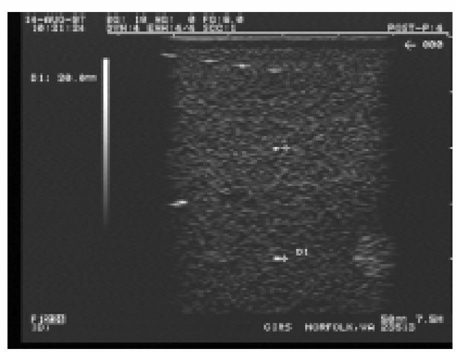
Model 040

Complies with AIUM Standard for Quality Assurance.

The CIRS series of ultrasound phantoms, unlike human subjects or random scannable materials, offers a reliable medium which contains specific, known test objects for repeatable qualitative assessment of ultrasound scanner performance over time.

This phantom is constructed from the patented solid elastic material, Zerdine® (1). Zerdine®, unlike other phantom materials on the market, is not affected by changes in temperature. It can be subjected to boiling or freezing conditions without sustaining significant damage. Zerdine® is also more elastic than other materials and allows more pressure to be applied to the scanning surface without subsequent damage to the material. At normal or room temperatures the Zerdine® material found in the Model 040 will accurately simulate the ultrasound characteristics found in human liver tissue. The Model 040 was designed to allow for assessment of uniformity, axial and lateral resolution, depth calibration, dead zone measurement, and registration within two different backgrounds of 0.5 and 0.7 dB/cm/MHz.





(1)US PATENT # 5196343

Tissue Simulation & Phantom Technology
CIRS
2428 Almeda Avenue • Suite 212 • Norfolk, Virginia 23513 • USA
(800) 617-1177 • (757) 855-2765 • FAX (757) 857-0523
www.cirsinc.com • admin@cirsinc.com

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Model 040 Specifications:

MATERIAL: Zerdine®, solid elastic water-based polymer
Freezing Point: 0° C
Melting Point: Above 100° C

ATTENUATION COEFFICIENT:
0.5 dB/cm/MHz
0.7 dB/cm/MHz

SPEED OF SOUND:
1540 m/s

SCANNING WELL:
1 cm deep

SCANNING MEMBRANE:
Saran

TARGETS:
Material: Nylon Monofilament
Wire Diameter: 0.1 mm

VERTICAL PLANE TARGETS
Number of Groups: 1
Number of Targets Per Group: 16
Depth Range: 16 cm
Spacing: 1 cm

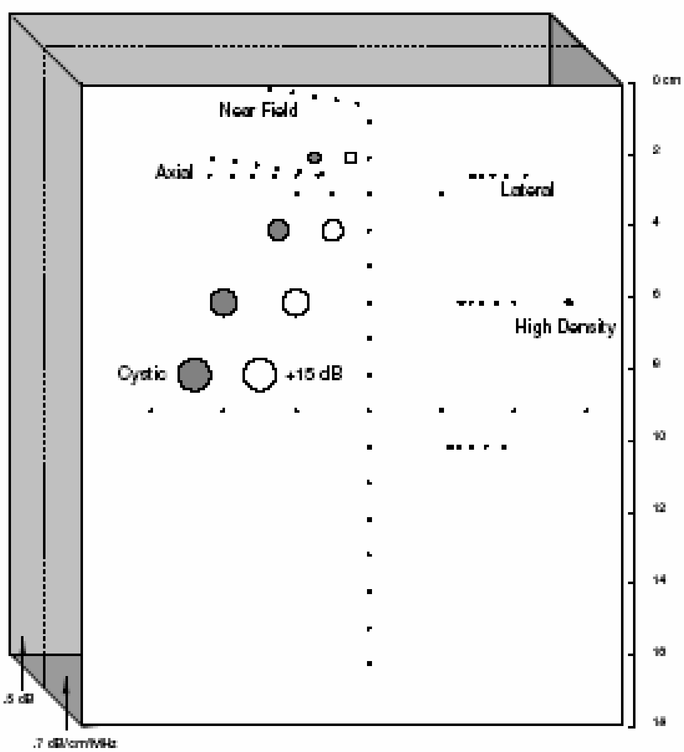
HORIZONTAL PLANE TARGETS
Number of Groups: 2
Number of Targets: 4 and 7
Depth Range: 3 cm and 9 cm
Spacing: 1 cm and 2 cm

RESOLUTION TARGETS:
Number of Arrays: 4
Depths: 2.5 cm, 6 cm and 10 cm
Axial Intervals: 0.5, 1 , 2, 3, 4, and 5 mm
Horizontal Intervals: 1, 2, 3, 4, and 5 mm

CYSTIC TARGETS:
Number of Targets: 4
Diameter of Targets: 2, 4, 6 and 8 mm
Depth of Targets: 2, 4, 6, and 8 cm
Attenuation: <0.07dB/cm/MHz
Speed: 1540 m/s
Contrast: anechoic

HIGH CONTRAST TARGETS:
Number of Targets: 4
Diameter of Targets: 2, 4, 6 and 8 mm
Depth of Targets 2, 4, 6, and 8 cm
Attenuation: 1.0 dB/cm/MHz
Speed: 1540 m/s
Contrast: +15 dB v.s. background

HIGH DENSITY TARGET:
Material: PMMA
Diameter: 1/16"
Depth: 6 cm



Phantom comes with detachable scanning wells to accommodate large sector probes and small endocavity probes. It is packaged in a hermetically sealed, air tight, rugged carrying case.

General Purpose Ultrasound Phantom

The basic standard for ultrasound quality assurance

The CIRS series of ultrasound phantoms, unlike human subjects or random scannable materials, offers a reliable medium which contains specific, known test objects for repeatable qualitative assessment of ultrasound scanner performance over time.

This phantom is constructed from the patented solid elastic material Zerdine®[1]. Zerdine®[1], unlike other phantom materials on the market, is not affected by changes in temperature. It can be subjected to boiling or freezing conditions without sustaining significant damage. Zerdine®[1] is also more elastic than other materials and allows more pressure to be applied to the scanning surface without subsequent damage to the material. At normal or room temperatures, the Zerdine®[1] material found in the Model 054 will accurately simulate the ultrasound characteristics found in human liver tissue.

Model 054

Complies with AIUM Standard for Quality Assurance.

The Model 054 was designed to allow for axial resolution, lateral response width, uniformity, dead zone measurements, depth of visualization, high and low contrast mass imaging, and distance calibration.

[1] US PATENT# 5196343

Tissue Simulation & Phantom Technology

CIRS

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www.cirsinc.com • admin@cirsinc.com

Model 054 Specifications

MATERIAL: Zerdine®[1], solid elastic water-based polymer
Freezing Point: 0° C
Melting Point: Above 100° C

ATTENUATION COEFFICIENT:
0.5 dB/cm/MHz
0.7 dB/cm/MHz available upon request

SPEED OF SOUND:
1540 m/s

SCANNING WELL:
1 cm Deep

SCANNING MEMBRANE:
Saran

VERTICAL PLANE TARGETS:
Number of Groups: 1
Number of Targets Per Group: 9
Depth Range: 18 cm
Spacing: 2 cm
Material: 0.1 mm Nylon monofilament

HORIZONTAL PLANE TARGETS:
Number of Groups: 1
Number of Targets Per Group: 7
Depth Range: 9 cm
Spacing: 2 cm
Material: .1 mm Nylon monofilament

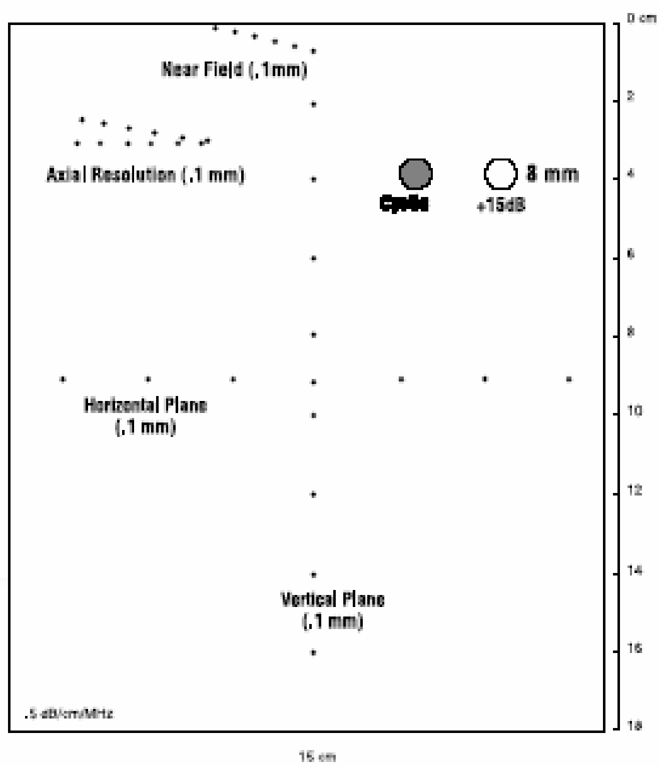
Phantom includes detachable scanning wells and air tight case.

NEAR FIELD TARGETS:
Number of Groups: 1
Number of Targets Per Group: 6
Depth of Targets: 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, and 6 mm.
Material: 0.1 mm Nylon wire

AXIAL RESOLUTION TARGETS:
Number of Groups: 1
Number of Targets Per Group: 12
Depth: 3 mm
Spacing: .5 mm, 1 mm, 2 mm, 3 mm, 4 mm, and 5 mm
Material: 0.1 mm Nylon wire

ANECHOIC TARGET:
Number of Targets: 1
Diameter of Target: 8 mm
Depth of Target: 4 cm
Contrast: -15dB to Background Material

HIGH CONTRAST TARGET:
Number of Targets: 1
Diameter of Target: 8 mm
Depth of Target: 4 cm
Contrast: +15dB to Background Material



[1] US Patent # 5196343