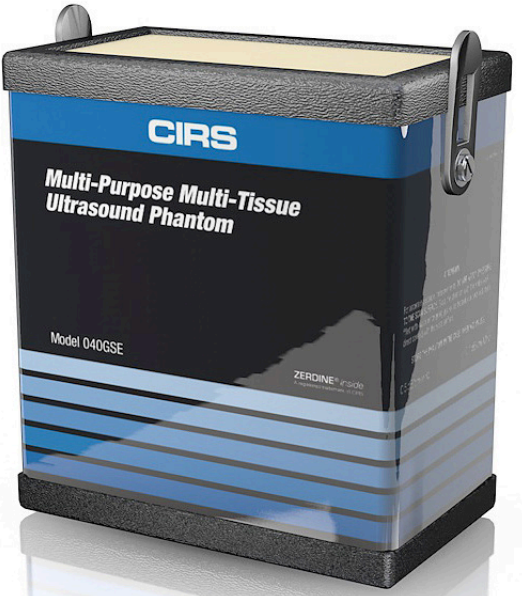
Multi-Purpose, Multi-Tissue Ultrasound Phantom

Model 040GSE



ZERDINE® *Inside*
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ULTRASOUND QUALITY ASSURANCE

USER GUIDE

CIRS
900 Asbury Ave • Norfolk, Virginia 23513 • USA • Tel: 757-855-2765 • **WWW.CIRSINC.COM**

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OVERVIEW

The Model 040GSE Multi-Purpose, Multi-Tissue Ultrasound Phantom is a sturdy, reliable phantom for testing the imaging performance of ultrasonic systems.

The phantom is made of CIRS' proprietary Zerdine® hydrogel polymer, which has been formulated to provide tissue mimicking properties under B-mode ultrasound and other features such as harmonic imaging. To maximize phantom lifetime, this gel is contained in a rugged ABS plastic housing with a Saran-based laminate membrane.

The Model 040GSE has two attenuation zones to allow use over the widest range of transducer types possible. The high attenuation zone ensures that even low-frequency probes (5 MHz and below) do not penetrate to the bottom of the phantom when measuring penetration depth. The low attenuation zone allows high frequency probes (greater than 5 MHz) to image key testing targets within the first 4 cm of the phantom. This combination allows testing of most transducers in clinical imaging frequencies from 2 to 20 MHz, and, unlike other phantoms with lower attenuation values, this phantom complies with IEC Technical Standard 62736.

Key Tests with Model 040GSE

- Uniformity
- Depth of Penetration
- Beam Profile/ Focal Zone/ Lateral Response Width
- Vertical Distance Measurement
- Horizontal Distance Measurement
- Axial and Lateral Resolution
- Elevational Resolution
- Contrast Resolution
- Grayscale Contrast Sensitivity
- Elasticity Sensitivity
- Dead Zone Assessment

For more information on these tests, see "Testing Procedures" starting on page 5

CIRS is certified to ISO 13485:2016 standards. We have an in-house test facility to measure acoustic properties of materials. In addition, ultrasound imaging systems are used to inspect each phantom. Every ultrasound phantom that CIRS distributes has passed thorough testing during manufacture and completion to ensure the highest quality product available. A Certificate of Compliance is issued with each phantom.

Additional guidance on establishing a quality assurance program can be found in the accreditation programs established by the ACR and AIUM at www.acr.org or www.aium.org.

INSTRUCTIONS FOR USE

HANDLING AND CARE

With proper care, the Model 040GSE will withstand years of normal use. Below are some guidelines to follow.

The scanning surface is the most important item on the phantom to protect. It can withstand normal scanning pressure but DO NOT press on the scanning surface with your fingernails or any other sharp objects. If the scanning surface becomes damaged, seal the phantom in an airtight container and IMMEDIATELY contact CIRS for return authorization. Call 800-617-1177, email at rma@cirsinc.com or fax RMA Request form to 757-857-0523.

The phantom may be cleaned with mild soap and water ONLY. Avoid solvent-based, alcohol-based, or abrasive cleaning agents.

For longest life, the phantom should be cleaned after each use and stored at room temperature in the provided carry case. The primary concern is gel desiccation due to loss of water vapor through the membrane. In addition, the thermal stresses associated with the freeze/thaw cycle may cause the gel to crack or damage the housing integrity, while extreme heat may accelerate water vapor transmission through the membrane. To minimize desiccation, always store the phantom in the air-tight carry case with the removable storage cover attached.

Inspect your phantom regularly for signs of damage and weight loss. If any noticeable changes to the phantom are detected, return the phantom IMMEDIATELY for repair or replacement.

At least once a year, weigh your phantom and compare to original weight noted on certificate of compliance. If the phantom has lost or gained more than 1% of its original weight and you notice a difference in vertical distance measurements, or if the scan surface appears depressed, call CIRS at (800) 617-1177.

This product contains Zerdine, a non-flowing water-based, polyacrylamide material which is fully sealed within the phantom housing. Zerdine contains trace amounts of the residual monomer acrylamide CAS#79-06-1. There are no known hazards when the phantom is used and stored as intended. Zerdine is fully cured and will not leak from the housing. Damage to the integrity of the housing may expose the user to trace amounts of acrylamide monomer. The amount is not sufficient to pose an acute health risk, but it is still advised to wear protective gloves if handling exposed Zerdine gel due to the potential long-term hazards of the monomer. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.

HANDLING AND CARE (CONTINUED)

Regulations regarding disposal of materials with trace acrylamide monomer vary by locality. Contact your local authority for instructions. If assistance is desired in the proper disposal of this product, including accessories and components, after its useful life, please return to CIRS.

USE OF THE REMOVABLE WATER WELL AND COVERS

The phantom is shipped with the protective cover attached to the phantom. This can be removed by stretching the elastic latches on either side of the phantom up and off of the protective cover. The included water well and covers are easily secured to the phantom with these same rubber latches. Simply place the water well or cover on top of the phantom and stretch the elastic latches up and over the attachment point on either side of the accessory.

Cover on for storage

Attach cover with latches

Coupling gel can be applied directly to the scan surface. This option is best used with linear transducers. For curved arrays, the water well may be attached and filled with water to provide better coupling. Side Fire transducers can be particularly challenging to scan with a standard phantom. CIRS has designed a removable endocavity cover for these transducers. When this accessory is attached, the phantom should be placed on its back and the cover should be filled with water.

Water well for coupling curved probes

Endocavity well

When finished scanning, it is best to clean the scan surface of any water or coupling gel and replace the protective cover.

GENERAL GUIDELINES FOR PERFORMING MEASUREMENTS

It is recommended that all measurements be performed at the most frequently used imaging arrangements. The importance of these tests is to make sure that system performance remains constant over an extended period of time. Measurements may also be used to compare the performance of various setups of the same machine or to compare different machines in a quantitative manner.

The following are general steps for imaging all targets:

- Some wires will appear as short lines rather than dots. When using the electronic calipers, always take measurements from a point on one echo to the same point on the next (i.e., center to center). Otherwise, errors may be introduced.
- 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 vertical distance measurements, DO NOT press on the scanning surface. Pressure on the scanning surface causes the wires to become temporarily displaced, making vertical distance measurements inaccurate.
- When assessing horizontal distance accuracy, ensure that the scan plane is perpendicular to the horizontal target group. Rotation of the probe will result in inaccurate distances.
- Always be sure the phantom is scanned while 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, the perceived measurements. The phantom should be stored at room temperature for at least 24 hours before use to ensure its core temperature is correct.
- The most accurate measurements will be made with the phantom 22˚C ± 1˚C (70˚F–73˚F).

ESTABLISHING A BASELINE

Before performing routine quality assurance measurements, establish:

1. System settings for each measurement:

System setup can have a dramatic impact on the results obtained from quality assurance measurements. You must establish and record what system settings should be used for each of the quality assurance tests. These same settings should be used each time the test is performed. If not, then the conclusions drawn may not be valid. CIRS recommends that you use the most commonly used settings for the type of probe tested - i.e. the liver preset values for an abdominal probe - which are called a "normal" technique in the sections that follow.

2. **Baseline measurements:**

   The first set of measurements taken will be the baseline measurements for the combination of system settings and phantom. Record the system settings and phantom serial number used to acquire each measurement along with your measurement results. On subsequent scans, refer to the baseline results to determine if the ultrasound system has drifted to an unacceptable level. It is each facility's responsibility to establish the magnitude of drift allowed before corrective action is warranted.

3. **Allowable deviation from baseline measurements:**

   The difference between the original baseline measurements and subsequent measurement should be calculated and recorded. At some point the difference will be large enough that some action is required (call service, replace system, etc.). Each facility needs to determine the action level for each test. You should 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 conclusion made when evaluating the ultrasound system. For example, if the measurement accuracy for your system is 10% for distances up to 2 cm, the scanner may detect 2.0 cm as being any where from 1.8 cm to 2.2 cm and still be functioning properly. The user is responsible for establishing action levels.

4. **Frequency of system assessment:**

   How often each system is evaluated is also up to each facility to determine. CIRS recommends at least annually.

Reference the accreditation programs established by the ACR and AIUM at www.acr.org or www.aium.org for further guidance on establishing a QA program.

TESTING PROCEDURES

The following sections outline procedures for routine quality control tests with the Model 040GSE. It may be useful to refer to the target map, shown in the Specifications section of page 14, when reviewing these procedures.

UNIFORMITY TESTING

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.

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer on the scanning surface in a region with a minimum number of targets.

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

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 the phantom. Note if all regions at the same depth are displayed with the same intensity across the image.

7. Record your observations.

DEPTH OF PENETRATION TESTING

Depth of penetration, also called maximum depth of visualization or sensitivity, is the greatest distance in a phantom for which echo signals caused by scattering in the 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.

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

2. Position the transducer to acquire an image of a vertical plane target. (The wires should appear as dots, not lines).

3. Adjust the instrument settings (gain, TGC, output, etc.) as for a “normal” 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 backscattered echoes within the background material disappear. Be careful not to confuse electronic noise with the background backscattered echoes. Electronic noise will move but back-scattered echoes will remain stationary while maintaining the transducer in a fixed position.

6. Freeze the image.

7. With electronic calipers measure the distance between the scanning surface and the last identifiable echoes due to scattering. Note: Usually the wires stay visible even though the back scattered echoes are not. Remember to measure the distance to the scattered echoes, not to 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 Figure 1. The narrowest region within the beam profile is indicative of the focal point. By convention, the region surrounding the focal point with intensity within 3 dB of maximum is the focal zone. The best images are obtained while within the focal zone. The vertical wire target group is useful for determining the beam profile and the focal zone of a system, as follows:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer in a vertical plane. (The wires should appear as dots, not lines).
3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" 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 to ensure the transducer is imaging a vertical plane.
5. Freeze the image and obtain a hard copy. Note: Some of the targets will appear as short horizontal lines rather than dots on the frozen image.
6. Measure the horizontal length of the targets. These measurements represent the lateral response width of the system at the different depths and setup. The minimum length is indicative of the location of the focal point.

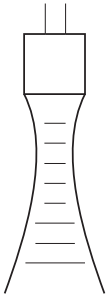


Figure 1 - Typical Beam Profile

7. If a smooth curve is drawn to connect the edges of the targets, the beam profile is easily discernible.
8. If using a variable focused transducer, repeat the above procedure for several different focal zones (those settings most commonly used are recommended).
9. Record the focal point and save the hard copy.

VERTICAL DISTANCE MEASUREMENTS

A vertical distance is defined as the distance along the axis of the beam. The vertical wire targets are used to assess the accuracy of vertical distance measurements as follows:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer in a vertical plane. (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" 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.

HORIZONTAL DISTANCE MEASUREMENTS

The horizontal target group is used to determine the accuracy of measurements made perpendicular to the beam axis. There are two horizontal plane target groups. The 4 cm deep group contains 4 wires with spacing of 10 mm and 20 mm. The 9 cm deep group has 20 mm spacing between each of the 7 wires. Refer to the target diagram attached to your phantom. Testing is performed as follows:

1. Fill the water trough with tap water.
2. Position the transducer in a vertical plane. (The wires should appear as dots, not lines).
3. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" 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.

AXIAL AND LATERAL RESOLUTION TESTING

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, it determines how close two objects can 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.

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.

AXIAL AND LATERAL RESOLUTION TESTING (CONTINUED)

The Model 040GSE has three combined axial and lateral resolution target groups. The first two groups, at depths of 3 cm and 6.5 cm, are designed for probes of 5 MHz and above. They consist of 13 parallel nylon wires of 80 microns diameter. The third target is located at 10.5 cm depth for evaluation of low frequency probes. It consists of 11 parallel nylon wires of 80 microns diameter.

To measure axial and lateral resolution, refer to Figures 2 and 3 for the layout of the axial/lateral target groups and perform the following steps:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer above the axial resolution targets in a vertical plane. (The wires should appear as dots, not lines).
3. Adjust the instrument settings (gain, TGC, output, etc.) as for a “normal” 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 is separated by a distance of 1 mm then record the axial resolution as being “in between 0.5 mm and 1.0 mm”.

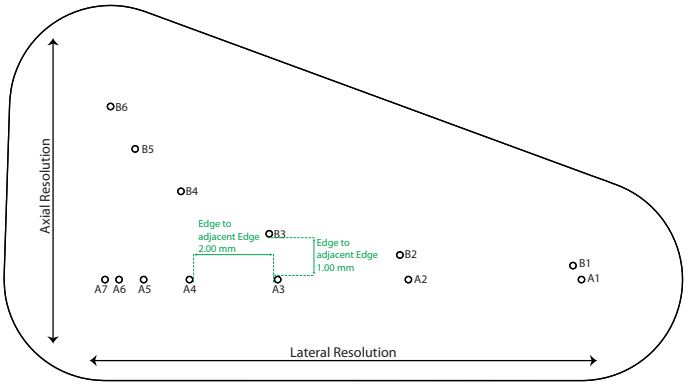


Figure 2 - Combined Axial/Lateral Resolution Targets at 3 and 6.5 cm depth(top) and a table listing distances between them (bottom)

	Targets					
	A1-B1	A2-B2	A3-B3	A4-B-4	A5-B5	A6-B6
Axial Resolution (mm)	0.25	0.5	1.0	2.0	3.0	4.0
	Targets					
	A1-A2	A2-A3	A3-A4	A4-A5	A5-A6	A6-A7
Lateral Resolution (mm)	4.00	3.0	2.0	1.0	0.5	0.25

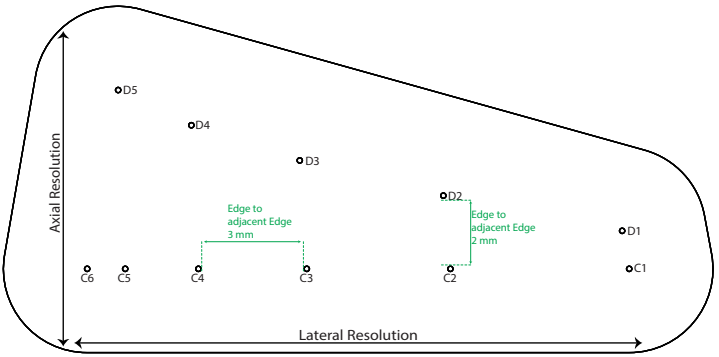


Figure 3 - Combined Axial/Lateral Resolution Target at 10.5 cm depth (top) and a table listing the distances between them (bottom)

	Targets				
	C1-D1	C2-D2	C3-D3	C4-D4	C5-D5
Axial Resolution (mm)	1.0	2.0	3.0	4.0	5.0
	Targets				
	C1-C2	C2-C3	C3-C4	C4-C5	C5-C6
Lateral Resolution (mm)	5.0	4.0	3.0	2.0	1.0

ELEVATIONAL TESTING

A full characterization of system resolution requires measurement of elevational resolution, or slice thickness. Slice thickness is typically much coarser than axial and lateral resolution as most ultrasound transducer arrays are mechanically focused in the thickness dimensions.

Two methods are described for measuring elevational resolution. The first method, first described by Skolnick[1], uses the vertical wire targets as follows:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing
3. Orient the transducer to image the length of the vertical target wires, taking care to adjust the tilt so that the wires are lined up in a vertical column.
4. Rotate the transducer 45° so that only a partial length of the wires is now visible.
5. Freeze the image and measure the length of each wire segment with the electronic calibers.
6. Record the measurements.

1.Skolnick, ML. "Estimation of ultrasound beam width in the elevation (section thickness) plane." Radiology. 1991 Jul;180(1):286-8.

In the second method, the anechoic cylinders are used as simulated focal lesions as follows:

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

2. Adjust the instrument settings (gain, TGC, output, etc.) as for a “normal” technique. Record these settings for use on subsequent testing.

3. Orient the transducer to image the length the anechoic cylinder, taking care to adjust the tilt so that the cylinders are lined up in a vertical column.

4. Freeze the image and save a copy.

5. At each depth, record the smallest detectable cylinder diameter.

CONTRAST RESOLUTION

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. Ideally, the fill-in effect will be minimal.

The Model 040GSE has 12 anechoic stepped cylinders at various depths with multiple diameters. This design provides a better range of steps for assessment of the anechoic void perception and the response of the system for small cysts. The first two cylinders have smaller-sized cysts than the four deeper cylinders. (See Table 1, page 16, for the size and depth of each cylinder.)

By design, the ratio of cross-sectional areas for any two adjacent steps has been fixed at 1.5. In other words, the ratio of the cross sectional area of 2.00 mm diameter mass divided by the cross sectional area of the next 1.33 mm diameter mass is 1.49, and so on. This feature provides even increments for assessing the response of the system to small cysts.

The anechoic stepped cylinders are arranged in parallel pairs and flipped 180 degrees to each other, allowing all diameters in both the low attenuation zone background and the high attenuation zone to be available. See Table 1, page 16, and Figure 5 for location and arrangement of the cystic masses.

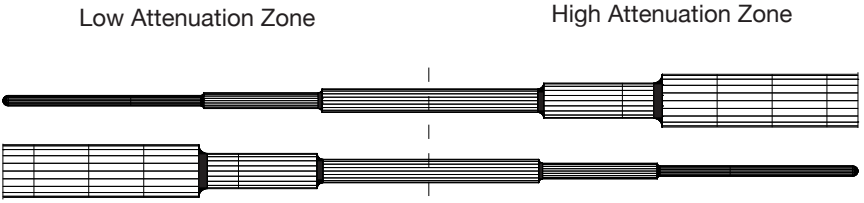


Figure 5 - Top View of the Anechoic Stepped Cylinders Arrangement

Testing for low-contrast target detectability is performed as follows:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer above the cyst of interest and perpendicular to the wires. 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.

GRAYSCALE CONTRAST SENSITIVITY

In the Model 040GSE contrast sensitivity is evaluated using 2 gray scale target groups. The first group, at 3 cm depth, is designed for probes of 5 MHz and provides grayscale contrast levels from –9 dB to +6 dB (relative to the background), plus an extra hyperechoic target whose contrast level varies with the transducer used. The second group, at 11.5 cm deep, provides grayscale contrast from -6 dB to +6 dB, along with a hyperechoic target. See Table 2, page 17.

The dynamic range of an ultrasound imager can be evaluated using the gray scale masses in conjunction with the cystic masses and the hyperechoic masses. Testing of grayscale contrast is performed as follows:

1. Apply coupling gel to the scanning surface 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" 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.

ELASTICITY CONTRAST SENSITIVITY

The Model 040GSE provides elasticity targets for the next generation of ultrasound imagers using elastography. The elasticity value for the background is 20 kPa.

The target group at a depth of 1.5 cm has a diameter of 6mm, while the target group at 5 cm has a diameter of 8 mm. Both groups provide elasticity values of 10, 50 and 100 kPa.

These targets are suitable for qualitative assessment of sonoelastography systems, and checking system performance over time. Elasticity contrast is assessed as follows:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer above the elasticity targets and perpendicular to the wires.
3. In sonoelastography mode adjust the instrument settings.
4. Change settings to acquire optimal images.
5. Observe the general appearance of each tumor. Note how well you are able to see each of the masses. Quantitative measurements based on the elastography color scale, or the shear wave speed reading, may be used for tracking the consistency of elastography measurements over time.
6. Record your observations.

Note: Due to the limited spatial resolution of some shear wave elastography systems, the modulus readings of the elastography targets may get averaged with the modulus of the background. In this case, you may want to test your readings against the 040GSE background (nominal modulus of 20 kPa) or obtain the Model 039 Shear Wave Elastography set.

The modulus readings provided are tested using a stress/strain compression stand based on ASTM standard D575-91, and your readings may differ slightly due to differences in test methodology. For more information, refer to the following reference:

Oudry J, Lynch T, Vappou J, Sandrin L, Miette V. "Comparison of four different techniques to evaluate the elastic properties of phantom in elastography: is there a gold standard?" Phys Med Biol. 2014 Oct 7;59(19):5775-93.

DEAD ZONE ASSESSMENT

The near field group is used to assess 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," "ring-down distance," or "near field resolution." 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.

DEAD ZONE ASSESSMENT CONTINUED

The near field group consists of parallel, 100 micron diameter, nylon, monofilament wires horizontally spaced 6 mm apart from center to center (Figure 4, page 13). Vertical distance from the center of each wire to the top edge of the scanning surface ranges from 5 mm down to 1 mm in 1 mm increments.

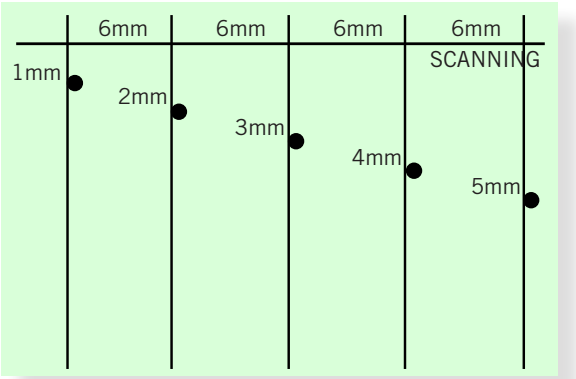


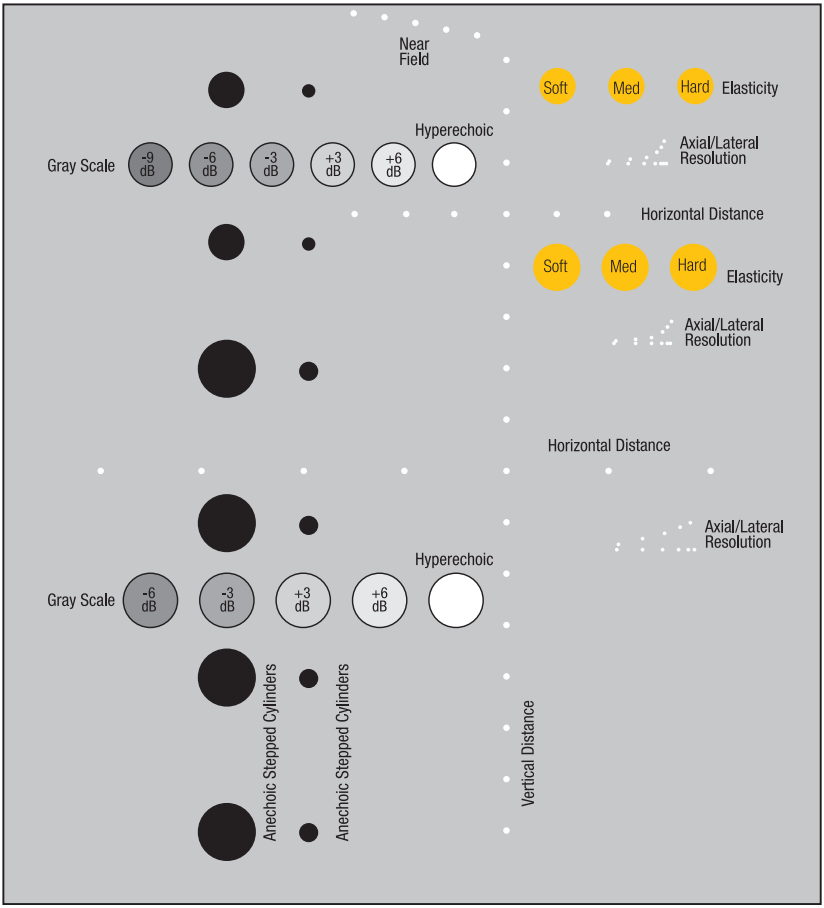
Figure 4 - Near Field Target

The depth of the dead zone may be measured as follows:

1. Apply coupling gel to the scanning surface 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. Measure Dead Zone distance using one of these two methods:
    - 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. For instance, if 3 targets are visible, the dead zone distance = 2 mm (5mm-3mm).
    - Use 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 4 mm”.
6. Record this distance and compare with baseline measurements.

SPECIFICATIONS

TARGET LAYOUT



PHANTOM

Housing	ABS Plastic
Outer Dimensions	17.8 x 12.7 x 20.3 cm (7 x 5 x 8")
Scanning Surface	14 x 9 cm Saran-based laminate
Scanning Material	Zerdine® tissue mimicking gel
Speed of Sound	1540 m/s
Attenuation	Low: 0.7 dB/cm/mHz; High: 0.95 dB/cm/mHz
Other	Compatible with harmonic imaging

WIRE TARGETS

Material	Nylon monofilament

NEAR FIELD GROUP

Number of targets	5
Diameter	100 microns
Depth range	1 to 5 mm
Vertical distance between targets	1 mm

VERTICAL DISTANCE GROUP

Number of targets	16
Diameter	100 microns
Depth range	1 to 16 cm
Vertical distance between targets	10 mm

HORIZONTAL DISTANCE GROUPS

Number of groups	2
Diameter	100 microns
Depths	4 & 9 cm
Number of targets	6 & 7 respectively
Horizontal distance between targets	10 & 20 mm respectively

AXIAL / LATERAL RESOLUTION GROUPS

Group 1 and 2

Diameter	80 microns
Depths	3 & 6.5 cm
Axial & Lateral separation between targets	4, 3, 2, 1, 0.5 & 0.25 mm

Group 3

Diameter	80 microns
Depths	10.5 cm
Axial & Lateral separation between targets	5, 4, 3, 2, & 1 mm

ANECHOIC STEPPED CYLINDERS

Material Zerdine

Depth (cm)	Diameter (mm) 1.3	2.0	3.0	4.5	6.7	10.0
1.5	X	X	X	X	X	-
4.5	X	X	X	X	X	-
7	-	X	X	X	X	X
10	-	X	X	X	X	X
13	-	X	X	X	X	X
16	-	X	X	X	X	X

LEGEND:

X = Apply

- = Do Not Apply

Table 1 - Cystic Masses Location and Size

GRAY SCALE TARGETS

Material Zerdine

Depth & Diameter	Contrast, dB -9	-6	-3	+3	+6	>15
3 cm, Ø 8mm	X	X	X	X	X	X
11.5 cm, Ø 10mm	-	X	X	X	X	X

Table 2 - Gray Scale Targets Location, Contrast and Size

ELASTICITY TARGETS

Group 1: 1.5 cm deep, Ø 6 mm
Group 2: 5 cm deep, Ø 8 mm
Elasticity*: Soft (10 kPa), medium (50 kPa) & hard (100 kPa)
Grayscale Contrast: -3 db with respect to background
*Modulus values are nominal; details are available upon request.

ACCESSORIES

Removable water well, Removable endocavity cover, Removable storage cover, Carry case, Certificate of Compliance, Model 040GSE User Guide & Technical Information.

NOTES

All dimensions without tolerances are nominal
All measurements made at 22˚C ± 1˚C

ZERDINE®

The Model 040GSE is constructed from a patented, solid elastic material developed at CIRS called Zerdine. Phantoms constructed from Zerdine will not melt or leak when punctured and they do not require refrigeration. 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 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 formulation system established at CIRS is geared to independently control:

- The speed of sound in the optimal range of 1510 to 1700 m/s.
- Attenuation in the optimal range of 0.05 and 1.5 dB/cm-MHz.
- Scatter or relative contrast in the optimal range of -15 to +15 dB in relation to a scatter baseline equivalent to human liver tissue.
- Elasticity with a Young Modulus in the optimal range of 4 to 100 kPa.

At normal room temperature, Zerdine response to ultrasonic excitations will simulate the ultrasonic response of human tissue. 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, and are fully compatible with harmonic imaging. 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 provided, your phantom should last many years.

WARRANTY

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. 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.

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 said repair or replacement.

RETURNS

If you are not satisfied with your purchase for any reason, please contact Customer Service or your local distributor prior to returning the product. Visit https://www.cirsinc.com/distributors/ to find your local distributor. Call 800-617-1177, email rma@cirsinc.com, or fax an RMA request form to 757-857-0523. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or "customized" products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

WITH RMA NUMBER, ITEMS MAY BE RETURNED TO:

CIRS
Receiving
900 Asbury Ave,
Norfolk, Virginia, 23513 USA

PRODUCT	WARRANTY PERIOD
Model 040GSE - Multi-Purpose, Multi-Tissue Ultrasound Phantom	48 Months

APPENDIX 1: QUALITY ASSURANCE RECORD FOR MODEL 040GSE

MODEL 040GSE

MULTI-PURPOSE MULTI-TISSUE ULTRASOUND PHANTOM

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_____ **Post Processing**_____**Dynamic Range** _____

Other: _____

TEST		BASELINE REMARKS	TEST RESULTS	VARIANCE	COMMENTS
Uniformity					
Depth of Penetration					
Beam Profile/ Focal Zone/ Lateral Width Response					
Vertical Distance					
Horizontal Distance	4 cm				
	9 cm				
Axial Resolution	3 cm				
	6.5 cm				
	10.5 cm				
Lateral Resolution	3 cm				
	6.5 cm				
	10.5 cm				
Elevational Resolution					
Contrast Resolution					
Gray Scale Contrast Sensitivity	3 cm				
	11.5 cm				
Elasticity Contrast Sensitivity	1.5 cm				
	5 cm				
Dead Zone Assessment					

Duplicate as Needed

One Sheet Per System Setup

COMPUTERIZED IMAGING REFERENCE SYSTEMS, INC.
900 Asbury Ave
Norfolk, Virginia 23513 • USA
TOLL FREE 800.617.1177
TEL: 757.855.2765
FAX: 757.857.0523
EMAIL: admin@cirsinc.com
www.cirsinc.com

Technical Assistance
1.800.617.1177

Publication: 040GSE UG 093021

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