Multi-Purpose, Multi-Tissue Ultrasound Phantom

Model 040GSE

ZERDINE® *Inside*
A registered trademark of CIRS

USER GUIDE

CIRS
2428 Almeda Avenue Suite 316 • Norfolk, Virginia 23513 • USA • Tel: 757-855-2765
WWW.CIRSINC.COM

CONTENTS

Handling Precautions and End of Life Disposal 1
Overview 2
Phantom Description 2
Specifications 3
Zerdine® 6
Use of the Removable Water Well and Covers 6
Establishing a Baseline With Your New Phantom 7
Routine Quality Control Measurements 8
Uniformity 9
Near Field Group 9
Vertical Distance Group 10
Horizontal Distance Group 13
Axial / Lateral Resolution Groups 14
Anechoic Stepped Cylinders 16
Gray Scale Targets 17
Elasticity Target Groups 18
Analysis 18
Warranty 19

HANDLING PRECAUTIONS AND END OF LIFE DISPOSAL

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 stored at room temperature. The phantom SHOULD NOT be subjected to freezing or boiling conditions such as those encountered in the trunk of a car during a South Dakota winter or Arizona summer. The most accurate measurements will be made with the phantom 22˚C ± 1˚C (70˚F – 73˚F).

Always store the phantom with the removable storage cover attached and in the air-tight carry case provided to maximize life expectancy.

Zerdine® will desiccate over time if the phantom is not stored properly. If there is a noticeable change in the phantom the phantom should be returned IMMEDIATELY for repair or replacement.

Inspect your phantom regularly for signs of damage.

Regular inspection for weight loss is essential to maintaining your phantom. At least once a year, weigh your phantom and compare to original weight noted on certificate of compliance. If phantom has lost or gained more than 1% of its original weight and you notice a difference in vertical distance measurements, or 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 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 Zerdine containing trace monomer acrylamide below levels necessary to cause adverse health effects. Nonetheless, it is advised to wear protective gloves if handling exposed Zerdine gel. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.

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.

OVERVIEW

The Model 040GSE Multi-Purpose, Multi-Tissue Ultrasound Phantom was designed to provide a sturdy, reliable phantom containing the fundamental tests to assess imaging performance of an ultrasonic system over time. The Model 040GSE contains features which make it compatible with diagnostic ultrasound systems that integrate enhanced tissue characterization and elastography.

PHANTOM DESCRIPTION

Unlike human subjects or random scannable material, the Model 040GSE Multi-Purpose, Multi- Tissue Ultrasound Phantom offers a stable medium and contains specific, known test objects. The phantom is constructed from Zerdine, which simulates the acoustic properties of human soft tissue. It is housed in rugged ABS plastic for added durability. The phantom is designed to accommodate a wide variety of transducer shapes and frequencies.

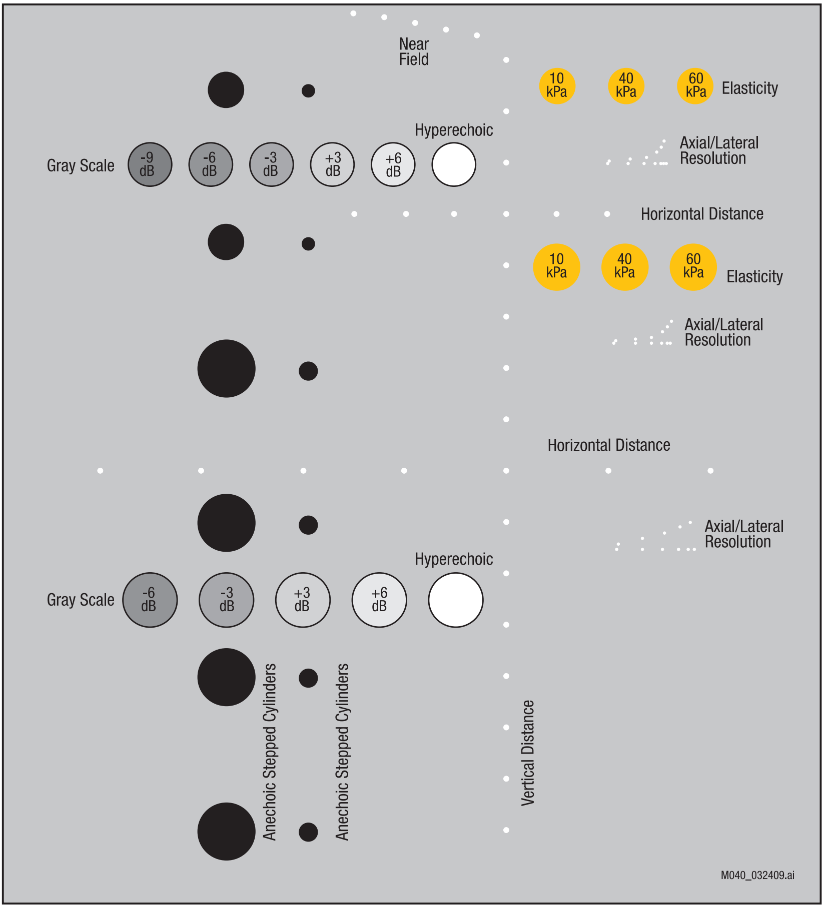
The Model 040GSE has a series of wire targets that will appear as bright dots or lines on the ultrasound image. These targets are made from nylon monofilament with a diameter of 0.1 mm and 0.08 mm. The phantom also contains grey scale targets at two depths to assess contrast sensitivity between -9dB and +15DB with respect to the background. Elasticity targets have been set at two depths with stiffness of 10, 40, and 60kPA. By design, the background elasticity is 24 kPa. Targets to measure axial and lateral resolution and anechoic stepped cylinders to measure response to small cysts are standard to Model 040GSE.

To maximize the frequency range in which the phantom may be used, the background material has two different attenuations: 0.5 and 0.7 dB/cm-MHz. The scanning surface is marked to indicate the nominal attenuation on each half and a centerline to show where the attenuation change occurs. It is recommended to use the 0.5 dB/cm-MHz side for frequencies 5 MHz and above and to use the 0.7 dB/cm-MHz side for frequencies 5 MHz and below.

CIRS is certified to ISO 9001:2008 standards. We have an in-house test facility to measure acoustic properties of speed and attenuation. In addition, ultrasound systems are used to assess relative contrast and visually inspect each phantom. Every ultrasound phantom 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.

For further guidance on establishing a quality assurance program, reference the accreditation programs established by the ACR and AIUM at www.acr.org or www.aium.org.

SPECIFICATIONS



PHANTOM HOUSING

Material	ABS
Outer Dimensions	17.8 x 12.7 x 20.3 cm (7 x 5 x 8")

SCANNING SURFACE

Material	Saran-based laminate
Dimensions	14 x 9 cm (5.5 x 3.5")

BACKGROUND MATERIAL ONE

Material	Zerdine
Speed of Sound	1540 m/s ± 10 m/s
Attenuation Coefficient	0.5 dB/cm-MHz & 0.7 dB/cm-MHz
Other	Compatible with harmonic imaging

BACKGROUND MATERIAL TWO

Material	Zerdine
Speed of Sound	1540 m/s
Attenuation Coefficient	0.7 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	4 & 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

Diameter (mm)							
Depth (cm)		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

Contrast, dB							
Depth & Diameter		-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

Material Zerdine
Background Elasticity 24 kPa

Elasticity value, kPa				
Depth & Diameter		10	40	60
	1.5 cm, Ø 6 mm	X	X	X
	5 cm, Ø 8 mm	X	X	X

Table 3 - Elasticity Targets Location, Elasticity Value and Diameter:

ACCESSORIES

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

NOTES

All dimensions without tolerances are nominal
All measurements made at 22°C ± 1°C
All speed of sound and attenuation measurements made with 5 MHz focused transducer

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 90 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.

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.

Coupling gel can be applied directly to the scan surface. This option is best used with linear transducers. If a curved array is utilized, coupling may be better with water and a removable water well is provided. 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 it’s back and the cover should be filled with water.

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

ESTABLISHING A BASELINE WITH YOUR NEW PHANTOM

Please read the following sections of this manual carefully before embarking on a QA program.

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.

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 conclusions 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 anywhere 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.

ROUTINE QUALITY CONTROL MEASUREMENTS

The Model 040GSE can be used to assess:

- Uniformity
- Dead Zone
- Depth of Penetration
- Beam Profile/Focal Zone/Lateral Response Width
- Vertical Distance Measurement
- Horizontal Distance Measurement
- Axial Resolution
- Lateral Resolution
- Anechoic Masses
- High Contrast Masses
- Contrast Sensitivity
- Elasticity

Using the correct instrument settings is also imperative to the proper evaluation of the ultrasound system.

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 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.

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.

Uniformity Testing Procedures

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” liver 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.

NEAR FIELD GROUP

The near field group 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”, “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.

The near field group consists of parallel, 100 micron diameter, nylon, monofilament 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 5 mm down to 1 mm in 1 mm increments.

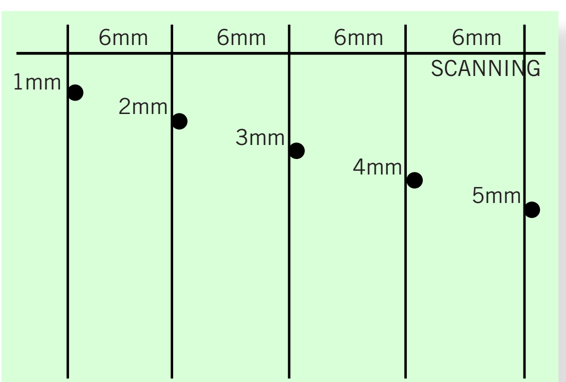


Figure 1 - Near Field Target
Wire Diameter 0.1 mm

Near Field Testing Procedures

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. 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.

   Example:
   Total # of targets in group = 5
   # of targets actually seen = 3
   Dead-Zone Distance = 5 - 3 = 2 mm

   An alternative method 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 4 mm".
6. Record this distance and compare with baseline measurements.

VERTICAL DISTANCE GROUP

The Vertical Distance Group is useful for many different measurements. This group assesses the depth of penetration, beam profile, lateral response width, vertical distance calibration, and focal zone of an imaging system. A Vertical Plane is a plane perpendicular to the scanning membrane plane and perpendicular to the target wires.

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 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.

Depth of Penetration Testing Procedures

ATTENTION:
To register accurate vertical distance measurements, DO NOT APPLY PRESSURE TO THE SCANNING SURFACE! CIRS strongly encourages 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 scanning surface. As with a patient, even the slightest amount of pressure on the scanning surface will cause incorrect distances to be measured.

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" 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 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 backscattered 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 2***. 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.

Beam Profile, Focal Zone, and Lateral Response Width Testing procedures

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" 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 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.

7. 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.

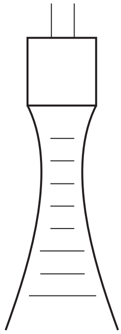


Figure 2 - Typical Beam Profile

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 and save the hard copy.

Vertical Distance Calibration

A vertical distance is defined as the distance along the axis of the beam.

Vertical Distance Testing Procedures

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” 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.

HORIZONTAL DISTANCE GROUP

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. There are two horizontal plane target groups. The 3 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 target diagram attached to your phantom.

Horizontal Distance Testing Procedures

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” 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.

AXIAL / LATERAL RESOLUTION GROUPS

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 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.

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.

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. In *Figure 3* they are labeled from A1 to A7 to assess the lateral resolution and B1 to B6 to assess the axial resolution. *Table 4* shows which wires to use to assess the various distance resolution.

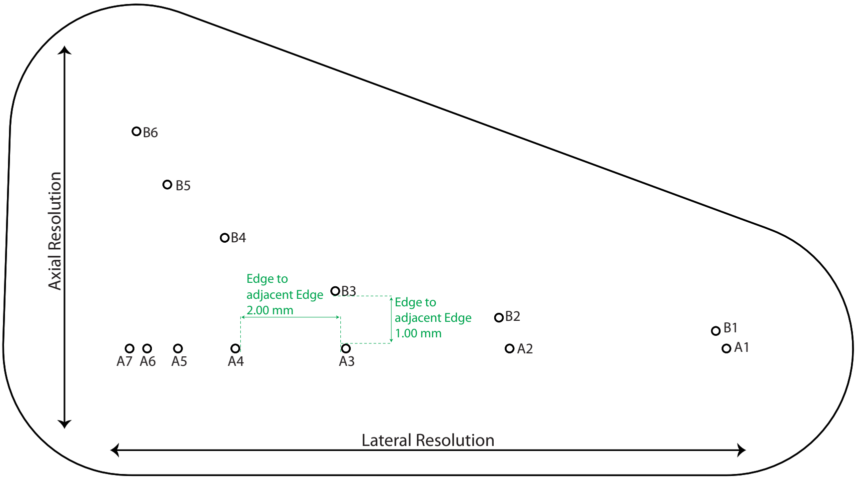


Figure 3 - Combined Axial/Lateral Resolution Targets at 3 and 6.5 cm depth

	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

Table 4 - Assessing Distance Resolution

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. In *Figure 4* targets are labeled from C1 to C6 to assess the lateral resolution and D1 to D5 to assess the axial resolution. *Table 5* shows which wires are used to assess the various distance resolution.

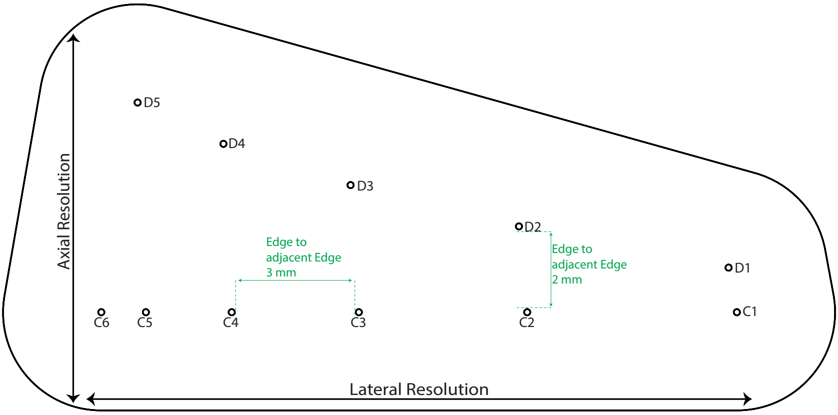


Figure 4 - Combined Axial/Lateral Resolution Target at 10.5 cm depth

	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

Table 5 - Assessing Distance Resolution

Axial or Lateral Resolution Testing Procedures

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” 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 is separated by a distance of 1 mm then record the axial resolution as being “in between 0.5 mm and 1.0 mm”.

ANECHOIC STEPPED CYLINDERS

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. Then the four deeper cylinders. (see table 1 for the size and depth of each cylinder)

By design, the cross-sectional area ratio of any two adjacent steps has been fixed at 1.5. In other words, the ratio of the cross section area of 2.00 mm diameter mass divided by the cross section area of the next 1.33 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 pairs parallel and flipped 180 degrees to each other allowing all diameters in the 0.5 dB background as well as the 0.7 dB background to be available. *See* ***Table 1***, and ***Figure 5*** for location and arrangement of the cystic masses.

To minimize the effects of shadowing and enhancement behind targets, all targets have an attenuation of 0.5 dB.

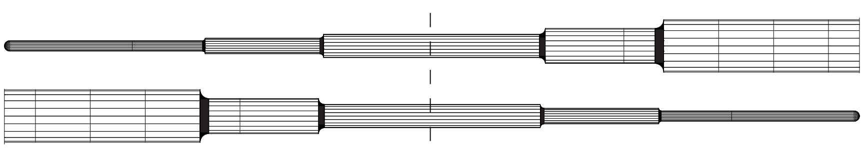


Figure 5 - Top View of the Anechoic Stepped Cylinders Arrangement

Anechoic Stepped Cylinder Testing Procedures

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.

GRAY SCALE TARGETS

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 higher for low contrast values between –9 dB up to > +15 dB. The second group at depth of 11.5 cm depth provide low contrast scale from -6 dB to > +15 dB. *See* ***Table 2.***

The dynamic range of an ultrasound imager can be evaluated using the gray scale masses in conjunction with the cystic masses and the hyper echoic masses. We added a -9 dB mass in the first group to extend the range of low-level contrast for the new generations of transducers.

Gray Scale Targets Testing Procedures

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” 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.

ELASTICITY TARGET GROUPS

The Model 040GSE provides elasticity targets for the next generation of ultrasound imagers using elastography. The elasticity value for the background is 24 kPa.

The target group at 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 value of 10, 40 and 60 kPa.

Those targets are suitable for assessing the dynamic range of sonoelastography systems, for optimizing the imaging settings and for checking their performances over time. To demonstrate the capabilities of the system the B-mode contrast of the target is equivalent to the background so that those targets are clearly visible only under sonoelastography.

Elasticity Targets Testing Procedures

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. (The targets may not be visible at all, use label for positioning).
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.
6. Record your observations.

ANALYSIS

It is recommended that these measurements be performed at the most frequently used imaging arrangements. The importance of these tests is to make sure the 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.

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.

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 prior to returning the product. 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
2428 Almeda Avenue Suite 218,
Norfolk, Virginia, 23513 USA

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

CIRS
COMPUTERIZED IMAGING
REFERENCE SYSTEMS, INC.
2428 Almeda Avenue • Suite 316
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 101915

Computerized Imaging Reference Systems, Inc. has been certified by UL DQS Inc. to **(ISO) 9001:2008**. Certificate Registration No.10000905-QM08.