Small Parts Ultrasound Phantom

Model 050

ZERDINE® *Inside*
A registered trademark of CIRS

ULTRASOUND QUALITY ASSURANCE

USER GUIDE

CIRS

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

TABLE OF CONTENTS

OVERVIEW

The Model 050 is a sturdy, reliable phantom for testing the imaging performance of ultrasound systems. It's small form factor and feature set is designed specifically for small parts testing.

The phantom is made of CIRS' proprietary Zerdine® hydrogel polymer, which has been formulated to provide tissue mimicking properties including compatibility with harmonic imaging. To maximize phantom lifetime, this gel is contained in a rugged ABS plastic housing with a Saran-based laminate membrane.

The Model 050 has a series of wire targets that will appear as bright dots or lines on the ultrasound image. These targets are made from nylon with a diameter of 0.10 mm and a positional accuracy of ± 0.2 mm. There are also two known volumes, a 10 mm anechoic/+15 dB mass and anechoic focal lesions embedded within the phantom. These "masses" are made from Zerdine that has a different contrast and attenuation relative to the background material.

Key Tests with Model 050

- Focal Lesion Detectability
- Uniformity
- Depth of Penetration
- Beam Profile/ Focal Zone/ Lateral Response Width
- Vertical Distance Measurement
- Horizontal Distance Measurement
- Axial and Lateral Resolution
- Elevational Resolution
- Low-Contrast Target Detectability
- High-Contrast Target Detectability
- Volumetric Measurement Accuracy
- 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 speed, attenuation and relative contrast. In addition, two ultrasound systems are used to visually inspect each phantom. As a result, every ultrasound phantom is subjected to rigorous testing both during manufacture and upon completion. The user may observe very minor imperfections within the product such as: very slight inhomogeneities with the background speckle pattern and only seen under certain conditions or a very small air bubble in a place that does not impact utility or integrity of the phantom. Any such anomalies have been determined, by CIRS engineers, to not impact the quality, performance or usability of the product and are deemed "aesthetic imperfections". A Certificate of Compliance is issued with each phantom.

For further guidance on establishing a quality assurance program, you may want to reference the accreditation programs established by the ACR and AIUM. You can access this information at www.acr.org or www.aium.org. If additional information is required, please call CIRS technical service at 1-800-617-1177.

INSTRUCTIONS FOR USE

HANDLING AND CARE

With proper care, the Model 050 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 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 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.

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.
- 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.

TEST PROCEDURES

The following sections outline procedures for performing routine quality control tests with the imaging targets contained within the Model 050. It may be useful to refer to the target map, shown in the Specifications section, when reviewing these procedures.

FOCAL LESION DETECTABILITY

Detection of focal lesions is also extremely important in diagnostic ultrasound exams. The ability to see these lesions at various depths is dependent on axial, lateral, and elevational resolution. To achieve a better exam it is important for the sonographer to know, for each transducer, over what depth range focal lesions of various sizes are visible. The Model 050 contains two sections of randomly distributed focal lesions: one with 3 mm diameter anechoic spheres and the other with 5 mm diameter anechoic spheres. Measurement of focal lesion detectability is performed as follows:

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

FOCAL LESION DETECTABILITY (CONTINUED)

2. Position the transducer above focal lesions.
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. Slide the transducer back and forth until a plane of lesions over a wide depth range are visible.
5. Observe when you can begin to see the lesions and at what depth you can no longer detect the lesions.
6. Record depth range lesions are visible.

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, and is performed as follows:

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 width of 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 due to scatterers can be detected on the display. The depth of penetration is determined by the frequency of the transducer, the attenuation and scattering properties of the medium being imaged, and the system settings. Depth of penetration is tested as follows:

1. Apply coupling gel to the scanning surface 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” 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

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 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 1. The narrowest region within the beam profile is the focal point. 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 plane targets are useful for determining the beam profile and the focal zone of a system, as follows:

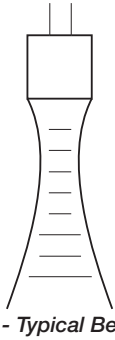


Figure 1 - Typical Beam Profile

1. Apply coupling gel to the scanning surface 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 and save the hard copy image.

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.

AXIAL 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, 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.

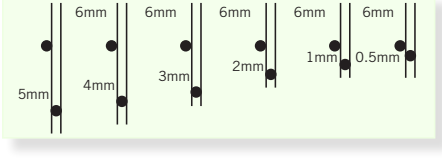


Figure 2 - Axial Resolution Target

The axial resolution target consists of six pairs of parallel, 0.10 mm diameter wires horizontally spaced 6 mm apart from center to center (see figure 2). The lower wire in each pair is horizontally offset from the upper wire by 1 mm 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 2.0 cm using the following procedure:

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

LATERAL RESOLUTION TESTING

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. Within the focal zone, the lateral resolution is at its best.

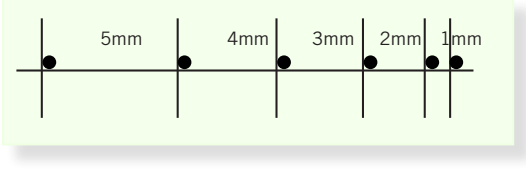


Figure 3 - Lateral Resolution Target
Wire Diameter - 0.1 mm Positional Accuracy ±0.2 mm

The lateral resolution target is positioned at a depth of 1.5 cm (see figure 3). Six parallel wires are horizontally spaced 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, as follows:

1. Apply coupling gel to the scanning surface 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” 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.

ELEVATIONAL TESTING

A full characterization of system resolution requires a 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.

The vertical wire targets may be used to assess elevational resolution using the method first described by Skolnick[1] . As implemented in the Model 050, this procedure is 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.

HORIZONTAL DISTANCE MEASUREMENTS

The axial and lateral resolution target groups have wires spaced in a horizontal line that may be used to determine the accuracy of measurements made perpendicular to the beam axis. See figures 2 and 3, shown on pages 8 & 9. 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.

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

7. Record these measurements.
8. Compare the measured values with the known distances between the targets.

LOW-CONTRAST TARGET DETECTABILITY

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 050, a cylinder having no scatter on one half is provided in the phantom to test a machine's ability to image cyst-like structures. The cylinder diameter is 10 mm at a depth of 1 cm. Because of the low attenuation in this mass, you may notice brightening underneath them.

Use the following procedure to determine the accuracy of the machine's representation of the mass (proper size and shape):

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" 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 the mass.
8. Record your observations and measurements on a data sheet.

HIGH-CONTRAST TARGET DETECTABILITY

In the Model 050, a cylinder having contrast that is +15 dB with respect to the background material is provided on one side of the phantom to test a machine's ability to image a solid tumor. The cylinder diameter is 10 mm at a depth of 1 cm. This mass is useful in determining the ultrasonic system's capability of distinguishing high scatter targets. Because of the high attenuation in this mass, you may notice shadowing behind the target.

Use the following procedure to determine the accuracy of the machine's representation of the mass (proper size and shape):

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).

HIGH-CONTRAST TARGET DETECTABILITY (CONTINUED)

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. 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.

VOLUMETRIC MEASUREMENT ACCURACY

Many patient exams involve measuring and tracking the rate of change in the volume of various structures within the body. The Model 050 contains two different calibrated test objects designed to assess volume measurement accuracy. The volume of each test object is physically measured with a tolerance of ± 0.5 cc using Archimedes Principle before insertion within the phantom. The volumes are recorded on the accompanying certification sheet. Volume measurements are as much dependent on user ability as system performance.

Volume measurements may be performed on the Model 050 as follows:

1. Apply coupling gel to the scanning surface or fill the water trough with tap water.
2. Position the transducer above the volume of interest.
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. The volume of each test object should be computed using the methods/software provided with the ultrasound system or as performed on a patient.
6. Record measurements.
7. Compare measured volumes with baseline volumes.
8. Repeat steps for each volume within phantom.

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” 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.

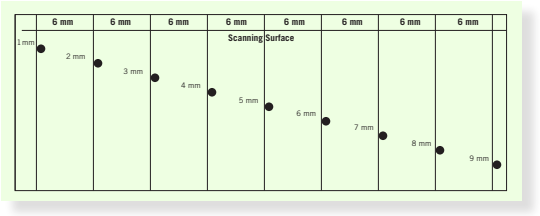


Figure 1 - Near Field Target
Wire Diameter - 0.10 mm Positional Accuracy ±0.2 mm

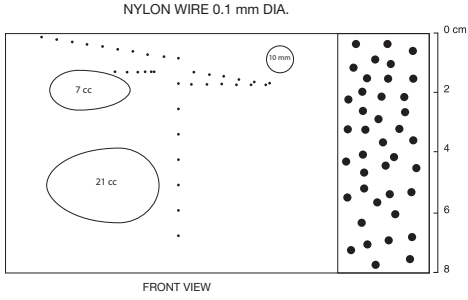
The near field target consists of parallel, 0.10 mm diameter, stainless steel wires horizontally spaced 6 mm apart from center to center (Figure 1). Vertical distance from the center of each wire to the top edge of the scanning surface ranges from 5 mm down to 1 mm in 1 mm increments.

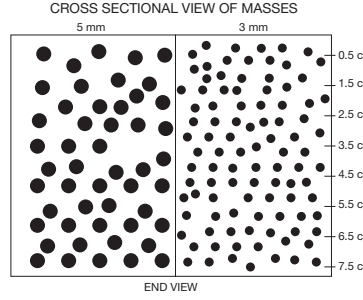
The depth of the dead zone may be measured as follows:

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





CONTAINER
Dimensions: 200 x 150 x 100 mm
Weight: 18 lbs (6.7 kg)
Material: ABS Housing

BACKGROUND GEL
Zerdine, solid elastic water-based polymer
Freezing Point: 0º C
Melting Point: Above 100º C
Attenuation Coefficient: 0.5 dB/cm-MHz
Speed of Sound: 1540 m/s

SCANNING WELL
165 x 100 x 10 mm deep

SCANNING MEMBRANE
Saran-based laminate[1]

WIRE TARGETS
Material: Nylon Wire
Diameter: 0.10 mm

NEAR FIELD GROUP
Number of Targets: 10
Depth Range: 1 to 10 mm
Vertical Spacing: 1.0 mm

VERTICAL GROUP
Depth Range: 10 to 80 mm
Spacing: 10 mm
Material: 0.1 mm Nylon Wire

AXIAL RESOLUTION GROUP
Number of targets: 12
Depth: 20 mm
Spacing: 0.5, 1, 2, 3, 4 & 5 mm

NOTES
All dimensions without tolerances are nominal

All measurements made at 22˚C ± 1˚C

LATERAL RESOLUTION GROUP
Number of targets: 6
Depth: 15 mm
Spacing: 1, 2, 3, 4 & 5 mm

HIGH CONTRAST/ CYSTIC ROD
Material: Zerdine
Diameter: 10 mm
Depth: 10 mm
Attenuation Coefficient- Cystic Half: less than 0.1 dB/cm-MHz
Contrast- Cystic Half: anechoic
Attenuation Coefficient- High Contrast: 1.2 dB/cm-MHz
Contrast- High Contrast: hyperechoic

FOCAL LESIONS
Diameter of Targets: 3 & 5 mm
Random Distribution

VOLUMETRIC TEST OBJECTS
Target 1:
Contrast: +9 dB
Depth: 20 mm
Volume: 7 cc
Long axis length: 39 mm
Short axis diameter: 18 mm

Target 2:
Contrast: +9 dB
Depth: 47 mm
Volume: 21 cc
Long axis length: 46 mm
Short axis diameter: 29 mm

MODEL 050 INCLUDES
Small Parts Ultrasound Phantom
Certificate of Compliance
Carry Case
Removable Scanning Wells
User Guide
QA Worksheet
48-month Warranty

[1] The standard Saran laminate has been validated for use with clinical small parts probes up to 15 MHz. Users wishing to test higher frequency preclinical imaging systems should contact CIRS for alternate membranes more suitable for high frequency imaging.

ZERDINE®

The Model 050 is constructed from a patented, solid elastic material developed at CIRS 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 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, 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 your local distributor prior to returning the product. Visit https://www.cirsinc.com/distributors/ to find your local distributor. If you purchased your product direct through CIRS, call Customer Service at 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 050 - Small Parts Ultrasound Phantom	48 Months

APPENDIX 1: QUALITY ASSURANCE RECORD FOR MODEL 050

MODEL 050
SMALL PARTS 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					
Axial Resolution					
Lateral Resolution					
Elevational Resolution					
Contrast Resolution					
Gray Scale Contrast Sensitivity					
Elasticity Contrast Sensitivity					
Near Field					

WORKSHEET INSTRUCTIONS

TEST	EXAMPLE TEST RESULTS	COMMENTS (See User's Guide 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
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	no distortion	Note general appearance and diameter
High Scatter Mass	no distortion	Note general appearance and diameter
Shallow Volume	6.8 cc (manual)	Compare measured volume with known volume also indicate technique used to acquire volume.
Deep Volume	21.3 cc (manual)	Compare measured volume with known volume also indicate technique used to acquire volume.
3 mm Focal Lesions	0.5 cm – 4.7 cm	Indicate range of depths lesions are visible
5 mm Focal Lesions	scan surface – 7 cm	Indicate range of depths lesions are visible

Duplicate as Needed:
One Sheet Per System Setup
*(800) 617-1177 * (757) 855-2765 or Fax (757) 857-0523*

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: 050 UG 121619

Computerized Imaging Reference Systems, Inc. has been certified by UL DQS Inc. to **(ISO) 13485:2016**. Certificate Registration No.10000905-MP2016.