Three-Dimensional Wire Test Object

Model 055A

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 055A 3D Wire Test Object is a sturdy, reliable phantom for assessing volumetric measurement accuracy in either 3D scanning systems or free hand measurements.

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

Spatial Measurements with Model 055A

- Linear Distance
- Perimeter
- Area
- Volume (3D system or freehand calculations

The phantom may also be used to determining image uniformity and depth of penetration.

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. 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 055A 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 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 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 ultra sound 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 deter mine. 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 performing routine quality control tests with the imaging targets within the Model 055A. It may be useful to refer to the target map, shown in the Specifications section, when reviewing these procedures.

DISTANCE

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.

DISTANCE (CONT)

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.

The horizontal target group is used to determine the accuracy of measurements made perpendicular to the beam axis. The figure and table on page 9 provide a wire target map that can be used to find the position of horizontal wire target. 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.

PERIMETER, AREA AND VOLUME MEASUREMENTS

Ultrasound imaging systems may detect differences in echogenicity of tissue structures and determine the dimensions of those structures through boundary detection. Spatial measurement data collected will give an indication of the accuracy that the system is capable of. For more information see "Standard Methods for Calibration of 2-Dimensional and 3-Dimensional Spatial Measurement Capabilities of Pulse Echo Ultrasound Imaging Systems." AIUM: 2004.

Using the 2D shapes shown in the taget diagram on page 9, areas and perimeters may be determined by connecting lines between the filament targets. Linear measurements are taken from an image which is on a plane perpendicular to the line targets.

To calculate a surface area or volume, an image is taken at a particular scan plane. Using the calipers, the dimensions of the 2D shape are taken and the area is determined using the system's algorithms. Next, perform a 3D scan of the line targets with the scan planes parallel to each other and the scan direction perpendicular to the axes of the line targets. The distance between the first scan plane and the last, multiplied by the 2D area will give the 3D volume. This system calculated value may then be compared to the actual volumes calculated from the rod lengths, and the areas coincident with the 2D shape utilized.

Testing Procedure:

1. Place the phantom on a clean, flat surface with scanning surface #1 positioned for use.
2. Apply an adequate amount of low viscosity gel the scan surface.
3. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for a "normal" technique. If the bottom of the phantom is seen, adjust the gain settings until the bottom of image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
4. Position the transducer over the line target group until a clear image is obtained.
5. Freeze image and obtain a hard copy.
6. Measure the appropriate 2D dimensions
7. Perform a 3D scan.
8. Compare computed and system algorithm spatial measurements
9. All findings should be documented on the quality assurance record

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 image.
7. Record your observations.

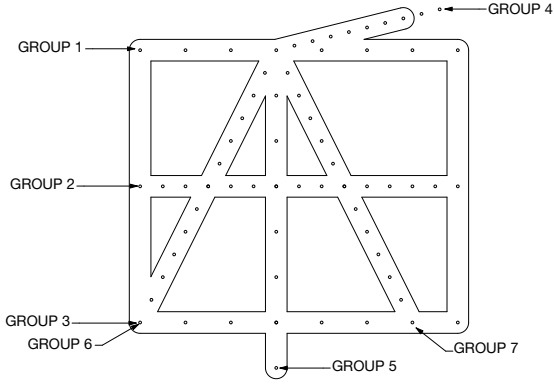
DEPTH OF PENETRATION TESTING

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. It is measured with the aid of the vertical distance group of wire targets, as follows:

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 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.

SPECIFICATIONS – MODEL 055A

TARGET LAYOUT



GROUP	STARTING POSITION (X, Y)	SUBSEQUENT WIRE MOVES
1	(0 cm, 0 cm)	Δx= 1 cm, Δy= 0 cm
2	(0 cm, 3 cm)	Δx= 0.5 cm, Δy= 0 cm
3	(0 cm, 6 cm)	Δx= 1 cm, Δy= 0 cm
4	(3 cm, 0 cm)	Δx= 0.4 cm, Δy= -0.1 cm
5	(3 cm, 0 cm)	Δx= 0 cm, Δy= 1 cm
6	(3 cm, 0 cm)	Δx= -0.25 cm, Δy= 0.5 cm
7	(3 cm, 0 cm)	Δx= 0.25 cm, Δy= 0.5 cm

PHANTOM HOUSING

Material	1/4” Black ABS
Dimensions (Outer)	18 cm x 13 cm x 11 cm
Dimensions (Inside)	11.5 cm x 16.5 cm x 11 cm
Scanning Surface	Saran-based Laminate

BACKGROUND MATERIAL

Material	Zerdine®
Speed of Sound	1540 m/s
Other	Compatible with harmonic imaging

WIRE TARGETS

Material	Nylon monofilament
Diameter	0.1 mm

NEAR FIELD GROUP

Number of targets	10
Depth range	1 mm to 10 mm
Vertical distance between targets	1 mm

VERTICAL GROUP

Number of groups	3
Depth range	1-8 cm
Number of targets	Groups 6 & 7: Qty. 13 Group 5: Qty. 8
Vertical distance between targets	Groups 6 & 7: 0.5 cm Group 5: 1 cm

HORIZONTAL GROUP

Number of groups	3
Depth of each group	1, 4, & 7 cm
Horizontal distance between targets	Groups 1 & 3: 1 cm Group 2: 0.5 cm

ACCESSORIES

- Removable water well (made of 1/8" ABS with a 14.4x9.5x1.0 cm opening)
- Removable endocavity cover (made of 1/8" ABS plastic)
- Removable storage cover (made of 1/8" ABS plastic)
- Carry case, Certificate of Compliance
- Model 055A User Guide

NOTES

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

ZERDINE®

The Model 055A 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 055A - 3D Wire Test Object	48 Months

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: 055A UG 032520

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