Three-Dimensional Ultrasound Calibration Phantom

Model 055

ZERDINE® *Inside*
A registered trademark of CIRS

ULTRASOUND QUALITY ASSURANCE

USER GUIDE

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OVERVIEW

The Model 055 3D Ultrasound Calibration phantom is a sturdy, reliable phantom for assessing volumetric measurement accuracy in either 3D scanning systems or free hand measurements. The ellipsoidal (egg) object geometry of the Model 055 targets provides a full system test, including sonographer care and ability.

Assessing Accuracy of Spatial Measurements with Model 055

- Linear Dimensions
- Maximum Cross-Sectional Dimensions
- Perimeter
- Area
- Volume (3D system or free-hand calculations

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 055 contains two calibrated volumetric test objects that hypoechoic with respect to the phantom background material. The nominal volume of the eggs are 6.9 cc and 69 cc with the smaller egg placed closer to the scanning surfaces than the larger volume shape. The phantom provides two scan windows to facilitate the many different methodologies of determining the volume of an object.

The difficulty of accurate measurements differs on the two eggs, with the larger being more challenging as none of the cross-sections to be measured can be relied on to be circular.

For Additional information reference AIUM Publication: Standard Methods for Calibration of 2-Dimensional and 3-Dimensional Spatial Measurement Capabilities of Pulse Echo Ultrasound Imaging Systems.

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 055 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.

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:

- 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.
- 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 Model 055 is designed for evaluation of spatial measurements and volumetric calculations. The targets are not centered within the background material. Depending upon what side you scan, the test object is located at distances ranging from 1 cm to 6 cm from the scanning surface. The volume of each test object is physically measured with a tolerance of 0.5 cc using the water displacement tech nique before insertion within the phantom. The volume is recorded on the certification sheet that accompanies each phantom.

This phantom can be used as a training and test device for sonographer's abilities to make 1, 2 and 3D measurements on complex shapes. To make the test more difficult and objective, the test object could be immersed in a small water tank where none of its surfaces are parallel to surfaces of the water tank. No actual measurements on the screen should be allowed until each of the required image plans is accepted and frozen. For fairness, several attempts with different phantom positions in the water tank should be allowed.

LINEAR DIMENSIONS

Place the caliper markers on the ends of the largest vertical diameter obtainable and record this value. A horizontal diameter is measured in a similar way. Compare these values with the known values included with the phantom.

MAXIMUM CROSS-SECTIONAL DIMENSIONS

In both eggs, the longest linear dimension, the length of the egg, can be found with relative ease. The other two linear dimensions can be measured in the small egg by finding the views in which the cross-section of the phantom is circular. Then scan back and forth to find the plane in which the cross-sectional area is maximized. For the large egg, there is no circular cross-section and every slice through it from any angle will be an ellipse. After obtaining a view of the longest axis of the egg, rotate the transducer 90 degrees around the central beam line of the array. Now scan the transducer, keeping the image planes parallel to each other and therefore keeping the same length to width ratio in that image plane. Continue scanning linearly without tilting or rotating the transducer until the view with the maximum area of the egg is found. From these images the three largest perpendicular axis of the ellipse can be measured.

PERIMETER AND AREA

Most ultrasound machines on the market today will compute perimeters and areas of various elliptical shapes. Simply follow the operator manual's procedures and compare the results with the known dimensions of the test object. You can also manually position caliper markers around the perimeter of the test object to estimate the perimeter. The estimated perimeter, in this instance, would be the sum of the lengths of all the line segments created to form the object. Again, compare the results when the enclosed area is calculated when the perimeter is measured. The measured area values should be compared against the known areas for the egg cross sections.

VOLUMES

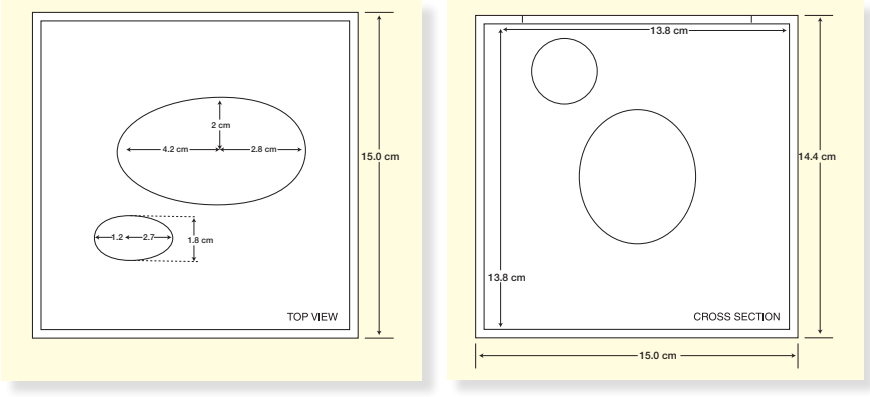
The volume of the test object can be computed by using methods provided by the machine being used or with the methods suggested below. One way to approximate the volume is to measure the length of the axis in the two orthogonal planes.

$$\text{Volume} = \frac{4}{3} \cdot \prod \cdot (a \cdot b \cdot c)$$

Where a, b, and c are the measured lengths of the axis.

Repeat the above procedures for the other transducers of the imaging system. Record enough information to allow another operator to repeat the calibrations at a later date. Calculate and tabulate the percent errors. The whole process is repeated for the various depths at which the target is positioned.

Specifications



PHANTOM HOUSING

Material	1/4” Black ABS
Outer Dimensions	15 x 15 x 15 cm

TOP SCAN WINDOW

Scanning Membrane	Saran-based laminate
Membrane Retainer	1/16” Black ABS
Dimensions of scan opening	12 cm x 12 cm x 1/16”

SIDE SCAN WINDOW

Scanning Membrane	Saran-based laminate
Dimensions of scan opening	11 cm x 11 cm x 1/4”

BACKGROUND GEL

Material	Zerdine, solid elastic water-based polymer
Speed of Sound	1540 m/s
Attenuation Coefficient	0.5 dB/cm-MHz
Contrast	0 dB
Freezing Point	0°C
Melting Point	Above 100°C
Other	Compatible with harmonic imaging

SMALL VOLUME

Material	Zerdine
Speed of Sound	1540 m/s
Attenuation Coefficient	0.5 dB/cm-MHz
Contrast	-9 dB
Nominal Volume	6.9 cc
Depth of target	2-6 cm from scanning surface

LARGE VOLUME

Material	Zerdine
Speed of Sound	1540 m/s
Attenuation Coefficient	0.5 dB/cm-MHz
Contrast	-9 dB
Nominal Volume	75 cc
Depth of target	2-6 cm from scanning surface

ACCESSORIES

Carry Case, Certificate of Compliance, Model 055 User Guide and Technical Information,

NOTES

All dimensions are nominal
All measurements made at 22˚C ± 1˚C

ZERDINE®

The Model 055 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.

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 055 - Three-Dimensional Ultrasound Phantom	48 Months

APPENDIX 1: QUALITY ASSURANCE RECORD FOR MODEL 055

MODEL 055
3D ULTRASOUND CALIBRATION 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				
Near Field				
Depth of Penetration				
Focal Point				
Vertical Distance				
Horizontal Distance				
Axial Resolution				
Lateral Resolution				
Low Scatter				
High Scatter				

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

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
Horizontal Distance	2.0 cm	Record distances between targets
Axial Resolution	0.5 mm is best	Record smallest distance seen between wires
Lateral Resolution	1 mm is best	Record distance between last two resolvable objects
Low Scatter	all visible, no distortion	Note masses which can be seen and measurement of diameter
High Scatter	all visible, no distortion	Note masses which can be seen and measurement of diameter

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