

Elasticity QA Phantoms

Models 049 & 049A



ZERDINE® Inside
A registered trademark of CIRS



USER GUIDE

CIRS

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Overview

The Model 049 and 049A Elasticity QA Phantoms are elasticity reference tools developed for both shear wave and compression elastography. The phantoms contain targets of known stiffness relative to the background material and range in stiffness, diameter and depth.

Both phantoms are made of CIRS' proprietary Zerdine® hydrogel polymer, which has been formulated to produce lesions of differing Young's modulus. To maximize phantom lifetime, this gel is contained in a rugged ABS plastic housing with a Saran-based laminate membrane.

The Model 049 Elasticity QA Phantom contains 10 mm and 20 mm diameter spheres of varying hardness relative to the background material. The spheres are located at depths of 15 mm and 35 mm respectively and will appear hyperechoic to the background using standard B-mode imaging.

The Model 049A contains sets of stepped cylinders that vary in diameter from 1.6 mm to 16.7mm. The stepped cylinders in each set are located at depths of 3 cm and 6 cm. Each set has a different hardness relative to the background material and will appear almost isoechoic to the background using standard B-mode imaging.

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". The embedded lesions may contain random inhomogeneities. Such inhomogeneities may prove useful in demonstrating the ability of sonoelastography techniques to discriminate subtle differences in material properties. A Certificate of Compliance is issued with each phantom.

Models 049 & 049A are Suitable for:

- Determining dynamic range
- Checking system performance over time
- Training and demonstrating of system features
- Research and development

INSTRUCTIONS FOR USE

HANDLING AND CARE

With proper care, the Model 049 and 049A 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, poly-acrylamide 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:

- 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 $22^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (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 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.

TEST PROCEDURES

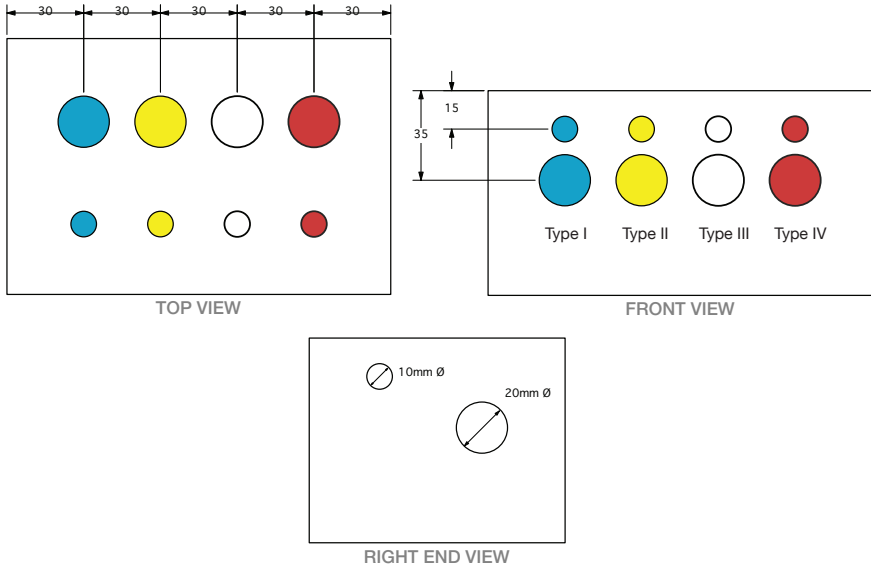
The Model 049 and 049A phantoms are designed as reference tools for performance assessment and training in both shear wave and strain imaging elastography.

Note that, due to differences in measurement methodology, the certified values for Young's modulus that are provided with the phantom may disagree with the values measured with your system. For more information, see:

Oudry J, Lynch T, Vappou J, Sandrin L, Miette V. Phys Med Biol. Comparison of four different techniques to evaluate the elastic properties of phantoms in elastography: is there a gold standard? 2014 Oct

Specifications - Model 049

TARGET LAYOUT



PHANTOM HOUSING

Material	1/4" Black ABS
Outer Dimensions	210 x 150 x 107 mm

SCANNING SURFACE

Material	Saran-based laminate
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MEMBRANE RETAINER

Material	1/16" Black ABS
Dimensions of scan opening	165 mm x 97 mm x 1/16"

REMOVABLE STORAGE COVER

Material	1/8" Black ABS
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BACKGROUND MATERIAL

Material	Zerdine
Speed of Sound	1540 m/s

LESIONS

Material	Zerdine
Speckle Contrast	Hyperechoic to background

ELASTICITY¹

Background	18
Lesion Type I	6
Lesion Type II	9
Lesion Type III	36
Lesion Type IV	70

10 MM DIAMETER LESION

Quantity	4 each at 15 mm depth One of each hardness
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20 MM DIAMETER LESION

Quantity	4 each at 35 mm depth One of each hardness
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ACCESSORIES

Carry case, Certificate of Compliance, Model 049 User Guide

NOTES

All dimensions without tolerances are nominal.

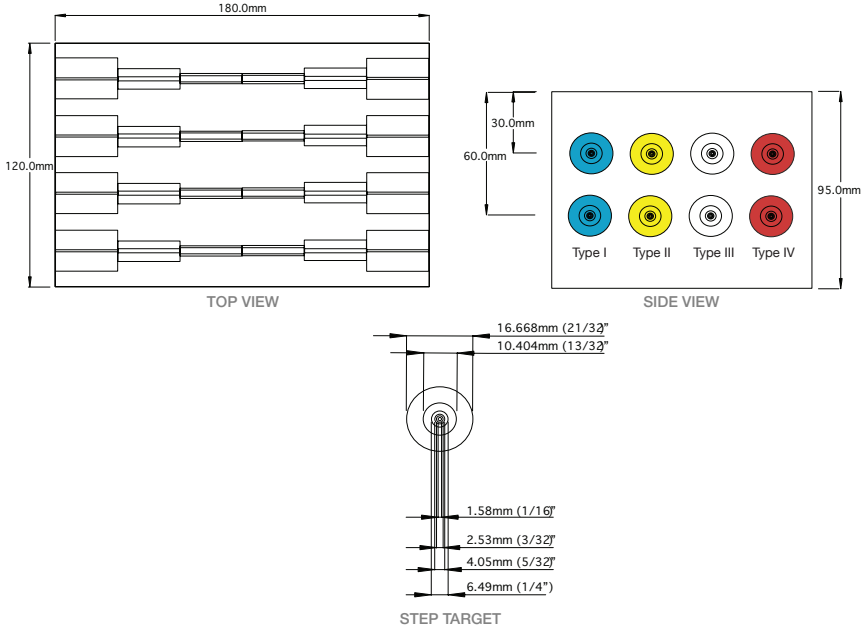
¹Elasticity values will vary depending on the measurement of the system used.

Batch sample measurements, made using a quasi-static compression load frame, are provided with the included certification sheet.

All measurements made at 22°C ± 1°C.

Specifications - Model 049A

TARGET LAYOUT



PHANTOM HOUSING

Material: 1/4" Black ABS
 Outer Dimensions: 210 x 150 x 107 mm

SCANNING SURFACE

Material: Saran-based laminate

MEMBRANE RETAINER

Material: 1/16" Black ABS
 Dimensions of scan opening: 165 mm x 97 mm x 1/16"

REMOVABLE STORAGE COVER

Material: 1/8" Black ABS

BACKGROUND MATERIAL

Material: Zerdine
 Speed of Sound: 1540 m/s

LESIONS

Material: Zerdine
 Speckle Contrast: Hyperechoic to background

ELASTICITY ²

Background	18
Lesion Type I	6
Lesion Type II	9
Lesion Type III	36
Lesion Type IV	70

STEPPED CYLINDERS

Quantity	8 Two of each hardness
Depths	3 & 6 cm deep
Diameters	1.6, 2.5, 4.1, 6.5, 10.4, 16.7 mm

ACCESSORIES

Carry case, Certificate of Compliance, Model 049A User Guide

NOTES

All dimensions without tolerances are nominal.

²Elasticity values will vary depending on the measurement of the system used.

Batch sample measurements, made using a quasi-static compression load frame, are provided with the included certification sheet.

All measurements made at 22°C ± 1°C.

All speed of sound and attenuation measurements made with 5 MHz focused transducer.

Zerdine[®]

The Model 049 and 049A 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 $A = A_0 F^n$ 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
Models 049 & 049A - Elasticity QA Phantoms	48 Months

CIRS

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