Elasticity QA Phantoms User Guide

Models 049 & 049A

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Elasticity QA Phantoms User Guide

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1 Introduction

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's 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.

Model 049A contains sets of stepped cylinders that vary in diameter from 1.6 mm to 16.7 mm. 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 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 and 049A

Models 049 and 049A are suitable for:

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

Figure 1-1. Model 049

2 Setup and Measurements

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 that 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 that 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 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.

3 Testing 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

4 Support and Maintenance

Hardware Maintenance

Inspection

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.

Note: *At least once a year, weigh your phantom and compare to the original weight noted on the 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, contact Sun Nuclear Support.*

Repair

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 Sun Nuclear Support for return authorization.

Cleaning

The phantom may be cleaned with mild soap and water ONLY. Avoid solvent-based, alcohol-based, or abrasive cleaning agents.

Storage

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.

CAUTION: 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.

Disposal and Recycling

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 Sun Nuclear.

Contacting Sun Nuclear Support

You may request support in two ways:

- Submit a support request using our online form. See *Support Website* below.
- Contact the Sun Nuclear Support team by telephone:
  - U.S.A.: +1 321-259-6862, Option 3
  - Netherlands: +31 20 399 90 41, Option 1
  - Germany: +49 61 02 50 49 500, Option 2

Support Website

1. Open an internet browser and navigate to sunnuclear.com/support.
2. Enter your email address and password and then click **Login**.
   - To download product information, click **Products and Devices**, select the product, and then select the download type.
   - To open a Support request, click **Open New Case**, complete the form, and then click **Create Case**.

5 Specifications - Model 049

Target Layout

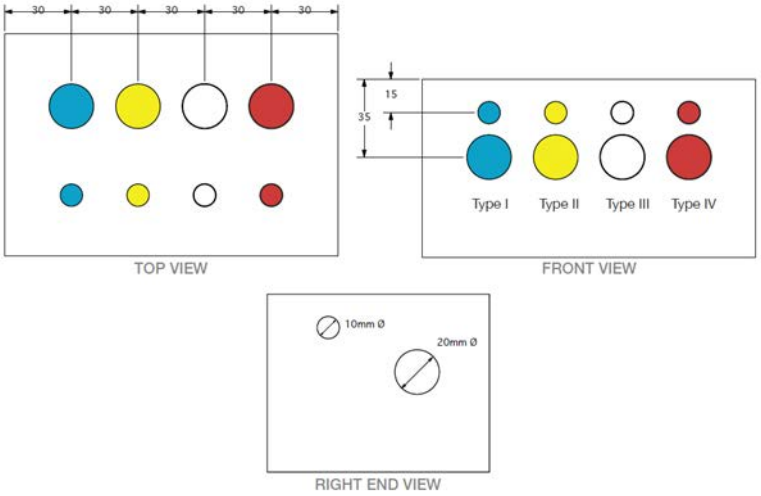


Figure 5-1. Target Views

Phantom Housing

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

Scanning Surface

Characteristic	Specification
Material	Saran-based laminate

Membrane Retainer

Characteristic	Specification
Material	1/16" Black ABS
Dimensions of Scan Opening	165 mm x 97 mm x 1/16"

Removable Storage Cover

Characteristic	Specification
Material	1/8" Black ABS

Background Material

Characteristic	Specification
Material	Zerdine
Speed of Sound	1540 m/s

Lesions

Characteristic	Specification
Material	Zerdine
Speckle Contrast	Hyperechoic to background

Elasticity[1]

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

10 MM Diameter Lesion

Characteristic	Specification
Quantity	4 each at 15 mm depth One of each hardness

20 MM Diameter Lesion

Characteristic	Specification
Quantity	4 each at 35 mm depth One of each hardness

Accessories

- Carry Case
- Certificate of Compliance
- Models 049 & 049A Elasticity QA Phantoms User Guide

Note:

- *All dimensions without tolerances are nominal.*
- *[1]Elasticity 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 ℃ ± 1 ℃.*

6 Specifications - Model 049A

Target Layout

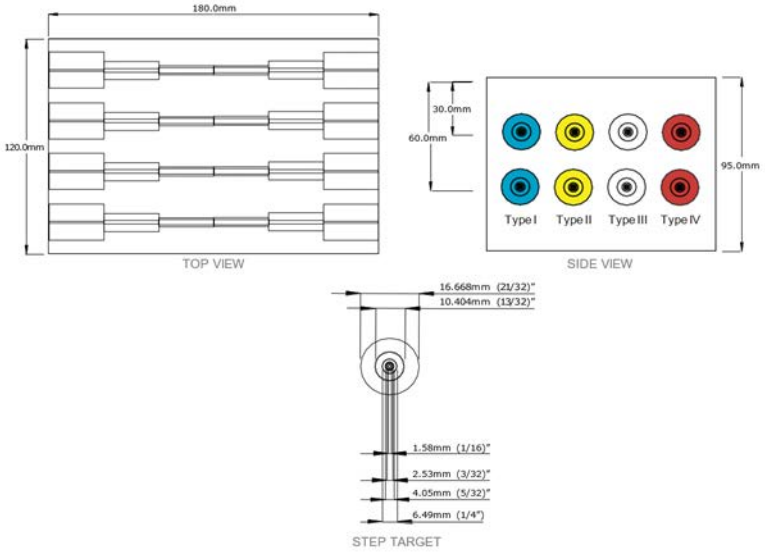


Figure 6-1. Target Views

Phantom Housing

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

Scanning Surface

Characteristic	Specification
Material	Saran-based laminate

Membrane Retainer

Characteristic	Specification
Material	1/16" Black ABS
Dimensions of Scan Opening	165 mm x 97 mm x 1/16"

Removable Storage Cover

Characteristic	Specification
Material	1/8" Black ABS

Background Material

Characteristic	Specification
Material	Zerdine
Speed of Sound	1540 m/s

Lesions

Characteristic	Specification
Material	Zerdine
Speckle Contrast	Hyperechoic to background

Elasticity[2]

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

Stepped Cylinders

Characteristic	Specification
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
- Models 049 & 049A Elasticity QA Phantoms User Guide

Note:

- *All dimensions without tolerances are nominal.*
- *[2]Elasticity 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 ℃ ± 1 ℃.*
- *All speed of sound and attenuation measurements made with 5 MHz focused transducer.*

7 Zerdine

Models 049 and 049A are 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.

Appendix A: Regulatory Supplement

In addition to the regulatory information contained in the body of this manual, the following supplemental regulatory information is provided.

Sun Nuclear Corporation Symbols

The following symbols are used in this guide and in Sun Nuclear Corporation's product labels.

WARNING: This symbol indicates a hazard that could result in major injury or equipment damage. (EN ISO 7010, W001)

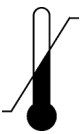
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

CAUTION: This symbol indicates a pinch hazard. (EN ISO 7010, W024)

Note: *Important or supporting information.*

Manufacturer's Identification (name and address). (EN ISO 15223-1, 5.1.1)

Date of Manufacture. (EN ISO 15223-1, 5.1.3)



Temperature limitation. (EN ISO 15223-1, 5.3.7)

Humidity limitation. (EN ISO 15223-1, 5.3.8)

Atmospheric pressure limitation. (EN ISO 15223-1, 5.3.9)

Serial Number. (EN ISO 15223-1, 5.1.7)

Catalog Number. (EN ISO 15223-1, 5.1.6)

Consult instructions for use. This equipment must be used in accordance with the instructions in this manual. Read all instructions and safety labels before use. (EN ISO 15223-1, 5.4.3)

Do not throw in trash; dispose of in an environmentally friendly way. (EN 50419)

Operator Responsibility

The instructions in this manual are intended for trained clinical personnel. The operator is solely responsible for the accurate setup and use of the phantom.

Reporting Health or Safety Related Issues or Concerns

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

Modifications to Equipment

Any changes or modifications to the device that are not expressly approved by Sun Nuclear Corporation could void your warranty.

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