Shear Wave Liver Fibrosis Phantom User Guide

Model 039

SUN NUCLEAR
A MIRION MEDICAL COMPANY

Shear Wave Liver Fibrosis Phantom User Guide

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1 Introduction

Shear wave elasticity imaging is an emerging biomarker with many possible applications, most prominently for determining the stage of liver fibrosis in a patient without the need for invasive biopsies. The Shear Wave Liver Fibrosis Phantom provides a set of reference phantoms for performing quantitative measurements of tissue stiffness using clinical and emerging research systems alike. The design of the CIRS Model 039 was developed and validated in a joint study sponsored by the Quantitative Imaging Biomarkers Alliance (QIBA), and has emerged as the standard for testing shear wave ultrasound systems (see *References* on page 11).

The Model 039 consists of four phantoms—each filled with Zerdine® gel formulated with differing values of Young's Modulus, a tissue-average speed of sound of 1540 m/s and speckle contrast levels matching that of a healthy liver.

Certification of shear wave speed will be provided with each phantom, with tests run on Verasonics Vantage™ research platform running open source code developed for the Quantitative Imaging Biomarkers Alliance Ultrasound Shear Wave Speed Committee. The certification sheet provides the full dispersive analysis of shear wave speed, allowing performance assessment at different frequencies.

Parts

No.	Qty	Description
1	4	Shear Wave Liver Fibrosis Phantoms
2	1	Carry case
--	--	48-month warranty

Figure 1-1. Model 039 Parts

No.	Qty	Description
–	1	*Shear Wave Liver Fibrosis Phantom User Guide* (not shown)
–	1	Certificate of Compliance (not shown)

Figure 1-1. Model 039 Parts (Continued)

Key Features of Model 039

- Set of 4 phantoms, each with a different stiffness (Young's Modulus ranges from 2 to 36 kPa)
- Enables quantitative assessment of shear wave speed measurements used in the diagnosis of diffuse liver disease
- Certified measurement of shear wave speed according to protocol developed by Quantitative Imaging Biomarkers Alliance Ultrasound Shear Wave Speed Committee
- Recertification of phantoms available

2 Performing Measurements

General Guidelines for Performing Measurements

When used properly, the phantoms in the Model 039 can serve as stable reference standards for assessing sources of variation in quantitative measurements of tissue elasticity. The hydrogel polymer used in Zerdine gel is chemically and thermally stable in normal room temperature storage. However, water loss through desiccation can cause a change in tissue elasticity. Thus, any changes in phantom weight should be noted carefully when assessing the variance in elasticity measurements over time. If you have any questions about your results, please contact Sun Nuclear Support. See *Contacting Sun Nuclear Support* on page 8.

The phantoms come with a certificate of compliance with the batch sample measurements of Young's Modulus, speed of sound, and density for each of the four phantoms in the set.

Shear wave speed characterization performed at Nightingale Lab, Duke University, with a Verasonics Vantage™ system using techniques described by Rouze and colleagues (2018). This methodology allows us to provide a full dispersion analysis of the ultrasonic shear wave speed, and allows production of viscoelastic phantoms (contact Sun Nuclear Support for a quote). These shear wave speeds differ significantly from the nominal values quoted on the data sheet for the Model 39 as there is significant measurement bias between this new test methodology and the batch sample testing previously performed at CIRS.

This new test methodology also permits CIRS to recertify the mechanical properties of your phantom at future dates, should the need arise. While Zerdine hydrogel has proven to be remarkably stable over time, a small amount of water vapor loss can occur through the membrane, particularly if the phantom is stored in warm, dry environments. If you see signs of desiccation in your phantom, which can be monitored by periodically weighing the phantom, or if you would like to have the phantom periodically recertified to verify phantom stability, please contact Sun Nuclear Support to receive a quote for phantom recertification.

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3 Testing Procedures

The Model 039 phantoms are designed as reference tools for determining sources of variance in shear wave elasticity measurements. As such, the scanning protocol should be designed to isolate specific sources of variance such as operator, focal depth, transducer used, or other system settings.

The phantom is equipped with a small water well. When performing measurements, the coupling gel or liquid should be used to couple wave energy from the transducer into the phantom.

When scanning the phantom with a curvilinear probe, best results will be obtained when the scanning well is filled with a saltwater, propanol/water or ethylene glycol/water solution that matches the speed of sound in the underlying gel (1540 m/s). These solutions minimize the defocusing effects that can reduce the accuracy of shear wave measurements made with curvilinear probes (see *References*, Martin and Spinks (2001), and Goldstein and Langrill (1980)).

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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 original weight noted on certificate of compliance. If the phantom has lost or gained more than 1% of its original weight, or if 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

Product Specifications

Phantom

Table 5-1. Phantom Specifications

Characteristic	Specification
External Dimensions	Ø 11.6 cm, height 14 cm
Internal Dimensions	Ø 10 cm, height 12 cm
Phantom Weight	6.7 lbs (3 kg)
Housing Material	ABS Plastic
Membrane	Saran Laminate
Scanning Well	16.5 cm x 10 cm x 1 cm deep
Tissue-Mimicking Material	Zerdine solid elastic hydrogel

Zerdine Properties

Table 5-2. Zerdine Properties

Characteristic	Specification
Freezing Point	0°C
Melting Point	Above 100°C
Speed of Sound	1540 m/s
Density	1.03 g/cc
Poisson's Ratio	0.5

Phantom Stiffness (Nominal)*

Table 5-3. Phantom Stiffness Specifications

Phantom	Young's Modulus	Shear Wave Velocity
Phantom 1	2 +2/-1 kPa	0.8 +0.34/-0.24 m/s
Phantom 2	8 +3/-2 kPa	1.6 +0.28/-0.22 m/s
Phantom 3	18 ± 4 kPa	2.5 +0.26/-0.29 m/s
Phantom 4	36 ± 6 kPa	3.5 +0.28/-0.30 m/s

* Nominal values and expected range are based on mechanical compressional testing based on ASTM Standard D575-91. Certified shear wave speed values may vary.

6 Zerdine

Each phantom in the Model 039 set 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 Young's Modulus in the optimal range of 4 to 90 kPa.

At normal room temperature, the 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.

7 References

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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)

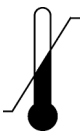
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

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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