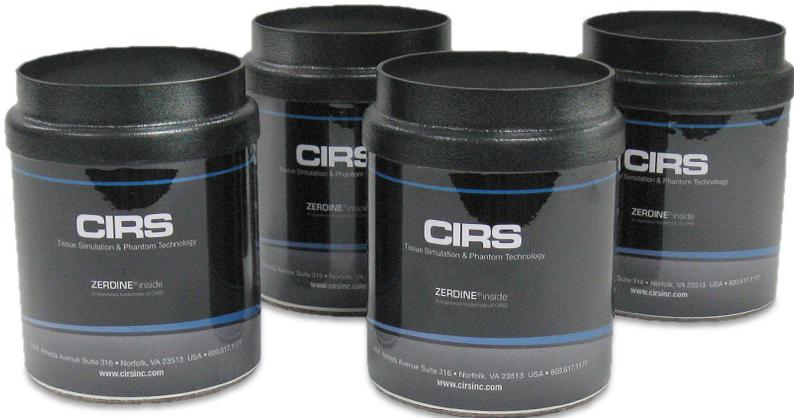


Shear Wave Liver Fibrosis Phantom

Model 039



ZERDINE® Inside
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USER GUIDE

CIRS

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OVERVIEW

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 Biomarker Alliance, and has emerged as the standard for testing shear wave ultrasound systems (see "References").

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 (QIBA) Ultrasound Shear Wave Speed Committee. The certification sheet provides the full dispersive analysis of shear wave speed, allowing performance assessment at different frequencies.

INSTRUCTIONS FOR USE

HANDLING AND CARE

With proper care, the Model 039 phantoms 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.

Key Features for Model 039

- Set of 4 phantoms, each with a different stiffness (Young's modulus ranges from 2 – 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
- Re-certification of phantoms available

INSTRUCTIONS FOR USE (CONT)

HANDLING AND CARE (CONT)

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, 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.



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

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 CIRS, Inc. at (800) 617-1177.

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 CIRS 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 re-certify 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 re-certified to verify phantom stability, please contact CIRS to receive a quote for phantom recertification.

TEST PROCEDURE

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 Martin and Spinks: 2001 and Goldstein and Langrill: 1980)

SPECIFICATIONS

EXTERNAL DIMENSIONS	Ø 11.6 cm, height 14 cm
INTERNAL DIMENSIONS	Ø 10 cm, height 12 cm
PHANTOM WEIGHT	6.7 lbs (3kg)
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

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)*

PHANTOM	YOUNG'S MODULUS*	SHEAR WAVE VELOCITY
Phantom 1	2 kPa	0.8 m/s
Phantom 2	8 kPa	1.6 m/s
Phantom 3	18 kPa	2.5 m/s
Phantom 4	36 kPa	3.5 m/s

*Certified values may vary (see Oudry et al: 2014)

MODEL 039 INCLUDES

QTY	COMPONENT DESCRIPTION
4	Shear Wave Liver Fibrosis Phantoms
1	Carry Case
1	Removable Scanning Well
-	48-Month Warranty
-	User Guide
-	Certificate of Compliance

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 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 $A = A_0 F^n$ 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.

REFERENCES

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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 039- Shear Wave Liver Fibrosis Phantom	48 Months

CIRS

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