

# Multi-Modality Breast Biopsy and Sonographic Trainer

Model 073



## USER GUIDE

# CIRS

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## OBJECTIVE

The Multi-Modality Breast Biopsy and Sonographic Trainer is designed to train users in various aspects of breast imaging and image-guided interventional procedures. The phantom accurately mimics the heterogeneous appearance of breast tissue under ultrasound, mammography and MRI, and has five cystic lesions and ten dense lesions embedded within the breast background. Half of the dense lesions are spherical and have a 100-300  $\mu\text{m}$  microcalcification embedded within it, while the other half have a spiculated shape. In addition to helping users identify different types of masses in the complex structure of the breast, the calcifications are useful markers for image registration between modalities.

## DESCRIPTION OF THE PHANTOM

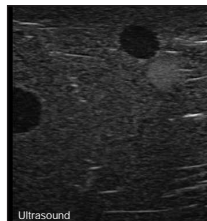
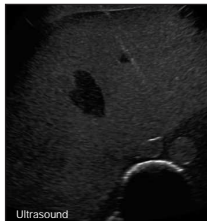
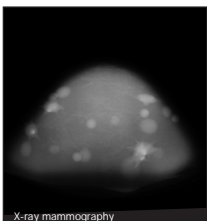
CIRS Model 073 includes a patent-pending<sup>1</sup> Z-Skin™ elastomer membrane that simulates the look and feel of skin during scanning and biopsy. The skin material closes up on itself after puncture with a needle, providing good protection from dessication even after multiple training sessions.

The material inside the phantom is formulated to minimize the effect of needle tracks while practicing biopsy techniques on the embedded masses. This material also has remarkable self-healing properties, and tracks will usually disappear within minutes (sometime seconds) of needle removal. Each mass may be biopsied multiple times.

## SPECIFICATIONS

<b>DIMENSIONS</b>	12 cm x 10 cm x 9 cm (4.7" x 4" x 3.5")
<b>WEIGHT</b>	1 lb (0.4 kg)
<b>SIZE</b>	500 cc
<b>MEMBRANE MATERIAL</b>	Z-Skin™ elastomer
<b>BACKGROUND GEL MATERIAL</b>	Zerdine®
<b>CYSTIC MASSES</b>	Qty: 5-10 Material: Zerdine®-based, anechoic under ultrasound Size: 5 -10 mm in diameter Shape: Spherical shape
<b>DENSE MASSES</b>	Qty: 10-15 Material: Zerdine-based, hyperechoic under ultrasound Size: 5-10 mm in diameter Half spherical with embedded microcalcifications (100-300 microns) Half spiculated

Custom Lesions available upon request.



<sup>1</sup>PCT/US2006/039597

## **USE OF THE PHANTOM**

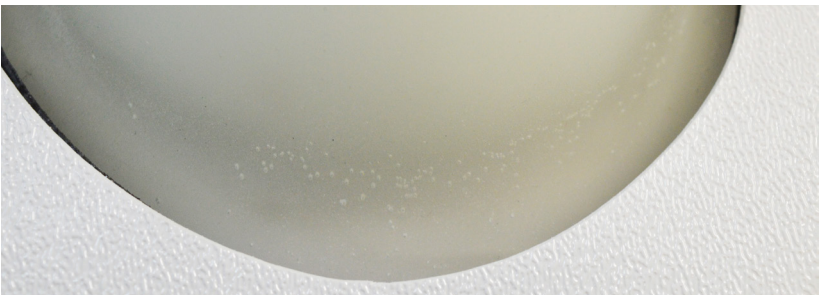
1. For ultrasound imaging, apply coupling gel to the membrane
2. The phantom may be biopsied multiple times. Needle tracks will generally disappear soon after needle removal, but air bubbles and debris can sometimes be caught in the gel, and will be visible when imaged. Filling the needles or wetting them prior to insertion will reduce the incidence of these artifacts, as will the use of higher gauge needles.
3. When not in use, the phantom should be stored in an air-tight container to avoid desiccation.

## **CARE AND HANDLING**

The phantom is designed for use with interventional procedures and the lifetime will vary considerably from user-to-user depending on the type of procedure tested. The following general care guidelines should be followed to maximize the life of the phantom.

- The phantom surface may be cleaned with mild soap and water ONLY. Avoid solvent-based, alcohol-based, or abrasive cleaning agents. After cleaning, dry the phantom and re-apply the provided skin conditioner (talc).
- For maximum product lifetime, store the phantom in standard room temperature and humidity. Sub-freezing temperatures should be avoided during shipping, as the freeze-thaw cycle may damage housing integrity and displace the targets. High temperatures may accelerate desiccation. If signs of weight loss are seen (such as a sunken scanning surface), contact CIRS for assistance.
- Inspect your phantom regularly for signs of damage, particularly the membrane integrity. Tears in the membrane should be covered to prevent desiccation.
- The phantom is designed to tolerate the rough handling that may occur during mammography compression.
- Technical questions should be referred to CIRS customer service at (800) 617-1177.

**Please note:** Each phantom is individually hand crafted and as such will have minor variations and anomalies. Our QA system has established processes to review these various anomalies to ensure they do not jeopardize the utility of the phantom. Minor surface blemishes will not adversely affect ultrasonic scans.



# 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](mailto: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 073 - Multi-Modality Breast Biopsy and Sonographic Trainer	12 Months*

\*Please note: once any device has been inserted into the phantom (such as biopsy needles, localization wires, etc.) the 12 month warranty will not cover claims related to material desiccation or needle tracking.

