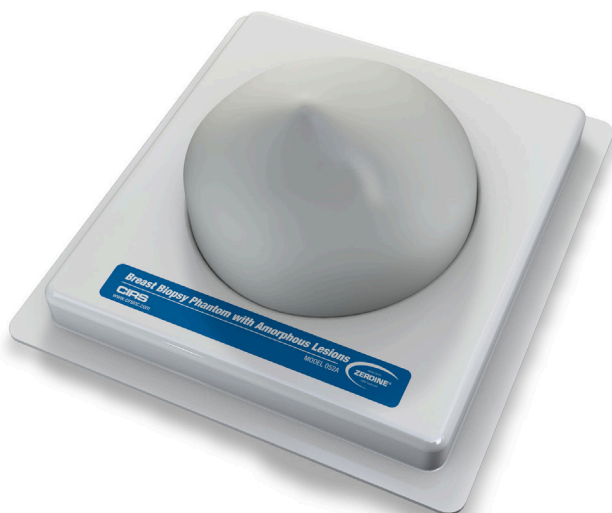


Ultrasound Needle Breast Biopsy Phantom

Model 052A



ZERDINE[®] Inside
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USER GUIDE

CIRS

900 Asbury Ave • Norfolk, Virginia 23513 • USA • Tel: 757-855-2765 • WWW.CIRSI.COM

OBJECTIVE

The Model 052A, Ultrasound Needle Breast Biopsy Phantom with Amorphous Lesions, was designed specifically for ultrasound-guided needle biopsy training and experimentation. The non-spherical shape of the embedded targets enable practice with 2D, 3D and 4D image acquisition.

DESCRIPTION OF THE PHANTOM

The Model 052A accurately mimics the ultrasonic characteristics of tissues found in the average human breast. The size and shape of the phantom simulates that of an average patient in the supine position.

Each phantom measures approximately 14 cm long x 12 cm wide x 7.5 cm high with a volume of 600 cc. Within each phantom, there are six cystic masses and six dense masses which are randomly positioned. The masses are not spherical in shape but rather amorphous. Because it is constructed of a self-healing formulation of Zerdine®, the phantom will allow multiple biopsy insertions with minimal needling tracking. Needle tracks will usually disappear within minutes (sometimes seconds) of needle removal. Each cystic mass may be aspirated once and each dense mass may be biopsied multiple times.

A special holding tray facilitates proper hand position during the training procedures.

SPECIFICATIONS

GENERAL SPECIFICATIONS

Tray Dimensions: 22.5 cm x 20.0 cm
Breast size & weight: 600 cc
(14 cm x 12 cm x 7.5 cm)

BACKGROUND

Material: Zerdine
Color: White
Characteristics: Mimics average human breast tissue

CYSTIC MASSES

Color: Green
Size Range: 8 mm -15 mm
Quantity: 6

Positioning: Random

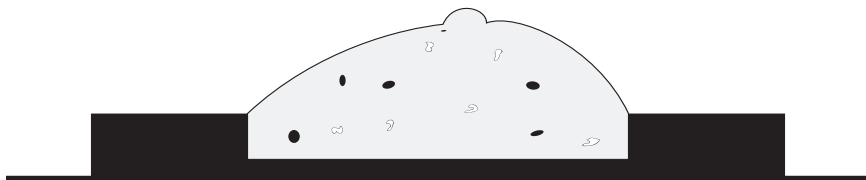
DENSE MASSES

Color: Black
Size Range: 6 mm-12 mm
Quantity: 6
Positioning: Random

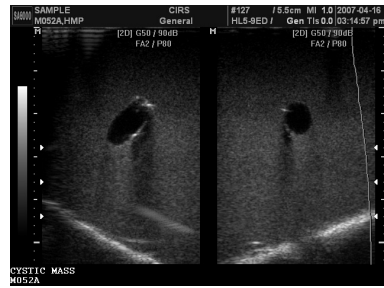
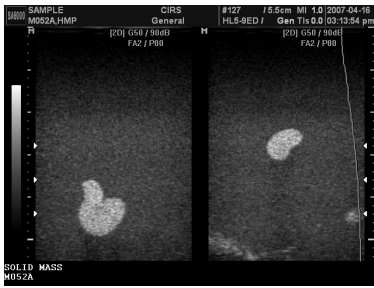
MODEL 052 INCLUDES

Ultrasound Needle Breast Biopsy Phantom
User Guide
12-Month Warranty*

*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.



USE OF THE PHANTOM



The phantom is designed to be used in the white holding tray. **The membrane covering the phantom should never be removed.**

Before imaging, be sure to place an ample amount of coupling gel on the probe or the polyethylene membrane which covers the phantom.

The phantom can be punctured many times before being “tracked out”. Side to side manipulation of the needle within the phantom can produce significant echoic artifacts because this motion tends to introduce air.

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.

- 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.
- The phantom surface may be cleaned with mild soap and water ONLY. Avoid solvent-based, alcohol-based, or abrasive cleaning agents.
- When not in use, the phantom must be stored in an air-tight container such as a ziplock bag to minimize dessication.
- Inspect your phantom regularly for signs of damage, particularly the membrane integrity. Tears in the membrane should be covered to prevent dessication.
- Technical questions should be referred to CIRS customer service at (800) 617-1177.

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 Customer Service or your local distributor prior to returning the product. Visit <https://www.cirsinc.com/distributors/> to find your local distributor. Call 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 052A - Ultrasound Needle Breast Biopsy Phantom with Amorphous Lesions Phantom	12 Months*

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