

Stereotactic Needle Biopsy Phantom

Model 013



USER GUIDE

CIRS

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OVERVIEW

The CIRS Stereotactic Needle Biopsy Phantom provides a leak-free, compressible test medium for performing the localization accuracy test in the American College of Radiology's stereotactic breast biopsy accreditation program¹. The phantom should be used whenever a new system is installed or repaired to ensure accurate needle placement. The phantom may also be used as a practice medium for both stereotactic and standalone biopsies.

The phantom body is shaped to represent a partially compressed breast. This allows the user to easily compress the breast to 4.5 cm thickness for optimum imaging. The shape also enables the phantom to be used in systems where the patient is either prone or sitting. The phantom has an elasticity similar to human tissue and, since the gel inside is a non-flowing material, it won't leak out when punctured. The gel is surrounded by a skin-like membrane to simulate realistic needle resistance.

Features

- **Compressible:** anthropomorphic shape allows accurate simulation of breast compression
- **Re-usable:**
 - Does not leak when punctured
 - Will not dry out
 - Masses can be biopsied multiple times
- Eleven dense masses in three different sizes
- Two microcalcification clusters
- Simulates needle resistance during biopsy
- Compatible with both stand alone and add-on stereotactic biopsy systems
- Works on digital systems

Embedded within the phantom are numerous solid masses in a range of sizes. These radiographically visible masses can be biopsied multiple times. The masses are colored black for easy visualization of a successful biopsy. These solid masses are randomly positioned so each phantom provides a unique training experience.

Two calcification clusters are positioned within the medial transverse plane at the right and left edge of the phantom. These calcifications can be biopsied or used for QA checks on the mammography system. To aid in visualizing the location of the calcifications, the two groups are each clustered around a white mass.

The CIRS Model 013 can be reused multiple times with no special storage requirements. Note that extracted material from the phantom may be difficult to remove from the biopsy needle, preventing cleaning and re-use of the needle and other components. Thus, the phantom is not recommended for use with vacuum-assisted biopsy systems or any other system whose components are not disposable.

¹American College of Radiology, Stereotactic Breast Biopsy Quality Control Manual. 1999.

SPECIFICATIONS

TARGETS	SHAPE	COLOR	SIZE RANGE	QTY	POSITIONING
Dense Masses (small)	Round	Black	6 mm	3	Random
Dense Masses (med)	Round	Black	9 mm	4	Random
Dense Masses (large)	Round	Black	11 mm	4	Random
Microcalcifications	Round	Orange	300 - 350 microns	2 clusters	Mid-Plane on right and left sides

Note: Calcifications are grouped around radiographically transparent white mass

Overall Size	10 cm x 16.5 cm x 5 cm thickness
Phantom Volume	530 cc
Phantom Weight	1 lbs. (0.4 kg)

USE OF THE PHANTOM

The CIRS Model 013 is intended for use with tissue sampling methods where parts that receive the extracted material may be disposed of after use. Extracted material may be difficult to remove from the biopsy needle or other parts. Thus, the phantom is not recommended for use with vacuum-assisted biopsy systems and other systems whose components are not disposable. Instructions for performing the localization accuracy test and general training guidelines are provided in the sections that follow.

Localization Accuracy Test: The following instructions have been adapted from the ACR Stereotactic Breast Biopsy Quality Control Manual for use with the CIRS Model 013.

Image Acquisition and Biopsy

1. Remove the phantom from its polyethylene packaging.
2. Place the phantom in the beam with the compression plate centered over a simulated lesion.
3. A 0° scout-view image of the phantom should be acquired with the image receptor used clinically to conform proper positioning of the lesion within the biopsy window.
4. Two stereo views (usually +15° and -15°) are acquired and the center of the simulated lesion marked in each.
5. Once the simulated lesion's center location is determined by the system, the needle should be installed in the biopsy device and the biopsy device assembly securely attached to the device holder.
6. For some units, the z-axis must be zeroed.
7. The horizontal, vertical and depth coordinates determined by the system must be entered on the unit. This will require advancing the needle into the phantom.

USE OF THE PHANTOM (CONT)

8. Acquire stereotactic pre-fire images; if the unit is well calibrated, the needle tip should be within the targeted lesion. On some units a small amount of needle pull-back is required before firing.
9. Once the gun is fired, a second set of stereotactic images should show the tip of the needle beyond the center of the lesion.

Data Analysis and Interpretation:

1. View the pre-fire and post-fire images to ensure that the needle tip is within the lesion in the pre-fire images and beyond the lesion in the post-fire images.
2. Verify that phantom lesion material is in the biopsy needle.

Other Uses: The CIRS Model 013 may also be used as a practice medium for any x-ray based breast-biopsy system, including manual procedures or stereotactic equipment. The phantom can be positioned, compressed and imaged using normal techniques. All targets in the phantom are designed for removal. The black targets simulate dense masses while the small orange clusters surrounding the two white spheres simulate microcalcifications.

CARE AND HANDLING

Clean by hand using water and mild dish washing liquid. Rinse thoroughly and allow to air dry. Store at normal room temperature. To maintain cleanliness, phantom may be stored in re-sealable plastic bag. Phantom will not leak or dehydrate.

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
Training Phantoms and Disposable Products	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.

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