

# **Stereotactic Needle Biopsy Phantom User Guide**

Model 013



**SUN NUCLEAR**  
A MIRION MEDICAL COMPANY

# Stereotactic Needle Biopsy Phantom User Guide

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# 1 Introduction

## Product Description

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The 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 program.<sup>1</sup> 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 will not leak out when punctured. The gel is surrounded by a skin-like membrane to simulate realistic needle resistance.

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.

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 reuse 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.

## Features of Model 013

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- Compressible: anthropomorphic shape allows accurate simulation of breast compression
- Reusable:
  - Does not leak when punctured
  - Will not dry out
  - Masses can be biopsied multiple times

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

- Eleven dense masses in three different sizes
- Two microcalcification clusters
- Simulates needle resistance during biopsy
- Compatible with both standalone and add-on stereotactic biopsy systems
- Works on digital systems

## 2 Use of the Phantom

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 below.

### Localization Accuracy Test

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The following instructions have been adapted from the ACR Stereotactic Breast Biopsy Quality Control Manual for use with 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.
- 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

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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.



# 3 Support and Maintenance

## Hardware Maintenance

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### Inspection

Periodically inspect your phantom and accessories for damage. If damage is visible, if any mechanical or electrical degradation is suspected, or if errors are suspected, discontinue use and contact Sun Nuclear Support. See *Contacting Sun Nuclear Support* below.

### Repair

The phantom is designed for use with biopsy systems, and therefore has a limited lifespan based on the rate of usage. It cannot be repaired. If manufacturing defects are found in the phantom, contact Sun Nuclear Support.

### Cleaning

Clean by hand using water and mild dish washing liquid. Rinse thoroughly and allow to air dry.

### Storage

Store at normal room temperature. To maintain cleanliness, phantom may be stored in resealable plastic bag. Phantom will not leak or dehydrate.

### Disposal and Recycling



*Do not discard unit as waste. Recycle the components in accordance with local regulations.*

## Contacting Sun Nuclear Support

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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](http://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**.

# 4 Specifications

## Product Specifications

### Targets

Table 4-1. Target 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 |
| <b>Note:</b> Calcifications are grouped around radiographically transparent white mass. |       |        |                 |            |                                   |

### Phantom

Table 4-2. Phantom Specifications

| Characteristic | Specification                    |
|----------------|----------------------------------|
| Overall Size   | 10 cm x 16.5 cm x 5 cm thickness |
| Phantom Volume | 530 cc                           |
| Phantom Weight | 1 lb (0.4 kg)                    |

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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

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The following symbols are used in this guide and in Sun Nuclear Corporation's product labels.



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**WARNING:** This symbol indicates a hazard that could result in major injury or equipment damage. (EN ISO 7010, W001)

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

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**CAUTION:** This symbol indicates a pinch hazard. (EN ISO 7010, W024)

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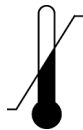
**Note:** *Important or supporting information.*



*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**

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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**

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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**

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Any changes or modifications to the device that are not expressly approved by Sun Nuclear Corporation could void your warranty.



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