

Image-Guided Abdominal Biopsy Phantom

Model 071B



USER GUIDE

CIRS

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OVERVIEW

The Model 071B Image-Guided Abdominal Biopsy Phantom is based on the need for simplified abdominal training phantoms. The phantom does not contain organs but the randomly positioned lesions are visible under ultrasound and CT, with key features outlined in the table below. The polymer gel will not leak when punctured. This phantom is well suited for training and demonstrating image-guided navigation technologies or any other procedure where visually locating the needle is important. The background gel is designed to minimize needle tracks when punctured, allowing many uses over time, is soft enough to allow puncture with 21 gauge needles or larger, yet stiff enough that the lesions remain stable in position. The 071B has re-designed cluster sizes and a new muscle/fat layer combination that allows us to make a softer background gel for reduced needle tracking. For most users, this phantom will still provide an excellent imaging testbed, even after several hundred needle punctures.

SPECIFICATIONS

DIMENSIONS

28 x 20 x 12.5 cm

Weight: 5.5 kg

BACKGROUND

Material: Optically clear Zerdine^{®(1)} gel

Speed of sound: 1540 m/s (nominal)

MASSES

Material: Zerdine, soft tissue

Quantity: 12

Diameter: 5 - 12mm

RIBS & VERTEBRAE

Material: Radio-opaque epoxy

SCAN SURFACE

Material: Z-skin[™] elastomer

MUSCLE LAYER

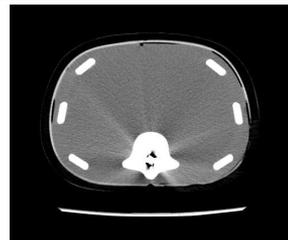
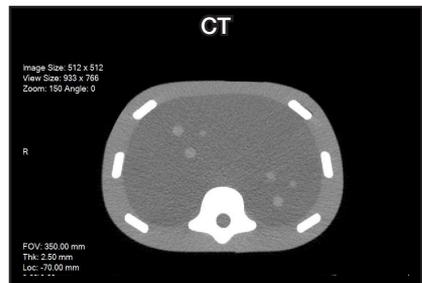
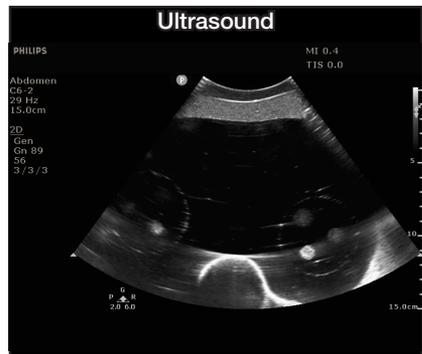
Material: Hyperechoic Zerdine[®] gel
(ensures phantom retains shape over time)

OTHER

CT visible, MRI-compatible “H” marker
to indicate head/ foot orientation (see figure)

USE OF THE PHANTOM

The phantom was designed for demonstration and training of image-guided navigation technologies. However, it is also well suited for training and demonstration of any biopsy procedure.



USE OF THE PHANTOM (CONTINUED)

1. Remove phantom from the case.
2. Scan using normal abdominal scan protocol for Ultrasound, MRI, or CT.
3. Phantom can be biopsied.
4. For best results under ultrasound, scan under a low gain setting. Due to the low attenuation coefficient of the gel, microbubbles may be present in the background, especially around the lesion cluster, that are highly visible under high gain. Our pass/fail criteria allow the presence of these microbubbles so long as they do not interfere with the ability to detect the lesions inside the gel.

CARE AND HANDLING

- Clean phantom with provided wipes. Mild soap and water may also be used, but avoid solvent or abrasive cleaning agents.
- Some permanent tracking may be evident if debris and air bubbles are entrained in the gel during the biopsy procedure, so the use of higher gauge needles that have been wetted and de-aired prior to insertion is recommended to extend the lifetime of the phantom.
- For maximum product lifetime, store the phantom in the provided carry case. Standard room temperature and humidity is acceptable for storage. 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.
- Each lesion can be punctured multiple times. To maximize use of the phantom for interventional procedures, it is best not to follow the same needle track repeatedly.
- Technical questions should be referred to CIRS customer service at (800) 617-1177.

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, 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 071B - Image-Guided Abdominal Biopsy Phantom	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.

