

USER MANUAL

RaySafe Pro-Mam Biopsy Phantom



ABOUT THE BIOPSY PHANTOM

This phantom is designed to provide a fast and easy way to test image quality on digital biopsy mammography units without having to do multiple exposures. It is designed to meet the requirements for use in the ACR stereotactic breast biopsy accreditation program, but does not hold an accreditation.

Regular quality control performed with the RaySafe Pro Mam Biopsy phantom allows you to detect changes in imaging quality, enabling you to maintain the system according to manufacturer specifications.

Test objects are similar to those specified in the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual. Objects within the phantom are designed to simulate fibrous lesions, microcalcifications, and tumor masses.

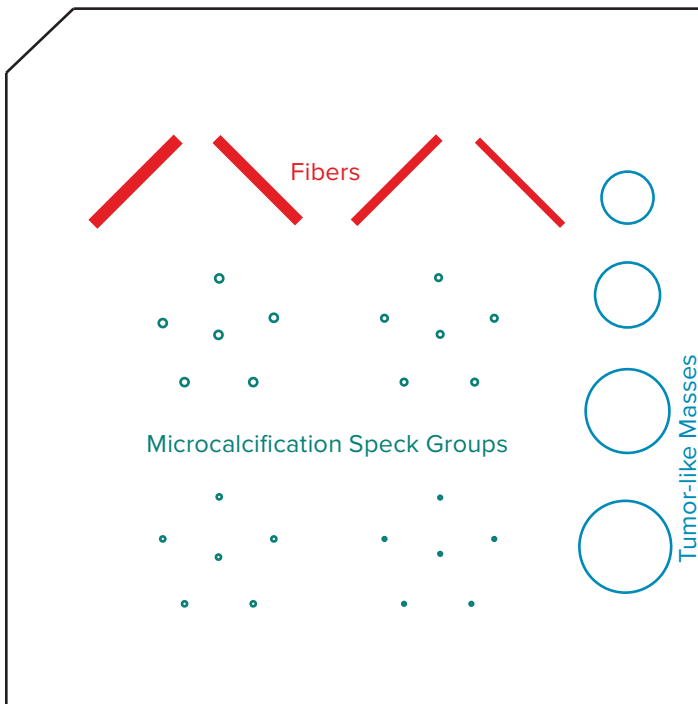


Figure 1. RaySafe Pro-Mam Biopsy Phantom wax insert: object sizes range from what should be visible on any system to what would be challenging to detect even for the best mammography units.

SPECIFICATIONS

Phantom body	
Material	Acrylic (PMMA)
Dimensions and weight	
Overall dimension (h x w x d)	46 x 80 x 70 mm (3.1 x 2.8 x 1.8 in.)
Cut-out dimension (h x w x d)	6.25 x 60 x 60 mm (0.25 x 2.4 x 2.4 in.)
Simulates	42 mm (1.7 in.) compressed breast of average glandular/adipose composition
Weight	316 g (0.70 lb)
Wax insert test elements	
Nylon fiber diameters (4)	0.93, 0.74, 0.54, 0.32 mm (0.037, 0.029, 0.021, 0.013 in.)
Aluminium oxide microcalcifications specks (4)	0.54, 0.32, 0.24, 0.20 mm (0.021, 0.013, 0.0094, 0.0079 in.)
Tumor like masses (thickness) (4)	0.25, 0.50, 0.75, 1.00 mm (0.0098, 0.020, 0.030, 0.039 in.)
Standards	
Compliance	Designed to meet requirements, but does not hold an accreditation for: <ul style="list-style-type: none"> • 1999 ACR Stereotactic Breast Biopsy Quality Control Manual

Note: The phantom is made of a 6.25 mm (0.25 in.) wax block insert containing 12 sets of test objects, a 36.75 mm (1.45 in.) thick acrylic base, and a 3 mm (0.12 in.) thick cover.

The phantom approximates a compressed breast of average glandular/adipose composition.

Included in the wax insert are four aluminium-oxide (Al₂O₃) specks that simulate microcalcifications, four different nylon fibers simulate fibrous structures, and four different size lens-shaped masses simulate tumors.

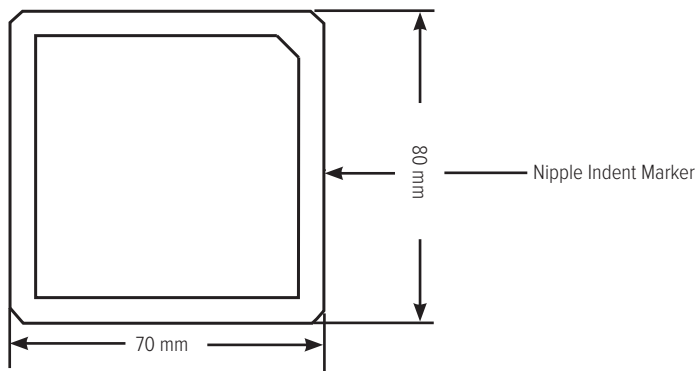
Each phantom includes a 4 mm (0.16 in.) thick, Ø 10 mm (0.39 in.), 6 g (0.2 oz) acrylic contrast test disk, and a magnifying glass.

TEST PROCEDURE

This is an example based on the American College of Radiology (ACR). Be sure to comply with your local regulations.

General System Monitoring

1. Place the phantom on the image receptor surface/breast support table in the same position as a breast, and aligned with the edge of the table. The nipple indent marker should be positioned away from the chest wall, just as the nipple of the patient’s breast would be. If a phototimer is used, place it under the wax portion of the phantom.
2. Install a paddle, and compress the phantom gently.



3. Make an exposure using the clinical exposure parameters typically used for a 4-4.5 cm thick compressed breast. The resulting image represents the imaging capabilities of your machine using the chosen machine settings.

Interpretation of Image

4. Once an acceptable image has been obtained, identify and record which objects are seen.
5. The zoom tool, the window width and level (contrast and brightness) should be adjusted to obtain optimal visualization.
6. Count the number of visible structures of a given type, starting from the largest structure, and use the scoring key table on page 5. Stop counting if you reach 0 or 0.5.

Digital	Screen Film
<ul style="list-style-type: none"> • Fiber score ≥ 3.0 • Speck group score ≥ 3.0 • Mass score ≥ 2.5 	<ul style="list-style-type: none"> • Fiber score ≥ 2.0 • Speck group score ≥ 2.0 • Mass score ≥ 2.0

Test structure	Full point	Half point
Fiber	<ul style="list-style-type: none"> • Full length visible (≥ 8 mm/0.31 in.) • Correct location • Correct orientation • 1 break allowed (must be \leq width of fiber) 	<ul style="list-style-type: none"> • At least half of length visible (≥ 5 mm/0.20 in. and < 8 mm/0.31 in.) • Correct location • Correct orientation • 1 break allowed (must be \leq width of fiber)
Speck Group	3-5 speck groups available, correct location	1-2 speck groups available, correct location
Mass	<ul style="list-style-type: none"> • Density difference visible • Border is continuous and generally circular ($\geq 3/4$ border visible) • Correct location 	<ul style="list-style-type: none"> • Density difference visible • Border is not continuous or generally circular ($\geq 1/2$ and $< 3/4$ border visible) • Correct location



Number of Test Structures	Fiber	Speck Group	Mass
	Diameter (mm)	Diameter (mm)	Thickness (mm)
1	0.93	0.54	1.00
2	0.74	0.32	0.75
3	0.54	0.24	0.50
4	0.32	0.20	0.25

WARRANTY

Unfors RaySafe warrants to the original product purchaser that each product it manufactures will be free from defects in material and workmanship under normal use and service. The warranty period is 12 months and begins on the date of delivery.