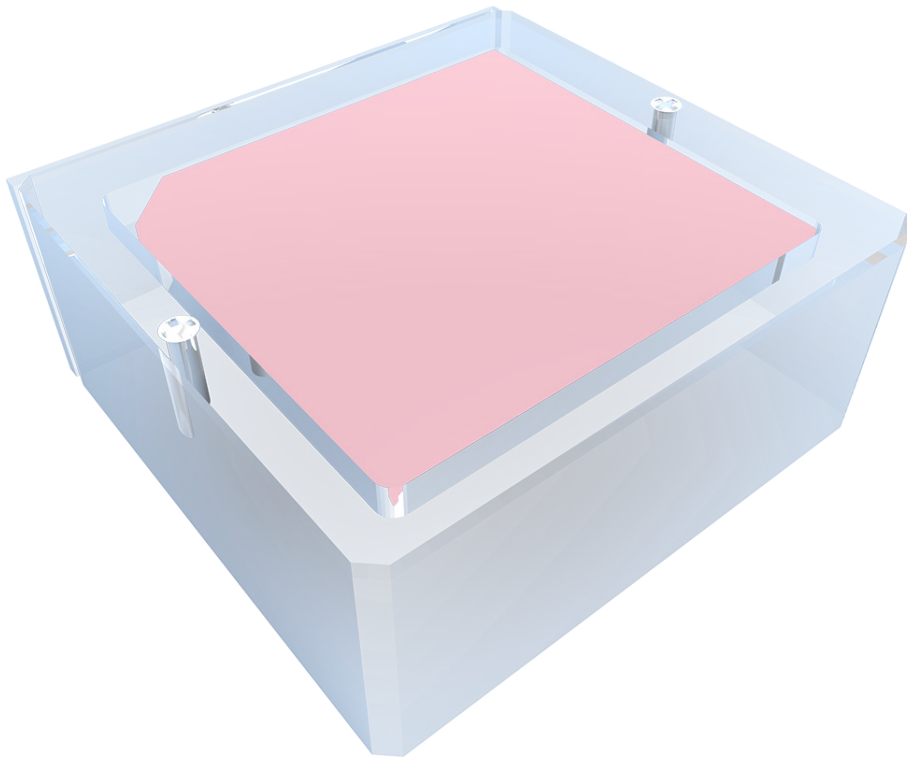


USER MANUAL

RaySafe Pro-Mam Accreditation Phantom



ABOUT THE ACCREDITATION PHANTOM

The Mammography Accreditation Phantom is designed to meet the requirements of the Mammography Quality Standards Act (MQSA) and the ACR Mammography Accreditation Program. The phantom is approved by the American College of Radiology (ACR) for use in its Mammography Accreditation Program.

The phantom is intended for quality control testing of Full-Field Digital Mammography (FFDM) systems and is used to evaluate the system’s ability to image small structures important in the early detection of breast cancer. Objects within the phantom simulate fibrous lesions, microcalcifications, and tumor masses.

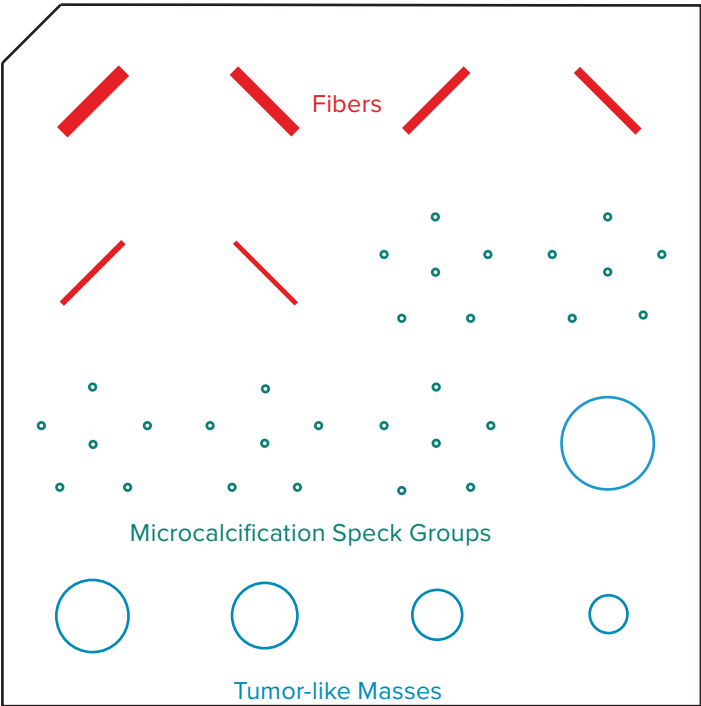


Figure 1. Object sizes range from what should be visible on any system to what would be challenging to detect even for the best mammography units.

SPECIFICATIONS

Phantom Body	
Material	Acrylic (PMMA)
Dimensions and Weight	
Overall dimension (h x w x d)	44 x 102 x 108 mm (1.7 x 4.0 x 4.3 in.)
Cut-out dimension (h x w x d)	7.25 x 81.5 x 82 mm (0.29 x 3.21 x 3.23 in.)
Simulates	42 mm (1.7 in.) compressed breast of average glandular/adipose composition
Weight	556 g (1.23 lb)
Wax Insert Test Elements	
Nylon fiber diameters (6)	1.56, 1.12, 0.89, 0.75, 0.54, 0.40 mm (0.061, 0.044, 0.035, 0.030, 0.021, 0.016 in.)
Aluminium oxide microcalcifications specks (5)	0.54, 0.40, 0.32, 0.24, 0.16 mm (0.021, 0.016, 0.013, 0.0094, 0.0063 in.)
Tumor like masses (thickness) (5)	2.00, 1.00, 0.75, 0.50, 0.25 mm (0.079, 0.039, 0.030, 0.020, 0.010 in.)
Standards	
ACR-approved for use in the Mammography Accreditation Program	

Note: The phantom is made of a 7.25 mm (0.29 in.) wax block insert containing 16 sets of test objects, a 33.75 mm (1.33 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 five aluminium-oxide (Al₂O₃) specks that simulate microcalcifications. Six different nylon fibers simulate fibrous structures and five different size lens-shaped masses simulate tumors.

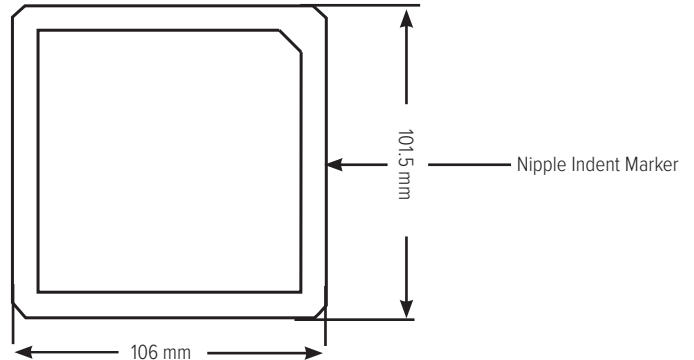
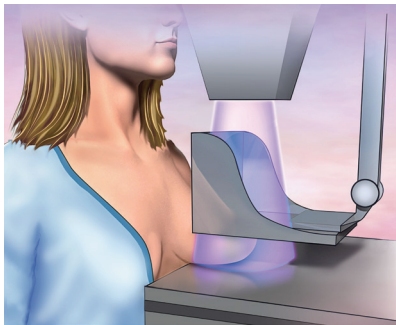
Each phantom includes a 4 mm (0.16 in.) thick, Ø 10 mm (0.39 in.), 6 g (0.2 oz) acrylic contrast test disk, and a magnifying glass.

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 (50 N). If the unit has selectable AEC sensor positions, always use the same position (under the wax insert).



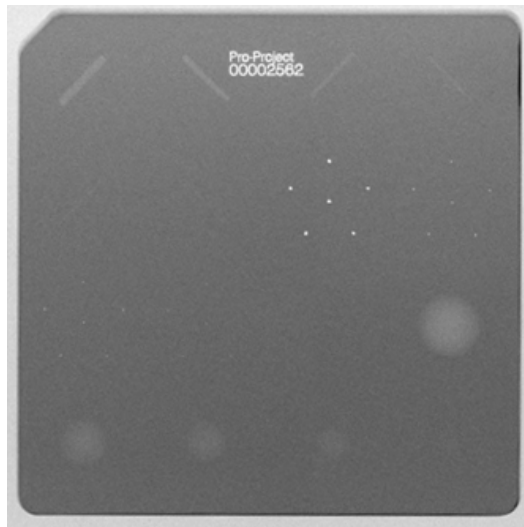
3. Make an exposure using the clinical AEC mode. The resulting image represents the imaging capabilities of your machine using the chosen machine settings.

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 which complies with the ACR protocol. Stop counting if you reach 0 or 0.5.
Fiber score ≥ 4.0
Speck group score ≥ 3.0
Mass score ≥ 3.0

RaySafe Pro-Mam Accreditation Phantom User Manual – Test Procedure

Test structure	Full point	Half point
Fiber	- Full length visible (≥ 8 mm/0.31 in.) - Correct location - Correct orientation 1 break allowed (must be $\leq$ width of fiber)	- 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	- Density difference visible - Border is continuous and generally circular ($\geq 3/4$ border visible) - Correct location	- Density difference visible - Border is not continuous or generally circular ($\geq 1/2$ and $< 3/4$ border visible) - Correct location



A good imaging system should be able to detect the 3rd microcalcification speck group, 4th fiber and the 3rd mass correctly.

Number of Test Structures	Fiber	Speck Group	Mass
	Diameter (mm)	Diameter (mm)	Thickness (mm)
1	1.56	0.54	2.00
2	1.12	0.40	1.00
3	0.89	0.32 (minimal requirement)	0.75 (minimal requirement)
4	0.75 (minimal requirement)	0.24	0.50
5	0.54	0.16	0.25
6	0.40	N/A	N/A

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.