

Contrast Enhanced Spectral Mammography Phantom (CESM)

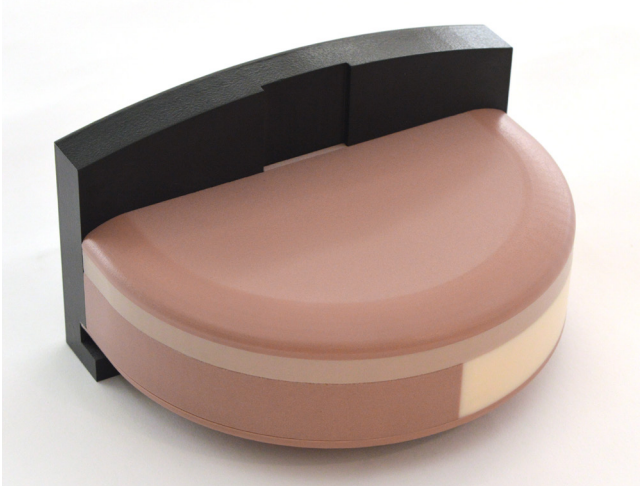
Model 022



USER GUIDE

CIRS

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OBJECTIVE

The CIRS Contrast Enhanced Spectral Mammography (CESM) Phantom is designed to address the need for QC of CEDM systems. The phantom demonstrates the presence and absence of iodine in tissues by containing different iodine concentrations and non-iodine breast tissue substitutes. The CESM phantom represents an average human breast in size and shape.

DESCRIPTION OF THE PHANTOM

The phantom consists of four slabs. A target slab is made from breast-equivalent material in 50/50 ratio of gland and adipose tissue. The slab contains two sets of five plugs. Four plugs have iodine concentrations of 0.2, 0.5, 1.0 and 2.0 mg/cm². These concentrations have been chosen to cover the clinical range of iodine concentrations. A fifth plug is made of 100% glandular tissue equivalent material. This plug is positioned in the center of each plug group to mimic a glandular reference. The contrast slab consists of half 100% adipose material and half 100% glandular material to test iodine separation from the background of fatty and dense breasts. The top and bottom slabs are made from 100% Adipose material and have rounded edges to mimic the realistic shape of a compressed breast.

The phantom includes a magnetic fixture for easy repeatable alignment and positioning.

PHANTOM SET UP

A number of optional breast tissue-equivalent slabs used with the magnetic fixture allows for creating different thickness breast (up to 75 mm) with a 50/50 % Glandular/Adipose ratio. Target slabs can be used together or individually at two different vertical positions (Z direction) with precision and repeatability. The magnetic fixture has a bottom lip to ensure proper use of the compression paddle.



IMAGING THE PHANTOM

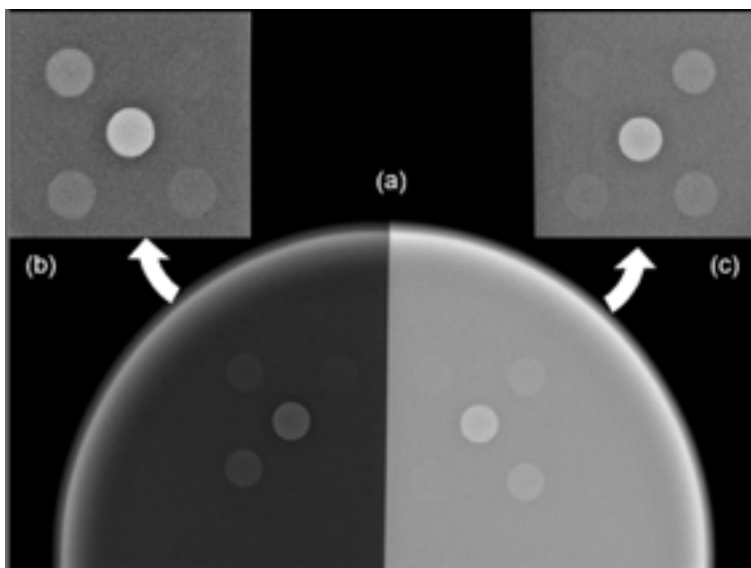
Doing a quick imaging session of the phantom will show nominal operation and give users full confidence before starting the examination.

The criteria to meet on the images are as follows:

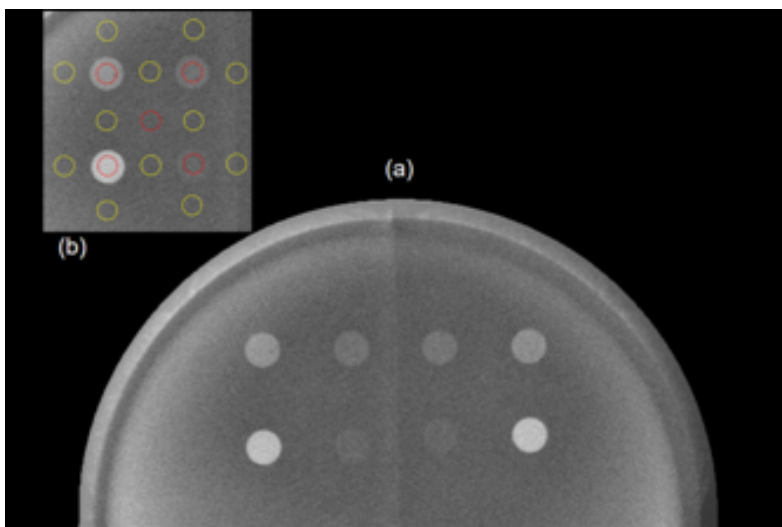
- Removal of contrasts between the tissue equivalent materials
- Iodinated inserts are visible
- Insensitivity of the iodine contrasts to the background material
- Correlation between iodine concentration and contrast in images

The criteria can quickly be visually checked making it a simple and effective test.

The user can use different contrast window settings for each half of the contrast slab allowing better demonstration different contrasts, good visibility of the glandular inserts and weak contrast of the iodine inserts



Regular mammogram of the complete phantom (Low energy component of the CESM pair) a) complete phantom; b) and c) details of adipose and glandular halves with different window settings



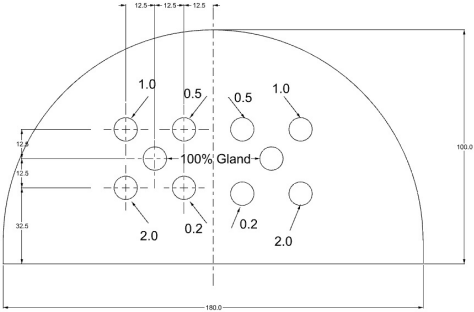
a) complete phantom; b) positions of the ROIs for measuring the image levels in the inserts (red) and the surrounding background (yellow). Applies on both sides.

References:

1. Klausz, R, et al. Introduction of a Comprehensive Phantom for the Quality Control of Contrast Enhanced Spectral Mammography. 2018. Poster No.: ECR 2018, DOI: 10.1594/ecr2018/C-2647

PHANTOM SPECIFICATIONS

OVERALL DIMENSIONS	180 mm x 110 mm x 100 mm
INDIVIDUAL SLAB DIMENSIONS	3 Slabs: 180 mm x 100 mm x 10 mm, 1 Slab: 180 mm x 100 mm x 25 mm,
PHANTOM WEIGHT	1.4 kg (3.09 lb)
MATERIALS	BR50/50, 100% Gland and Adipose



TARGET SLAB

PLUGS
 Qty: 4 with Iodine, 1 100% Gland
 Equivalent Material
 Size: 10 mm x 10 mm
 Concentration: 0.2, 0.5, 1.0 & 2.0
 mg/cm²

Model 022 Includes

PART #	QTY	COMPONENT DESCRIPTION
-	2	Solid Homogeneous Slabs 10 mm thick
-	1	Target Slab 10 mm thick
-	1	Contrast Slab 25 mm thick
-	1	Positioning Holder with Magnetic Fixation
-	-	60-month warranty

Optional Accessories

PART #	COMPONENT DESCRIPTION
021-01	BR3D Background Slab
021-02	Solid Homogeneous Slab (50/50 % Glandular/Adipose ratio)

CARE AND HANDLING

Phantom may be cleaned with mild soap and water. Avoid solvent or abrasive cleaning agents.

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 022 - Contrast Enhanced Spectral Mammography Phantom (CESM)	60 Months

CIRS

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