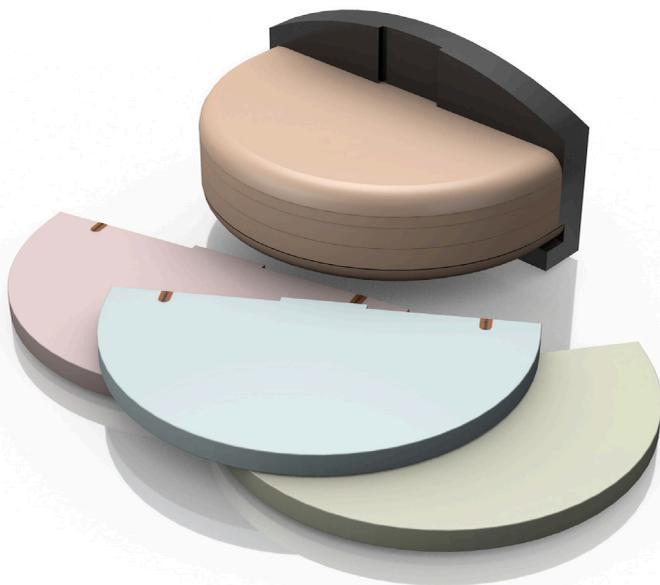


Digital Breast Tomosynthesis QC Phantom

Model 021



USER GUIDE

CIRS

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OBJECTIVE

The CIRS Digital Breast Tomosynthesis QC Phantom is designed to address quality control for Digital Breast Tomosynthesis systems (DBT). The phantom can be used for software analysis and “traditional” visual tests.

DESCRIPTION OF THE PHANTOM

Model 021 consists of eight homogeneous slabs made from breast-equivalent material in 50/50 ratio of gland and adipose tissue (BR50/50). Optional swirled slabs, that can be purchased separately, are comprised of 100% adipose and 100% gland tissues together in an approximate 50/50 ratio by weight. Three homogeneous slabs include imaging targets. The imaging portion of each semicircular shaped slab measures 100 x 180 x 10 mm. This allows for using a combination of homogeneous and swirled slabs to test the influence of scatter radiation on image quality in more clinically-relevant, inhomogeneous conditions.

All slabs can be easily assembled in different configurations using the magnetic holder. Top and bottom slabs have a rounded external edge for minimal artifacts.

PHANTOM SET UP

A number of homogeneous breast tissue-equivalent slabs used with a magnetic Positioning Holder allows for creating different thickness breast (up to 75 mm) with a “standard” 50/50 % Glandular/Adipose ratio. Target slabs can be used together or individually at different vertical positions (Z direction) with precision and repeatability. However, it is recommended to use only one imaging Target slab at a time to avoid additional artifacts. This does not apply for a grid Target slab.

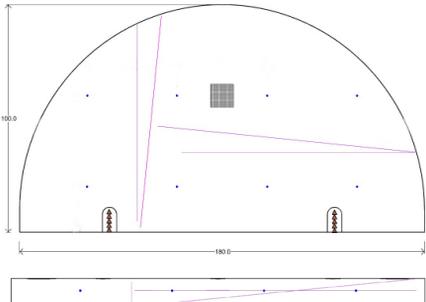
Additionally, solid homogeneous slabs put together provide 4.5 cm reference thickness of BR50/50 for performing homogeneity tests of the reconstructed tomosynthesis image.

The phantoms geometry allows for using one or two “swirled” slabs for an additional scatter. The “swirled” slabs are more representative for the real breast in terms of scatter that affects the reconstruction algorithms in DBT. These slabs or a slab of “swirl” material can be used for QC consistently on a single machine or on a number of machines at the same set-up so the conditions for every DBT scanner will be identical.

TARGET SLAB 1

Target slab 1 is equipped with targets that are similar to the EUREF Draft 0.10 and 0.15 proposals.

- Ceramic balls, geometrically arranged in 40x40 mm grid pattern, can be used for MTF, PSF and geometrical distortion in X and Y directions.
- Pure Al 10x10 mm by 200 μm thick sheet has enough surrounding space to perform SDNR and SNR.
- A tungsten wire in a mid-horizontal plane that has a tilt vs. X axis providing a similar feature as a referenced EUREF one.
- Another wire tilted vs. Y axis, might additionally help in a 90 degree direction since the DBT image acquisition process is not symmetrical in a XY plane.
- An additional pair of tungsten wires that are tilted in Z direction might help with MTF in Z direction and also a slice image reconstruction quality and Z artifact spread.
- Missed tissues targets are positioned on the slab surface in breast wall to nipple direction and provide an easy visual detection because they are made of 2 mm elements with a total length 10 mm.

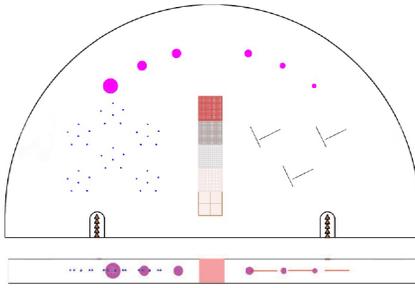


Target Slab 1 (Blue): Target Map, Top & Front View

TARGET SLAB 2

Target slab 2 is loaded with more traditional targets. They can be used for a visual evaluation when software is not available and as a reference for a single system performance over time.

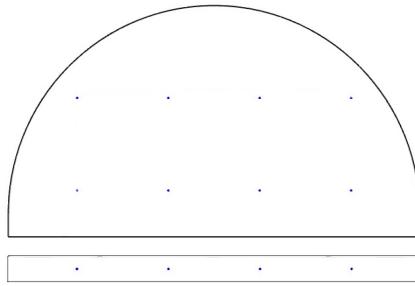
- Specs and spheroidal masses are used for a visual pass-fail evaluation.
- Step wedge with different glandular content used for a reference and dynamic range evaluation.
- A set of 6 fibers provide a threshold for visual pass-fail assessment.
- Similar but differently shaped missed tissue targets are positioned on the slab surface in breast wall to nipple direction and provide an easy visual detection because they are made of 2 mm elements with a total length 10 mm.



Target Slab 2 (Pink): Target Map, Top and Front View

TARGET SLAB 3

Target slab 3 is equipped with ceramic balls geometrically arranged in 40x40 mm grid pattern and can be used for MTF, PSF and geometrical distortion in X and Y directions. Target slab 3, used jointly with Target slab ,1 creates a 3D grid and allows for geometrical measurements in Z direction at different distances and locations.



Target Slab 3 (Green): Target Map, Top and Front View

PHANTOM SPECIFICATIONS

OVERALL DIMENSIONS	127 mm x 180 mm x 100 mm
INDIVIDUAL SLAB DIMENSIONS	6 Slabs: 110 mm x 180 mm x 10 mm, 1 Slab: 115 mm x 180 mm x 10 mm, (support slab) 1 Slab: 110 mm x 180 mm x 5 mm, semicircular shape
PHANTOM WEIGHT	1.62 kg (3.55 lb)
MATERIALS	BR50/50, BRSW5050

Breast Tomosynthesis QC

PART #	QTY	COMPONENT DESCRIPTION
-	4	Solid Homogeneous Slabs 1 cm thick
-	1	Solid Homogeneous Slabs 0.5 cm thick
-	1	Target Homogeneous Slab 1 (Blue): 1 cm thick
	1	Target Homogeneous Slab 2 (Pink): 1 cm thick
	1	Target Homogeneous Slab 3 (Green): 1 cm thick
-	1	Positioning Holder with Magnetic Fixation
-	-	60-month warranty
021-01	Optional	BR3D Background Slab for DBT phantom 021. Optional slab made of BRSW5050 compatible with 021 magnetic Holder

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 021 - Digital Breast Tomosynthesis QC Phantom	60 Months

CIRS

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