Tissue-Equivalent Phantoms for Mammography

Model 011A

USER GUIDE

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OVERVIEW

The American Cancer Society and American College of Radiology have published guidelines for the screening of asymptomatic women, making over 50 million women candidates for mammography. With such a high-quantity of procedures being performed, it is critically important that simple, reliable methods be developed to assess system performance and to ensure consistent imaging.

PHANTOM DESCRIPTION

Model 011A is a tissue-equivalent, anthropomorphic phantoms designed to test performance of any mammographic system. Simulated calcifications, fibrous ducts, and tumor masses are embedded into the phantom as test objects. Test objects range in size to allow system checks at varying levels of difficulty.

CIRS resin material mimics the photon attenuation coefficients of a range of breast tissues. The average elemental composition of the mimicked tissue is based on the individual elemental compositions of adipose and glandular tissues as reported by Hammerstein.

Attenuation coefficients are calculated by using the "mixture rule" and the Photon Mass Attenuation and Energy Absorption Coefficient Table of J.H. Hubbell.

Model 011A addresses all desirable features of breast-equivalent phantoms as described by NCRP Report No. 95 p 73 (see page 7). Phantoms are realistically shaped and are designed to mimic tissue of average firm breast. Breast detail components closely simulate the radiographic properties and shapes of normal and pathological breast structures. Phantoms can be used to evaluate radiation dose and image quality. The subjective assessment of detail visibility is easy to use for routine clinical assessment, while densitometry analysis provides necessary accuracy for laboratory work. The phantoms may be used for screen-film mammography or digital mammography.

Phantom Comparisons

Table 3 on page 8 provides a comparison of composite attenuation for various commercially-available mammographic phantoms and Hammerstein's references.(11)

Shape

Standard dental modeling techniques were used to obtain molds of the compressed right breast of a volunteer female subject.

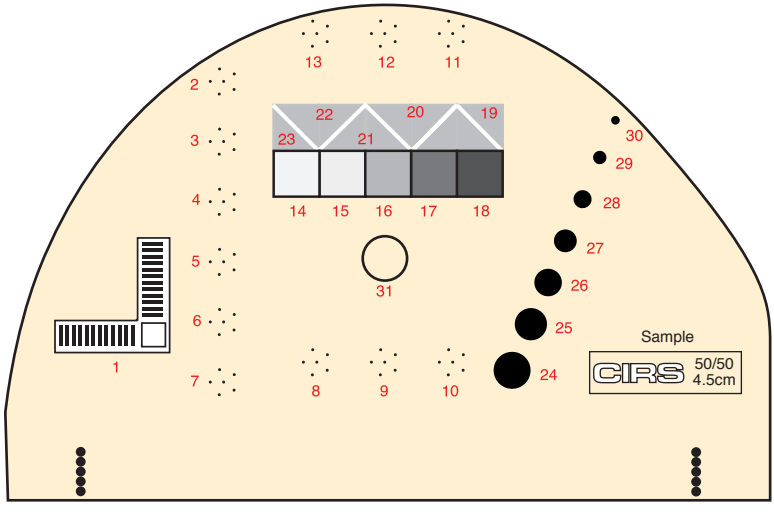
Materials

Tissue-equivalent resin molding techniques are used in the manufacturing process. Our resin molding system has been developed over the past 30 years to allow tissue mimicking at a range of energy levels. Refer to pages 7 and 9 for comparisons of linear attenuation coefficients of actual breast tissue and CIRS simulated tissue.

The materials used in each phantom have been formulated for optimum response in the film screen mammographic range of x-ray exposure (24 to 34 kVp). CIRS resin materials mimic the photon attenuation coefficients of a range of breast tissues. The average elemental composition of the mimicked human breast is based on the individual elemental compositions of adipose and glandular tissues as reported by Hammerstein. (11) See *Table 2 and 3* for comparative data (pages 7 and 8).

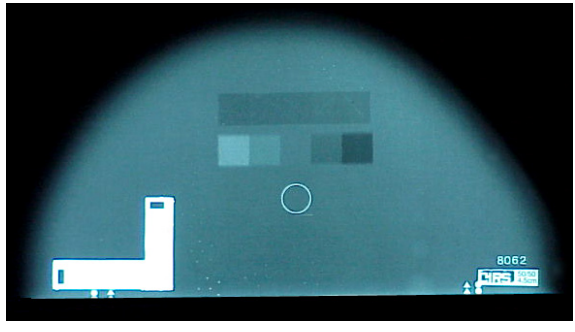
The attenuation coefficients are calculated using the "mixture rule" and the photon mass attenuation and energy absorption coefficients table of J. H. Hubbell. (16)

SPECIFICATIONS



1 Line Pair target 20 lp/mm	$CaCO_3$ specks grain size (mm)	Step Wedge 1 cm thick	Nylon Fibers diameter size (mm)	Hemispheric Masses 75% glandular/ 25% adipose thickness (mm)
31 Optical Density reference zone	2. 0.130	14. 100% gland	19. 1.25	
	3. 0.165	15. 70% gland	20. 0.83	
	4. 0.196	16. 50% gland	21. 0.71	
	5. 0.230	17. 30% gland	22. 0.53	
	6. 0.275	18. 100% adipose	23. 0.30	
	7. 0.400			
	8. 0.230			
	9. 0.196			
32 Edge of Beam localization target	10. 0.165			
	11. 0.230			
	12. 0.196			
	13. 0.165			

Phantom Body: Length 12.5 cm Width 18.5 cm Height 4-6 cm
Material: Epoxy



GENERAL USE OF PHANTOM

1. Select the technique you would use on a normal 4.5 cm compressed breast of average glandular composition.

2. Take one photo-timed image using standard technique for an average breast imaging patient.

3. With standard densitometer, read central background density in the center of the phantom image. This background density should be 1.2 to 1.4 optical density.

4. If first film does not give OD of 1.2 to 1.6, then adjust technique to obtain a background OD within this range.

5. Record technique and retain image. This becomes your Image Control Film.

QUANTITATIVE PROCEDURES

At least once a week, take an image of the phantom.

1. Count the number of microcalcification groups visible and record the number.

2. Count the number of simulated tumors and record the number.

3. With optical densitometer, read fat and gland steps of the step wedge. Record the values and the difference (i.e.: contrast). The Fat/Gland - Step 1 vs. Step 5 should be 0.34 or greater.

4. With microscope or magnification lens, identify the number of line pair/mm, which are discernible.

5. Record values on the record sheet provided by CIRS *(Figure 4, page 10)*.

INTERPRETATION OF MICROCALCIFICATION VISIBILITY

The specks in these phantoms are manufactured from pure calcium carbonate - ($CaCO_3$) the most common mineral composition found in microcalcifications in breast tissue.

The $CaCO_3$ is size selected in a two-part process. The first is a size grouping using ASTM standard laboratory sieves. The second is hand selection of individual specks by technicians trained to select the most uniform specks from each sieve size group.

MICROCALCIFICATION (CONT.)

The visibility of the resulting specks embedded in the phantom will be affected by the following conditions:

1. The individual speck is "pure $CaCO_3$" (There is a 1 percent impurity in the natural mineral).

2. The individual speck is round verses elongated in shape.

3. The broadest face of the speck, when imaged, is perpendicular to the beam.

4. The cassette screen is functioning optimally over the position of the speck.

Thus, while each group of the specks is positioned carefully, there are times when one or two specks in a group, especially the smaller sizes, will not always be visible when being imaged. This is normal.

TEST OBJECT DETECTABILITY

1. Detectability is a function of the combination of X-ray machine / Film type / Screen/ processor total system. As such, there is no singular answer to the question of detectability. Some machine/ film / processor combinations permit greater detectability than others. Because of this variability, QA record-keeping approach (*Figure 4, page 10*) is recommended.

2. For reference, detectability minimums (with film density = 1.2 to 1.6) are in the range set forth below.
   - — Line pair — 15 to 16 lp/mm identifiable
   - — Speck Group — All specks larger than 0.196 visible
   - — Nylon fibers — 4 largest visible
   - — Masses — 4 largest visible

LONG - TERM COMPARISONS

Once a quarter, take one of the weekly test films and compare visually to the initial Control Image Film *(Step 1 under - "What to do first")*. You should see identical images. If not, then corrective actions should be initiated.

RECORD KEEPING

1. Daily record of processor function (temperature and OD of Step 10 or 11). This requirement is well understood and not discussed further in this paper.

2. Weekly record of step wedge contrast and detail visibility.

3. Retained films of weekly phantom checks.

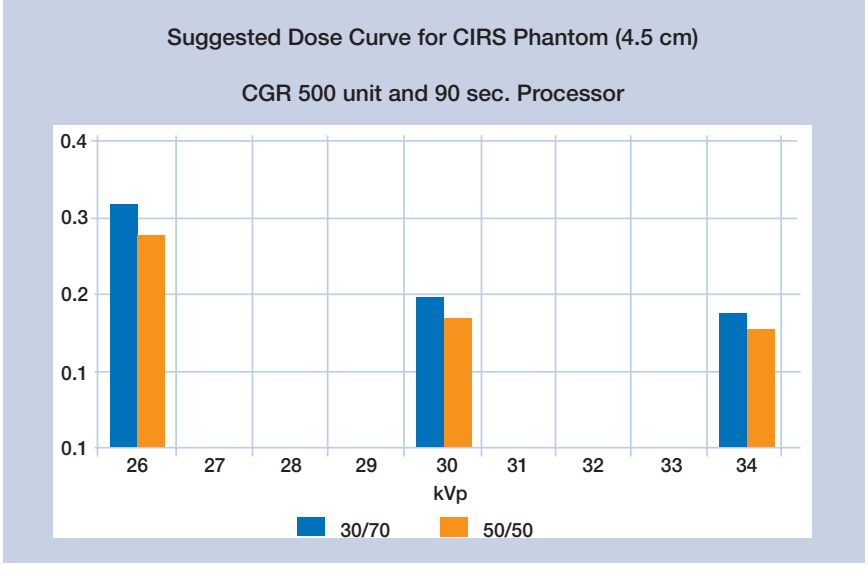
4. Keep the QA record sheets *(page 10)* in a file as proof of acceptable system performance.

STANDARD REFERENCE DEVELOPMENT

Phantoms for use in mammography should simulate a real breast as closely as possible. (2) A list of desirable features for such a phantom appears in Table 1 (page 7). Note that the phantom should be able to test for both image quality and dose if system performance is to be evaluated. The phantoms must also be easy to use and yield images that may be unambiguously interpreted.

Image Contrast may be measured quantitatively with standard densitometers through the use of the embedded step wedge.

Dose may be calculated by "TLD" or by ion chamber placed on top of the phantom and converted to average glandular dose through conversion tables (3.6 and 3.7) in NCRP Report #85. (2)



Resolution - Simulated tumors and microcalcifications of known size and location are embedded in the phantom for qualitative evaluation. The smallest microcalcifications and tumors are small enough that they will not normally be detected.

NOTES:

(1) 1/2 RAD is considered the maximum acceptable dose for 1 view mammogram of the average patient per NCRP- 80 criteria (NCRP-80 Pgs. 40 - 56.)

(2) Measurements were taken at exposure settings which produced background photographic density of 1.0 using ortho-m film, Min-R screen, grid, and general purpose processor.

DESIRABLE FEATURES OF A BREAST PHANTOM [1]

(TABLE 1)

1. Structural characteristics of the phantom

A.	Phantom should be realistically shaped.
B.	The phantom should be Tissue equivalent.
C.	Phantom should have realistic background.
D.	Phantom components should mimic features of breast disease\ (calcifications, tumors).

2. Phantom should be easy to use.

3. Phantoms should test relevant parameters including absorbed dose an image quality.

4. For phantom images it should be easy to interpret and provide accurate, unambiguous measure of image quality.

[1]According to NCRP Report No. 95, pg.73

LINEAR ATTENUATION COEFFICIENTS ACTUAL VS SIMULATED

(TABLE 2)

	100% Adipose		*70% Glandular*		*30% Glandular*		*100% Glandular*		*50% Glandular*	
KEV	Actual	Simulated	Actual	Simulated	Actual	Simulated	Actual	Simulated	Actual	Simulated
10	2.8211	2.7891	4.2396	4.0294	3.4026	3.3013	4.9195	4.6330	3.8120	3.6612
15	0.9424	0.9388	1.3600	1.3364	1.1136	1.1030	1.5602	1.5300	1.2341	1.2194
20	0.5011	0.5009	0.6815	0.6805	0.5751	0.5751	0.7680	0.7681	0.6272	0.6272
30	0.2770	0.2772	0.3388	0.3407	0.3023	0.3034	0.3684	0.3719	0.3202	0.3219
40	0.2194	0.2194	0.2528	0.2537	0.2331	0.2336	0.2688	0.2708	0.2428	0.2436
50	0.1956	0.1954	0.2188	0.2191	0.2051	0.2052	0.2220	0.2309	0.2118	0.2121
60	0.1824	0.1821	0.2010	0.2009	0.1900	0.1899	0.2099	0.2103	0.1954	0.1954
80	0.1668	0.1665	0.1813	0.1909	0.1727	0.1725	0.1883	0.1883	0.1770	0.1767
100	0.1566	0.1563	0.1693	0.1688	0.1618	0.1615	0.1754	0.1753	0.1655	0.1652

TOTAL ATTENUATION COMPARISON FOR VARIOUS PHANTOM DENSITIES AND SIZES (TABLE 3)

TISSUE	Acrylic	Acrylic	BR-12	50/50	30/70	50/50	30/70	50/50	20/80	50/50	50/50
THICKNESS (cm)	4.4	4.55	4.5	4.0	4.5	4.5	5.0	5.0	6.0	4.2	4.5
MFGR	ACR	Mfgr #2	CIRS	CIRS	CIRS	CIRS	CIRS	CIRS	CIRS	CIRS Slab	MTM 100
FAT LAYER	n/a	n/a	n/a	yes	yes	yes	yes	yes	yes	n/a	yes
KEV											
10	15.5565	17.0861	15.966	13.7728	14.3436	15.6034	15.9943	17.4341	18.4018	15.3772	15.6034
15	5.1325	5.6061	5.3214	4.5971	4.7993	5.2068	5.3508	5.8165	6.1676	5.1216	5.2068
20	2.6875	2.9129	2.7471	2.3826	2.5136	2.6962	2.8012	3.0098	3.2472	2.6344	2.6962
30	1.4487	1.5496	1.4186	1.2429	1.3391	1.4038	1.4908	1.5648	1.7488	1.3521	1.4038
40	1.1322	1.2024	1.0777	0.9502	1.0368	1.0720	1.1536	1.1938	1.3628	1.0232	1.0720
50	1.0027	1.0612	0.9404	0.8318	0.9136	0.9379	1.0162	1.0439	1.2047	0.8909	0.9379

This chart compares the composite attenuation for various phantom size/ density combinations. The linear attenuation coefficient for each type of material (wax, acrylic, gland, etc.) applied to the thickness of the material in each phantom design permits calculation of the coefficient of total attenuation for each design.

ACTUAL BREAST TISSUES

per Hammerstein

TISSUE	50/50	50/50	30/70	20/80	50/50	50/50
THICKNESS (cm)	4.5	5.0	5.0	6.0	4.2	4.0
MFGR	Actual	Actual	Actual	Actual	Actual	Actual
FAT LAYER	yes	yes	yes	yes	no	yes
KEV						
10	16.1631	18.0691	16.4315	18.8438	16.0104	14.2571
15	5.2618	5.8788	5.3966	6.2186	5.1833	4.6447
20	2.6962	3.0098	2.8015	3.2506	2.6341	2.3826
30	1.3976	1.5577	1.4864	1.7456	1.3447	1.2375
40	1.0691	1.1905	1.1519	1.3616	1.0196	0.9477
50	0.9370	1.0429	1.016	1.2049	0.8897	0.8311

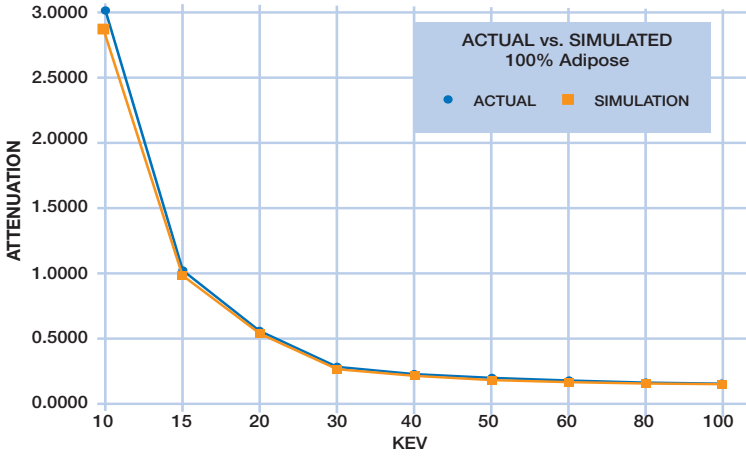


Figure 1

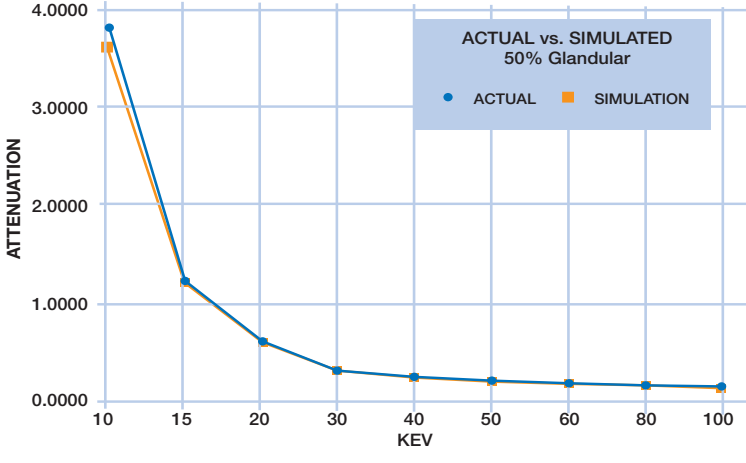


Figure 2

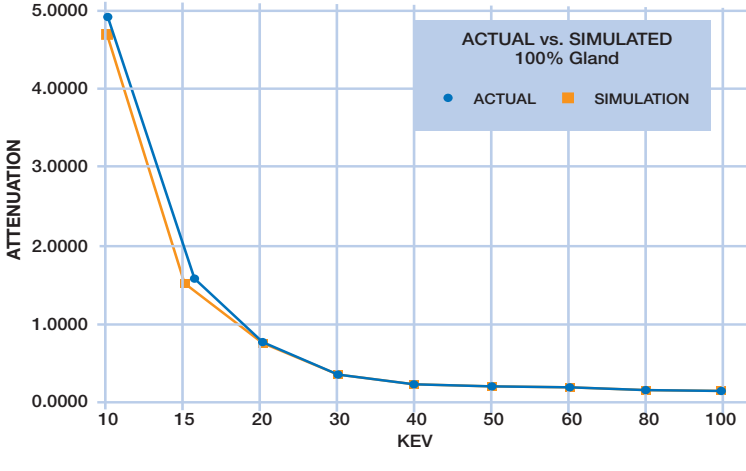


Figure 3

MAMMOGRAPHY
Quality Assurance Record

LOCATION _____ PROCESSOR TYPE _____ WEEK/MONTH _____
MAMMO UNIT _____ PROCESSOR CYCLE 90 sec/2.5 min/3.0 min QC PHANTOM # _____

	BASELINE	DAY/WK 1	2	3	4	5		REMARKS
Film Type								Record film type and serial number of film box in use.
KVP with phototimer)								Record KVP used for phantom test measurement. Use KVP normally used for average density 4.5cm breast.
mAs								Record mAs value.
Processor Temperature F								Record processor temperature at 9:00 a.m. each day.
Processor Contrast Step 911								Keep a box of film set aside-sensitize and process. Read step 10 with optical densitometer. Record value.
Processor Speed Sensitivity step 10								Again, read steps 9-11 on the sensitize film. Subtract step 9 value from step 11. Record contrast.
Phantom Contrast Step 1 to 5								On the phantom test image, read step wedge it Step1 and step 5. Subtract values. Record contrast.
Phantom Central Background Density								On the phantom test image, read background density in the middle of phantom With optical densitometer. Record values.
Phantom Calcifications								On phantom test image, count the number of micro calcification groupings visible. Record value.
Pantam Low Contrast Masses								On the phantom test image, count the number of low contrast masses visible. Record value.
Phantom Fibers								On phantom test image, count the number of fibers visible. Record value.
Phantom Line Pair Visible								On phantom test image, view line pair test target with microscope. Record the number of line pairs/mm resolvable
Edge of Beam								On phantom test image, count the number of dots in record. (One dot equates to 2 mm from edge of bucky.
Dose (Mean glandular dose for a 4.5cm 50% glandular breast)								Calculate the exposure monthly with ION chamber and convert to mean glandular dose or, contact CIRS for QC kit

FORM QC/01/02 Order replacement forms from: CIRS 2428 Almeda Ave. Suite 212, Norfolk, VA 23513 • (804) 855-2765

For daily readings, use 1 sheet/week.
For weekly readings, use 1-sheet/month.

Figure 4

CARE AND HANDLING

These phantoms are manufactured from high quality materials; but like the anatomy they represent, should be handled with care. Well-maintained equipment will last many years.

- When not in use, store in a safe location at normal room temperature. If subjected to temperatures above 110°F for any extended period of time, return the phantom to CIRS for recertification.

- Clean using mild soap and water solutions. Avoid contact with corrosive substances and with radiographic contrast media. Wash thoroughly if such contact occurs.

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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:

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Product	Warranty Period
Model 011A - Tissue Equivalent Phantom for Mammography	60 Months

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