Mammography Research Set

DISCONTINUED

MODEL 012A
USER GUIDE

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CIRS
Tissue Simulation & Phantom Technology

Mammography Research Set

The American Cancer Society and American College of Radiology guidelines for the screening of asymptomatic women have made over 50 million women candidates for mammography. In view of the staggering numbers involved, it is critically important that simple but reliable methods be developed to assess system performance and to assure consistent production of diagnostically useful images.

Contents

Clinical Usefulness

The phantom approaches the desirable features listed in *Table I.* The phantom is realistically shaped and has the tissue equivalency of an average, firm breast. Breast detail components closely mimic the radiographic properties and shapes of normal and pathological breast structures. The shape and configuration of the phantom make it easy to use by both technologists and physicists. Since the phantom is both realistically shaped and tissue equivalent, it can be reliably used to test for radiation dose as well as image quality. (6) Finally, the phantom provides valuable image quality information. The subjective assessment of detail visibility is easy to use for routine clinical assessment while densitometric analysis provides necessary accuracy for laboratory work. Hence, the phantoms may be used to assess the mammographic process as well as assuring consistent image performance.

Comparison With Other Phantoms

Table 3 provides a comparison of composite attenuation for various mammographic phantoms currently commercially available. Also shown are similar calculations for breast tissue using Hammerstein's references. (11)

Optional tissue densities - CIRS can manufacture any glandular/adipose combination from pure gland to pure fat.

Realistically Shaped Tissue Equivalent Breast Phantom

Shape - Standard dental modeling techniques were used to obtain molds of the compressed right breast of a volunteer female subject. This breast is 4.5 cm thick and approximately 18 cm in width.

Materials - Tissue-equivalent resin molding techniques were used. The system of resins used has been developed over the past 20 years to permit mimicking of any body tissue at different energy levels. Also shown in *Table 2 and Figures 1, 2 & 3* are comparisons of linear attenuation coefficients for actual breast tissue and CIRS simulated tissue.

The basic phantom, including a removable 0.5 cm adipose-equivalent tissue layer, matches the composition of an average 4.5 cm breast consisting of 50% glandular tissue and 50% adipose tissue and is realistically shaped. The phantom is suitable for evaluating the mammographic process in the laboratory as well as for monitoring system performance in the clinic. The Phantom may be used for screen-film mammography or digital mammography.

The materials used in this phantom have been formulated for optimum response in the film screen mammographic range of x-ray exposure (24 to 34 kVp). The CIRS resin materials mimic the photon attenuation coefficients of a range of breast tissues. The average elemental composition of the human breast being mimicked 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.

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

Optional sizes - The normal phantom is 4.5 cm in compressed thickness. Other sizes available are 4 cm, 5 cm, and 6 cm thickness.

How to use the CIRS Mammographic Phantom

What to do first

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 at the technique normally used for the 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).

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.

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.

Detectability of Test Objects in CIRS Model 012A

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 and it is for this reason that the QA record-keeping approach *(Figure 4)* is recommended.

2. For reference as a place to start , 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

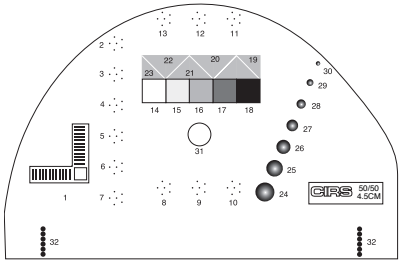
1. Daily record of processor function (temperature and OD of Step 10 or 11). This requirement is well understood and not discussed further in this paper.

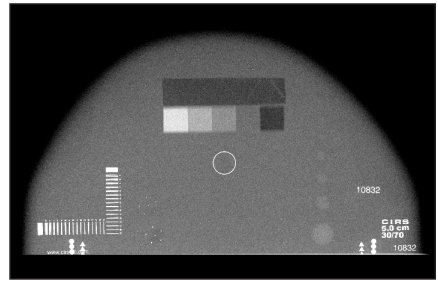
2. Weekly record of step wedge contrast and detail visibility.

3. Retained films of weekly phantom checks.

4. Keep the QA record sheets *(see Figure 4)* in a file. These records of system performance are valuable to you as a management tool and as proof of good "QA" should your system performance ever be challenged.

Specifications:
Model 012A Targets





1 Line Pair target 20 lp/mm **31** Optical Density reference zone **32** Edge of Beam localization target	**$CaCO_3$ specks grain size (mm)** 2. 0.130 3. 0.165 4. 0.196 5. 0.230 6. 0.275 7. 0.400 8. 0.230 9. 0.196 10. 0.165 11. 0.230 12. 0.196 13. 0.165	**Step Wedge 1 cm thick** 14. 100% gland 15. 70% gland 16. 50% gland 17. 30% gland 18. 100% adipose	**Nylon Fibers diameter size (mm)** 19. 1.25 20. 0.83 21. 0.71 22. 0.53 23. 0.30	**Hemispheric Masses 75% glandular 25% adipose thickness (mm)** 24. 4.76 25. 3.16 26. 2.38 27. 1.98 28. 1.59 29. 1.19 30. 0.90

Phantom Body: Length 12.5 cm Width 18.5 cm Height 4.5 cm
Material: Epoxy

Hemispheric Masses

Breast Thickness	Glandularity	
	Background	Mass
4 cm	50/50	75/25
5 cm	30/70	55/45
6 cm	20/80	55/45

Embedded Detail For Phototimer Compensation Plate

- **Contrast Stepwedge (5 mm thickness)**
  1. Adipose tissue
  2. Glandular tissue

- **Hemispheric Masses 75% Glandular Tissue Thickness (mm)**
  3. 3.16
  4. 2.38
  5. 1.98
  6. 1.59
  7. 1.19
  8. 0.90

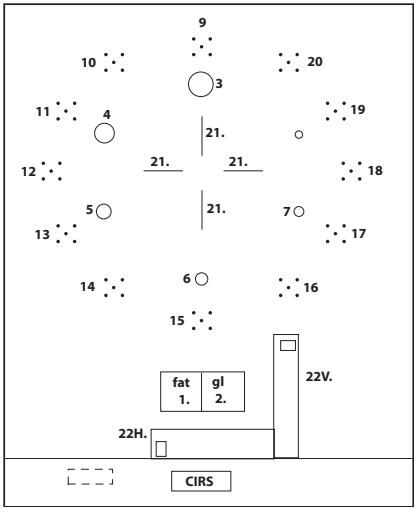
- **Specs Calcium Carbonate (mm)**
  9. 0.39
  10. 0.27
  11. 0.23
  12. 0.20
  13. 0.16
  14. 0.13

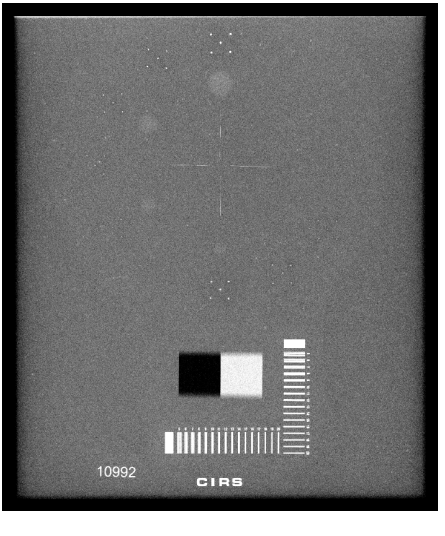
Alumina (mm)
15. 0.39
16. 0.27
17. 0.23
18. 0.20
19. 0.16
20. 0.13

- **Fibril**

21. Diameter = 25 Microns
    High Contrast

22. Line pair test target



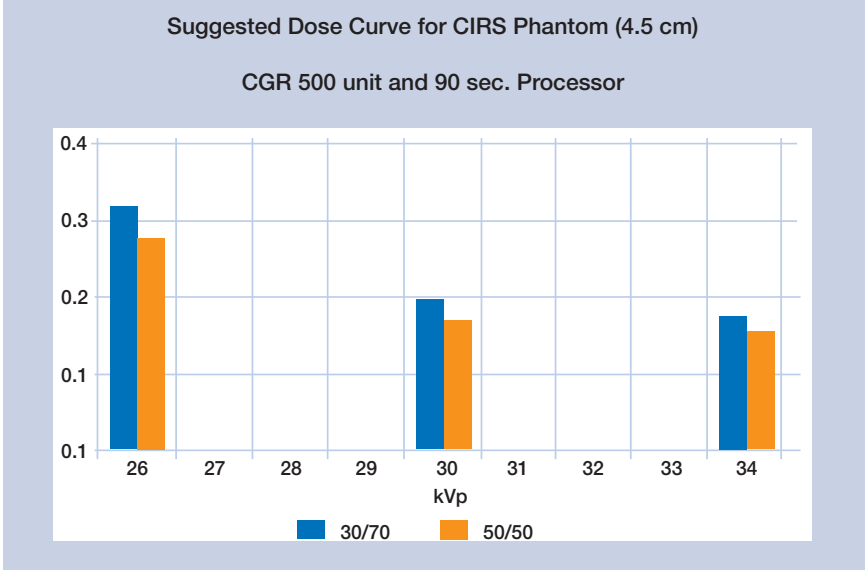


Standard Reference Development

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.* 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 (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.

For phantom images it should be easy to interpret and provide accurate, unambiguous measure of image quality. **NCRP Report No. 95, pg. 73

Linear Attenuation Coefficients Actual vs Simulated (TABLE 2)

100% Adipose		
KEV	ACTUAL	SIMULATED
10	2.8211	2.7891
15	0.9424	0.9388
20	0.5011	0.5009
30	0.2770	0.2772
40	0.2194	0.2194
50	0.1956	0.1954
60	0.1824	0.1821
80	0.1668	0.1665
100	0.1566	0.1563

70% Glandular		
KEV	ACTUAL	SIMULATED
10	4.2396	4.0294
15	1.3600	1.3364
20	0.6815	0.6805
30	0.3388	0.3407
40	0.2528	0.2537
50	0.2188	0.2191
60	0.2010	0.2009
80	0.1813	0.1909
100	0.1693	0.1688

30% Glandular		
KEV	ACTUAL	SIMULATED
10	3.4026	3.3013
15	1.1136	1.1030
20	0.5751	0.5751
30	0.3023	0.3034
40	0.2331	0.2336
50	0.2051	0.2052
60	0.1900	0.1899
80	0.1727	0.1725
100	0.1618	0.1615

100% Glandular		
KEV	ACTUAL	SIMULATED
10	4.9195	4.6330
15	1.5602	1.5300
20	0.7680	0.7681
30	0.3684	0.3719
40	0.2688	0.2708
50	0.2220	0.2309
60	0.2099	0.2103
80	0.1883	0.1883
100	0.1754	0.1753

50% Glandular		
KEV	ACTUAL	SIMULATED
10	3.8120	3.6612
15	1.2341	1.2194
20	0.6272	0.6272
30	0.3202	0.3219
40	0.2428	0.2436
50	0.2118	0.2121
60	0.1954	0.1954
80	0.1770	0.1767
100	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

The formula $\frac{I}{I_0} = e^{-ux}$ is applicable.

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

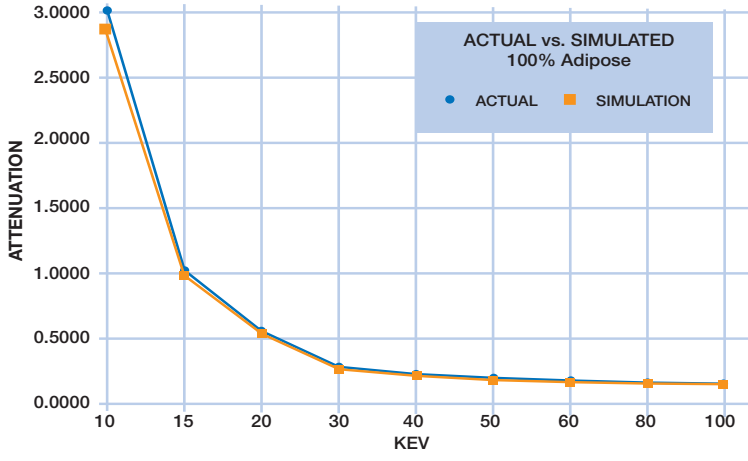


Figure 1

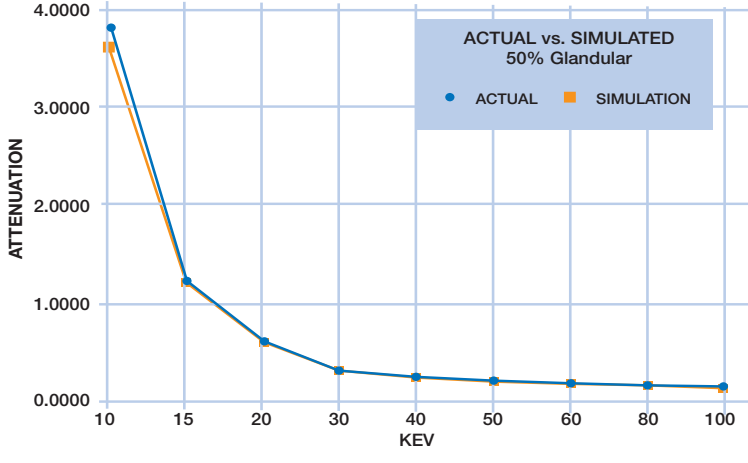


Figure 2

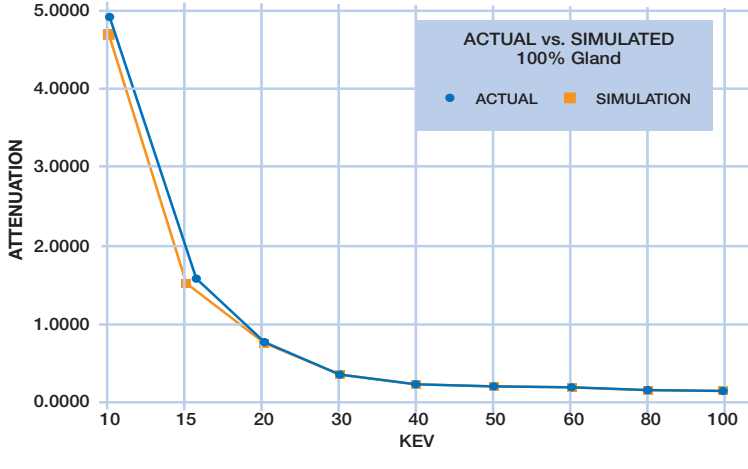


Figure 3

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, handle with care.

- If you will treat these phantoms as you would any fragile piece of technical equipment, they will serve you well for many, many years.

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

- Cleaning may be accomplished by 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:

CIRS
Receiving
900 Asbury Ave,
Norfolk, Virginia, 23513 USA

Product	Warranty Period
Model 012A - Mammography Research Set	60 Months

NOTES:

COMPUTERIZED IMAGING
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