Mammography Phototimeter Consistency Testing Slabs User Guide

Model 014A

SUN NUCLEAR
A MIRION MEDICAL COMPANY

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1 Introduction

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.

Product Description

Materials

Tissue-equivalent resin molding techniques are used. The system of resins used have been developed over the past 20 years to permit mimicking of any body tissue at different diagnostic X-ray energy levels. The elemental composition of CIRS simulating tissue as compared to Hammerstein's analysis[11] of human tissue is shown in *Specifications*. Also shown in Table A-3 and Figures A-1, A-2, and A-3 are comparisons of linear attenuation coefficients for actual breast tissue and CIRS simulated tissue.

The materials used have been formulated for optimum response in the film screen mammographic range of X-ray exposure (24 to 34 kVp), but will generally provide similar results at higher (xeromammographic) exposure ranges.

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 *Specifications* and Appendix A for comparative data.

Figure 1-1. Model 014A

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2 Use of the Phantom

General Use of Phantom

1. For testing slabs, make a series of exposures at different thicknesses by combining the slabs available. Make sure when stacking the slabs that they all have the same glandularity. For example make an exposure at 2, 3, 4, 4.5, and 5 cm.

   For an artifact evaluation phantom, make one exposure.
2. Mark each exposure so you can identify the film.
3. Measure each film's background density using an optical densitometer. Be sure to take your measurements in the same position on each film.
4. Calculate the mean optical density over all performance capability tests and determine the range of densities measured.
5. Record your results and compare variances in optical densities.
6. The optical density measurements should be relatively the same for each image taken.

Recordkeeping

Record test results:

Table 2-1. Test Results

Image#	Thickness	OD	Variance from the mean*
1	2 cm		
2	3 cm		
3	3.5 cm		
4	4 cm		
5	4.5 cm		
6	5 cm		
7	6 cm		
	Mean OD		

* For detailed test procedure steps and data analysis, refer to the *ACR Mammography Quality Control Manual*.[17]

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3 Support and Maintenance

Hardware Maintenance

Inspection

Periodically inspect your phantom and accessories for damage. If damage is visible, if any mechanical or electrical degradation is suspected, or if errors are suspected, discontinue use and contact Sun Nuclear Support. See *Contacting Sun Nuclear Support* below.

Repair

The phantom and the parts provided with the phantom cannot be repaired by the user. Most phantoms can be easily repaired, and if damaged, contact Sun Nuclear Support.

Cleaning

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.

Storage

The phantom is manufactured from epoxy resin. Various other chemicals and fillers have been added to the resin using a proprietary tissue simulation technology. As with most other epoxy plastics, your phantoms may discolor over time. This process can be accelerated by direct exposure to sunlight or extreme temperatures. Epoxy is quite durable, but can still be damaged if it is dropped on a hard surface so handle with care.

Epoxy plastics are flexible in nature and will creep (warp/bow/deform) under constant stress over time, even under its own weight. Creeping is not as common in smaller slabs. The slab will self-correct and recover its original shape if placed back in its original geometry. An easy way to maintain slab flatness and minimize creep is to store the slabs, clean and free of debris, on or in between flat surfaces. If slabs are to be shipped, special care should be given to packaging or the use of a specially fitted carry case which will protect flatness.

Disposal and Recycling

Do not discard unit as waste. Recycle the components in accordance with local regulations.

Contacting Sun Nuclear Support

You may request support in two ways:

- Submit a support request using our online form. See *Support Website* below.
- Contact the Sun Nuclear Support team by telephone:
  - U.S.A.: +1 321-259-6862, Option 3
  - Netherlands: +31 20 399 90 41, Option 1
  - Germany: +49 61 02 50 49 500, Option 2

Support Website

1. Open an internet browser and navigate to sunnuclear.com/support.
2. Enter your email address and password and then click **Login**.
   - To download product information, click **Products and Devices**, select the product, and then select the download type.
   - To open a Support request, click **Open New Case**, complete the form, and then click **Create Case**.

4 Specifications

Product Specifications

Standard Dimensions

Table 4-1. Standard Dimensions

Standard Glandularity	Model	Quantity	Length	Width	Thickness
BR12	014A	3	12.5 cm	10 cm	2 cm
		2	12.5 cm	10 cm	1 cm
		1	12.5 cm	10 cm	0.5 cm

For custom-ordered slabs with embedded detail plates, it is important to note that, unless otherwise requested, the background material will vary while the embedded targets will remain the same. Masses are composed of 75% Glandular/25% Adipose Breast-Equivalent material. The detectability of the mass will vary with the changing background composition to the point that even the largest mass may not be detectable (i.e., 5% contrast with the 70/30 background and the 75/25 mass).

Elemental Composition of CIRS BR12[1] Formula

C: 0.704 O: 0.169 H: 0.096 N: 0.019 Ca: 0.009 Cl: 0.002
Density = 0.97 g/cc

Calculated Attenuation Values[2]

10 keV	$\mu = 3.550\ cm^{-1}$
15 keV	$\mu = 1.183\ cm^{-1}$
20 keV	$\mu = 0.610\ cm^{-1}$
30 keV	$\mu = 0.315\ cm^{-1}$
40 keV	$\mu = 0.239\ cm^{-1}$
50 keV	$\mu = 0.209\ cm^{-1}$
60 keV	$\mu = 0.193\ cm^{-1}$
80 keV	$\mu = 0.174\ cm^{-1}$
100 keV	$\mu = 0.163\ cm^{-1}$

1. White, D.R., R.J. Martin, and R. Darlison, Epoxy resin based tissue substitutes, British Journal of Radiology, 5, 814-821, 1977.
2. Materials are formulated to maximize simulation properties at 20 keV for the mammographic range, 80 keV for the diagnostic range and 0.5 MeV and above for the therapeutic range.

Specify Glandular Equivalency When Ordering Other Than Standard

Table 4-2. Glandular Equivalency

Tissue Substitute	% Gland / % Adipose
BR-FAT	0/100
BR-3070	30/70
BR12	47/53
BR-5050	50/50
BR-7030	70/30
BR-GLAND	100/0

See *Material Specifications* on page 11 for more information.

5 References

1. *American Cancer Society*; CA32: 226-230; 1982.
2. *National Council on Radiation Protection and Measurements (NCRP)*; Report #85; March 86.
3. Stanton L., Villafana, Day, Lightfoot; *Dosage Evaluation in Mammography*; RADIOLOGY; 50:577-584; 1984.
4. Johns H.E., Cunningham J.R.; *THE PHYSICS OF RADIOLOGY*; 4th Edition.
5. McCrohon J.L., Thompson W.E., Butler P.F., Goldstein H.A., Phillips P.R., Jans R.G.; *Mammographic Phantom Evaluation Project*; HHS Publication; 83:8213; 1983.
6. Fatouros P.F., Skubic S.; *The Development and Use of Realistically-Shaped, Tissue Equivalent Phantom for Assessing the Mammographic Process*; RADIOLOGY; 157P:32; 1985.
7. Fatouros P.F.; *Resolution and Noise in Xeromammography*; MEDICAL PHYSICS; 9:819-829; 1982.
8. Fatouros P.F., Goodman H., Rao G., Beachley M., Janis S., Bourland P.; *Absorbed Dose and Image Quality in Xeromammography*. Proceedings SPIE; Vol 419; 1983.
9. White D.R., Tucker A.; *A Test Object for Assessing Image Quality in Mammography*; BJR 53:331-335; 1980.
10. Hessler C., Depeursinge C., Greceescu M., et al.; *Objective Assessment of Mammography Systems*, Part I: Method; RADIOLOGY; 156:215-219; 1985.
11. Hammerstein R., Miller D., White D., et al.; *Absorbed Dose in Mammography*; RADIOLOGY; 130:485-491.
12. Skubic S.; *An Investigation of the Relationship Between Image Quality and Breast Dose in Xeromammography*. Dissertation; Medical College of Virginia; May, 1986.
13. Skubic S., Fatouros P.F.; *The Dependence of Absorbed Breast Dose on X-Ray Modality, X-Ray Technique, and Breast Thickness*; RADIOLOGY; 161:263-270; 1986.
14. Fewell, Shuping; *Handbook of Mammographic Spectra*; FDA Publication.
15. Skubic S.E., Fatouros P.P., Goodman H.; *The Effect of Breast Composition on Absorbed Dose and Image Contrast*; In Publication.
16. Hubbell J.H.; *INTERNATIONAL JOURNAL RADIATION ISOT*; Vol. 33:1269-1290; 1982.
17. *American College of Radiology Guidelines on Mammographic Screening*; 1999.

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Total Attenuation Comparison for Various Phantom Densities and Sizes

Table A-1. Linear Attenuation Comparison for Various Phantom Densities and Sizes

Tissue Substitute	Acrylic	Acrylic	BR12	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	**Attenuation Coefficients**										
10	15.5565	17.0861	15.9660	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

Table A-2. 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	**Attenuation Coefficients**					
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

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

Table A-3. Linear Attenuation Coefficients Actual Vs. Simulated

keV	100% Adipose		70% Glandular		30% Glandular		100% Glandular		50% Glandular	
	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

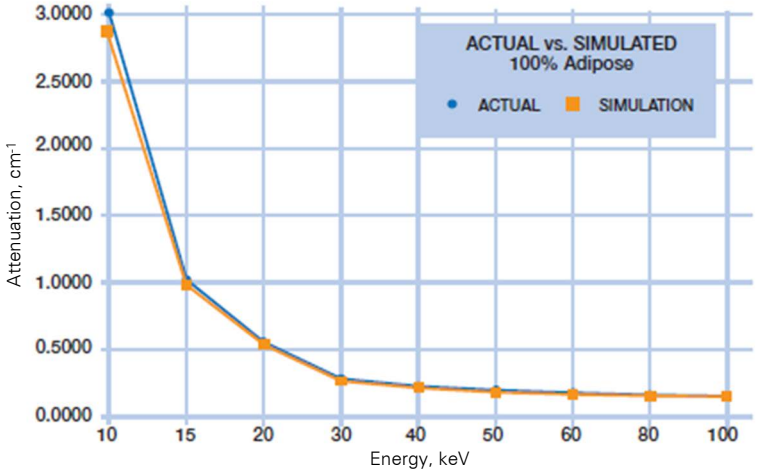

Figure A-1. 100% Adipose

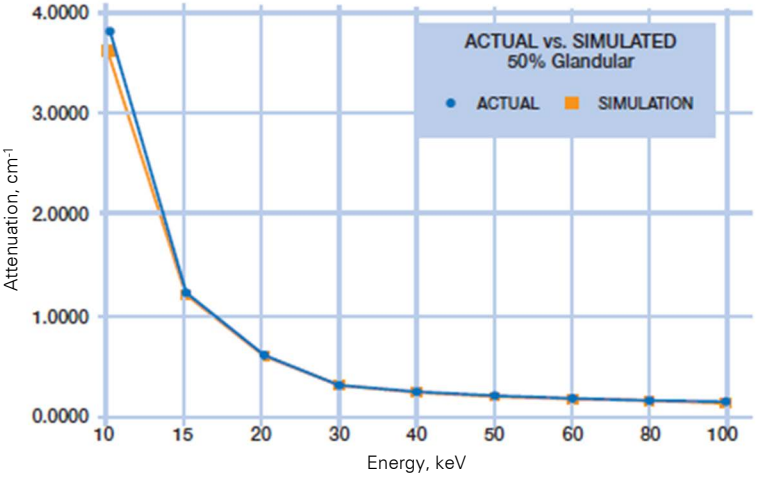

Figure A-2. 50% Glandular

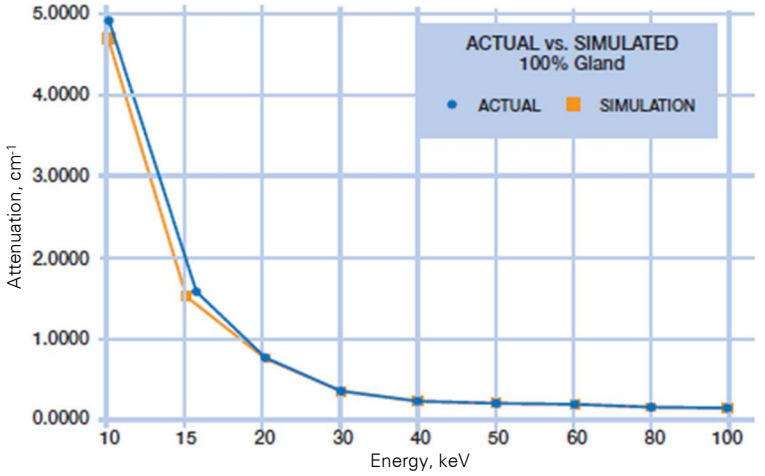

Figure A-3. 100% Glandular

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Appendix B: Regulatory Supplement

In addition to the regulatory information contained in the body of this manual, the following supplemental regulatory information is provided.

Sun Nuclear Corporation Symbols

The following symbols are used in this guide and in Sun Nuclear Corporation's product labels.

WARNING: This symbol indicates a hazard that could result in major injury or equipment damage. (EN ISO 7010, W001)

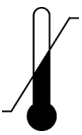
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

CAUTION: This symbol indicates a pinch hazard. (EN ISO 7010, W024)

Note: *Important or supporting information.*

Manufacturer's Identification (name and address). (EN ISO 15223-1, 5.1.1)

Date of Manufacture. (EN ISO 15223-1, 5.1.3)



Temperature limitation. (EN ISO 15223-1, 5.3.7)

Humidity limitation. (EN ISO 15223-1, 5.3.8)

Atmospheric pressure limitation. (EN ISO 15223-1, 5.3.9)

Serial Number. (EN ISO 15223-1, 5.1.7)

Catalog Number. (EN ISO 15223-1, 5.1.6)

Consult instructions for use. This equipment must be used in accordance with the instructions in this manual. Read all instructions and safety labels before use. (EN ISO 15223-1, 5.4.3)

Do not throw in trash; dispose of in an environmentally friendly way. (EN 50419)

Operator Responsibility

The instructions in this manual are intended for trained clinical personnel. The operator is solely responsible for the accurate setup and use of the phantom.

Reporting Health or Safety Related Issues or Concerns

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

Modifications to Equipment

Any changes or modifications to the device that are not expressly approved by Sun Nuclear Corporation could void your warranty.

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