Tissue-Equivalent Phantoms for Mammography User Guide

Model 011A

SUN NUCLEAR
A MIRION MEDICAL COMPANY

Tissue-Equivalent Phantoms for Mammography User Guide

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1 Introduction

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 ensure consistent imaging. Model 011A is an optional tool to enhance any mammography Quality Assurance Program by providing additional test objects and expanded range to better understand the performance of the mammography system being used.

Product Description

Model 011A is a tissue-equivalent, anthropomorphic phantom designed to test performance of any mammographic system beyond those tests required by equipment manufacturers' validation and quality control maintenance written instructions. 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.[11]

Attenuation coefficients are calculated by using the "mixture rule" and the Photon Mass Attenuation and Energy Absorption Coefficient Table of J.H. Hubbell.[16]

Model 011A addresses all desirable features of breast-equivalent phantoms as described by NCRP Report No. 85 p 73 (see *References*). 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 A-2 on page 15 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 14 and 17 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 A-1 on page 14 and Table A-2 on page 15 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]

Figure 1-1. Model 011A

2 Use of the Phantom

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 the 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.
6. General test procedure steps listed can follow the ACR mammography QC test protocols.[17]

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 Wedge Item 14 vs. Item 18 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 (see Figure A-4, page 19).

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.

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 recordkeeping approach (Figure A-4, page 19) 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[17] (refer to Step 1 on page 175, *American College of Radiology Guidelines on Mammographic Screening*). You should see identical images. If not, then corrective actions should be initiated.

Recordkeeping

1. Daily record of processor function[17] (temperature and OD of Step 10 or 11 on pages 175-176, *American College of Radiology Guidelines on Mammographic Screening*). This requirement is well understood in the *ACR Mammography Quality Control Manual* 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 19) 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 page 13. 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]

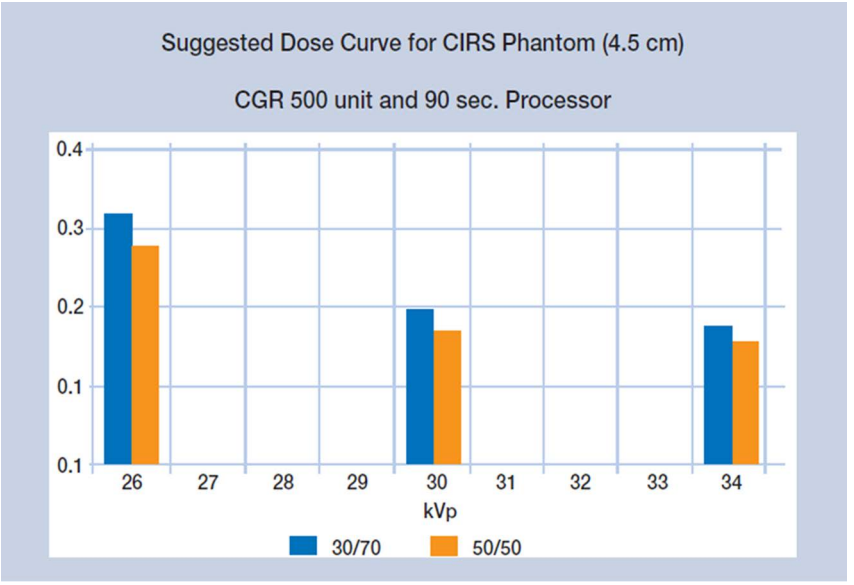


Figure 2-1. Suggested Dose Curve

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.

Note:

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

3 Support and Maintenance

Hardware Maintenance

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.

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

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

Storage

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 Sun Nuclear for recertification.

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:

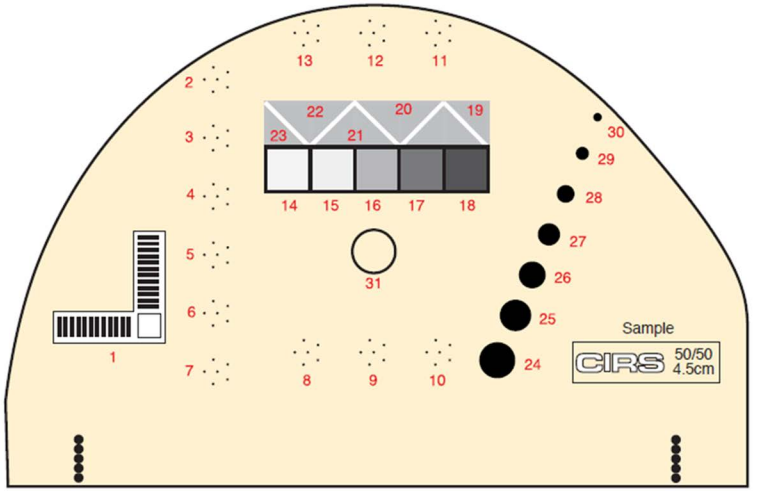
- Submit a support request using our online form. See *Support Website* below.
- Contact the Sun Nuclear Support team by telephone:
  - U.S.A.: +1 321-259-6862, Option 3
  - Netherlands: +31 20 399 90 41, Option 1
  - Germany: +49 61 02 50 49 500, Option 2

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

Target Layout



1 Line Pair target 5 to 20lp/mm (16 segments with 5 lines each: 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and 20) 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)

Figure 4-1. Target Map

Phantom Body:

- Length: 12.5 cm
- Width: 18.5 cm
- Height: 4–6 cm

Material: Epoxy

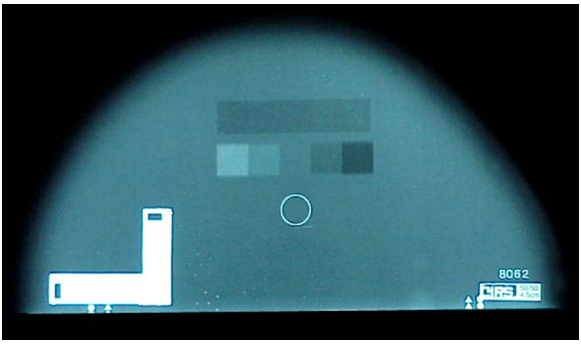


Figure 4-2. Phantom Image

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.
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10. Hessler C., Depeursinge C., Greceescu M., et al.; *Objective Assessment of Mammography Systems*, Part I: Method; RADIOLOGY; 156:215-219; 1985.
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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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Appendix A: Material Specifications

Desirable Features of a Breast Phantom

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

Table A-1. Linear Attenuation Coefficients Actual Vs. Simulated

	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

Table A-2. Linear Attenuation Comparison for Various Phantom Densities and Sizes

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	15.9660	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-3. 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

Actual Versus Simulated

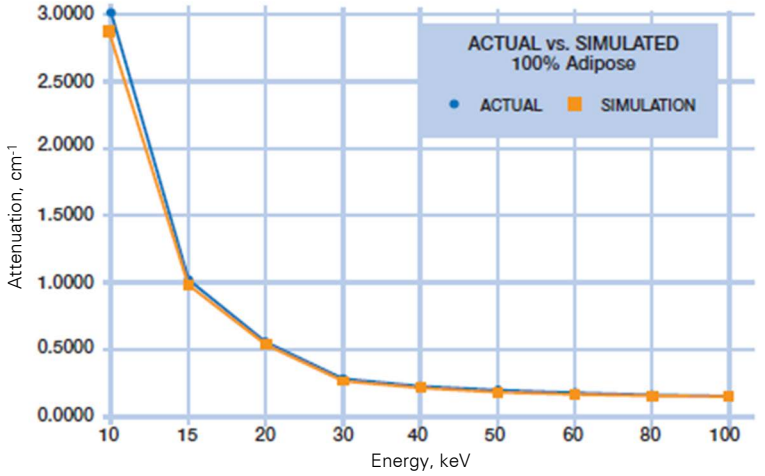

Figure A-1. 100% Adipose

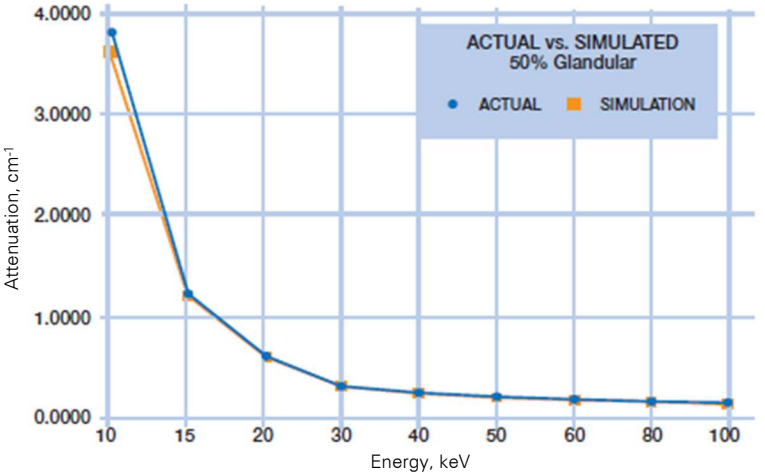

Figure A-2. 50% Glandular

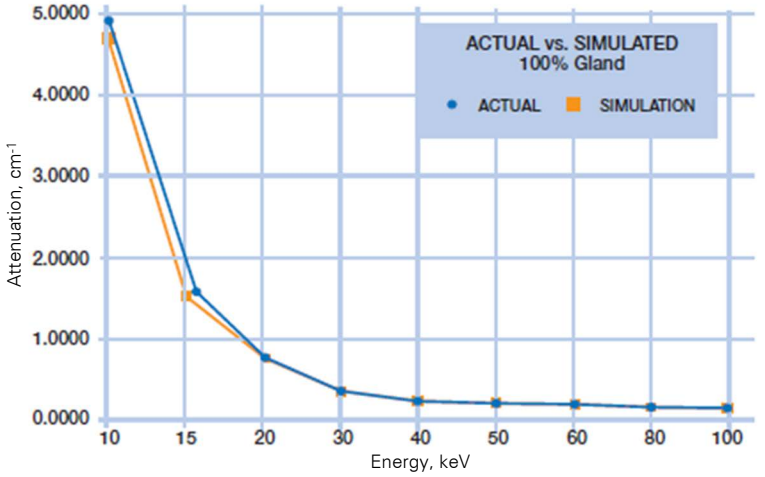

Figure A-3. 100% Glandular

MAMMOGRAPHY Quality Assurance Record	LOCATION _____ MAMMO UNIT _____			PROCESSOR TYPE _____ PROCESSOR CYCLE 90 sec/2.5 min/3.0 min			WEEK/MONTH _____ 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.
Phantom 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							For daily readings, use 1 sheet/week. For weekly readings, use 1-sheet/month.

Figure A-4. Mammography Quality Assurance Record

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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)

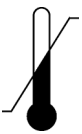
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

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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