Brachytherapy QA Phantom User Guide

Model 045B

SUN NUCLEAR
A MIRION MEDICAL COMPANY

Brachytherapy QA Phantom User Guide

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1 Introduction

Model 045B is a sturdy, reliable phantom for testing the imaging performance of side-fire and bi-plane probes used for transrectal ultrasound imaging in prostate brachytherapy seed implantation. The Model 045B phantom offers a complete solution for implementing a brachytherapy QA program as recommended by AAPM Task Group 128.[1]

The phantom is supplied with a water tank for vertically coupling a transducer to the scanning membrane. Brachytherapy needle grid QA can be accomplished using the space available inside the water tank as specified by Goldstein et al.[2] The tank has two angled slots to allow the phantom to be positioned at a 30° angle which simplifies use with floor-mounted TRUS systems. When testing table-mounted TRUS systems, the phantom membrane can be oriented vertically. (See pages 2 and 3 for images.)

Model 045B has a series of monofilament targets that will appear as bright dots or lines on the ultrasound image. These targets are made from monofilament nylon wire with a diameter of 0.4 mm and a positional accuracy of ±0.2 mm. There are also three volumetric targets. These targets are made from Zerdine® that has a different contrast relative to the background material.

CIRS is certified to ISO 13485:2016 standards. We have an in-house test facility to measure acoustic properties of speed, attenuation, and relative contrast. In addition, two ultrasound systems are used to visually inspect each phantom. As a result, every ultrasound phantom is subjected to rigorous testing both during manufacture and upon completion. A Certificate of Compliance is issued with each phantom.

For further guidance on establishing a quality assurance program, you may want to reference the accreditation programs established by the ACR and AIUM. You can access this information at www.acr.org or www.aium.org. If additional information is required, contact Sun Nuclear Support. (See *Contacting Sun Nuclear Support* on page 14.)

1. Pfeiffer, Douglas, et al., AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems. Med. Phys., vol. 35 (12), pp. 5471–5489, December 2008.
2. Goldstein, A., Yudelev, M., Sharma, R.K. and Arterbery, E. (2002), Design of Quality Assurance for Sonographic Prostate Brachytherapy Needle Guides. Journal of Ultrasound in Medicine, 21: 947-954. doi:10.7863/jum.2002.21.9.947

- Uniformity
- Depth of Penetration
- Vertical Distance Measurement Accuracy
- Horizontal Distance Measurement Accuracy
- Electronic Grid Accuracy
- Stepping Mechanism Accuracy
- Volume Measurement Accuracy
- Needle Alignment Testing

Figure 1-1. Phantom is placed vertically in water tank for testing.

Figure 1-2. Tank needs to be filled with water prior to use.

Figure 1-3. Phantom can be positioned at 30 degrees for compatibility with floor mounted brachytherapy systems.

Figure 1-4. Tank needs to be filled with water prior to use.

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2 Setup and Measurements

General Guidelines for Performing Measurements

It is recommended that all measurements be performed at the most frequently used imaging arrangements. The importance of these tests is to make sure that system performance remains constant over an extended period of time. Measurements may also be used to compare the performance of various setups of the same machine or to compare different machines in a quantitative manner.

The following are general steps for imaging all targets:

- Some wires will appear as short lines rather than dots. When using the electronic calipers, always take measurements from a point on one echo to the same point on the next (i.e., center to center). Otherwise, errors may be introduced.
- When assessing vertical distance measurements, DO NOT press on the scanning surface. Pressure on the scanning surface causes the wires to become temporarily displaced, making vertical distance measurements inaccurate.
- When assessing horizontal distance accuracy, ensure that the scan plane is perpendicular to the horizontal target group. Rotation of the probe will result in inaccurate distances.
- Always be sure the phantom is scanned while at room temperature. A phantom just received may be colder or hotter than room temperature depending on where it was stored during shipping. Temperature affects the speed of sound and, ultimately, the perceived measurements. The phantom should be stored at room temperature for at least 24 hours before use to ensure its core temperature is correct.
- The most accurate measurements will be made with the phantom 22°C ± 1°C (70°F–73°F).

Establishing a Baseline

Before performing routine quality assurance measurements, establish:

1. System settings for each measurement:

   System setup can have a dramatic impact on the results obtained from quality assurance measurements. You must establish and record what system settings should be used for each of the quality assurance tests. These same settings should be used each time the test is performed. If not, then the conclusions drawn may not be valid. CIRS recommends that you use the most commonly used settings for the type of probe tested (i.e., the brachytherapy preset values) which are called a “normal” technique in the sections that follow.

2. Baseline measurements:

   The first set of measurements taken will be the baseline measurements for the combination of system settings and phantom. Record the system settings and phantom serial number used to acquire each measurement along with your measurement results. On subsequent scans, refer to the baseline results to determine if the ultrasound system has drifted to an unacceptable level. It is each facility's responsibility to establish the magnitude of drift allowed before corrective action is warranted.

3. Allowable deviation from baseline measurements:

   The difference between the original baseline measurements and subsequent measurement should be calculated and recorded. At some point, the difference will be large enough that some action is required (call service, replace system, etc.). Each facility needs to determine the action level for each test. You should refer to the user manual of your ultrasound scanner and note the stated accuracies of the system's general imaging measurements. These stated ac- curacies may greatly influence the conclusion made when evaluating the ultrasound system. For example, if the measurement accuracy for your system is 10% for distances up to 2 cm, the scanner may detect 2.0 cm as being anywhere from 1.8 cm to 2.2 cm and still be functioning properly. The user is responsible for establishing action levels.

4. Frequency of system assessment:

   How often each system is evaluated is also up to each facility to determine. CIRS recommends at least annually.

Reference the accreditation programs established by the ACR and AIUM at www.acr.org or www.aium.org for further guidance on establishing a QA program.

3 Testing Procedures

The following sections outline procedures for performing routine quality control tests with the imaging targets contained within Model 045B. The water tank should be filled with water and phantom placed inside the tank when performing test procedures. See the following references for further test procedure details:

- Pfeiffer, Douglas, et al., AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems. Med. Phys., vol. 35 (12), pp. 5471–5489, December 2008.
- Goldstein, A., Yudelev, M., Sharma, R.K. and Arterbery, E. (2002), Design of Quality Assurance for Sonographic Prostate Brachytherapy Needle Guides. Journal of Ultrasound in Medicine, 21: 947-954. doi:10.7863/jum.2002.21.9.947

Uniformity Testing

Uniformity is defined as the ability of the machine to display echoes of the same magnitude and depth with equal brightness on the display. This is a good test to ensure all crystals within the transducer are functioning. Uniformity testing is performed as follows:

1. Position the transducer on the scanning surface in a region with a minimum number of targets.
2. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
3. Align the probe so that the targets are maximized.
4. Freeze the image and obtain a hard copy.
5. Observe the general appearance of the phantom. Note if all regions at the same depth are displayed with the same intensity across the width of the image.
6. Record your observations.

Depth of Penetration Testing

Depth of penetration, also called maximum depth of visualization or sensitivity, is the greatest distance in the phantom for which echo signals caused by scattering in the background material can be detected on the display. The depth of penetration is determined by the frequency of the transducer, attenuation of the medium being imaged, and system settings. It is measured with the aid of the "N" group wire targets as follows:

1. Position the transducer above the "N" Group and perpendicular to the wires. (The wires should appear as dots, not lines.)
2. Adjust the instrument settings (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.

3 Align the probe so that all the vertical targets are displayed at their maximum intensity level.

4 While actively scanning, look to see where the scatterers within the background material disappear. Be careful not to confuse electronic noise with the background scatterers. Electronic noise will move; scatterers will remain stationary.

5 Freeze the image.

6 With electronic calipers, measure the distance between the scanning surface and the last identifiable echo due to scattering.

Note: *The wires may be visible even though the scatterers are not. Remember to measure the distance to the scatterers, not the last visible wire.*

7 Record this distance on a record sheet and compare with baseline depth.

Vertical and Horizontal Distance Accuracy - Using Electronic Calipers

If the displayed grid does not line up with the N-shaped target group or you want a more precise measure of distance accuracy, electronic calipers may be used. Vertical distance is defined as the distance along the axis of the beam. Horizontal distance is defined as the distance along the length of the transducer. Distances are used to measure areas, volumes, depths, and sizes of objects. The vertical array of targets at column B and F on the phantom diagram allow one to assess the accuracy of the vertical measurements, while the horizontal array of targets at row 1 through 5 assess horizontal measurement accuracy. For bi-plane probes, the crossing wires in the z-axis can also be used for horizontal measurements and provide spacing from 0.5 cm to 5.0 cm.

1 Adjust the instrument setting (gain, TGC, output, etc.) as for a “normal” technique. Record these settings for use on subsequent testing.

2 Align the probe so the N-shaped target group is maximized.

3 Freeze the image.

4 Using electronic calipers, measure the distances between two wires at various depths or align the echoes to the ultrasound system display markers for comparison.

5 Record measurements.

6 Compare measured values with baseline distances.

7 Repeat steps using horizontal targets in the N-shaped group.

Vertical and Horizontal Distance Accuracy

Vertical distance is defined as the distance along the axis of the beam, while horizontal distance is defined as the distance along the length of the transducer. Distances are used to measure areas, volumes, depths, and sizes of objects. Using the "N" target group, the vertical array of targets at column B and F on the phantom diagram allow one to assess the accuracy of the vertical measurements, while the horizontal array of targets at row 1 through 5 assess horizontal measurement accuracy. For bi-plane probes, the crossing wires in the z-axis can also be used for horizontal measurements and provide spacing from 0.5 cm to 5.0 cm.

For the most precise assessment of vertical and horizontal distance measurement accuracy, use the electronic calipers as follows:

1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
2. Align the probe so the N-shaped target group is maximized.
3. Freeze the image.
4. Using electronic calipers, measure the distances between two wires at various depths or align the echoes to the ultrasound system display markers for comparison.
5. Record measurements.
6. Compare measured values with baseline distances.
7. Repeat steps using horizontal targets in the N-shaped group.

Electronic Grid Accuracy

One important aspect for any brachytherapy procedure is accurate placement of seeds within the prostate. An integral part of seed placement and treatment planning is the accuracy of the distances measured. By aligning this grid to the "N" target of the phantom, users can perform a quick check of vertical and horizontal distance accuracy as follows:

1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
2. Align the probe so the N-shaped target group is maximized.
3. Secure your transducer and position the stepping/stabilization unit accordingly. For ease of alignment you may want to place the front surface of the phantom in contact with the needle template. Adjust the probe/phantom position until the targets are aligned with the displayed grid. It may be easiest to align the center target with the center-displayed target and then try to align the rest of the grid.
4. Proper alignment is achieved when the displayed grid is superimposed on wire target echoes. The wires may appear larger or smaller than the displayed grid dots. If the targets appear larger, try to align the centers of the

targets with the displayed grid dots. Depending on the manufacturer of your brachytherapy system and ultrasound machine, row 1 on the phantom may or may not represent row 1 on the displayed grid. If you have difficulty aligning the targets with the displayed grid, you can assess horizontal and vertical distance accuracy by using the electronic calipers.

5 Record results.

Stepping Mechanism Accuracy

Just as vertical and horizontal distance measurements are important for accurate seed placement in the x-axis and y-axis, the condition of the stepping mechanism is critical to accurate seed placement in the z-axis. Perpendicular to the N-shaped target group are five wires all at the same distance from the transducer, but separated by 0.5 cm and 1.0 cm in the z-axis.

1 Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.

2 Align the probe so targets are maximized.

3 Insert the transducer towards the back of the scanning cavity and align the beam with crossing wire number 6 as indicated on the side of the phantom. This target will appear as a short line in row 4 above the transducer. Once this target is visualized, secure the stepping mechanism in place.

4 The next crossing wire (#5) is exactly 1.0 cm from wire #6 in the z-axis. Using the stepping mechanism, retract the transducer by 1 cm (in most cases this is two "clicks" on the stepping mechanism). Wire #5 will now be visible if the mechanism is working. If no wire is visible, the stepper has either retracted the transducer too much or too little. Manual manipulation of the transducer forward and backward to the target may give you some approximation as to the degree of error.

Note: *The accuracy of this assessment is dependent on the width of the ultrasound beam.*

5 Record results.

6 Repeat for various retraction distances as specified in your QA plan.

Volume Measurement Accuracy

Dose mapping is heavily dependent on accurate assessment of prostate volume. Model 045B contains three different calibrated test objects specifically designed to assess volume measurement accuracy. The volume of each test object is physically measured with a tolerance of ±0.5 cc using Archimedes Principle before insertion within the phantom. The volumes are recorded on the accompanying certification sheet. Perimeters which are estimated from the measured volume with the equations listed below, are also provided. Perimeters stated in the certifications are only intended to be used nominally. The small and

medium volumes are spherical, but the large volume is egg-shaped as seen in Figure 3-1 and Figure 3-2.

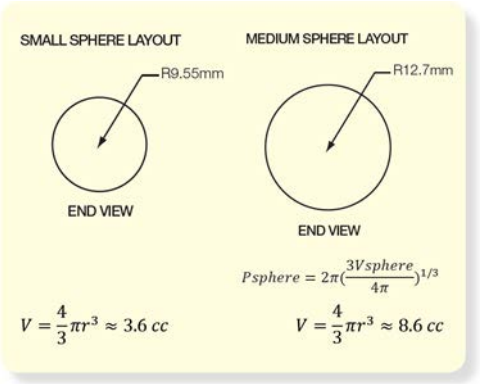

Figure 3-1. Sphere volumes and perimeters (see certification sheet for actual values in your phantom)

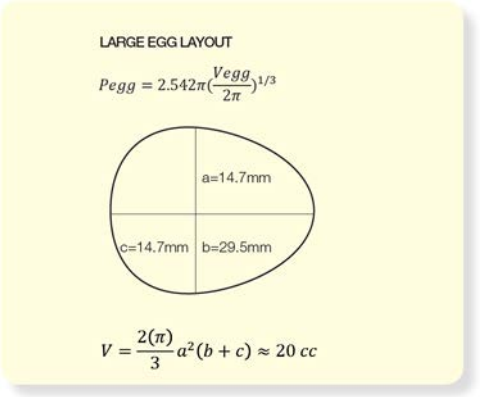

Figure 3-2. Egg volume and perimeter (see certification sheet for measured values in your phantom)

Volume measurements are performed as follows:

1. Adjust the instrument setting (gain, TGC, output, etc.) as for a "normal" technique. Record these settings for use on subsequent testing.
2. Align the probe so targets are maximized.
3. Retract the probe as far as possible. If the probe is still within the phantom, move the phantom away from the needle template until only the tip of the transducer is inside the cavity.
4. Rotate the probe 60 degrees clockwise or counterclockwise depending on what size mass you wish to visualize.
5. Step the transducer forward until the mass is in view.

6 The volume of each test object should be computed using the methods/ software provided with the ultrasound system or as performed on a patient.

7 Record measurements.

8 Repeat steps for each volume within phantom.

Needle Alignment Testing

Needle alignment testing of the brachytherapy system is important to ensure potential accuracy in guiding radioactive seeds respective of the overlay grid on the sonographic image.

1 Fill the water tank with water. Remove the phantom from the water tank or position the transrectal probe into an area that only images the water bath.

2 The transrectal probe needs to be arranged vertically so that needles are held parallel to the probe's long axis.

3 Adjust the system settings as for a "normal" technique. Record these settings to use on subsequent testing.

4 Place brachytherapy needles through the brachytherapy template grid. The needles should pass into the water bath.

5 Measurements are performed to assess the displacement between echoes of the needles and the on-screen grid. Use the caliper tools on the imaging system to measure the difference between the template position indicated on the sonographic image and the needle "flash" or echo.

6 Record measurements. Record template grid positions of needles to use on subsequent testing.

7 Compare measured values with baseline or clinically acceptable deviations.

4 Support and Maintenance

Hardware Maintenance

Inspection

Inspect your phantom regularly for signs of damage and weight loss. If any noticeable changes to the phantom are detected, return the phantom IMMEDIATELY for repair or replacement.

Note: *At least once a year, weigh your phantom and compare to the original weight noted on the Certificate of Compliance. If the phantom has lost or gained more than 1% of its original weight and you notice a difference in vertical distance measurements, contact Sun Nuclear Support.*

Repair

The scanning surface is the most important item on the phantom to protect. It can withstand normal scanning pressure but DO NOT press on the scanning surface with your fingernails or any other sharp objects. If the scanning surface becomes damaged, seal the phantom in an airtight container and IMMEDIATELY contact Sun Nuclear Support for return authorization.

Cleaning

The phantom may be cleaned with mild soap and water ONLY. Avoid solvent-based, alcohol-based, or abrasive cleaning agents.

Storage

For longest life, the phantom should be cleaned after each use and stored at room temperature in the provided zip-lock bag. The primary concern is gel desiccation due to loss of water vapor through the membrane. In addition, the thermal stresses associated with the freeze/thaw cycle may cause the gel to crack or damage the housing integrity, while extreme heat may accelerate water vapor transmission through the membrane. To minimize desiccation, always store the phantom in a sealed zip-lock bag or an equivalent air-tight, sealed container.

CAUTION: This product contains Zerdine, a non-flowing, water-based, polyacrylamide material which is fully sealed within the phantom housing. Zerdine contains trace amounts of the residual monomer acrylamide CAS#79-06-1. There are no known hazards when the phantom is used and stored as intended. Zerdine is fully cured and will not leak from the housing. Damage to the integrity of the housing may expose the user to trace amounts of acrylamide monomer. The amount is not sufficient to pose an acute health risk, but it is still advised to wear protective gloves if handling exposed Zerdine gel due to the potential long-term hazards of the monomer. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.

Disposal and Recycling

Regulations regarding disposal of materials with trace acrylamide monomer vary by locality. Contact your local authority for instructions. If assistance is desired in the proper disposal of this product, including accessories and components, after its useful life, please return to Sun Nuclear.

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**.

5 Specifications

Target Layout

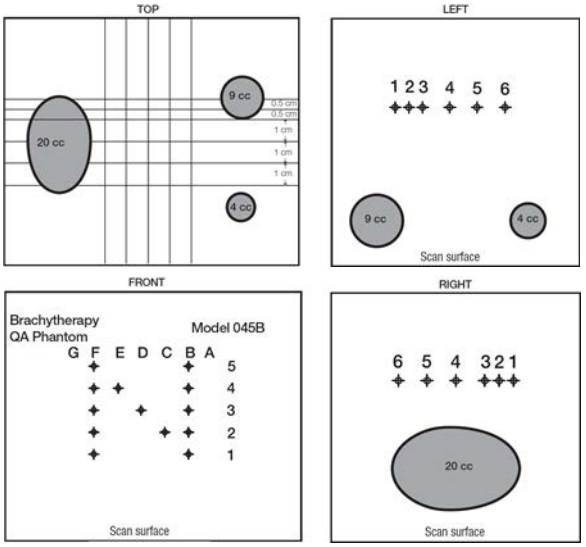

Figure 5-1. Target Views

Front view shows the N wire target group while the side views show the Cross Axis wire targets.

Volumes are rounded to the nearest cubic centimeter. Refer to phantom certification for measured volume.

Phantom Housing

Characteristic	Specification
Material	1/4" White PVC
Outer Dimensions	14 x 11 x 7.5 cm

Scanning Surface

Characteristic	Specification
Material	Saran-based laminate

Water Tank

Characteristic	Specification
Material	3/16" White ABS

Background Material

Characteristic	Specification
Material	Zerdine
Speed of Sound	1540 m/s
Other	Compatible with harmonic imaging

Wire Targets

Characteristic	Specification
Material	Nylon monofilament
Diameter	0.10 mm

"N" Group

Characteristic	Specification
Number of Targets	13
Depth Range	2.0 cm to 6.0 cm
Vertical Distance Between Targets	10.0 mm
Horizontal Distance Between Targets	10.0 mm

Cross-Axis Group

Characteristic	Specification
Number of Targets	5
Depth	Row 3
Horizontal Distance Between Targets	5.0 mm, 10.0 mm

Calibrated Volumes

Characteristic	Specification
Material	Zerdine
Speed of Sound	1540 m/s
Attenuation Coefficient	0.5 dB/cm/MHz
Contrast	~+9 dB
Nominal Volumes	4 cc (S), 9 cc (M), 20 cc (L)

Accessories

- Certificate of Compliance
- Water Tank
- Model 045B User Guide & Technical Information
- QA Worksheet

Note:
All dimensions without tolerances are nominal.
All measurements made at 22°C ± 1°C.

6 Zerdine

Model 045B is constructed from a patented, solid elastic material developed at CIRS called Zerdine. Zerdine, unlike other phantom materials on the market, is not affected by changes in temperature. It can be subjected to boiling or freezing conditions without sustaining significant damage. Zerdine is also more elastic than other materials and allows more pressure to be applied to the scanning surface without subsequent damage to the material. At normal room temperatures, Zerdine will accurately simulate the ultrasound characteristics found in human liver tissue. Specific proprietary fabrication procedures enable close control over the homogeneity of Zerdine and the reliability of its acoustic characteristics from batch to batch.

The speed of sound in Zerdine can be adjusted between 1430 and 1650 meters per second. The acoustic attenuation can be adjusted between 0.05 dB/cm/MHz and 1.50 dB/cm/MHz. The relation between the acoustic attenuation, A, and the acoustic frequency, F, is of the form $A = A_o F^n$ with values of the power coefficient, n, in the range of 0.8 to 1.10, indicating the proportional increase of the acoustic attenuation with frequency. Backscatter characteristics can be adjusted through the addition of predetermined amounts of calibrated scatter material. Zerdine can be molded into very intricate shapes, and the material can be cured in layers allowing the production of "multi-tissue" phantoms. Zerdine, like most other phantom materials, will desiccate if unprotected; thus, all phantoms must be stored properly. If stored in the case provided, your phantom should last many years.

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Appendix A: Quality Assurance Record

MODEL 045B

BRACHYTHERAPY QA PHANTOM

QUALITY ASSURANCE RECORD

Name:_____ Date:_____ Phantom Info:

_____

Baseline System I.D._____

_____

Date:_____ Transducer I.D._____

_____

System Settings

Overall Gain:_____ Post Processing:_____ Depth of

Field:_____

TGC Settings:_____ Dynamic Range:_____

Power:_____

Focal Points:_____ Preprocessing:_____

Other:_____

Parameter	Actual Value	Baseline Value	Measured Value	Drift	Corrective Action	Comments
Uniformity						
Depth of Penetration						
Small Volume						
Vertical and Horizontal Distance						
Electronic Grid Accuracy						
Stepping Mechanism						
Volume Measurement Accuracy						
Needle Alignment Test						

Miscellaneous Checks

Check for damage on the following items: (space provided for comments)

- ☐ Transducer (cord, housing, & face)_____
- ☐ System (cord, knobs, wheels)_____

Clean the following items: (Space provided for comments)

- ☐ Transducer_____
- ☐ Monitor_____
- ☐ Keyboard & Knobs_____
- ☐ Air filters_____
- ☐ Misc._____

Directions for Use:

1. *Use this form to plan and record your quality assurance program.*
2. *Use one form for each transducer.*
3. *For Baseline measurements fill out system settings and baseline measurements.*
4. *Use comments section to indicate changes in system settings for a particular measurement and other observations.*
5. *Use a photocopy of baseline form for subsequent test results (one for each test date).*

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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)

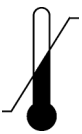
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

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

A notice to the user and/or patient that 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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