General & Small Parts Phantom User Guide

DISCONTINUED

Model 549

SUN NUCLEAR
A MIRION MEDICAL COMPANY

General & Small Parts Phantom User Guide

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1 Introduction

Tissue-mimicking (TM) phantoms are used to evaluate the performance of diagnostic ultrasound imaging systems. The phantoms mimic the acoustic properties of human tissue and provide target structures within the simulated environment. They are essential to detect the performance changes that occur through normal aging and deterioration of system components. Routine equipment performance monitoring can reduce the number of repeat examinations, duration of examinations, and maintenance time. Phantoms are employed in the areas of Clinical Quality Assurance, Preventative Maintenance Programs, Field Service Testing, Research and Development, Manufacturing, Teaching, and Sales & Marketing.

Tissue-Mimicking Materials

ATS offers a choice between standard hydrogel-based (water) or rubber-based, tissue-mimicking material. The choice between rubber-based or Hydrogel TM material is a trade-off of benefits.

Sound Velocity of Rubber-Based TM Material

The sound velocity of most diagnostic imaging systems is calibrated to 1540 meters per second (mps), the assumed average velocity of sound through human soft tissue. The rubber-based, tissue-mimicking material has a sound velocity of 1450 mps at room temperature (23°C). The line targets and anechoic target structures have been physically positioned to compensate for the differences in the speed of sound, assuring accuracy of measurements.

Effect of Temperature

The acoustic properties of all biologic and non-biologic materials are affected by temperature variations. Most diagnostic imaging systems and tissue-mimicking phantoms are calibrated at room temperature, commonly referred to as 23°C. ATS has affixed a thermometer strip to the outside surface of the phantom housing; room temperature is reflected on the strip, not the interior of the phantom. Therefore, if a rubber-based phantom is exposed to extreme temperatures for several hours, it will take the equivalent amount of time to reach room temperature once again. If leaving the phantom in your car overnight during a typical New England winter, while the phantom will not be damaged, you will need to wait approximately 24 hours for it to reach room temperature.

Product Description

The Model 549 General & Small Parts Phantom is an easy, comprehensive means of evaluating imaging systems with an operating frequency range of 2.25 to 15.0 MHz. The first 6 cm of this model has been designed to accommodate the higher frequencies, whereas the area between 6-30 cm is reserved for frequencies less than 7.5 MHz. When filled with water, the scanning wells provide an ideal means to evaluate endoscopic probes. Simply place the active area of the transducer on the surface of the phantom. The procedure is the same as for any standard linear transducer.

Model 549 is designed with a combination of monofilament line targets for distance measurements and tissue-mimicking target structures of varying sizes and contrasts. One hundred and twenty cystic-like target structures are positioned inline vertically, thereby permitting an entire target group to be displayed in one view. Due to the acoustic similarity of the background material and the target structures, artifacts caused by distortion, shadowing, or enhancement have been eliminated. Six gray scale targets ranging in contrast from +15 to -15 dB are provided to evaluate the system's displayed dynamic range and gray scale processing performance.

Tests Performed

The following tests are performed:

- Dead Zone or Ring-Down
- Vertical Measurement Calibration
- Horizontal Measurement Calibration
- Focal Zone
- Sensitivity/Penetration
- Axial & Lateral Resolution
- Functional Resolution
- Image Uniformity
- Gray Scale & Displayed Dynamic Range

2 Setup

Baseline Values

The baseline represents the instrument's peak performance. Ideally, the baseline values are established immediately following the installation and acceptance of a new imaging system. If this is not possible, then they are established immediately after preventive maintenance and servicing by a qualified service engineer.

Scan the Model 549 General & Small Parts Phantom, while adjusting the controls to produce the best possible image. If the bottom of the phantom is visualized, adjust the depth of penetration until only the lower targets are visualized without artifacts produced from the work surface. One should take care to avoid over emphasizing a particular area of the image. Make the display monitor's brightness and contrast settings and the room lighting conditions reflect a clinical environment.

When an acceptable image has been obtained with a particular scanner-transducer pair, the system settings must be accurately documented on the quality assurance record. The settings that should be included are as follows: dynamic range, gray scale level, power level, gain level, and time gain compensation (TGC).

Remember, the accuracy or the baseline values obtained and recorded are extremely important. These values will become the basis for all future performance testing. Some systems have the ability to save the baseline values. When recalled, the system is automatically set up to reflect the programmed baseline values, thereby reducing the potential for errors.

General Guidelines for Setting Up the Phantom for Scanning

1. Place the phantom on a clean, flat surface with scanning surface #1 positioned for use.
2. Apply an adequate amount of low viscosity gel or water to the scan surface. If water is used, fill the scanning well slowly to avoid introduction of air bubbles.
3. Set up the imaging system-transducer pair in accordance with the established baseline values. Record these settings on the quality assurance record.

Phantom Recertification

Recertification of an ATS rubber-based phantom can be performed at any time in accordance with an individual institution's quality assurance procedure. ATS produces a test block of TM material for every rubber-based phantom sold. The test block is used to measure the acoustic properties of the phantom as part of the product's final quality assurance procedure. The test block is retained at the company for future reference and testing during the recertification process.

The procedure for phantom recertification is simple. The phantom is returned to our facility with all shipping charges paid by the customer. The following steps are performed:

1. Upon arrival, the phantom is inspected for physical damage.
2. The test block is retrieved from the storage library, and the acoustic properties are measured.
3. The phantom is than scanned repeating all of the original tests.
4. Results are than compared with the original results on file.
5. A new Quality Assurance certification document similar to the one originally received when the phantom was purchased will be issued. The phantom is then returned to the customer.

3 Testing Procedures

Dead Zone

Description and Reason for Testing

The dead zone is the distance from the front face of the transducer to the first identifiable echo at the phantom/patient interface. The dead zone occurs because an imaging system cannot send and receive data at the same time. Therefore, no clinical data can be collected in this region. However, if artifacts are noted within the dead zone, they may indicate fluctuations in the input power to the system. The depth of the dead zone depends upon the frequency and performance of the transducer and the pulsing/receiving section of the system.

Testing Procedure

6. Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.
7. This group is composed of 9 line targets. The first target is positioned 2 mm below the scan surface. Subsequent targets are spaced 1 mm apart, to a depth of 10 mm.
8. Using the electronic calipers, measure the distance between the first target imaged and the echo produced by the scan surface. The resulting value will be the depth of the dead zone.
9. Document the depth measurement on the quality assurance record.

Results

The system's dead zone should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

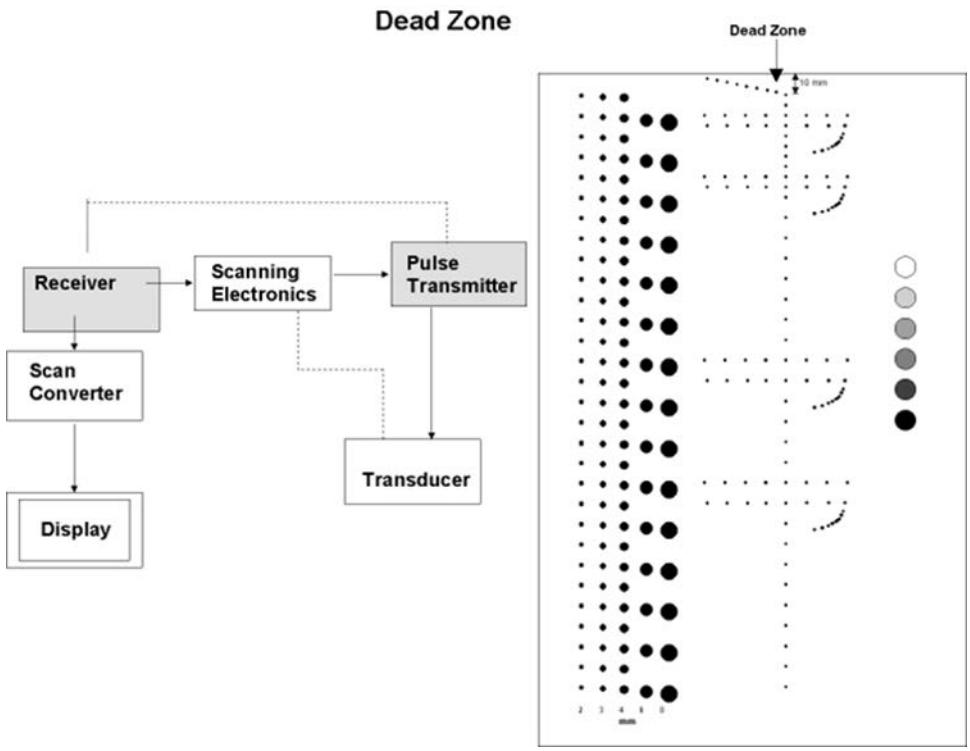

Figure 3-1. Dead Zone Dataflow and Target Diagram

Vertical Measurement Calibration

Description and Reason for Testing

Vertical distance measurements are obtained along the axis of the sound beam. Accurate representation of the size, depth, and volume of a structure is a critical factor in a proper diagnosis. Most imaging systems use depth markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained using the timing markers and/or electronic calipers. The resulting measurement is then compared to the known distance between the line targets in the phantom. The accuracy of vertical distance measurements depends on the integrity of the timing circuitry of the imaging system.

Testing Procedure

1. Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display.
2. Using the electronic calipers or the timing markers, measure the greatest distance that can be clearly imaged between line targets.
3. Document the measurement obtained on the quality assurance record.

Results

The system's vertical distances measurements should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

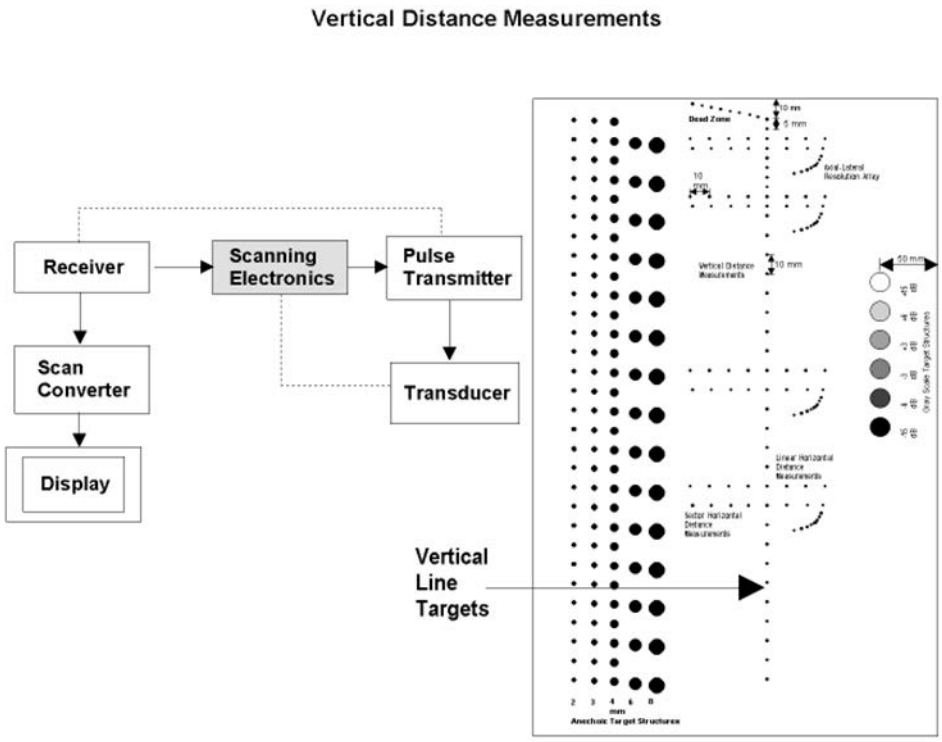

Figure 3-2. Vertical Distance Measurements Dataflow and Target Diagram

Horizontal Measurement Calibration

Description and Reason for Testing

Horizontal distance measurements are obtained perpendicular to the axis of the sound beam. Proper diagnosis is dependent upon the accurate representation of the size and volume of a structure being examined. Most imaging systems use distance markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained. The resulting measurement is then compared to the known distance in the phantom. The accuracy of the horizontal distance measurements depends on the integrity of the transducer scanning assembly, the output intensity, and the resolution of the imaging system.

Testing Procedure

Note: *The Model 549 phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Due to the geometry and variety of sector scan transducers, a separate set of horizontal line targets are provided to evaluate lateral resolution. Please refer to Specifications on page 14 for the location of these groups.*

1. Position the transducer over the horizontal group of line targets until a clear image is obtained. Freeze the image.
2. Using the electronic calipers or the timing markers, measure the greatest distance that can be clearly imaged between line targets displayed.

Note: *Some sector scanners have distance markers on the outside edges of the sector image with no other indicators available. Hand-held calipers must be used for distance measurements within the image on the monitor.*

3. Document all of the measurements on the quality assurance record.

Results

The system's horizontal distance measurements should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

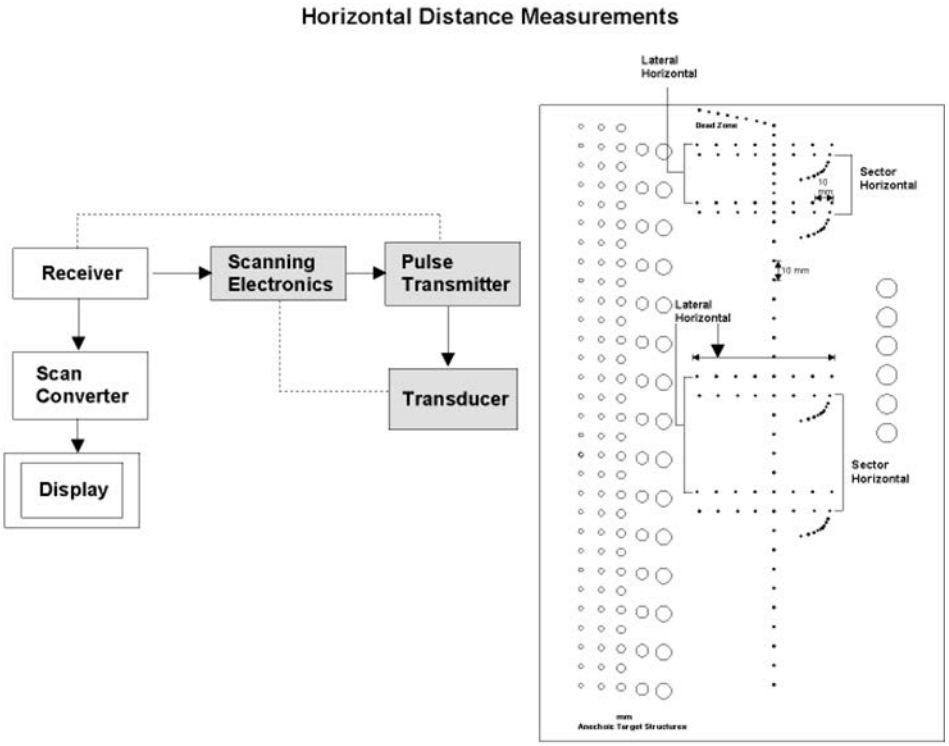

Figure 3-3. Horizontal Distance Measurements Dataflow and Target Diagram

Axial and Lateral Resolution

Description and Reason for Testing

Resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately along the axis of the beam, whereas lateral resolution defines the system's ability to image objects separately that lie perpendicular to the axis of the sound beam. If a system has poor resolution capabilities, small structures lying close to each other will appear as one image, causing improper interpretation of the ultrasound findings. Axial resolution depends on the transducer's center frequency, damping characteristics, and pulse length. Generally, the higher the frequency, the better the system's axial resolution. Lateral resolution depends on the beam width, focusing characteristics of the transducer, number of displayed scan lines, and the system's sensitivity and gain settings.

Testing Procedure

Model 549 provides three scanning surfaces to evaluate axial-lateral resolution at nine given depths. Target locations in the phantom are referenced from the first axial target.

The line targets are spaced at 4.0, 3.0, 2.0, 1.0, and 0.05 mm intervals both axially and laterally. The last point of the axial array target group is also the first target point in the lateral array group.

1. Position the transducer over the axial-lateral resolution group of line targets on the phantom until a clear image is obtained. Freeze this image.
2. Examine the image to determine if all of the line targets within the group are clearly displayed as separate target points. Record the closest spaced target points which can be imaged (refer to specification drawing). Obtain a hard copy of the display.
3. Document all observations made on the quality assurance record.
4. If required, repeat the above procedure for the remaining 8 depths, using scanning surfaces #2, #3, and #4.

Results

The system's ability to resolve the array targets at given depths should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

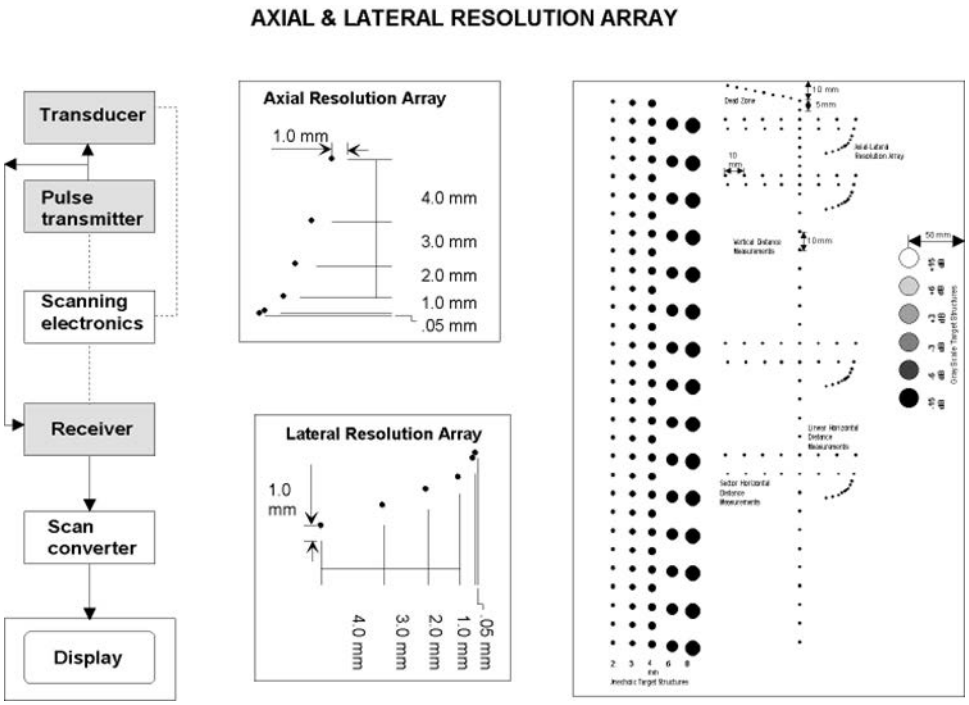

Figure 3-4. Axial and Lateral Resolution Dataflow and Target Diagram

Focal Zone

Description and Reason for Testing

The focal zone is the region surrounding the focal point in which the intensity and lateral resolution are the greatest. Clinically, structures examined within the focal zone will provide the best diagnostic information obtainable. The focal zone can be affected by changes in the pulsing/ receiving section of the imaging system or damage to the transducer.

Testing Procedure

1. Position the transducer over the vertical group of line targets on the phantom until a clear image is obtained. A line rather than a dot is produced on the display. The length of the line is indicative of the width of the beam. Therefore, targets inside the focal zone form a shorter line than those outside of the focal zone. Adjustments in the gain settings will change the length of the line targets displayed. Freeze the display and obtain a hard copy.
2. For a variable focused transducer, scans with several different focal zone settings should be performed. Dynamically focused transducers may not display changes in the width of the line targets. However, a change in the intensity can be observed upon adjustment of the transmitting focus of the transducer.
3. Using the hard copy, draw a line connecting the ends of the echoes received from the line targets (both sides); the line should form a smooth curve. This will illustrate the shape of the sound beam. Now locate the narrowest portion; this is the focal zone. Measure the width of the beam and the depth at this point.
4. Document the depth of the focal zone and the measurement of the focal width on the quality assurance record.

Results

The system's focal zone should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

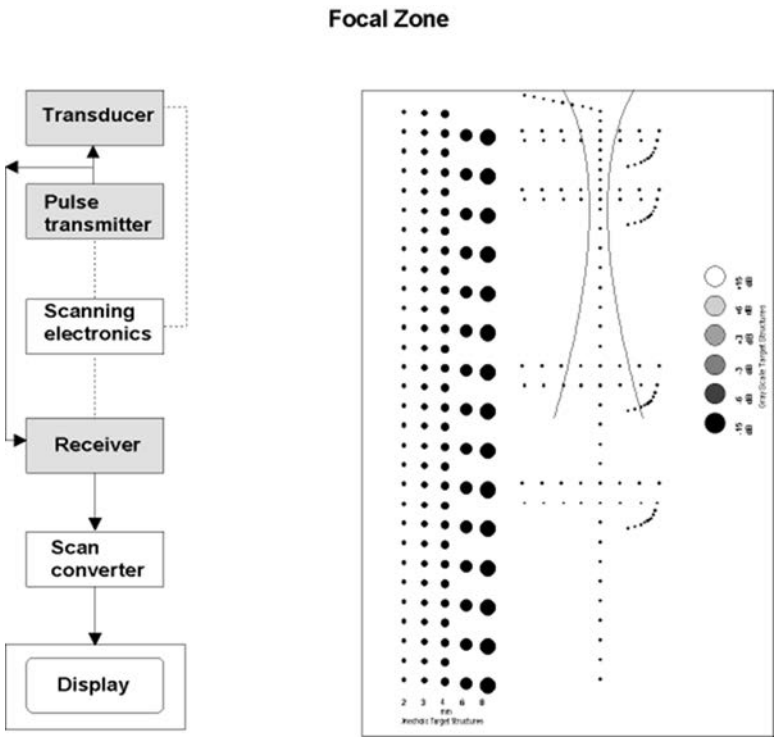

Figure 3-5. Focal Zone Dataflow and Target Diagram

Sensitivity (Maximum Depth of Penetration)

Description and Reason for Testing

The ability of an imaging system to detect and display weak echoes from small objects located at specified depths (penetration) is referred to as sensitivity. Clinically, weak reflecting echoes are commonly produced from internal structures of organs. Definition of these structures can be extremely important in the interpretation of the ultrasound findings. Sensitivity can be affected by the pulser/receiver section of the system, degree of focusing of the transducer, attenuation of the medium, depth and shape (geometry) of the reflecting object, and electromagnetic interference from the local surroundings. A system's maximum depth is limited by output power, TGC, gain, transducer frequency, focal depth, number of scan lines, and electrical noise.

Testing Procedure

1. Position the transducer over the 8 mm group of anechoic targets.
2. Freeze image and obtain a hard copy.
3. Examine the image to determine the last or deepest target structure displayed. Using the electronic calipers or the timing markers, measure the depth of this target.
4. This test should also be performed with output levels set at the highest and lowest settings. This enables any changes in output to be more easily detected.
5. Document the depth measurement on the quality assurance record.

Results

The system's depth of penetration should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

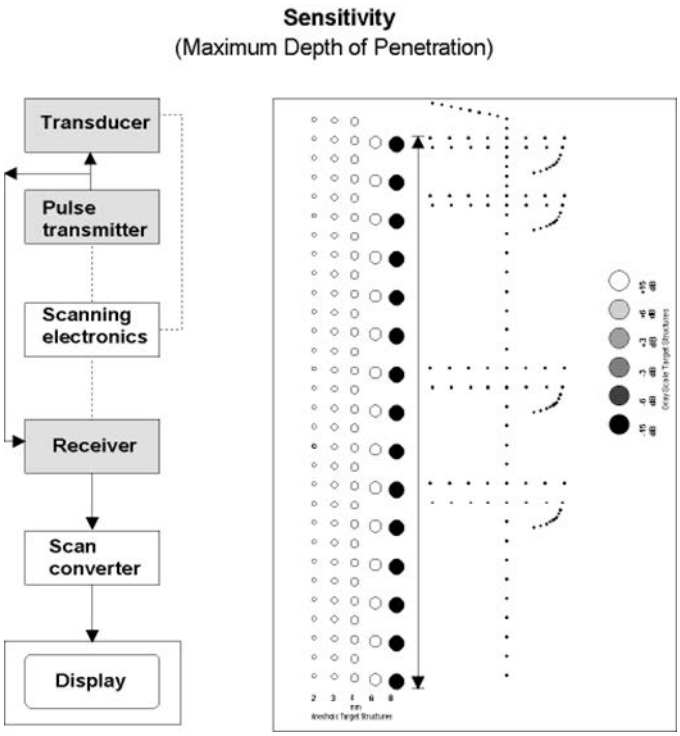

Figure 3-6. Sensitivity Dataflow and Target Diagram

Functional Resolution and Image Uniformity

Description and Reason for Testing

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of the non-echogenic target structures within the TM matrix of the test phantom. The targets should appear circular with sharp clearly defined edges, indicating an abrupt transition from the echogenic to the non-echogenic region. The targets are anechoic and should be free of any internal echoes or fill-in.

Bright artifacts may be observed at the top and bottom of the targets.These are normal specular reflections and do not present a problem. However, an observable shade of gray within the anechoic target usually is indicative of internal system noise and/or the presence of side lobes. Should the targets appear flattened, a geometric distortion problem should be considered. In practice, the data obtained will give a direct indication of the smallest diameter target the system is capable of resolving at a given depth. The functional resolution capabilities of a system can be affected by side lobes in the transducer beam, electrical noise, and problems in the imaging processing hardware.

These artifacts can be the result of transducer malfunction, poor electrical contacts, failure in the image processing and/or system's software, and poor acoustic coupling between the transducer/patient interface causing the introduction of reverberations artifacts. Generally, horizontal bands are often caused by circuitry and focusing problems while vertical bands indicate a damaged transducer element.

Testing Procedure

1. Position the transducer over the anechoic target structures until a clear image is obtained.
2. Freeze image and obtain a hard copy.
3. Examine the image to determine the first and last target in each size group displayed. Record the range of depths visualized for each group. Due to the configuration of the sound beam, small targets in the near field may not be imaged.
4. Scan this region to determine if there are any areas of nonuniformity. If the initial image demonstrates nonuniformity or artifacts of this type, repeat the scan at a different location using the same phantom to rule out a defect in a particular region of the phantom. If the artifacts are still present, note the gain settings, gray scale level, and focal setting, and document with a photograph. Repeat the scan using a different gain and focal setting.
5. Document all findings on the quality assurance record.

Results

The system's functional resolution and image uniformity should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, or major areas of image nonuniformity are observed, corrective action should be considered.

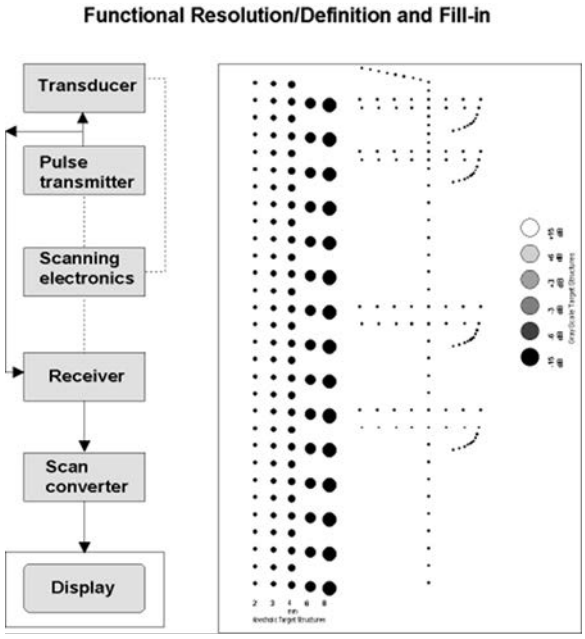

Figure 3-7. Functional Resolution and Image Uniformity Dataflow and Target Diagram

Gray Scale & Displayed Dynamic Range

Description and Reason for Testing

Gray scale or gray scale processing uses the amplitude of the echoes received to vary the degree of brightness of the displayed image. The adjustment of the echo signal required to go from a just noticeable (lowest gray scale level) echo to the maximum echo brightness is referred to as the displayed dynamic range. Clinically, gray scale processing and displayed dynamic range allow echoes of varying degrees of amplitude to be displayed in the same image.

Testing Procedure

1. Position the transducer over the gray scale target group until a clear image is obtained.
2. Freeze image and obtain a hard copy.

3 Examine the image. The targets should appear circular in shape with clear sharp edges and vary in the degree of brightness ranging from low to high levels of contrast. The presence or absence of any shadowing behind the structures should be noted.

4 All findings should be documented on the quality assurance record.

Results

This target group varies in echogenicity and provides a good indication of the performance of the gray scale processing and displayed dynamic range. The system's gray scale processing should remain consistent from week to week when using the same instrument settings and the Model 549 phantom. Compare the test results obtained from the baseline records.If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

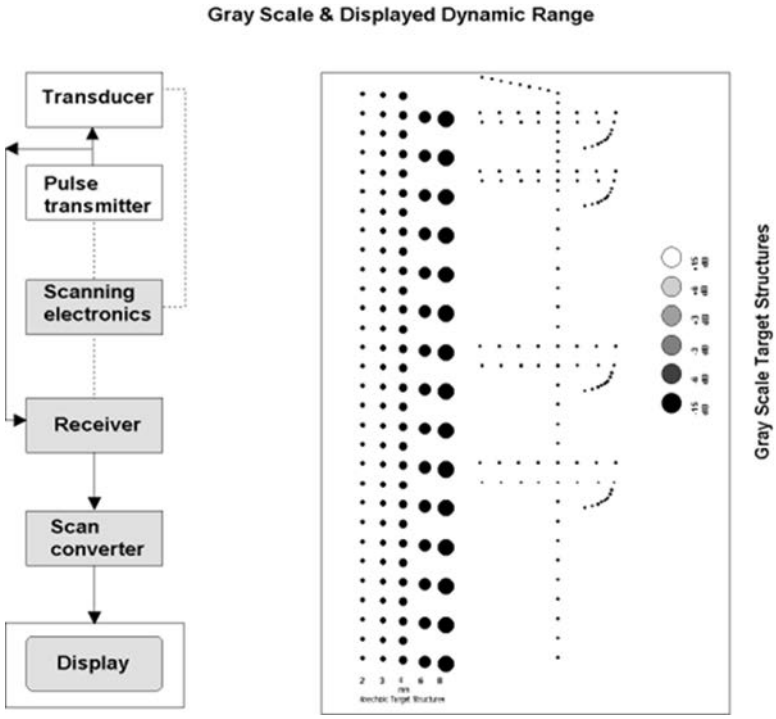

Figure 3-8. Gray Scale & Displayed Dynamic Range Dataflow and Target Diagram

References:

Michell M. Goodsitt, Paul Carson; "Real-Time B-mode Ultrasound Quality Control Test Procedures, Report of AAPM Ultrasound Task Group No. 1," Medical Physics, 25 (8) August 1998

W. N. McDicken, PhD, "Diagnostic Ultrasonics, Principles and Use of Instruments," John Wiley & Sons, 1976.

Sandra L. Hagen-Ansert; "Textbook of Diagnostic Ultrasonography," Mosby, 1989.

4 Support and Maintenance

Hardware Maintenance

Inspection

Periodically inspect the 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*.

Repair

The phantoms and the parts provided with the phantoms cannot be repaired by the user. If there are problems with any of the devices, contact Sun Nuclear Support.

Cleaning

For best results, the phantom should be kept clean at all times. In particular, a buildup of dried coupling gel on the scan surface should be avoided. The phantom may be cleaned with mild hand soap and warm water. Particularly stubborn stains and dirt may be removed with a mild household cleaner. The use of petroleum solvents should be avoided since they may adversely react with the rubber-based material.

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 www.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 Diagram

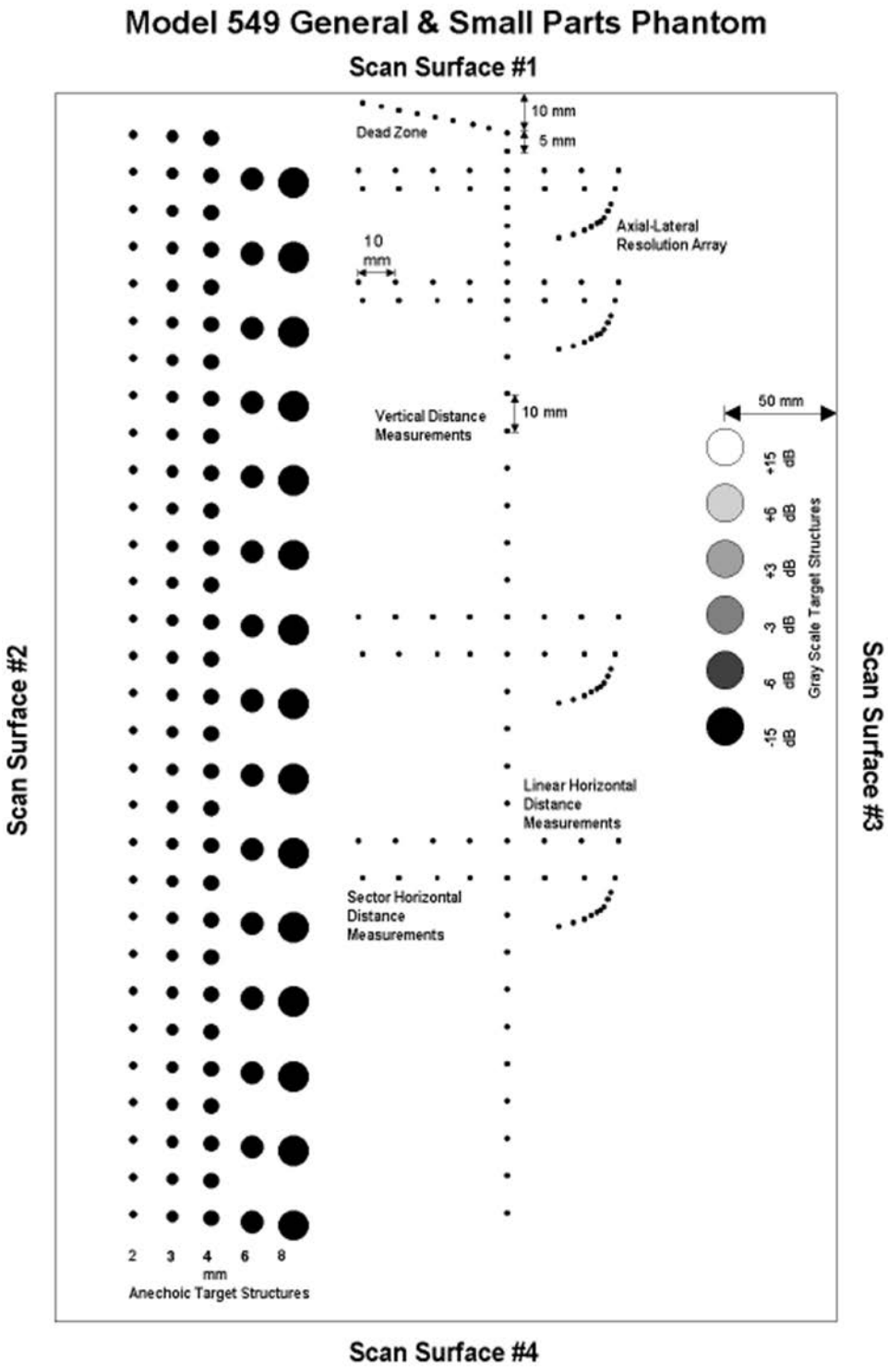

Figure 5-1. Model 549 Target Diagram

Product Specifications

General

Characteristic	Specification
Overall Dimensions	36.5 x 25.7 x 9.5 cm*
Housing Material	PVC
Wall Thickness	1.0 cm*
Scan Surfaces	4
Scan Surface Dimensions	21.0 x 7.0 cm 31.5 x 7.0 cm
Weight	7.1 kg (15.5 lb)

Tissue-Mimicking Material

Characteristic	Specification
Type	Urethane rubber
Freezing Point	< -40°C
Melting Point	> 100°C
Attenuation Coefficient	0.5 dB/cm/MHz ± 10.0% Measured at 3.5 MHz
Speed of Sound	1450 mps ± 1.0% at 23°C

Line Targets

Characteristic	Specification
Material	Monofilament nylon
Diameter	0.08 mm & 0.12 mm

Vertical Group

Characteristic	Specification
Interval Spacing • Depth 1.0–6.0 cm • Depth 6.0–30.0 cm	 • 0.5 cm • 1.0 cm
Depth	1.0–30.0 cm

Horizontal Group

Characteristic	Specification
Number of Groups	8
Interval Spacing	1.0 cm
Depths • Linear Array Group • Sector/Convex Array Group	 • 2.0, 5.0, 14.0, 20.0 cm • 2.5, 5.5, 15.0, 21.0 cm

Dead Zone Group

Characteristic	Specification
Lateral Displacement	5.0 mm
Interval Spacing	1.0 mm
Depth	2.0–10.0 mm

Axial-Lateral Resolution Group

Characteristic	Specification
Depths (first axial target) • Scan Surface 1 • Scan Surface 2 • Scan Surface 4	 • 2.5, 5.5, 15.0, 21.0 cm • 7.0 cm • 13.0, 19.0, 28.5, 31.5 cm
Interval Spacing	0.5, 1.0, 2.0, 3.0, 4.0 mm

Anechoic Target Structures

Group 2, 3, 4 mm

Characteristic	Specification
Type	Non-echogenic, cylindrical
Targets in each group	30
Diameters	2.0, 3.0, 4.0 mm
Interval Spacing (center to center)	1.0 cm
Depth Scan Surface 1	1.0–30.0 cm

Group 6, 8 mm

Characteristic	Specification
Targets in each group	15
Diameters	6.0, 8.0 mm
Interval Spacing (center to center)	2.0 cm
Depth Scan Surface 1	2.0–30.0 cm

Gray Scale Target Structures

Characteristic	Specification
Type	Echogenic, cylindrical
Diameter	10.0 mm
Depth	5.0 cm
Contrast relative to background material (dB)	+15, +6, +3, -3, -6, -15

*Nominal dimensions

Appendix A: Regulatory Supplement

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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