# Multi-Purpose Phantom User Guide

Model ATS539

SUN NUCLEAR
A MIRION MEDICAL COMPANY

# Multi-Purpose Phantom User Guide



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# Contents

# 1 Introduction

## Overview

The Model ATS539 Multipurpose phantom is an easy, comprehensive means of evaluating imaging systems over most clinical imaging frequencies (approximately 2-20 MHz).

The phantom is designed with a combination of monofilament line targets for distance measurements and tissue mimicking target structures of varying sizes and contrasts. Cystic-like target structures are positioned in-line 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. All ATS urethane phantoms are guaranteed for the useful life of the phantom, defined as 10 years.

### Key Tests with Model ATS539

You can perform the following tests with a Model ATS539 Multipurpose:

- Uniformity
- Depth of Penetration
- Beam Profile/ Focal Zone/ Lateral Response Width
- Vertical Distance Measurement
- Horizontal Distance Measurement
- Axial and Lateral Resolution
- Elevational Resolution
- Contrast Resolution
- Grayscale Contrast Sensitivity
- Dead Zone Assessment

For more information on these tests, see Testing Procedures starting on page 5

### Model ATS539 Standards

CIRS is certified to ISO 13485:2016 standards. We have an in-house test facility to measure acoustic properties of materials. In addition, ultrasound imaging systems are used to inspect each phantom. Every ultrasound phantom that CIRS distributes has passed thorough testing during manufacture and completion to ensure the highest quality product available. A Certificate of Compliance is issued with each phantom.

Additional guidance on establishing a quality assurance program can be found in the accreditation programs established by the ACR and AIUM at www.acr.org or www.aium.org.

## Parts

The model ATS539 includes the parts listed in the table below.

*Table 1. Model ATS539 Parts*

| Quantity | Component Description |
|---|---|
| 1 | Multi-Purpose Phantom |
| 1 | Carry Case |
| | 10-Year Warranty |
| | User Guide |
| | Certification of Compliance |

# 2 Instructions for Use

## General Guidelines for Performing Measurements

- To evaluate the performance of diagnostic ultrasound imaging systems, the Model ATS539 has a combination of monofilament line targets and tissue-mimicking cylindrical targets of varying sizes and contrasts.
- 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.
- If a convex probe is used, center the target within the scan plane in order to minimize degradation and distortion introduced on the outer edges of the probe.
- 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 measure- ments 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 de- pending 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).

## Establish a Baseline

Before performing routine quality assurance measurements, establish the following:

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 might not be valid. CIRS recommends that you use the most commonly used settings for the type of probe tested- i.e. the liver preset values for an abdominal probe- which are called a "normal" technique in the sections that follow.

2 **Baseline measurements**

The first set of measurements taken are 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, for example a call for service or replacing the system. Each facility needs to determine the action level for each test. You should refer to the user’s manual of your ultrasound scanner and note the stated accuracies of the system’s general imaging measurements. These stated accuracies should 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 any where 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.

## Testing Procedures

The following sections outline procedures for routine quality control tests with the Model ATS539. It might be useful to refer to the target map, shown in the Specifications section of page 14, when reviewing these procedures.

### 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.

1 Apply coupling gel to the scanning surface or fill the water trough with tap water.

2 Position the transducer on the scanning surface in a region with a minimum number of targets.

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

4 Align the probe so that the targets are maximized.

5 Freeze the image and obtain a hard copy.

6 Observe the general appearance of the phantom. Note if all regions at the same depth are displayed with the same intensity across the image.

7 Record your observations.

### Depth of Penetration 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, the 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. Testing is performed as follows:

1 Place the phantom on a clean, flat surface with #1 scanning surface 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 Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, lower the gain settings until the bottom of the image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

**Note:** In addition to the above, 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.

4 Position the transducer over the 8 mm group of anechoic targets.

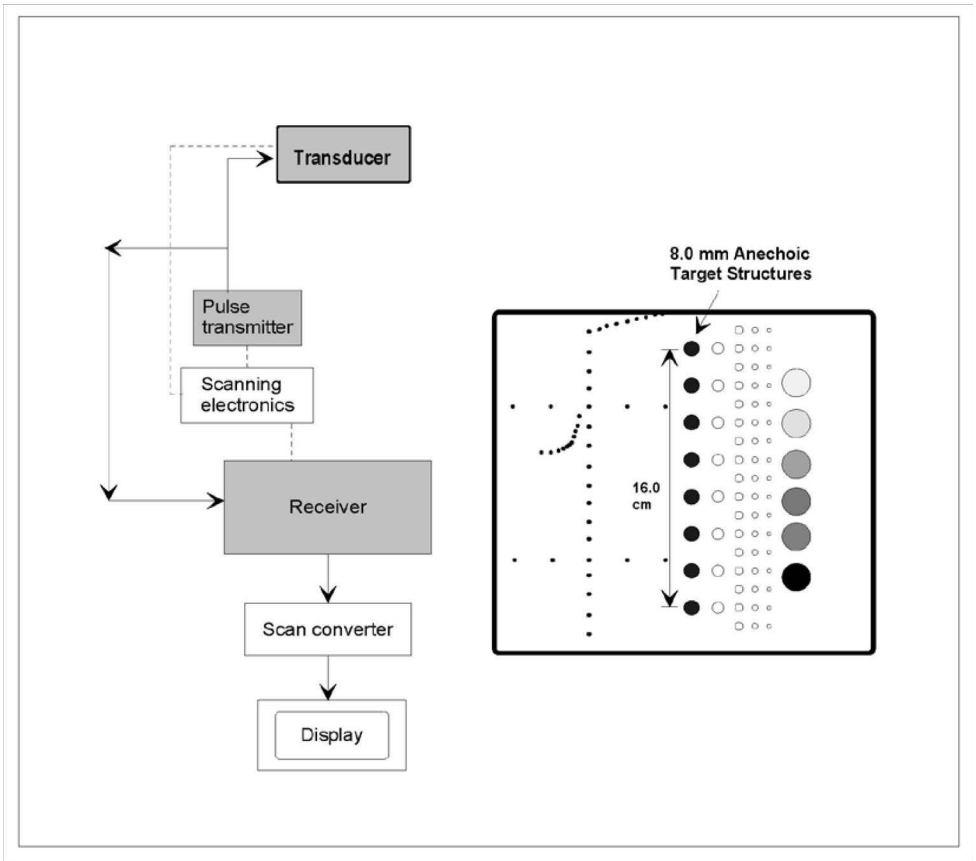
5 Freeze image and obtain a hard copy.

6 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.

7 Document the depth measurement on the quality assurance record.

### Depth of Penetration Testing Results

The depth of penetration should not shift by more than 1.0 cm, when using this phantom at same instrument settings and transducer. If a discrepancy occurs corrective action should be considered by the individual Ultrasound Department.




## Beam Focal Zone and Lateral Response Width

The focal zone is the region surrounding the focal point in which the intensity and the lateral resolution is 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.

1. Place the phantom on a clean, flat surface with #1 scanning surface 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
4. Position the transducer over the vertical group of line targets on the phantom, until a clear image is obtained. Freeze the display and obtain a hard copy.

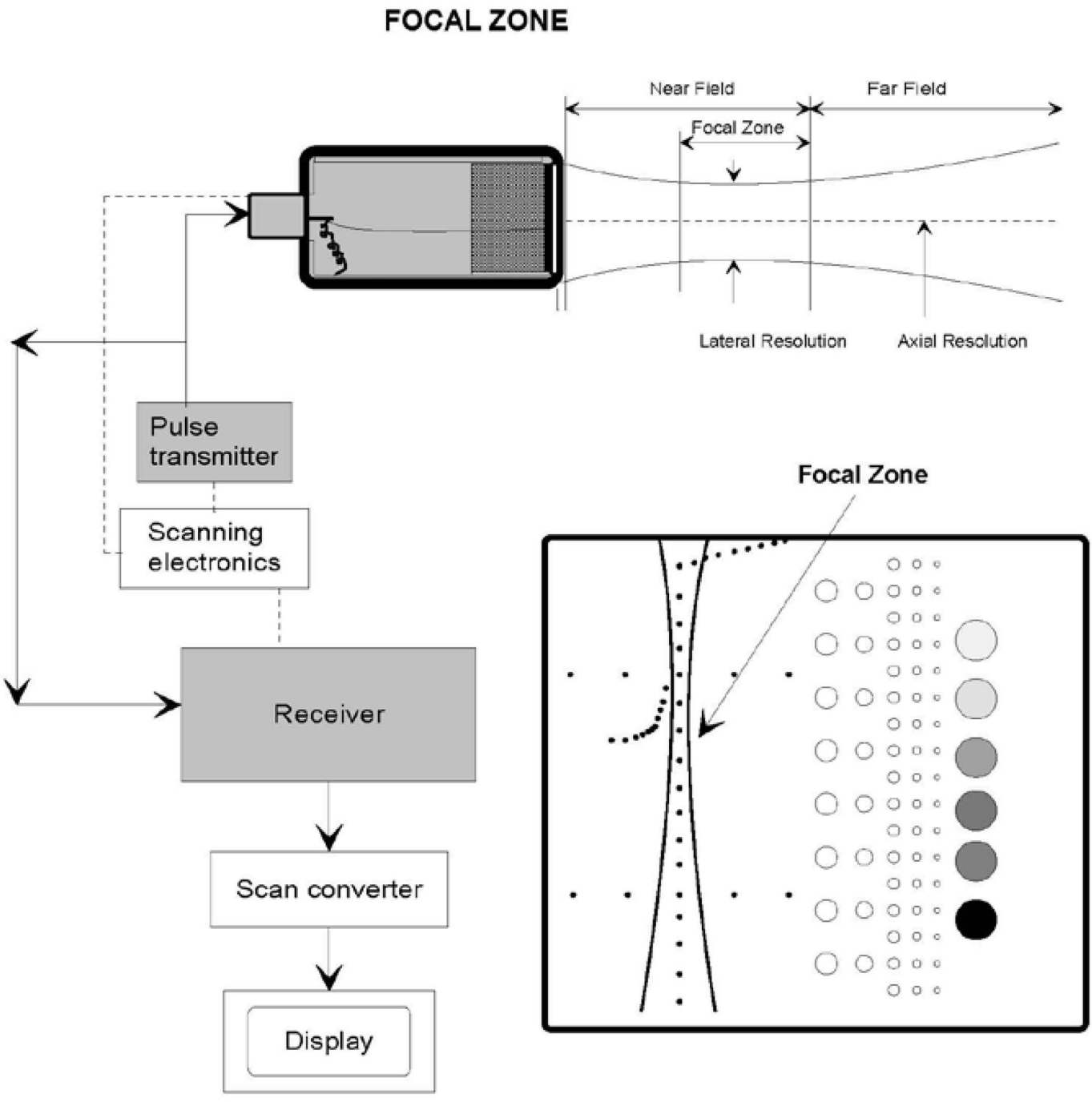
   **Note:** A line rather than a dot is produced on the display. The length of the line is indicative of the width of the beam. Therefore, targets inside the focal zone form a shorter line than those outside of the focal zone. Adjustments in the gain settings will change the length of the line targets displayed.
5. 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.

6 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.

7 Document the depth of the focal zone and the measurement of the focal width on the quality assurance record.

## Beam Focal Zone and Lateral Response Width Results

The location of the focal zone should agree with the manufacturer's specifications and should not change with time. This applies to both fixed and dynamically focused systems. If changes occur corrective action should be considered.



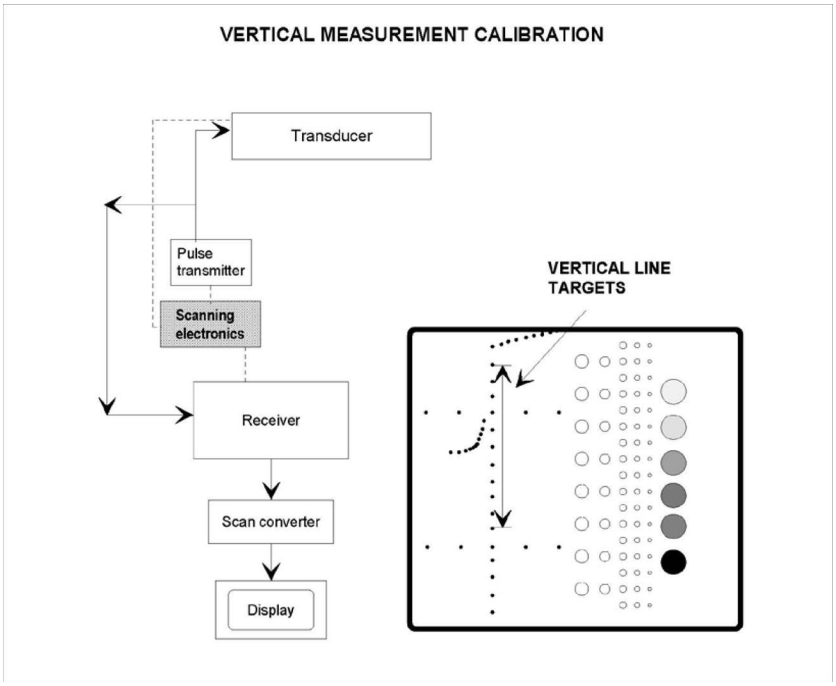
## Vertical Distance Measurements

Vertical distance measurements obtained along the axis of the sound beam. The 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 is dependent upon the integrity of the timing circuitry of the imaging system.

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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, adjust the gain settings until the image goes entirely black. Record these settings on the quality assurance record. These setting should be used for subsequent testing.
4. Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display.
5. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets.
6. Document the measurement obtained on the quality assurance record.

### Vertical Distance Measurements Results

Vertical Spacing: 1.0 cm center to center ± 0.1 mm. If a discrepancy occurs which is greater than 1.0 mm, corrective action should be considered by the individual Ultrasound Department.




## Horizontal Distance Measurement

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.

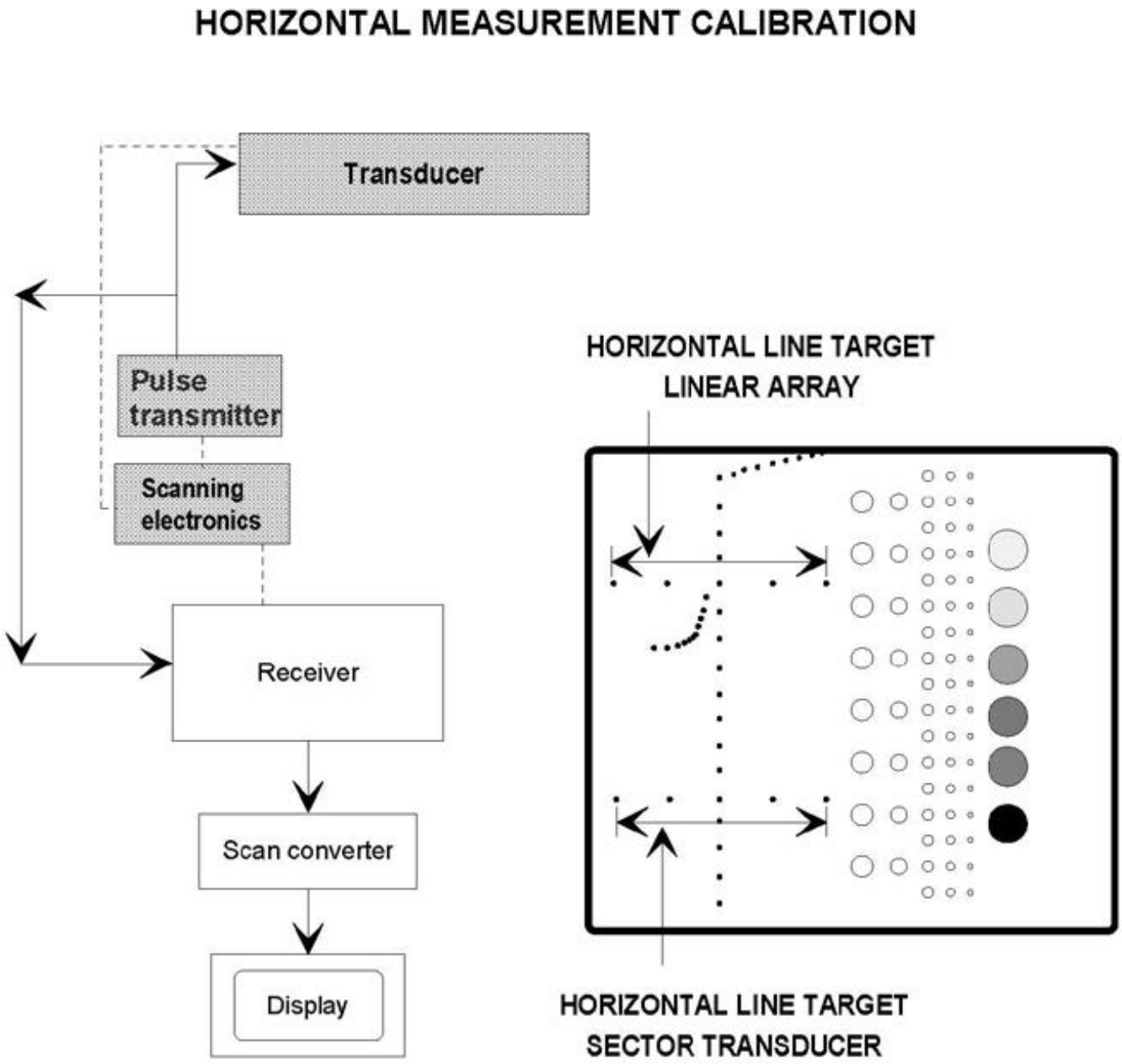
The resulting measurement is then compared to the known distance in the phantom. The accuracy of the horizontal distance measurements is dependent upon the integrity of the transducer, the output intensity and the resolution of the imaging system.

***Note:*** *The Model ATS539 Multipurpose phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Linear array scanning systems should use #1 scanning surfaces. Sector scanning systems should use #3 scanning surfaces.*

1. Place the phantom on a clean, flat surface.
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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, adjust the gain settings until the image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
4. Position the transducer over the horizontal group of line targets until a clear image is obtained. Freeze the image.
5. 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.

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




### Horizontal Distance Measurement Results

Interval Spacing: 2.0 cm ± 1 mm. Depths: 5.0 cm ±.1 mm (Scan surface #1) 5.0 cm ±.1 mm (Scan surface #3).

## Axial and Lateral Resolution Testing

Resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately. 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.

Resolution along the axis of the sound beam is referred to as Axial Resolution. Axial Resolution is affected by the pulsing section of the imaging system and the condition of the transducer.

Resolution perpendicular to the axis of the sound beam is termed Lateral Resolution. Lateral Resolution is dependent upon the beam width, increased beam width will reduce the Lateral Resolution.

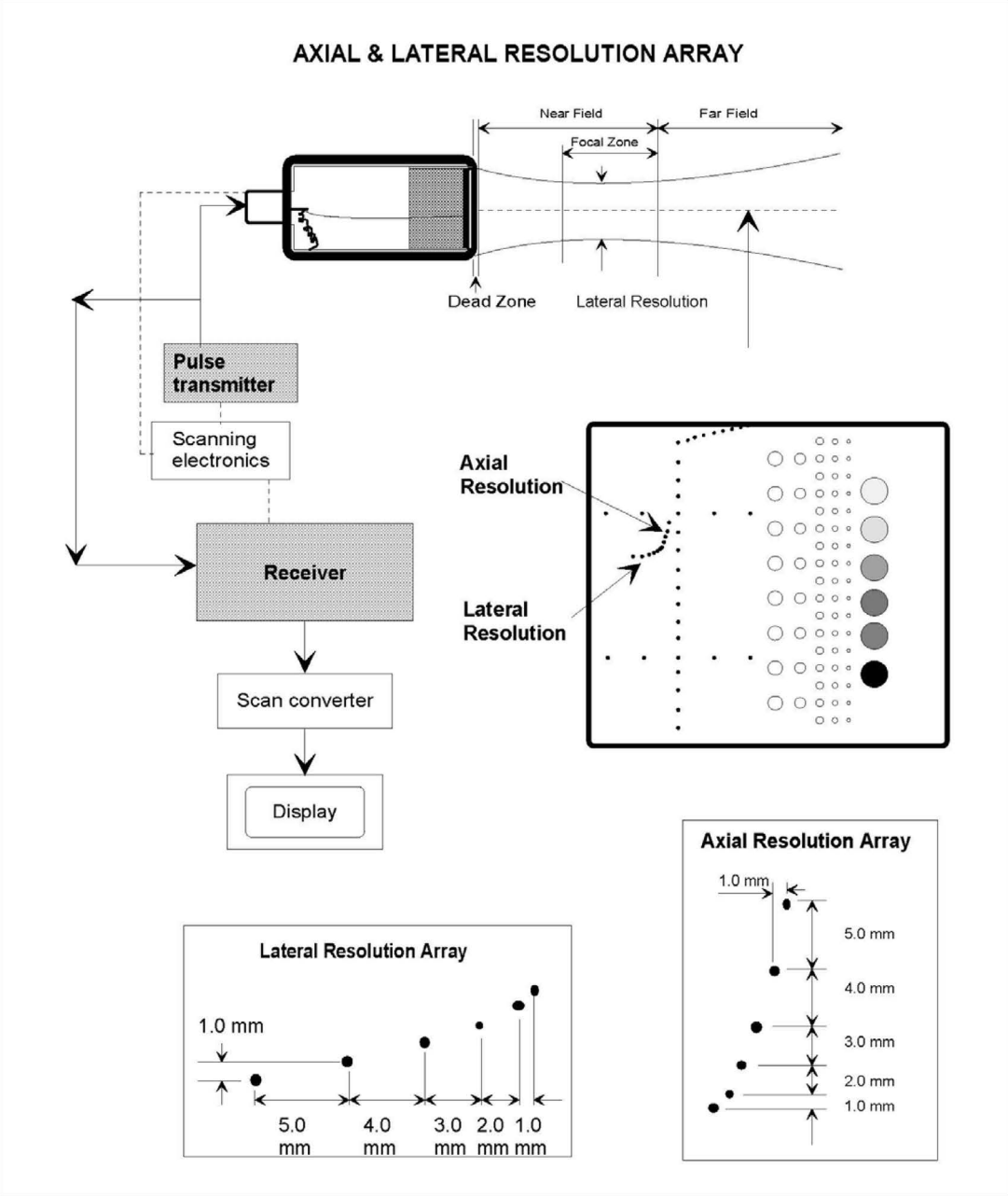
The Model ATS539 provides four scanning surfaces to evaluate axial-lateral resolution at four given depths. Target locations in the phantom are referenced from the center of the array at target point 5.

The line targets are spaced at 5.0, 4.0, 3.0, 2.0 and 1.0 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. 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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
4. Position the transducer over the axial-lateral resolution group of line targets on the phantom until a clear image is obtained. Freeze this image.
5. 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.
6. Document all observations made on the quality assurance record.
7. Repeat the above procedure for the remaining three depths, using scanning surfaces #2, #3, and #4.

### Axial and Lateral Resolution Testing Results

The system's ability to resolve the array targets at all four depths should remain consistent from week to week when using the same instrument settings and the Model ATS539 phantom. Compare the test results obtained with a baseline or previous test. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.




## Elevational Testing

A full characterization of system resolution requires measurement of elevational resolution, or slice thickness. Slice thickness is typically much coarser than axial and lateral resolution as most ultrasound transducer arrays are mechanically focused in the thickness dimensions.

Two methods are described for measuring elevational resolution. The first method, first described by ML Skolnick[1], uses the vertical wire targets as follows:

1 Apply coupling gel to the scanning surface or fill the water trough with tap water.

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

1. *Skolnick ML. Estimation of ultrasound beam width in the elevation (section thickness) plane. Radiology. 1991 Jul;180(1):286-8. doi: 10.1148/radiology.180.1.2052713. PMID: 2052713.*

3 Orient the transducer to image the length of the vertical target wires, taking care to adjust the tilt so that the wires are lined up in a vertical column.

4 Rotate the transducer 45° so that only a partial length of the wires is now visible.

5 Freeze the image and measure the length of each wire segment with the electronic calibers.

6 Record the measurements.

## Grayscale Contrast Sensitivity

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 of grayscale contrast is performed as follows:

1 Place the phantom on a clean, flat surface with scan surface #4 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 Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4 Position the transducer over the gray scale target group until a clear image is obtained.

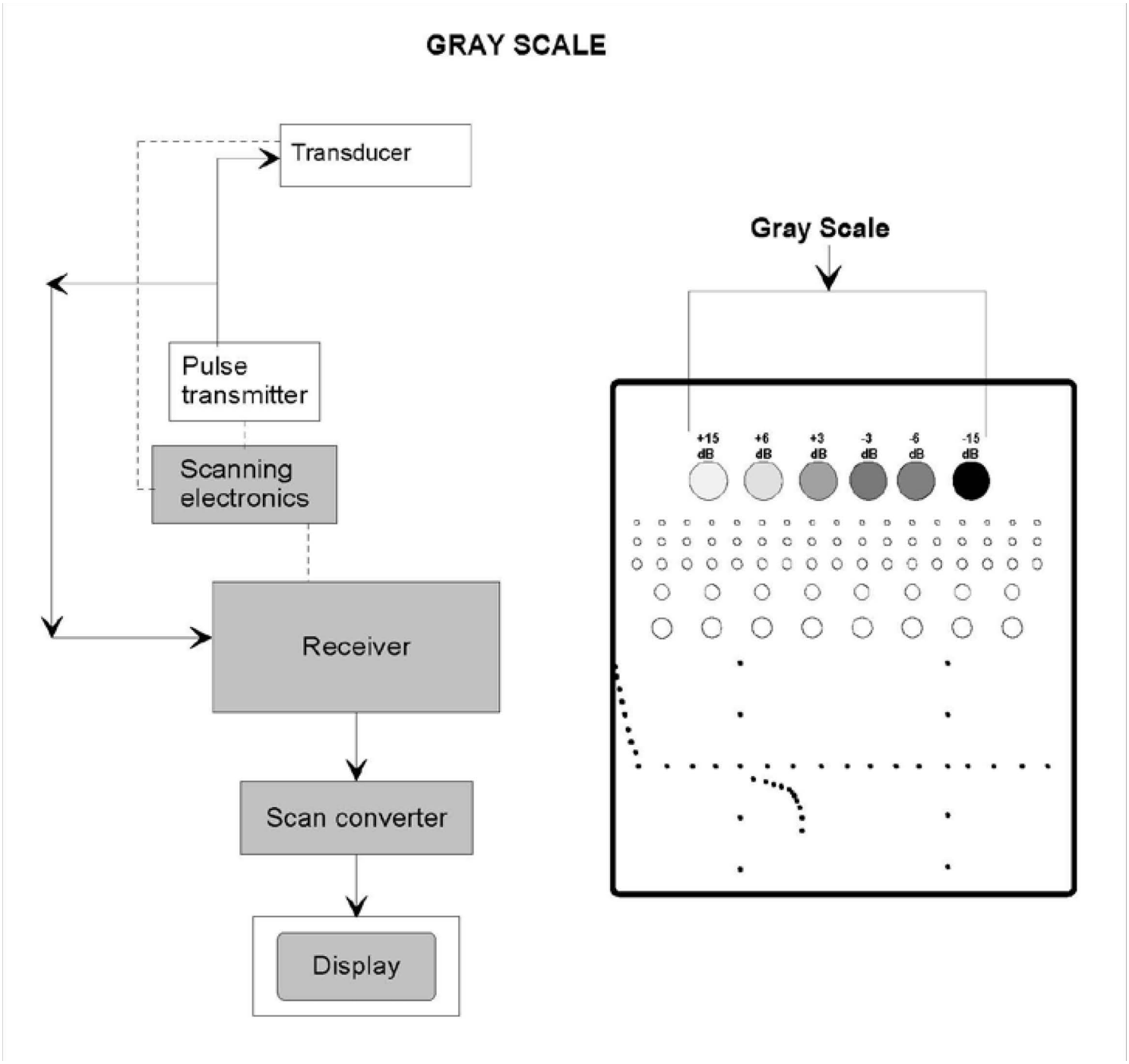
5 Freeze the image and obtain a hard copy.

6 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.

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

### Grayscale Contrast Sensitivity 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 test should be compared with a baseline test using the same instrument settings, to determine if any change in the characteristics of the target group has occurred with time. If changes are noted, they should be investigated.




### Contrast Resolution

Contrast resolution is an imaging system's ability to detect and display the size, shape, and depth of an anechoic structure within the test phantom. In practice, the data obtained will give a direct indication of the minimum size structure the system is capable of resolving at a given depth.

Definition and fill-in describes the imaging system's ability to detect and display the shape and echogenic characteristics of a structure. Clinically, a correct diagnosis is dependent upon the system's ability to differentiate between a cystic or solid structure versus echo patterns originating from the surrounding normal tissue.

Testing for low-contrast target detectability is performed as follows:

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 Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.

4 Position the transducer over the anechoic circular target group on the phantom, until a clear image is obtained.

5 Freeze the image and obtain a hard copy.

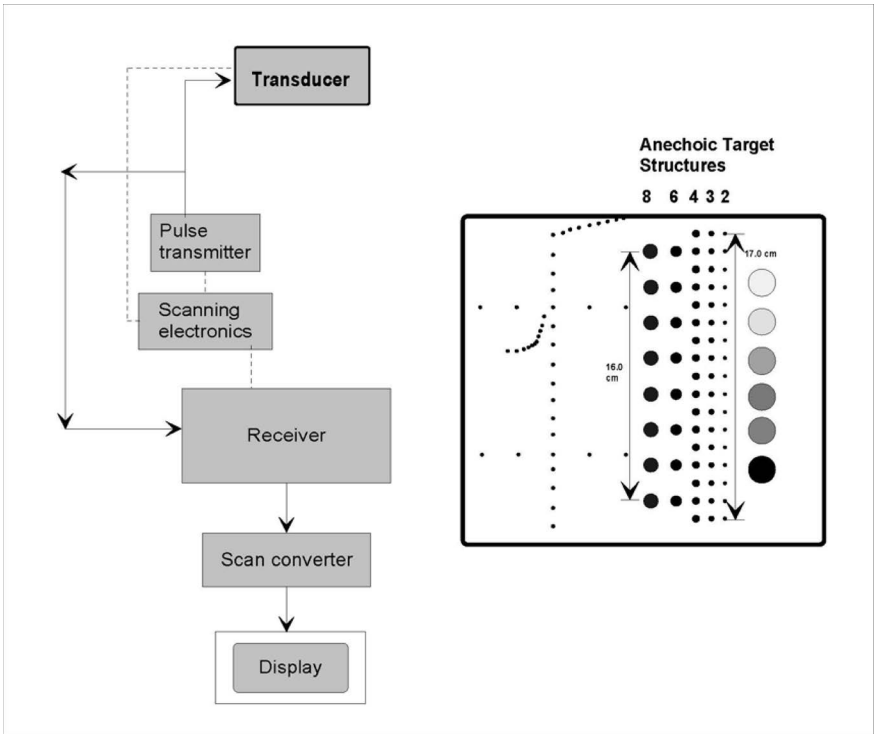
6 Examine the image to determine the first and last target in each size group displayed. Record the range of depths visualized for each group. Due to the configuration of the sound beam small targets in the near field may not be imaged.

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

## Contrast Resolution Test

The targets should appear circular with sharp clearly defined edges, indicating an abrupt transition from the echogenic to the anechoic region. The targets are anechoic and should be free of any internal echoes or fill-in. However, the presence of internal system noise may manifest itself by producing an observable shade of gray within the target area.

The specific values determined, while significant in their own right, are somewhat less important than stability over time. Performing this test on a routine basis at the same instrument settings should produce the same results. Any changes should be investigated.



## Dead Zone Assessment

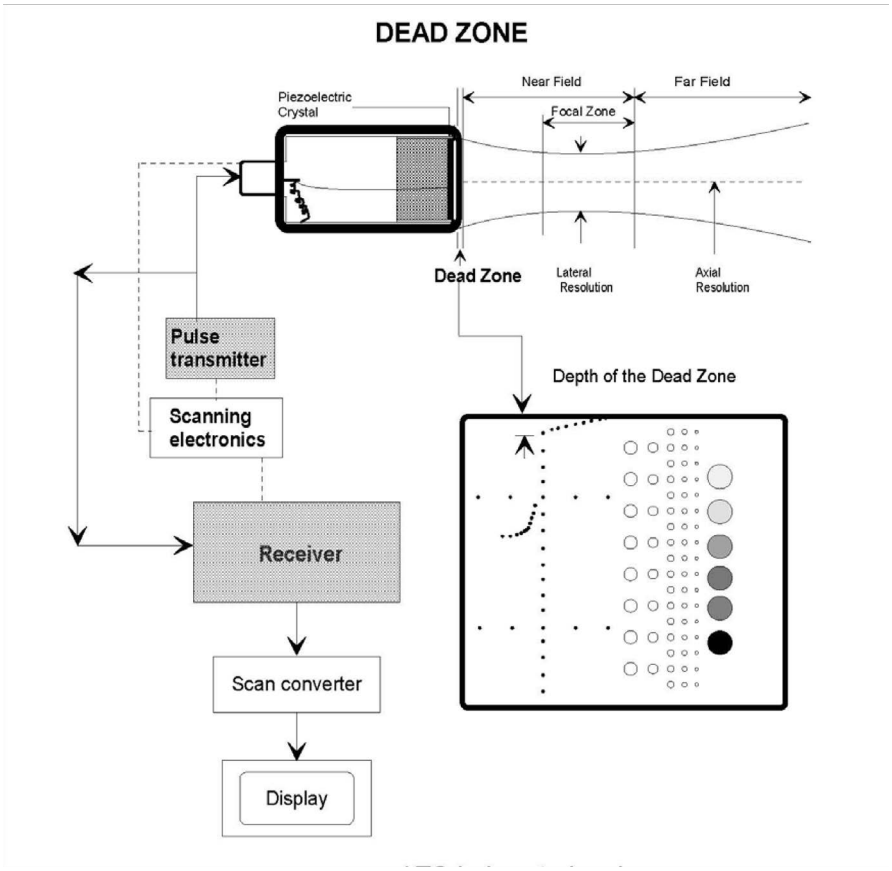
The dead zone is the distance from the front face of the transducer to the first identifiable echo at the phantom/patient interface. In the region of the dead zone no clinical data can be collected. The dead zone occurs because an imaging system cannot send and receive data at the same time. The depth of the dead zone depends upon the frequency and performance of the transducer and the pulsing/receiving section of the system.

The depth of the dead zone may be measured as follows:

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. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for normal scanning. If the bottom of the phantom is visualized, adjust the gain settings until the image goes entirely black. Record these settings on the quality assurance record. These setting should be used for subsequent testing.
4. Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.
5. 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.
6. 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.. Document the depth measurement on the quality assurance record.

### Dead Zone Results

If the depth of the dead zone is greater than 10.0 mm, corrective action should be considered by the individual Ultrasound Department.



# 3 Support and Maintenance

## Handling and Care

For best results the phantom should be kept clean at all times and stored at room temperature. In particular a build-up of dried coupling gel on the scan surface should be avoided. The phantom may be cleaned with warm water using a lint free cloth. 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.

### Repair

Model ATS539 and the parts provided with the Model ATS539 cannot be repaired by the user. If there are problems with any of the devices, contact Sun Nuclear Support.

## Contacting Sun Nuclear Support

You can 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**.

## Warranty

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer's option.

This warranty does not apply if the product, as determined by the manufacturer,

is defective because of normal wear, accident, misuse, or modification.

### Non-Warranty Service

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with said repair or replacement.

## Returns

If you are not satisfied with your purchase for any reason, please contact Customer Service prior to returning the product. Call 800-617-1177, email rma@cirsinc.com, or fax an RMA request form to 757-857-0523. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or “customized” products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

### With RMA Number, items may be returned to:

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

| Product | Warranty Period |
|---|---|
| Model ATS539 - Multi-Purpose Phantom | 120 Months |

# 4 Specifications

## Product Specifications

### Target Layout

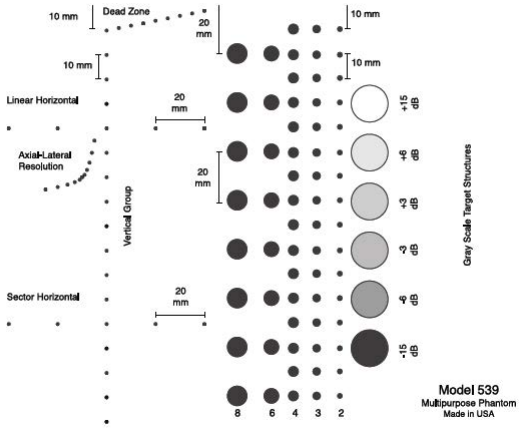



*Table 4-1. Model 539 Product Specifications*

| Category | Characteristic | Specification |
|---|---|---|
| **Phantom** | Housing | PVC |
| | Outer Dimensions | 23.4 cm x 20.5 cm x 9.5 cm (9.2 in. x 8.1 in. 3.7 in.) |
| | Scanning Surface | 17.5 cm x 7.5 cm 14.0 x 7.5 cm (6.9 in. x 3 in.) |
| | Scanning Material | Urethane Rubber |
| | Speed of Sound | 1450 m/s at 23° |
| **Wire Targets** | Material | Nylon monofilament |
| | Size | 6-12 mm |
| **Near Field Group** | Number of Targets | 9 |
| | Depth Range | 20 - 100 mm |
| | Spacing | 1.0 mm |
| **Vertical Distance Group** | Number of Targets | 17 |
| | Depth Range | 1.0 - 18.0 |
| | Spacing | 1.0 cm[a] |
| **Horizontal Distance: Linear Probes** | Number of Targets | 5 |
| | Depth from Scan Surface #1 | 5.0 cm |
| | Spacing | 2.0 cm[b] |
| **Horizontal Distance: Sector Scanning Probes** | Number of Targets | 5 |
| | Depth from Scan Surface #1 | 13.0 cm |
| | Spacing | 2.0 cm[c] |

[a] Corrected distance. The physical distance between pins has been adjusted to account for the difference in sound speed between urethane and tissue.

[b] Uncorrected distance. Sound speed does not affect horizontal distance measurements when using a linear probe

*Table 4-1. Model 539 Product Specifications*

| Category | Characteristic | Specification |
|---|---|---|
| [c] Corrected distance. Sound speed will affect horizontal distance measurements when using a sector scanning probe | | |
| **Axial/Lateral Resolution Groups** | Number of Targets | 11 |
| | Lateral Displacement | 1.0 mm |
| | Spacing | 4, 3, 2, 1, 0.5, 0.25 mm |
| | Depth | 7.0, 11.0, 4.0, 16.0 cm |
| **Contrast Targets (Cysts)** | Type | Non-echogenic, cylindrical |
| | Number of Groups | 5 |
| | | |
| | Group 2, 3, 4 | |
| | Number of Targets | 17 |
| | Diameter of Targets | 2.0, 3.0, 4.0 mm |
| | Depth of Targets | 1.0 - 17.0 cm |
| | Spacing | 1.0 cm |
| | | |
| | Group 6, 8 | |
| | Number of Targets | 8 |
| | Diameter of Targets | 6.0, 8.0 mm |
| | Depth of Targets | 1.0 - 17.0 cm |
| | Spacing | 2.0 cm |
| **Gray Scale Targets** | Type | Echogenic, Cylindrical |
| | Number of Targets | 6 |
| | Spacing | 2.0 cm (center to center) |
| | Depth | 4.0 cm |
| | Contrast | +15,+6, +3,-3,-6, -15 dB with respect to background |
| Notes<br>• All dimensions without tolerances are nominal<br>• All measurements made at 22˚C ± 1˚C | | |

# Appendix A: Regulatory Supplement

## Symbols

The following symbols are used in this guide and in our product labels.

**WARNING: This symbol indicates a risk of electric shock. (EN ISO 7010, W012)**

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

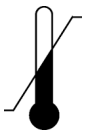
**CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)**

**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)*

*This symbol indicates a general mandatory action. (EN ISO 7010, M001)*

*Fragile. Handle with care (EN ISO 15223-1, 5.3.1)*

## Operator Responsibility

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

## Reporting Health or Safety Related Issues or Concerns

Should the need arise to report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

CIRS
900 Asbury Ave
Norfolk, VA 23513
Phone +(757) 855-2765

## 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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# Appendix B: Quality Assurance Record

MODEL ATS 570

MULTI-PURPOSE & ENDOSCOPIC PHANTOM

QUALITY ASSURANCE RECORD

**Ultrasound Performance Testing Record**

Date _____
__ Routine Testing
__ Baseline
__ Initial Setup
__ Software Upgrade
__ New Phantom
__ New Transducer

Facility: _____ Department: _____
Technician / Sonographer: _____

**System Identification**
System Manufacturer: _____ Model: _____ S/N: _____
Transducer Type: _____ Model #: _____ S/N: _____
ATS Phantom Model: _____ S/N: _____

| **General Inspection** | Pass | Fail | | Pass | Fail |
|---|---|---|---|---|---|
| Power Cord (cracks, plugs, discoloration) | | | Transducer (Cable, housing, plug, transducer face) | | |
| Dust Filters (clean & dust free) | | | Scanner console (free of damage) | | |
| Controls (Clean, broken knobs & switches) | | | Wheels (rotate freely, locks hold properly) | | |
| Display (clean, free scratches, Brightness/ contrast controls) | | | Comments | | |

| **System Settings** | | | | | |
|---|---|---|---|---|---|
| Power | dB | Gain | dB | Dynamic Range | dB |
| Pre-Processing | | Post-Processing | | Programed Presets | |
| Transmit Focus | cm | Image Magnification | | Room Temperature: | |

| **Geometric Accuracy Testing** | Phantom Distance | Baseline Measured | Distance Measured | Error/Change |
|---|---|---|---|---|
| Vertical Distance Measurements | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |
| Horizontal Distance Measurements | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |
| Dead Zone (Ring-down ramp) | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |

| **Spatial Resolution** | Phantom Distance | Baseline Measured | Distance Measured | Error/Change |
|---|---|---|---|---|
| Axial Resolution | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |
| Lateral Resolution | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |

| **Focal Zone & Sensitivity** | System's Mfg. Specification | Baseline Depth | Measured Depth | Error/Change |
|---|---|---|---|---|
| Focal Zone | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |
| Sensitivity | | | | |
| Electronic Calipers | mm | mm | mm | mm |
| Display Devices used for interpretation | mm | mm | mm | mm |

| **Functional Resolution** | Range of Depths Displayed | | Target Shape | | Target Edges | | Change Yes/No |
|---|---|---|---|---|---|---|---|
| Target Sizes (mm) | Baseline | Display** | Baseline | Display** | Baseline | Display** | |
| 1.0 | mm | mm | | | | | |
| 2.0 | mm | mm | | | | | |
| 30 | mm | mm | | | | | |
| 4.0 | mm | mm | | | | | |
| 6.0 | mm | mm | | | | | |
| 8.0 | mm | mm | | | | | |
| 10.0 | mm | mm | | | | | |
| **Display Devices used for interpretation | | | | | | | |

| **Image Uniformity -** Display Devices used for interpretation | __ No Artifact Detected __ Artifact Detected | | | |
|---|---|---|---|---|
| Image Uniformity Artifact Detected | Gain Settings | Gray Scale Level | Focal Setting | Change Yes/No |
| First Scan System Settings | | | | |
| Repeat Scan at a different region in the phantom and at different gain and focal distance settings. | | | | |
| If artifact persists, further investigation and/or corrective action is recommended. | | | | |

| **Gray Scale - Displayed Dynamic Range** | | | | | | **Display Devices used for interpretation | |
|---|---|---|---|---|---|---|---|
| | Range of Contrast | | Target Shape - Circular | | Target Edges - Clear/Sharp | | Change Yes/No |
| Targets (dB) | Baseline Yes/No | Display** Yes/No | Baseline Yes/No | Display** Yes/No | Baseline Yes/No | Display** Yes/No | |
| +15 | mm | mm | | | | | |
| +6 | mm | mm | | | | | |
| +3 | mm | mm | | | | | |
| -3 | mm | mm | | | | | |
| -6 | mm | mm | | | | | |
| -15 | mm | mm | | | | | |

| Summary of Results: |
|---|
| |
| Signature: |

**+1 321 259 6862** // **sunnuclear.com**
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