Beam Profile & Slice Thickness Phantom User Guide

Model ATS 538NH

SUN NUCLEAR
A MIRION MEDICAL COMPANY

Beam Profile & Slice Thickness Phantom User Guide

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1 Introduction

The Model 538NH can measure the beam profile and slice thickness of ultrasound imaging systems by evaluating the appearance of a thin plane of echogenic material against an anechoic background.

Scanning the scattering plane from one surface, perpendicular to the thin plane, obtains an image of the beam profile at varying depths of the 538NH. This image contains a great deal of information about the sound beam as it propagates through the tissue-mimicking media, such as the focal length, focal zone, beam width, side and grating lobes, and far-field beam divergence. In addition, the near-field region of the beam can be easily distinguished from the far field as varying degrees of brightness close to the scan surface versus the homogeneous amplitude further down.

Scanning the scattering plane from a second surface, 45 degrees from the scattering plane, allows users to evaluate the slice thickness of an imaging system at varying depths. Slice thickness or elevational resolution, the third component of spatial resolution, displays reflections produced by structures in front of or behind the beam's main axis. The effect of changes in the slice thickness is identical to those seen with axial and lateral resolution. The thinner the slice thickness, the better the resolution: as the slice thickness increases, the degree of spatial resolution decreases. All ATS urethane phantoms are guaranteed for the useful life of the phantom, defined as 10 years.

Key Tests with Model ATS 538NH

- Tissue Harmonic Imaging Compatibility
- Beam Profile/Focal Zone/Lateral Response Width

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

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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:

- 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.
- 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.
- Most diagnostic imaging systems and tissue-mimicking phantoms are calibrated at room temperature, commonly referred to as 23°C. To ensure measurement accuracy, a thermometer strip is affixed to the outside surface of the phantom housing.
- The sound velocity of most diagnostic imaging systems is calibrated to 1,540 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 at 0.5 dB/cm/MHz at room temperature (23°C). The differences in the speed of sound between the assumed calibrated value of the imaging system of 1540 mps and the rubber-based phantoms as given above, if gone uncorrected, will cause distortion of the measurements obtained. A simple measurement conversion calculation has been provided, and should be used when indicated in the test procedure.

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 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 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 accuracies 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 routine quality control tests with the Model ATS 538NH. It may be useful to refer to the target map, shown in *Support and Maintenance* on page 13, when reviewing these procedures.

Beam Profile, Focal Zone, and Lateral Response Width

The beam profile or cross-sectional display of the sound beam (termed Lateral Response Width) contains a great deal of information regarding the configuration of the sound beam as it propagates through the tissue-mimicking media. The beam profile clearly displays the near field, focal length, focal zone, beam width, side and grating lobes, and beam divergence in the far field. In addition, amplitude variations in the near field, are displayed as varying degrees of brightness versus the almost homogeniticity of the amplitude in the far field. The beam profile is affected by the performance of the transducer and the pulser/ receiver section of the imaging system.

1. Place the phantom on a clean, flat surface with #1 scanning surface positioned for use.
2. Apply a liberal amount of acoustic coupling gel to the scanning surface. It is suggested, when evaluating array systems, a low viscosity coupling agent be used to minimize a “snowplowing” affect on the surface of the phantom. When testing transducer faces with a high degree of curvature, the use of a high viscosity gel is recommended to maintain good coupling.
3. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for “normal” liver scanning. If the penetration is such that the bottom of the phantom is seen, the gain settings are reduced such that the image fades and goes entirely black. These settings should be noted on the quality assurance record and used for subsequent testing.

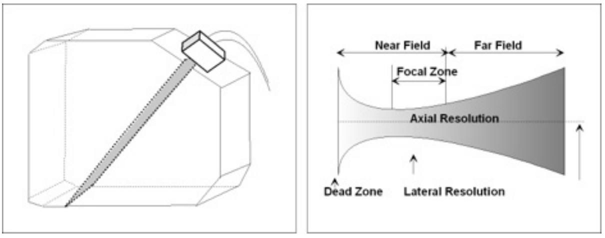

Figure 3-1. Beam Profile

4. The phantom is constructed with a scattering plane located in the center of and at 90° to the scanning surface. Place the transducer on scan surface #1. Adjust the position until the profile of the beam is clearly displayed.

Note: *For sector imaging systems, the beam will sweep back and forth as it passes through the scattering plane, imaging the cross-section of the beam. In a multitransducer sector scan head, the image will be the integrated sum of all the beam profiles. To examine the beam profile of the individual transducer, the frame rate must be decreased until the individual beam profile is displayed. Depending upon the system, it may be necessary to reduce the frame rate to zero.*

5. Freeze the image and obtain a hard copy.
6. Examine the display. The image should be "hour-glass" in shape. Note the presence or absence of any grating lobes, which will be displayed as two "horns" on either side of the main beam, usually in the near field. Using the electronic calipers, measure the focal length and beam width at the focal point. If you desire, measurements of the near and far fields can also be obtained.

Note: *A correction factor of 0.94 adjusts for the speed of sound in ATS urethane (1450 m/s).*

7. Document all measurements and observations on the quality assurance record.

Results

The beam profile should remain consistent from week to week, when using the same instrument settings, transducer, and the Model 538NH phantom. Compare the test results obtained with a baseline or previous test. If the current image demonstrates changes in the system, investigation should be made to determine the cause.

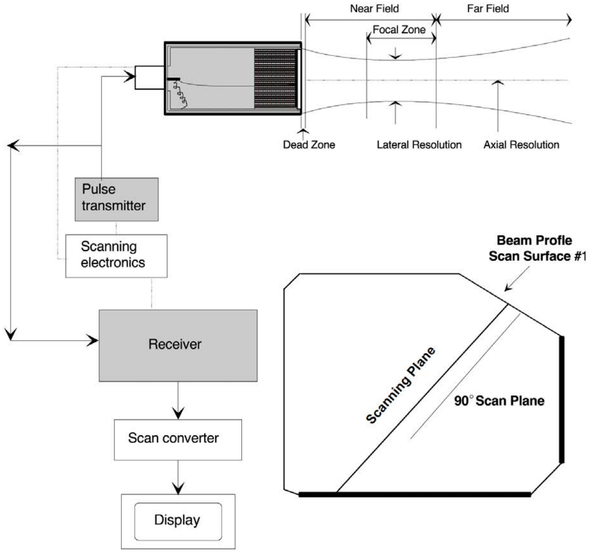

Figure 3-2. Beam Profile Results Dataflow

Elevational Testing

A third component of spatial resolution, the slice thickness, is often referred to as the elevation resolution. A sound beam travels through a medium along the beam axis until it reaches an interface which is perpendicular to the axis of the sound beam, creating a two-dimensional image. The image resolution is dependent upon the degree of axial and lateral resolution of the diagnostic system. Elevational resolution displays reflections produced by structures in front of or behind the beam's main axis. The effect of changes in the slice thickness measurements are identical to those seen with axial and lateral resolution. The smaller the slice thickness measurement, the better the resolution; as the slice thickness increases, the degree of spatial resolution decreases. In diagnostic ultrasound, this factor becomes critical in determining an imaging system's ability to detect and display small isolated lesions or structures of low contrast, which may appear to be filled-in and go undetected.

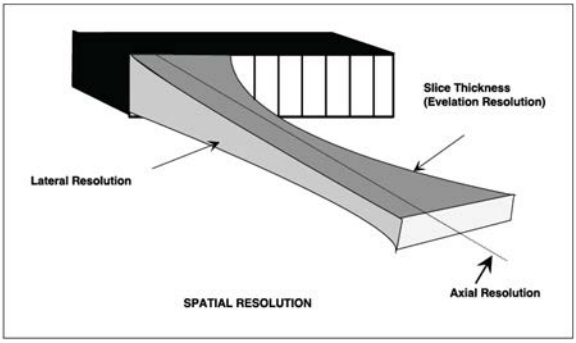

Figure 3-3. Spatial Resolution

1 Two scan surfaces are provided for obtaining slice thickness measurements. For depths ranging from 8.0 to 22.0 cm, scan surface #2 should be used. Scan surface #4 is used when the scanning depths required range from 0 to 18.0 cm. Place the phantom on a clean, flat surface with the proper scan surface positioned for use.

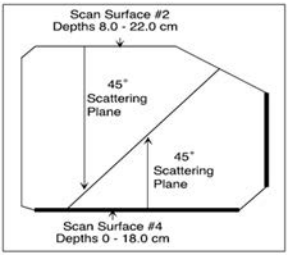

Figure 3-4. Scan Surfaces

2 Apply a liberal amount of acoustic coupling gel to the scanning surface. It is suggested, when evaluating array systems, a low viscosity coupling agent be used to minimize a “snowplowing” affect on the surface of the phantom. However, when testing transducer faces with a high degree of curvature, the use of a high viscosity gel is recommended to maintain good coupling.

3 Adjust the instrument settings (TGC, output, etc.) to establish baseline values for “normal” liver scanning. If the penetration is such that the bottom of the phantom is seen, the gain settings should be reduced such that the image fades and goes entirely black. These settings should be noted on the quality assurance record and used for subsequent testing.

4 Position the transducer on the scan surface providing the proper depth range. The image displayed will appear as a band or thick line positioned at a given depth in an angular plane.

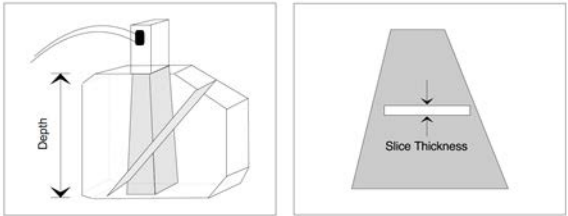

Figure 3-5. Transducer on Scan Surface

5 Rotate the transducer until the image displayed is positioned in the horizontal plane. This is the slice thickness of the sound beam at a given depth.

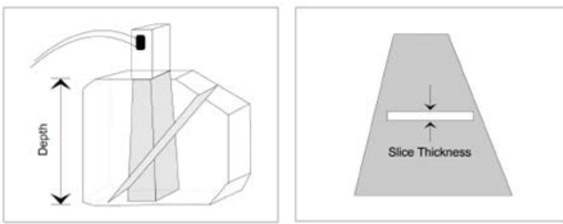

Figure 3-6. Slice Thickness of Sound Beam

> ***Note:*** *For sector imaging systems, the beam will sweep back and forth as it passes through the scattering plane, imaging the cross-section of the beam. In a multitransducer sector scan head, the image will be the integrated sum of all the slice thickness. To examine the slice thickness of the individual transducers, the frame rate must be decreased permitting a single slice thickness to be displayed. Depending upon the system, it may be necessary to reduce the frame rate to zero.*

6 Freeze the image.

7 Using the electronic calipers, measure the distance from the scan surface to the center of the displayed slice thickness image.

8 Again using the electronic calipers, measure the thickness of the image. This is the slice thickness of the sound beam at a given depth.

9 Obtain a hard copy and document all measurements on the quality assurance record

10 To obtain a series of slice thickness measurements at various depths, slide the transducer along the scan surface. Repeat steps **4** through **9**.

11 Using graph paper, plot the slice thickness measurements obtained at each given depth. Draw a connecting line on each side of the results plotted. The resulting drawing will be a graphical representation of the slice thickness beam profile. Document the smallest measurement of the slice thickness and depth at which it occurred; this area is the focal zone.

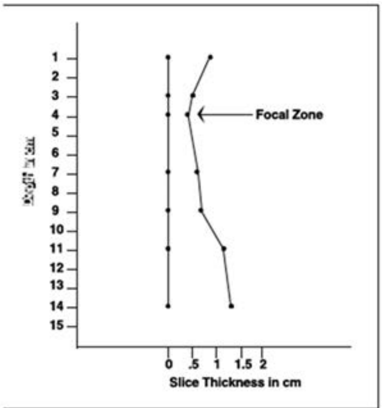

Figure 3-7. Slice Thickness Beam Profile Graph

Note: *A correction factor of 0.94 adjusts for the speed of sound in ATS urethane (1450 m/s).*

Results

The slice thickness of the beam should remain consistent from week to week, when using the same instrument settings, transducer, and the Model 538NH phantom. Compare the test results obtained with a baseline or previous test. If the current image demonstrates changes in the system, investigation should be made to determine the cause.

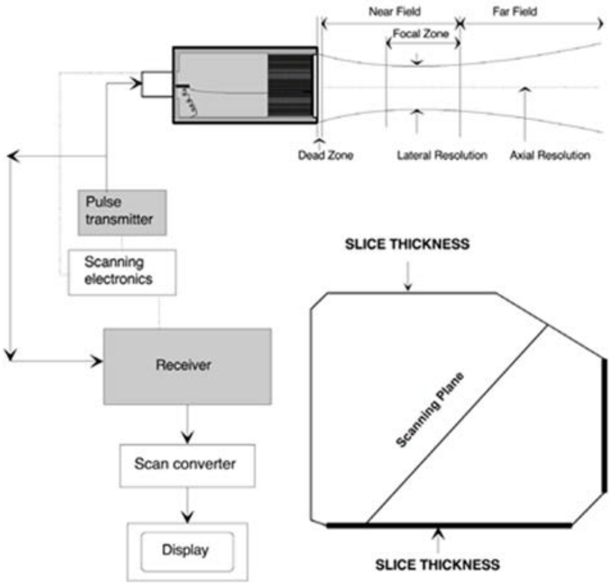

Figure 3-8. Slice Thickness Results Dataflow

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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 phantom and the parts provided with the phantom 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 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.

Disposal and Recycling

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

Contacting Sun Nuclear Support

You may request support in two ways:

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

Support Website

1. Open an internet browser and navigate to sunnuclear.com/support.
2. Enter your email address and password and then click **Login**.
   - To download product information, click **Products and Downloads**, 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

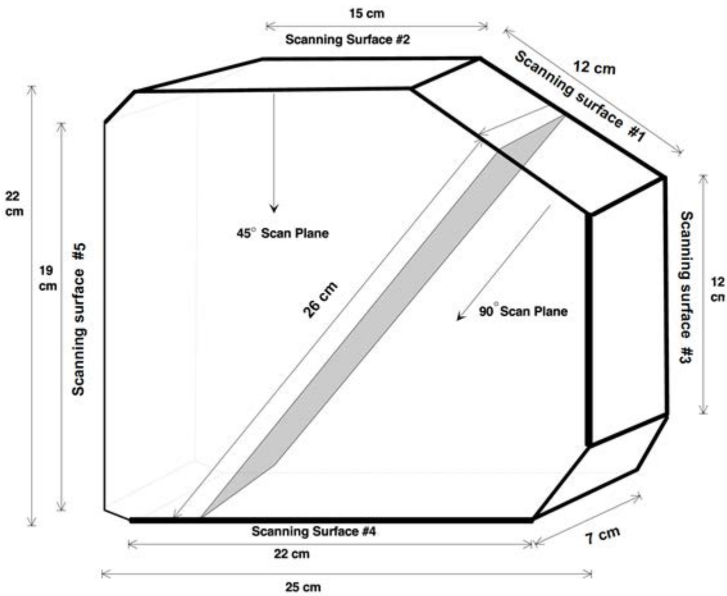


Figure 5-1. Target Map

Phantom

Table 5-1. Phantom Specifications

Characteristic	Specification
Housing	PVC
Overall Dimensions	25 x 22 x 7 cm (10″ x 9″ x 3″)
Weight	5.1 kg
Scanning Surface Dimensions	15.0 x 7.0 cm, 12.0 x 7.0 cm, 12.0 x 7.0 cm, 22.0 x 7.0 cm, 19.0 x 7.0 cm

Urethane Properties

Table 5-2. Urethane Properties

Characteristic	Specification
Freezing Point	< -40°C
Melting Point	Above 100°C
Speed of Sound	1450 m/s at 23°
Attenuation Coefficient	0.5 dB/cm/MHz (measured at 3.5 MHz)

Targets

Scattering plane oriented at 45° to the scan planes used to measure slice thickness, and 90° to the beam profile scan plane

Table 5-3. Target Specifications

Characteristic	Specification
Size	26 x 7 cm
Depth	0 to 22 cm

Appendix A: 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)

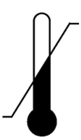
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

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

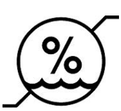
Note: *Important or supporting information.*

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

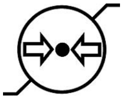
Date of Manufacture. (EN ISO 15223-1, 5.1.3)



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



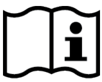
Humidity limitation. (EN ISO 15223-1, 5.3.8)



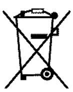
Atmospheric pressure limitation. (EN ISO 15223-1, 5.3.9)

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

REF *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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