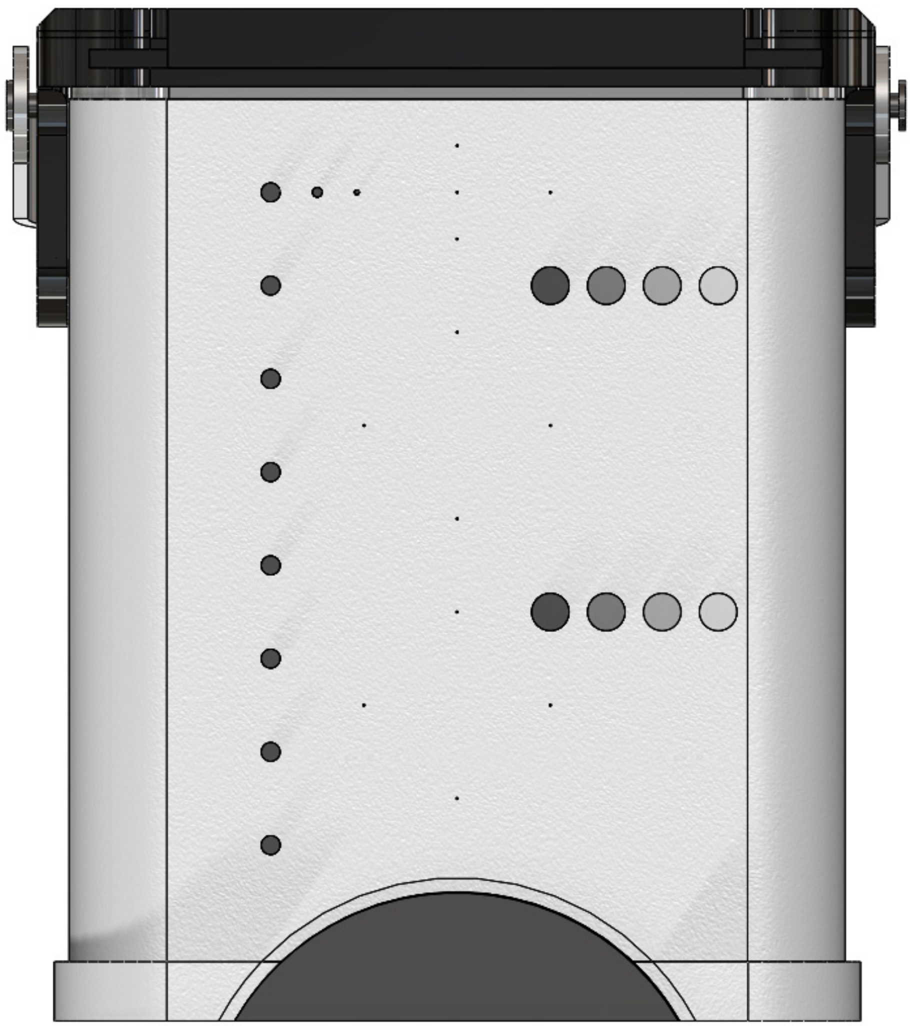
ULTRASOUND

410 Series

Multi-Purpose Accreditation Phantom



User's Guide

Gammex

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Introduction

The 410 series phantoms are designed to meet all ACR requirements for biannual or annual system performance evaluation and routine quality control tests. With two scanning windows the 410 model offers optimal contact between curvilinear as well as linear array transducers and the tissue mimicking phantom.

The basic 410 S phantom is intended for verifying image uniformity and identifying the presence of artifacts, geometric accuracy and system sensitivity. Anechoic targets are provided in model 410 SC and anechoic as well as grey scale targets are provided in model 410 SCG for monitoring contrast resolution, distinguishing different echo intensities and assessing border delineation capabilities of the ultrasound system.

The top model 410 SCG phantom offers carefully placed targets to measure resolution, depth of penetration and electronic caliper distance accuracy. Grey Scale targets are set at -6 dB, +6 dB and +12 dB, relative to the background material, and with equivalent attenuation properties. Two 8 mm anechoic targets at different depths are also provided to evaluate system noise and geometric distortion. The phantom incorporates the latest technology in tissue mimicking gel which provides a smooth background texture. The phantom is fully compatible with the latest tissue harmonics equipment and technology.

Note: See ACR website for current accreditation requirements.

Product development of the 410 series have benefited from open discussion and tests conducted by Jim Zagzebski, Ph.D., Professor Emeritus.

Limitations of Use

The 410 series phantoms are designed to be used to aid in Quality Control testing and monitoring of ultrasound instruments only. The 410 series is not to be used to make diagnostic decisions.

Caring for your 410 phantom

The 410 phantom comes ready to scan. Do not remove surface window material.

Store your 410 securely with its cover in place.
Always attach the scanning surface cover and store the phantom out of direct sunlight when it is not in use.

Store your 410 at 35º–105ºF (2º–40ºC).
Freezing temperatures will damage the phantom and high temperatures will accelerate desiccation.

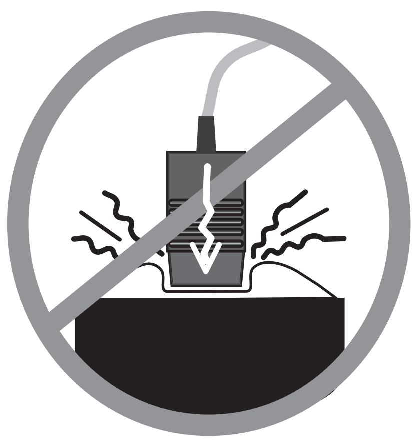
Weigh your 410 to monitor desiccation.
Weigh the phantom when you first receive it and then every 6 months. Record the values on the data sheet.

Do not drop or damage the phantom.
Return the phantom for inspection and/or repair if it has been dropped or damaged. Physical damage to the case will cause premature desiccation.

Gammex strongly recommends annual servicing of your 410 to ensure proper operation. Our qualified service technicians will check for desiccation and provide any needed rejuvenation, scanning/ validation to original specifications, and repairs.

Scanning your 410

- Always place the phantom on a stable, level surface for scanning.
- **The phantom comes ready to scan. Do not attempt to peel off the surface material that forms the scanning window.**
- Use water or a generous amount of coupling gel to ensure good transmission. **Do not** use mineral oil, baby oil or lanolin-based gels as a coupling medium. Poor transmission may be a result of insufficient coupling.
- **Do not press the transducer into the scanning surface.** This damages the scanning surface and will shorten the life of the phantom.
- Clean the scanning surface immediately after use. Use a soft cloth or paper towel and soap and water, if needed.



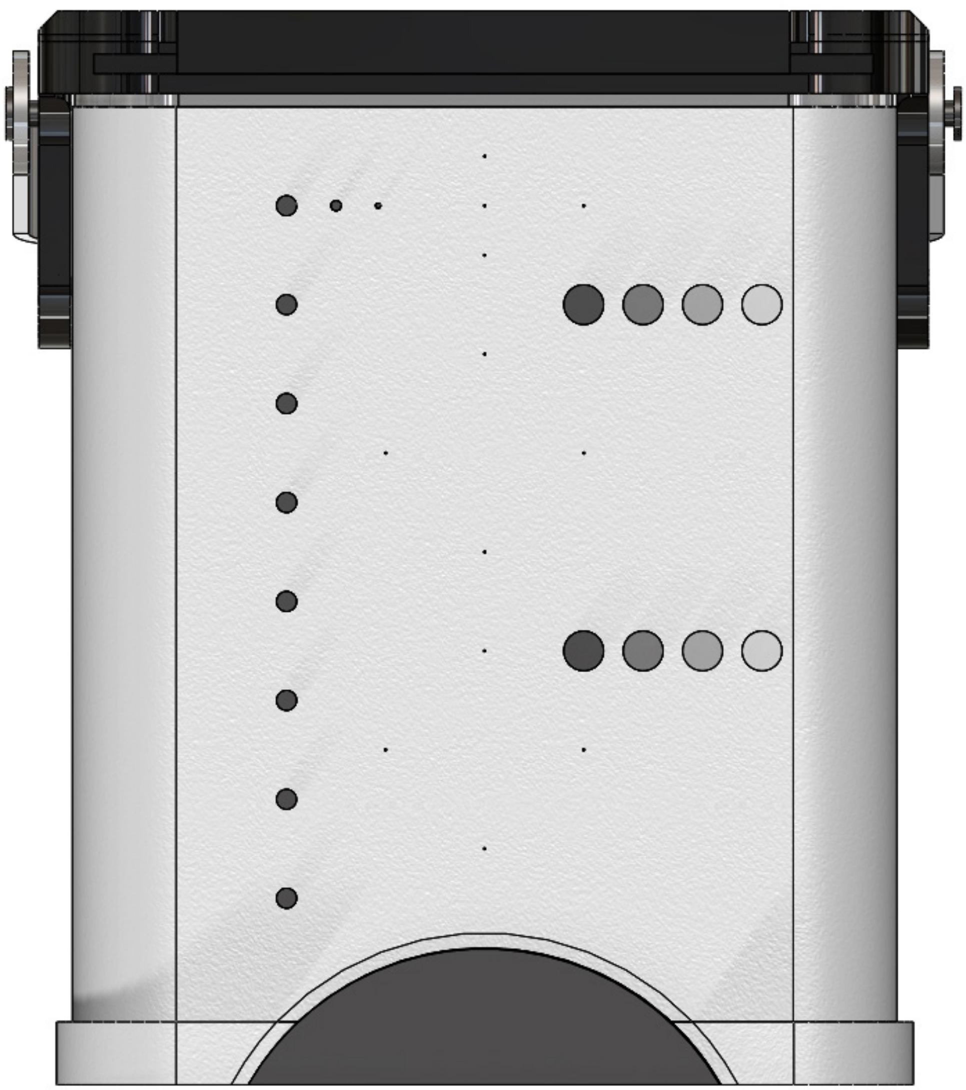
Caution:
Do not press the transducer into the scanning surface.

A Guided Tour of your 410SCG

The 410SCG LE Multi-Purpose Accreditation Phantom provides a means for monitoring the image quality of ultrasound scanning systems. The tissue mimicking gel in the 410 LE is ultrasonically similar to human tissue. This allows the use of normal scanner control settings and ensures that the measured performance closely approximates the scanner's performance in a clinical examination.

Scanning is the best way to familiarize yourself with the features and functions of the 410 SCG LE. A guided tour of the phantom is provided on the following pages.

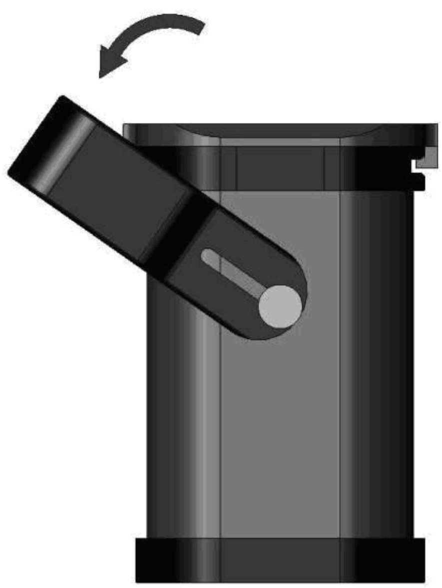
Note: The “SCG” stands for Strings, Cysts and Grey scale. A 410 LE phantom contains background gel only with no targets and it is intended for image uniformity and artifact identification as well as penetration tests.

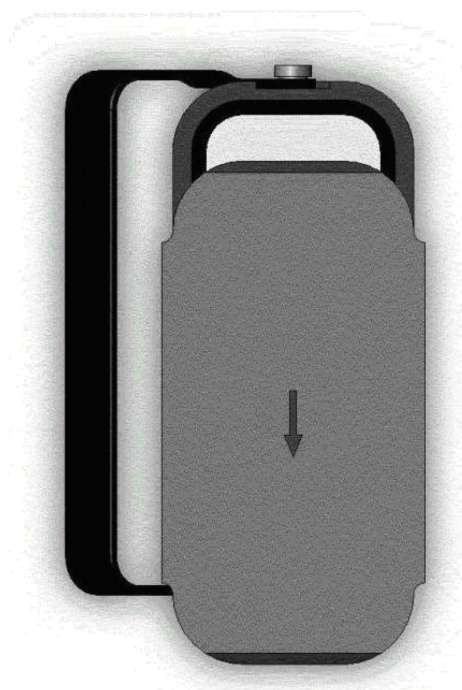


Evaluating the Phantom

Remember

- **The phantom comes ready to scan. Do not peel off the surface materials.**
- **Never press the transducer into the scanning surfaces.**
- Always clean and dry the scanning surface after each use. Never leave coupling gel or water on the scanning surface for more than a few hours.
- **Do not** use mineral oil, baby oil, or lanolin-based gels as a coupling medium.
- The contours of the Full Contact™ surface may vary depending upon phantom orientation. These variations do not affect performance. Store for a short while with the Full Contact™ curved surface up to minimize variations.





A 4-5 MHz probe will provide a good overall view of the phantom for this demonstration.

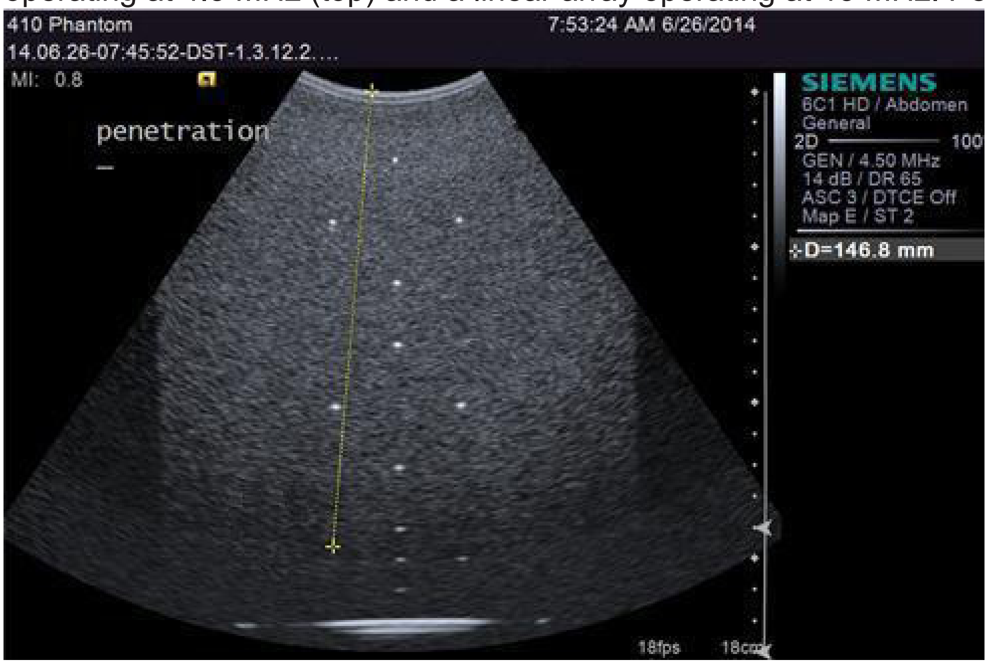
1. To scan the flat surface, turn the handle out of the way and slide the cover off the phantom.

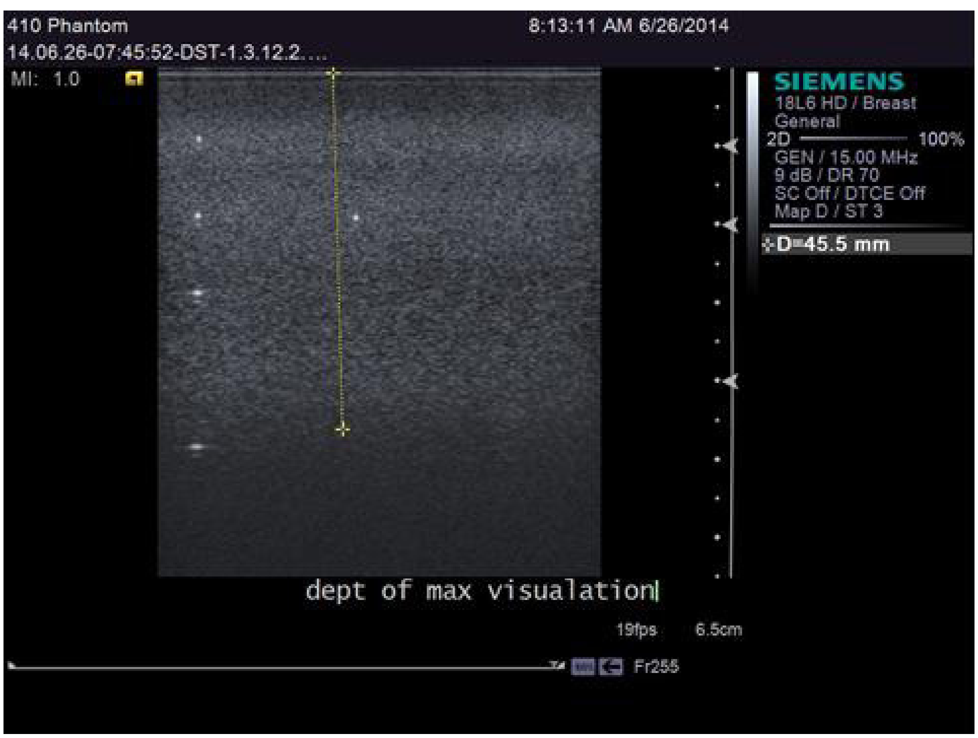
2. To couple with water, fill the dam with distilled water. For a better image quality, use coupling gel.

3. Rest the transducer on the scanning surface. Adjust the scanner to display the full depth of the phantom.

4. You may notice that the tissue echoes near the bottom of the phantom fade into noise. The depth at which usable echoes disappear is called the ***depth of penetration***. When testing the depth of penetration for a particular transducer, turn the transmit power to its maximum level (100%), and adjust the transmit focus so it is at or near the maximum depth, then increase the receiver gain to view backgrund echoes as deeply into the phantom as possible. It may be necessary to reposition the transmit focus so that the focal zone is near the maximum depth.

The depth of penetration is shown below for two different transducers, a curvilinear array operating at 4.5 MHz (top) and a linear array operating at 15 MHz. Penetration





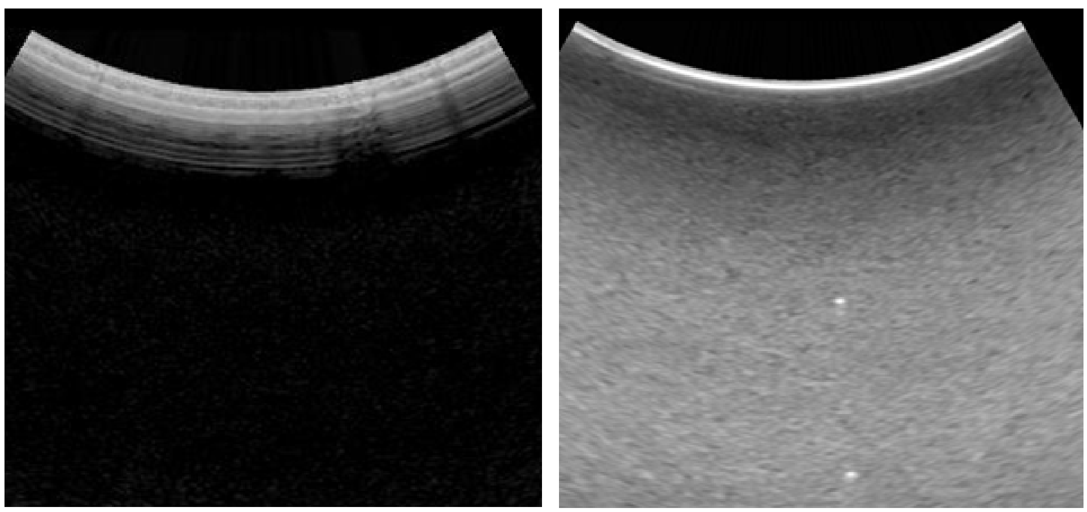
is about 14.7 cm for the lower frequency probe while it is only 4.5 cm for the high frequency linear array. Both ar typical values for these frequencies when the attenuation coefficient of the phantom is 0.7 dB/cm-MHz.

Another useful feature of the 410 phantom (models SC and SCG) is the presence of 4mm diameter anechoic cylinders ("cysts") at different depths. These may be used for assessments of maximum depth of visualization, checking to determine the furthest anechoic object that can be visualized above the electronic noise.

4. Move the transducer across the scanning surface while observing the locations of the targets.

   Notice how the smooth texture of the tissue mimicking gel emphasizes image non-uniformities and artifacts, making them easier to detect. Scanning an area without targets is a good way to test for ***image uniformity***.

   Many artifacts created by damaged or weakened transducer elements may be seen in air scans but this can also be deceiving. In the images below, see an air image (left) next to one taken using the same transducer on a 410 S phantom.



   The air image suggests several regions that might have element dropout, as evidenced by the shadows emanating through the "ring-down" signals. The phantom image, on the other hand, does not exhibit evidence of transducer damage.

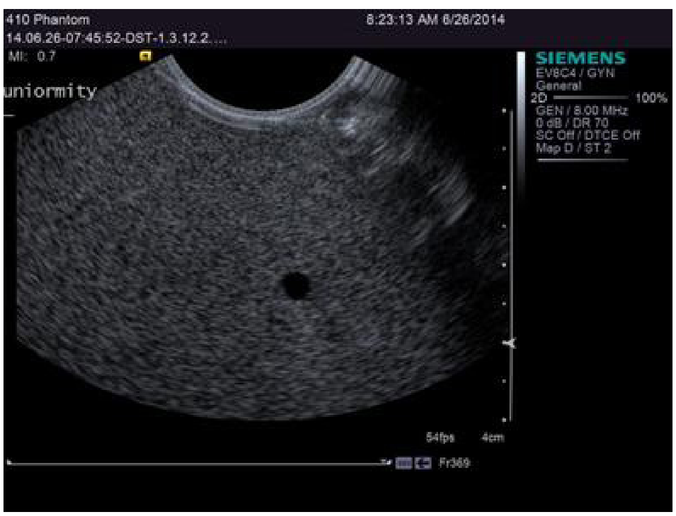
   If any noticeable flaws are seen, it is important to make sure that the problem is reproducible and is not caused by coupling between transducer and phantom.

   A phantom with the correct speed of sound and attenuation is a valuable tool because you can check the extension of the artifact in depth. For example, in the image below, nylon strings of different diameters were used in between the transducer and the scanning window. These very effectively mimic dead transducer elements, a common flaw seen in ultrasound QA.

   Although the curved window on the 410 provides good contact with intercavitary curvilinear arrays, uniformity checks still may require "rocking" the transducer over its surface, creating 2 images to assess the entire array. The process is illustrated below. No evidence of dead elements is seen over the contact surface of either image.

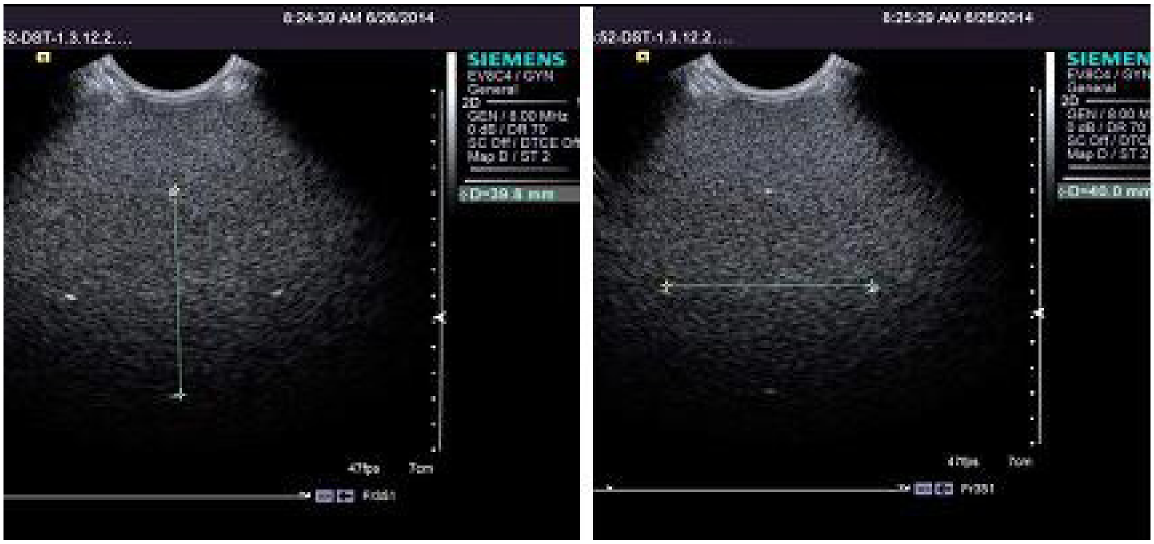
5. Scan the vertical pin targets and freeze the image. Use the electronic calipers to measure the distance between two of the vertical pin targets. Repeat for two of the horizontal pin targets. The vertical pins have 1, 2 or 4 cm spacing while the horizontal pins have 2 or 4 cm spacing.

   Use these pin targets to determine *vertical distance accuracy* and *horizontal distance accuracy*.



6. With high frequency linear arrays, both pin targets and anechoic cylinders near the flat scanning window allow an assessment of lateral resolution properties. The image below left was obtained using a high frequency array along with a breast imaging preset. On the scanner the beam-former is programmed to assume the propagation path in breast is mostly fat, with a speed of sound of approximately 1480 m/s (CTI=1). The pin targets appear broad, and it is difficult to visualize the smallest anechoic cylinder, which is 1 mm diameter. Much better lateral resolution can be seen in images taken using a beam former speed of sound of 1540 m/s (CTI=0), matching the speed in the phantom, as in the image at the lower right. Notice the pin targets are point-like, and the 1 mm anechoic cylinder, hardly visible on the left image, now stands out.

7. Scan the nearest cystic target group. Each target should be round with a clean black appearance and well defined edges. Bright specular echoes at the top and bottom of the targets are normal.

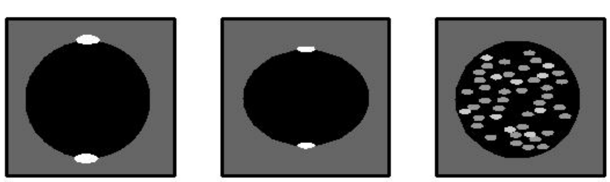


Measure the dimensions of the 8 mm cystic target to check the image geometry. Use the calipers to measure from top to bottom and side to side.

8. Scan the four grey scale targets and observe the difference in their grey levels. Adjust the gain control and observe how this affects the brightness of the targets.

Notice how noise in the anechoic target becomes apparent as the gain increases. If your system has image "post-processing" capabilities, observe how the contrast between targets changes with different settings.

Adjust the gain control to the lowest noise level. This is the point at which you eliminate noise in the anechoic cyst (lower the gain until it just disappears). Record this gain setting and use it for future grey scale measurements. Freeze the image and visually evaluate the grey scale targets. Match each target with a step on the grey bar in the image. Make a hard copy and



Normal Distorted System noise

compare the hard copy with the image on the scanner.

9. When you are done scanning the phantom, empty the water dam or completely clean off the coupling gel with a soft cloth or paper towel. Replace the cover and secure by lifting the handle to protect the phantom.

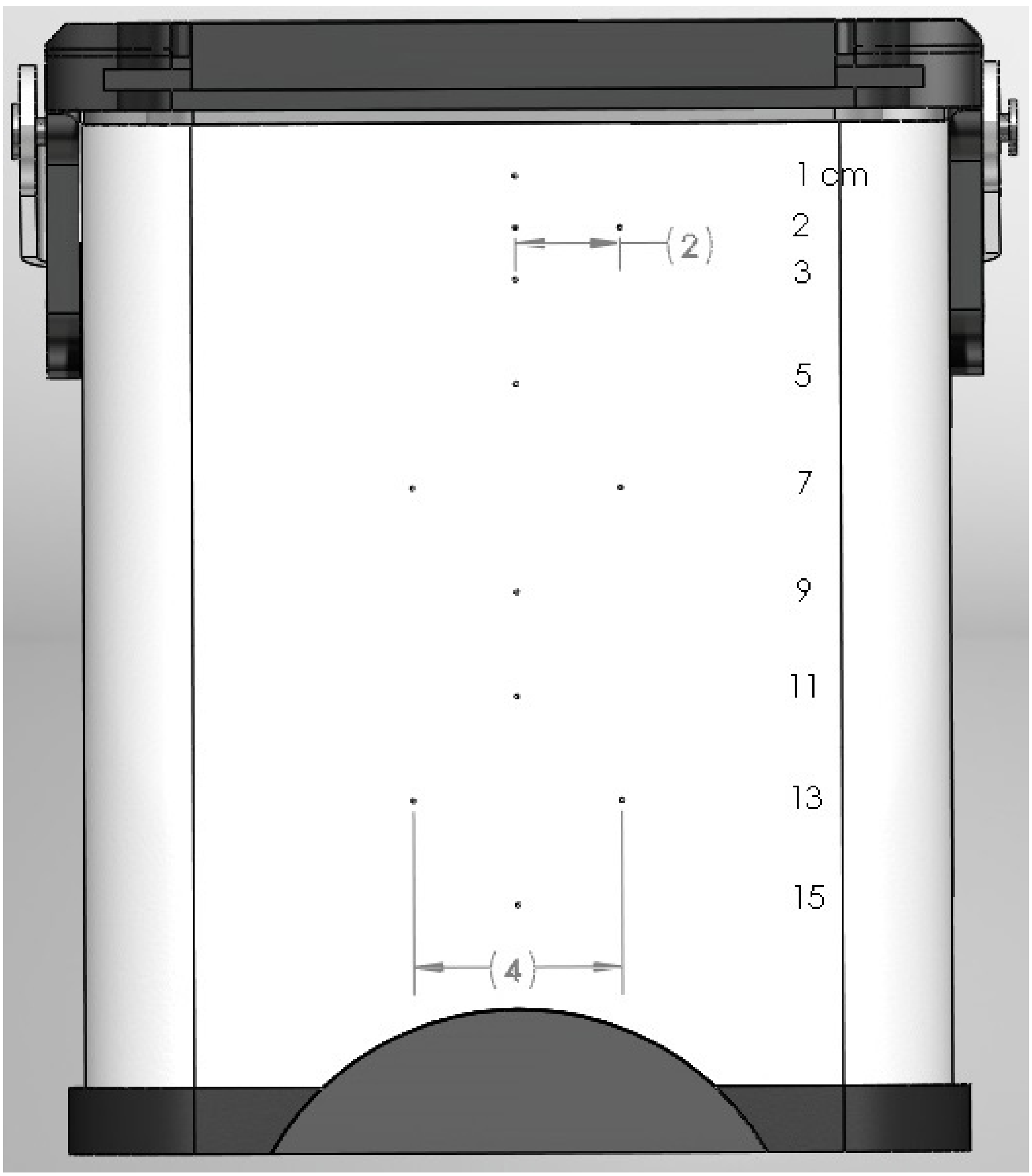
4 Store in an airtight container or plastic bag.

410S Specifications

Speed of sound .... 1540±10 m/s
Attenuation Coefficient .... 0.5 or 0.7 ± 0.05 dB/cm/MHz (see side label)

Pin Targets (nylon monofilament), from flat surface down:

Diameter 0.1mm
Vertical spacing .... 1, 2 and 4 cm from 1 to 15 cm deep
Horizontal spacing .... 2 cm at 2 cm deep, 4 cm at 7 and 13 cm deep



410 SC Specifications

The 410 SC contains the same gel and all pins from model 410S, plus Cystic Targets.

Cystic Target Specifications:

Diameters .... 1, 2 and 4mm
Placement.. 2, 4, 6, 8, 10, 12, 14 and 16 cm deep
Speed of sound .... 1540 ± 10 m/s
Attenuation coefficient .... 0.05 ± 0.01 dB/cm/MHz

<u>410 SCG Specifications</u>

The 410 SCG contains all targets of model SC plus Grey Scale Targets.

Grey Scale Target Specifications:

Diameter .... 8 mm
Placement .... 4 and 11 cm deep
Speed of sound .... 1540 ± 10 m/s
Temperature dependence on speed of sound .... 1.5 m/s/ºC
Contrast .... -6 dB, +6 dB, high scatter relative to background

All acoustic measurements made at 4.5 MHz, 22ºC.

Due to our philosophy of continuous quality improvement,
all specifications are subject to change.

Phantom Specifications

<u>Physical Specifications</u>

Weight .... Approx. 2.8 kg (6 lbs. 5 oz.)
Dimensions.. 21.8 x 9 x 19.2 cm
.... (8.6 x 3.5 x 7.5 in.)
Scanning surface.. Aluminum Composite Film
Case material .... Extruded ABS plastic
Pin target material .... Nylon monofilament

<u>Tissue Mimicking Background Material</u>

Water-based gel with appearance of human tissue.

Speed of sound .... 1540±10 m/s
Attenuation coefficient .... 0.7±0.05 dB/cm/MHz
.... 0.5±0.05 dB/cm/MHz
.... refer to phantom side label
Nonlinearity parameter (B/A).. 6.6±0.3
.... 6.7 (Accepted value for human liver tissue)

All acoustic measurements made at 4.5 MHz, 22ºC.

Due to our philosophy of continuous quality improvement, all specifications are subject to change.

Harmonic Imaging

Harmonic imaging has become an important scanning mode in medical ultrasound. Harmonic imaging is done by transmitting a pulse from the transducer at a nominal frequency, the fundamental frequency, and processing the received signals to detect echoes at twice that frequency, which is the second harmonic. The result is that better resolution may be attained at a given depth than if the reception had been at the fundamental frequency, as in conventional ultrasound. Artifacts such as reverberations and side lobe artifacts are reduced, axial and lateral resolution is increased, and the signal to noise ratio may be greater than that obtained when transmitting and receiving at the frequency of the harmonics. In many cases, image quality is improved by using harmonic imaging.

There are three tissue properties that determine the effectiveness of harmonic imaging:

1. pulse propagation speed
2. attenuation (rate of pulse energy loss with depth)
3. the value of the nonlinearity parameter: B/A

In order for phantoms to present valid resolution results for harmonic imaging, these three properties must adequately correspond to human tissue.

The B/A value quantifies the rate of transfer with respect to propagation distance of ultrasonic fundamental frequency energy to harmonic frequencies. The greater the B/A value, the greater the energy transfer rate. Generally, the beam profile for the harmonic is narrower than for the fundamental, which means better lateral and elevational resolution in the harmonic signal.

Tissue-mimicking phantoms will be appropriate for assessing harmonic imaging only if the B/A value for the tissue-mimicking material in the phantom adequately approximates that of soft tissues. Measurements of the value of B/A for the tissue-mimicking materials in Gammex phantoms indicate results lie in the range for non-adipose soft tissue, meaning B/A is between 6 and 7[1].

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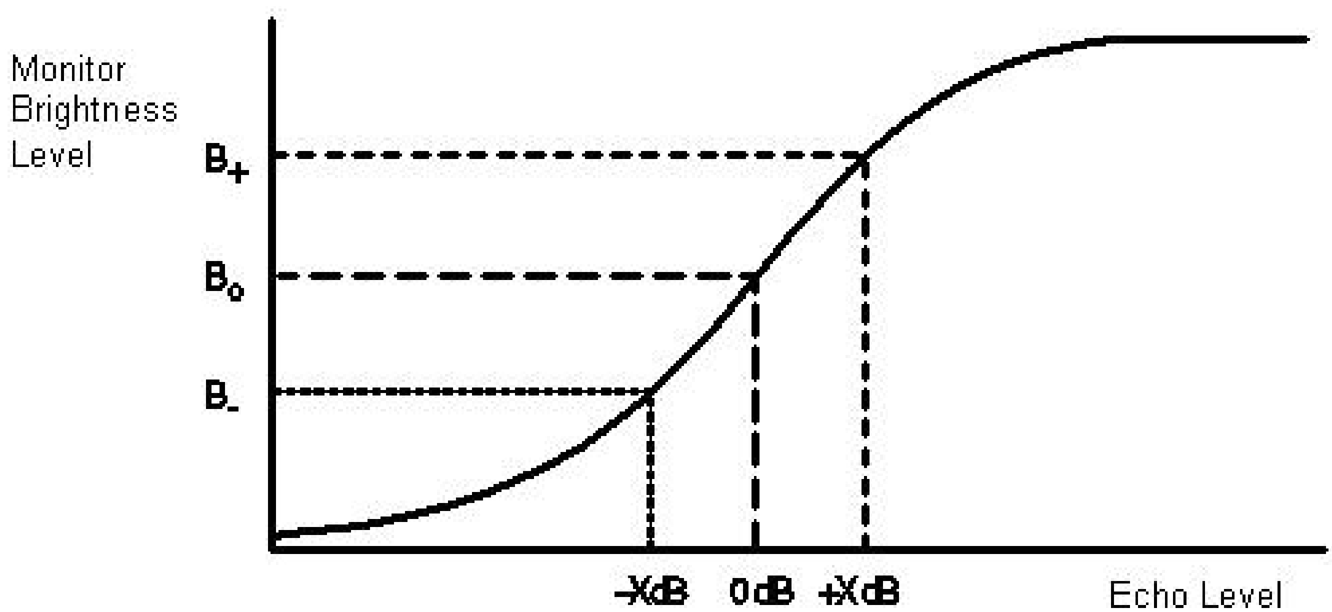
[1]Gong, X. F., Zhu, Z. M., Shi, T., Huang, J. H. (1989) Determination of the acoustic nonlinearity parameter in biological media using FAIS and ITD methods, J. Acoust. Soc. Am. 86 (1), pp 1-5.

Grey Scale Applications

Metastases are sometimes slightly hyperechoic or hypoechoic compared with the surrounding tissue. If the scanner is not measuring grey levels accurately, the metastases may not be detected. A simple scan of the gray scale targets and visual inspection of the resultant image can help verify that these objects are displayed on the monitor consistently and are detected satisfactorily. This can be done using the Qualitative Measurement on the Data Sheet located on your manual CD. In addition, a Quantitative Measurement ensures that the grey level signals are measured consistently. By performing these tests, the user can determine the optimal system settings for measuring grey levels.

System Linearity

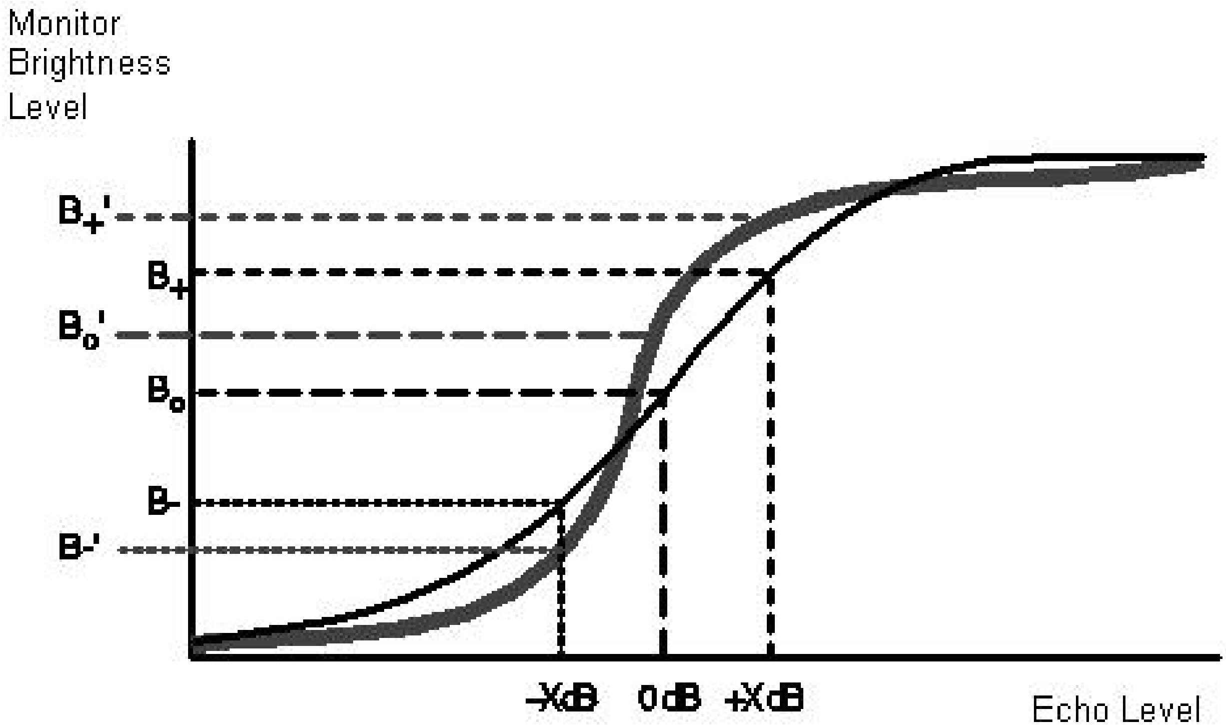
Ultrasound systems use special processing circuits to translate the amplitude of echoes into brightness levels on the display monitor. These circuits use mathematical functions that often produce an S-shaped curve when the mean pixel value data are plotted vs the target echo level. As shown in the figure below, for a given set of operating conditions, each echo level produces a corresponding brightness level on the monitor.



An S-shaped curve is used to translate echo levels into brightness levels on the video display. Notice how different echo levels, –X, 0 and +X dB produce corresponding brightness values B_-, B_O and B_+.

The shape of this curve is affected by the dynamic range setting on the scanner and on the post-processing mapping function. If the shape of the S-curve changes, the relative image brightness for each echo level will also change.

For example, image post-processing techniques help the user identify subtle tissue variations by modifying the shape of the S-curve to emphasize certain ranges of echo levels. Degradation in the system hardware can also affect the shape of the curve and produce unexpected variations in the contrast between echo levels. The distortion in the information displayed to the user may affect the interpretation of the ultrasound image.



Changes in the shape of the S-curve result in different brightness levels for the same echo levels. Notice how the positions of the original brightness levels B_-, B_O and B_+ have moved to B_-^1, B_O^1 and B_+^1.

Changes in the system response can be identified by measuring the average pixel value of the grey scale targets and the background material. Pixel values can be estimated qualitatively by eye. They are measured with image analysis tools provided on some ultrasound instruments or from workstations associated with PACS systems.

Quantitative Measurement

A target's brightness level can be most accurately measured using digital image data. On scanners so equipped, the user defines a region of interest and the scanner determines the average pixel value. Similarly, on PACS workstations, ROI tools to reduce the effect of speckle and small variations in the targets are used; several measurements are taken and averaged.

Note: If your system does not have a region of interest (ROI) tool, you will not be able to perform this test. As an alternative, refer to the Qualitative Measurement section of this document.

Note: All values determined by the quantitative measurement test depend on scanning technique. Great care should be taken to perform the test in the same manner each time.

Method

Define a region of interest and measure the average echo level.

Procedure

Baseline Test

1. Scan the grey scale targets and display them as large as possible. Freeze the image.
2. Measure the echo level of the anechoic target.
3. Record this setting and reuse for all subsequent tests.

Subsequent Tests

1. Scan the grey scale targets and display them as large as possible. Adjust the system control settings as recorded on the data sheet, which can be found on your manual CD.
2. Freeze the image and place the region of interest (ROI) tool completely inside the grey scale target image. The ROI should be approximately 2/3 – 3/4 the diameter of the target image, and it should be centered in the target.
3. Measure and record the echo level of each target.
4. Measure and record the echo level of the background material directly beside the anechoic target. Use as close to the same ROI as the target as possible. Unfreeze the image.
5. Perform this process three times and record the average echo level for each grey scale target and for the background material on the data sheet.

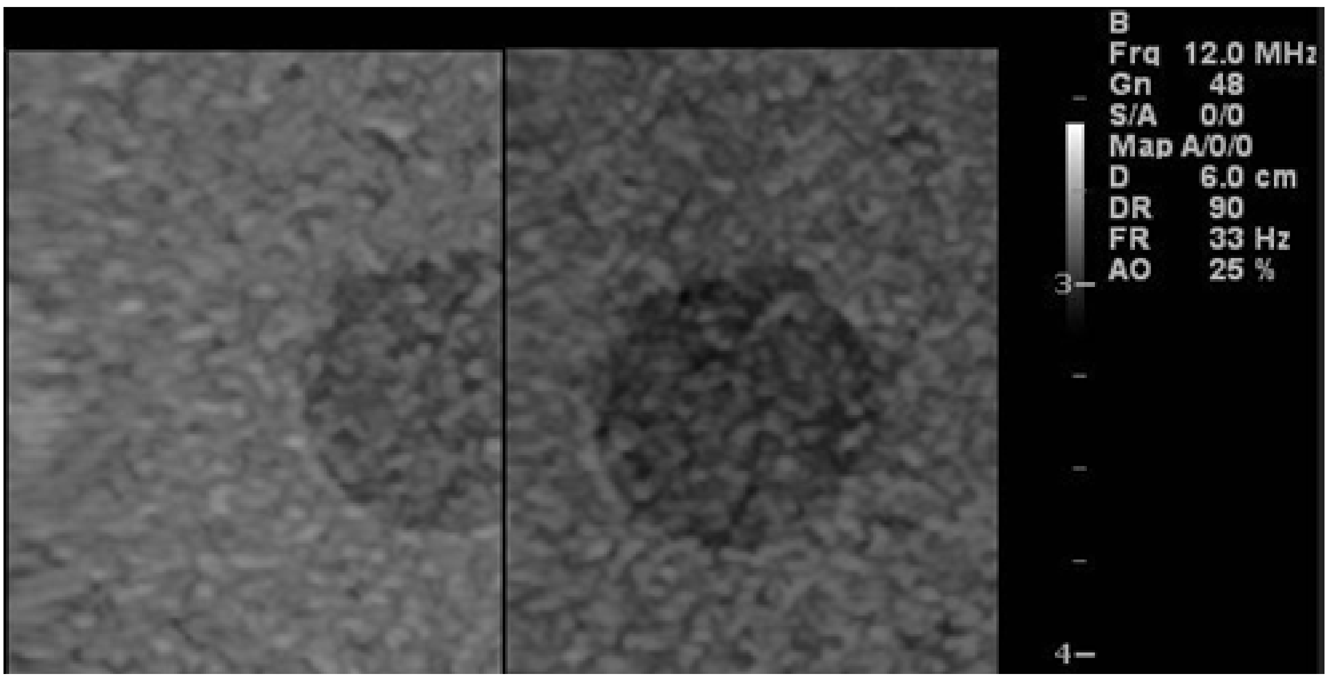
Analysis

Contact your service engineer if target 2, 3, or 4 varies from the baseline by 10% or more.

If a dual display mode is available on your scanner, then another, more subjective, method is possible to test the grey scale and it is described below.

- Activate the Left and Right displayed images.
- On the active image, i.e. the left one, scan one of the grey scale objects. Using the zoom function helps in locating the target at one side of the image.
- Switch dual mode to the second image, i.e. the right one, and scan a region close to the same target.
- Note the gain value displayed by the scanner. Then, in the active image, adjust the gain until the level of gray of the target in the left image matches the background in the right image. If the gain is calibrated in decibels, the difference between the two gain values represents the grey scale value in dB.

In the image below, the same grey scale target is imaged but the gain values are 48 (left image) and 42 (right image), The overall brightness of the background region on the right image appears to match the brightness of the target on the left, taken with 6 dB higher gain. This means that the grey scale target has a -6 dB contrast relative to the background.



Note: Ultrasound scanners typically have preset grey scale maps and most of them are not linear (if the contrast resolution is defined as the slope regression line through a plot of the image pixel values versus gain levels (dB)).

Qualitative Measurement

Image monitors on most ultrasound systems contain a “grey bar” which shows the grey levels available for display. Grey bars normally contain between sixteen and sixty-four steps of increasing brightness. Pixel values can be estimated by locating a grey bar step that approximates the brightness of the region of interest.

Note: It is absolutely critical that all system control settings be precisely reproduced for these tests. Errors will introduce variations in your data and potentially invalidate your results.

Method

Assign a step on the grey bar to each grey scale target and the background.

Procedure

1. Assign a unique number to each grey level on the grey bar.

2. Scan the grey scale targets and display them as large as possible. Freeze the image.

3. For each target, determine which step on the grey bar is the same brightness as the target and record this number on the data sheet. Do the same for the background material directly beside the anechoic target. Keep a print out of the image for reference.

Analysis

Contact your service engineer if any target varies from the baseline by more than two steps.

Phantom Desiccation

Over time, the phantom's water-based gel will slowly lose moisture. This process is accelerated by high temperatures, incorrect storage, and damage to the case or scanning surface. Consistently storing the phantom in an air-tight container will contribute greatly to a long phantom life. Properly storing your phantom will reduce the amount of moisture lost per year. For instructions on how to properly store and take care of your phantom, go to the Caring for Your Phantom section.

For most climate-controlled environments, the phantom weight should be checked every six months. Phantoms used in high temperature/low humidity environments or in mobile situations should be tested more frequently. As the phantom desiccates, the scanning surface may flatten out. It is suggested that the phantom be sent in for rejuvenation once it has lost 10-15 grams of its original weight. If the phantom has lost more than 20 grams, Gammex cannot guarantee that the phantom will be able to rejuvenate successfully.

Product Warranty

WARRANTY, DISCLAIMERS AND LIMITATION OF LIABILITY:
The Products are covered by the warranty set forth in the following paragraphs. The warranty is extended only to the original purchaser of the Products directly from the Seller (or an authorized dealer of Seller) as new merchandise. For a period of twelve (12) months from the date of original delivery to Buyer, the Products manufactured by the Seller are warranted to be free from functional defects in materials and workmanship, provided they are operated under conditions of normal use, and that repairs and replacements are made in accordance herewith. Products manufactured by third parties are warranted only under the warranty provided by such third party manufacturer for such products. Seller does not warrant bulbs. The foregoing warranties shall not apply to Seller's Products or Products manufactured by third parties that have been disassembled, altered or repaired (other than proper replacement of bulbs) other than by Seller or if the Product has been subject to abuse, misuse, negligence or accident.

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Your warranty may be registered at http://www.gammex.com/warranty.asp

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GAMMEX is committed to satisfying our customer’s needs. If you have any questions, comments, or suggestions regarding our products and service, please call or fax us.

Sales Department hours are Monday through Friday, 7:30 am to 5:00 pm Central Time.

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