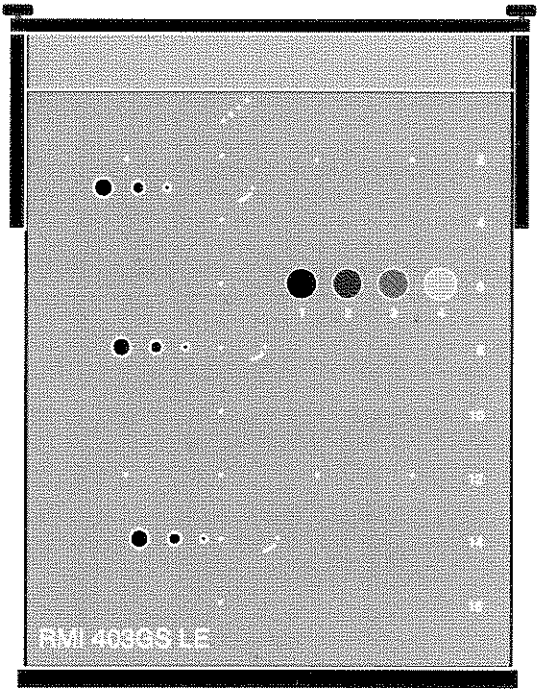
Quality Control in Ultrasound

RMI 403GS
RMI 403GS LE

Precision Multi-Purpose Grey Scale Test Instrument



A User's Guide

Gammex

GAMMEX RMI®

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Introduction

The 403 GS LE phantom is designed for measuring the image quality of high resolution ultrasound systems. Grey scale targets are provided for monitoring contrast and temporal resolution and distinguishing different intensities of brightness and border delineation capabilities of the ultrasound system.

The 403 GS LE offers carefully placed targets to measure resolution, depth of penetration and electronic caliper distance accuracy. Axial resolution pin spacing patterns are small, offering better axial resolution tests. Grey Scale targets are set at -6, +6 and +12 dB relative to the background material and with equivalent attenuation properties. A 10 mm anechoic cyst is also provided to valuate system noise and geometric distortion. The phantom incorporates the latest technology in Tissue Mimicking gel which provides a smoother background texture and which reduces backscatter. The phantom is fully compatible with the latest Tissue Harmonics equipment and technology.

The 403 GS LE is designed to be used to aid in the Quality Control testing and monitoring of ultrasound instruments only.

Caring for the RMI 403GS/403GS LE

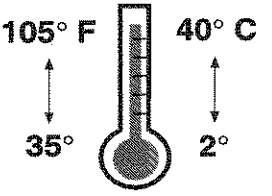
Phantom comes ready to scan.
Do not remove surface material.

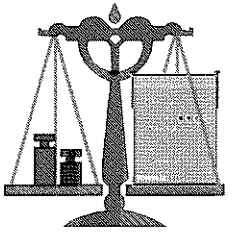
Store the RMI 403GS/403GS LE with water dam and cover closed securely.

Always attach the scanning surface cover and store the phantom out of direct sunlight when it is not in use.

Store the RMI 403GS/403GS LE at 35° - 105° F (2° - 40° C).

Freezing temperatures will damage the phantom and high temperatures will accelerate desiccation.



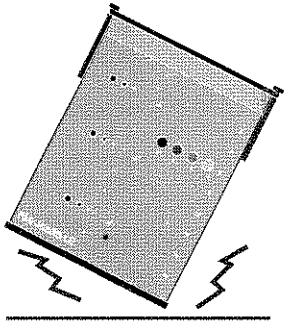


Weigh the RMI 403GS/403GS LE to monitor desiccation.

Weigh the phantom when you first receive it and then every 6 months. Record the values.

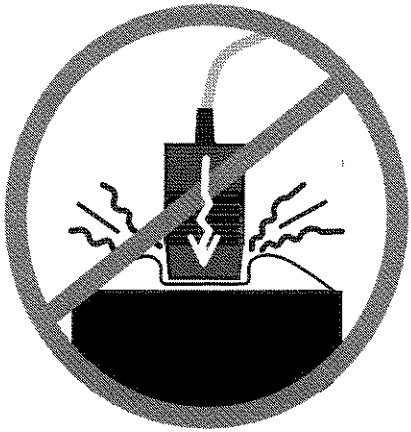
Do not drop or damage the phantom.

Return the phantom for inspection and/or repair if it has been dropped or damaged. Physical damage to the case will cause premature desiccation.



Scanning the RMI 403GS/403GS LE

- Always place the phantom on a stable, level surface for scanning.
- **The phantom comes ready to scan. Do not peel off the surface material.**
- 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 is 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. For curved transducers, use water, or a gel layer.
- 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 the RMI 403GS/403GS LE

The Precision Multi-Purpose Grey Scale Test Instrument RMI 403GS/403GS LE provides a means for monitoring the image quality of ultrasound scanning systems. The tissue mimicking gel in the RMI 403GS/403GS LE is ultrasonically similar to human tissue. This allows the use of normal scanner control settings and ensures that the performance measured 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 RMI 403GS/403GS LE. A guided tour is provided on the following pages.

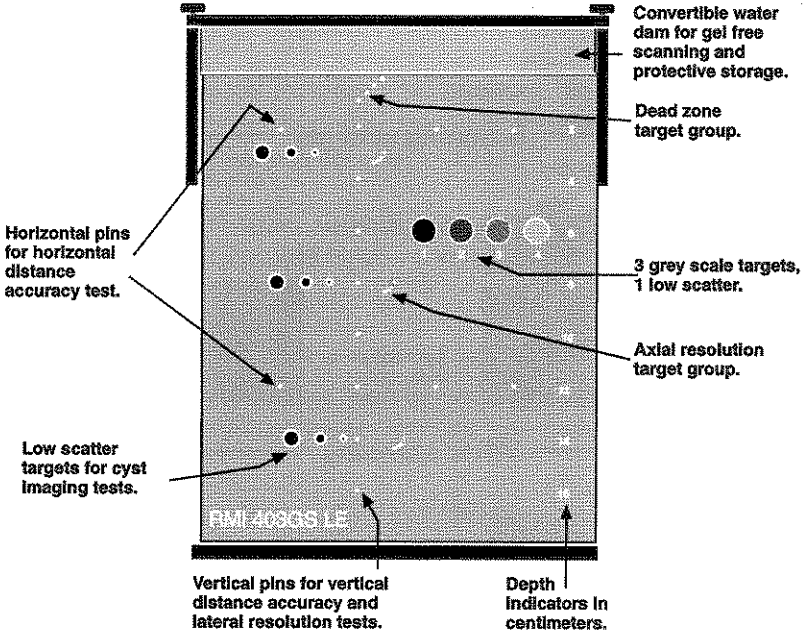
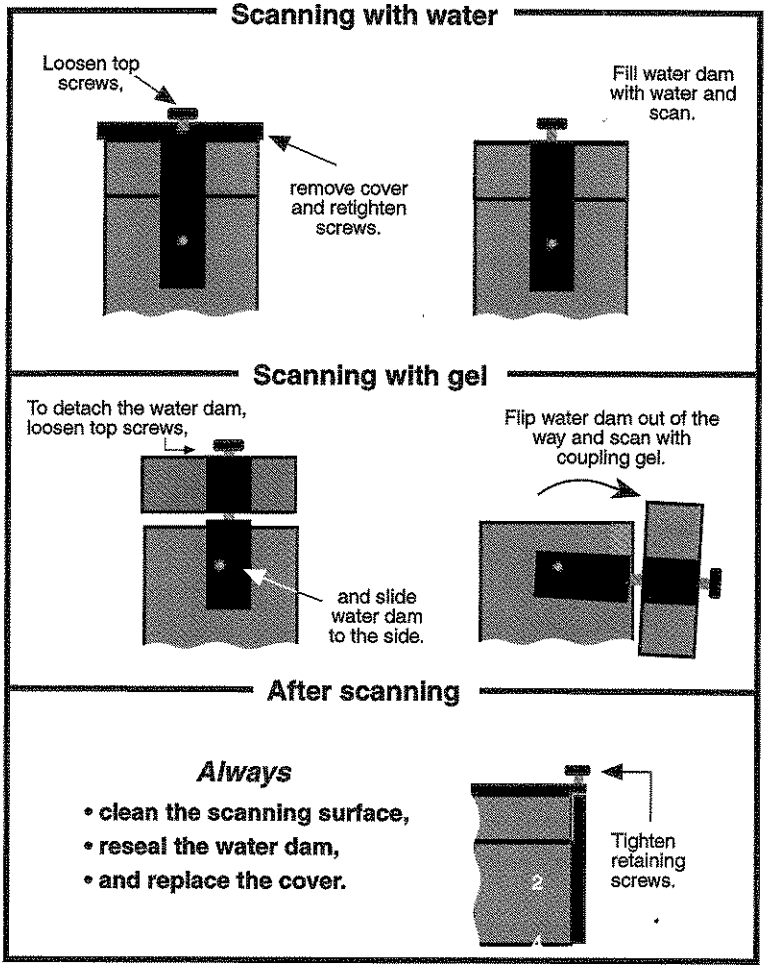


Figure 1: Targets and features of the RMI 403GS LE.

Using the Convertible Water Dam

The convertible water dam and cover make it easier for you to use and protect your test instrument. The water dam cover helps reduce desiccation which extends the usable life.

The water dam allows scanning with water. Water-coupled scanning is easier to clean up; however, where extra transducer clearance is needed or gel-coupled scanning is desired, the water dam can be flipped out of the way.



Scanning the Phantom

Remember

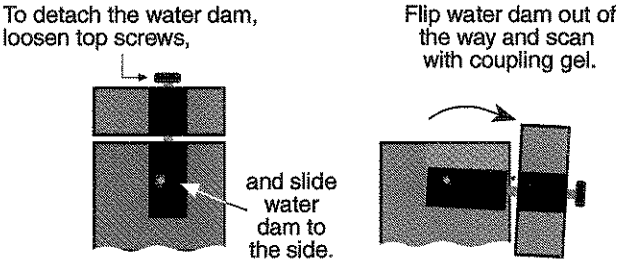
- **The phantom comes ready to scan. Do not peel off the surface material.**
- **Never press the transducer into the scanning surface.**
- Always clean and dry the scanning surface after each use. Never leave coupling gel or water on the scanning surface for more than a few hours.
- **Do Not** use mineral oil, baby oil or lanolin-based gels as a coupling medium.

A 4.5 MHz probe will provide a good overall view of the test instrument for this demonstration.

1. Remove the water dam cover by loosening the two thumbscrews on the top, then slide the cover sideways, and pivot on the thumbscrew to remove.

2. To couple the transducer with water, leave the water dam in place, press down and tighten with the thumbscrews. Once secure, fill with water.

   To couple the transducer with gel, move the water dam out of the way by loosening the two thumbscrews on top of the water dam. Slide the water dam over and then swing it off to the side.

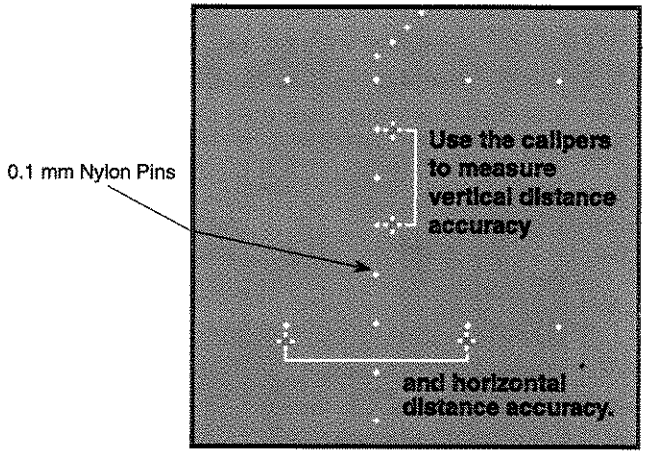


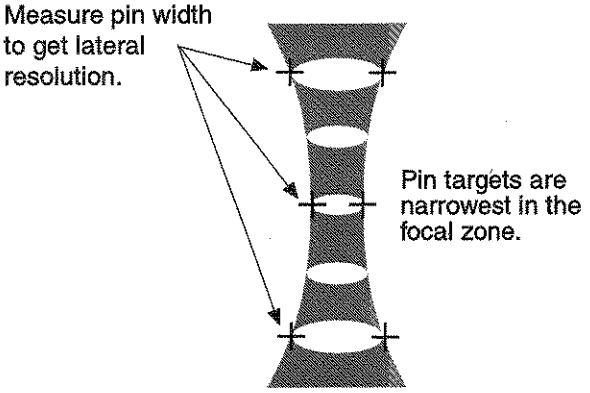
3. Rest the transducer on the scanning surface. Adjust the scanner to display the full depth of the test instrument. You may notice that the tissue echoes near the bottom of the phantom fade into noise. The depth at which usable echoes disappear is called the depth of penetration. The depth markers on the phantom label wil help you determine the depths of the targets.

4. Move the transducer across the scanning surface observing the locations of the targets. Notice how the smooth texture of the tissue mimicking gel emphasizes image nonuniformities and artifacts, making them easier to detect. Scanning an area without targets is a good way to test for image uniformity.

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 2 cm spacing while the horizontal pins have 3 cm spacing. Use these pin targets to determine vertical distance accuracy and horizontal distance accuracy.

   To make these measurements easier, adjust the time gain controls (TGC's) and system gain to minimun. Then increase the system gain until all targets are visible. Record the gain settihgs for future measurements.

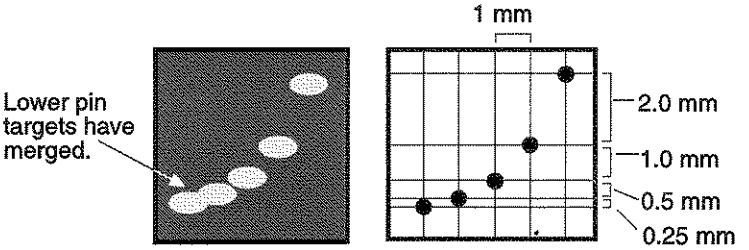




6. Freeze an image of the vertical pin targets. Use the electronic calipers to measure the horizontal width of the pin targets in the near, mid and far fields of the image. Notice how the pin targets are narrowest in the focal zone. Target width demonstrates the width of the ultrasound beam at that depth and approximates the ultrasound system's **lateral resolution**.

7. Decrease the image depth and freeze an image of the axial resolution target group at 3 cm. Notice how the images of the lower pin targets may begin to merge. The smallest distance between two pins is called the ultrasound system's **axial resolution**.

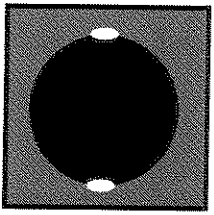
   Examine the other axial resolution target groups and compare the resolution at various depths. Axial resolution may change with depth.



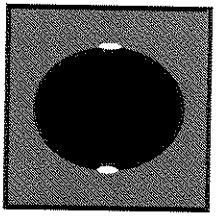
Axial resolution of this scan is 0.5 mm.

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

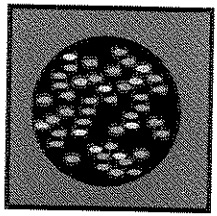
   Measure the diameter of the 6 mm cystic target to check the image geometry. Use the calipers to measure from top to bottom and side to side. Repeat with the other cystic target groups as part of the **cyst imaging** test.



Normal



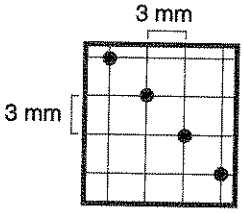
Distorted



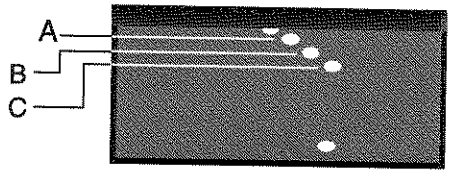
System noise

9. Decrease image depth to the minimum and examine the dead zone target group. Determine the depth of the shallowest visible pin target to measure the scanner's **dead zone**.

   The dead zone targets can also be used to measure lateral resolution in the extreme near field of the transducer.



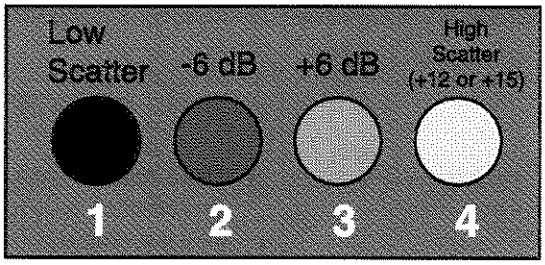
Dead Zone Target Group

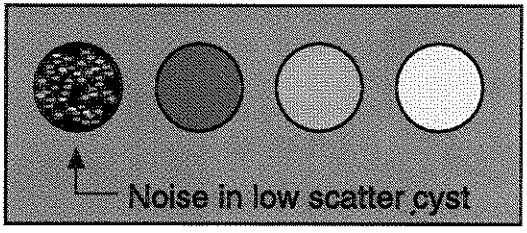


The depth of an instrument's dead zone is determined by identifying the shallowest pin target that can be clearly visualized. In this example the dead zone is at the depth of target A.

10. 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 target #1 (the low scatter 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 compare the hard copy with the image on the scanner.

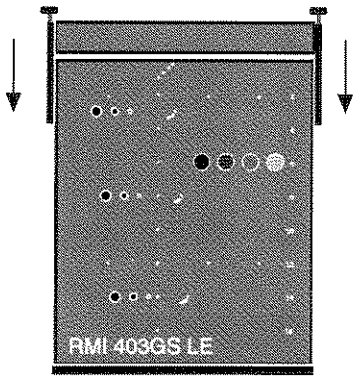




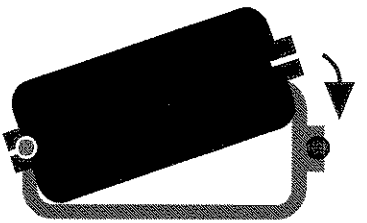
11. When you're done scanning, empty the water dam or completely clean off the coupling gel with a soft cloth or paper towel.

    Secure the water dam and replace the cover.

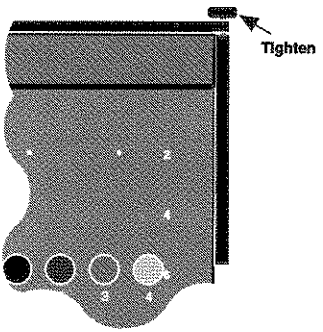
1 **Return the water dam to the top of the RMI 403GS LE.**



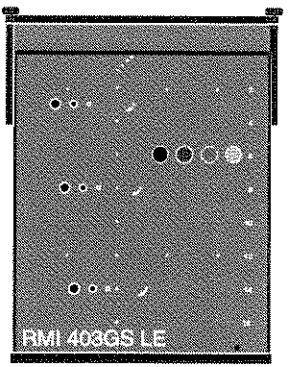
2 **Return the cover to the top of the water dam.**



3 **Tighten the top thumbscrews.**



4 **Store in an airtight container or plastic bag with a moist sponge.**



Target Configuration

Low Scatter (Anechoic) Targets

Diameters . . . . . .2, 4, 6, and 10 mm
Placement . . . . . .3, 6, 8, and 14 cm deep
Speed of sound . . . . . .1540 ± 10 m/s
Attenuation coefficient . . . . . .0.05 ± 0.01 dB/cm/MHz

Grey Scale Targets

Diameter . . . . . .10 mm
Placement . . . . . .6 cm deep
Speed of sound . . . . . .1540 ± 10 m/s
Temperature dependence
on speed of sound . . . . . .1.5 m/s/ C
Contrast . . . . . .-6 dB, +6 dB, High Scatter (+12dB or +15dB) relative to background

Pin Targets

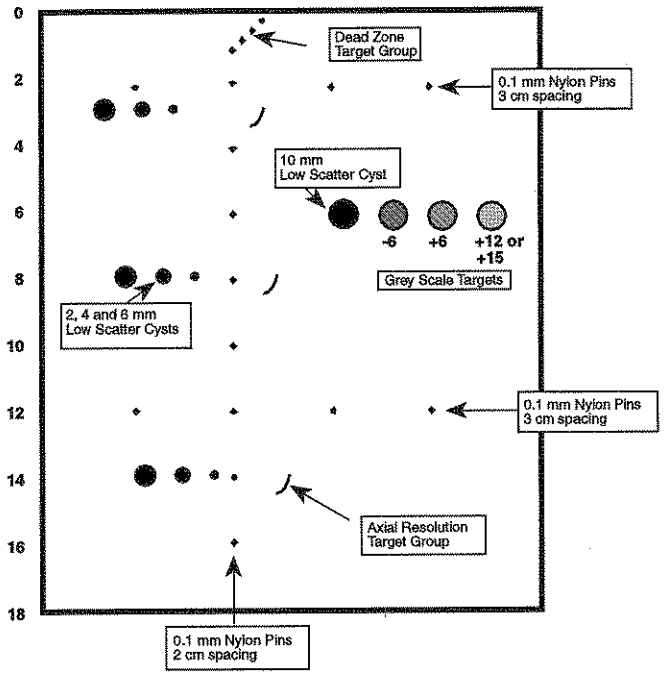
Diameter . . . . . .0.1 mm
Vertical spacing . . . . . .2 cm at 2-16 cm deep
Horizontal spacing . . . . . .3 cm at 2 and 12 cm deep

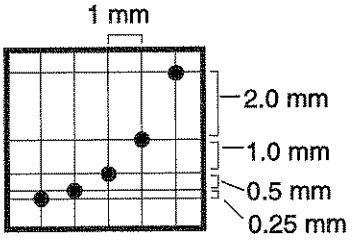
Axial Resolution Target Group

. . . . . .at 3, 8, and 14 cm deep

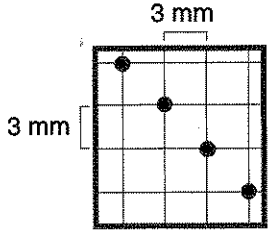
All acoustic measurements at 4.5 MHz, 22 C.

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





Axial Resolution Target Group



Dead Zone Target Group

Specifications

Physical Specifications

Weight . . . . . .Approx 2.8 kg (6 lbs. 5 oz.)
Dimensions . . . . . .23.2 x 8.25 x 18.5 cm
. . . . . .(9.25 x 3.25 x 7.25 in.)
Scanning surface . . . . . .Composite film
Case material . . . . . .Extruded ABS plastic
Pin target material . . . . . .Nylon monofilament

Tissue Mimicking Background Material

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
Nonlinear parameter (B/A) . . . . .5.8 ± 0.4 (RMI 403)
. . . . . .6.6 ± 0.3 (RMI 403 LE)
. . . . . .6.7 (Accepted value for
. . . . . human liver tissue)

All acoustic measurements at 4.5 MHz, 22 C.

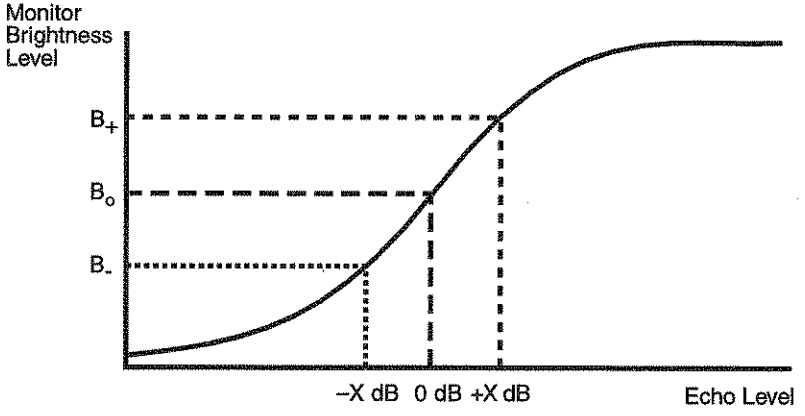
Due to our philosophy of continuous quality improvement, all specifications are subject to change.

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. The Quantitative Measurement ensures that the grey level signal is measured consistently. The Qualitative Measurement ensures that grey levels are displayed on the monitor consistently. By performing these tests, the user can determine the optimal system control settings for measuring grey levels. These settings can then be used in clinical applications.

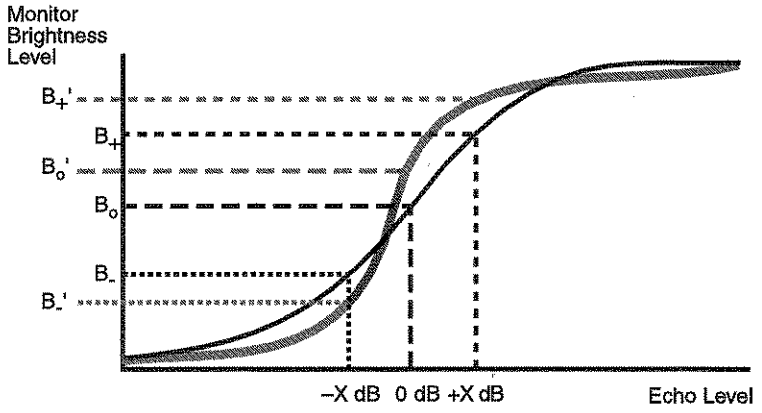
System Linearity

Ultrasound systems use special processing circuits to translate the amplitude of echoes into brightness levels on the video monitor. These circuits use mathematical functions that often produce an S-shaped curve when graphed. As shown in the figure below, 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 each echo level, -X, 0 and +X dB produce the corresponding brightness values B_- , B_o and B_+.

As long as the shape of the curve remains constant, the contrast or difference in brightness between different echo levels will remain constant. 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. This distortion in the information displayed to the user may affect the interpretation of the ultrasound image. An example of these distortions is shown below.



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 as displayed on the video monitor. Pixel values can be measured with image analysis tools provided on some ultrasound instruments or computers equipped with video "frame grabbers" and special software (see next page).

Quantitative Measurement

A target's brightness level can be more accurately measured electronically. The user defines a region of interest and the scanner determines the average pixel value. To reduce the effect of speckle and small variations in the targets, 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 on page 20.

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. Adjust the system gain so that the measurement is approximately 1. This ensures that the system's noise floor is barely reaching the visible level.
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.

2. Freeze the image and place the region of interest (ROI) tool completely inside the grey scale target image. The ROI should be as large as possible.

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. 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.

Qualitative Measurement

Video 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 long phantom life. Properly storing your phantom will reduce the amount of moisture lost per year.

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. If this occurs, contact GAMMEX RMI (1-800-GAMMEX-1).

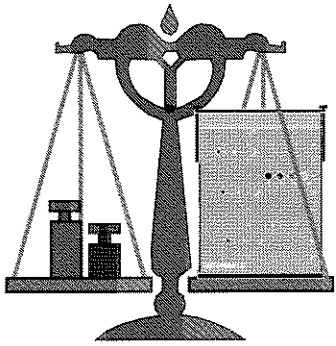


Figure 2: Periodically weighing the RMI 403GS/403GS LE is the best way to monitor desiccation.

Charts and Graph Sheets

Photocopy the charts and graph sheets on the following pages and add them to the other graph sheets in your QA Cookbook.

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 purchaser of the Products directly from Seller (or an authorized dealer of Seller) as new merchandise. For a period of 12 (twelve) months for the 403GS from the date of original delivery to Buyer, the Products are warranted to be free from functional defects in materials and workmanship, provided they are operated under condition of normal use, and that repairs and replacements are made in accordance herewith. Seller does not warrant bulbs. The foregoing warranty shall not apply to Products that have been disassembled, altered or repaired (other than proper replacement bulbs) other than by Seller or if the Product has been subject to abuse, misuse, negligence or accident.

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e-mail: sales@gammex.com

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

1-800-232-9699
1-608-828-7000
1-608-831-0964 Fax
e-mail: support@gammex.com

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Data Sheet

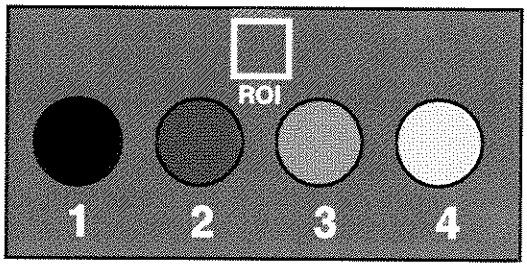
Machine Serial #	Transducer Serial #	Room
Technologist	Serial #	

Power	Gain	Dyn Rng	Pre	Post	Persis

		Measurement Date							Action Level
Target 1 Anechoic	1								
Grey bar step #	2								
	3								
_____	Avg								
Target 2	1								
Grey bar step #	2								
	3								
_____	Avg								
Target 3	1								
Grey bar step #	2								
	3								
_____	Avg								
Target 4	2								
Grey bar step #	3								
_____	Avg								
Background	1								
	2								
	3								
	Avg								

Avg = [(1) + (2) +(3)] / 3

Target Numbers/Locations



Graph data immediately after performing QC tests.

Name _____ **Quantitative Measurement**

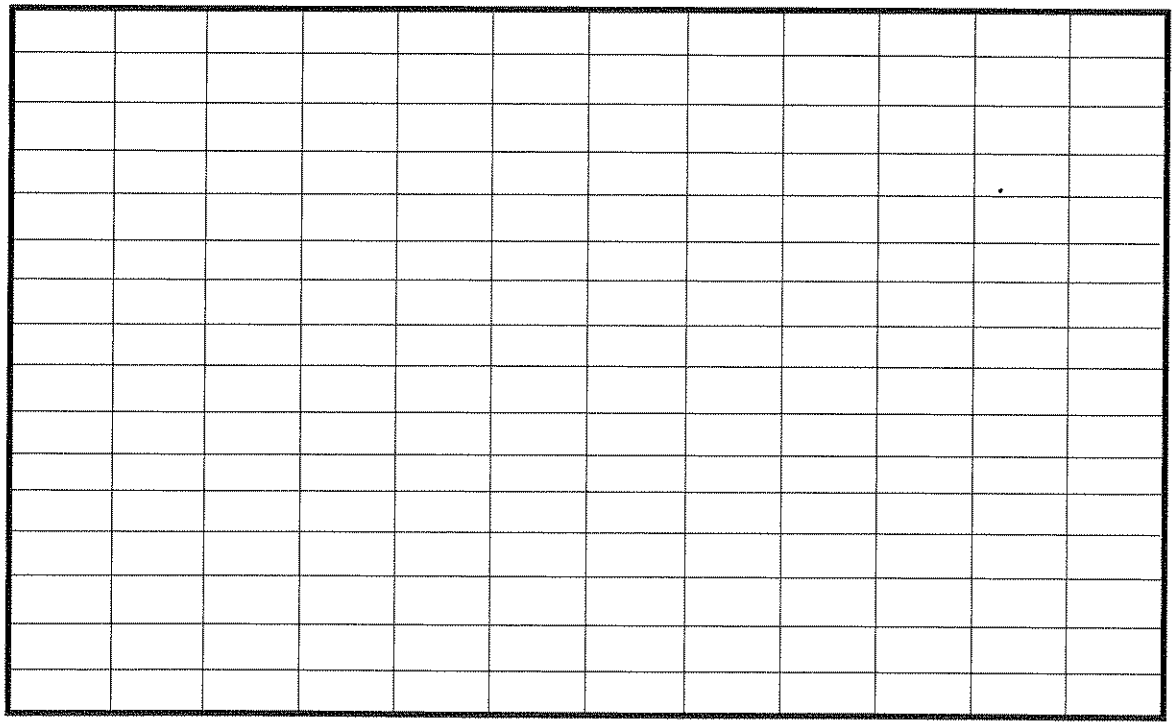
Test Period _____ **Depth** _____

Target # _____ (Make a copy of this chart for each grey scale target.)

Circle values which reach an action level. Document events in the event log.

Date	Event Log

Average Echo Level



Date