

1430 LE Mini-Doppler Flow Systems



User's Guide



Table of Contents

Introduction4
Caring for your 1430 LE5
Scanning your 1430 LE6
A Guided Tour of your 1430 LE7
Evaluating the B-Mode System8
Target Specifications12
Cystic Targets12
Grey Scale Targets12
Pin Targets12
Resolution Target Groups12
Phantom Specifications13
Physical Specifications13
Tissue Mimicking Background Material13
Low Scatter (Anechoic) Cysts13
Grey Scale Targets13
Harmonic Imaging14
Grey Scale Applications15
System Linearity16
Quantitative Measurement18
Baseline Test18
Subsequent Tests18
Qualitative Measurement20
Phantom Desiccation21

Charts and Graphs	21
Doppler Guided Tour	22
Pulse Mode	22
Evaluating the Doppler System	23
Doppler Quality Control Tests	25
Doppler Signal Sensitivity	25
Color Flow Sensitivity	25
Flow Sensitivity at Depth	26
Color Flow B-Mode Image Congruency	26
Directional Discrimination	26
Accuracy of Flow Velocity Readout	27
Accuracy of Sample Gate Positioning	29
Doppler Mode Phantom Specifications	30
Electrical Ratings	
Environmental Conditions	
Tissue Mimicking Blood Material	
Vessel	30
Flow Meter	
Rechargeable Battery	31
References	32
Product Warranty	33
Sales and Service	34

Introduction

The Gammex 1430 LE phantom is designed to measure both Doppler and B-mode ultrasound systems. This instrument consists of a tissue mimicking phantom and a flow system with an electronic flow controller. The tissue mimicking phantom is designed to measure image quality of high frequency transducers, small parts and intra-cavity ultrasound scanning systems, contrast, temporal resolution and system linearity.

This Precision Small Parts Tissue Mimicking Phantom permits precise measurements of resolution for testing the following image indicators:

- dead zone
- axial and lateral resolution at various depths
- cyst imaging
- accuracy of electronic calipers
- depth of penetration
- image uniformity
- vertical and horizontal distance calibration
- focal zone registration

The 4mm ID tube mimicking a blood vessel and used for Doppler tests meets the FDA Doppler sensitivity recommendations. The microprocessor-based flow controller within the 1430 produces accurate flow rates from 1.0 to 10 ml/sec with better than 1.5% Full Scale Accuracy. However, the accuracy of the 1430 system as a whole is based on a number of factors, including (but not limited to) temperature, flow setting, ultrasound settings, etc. The accuracy of the complete 1430 system may vary. For more information, see page 27 – Accuracy of Flow Velocity Readout.

The Gammex 1430 LE phantoms use a tissue mimicking gel that provides a smoother background texture.

Limitations of Use

The 1430 LE is designed to be operated in battery mode. Using the system with the charger plugged in may introduce unwanted noise.

The 1430 LE phantom is designed to be used to aid in the Quality Control testing and monitoring of ultrasound instruments only. It is not to be used for diagnostic decisions.

Caring for your 1430 LE

Phantom comes ready to scan. <u>Do not</u> remove surface material.

Store your 1430 LE with cover closed securely.

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

Store your 1430 LE at 35°-105°F (2°-40°C).

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

Weigh your 1430 LE to monitor desiccation.

Weigh the phantom when you first receive it and then every 6 months after that. Record the values on the <u>data sheet</u>.

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.

If your 1430 LE is not regularly in use, step the 1430 through the constant and pulsatile flow settings for a period of 1-2 hours on a monthly basis. This will keep the scatterers in the blood mimicking fluid in suspension.

Caution: As with any electronic device, large temperature variation can cause moisture and condensation problems which can result in errant readings. Therefore, before operating the 1430, please allow the unit to reach room temperature of 20-25°C for at least four hours.

Please keep the top of the 1430 dry to avoid equipment damage.

Gammex recommends annual servicing of your 1430 LE to ensure proper operation. Our qualified service technicians will check fordesiccation and provide any needed rejuvenation, scanning/certification to original specifications, and repairs.

Scanning your 1430 LE

- Always place the phantom on a stable, level surface for scanning.
- The phantom comes ready to scan. <u>Do not</u> 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 thick gel layer.
- Clean the scanning surface immediately after use. Use a soft cloth or paper towel and soap and water, if needed.

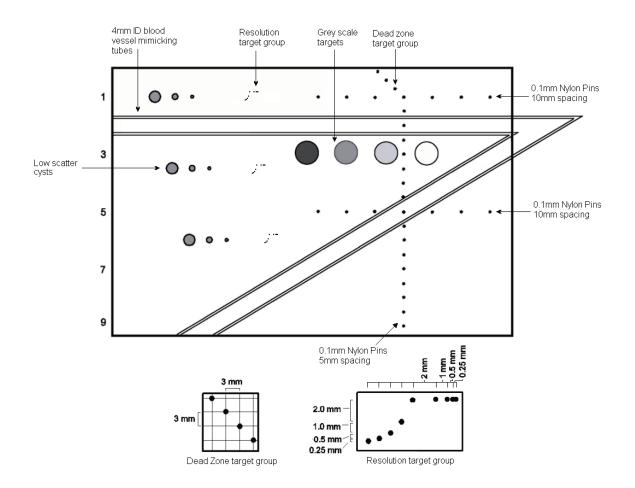


Caution: Do not press the transducer into the scanning surface

A Guided Tour of your 1430 LE

The Gammex 1430 LE Precision Small Parts Doppler Phantom is an instrument for measuring the image quality of small parts and intra-cavity ultrasound scanning systems. The tissue mimicking gel is ultrasonically similar to human tissue. This allows the use of normal scanner control settings and ensures that the performance measured with the phantom 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 Gammex 1430 LE. A guided tour of the phantom is provided on the following pages.



Evaluating the B-Mode System

Remember

- The phantom comes ready to scan. <u>Do not</u> 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 phantom for this demonstration.

- 1. To couple with water, fill the dam with distilled water. For a better image quality, use gel.
- 2. Rest the transducer on the scanning surface. Adjust the scanner to display the full depth of the phantom.

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 will help you determine the depths of the targets.

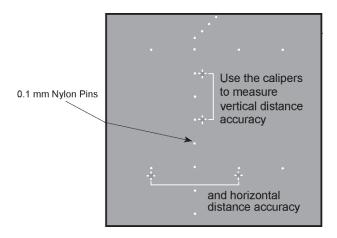
3. Move the transducer across the scanning surface while observing the locations of the targets.

Notice how the smooth texture of the tissue mimicking gel emphasizes image non-uniformities and artifacts, making them easier to detect.

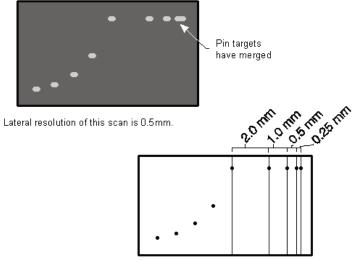
Decrease gain controls to highlight pin targets.

4. 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 5 mm spacing while the horizontal pins have 10 mm spacing.

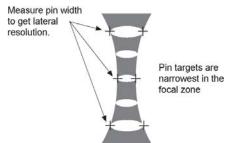
Use the pin targets to determine *vertical distance accuracy* and *horizontal distance accuracy*. Note that the highest dead zone pin you can see should be the point of reference not the scanning surface.



5. Freeze an image of the resolution target group at 1 cm. Examine the horizontal row of pins at the top of the target group. The pins that are closest together with out touching indicates the scanner's *lateral resolution*.

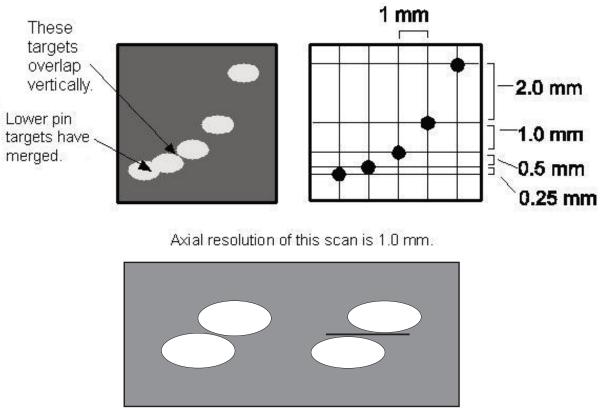


Repeat this procedure with the other resolution target groups. Notice how lateral resolution is narrowest in the focal zone. For a transducer whose focal zone is in the area between the resolution targets, an alternate test can be performed. Freeze an image of the vertical pin targets. Use the electronic 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. The pin width demonstrates the width of the ultrasound beam at that depth and approximates

6. Decrease the image depth and examine the resolution target group at 1 cm. Notice how the images of the lower pin targets may begin to merge. The smallest distance between two pins that can be clearly resolved with no vertical overlap is called the scanner's **axial resolution**.



Unresolved Resolved

Pin targets are resolved axially if an imaginary horizontal line can be drawn between the targets without touching either target. The targets on the left are not resolved. The targets on the right are resolved.

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

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 4 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.

- 8. Decrease image depth to the minimum and examine the dead zone target group. The dead zone targets can be used to measure lateral resolution in the extreme near field of the transducer. Note the highest dead zone pin you can see should be the point of reference for all measurements not the scanning surface.
- 9. 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 compare the hard copy with the image on the scanner.

10. 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.

Target Specifications

Pin Targets

Diameter	0.1 mm
Vertical spacing	5 mm at 1–9 cm deep
Horizontal spacing	10 mm at 1 and 5 cm deep

Resolution Target Groups

	1,	3.5 and	6 cm	deep
--	----	---------	------	------

All acoustic measurements made at 4.5 MHz, 22°C.

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

Phantom Specifications

Physical Specifications

Weight	Approx. 1.75 kg (3 lbs. 13 oz.)
Dimensions	
	(6.75 x 3.25 x 4.50 in.)
Scanning surface	
Case material	
Pin target material	Nylon monofilament

Tissue Mimicking Background Material

Water-based gel with appearance of human tissue.

Speed of sound	1540±10 m/s
Temperature dependence of speed of sound	
Attenuation coefficient	
	0.5±0.05 dB/cm/MHz
	refer to phantom side label

Low Scatter (Anechoic) Cysts

Speed of sound	1540±10 m/s
Temperature dependence of speed of sound	1.5 m/s/°C
Attenuation coefficient	0.05±0.01 dB/cm/MHz

Grey Scale Targets

Speed of sound	1540±10 m/s
Temperature dependence of speed of sound	1.5 m/s/°C
Contrast (in dB)6, +6 an	d high scatter relative to background

All acoustic measurements made at 4.5 MHz, 22°C.

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

Harmonic Imaging

Harmonic imaging has become an important addition to the medical ultrasound community. Harmonic imaging is when a pulse is sent from the transducer at a nominal (fundamental) frequency, but the signal received by the transducer is twice that frequency, which is the second harmonic. The result is that better resolution is attained at any given depth than if the reception had been at the fundamental frequency, as in conventional ultrasound.

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. Attenuation increases with frequency and much of the propagation involves the fundamental frequency, so in harmonic imaging, there is enhanced resolution without as much attenuation as there would be if the higher frequency were used to generate the pulses at the transducer. So, higher frequency resolution occurs for greater depths within the subject than if conventional ultrasound was used.

The ratio of B/A quantifies the rate of transfer with respect to propagation distance of ultrasonic fundamental frequency energy to harmonic frequencies. The greater the amplitude, the greater the energy transfer rate; thus, the beam profile for the harmonic is smaller than for the fundamental, which means better lateral and elevational resolution.

Tissue-mimicking phantoms will be appropriate for assessing harmonic imaging only if B/A for the tissue-mimicking material in the phantom adequately approximates that of soft tissues. Recently, we have developed the capacity to measure the value of B/A for the tissue-mimicking materials in Gammex phantoms and have found it to lie in the range for human soft tissue, meaning B/A is between 6 and 7¹.

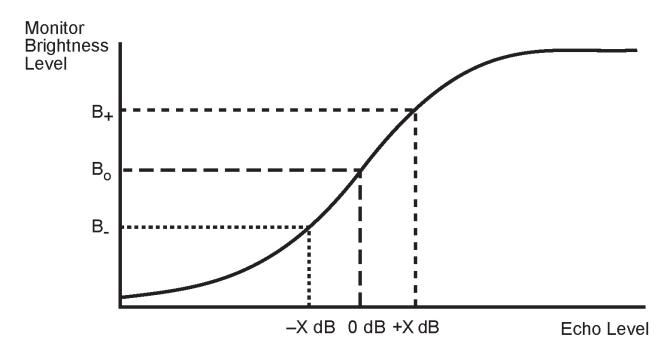
¹Gong, X. F., Zhu, Z. M., Shi, T., Huang, J. H. (1989) Determination of the acoustic nonlinearity parameter in biological media using FAIS and ITD methods, J. Acoust. Soc. Am. 86 (1), pp 1-5.

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

System Linearity

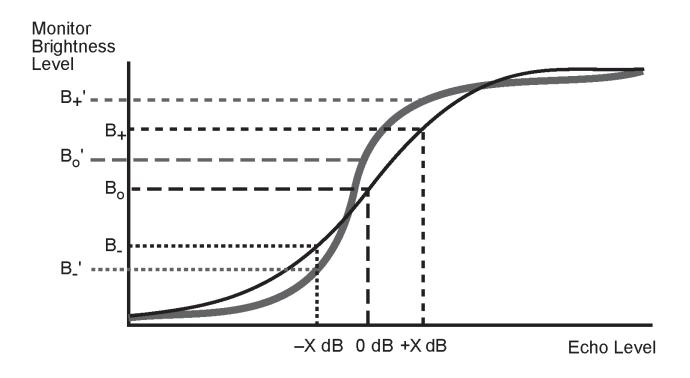
Ultrasound systems use special processing circuits to translate the amplitude of echoes into brightness levels on the video monitor. These circuits use mathematical functions that often produce an S-shaped curve when graphed. As shown in the figure below, each echo level produces a corresponding brightness 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_, B₀ 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. The distortion in the information displayed to the user may affect the interpretation of the ultrasound image. This is why it is important to do quality measurement with as little post-processing as possible. An example of these distortions is shown on the following page.



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_{0} and B_{+} have moved to B_{-}^{1} , B_{0}^{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 estimated by eye or measured with image analysis tools provided on some ultrasound instruments or computers equipped with video "frame grabbers" and special software.

Quantitative Measurement

A target's brightness level can be most accurately measured using electronic methods. 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 section of this document (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 approximately 2/3 3/4 the diameter of the circle, and it should be centered in the circle.

- 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.

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 back ground 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 and blood-mimicking material 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 instructions on how to properly store and take care of your phantom, go to the <u>Caring for Your Phantom</u> 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 15 grams of its total weight.

When this occurs, contact GAMMEX (1-800-GAMMEX-1).

Charts and Graphs

Refer to the <u>Charts and Graphs</u> section of the manual to find the appropriate charts and graphs for your 1430 LE phantom, which include:

Phantom Weight Chart Data Sheet Quantitative Measurement Qualitative Measurement Doppler QC Test Data Sheet

Doppler Quality Control Instruments

Flow instruments and string test objects are two types of Quality Control test tools for Doppler ultrasound scanners. Flow instruments, such as the Gammex 1430 LE, produce physiological flow rates and can be used to perform the full range of quality and acceptance tests. "Flow phantoms provide a more realistic signal environment in which a spectrum of velocities is produced across the flow profile of a simulated vessel. Flow instruments can be calibrated in terms of absolute flow rates (and, therefore, maximum velocities)."⁴ Flow phantoms mimic blood flow in the body; the continuous stream simulates venous flow.⁵

The angled vessel is used to measure sensitivity for different frequency transducers and accuracy of the Doppler angle (refer to Gammex 1425A Optimizer). The variable flow speeds test the accuracy of the Doppler shift. Good flow instruments are self-contained and provide an accurate speed of sound. They are also practical for routine quality control and comparison of ultrasound systems as well as teaching the principles of Doppler ultrasound.¹

String phantoms are not physiological.⁷ String phantoms display a specular-like reflection from the string surface which could produce uncertainties in specifying the exact Doppler angle.¹⁰ The knot signal on the spectral display shows as a regular spike, this can interfere with visualization of the Doppler spectrum.⁷ Also, the water tank can produce unwanted reverberations and reflections.

Doppler Guided Tour

When the unit is first turned on, the "CONTINUOUS" mode is entered and the pump spins at approximately one-half maximum speed.

The LED is lit when the pump is running.

Momentarily pressing the "FAST" button increases the speed a small amount. Pressing and holding down the "FAST" button increases the speed at a rate of 4 times faster. The same can be said about the "SLOW" button as it relates to decreasing the speed. The LED will turn off when the pump is off.

There are 180 discrete speed steps.

Pulse Mode

Simultaneously pressing the "FAST" and "SLOW" buttons enters the "PULSE" mode. The first time that the "PULSE" mode is entered, the pump pulses for 0.5 seconds ON and 0.5 seconds OFF. The speed of the pump is set in "CONTINUOUS" mode.

Pressing the "FAST" button pulses the pump faster. Pressing the "SLOW" button pulses the pump slower.

The Pulse rates are:

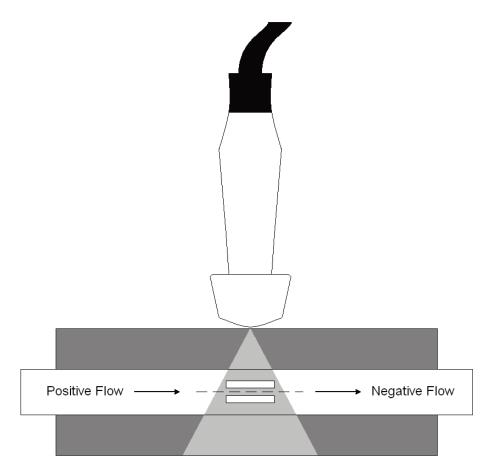
- 1) 0.125 sec ON, 0.125 sec OFF
- 2) 0.250 sec ON, 0.250 sec OFF
- 3) 0.375 sec ON, 0.375 sec OFF
- 4) 0.500 sec ON, 0.500 sec OFF
- 5) 0.625 sec ON, 0.625 sec OFF
- 6) 0.750 sec ON, 0.750 sec OFF
- 7) 0.875 sec ON, 0.875 sec OFF
- 8) 1.000 sec ON, 1.000 sec OFF

To return to "Continuous" mode, simultaneously press the "FAST" and "SLOW" buttons.

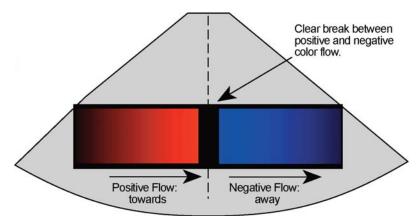
Evaluating the Doppler System

For the Doppler demonstration:

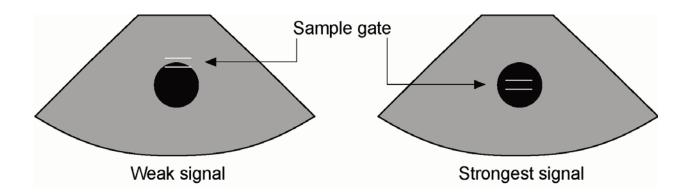
- Use a 5 MHz transducer
- Turn on the Doppler Mode
- 1. Select a flow rate preset using Up/Down buttons. It takes a few seconds for the flow to reach the selected rate.
- 2. Use a sector transducer to scan the blood vessel. Place the transducer so that the central acoustic axis of the color image is perpendicular to the axis of the vessel. This can be determined by visualizing the inner and outer surface of the vessel wall, both on the top and bottom.



3. Examine the image. The "positive" color flow segment should mirror the "negative" color flow segment across the image of the vessel. Proper color balance demonstrates the scanner's directional discrimination.



4. Scan the blood vessel so that the image displayed is a cross-section of the vessel. With the flow phantom in constant flow mode, place the cursor at several locations across the vessel and measure the velocity. The highest velocity reading should occur when the cursor is placed in the center of the vessel. This test evaluates the accuracy of the sample gate positioning.



- 5. Scan the vessel along its length with the flow phantom in continuous flow mode. Close the sample gate to the smallest opening. Compare the displayed peak value on the scanner with the estimated peak value, corresponding to the displayed flow on the control module, to determine the accuracy of the maximum velocity readout. Use the provided chart to translate "Flow" measurements into "Estimated Speed".
- 6. Use color tagging techniques to verify the maximum velocity readout. By using tagging techniques, isolate each flow rate and identify the maximum flow rate. This value should be near the value in step 5.
- 7. When you have finished scanning the phantom, completely clean off the coupling gel or water with a soft cloth or paper towel. Turn off the Doppler Mode and close the cover to protect the phantom.

Doppler Quality Control Tests

Doppler Signal Sensitivity

This test determines the depth at which usable Doppler signal is detected. Measuring the maximum range at which the Doppler signal is detected with the audible Doppler signal and the Doppler spectral display indicates the Doppler Signal Sensitivity.

- 1. Set the 1430 Phantom to produce a pulsatile or constant flow in the mid-range of flow rates.
- 2. Scan the angled vessel. Start with the shallow end and move down the vessel until the flow waveform disappears into noise.
- 3. The depth just before the signal fades out is the system's Doppler Signal Sensitivity.
- 4. Repeat this test at a range of flow rates from low to high.
- 5. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Color Flow Sensitivity

Similar to the Maximum Depth of Penetration test, this test determines from what depth into the test instrument color flow information can be received.

- 1. Set the 1430 Phantom to produce a pulsatile or constant flow in the mid-range of flow rates. Record the rates.
- 2. Scan the angled vessel. Start with the shallow end and move down the vessel until the color flow information disappears.
- 3. The depth just before the signal fades out is the system's color flow sensitivity.
- 4. Repeat this test at a range of flow rates from low to high.
- 5. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Flow Sensitivity at Depth

This test determines the lowest flow rate that can be detected at a given depth.

- 1. Set the 1430 Doppler Phantom to produce a pulsatile or constant flow in the mid to high-range of flow rates.
- 2. Scan the angled vessel at a depth of 5 cm.
- 3. Decrease the flow rate until the Doppler display disappears. The lowest flow rate at which a useful Doppler signal is obtained is the flow sensitivity.
- 4. Repeat this test at various depths in the phantom.
- 5. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Color Flow B-Mode Image Congruency

Verify that the B-mode image vessel is where the Doppler signal is. The flow should fill the vessel to the walls and should not overlap the walls.

- 1. Set the 1430 Doppler Phantom to constant flow mode.
- 2. Set the scanner's color flow output power and color gain for maximum sensitivity without excessive noise.
- 3. Toggle between color flow and B-mode. Observe whether the color flow information is displayed only in the vessels. Record scanner settings that produce poor congruency. Also note whether the highest flow occurs at the vessel's center and the lowest flow at the vessel wall.
- 4. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Directional Discrimination

Flow moves either toward or away from the transducer. The Directional Discrimination test evaluates the scanner's ability to accurately display flow direction.

With the flow perpendicular to the Doppler beam, Doppler signals resulting from spectral broadening are usually obtained. If the beam is perpendicular to flow, the spectral broadening artifact should be equally positive and negative and the magnitude of the signals should be the same.

- 1. Set the 1430 Phantom in constant flow mode and produce a laminar flow with a velocity low enough that aliasing does not occur.
- 2. Scan the horizontal vessel with a sector transducer. Place the transducer so that the central acoustic axis of the color image is perpendicular to the axis of the vessel. To do this, adjust the transducer until the top wall and bottom wall of the vessel are both clear on the image.
- 3. The "positive" color flow segment should mirror the "negative" color flow segment across the image of the vessel.
- 4. The spectral display should be equally positive and negative, mirroring across the baseline.
- 5. Angle the Doppler beam to display flow in one direction only. There should be no evidence of flow in the other channel.
- 6. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Accuracy of Flow Velocity Readout

An accurate estimate of the velocity within a flow pipe, given the volume flow rate, depends on the velocity profile within the tube. If the profile is assumed parabolic, the maximum velocity inside the tube is 2x the average velocity. If the flow is turbulent or has some characteristic other than laminar, then the velocity calculation becomes much more challenging.

Generally, as flow enters a tube, the velocity profile will not be parabolic, but will gradually become so, depending on flow conditions, rate, and tube diameter. The distance it takes depends on the nature of the flow profile entering the tube.

The Reynolds number (**Re**) is used to distinguish between different flow classifications, namely laminar and turbulent flow. Laminar flow occurs at low Reynolds numbers, where viscous forces are dominant, and is characterized by smooth, constant fluid motion. Within circular pipes, the critical Reynolds number is generally accepted to be 2100⁹. In order to assume well-known flow conditions at a measuring point, the inner area of the tube shall be uniform over an entrance length L that is for a laminar flow.

$$L = 0.06 \times D_i \times \text{Re}$$

Where D_i is the inner diameter of the tube.

The Reynolds number is:

$$\operatorname{Re} = \frac{l \times V \times \rho}{\mu}$$

Where μ is the dynamic viscosity of the fluid, ρ is the density, and *I* is the characteristic length, which is conventionally considered the inner diameter.

The velocity averaged over a cross-section of the tube is:

$$V_{avg} = \frac{Q}{\pi R_i^2}$$

Where Q is the flow rate and R_i is the radius of the inside of the tube. The flow rate, Q, is described as:

$$Q = \frac{\pi R_i^4 \Delta p}{8 \mu l}$$

Where Δp is the drop in pressure along the tube over length *I*.

In case of a parabolic velocity profile, the axial velocity is:

$$V_{\rm max} = 2 \times V_{avg}$$

We cannot assume that the flow of the fluid as it enters the 1430 system is laminar. Therefore, the entrance length can only be estimated to be some value between the value found by the above equation, and the value from the equation of the entrance length for turbulent flow, which is described as:

$$L = 4.4 \times D \times \mathrm{Re}^{\frac{1}{6}}$$

- 1. Set the Doppler phantom to produce a constant flow at a low flow rate.
- 2. Close the gate to the smallest size available and center it in the vessel. This will sample the flow rate at its highest velocity.
- 3. Compare the measured peak velocity value to the estimated velocity value on the 1430 LE Flow/Speed conversion chart.
- 4. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Accuracy of Sample Gate Positioning

The sample gate or volume cursor indicates the region in space from which Doppler information is collected for analysis. The location of the cursor in the phantom should be accurately represented on the B-mode image.

Note: A small gate size is preferred.

- 1. Set the Doppler phantom to produce a constant flow.
- 2. Scan the vessel so that the image displayed is a cross-section of the vessel.
- 3. Place the cursor at several places across the vessel and measure the flow rate. The highest velocity reading should occur when the cursor is placed in the center of the vessel. If the strongest signal occurs when the cursor is off-center, on the edge, or outside the vessel, service is recommended.
- 4. Record the results on the <u>Doppler QC Test Data Sheet</u>.

Doppler Mode Phantom Specifications

Electrical Ratings	
Li-Ion Battery Charger	100-240V AC Input

INDOOR USE ONLY!

Environmental Conditions

IPXXNo	o special protection against ingress of liquids or dust.
Operating Temperature	0 to +400°C
Storage Temperature	0 to +400°C
Humidity	30-85% Relative Humidity (No dew condensation)

Tissue Mimicking Blood Material

Speed of Sound	1550±10 m/s
Density	
Average Particle diameter	
Particle concentration	
Total volume	approximately 100 ml
Viscosity	

Vessel

Speed of sound	1550±10 m/s
Density	1.03 g/cm ³
Inner Diameter	4 mm
Wall thickness	1 mm
Positions	
Horizontal	at 2 cm deep
Diagonal	
Re	
L	

Flow Meter

Type in-line turb	oine
Accuracybetter than 1.5% F	.S.*

*The microprocessor-based flow controller within the 1430 produces accurate flow rates from 1.0 to 10 ml/sec with better than 1.5% Full Scale Accuracy. However, the accuracy of the 1430 system as a whole is based on a number of factors, including (but not limited to) temperature, flow setting, ultrasound settings, etc. The accuracy of the complete 1430 system may vary. For more information, see pages 27-29, Accurracy of Flow Velocity Readout.

If equipment is used in a manner not specified by Gammex, the protection provided by this equipment may be impaired. Use only the approved AC/DC converter supplied by Gammex.

Rechargeable Battery

Detailed Description

- 14.8 V Li-Ion rechargeable battery made of 4 high quality cylindrical 18650 cells, with PCB and poly-switch for full protection
- Capacity: 2200 mAh
- Voltage: 14.8 V (Peak at 16.8 V)
- Dimension: 3" x 0.8" x 2.9" (Width x Thickness x Length)
- Weight: 6.9 oz
- Max charge current: 1 C (2.4 A)
- Max discharge current: 2.5 C (5 A)
- Cut-off voltage: 11 V
- No memory effect and longer storage life than NiMH battery
- Completely environmentally friendly, 100% recyclable
- Light-weight and higher energy density than any rechargeable battery
- Installed IC chip prevents battery pack over-charge and over-discharge, helps protect battery chemistry integrity and prolongs battery life.
- The time for full charge is approximately 7.2 hours.

Caution:

Li-Ion battery <u>may explode</u> if charging or discharging improperly. User must have the knowledge of how to charge and discharge Li-Ion battery **before** using Li-Ion battery pack. It is strongly suggested that you use our smart Li-Ion battery charger to recharge the battery pack. <u>Never</u> use a conventional DC adapter to charge the battery module. We are **NOT** responsible for any damage that is caused by the misuse of the Li-Ion battery.

References

- 1 AIUM. (1994) Performance Criteria and Measurements for Doppler Ultrasound Devices (pp. 28 33) Laurel, MD: American Institute of Ultrasound in Medicine.
- 2 AIUM. (1995) AIUM Quality Assurance Manual for Gray-Scale Ultrasound Scanners Laurel, MD: American Institute of Ultrasound in Medicine.
- 3 Boote, E.A., & Zagzebski, J.A., (1988) Performance Tests of Doppler Ultrasound Equipment With a Tissue and Blood-Mimicking Phantom. Journal of Ultrasound in Medicine 7, 137-147.
- 4 Groth, D.S., Zink, F.E., Felmlee, J.P., Kofler, J.M., James, E.M., Lindsey, J.R. & Pavlicek, W. (1994). Blood Flow Velocity measurements: A Comparison of 25 Clinical Ultrasonographic Uits. Journal of Ultrasound in Medicine 14, 273-277.
- 5 Hendrick, W.R., (1995) Quality Control and Acceptance Testing. In W.R. Hendrick, S.D.L. Hykes, & D.E. Starchman (Ed.), Ultrasound Physics and Instrumentation (3rd Edition) (pp. 280 – 313). Mosby Yearbook
- 6 IEC 61685:2001, International Standard
- 7 IPSM. (1994) P.R. Hoskins, S.B.Sheriff, & J.A. Evans (Ed.), Testing of Doppler Ultrasound Equipment (Report No. 70). York, Great Britain: The Institute of Physical Sciences in Medicine.
- 8 IPSM. (1995) Robert Price (Ed.), Routine Quality Assurance of Ultrasound Imaging Systems (Report No. 71). York, Great Britain: The Institute of Physical Sciences in Medicine.
- 9 Munson, B.R., Young, D.F., Okiishi, T.H. (2006) Fundamentals of Fluid Mechanics, Fifth Edition. John Wiley & Sons, Inc., Hoboken, N.J.
- 10 Zagzebski, J.A., (1995) Acceptance Tests for Doppler and Color Flow Imaging Equipment. In Lee Goldman & Brian Towlhes (Ed.) Medical CT and Ultrasound: Current Technology and Applications (pp. 197-209). Madison, WI: Advanced Medical Publishing

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 twelve (12) months 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.

Seller's sole and exclusive warranty obligation and Buyer's sole and exclusive warranty consists of Seller, at its option, repairing or replacing free or charge Products: (a) which contain a defect covered by the above warranty; (b) which are reported in writing to Seller not later than seven (7) days after the expiration of the warranty period; (c) which are returned to Seller promptly after discovery of the defect; and (d) which are found to be defective by Seller upon Seller's examination. Buyer shall pay all transportation charges. SELLER SHALL NOT BE OTHERWISE LIABLE FOR ANY DAMAGES, INCLUDING BUT NOT LIMITED TO INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES, OR SPECIAL DAMAGES OR FOR ANY OTHER LOSS, DAM-AGE, PENALTY OR EXPENSE OF ANY KIND, INCLUDING BUT NOT LIMITED TO, INCIDEN-TAL DAMAGES, CONSEQUENTIAL DAMAGES, OR SPECIAL DAMAGES OR FOR ANY OTHER LOSS, DAMAGE, PENALTY OR EXPENSE OF ANY KIND, INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS OR OVERHEAD, REIMBURSEMENT, PERSONAL INJURY OR PROPERTY DAMAGE. THE AFORESAID WARRANTY OBLIGATION OF SELLER CON-STITUTES ITS SOLE LIABILITY, AND UNDER NO CIRCUMSTANCES, SHALL THE MAXI-MUM LIABILITY OF SELLER UNDER ANY LEGAL THEORY (e.g. CONTRACT, WARRANTY, NEGLIGENCE, PROMISSORY, ESTOPPEL, STRICT LIABILITY, MISREPRESENTATION, TORT) AND FOR ANY REASON WHATSOEVER (e.g. DEFECT, DELAY OR OTHERWISE) EX-CEED THE PURCHASE PRICE OF THE DEFECTIVE PART, REGARDLESS WHETHER THE CLAIM IS ASSERTED BY BUYER OR ANY OTHER PERSON OR ENTITY. THE LIABILITIES OF SELLER, AS ABOVE SET FORTH, SHALL NOT BE EXTENDED BECAUSE OF ADVICE GIVEN BY IT IN CONNECTION WITH THE DESIGN, INSTALLATION OR USE OF THE PROD-UCTS OR PARTS THEREFOR.

THERE ARE NO EXPRESS OR IMPLIED WARRANTIES WHICH EXTEND BEYOND THE WARRANTIES SET FORTH ABOVE. SELLER MAKE NO WARRANTY OF MERCHANTABIL-ITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCTS OR ANY PARTS THEREOF.

© 2003 GAMMEX 007809-00-04

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

Sales and Service

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.

1-800-GAMMEX-1 (426-6391) 1-608-828-7000 1-608-828-7500 Fax e-mail: sales@gammex.com

<u>Service Department hours</u> are Monday through Friday, 7:30 am to 5:00 pm Central Time.

1-800-232-9699 1-608-828-7000 1-608-828-7500 Fax e-mail: support@gammex.com

GAMMEX, Inc. 7600 Discovery Drive P.O. Box 620327 Middleton, WI 53562-0327 U.S.A.

http://www.gammex.com

Notes:

Gammex, Inc.

P.O. Box 620327 Middleton, WI 53562-0327 USA **1 800 GAMMEX 1** (426-6391) 1 608 828 7000 Fax: 1 608 828 7500 www.gammex.com e-mail: sales@gammex.com

Gammex-RMI LTD

Broadway Business Centre 32A Stoney Street Nottingham NG1 1LL United Kingdom +44 0115 9247188 Fax: +44 0115-9247189 e-mail: uksales@gammex.com

Gammex-RMI GMBH

Bergstrasse 2 35398 Giessen Germany +49 6403 774 2293 Fax: +49 6403 774 2526 e-mail: desales@gammex.com

ISO 13485 Certified Quality System

