



ULTRASOUND

408 LE Spherical Lesion Phantom



User's Manual



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Introduction

The 408 LE is designed to evaluate all three of the different types of resolution that occur in ultrasound scanners. Axial, lateral, and elevational resolution can be tested with this unique phantom that has 3-dimensional anechoic cysts tucked inside. This phantom features 2 mm and 4 mm diameter tissue mimicking spherical lesions that lie in a single plane at the center of the phantom. These small sizes create an opportunity to test the resolvability of features that are small in all three dimensions.

Target depths of the phantom extend to 16 cm. This provides the phantom with greater scanner and transducer performance resolution testing capability, and electronic caliper measurement.

Limitations of Use

The 408 LE is designed to be used to aid in the Quality Control testing and monitoring of ultrasound instruments only. The 408 LE is not to be used to make diagnostic decisions.

Caring for your 408 LE

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

Store your 408 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 your 408 LE at 35°-105°F (2°-40°C).

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

Weigh your 408 LE to monitor desiccation.

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

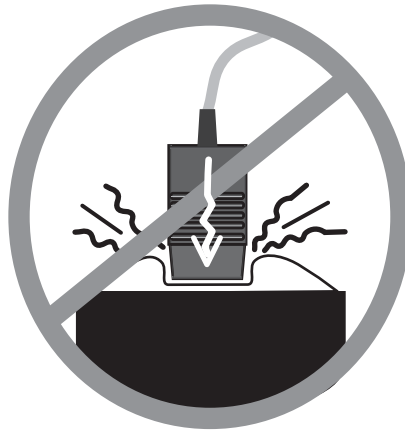
Do not drop or damage the phantom.

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

Gammex recommends annual servicing of your 408LE to ensure proper operation. Our qualified service technicians will check for desiccation and provide any needed rejuvenation, scanning/certification to original specifications, and repairs.

Scanning your 408 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.**
- **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 layer of gel.
- 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.
- Clean the scanning surface immediately after use. Use a soft cloth or paper towel and soap and water, if needed.



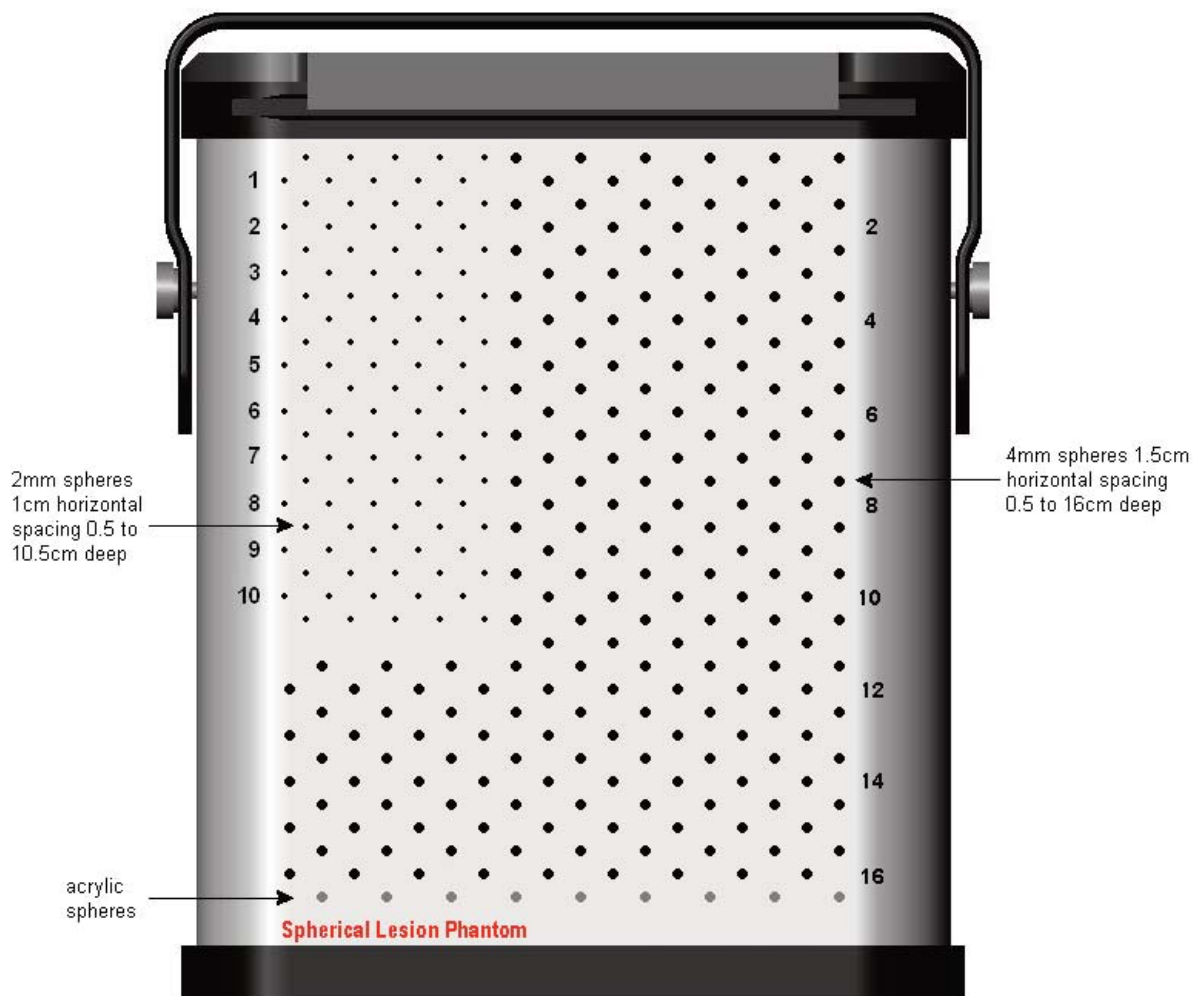
Caution:
Do not press the transducer
into the scanning surface.

A Guided Tour of the 408 LE

The Spherical Lesion Phantom 408 LE provides a unique way of testing resolution performance of ultrasound scanners. The 408 LE contains 2 mm and 4 mm diameter tissue mimicking spherical lesions. The lesions lie in a single plane at the center of the phantom.

Axial, lateral and elevational resolution are accounted for simultaneously and equally for all types of ultrasound systems and configurations. In the 2 mm section, there are 105 anechoic spheres equally spaced 0.5 mm from each other and in the 4 mm section, there are 211 anechoic spheres equally spaced 0.75 mm apart.

Scanning is the best way to familiarize yourself with the features and functions of the 408 LE. A guided tour of the phantom is provided on the following pages.



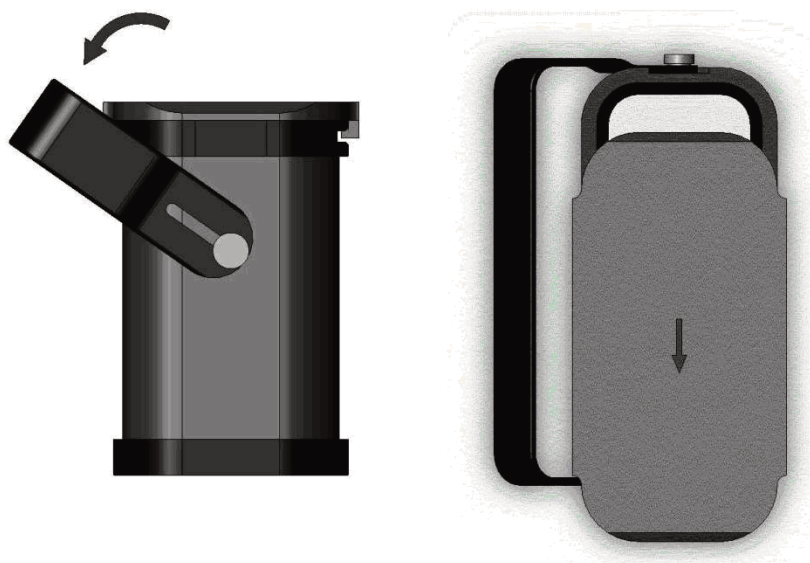
Evaluating the Phantom

Remember

- The phantom comes ready to scan. **Do not peel off 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. 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 gel.
3. Rest the transducer on the scanning surface. Adjust the scanner to display the full depth of the phantom. Be careful to position the scan head parallel to the plane containing the spheres so that the scan slice is placed over the spheres.

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***. There should be two separate depths of penetration – one for each lesion.

diameter. The depth markers on the phantom label will help you determine the depths of the targets.

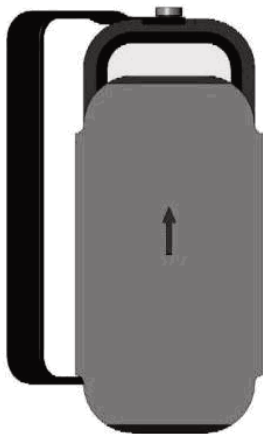
Once you are sure the scan head is perfectly aligned with the sphere plane, record the image as a reference.

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

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**.

5. Using the electronic calipers, measure the lateral distance between the centers of two spheres on the same horizontal level and note on the monitor the actual distance between those spheres based on the fact that the lateral spacing between spheres is exactly 1.5cm. This will give you the **horizontal distance measurement accuracy**.
6. 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.

- 1 Slide the cover to the top of the water dam.



- 2 Return the handle to the top of the phantom.



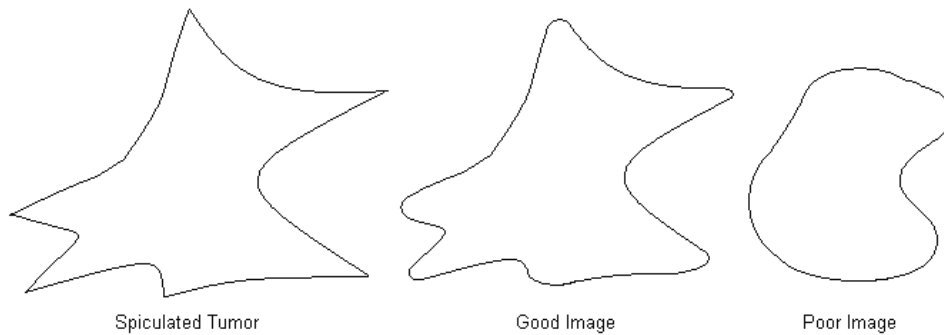
- 3 Slide the handle down, secure with screws.



- 4 Store in an airtight container or plastic bag.

Note about 408 LE

This phantom's purpose is to determine the depth range over which small spheres can be detected in the background speckle pattern. The smaller the detectable sphere, the better the scanner will delineate the boundary of an object such as a spiculated tumor or a blood vessel that is not perpendicular to the scan slice.



There are two arrays of coplanar very low echo spheres; one set has a diameter of 2 mm and the other set has a diameter of 4 mm. The plane of symmetry of the scan slice ("center" of the scan slice) must be superimposed on the plane containing the centers of the spheres so the detectability of the spheres is optimized.

Target Configuration

Low Scatter (Cystic) Targets

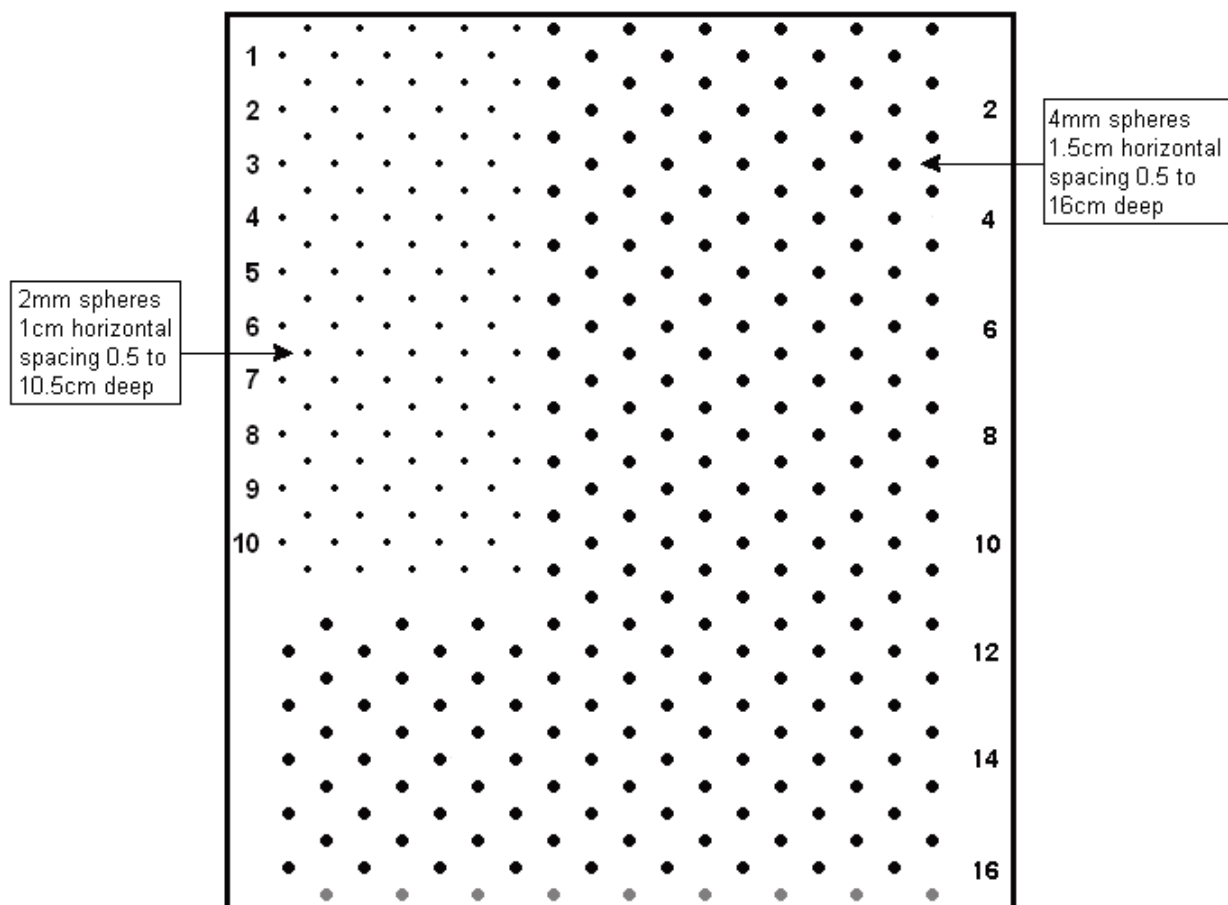
Diameters.....2 and 4 mm

Placement.....2 mm at 0.5 to 10.5cm deep

..... 4 mm at 0.5 to 16cm 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. 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

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
Nonlinearity parameter (B/A).....6.6±0.3
.....6.7 (Accepted value for human liver tissue)

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

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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.

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

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. A properly stored 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. 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 Charts and Graphs section of the manual to find the appropriate charts and graphs for your 408 LE phantom, which include:

Quality Assurance Work Sheet

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, DAMAGE, PENALTY OR EXPENSE OF ANY KIND, INCLUDING BUT NOT LIMITED TO, INCIDENTAL 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 CONSTITUTES ITS SOLE LIABILITY, AND UNDER NO CIRCUMSTANCES, SHALL THE MAXIMUM 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) EXCEED 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 PRODUCTS OR PARTS THEREFOR.

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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.

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