TESTS PERFORMED

DEAD ZONE (RING-DOWN RAMP)
(Figure 1)

Description and Reason For Testing

The dead zone is the distance from the front face of the transducer to the first identifiable echo below the transducer/ phantom interface. The dead zone occurs because an imaging system cannot send and receive a signal at the same time. Therefore, no clinical data can be collected in this region. However if artifacts are noted within the dead zone, they may indicate fluctuations in the input power to the system. The depth of the dead zone depends upon the frequency (higher frequency decreases the depth of the dead zone) and performance of the transducer and the pulsing/receiving section of the system.

Testing Procedure

1. Scan the phantom until the dead zone target group is clearly displayed. Freeze this image.
2. The first target is positioned 1 or 2 mm below the scan surface. Subsequent targets are spaced 1 mm apart. Refer to the individual Model specifications for specific details on this target group.
3. Using the electronic calipers, measure the distance between the first target imaged and the echo produced by the scan surface. The resulting value will be the depth of the dead zone.
4. Document the depth measurement on the quality assurance record.

Results

The system's dead zone should remain consistent from week to week when using the same instrument settings and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability

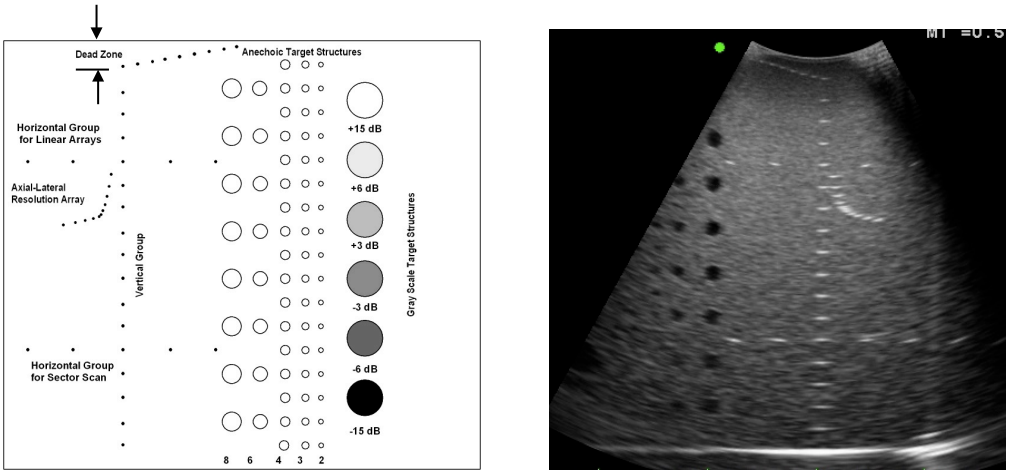


Figure 1

Geometric Accuracy - Vertical Measurement Calibration (Figure 2)

Description and Reason For Testing

Vertical distance measurements are obtained along the axis of the sound beam. Accurate representation of the size, depth and volume of a structure is a critical factor in a proper diagnosis. Most imaging systems use depth markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained using the timing markers and/or electronic calipers. The resulting measurement is then compared to the known distance between the line targets in the phantom. The accuracy of vertical distance measurements depends on the integrity of the timing circuitry of the imaging system. Vertical distance errors are far less likely to occur than horizontal errors.

It is important to verify that the phantom has been allowed to reach temperature equilibrium with ambient room temperature, nominally 23°C. If room temperature varies excessively from 23°C, distance measurement error will be introduced. Thermal gradients within the phantom may also introduce measurement error.

Testing Procedure

Position the transducer over the vertical group of line targets until a clear image is obtained. Freeze the display.

1. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets.
2. Document the measurement obtained on the quality assurance record.

Results

The system's vertical distances measurements should remain consistent from week to week when using the same instrument settings and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

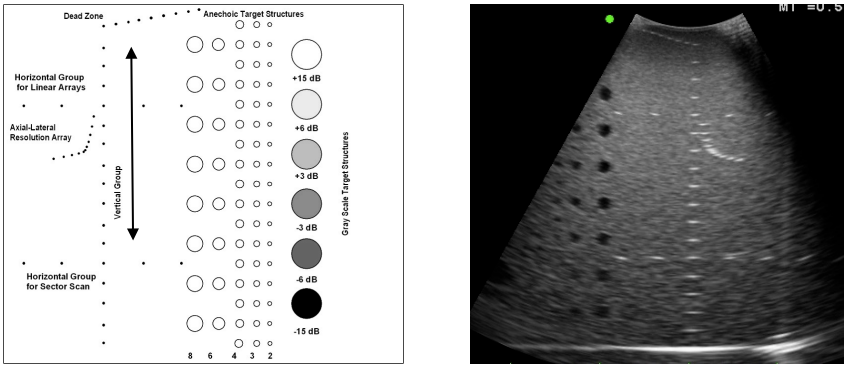


Figure 2

Geometric Accuracy - Horizontal Measurement Calibration (Figure 3)

Linear Horizontal Group, Sector Horizontal Group

Description and Reason For Testing
Horizontal distance measurements are obtained perpendicular to the axis of the sound beam. Proper diagnosis depends on the accurate representation of the size and volume of a structure being examined. Most imaging systems use distance markers and/or electronic calipers to obtain these measurements. The phantom is scanned and a distance measurement obtained. The resulting measurement is then compared to the known distance in the phantom. The accuracy of the horizontal distance measurements depends on the integrity of the transducer scanning assembly, the output intensity and the resolution of the imaging system.

It is important to verify that the phantom has been allowed to reach temperature equilibrium with ambient room temperature, nominally 23°C. If room temperature varies excessively from 23°C, distance measurement error will be introduced. Thermal gradients within the phantom may also introduce measurement error.

Testing Procedure
Note: Due to the geometry and variety of sector scan transducers a separate set of horizontal line targets are provided to evaluate the horizontal distance. Please refer to the specification page for the location of these groups Models 539 & 535 phantom provides two scanning surfaces used to evaluate horizontal measurement calibration. Model 570 & 549 have two or four sets of horizontal targets (linear/sector) at different depths..

1. Position the transducer over the horizontal group of line targets until a clear image is obtained. Freeze the image.
2. Using the electronic calipers or the timing markers measure the greatest distance that can be clearly imaged between line targets displayed.
3. Note: Some sector scanners have distance markers on the outside edges of the sector image with no other indicators available. Hand-held calipers must be used for distance measurements within the image on the monitor.
4. Document all of the measurements on the quality assurance record.

Results
The system's horizontal distance measurements should remain consistent from week to week when using the same instrument settings and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve the correct spacing of these targets, corrective action should be considered.

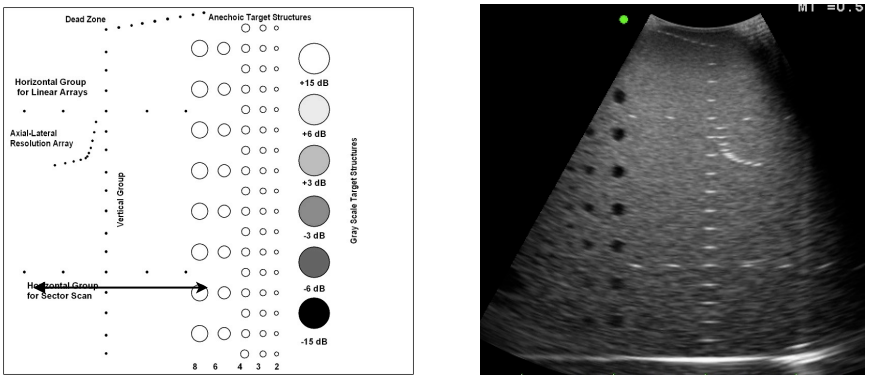


Figure 3

Axial - Lateral Resolution Arrays (Figure 4)

Description and Reason For Testing

Axial resolution is the minimum reflector separation between two closely spaced objects which can be imaged separately along the axis of the beam, whereas lateral resolution defines the system's ability to image objects separately that lie perpendicular to the axis of the sound beam. If a system has poor resolution capabilities, small structures lying close to each other will appear as one image, causing improper interpretation of the ultrasound findings. Axial Resolution depends on the transducer's center frequency, damping characteristics and pulse length. Generally, the higher the frequency the better the system's axial resolution. Lateral resolution is approximately equal to beam width, and varies with depth, focusing characteristics of the transducer, number of displayed scan lines and the system's sensitivity and gain settings.

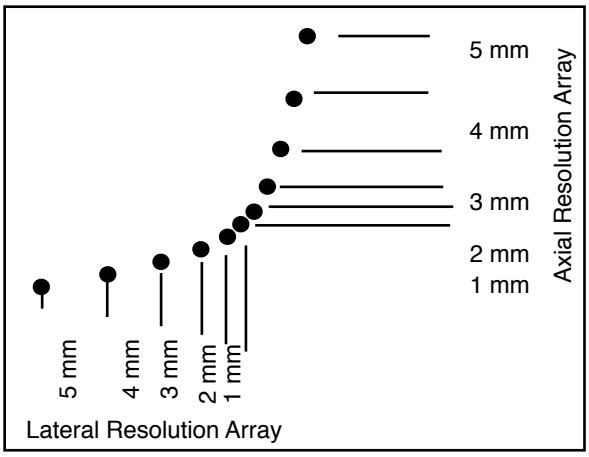
Testing Procedure

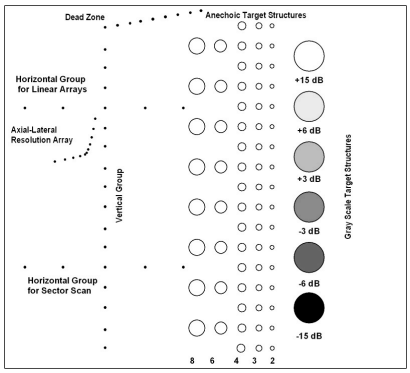
The locations in the phantom are referenced from the first axial target. Refer to the individual Model specifications for specific details on this target group.

1. Position the transducer over the axial-lateral resolution group of line targets on the phantom until a clear image is obtained. Freeze this image.
2. Examine the image to determine if all of the line targets within the group are clearly displayed as separate target points. Record the closest spaced target points which can be imaged (refer to specification drawing). Obtain a hard copy of the display.
3. Document all observations made on the quality assurance record.

Results

The system's ability to resolve the array targets at given depths should remain consistent from week to week when using the same instrument settings and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.





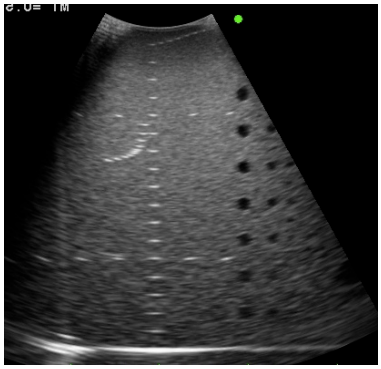


Figure 4

Sensitivity (Maximum Depth of Penetration)
(Figure 5)

Description and Reason For Testing

The ability of an imaging system to detect and display weak echoes from small objects located at specified depths (penetration) is referred to as sensitivity. Clinically, weak reflecting echoes are commonly produced from internal structures of organs. Definition of these structures can be extremely important in the interpretation of the ultrasound findings. Sensitivity can be affected by the pulser/receiver section of the system, the degree of focusing of the transducer, attenuation of the medium, depth and shape (geometry) of the reflecting object, and electromagnetic interference from the local surroundings. A system's maximum depth is limited by output power, TGC, gain, transducer frequency, focal depth, number of scan lines and electrical noise.

Testing Procedure

1. Position the transducer over the largest group of anechoic targets. Refer to the individual Model specifications for specific details on this target group.
2. Freeze image and obtain a hard copy.
3. Examine the image to determine the last or deepest target structure displayed. Using the electronic calipers or the timing markers, measure the depth of this target.
4. This test should also be performed with output levels set at the highest and lowest settings. This enables any changes in output to be more easily detected.
5. Document the depth measurement on the quality assurance record.

Results

The system's depth of penetration should remain consistent from week to week when using the same instrument settings and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.

Functional Resolution (Figure 5)

Description and Reason For Testing

Functional resolution is an imaging system's ability to detect and display the size, shape, and depth of an anechoic structure within the test phantom. In practice, the data obtained will give a direct indication of the minimum size structure the system is capable of resolving at a given depth.

Definition and Fill-in describes the imaging system's ability to detect and display the shape and echogenic characteristics of a structure. Clinically, a correct diagnosis is dependent upon the system's ability to differentiate between a cystic or solid structure versus echo patterns originating from the surrounding normal tissue.

Testing Procedure

1. Position the transducer over the anechoic target structures until a clear image is obtained.
2. Freeze image and obtain a hard copy.
3. Examine the image to determine the first and last target in each size group displayed.
4. Record the range of depths visualized for each group. Due to the configuration of the sound beam small targets in the near field may not be imaged.
5. Document all findings on the quality assurance record.

Results

The system's functional resolution should remain consistent from week to week when using the same instrument settings, transducers and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets are observed, corrective action should be considered.

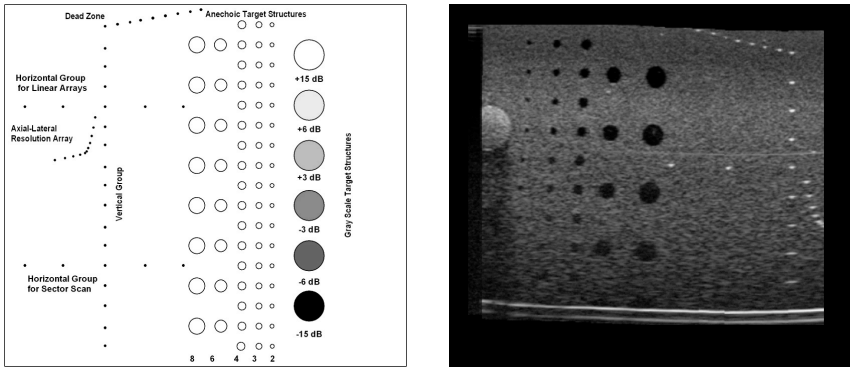


Figure 5

Image Uniformity

Description and Reason For Testing

Image non-uniformity can mask subtle changes in the tissue texture, which may increase the risk of false negative diagnoses.

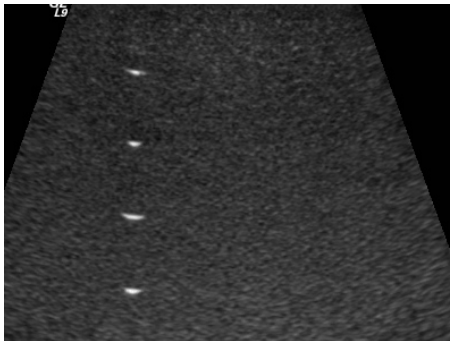
Imagine uniformity can be affected by side lobes in the transducer beam, electrical noise, and problems in the imaging processing hardware. Some artifacts can be the result of transducer malfunction, poor electrical contacts, failure in the image processing and/or system's software, and poor acoustic coupling between the transducer/patient interface causing the introduction of reverberation and banding. Horizontal bands are often caused by reflections from interfaces or circuitry and focusing problems while vertical bands may indicate a damaged transducer element.

Testing Procedure

1. Position the transducer over an area of the phantom which is relatively free of target structures.
2. Take particular care to ensure the transducer is properly coupled to the phantom.
3. Scan this region to determine if there are any areas of non-uniformity or artifacts. If demonstrated, repeat the scan at a different location using the same phantom to rule out a defect in a particular region of the phantom. If the artifacts are still present, note the gain settings, gray scale level and focal setting and document with a photograph. Repeat the scan using a different gain and focal setting.
4. Document all findings on the quality assurance record.

Results

The system's image uniformity should remain consistent from week to week when using the same instrument settings, transducers and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates major areas of image non-uniformity corrective action should be considered.



GRAY SCALE & DISPLAYED DYNAMIC RANGE - (Figure 6)

Description and Reason For Testing

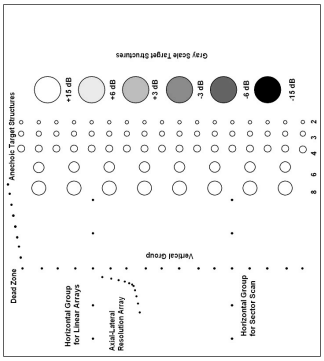
Gray scale or gray scale processing uses the amplitude of the echoes received to vary the degree of brightness of the displayed image. The adjustment of the echo signal required to go from a just noticeable (lowest gray scale level) echo to the maximum echo brightness is referred to as the displayed dynamic range. Clinically, gray scale processing and displayed dynamic range allow echoes of varying degrees of amplitude to be displayed in the same image.

Test Procedure

1. Position the transducer over the gray scale target group until a clear image is obtained. Refer to the individual Model specifications for specific details on this target group.
2. Freeze image and obtain a hard copy.
3. Examine the image. The targets should appear circular in shape, with clear sharp edges and vary in the degree of brightness ranging from low to high levels of contrast.
4. All findings should be documented on the quality assurance record.

Results

This target group varies in echogenicity and provides a good indication of the performance of the gray scale processing and displayed dynamic range. The system's gray scale processing should remain consistent from week to week when using the same instrument settings and phantom. Compare the test results obtained from the baseline records. If the current image demonstrates changes in the system's ability to resolve these targets, corrective action should be considered.



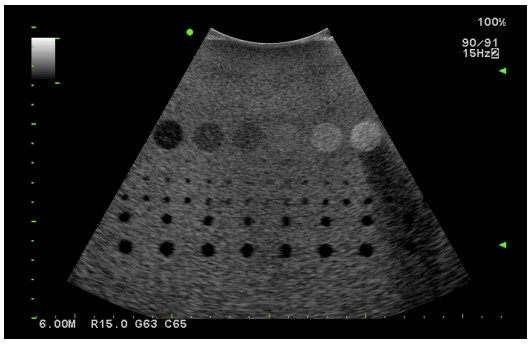


Figure 6

2D/3D Calibration - (Figure 7)

Description and Reason For Testing

Ultrasound imaging systems may detect differences in echogenicity of tissue structures and determine the dimensions of those structures based on user or automated boundary detection. Spatial measurement data collected will give an indication of the accuracy the system is capable of.

Testing Procedure

Using the 2D shapes shown in the target diagram in Figure 7, areas and perimeters may be determined by connecting lines between the filament targets. Linear measurements are taken from an image which is on a plane perpendicular to the line targets. For ultrasound systems which have only linear interpolation between points defining a curve, circular or ellipsoid shapes should not be used. Utilize rectangles or triangles instead. In ultrasound systems which utilize a circle or ellipse measurement algorithm, its accuracy may be tested by defining 3 points to make a circle or 4 points to make an ellipse as shown. The following formulae are useful:

	Rectangle	**Circle**	**Ellipse**
Area	**A = ab**	**A = πr^2**	**A = π (ab)/4**
Perimeter	**P = 2(a+b)**	**P = πd**	**P = π $((a^2 + b^2)/2)^{0.5}$**

For example, the target diagram shows a circle with a radius of 2.0 cm. Its computed area is 12.57cm^2. Its perimeter is 12.57cm (the identical value for the perimeter and area is a coincidence). These computed values may be compared with those calculated from the ultrasound system's algorithm.

Determination of volume or surface area may be accomplished using the line targets or the 3D egg test object (Model 560 only). If using line targets, the volume or surface area corresponds to a cylindrical rod, rectangular bar, or prism outlined by the 2D geometrical shape normal to the notional rod or bar.

To calculate a surface area or volume, an image is taken at a particular scan plane. Using the calipers, the dimensions of the 2d shape are taken and area determined based on the system's algorithms. Next, perform a 3D scan of the line targets with the scan planes parallel to each other and the scan direction perpendicular to the axes of the line targets. The distance between the first scan plane and the last multiplied by the 2D area will give the 3D volume. This system calculated value may then be compared to the actual volumes calculated from the rod lengths and the areas coincident with the 2D shape utilized.

A volume measurement of the 3D egg test object may be accomplished by measuring the linear dimensions of the two major axes. Position the transducer so that the scan plane coincides with the maximum cross-sectional area along the length of the object. That is dimension a. Re-position the transducer to measure the maximum circular cross-section, dimension b. Multiple measurements should be made and averaged. The volume of an ellipse with circular cross sections is given by:

$$V = (4/3)\,\pi\,(a/2)\,(b/2)^2$$

The Model 560 3D egg test object has nominal dimensions of 7.0 cm (major axis = a) and 5.0 cm (minor axis = b). The calculated volume is 91.6 cm^3.

1. Place the phantom on a clean, flat surface with scanning surface #1 positioned for use.
2. Apply an adequate amount of low viscosity gel the scan surface.
3. Adjust the instrument settings (TGC, output, etc.) to establish baseline values for "normal" liver scanning. If the bottom of the phantom is seen, adjust the gain settings until image goes entirely black. Record these settings on the quality assurance record. These settings should be used for subsequent testing.
4. Position the transducer over the line target target group or 3D egg test object in the phantom, until a clear image is obtained.
5. Freeze image and obtain a hard copy.
6. Measure the appropriate 2D dimensions
7. Perform a 3D scan.
8. Compare computed and system algorithm spatial measurements
9. All findings should be documented on the quality assurance record.

Results

Spatial measurements are compared with known areas and volumes and compared with the system manufacturer's specifications. Computed values, when compared to baseline measurements should not vary over time.

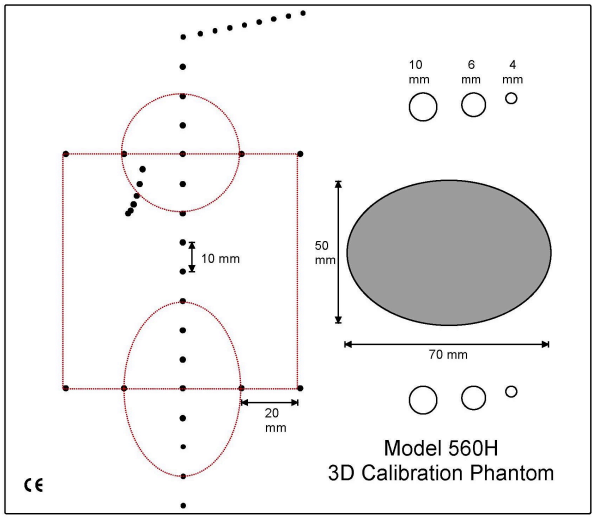


Figure 7