Sononerds in the classroom

ARDMS Topic: Clinical Safety, Patient Care, and Quality Assurance

Unit 22: Quality & Performance

Sononerds Ultrasound Physics Workbook & Lectures

Unit 22: Quality & Performance

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Unit 22: Quality & Performance

Entire Unit 22 Lecture:

Did you know you can time jump to each section by using the “chapters” in the YouTube video playbar OR timestamps in the video description?

Unit 22: Quality & Performance

The quality of exams that are produced by an ultrasound department depend heavily on the machine being in proper working order and that the person using the ultrasound equipment is competent in all things sonography.

To ensure both quality and performance, every department must have a quality assurance program in place and hold the sonographers to high industry standards. This is often done through lab accreditation.

Section 22.1 Quality Assurance

To make sure the equipment is in good working order, a quality assurance program should be in place.

- ➔ **A quality assurance program should occur at regularly scheduled intervals to ensure optimal performance of equipment.**

For most departments, this will occur every 6 months or 12 months. In large healthcare settings, the biomed department will perform the test and document the results. In smaller setting the QA activities can be contracted out or may be part of the sonographer job duties.

- ➔ **Every sonographer is responsible for cleaning and inspecting the equipment prior to use on patients and should report any quality concerns immediately.**

As a sonographer, you should inspect the cords and face of the transducer prior to using the equipment on a patient. Also pay attention to transducers that are not working properly, button and knobs that are “sticky,” and other machine tools that have objectively worsened with use.

Cleaning filters and general upkeep of the machine is important to preventative measures that will help keep the the machine operating appropriately as well. Only use cleaning agents that are approved by your infection control department and the manufacturer.

22.1.1 Creating a QA Program

The goals of a QA program are to ensure that image quality is optimal and to reduce downtime by detecting machine malfunctions earlier when they are easier to fix. They are also legally required. Due to the legality surrounding QA programs, it will imperative that documentation is accurate and organized.

By implementing a QA program the department will be able to confidently image patients and reduce the number of repeat exams as well.

The periodic QA activities should:

- **Assess system components**
  - **Test each transducer**
  - **Use phantoms and test objects for accuracy tests**
  - **Run diagnostic computer programs**
- **Perform repairs**
  - **Replace malfunctioning transducers**
  - **Replace broken knobs/buttons**
  - **Replace locking mechanisms**
- **Perform preventative maintenance**
  - **Clean keyboard**
  - **Clean filters**
  - **Calibrate touch screens**
- **Keep records**

Labs that seek accreditation can find more QA standards through the accrediting bodies.

Link to sad, but interesting case regarding a lawsuit due to a malfunctioning machine that had no record of QA and the importance of competent users

Another link to lawsuit over transducers not being cleaned and no QA records involving cleaning.

Fig.25 Broken case of probe

Fig.26 Holes in the lens

Fig.27 Cable runs over

Fig.28 Scratches in the cable

Section 22.2 Performance Testing

Part of the quality assurance program is to do performance testing. When a sonographer notices that a machines is imaging too dark or that the image is blurry, this is a **subjective test.** It is the opinion of the sonographer and another user might not notice the same things.

Performance testing in a QA program is done as an **objective test.** The machine tools are used under the same settings and the results are repeatable. This is an unbiased, factual representation of the machine performance.

➔ **Objective tests are performed using phantoms and test objects.**

The phantoms and test objects are used for every periodic QA event to minimize outside factors affecting machine performance. Keeping system parameters like the transducer, gain, focus, compression and other tools at the same settings is important for objective testing as well. Even room lighting and monitor settings should be the same.

There are phantoms for both 2D imaging and Doppler imaging.

22.2.1 2D Imaging Performance Testing

When performing 2D testing, the operator will test 5 parameters of the system:

➔ **Detail Resolution**

Detail resolution includes axial resolution, lateral resolution and elevational resolution. These tests are performed by observing the distance at which point spread artifact occurs in a tissue phantom or pin object and observing the size of the beam with a slice thickness phantom.

➔ **Contrast Resolution**

Contrast resolution looks at the machine ability to display varying grays accurately. This is tested through a tissue phantom.

- **Penetration (sensitivity)**

Penetration is also tested through a tissue phantom, looking to see if the machine can detect weak echoes at all depths.

- **Range Accuracy**

Using a pin test object or a tissue phantom, range accuracy aims to prove the machine can detect accurate size, spacing and depth of reflectors in both the vertical plane. Registration in general also looks at horizontal reflectors and the accuracy of the pins in the very near field, known as the **dead zone.**

- **Measurement Accuracy**

Measurement accuracy is assessed with a tissue phantom. Calipers are placed on reflectors imaged in the phantom and compared to the known value of the reflectors.

22.2.2 Tissue -Equivalent Phantoms

You may have noticed that many of the 2D imaging parameters are tested via tissue phantom.

- **Tissue phantoms mimic soft tissue propagation speed of 1540 m/s.**
  - **Attenuates like soft tissue**
  - **Made of aqueous gel and graphite particles**
  - **Contain metal or nylon pins for accuracy calibration**
  - **Contain solid and cystic mass mimicking structures**

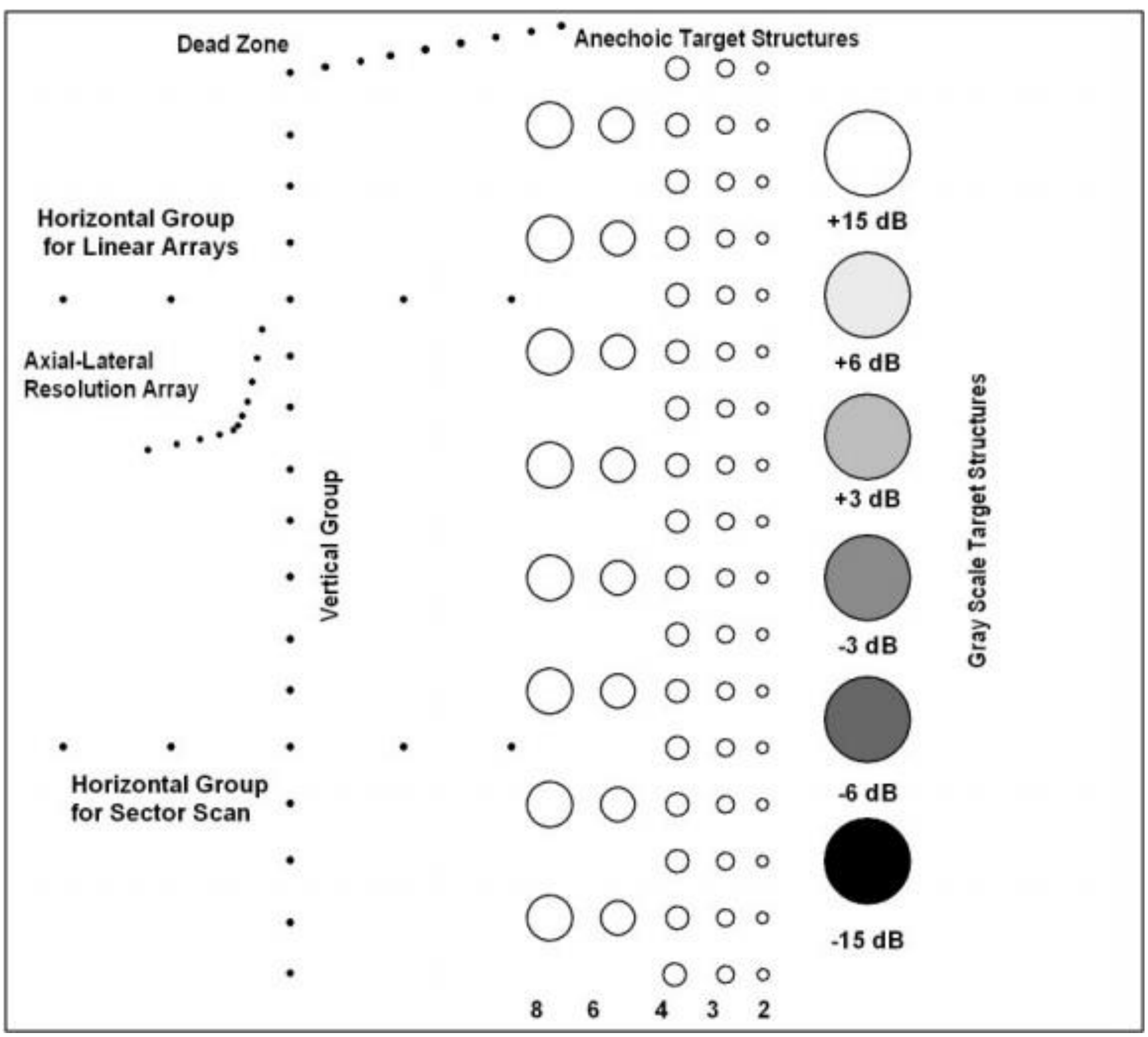
The soft tissue phantom has multiple windows to image through. Depending on the window, the user is testing different parameters of the machine with the phantom. The soft tissue phantom contains a "map" of the reflectors found within. By using this map for comparison, the QA tester can determine if the machine is accurately representing the "anatomy" in the phantom.

As a sonographer, you should understand what is being tested with each set of reflectors found on the map.

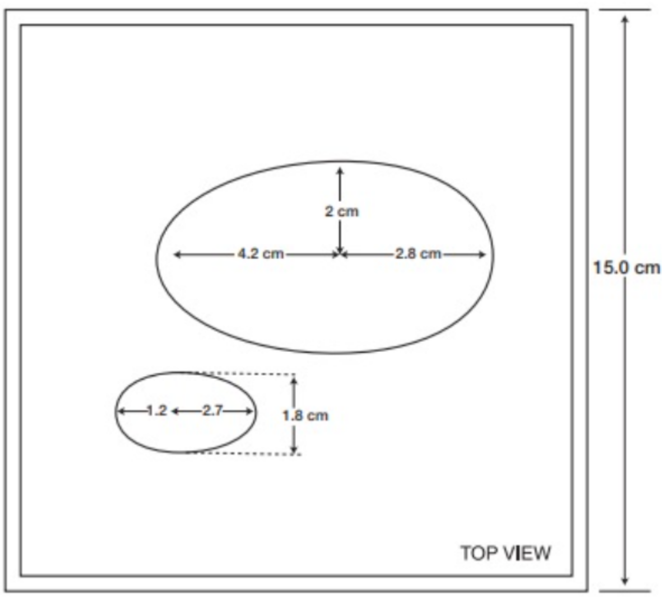
Image of ATS530 Multi-purpose phantom.

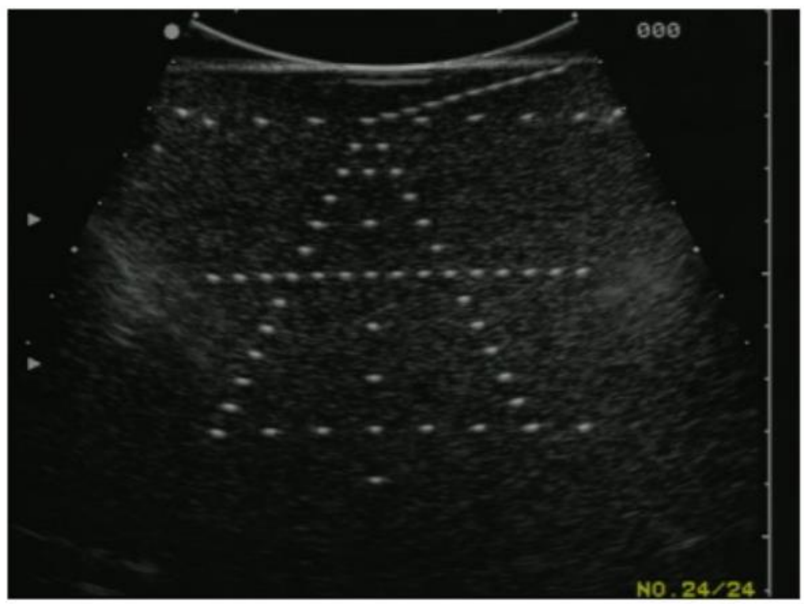
Notice the scanning window on the top and side of the unit.

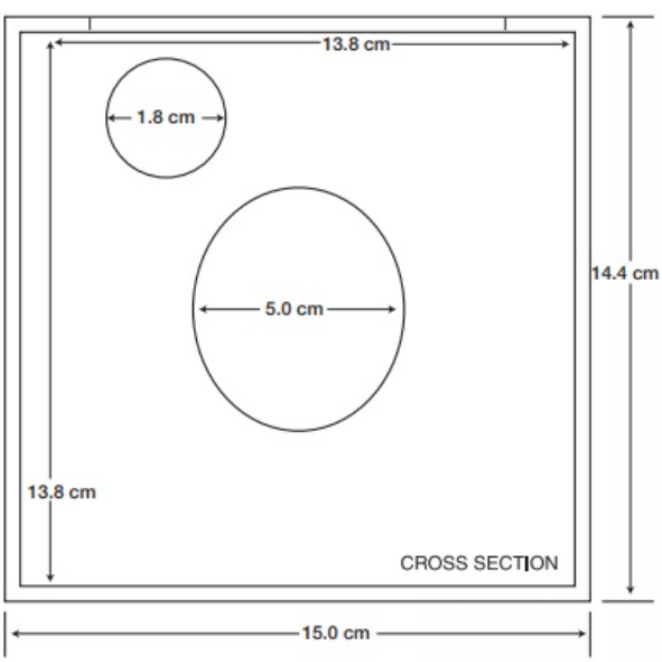
Below is the "map" of the anatomy inside the phantom.

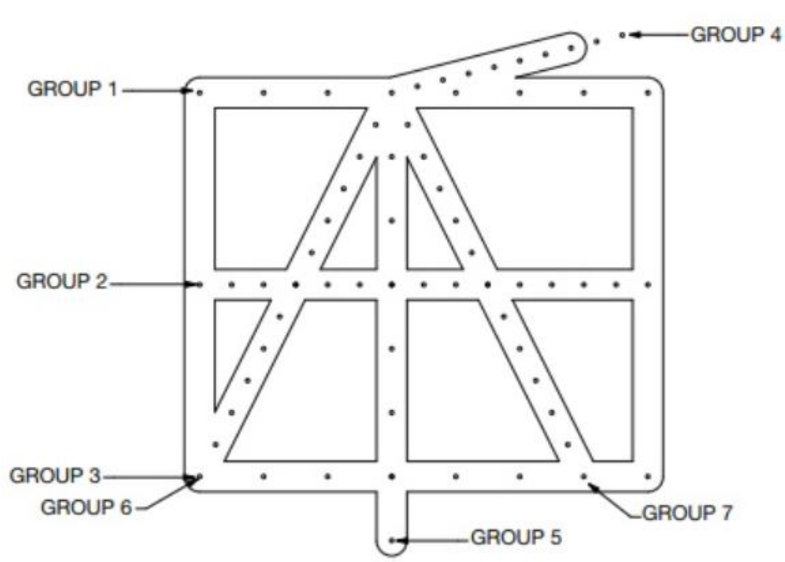


Other phantom models that can test measurement accuracy in 2D and 3D application. With an ultrasound image and map below of the CIRS phantoms.

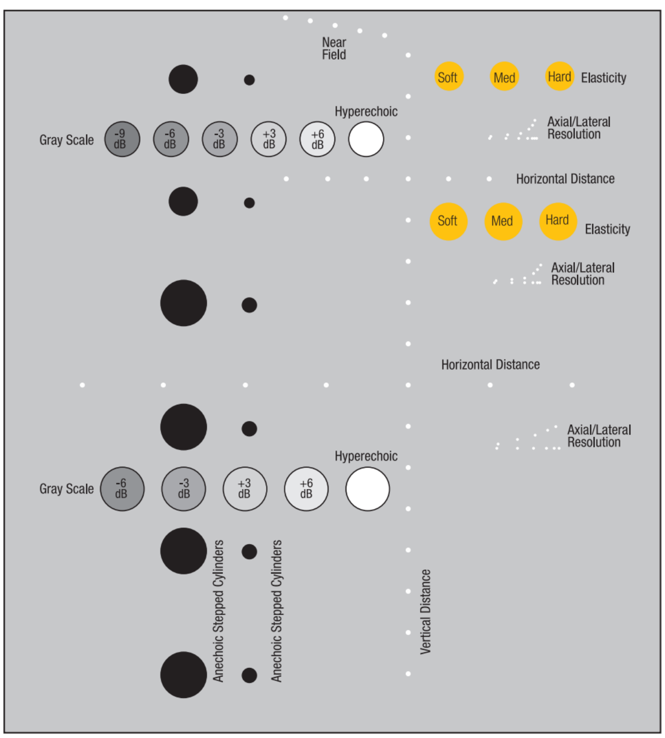








Another example of a tissue phantom with map and image.

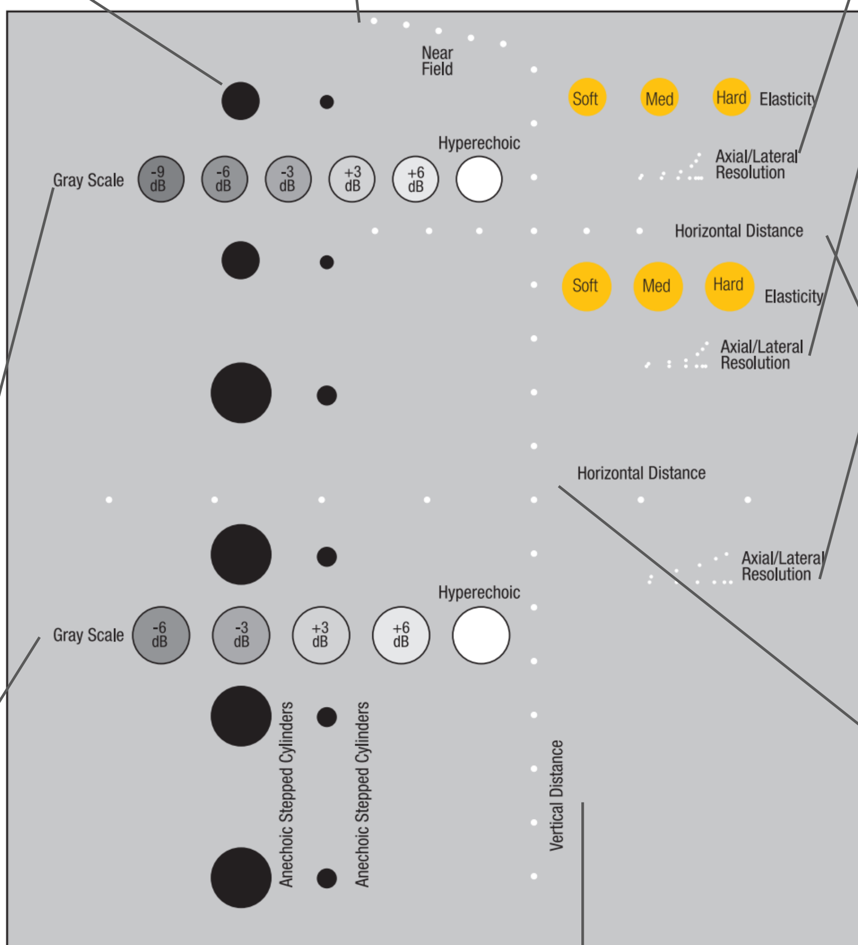


Overall Ultrasound image of Model 040GSE

Dead Zone - determines how accurate the machine is in the first centimeter of the image. You can count the pins on the map and match it to the image

Axial & Lateral Resolution - pins are placed at very specific distances apart. The user observers at what point the pins "merge" together.

Measurement - how accurate is the machine at measuring structures at different depths

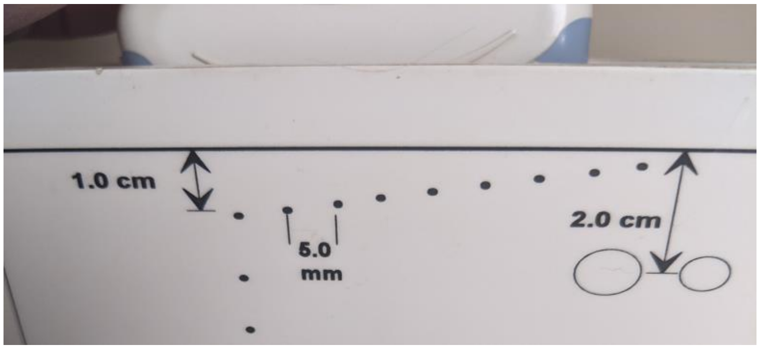


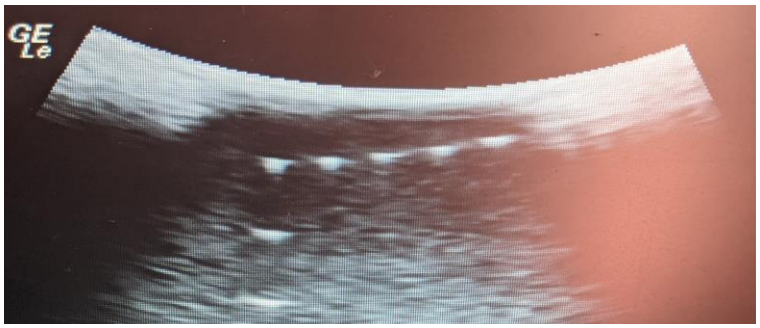
Contrast - how well can the machine detect different grays. This phantom tests it at different depths.

Range Accuracy (Vertical) - Determines if the machine can accurately place reflections at the correct depth and size. Each pin is the same size and equidistant from each other. Calipers are used to measure these on the image.

Registration Accuracy (Horizontal) - Determines if the machine can accurately place reflections at the correct location across the image.

Dead zone testing looks at the pins that are very close to the near field. It allows the tester to see at what point the machine begins to register real reflectors.



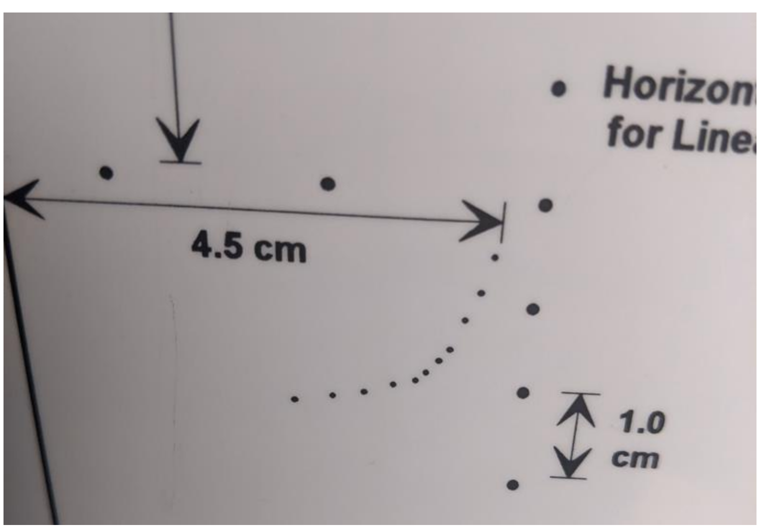


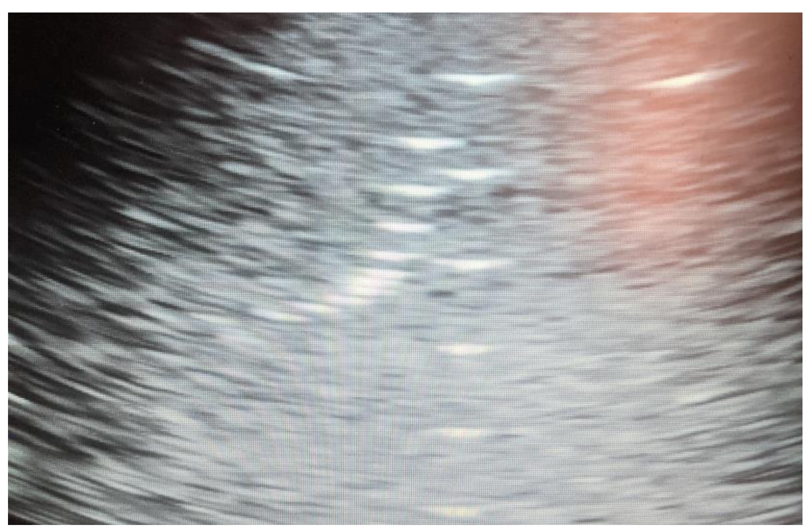
In the first centimeter of this image, 9 pins should be able to be visualized according to the map.

However, only 5 pins are seen. There is too much interference & artifact to see the pins shallower than this.

- ➔ **A stand off pad, or a gel pad placed on the surface allows for more space and normalization of the sound beam so superficial structures can be seen.**

Axial & Lateral Resolution are tested with pins that are closely placed, parallel & perpendicular to the sound beam. The tester pays attenuation to how many pins can be seen at what point they merge into one pin, thus setting the resolution limit.

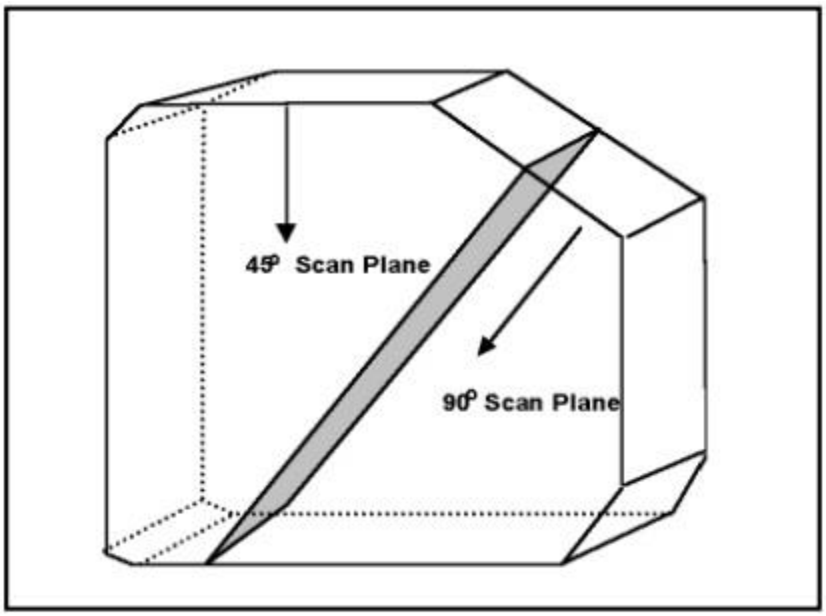




22.2.3 Slice Thickness Phantom

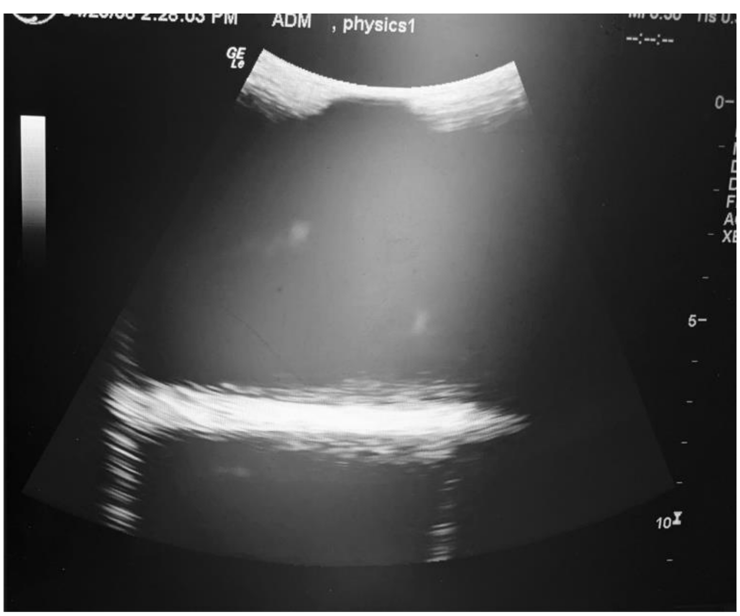
➔ **The slice thickness phantom is used to evaluate the elevational plane and the beam profile.**

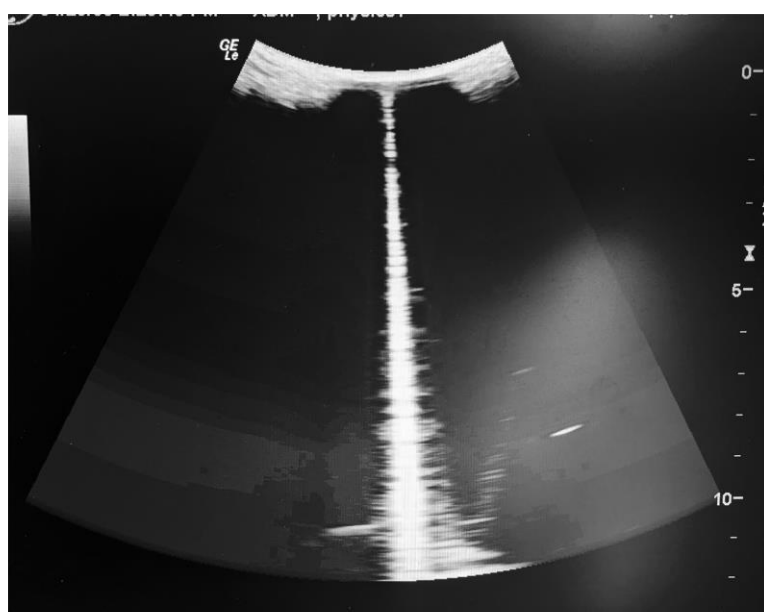
The slice thickness phantom also has multiple scan windows to better assess the beam profile. It is made of a tissue equivalent gel and an echogenic band.



When scanning at the 45 degree window, a bar will show up in the image. The height of the bar tell you the the height of the beam.

When scanning at the 90 degree plane, the beam width can be seen. Notice how it is narrow at the focus and diverges beyond this point.





22.2.4 Pin Test Object

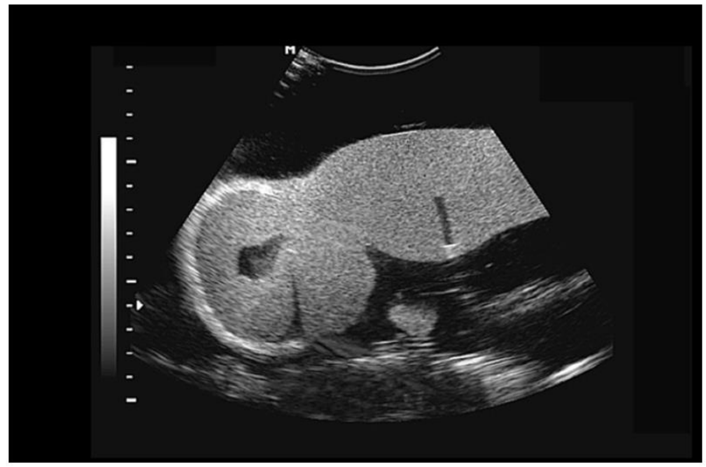
Not as commonly used anymore now that the tissue phantoms also have pins, the **AIUM 100 mm test object i**s a clear case that is filled with water. The stainless steel pins are visible within. They are used to assess for registration accuracy.

22.2.5 Other Models

There are other soft tissue models available for scanning that are useful in teaching the basics of ultrasound when a real patient is not available. These models use tissue mimicking substances to attenuate sound the same way and provide a semi-realistic scanning experience.

Many of these models are helpful to practice image guided needle procedures like biopsies.

Even more recently, simulation computer programs are being utilized to to teach ultrasound. Sensors in a model transducer are used to recognize the users motions and are reflected visually in the program. Some of the simulator come with a tissue model.   Some companies are even using virtual reality to simulate the scanning experience.

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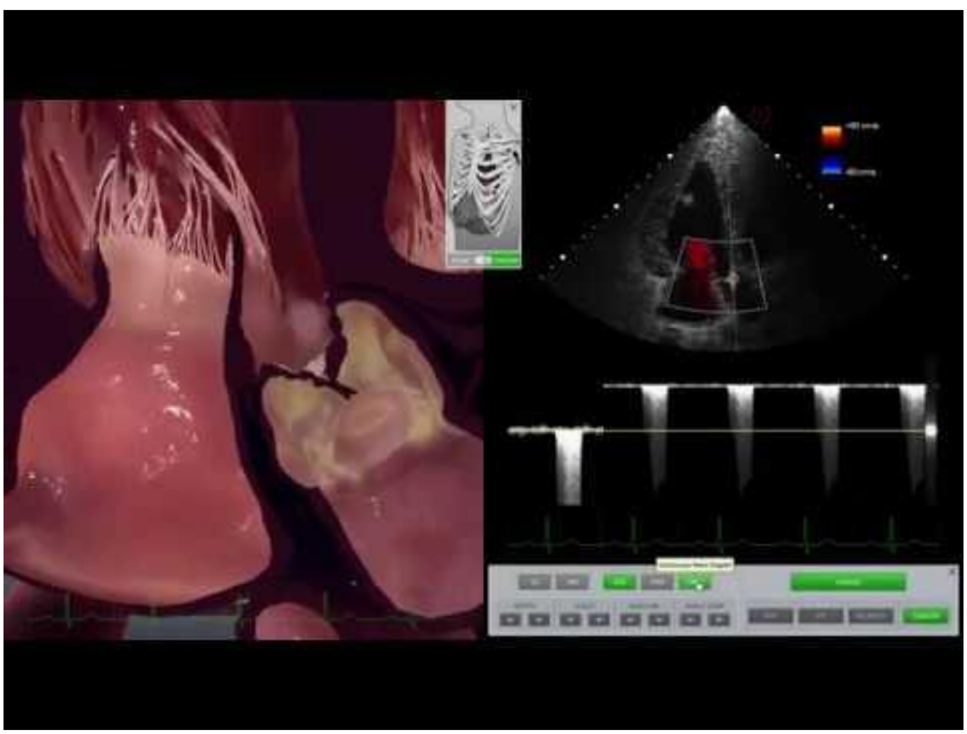


Section 22.3 Doppler Phantoms

Doppler phantoms are used to assess different parameters of Doppler ultrasound such as:

- ➔ **Penetration (sensitivity)**

How well the machine can detect PW spectral, CW spectral and color Doppler at different depths.

- ➔ **Range Accuracy**

Can the machine accurately place a sample gate and detect flow direction accurately at different locations.

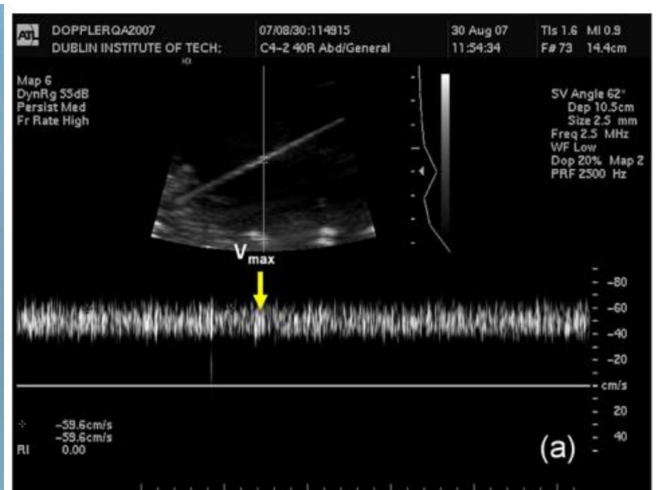
- ➔ **Peak Velocity Accuracy**

Can the machine accurately record fast velocities.

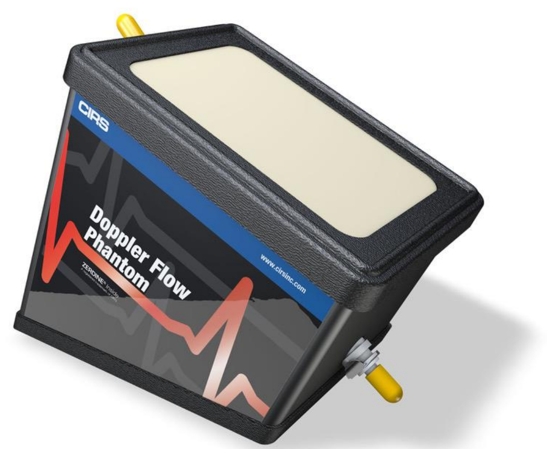
- ➔ **Spectral Broadening**
- ➔ **Lateral Resolution**

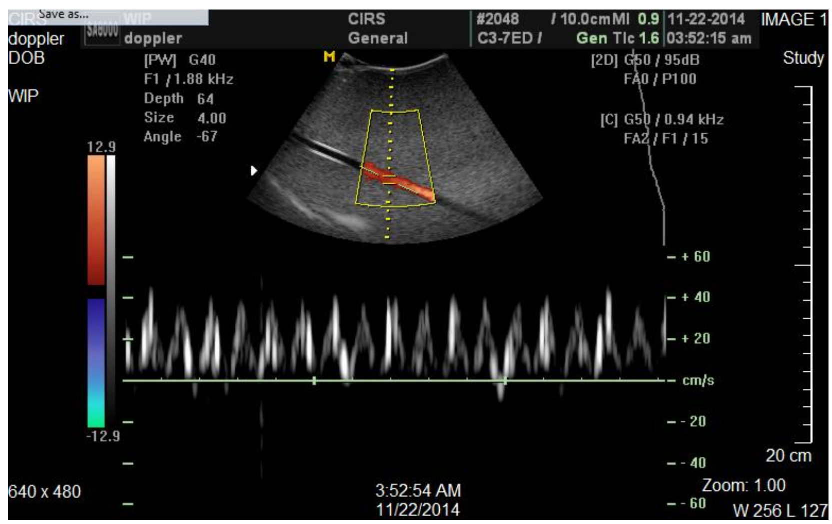
To test Doppler instrumentation, the phantom must have some moving parts or fluid. There are three ways this is accomplished:

- ➔ **Vibrating String Models**
- ➔ **Moving Belt Models**
- ➔ **Doppler Flow (pump) Models**



Doppler string phantom





Doppler phantom that requires a pump and blood like fluid.

Section 22.4 Transducer Element Integrity Tests

Each transducer should be tested to make sure that the elements are working too. In the sequential transducers, it is a little more obvious when a crystal is broken due to the drop out that occurs in the image, but it is not as obvious in phased arrays or when only one or two crystals are damaged.

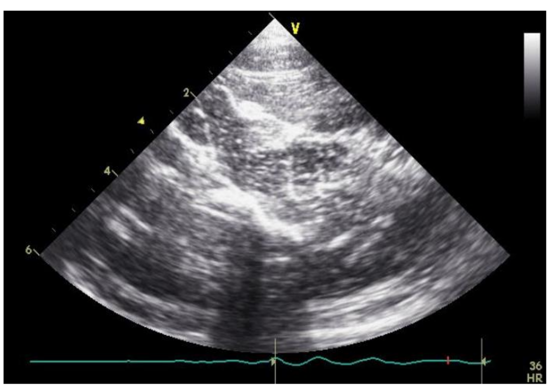
Each element can be tested directly through an integrity test using a water bath and other mechanicals. The report will determine which elements are working as expected and which are needing replacement.

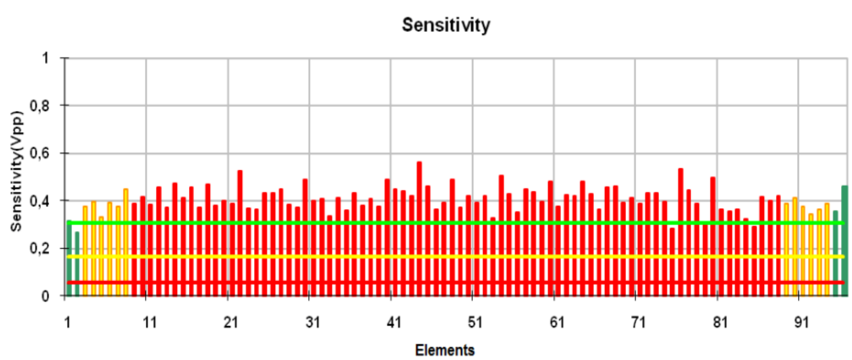
Fig.13 Probe holder

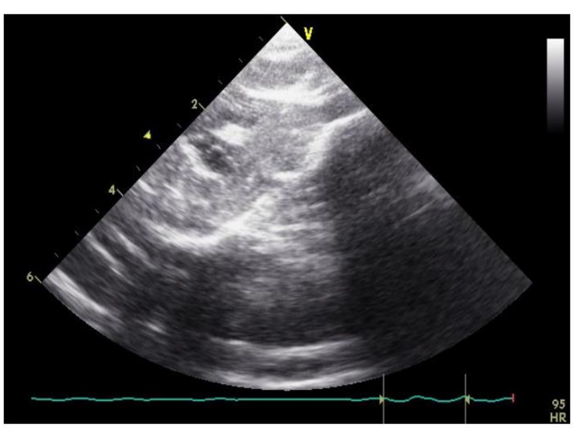
Fig.14 Linear and phased probe alignment

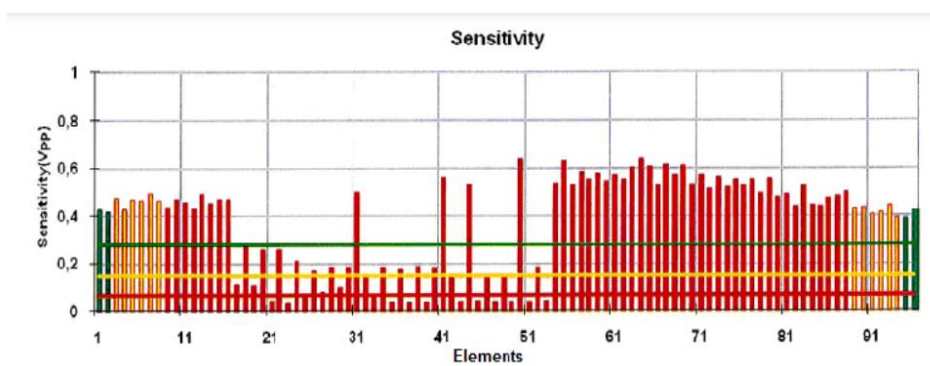
Fig.15 Curved probe alignment

Fig.16 Vaginal probe alignment









Section 22.5 Accreditation & Credentialing

Sonography labs can be accredited through 3 main accrediting agencies in the United States:

- American College of Radiology (ACR)
- American Institute of Ultrasound in Medicine (AIUM)
- Intersocietal Accreditation Commission (IAC)

Being awarded accreditation means the sonography lab and its sonographers adhere to the best practices put forth by the agencies. Accreditation is maintained by submitting cases, quality assurance data and other resources to show compliance. Often times, part of the accreditation process is to have credentialed sonographers.

Sonographers and interpreting physicians can seek personal credentials through 3 main accrediting agencies as well. Personal credentials are not legally required everywhere, but are often used as the metric for qualified sonographers. The three agencies are:

- American Registry for Diagnostic Medical Sonography (ARDMS)
- American Registry of Radiologic Technologies (ARRT)
- Cardiovascular Credential International (CCI)

Section 22.6 Quality Assurance Statistics

Part of being an accredited lab is providing statistics about the quality of exams being performed. You should be able to correlate the ultrasound findings to other modalities.

Let's take a very high level look at quality assurance statistics as it is an area of knowledge outlined by the SPI, but not an area that will be heavily tested.

First, let's start with some definitions:

Gold standard test - indicates the best test for a certain disease or pathology. For example, CT is the gold standard for evaluating appendicitis. Ultrasound can do it too, it just isn't as sensitive or specific. An ideal "gold standard" test has a sensitivity and specificity of 100%.

Sensitivity - (True Positive Rate) ability of a test to correctly identify all patients with the disease.

Specificity - (True Negative Rate) measures the proportion of actual negatives that are correctly identified as such (e.g., the percentage of healthy people who are correctly identified as not having the condition).

Positive predictive value- is the probability that subjects with a positive screening test truly have the disease.

Negative predictive value- is the probability that subjects with a negative screening test truly don't have the disease.

Prevalence- The proportion of individuals in a population having a disease or characteristic. Prevalence is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time

Accuracy - How good a test is overall. Is it capable of finding positive & negative results?

Reliability - How consistent a test is. Does the test consistently provide accurate results.

Next, let's take a look at how these values are related to each other.

We want to know how a test does when compared to the gold standard.

Some things to keep in mind:

- Gold standard is perfect (even if it really isn't)
- TRUE means it matches the gold standard finding
- FALSE means it doesn't match the gold standard finding

When looking at a new test, remember it is ALWAYS compared to the gold standard. We often represent the new test comparison through a 4 square chart. In the chart we will find 4 data points of the comparison test.

	GOLD STANDARD	
COMPARISON TEST	**TRUE POSITIVE (TP)** ● Results that are correct. ● Test is positive. ● Patient has disease. ● Matches gold standard	**FALSE POSITIVE (FP)** ● Results are incorrect. ● Test is positive. ● Patient does NOT have disease. ● Does not match gold standard
	FALSE NEGATIVE (FN) ● Results are incorrect. ● Test is negative. ● Patient has disease. ● Does not match gold standard.	**TRUE NEGATIVE (TN)** ● Results are correct ● Test is negative ● Patient does NOT have disease ● Matches gold standard.

From here, there are many formulas that give values to the terms we previously defined. Since this section of content will most likely have 1 or 2 questions, we won't spend a ton of time on it, but I will present the formulas and numerical example for your reference.

If this topic is of interest to you, there are a TON of videos on YouTube.

$$Sensitivity = \frac{TP}{TP + FN} \times 100\%$$

$$Specificity = \frac{TN}{TN + FP} \times 100\%$$

$$Accuracy = \frac{TP + TN}{TP + FN + TN + FP} \times 100\%$$

$$Positive\ Predictive\ Value = \frac{TP}{TP + FP} \times 100\%$$

$$Negative\ Predictive\ Value = \frac{TN}{TN + FN} \times 100\%$$

TP 30	FP 5
FN 3	TN 300

Sensitivity = 91% → test is good at finding positive cases

Specificity = 98% → test is good at not making everyone a positive case

Accuracy = 98% → test is correct 98% of the time - pretty good

Positive Predictive Value = 86% → test is ok at predicting if a patient has disease

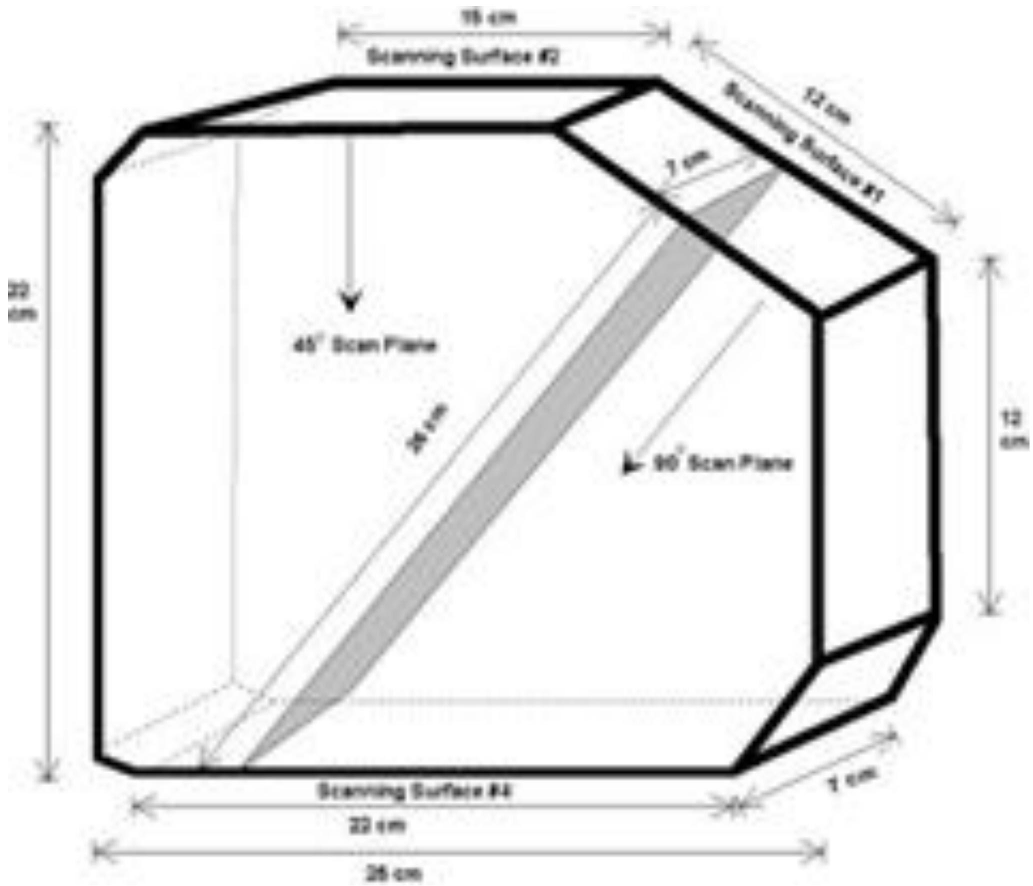
Negative Predictive Value = 99% → test is very good at predicting if a patient will not have the disease

Section 22.7 Activities ← Link to Answers

Sort the terms as Subjective or Objective

Subjective	Objective

What type of phantom is this?	
How fast does sound travel?	

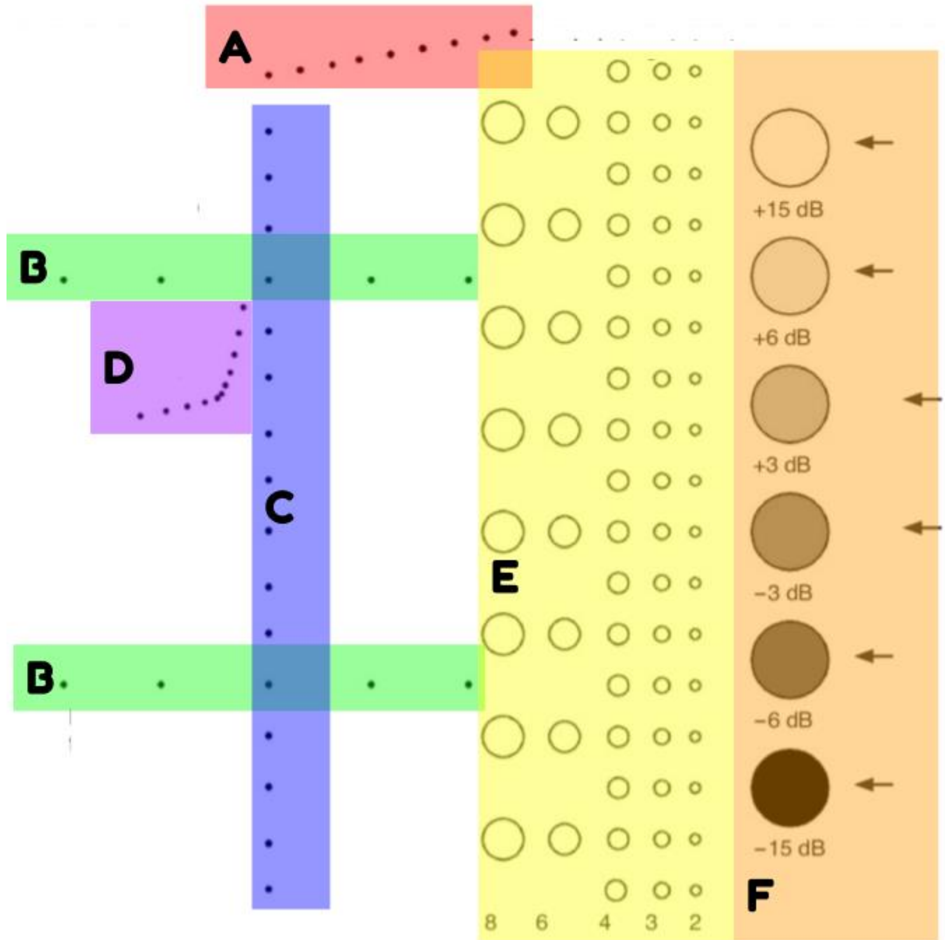


What type of phantom is this?	
What does it test?	

What are the 3 types of Doppler phantoms?

1.	
2.	
3.	

Match the letter to phantom map:



	Horizontal Registration
	Axial & Lateral Resolution
	Vertical Registration
	Dead Zone
	Measurement Accuracy
	Contrast Resolution

Match the term with its definition

	This is tested by very closely spaced pins perpendicular to the beam to see how many pins are displayed vs. the key.
	These should appear anechoic no matter where in the field they appear
	This is tested by equally spaced pins in both horizontal and vertical planes to make sure they are seen
	This is tested by mock masses with increasing depth to ensure similarity throughout
	This is tested by very closely spaced pins parallel to the beam to see how many pins are displayed vs. the key.
	This is tested by pins in the near field.
	This tests the ability to detect weak echoes

A. Sensitivity
B. Dead Zone
C. Registration Accuracy
D. Axial Resolution
E. Lateral Resolution
F. Contrast Resolution
G. Mock Cysts

Match the term to the definition:

	The ability of a test to correctly identify people who have the disease in question. Fewer false negatives improves this number.
	If a person tests negative for a test, what are the chances the patient truly does not have the disease
	This is the ideal test for a disease as it would be as close to 100% accurate as possible.
	If a person tests positive in a screening test, what are the chances the patient truly has the disease
	This is how many cases are in a population. Often seen as something similar to 10 cases per 1000 people.
	The ability of a test to correctly identify people who do not have the disease in question. Fewer false positives improves this number.

A. Prevalence
B. Gold Standard
C. Sensitivity
D. Specificity
E. Positive Predictive Value
F. Negative Predictive Value

Section 22.8 Nerd Check!

1. What are two ways to ensure quality exams are being put out by a department?
2. What is a quality assurance program?
3. How often should QA activities be performed?
4. Who performs the QA activities?
5. How can sonographers help with the QA process?
6. What things should a s sonographer look for?
7. What are the 4 things that a QA program should include?
8. What are the goals of a QA program?
9. Where can labs get more information about the QA process?
10. What is a subjective test?
11. What is an objective test?
12. Under what circumstances should QA be performed?
13. How does ultrasound QA stay objecive?
14. What parameters are assessed with 2D image performance testing?
15. What are tissue equivalent phantoms?
16. How does the tester know what is in a tissue equivalent phantom?
17. How is the dead zone tested?
18. How are axial and lateral resolution tested?
19. How are horizontal and vertical range accuaracy tested?
20. How is contrast resolution tested?
21. How is measurement accuracy tested?
22. What is a slice thickness phantom?
23. What 2 things can a slice thickness phantom test?
24. What is a pin test object?
25. How else can models be used in ultrasound?
26. What parameters can be tested with a Doppler phantom?
27. What are the three types of Doppler phantoms?
28. How can we tell is an element is working correctly?
29. What is lab accreditation and what are the agencies?
30. What is personal credentialing and what are the agencies?
31. What is a gold standard test?
32. What does sensitivity and specificity mean?
33. What are the positive and negative predictive values?
34. What do prevalnece, accuracy and reliability mean?
35. What is the comparison test compared to?
36. For TP, FP, FN, and TN, determine the following for the compariason test:
    - Results, positve/negative test, positive/negative patient, match GS test