Setting up a New Ultrasound Quality Control Program

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Overview

- Where to start?
- Main Accreditation bodies
- Required and Recommended tests
  - Image quality tests
  - Testing tools
  - Frequency of testing
  - Who is required to perform tests
- Value added since developing our program

Where to start?

- First determine which ultrasounds, if any need to be accredited
- If your facility is a Breast Imaging Center of Excellence (BICOE) they are required to have their breast ultrasounds accredited (including the ultrasound-guided breast biopsy module) by the ACR
- California has a prenatal screening program that requires accredited machines for specific exams (https://www.cdph.ca.gov/programs/pns/Pages/NTPractitioner.aspx)
- If your ultrasound units are not accredited, is there any QC that should still be performed on any of these units?
- What kind of man power do you have? Who can you employ to help?

How to get Accredited?

Two main accrediting bodies for ultrasound

- ACR
  - https://www.acr.org/Quality-Safety/Accreditation
- AIUM
  - http://www.aium.org/accreditation/accreditation.aspx

Smaller accreditation bodies that accredit for specific departments Example: IAC for vascular studies

ACR - Ultrasound Accreditation Program Requirements

- Effective, June 1, 2014, documentation of quality control (QC) is required as part of the application process. All facilities applying for accreditation must comply with the minimum frequencies listed below. As part of the accreditation application, facilities must demonstrate compliance with the ACR requirements for QC by providing:
  - Report from the most recent annual survey performed by the medical physicist or designee
  - Documentation of corrective action (if the annual survey and/or QC data identify performance problems)
- Currently Identical QC sections for both Ultrasound and Breast Ultrasound Accreditation programs

ACR - Acceptance testing (Optional)

- Initial performance testing of newly installed imaging equipment should be performed, and should be completed before clinical use
- While not required, there is value to be gained in doing acceptance testing,
  - It will give the end user confidence that the equipment will perform as expected when purchasing new imaging systems.
  - We need a baseline!
  - It will also establish the timeframe for the following annual surveys.

ACR - Routine Quality Control Tests (Optional)

QC Test	Recommended Minimum Frequency
Physical and Mechanical Inspection	Semiannually
Image Uniformity and Artifact Survey	Semiannually
Geometric Accuracy (mechanically scanned transducers only)	Semiannually
Ultrasound Scanner Electronic Image Display Performance	Semiannually
Primary Interpretation Display Performance	Semiannually, or as judged appropriate based on the specific display technology, or prior QC testing data

Breast Ultrasound QC Log

(Keep this record for at least 3 years)

System No.	Facility	Department	Manufacturer/Model	Transducer Model	Transducer Serial No.

Default Setting Frequency:

QC Results (RMI 404GS LE Phantom)

Date	Physical & Mechanical Inspection (Mechanical Integrity, Patient & Operator Safety)	Image Uniformity and Artifact (No Axial or Lateral Streak)	Geometric Accuracy			US Scanner Display Check (SMPTE Pattern)		Diagnostic Review Workstation Image Quality Check	Tech Initials
			Vert Pin Spacing between Top 2 Rows 4.0±0.04 cm	Horz. Pin Spacing 2.0 ± 0.2 cm		5% & 95% Patch Visible	Bars at Four Corners Resolved		
				@ 1 cm depth	@ 5 cm depth				

	Comments

ACR - Preventative Maintenance

- Regular preventive maintenance should be performed and documented by a qualified equipment service engineer following the recommendations of the equipment vendor.

ACR – Required Annual Testing

- Physical and Mechanical Inspection
- Image Uniformity and Artifact Survey
- System sensitivity
- Ultrasound Scanner Electronic Image Display Performance
- Primary Interpretation Display Performance
- Evaluation of QC Program (if applicable)

ACR - Optional Annual Testing

- Geometric Accuracy (Now Optional)
- Contrast Resolution
- Spatial Resolution

AIUM - Requirements

ULTRASOUND EQUIPMENT MAINTENANCE AND QUALITY ASSURANCE

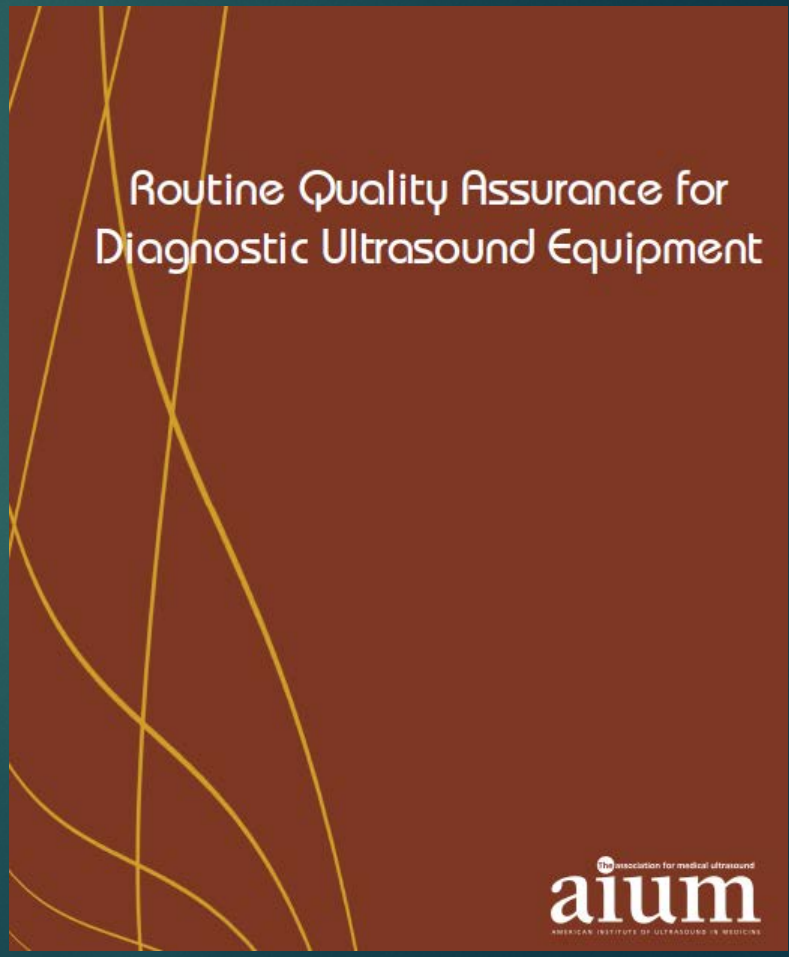
- The ultrasound equipment must meet all state and federal guidelines.
- Studies must be conducted with real-time equipment, and transducers must be available with a frequency range that will optimize beam penetration and resolution.
- Practices must meet or exceed the QA guidelines specified in Routine Quality Assurance for Diagnostic Ultrasound Equipment.
- Instrumentation used for diagnostic testing must be maintained in good operating condition and undergo routine calibration at least once a year. All ultrasound equipment must be serviced at least annually or more frequently if problems arise.
- There must be routine inspection and testing for electrical safety of all existing equipment.
- Manufacturers' statements that maintenance on their machines is not needed are unacceptable.

Standards and Guidelines for the Accreditation of Ultrasound Practices, Approved October 31, 2015 (http://www.aium.org/officialStatements/26)

AIUM

Routine Quality Assurance for Diagnostic Ultrasound Equipment

- Good Agreement with the ACR
- Limited information on methodology
- Requires a phantom
- Phantom left to users



AIUM Accreditation Application Checklist

- http://www.aium.org/accreditation/appChecklist.pdf

_____ Copy of each sonographers' current ARDMS or ARRT registry card

_____ Most recent preventative maintenance report for each ultrasound machine

_____ Case studies for the specialties in which you are seeking accreditation

_____ Online application completed and submitted

_____ Payment for the Accreditation fee submitted by check or credit card

SAMs Mishap!

2. ACR is the only accreditation body that requires QC for Ultrasound:

- True
- False

The important thing to remember is that the ACR does require documented annual QC to be submitted during accreditation

ACR

- Ultrasound QC Manual does not yet exist
- No specific testing is mandated
  - Subjective or Objective approaches may be used
- No pass/fail performance criteria are prescribed

Testing Phantoms

Use of a phantom is required for annual testing but specific phantom not defined.

- Water-based gel phantoms
  - speed of sound = 1540 m/s
  - However, they can be subject to desiccation so take care to ensure this is not the reason for poor image quality

Testing Phantoms

- Urethane (non-water-based materials)
  - No desiccation!
  - But the speed of sound is only around 1450m/s
  - Take care not to damage surface

Mechanical and safety inspection

- Check transducer cables, transducer housings and transmitting surfaces for cracks, separations or discolorations.
- Check power cord for cracks, discoloration and damage to cable and plug.

Mechanical and safety inspection

- Check acquisition control for dirty or broken switches and knobs and burnt out lights. Note any controls that function intermittently.
- Dust filters should be clean and relatively free of lint and clumps of dirt.
- Check scanner housing for dents or other damage that could indicate damage to the internal electronics.

Image Uniformity and Artifact Evaluation

- Considered to be the most important and useful test!

Studies such as the 4-year Experience with a clinical ultrasound quality control program (Hangiandreou et al., Ultrasound Med Biol 37, 1350-1357, 2011) show this to be the highest percentage of detected failures

Evaluation Method	# of detected "failures"	% of detected "failures"	Recommendation
Mechanical Integrity	47	25.1	Quarterly
Image uniformity	124	66.3	Quarterly
Distance Accuracy	0	0.0	Annually
DOP (penetration)	3	1.6	Annually, (if done with software)
Clinical Problems	13	7.0	Sonographer's daily inspections
TOTAL	187	100.	

Image Uniformity and Artifact Evaluation

- Scan a uniform test object/phantom
  - Inspect while scanning
  - Scanning a changing speckle pattern ups your ability to see issues
  - Search for “shadows” emanating from the transducer
- Use shallow focus

Image Uniformity and Artifact Evaluation

A uniform image has:

- No loss of sensitivity near edges of the image
- No evidence of element dropout
- No vertical shadows

Image Uniformity and Artifact Evaluation

Is it an actual fault of the transducer

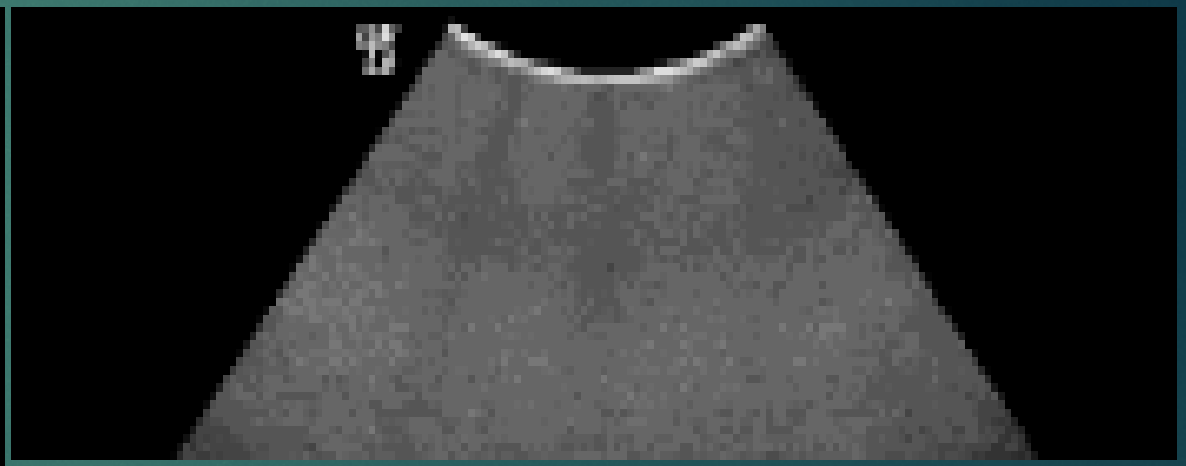
- It is extremely important to know your scanner. These tests are only as good as we are

Issues

- The transducer needs to be coupled well to the phantom (A challenge with a flat surface and a curvilinear transducer)
  - Rocking motion
  - Special phantom
- Spatial Compounding can also mask uniformity issues!

Image Uniformity and Artifact Evaluation

Spatial Compounding Example



Objective Uniformity Tests

FYI: Objective test are available (References to learn more)

- IEC 62736 Ultrasonics (2016) Pulse-echo scanners – Simple methods for periodic testing to verify stability of an imaging system's elementary performance
- AAPM Ultrasound Subcommittee Task Group

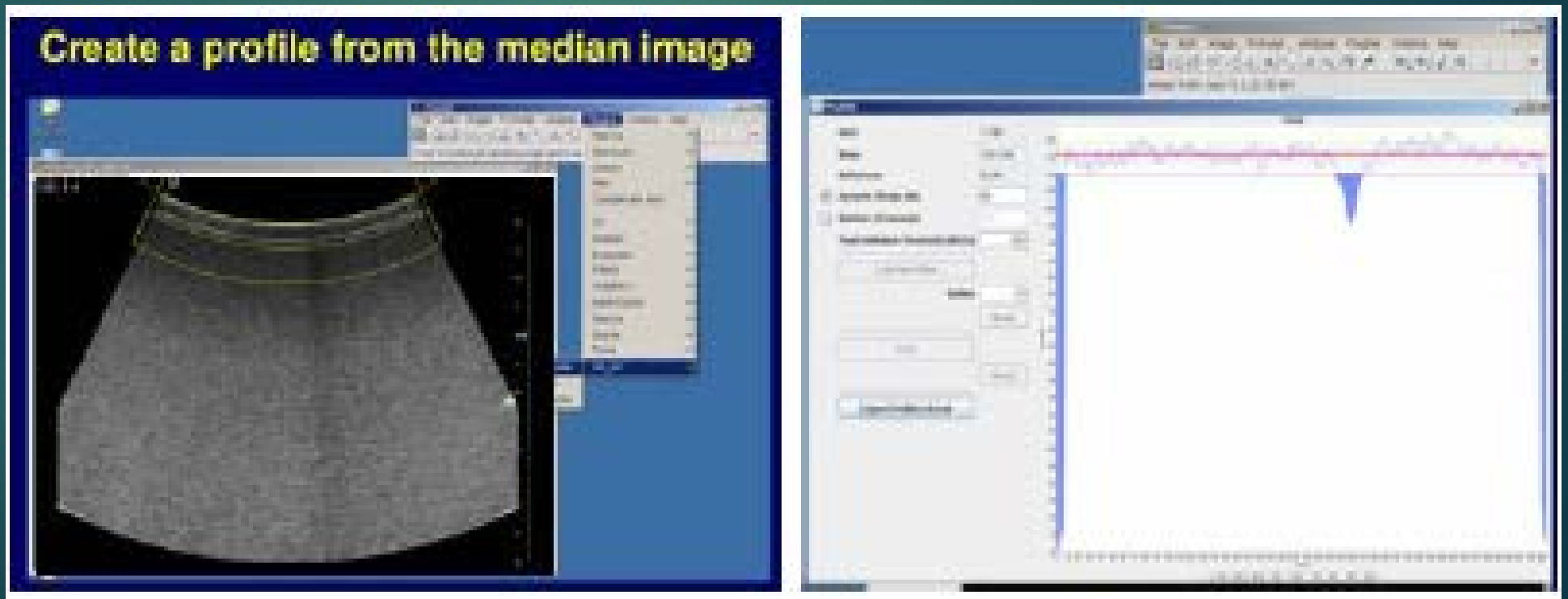


Image Uniformity and Artifact Evaluation

- What to do if you see flaws?
  - First – troubleshooting
    - Is this a flaw of the transducer? Use transducer in different port on a different system
  - Recommendations on if they should replace right away, if they can continue use, etc
- Can develop your own rating system to keep track of the degree of non-uniformity

Image Uniformity, Artifact, and Element Dropout

Non-uniformity: 1=None, 2=Noticeable nonuniformities, 3=Serious nonuniformities, 4=Element dropout	Status
1	Acceptable
Artifact Description If Non-Uniformities Observed	
None	

System Sensitivity, Maximum Depth of Penetration

A good overall check of the integrity of the system

- FOV large enough to see end of speckle
- Set output power to max
- Deep focus
- Set gain and TCG to max visualization

Subjective

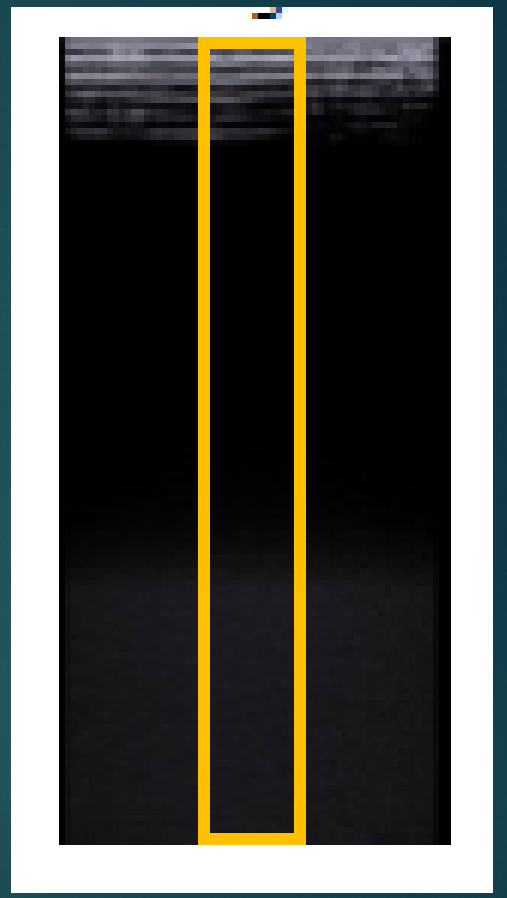
- How far can you see the speckle pattern?

*Can change drastically depending on ultrasound settings.

System Sensitivity, Maximum Depth of Penetration

- Compute mean pixel value vs. depth for the phantom and then for noise only
- DOP = Depth where

  signal+noisie/noise =1.4



References:
Gorny, Tradup, Bernatz, Stekel, and Hangiandreou, "Evaluation of an Automated Depth of Penetration Measurement for the Purpose of Ultrasonic Scanner Comparison", (abstract only), J. Ultrasound Med 23: S76, 2004.

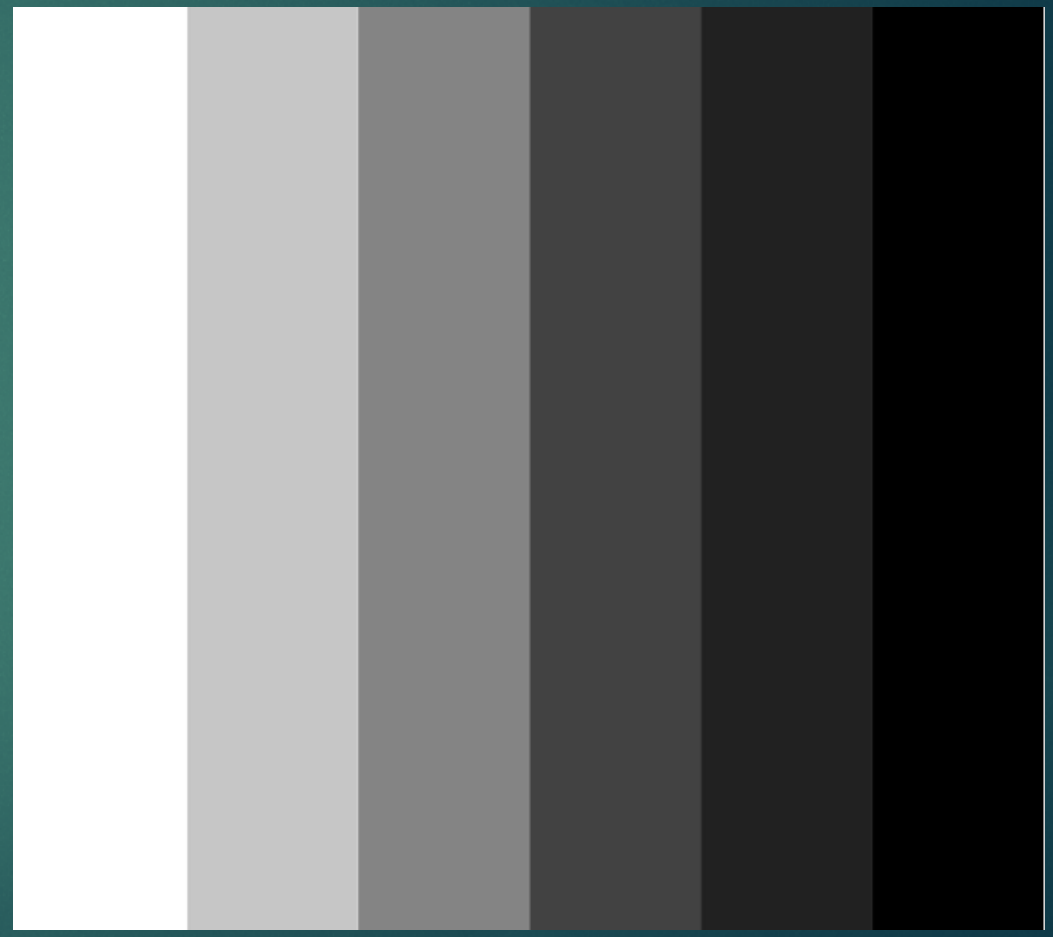
•Specified in IEC International Standards 61391-2 (2010) and 62736 ("Maximum Relative Depth of Penetration" in 62736)

Ultrasound Scanner Electronic Image Display Performance

- Maintaining the performance of the image display is critical for providing the greatest diagnostic benefit of the scanner. Display characteristics that are evaluated may include
  - gray scale response
  - luminance calibration
  - presence of pixel defects
  - overall image quality.
- These evaluations are typically performed using specialized test pattern images, and may also require photometric equipment. See ACR Technical Standard for Electronic Practice of Medical Imaging.
- The scanner is only as good as its display output

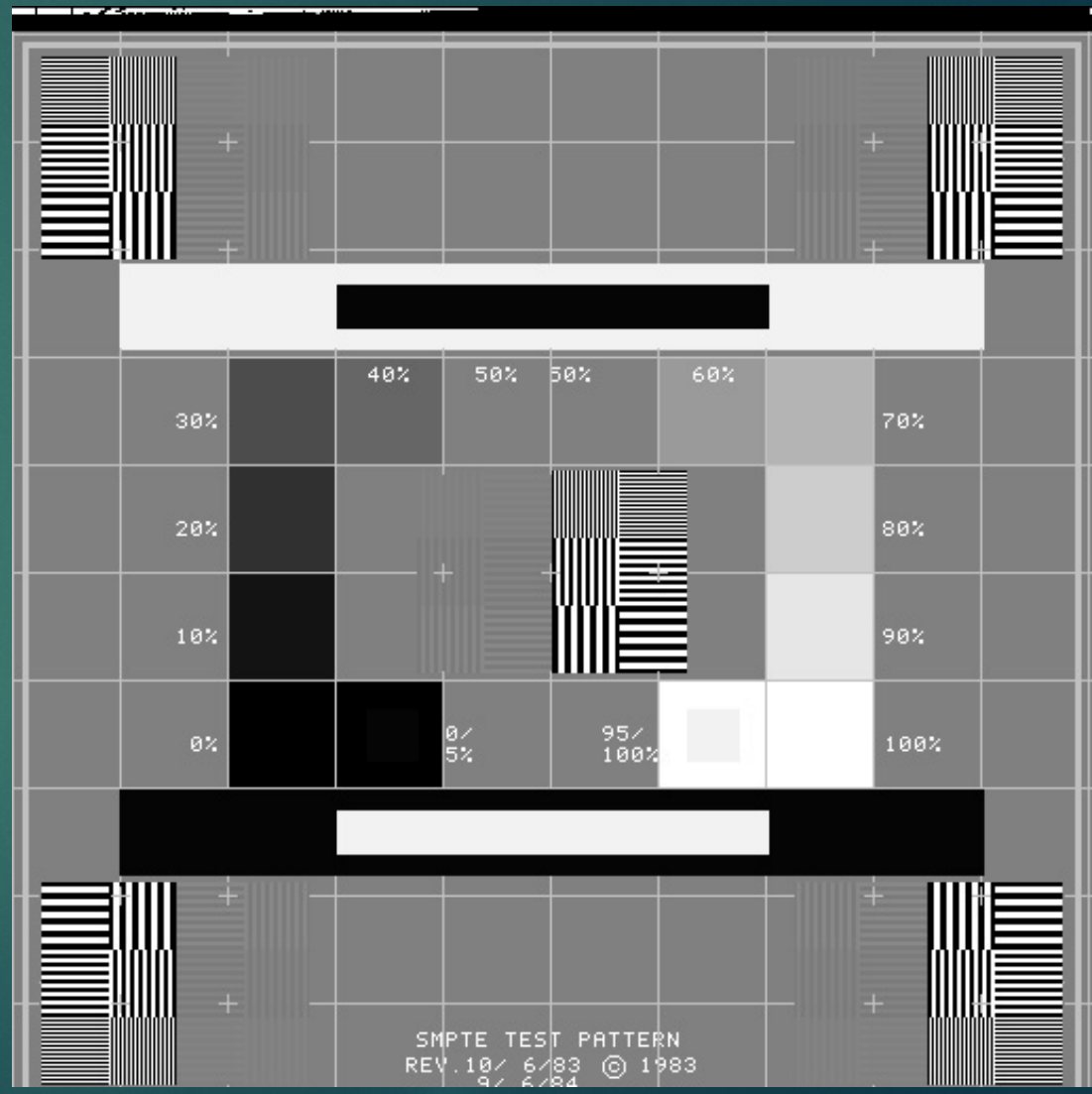
Ultrasound Scanner Electronic Image Display Performance

- If grey scale is not available on unit ask the vendor. Most can upload
- At acceptance system should be setup and adjusted to resolve all grey bars
- Important because gray scale resolution allows for the differentiation of subtle changes in the tissue



SMPTE pattern

- 0% to 100% gray bar pattern
- geometric distortion
- 0/5% and 95/100% visibility

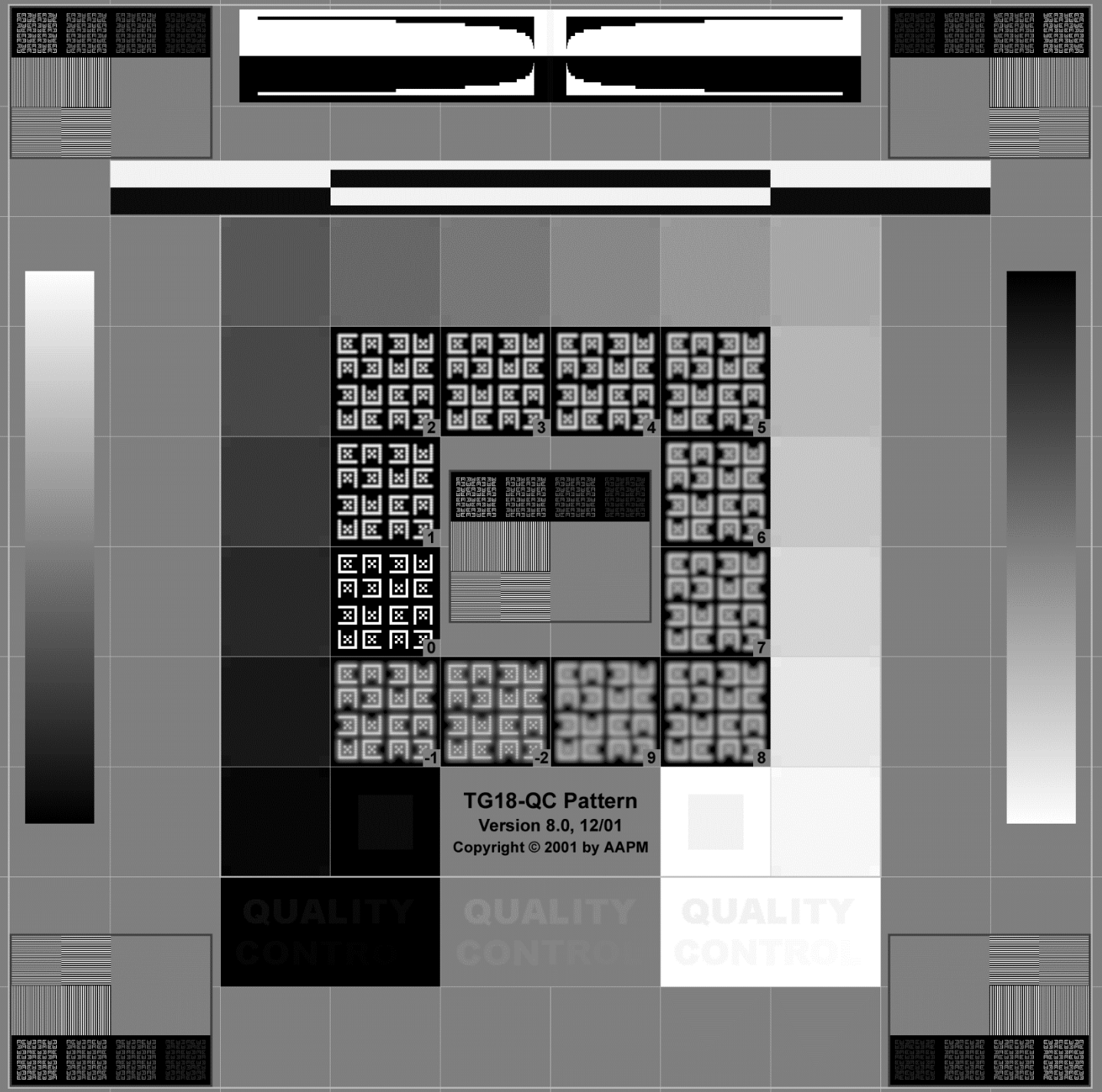


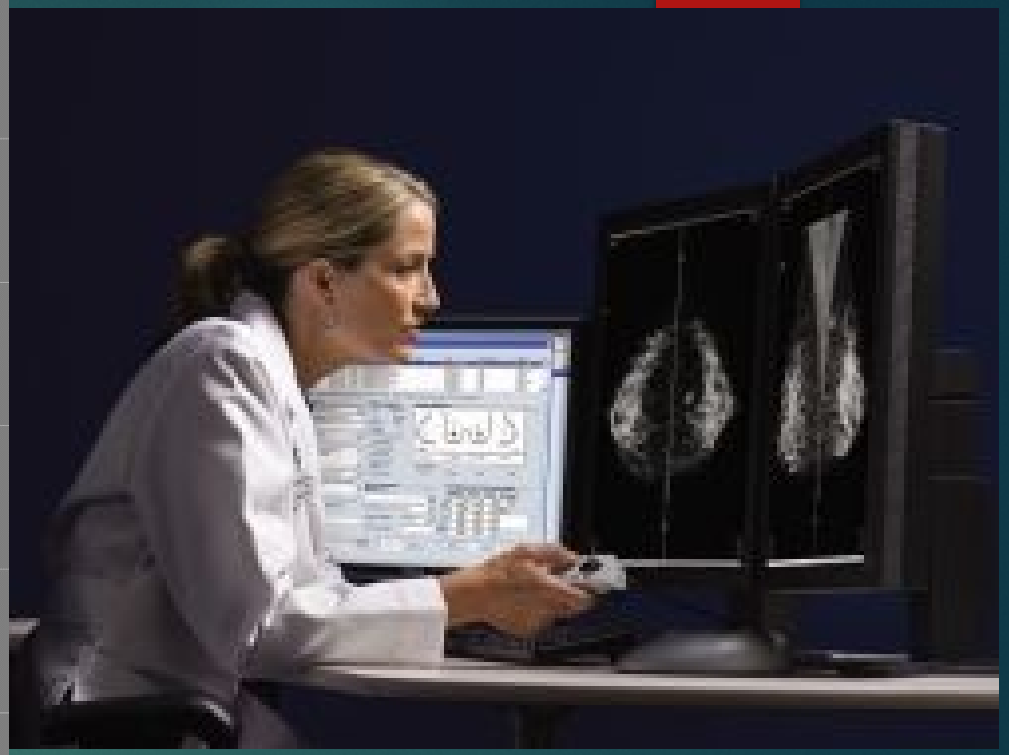
Ultrasound Scanner Electronic Image Display Performance

- Most often see the 0-5% fail on the system monitor.
- Opportunities to match system monitor with PACS workstation
  - Blacks seem black on system monitor but may not present that way on the interpreting workstation

Primary Interpretation Display Performance

- Primary diagnostic displays are typically electronic soft-copy displays on a PACS workstation. They should also include worklist monitors only if used for primary interpretation (other than color analysis).
- Display characteristics that are evaluated may include:
  - gray scale response
  - luminance calibration
  - presence of pixel defects
  - overall image quality.
- Reference: **ACR–AAPM–SIIM TECHNICAL STANDARD FOR ELECTRONIC PRACTICE OF MEDICAL IMAGING (https://www.acr.org/~/media/ACR/Documents/PGTS/standards/ElectronicPracticeMedImg.pdf)**
- * Only required if located at the facility where ultrasound is performed.





Test with external photometer?

We have determined that internal pucks are not always properly calibrated and have found multiple failures when the internal luminance is reading pass

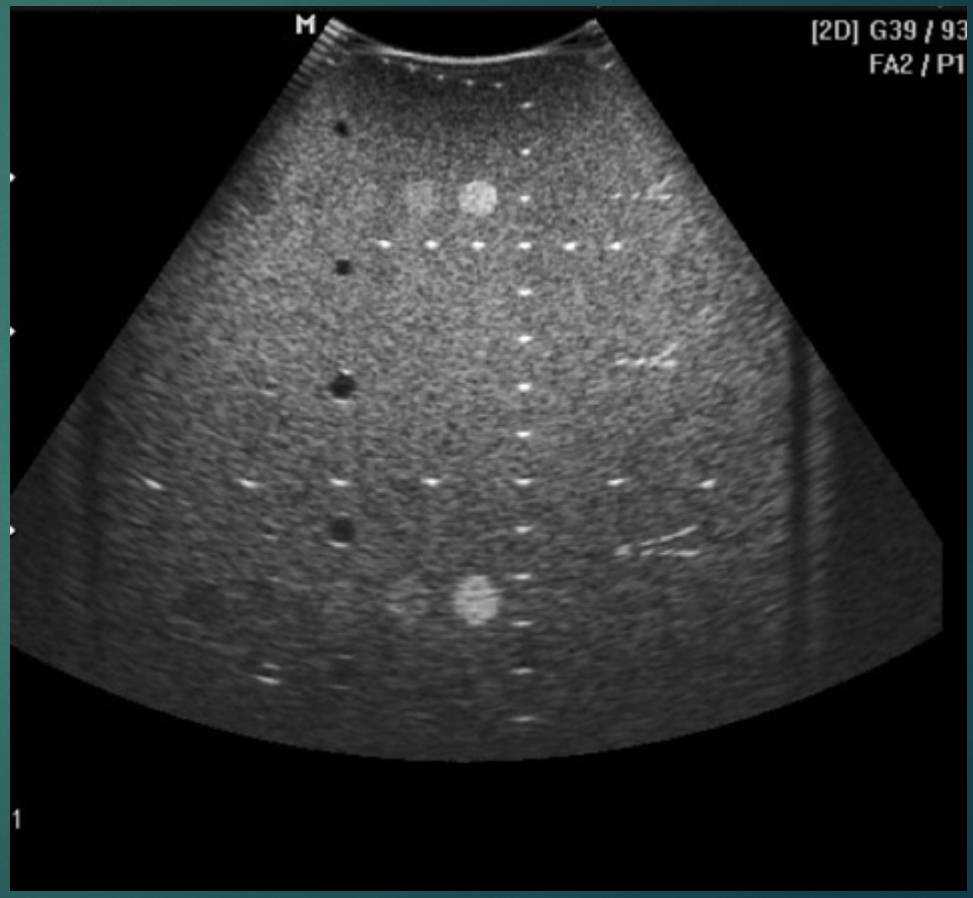
ACR - Optional Annual Tests

- Geometric Accuracy (Now Optional)
- Contrast Resolution
- Spatial Resolution

Geometric Accuracy

Vertical

- *Action: >1.5mm or 1.5%
- *Defect: >2mm 0r 2%



*Goodsitt M M et al 1998 Real-time B-mode ultrasound quality control test procedures. Report of AAPM Ultrasound Task Group No. 1 Med. Phys. **25** 1385

Geometric Accuracy

Horizontal

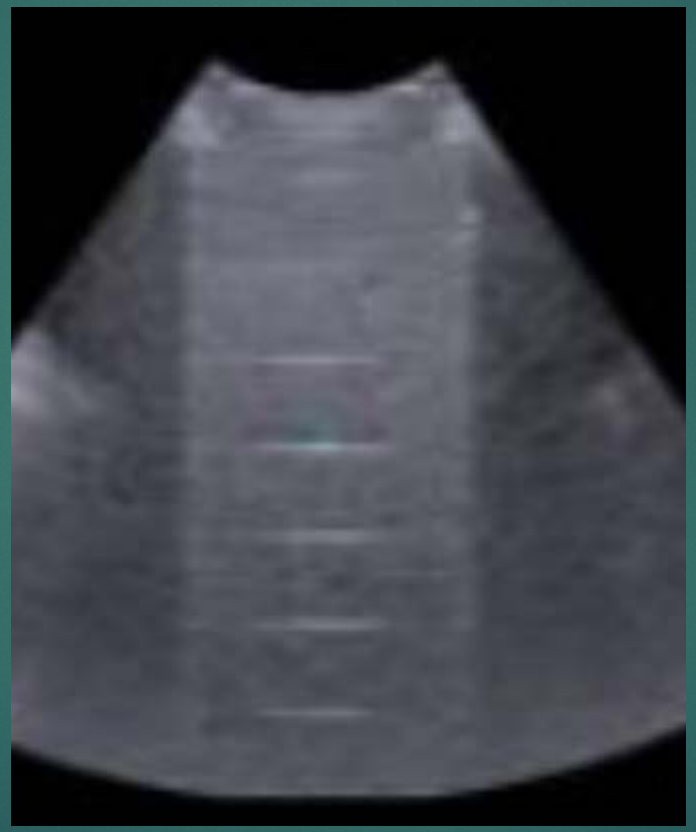
- *Action: >2mm or 2%
- *Defect: >3mm 0r 3%

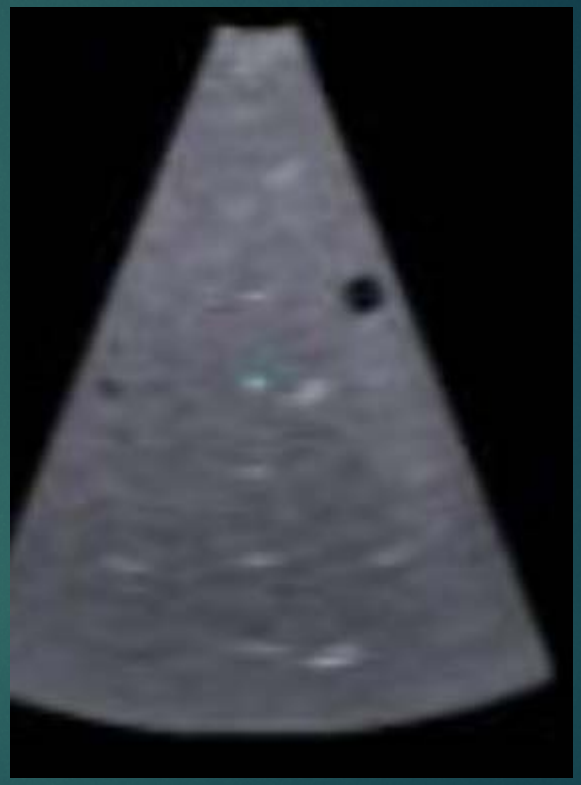
*Goodsitt M M et al 1998 Real-time B-mode ultrasound quality control test procedures. Report of AAPM Ultrasound Task Group No. 1 Med. Phys. **25** 1385

Geometric Accuracy

Elevational

- Scanned in plane perpendicular to the phantom



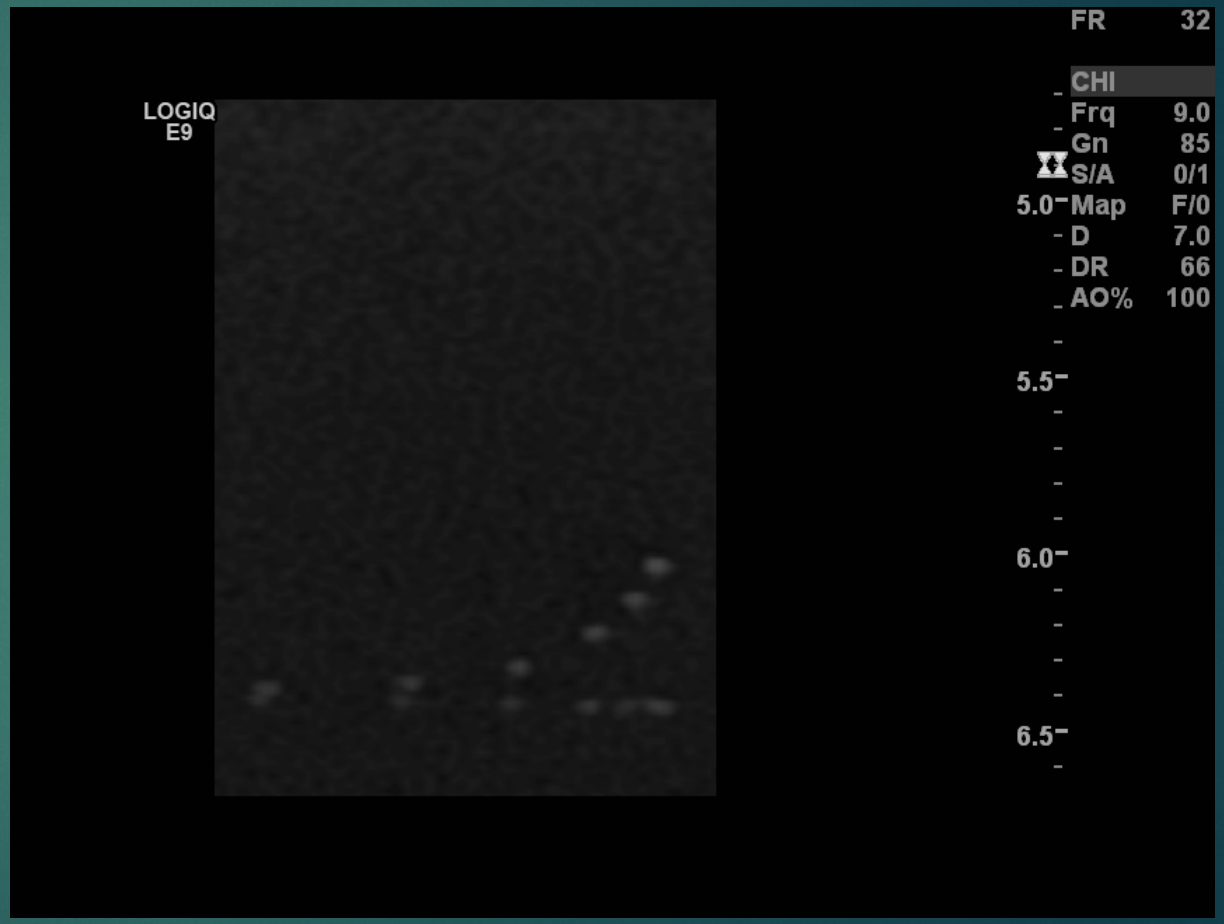


Contrast Resolution

- Can be scored using most phantoms
- Anechoic object diameter that can be visualized.

Spatial Resolution

- For meaningful results it is very important to create a reproducible test
  - Standardized settings!
- Can score lateral and axial resolution with common phantoms



Evaluation of QC Program (if applicable)

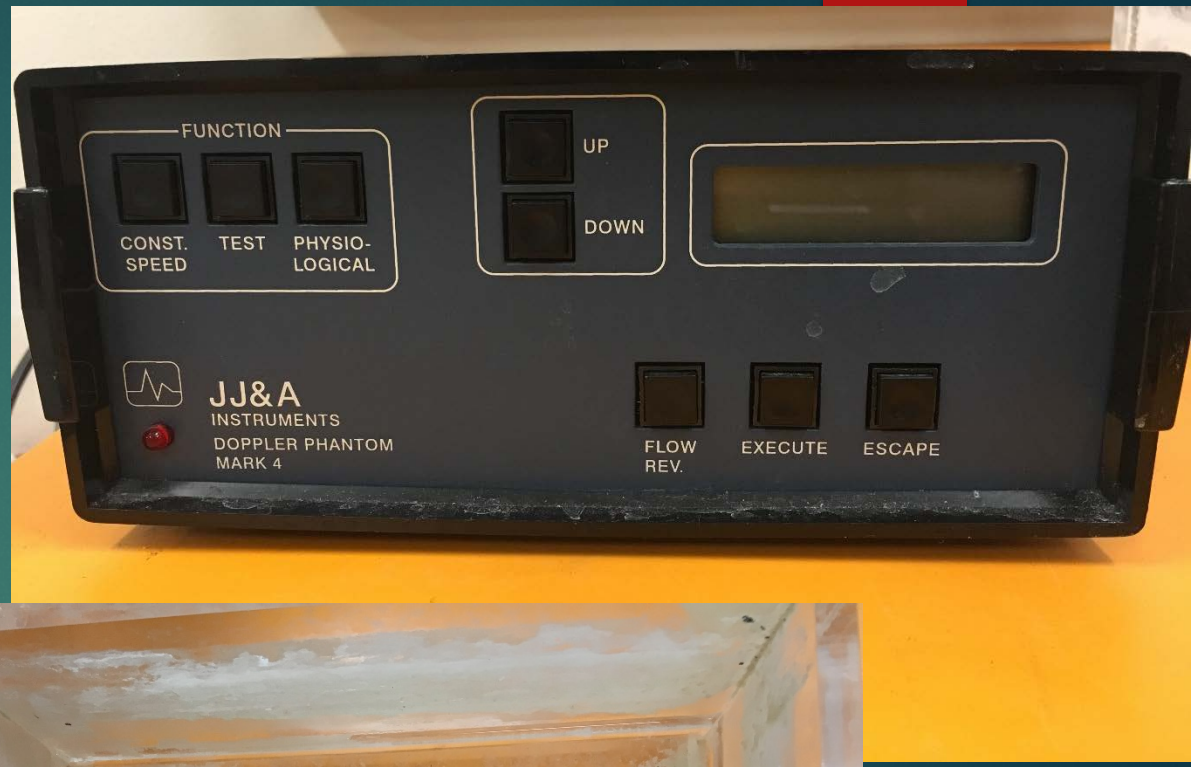
- Provides an independent assessment of the QC program, checks that appropriate actions are taken to correct problems, identifies areas where quality and QC testing may be improved, and enables a comparison of QC practices with those of other ultrasound sites.

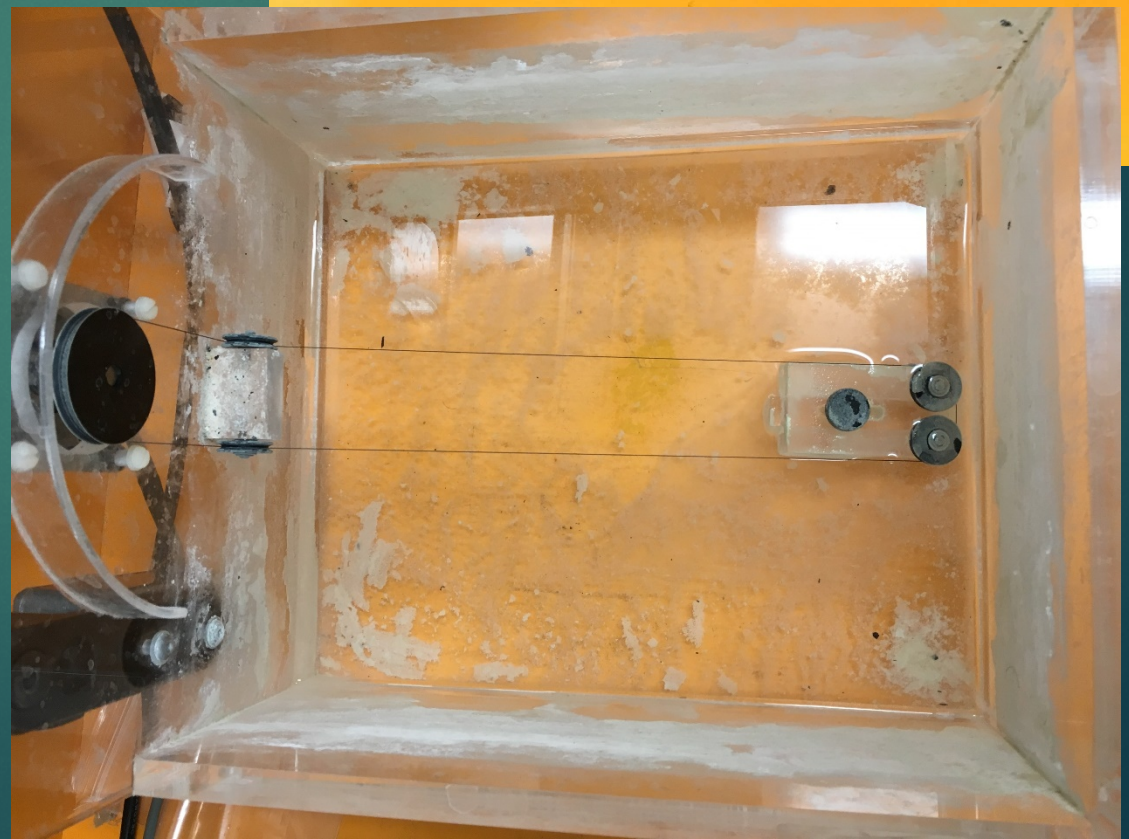
Quality Control Program Review

	Status
Policies and Procedure Manual – available and followed	Acceptable
Accreditation and Certification	Acceptable
Physical and Mechanical Inspection (Semiannually)	Acceptable
Image Uniformity and Artifact Survey (Semiannually)	Acceptable
Geometric Accuracy (mechanically scanned transducers only) (Semiannually)	N/A
Ultrasound Scanner Image Display Performance (Semiannually)	Acceptable
Primary Interpretation Display Performance (Semiannually)	Acceptable

Doppler

- Evaluation of Doppler is not required but it is recommended to be done at acceptance in the **ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF REAL TIME ULTRASOUND EQUIPMENT**





Personnel Required to perform tests

ACR

- **A Qualified Medical Physicist should carry out acceptance testing and monitoring of ultrasound equipment.**
- "The ACR strongly recommends that QC be done under the supervision of a qualified medical physicist. The qualified medical physicist may be assisted by properly trained individuals in obtaining data, as well as other aspects of the program. These individuals should be approved by the qualified medical physicist, if available, in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The qualified medical physicist should review, interpret, and approve all data. If it is not possible for a qualified medical physicist to perform the tasks designated for a medical physicist, these tasks may be performed by other appropriately trained personnel with ultrasound imaging equipment experience. These individuals must be approved by the physician(s) directing the clinical ultrasound practice. "

AIUM

- Many facilities do not have a medical physicist or biomedical engineer available to do ultrasound QA procedures. Here, a sonographer, physician, or other qualified staff member usually is designated to organize and run the program.

Partner up!

- There are many opportunities to work with physicians and sonographers
  - It will help us better understand what their needs
- Sonographers usually are familiar with complex ultrasound equipment and how to set it up properly for scanning.
- Understanding what a physician is looking for is extremely valuable to developing a useful quality control progrram

Evaluation of new products

- Great opportunity to work closely with your physicians and so your value
- What does the physician or sonographer want to see? What are their issues? Where is their current piece of equipment lacking? Will a new unit solve these issues?

Evaluation of new products

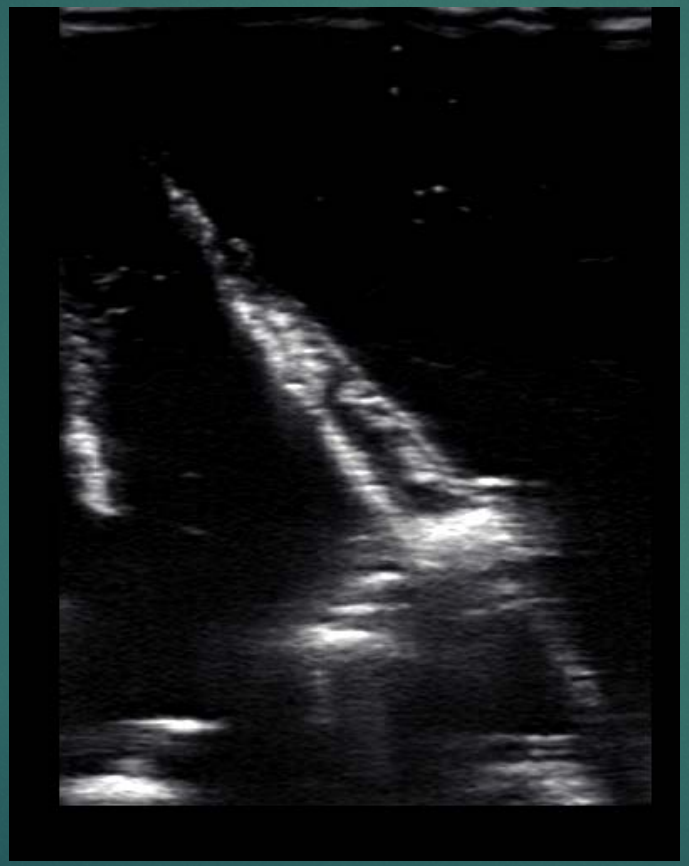
Physicians were unable to view the needle during biopsy

Will the next version of the same unit solve the problem?

Evaluation of new products

Compare vendors

Does a different vendors unit solve the problem?



Evaluation of new products

We were able to help physicians make a case as to why higher quality ultrasound is need!

- “The entire procedure from start to finish took me 18min !! That is remarkable (it is non unheard of for this procedure in the absence of high quality ultrasound to take 2 - 3 hours!) and that is solely due to the superior imaging of [this unit] allowing me to visualize the structures and needle clearly and gain access in a single pass. “

  “This new unit not only saved time for me and the IR techs and nurses but it saved anesthesia time for the patient, it reduced fluoroscopy dose to the patient, and reduce the amount of needle sticks into the liver greatly reducing bleeding risk for the patient.”

  “This is a textbook case of why high quality ultrasound is needed in the IR suite. It unquestionably allows us to deliver higher quality and safer care to the patients”

Summary

- Setting up and maintaining an equipment QA program is straight forward
- There are great references that can guide your practice in determining where you can add value
- We are headed toward a much more objective approach to ultrasound quality control
- Working closely with a team of sonographers, physicians, engineers can provide a great benefit
- There are many opportunities for improved image quality!!!

Thank you!

QUESTIONS?