

AAPM Meeting
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Diagnostic Ultrasound QA: Overview of Methods and Accreditation Updates



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Outline

- Introduction
- ACR ultrasound accreditations
- Ultrasound QC testing procedures
- Efficacy of ultrasound QC program

- The goal of an ultrasound quality assurance program is to maintain clinical ultrasound imaging equipment at an optimal and consistent level of performance.
- One crucial aspect of such programs is to include comprehensive quality control (QC) testing so equipment defects can be detected and corrected before they affect clinical outcomes.

Ultrasound Phantoms

Tissue-mimicking


- Speed of sound propagation
- Attenuation coefficient
- Backscatter coefficient (echogenicity)
- Nonlinearity parameter (B/A)
- Shear wave elasticity properties
- Thermal properties for HIFU

Water-based versus rubber-based

- Caution about phantom desiccation
- Caution about sound speed effect



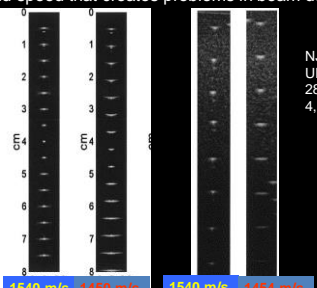
Water-based: Phantom Desiccation



- Water-based phantom has a potential dehydration problem over time.
- This problem can be minimized by properly handling the phantom.

Rubber-based: Sound Speed Effect

- No phantom desiccation; thus good for long-term consistency tests
- Slower sound speed that creates problems in beam defocusing



Q Chen and JA Zagzebski, UMB, 30(10):1297-306, 2004

NJ Dudley et al, UMB, 28(11-12):1561-4, 2002



Various Levels of QC Testing

	Testing Time	Testing Frequency	Testing Personnel
Level 1	•Quick check; •no special tool needed;	Daily or weekly or monthly	By ultrasound system users and overseen by medical physicists
Level 2	Quick QC tests with a simple phantom;	Quarterly or semi-annually	By ultrasound system users and overseen by medical physicists
Level 3	Comprehensive QC tests with phantoms;	Annual or every two years	By medical physicists IEC 62736

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- Ultrasound QC testing procedures
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ACR Accreditation
www.acr.org

- Breast Ultrasound Accreditation Program (including Ultrasound-guided Breast Biopsy)
- General Ultrasound Accreditation Program
 - Obstetrical
 - General
 - Combination of the above
 - Gynecological
 - Vascular
- ACR QC requirements are same now for both ultrasound accreditation programs
- Includes descriptions of acceptance testing, annual survey, continuous QC, and preventative maintenance
- There is no ACR designated ultrasound phantom
- There is no ACR ultrasound QC manual

Breast Ultrasound Accreditation Program Requirements	
Ultrasound Accreditation Program Requirements	
OVERVIEW MANDATORY ACCREDITATION TIME REQUIREMENTS 2 PERSONNEL QUALIFICATIONS INTERPRETING PHYSICIAN 3 SONOGRAPHER TECHNOLOGIST 3 EQUIPMENT QUALITY CONTROL ACCEPTANCE TESTING 4 ANNUAL SURVEY 4 QUALITY CONTROL TESTS 7 PREVENTATIVE MAINTENANCE 9 QUALITY ASSURANCE PHYSICIAN PEER REVIEW REQUIREMENTS 9 OXYGEN SAT. ULTRASOUND/ELIOT/BREAST BIOPSY AC 9 REPORTING ACCREDITATION TESTING CLINICAL IMAGES 10 CLINICAL IMAGES - BREAST ULTRASOUND ACCREDITATION 10 CLINICAL IMAGES - ULTRASOUND/BIOPSY/BREAST BIOPSY AC 10 EXAM HISTORICAL DATA AND LABELING 10	OVERVIEW 2 MANDATORY ACCREDITATION TIME REQUIREMENTS 2 PERSONNEL QUALIFICATIONS 3 PHYSICIAN QUALIFICATIONS 3 SONOGRAPHER TECHNOLOGIST QUALIFICATIONS 3 QUALITY CONTROL 4 ACCEPTANCE TESTING 4 ANNUAL SURVEY 4 QUALITY CONTROL TESTS 7 PREVENTATIVE MAINTENANCE 9 QUALITY ASSURANCE 9 PHYSICIAN PEER REVIEW REQUIREMENTS 9 ACCREDITATION TESTING 10 CLINICAL IMAGES 10 CLINICAL IMAGES - BREAST ULTRASOUND ACCREDITATION 10 CLINICAL IMAGES - ULTRASOUND/BIOPSY/BREAST BIOPSY AC 10 REPORTING OF RESULTS 10 ACCREDITATION 10
http://www.acr.org/Quality-Safety/Accreditation/Ultrasound	

ACR Continuous QC		Routine QC	
QC Test	Description	Minimum Frequency	
1. Physical and Mechanical Inspection	Assures the mechanical integrity of the equipment, and the safety of patient and operator.	Semiannually	
2. Image Uniformity and Artifact Survey	Identifies the presence of artifacts, often axial or lateral streaks in scans of uniform sections of a phantom. The use of "in-air" images (i.e., images acquired without the use of gel or phantom) may also be useful in detecting superficial artifacts. All transducer ports on each scanner should be tested using at least 1	Semiannually	
3. Geometric Accuracy (mechanically scanned transducers only)	Commonly involves use of the scanner calipers to measure known distances between test targets. Measurement is required only in the mechanically scanned directions.	Semiannually	
4. Ultrasound Scanner Electronic Image Display Performance	Maintaining the performance of the image display is critical for providing the greatest diagnostic benefit of the scanner. 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, presence of pixel defects, and overall image quality. These evaluations are typically performed using specialized test pattern images. See ACR Technical Standard for Electronic Practice of Medical Imaging for additional information on tests and testing methods.	Semiannually	
5. Primary Interpretation Display Performance*	Primary diagnostic displays may be electronic soft-copy displays on a PACS workstation or hard-copy films. Display characteristics that are evaluated may include gray scale response and luminance calibration, presence of pixel defects, and 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 for additional information on tests and testing methods. (* Only required if located at the facility where ultrasound is performed.)	Semiannually, or as judged appropriate based on the specific display technology, or prior QC testing data	

ACR Continuous QC Program (Level 1&2)

- A continuous QC program is essential to identify problems before the diagnostic utility of the equipment is impacted.
- To be performed by trained sonographers or service engineers
- Semi-annual
- Any issue revealed by the continuous QC should trigger more advanced testing
- List of tests:
 1. Physical and Mechanical Inspection
 2. Image Uniformity and Artifact Survey
 3. Geometric Accuracy (mechanically scanned transducers only)
 4. Ultrasound Scanner Electronic Image Display Performance
 5. Primary Interpretation Display Performance

Optional

ACR Acceptance Testing

- To be done before clinical usage
- Should be comprehensive to provide complete baseline for comparison with future test results
- Include new system, new transducer, major repair and major equipment upgrade as well as an existing equipment pulled from storage

Optional

ACR Annual QC Program (Level 3)

- Effective June 1, 2014, QC documentation is required.
- Annual survey reports and corrective actions must be documented and provided as part of accreditation application.
- The required QC tests must be performed at least annually on **all** machines and transducers in routine clinical use.
- To be performed by a qualified medical physicist or designee

Required

Question:

For ACR ultrasound accreditation, who is eligible to perform the required annual survey?







1. A medical physicist
2. A service engineer
3. A sonographer
4. A physician
5. All of the above

Answer 5. all of the above

(<http://www.acr.org/Quality-Safety/Accreditation/Ultrasound>)

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.

ACR Annual QC Program (Level 3)

- List of tests:
- 1. Physical and Mechanical Inspection 
- 2. Image Uniformity and Artifact Survey 
- 3. Geometric Accuracy (optional) 
- 4. System Sensitivity 
- 5. Ultrasound Scanner Electronic Image Display Performance 
- 6. Primary Interpretation Display Performance 
- 7. Contrast Resolution (Optional)
- 8. Spatial Resolution (Optional)
- 9. Evaluation of QC Program (if applicable)

Required

Outline

- Introduction
- ACR ultrasound accreditations
- **Ultrasound QC testing procedures**
- Efficacy of ultrasound QC program

1. Physical and Mechanical Inspection

- to assure mechanical integrity and patient safety

Transducer

- Cables
- Housings
- transmitting surfaces
- Plug-in easy and secure?
- Prongs bent or loose?

Power Cord

- Cracks?
- Discoloration?
- Damage?

System

- Monitor clean?
- Monitor no scratch?
- Dust filter clean?
- Wheels moved smoothly?
- Wheel locks secure?
- Accessories secure?

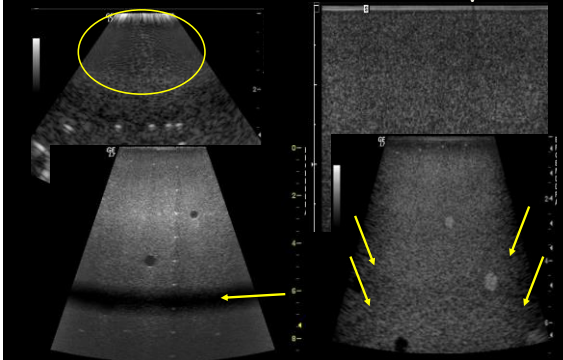
Operator's Console

- Buttons and knobs
- Burnt out lights?
- Any cracks?

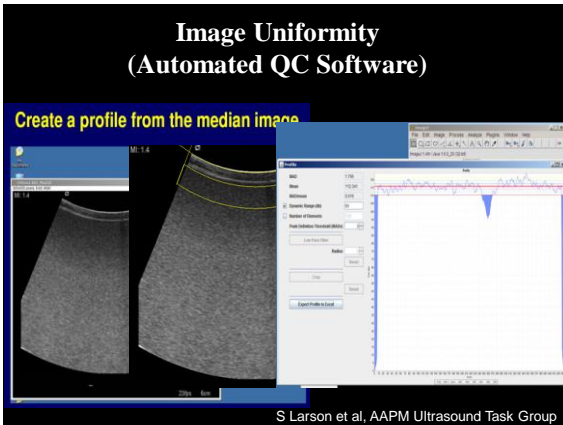
Examples of deficiencies revealed by visual inspection



2. Image Uniformity and Artifact Survey







Debugging uniformity artifacts

- *Many artifacts seen are not reproducible (e.g. due to dirty contacts in connector)*
- *Artifacts may be due to problems with the probe (elements, conductors, connector) or scanner (port, components of data channel)*
- *Want to be sure we're dealing with a real equipment problem, and ordering repair or replacement of the right component*

()

Nicholas Hangiandreous, AAPM 2013 Annual Meeting

Debugging uniformity artifacts

- When an artifact is initially noted, try...
 - Assuring good coupling to the phantom
 - Checking for dirt/debris on probe face, probe connector or scanner port
 - Inspect equipment for dirt, etc
 - Remove and re-seat probe in same scanner port
 - Blow out probe connector & scanner port with canned air
 - Checking different combinations of probes and ports (and scanners if possible)
 - Rebooting the scanner, and retesting
 - Flexing the probe cable to assess artifact stability...

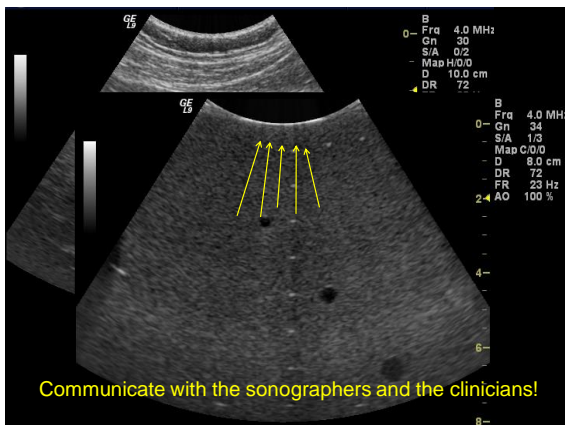
Nicholas Hangiandreous, AAPM 2013 Annual Meeting

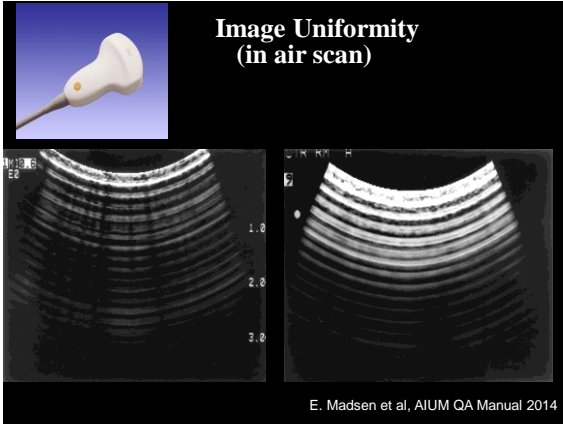
Performance criteria for uniformity artifacts (and other tests): When to fix or replace?

- *Risk versus cost equation can be very subjective & can potentially vary over time*
- These factors should be considered:
 - Patient and operator safety
 - Abrasion or pinching, electrical, infection/cleaning
 - Risk of incorrect diagnosis

(Mårtensson M, Olsson M, Segall B, et al. High incidence of defective ultrasound transducers in use in routine clinical practice. Eur J Echocardiogr 2009, 10:389-94.)

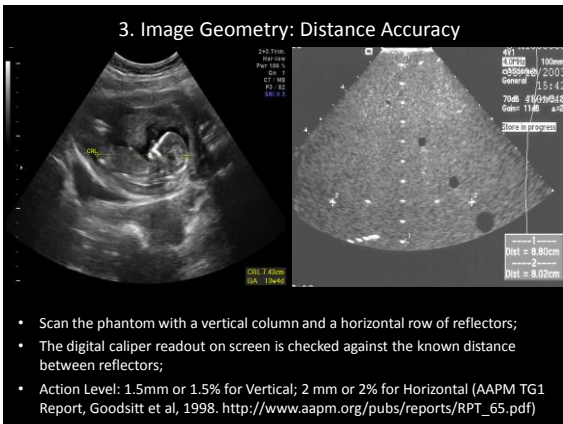
Nicholas Hangiandreous, AAPM 2013 Annual Meeting





Question: Must all transducer ports be checked for ACR accreditation?
Answer: Ideally each transducer and port should be tested. In the case of single probe, it is likely left plugged into the same port all the time, and other ports are not used. Due to this, not testing the other ports would be acceptable.

<http://www.acr.org/Quality-Safety/Accreditation/Ultrasound>



More Image Geometry

- 3-D calibration
- Extended FOV

Standard Methods for Calibration of 2-Dimensional and 3-Dimensional Spatial Measurement Capabilities of Pulse Echo Ultrasound Imaging Systems

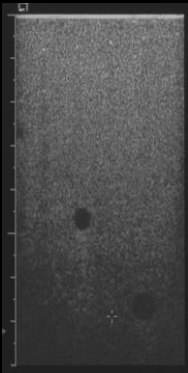
$Rh1 = lhm1 / h1$

$Rh1 = lhm1 / h1$

AIUM 2004



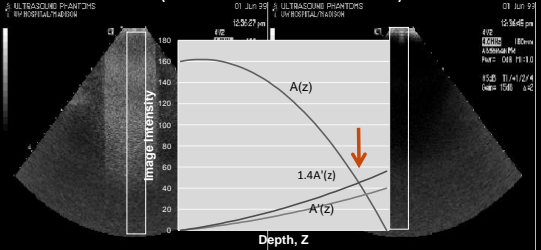
4. System Sensitivity/Penetration



This test should be done with following settings:

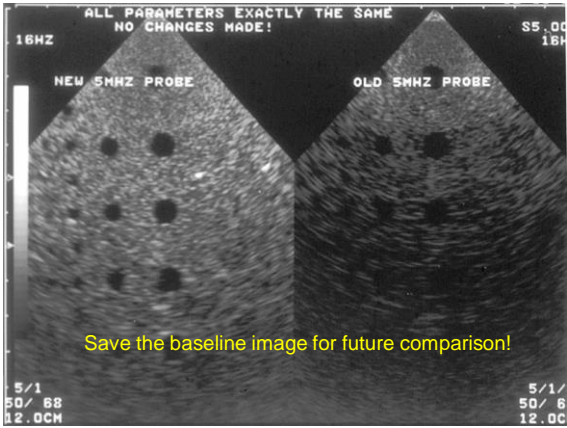
- maximum transmit power,
- proper receiver gain and TGC that allows echo texture to be visible in the deep region,
- transmit focus at the deepest depth.

System Sensitivity/Penetration (Automated QC Software)



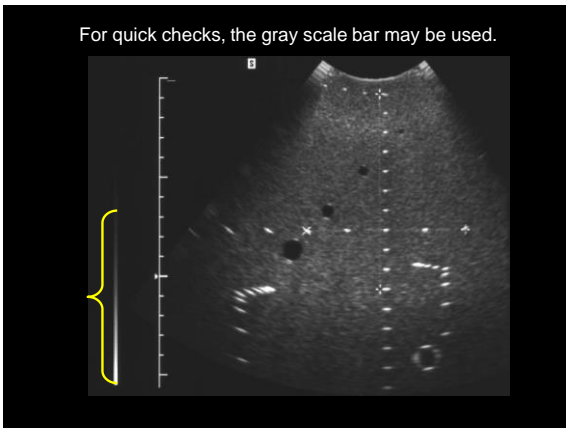
• Action Level: >0.6 cm from baseline (AAPM TG1 Report, Goodstitt et al, 1998. http://www.aapm.org/pubs/reports/RPT_65.pdf)

E. Madsen et al, AIUM QA Manual 2014



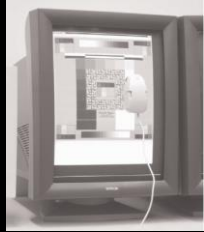
5. Ultrasound Scanner Electronic Image Display Performance

- Use the built-in test patterns on ultrasound scanner
- Reference to "ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging"
- QC: Verify luminance response; Visual assessment of general display quality; Artifact survey



6. Primary Interpretation Display Performance

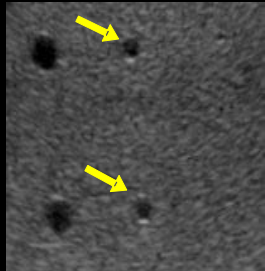
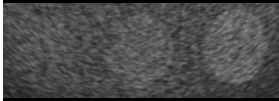
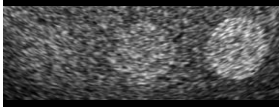
- This means the workstation monitors in the reading room for ultrasound imaging diagnosis
- This doesn't include those remote workstations
- This also includes the hard copy devices



AAPM TG-18 Report, 2005

7. Contrast Resolution (optional)

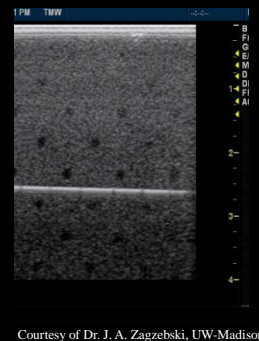
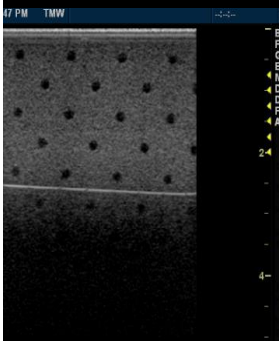
- Low contrast lesions
- Anechoic targets
- Cylindrical targets vs spherical targets



Spherical Lesion Detectability

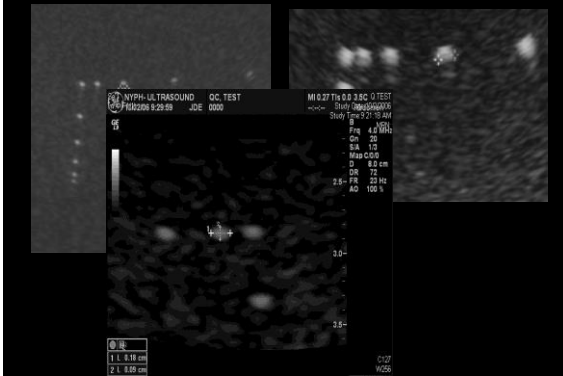
1 1/2 D (Matrix) Transducer

Conventional Linear Array Transducer



Courtesy of Dr. J. A. Zagzebski, UW-Madison

8. Spatial Resolution (optional)



9. Evaluation of QC Program

- 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
- Enables a comparison of QC practices with those of other ultrasound sites

Facility UAP # Facility BUAP # Survey Date

Evaluation of Site's Routine QC Program

Test	Minimum Frequency	Pass/Fail	Comments
1. Physical and Mechanical Inspection	semiannually		
2. Image Uniformity and Artifact Survey	semiannually		
3. Geometric Accuracy (mechanically scanned transducers only)	semiannually		
4. Scanner Electronic Image Display Performance:	semiannually		
5. Image Integration Display Performance**	semiannually		

* If located at the facility where ultrasound is performed
** Semiannually, or as judged appropriate based on the specific display technology, or prior QC testing data

Specific Comments:

<http://www.acr.org/Quality-Safety/Accreditation/Ultrasound>

**Annual System Performance Evaluation Report
Ultrasound/Breast Ultrasound Equipment Evaluation Summary**

Site:

Facility UAP #: Report Date:

Facility BUAP #: Survey Date:

System Manufacturer: Model:

System SN: Serial ID:

Building/Room #:

Medical Physician (or designee):

Signature:

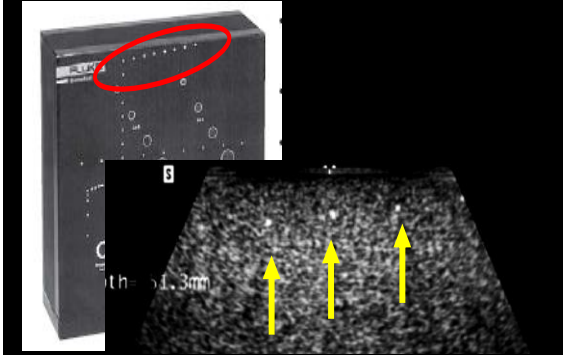
Equipment Evaluation Tests

Test	Pass/Fail	Comments
1. Physical and Mechanical Inspection		
2. Image Uniformity and Artifact Survey		
3. Geometric Accuracy		
4. System Sensitivity		
5. Scanner Electronic Image Display Performance		
6. Primary Integration Display Performance*		
7. Contrast Resolution (Optional)		
8. Spatial Resolution (Optional)		

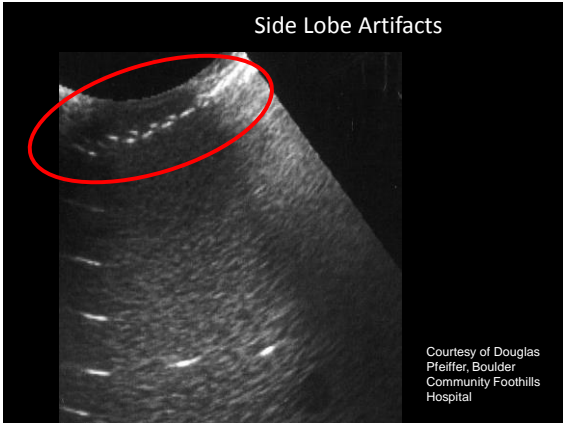
* If located at the facility where ultrasound is performed

Medical Physician's (or designee's) Recommendations for Quality Improvement:

More QC Tests Not on ACR List:
Ring Down: Can the targets near surface be detected?



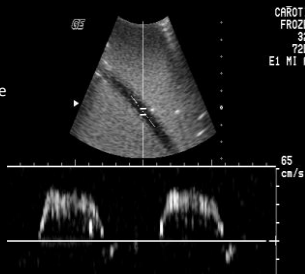
Side Lobe Artifacts



Ultrasound Doppler QC Testing

Doppler QC tests include

- Doppler signal sensitivity;
- Doppler angle accuracy;
- Color display and Gray-scale image congruency;
- Range-gate accuracy;
- flow readout accuracy.



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Efficacy of Ultrasound QC Tests

- NM Donofrio et al, JCU 12: 251-260; 1984
(They found QC tests such as depth of penetration, axial resolution, gray scale efficacious.)
- SC Metcalfe et al, BJR 65: 570-575; 1992
(They found poor correlation between subjective operator assessment and QC parameters including lateral resolution, dynamic range and slice thickness.)
- NJ Dudley et al, UMB 22:1117-1119; 1996
(They emphasize the importance of rigorous testing of circumference measuring calipers in obstetric ultrasound applications.)
- NJ Dudley et al, EJU 12: 233-245; 2001
(The analysis of an ultrasound QA program results lead to adjust of testing frequency.)

Efficacy and Sensitivity of Current QC

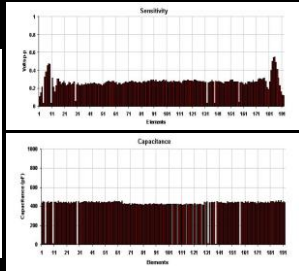
- Four-year experience with a clinical ultrasound quality control program (NJ Hangiandreou et al, Ultrasound Med Biol (2011)37:1350-1357)
- More than 45 scanners and 265 transducers were included.
 - QC frequency was semi-annual at the beginning and quarterly towards the end of the four-year study period.
 - 88.2% of the failures were transducers and the rest scanner components.
 - The phantom uniformity evaluation detected 66.3% of all failures.
 - The mechanical integrity check detected 25.1% of all failures.
 - Depth of penetration and distance accuracy tests were not effective in detecting equipment failures.

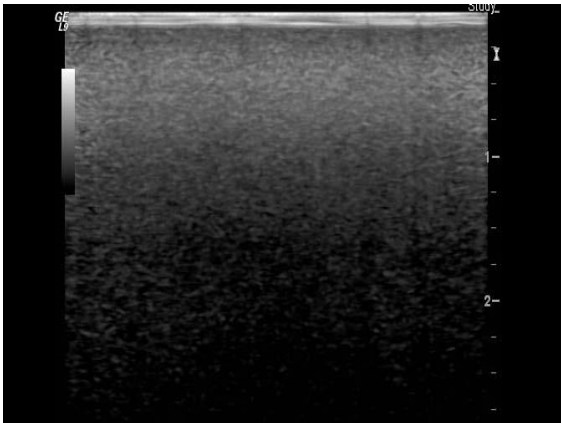
Efficacy and Sensitivity of Current QC

If the transducer defect is the main cause of ultrasound system performance degradation, tests should be done periodically to check all the transducers.



<http://www.mides.com>





Efficacy and Sensitivity of Current QC

- Studies on ultrasound transducer testing (M Martensson et al, Eur J Echocardiogr (2009)10:389-394 and (2010)11:801-805)
- Used the transducer testing device on annual basis in 13 clinics at 5 hospitals in the Stockholm area.
 - Initial failure rate of 39.8% was found among transducers in routine clinical practice.
 - Three years after the introduction of annual transducer testing, the failure rate was lowered to 27.1%.
 - It is difficult for the user to realize when the transducer function is deteriorating.
 - Main causes for transducer failure: transducer handling, workload.
 - Transducer failure happened to both newer and older ones.

Efficacy and Sensitivity of Current QC

Accuracy of Volumetric Flow Rate Measurements (K Hoyt et al, J Ultrasound Med 2009; 28:1511-1518)

- 5 ultrasound scanners, 3 experienced operators, 1 Doppler flow phantom and control system
- Flow rate from 100 – 1000 ml/min.
- Accuracy is better at lower flow rate
- Some scanner is poorer than others in flow rate accuracy
- Doppler QC is needed to ensure accurate flow rate measurements

The scatter plot shows Measured Volumetric Flow (ml/min) on the y-axis (0-1200) and True Volumetric Flow (ml/min) on the x-axis (0-1000). Five data series (A-E) are plotted, showing a strong positive linear correlation between measured and true flow rates.

AIUM Accreditation

www.aium.org

- Ultrasound practices in various specialties:**
 - Abdominal/General
 - Breast
 - Gynecologic
 - Urologic
 - Head/Neck (start 1/1/2015)
 - Dedicated Musculoskeletal
 - Dedicated Thyroid/Parathyroid
 - Fetal Echocardiography
 - Obstetric or Trimester-Specific Obstetric
- Ultrasound equipment quality assurance:**
 - QA Program should be in place.
 - Routine calibration is required at least once a year.
 - Practices must meet or exceed the AIUM quality assurance guidelines.

Routine Quality Assurance for Diagnostic Ultrasound Equipment
aium

Examples: Level 1 QC Tests

Failure in Level 1 tests may activate level 2 or level 3 tests

Section A: Cleanliness and Safety						
Task	Personnel	Minimum Frequency				Mandatory or Recommended
		Multidaily	Daily	Weekly	Monthly/Annually	
A.1	Sonographer		X			Mandatory
A.2	Sonographer		X			Mandatory
A.3	Sonographer			X		Mandatory
A.4	Sonographer	X				Mandatory

Section B: Image Display and Performance						
Task	Personnel	Minimum Frequency				Mandatory or Recommended
		Multidaily	Daily	Weekly	Monthly/Annually	
B.1	Sonographer			X		Mandatory
B.2	Sonographer			X		Mandatory
B.3	Sonographer			X		Mandatory
B.4	Sonographer		X			Mandatory

AIUM Routine QA for Diagnostic Ultrasound Equipment 2008

Section B: Image Display and Performance							
Test	Personnel	Minimum Frequency					Mandatory or Recommended
		Multiplicity	Daily	Weekly	Monthly	Annually	
B.1	Sonographer		X				Mandatory
B.2	Sonographer		X				Mandatory
B.3	Sonographer		X				Mandatory
B.4	Sonographer		X				Mandatory
B.5	Physicist, engineer, or sonographer					X	Mandatory
B.6	Physicist, engineer, or sonographer					X	Mandatory
B.7	Physicist, engineer, or sonographer					X	Mandatory
B.8	Physicist, engineer, or sonographer					X	Recommended
B.9	Physicist, engineer, or sonographer					X	Mandatory

Standards and Guidelines

- AIUM**
- AIUM Quality Assurance Manual for Gray-Scale Ultrasound Scanners, 1995, updated in 2013.
 - Routine Quality Assurance for Diagnostic Ultrasound Equipment, 2008.
 - Recommended Ultrasound Terminology, Third Edition, 1996; revised 2008.
 - Performance Criteria and Measurements for Doppler Ultrasound Devices: Technical Discussion – 2nd Edition, 2002; reapproved 2007.
 - Standard Methods for Calibration of 2D and 3D Spatial Measurement Capabilities of Pulse Echo Ultrasound Imaging Systems, 2004.

- AAPM**
- Quality assurance tests for prostate brachytherapy ultrasound systems: Report of TG 128, 2008. Med Phys 35(12)
 - Real-time B-mode ultrasound quality control test procedures, Report of Ultrasound TG #1, 1998. Med Phys 25(8)
 - Pulse echo ultrasound imaging systems; performance tests and criteria, AAPM Report No. 8, 1980.

Standards and Guidelines

- ACR**
- ACR technical standard for diagnostic medical physics performance monitoring of real time ultrasound equipment, Revised 2011 (Resolution 3).
- IPSM**
- Routine Quality Assurance of Ultrasound Imaging System, The Institute of Physical Sciences in Medicine, Ultrasound and Non-Ionising Radiation Topic Group, chaired and edited by Price R, 1995.
 - Testing of Doppler Ultrasound Equipment, edited by PR Hoskins, SB Sherriff and JA Evans, 1994.

Standards and Guidelines

- IEC/TR 60854 Ed. 1.0 (1986): Ultrasonics – Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment
- IEC/TS 61390 Ed. 1.0 (1996): Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications
- IEC 61391-1 Ed. 1.0 (2006): Ultrasonics – Pulse-echo scanners – Part 1: Techniques for calibrating spatial measurement systems and measurement of systems and measurement of system point-spread function response
- IEC 61391-2 Ed. 1.0 (2010): Ultrasonics – Pulse-echo scanners – Part 2: Measurement of maximum depth of penetration and local dynamic range
- IEC 61685 Ed. 1.0 (2001): Ultrasonics – Flow measurement systems – Flow test object
- IEC 61895 Ed. 1.0 (1999): Ultrasonics – Pulsed Doppler diagnostic systems – Test procedures to determine performance
- IEC/TC 62558 Ed. 1.0 (2011): Ultrasonics – Real-time pulse-echo scanners – Phantom with cylindrical, artificial cysts in tissue-mimicking material and method for evaluation and periodic testing of 3D-distributions of void-detectability ratio (VDR)

ANY QUESTIONS?
OR
COMMENTS?



References

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