Ultrasound Quality Control: A Practical Overview of Tests, Methods, and ACR Accreditation Requirements

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Outline of topics

> Overview of new QC requirements in the ACR Ultrasound and Breast Ultrasound accreditation programs

Annual survey test methods
 Routine QC test methods
 Does QC testing add value in ultrasound?
 Conclusions



New QC requirements in the ACR Ultrasound and Breast Ultrasound accreditation programs

Effective June 1, 2014

- Includes acceptance testing, annual performance survey, routine QC, and preventive maintenance
 - Maximize the value of QC investment
- > Application & renewal submissions require annual survey reports
- Physicist involvement is "strongly recommended"

Ultrasound Accreditation

Program Requirements



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Specific tests are required for annual survey and routine QC

- All probes must be tested
- Acceptance test ~ annual survey tests
- An Ultrasound QC Manual does not yet exist
 - Specific testing methods are not prescribed (subjective and objective methods are acceptable)
 - Use of phantom(s) or test object(s) is required, but no specific vendor or model is given, and custom test objects are acceptable
 - No specific pass/fail performance criteria are prescribed

Breast Ultrasound Accreditation Program Requirements



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Overview

The American College of Radiology's Breast Ultrasound Accreditation Program provides facilities performing breast ultrasound and ultrasound-guided breast biopsies peer review and constructive feedback on their staff's qualifications, equipment, quality control (QC), quality assurance (QA), accuracy of needle placement and image quality. The Breast Ultrasound Accreditation Program can accommodate a variety of practice settings. A facility that performs only breast ultrasound should apply for breast ultrasound accreditation; a facility that performs both breast ultrasound and ultrasound-guided breast biopsies must also apply for the Ultrasound-Guided Breast Biopsy Module.

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Annual survey tests

	Annual System Performance Evaluation					
	QC Test	Description				
1.	Physical and Mechanical Inspection	Assures the mechanical integrity of the equipment, and the safety of patient and operator.				
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.				
3.	Geometric Accuracy	Commonly involves use of the scanner calipers to measure known distances between phantom test targets in the axial and lateral directions. Other tests of geometric accuracy are acceptable, e.g. verifying accuracy of the pixel size calibration in the image header.				
4.	System Sensitivity	Methods relying on visual determination of the maximum depth of visualization of speckle patterns or phantom targets, and quantitative measurements of signal-to-noise ratio (SNR), have been reported.				
5.	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 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 <u>ACR Technical Standard for Electronic Practice of Medical Imaging</u> .				
6.	Primary Interpretation Display Performance*	Primary diagnostic displays may be electronic soft-copy displays on a PACS workstation or hard-copy films. 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 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 <u>ACR Technical</u> <u>Standard for Electronic Practice of Medical Imaging</u> . (* Only required if located at the facility where ultrasound is performed.)				
7.	Contrast Resolution (Optional)	The use of both anechoic and low contrast echogenic targets has been suggested, as has the use of 2D cylindrical targets and 3D spherical targets.				
8.	Spatial Resolution (Optional)	Should be measured in the axial, lateral, and elevational directions. Various approaches have been described for these measurements via visual interpretation of groups of phantom pin/fiber targets and using computer-based algorithms to measure pin dimensions ¹⁻⁴ .				
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, and enables a comparison of QC practices with those of other ultrasound sites.				

Annual survey test methods

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Physical and mechanical inspection

Scanner

- Wheel locks
- Monitor bezel
- Keyboard
- Power cable
- Probe ports
- Ancillary equipment (auxiliary display, probe tracking system, etc)
- etc

Probes

- Face
- Handle / housing
- Cable connection to handle, strain relief
- Cable
- Connector
- etc

Examples



Power Cord Pulled



Control Panel Cracked



Inoperable wheel locks



Grommet/Housing Separation



Examples

Grommet/Housing Separation



Lens Delamination



Loose Scan Head



Separation of Handle

Pass / fail decisions are often subjective



Lens Pitting



Partial Cable Tear



Bent Connector Pins



Lens Peeling / Delamination



Complete Cable Tear



Connector Damage



Cracked Housing/Lens Damage



Peeling of Housing Layer





Image uniformity & artifact survey

- > Most effective test for identifying problems
- Scan a test object/phantom
 - Optimize scan parameters for greatest sensitivity
 - Time-varying phantom speckle signal
- View live scan images
 - Debug any artifacts observed
- Export phantom & in-air clips
 - Retrospectively cine review
 - Process → median or mean image

> Assess severity of detected artifacts, and determine needed action



Phantoms

















Also...

Bi-plane prostate probe Automated breast volume scanner Endoscopic US probe Scan parameters for high sensitivity uniformity assessment Maximize acoustic output > Highest fundamental frequency Minimum depth that utilizes full array > Single, superficial transmit focal zone > Dynamic range at/near minimum Gain and TGC adjusted to provide ~uniform field with good signal at probe face Disable spatial compounding



- Median/mean image > live scanning >> still image in terms of artifact detection sensitivity
- Artifacts of concern are typically superficial and oriented along axial direction
- Hypoechoic artifacts more common than hyperechoic artifacts



Intrinsic uniformity artifacts

Patterns of signal non-uniformity seen in multiple instances of the same probe model

- Large scale non-uniformities
- Corduroy, moire, cross-hatch, etc, patterns
- > These are not QC (or acceptance test) failures

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

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...

Cable flex artifact - Example

Cable flex artifact - Example

All in-air and phantom clips acquired in a span of 3 minutes Are these problems prone to ~rapid decline?

Typical behavior of uniformity artifacts over time

- Analyzed uniformity QC findings for 210 probes over a period of 2.5 years
 - Visual artifact detection from median images
 - Subjective, visual assessment of artifact severity
 - Scale: P, P1, P2, P3, F -- considering artifact visibility (air, phantom, & clinical images), location, size, number

Primary question: How does artifact severity change over time?

Reference: Stekel S, Hangiandreou N, Tradup D. Analysis of Uniformity Artifacts Detected During Clinical Ultrasound Quality Control. J Ultrasound Med 32(suppl):S109, 2013.

> Results

58 probes with artifacts were detected

- 22 probes failed at initial artifact detection, ~spontaneous
- <u>36</u> probes initially detected with "subcritical" artifacts
 - <u>9</u> probes with "subcritical" initial severity scores (P1, P2, or P3) failed during the 2.5 yr study period
 - Time to failure ranged from 3-14 months (mean = 9.1 mo)
 - A pattern of progressive worsening was not seen, ~spontaneous
 - <u>27</u> probes with "subcritical" initial severity scores did not fail during the study
 - Observation time ranged from 0.5-16 mo (mean = 10.5 mo)
 - During 6 months after study period, 4 of these did fail
 - A pattern of progressive worsening was not seen

Conclusions

- Most failures were "spontaneous" (i.e. occurred after a previous "perfect" uniformity evaluation)
- Once detected, "subcritical" artifact severity remains stable
 - 25% failed within 3-14 months, but without gradual increases in severity (i.e. "spontaneously")
- No reliable trend of gradual progressive worsening of detected transducer artifacts was seen
 Implications for QC frequency?
- Limitation of the study
 - Subjective severity assessment

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.)

When to fix or replace?

> These factors should be considered (cont.):

- Use for procedures
 - Impact on consistent visibility of needle/device
- Visibility in clinical exams
 - Artifact contrast, size, position, number
 - Quality indicator of practice (patient, outside MD)
- Reduced functionality and effectiveness
 - Limited useful FOV
 - Spectral Doppler (?)
- Likelihood of rapid performance decline
- Service contract / financials

When to fix or replace?

- Practical impact to clinical ultrasound practice can be lessened by notifying users of the issue
 - Greater care when cleaning or disinfection
 - Avoid use of probe for procedures
 - Avoidance of problem regions of array
- Sonographers/MDs are used to recognizing and effectively dealing with many artifacts in every exam
- Discuss potential equipment failures with the practice

Example 1

Example 2

Example 2

<u>Geometric accuracy:</u> Axial and lateral directions

- Measure known axial (vertical) and lateral (horizontal) distances with scanner calipers
 - Verify image geometry & proper operation of scanner caliper tool

> Automated "distance" measurements

- Verification of image geometry/pixel size calibration
- Performance limits
 (Goodsitt et al, Medical Physics
 1998; 25:1385-406)

<u>Geometric accuracy:</u> Elevational direction, for 3D or 4D probes

> Performance limits

- Goodsitt et al, 1998, ≥lateral (potential acquisition errors)
- Scanner vendor specification

System sensitivity

Common approaches

- Visual DOP estimation
- Calculation of DOP from SNR vs depth curve falling to a specified threshold value
 - Variety of proprietary algorithms have been reported
 - IEC 61391-2
- Goodsitt et al provide recommended action
 & defect levels
 - Independent of target DOP value

Visual DOP estimation

Visually estimate greatest depth of reliable visualization of speckle → subjective, ~biased
Maintaining highly-consistent control settings is critical, and can be challenging (e.g. TGC)

> IEC DOP algorithm Obtain uniform phantom and in-air image pair SNR & DOP are calculated as follows:

$$SNR_{IEC}(d) = \sqrt{\frac{SN(d)^2}{N(d)^2} - 1}$$

d = distance from transducer face SN = mean pixel values from phantom image N = mean pixel values from in-air image

$$SNR_{IEC}(DOP) = 2$$

Vascular Center 03/25/11 12:38:41 PM	9L 7CP a DOP A p5 20110325 ¹ 228 051.dcm MI 0.5 Tis 1. DJ*0 of 91816 image pixels are >= 253	1 9L Small Pa	arts
TX7CP,PH5,DOP	9909 of 91816 image pixels are <= 2	FR - Frq - Gn - S/A - DR - DR - AO% - - - - - - - - - - - -	34 90 0/0 D/0 12.0 90 100
in-air N = noise		10- _	

> Nuances

- Using phantoms with targets
- Curved and sector/ vector images
- Number of pixels at each depth
- Filtering the SNR vs depth function
- Averaging DOP from multiple image pairs

> Gorny et al. Implementation and validation of three automated methods for measuring ultrasound maximum depth of penetration: application to ultrasound quality control. Med Phys. 2005 Aug;32(8):2615-28

> Stekel et al. Evaluation of the International Electrotechnical Commission Standard Technique for Measuring the Ultrasound Depth of Penetration. Presented at AIUM 2012.

<u>Ultrasound scanner electronic</u> image display performance

- Critical component of performance assessment: Ultrasound scanner monitor is effectively a primary diagnostic display device
- No requirements of specific tests
 - Reference to "ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging"
- Three main components of eval:
 - Verify luminance calibration
 - Visual assessment of general display quality
 - Artifact survey

Calibration and luminance measurement

- Measure luminance with photometer at ~3-5 grayscale levels
 - But may be limited in number of grayscale test patterns available on the scanner, especially older units
- Should be performed at a frequency appropriate to the specific display technology in use (auto calibration, stabilization), and previous QC data

Visual assessment of general display quality using a SMPTE or similar test pattern

- Visibility of contrast patches
- Image blur
- Geometric distortion
- Other display artifacts (e.g. banding, "tearing", etc)
- Many of these artifacts are more relevant to CRTs (which are becoming more and more uncommon)

> Artifact survey – Flat panel display pixel defects

- Dead (black) pixels
- Stuck (bright) pixels

TG18-UN80 Pattern Version 8.0, 12/01 Copyright © 2001 by AAPM TG18-UN10 Pattern Version 8.0, 12/01 Copyright © 2001 by AAPM

Primary interpretation display performance

- This most likely means PACS workstations, or dedicated US workstation (e.g. Siemens ABVS workstation)
- Testing only required for diagnostic workstations used for US exam primary interpretation, and located at same facility as the US scanner
- No requirements of specific tests
 - Reference to "ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging"
- Inclusion of display testing results obtained by PACS team or service group would be acceptable

Evaluation of (routine) QC program

Review of routine QC tests performed by sonographer (or service engineer)

- Recorded on a logbook form (provided by the physicist)
- Are tests being done on the desired schedule?
- Are tests being performed and interpreted correctly?

Da	.te:			Initials:				
Tra	neducor	Inventory		P=Pass F=Fa	i NA	=Not Applicabi Image Unit	le formi	ity and
Xducer Model (special location	Xducer ID	X ducer Serial	Xducer Located	Mechanical Inspection	4	Artifact Su Phan	rvey (tom)	(Air &
info)	_	Number	P/F	P/F	Ar	tifact Noted:	P/F	P/F
\$ 1-5					Air	Ph		
\$4-10					Air	Ph		
C1-5					Air	Ph		
M6C					Air	Ph		
9L					Air	Ph		
11L					Air	Ph		
ML6-15					Air	Ph		
L8-18i					Air	Ph		
IC5-9					Air	Ph		
	-				-			

Routine US OC: Transducer Evaluation (v1.0)

Transducer Inventory: The purpose of documenting the Transducer Inventory is to maintain an accurate count of an ultrasound scanner's assigned transducers (Xducer). The location of each assigned Xducer listed under the Transducer Inventory should be verified. Xducers that are shared between scanners and not stored with the assigned scanner should have a special location noted and it's presence verified. Xducer ID and serial numbers should be verified during the inventory check.

Physical & Mechanical Inspection: Assure the mechanical integrity of the equipment, and the safety of patient and operator, including assessments of: (1) cables are free of kinks and other damage; (2) connectors and contacts are free of damage; (3) connector lock is functional; (4) lens is free from damage and delamination.

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 transducer.

Geometric Accuracy: Elevational (3D transducers only)

RIC5-9

Scannor III.	- Vd	ncor D.	Reconstructed	Horiz, Dist	ance (cm)	D/F
Scanner ID. Mod	el:	Auter ID.	Measured	L.C.L.	U.C.L.	
RIC	5-9					

L.C.L.= lower control limit U.C.L= upper control

See Notes Page for any failed (F) items, or resuts marked with an asterisk ()

Mayo Clinic | Department of Radiology | Division of Medical Physics

Provides an opportunity for education and practice quality improvement

Routine QC tests

Likely performed by sonographer(s) in the clinical practice twice per year (quarterly testing is recommended)

Specific methods prescribed by medical physicist

	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 transducer.	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 <u>ACR Technical Standard for Electronic Practice of Medical Imaging</u> .	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 <u>ACR Technical Standard for</u> <u>Electronic Practice of Medical Imaging</u> . (* 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

Same as Annual Survey

Sample findings provided by physicist will be helpful

	Routine OC					
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Only needed for mechanically scanned probes (mechanical 3D4D probes; 360-deg probe?)

Testing only needed for the mechanically scanned direction (e.g. elevational/slice)

Dedicated, inexpensive test object and methods

	Routine QC						
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No requirements of specific tests

Visual inspection of test patterns (no photometer measurements)

Guidance from physicist regarding specifics of this evaluation will be helpful

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Routine QC test methods

Only required for PACS displays in same facility as scanner

No requirements of specific tests

Visual inspection of test patterns, as for scanner monitor evaluation

Physicist could recommend that no testing by the sonographers is needed, if adequate QC is being done by another group, e.g. PACS team

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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 <u>ACR Technical Standard for Electronic Practice of Medical Imaging</u> .	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 <u>ACR Technical Standard for</u> <u>Electronic Practice of Medical Imaging</u> . (* 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

Image uniformity & artifacts survey

Complexity of uniformity evaluation as done by physicist poses potential problems for sonographers (avoiding false-positives)

Methods with reduced sensitivity and increased efficiency compared with those used for annual survey may be advantageous

- Phantom
- Scan parameters
- Visual inspection during live scanning (versus processed images)
- Examples of significant and insignificant findings

Physicist will be essential to success of routine US QC program

- Provide straightforward, well-documented testing methods and results forms
 - Emphasize low-cost, easy-to-use phantoms & test objects
 - Provide good, hands-on training
- Document clear criteria for passing and failing test results, with examples
 - Also supply guidance for the types of results for which a physics consult is appropriate

Enable the ability to easily forward US images from the practice to the physicist for consultation

Does QC testing add value in ultrasound?

- > Experience at Mayo Rochester \rightarrow "Yes"
 - Acceptance testing
 - 45 scanners, 249 transducers and 1 US workstation
 - 3 vendors, 3 system models
 - Issues found with 6.7% of scanners, 12% of probes, and one 3D US workstation
 - Quality control testing
 - 45 scanners, 265 transducers
 - 4 vendors, 9 system models
 - Average annual failure rates of 10.5% (scanners) and 13.9% (probes) were observed over 4 year period

Conclusions

 New QC requirements in the ACR ultrasound and breast ultrasound accreditation programs
 Effective June 1, 2014

Goal: Maximize the value of QC investment

These requirements can be met without great investments of time or money

• Physicist involvement will be critical

Should have a positive impact on the quality of ultrasound practices

Conclusions

> Opportunities

- Continued development of objective, validated, testing methods
 - Improved availability of effective, efficient image processing and analysis software
 - Development of clinically-correlated performance benchmarks and failure thresholds
- Analysis of testing needs for additional scanner modes
 - Spectral and color Doppler
 - Elastography

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