

HTM's Critical Role In Ultrasound Accreditation

- Why It Matters To Departments And YOU!



Agenda

Beyond understanding the purposes and objective of accreditation, attendees will learn:

- Testing criteria that each board requires relative to ultrasound image quality
- Performing common tests using several transducer models
- Assessing transducer performance in the field per the various boards' requirements
- Acquiring and assembling Quality Control data required for accreditation
- Affordable tips to reduce your operational costs while maintaining accreditation standards



What is accreditation?

- A series of peer review processes that allow practices to demonstrate that they meet or exceed nationally recognized standards in the performance of and interpretation of diagnostic ultrasound examinations
- Why might a site seek accreditation?
 - Encourages providers of diagnostic ultrasound services to assess their strengths and weaknesses and initiate changes to improve their practices
 - Similar to a Continuous Quality Improvement model





What is accreditation?

- Accreditation, by any board, is purely voluntary
 - Costs: \$1500 \$4000
 - Not required by the CMS (Centers for Medicare & Medicaid Services) or any insurance provider
 - Can assist in filling certain requirements from CMS or insurance providers for performance standards (i.e. Health Grades, Medicare's Hospital Compare)
 - Typically, a department will select a single accreditation board, based upon their specialty
 - All departments on a site are not required to subscribe to the same accreditation board standards, i.e. a site's Radiology department may follow ACR, while its Echocardiology department may follow IAC
 - Today, we will introduce you to three popular boards: ACR, AIUM, IAC



What is accreditation?

- Common requirements for accreditation
 - Case study submissions
 - Personnel education, continued training, and experience levels
 - Document storage and record keeping
 - Policies and procedures safeguarding patients, ultrasound personnel, and equipment
 - Today, we will focus on the instrumentation practices and quality assurance for ultrasound transducers

Let's begin by reviewing basic transducer construction





• Lens

- Mechanical focus of ultrasound beams
- Single or multilayer materials
- Must be ISO 10993 compliant
- Matching layer(s)
 - Maximizes transmission of energy from crystal array to tissue by reducing reflection and increases spectrum of frequencies (bandwidth) emitted by transducer
 - Generally ¼ wavelength of center frequency of array in thickness





- Array
 - Converts electrical energy to mechanical energy (pressure wave) and vice versa
 - From 1 to thousands of individual elements/crystals
- Shielding
 - Reduces electro-magnetic interference
 - Typically around array and backing material
- Backing Material
 - Dampens crystal vibrations to reduce pulse duration which increases resolution





- Flex circuit
 - Flexible circuit board which connects the interconnect board to the individual elements
- Interconnect
 - Bridge between individual coaxial cables and flex circuit
 - May have multiplexing circuitry and beamforming circuitry
- Miniature coax
 - Used to transmit pulses and receive echoes
 - Model specific impedance and capacitance





- Strain relief
 - Reduces stress on main and coaxial cables
 - Allows for hundred of thousands of flexes throughout the lifecycle
- Cable jacket
 - Protects main transducer cable
- Main Cable
 - Contains 64-128 coaxial cables
 - Model specific shielding





Review ground rules for image testing

- Consistency between testing is key
 - **SAME** model/type of phantom between each assessment
 - IDENTICAL system settings/presets, i.e. every Philips C5-1 needs to be tested using the identical settings. Here are some suggested presets:
 - Linear probes: Vascular preset
 - Curved probes: Abdominal preset
 - Endo-cavity: OB present
 - Sector: Cardiac preset
 - Number of focal points should be *MINIMAL* (1-2)
 - **DISABLE** software corrections, for example:
 - Philips: X-res, Sono-CT, THI
 - GE: Crossbeam, Octave, CHI
 - Siemens: THI, SieClear, MultiHz



ACR: American College of Radiology

- History and Mission
 - Founded in 1924
 - "Professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science and professions of radiologic care"
 - Accreditation is available in the following fields: Nuclear Medicine & PET, Radiation Oncology, MRI, Ultrasound, and CT
 - Related to ultrasound, ACR can accredit: general ultrasound, breast ultrasound, stereotactic breast biopsy

Departments that are ACR accredited will display the logo to the right



https://www.acr.org/About-Us



ACR: Accreditation Requirements

- "The Ultrasound Accreditation Program involves:
 - Acquisition of clinical images
 - Submission of relevant physician reports corresponding to clinical images
 - Quality control documentation"



ACR: Quality Control

- "As part of the accreditation application, facilities must demonstrate compliance with the ACR requirements" for Quality Control, which can be met by completing the Annual Survey
 - Needs to be completed at least once within a 14 month period
 - Requirements:
 - "QC reports from the most recent annual survey performed by the medical physicist or designee"
 - "Documentation of corrective action if the annual survey identifies performance problems"
 - The ACR states that "tests of uniformity, geometric accuracy, system sensitivity and contrast and spatial resolution *must be made using an ultrasound phantom or test object"*



ACR: Annual Survey

- The Annual Survey, also called the System Performance Evaluation, consists of:
 - Physical and Mechanical Inspection (system & probes)
 - Image Testing:
 - Uniformity and Artifact Inspection
 - System Sensitivity
 - System display settings
 - Optional Testing:
 - Geometric Accuracy (system & probes)
 - Contrast Resolution (system & probes)
 - Spatial Resolution (system & probes)
 - Primary interpretation display performance (PACS workstation)





ACR – Annual Survey: Uniformity and Artifact Inspection

- Note image artifact in near field of image
 - Artifacts are typically hypoechoic vs hyperechoic



- Potential root causes for the artifact:
 - Probe array
 - A single missing or weak element *may* show small artifact
 - Probe cable
 - Typically 128 coaxial cables in main cable assembly
 - Probe pins/connector
 - Inspect regularly
 - Clean pin-less connector interfaces
 - Connector board
 - Inspect regularly
 - System Front End Board

ACR – Annual Survey: Geometric Accuracy (Optional)

- Geometric Accuracy (Optional)
 - System calipers are used to measure known axial, lateral and elevational distances within a test object





ACR – Annual Survey: System Sensitivity

- System sensitivity
 - "Measures the maximum depth of visualization of speckle patterns or phantom targets"
 - *Must use* consistent settings every time test is performed
 - **Best practice:** Photo-document system settings



ACR – Annual Survey: System Display Settings

System Display Settings

- Ensure contrast and brightness are set correctly
- Ensure no pixel defects
- Ensure proper focus (legacy CRT-based units)







ACR – Annual Survey: System Display Settings

- System display settings must be correct before making any image evaluations or adjustments
 - Adjust room lighting to typical scanning room intensity
 - Use system grayscale bar to adjust brightness bottom should be barely visible
 - Bars are graduated or step
 - Contrast is adjusted for "white whites" but not blooming

Ensure customer approves of and understands any changes made!



Pop Quiz!

Will adjusting the system's main display settings have any effect on the image presentation on a Picture Archiving and Communication System (PACS) display?





ACR – Annual Survey: Primary Interpretation Display

- Primary Interpretation Display Performance (Optional)
 - Same tests as system display but performed for on-site PACS workstations
 - Proceed with caution...



ACR – Annual Survey: Contrast Resolution (Optional)

- Contrast Resolution (Optional)
 - Ability to distinguish between two regions of similar echogenicity / amplitude
 - Use anechoic (absence of echoes) and low contrast echogenic (reflects sound waves) targets
 - Determine system and probe ability to distinguish between objects of similar and varying intensities



ACR – Annual Survey: Spatial Resolution (Optional)

- Spatial Resolution (Optional)
 - Lateral (X)
 - Ability to distinguish between two objects perpendicular to ultrasound beam
 - Varies with depth
 - Axial (Y)
 - Ability to distinguish between two objects parallel to ultrasound beam
 - Does not vary with depth
 - Elevational (Z)
 - Ability to distinguish between two objects perpendicular to scan plane (slice thickness)
 - Varies with depth
- Temporal Resolution
 - Ability to distinguish change over time





ACR: Quality Control Program

- Evaluation of QC Program (Optional)
 - 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 practices





ACR: Equipment Evaluation Summary Form

Equipment Evaluation Summary Form

The Annual Survey must include:

· System sensitivity and/or penetration capability.

· Image uniformity and artifact survey

· Electronic Image Display Performance and detail the results of the testing.

(Please refer to the Program Requirements for additional information.)

The Equipment Evaluation Summary Form may be used to detail the results of the Annual Survey. Please submit one form per transducer.

Note: Facilities can submit either this form (one per transducer) or a complete QC report from the system engineer/physicist. Facilities do not need to submit both.

UAP/BUAP#			Report Date:
System Manufacturer:		Model:	Survey Date:
System SN#		•	Transducer#
Medical Physicist/designee:			Title:
Signature:			
	Syst	em Sensitivity (Req	uired)
With system sensitivity se	t up for visualizing ec	hogenicity as deeply as p	ossible, what is the maximum depth
you can visualize the bac	kground echographic	pattern?	
	Markt	ne appropriate box.	
Less than 3 cm	□ 6 cm	9.5 cm	13 cm
3 cm	G.5 cm	10 cm	113.5 cm
	175 cm	11 m	15 cm
45 cm	□ 8 cm	11.5 cm	□ 16 cm
5 cm	3 5 cm	12 cm	
5.5 cm	9 cm	12.5 cm	
	U	NIFORMITY (Requir	ed)
With gains set to obtain a	uniform image, freez	e the image. Complete th	e questions regarding the uniformity of the
image by marking the app	propriate box using thi	s key:	
1) Agree 2) Disa	agree, slight non uni	formities present 3) Dis	agree, major non uniformities present
1) The average brightne	ss at edge of the scar	n is the same as the avera	age brightness in the middle.
D1	02 03		• •
2) There are no verticall	v or radially oriented s	shadows from array eleme	ent dropout.
	□2 □3		
3) There are no brightne	ess transitions betwee	n focal zones	
	2 3		
	Scanner Elect	tronic Image Display	Performance (Required)
			an and humines and therefore an an and
Display characteristics that	at are evaluated may	include gray scale respon	se and iuminance calibration, presence of
Display characteristics that defects, and overall image	at are evaluated may i e quality	include gray scale respon	se and iuminance calibration, presence of
Display characteristics that defects, and overall image	at are evaluated may i e quality	include gray scale respon	se and iuminance calibration, presence of
Display characteristics the defects, and overall image Completed	at are evaluated may i e quality	include gray scale respon	se and iuminance calibration, presence of



Revised: 12/22/16

ACR: Equipment Evaluation Summary Form

Primary Interpretation Display Performance (Opt	tional)	
Display characteristics that are evaluated may include gray scale response and luminan defects, and overall image quality	ce calibrat	ion, presence of pixel
Completed Not Completed NVA (Only required if located at the facility where ultrasound is performed.)		
ELECTRICAL AND MECHANICAL SAFETY AND CLEANLIN	IESS (Re	equired)
Are all cords and cables intact (no frays)?	YES	NO
Are all transducers intact without crack or delamination?	YES	NO
Are the transducers cleaned after each use?	YES	NO
Are the image monitors clean?	YES	NO
Are the air filters clean?	YES	NO
Are the wheel locks in working condition?	YES	NO
Are the wheels fastened securely to the US unit and do the wheels rotate easily?	YES	NO
Are all accessories (VCR, cameras, etc.) fastened securely to the US unit?	YES	NO

Corrective Action Required?

YES NO

If so, please describe:

Additional Comments:



ACR: Acceptance Testing

• Acceptance testing (optional) is performed when equipment is:

ACCEPTANCE

- New and being installed
- In storage and returned to service
- Image related assemblies repaired or replaced
 - This includes probes
- Includes all required tests in Annual Survey

ACR: Quality Control Program

- A Quality Control Program is in *addition* to the Annual Survey
 - ACR states these are optional but... then states "A continuous QC program is essential"
 - Includes:
 - Physical and Mechanical Inspection
 - Image Uniformity and Artifact Survey
 - Geometric Accuracy
 - Ultrasound Scanner Display Performance
 - Primary Interpretation Display Performance
 - Minimum frequency of QC Tests is semi-annually



ACR: Preventative Maintenance

- ACR states "regular preventive maintenance should be performed and documented by a qualified equipment service engineer following the recommendations of the equipment vendor"
 - OEM recommendations vary from several per year to not necessary



AIUM

- History and Mission
 - Established in 1952
 - "AIUM is a multidisciplinary professional association dedicated to advancing its mission by providing education, fostering best practices, and facilitating research."
 - Accreditation is only available for the ultrasound modality

Departments that are AIUM accredited will display the logo to the right



http://www.aium.org/aboutUs/constitution.aspx



AIUM: Quality Assurance Program

- All encompassing and is not the responsibility of a single individual
 - With respect to scanners and probes there are 20 total tasks
 - 15 need to be performed *daily* by end-users, these include:
 - System/transducer cleaning and hygiene
 - Daily physical and functional checks of the system/transducers
 - Weekly filter cleaning
 - The remaining 5 need to be performed annually by a *physicist, service* engineer or sonographer
- With respect to the imaging hardware and testing, the AIUM provides guidelines for:
 - Maintaining equipment

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- Acceptance criteria for image quality
- Performing tests and documenting test results



AIUM: Quality Assurance Program

- Visual inspection of the probe (daily inspection)
 - **Lens**: holes, cuts, missing sealant, bulges, air bubbles, separation in materials
 - **Housing**: cracks, separation, missing sealant, sharp edges
 - **Strain reliefs**: separation from housing, cuts, holes, excessive stiffness
 - **Cable**: cuts, holes, exposed wiring, roll-over damage, excessive stiffness
 - **Connector**: deformations, cracks, missing/malfunctioning hardware
 - **Pin-bank**: bent pins, corrosion, burn marks, excessive dust/debris





AIUM: Element or Channel Failure

- Also called image uniformity
- Purpose: Perform element-to-element or channel-to-channel comparison
- Visual Criteria
 - − Fine shadow (single channel) \rightarrow minor flaw
 - Multiple fine shadows or a wide shadow (multiple channels or element failures)
 → major flaw





AIUM: Element or Channel Failure

• Ranking and action levels

Ranking	Visual Criteria	Potential Impact	Action
1	No flaws are present	Operating as expected	No action required
2	One or two minor flaws are present	Considered operational and can be used for scanning	Inspect occasionally for possible additional deterioration over time
3	Three or more minor flaws are present	Borderline based upon location	Replace as soon as convenient
4	Major flaws are present	Unacceptable for clinical use	Remove from service immediately



AIUM: Element or Channel Failure

- Recommended scanner settings for testing
 - Frequency: *Highest* possible
 - Depth: Use a *shallow* field of view, such as 6cm for abdominal and sector transducers and 3cm for linear transducers
 - Focus: *Single* focal point located in the very near field
 - Gain: Adjust overall gain and TGC so that *mid-range* gray level exists over the entire image
 - Turn off all options such as harmonic imaging, spatial compounding and image smoothing as these mask probe and scanner deficiencies
 - Philips: THI, SonoCT and xRes
 - Siemens: THI, MultiHz and SieClear
 - GE: Octave, Crossbeam and CHI



AIUM: Maximum Depth of Penetration

- Also referred to visualization or relative penetration
- Purpose: Provides an indication of overall sensitivity of a scanner to detect weak signals
- *Must* use same model phantom for each inspection over-time
- *Must* use same preset for each individual probe model
- Best practice: Photo-document system settings



AIUM: Maximum Depth of Penetration

- Recommended scanner settings for testing
 - Preset: *Typical* for the probe type (suggest a factory default preset)
 - Frequency: Close to the *center* frequency of the transducer
 - Depth: Deep enough to allow visualization of bottom of phantom or to the maximum depth of penetration
 - Focus: *Single* focal point located at the very far field
 - Acoustic output: *Maximum* or 100%
- Scan a uniform section of the phantom
 - Freeze the image. Utilize cursors to estimate the maximum depth that speckle echoes can be distinguished from the background noise on the image.



AIUM: Maximum Depth of Penetration

Ranking and action levels



A 5% decrease in maximum depth of penetration (from the first measurement) is cause of concern.



A 10% decrease is cause for corrective action to the probe or scanner.



AIUM: Distance Measurement Accuracy

- Verify both horizontal and vertical caliper accuracy
- Recommended scanner settings for testing
 - Preset: *Typical* for the probe type (suggest a factory default preset)
 - Frequency: Close to the *center* frequency of the transducer
 - Depth: Depth *consistent* with default preset
 - Focus: *Single* focal point located in the center of the area to be measured



AIUM: Distance Measurement Accuracy

Vertical measurement

- Align the column of reflector targets in the *center* of the image
- Choose two targets separated by a distance that is *consistent* with the type of transducer
- Place cursors in the *middle* of each target
- Verify that the target distance is with 1.5% or 1.5mm (whichever is GREATER)





AIUM: Distance Measurement Accuracy

Horizontal measurement

- Choose two targets that are separated by a distance of at least *half* of the image width
- Place cursors in the *middle* of each target
- *Verify* that the target distance is with 2% or 2mm (whichever is GREATER)





AIUM: Overall System Quality

- Recommended scanner settings for testing
 - Preset: *Typical* for the probe type (suggest a factory default preset)
 - Frequency: Close to the *center* frequency of the transducer
 - Depth: Depth *consistent* with default preset
 - Focus: *Single* focal point located in the center of the region of interest
 - Areas of interest
 - Cystic/Anechoic targets
 - Grey scale targets (+/- 3dB targets)
 - Wire/fiber targets



AIUM: Overall System Quality

- Areas of interest
 - Cystic/Anechoic targets
 - Targets are *round*/versus oblong
 - Changes in fill-in/background speckle within the target
 - Grey scale targets (+/- 3dB targets)
 - All targets are *visible*
 - Wire/fiber targets
 - Targets are *round*/versus elongated





AIUM: Documentation

- The AIUM does not offer a standardized form for assessing image quality
- Products such as Microsoft Word or Excel could be used to create a form that is suitable for submission, like the sample to the right
 - It would also allow for electronic archival

11	THERE		Probe Mode	Number:		
	AIUM Evaluati	ion Form	Probe Serial	Number:		
	Ultrasound Transduc	er QC and	U.S. System	I.D:		
	Acoustic Performace	Evaluation	Preset used:			
			·			
sual Inspection					Fail	Pass
Lens	Cut/Hole	Worn	Open Seals	Other		
Probe Housing	Cracked	Stained	Open Seals	Other		
Strain Relief	Cut/Hole	Separated	Worn	Other		
Cable	Cut/Hole	Stained		Other		
Strain Relief	Cut/Hole	Separated	_	Other		
Connector	Cracked	Paint Chipped	Locking Knob	Other		
Pins	Bent	Burned	Broken/Missing	Other		
nantom/Scan Testi Imace Uniformity	ng Rankino	Acceptable	e Unacceptable			
nantom/Scan Testi Image Uniformity Maximum Penetrat	ng Ranking on	Acceptable	Unacceptable			
nantom/Scan Testi Image Uniformity Maximum Penetrat Cystic targets	ng on Acceptable	Acceptable cm e Unacceptable	Unacceptable			
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hantom/Scan Testi Image Uniformity Maximum Penetrat Cystic targets Gray Scale Wire targets	ng Ranking Acceptable Acceptable	Acceptable 	: Unacceptable			
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IAC: Intersocietal Accreditation Commission

- History
 - Founded in 1991
 - IAC is "dedicated to ensuring quality patient care and promoting health care through accreditation"
 - Accreditation is available in the following fields: Nuclear Medicine & PET, Vascular testing, Echo-cardiology, MRI, CT
 - Related to ultrasound, IAC can accredit: vascular testing and echo-cardiology

Departments that are IAC accredited will display the logo to the right



https://www.intersocietal.org/ct/



IAC: Facts and Focus

- With respect to ultrasound, only Echocardiology and Vascular Labs would seek accreditation
- The IAC is similar to the ACR and AIUM with respect to departmental practices, policies and procedures
- With respect to the imaging hardware and testing, the IAC...
 - Provides guidelines for maintaining equipment (consistent with OEM guidelines)
 - Does not provide guidance to the level of the ACR or AIUM with respect to quality assurance or image quality testing



IAC: Facts and Focus

- Applies to cardiac and vascular equipment
 - Equipment must be maintained and in good operating condition
 - Routine safety inspections of all department electrical equipment must occur
 - Certain equipment must be included in a comprehensive PM program
 - IAC does not define specific criteria
 - Must have a policy for instrument cleaning, which includes:
 - Transducers, filters, equipment parts, etc.
 - IAC recommends departments follow the equipment manufacturer's guidelines for cleaning
 - Department must collect and provide maintenance and cleaning data to the IAC



IAC: Facts and Focus

- *TEE leakage testing* is one notable standard that has recently been promoted in the industry that is required by the IAC
 - Follow the manufacturer's guidelines for the appropriate care and cleaning
 - The *structural* and *electrical* integrity of the transducer must be checked between each use, using an ultrasound transducer leakage tester
 - "Passed" or "Failed" must be documented
 - Record and take correction action taken if the test fails



Let's review some no-cost tips to reduce your operational costs for while maintaining accreditation standards.

- Wear is going to occur, accidents will occur
- OEM's and service engineers may only inspect systems (and probes) once per year
- Prevention and early detection is the best manner in which to reduce high cost catastrophic damage





We've developed a visual inspection guide, designed to keep inspections *TOP-OF-MIND*

NNCVATUS IMAGING 175 Epision Drive - Pittsburgh, PA 15230

CLISTOMED CADELOODERS





- Even if your departments aren't accredited... •
 - Engage your customers. End-users touch the probes, multiple times, EVERY DAY
 - 1. **BEGIN** with department managers to gain acceptance and understanding
 - 2. ASK to have 15 minutes of their department meeting
 - **EXPLAIN** that end-users play a key role in helping to reduce costs 3.
 - **ENCOURAGE** frequent, if not daily, visual inspections 4.
 - 5. **POST** the visual inspection guides in each scan room and cleaning areas to raise awareness

Each week(same time, same day), assign a different sonographer to visually inspect every probe in the department.





Remove scan gel from all probes at the end of each scan

DON'T let scan gel dry on the probe
DON'T let residual disinfectants air-dry on the probe



Alcohol removes plasticides from plastic and rubber materials

- •Only use OEM approved chemicals
- •Use cleaners and disinfectants with the LOWEST alcohol concentration
- •REMOVE residual disinfectants from the probe with a water-moistened cloth



Cable management

• Poor cable management is the primary root cause of cable and wiring damage



Endo-cavity and TEE probes

- •Store endo-cavity probes off-scanner
- •Transport TEE probes in bins (not pillow cases or trash bags)
- Mandate TEE tip protection



Summary

- Discussed the purposes and objectives of accreditation
- Highlighted the ACR, AIUM and IAC standards, relative to the imaging/service community
- Presented techniques for completing the requirements
- Presented best-practices for extending probe lifecycles



QUESTIONS?

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 - Resources Section: Educational content, visual inspection guides, whitepapers and past presentations

