

Diagnostic Ultrasound Performance Testing & Accreditation

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Outline of topics

- Background
- US performance testing at Mayo-Rochester, methods and recent experience:
 - Quality control
 - Acceptance testing
- Overview of US practice accreditation



Background

Med Phys. 1998 Aug;25(8):1385-406.

Real-time B-mode ultrasound quality control test procedures. Report of AAPM Ultrasound Task Group No. 1.

Goodsitt MM, Carson PL, Witt S, Hykes DL, Kofler JM Jr.

Department of Radiology, University of Michigan, Ann Arbor 48109-0030, USA. goodsitt@umich.edu

- Good benchmark publication for US QC
- Comprehensive list of performance tests
 - Primarily manual, subjective methods
 - Discussed advantages of computer-based methods
 - Detailed test procedures
 - Suggested performance benchmarks
 - Discussion of phantom design

➤ Performance tests discussed by Goodsitt, et al

- Mechanical inspection
- Distance accuracy
- Depth of penetration
- Image uniformity
- Display monitor setup and fidelity
- Hard copy fidelity

*Perform more
frequently*

-
- Anechoic object imaging
 - Spatial resolution (axial, lateral, elevational)
 - Dead zone

*Perform less
frequently*

Ultrasound phantom overview

➤ Key physical characteristics

- Speed of sound
- Echogenicity and echotexture (scatter)
- Attenuation and frequency dependence
- *Aqueous gels most closely mimic tissue properties*

➤ Test targets

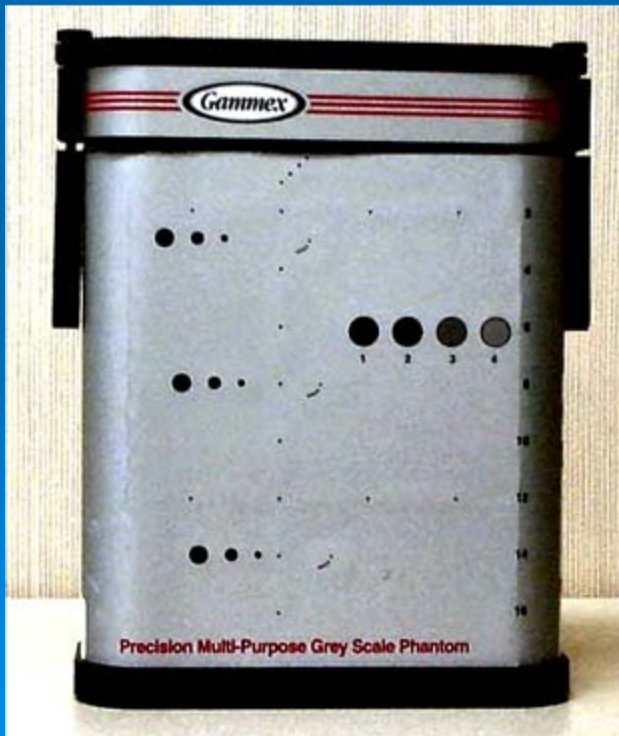
- Variably echogenic columns
- Arrays of fibers (“pins”)
- Anechoic spheres

➤ No single phantom product or design was endorsed by the authors



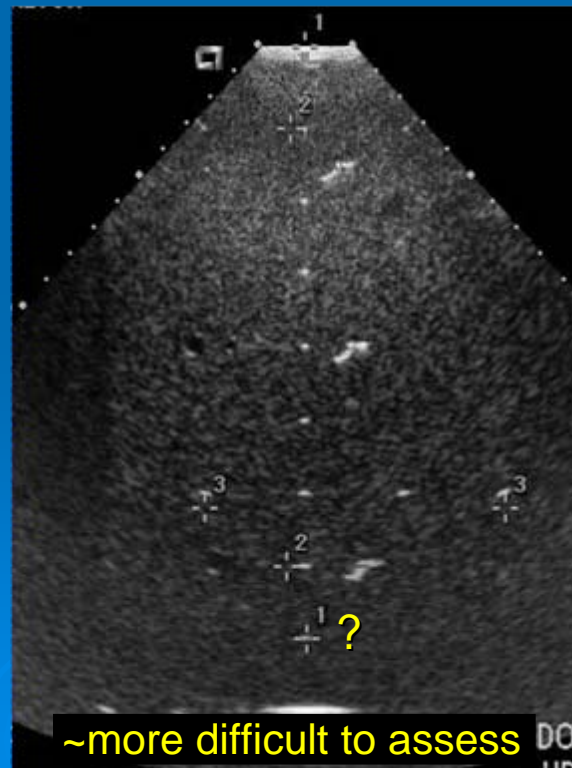
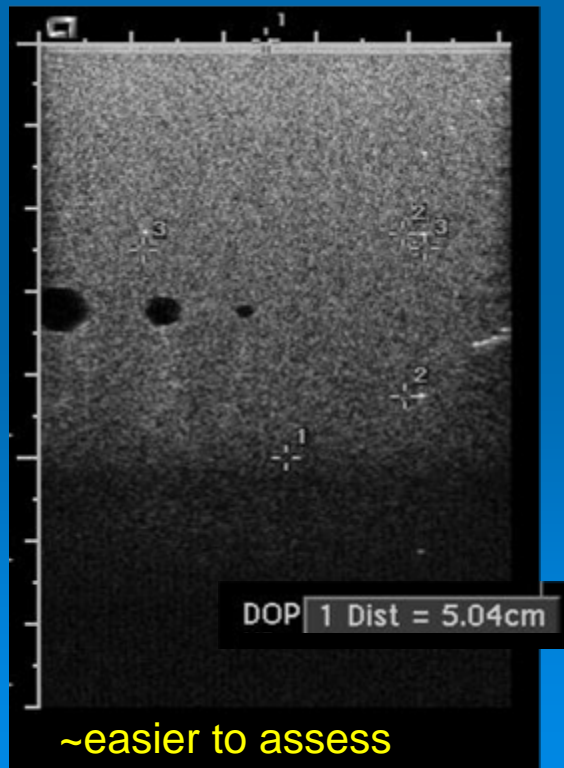
➤ Distance accuracy

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



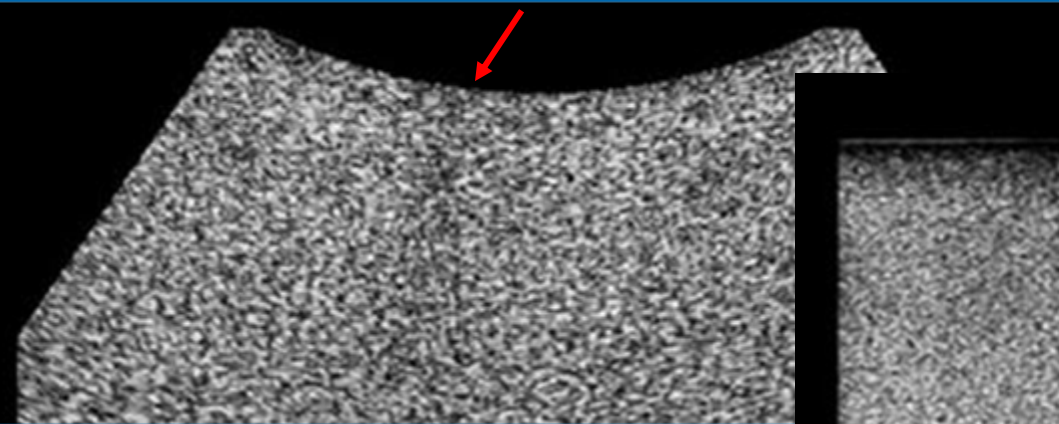
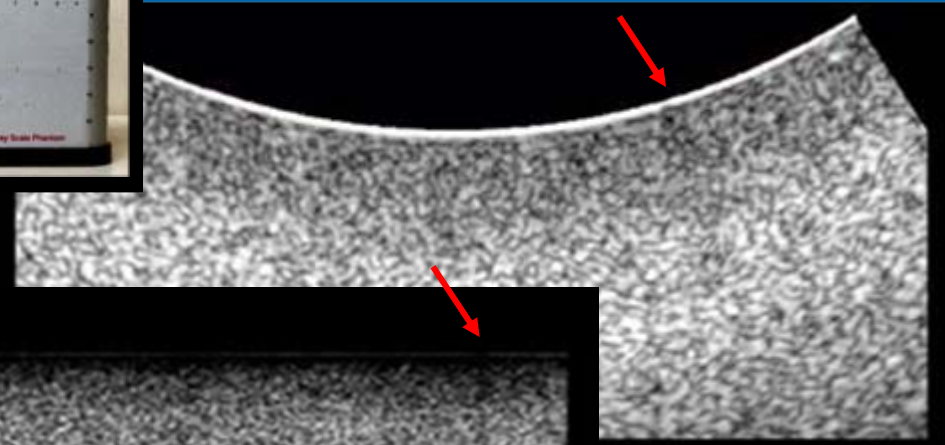
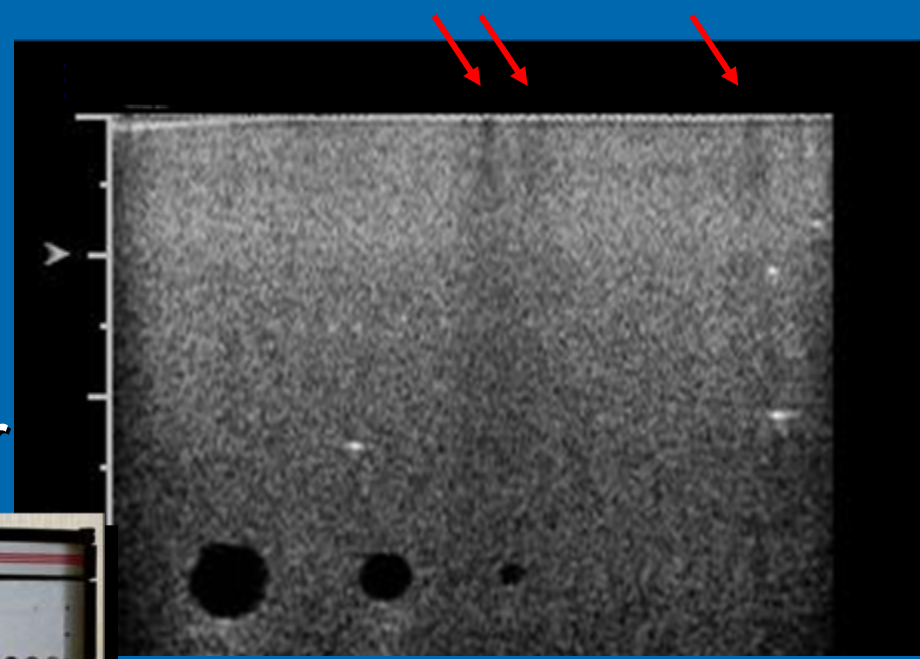
➤ Depth of penetration (DOP)

- Greatest depth of *reliable visualization* of speckle
- Closely related to system noise, SNR, sensitivity
- Maintaining consistent control settings is critical, & can be challenging (e.g. TGC)



➤ Image uniformity

- Survey for artifacts (usually superficial & axial)
- Live scanning w transducer motion is best
- Malfunctioning PE element or channel (*may need to debug*)



- Computer-based US testing methods have been reported, but availability is limited

Ultrasound Med Biol. 2001 Dec;27(12):1697-711.

A computerised quality control testing system for B-mode ultrasound.

Gibson NM, Dudley NJ, Griffith K.

Medical Physics Department, Nottingham City Hospital NHS Trust, Hucknall Road, Nottingham NG5 1PB, UK. ngibson@ncht.org.uk

Ultrasound Med Biol. 2001 Dec;27(12):1667-76.

Improved method for determining resolution zones in ultrasound phantoms with spherical simulated lesions.

Kofler JM Jr, Madsen EL.

Department of Radiology, Mayo Clinic, Rochester, MN 55905, USA. jkofler@mayo.edu

Med Phys. 2005 Aug;32(8):2615-28.

Implementation and validation of three automated methods for measuring ultrasound maximum depth of penetration: application to ultrasound quality control.

Gorny KR, Tradup DJ, Hangiandreou NJ.

Department of Radiology, Mayo Clinic, Rochester, Minnesota 55905, USA.

Ultrasound Med Biol. 2007 Mar;33(3):460-71.

Objective performance testing and quality assurance of medical ultrasound equipment.

Thijssen JM, Weijers G, de Korte CL.

Clinical Physics Laboratory, University Children's Hospital, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands. j.thijssen@cukz.umcn.nl

➤ Common perceptions of ultrasound QC

- Necessary tools (e.g. phantoms, probe testers) are very expensive
- Testing process is very time-consuming
- Sensitivity and repeatability of manual, subjective test methods are limited
- Poor availability of computer-based testing SW
- *Is US QC by the end-user really needed?*
 - *Scanners will alert you when problems arise*
 - *Sonographers will identify all the important issues*
 - *The equipment service folks are already doing QC*
 - *Besides, ultrasound is safe, right?*



➤ Current status of ultrasound QC:

- Relatively poor participation in ultrasound equipment testing in clinical practice, especially compared with other modalities
- “Half-hearted” current QC recommendations in some US practice accreditation programs
 - Only need to test 2 probes
 - Only need to test every 12 months
 - All required tests may be done *without a phantom*
 - Quality control is suggested, not absolutely required

Ultrasound phantoms that most accurately mimic the acoustic properties of human tissue are primarily comprised of:

- 0%** 1. A mixture of water and alcohol
- 0%** 2. Plexiglas
- 0%** 3. Urethane rubber
- 0%** 4. Water held at 20 degrees Celsius
- 0%** 5. Aqueous gel

Ultrasound phantoms that most accurately mimic the acoustic properties of human tissue are primarily comprised of:

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- 0% 3. Urethane rubber
- 0% 4. Water held at 20 degrees Celsius
- 0% 5. Aqueous gel ← *is correct!*
- 0%

Reference:

Diagnostic Ultrasound, Principles and Instruments, 7th Edition. FW Kremkau.
Saunders Elsevier, St Louis MO, 2006. Page 307.

The maximum depth of penetration is most closely correlated with which of the following parameters?

0%

1. Caliper accuracy

0%

2. Axial resolution

0%

3. Post-processing lookup table

0%

4. System noise

0%

5. Scanner display calibration

The maximum depth of penetration is most closely correlated with which of the following parameters?

0%

1. Caliper accuracy

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2. Axial resolution

0%

3. Post-processing lookup table

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4. System noise

← *is correct!*

0%

5. Scanner display calibration

Reference:

Goodsitt MM, Carson PL, Witt S, Hykes DL, Kofler JM Jr. Real-time B-mode ultrasound quality control test procedures. Report of AAPM Ultrasound Task Group No. 1. Med Phys. 1998 Aug;25(8):1385-406.

Ultrasound QC at MCR

➤ Study of 4 years of US QC data

GOALS

- What US QC tests actually detect problems?
 - Make our program more efficient / cost effective
- What is the rate of US equipment failures?

Ultrasound Med Biol, 2011 Aug;37(8):1350-7. Epub 2011 Jun 16.

Four-year experience with a clinical ultrasound quality control program.

Hangiandreou NJ, Stekel SF, Tradup DJ, Gorny KR, King DM.

Department of Radiology, Mayo Clinic, Rochester, MN 55905, USA. hangiandreou@mayo.edu

Abstract

Ultrasound (US) quality control (QC) program data over a 4-year period from more than 45 scanners and more than 265 transducers were reviewed to optimize the program in terms of efficiency and effectiveness. Our program included evaluations of mechanical integrity, image uniformity, distance measurement accuracy and maximum depth of penetration (DOP). We computed failure rates and fraction of failures detected by each test. A total of 187 equipment problems were identified. Average annual scanner component and transducer failure rates were 10.5% and 13.9%, respectively. The mechanical integrity and uniformity evaluations detected 25.1% and 66.3% of all failures, respectively. Those evaluations plus defects detected by sonographers accounted for 98.4% of all detected failures. DOP and distance measurement accuracy were not effective at detecting equipment failures. For routine US QC, we recommend quarterly mechanical integrity and uniformity assessments of all transducers. A scanner with five transducers could be tested in an estimated 30 min or less.

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PMID: 21683511 [PubMed - indexed for MEDLINE]

➤ Study of 4 years of US QC data

METHODS

- QC program included (1) mechanical inspection, (2) uniformity, (3) geometric accuracy, and (4) DOP
- All transducers were tested at each QC session
- Subjective/manual and objective/PC-based measurements were used
- Testing was biannual → quarterly, from 2004-2007

Results

Ultrasound equipment inventory from 2004 through 2007

			2004	2005	2006	2007
Siemens (Acuson)	128XP	scanners	2	2	2	1
		transducers	4	4	4	4
	Sequoia	scanners	36	37	41	42
		transducers	237	262	268	285
	G40	scanners	0	0	4	4
		transducers	0	0	10	10
Philips (ATL)	HDI 5000	scanners	4	4	1	1
		transducers	10	10	3	3
	iU22	scanners	0	0	4	4
		transducers	0	0	8	8
Bruel & Kjaer	Hawk	scanners	1	1	1	1
		transducers	4	4	4	4
	Leopard	scanners	1	1	1	1
		transducers	3	3	3	3
	Panther	scanners	1	1	1	1
		transducers	5	5	5	5
Aloka	Dyna View	scanners	2	2	0	0
		transducers	4	4	0	0
ALL		scanners	47	48	55	55
		transducers	267	292	305	322

4 vendors

**9 scanner
models**

~300 probes

Results

Number of equipment failures detected, & failure rate, by quarter

Time period	Scanner failures	Transducer failures	Transducer failure rate (# /100 transducers/quarter)
Q1, 2004	0	18	6.74
Q2, 2004	0	17	6.37
Q3, 2004	1	9	3.37
Q4, 2004	0	5	1.87
Q1, 2005	3	10	3.42
Q2, 2005	0	9	3.08
Q3, 2005	2	5	1.71
Q4, 2005	0	6	2.05
Q1, 2006	4	7	2.27
Q2, 2006	0	2	0.65
Q3, 2006	5	7	2.27
Q4, 2006	0	5	1.62
Q1, 2007	6	13	3.99
Q2, 2007	0	25	7.67
Q3, 2007	0	4	1.23
Q4, 2007	0	23	7.06
Total	21	165	

Failure rate statistics (# /100 transducers/quarter)	
Minimum	0.65
Maximum	7.67
Mean	3.46 ←
Median	2.67

Annual probe failure rate = 13.9%

Grand total of 186 failures found 11

Results

Methods of detection of scanner and transducer failures

Evaluation method	# of detected failures	% of detected failures
Mechanical integrity	46	24.7
Image uniformity	124	66.7
Caliper distance accuracy	0	0.0
Maximum DOP	3	1.6
Clinical use, sonographer	13	7.0
TOTAL	186	100.0%



➤ Study of 4 years of US QC data

CONCLUSIONS

- QC tests of DOP (1.6%) and image geometry (0%) were *ineffective QC tools*
- Uniformity evaluation and mechanical inspection were the most useful QC tests
 - **Uniformity eval (66.7%)** + mechanical inspection (24.7%) + *sonographer detection during clinical use (7%)* = 98.4% of detected equipment failures
- Effective, routine quality control testing can be performed utilizing *only* the mechanical inspection and uniformity evaluation (*plus display quality evaluation*)
 - **Testing a scanner & 5 probes required 30 min or less**

➤ Study of 4 years of US QC data

CONCLUSIONS

- Average annual failure rates
 - Scanner/component: 10.5%
 - Transducer: 13.9%

Eur J Echocardiogr. 2010 Oct;11(9):801-5. Epub 2010 Jun 8.

Ultrasound transducer function: annual testing is not sufficient.

Mårtensson M, Olsson M, Brodin LÅ.

School for Technology and Health, KTH, Campus Flemingsberg, Alfred Nobels Allé 10, Huddinge, Stockholm, Sweden. mmar@kth.se

Sonora (Unisyn) FirstCall probe tester
Transducer annual failure rate = 27.1%

Ultrasound QC at MCR

➤ Current US QC program

- Quarterly
 - Inventory, Mechanical inspection, **Scanner display** quality, **Uniformity** (all probe ports)
 - BK prostate scanners: Volume measurement
- Semiannually, add...
 - **DOP****, Geometric accuracy (*mechanical probes only*), Scanner display luminance, Diagnostic display luminance & quality (PACS and hard-copy)
- Annual, add...
 - **Geometric accuracy** (all probes)

****Current ACR
accreditation
requirement**

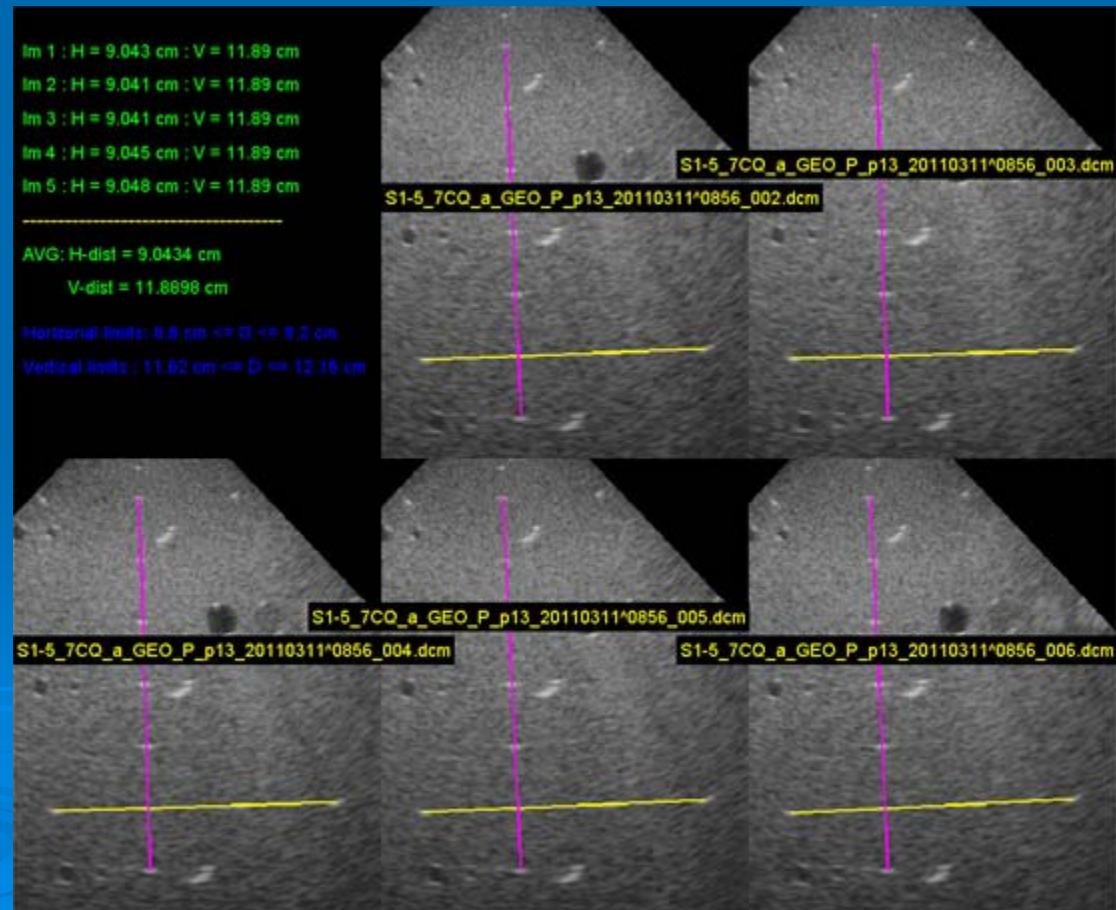
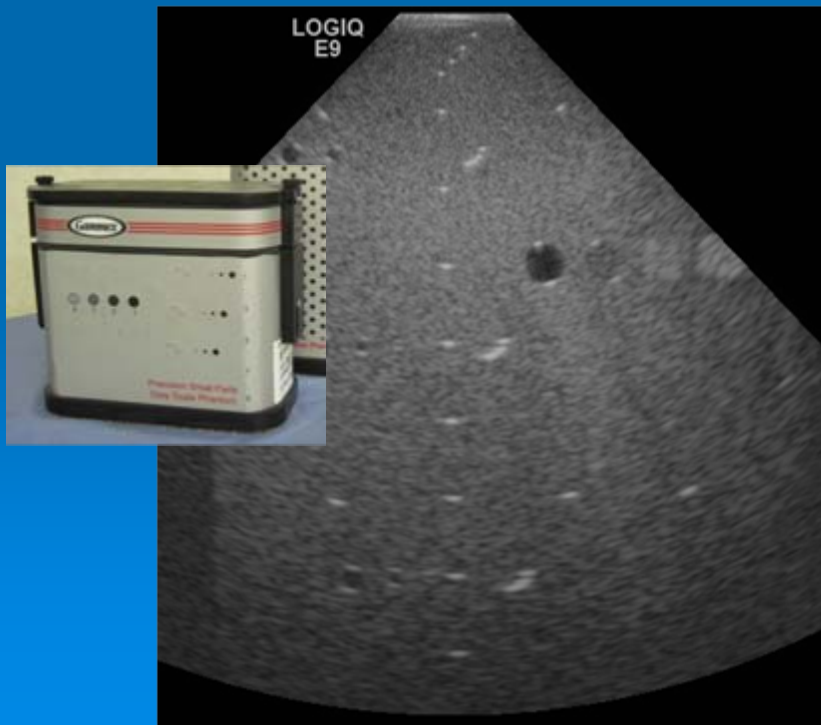
Ultrasound QC at MCR

- Current US performance testing at MCR utilizes commercial phantoms, except for uniformity

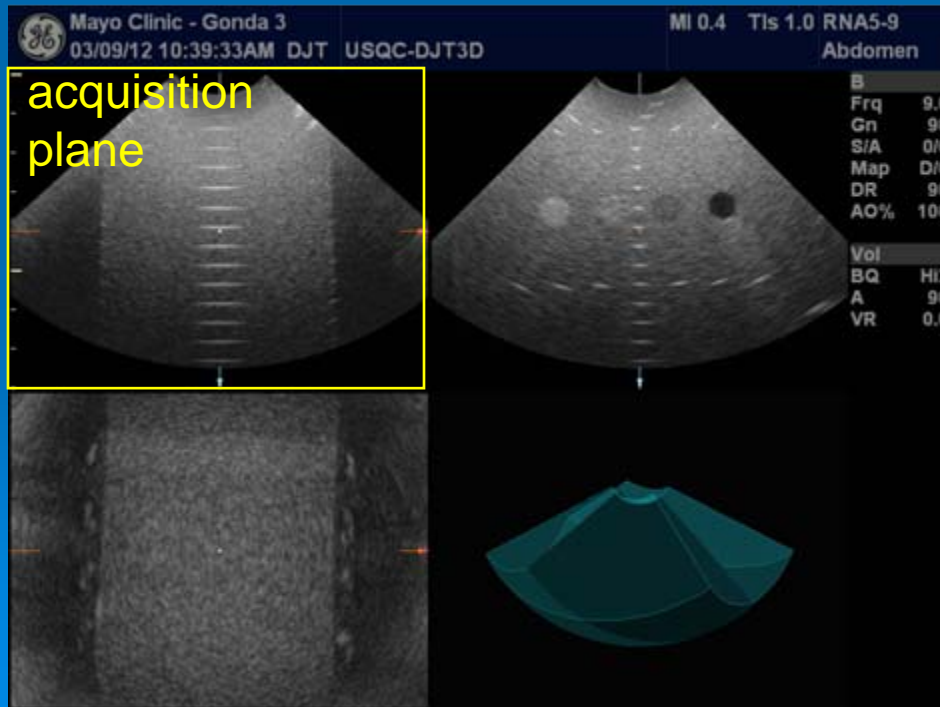


➤ Geometric accuracy

- Semi/automated “distance” measurements (verification of pixel size calibration)
- Location of maximum pixel value
- Average 5 repeat measurements



- Also measure elevational geometric accuracy from orthogonal reconstructed image for 3D4D probes



➤ Depth of penetration (DOP)

- IEC DOP algorithm
(IEC Standard 61391-2)
- 5 phantom-air pairs
- Automated SNR & DOP
is calculated as follows:

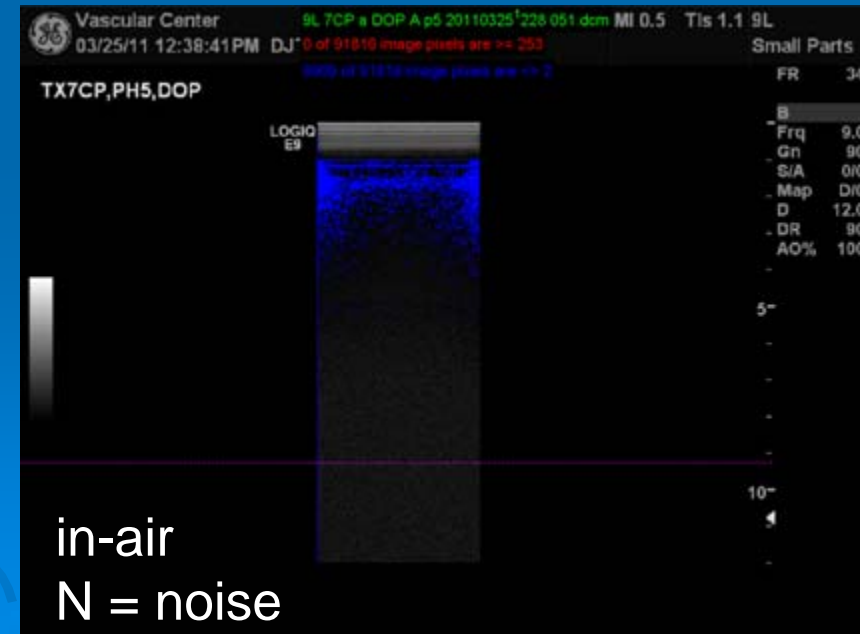
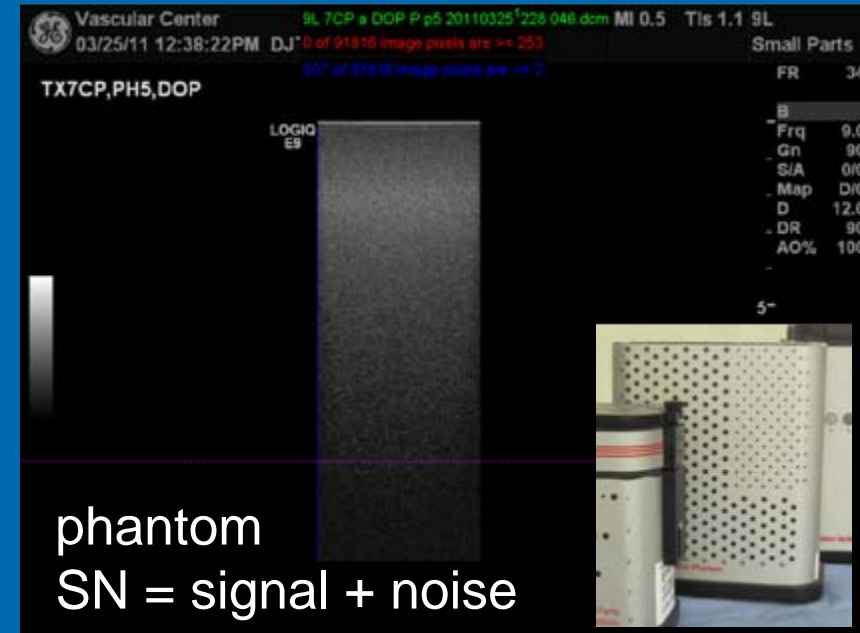
$$\text{SNR}_{\text{IEC}}(d) = \sqrt{\frac{\text{SN}(d)^2}{N(d)^2} - 1}$$

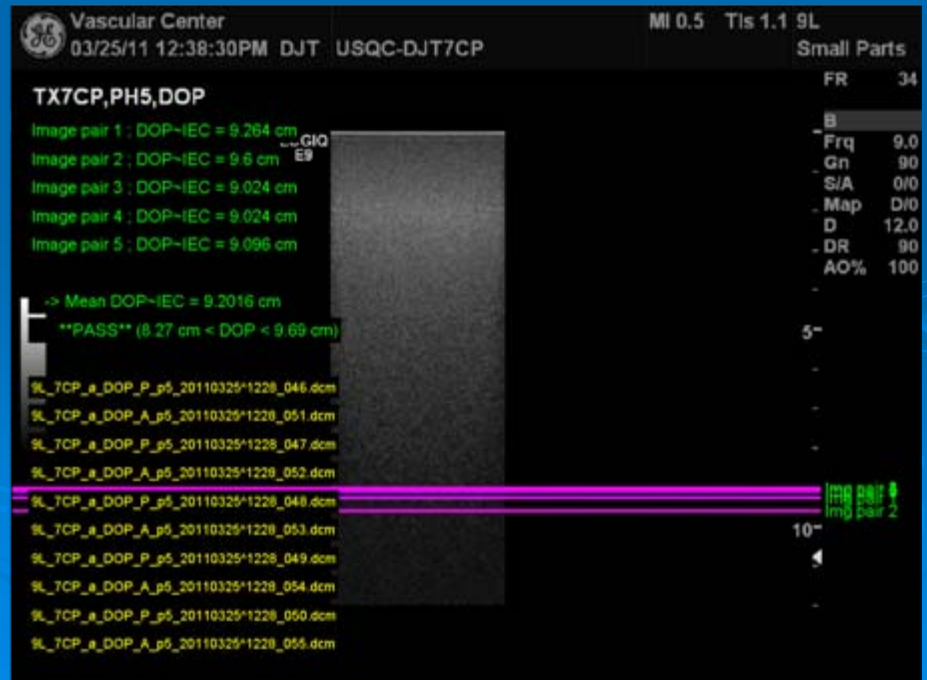
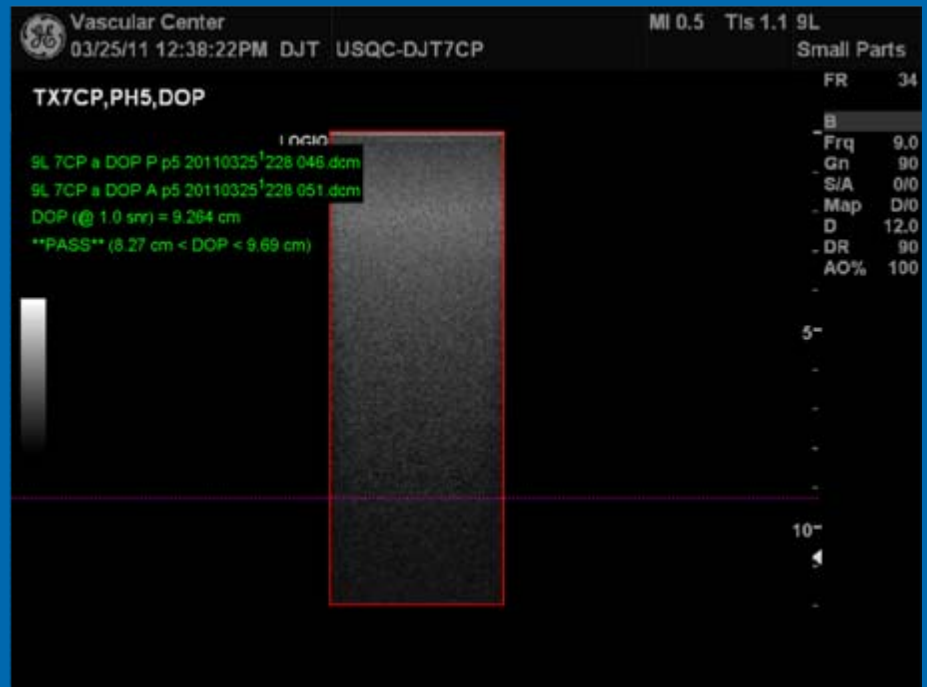
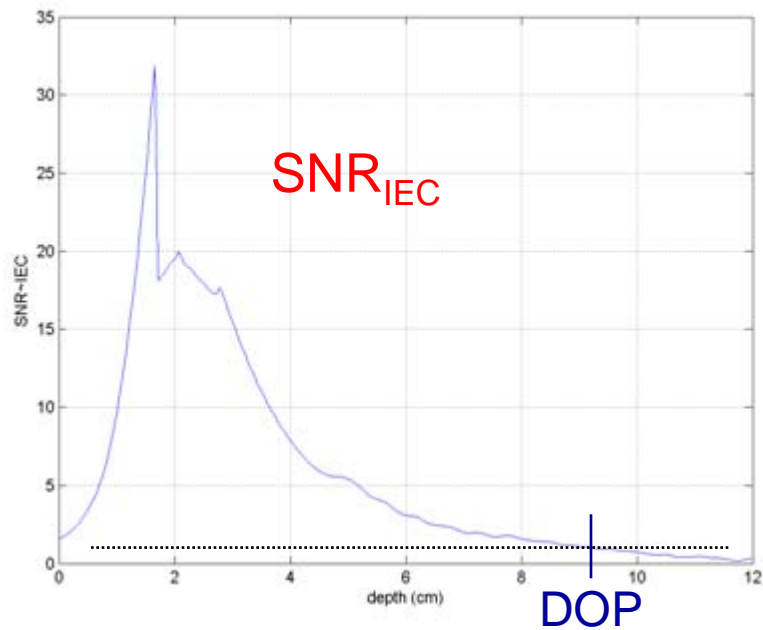
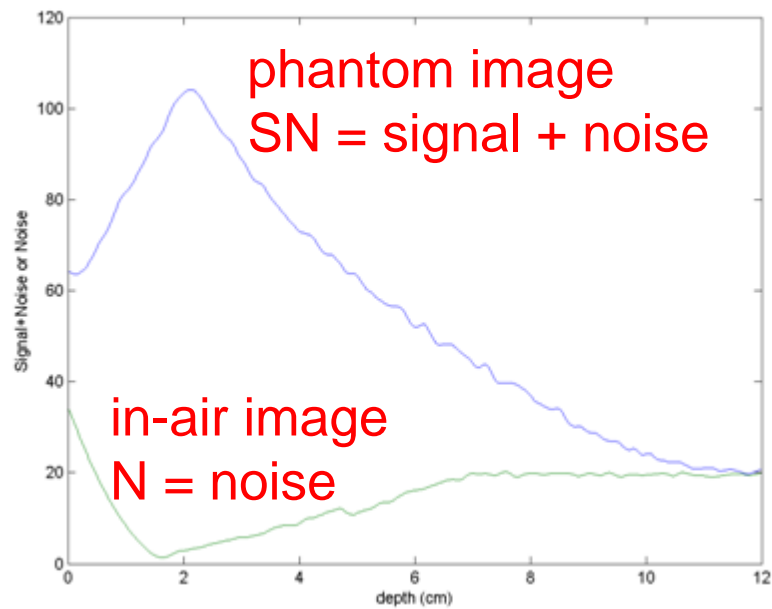
d = distance from transducer face

SN = mean pixel values from phantom image

N = mean pixel values from in-air image

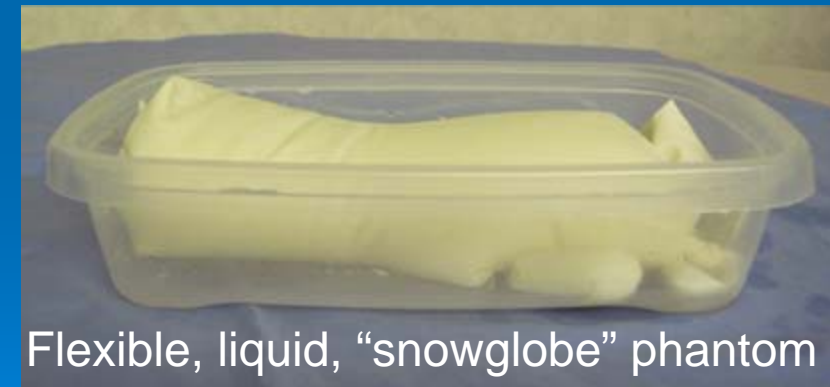
$$\text{SNR}_{\text{IEC}}(\text{DOP}) = 1$$





➤ Uniformity

- Current method utilizes a custom liquid phantom
 - Degassed water & cornstarch (4% by weight) in latex surgical glove
- Advantages over solid phantoms:
 - Complete coupling of full transducer array for all probe models tested
 - Dynamic speckle patterns easily obtained without probe motion across phantom surface
 - Agitate phantom, and “pulse” the probe during scanning



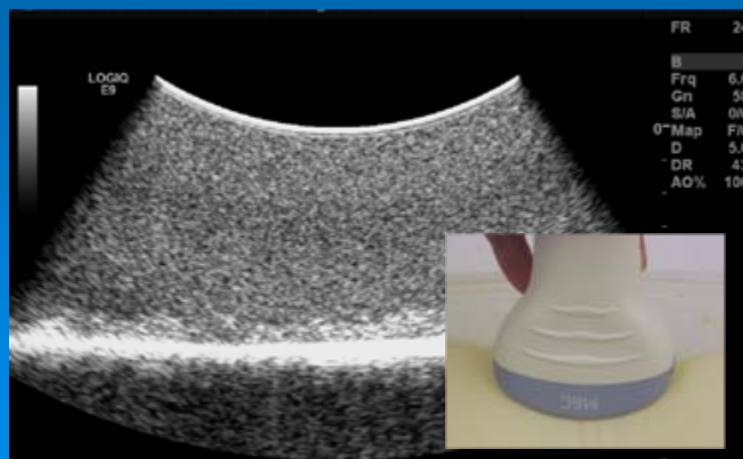
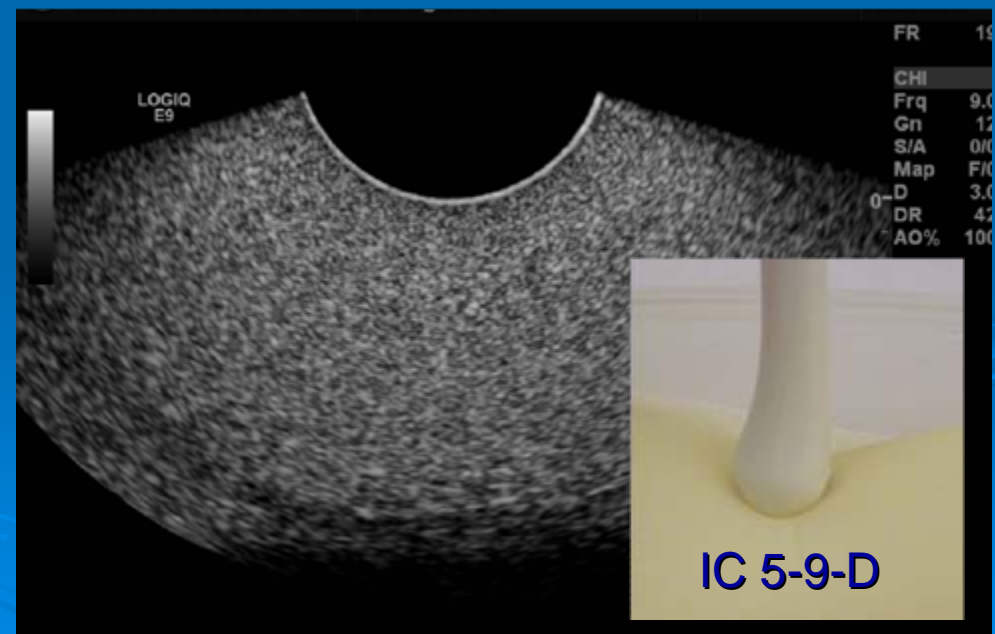
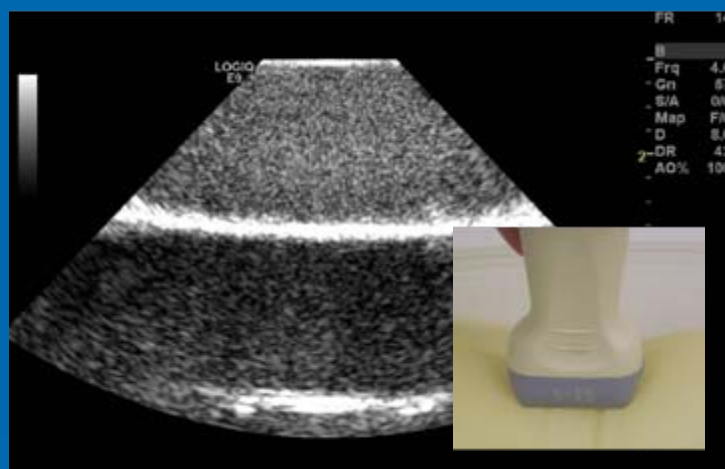
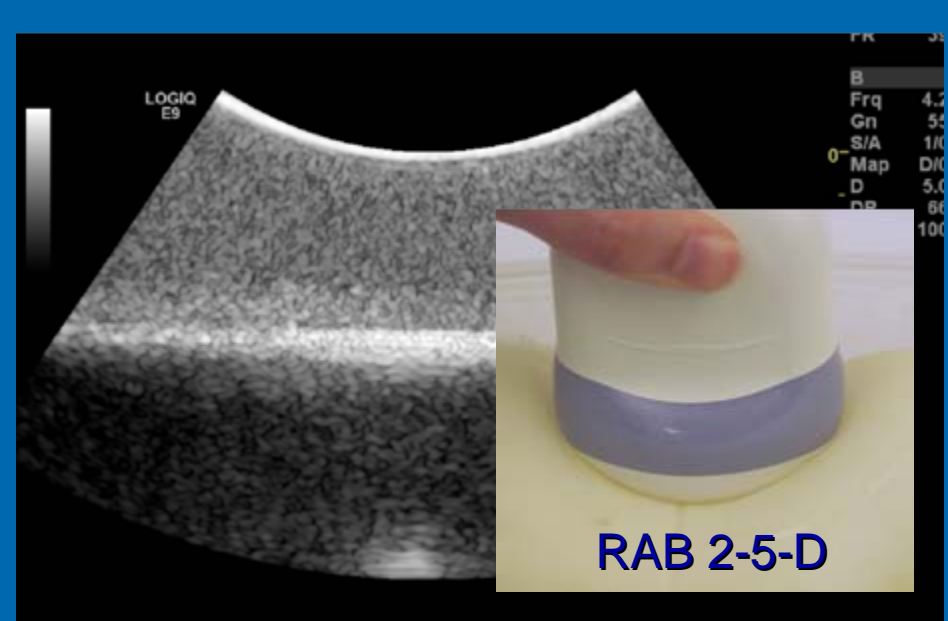
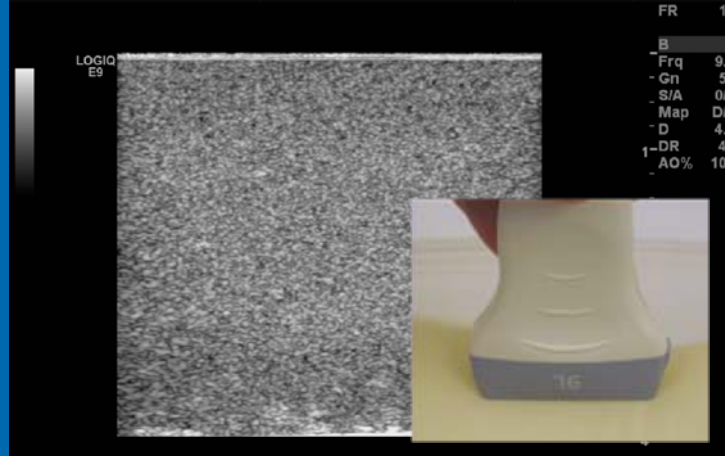
Flexible, liquid, “snowglobe” phantom

Phys Med Biol. 2010 Dec 7;55(23):N557-70. Epub 2010 Nov 16.

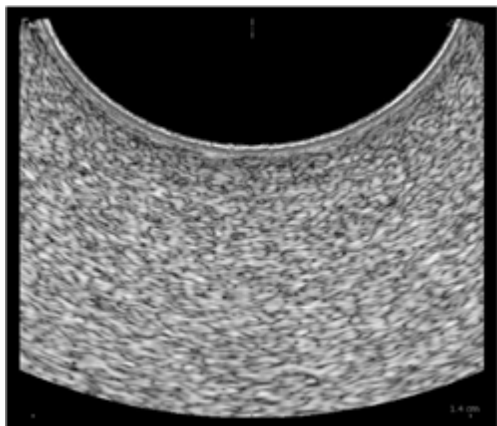
Evaluation of a low-cost liquid ultrasound test object for detection of transducer artefacts.

King DM, Hangiandreou NJ, Tradup DJ, Stekel SF.

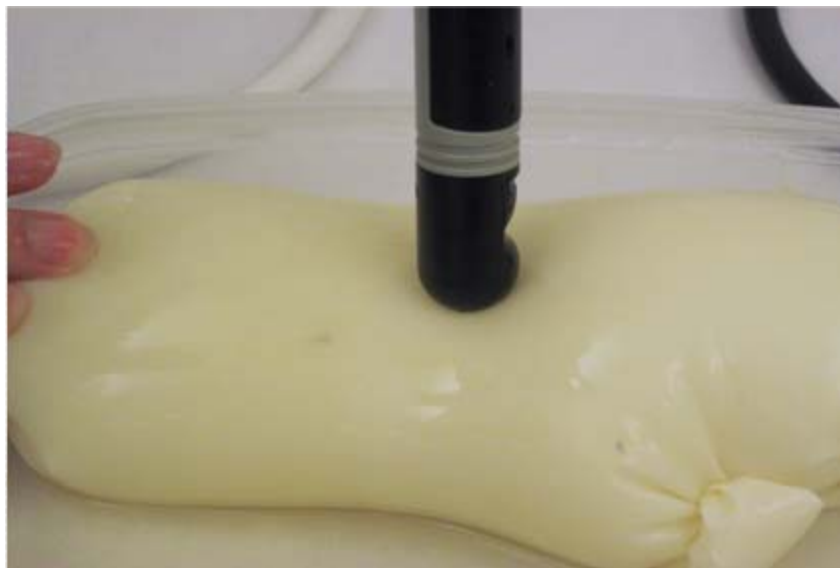
Department of Radiology, Mayo Clinic, Rochester, MN 55905, USA. king.deirdre@mayo.edu



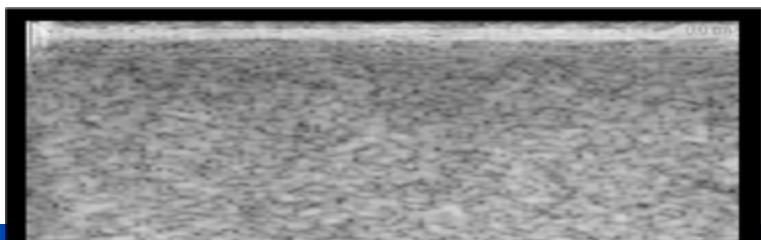
BK FlexFocus bi-plane prostate probe



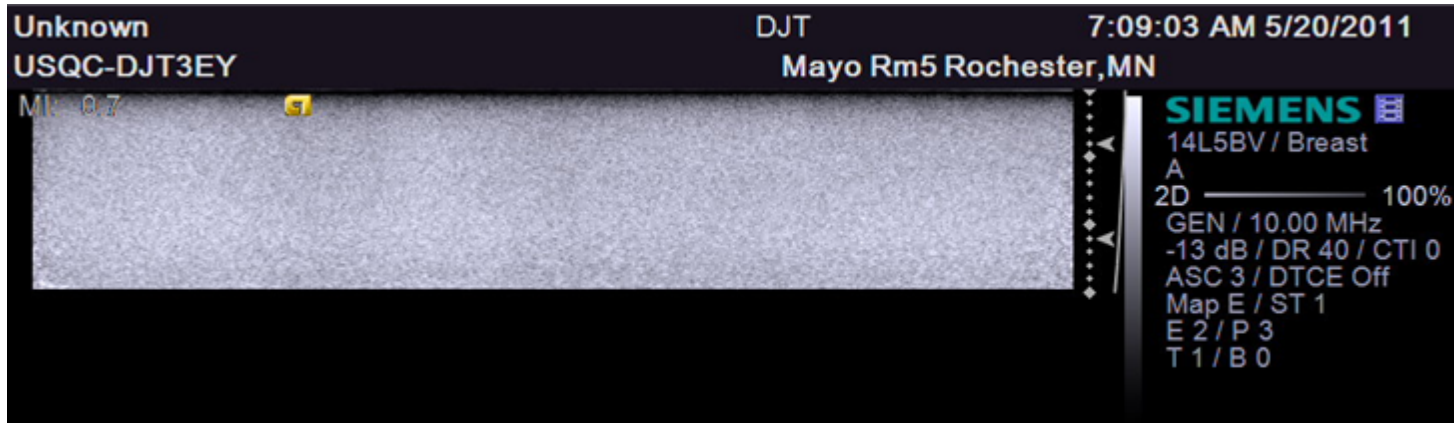
Sagittal Array



Transverse Array

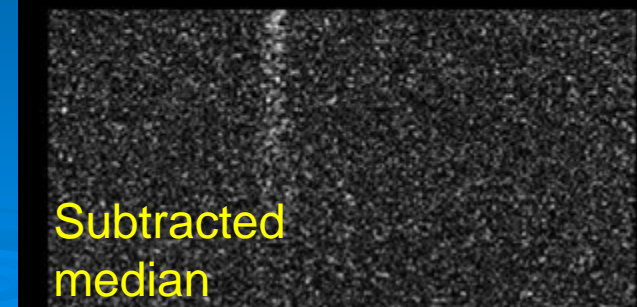
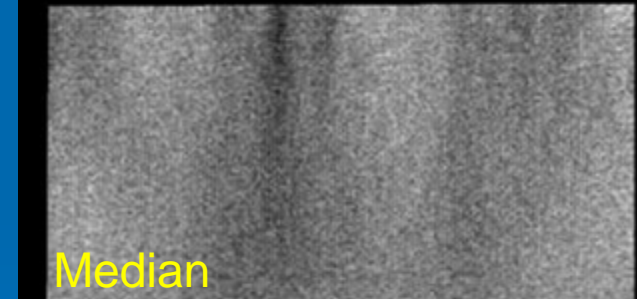
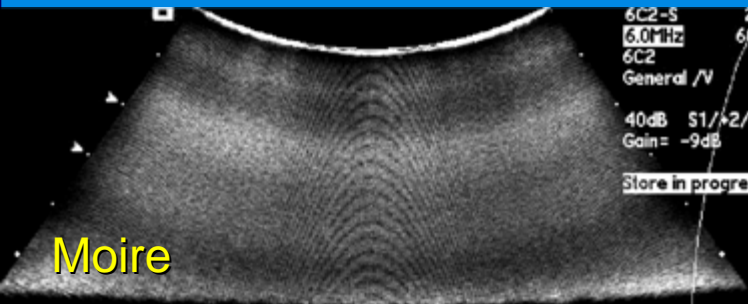
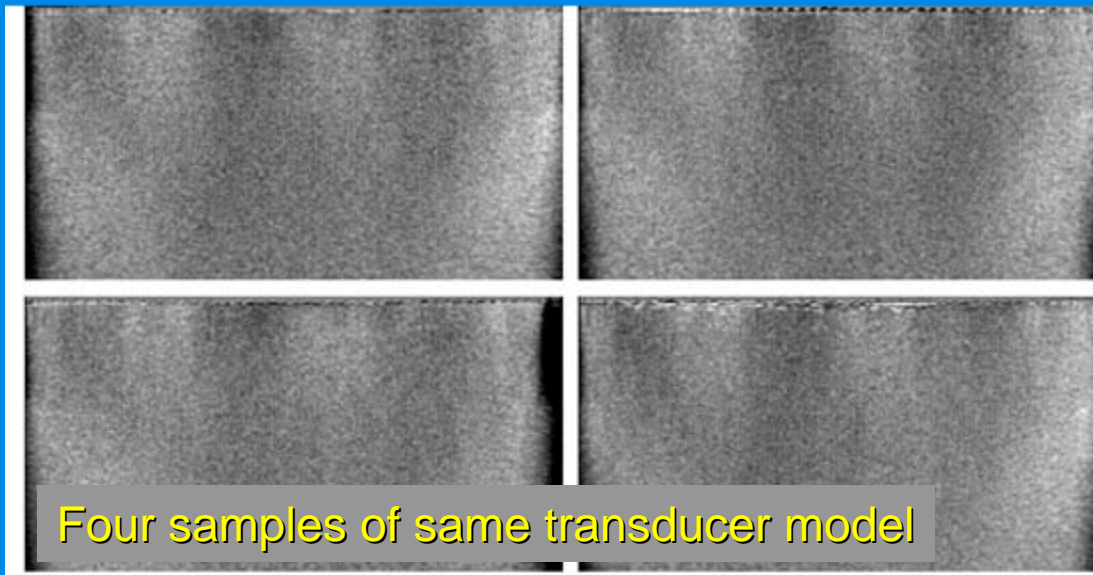


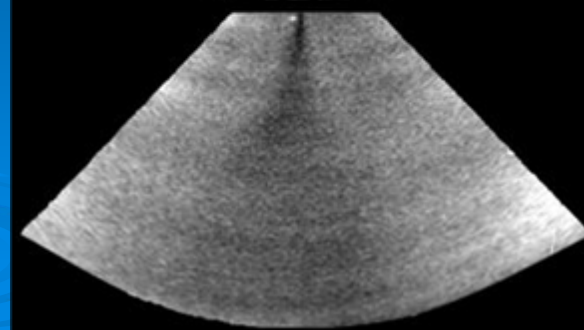
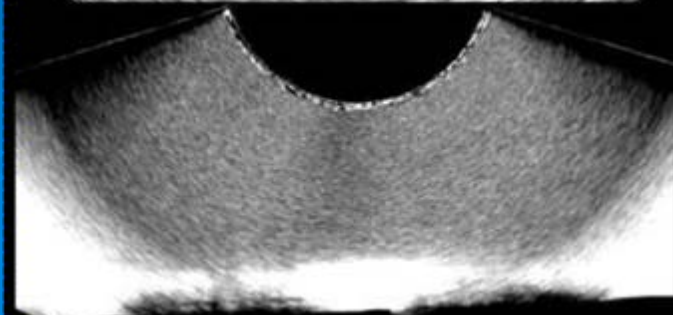
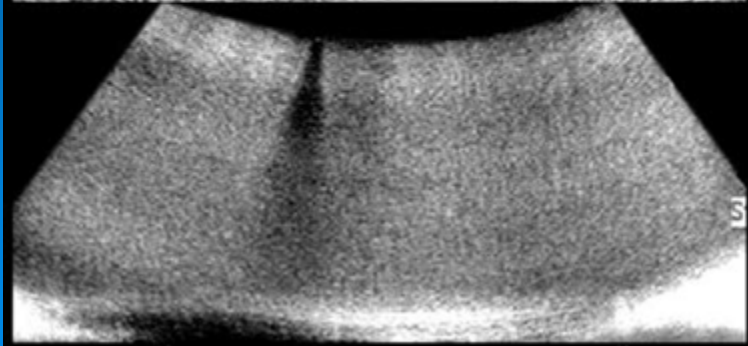
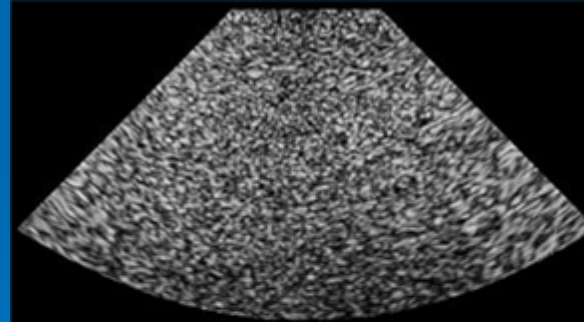
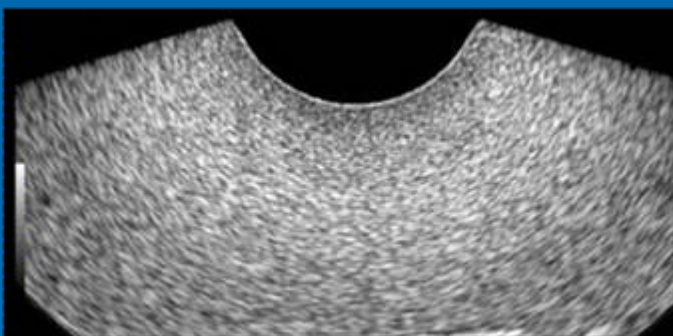
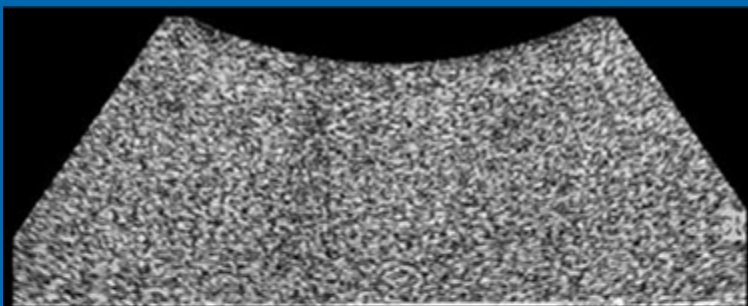
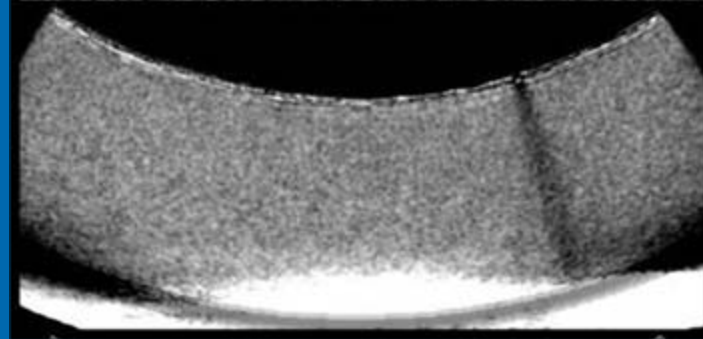
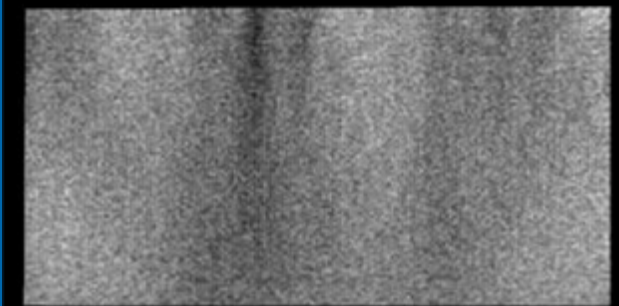
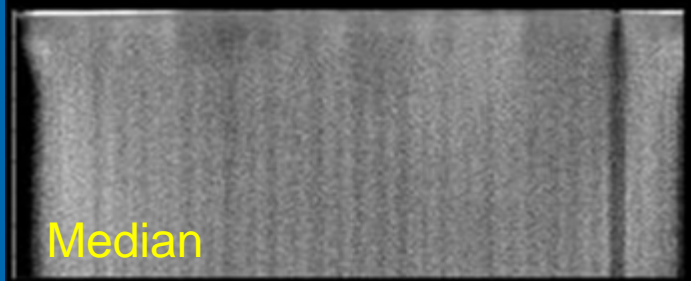
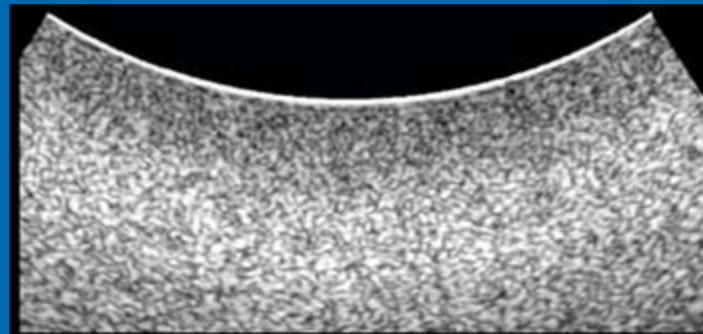
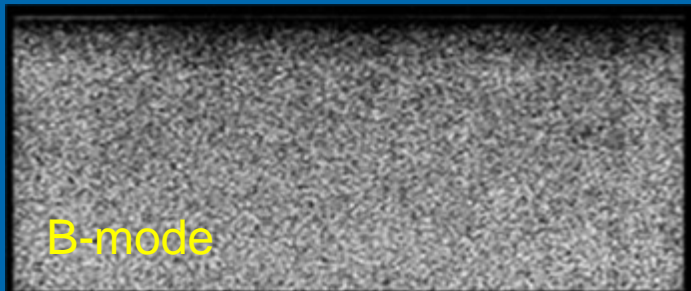
Automated 3D Breast ultrasound system



- Dynamic speckle signal provides increased sensitivity for detecting artifacts
 - Viewing of dynamic scan or clip
 - Median processing of clip

“Intrinsic artifacts”





➤ Multiple observer artifact detection study

RESULTS

METHODS

- > 6 observers
- > 56 probes, 28 w artifacts
- > 3 detection methods

Detection method	Sensitivity (%)	Specificity (%)	Average assessment time per image (sec)
Dynamic Clip	61	93	4.7
Median	96	77	3.3
Subtracted median	97	92	3.0

- Median processed images offer advantages, but visual inspection of dynamic clips is also effective

Med Phys. 2011 Nov;38(11):6216-21.

Assessment of three methods for detection of ultrasound artifacts.

King DM, Hangiandreou NJ, Tradup DJ, Stekel SF.

Department of Radiology, Mayo Clinic, Rochester, MN 55905, USA.

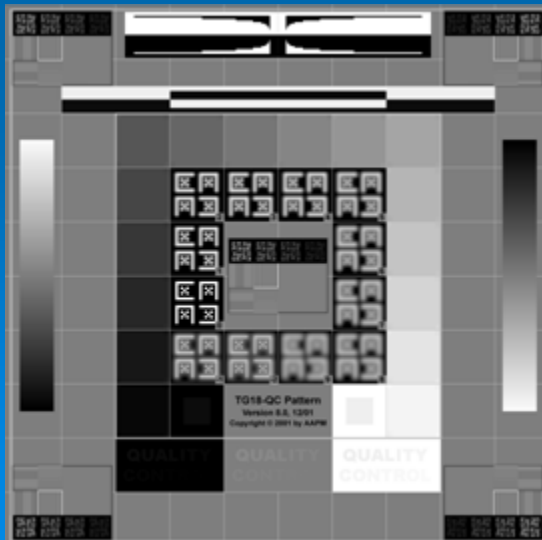


➤ Scanner display quality and luminance calibration

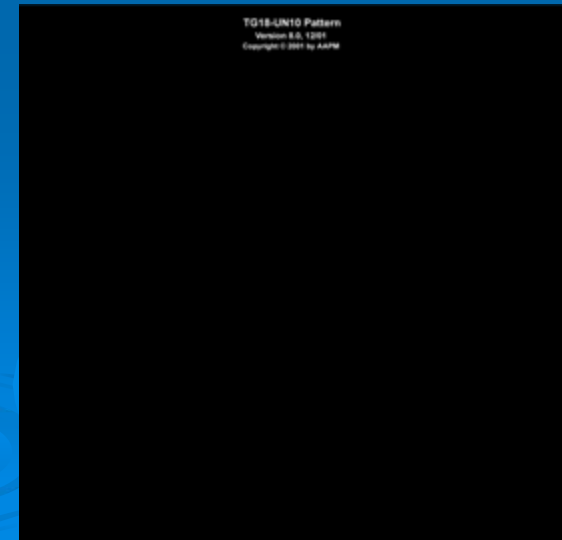
- *Ultrasound scanner monitor is a primary diagnostic display device*
- Display quality evaluation should be included as part of routine QC
 - Visual inspection of display test patterns (e.g. AAPM TG18)



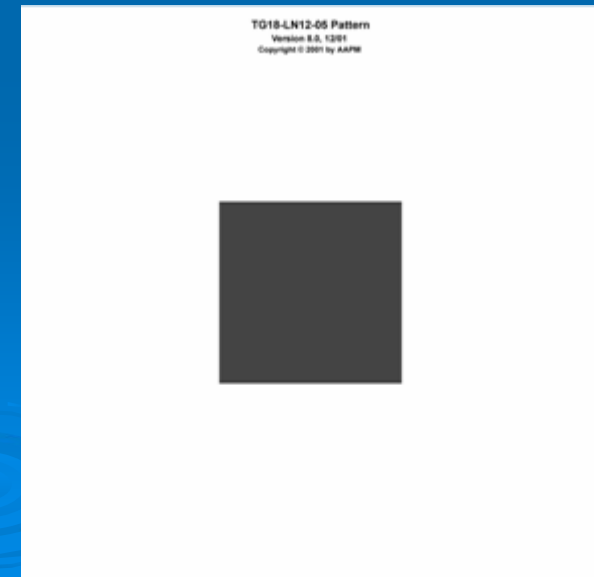
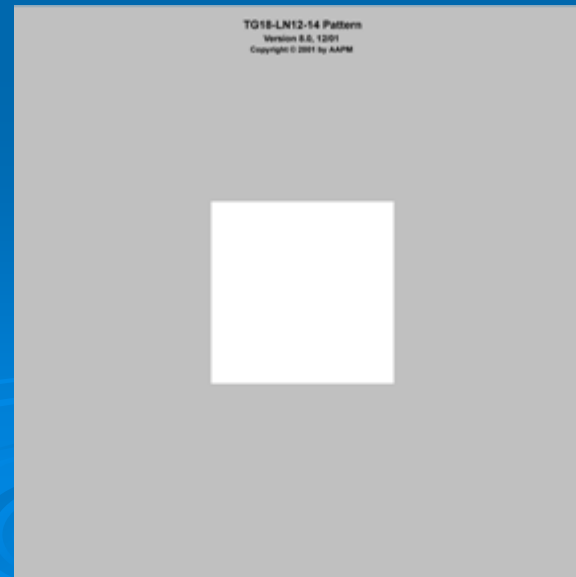
Geometry/distortion,
spatial resolution,
artifacts, contrast



Pixel defects

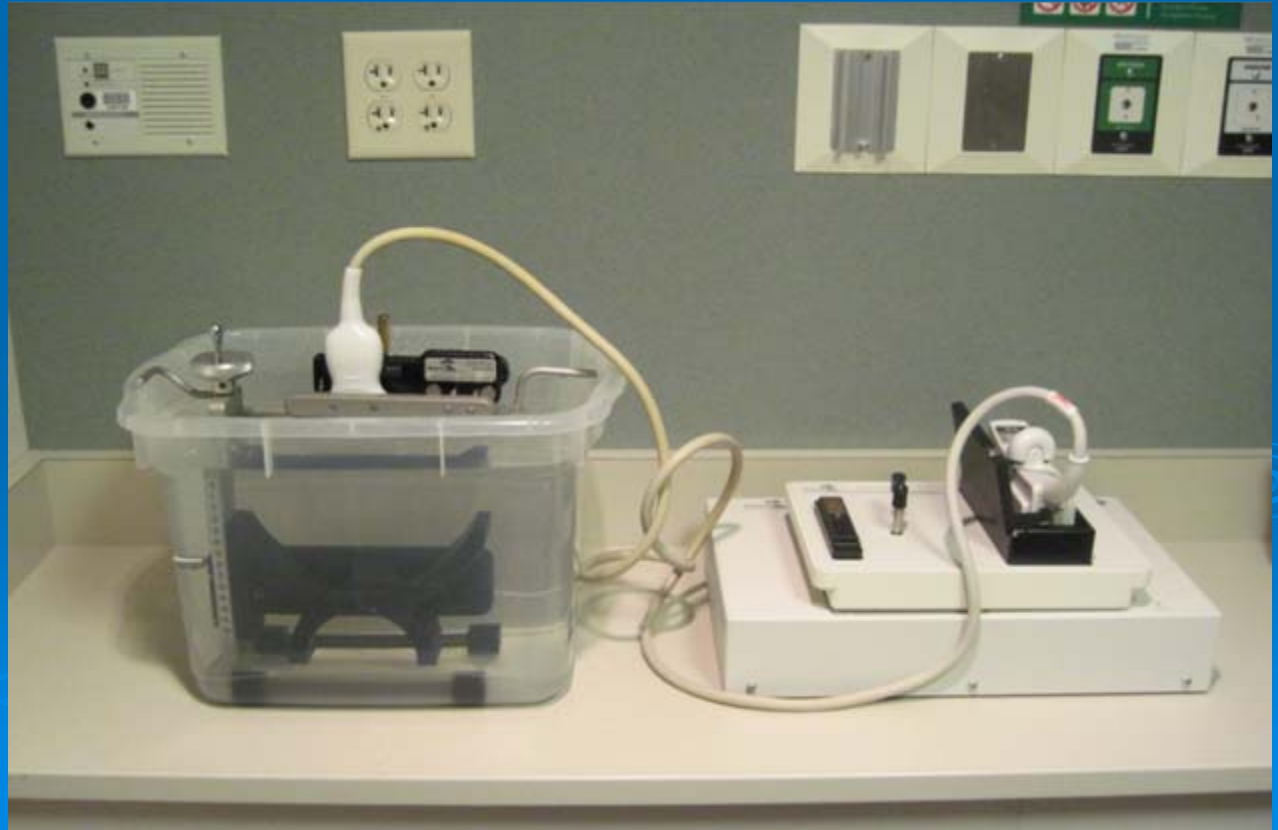


- Calibration and luminance measurement w photometer should be done at a frequency determined by the display technology (calibrated? stabilized?), and previous data
 - Semiannual measurement is a reasonable start
- Commercial US system displays may be lacking in calibration capability, and test patterns



Electronic Probe Test Systems

- Sonora (now Unisyn) FirstCall/aPerio
 - Acoustical and electrical testing of each individual array element



- Sensitivity, capacitance, center frequency, bandwidth, pulse shape, ...



➤ Role of probe testers in routine QC was limited in our practice

- Logistics involve with moving test equipment and PC (or probes) to same location
- Time to set up and test each probe
- Expensive to test multiple probe models, vendors (custom adapters for probe connector)
- Performance benchmarks for probe replacement
- Still need tests to assess *scanner* performance



➤ Useful for trouble-shooting problems

➤ Very useful for *acceptance testing* of probes

- However, availability of test system HW and SW for new US scanners and probes can be a limitation

Reported annual incidence rates of ultrasound transducer defects are best estimated as:

- 0%** 1. 0%
- 0%** 2. 1-5%
- 0%** 3. 10-30%
- 0%** 4. 40-60%
- 0%** 5. >75%
- 0%**

Reported annual incidence rates of ultrasound transducer defects are best estimated as:

- 0%** 1. 0%
- 0%** 2. 1-5%
- 0%** 3. 10-30% ← *is correct!*
- 0%** 4. 40-60%
- 0%** 5. >75%
- 0%**

References:

1. Mårtensson M, Olsson M, Brodin LÅ. Ultrasound transducer function: annual testing is not sufficient. Eur J Echocardiogr. 2010 Oct;11(9):801-5.
2. Hangiandreou NJ, Stekel SF, Tradup DJ, Gorny KR, King DM. Four-year experience with a clinical ultrasound quality control program. Ultrasound Med Biol. 2011 Aug;37(8):1350-7.

Which of the following is most effective at identifying ultrasound imaging system defects?

0%

1. Assessment of Doppler accuracy

0%

2. Uniformity evaluation

0%

3. Mechanical integrity assessment

0%

4. Depth of penetration measurement

0%

5. Clinical use of the system

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Effective, routine ultrasound quality control testing for a scanner and 5 transducers:

- 0%** 1. can be performed in 30 minutes or less
- 0%** 2. requires that 5 or more different phantom tests be performed
- 0%** 3. requires the use of an expensive commercial phantom
- 0%** 4. must include an evaluation of spatial resolution
- 0%** 5. is not needed - sonographers find all important problems
- 0%**

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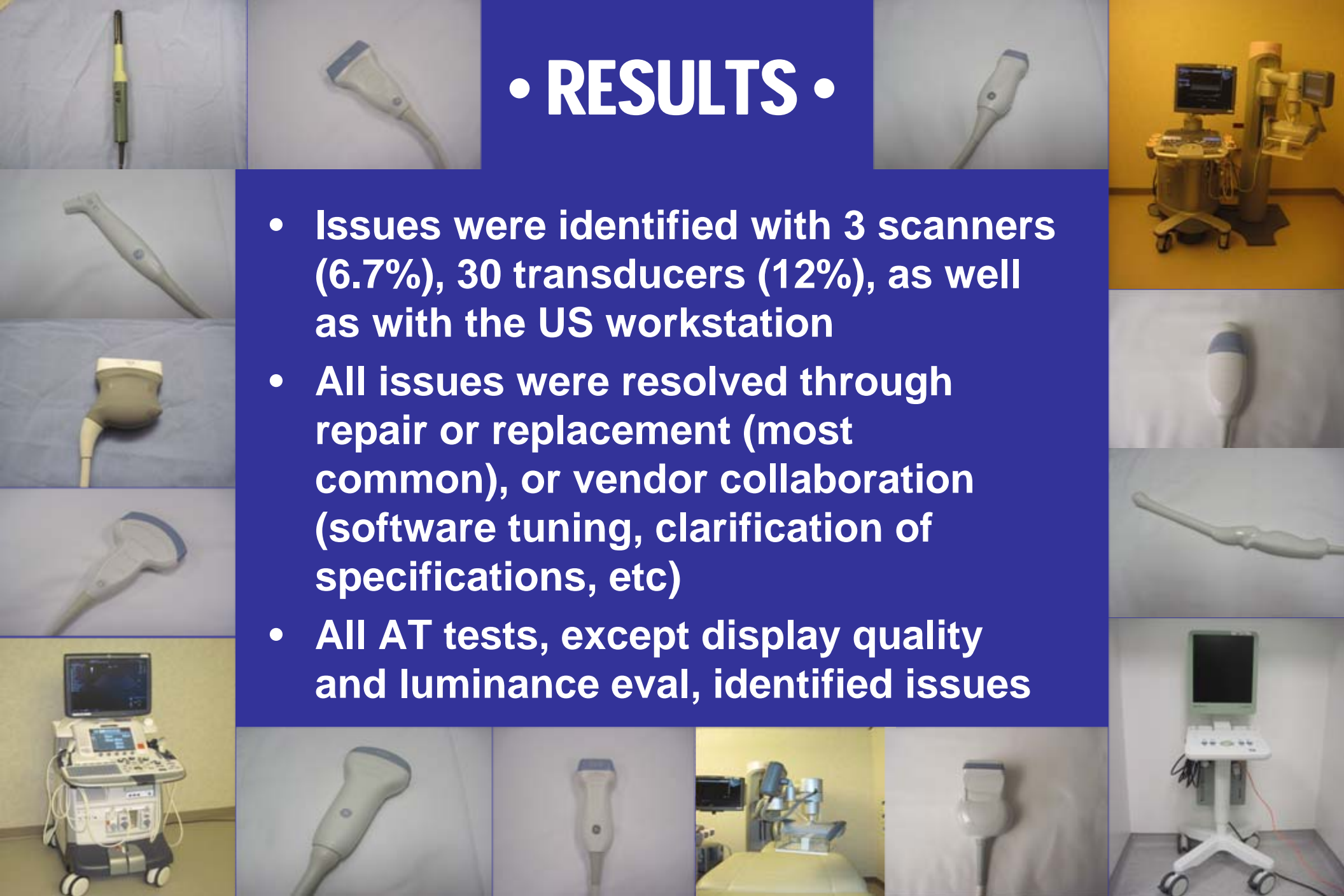
Ultrasound Med Biol. 2011 Aug;37(8):1350-7.

US Acceptance Testing at MCR

- Tests: Basic connectivity, scanner display quality and luminance, mechanical inspection, image geometry (2D&3D), uniformity (all ports), DOP
- Overview of equipment AT'ed in last ~2 years:
 - 3 vendors and scanner models
 - 45 scanners
 - 249 transducers, including linear, curved linear, sector, and endocavitary arrays, biplane prostate probes, handheld mechanical 3D4D probes, and automated breast volume scanning arrays
 - 1 US modality workstation

• RESULTS •

- Issues were identified with 3 scanners (6.7%), 30 transducers (12%), as well as with the US workstation
- All issues were resolved through repair or replacement (most common), or vendor collaboration (software tuning, clarification of specifications, etc)
- All AT tests, except display quality and luminance eval, identified issues



Ultrasound Practice Accreditation

- US not currently included in MIPPA - Medicare Improvements for Patients & Providers Act
- Several organizations offer programs

- American College of Radiology

- Ultrasound
 - Breast ultrasound



- American Institute of Ultrasound in Medicine

- 8 different US practice areas



- Intersocietal Accreditation Commission

- Vascular testing (ICAVL)
 - Echocardiography (ICAEL)



- Commonly required elements of US practice accreditation programs
 - Qualifications of all personnel in practice
 - Documented practice processes and policies
 - Quality control program
 - US System performance testing
 - Physician peer-review
 - Practice outcome data (e.g. ACR, US-guided breast bx)
 - Quality assessment of sample clinical exams
- *A team of people is needed to best assure all accreditation requirements are met*

➤ Quality control program

- May specify performance characteristics and minimum assessment frequencies
- Few requirements of specific testing methods or tools (phantoms), or absolute performance criteria
- **QC requirements vary widely between programs**

➤ Work is underway to revise QC requirements for ACR and AIUM US accreditation programs

- ACR req's will ~mirror recently revised "ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment"

Ultrasound practice accreditation programs address which of the following items?

0%

1. Physician qualifications

0%

2. Equipment quality control testing

0%

3. Sonographer or technologist qualifications

0%

4. Quality of sample clinical exams

0%

5. All of these are typically addressed

Ultrasound practice accreditation programs address which of the following items?

- 0% 1. Physician qualifications
- 0% 2. Equipment quality control testing
- 0% 3. Sonographer or technologist qualifications
- 0% 4. Quality of sample clinical exams
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References:

1. ACR Ultrasound Accreditation Program Requirements,
http://www.acr.org/accreditation/ultrasound/ultrasound_reqs.aspx
2. The Complete ICAVL STANDARDS FOR ACCREDITATION IN VASCULAR TESTING, http://www.intersocietal.org/icavl/standards/2010_ICAVL_Standards.pdf
3. AIUM accreditation, Getting started,
<http://www.aium.org/accreditation/gettingstarted.aspx>

Conclusions

- Ultrasound performance testing is worth doing
 - There is significant benefit to be gained
 - Routine QC
 - Acceptance testing
 - (Pre-purchase evaluations)
- Effective routine US QC can be done with a minimum of tests, in a reasonable time, with inexpensive equipment
 - Should include qualitative monitor assessment

Conclusions

- Objective, computer-based US performance testing tools are not widely available
 - Especially useful for acceptance testing (and pre-purchase system evaluations)
 - Tracking progression of sub-clinical uniformity artifacts identified at routine QC?
- Scope of current, commonly discussed US testing methods is limited
 - Color and spectral Doppler (some literature exists)
 - Elastography

Conclusions

- US accreditation QC requirements
 - Currently vary widely between programs
 - Will likely increase and should become better defined in the near future
 - ACR and AIUM currently under revision

Acknowledgements

- Don Tradup, RDMS
- Scott Stekel, BS
- Eric Kischell, BS
- Deirdre King, PhD

