

ACR Ultrasound Practice Accreditation and Technical Standard for Ultrasound Performance Monitoring

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Breast Ultrasound Accreditation Program Requirements



OVERVIEW

MANDATORY ACCREDITATION TIME REQUIREMENTS

PERFORMANCE

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if advised.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council, the ACR Council on Quality and Safety, and the ACR Council on Quality and Safety. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2011 (Resolution 3)*

ACR TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF REAL TIME ULTRASOUND EQUIPMENT

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be construed, as establishing a legal standard of care. For purposes of accreditation, the following guidelines are intended to be used as a minimum standard of practice. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the individual medical physicist in light of all the circumstances. The guidelines are intended to be used as a minimum standard of practice. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the individual medical physicist in light of all the circumstances.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of these guidelines is to assist practitioners in providing appropriate radiation oncology care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be construed, as establishing a legal standard of care. For purposes of accreditation, the following guidelines are intended to be used as a minimum standard of practice. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the individual medical physicist in light of all the circumstances.

All ultrasound equipment must be evaluated upon installation (acceptance testing) and routinely thereafter to ensure that it is functioning properly. Acceptance testing and performance evaluations should be performed or supervised by a Qualified Medical Physicist. In addition, maintenance should be performed and supervised by a qualified equipment service engineer following the recommendations of the equipment vendor. Although it is not possible to consider all possible variations of equipment performance to be monitored, reference to this standard will maximize image quality. Points to consider are performance characteristics to be monitored, qualifications of personnel, and follow-up procedures.

II. GOAL

The goal of this document is to establish a standard that will allow production of the highest quality diagnostic images consistent with the safety of the equipment and the uniformity of the results.

Ultrasound Accreditation Program Requirements



REQUIREMENTS

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- Overview of each document
- Ongoing evolution of the accreditation programs
- Practical aspects of QC testing
- Future considerations

ACR TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF REAL TIME ULTRASOUND EQUIPMENT

- Performance evaluations are distinguished from preventive maintenance
- Recommended that performance evaluations be done by a physicist, but flexibility is allowed
- Subjective or objective testing methods may be used
- Phantoms must be used (commercial or custom)
- Probe testing systems may be used
- *All* probes must be tested at QC at least semiannually
- Electronic scanner (and primary diagnostic) image displays must be tested

Test	Acceptance Testing** (M)	Quality Control	Annual Testing**
Physical and mechanical inspection	S	M	M
Image uniformity and artifact survey	S	M	M
Geometric accuracy	S	M*	M
System sensitivity	S	S	M
Spatial resolution	S	S	S
Contrast resolution	S	S	M
Fidelity of US scanner electronic image display	S	S	M
Fidelity of display devices used for primary interpretation	S	S	S
Qualitative evaluations of Doppler functionality	S	S	S

M = "must do" / required

S = "should do" / optional

* Only needed for mechanically-scanned probes

** All tests done for QC must be included

- General approach: Make the best use of time invested by the practice in routine QC by requiring efficient tests with demonstrated utility

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

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

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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]

- The accreditation program QC requirements are meant to align with those in the technical standard, which should serve as minimum requirements
- It might be expected that QC requirements in accreditation programs involving the same modality would be very similar, if not identical

Ultrasound Accreditation Program Requirements



(Revised 3/23/12)

- Short list of "must do" tests (sensitivity, uniformity, electrical & mechanical safety, photo and hard-copy)
- Only 2 most commonly used transducers must be tested at QC
- Use of phantom is stated as optional
- Scanner display testing not mentioned (hard copy is included)
- Fairly detailed methods for some tests are embedded in the program document

Continuous Quality Control

Routine quality control testing must occur regularly; *a minimum requirement is semiannually*. The same tests must be performed during each testing period so that changes can be monitored over time and effective corrective action can be taken. Testing results, corrective action, and the effects of corrective action must be documented and the documentation maintained on site. In the event of a site survey, reviewers will expect to see such documentation.

The QC program must evaluate at least the following items in gray-scale imaging mode:

- System sensitivity and/or penetration capability.
- Image uniformity.
- Assurance of electrical and mechanical safety and cleanliness
- Photography and other hard-copy recording.

In addition, it is recommended that users verify the accuracy of vertical and horizontal distance measurement when a QC program is initiated for an ultrasound unit.

These items may be assessed using a commercially available phantom test object. At the present time, no one type of phantom is preferred; users should select one that is commercially available. Using a phantom will be helpful in responding to questions about low-contrast detectability in the quality control part of the testing material. However, the use of a phantom is *optional* at this time. Questions relating to characteristics associated with system sensitivity and image uniformity may be answered without the use of a phantom as a test object.

Breast Ultrasound Accreditation Program Requirements



Revised 6/21/12

- Long list of “recommended” tests, but no “must do” tests
- Scanner display testing not mentioned (but hard copy testing is included)
- Large loophole is offered...

Quality Control

The following routine QC should be performed on all ultrasound units used for breast imaging as recommended in the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment:

Recommended Quality Control for Breast Ultrasound		
Test	Frequency	Performed By
Maximum depth of visualization and hardcopy recording with a tissue-mimicking phantom	Semiannually	Service engineer/medical physicist
Vertical and horizontal distance accuracy	Semiannually	Service engineer/medical physicist
Uniformity	Semiannually	Service engineer/medical physicist
Electrical-mechanical cleanliness condition	Semiannually	Service engineer/medical physicist
Anechoic void perception	Semiannually	Service engineer/medical physicist
Ring down	Semiannually	Service engineer/medical physicist
Lateral resolution	Semiannually	Service engineer/medical physicist
Quality control checklist	Semiannually	Service engineer/medical physicist
Adherence to universal infection control procedures	After each biopsy	Technologist
Clean transducers	After each patient	Technologist
Vertical and horizontal distance accuracy	Quarterly	Technologist
Grey-scale photography	Quarterly	Technologist

As part of accreditation, facilities must submit a copy of the service engineer's most recent preventive maintenance report or the medical physicist's most recent equipment survey. Although the ACR will not initially use this information to determine whether a facility passes or fails accreditation, it may be used in the future to set criteria.

Ongoing evolution of the accreditation programs

- Currently developing a new ultrasound performance testing section
 - Used in both US-related Accreditation Programs
 - Correlate closely with the Technical Standard
 - Consider acceptance testing, quality control, and an annual survey
 - No additional specific testing for re/application
 - Include an appendix describing sample methods for performing QC tests

➤ Ultrasound Quality Control Manual

- Standard phantom?
- Standard testing methodology?
- Specific performance targets?



Practical aspects of QC testing

- Physical and mechanical inspection +
- Image uniformity and artifact survey +
sonog reported problems > *98% of failures*
- Ultrasound scanner electronic image display



➤ Physical and mechanical inspection



➤ Image uniformity and artifact survey



ATS



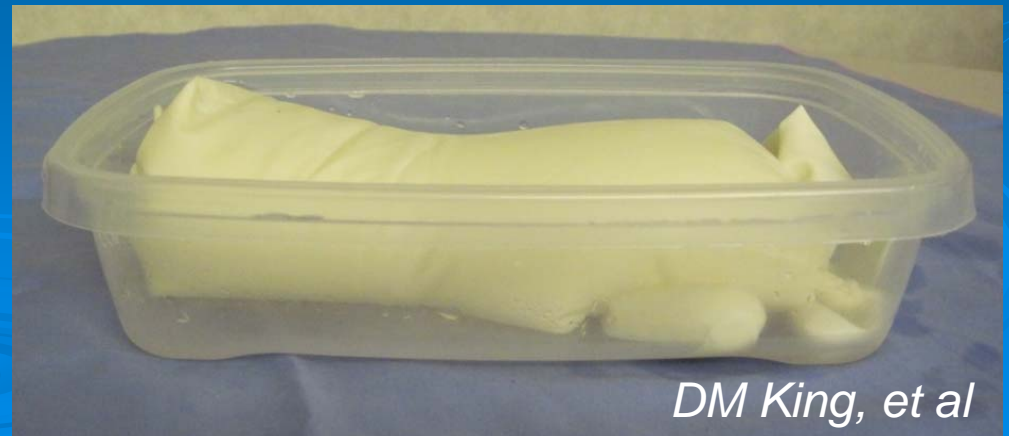
Gammex



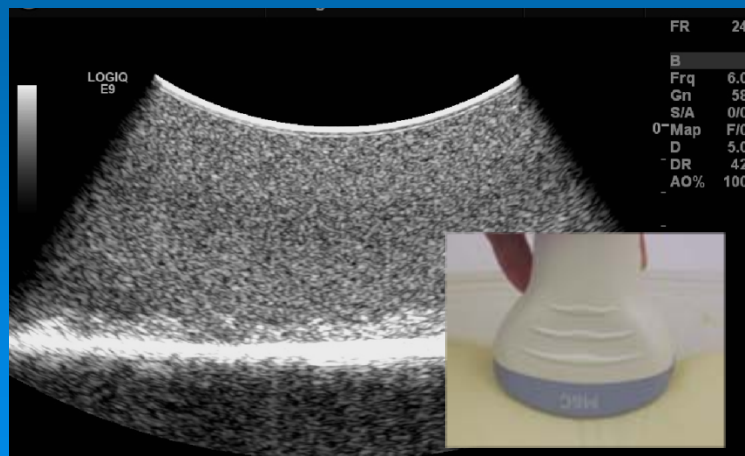
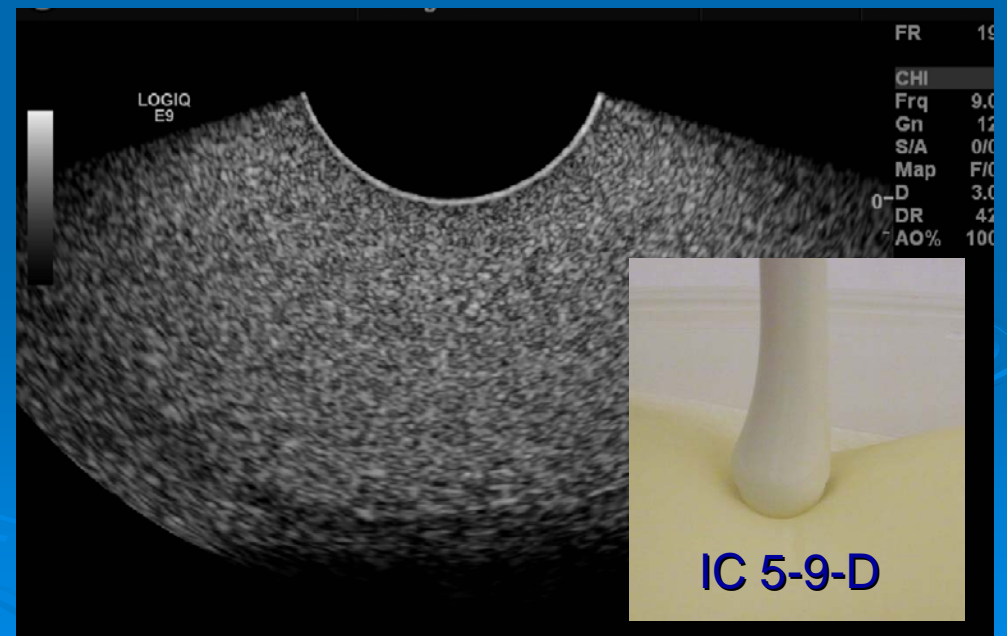
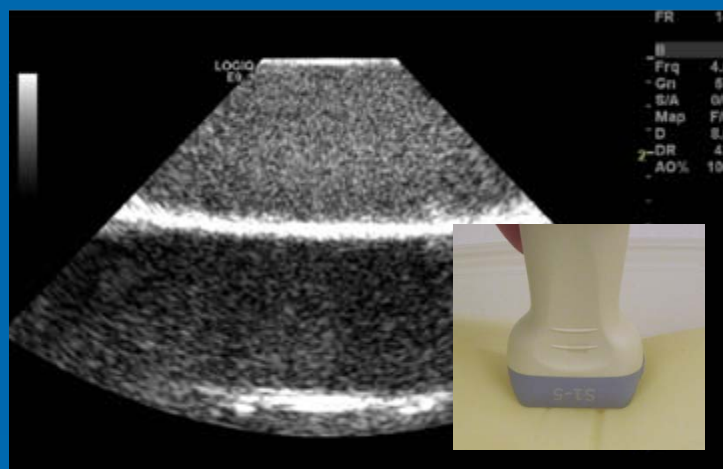
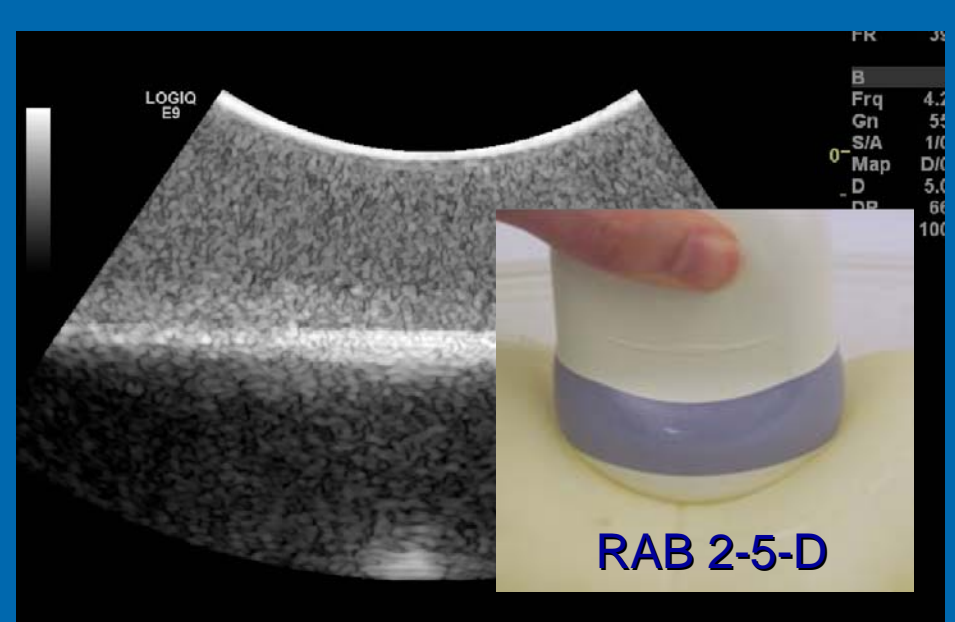
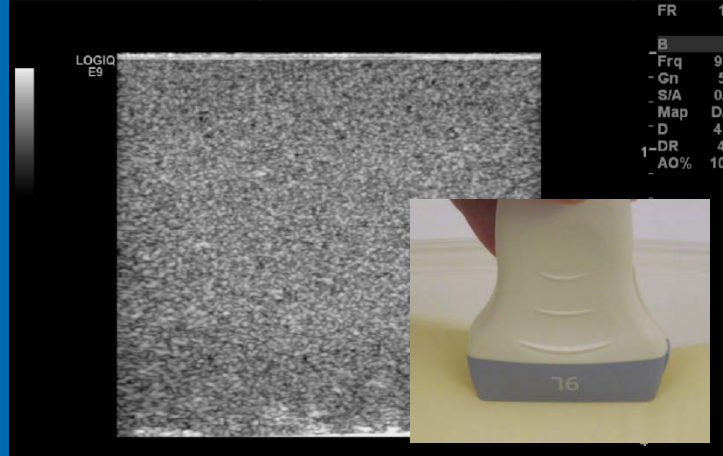
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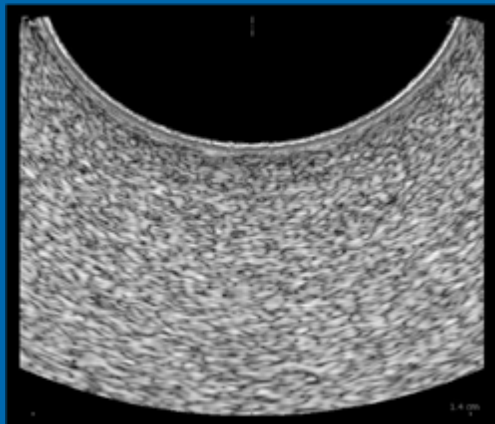
Gammex



DM King, et al



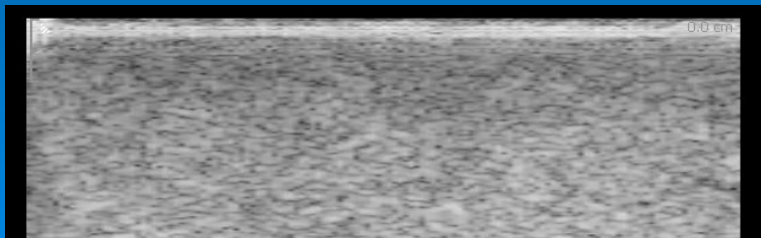
BK FlexFocus bi-plane prostate probe



Sagittal Array

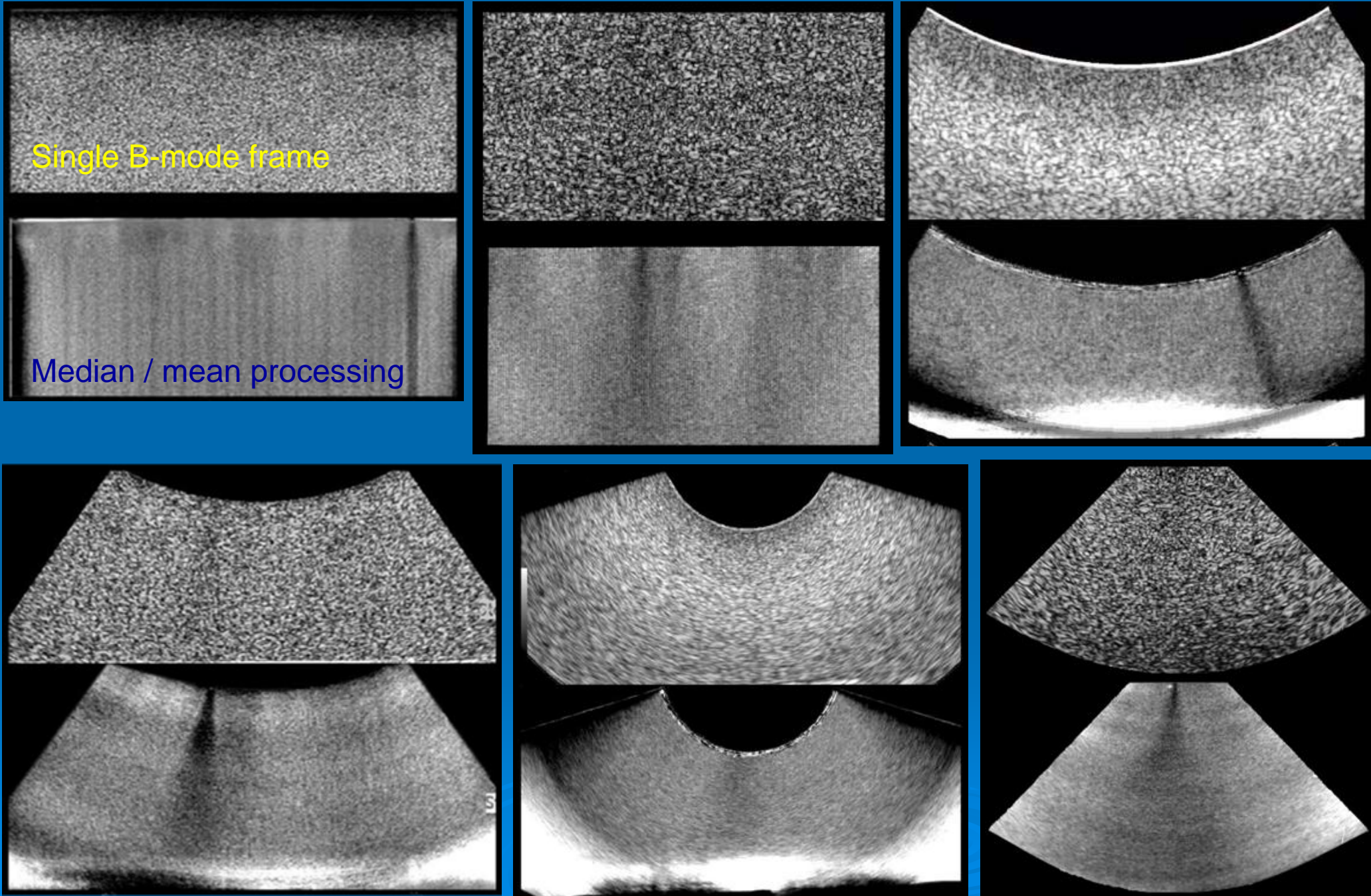


Transverse Array



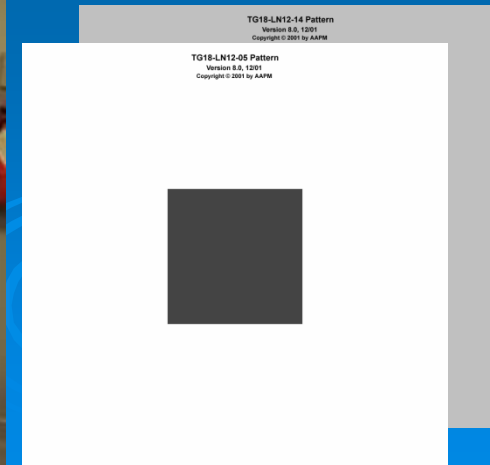
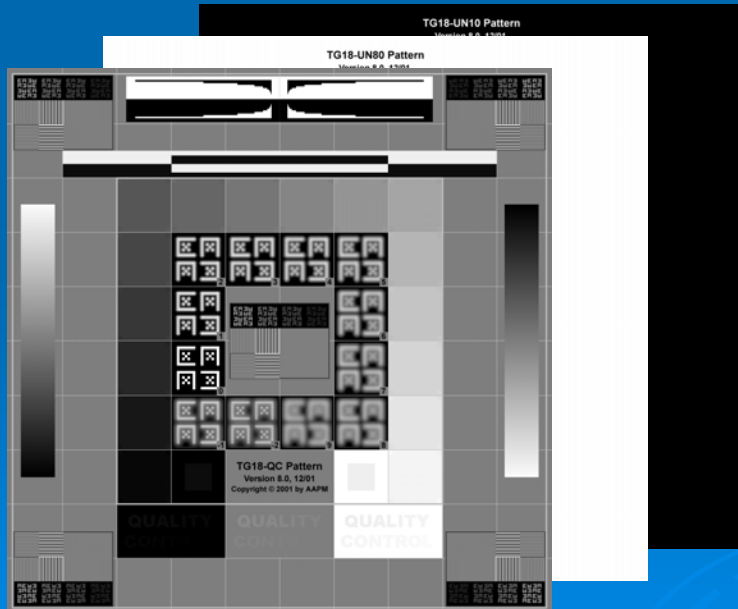
Single B-mode frame

Median / mean processing



➤ Ultrasound scanner electronic image display

- Ultrasound scanner monitor is a *primary diagnostic* display device
 - Overall display quality
 - Luminance calibration



Future considerations

- Continued assessment of the utility of existing QC tests and tests proposed in the future
 - Spectral and color Doppler?
- Increased availability of software tools: migration from subjective to objective methods
 - E.g. median or mean processing of US clips (AAPM)
- Improved correlation of equipment flaws and impacts on clinical utility

Acknowledgements

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

