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 indicated.

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 Steering Committee, and the ACR Council. 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.

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

PREAMBLE

These standards are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these standards in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the standards, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the standards when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the standards. However, a practitioner who employs an approach substantially different from these standards is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these standards 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 sole purpose of these standards is to assist practitioners in achieving this objective.

I. INTRODUCTION

All ultrasound equipment should be evaluated upon installation and at least annually thereafter to ensure that it is functioning properly. Performance evaluations are the responsibility of the medical physicist and should include acceptance testing and routine quality control testing. In addition, regular preventive maintenance should be performed and documented 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, adherence to this standard will maximize image quality. Key points to consider are performance characteristics to be monitored, qualifications of personnel, and follow-up procedures.

II. GOAL

The goal is to produce the highest quality diagnostic image consistent with the clinical use of the equipment and the information requirement of the examination and to establish performance standards.
III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this standard are Diagnostic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

The medical physicist must be familiar with the principles of ultrasound safety and bioeffects; regulations pertaining to the performance of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments used for testing performance.

The medical physicist is responsible for:

1. The design of the overall program of performance monitoring including selection of specific methods for acceptance testing and quality control testing.
2. Documentation of program goals, policies and procedures.
3. Documentation of the results of all performance measurements.
4. Review and approval of all measurements performed by other designated personnel.

Properly trained individuals may assist the medical physicist in the overall program design and documentation and in obtaining test data for performance monitoring. These individuals must be trained and approved by the medical physicist in the techniques of performing the tests, the function and limitations of the imaging equipment, test instruments, measurement methods, the reasons for the tests, and the importance of the test results. The medical physicist must periodically review and approve all performance measurements.

IV. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A. Performance Evaluation

Ultrasound system performance should be evaluated periodically. This evaluation should include, but not be limited to, the following tests (as applicable) [1-3] (see Appendix):

1. Physical and mechanical inspection.
2. Image uniformity and artifact survey.
3. Geometric accuracy.
5. Spatial resolution.
6. Contrast resolution.
7. Fidelity of the ultrasound scanner electronic image display(s).
8. Fidelity of the display device(s) used for primary interpretation.
9. Qualitative evaluations of Doppler functionality.

Either subjective visual methods or objective computer-based approaches may be used to make these measurements [1,3-6]. If subjective methods are used, it is recommended that the images used to perform the tests be retained for comparison with subsequent test images.

Image-based performance measurements must be made using an ultrasound phantom. Acceptable phantoms are available from a variety of commercial vendors. Other approaches to performance measurement not requiring ultrasound images of phantoms have been reported, e.g., the “paper-clip test” [4] and use of the FirstCall transducer test device from Sonora Medical Systems [5] which tests the electrical and acoustic characteristics of each individual transducer array element. These approaches may be used for evaluating some performance characteristics if they are appropriately described by the medical physicist in the overall program documentation. The topic of display device performance assessment is discussed in the ACR Technical Standard for Electronic Practice of Medical Imaging.

B. Quality Control Program

A continuous quality control (QC) program is essential to assure the proper functioning of all ultrasound equipment. Transducers are a weak link in the ultrasound imaging chain since cables may be easily kinked and stressed, they are easy to drop, and the active elements are relatively fragile.

All scanners and all transducers should be tested quarterly. This should allow problems to be identified at an early stage and before the diagnostic utility of the equipment is significantly impacted.
Quarterly tests should include:

1. Physical and mechanical inspection.
2. Image uniformity and artifact survey.
3. Geometric accuracy (only for mechanically scanned transducers).

All transducer ports on each scanner should be tested using at least 1 transducer. Electronic image displays, both those on the ultrasound equipment and those used for primary interpretation (e.g., workstation displays), should be tested according to the recommendations in the ACR Technical Standard for Electronic Practice of Medical Imaging, in terms of specific tests and testing frequency. Test methods for hard-copy display equipment are described in Siegel et al [7] and Goodsitt et al [2].

All scanners and transducers should be tested annually for geometric accuracy and system sensitivity.

C. Acceptance Testing

The performance of all ultrasound imaging equipment must be extensively evaluated at the time it is acquired. This includes purchases of new scanners and/or transducers, as well as replacement equipment obtained under warranty or service contract. Acceptance testing should be done following equipment repair, and may also be warranted following major equipment upgrade. Equipment pulled from storage should also undergo acceptance testing. These tests should provide complete performance baselines for comparison with future test results.

1. Ultrasound scanners. Acceptance testing of a scanner alone (i.e., without testing transducers) may be performed using a single transducer. These tests should include:

   a. Physical and mechanical inspection.
   b. Image uniformity/artifact survey (each transducer port on the scanner should be tested).
   c. Geometric accuracy.
   d. System sensitivity.
   e. Spatial resolution.
   f. Contrast resolution.
   g. Fidelity of ultrasound scanner electronic image display(s).

   For those systems with tissue harmonic imaging capabilities, at minimum, tests d, e, and f above should be repeated in this mode.

   For those systems with spectral Doppler and color-flow imaging capabilities, qualitative evaluations of these capabilities should be performed.

2. Ultrasound transducers. Acceptance tests should include:

   a. Physical and mechanical inspection.
   b. Image uniformity/artifact survey.
   c. Geometric accuracy.
   d. System sensitivity.
   e. Spatial resolution.
   f. Contrast resolution.

D. Written Survey Reports and Follow-up Procedures

If test results fall outside of the acceptable limits, corrective action should be taken, typically by an equipment service engineer. If appropriate, the medical physicist should initiate the required service. Appropriate action and notification shall occur immediately if there is imminent danger to patients or staff using the equipment due to unsafe conditions. A medical physicist should be available to assist in prescribing corrective actions for unresolved problems. After a problem has been addressed, acceptance testing should be performed to assure adequate resolution of the problem, and these test results should be documented.

The medical physicist shall report results of the acceptance tests and QC program testing to the physician(s) directing the clinical ultrasound practice, the responsible professional(s) in charge of obtaining or providing necessary service to the equipment and, in the case of the consulting physicist(s), to the representative of the hiring party. This communication shall be provided in a timely manner consistent with the importance of any adverse findings.

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**REFERENCES**


**Suggested Reading**


**Appendix A**

1. Physical and mechanical inspection – this assures the mechanical integrity of the equipment, and the safety of patient and operator.

2. Image uniformity/artifact survey – this test aims to identify 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 – tests often involve use of the scanner calipers to measure known distances between phantom test targets in the axial and lateral directions, although other tests of geometric accuracy have been described. The use of a phantom with a sound speed closely matching 1.540 m/s is recommended for determining absolute performance.

4. System sensitivity – visual determination of the maximum depth of visualization of speckle patterns or phantom targets, and quantitative measurements of signal-to-noise ratio (SNR), have both been reported.

5. Spatial resolution – this should be measured in the axial, lateral, and elevational directions. Various approaches have been described for making axial and lateral resolution measurements, including visual interpretation of groups of phantom pin/fiber targets and measurement of pin target dimensions. Similarly, various approaches for making elevational resolution measurements have been discussed, one requiring a special phantom, and one compatible with multipurpose phantoms [4]. The use of a phantom with a sound speed closely matching 1.540 m/s is recommended for determining absolute performance.

6. Contrast resolution – 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. The use of larger 2D targets emphasizes contrast resolution performance, while the use of small targets also tests spatial resolution capabilities.

7. Fidelity of ultrasound scanner electronic image display(s) – when used for diagnostic purposes, the electronic displays on the scanner and any modality workstations should be considered as primary diagnostic devices. This would not necessarily be the case for scanners used exclusively as an aid to guide procedures.

8. Fidelity of display device(s) used for primary interpretation – these primary diagnostic displays...
may be electronic soft-copy displays on a workstation or hard-copy films.

9. Qualitative evaluations of Doppler functionality – for spectral Doppler mode, the tests include positioning of the Doppler sampling volume, specification of Doppler angle, Doppler spectral display, directionality of flow, and lack of velocity signal where no flow is present. For color flow imaging mode, the tests include color map and flow direction, and color signal superimposition on the grayscale image. As these are visual, qualitative tests, the use of a phantom is not required.

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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