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The American College of Radiology will periodically define new practice parameters 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 parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter 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 and approval. The practice parameters 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 parameter and technical standard by those entities not providing these services is not authorized.

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## **ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF A BREAST ULTRASOUND EXAMINATION**

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### **PREAMBLE**

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>1</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practice parameters, 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 practice parameters 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 practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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 practice parameters 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 practice parameters is to assist practitioners in achieving this objective.

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<sup>1</sup> *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, \_\_\_ N.W.2d \_\_\_ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

## I. INTRODUCTION

This practice parameter has been developed to assist practitioners performing ultrasound examination of the breast. When ultrasound is used as guidance for interventional procedures or biopsy, relevant American College of Radiology (ACR) practice parameters should be consulted.

## II. INDICATIONS

Appropriate indications for breast sonography include, but are not limited to:

1. Evaluation and characterization of palpable masses and other breast-related signs and/or symptoms [1-4]
2. Evaluation of suspected or apparent abnormalities detected on mammography (with or without digital breast tomosynthesis), breast magnetic resonance imaging (MRI), or other imaging modalities [5,6]
3. Initial imaging evaluation of palpable breast masses in patients under 30 years of age who are not at high risk for development of breast cancer and in lactating and pregnant women
4. Evaluation of problems associated with breast implants [7]
5. Guidance for breast biopsy and other interventional procedures [8]
6. Treatment planning for radiation therapy [7]
7. As a supplement to mammography, screening for occult cancers in certain populations, including of women with heterogeneously or extremely dense breasts who are determined to be at elevated risk of breast cancer or with newly suspected breast cancer, who are not candidates for MRI [9-13] or have no easy access to MRI
8. Identification of and biopsy guidance for abnormal axillary lymph node(s), for example, in patients with newly diagnosed or recurrent breast cancer [14-16] or with findings highly suggestive of malignancy or other significant pathology

## III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PHYSICIAN

### A. Physician

Physicians who supervise, perform, and/or interpret breast ultrasound examinations should be licensed medical practitioners who have a thorough understanding of the indications for ultrasound examinations as well as a familiarity with the basic physical principles and limitations of the technology of ultrasound imaging. They should be familiar with alternative and complementary imaging and should be capable of correlating the results of these with the sonographic findings. They should have a thorough understanding of ultrasound technology and instrumentation, ultrasound power output, equipment calibration, and safety. Physicians responsible for breast ultrasound examinations should demonstrate knowledge of breast anatomy, physiology, and pathology. These physicians should provide evidence of the training and competence needed to perform breast ultrasound examinations successfully.

The initial qualifications as outlined for [Breast Ultrasound Accreditation Program Requirements](#) provide this foundation [17].

### Maintenance of Competence

The physician should perform a sufficient number of procedures to maintain their skills. Continued competence should depend on participation in a quality control program as laid out under section VIII of this practice parameter.

### Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [18] and should include CME in ultrasonography as is appropriate to his or her practice.

## B. Sonographer or Technologist

The sonographer or technologist performing the examination should be certified or eligible for certification by a nationally recognized certifying body.

## IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for a breast ultrasound examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

## V. SPECIFICATIONS FOR INDIVIDUAL EXAMINATIONS

### A. Examinations should include a permanent identification label that contains:

1. Facility name and location
2. Examination date
3. Patient's first and last name
4. Identifying number and/or date of birth
5. Designation of right or left breast
6. Sonographer's and/or physician's identification number, initials, or other symbol

### B. Lesion Characterization and Technical Factors [4]

1. The breast sonogram should be correlated with clinical signs and/or symptoms and with mammographic and other appropriate breast imaging studies. If sonography has been performed previously, the current examination should be compared with prior sonograms, as appropriate. A lesion or any area of the breast being studied should be viewed in 2 perpendicular projections, and real-time scanning by the interpreter is encouraged.
2. The images should be labeled as to right or left breast, and the location of the lesion should be recorded using clock-face notation, distance from the nipple, and the orientation of the transducer with respect to the breast (eg, transverse or longitudinal, radial or antiradial). It may also be shown on a diagram of the breast. Distance from the nipple should not be measured from the edge of the areola but from the nipple itself, as areolar width is variable.
3. The size of a lesion should be determined by recording its maximal dimensions in at least 2 planes; orthogonal planes are recommended. At least 1 set of images of a lesion should be obtained without calipers. A set of images of the lesion with color/power Doppler to assess/document vascularity of the lesion is also recommended.
4. Sonographic features are important in accurately characterizing breast masses. These feature categories and their descriptors are listed and exemplified in the [ACR Breast Imaging Reporting and Data System®](#)

([BI-RADS®](#)). The BI-RADS sonographic categories include shape, orientation, margins, echo pattern, posterior acoustic features, special characteristics, vascularity, and surrounding tissue [4].

5. Elasticity assessment is among the feature categories applicable to sonographic analysis of masses to be included in the associated features section in BI-RADS – Ultrasound, 5th Edition [4]. To minimize errors in communication or interpretation, if elastography is performed, the color scales should be annotated to denote hardness or softness.
6. Mass characterization with ultrasonography is highly dependent on technical factors.

Breast ultrasound should be performed with a high-resolution scanner and transducer (see section VII). Gain settings, focal zone selections, and field of view should be optimized to obtain high-quality images. The patient should be positioned to minimize the thickness of the portion of the breast being evaluated. For evaluation of lesions in, on, or just beneath the skin, a standoff device or thick layer of gel may be helpful.

### C. Guidance for Interventional Procedures

(See the [ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures](#) [19].)

When ultrasound guidance is used to assist in needle placement for interventional procedures, care should be taken to ensure that scanning geometry and transducer placement permit adequate visualization of the entire portion of the needle within the breast.

## VI. DOCUMENTATION

Images of all important findings, including, in the case of interventional procedures, the relationship of the needle to the lesion, should be recorded in a retrievable and reviewable image storage format. It is recommended that documentation of a negative targeted or whole-breast ultrasound examination be performed.

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Comparison with prior relevant imaging studies may prove helpful. Images of all appropriate areas, both normal and abnormal, should be recorded. Lesions denoted as abnormal should generally be measured. The initials of the operator should be accessible on the images or electronically on PACS. Images should be labeled as described in section V. An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record. It is recommended that the report include a description of the area scanned. Retention of the ultrasound examination images should be based on clinical need and with relevant legal and local health care facility requirements.

If ultrasound is performed for evaluating clinical signs and/or symptoms or a finding on mammography, MRI, or other imaging modality, the indication for the examination and finding(s) should be referred to in the report. Reporting of lesions should generally include measurements. Use of an accepted reporting system, such as BI-RADS® US, is recommended.

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [20].

## VII. EQUIPMENT SPECIFICATIONS

Breast ultrasound should be performed with a high-resolution, real-time, linear-array, broad-bandwidth transducer operating at a center frequency of at least 12 MHz and preferably higher. Other transducers may be utilized in special circumstances. Focal zones should be electronically adjustable. In general, the highest frequency capable of adequate penetration to the depth of interest should be used. For evaluating superficial lesions, scanning

through a thin standoff device or thick layer of gel may be helpful in offsetting the transducer face from the uppermost layer of skin to bring it into the focal zone of the transducer.

## **VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION**

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>).

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [21].

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\*Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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