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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 DIAGNOSTIC 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, 831 N.W.2d 826 (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 revised to assist practitioners performing diagnostic ultrasound examination of the breast and the axilla. 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 diagnostic sonography of the breast and axilla 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
4. Evaluation of symptoms in lactating and pregnant patients [7]
5. Evaluation of problems associated with breast implants [8]
6. Guidance for biopsy and other interventional procedures for breast and axilla [9]
7. Treatment planning for radiation therapy [8]
8. Identification of abnormal axillary lymph node(s) in patients with newly diagnosed or recurrent breast cancer [10-13], or in patients with findings highly suggestive of malignancy or palpable findings in the axilla. Current automated breast ultrasound systems, which can be used for diagnostic purposes, such as breast cancer staging, are inadequate to depict the axilla. If the axilla is evaluated during supplemental screening, handheld, conventional high-resolution imaging is required [14].

Supplemental screening for occult cancers in certain populations, including patients with heterogeneously or extremely dense breasts, determined to be at elevated risk of breast cancer or with newly suspected breast cancer, who are not candidates for MRI [15-19], are addressed in the [ACR Practice Parameter for the Performance of Whole-Breast Ultrasound for Screening and Staging](#) [20].

## III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

### 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 in the [Breast Ultrasound Accreditation Program Requirements](#) provide this foundation [21].

Real-time performance and interpretation of diagnostic breast ultrasound are preferred, if possible, because ultrasound is operator dependent. Remote supervision and interpretation of diagnostic breast ultrasound by a qualified radiologist can be performed in specific situations in which patients would otherwise not have access to diagnostic imaging.

### 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 in 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 \(CME\)](#) [22] and should include CME in ultrasonography as appropriate.

### 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 diagnostic 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 – revised in 2016, Resolution 12-b)

## V. SPECIFICATIONS FOR 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 breast or axilla and its laterality
6. Sonographer's and/or physician's identification number, initials, or other symbol

### B. Breast 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 orthogonal projections, and real-time scanning by the interpreter radiologist frequently aids in correlating ultrasound findings with clinical and imaging findings.
2. The images should be labeled as right or left breast, or axilla, and the location of the lesion should be recorded using clockface notation, distance from the nipple (as CM FN), 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 (in addition, but not in place of clockface) of the breast. Distance from the nipple should not be measured from the edge of the areola but from the nipple itself with a ruler, as areolar width is variable.

3. Mass characterization with ultrasonography is highly dependent on technical factors. Breast ultrasound should be performed with a high-resolution transducer (see section VII). Gain settings, focal zone selections, and fields 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.
4. The size of a lesion should be determined by recording its dimensions in 3 orthogonal planes if possible; the largest measurement should represent the longest axis of a lesion. Volume can be calculated as needed. Images of a lesion should be obtained without and with calipers. One or more color or power Doppler images of the lesion are recommended to be obtained to assess/document internal vascularity of the lesion.
5. 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, and associated features including effect of a lesion on the surrounding tissue (architectural distortion), ductal and skin changes, vascularity, and tissue stiffness. Lymph nodes are categorized as “special cases” [4].
6. Elasticity assessment may be performed but should not be used to override the more predictive morphologic features of malignancy. To minimize errors in communication or interpretation, the performer and interpreter should be knowledgeable and trained in the type of elastography used: strain, shear wave, and/or acoustic resonance frequency impulse (ARFI). The color scales representing velocity or elasticity should be annotated to denote hardness or softness.

#### C. Axillary Lymph Node Characterization and Technical Factors

1. The imaging modality of choice for the axilla is ultrasound. Sonographic features of axillary nodes are important. These features and their descriptors are listed and exemplified in the BI-RADS [23]. The BI-RADS ultrasound features for assessing lymph nodes include size, shape, cortical thickness, margin, and observation of hilar compression or displacement [23].
2. The number and size of normal axillary lymph nodes vary from individual to individual; because there is considerable normal variation, bilateral evaluation may help establish a normal pattern for an individual. In general, a normal axillary lymph node may be up to 2 cm in its longest dimension, could have a cortical thickness  $\leq 0.3$  cm, and contains a hyperechoic fatty hilum [23]. Predominantly fatty lymph nodes larger than 2 cm may be normal when a very thin cortical rim is seen, whereas small nodes with no fatty hilum or compressed hilum may be abnormal. Depiction of a cortical bulge or altered echogenicity suggests the presence of metastasis in a patient with newly diagnosed breast cancer. Because there is no specific sonographic feature that reliably distinguishes a nodal metastasis from a benign reactive node, side-to-side symmetry of size, number, and shape of nodes may help distinguish normal from abnormal.
3. Presence of fat in a nodal hilum does not exclude metastatic involvement, as the hilar fat may be gradually displaced by tumor over time. Interval changes are best detected in comparison with serial mammograms and ultrasounds if available. Increasing nodal size and number at mammography may be a cause of concern and support a recommendation for biopsy.
4. Preoperative axillary ultrasound remains important for staging, although it is optional for inclusion in ultrasound supplemental screening if the axilla is well depicted on mammography, as the axillary nodal stage is an important prognostic indicator of outcome for patients with breast cancer. The publication of the American College of Surgeons Oncology Group (ACOSOG) Z0011 trial resulted in a paradigm shift in the axillary management of early T1 and T2 breast cancers [24,25]. The study showed no benefit for axillary lymph node dissection over surgical sentinel node biopsy for patients with a low burden of axillary disease, who underwent breast conservation therapy. Although the decision to preoperatively biopsy abnormal axillary nodes varies among different centers, ultrasound evaluation and biopsy of axillary lymph nodes are

essential for the majority of patients with breast cancer, who are not affected by the Z0011 trial results, including those with large tumors or those receiving neoadjuvant therapy. It has been reported that < 7% of T1 and T2 breast cancers meet the inclusion criteria in the Z0011 trial [26,27]. The decision to evaluate the axilla preoperatively with ultrasound varies by practice, and consensus between the radiologists, medical oncologists, and breast surgeons is beneficial for optimal patient management.

#### D. Guidance for Interventional Procedures

See the [ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures](#) [28].

### VI. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [29].

Images of all important findings should be recorded in a retrievable and reviewable image storage format. It is recommended that documentation of a negative handheld or automated whole-breast ultrasound examination be completed.

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 regard to relevant legal and local health care facility requirements.

If ultrasound is performed to evaluate 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 include measurements. Use of an accepted reporting system, such as BI-RADS® US, is recommended.

### VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [30].

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, but 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. Automated breast ultrasound systems for supine and prone patients are discussed in the [ACR Practice Parameter for the Performance of Whole-Breast Ultrasound for Screening and Staging](#) [20].

### 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 Quality Control & Improvement, Safety,*

*Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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