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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.

2019 (Resolution 34)\*

## **ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF WHOLE-BREAST ULTRASOUND FOR SCREENING AND STAGING**

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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 practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 the guidance in this document 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 this document 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 developed to assist practitioners performing ultrasound examination of an entire breast. When ultrasound is used in a focused manner to evaluate specific areas of clinical or imaging concern, or as guidance for interventional procedures or biopsy, relevant American College of Radiology (ACR) practice parameters (see the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination](#) and the [ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures](#) [1,2]) should be consulted.

## **II. INDICATIONS**

Although x-ray mammography is the only imaging modality proven through randomized controlled trials to reduce breast cancer-related mortality, mammography has limitations in depicting cancers in dense fibroglandular tissue. Many states have passed legislation mandating direct notification to women regarding breast density. In addition to the masking phenomenon of dense breast tissue on mammograms, concern for dense fibroglandular tissue as an independent risk factor for breast cancer has led many practices to offer supplemental screening for dense-breasted women, often with ultrasound (US). The potential additive benefit of supplemental screening ultrasound is supported by ACRIN 6666, an American College of Radiology Imaging Network multicenter screening trial of physician-performed handheld whole-breast ultrasound combined with mammography compared with mammography alone in women with elevated risk and dense breasts. First-year results of that study were 4.2 cancers per 1,000 women screened in addition to those detected with mammography [3] but with less than 10% positive predictive value for biopsies (PPV3). Additional screening studies, both multiple and single site, initially had similar results. A report of combined results for years 2 and 3 of ACRIN 6666 showed doubling of PPV3, with an increase also of PPV3 for mammography [4]. Thus, high false-positive rates were expected to diminish after continuing experience with adjunctive screening using US and did so in one 4-year follow-up report of several Connecticut practices, where the aggregate PPVs for biopsy nearly tripled [5].

Indications for whole-breast US may include, but are not limited to:

1. Screening, as an optional adjunct to screening mammography, for:
  - a. Women with a high lifetime breast cancer risk (20% or greater) who are not candidates for breast MRI or cannot easily access breast MRI;
  - b. Women with heterogeneously or extremely dense breasts for whom supplemental screening options have been suggested [6,7].
2. Cancer staging, in patients newly diagnosed with breast cancer who are not candidates for breast MRI or who cannot easily access breast MRI [8,9].

## **III. QUALIFICATIONS AND RESPONSIBILITIES OF THE PERSONNEL**

### **A. Physician**

Physicians who supervise, perform, and/or interpret breast US examinations should be licensed medical practitioners with training and experience in breast US. These physicians should understand the appropriate indications for and the benefits and limitations of breast ultrasound as well as ultrasound technology and instrumentation, equipment operation and calibration, and ultrasound safety. They should be knowledgeable in the anatomy, physiology, and pathology of the breast and axilla. They should be familiar with mammography and other complementary imaging modalities and capable of correlating the results of these studies with breast ultrasound findings.

### Maintenance of Competence

Physicians should perform and interpret 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 \(CME\)](#) and should include CME in ultrasonography as is appropriate to his or her practice [10].

### B. Sonographer or Technologist

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

## IV. WRITTEN REQUEST FOR THE EXAMINATION

The written or electronic request for a whole-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 INDIVIDUAL EXAMINATIONS

### A. Examinations should include permanent identification containing:

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 and/or left breast
6. Sonographer's and/or physician's identification number, initials, or other identifier

### B. Methods and Technical Factors [7]

1. Whole-breast ultrasound can be performed with a general-purpose ultrasound machine or any of several systems designed specifically for whole-breast ultrasound. If a general-purpose machine is employed, a linear high-frequency transducer with a center frequency of at least 12 MHz if possible should be used for breast scanning. Handheld whole-breast screening ultrasound relies on the operator to identify and capture images of any findings. Because lesion characterization by ultrasonography is highly dependent on technical factors, operators should optimize gain settings, focal zone selections, and fields-of-view when capturing images of specific findings. Please see the [ACR Practice Parameter for the Performance of a Breast Ultrasound Examination](#) [1].
2. Semiautomated whole-breast ultrasound involves adding to a general-purpose ultrasound machine of a robotic arm on which the high-frequency linear transducer is mounted. The arm guides the transducer over the breast, producing uniplanar images in sequential scan rows that are stitched together into a single continuous video for each breast. As a trained operator is needed to position the transducer for each scan and maintain appropriate pressure throughout the examination, this technique is considered semiautomated. Proprietary viewing software enables the localization of findings by using the nipple, scan row, and frame number as reference points.

3. Several manufacturers have developed or are developing dedicated automated breast ultrasound systems with special transducers and proprietary viewing applications. These scanners vary in patient positioning (supine or prone), transducer configuration, and multiplanar image reconstruction algorithms, but all have methods for imaging the entire breast and depicting it in the coronal plane. Supine automated systems cover the whole breast by obtaining at least three acquisitions in the transverse plane using wide linear or reverse curvilinear high-resolution transducers. Prone automated systems ordinarily obtain a single acquisition for each breast in the coronal plane using helical or torus-type transducers, some with the breast suspended in a water bath. Examinations are interpreted on workstations using proprietary software tools that localize and correlate findings on each of the views. A detailed description of the unique features and operational parameters of each of these devices is beyond the scope of this document.
4. Prior to beginning a whole-breast ultrasound screening examination, careful note should be taken of any clinical signs, symptoms, or previously identified abnormalities for which further imaging evaluation has been recommended. The interpreting physician should be advised of any such circumstances. If any of these exists, diagnostic examination is appropriate and should be recommended.

### C. Practice Considerations

1. Except when whole-breast ultrasound is performed by the interpreting physician using a handheld high-resolution transducer, image acquisition is uncoupled from interpretation. For this reason, whole-breast ultrasound primarily is a screening examination; as outlined in section II, the exception is cancer staging for patients who cannot or may not undergo breast MRI. If a patient who needs diagnostic breast imaging undergoes screening whole-breast ultrasound, the report should note this and include recommendation for appropriate diagnostic imaging.
2. Whole-breast ultrasound should be interpreted in the context of mammography if performed. Contemporaneous mammograms are not necessary for all patients, but recent mammographic images if any should be available to the physician interpreting whole-breast ultrasound. Older mammograms also may prove useful by confirming stability of mammographic correlates for benign-appearing sonographic findings. If whole-breast ultrasound has been performed previously, the current examination should be compared with prior studies, if available.
3. Interpretation of whole-breast ultrasound performed as a screening examination should focus on identifying any findings meriting diagnostic evaluation. Such findings may or may not be sufficiently characterized by semiautomated, automated whole-breast ultrasound, or technologist-performed handheld whole-breast ultrasound. Patients with indeterminate findings should receive an [ACR Breast Imaging Reporting and Data System® \(BI-RADS®\)](#) assessment of Incomplete: Need Additional Imaging Evaluation (BI-RADS® Category 0) and be recalled for diagnostic imaging.
4. Handheld whole-breast ultrasound negative images obtained for documentation—those not showing a lesion—should be annotated with breast side (right or left), clock-face notation, distance from the nipple, and transducer orientation (radial or antiradial; sagittal or transverse). One view of each quadrant and the retroareolar region in a single plane, such as radial, may be sufficient for documentation. Images of specific findings captured during handheld whole-breast ultrasound should be obtained in two projections, preferably orthogonal, and labeled with laterality, clock-face location, distance from the nipple, and transducer orientation (radial or antiradial, transverse or longitudinal, or oblique). It is preferable to use clock-face rather than quadrant notation for specific findings. Distance from the nipple should be measured from the nipple itself rather than the edge of the areola, as areolar width varies.
5. Assigning BI-RADS® assessments of Category 0 (Incomplete), Category 1 (Negative), or Category 2 (Benign) to whole-breast ultrasound screening will facilitate outcomes tracking and auditing, as these functions should be performed separately for screening and diagnostic examinations [7].

6. Patients may undergo screening whole-breast ultrasound and subsequent diagnostic breast imaging on the same date. Each examination should receive its own assessment, although a single report may be generated with an overall assessment and management recommendations for the combined examinations. Therefore, physicians performing handheld whole-breast ultrasound screening may wish to consider ending the screening examination before performing diagnostic (ie, focused) evaluation of any findings.
7. For the minority of whole-breast ultrasound studies performed in the diagnostic setting, the practice parameters for focused breast ultrasound apply. Lesions should be characterized by feature categories and descriptors as listed and exemplified in BI-RADS®. The BI-RADS® sonographic feature categories for interpreting masses include shape, orientation, margin, echo pattern, posterior acoustic features, and associated features, and special cases, such as cysts and lymph nodes [7].
8. In accordance with BI-RADS® [7,8], at least three measurements should be given for each lesion when possible. To facilitate reproducibility, lesions should be evaluated and measured in two orthogonal planes: either radial versus antiradial or transverse versus longitudinal. The longest dimension in each plane should be given, as well as a third measurement perpendicular to either of the first two. If the maximum dimension is on a plane oblique to the standard orientation used, it also should be recorded.
9. As for all radiographic imaging, interpreting physicians are responsible for assessing image quality. Facilities should have policies and protocols for remediating technically inadequate studies.

## **VI. DOCUMENTATION**

Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. Images should be recorded in a retrievable and reviewable image storage format. Retention of the ultrasound examination images should be based on clinical need and in accordance with relevant legal and local health care facility requirements.

A whole-breast handheld ultrasound screening examination should document at minimum each of the four quadrants and the subareolar region [11]. The axilla may be included per facility practice and as per exam indication.

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: the indication, specifically whether the examination was performed for screening or diagnostic purposes, and the areas scanned. Any findings should be described by location, applicable descriptors, and measurements, if appropriate. The 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](#) [12].

## **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, if possible, and preferably higher. Automated whole-breast ultrasound may be performed with a dedicated system that has been cleared by the food and drug administration (FDA). Focal zones should be electronically adjustable. In general, the highest frequency capable of adequate penetration to the depth of interest should be used.

## **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 (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [13].

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