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Adopted 2018 (Resolution 36)\*

## **ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF DIGITAL BREAST TOMOSYNTHESIS (DBT)**

### **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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole 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, \_\_\_ 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 guide physicians performing and interpreting digital breast tomosynthesis (DBT). Mammography is the only screening modality that has proven through randomized controlled trials to decrease breast cancer mortality [1]. Because of this benefit, mammography is recognized as the standard of care for breast cancer screening. However, the sensitivity of mammography varies, depending on breast tissue type, because of the masking effect of superimposed breast tissue [2]. With traditional digital mammography (DM), superimposed tissue can obscure true lesions and create the appearance of spurious lesions. DBT is a technique that obtains multiple low-dose 2-D images in an arc across the breast. These images are then reconstructed to generate a 3-D–like image set containing numerous “slices,” the number of which depends on many factors, including breast thickness, reconstruction options, and radiologist preference [3]. DBT helps mitigate the masking effect of superimposed tissue, resulting in a decrease in false positive examinations with a concomitant increase in detection of malignancy [4-7].

As screening DBT becomes increasingly widespread, indications, qualifications, and specifications of the examination must be standardized to ensure consistent performance. DBT also plays an important role in diagnostic breast imaging including, but not limited to, enhancing the visualization and localization of lesions identified on screening; evaluating areas of concern identified by patients or referring clinicians; and characterizing probably benign mammographic findings. The following document has been written to guide practitioners who have implemented DBT. These guidelines supplement the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [8].

## II. INDICATIONS

A. Screening Mammography: The indications for screening DBT are the same as for DM. See the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [8].

B. Diagnostic Mammography: The indications for diagnostic DBT are the same as for DM. See the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [8].

## III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, medical physicists, and radiologic technologists who work in mammography, including DBT, must meet the requirements in the Mammography Quality Standards Act (MQSA) final rule published by the Federal Drug Administration (FDA) [9].

Under MQSA, DBT is considered a new modality. The FDA regulations specify “before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician must have at least 8 hours of training in the new mammographic modality” [10]. For all personnel, the FDA considers 8 hours of DBT training, whether general or specific to a particular DBT system, sufficient to fulfill the MQSA new modality training requirement for DBT [11].

Several training options exist, including applications training and/or instruction materials offered by specific DBT manufacturers as well as independent training courses. The initial 8 hours of training does not have to be awarded the American Medical Association PRA Category 1 Continuing Medical Education credit [12].

For interpreting physicians, initial training may be obtained during residency as long as attestation is provided by the residency program. The FDA provides a sample Residency Letter on its website [13].

## IV. SPECIFICATIONS OF THE EXAMINATION

A. Screening Mammography: A full examination should consist of at least two DBT acquisitions (CC and MLO) per breast with the correlative standard or synthetic CC and MLO views.

- B. Diagnostic Mammography: At minimum, a diagnostic examination should include one DBT view. This may be a full-field view, spot compression view, or any other special view with the correlative standard or synthetic view.
- C. Special Scenarios:
- Implants: Patients with breast implants may be imaged with DBT. Regardless of whether synthesized imaging is being utilized, it is recommended that only implant displaced views be performed using DBT. This is to minimize the radiation dose when utilizing DM and to minimize artifact generated by the implant when utilizing synthesized imaging (see below).
  - Breasts larger than the detector: DBT may be used when patients with large breasts require multiple exposures in the same view to image the entire breast. If both DM and DBT images are being acquired, DBT should be applied only to the largest portion of the breast for each projection to minimize radiation dose. In such situations, the remainder of the breast still must be imaged with tiled DM. If synthesized images are being viewed in lieu of a separate DM exposure, DBT may be used for all portions of the examination (see below).
- D. Synthesized Mammography: Computer software programs are now available to generate a synthesized 2-D image (SM) from the DBT dataset. The dose of SM + DBT is equivalent to DM for the phantom image at approximately 2 mGy [14]. Several recent studies have demonstrated that radiologist performance with SM + DBT is comparable to that shown with DM + DBT [15-18]. Specifically, screening with SM + DBT results in decreased recall rates and increased positive predictive values compared to DM + DBT, while maintaining equivalent cancer detection rates [17]. Therefore, synthesized mammography is an acceptable alternative to DM when used in conjunction with DBT, allowing for elimination of a separate DM exposure. Because SM is generated from the DBT dataset, SM should be interpreted in conjunction with the DBT image set.
- E. Request for Tomosynthesis: A separate physician order is not required for DBT. The performance of DBT should be at the discretion of the interpreting radiologist, the patient, and in accordance with individual breast center imaging protocols.
- F. Image Labeling: The DM component of the examination should follow the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [8]. For DBT images, there must be a way to determine the relative position of a slice within the breast. Slice numbers alone are insufficient; the orientation of the first slice relative to the detector must be specified, as slice numbering varies by DBT manufacturer and picture archiving and communication system (PACS). Breast imaging facilities should be aware of their equipment parameters, and the interpreting physician should be knowledgeable about how the DBT slices are labeled. Slice number, thickness, and location relative to the side of the breast should be indicated on the workstation display as well as on printed images. It is recommended that if a facility uses DBT systems from more than one manufacturer, slice numbering should be standardized across the systems to avoid confusion.
- Synthesized imaging: If a synthesized image is generated, it must be labeled as such to distinguish it from a DM exposure.
- G. Image Transfer: Some manufacturers generate DBT images in proprietary format. It therefore is recommended that any DBT images in proprietary format be converted to the DICOM standard of Breast Tomosynthesis Object (BTO) before being sent to other facilities. Conversion to BTO format preferably would be performed at the host institution [19].
- If DBT images are being sent to a site that does not have the capability of viewing DBT, or if the practitioner at the receiving facility is not qualified to interpret DBT, it is acceptable, although not optimal, to review only the DM portion of the examination. In this circumstance, it is advised that the report state clearly that the interpretation was without the benefit of all the information acquired at the host institution.

## H. Guidance for Interventional Procedures

- a. One study has demonstrated that approximately 7% of breast lesions recommended for biopsy are visible only on DBT [20]. Therefore, access to biopsy equipment capable of localizing lesions with DBT is recommended but not mandatory.
- b. Physicians performing DBT image-guided biopsies must be qualified to interpret DBT images and therefore must have successfully completed the required 8 hours of DBT training mandated by the FDA (see section III).
- c. DBT-guided biopsy technique may be used instead of stereotactic guidance for lesions or calcifications that are identified on DM. Documentation of images for DBT biopsy should follow the [ACR Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedure](#) [21]. However, there are occasions when both stereotactic and DBT guidance may be used to obtain tissue. The current CPT codes for DBT biopsy differ depending on whether or not stereotactic guidance was incorporated during the procedure. Therefore, documentation in the report that stereotactic images were obtained in addition to DBT is recommended and CPT code assignment must reflect what was performed.
- d. If DBT guidance is not available for a tomosynthesis-only finding, it is acceptable to perform a stereotactic biopsy using adjacent tissue landmarks for guidance. However, a biopsy marker should be placed with postprocedure DBT images in two projections to demonstrate that the original finding was properly targeted.

The written or electronic request for a diagnostic mammography 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 stated scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

## V. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [22].

The report should follow the guidelines for terminology, including descriptions of lesion features and location, as published in the ACR BI-RADS<sup>®</sup> Lexicon. To aid identification of lesions seen only on DBT, it is suggested that the view and slice number(s) on which tomosynthesis findings are identified be included in the report. The Breast Imaging Reporting and Data System (BI-RADS<sup>®</sup>) assessment category should be included in the conclusion of the report.

## VI. EQUIPMENT SPECIFICATIONS

Mammography equipment must meet the MQSA regulations published by the FDA [9]. [ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality In Digital Mammography](#) provides additional guidance for digital mammography and DBT acquisition and display equipment [23].

Because different clinical DBT protocols have been the basis for FDA approval of different vendor products, radiologists should consider how to best incorporate such protocols into their clinical practice to optimize both the current examination and provide a basis for future comparison studies. When necessary, judicious use of off-label approaches that cannot be formally recommended by a vendor can be considered so long as they are consistent with FDA guidelines.

## VII. 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/Clinical-Resources/Practice-Parameters-and-Technical-Standards>).

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examinations. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, reported, and periodically reviewed to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures to ensure the confidentiality of the peer-review process.

In accordance with current standards of DM imaging, each facility should establish and maintain a medical outcome audit program to follow up positive assessments and to correlate pathology results with the interpreting physician's findings. In the screening setting, it is recommended to separate DBT from DM to distinguish between the two modalities with respect to performance. If a facility does not perform DBT-guided intervention and refers tomosynthesis-only findings for biopsy to another accredited facility, it should have access to correlative pathology results from the procedure facility. The audit should assess the accuracy of interpretation as well as the clinical appropriateness of the examination. Facilities should use the BI-RADS<sup>®</sup> final assessment codes and terminology for reporting and tracking outcomes. The BI-RADS<sup>®</sup> Atlas contains guidance on monitoring outcomes and conducting the audit. Summary statistics and comparisons generated for each physician and each facility should be reviewed annually by the lead interpreting physician.

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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.

#### Development Chronology for this Practice Parameter

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