



# **DIGITAL BREAST TOMOSYNTHESIS (DBT) GUIDANCE**

(A supplement to ACR BI-RADS® Mammography 2013)

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## INTRODUCTION

Digital breast tomosynthesis (DBT) was first FDA approved in 2011 as a technique for breast imaging. Since then, multiple studies have demonstrated the usefulness of this modality in both the screening and diagnostic settings [1-12]. With DBT, multiple low-dose mammographic images of the breast are obtained as the x-ray tube moves across an arc. The images are then reconstructed to produce a volume rendering of the breast. Tomosynthesis has sometimes been referred to as “3D” mammography. However, the images are not truly three dimensional as the third axis is derived from the planar data. Therefore, the term “3D” should not be used when referring to tomosynthesis. Either “DBT” or “tomo” are appropriate terms.

Inclusion of digital breast tomosynthesis with standard two-dimensional digital mammography (DM) improves cancer detection while simultaneously reducing the rate of false positive examinations. When used for screening, DBT has been shown to decrease the recall rate by 15-37% [1-8] and increase the cancer detection rate by 1.2-2.7 per 1000 [4]. These metrics are achieved largely because DBT reduces the effects of superimposed tissue, allowing better visualization of true lesions and decreasing summation shadows that can lead to a recall. Additionally, the increased conspicuity and localization of lesions may preclude the need for additional diagnostic mammographic views.

Although the dose of the combined DM-DBT examination is below the FDA limit of 3mGy for a phantom image, efforts are underway to further decrease the modest dose of radiation associated with mammography. In 2014, software that enabled the creation of a synthesized 2D mammogram from the tomosynthesis acquisition was approved for use by the US Food and Drug Administration (FDA). Using a synthesized view rather than obtaining a direct digital mammogram decreases the dose associated with a DBT examination to that similar to a standard digital mammogram. The term “SM” should be used to refer to the synthesized image.

## A. LEXICON

Lesions identified with DBT are described in a similar fashion as standard analog or digital mammography findings. However, there are several descriptors commonly encountered with DBT that require further clarification and are addressed in the following section.

### 1. Terminology

Proper terminology for tomographic imaging of the breast is “digital breast tomosynthesis” abbreviated as DBT, tomosynthesis, or tomo. DBT reconstructed slices are not true three-dimensional images of the breast. However, the term tomosynthesis may not be understandable to the non-radiologist. Therefore, 3D mammography should be reserved for use in only a non-technical context to help explain the concept of DBT imaging to the layperson.

The preferred terminology for the synthesized image is “SM”. The standard 2D digital mammogram can be referred to as “DM” or “2D mammogram.”

### 2. Asymmetries (true abnormalities versus superimposed tissue)

In BI-RADS®, an asymmetry is defined as a finding visible on only one mammographic projection. An asymmetry may be a true abnormality that is obscured (masked) by adjacent isodense fibroglandular tissue or not included in the image field on one of the two standard projections. Alternatively, an asymmetry may represent superimposition of normal breast structures (pseudolesion). If a radiologist using information from DBT can reliably and confidently recognize that a questioned asymmetry is due to normal but superimposed breast structures, no further imaging evaluation will be needed. If, on the other hand, a true lesion cannot be excluded with confidence, the patient should be recalled for diagnostic imaging evaluation.

### 3. Masses

Masses have a similar appearance on DBT images when compared to digital mammography (DM), or they may be more conspicuous on DBT. This is largely due to effective removal of the superimposed tissue with the reconstructed slices, resulting in better appreciation of the

margins. Masses identified on DBT should be managed as one would with DM. However, it is important not to assume that well visualized circumscribed masses are definitively benign. [13] Therefore, masses with circumscribed margins continue to require further evaluation with diagnostic mammography and/or ultrasound. Exceptions to this would be multiple bilateral circumscribed masses, where a benign assessment would be appropriate [13] or masses that have been stable for at least 2 years.

#### **4. Calcifications**

Synthesized mammography (SM) is a technique in which a digital mammogram is generated from the DBT data set. Because the back-projection algorithm used in the reconstruction of synthetic images is designed to preserve high-attenuating voxels, calcifications may appear enhanced [14]. In addition, synthesized images may contain artifacts which may be misconstrued as microcalcifications. Alternatively, calcifications may appear less well defined when compared to traditional digital mammography because as the x-ray tube moves in the arced pathway, the voxels are shifted very slightly perpendicular to the movement of the tube, which causes blurring of fine features such as microcalcifications [15]. Phantom studies have shown that synthetic images have lower-contrast spatial resolution than 2D digital mammography [16]. Despite this, early studies evaluating the performance of synthesized images have demonstrated no statistically significant difference in detection of calcifications [17]. When indeterminate calcifications are identified, further diagnostic imaging should be obtained with DM spot-compression magnification views for complete evaluation.

#### **5. Ectatic ducts**

Similar to masses, ductal ectasia may be more conspicuous on DBT than on digital mammography. However, improved conspicuity should not be the sole indication for recalling a patient for additional evaluation. Review of prior mammograms may demonstrate stability, precluding the need for further evaluation. However, if unilateral ductal ectasia is new, additional imaging may be warranted, particularly if it is a solitary duct [18].

## 6. Breast density

Breast density should be assessed on the standard DM or on the synthesized mammogram, not on the tomosynthesis slices. As with DM, if the two breasts differ in density, classification should be based on the denser breast.

## 7. Descriptors for lesion location

Suspicious findings identified on DBT slices should be described with standard nomenclature, and indicate the general location in the breast (i.e., laterality, quadrant, and clock-face location; anterior, middle, or posterior depth; distance from nipple). However, it is particularly important to specify the slice numbers where the abnormality is in focus. For example: focal asymmetry, left breast, upper outer quadrant, 1:00, posterior depth, 5 cm from the nipple (CC view slice 43/55, MLO view slice 14/50)

## 8. Use of radiopaque markers for skin lesions

Markers of any kind on tomosynthesis examinations result in reconstruction artifacts on the DBT images in the same plane as the gantry motion. Since some skin lesions are confidently identified solely by the superficial location of the reconstructed slice(s) on which they are visible, placement of radiopaque skin markers may be obviated in some cases. However, there are several scenarios in which the skin lesions appear to be deeper in the breast based on the slice indicator. Therefore, it may be helpful to routinely mark raised skin lesions for the interpreting radiologist despite the resulting artifacts. Additionally, marking raised skin lesions facilitates image interpretation because it eliminates time spent determining whether a lesion is in the skin. Alternatively, some facilities choose to mark and save an accompanying diagram of the location of moles and skin scars rather than place markers, which may be helpful in interpretation while avoiding artifacts on the images.

## B. REPORT ORGANIZATION

DBT mammography reporting should follow digital mammography reporting as described in the 5th edition of the BI-RADS® Atlas published in 2013. Due to the different DBT imaging techniques available, facilities should specify the imaging protocol used, such as DBT-only, 1-view DBT with 2-view DM, combination DM/DBT, or DBT plus synthetic views. Because DBT can provide improved characterization and localization of lesions at screening, the traditional diagnostic mammogram followed by US pathway may be altered. For example, if the margin of a mass is well characterized on a screening mammogram utilizing DBT and the location is readily determined, additional mammographic views may not be necessary, and the patient may proceed directly to ultrasound for further evaluation. This should be specifically stated in the report to avoid confusion.

### **Description Location of Finding**

If there is a mammographic finding, especially one seen only on DBT imaging, a description of the location of the finding, specifying the slice number, or a range of slices in which the lesion is best identified facilitates localization of the finding. DBT can generally guide the radiologist in determining the finding location using the scroll bar. However, there are several scenarios where the lesion location on the scroll bar may appear to contradict the true location. Most importantly, because DBT is not truly a three-dimensional reconstruction, the scroll bar estimates the location of the lesion on the orthogonal view. It is not an exact location, and there are additional reasons why lesion localization using DBT can be misleading.

First, it is important to keep in mind that the scroll bar on the CC view localizes the lesion on the lateral view (ML or LM), not on the oblique projection. Therefore, lateral lesions on the CC view will project lower on the scroll bar than on the MLO view. Conversely, medial lesions on the CC view will project higher on the scroll bar than on the MLO view.

Also, the scroll bar may appear inaccurate because superficial lesions tend to roll between projections. Because the breast is repositioned between the two views, there can be significant changes in the apparent location between views.

A further reason for the apparent inaccuracy is that some manufacturers add 5 extra reconstructed slices on the compression paddle side to eliminate the possibility of displaying the breast incompletely. Therefore, in small breasts, lesions will appear to localize closer to the detector side of the scroll bar. In larger breasts, the addition of 5 extra slices will be inconsequential to quadrant localization.

Additionally, because the scroll bar is a fixed length, it represents the thickest portion of the breast, which is usually the posterior aspect. If there is significant paddle flex, the anterior portion of the breast will appear to be thinner, possibly misrepresenting the true location of the lesion. Therefore, anterior lesions may localize closer to the detector on the scroll bar than their true location.

Finally, the nipple, and/or center of the breast, is not always located in the center of the scroll bar. Ideally, the center slice on the scroll bar will match up with the nipple. However, since occasionally a breast is not positioned properly for imaging; it is helpful to localize the nipple and determine the lesion location relative to the nipple, rather than the center slice [19].

The report should specify the type of imaging on which a finding is seen (i.e., if the finding is detected on DM imaging, DBT imaging, and/or the synthetic view). Depending on the facility protocol, annotated images demonstrating the finding may be utilized for reference.

### **Additional Mammographic Imaging Work-Up**

Because DBT often confirms the veracity of a finding without the need for additional diagnostic mammographic view, traditionally used work-up protocols may change. For example, if the margin and location of a mass are well seen on the tomosynthesis images, additional spot compression or magnification views may not be necessary and, at recall, the patient may proceed directly to ultrasound.

## Digital Breast Tomosynthesis (DBT) Assessment Categories

In general, the principles for assigning BI-RADS® assessment categories to examinations performed with tomosynthesis should be no different from those that apply to standard digital mammography. There are, however, some points of clarification that need to be made:

### Category 0

When a mass is visible on screening tomosynthesis, it may be sufficiently well seen that additional mammographic views are unlikely to add useful information. In such cases, there may be a temptation to assign a final assessment category and avoid a recall (BI-RADS® category 0). This would be a mistake because even though the margin of a mass may be clearly visible on DBT images, a recall for additional imaging evaluation with ultrasound is strongly recommended; hence the appropriate assessment would be category 0 (recall for additional imaging). If a mass is circumscribed, ultrasound can determine whether it is cystic or solid and help determine appropriate management. If a mass has an indistinct or spiculated margin on tomosynthesis, ultrasound will help determine the best biopsy method.

In a situation where a diagnostic mammogram is performed without DBT for a questionable finding and tomosynthesis is subsequently recommended for further evaluation (but cannot be performed at the same time), a category 0 assessment would be inappropriate. For these cases, a final assessment category should be assigned based on the information from the existing diagnostic work-up with a comment added that DBT could or should be considered for further evaluation. This is similar to the recommendation that a diagnostic mammogram should not be assigned BI-RADS® category 0 when an ultrasound was recommended and was unable to be performed to complete the evaluation (e.g., because the patient left the department, equipment failure, etc.) If, contrary to this BI-RADS® guidance, a category 0 assessment is rendered and tomosynthesis is recommended, the diagnostic report should clearly state (1) what the management should be if the subsequent DBT exam is positive or negative for an abnormality, (2) what the management should be if DBT is not obtained.



### Category 3

As stated in the mammographic guidance section, a BI-RADS® category 3 assessment should not be used as an intermediate assessment category when the radiologist cannot decide whether the examination should be assigned a category 2 or category 4 assessment.

Also, BI-RADS® strongly discourages a category 3 assessment directly from screening. Category 3 should be assigned only after a full diagnostic work-up. For example, even if a mass is completely circumscribed on tomosynthesis, suggesting a benign etiology, ultrasound is still needed as it may identify a simple cyst or morphologically normal lymph node and obviate the need for short-interval follow-up. It also may depict suspicious features of a mass that appears benign on tomosynthesis. By the same token, calcifications that appear likely to be benign on screening may be shown on magnification views to represent milk of calcium, requiring no further follow-up, or may be shown on magnification to be associated with additional calcifications with suspicious morphology.

### Category 4 and 5

As with standard DM, BI-RADS® discourages category 4 or 5 assessments directly from a tomosynthesis screening examination. Even when a finding is clearly depicted on DBT images, the addition of ultrasound for masses or asymmetries, and magnification images for calcifications, can yield important information, provide guidance for biopsy, and help determine the extent of disease.

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## C. FREQUENTLY ASKED QUESTIONS

1. *Since DBT can enable improved lesion characterization and visualization, can we give a BI-RADS® category 3 assessment at screening if the lesion appears to have typically benign characteristics?*

The existing guidance for use of BI-RADS® category 3 assessment applies to situations in which DBT imaging is performed; *a category 3 assessment should not be rendered at screening*. It is true that DBT can improve assessment of lesion characteristics and help to determine the likelihood of benignity or malignancy; however, further work-up is needed to adequately assess the lesion and determine whether surveillance imaging or a biopsy is warranted.

2. *Is it appropriate to assign a BI-RADS® category 4 at screening for a clearly suspicious lesion, such as a spiculated mass on DBT, for which additional mammographic views would not add important information?*

As with standard digital mammography, assigning BI-RADS® category 4 or 5 directly from a tomosynthesis screening examination is discouraged. Even if a finding is clearly depicted on DBT images, the addition of ultrasound for masses or asymmetries and magnification images for calcifications can yield important information and help provide guidance for biopsy and to indicate the extent of disease.

3. *We have one digital breast tomosynthesis (DBT) unit, but we service multiple outreach facilities that do not have DBT-capable units. Patients are being sent to our main facility from the outreach offices with category 4 assessments on their diagnostic mammograms, but the impression on the report recommends a DBT work-up followed by a DBT-guided biopsy if there is a suspicious finding.*

*This is happening because the finding isn't "real enough" to do a regular stereotactic biopsy and the ultrasound is negative. The workup of DBT is frequently negative, and the assessment gets downgraded to category 1. However, we have reserved a valuable DBT-guided biopsy slot that ends up not being used.*

***I would like to give the diagnostic mammogram from the outreach facility a category 0 and recommend DBT, then the final assessment could be given following the diagnostic tomosynthesis. Is it permissible to use this method?***

In the clinical scenario described, assigning a category 0 to the diagnostic mammogram is not appropriate. The BI-RADS® assessment should be based on the work-up of the diagnostic mammogram and ultrasound, as it would have been before tomosynthesis was available.

Using tomosynthesis to avoid biopsy of a suspicious finding on digital mammography is not recommended. Please refer to the guidance section for MRI in the atlas which discusses the use of BI-RADS® category 0 for diagnostic mammograms when MRI is recommended for problem solving.

- 4. *Can a lesion seen only on one view of DBT with a well characterized margin and occupying 3D space be called a “mass” rather than an “asymmetry” (due to its presence on only one view?).***

No. The finding should be termed an asymmetry because it is visible on only one mammographic projection. However, if the finding displays a circumscribed margin and is oval in shape, it may be judged to be a real finding, in which case additional diagnostic mammography may be averted. In this scenario, subsequent breast imaging work-up would involve only ultrasound.

- 5. *A patient has a screening mammogram with tomosynthesis and a screening ultrasound on the same day that are reported together. The mammogram shows a mass that is well characterized on tomosynthesis. On screening ultrasound, the mass is seen to be a simple cyst and the combined report is given a BI-RADS® category 2.***

***a) How should the mammogram be audited?***

***b) Won't this falsely decrease the recall rate?***

Both the BI-RADS atlas and the FDA recommend that when mammography and breast ultrasound examinations are performed concurrently, the two examinations should be reported together, with a single combined assessment that integrates the findings of the

component examinations. Using as a case example the clinical scenario presented in this FAQ, the combined assessment is benign (category 2) because the findings at ultrasound examination are characteristically benign. However, even though the combined-examination approach to reporting is clinically important, use of a combined-examination approach confounds auditing because performance at either of the component examinations cannot be determined accurately. Therefore, for those breast imaging facilities (and investigators) interested in measuring performance at the level of individual component examinations, BI-RADS® suggests that each combined assessment used for reporting be accompanied by separate individual-examination assessments to be used only for auditing. Using the same case example, a mass depicted as completely (100%) circumscribed at screening mammography with tomosynthesis does not require additional diagnostic mammography, but the mass does require additional imaging evaluation with ultrasound. Therefore, the screening mammography examination is properly assessed as needing additional imaging evaluation (category 0). The companion ultrasound examination, which establishes the diagnosis of simple cyst, is properly assessed as benign (category 2). These separate, individual examination assessments could be audited separately and included in the complete breast imaging report but a single overall final assessment (the most significant one) should be assigned at the end. The lay letter to the patient should also reflect the combined BI-RADS® final assessment.

***c) What if the exams are reported separately? The mammogram is given a BI-RADS® category 0, but the patient doesn't need to be contacted or given a recall letter because the ultrasound was already done.***

In this scenario, the patient could potentially receive a call-back letter inappropriately, possibly causing confusion and alarm. The best practice would be for the facility to intercept the call-back letter or not send it all so that the patient would be notified of only the final assessment. If this is not possible, the best course of action would be to report the studies together.

6. ***Given the scenario, when the screening mammogram and screening ultrasound are performed at the same visit, and a mass has a probably benign appearance on ultrasound: should the screening mammogram and ultrasound combined report be given a BI-RADS® category 3? Isn't giving a category 3 directly from screening discouraged?***

This BI-RADS® recommendation does not apply to screening mammography and ultrasound examinations *performed concurrently*. The strong recommendation in the BI-RADS® atlas against assigning category 3 assessments at screening mammography is based on stand-alone screening, because this would defer a more complete imaging evaluation for 6 months, including examination by ultrasound, potentially delaying the diagnosis of some cancers.