

ACCREDITATION APPLICATION PROCESS FOR FDA-APPROVED DIGITAL BREAST TOMOSYNTHESIS (DBT) SYSTEMS

SUBJECT: First-time accreditation of *Digital Breast Tomosynthesis (DBT)* units currently under the FDA certificate extension program

The FDA has approved the ACR to begin to accredit all previously FDA-approved DBT systems beginning **April 9, 2018**. Your facility has been identified as having a DBT unit(s) that received an extension of your MQSA certificate from the FDA to include this DBT unit(s). You must now accredit your DBT unit(s) with the ACR. You will begin the accreditation process of your FDA-approved DBT unit(s) based on your facility's MQSA certificate expiration date.

- **ACR-accredited facilities with MQSA certificates that expire within the next 8 months** will add the DBT unit(s) to your accreditation at the time of renewal. Your facility must renew the accreditation for all your existing mammography units, as well as accredit your DBT unit(s) at this time. Once approved, all your units will receive an ACR accreditation expiration date that is three years from your current expiration date.
- **ACR-accredited facilities that are currently in the reaccreditation process (renewal) with the ACR** must add the DBT unit(s) to your accreditation during this current reaccreditation (renewal) process. Once approved, all of your units will receive an ACR accreditation expiration date that is three years from your current expiration date
- **ACR-accredited facilities with more than 13 months left on their MQSA certificate** will add the DBT unit(s) to their accreditation at the time of renewal.

The ACR has outlined the accreditation testing process for DBT units in our [Mammography Accreditation Program FAQs](#). The testing materials that must be submitted for DBT accreditation are in the following chart.

Scenario 1. DBT - 2D Synthesized Images Available (whether or not 2D-Syn is used for interpretation)

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	Whatever is primarily used clinically: 2D clinical set (cc and mlo), or 2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set	2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

Scenario 2. DBT - 2D Synthesized Images Not Available on System

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	2D clinical set	2D clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

**The 3D best-slice phantom image allows for high-level evaluation of the impact of DBT-specific parameters (e.g., target, filter, etc) on image quality for accreditation. Best Slice is defined as the slice that demonstrates all the test objects in the phantom better than any other slice in the tomosynthesis set. As with all accreditation, the medical physicist's annual survey (and/or MEE) provides the detailed evaluation of system performance.*

When submitting your application for your FDA-approved DBT unit(s) you must upload the MQSA Certification Extension Approval Letter from the FDA that you received when your

certificate was extended to include your DBT unit(s), as well as the Medical Physicist Equipment Evaluation.

The following excerpted text are questions from the [Mammography Frequently Asked Questions](#) that pertain to DBT accreditation.

Testing – Clinical

Q. May I submit digital breast tomosynthesis (DBT) clinical images for FFDM or DBT accreditation?

A. No, and in fact we don't accept them. See the following table for the clinical image submission requirements for both FFDM and DBT accreditation.

Q. I am applying for accreditation for my FFDM unit that also has the capability to perform DBT. May I submit the same set of clinical images for the FFDM unit and the DBT unit?

A. Yes. The ACR recommends that you send different patients. However, you may submit the same fatty examination for both the FFDM and DBT testing, and the same dense examination for both the FFDM and DBT testing.

Testing – Phantom

Q. May I submit a 2D synthesized phantom image for the accreditation of my FFDM unit?

A. No. For FFDM accreditation the facility must submit *one* 2D phantom acquired image.

Q. May I submit the 2D acquired phantom image for the accreditation of my DBT system?

A. No. For DBT accreditation the facility must submit *one* image that best demonstrates all the test objects ("best-slice" image). See the following table for the phantom image submission requirements.

Testing – QC Documentation

Q. We plan to add DBT to our existing accredited FFDM system. Do we need to accredit this new DBT system?

A. Yes.

Q. I heard that if I have FFDM system with DBT, my facility must accredit that unit as two separate units; FFDM and DBT. Is that true?

A. Yes.

Q. My mammography system has the capability to perform both FFDM and DBT, but my administration has decided that they do not want to use DBT. Do we still need to accredit as two separate units?

A. No, if the DBT portion is not being used clinically, it does not have to be accredited.

Q. My mammography system has the capability to perform both FFDM and DBT, but my administration has decided that we will only do DBT. Do we still need to accredit as two separate units?

A. Yes, the FFDM portion of the unit must be accredited, whether used clinically, as it is the basis for some of the QC testing for the DBT portion.

For more information, please see the [Mammography Frequently Asked Questions](#) or contact the ACR at (800) 227-6440.