DBT Supplement to the ACR DM QC Manual

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DBT Accreditation

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 accredite 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 6 months will ask 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 acquire your DBT unit(s) at this time. Once approved, all your units will remain on an ACR accreditation expiration date that is three years from your current accreditation date.
- ACR-accredited facilities that are currently in the accreditation process (new) with the ACR must add the DBT unit(s) to your accreditation during this current accreditation renewal process. Once approved, all of your units will remain on an ACR accreditation expiration date that is three years from your current accreditation date.
- ACR-accredited facilities with more than 30 months left on their MQSA certificate will add the DBT unit(s) to their accreditation at the time of renewal.

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), in addition to the Medical Device Equipment Evaluation.

Please call the ACR at 800-227-4736 if you have questions. Thank you for continuing your support of quality mammography by accrediting with the ACR.

Background

- The Digital Mammography QC Manual took much longer to get approved than anticipated
- DBT came into being during the approval process
- Manufacturer DBT QC poses many of the same issues that were presented by manufacturer FFDM QC manual
- ACR desired to include DBT in the DM Manual
- ACR and the Committee on Quality Assurance in Mammography had a choice
  - Delay approval and include DBT
  - Proceed with approval and deal with DBT later
So here we are...

- Approval proceeded – and later is now

MQSA National Statistics

| Certification facilities, as of October 1, 2017 | 6,729 |
| Certification facilities, as of April 1, 2018 | 6,729 |
| Total certified facilities | 6,883 | 13,914 |
| Accredited FFDM units | 6,080 | 11,714 |
| Accredited DBT units | 4,724 | 8,000 |

- FFDM | 68% |
- DBT | 31% |
- F-S | 0.5% |

Typo in the quiz! Answer D and move on!

Current Status

- Supplement has been drafted
- Supplement has been provided to MITA for comment
- ACR has responded to MITA comments and made changes as appropriate
- Supplement has been submitted to FDA as an application to be an alternative standard
- Supplement is currently under review by FDA
- There will probably be changes based on the FDA review and comment
EVERYTHING I SAY FROM NOW ON IS SUBJECT TO CHANGE!

ACR DBT Tests - Technologist

Comparison of Manufacturer DBT Tests - Medical Physicist
RT Tests - ACR Digital Mammography (DM) Phantom Image Quality

- Performed weekly
- Must use ACR DM Phantom
- Align to chest wall
- Compress
  - Approximately 5 daN
  - Engage AEC
  - Be consistent
- Use clinical DBT factors for 4.2 cm 50/50 breast
- Use AEC
- Use combo mode if used clinically
- If synthesized 2D used, create that image
New Phantom

Cousins

ACR Phantom Prototype
Specks are lime glass spheres

Phantom Scoring

<table>
<thead>
<tr>
<th>Test Object</th>
<th>Full Points</th>
<th>Half Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiber (F)</td>
<td>• Full length visible (≥ 8 mm long)</td>
<td>• At least half of length visible (≥ 5 and &lt; 8 mm long)</td>
</tr>
<tr>
<td></td>
<td>• Correct location</td>
<td>• Correct location</td>
</tr>
<tr>
<td></td>
<td>• Correct orientation</td>
<td>• Correct orientation</td>
</tr>
<tr>
<td></td>
<td>• 1 break allowed (must be ≤ width of fiber)</td>
<td>• 1 break allowed (must be ≤ width of fiber)</td>
</tr>
<tr>
<td>Speck Group (G)</td>
<td>• 4-6 specks visible</td>
<td>• 2-3 specks visible</td>
</tr>
<tr>
<td></td>
<td>• Correct locations</td>
<td>• Correct locations</td>
</tr>
<tr>
<td>Mass (M)</td>
<td>• Density difference visible</td>
<td>• Density difference visible</td>
</tr>
<tr>
<td></td>
<td>• Border is continuous and generally circular (≥ ¾ border visible)</td>
<td>• Border is not continuous or generally circular (≥ ½ and &lt; ¾ border visible)</td>
</tr>
<tr>
<td></td>
<td>• Correct location</td>
<td>• Correct location</td>
</tr>
</tbody>
</table>

RT Tests - Phantom

- Score at AWS, or at RWS if necessary
- In DBT stack, find the slice that best demonstrates the test objects
  - Can use slabs if slices not available
- Optimize WW/WL to visualize test objects
- Observe the image for artifacts
RT Tests - Phantom

- Must be able to see
  - 2 fibers
  - 3 speck groups
  - 2 masses

- No clinically significant artifacts
  - Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image
  - Artifacts obscure test objects in the phantom
  - Artifacts could affect clinical interpretation

- Corrective action prior to clinical use
  - Repeat scoring for synthesized 2D, if applicable

- Pass/Fail
  - Corrective action prior to clinical use
  - Repeat scoring for synthesized 2D, if applicable
RT Tests - Visual Checklist

- Must be performed monthly
- Nothing magical
- Are all of the buttons buttoning and all of the whistles whistling?
- Have divided tests into critical and less critical categories
  - Critical items must be repaired prior to clinical use
  - Less critical items must be repaired within 30 days

RT Tests - Facility QC Review

- Must be performed quarterly
- Essentially the same as in the DM QC Manual
- Adds in DBT imaging modes
8. Facility QC Review

<table>
<thead>
<tr>
<th>Facility Date of QC Mtg</th>
<th>Room 1</th>
<th>Room 2</th>
<th>Room 3</th>
<th>Room 4</th>
<th>Room 5</th>
</tr>
</thead>
</table>

**1. Review Medical Physics Surveys and Results**

- Room ID
- Date of last Medical Physicist (MP) survey
- MP DM QC Test Summary reviewed by radiologist?
- All MP corrective actions completed?
- ACR DM Phantom Average Glandular Dose (mGy)
- Fiber Score
- Speck Score
- Mass Score

**2. Review Tech QC**

- ACR DM Phantom Image Quality (Weekly)
- CR Cassette Erasure (if app) (Weekly)
- Compression Thickness Indicator (Monthly)
- Visual Checklist (Monthly)
- AW Monitor QC (Monthly)
- RW Monitor QC (Monthly)
- Film Printer QC (Monthly)
- Viewbox Cleanliness (if app) (Monthly)
- Facility QC Review (Quarterly)
- Compression Force (Semiannual)
- Manufacturer Detector Calibration (if app) (Optional)
- Repeat Analysis As Needed

**3. Review and verify completion of all “Corrective Action”**

**4. Technique Chart review for each room (see MP report for recommendations) - (Annually)**

**5. Infection Control procedures followed**

**6. Offsite RW(s) & Film Printer(s) QC reviewed**

**7. Past and future service or service upgrades discussed (if app)**

**8. Past and future State and/or MQSA inspections discussed (if app)**

**9. Past and future ACR Accreditation issues discussed (if app)**

<table>
<thead>
<tr>
<th>Room 1</th>
<th>Room 2</th>
<th>Room 3</th>
<th>Room 4</th>
<th>Room 5</th>
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</thead>
</table>

**RT Tests - Manufacturer Calibrations**

- Must be performed at the frequency specified by the manufacturer
- Must follow manufacturers procedures and recommendations
- Document performance of the calibration

**Follow-up Confirmed (If App.)**

<table>
<thead>
<tr>
<th>Lead Interpreter Radiologist</th>
<th>Facilitator Manager</th>
<th>Lead Radiologist</th>
</tr>
</thead>
</table>

**Overall Pass/Fail**

Required:

Supervising radiologist and facility manager must review QC quarterly.

The test passes if meeting held.

Recommended:

Timeframe: Not applicable.

Action Limit:

Technologist and supervising radiologist should review technique charts at least annually for each DM system.
MP Tests - ACR Digital Mammography (DM) Phantom Image Quality

- Performed weekly
- Must use ACR DM Phantom
- Align to chest wall
- Compress
  - Approximately 5 daN
  - Engage AEC
  - Be consistent
- Use clinical DBT factors for 4.2 cm 50/50 breast
  - Use AEC
  - Use combo mode if used clinically
- If synthesized 2D used, create that image

MP Tests - Phantom

- Score at AWS, or at RWS if necessary
- In DBT stack, find the slice that best demonstrates the test objects
  - Can use slabs if slices not available
- Optimize WW/WL to visualize test objects
- Observe the image for artifacts
MP Tests - Phantom

• Distance measurement

MP Tests - Phantom

• Must be able to see
  ▫ 2 fibers
  ▫ 3 speck groups
  ▫ 2 masses

• No clinically significant artifacts
  ▫ Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image
  ▫ Artifacts obscure test objects in the phantom
  ▫ Artifacts could affect clinical interpretation

• Measured distance must be 70 mm ± 14 mm
• Corrective action prior to clinical use
• Repeat scoring for synthesized 2D, if applicable
MP Tests - Spatial Resolution

• Use
  ▫ ACR DM Phantom
  ▫ Line pair pattern up to 10 lp/mm
• Place phantom reversed from normal
• Please pattern on phantom at 45° to A-C axis
• Compress lightly
• Make DBT exposure using manual techniques as close as possible to phantom techniques
• Repeat for all targets used clinically for DBT

• Record the highest frequency for which at least half the length of the lines can be continuously resolved in each image
• Ensure that the polarity of the lines does not reverse
• Must visualize ≥ 3.0 lp/mm
• Corrective action within 30 days
Spatial Resolution - Synthesized

For 2D, spatial resolution must be \( \geq 4.0 \text{ lp/mm} \) for contact mode and 6.0 lp/mm for magnification mode.

For DBT, spatial resolution must be \( \geq 3.0 \text{ lp/mm} \) for contact mode.
MP Tests - Automatic Exposure Control System Performance

- **Use**
  - Approximately 2, 4, 6 cm of tissue-equivalent material
  - BR-12, BR-50, acrylic, salami...
- **Center** 2, 4, 6 cm at chest wall
- **Compress**
  - Phantom thickness
  - ~5 daN
  - Engage AEC
  - Be consistent
- If applicable, center AEC detector on phantom
- Expose using clinical settings

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MP Tests - Automatic Exposure Control System Performance

- **Place ROI**
  - Approximately 3 cm from chest wall edge
  - Centered laterally
- **Calculate SNR**
  - SNR is not strictly defined for DBT images
  - Values should remain consistent year-to-year if the AEC is performing consistently
  - SNR @ 4 cm ≥ 40
  - SNR @ 2, 6 cm ≥ 85% of prior year
  - Corrective action within 30 days
MP Tests - Average Glandular Dose

- Protect the detector
- Dosimeter is placed
  - 4.2 cm above breast support
  - Or inverse square correction to 4.2 cm
  - 4 cm from chest wall edge
- Centered laterally
- Select target, filter, kVp as used for phantom imaging
- Select mAs as close as possible to phantom value
- Perform manual DBT exposure
  - Tube parked at center position, if possible
- Repeat for combo mode technical factors, if applicable

### Data Analysis and Interpretation

1. Compare measured dose to system AGD
2. Calculate average glandular dose using Dance factors, if applicable
3. Perform manual DBT exposure
   - Tube parked at center position, if possible
4. Repeat steps

#### Breast

<table>
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<tr>
<th>Thickness</th>
<th>g</th>
<th>s</th>
<th>c</th>
<th>D[1.5]</th>
<th>D[2.0]</th>
<th>D[3.0]</th>
<th>D[4.0]</th>
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<td>4.2 cm</td>
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<td></td>
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<td>0.847</td>
<td>1.672</td>
<td>2.944</td>
<td>4.226</td>
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<tr>
<td>6 cm</td>
<td></td>
<td></td>
<td></td>
<td>0.748</td>
<td>1.471</td>
<td>2.702</td>
<td>4.308</td>
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<td>12 cm</td>
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<td></td>
<td></td>
<td>0.649</td>
<td>1.298</td>
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<td>3.945</td>
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<td>25 cm</td>
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<td>0.550</td>
<td>1.195</td>
<td>2.037</td>
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#### Table X

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<tr>
<th>W/Ag</th>
<th>W/Rh</th>
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<tr>
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<td>s</td>
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</table>

#### AGD ≤ 3.0 mGy

- Single DBT view
- Combined 2D, DBT view ("combo")
- Correction prior to clinical use
- Compare measured dose to system-reported dose
  - Must agree ±25%
  - Correction within 30 days
MP Tests - Unit Checklist

- Nothing magical
- Are all of the buttons buttoning and all of the whistles whistling?
- Have divided tests into critical and less critical categories
  - Critical items must be repaired prior to clinical use
  - Less critical items must be repaired within 30 days

Required:

- All items, both critical (*) and noncritical, must pass.

All indicators working properly.

Autodecompression can be overridden to maintain compression (and status displayed).

Operator protected during exposure by adequate radiation shielding.

Is the audible exposure indicator at an appropriate volume level?

Manual emergency compression release can be activated in the event of a power failure.

DBT assembly moves as designed through its range of motion.

Image receptor is held securely by assembly in any orientation (CR).

Patient or operator is not exposed to sharp or rough edges, or other hazards.

Free-standing unit is mechanically stable.

All locks and detents work properly.

Paddles are all intact with no cracks or sharp edges.

Other:

Other:

Other:

Other:

Operator technique charts are current and posted.

Mammography area is clean and free from significant dust and debris that may cause artifacts.
MP Tests - Manufacturer Calibrations

• Must be performed at the frequency specified by the manufacturer
• Must follow manufacturers procedures and recommendations
• Document performance of the calibration

Manufacturer Calibrations (if applicable)

Facility Name

MAP ID-Unit # (00000-0000)

Mfr & Model

Room ID

Survey Date

Follow manufacturer’s instructions.

Notes:

Overall Pass/Fail

Required:

Timeframe:

Action Limits

Unit must pass all manufacturer’s calibrations to pass overall. Failures must be corrected before clinical use.

Results (P/F)

Detector

2D w/Add-on DBT Device

Name of Calibration

DBT 2D

January 0, 1900

Procedure

Medical Physicist’s Section

MP Forms w-DBT_DRAFT_2018-01-11

MP Tests - DBT Volume Coverage

• Use
  • ACR Digital Mammography Phantom
  • Two 0.1 mm thick sheets of Al
• Select the largest receptor size and paddle
• Position phantom rotated 180°
  • Place 1 sheet Al under phantom
  • Place 1 sheet Al on top of phantom
• Perform DBT exposure
**MP Tests - DBT Volume Coverage**

- **Intent** is to ensure that the depth of the breast is fully imaged.
- **Criterion**
  - Must verify that both the top and bottom Al sheets appear well defined in a slice.

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2. **DBT SUPPLEMENT - QC PROCEDURES - DRAFT_2018 - 01-11**

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**Figure X.**

A. ACR DM Phantom with 0.1 mm Al sheets positioned for image acquisition.

B. Zoomed photograph of DBT Volume Coverage setup.
Equipment:
ACR DM Phantom, 2 sheets of 0.1 mm Al

Phantom Setup:
Place ACR DM Phantom on breast support in the usual position
Paddle size (IR size): Place Al sheets on top and bottom of DM phantom, diagonally across chest wall
Paddle type (reg or flex):
Acquire DBT image of phantom
View reconstructed image and verify that both Al sheets are in focus within the volume

Overall Pass/Fail
Required:
Timeframe:
January 0, 1900
0
00000 00
0

Procedure
Contact Mode
Contact
Mag factor
kVp
mAs
Target/filter

Action Limits
Both sheets must be focused in volume
Failures must be corrected before clinical use.

Setup
Techniques
Results
(Yes/No/NA)
Upper Al sheet in focus within the volume
Lower Al sheet in focus within the volume

Medical Physicist's Section
4. MP FORMS w-DBT_DRAFT_2018-01-11

Report Date MAP ID-Unit#
Survey Date Room ID
X-Ray Unit Manufacturer Model
Control Panel Serial # Manufacture Date Installation Date
Digital radiography (DR) Computed radiography (CR) Tomosynthesis (DBT)

Unit Use:
Diagnostic and screening mammography Diagnostic only Screening only
Mammography equipment evaluation (MEE)/Acceptance testing Routine annual survey

DM unit AW monitor RW monitor Viewbox Printer Other:
Medical physicist on-site Medical physicist oversight

Quality Control Manual Used for Survey and Facility QC:
("Pass" means all components of test passes; "Fail" means any or all components fail; if "CA" checked, see Corrective Action Summary)

CA
Fiber (≥ 2.0)
Speck group (≥ 3.0)
Mass (≥ 2.0)
AGD (≤ 3.0 mGy)

*or DBT acquisition only

Technologist QC Evaluation
8. Acquisition Workstation Monitor QC
4. Automatic Exposure Control System Performance
3. Spatial Resolution
5. Average Glandular Dose
6. Unit Checklist
7. Computed Radiography (if applicable)

MEE or Troubleshooting - Collimation
Troubleshooting - Ghost Image Evaluation
Troubleshooting - Viewbox Luminance

9. Radiologist Workstation Monitor QC
10. Film Printer QC (if applicable)
11. Evaluation of Site's Technologist QC Program
12. Evaluation of Display Device Technologist QC Program
13. Manufacturer Calibration (if applicable)
14. DBT Volume Coverage

Optional - Repeat Analysis
2D Add-on DBT 2D* DBT 2D Syn

8. Viewbox Cleanliness (if applicable)
7. Film Printer QC (if applicable)
9. Facility QC Review
10. Compression Force
11. Manufacturer Calibration (if applicable)

1. ACR DM Phantom Image Quality
2. Computed Radiography Cassette Erasure (if applicable)
3. Compression Thickness Indicator
4. Visual Checklist
5. Acquisition Workstation Monitor QC
6. Radiologist Workstation Monitor QC

MEE or Troubleshooting - Beam Quality (HVL) Assessment
MEE or Troubleshooting - kVp Accuracy and Reproducibility

Medical Physicist Tests
Your Phantom Results (2D)

2D Add-on DBT
2D* DBT 2D Syn

Medical Physicist Tests (cont)

2. ACR DM Phantom Image Quality
1. Mammography Equipment Evaluation - MQSA Reqs

3. Compression Thickness Indicator
4. Visual Checklist
5. Acquisition Workstation Monitor QC
6. Radiologist Workstation Monitor QC

3. Compression Thickness Indicator
4. Visual Checklist
5. Acquisition Workstation Monitor QC
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Medical Physicist Tests (cont)

2. ACR DM Phantom Image Quality
1. Mammography Equipment Evaluation - MQSA Reqs

3. Compression Thickness Indicator
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5. Acquisition Workstation Monitor QC
6. Radiologist Workstation Monitor QC

3. Compression Thickness Indicator
4. Visual Checklist
5. Acquisition Workstation Monitor QC
6. Radiologist Workstation Monitor QC
Other Questions

• Timing?
  ▫ Hard to say. FDA review continues.
  ▫ Once approved by FDA, ACR will integrate supplement into 2016 manual and reissue a new publication that covers both DM and DBT... hopefully before Penny Butler retires this summer

• Who can use it
  ▫ After approval by FDA and implementation by ACR, any facility doing FFDM or DBT can use the new manual
  ▫ Per MQSA Hotline: CESM “is an interventional procedure and therefore, [sic] not subject to the MQSA regulations”

Thank you!