Certification Extension Process for Digital Breast Tomosynthesis and Medical Physicists Role

Kish Chakrabarti, Ph.D., FAAPM
Division of Mammography Quality Standards
Center for Devices and Radiological Health
Food and Drug Administration
Department of Health and Human Services

Certificate Extension I

What is Certificate Extension?

- FDA's Division of Mammography provide the Certificate Extension for a newly cleared/approved mammography system or a modality where no accreditation body is available.

Why does FDA give Certificate Extension?

- FDA provides certificate extension to facilitate the use of a device which received marketing clearance or approval.

Certificate Extension II

Is Digital Breast Tomosynthesis (DBT) a new modality?

- Digital Breast Tomosynthesis is a new mammographic modality separate from Full Field Digital Mammography.

In order to use the tomosynthesis portion of the unit, the facility must apply to FDA to have its certificate extended to include that portion of the unit. The certification extension only applies to the DBT portion of the unit. The facility must have the 2D portion of the unit accredited by one of the accreditation bodies.
Certificate Extension III

The main items that FDA reviews:
- Mammography Equipment Evaluation test results as per the manufacturer’s requirements
- 3D phantom (image from a tomosynthesis plane will do)
- Lead Interpreting Physician Attestation to Staff Personnel Qualifications

Certificate extension IV

- MQSA statute requires that a facility can only be certified to perform mammography after it is being successfully accredited.
- In absence of an accreditation body for a new device or modality, FDA can thus only allow certificate extension to an already certified facility.

Certificate extension V

What does FDA review for Certificate Extension?

For a complete requirement consult FDA’s website:
MQSA Facility Certification Extension Requirements for Hologic Selenia Dimensions Digital Breast Tomosynthesis (DBT) System
http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm
Currently there are three FDA Approved DBT Systems:

Hologic Selenia Dimension

GE SenoClaire

Siemens Mammmomat Inspiration with DBT

Hologic Selenia Dimension

- Detector:
  - FF: direct (a-Se)
  - Image size: 24x29 cm
  - Pixel size: 140 μm
  - Rotated
- X-ray tube:
  - W/ 0.7 mm Al (for tomo option only)
  - Continuous motion
- Angular range:
  - 15 degrees
- Number of projections:
  - 15
- Scan time:
  - 3.7 seconds
- Reconstruction method:
  - FBP

Combo mode & Cview available
QC for the medical physicist

Zero degree tomo acquisition required

AEC Function Performance

Average Glandular Dose

AGD must not exceed 300 mrad (3 mGy) for 4.2 cm effective breast thickness
Dose measurements in tomosynthesis

- Follow 8(a), (b) and (c) of the QC manual
- Conventional 2D
- Tomosynthesis only
- 2D and DBT in Combo mode < 3.0 mGy
- Can exceed 3.0 mGy but can only be used in diagnostic mode

QC for the radiologic technologist

Evaluation of Image resolution & Phantom Image Quality Evaluation

- Conventional:
  - 5 fibers, 4 specks, 4 masses
- Tomosynthesis:
  - 4 fibers, 3 specks, 3 masses

Lower resolution is allowed for tomosynthesis images
1. Standard Tomosynthesis Dose Table: this is the default configuration on the system for both 15 and 30 projection acquisition modes. This is also the default table regardless the use of 2D or synthesized 2D images. The dose is set to about 1.45 mGy for this AEC table (ACR phantom). Dose increases as a function of breast thickness to maintain constant CNR.

2. Low Tomosynthesis Dose Table: this mode was introduced with the 30 projection acquisition mode. It uses lower kVp settings so that it can produce the same SNR as the Standard Tomosynthesis Dose table, but at a lower dose setting. The dose is set to about 1.0 mGy for this AEC table (ACR phantom). Dose increases as a function of breast thickness to maintain constant CNR.

3. Advanced Tomosynthesis Dose: this dose table was introduced with the introduction of synthesized 2D images. It allows for setting the system at a dose of 1.8 mGy when acquiring in tomosynthesis mode, only, and using C-View.

### CNR Correction for 30 Projections

<table>
<thead>
<tr>
<th>AEC Table 0 (Standard Tomosynthesis Dose)</th>
<th>Compression Thickness (CM)</th>
<th>Detector Serial #:</th>
<th>Detector Serial #:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>.91</td>
<td>.88</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>.90</td>
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<td></td>
<td>8</td>
<td>2.36</td>
<td>2.68</td>
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<table>
<thead>
<tr>
<th>AEC Table 1 (Low Tomosynthesis Dose)</th>
<th>Compression Thickness (CM)</th>
<th>Detector Serial #:</th>
<th>Detector Serial #:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>1.26</td>
<td>1.26</td>
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<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>8</td>
<td>2.59</td>
<td>2.93</td>
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</tbody>
</table>
**Table 3 (Advanced Tomosynthesis Dose)**

<table>
<thead>
<tr>
<th>Compression Thickness (CM)</th>
<th>Detector Serial #:</th>
<th>Detector Serial #:</th>
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</thead>
<tbody>
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<td>0.76</td>
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<td>0.91</td>
<td>0.89</td>
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<td>6</td>
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</tr>
<tr>
<td>8</td>
<td>2.48</td>
<td>2.89</td>
</tr>
</tbody>
</table>

Gur et al. (2017), Acad. Radiol. 19(7):166

**Clinical Images**
GE SenoClair Essential Features

- Amorphous silicon with CSI scintillator
- 9 Projections
- Stop-and-shoot
- Sweep angle 25° (± 12.5)
- Sweep time <10 sec*
- Detector pixel size 100 μm in 2D & 3D
- 2D/3D-grid for scatter reduction
- ASIR DBT Iterative Reconstruction
- No dose increase (3D vs. 2D)
- MDT
- BTO DICOM format (Breast Tomosynthesis Object)

Additional QC Tests for SenoClaire (with MTD installed):

1. Phantom IQ 2D Test with MTD
2. CNR and MTF Measurement with MTD
3. Flat-field 3D Test
4. Phantom IQ 3D Test
5. MTD Grid Texture Test

Additional QC Tests for SenoClaire (with MTD installed):

6. AOP 2D and SNR Check with MTD
7. AOP 3D Check
8. Visual Checklist
9. Compression Force Test
Medical Physicist Tests (in addition to repeating those above)

1. Compression paddle to chest wall alignment with MTD
2. Breast Entrance Exposure and AGD in 2D with MTD
3. Breast Entrance Exposure and AGD in 3D Mode
4. Artifact Evaluation and Flat-field Uniformity with MTD
5. Volume Coverage of DBT – new test subjective evaluation after image reconstruction
4. AOP 2D and SNR Check with MTD

<table>
<thead>
<tr>
<th>Acrylic Thickness (mm)</th>
<th>Exposure Parameters</th>
<th>SNR</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Mo/Mo 32.1 mAs 26 kV</td>
<td>&gt; 50</td>
<td>PASS</td>
</tr>
<tr>
<td>50</td>
<td>Rh/Rh 53.4 mAs 29 kV</td>
<td>&gt; 50</td>
<td>PASS</td>
</tr>
<tr>
<td>60</td>
<td>Rh/Rh 62.4 mAs 30 kV</td>
<td>&gt; 50</td>
<td>PASS</td>
</tr>
</tbody>
</table>

**Requirement:**

Acrylic Thickness (mm) | Exposure Parameters | SNR | Pass/Fail |
------------------------|---------------------|-----|----------|
| 25                     | Mo/Mo 20 mAs 60 kV  | > 50 | PASS     |
| 50                     | Rh/Rh 40 mAs 90 kV  | > 50 | PASS     |
| 60                     | Rh/Rh 45 mAs 95 kV  | > 50 | PASS     |

5. AOP 3D Check

<table>
<thead>
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<th>Exposure Parameters</th>
<th>SNR</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Mo/Mo 27 mAs 26 kV</td>
<td>&gt; 50</td>
<td>PASS</td>
</tr>
<tr>
<td>50</td>
<td>Rh/Rh 54 mAs 29 kV</td>
<td>&gt; 50</td>
<td>PASS</td>
</tr>
<tr>
<td>60</td>
<td>Rh/Rh 63 mAs 31 kV</td>
<td>&gt; 50</td>
<td>PASS</td>
</tr>
</tbody>
</table>

**Requirement:**

Acrylic Thickness (mm) | Exposure Parameters | SNR | Pass/Fail |
------------------------|---------------------|-----|----------|
| 25                     | Mo/Mo or Mo/Rh 20 mAs 70 kV | > 50 | PASS     |
| 50                     | Rh/Rh 40 mAs 90 kV | > 50 | PASS     |
| 60                     | Rh/Rh 50 mAs 120 kV | > 50 | PASS     |

If the system fails any of these tests, the source of the problem must be identified and corrective action taken before any further mammographic images are acquired using the MTD that failed.

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**Volume Coverage**

**Objective**
Ensure that the entire imaged object is reconstructed on the Z-axis (perpendicular to the detector)

**Equipment required**
Set of acrylic plates; 2 1-mm Al sheets

**Procedure**
- “Sandwich” 25 mm of acrylic plates in between the 2 Al sheets as showed in the picture
- Manual 3D exposure, clinically used compression force
- Search for the focal planes of the 2 Al sheets
- Repeat with 60 mm acrylic

**Action Limit**
The focal planes for the 2 Al planes must be in the reconstructed volume
Grid Texture Test (monthly)

**Objective**
Measures the amount of grid texture in 2D images

**Equipment required**
Flat field test object

**Procedure**
- Automatic acquisition of 10 2D images with increasing mAs
- Record the displayed test results

**Action Limit**
The texture level must not exceed 0.002

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Grid Texture of MTD

One will be set up for a 2D acquisition with the MTD installed.
Ten exposures will be made, starting at 50 kVp, 35 mA and changing for subsequent exposures under QC software control.

Reported Texture Result = 0.0004

**Action Limit**
Grid texture must be less than 0.002 or this test will FAIL. If the test attempt fails, take off the MTD, then re-apply the MTD and repeat the test. If the grid texture test fails a second time, then service must take corrective action.
Siemens Mammomat Inspiration with Tomosynthesis option:

In tomosynthesis mode,
The same amorphous selenium detector used in Hologic and Siemens mammomat DBT system, Detector pixel size: 85 micron

Tube motion: continuous

Target/filter: W/Rh

the X-ray tube of the MAMMOMAT Inspiration digital mammography system rotates in a circular motion around the breast; acquire an image every two degrees while moving through an angular range of 50 degrees.

Scan time: 25 s

The resulting 25 projections are reconstructed as three-dimensional (3D) digital breast tomosynthesis (DBT) images.

Reconstruction method: FBP
Important QC tests Siemens Inspiration with DBT option

Before conducting quality control tests for tomosynthesis, make sure that the quality control tests in FFDM mode have been performed without errors.

Glandular dose by MP, new method where acrylic plates and Dance et al table are used for AGD estimation automatically by the manufacturer software

Geometric accuracy in X and Y direction - MP

Z-resolution - MP, a new test that is performed after image reconstruction using existing ACR phantom
Review Workstation Soft Copy QC must be performed

Information about the RWS must be provided

Luminescence, ambient light level must be provided

Soft Copy Phantom Image
Options for sending the 3D phantom image for evaluation:

- Option 1 – Facilities can capture a 3D image (Softcopy) most preferred slice and send to FDA as an e-mail attachment for evaluation
- Option 2 – Facilities can send a CD/DVD (Softcopy) and mail to FDA for evaluation
- Option 3 - Facilities can send the 3D phantom image (Hardcopy) and to FDA for evaluation

Facilities can contact Hologic Helpdesk for instructions on printing the 3D phantom image. Facilities must evaluate the image before sending to our office.

All manufacturers provide guidance to generate soft copy Images

All three manufacturer will give presentation tomorrow, please make sure you get instructions from the manufacturers
SenoClaire DBT ACR Phantom e-Print Submission to FDA
Customer Help Guide

Acquire the ACR phantom in 3D manual mode using 29 kV at 56 mAs per the QAP instructions.

Push the volumes to the IDI MWS if not sent automatically.

From the IDI Mammo Workstation – select the ACR phantom from the Cache.
Double click/open to view the volumes – 1 on 1 format is best to score/window the image.

Using the Edit tool – rotate the image 90° to the left.

Select the individual plane displaying the highest IQ/most masses, specs and fibres. This is typically at phantom thickness 38mm ± 0.5mm – may vary depending on 0.5mm or 1mm reconstruction plus the phantom compressed thickness which is normally 42mm to 45mm – make sure to select the one plane with all content – scroll above and below to make sure.

Review the image to make sure the acceptance criteria of 4 fibers/3 spec groups and 3 masses is met.

Now change the format to display the image with the 2 on 1 monitor format to use this snipping method. You may need to rotate the image again and re-verify with the 2 on 1 format that the acceptance criteria are met/exceeded.

The FDA will accept All Pixels (1) for the zoom or Original zoom (2). Select this zoom from the drop down menu under the Zoom State tool on the 5mp monitor.

Review the image for the best visualisation of the content in this 2 on 1 format.

Using the Move tool:
- With the left mouse button, position the phantom in the middle of the 2 on 1 viewport so that it is not covered up by the thumbnails, the ruler or any annotations.
- Open the Snipping tool on the Windows (not an IDI interface) desktop normally on the lower left side of the small monitor.
- Select the Snipping Tool. It may be located under All Programs/Accessories.
- When the tool opens, click on the directional arrow next to New and select Rectangular Snip. (The monitors will turn gray/bright when the tool is active.)
- Right click the mouse cursor to the monitor viewport displaying the ACR Phantom in 2 on 1 format and while pressing the left mouse – place the cross shaped cursor in the upper monitor and holding down the left mouse down – outline the entire viewport containing the ACR phantom image.
- The snipping tool will not work with 1 on 1 format as it is too much data.
• Click on File and Save as on the Snipping Tool toolbar (upper left side)
• Select the destination – the Desktop is an easy place to store and find later
• Type the file name of the image – e.g., ACR Phantom
• Make sure the Save as type is PNG
• Submit the properly acquired/windowed image electronically to the FDA by attaching it to the e-Application or via email at mqsahotline@hcmsllc.com

SenoClaire DBT ACR Phantom Softcopy Submission to FDA
Customer Help Guide: Burn to CD/DVD

1. Acquire the ACR phantom in 3D manual mode using 29 kV at 56 mAs per the QAP instructions
2. Push the volumes to the IDI MWS if not sent automatically
3. From the IDI Mammo Workstation – select the ACR phantom from the Cache
4. Double click/open to view the volumes – 1 on 1 format is best to score/window the image
5. Using the Edit tool – rotate the image 90⁰ to the left to display best for counting
6. View the individual plane displaying the highest IQ/most masses, spicules and fibers. This is normally at phantom thickness 38mm +/- 1/2mm. Plane # may vary depending on 0.5mm or 1mm reconstruction plus the phantom compressed thickness which is normally 42mm to 45mm
7. Return to the browser and with the ACR Phantom selected/highlighted select the planes series only – do not send the V-Preview as the FDA needs the true image. They don’t need the raw data in this case either.

1. Select New CD/DVD as the send destination

8. Click on the Send To icon on the lower 1mp monitor
9. On the Search Tab under the Data source, click on New CD/DVD
10. Make sure the ACR Phantom is in the Patient list (green circle)
11. Select the Patient CD and burn (this will include the viewer)
12. After completion - review the ACR Phantom Plane images burned onto the CD on a PC and verify the GE Media Viewer is installed and the images open and can be viewed
13. Only the planes are needed for submission but per the GE QAP – the phantom should be reviewed in both planes and slabs to make sure IQ is consistent

14. Select the plane with the best IQ (37mm + or -) and using the zoom and other tools make sure the masses, specs and fibers are well visualized

15. Send the CD/DVD to the FDA.

What may cause delay in approval

- Incomplete application package
- Only summary page, not comprehensive MEE report
- All tests are not performed as required by the DBT manufacturer QC manual
- RWS test results are not included
- 3D phantoms are not included
- Phantom images cannot be opened from the CD/DVD

Send the 3D phantom image (CD, DVD or Hardcopy) to the following address:

FFDM and DBT Certification Extension Program
Division of Mammography Quality Standards
FDA/CDRH/OIR
10903 New Hampshire Ave., WO66-4456 (Attn: Denise Robinson)
Silver Spring, MD 20993-0002
Phone: 301-796-5919

With advent of soft copy images, FDA strongly encourages electronic submission at:

FDA Electronic DBT to: DBTelectronicsubmission@fda.hhs.gov