

Unique Features of the GE Senoclaire Tomosynthesis System

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Conflict of Interest Disclosure

- I have no conflicts to disclose.

Learning Objectives

- Overview of GE SenoClaire System
- Medical Physicist QC Testing Requirements
- Common Pit-Falls, Errors, and Issues
- Technologist QC Testing Requirements
- Review the FDA DBT Certificate Extension Program

Note: This presentation assumes the physicist is proficient with 2D GE Physics Testing Procedures

SenoClaire

GE Breast Tomosynthesis Quality Control Manual



Non-contractual image. Flowers on the Gantry are not delivered with the system as standard.



5415892-3-1EN

Revision 1

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SenoClaire System Summary

- Uses same Target/Filter combinations as 2D system.
- Similar Dose level in 3D as 2D
- FDA Approved for Screening as 2D CC and 3D MLO views.
 - “An exam consisting of one DBT MLO view plus one 2D CC view is clinically ***non-inferior*** to a standard two-view digital mammography examination... as measured by the area under the receiver operating characteristic (ROC) curve”¹
- Available as an add-on for all Senographe Essential systems currently installed.
- V-Preview reconstruction option - synthesized 2D image from 3D acquisition

1. “SenoClaire GE Breast Tomosynthesis Clinical and Non-Clinical Information, 5415896-3-1EN, Rev. 1, Page 7

SenoClaire Attachment

- 3 Available Paddles
 - 24 x 31, Elevated 24 x 31, Sliding 19 x 23
- 9 images acquired over a 25° sweep.
- Step and Shoot Acquisition
- 100 micron pixel size - no binning of pixels
- 5:1 Anti-Scatter grid
- MTD attachment weighs over 12 kg and is not counterbalanced - use caution if manually moving.
- Not available for Magnification, CESM, or negative angle exposures.

1 Motorized Tomosynthesis Device (MTD)

*Manual compression
adjustment knobs.
(One on either side
of the MTD)*

*3D light.
(Green when
illuminated)*

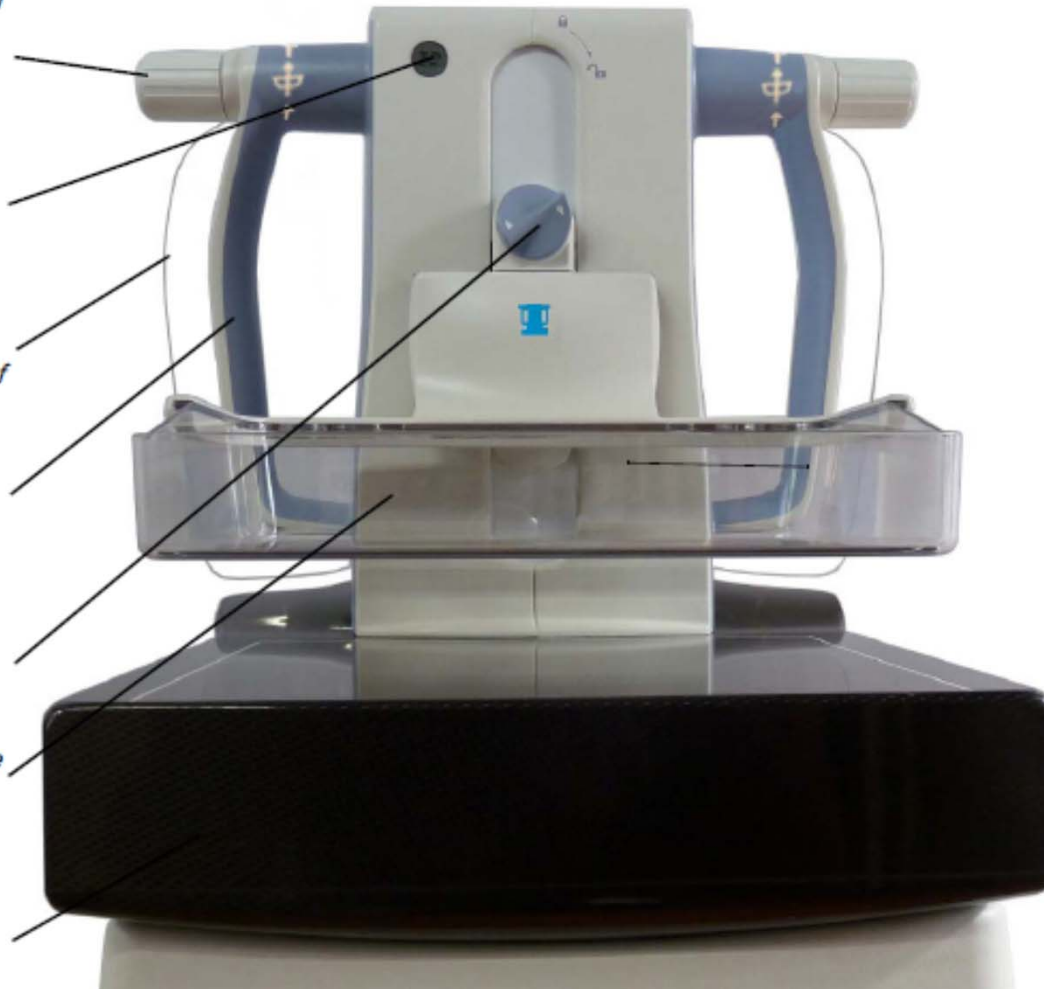
*MTD protection
shield.
(one on either side of
the MTD)*

*MTD handles.
(One on either side
of the MTD)*

*Paddle unlocking
button*

Compression paddle

*Carbon cover
Houses the Image
Receptor*



Installing the MTD



Caution!

- When installing and removing the MTD, proper care must be taken not to scratch, dent, or damage BOTH the Digital Detector and the MTD grid.
- The Cart that holds the MTD when not in use is helpful for initially placing the weight of the MTD on the Digital Detector, but should be removed before final alignment.
- Especially when removing the MTD, make sure that the MTD is clear of the guiderails before lowering the gantry out of the way. It is possible to shear the guiderails if the MTD is attached to the cart and the gantry is lowered prematurely.

Illustration 5 2D/3D motion selection buttons



Performing a 3D Acquisition

- Initialize 3D mode by pressing motion selection button on MTD until 3D light is illuminated.
- Move Tube Head into start position using the Gantry Arm Movement Control Buttons
- Select Right or Left Laterality at Control Console
 - From patient's perspective, Gantry starting to the left must be a Right Laterality acquisition.
 - Gantry starting on the right must be a Left Laterality acquisition.
- Press Foot Pedal, Prep, and Expose Buttons.
- Following completion of 3D acquisition, gantry is not ready for a second. Must manually move gantry into position again.



Image Processing

- Images are processed at Dr's Review Workstation using GE's Adaptive Statistical Iterative Reconstruction (ASiR) system.
 - Images should be Automatically Pushed to Review Workstation for Reconstruction. At acceptance, remind service that this must be functional for you to complete the testing.
- Both "slabs" (10 mm) and "planes" (0.5 mm or 1 mm) are reconstructed.
- Technologist Control Station only sees 9 acquired images to review positioning.
- For submission to FDA, must submit a slice of the phantom showing best score (usually at 37 mm or 38 mm) from the Review Workstation.
 - Image must have identifying data on it (kVp, mA, Unit Name, Type of Acquisition)
 - Important to remind service that you will need a way to print or burn the image from the Review Workstation.

Medical Physicist QC Tests

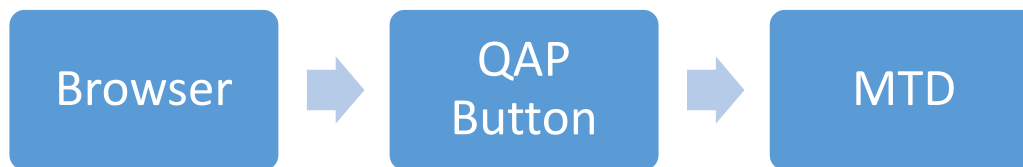
QAP (Quality Assurance Procedures)

- CNR and MTF Measurement with MTD
- Flat Field 3D Test
- Grid Texture Test
- AOP 2D and SNR Check with MTD
- AOP 3D Check

Non-QAP

- Phantom IQ Test with MTD
- Phantom IQ 3D Test
- Compression Paddle Border to Chest Wall Alignment with MTD
- Breast Entrance Exposure and Average Glandular Dose with MTD
- Breast Entrance Exposure and Average Glandular Dose in 3D Mode
- Artifact Evaluation and Flat Field Uniformity with MTD
- Volume Coverage

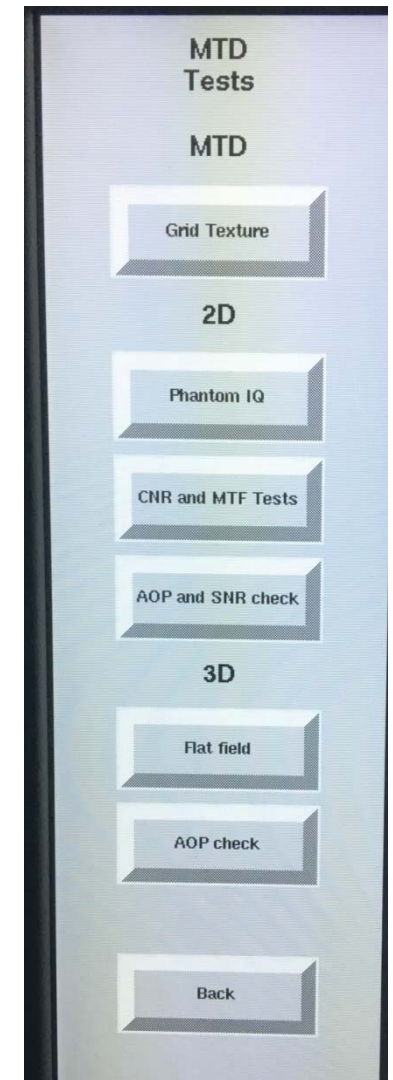
Many of the QAP tests are nearly identical to 2D tests, but with MTD system in place.



Flat Field 3D Test

CNR and MTF Measurement with MTD

2D AOP and SNR Check with MTD

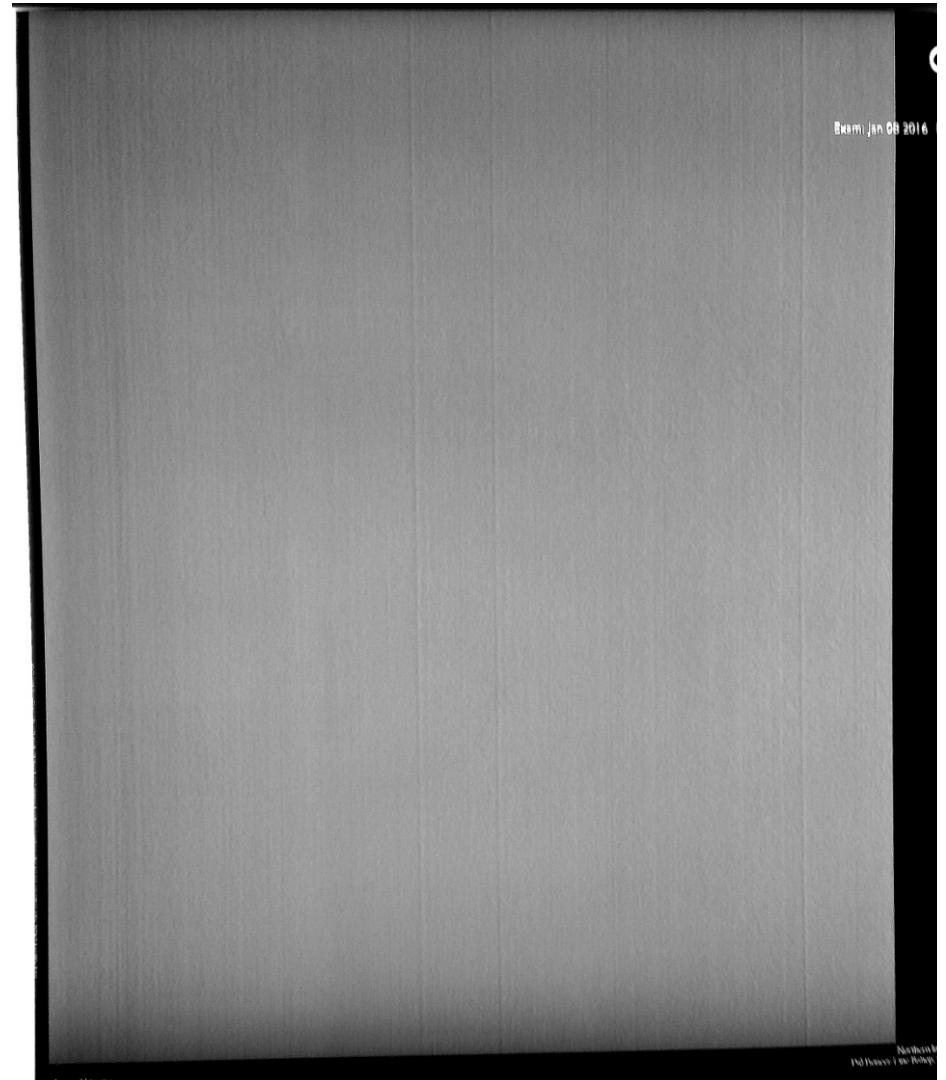


Grid Texture Test

- Objective: To measure the amount of grid texture in 2D Images.
Necessary due to differences in grid texture of MTD device compared to gain calibration of traditional system.
- Uses 25 mm thick flat field phantom.
- Acquire 10 images.
- Record Result.
- Action Limit: Texture Level must not exceed 0.002.
 - If this fails, try re-installing the MTD and performing the test again.

Grid Texture Test

- Measured 0.0164
 - 8 times the allowable 0.002
- Obvious gridlines in flat-field image
- Corrected by service with new Gain Calibration
- In this case, I did not allow facility to perform 3D imaging until issue was corrected.



AOP 3D Check

- Verifies that Correct Parameters are Selected in AOP 3D Mode
- Uses 25 mm, 50 mm, and 60 mm acrylic plates.
- No SNR Measurement as with 2D.

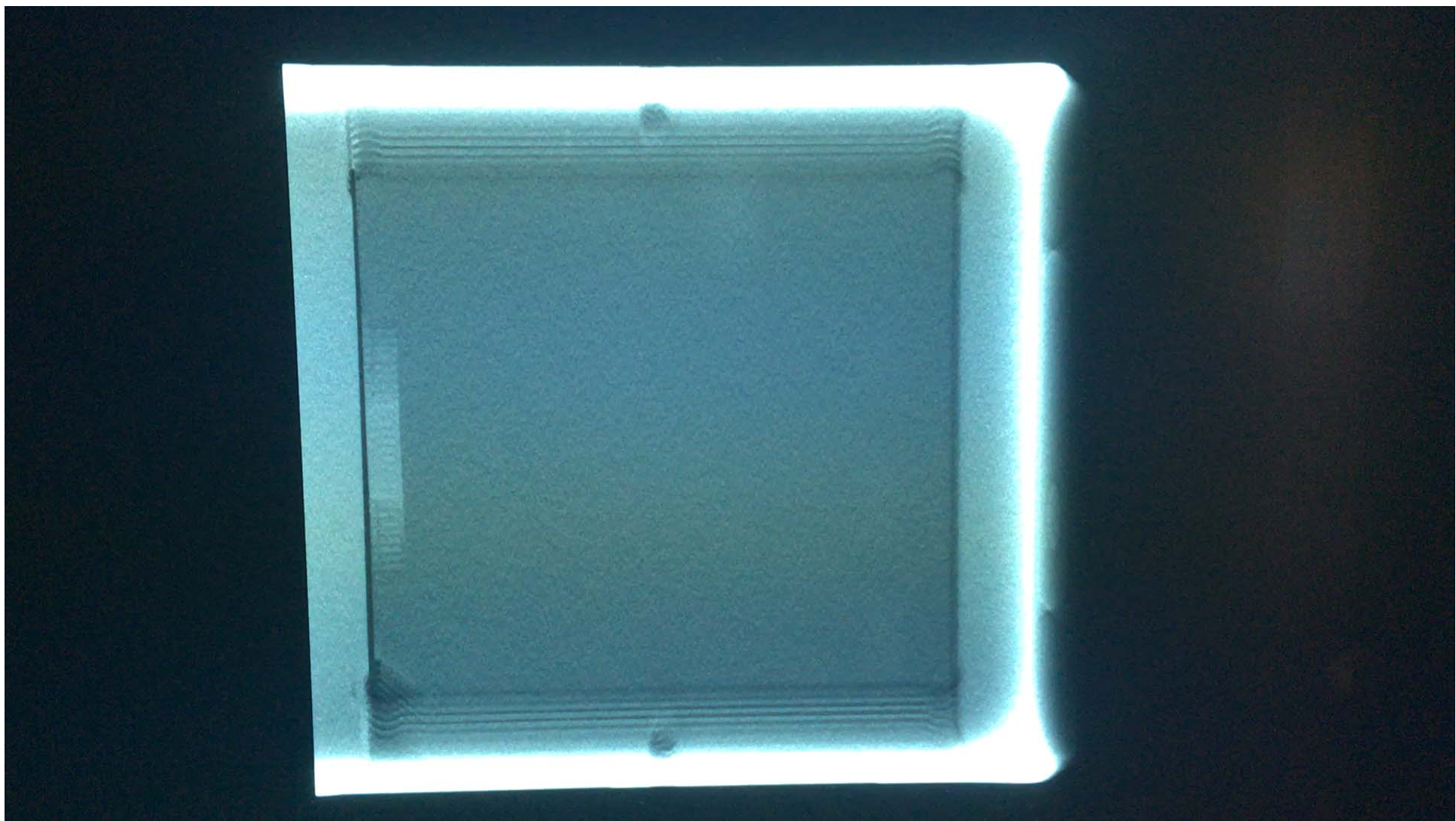
| Acrylic Thickness (mm) | Exposure Parameters For AOP 3D Mode Only | | |
|---------------------------|---|----------|----------|
| | Track/Filter | mAs | kV |
| 25 | Mo/Mo or Mo/Rh | 20 - 70 | 26 |
| 50 | Rh/Rh | 40 - 90 | 29 |
| 60 | Rh/Rh | 50 - 120 | 30 or 31 |

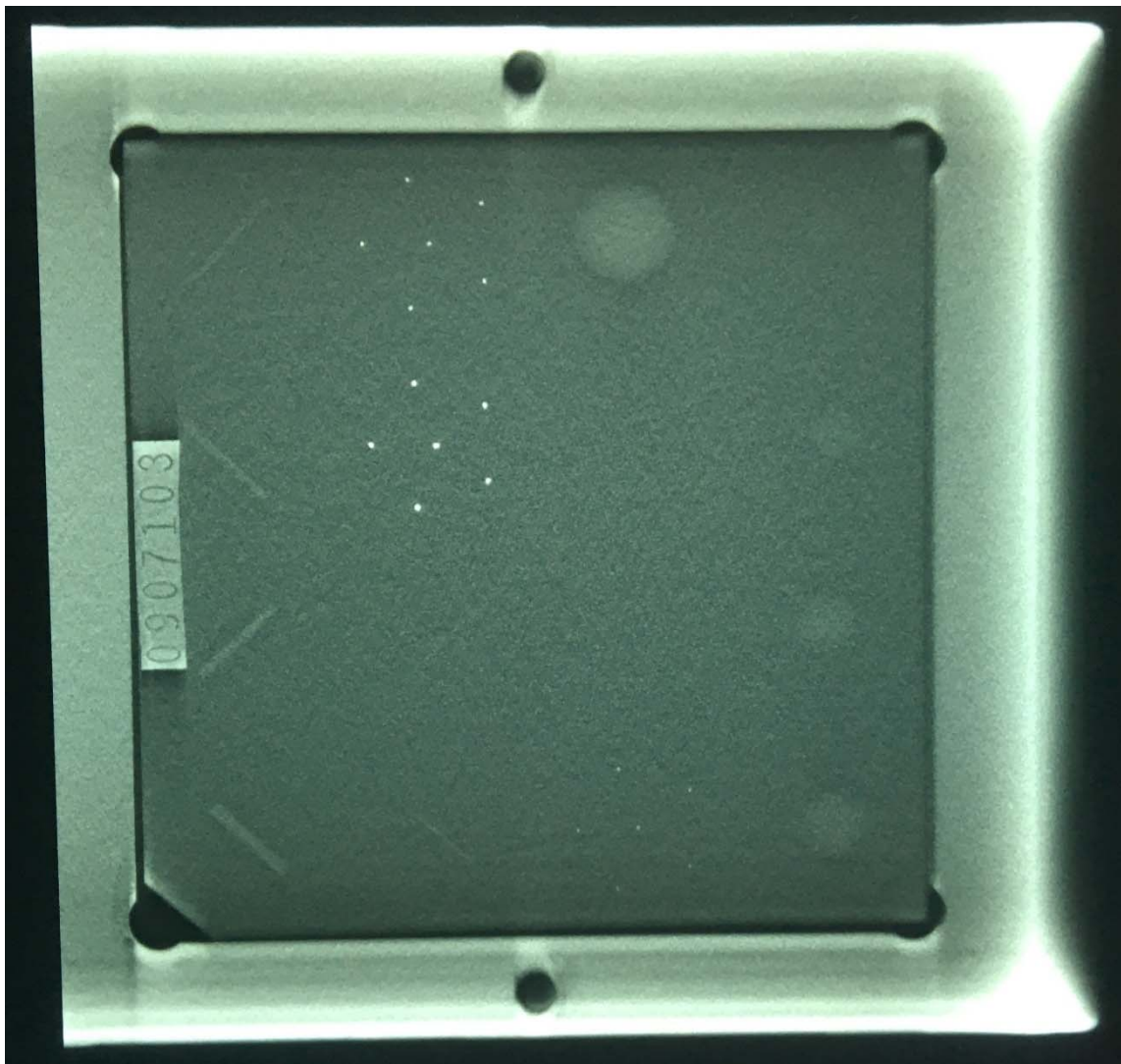
Phantom IQ Test with MTD

- Identical to 2D Phantom IQ Test but with MTD system in place.
- Rh/Rh, 29 kVp, 56 mAs
- Action Limit: 4 fibers, 3 speck groups, 3 masses.

Phantom IQ 3D Test

- Set system to acquire 3D acquisition
- Manual Technique: Rh/Rh, 29 kVp, 56 mAs
- Review Reconstructed Image on Dr.'s Review Workstation
 - View both slabs and planes.
 - Select “plane” image with best score for submission to FDA
- Action Limit: 4 fibers, 3 speck groups, 3 masses.





Compression Paddle Border to Chest Wall Alignment Test with MTD

- Objective: To assure the paddle chest wall side border aligns with the chest wall side of the detector.
- Both Mo and Rh targets must be tested.
- Must perform test with all 3 paddles (if used clinically)
 - 24 x 31 paddle
 - Elevated 24 x 31 paddle
 - Sliding 19 x 23 paddle
- FDA requires that you follow the test procedure as specified in the QC manual or show that your procedure is not significantly different.
 - Show your work

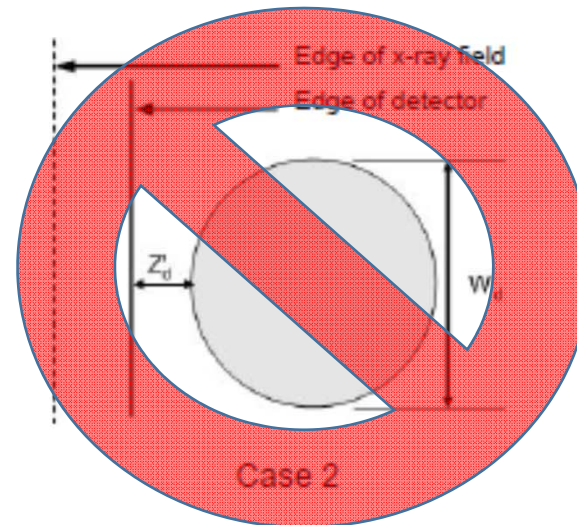
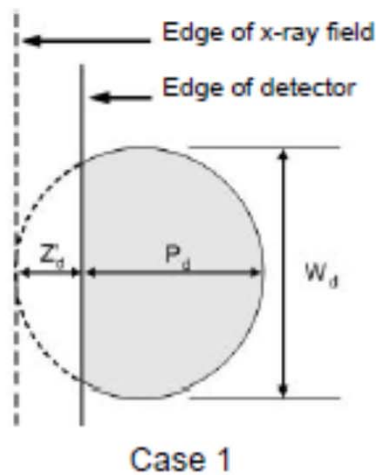
Compression Paddle Border to Chest Wall Alignment Test with MTD

- Coin must be as close as possible, but inside of the tangent to the inner vertical surface of the compression paddle.
- Recommend taping coin on top of compression paddle as close to chest wall edge as possible. Without tape, coin will slide away from chest wall edge.



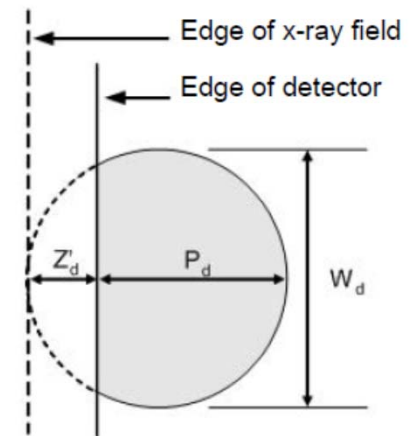
Compression Paddle Border to Chest Wall Alignment Test with MTD

- Set the paddle to approximately 4.2 cm above the breast support.
- There are 2 possible geometric cases for the coin:



Compression Paddle Border to Chest Wall Alignment Test with MTD

- Use segment tool to measure Full Diameter (W_d) & Partial Diameter (P_d)
 - Note the segment tool measures in a plane 2 cm above breast support
- Calculate Alignment Deviation $Z'd = (W_d - P_d)$
- Calculate $Z_d = Z'd * 1.063$
- Action Limit: Z_d must be < 6.6 mm.
- Enter Results in Table

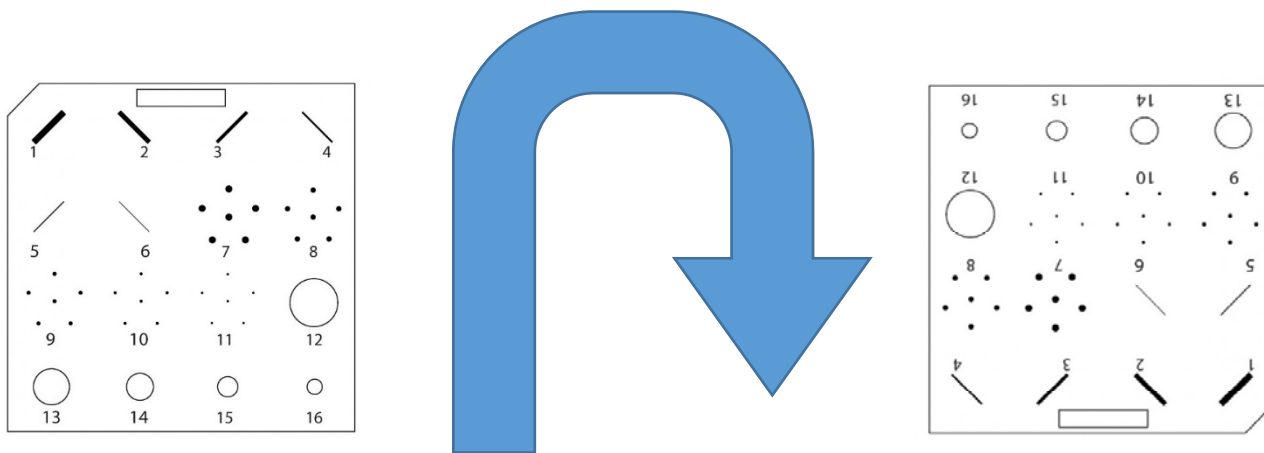


| | Geometric Case | W_d | P_d | Z'_d | Z_d ($1.063 \times Z'_d$) | Passed/ Failed |
|--------------------------------|----------------|-------|-------|--------|----------------------------------|-------------------|
| Mo/Mo 24x31 paddle | | | | | | |
| Rh/Rh 24x31 paddle | | | | | | |
| Mo/Mo Elevated 24x31 paddle | | | | | | |
| Rh/Rh Elevated 24x31 paddle | | | | | | |
| Mo/Mo 19x23 sliding paddle | | | | | | |
| Rh/Rh 19x23 sliding paddle | | | | | | |

Breast Entrance Exposure and Average Glandular Dose with MTD

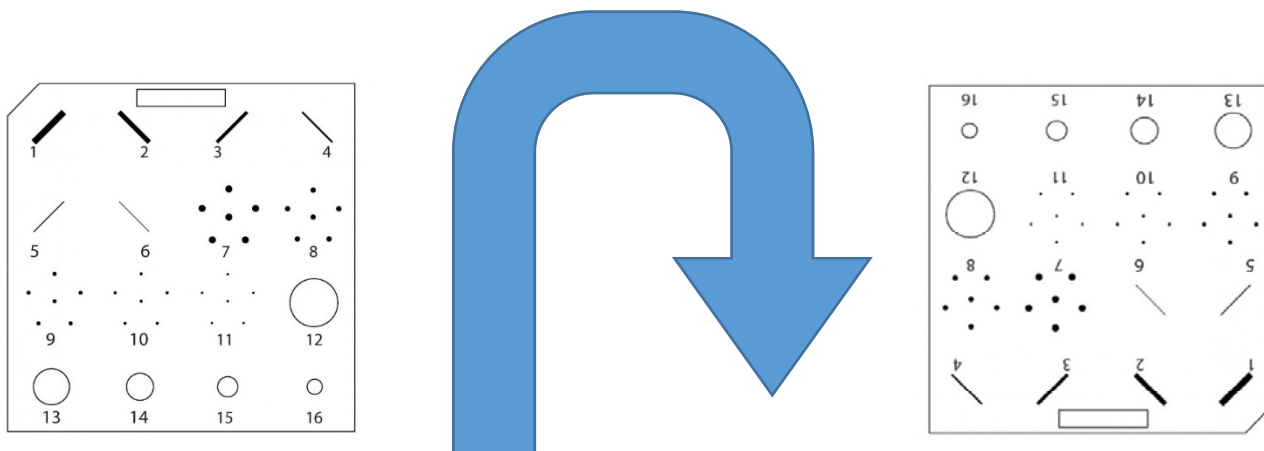
- Measure in AOP mode (STD, CNT, & Dose)
- Rotate Phantom 180° from Normal Orientation.

****Verify CNT Dose Setting with MTD****



3D Breast Entrance Exposure and Average Glandular Dose

- Perform a 3D Stationary Acquisition
- AOP Mode or Manual Mode @ Rh/Rh, 29 kVp, 45 mAs
- Rotate Phantom 180° from Normal Orientation.



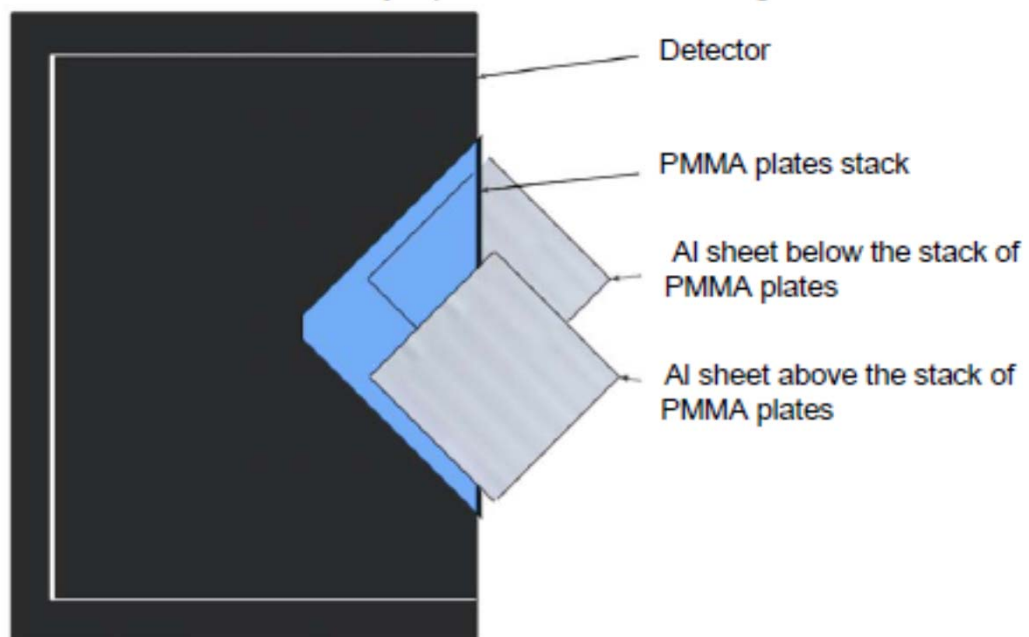
Artifact Evaluation and Flat Field Uniformity with MTD

- Objective: To assess the degree and source of artifacts and to assure that the Flat Field image is Uniform.
- 2D Acquisition in Mo/Mo, Mo/Rh, and Rh/Rh modes.
 - Review Raw Images from Browser
- There is a separate Gain Calibration for the MTD to create uniform images.

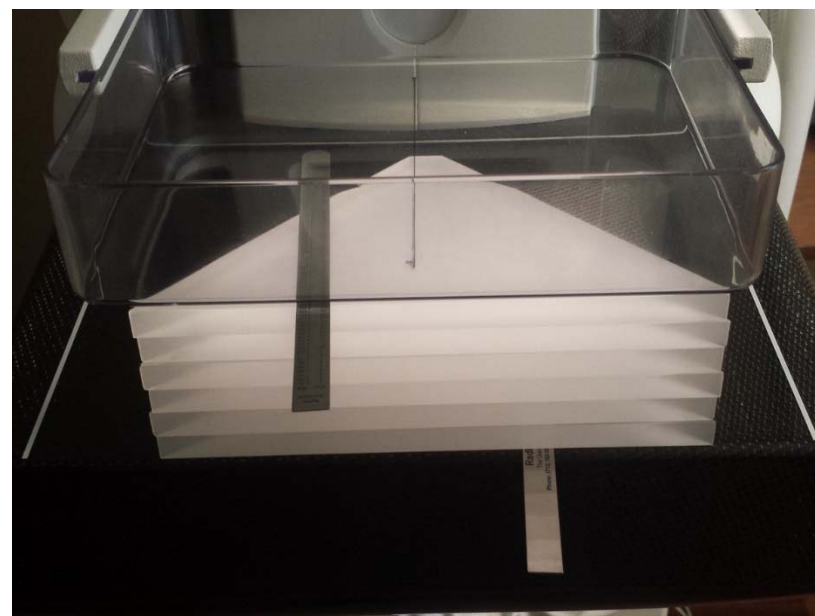
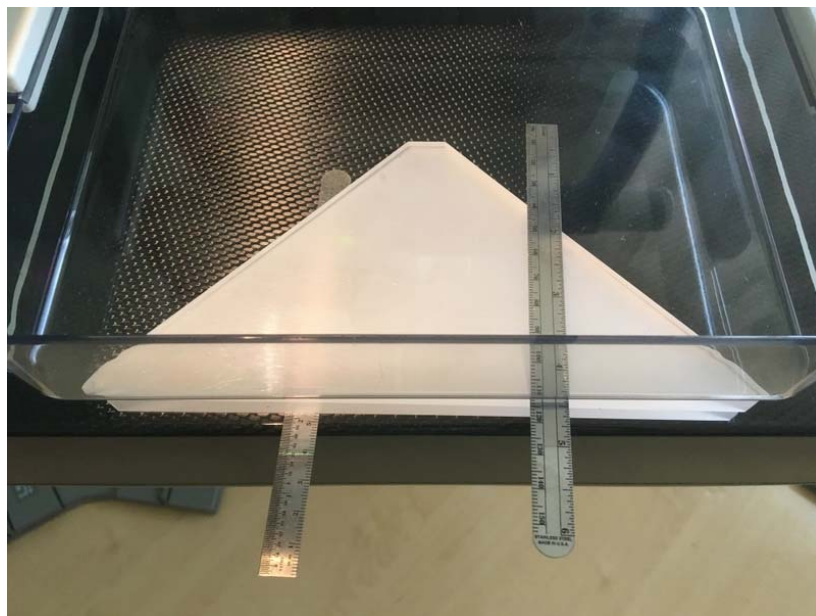
Volume Coverage

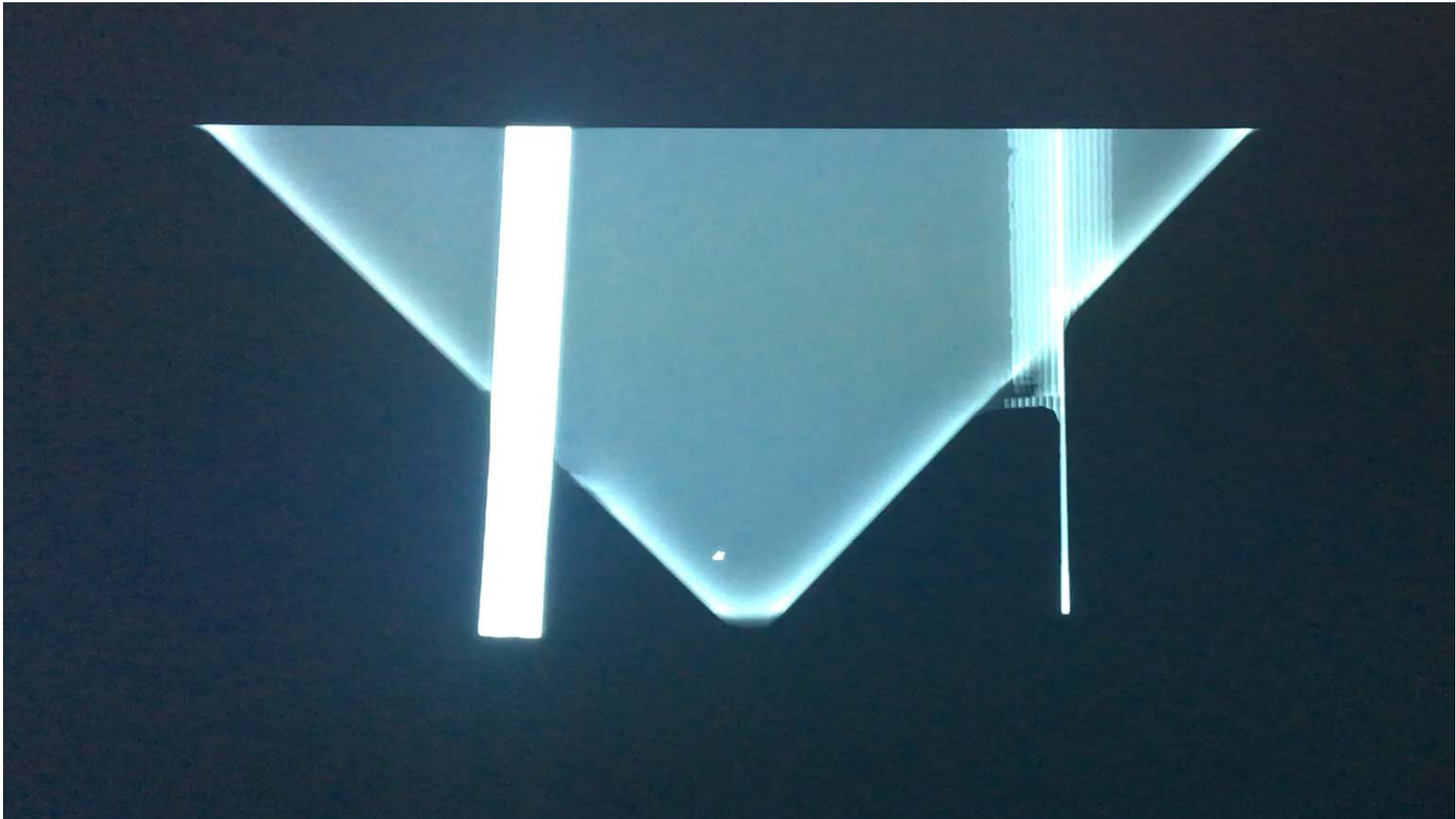
- Objective: To ensure that the entire imaged object is reconstructed on the Z-Axis.
- 3D Acquisition with 25 mm & 60 mm phantoms with aluminum sheets above and below.
- Manual Exposure Technique:
 - 25 mm: Mo/Mo, 26 kVp, 45 mAs
 - 60 mm: Rh/Rh, 29, kVp, 110 mAs
- Visually Verify that the top and bottom Al sheets are visible in the reconstructed volume.

Volume Coverage



Volume Coverage





Summary of Physics Tests

| Test | Pass/Fail Criteria | Timeframe to Correct |
|----------------------------------|--|--------------------------|
| Phantom IQ Test with MTD | 4 Fibers, 3 Speck Groups, 3 Masses | Immediate |
| CNR and MTF Measurement with MTD | MTF at 2 lp/mm > 49% MTF at 4 lp/mm > 18% Change in CNR < 0.20 | Immediate |
| Flat Field 3D Test | Brightness Non-Uniformity and SNR Non Uniformity Must Pass | Immediate |
| Phantom IQ 3D Test | 4 Fibers, 3 Speck Groups, 3 Masses | Immediate |
| Grid Texture Test | Texture Level < 0.002 | 30 Days (Use Discretion) |
| AOP 2D and SNR Check with MTD | Exposure Parameters within Limits SNR > 50 | Immediate |
| AOP 3D Check | Exposure Parameters within Limits | Immediate |

Summary of Physics Tests

| Test | Pass/Fail Criteria | Timeframe to Correct |
|--|---|--------------------------|
| Compression Paddle Border to Chest Wall Alignment with MTD | Chest Wall edge of Paddle Not in Image Chest Wall edge < 6.6 mm beyond detector | 30 Days |
| Breast Entrance Exposure and Average Glandular Dose with MTD | 3 mGy (300 mrad) | Immediate |
| Breast Entrance Exposure and Average Glandular Dose in 3D Mode | 3 mGy (300 mrad) | Immediate |
| Artifact Evaluation and Flat Field Uniformity with MTD | No Artifact or Non-Uniformity that is expected to mimic or obscure clinical information | 30 Days (Use Discretion) |
| Volume Coverage | Focal Plane of Top and Bottom Al sheets visible within the reconstructed volume | Immediate |

Technologist QC Tests

| Minimum Frequency | Procedure |
|-------------------|----------------------------------|
| Weekly | Phantom IQ Test with MTD |
| | CNR and MTF Measurement with MTD |
| | Flat Field 3D Test |
| | Phantom IQ 3D Test |
| Monthly | Grid Texture Test |
| | AOP 2D and SNR Check with MTD |
| | AOP 3D Check |
| | Visual Checklist |
| Semi-Annually | Compression Force Test |

All 2D QC TESTS MUST STILL BE PERFORMED! These tests are in-addition to the routine GE QC

FDA DBT Certificate Extension Program

- Under MQSA each *Manufacturer's* DBT system is considered a new modality, and the personnel training requirements apply.
- The certificate extension program only applies to the DBT portion of the system. The 2D portion of the system must be accredited by one of the approved accreditation bodies.
- The facility must have the approval of the FDA prior to DBT clinical use.

FDA DBT Application Process

- Available at: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm413117.htm>

- Includes Facility Information, Unit ID, Image Receptor ID, Monitor ID, Personnel Qualifications.
- 3D Phantom Image (Hardcopy or Softcopy)
- Include the Complete, Detailed Mammography Equipment Evaluation
- Include an Evaluation of the DBT Manufacturer's QC Program

MAP ID#: _____

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Code of Virginia 8.01-581.17

**MEDICAL PHYSICIST'S CHECKLIST
MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT**

Facility Name: _____

Unit Manufacturer: _____ Model: _____

Serial number: _____ Year Mfr: _____

Medical Physicist: _____ Room ID: _____

Signature: _____ Survey Date: _____

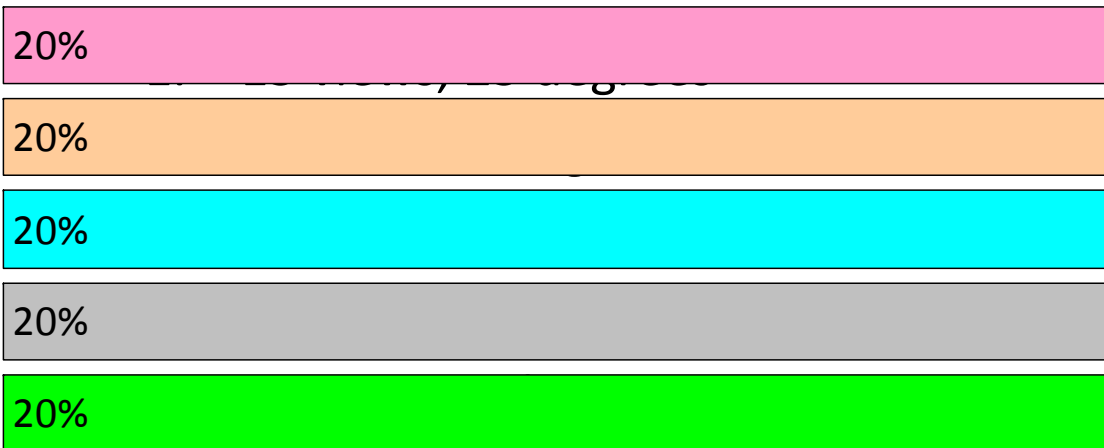
| Feature | FDA Rule Section | Requirement | Applies to | Meets FDA Requirements? (if NA, please explain) |
|--|------------------|--|------------|--|
| Motion of tube-image receptor assembly | 3(i) | The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. | S-F & FFDM | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA |
| | 3(ii) | This mechanism shall not fail in the event of power interruption. | S-F & FFDM | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA |
| | 4(i) | Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 cm and | S-F | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA |

FDA DBT Certificate Extension Submission

- Send All Application Materials to:

FFDM and DBT Certification Extension Program
Division of Mammography Quality Standards
FDA/CDRH/OIR
10903 New Hampshire Ave., WO66-4528
Silver Spring, MD 20993-0002
Phone: 301-796-5919
Fax: 301-847-8502

In order to acquire the DBT image set, the GE system uses _____ views over sweep angle of _____ degrees?

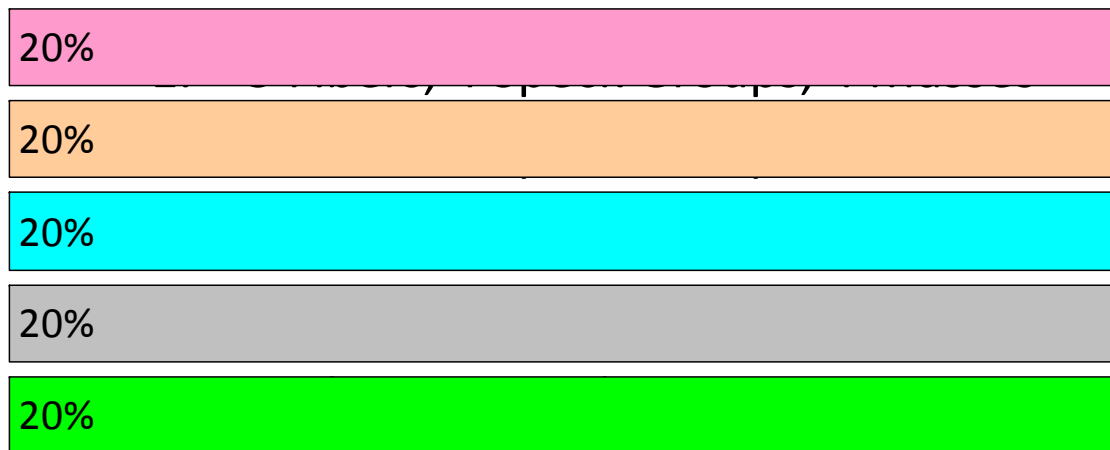


In order to acquire the DBT image set, the GE system uses_____ views over sweep angle of_____ degrees?

1. 15 views, 25 degrees
- 2. 9 views, 25 degrees**
3. 15 views, 15 degrees
4. 12 views, 15 degrees
5. 9 views, 15 degrees

Reference: GE Breast Tomosynthesis Operator Manual, 5415894-4-1EN,
Revision 1. Page #24.

What is the minimum acceptable phantom score for the 3D image?

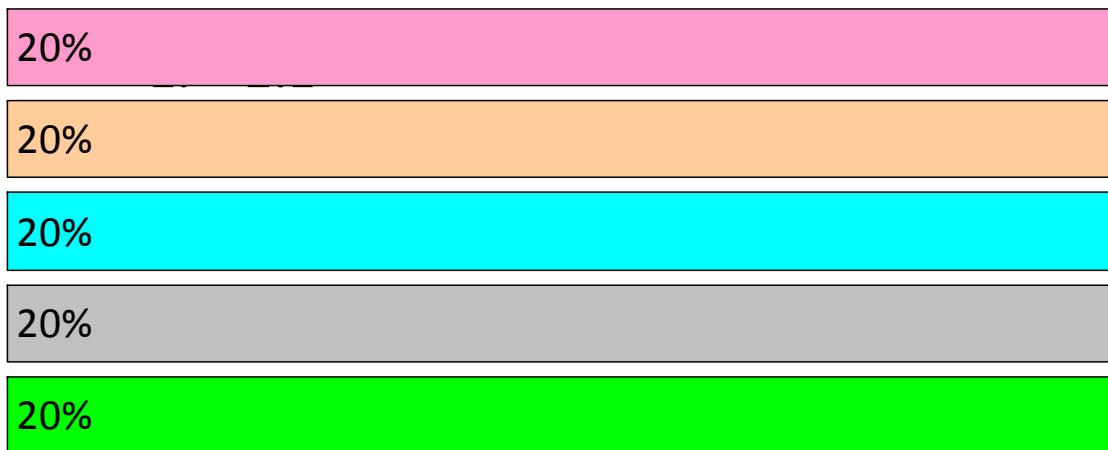


What is minimum acceptable phantom score for the 3D image?

1. 5 Fibers, 4 Speck Groups, 4 Masses
2. 4 Fibers, 4 Speck Groups, 4 Masses
3. 4 Fibers, 4 Speck Groups, 3 Masses
- 4. 4 Fibers, 3 Speck Groups, 3 Masses**
5. 3 Fibers, 3 Speck Groups, 3 Masses

Reference: GE Breast Tomosynthesis Quality Control Manual, 5415892-3-1EN, Revision 1. Page #21.

What is the Grid Ratio for the Anti-Scatter grid?



What is the Grid Ratio for the Anti-Scatter grid?

1. 2:1
2. 4:1
- 3. 5:1**
4. 8:1
5. 12:1

Reference: GE Breast Tomosynthesis Operator Manual, 5415894-4-1EN,
Revision 1. Page #198.