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Certification Extension Process for Digital Breast Tomosynthesis and Medical Physicists Role

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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.

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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.

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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

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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.

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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

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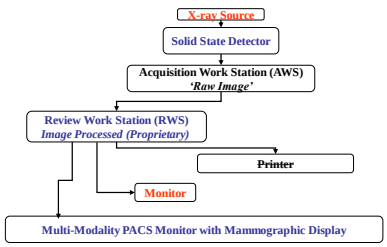
Currently there are three FDA Approved DBT Systems:

Hologic Selenia Dimension

GE SenoClaire

Siemens Mammomat Inspiration with DBT

Imaging Chain Scheme



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Hologic Selenia Dimension

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

Combo mode & Cview available

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QC for the medical physicist

Table A-1: Quality Control Tests To be Performed by the Medical Physicist on All Selenia Dimensions Systems

Quality Control Test	Frequency	Action Criteria	Chapter 2
Mammographic Unit Assembly Evaluation	Annually	Category C	Section 1.0, page 10
Collimation Assessment	Annually	Category C	Section 2.0, page 11
Artifact Evaluation	Annually	Category C	Section 3.0, page 18
kVp Accuracy and Reproducibility	Annually	Category C	Section 4.0, page 22
Beam Quality Assessment—HVL Measurement	Annually	Category C	Section 5.0, page 24
Evaluation of System Resolution	Annually	Category A	Section 6.0, page 26
Automatic Exposure Control (AEC) Function Performance	Annually	Category C	Section 7.0, page 29
Breast Entrance Exposure, AEC Reproducibility, and Average Glandular Dose	Annually	Category A Category C	Section 8.0, page 33
Radiation Output Rate	Annually	Category C	Section 9.0, page 39
Phantom Image Quality Evaluation	Annually	Category A	Section 10.0, page 42
Signal-To-Noise and Contrast-To-Noise Measurements	Annually	Category A	Section 11.0, page 45
Diagnostic Review Workstation Quality Control	Annually	Category B	Section 12.0, page 50
Detector Ghosting (troubleshooting use only)	—	Category A	Section 13.0, page 52

Zero degree tomo acquisition required

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AEC Function Performance

Contact Imaging, LFS with Grid

Phantom Thickness	AEC Mode	kVp	mAs	Filter	Exp Comp Step	Exposure Index	CNR Correction Factor*	Corrected Pixel Value*
2 cm	Auto Filter	26	35	Al	2.1	244.0	0.70	277.14
4 cm	Auto Filter	29	48	Al	3.9	297.0	0.91	271.43
6 cm	Auto Filter	33	64	Al	5.8	439.0	1.46	266.44
8 cm	Auto Filter	38	80	Al	8.0	889.0	2.37	269.62

Corrected Mean Pixel Value	Corrected Pixel Value Range		Allowed Corrected Pixel Value		
271.16	266.44	to 277.14	244.04	to	298.27

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Average Glandular Dose

- Conventional
- Tomosynthesis
- Combo: Conventional & Tomosynthesis simultaneously acquired

Part of Combo Exposure	Conventional	Tomosynthesis
Breast Thickness (cm)	4.2	4.2
KVp setting	26	29
Target Material	W	W
Filter Material	Rh	Al
AEC Mode	AF	AF
AEC Position	2	2
Exp. Compensation Step	0	0
Measure HVL (mmAl)	0.512	0.514

Average Glandular Dose:

Part of Combo Exposure	Conventional	Tomosynthesis
Inv. Sq. corrected Skin exp	0.907	0.907
Dose conversion factor from table 1-3 (mRad/R)	265.000	269.000
Computed average glandular dose (mrad)	130.547	135.301
Total Average Glandular Dose (mrad) *		266

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

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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

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QC for the radiologic technologist

Table B-1: Quality Control Tests To be Performed by the Radiologic Technologist on All Selenia Dimensions Systems

Quality Control Test Procedure	Frequency	FORMS: 1999 ACR Quality Control Manual	FORMS: Selenia Dimensions	Chapter 3
DICOM Printer Quality Control	Weekly		✓	Section 1.0, page 56
Detector Flat Field Calibration	Weekly		✓	Section 2.0, page 59
Geometry Calibration (Tomosynthesis Option)	Semiannually		✓	Section 3.0, page 61
Artifact Evaluation	Weekly		✓	Section 4.0, page 63
Phantom Control Chart for Printer and Diagnostic Review Workstation	Weekly		✓	Section 5.0, page 67
Signal-To-Noise and Contrast-To-Noise Measurements	Weekly		✓	Section 6.0, page 70
Compression Thickness Indicator	Biweekly		✓	Section 7.0, page 75
Diagnostic Review Workstation Quality Control	Weekly		✓	Section 8.0, page 76
Viewbox and Viewing Conditions	Weekly	✓		Section 9.0, page 78
Visual Checklist	Monthly	✓		Section 10.0, page 79
Repeat/Reject Analysis	Quarterly		✓	Section 11.0, page 80
Compression	Semiannually	✓		Section 12.0, page 81

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Evaluation of Image resolution & Phantom Image Quality Evaluation

Phantom used: 800004-0707011	Nuclear Associates	
Image type	Conventional	Tomosynthesis
Image detector size	18x24	18x24
Focal spot	large	Large
Anode	W	W
Filter	Rh	Al
Paddle	yes	yes
Phantom	4 cm PMMA	4 cm PMMA
kVp	28	30
mAs	120	50
Magnification	1	1
	Resolution (lp/mm)	
Resolution pattern / 45 degree to anode	10	5
Resolution pattern \ 45 degree to anode	11	6

- Conventional:
  - 7 cycle/mm
- Tomosynthesis:
  - 3 cycle/mm

10. Phantom Image Quality Evaluation — Phantom Common 800004-0707011

Phantom image scores: Fibers 5.0 Specks 4.0 Masses 5.0
Tomosynthesis Scores: 4.0 5.0 4.3

- 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.

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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

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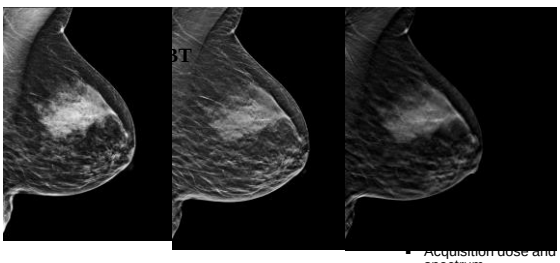
CNR Correction for 30 Projections

AEC Table 0 (Standard Tomosynthesis Dose)		
Compression Thickness (CM)	Detector Serial #: XX6XXXXX	Detector Serial #: XX8XXXXX
2	0.91	.88
4	0.90	.89
6	1.51	1.59
8	2.35	2.68

AEC Table 1 (Low Tomosynthesis Dose)		
Compression Thickness (CM)	Detector Serial #: XX6XXXXX	Detector Serial #: XX8XXXXX
2	1.26	1.25
4	1.05	1.05
6	1.59	1.67
8	2.59	2.93

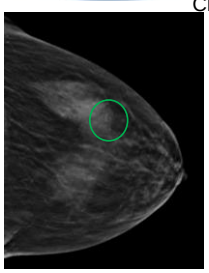
AEC Table 3 (Advanced Tomosynthesis Dose)		
Compression Thickness	Detector Serial #:	Detector Serial #:
(CM)	XX6XXXXX	XX8XXXXX
2	0.80	0.76
4	0.91	0.89
6	1.48	1.56
8	2.48	2.89

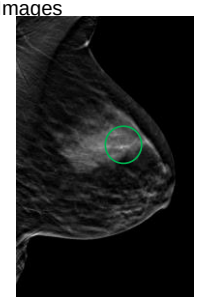


- Acquisition dose and spectrum

Gur et al. (2012). Acad. Radiol. 19(2):166

Clinical Images





GE SenoclaireEssential Features

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

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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

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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

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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

Chart 3. CNR and MTF Measurement with MTD Test Record

Year							
Date							
Initials							
MTF + CNR Measurements			IQST Device Reference No:				
	Result	Pass /Fail	Result	Pass /Fail	Result	Pass /Fail	Resu
MTF parallel at 2 lp/mm							
MTF parallel at 4 lp/mm							
MTF perpendicular at 2 lp/mm							
MTF perpendicular at 4 lp/mm							
Contrast-to-Noise Ratio (CNR)		NA		NA		NA	
Change in CNR							

SenoClaire QC Tests From the Technologist's Section of the Breast Tomosynthesis QC Manual

TS2. CNR & MTF with MTD IQST Reference Number: 2222686-3 S/N

Test	Physicist's Result	Previous Physics Result	Lower Level of Acceptance	Upp Lev Acc
MTF Parallel at 2 lp/mm	65.89		49.00	
MTF Parallel at 4 lp/mm	31.44		18.00	
MTF Perpendicular at 2 lp/mm	65.58		49.00	
MTF Perpendicular at 4 lp/mm	28.65		18.00	
Contrast-to-Noise Ratio (CNR)	32.31		N/A	
Operating Level	35.07		N/A	
Change in CNR	0.09		N/A	

Configuration: 30 kVp; 56 mAs; Rh/Rh; contact; with bucky; IQST & no

Result: Pass

TS3. 3D Flat Field Test of MTD Is Flat Field Phantom (25 mm acrylic) free of imperfections?

Test	Physicist's Result	Previous Physics Result	Lower Level of Acceptance	Upp Lev Acc
Brightness Non-Uniformity	5.83		N/A	
High Frequency Modulation	1.2000		N/A	
SNR Non-uniformity	31.69		N/A	

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4. AOP 2D and SNR Check with MTD

Results

Acrylic Thickness (mm)	Exposure Parameters AOP, STD Mode			SNR	Pass/Fail
	Track/filter	mAs	kV		
2S	Mo/Mo	32.1	26	121.84	**PASS**
50	Rh/Rh	53.4	29	107.18	**PASS**
60	Rh/Rh	62.4	30	98.74	**PASS**

Requirement:

Acrylic Thickness (mm)	Exposure Parameters AOP, STD Mode			SNR
	Track/filter	mAs	kV	
2S	Mo/Mo	20 - 60	26	> 50
50	Rh/Rh	40 - 90	29	> 50
60	Rh/Rh	45 - 95	30 or 31	> 50

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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5. AOP 3D Check

Results

Acrylic Thickness (mm)	Exposure Parameters AOP 3D Mode			Pass/Fail
	Track/filter	mAs	kV	
2S	Mo/Mo	27	26	**PASS**
50	Rh/Rh	54	29	**PASS**
60	Rh/Rh	63	31	**PASS**

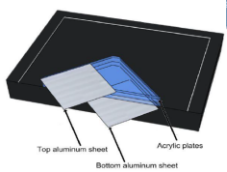
Requirement:

Acrylic Thickness (mm)	Exposure Parameters AOP 3D Mode		
	Track/filter	mAs	kV
2S	Mo/Mo or Mo/Rh	20 - 70	26
50	Rh/Rh	40 - 90	29
60	Rh/Rh	50 - 120	30 or 31

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.

Volume Coverage

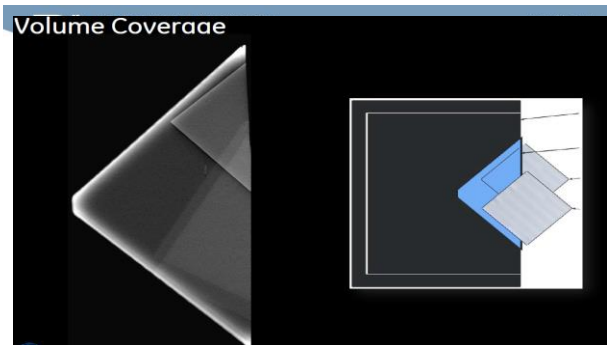
Objective
Ensure that the entire imaged object is reconstructed on the Z-axis (perpendicular to the detector)



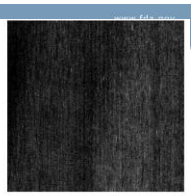
Equipment required
Set of acrylic plates; 2 1-mm Al sheets

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 for 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 dispayed test results

Action Limit
The texture level must not exceed 0.002

Grid Texture of MTD

Unit will be set up for a 2D acquisition with the MTD installed.
Ten exposures will be made, starting at 26 kVp, Mo/Mo, 5 mAs 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 first attempt fails, take off the MTD, then remount the MTD and repeat the test. If the grid texture test fails a second time, then service must take corrective action.

20. Compression Paddle to MTD Chest Wall Alignment

Source to Image Receptor Distance(SID) 66

Comp. Paddle	Target/Filter	Wd	Wd	Pd	Z'd	Zd	Pass/Fail
24X31	Mo/Mo	Mo/Mo	2.1	1.80	0.3	0.32	Pass
24X31	Rh/Rh	Rh/Rh	2.1	1.80	0.3	0.32	Pass
Elevated 24X31	Mo/Mo	Rh/Rh	2.1	1.80	0.3	0.32	Pass
Elevated 24X31	Rh/Rh	Mo/Mo	2.1	1.80	0.3	0.32	Pass
19x23	Mo/Mo	Rh/Rh	2.1	1.90	0.2	0.21	Pass
19x23	Rh/Rh	Rh/Rh	2.1	1.90	0.2	0.21	Pass

Action Limit: Zd<0.66 mm

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 el 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

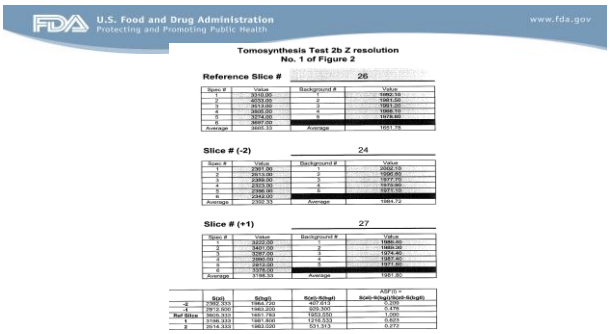
Slice # (-1) 25

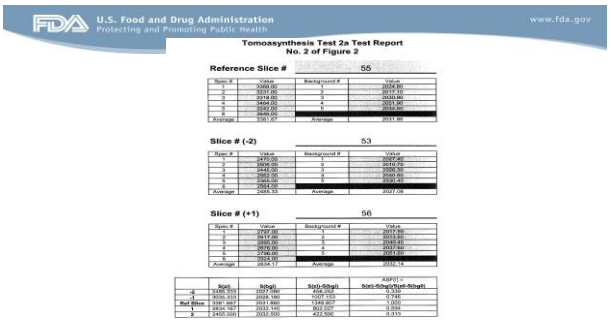
Spec #	Value	Background #	Value
1	3122.00	1	1991.90
2	2842.00	2	1985.40
3	2701.00	3	1975.60
4	2924.00	4	1967.30
5	2795.00	5	1985.80
6	3091.00		
Average	2912.50	Average	1983.20

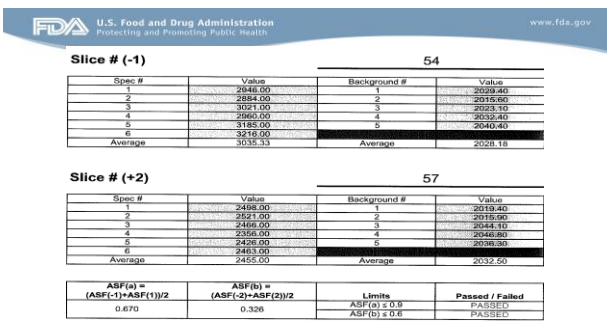
Slice # (+2) 28

Spec #	Value	Background #	Value
1	2568.00	1	1996.60
2	2491.00	2	1981.60
3	2555.00	3	1984.50
4	2490.00	4	1986.40
5	2399.00	5	1966.00
6	2574.00		
Average	2514.33	Average	1983.02

ASF(a) = (ASF(-1)+ASF(1))/2	ASF(b) = (ASF(-2)+ASF(2))/2	Limits	Passed / Failed
0.549	0.240	ASF(a) ≤ 0.9	PASSED
		ASF(b) ≤ 0.6	PASSED







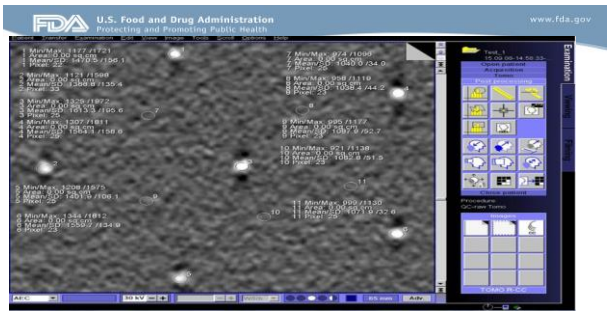
Slice # (-1) 54

Spec #	Value	Background #	Value
1	2846.00	1	2029.40
2	2884.00	2	2015.60
3	3021.00	3	2023.10
4	2960.00	4	2032.40
5	3185.00	5	2040.40
6	3216.00		
Average	3035.33	Average	2028.18

Slice # (+2) 57

Spec #	Value	Background #	Value
1	2498.00	1	2019.40
2	2521.00	2	2015.60
3	2468.00	3	2044.10
4	2356.00	4	2046.80
5	2426.00	5	2036.30
6	2463.00		
Average	2455.00	Average	2032.50

ASF(a) = (ASF(-1)+ASF(1))/2	ASF(b) = (ASF(-2)+ASF(2))/2	Limits	Passed / Failed
0.670	0.326	ASF(a) ≤ 0.8	PASSED
		ASF(b) ≤ 0.6	PASSED



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Review Workstation Soft Copy QC must be performed

Information about the RWS must be provided

Luminescence, ambient light level must be provided

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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

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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

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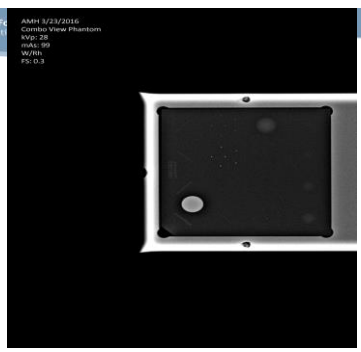

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SenoClaire DBT ACR Phantom e-Print Submission to FDA
Customer Help Guide

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 90^0 to the left

Select the individual plane displaying the highest IQ/most masses, specs and fibers. This is normally at phantom thickness 38mm + or – 1/2mm. Plane # 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

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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 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

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•Window (WW/WL) the image for the best visualization of the content in this 2 on 1 format
•Using the Move tool

with the Left mouse 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
•Go to the Start Menu
on the Windows (not on 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)
•Move 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** the L mouse down – outline the entire viewport containing the ACR phantom image
•This snipping tool will not work with 1 on 1 format as it is too much data

•Release the L mouse when the area is outlined – the snipped image will appear

•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. **e-ACR Phantom**
•Make sure the Save as type is **PNG**
•Submit this properly acquired/windowed image electronically to the FDA by attaching it to the e-Application or via email at: :
•mqsahotline@hcmsllc.com

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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 90^{o} to the left to display best for counting

6.View the individual plane displaying the highest IQ/most masses, specs and fibers. This is normally at phantom thickness 38mm + or – 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.

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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.

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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

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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