Acceptance Testing of a Digital Breast Tomosynthesis Unit

2012 AAPM Spring Clinical Meeting
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Objectives

- Review of technology and clinical advantages
- Acceptance Testing Procedures
- QC Testing Procedures
- Accreditation Process

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Selenia Dimensions

- 2D Digital Mammography System
- 3D Digital Breast Tomosynthesis
  - Received FDA Approval in February of 2011
  - For existing 2D system, a software upgrade is required to activate DBT
  - DBT is considered a new mammographic modality separate from Full Field Digital Mammography

Image from the Dimensions QC Manual

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Unit design

- Allows both 3D and 2D images to be acquired under the same breast compression
- Improved selenium detector, 70 µm pixel size
- High Transmission Cellular (HTC) anti-scatter grid in 2D
- Tungsten target x-ray tube
- Filter options
  - Rh and Ag (2D)
  - Al (3D)

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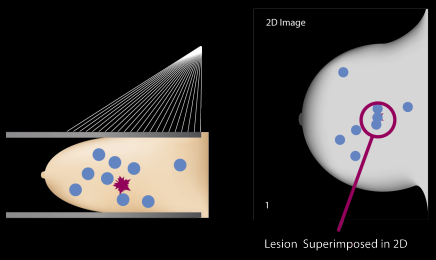
2D Breast Imaging

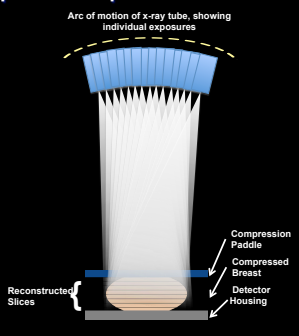
- Single projection results in tissue superimposition that is created by the overlap of normal breast structures



Slide courtesy of Hologic

3D Principle of Operation

- X-ray tube moves in an arc across the breast
- A series of low dose images are acquired from different angles
- Total dose approximately the same as one 2D mammogram
- Projection images are reconstructed into 1 mm slices



Slide courtesy of Hologic

1. The x-ray tube contains a tungsten target and the following material is the filter used in 3D imaging:

6%	1. tungsten
13%	2. silver
81%	3. aluminum
0%	4. rhodium
0%	5. molybdenum

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Correct Answer

1. tungsten – not in unit
2. silver – 2D only
3. aluminum
4. rhodium – 2D only
5. Molybdenum – not in unit

Reference: Ren, B., Ruth, C., Wu, T., Zhang, Y., Smith, A., Niklason, L, "A new generation FFDM/tomosynthesis fusion system with selenium detector", Proc. SPIE 7622, 76220B (2010).

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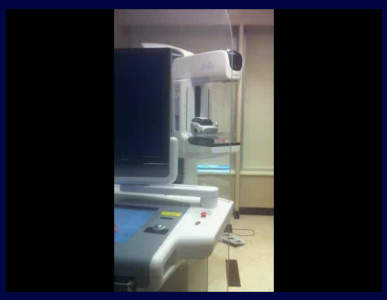

*video of combo exam of ACR Phantom

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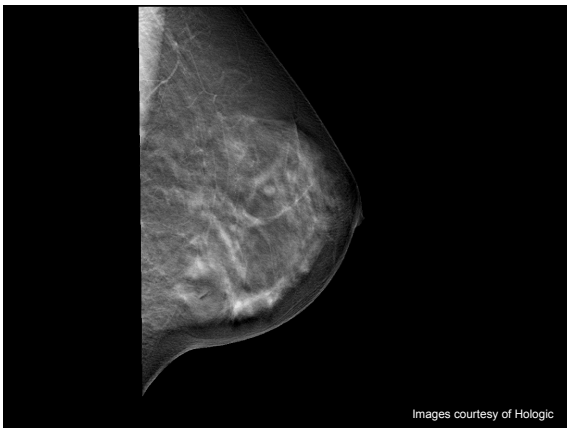
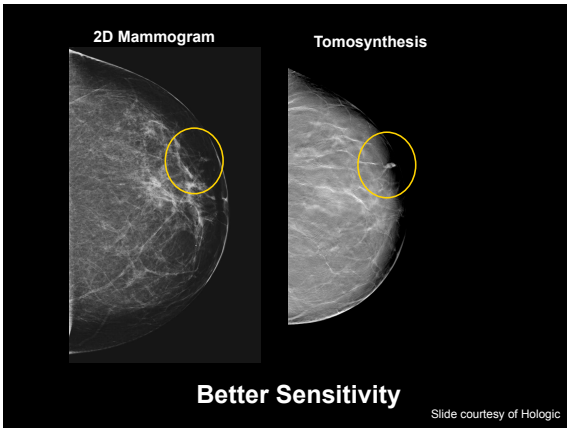
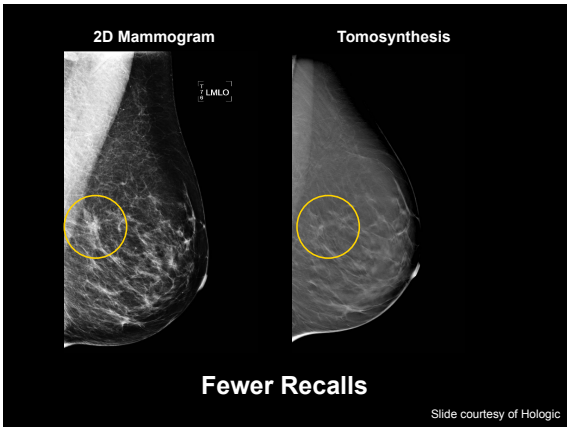

Images courtesy of Hologic


2D Mammogram
Tomosynthesis
Better Sensitivity
Slide courtesy of Hologic


2D Mammogram
Tomosynthesis
LMLO
Fewer Recalls
Slide courtesy of Hologic

Advantages

- Imaging dense breast tissue
- May decrease recall rate
- Addresses issue of tissue overlap
- Dose within existing limits for 2D mammography

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Personnel Requirements

- Required Training for a medical physicist:
  - Digital Mammography: MQSA Personnel requirements including 8 hours of training in surveying units of digital mammography
  - Digital Breast Tomosynthesis: Must receive at least 8 hours of training in digital breast tomosynthesis modality

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Responsibilities

- Unit must be evaluated by a medical physicist before clinical use commences after the equipment is first installed, moved, or significantly modified
- The medical physicist must review the results of the technologist's QC tests at least annually.
- The results of the overall Quality Assurance and Quality Control program must be reviewed by the medical physicist with the responsible interpreting physician at least annually.

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Acceptance Testing

- Required in the following situations:
  - New unit
  - Upgrade of 2D to include DBT
  - After major component upgrades including software, detector, tube, etc.
    - Release notes will indicate what tests must be performed after manufacturer upgrades

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Quality Control Manual

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Quality Control Tests to be Performed by the Medical Physicist Upon Installation – Table 1-1 QC Manual

*Mammographic Unit Assembly Evaluation	Collimation Assessment
Artifact Evaluation	*kVp Accuracy and Reproducibility
*Beam Quality Assessment – HVL	Evaluation of System Resolution
AEC Function Performance	Breast Entrance Exposure, AEC Reproducibility and AGD
Radiation Output Rate	Phantom Image Quality Evaluation
Signal to Noise and Contrast to Noise	Diagnostic Review Workstation Quality Control
DICOM Printer Quality Control	Detector Flat Field Calibration
Geometry Calibration for Tomosynthesis Option	Compression Thickness Indicator
*Compression	

***Described in the 1999 ACR Mammography QC Manual**

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Action Categories

Category A: If any of the following quality control tests that evaluate the performance of the *image acquisition components* of the Selenia Dimensions system produces results that fall outside the action limits as specified by the manufacturer, the source of the problem must be identified and corrective action must be taken before any further examinations are performed.

Category B: If any of the following quality control tests that evaluate the performance of a *diagnostic device used for mammographic image interpretation* (i.e. DICOM printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem must be identified and corrective action must be taken before that device can be used for mammographic image interpretation. Clinical imaging can be continued and alternative approved diagnostic devices must be used for mammographic image interpretation.

Category C: If any of the following quality control tests that evaluate the performance of *components other than the digital image receptor or the diagnostic devices used for mammographic image interpretation* produces results that fall outside the action limits as specified by the manufacturer, the source of the problem must be identified and corrective action must be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation can be continued during this period.

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Technologist QC to be performed by the medical physicist at acceptance

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Detector Flat Field Calibration

- Pre-programmed set of exposures of the flat-field acrylic phantom without a compression paddle
- Review preview images for foreign objects, gross artifacts, or other non-uniformities or collimation interference
- Performed weekly by technologist
- Category A

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Geometry Calibration for Tomosynthesis

- Image the provided geometry phantom as specified
- Evaluated automatically by software in the system
- Performed by technologist semi-annually
- Category A

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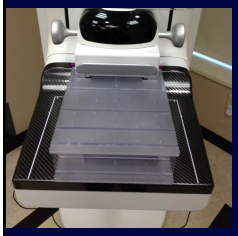
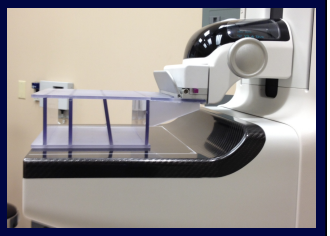
Geometry Calibration for Tomosynthesis





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Compression Thickness Indicator

- Compress the 7.5 cm spot contact compression paddle onto the ACR phantom using full automatic compression of approximately 30 pounds
- Record the thickness indicated
- Performed by the technologist bi-weekly
- Category C

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DICOM Printer QC

- A SMPTE pattern is printed from the imaging system and optical densities are measured.
- Mid density (40%), lower density (90%), and density difference (10%-40%)
- Limit: +/-0.15
- Performed by the technologist weekly
- Category B

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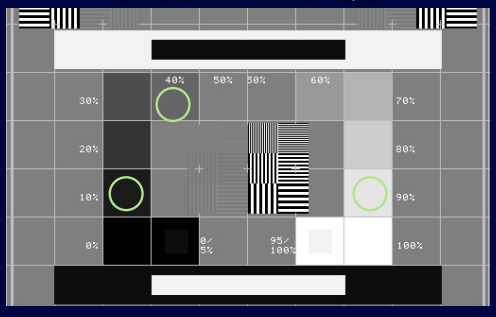
DICOM Printer QC



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Medical Physicist QC Tests

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Collimation

- Measure the deviation between x-ray field and edges of the image receptor: 24x29, 18x24 (L), 18x24 (C), 18x24 (R), and 18x29 cm tomo
- Measure distance with digital ruler
- X-ray field must not extend by more than 2% SID on any side of the detector
- Category C

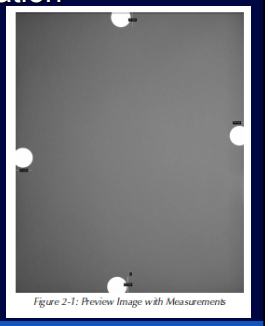

Figure 2-1: Preview Image with Measurements

Image from the Dimensions QC Manual

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Collimation

- Measure the deviation between x-ray field and light field: 24x29 cm paddle
- Use ready pack, GafChromic film, or other test tool to visualize x-ray field
- The total misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface must not exceed 2% of the SID
- Category C

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Collimation

- Measure the deviation between compression paddle and edges of the image receptor: 24x29, 18x24 cm, and small breast (if available)
- The anterior edge of the compression paddle must be aligned just beyond the chest wall edge of the image receptor so that it does not appear in the mammogram. The anterior edge must not extend beyond the chest wall edge of the image receptor by more than 1% of the SID.
- Category C

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Beam Quality Assessment

- Follow the ACR manual
- Protect the detector with lead
- To measure in 3D mode, use zero degree tomo mode
- Only minimum HVL limits apply
- Category C

Target material	W	W	W
Filter	Rh	Ag	Al*
Paddle in place	Yes	Yes	Yes

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Artifact Evaluation

- Image the flat field phantom (4 cm thick acrylic block – manufacturer provided)
  - No compression paddle
  - All filters in each imaging mode (conventional, tomo, magnification)
  - Rotate phantom 180* between exposures
  - View full resolution images for artifacts
  - Print flat field pattern as 2560x3328 for 8x10" film and 3328x4096 for 24x30 cm film, both as True Size Printing
  - Category C

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Image courtesy of Hologic

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Artifact Examples

- Dead pixels
  - cluster of 16 or more
  - complete or partial row or column

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System Resolution

- Uses system limiting spatial resolution as performance indicator
- 18x24 cm compression paddle
- High contrast resolution pattern that can test up to 15 lp/mm with 1 lp/mm steps from 3-15 lp/mm
- Pattern is placed on flat field phantom approximately 1 cm from chest wall edge, with pattern angled 45* to the anode-cathode axis

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Image courtesy of Hologic

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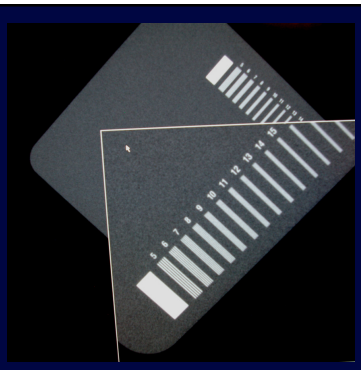

Image courtesy of Hologic

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System Resolution

- In 2D, limiting resolution must be greater than 7 lp/mm
- In 3D, must be greater than 3 lp/mm
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3. When the test pattern is approximately 45º to the anode-cathode axis and when imaging in tomosynthesis mode, the system limiting spatial resolution must be greater than:

82%	1. 3 lp/mm
0%	2. 5 lp/mm
18%	3. 7 lp/mm
0%	4. 9 lp/mm
0%	5. 11 lp/mm

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Correct Answer

1. 3 lp/mm
2. 5 lp/mm
3. 7 lp/mm – minimum in 2D mode
4. 9 lp/mm
5. 11 lp/mm

Reference: Hologic: Quality Control Manual Selenia Dimensions 2D FFDM Selenia Dimensions DBT, 2011 (Part Number MAN-01965 Revision 002) p. 35

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AEC Function Performance

- Record exposure index (and exposure parameters) for phantom thicknesses (BR-12 or acrylic) in various AEC modes used clinically in conventional, tomo, and magnification modes.
- Subtract DC offset (50)
- Apply CNR correction factor to convert to corrected pixel value
- The application of correction factors allows comparison of various thicknesses.

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7a. Automatic Exposure Control (AEC) Function Performance

AEC Position:	2
Exposure Compensation Step:	0

AEC Function Performance at Different Phantom Thickness

Contact Imaging, LFS with Grid							
Phantom Thickness	AEC Mode	Filter	kVp	mAs	Exposure Index	CNR Correction Factor	Corrected Pixel Value*
2 cm	Auto Filter	Rh	25	51	388	1	338.00
4 cm	Auto Filter	Rh	28	93	383	1	333.00
6 cm	Auto Filter	Rh	30	214	475	1.3	326.92
8 cm	Auto Filter	Ag	31	344	621	1.7	335.88
Magnification Imaging, SFS without Grid							
4 cm	Auto kV	Rh	29	71	445	1.15	343.48

Mean Pixel Value	Pixel Value Range			Allowed Pixel Value			
335.48	326.92	to	343.48	301.91	to	369.00	

*Pixel Value = (ROI mean - DC offset**) / CNR Correction Factor
**DC offset = 50

Pass

ACTION LIMIT: If the corrected pixel value of each individual image corresponding to a breast thickness between 2 and 8 cm at any operating mode varies more than 10% of the mean pixel value computed for all tested breast thicknesses and operating modes, seek service.

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7b. Automatic Exposure Control (AEC) Function Performance (Tomosynthesis Option)

AEC Position:	2
Exposure Compensation Step:	0

AEC Function Performance at Different Phantom Thickness

Contact Imaging, LFS with Grid							
Phantom Thickness	AEC Mode	Filter	kVp	mAs	Exposure Index	CNR Correction Factor	Corrected Pixel Value*
2 cm	Auto kV	Al	26	42	236	0.7	265.71
4 cm	Auto kV	Al	29	60	290	0.91	263.74
6 cm	Auto kV	Al	33	79	439	1.46	266.44
8 cm	Auto kV	Al	36	114	613	2.37	237.55

Mean Pixel Value	Pixel Value Range			Allowed Pixel Value			
258.36	237.55	to	266.44	232.52	to	284.20	

*Pixel Value = (ROI mean - DC offset**) / CNR Correction Factor
**DC offset = 50

Pass

ACTION LIMIT: If the corrected pixel value of each individual image corresponding to a breast thickness between 2 and 8 cm at any operating mode varies more than 10% of the mean pixel value computed for all tested breast thicknesses and operating modes, seek service.

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AEC Function Performance

- The system is trying to maintain a constant pixel value independent of AEC mode, operating mode, breast thickness, or technique
- The pixel value of each image at any operating mode must not vary by more than 10% of the mean pixel value.
- Category C

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AEC Performance at different compensation steps

- Image 4 cm of phantom at the range of compensation steps. Each step is designed to result in an additional 15% change in dose to the ACR phantom.
- Compensation steps are not used in 3D
- Calculate ratios by dividing pixel value at a given step by the mean pixel value at step zero. Allowed ratio at each step.
- Category C

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Exposure Compensation AEC Performance

Mean Pixel Value at Step 0: 332.00

Contact Imaging, LFS with Grid

Phantom Thickness	AEC Mode	Exp Comp	Pixel Value*	Ratio**	Allowed Ratio**		
4 cm	Auto-Filter	-3	195	0.59	0.56	to	0.66
4 cm	Auto-Filter	-2	237	0.71	0.66	to	0.78
4 cm	Auto-Filter	-1	283	0.85	0.78	to	0.92
4 cm	Auto-Filter	0	334	1.01			
4 cm	Auto-Filter	0	329	0.99			
4 cm	Auto-Filter	0	333	1.00			
4 cm	Auto-Filter	1	383	1.15	1.06	to	1.24
4 cm	Auto-Filter	2	450	1.36	1.22	to	1.43
4 cm	Auto-Filter	3	518	1.56	1.4	to	1.64
4 cm	Auto-Filter	4	606	1.83	1.61	to	1.89

*Pixel Value = Exposure Index - DC offset (50)
**Pixel value at given step divided by mean pixel value at step 0

ACTION LIMIT: If the pixel value at each exposure compensation step results in a ratio outside the allowed range, seek service

Pass

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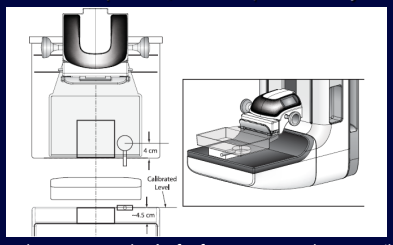
Breast Entrance Exposure, AEC Reproducibility and AGD



- Record exposure and mAs for four exposures in conventional and tomo. If COV of either exceeds 0.05, seek service.
- Category C

Image from the Dimensions QC Manual

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Breast Entrance Exposure, AEC Reproducibility and AGD

- Combine AGD for both conventional and tomosynthesis exposures for a total average glandular dose.
- If AGD exceeds 300 mrad for 4.2 cm effective breast thickness, seek service or technique adjustment.
- Category A

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Radiation Output Rate

- Exposure at maximum mAs setting and 28 kVp (W/Rh)
- Dose Rate (mGy/sec) = Exposure Rate (mR/s) x 0.00873 mGy/mR
- Seek service if output rate is less than 2 mGy/s (230 mR/sec)
- Category C

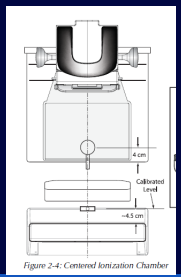

Figure 2-4: Centered Ionization Chamber

Image from the Dimensions QC Manual

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2. The total mean glandular dose to the ACR Mammographic Accreditation phantom must not exceed ___ mGy per view when combining the conventional and the tomosynthesis exposures at the recommended techniques for imaging an average breast:

6%	1. 2 mGy
89%	2. 3 mGy
6%	3. 4 mGy
0%	4. 5 mGy
0%	5. 6 mGy

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Correct Answer

1. 2 mGy
2. 3 mGy
3. 4 mGy
4. 5 mGy
5. 6 mgy

Reference: Hologic: Quality Control Manual Selenia Dimensions 2D FFDM Selenia Dimensions DBT, 2011 (Part Number MAN-01965 Revision 002) p. 35

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Phantom Image Quality Evaluation

- Image the ACR phantom in both conventional and tomo mode
- The largest 5 fibers, 4 spec groups and 4 masses must be visible or 4.5/4/3.5 is acceptable if SNR and high contrast resolution of the system are passing
- Performed by the technologist weekly
- Category A

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Signal-To-Noise and Contrast-To-Noise Measurements

- Conventional phantom image
- Automatic ROI creation available

$$SNR = \frac{mean_{background} - DC_{offset}}{std_{background}}$$

$$CNR = \frac{mean_{background} - mean_{disk}}{std_{background}}$$

$$Diff = \frac{CNR_{measured} - CNR_{base}}{CNR_{base}} \times 100$$

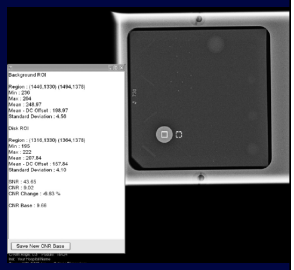

Image and equations from the Dimensions QC Manual

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Signal-To-Noise and Contrast-To-Noise Measurements

- SNR should be equal to at least 40 and the CNR should not change by more than +/- 15% of the baseline value
- Category A

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6. Failure of the phantom image quality evaluation is considered an action category

100%	1. A
0%	2. B
0%	3. C
0%	4. D
0%	5. E

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Correct Answer

1. A
2. B
3. C
4. D
5. E

Reference: Hologic: Quality Control Manual Selenia Dimensions 2D FFDM Selenia Dimensions DBT, 2011 (Part Number MAN-01965 Revision 002) p. 35

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4. Phantom image quality evaluation should be performed with the tomosynthesis acquisition by a technologist at least:

0%	1. yearly
12%	2. semi-annually
6%	3. monthly
82%	4. weekly
0%	5. daily

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Correct Answer

1. yearly
2. semi-annually
3. monthly
4. weekly
5. daily

Reference: Hologic: Quality Control Manual Selenia Dimensions 2D FFDM Selenia Dimensions DBT, 2011 (Part Number MAN-01965 Revision 002) p. 35

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Diagnostic Review Workstation Quality Control

- Suggested equipment – photometer supplied by the manufacturer with each diagnostic review workstation
- Measure the white level and the DICOM GSDF compliance for LCD monitors; also display black level and white level uniformity performance for each CRT display
- Pass/fail criteria varies by monitor type and model
- Category B

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Accreditation

- The 2D portion of the unit is accredited using standard FFDM procedures
  - ACR, SAR, SIA, and STX
- The DBT portion of the unit must apply to and be approved by the FDA for extension of their certificates to include the use of a DBT unit
  - MQSA Facility Certification Extension Requirements for Hologic Digital Breast Tomosynthesis

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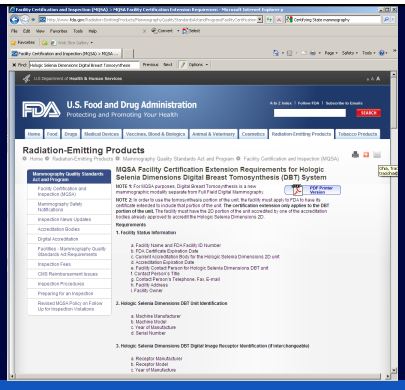

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5. The only approved accreditation body for the digital breast tomosynthesis portion of the Hologic Dimensions unit at this time is:

6% 1. The American College of Radiology
0% 2. The State of Texas
0% 3. The State of Iowa
0% 4. The State of Arkansas
94% 5. The US Food and Drug Administration

Correct Answer

1. The American College of Radiology
2. The State of Texas
3. The State of Iowa
4. The State of Arkansas
5. The US Food and Drug Administration

Reference: US FDA website: http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/