Role of the Medical Physicist
in
Clinical Implementation of Breast Tomosynthesis

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Digital Breast Tomosynthesis

was approved by FDA, finally !!!

On February 11, 2011, FDA approved Hologic to market Selenia Dimensions Digital Breast Tomosynthesis (DBT) system.

Tasks for DBT Implementation

Task	Performer
✓ Train staff for DBT	Hologic or 3rd party
✓ Evaluate shielding requirement	MP
✓ Install the DBT system	Hologic
✓ Perform Mammography Equipment Evaluation (MEE)	MP
✓ Obtain the certificate to operate	Clinical Manager

Staff Qualification for DBT

FDA considers the DBT as a new modality

- ✓ Each MP, tech, or radiologist must be qualified for FFDM
- ✓ Each MP, tech, or radiologist must have additional 8 hours training in DBT

  Hologic installation engineer can provide 5 hours hands-on training to MP. Additional 3 hours training can be acquired online from Hologic.

Facility Certification for DBT

- ✓ 2D portion of the system must be accredited by an approved accreditation body
- ✓ There is no approved accreditation body for DBT
- ✓ Apply to FDA for DBT certification extension

Shielding Requirement for DBT

Factors to consider:

- ✓ Selenia Dimensions operates up to 49 kVp

	W/Rh	W/Ag	W/Al
Mean kVp (MGH)	29.7	30.9	32.1

- ✓ Workload may be different
- ✓ NCRP 147 workload, scatter data and α, β, γ may not be applicable

Get Ready for MEE

Before starting MEE

- ✓ Know tests to be performed in 2D or 3D mode
- ✓ Know performance criteria for each test
- ✓ Collect required testing tools
- ✓ Get familiar with system and user interface

Selenia Dimensions MEE Tests

Quality Control Tests To Be Performed by the Medical Physicist Upon Installation (MEE)
Mammographic Unit Assembly Evaluation
Collimation Assessment
Artifact Evaluation
kVp Accuracy & Reproducibility
Beam Quality Assessment – HVL
Evaluation of System Resolution
AEC Function Performance
Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose
Radiation Output Rate
Phantom Image Quality Evaluation
Signal to Noise and Contrast to Noise
Diagnostic Review Workstation Quality Control
DICOM Printer Quality Control (Radiologic Technologist section)
Detector Flat Field Calibration (Radiologic Technologist section)
Geometry Calibration for Tomosynthesis Option (Radiologic Technologist section)
Compression Thickness Indicator (Radiologic Technologist section)
Compression (Radiologic Technologist section)

Selenia Dimensions QC Tests

There is no QC standard for all DBT systems.

Follow Equipment Vendor's QC manual

The Hologic QC manual MAN-01965 covers:
-Selenia Dimensions 2D FFDM system
-Selenia Dimensions DBT system

Selenia Dimensions QC Tests (MP)

Quality Control Test	2D	3D
Mammographic Unit Assembly Evaluation	Yes	
Collimation Assessment	Yes	Yes
Artifact Evaluation	Yes	Yes
kVp Accuracy and Reproducibility	Yes	
Beam Quality Assessment – HVL	Yes	Yes
Evaluation of System Resolution	Yes	Yes
Automatic Exposure Control (AEC) Function Performance	Yes	Yes
Entrance Exposure, AEC Reproducibility, and Dose	Yes	Yes
Radiation Output Rate	Yes	
Phantom Image Quality Evaluation	Yes	Yes
Signal-To-Noise and Contrast-To-Noise Measurements	Yes	
Diagnostic Review Workstation Quality Control	Yes	
Detector Ghosting (Troubleshooting Use Only)	Yes	

Selenia Dimensions QC Tests (MP)

Quality Control Test	Special Tools ?
Mammographic Unit Assembly Evaluation	
Collimation Assessment	Special film
Artifact Evaluation	
kVp Accuracy and Reproducibility	Special sensor
Beam Quality Assessment — HVL	More Al sheets
Evaluation of System Resolution	2-15 lp/mm
Automatic Exposure Control (AEC) Function Performance	
Entrance Exposure, AEC Reproducibility, and Dose	
Radiation Output Rate	
Phantom Image Quality Evaluation	
Signal-To-Noise and Contrast-To-Noise Measurements	
Diagnostic Review Workstation Quality Control	
Detector Ghosting (Troubleshooting Use Only)	

Selenia Dimensions: Image Acquisition Modes

1

Conventional Only

3

Combo: Tomo + Conv under the same compression

2

Tomosynthesis Only

Selenia Dimensions: Specifications

Conventional 2D Imaging

- a-Se detector, 24×29 cm area
- 70 μm pixel size
- Rh and Ag filters
- HTC grid in contact mode;
  No grid in magnification mode

Tomosynthesis 3D Imaging

- a-Se detector, 24×29 cm area
- 140 μm pixel size
- Al filter
- No anti-scatter grid
- Moving tube, 15° sweep
- Moving detector
- 15 projections
- 3-4 seconds acquisition
- Reconstruction
  - ~100 μm pixel size
  - 1 mm slice spacing

You are qualified for screen/film mammography, but not for FFDM. How many hours training do you need before you can perform acceptance test for DBT?

0%	1. 16 hours for FFDM
0%	2. 8 hours for FFDM
0%	3. 8 hours for DBT
0%	4. 8 hours for FFDM + 8 hours for DBT
0%	5. 16 hours for DBT

Answer: 4.

8 hours for FFDM + 8 hours for DBT

Explanation:

8 hours training is needed for each new modality.

Hologic Selenia Dimensions with DBT option is a 2-modality system (FFDM+DBT)

Reference: www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm

Your hospital just bought a Hologic Dimensions with DBT option. How do you get MQSA facility certificate for DBT?

0%	1.	Apply accreditation for both 2D and DBT from ACR, then apply to FDA for the certificate
0%	2.	Apply to FDA for the certificate for both 2D and DBT directly , bypass accreditation body
0%	3.	Apply for accreditation for 2D from ACR or other accreditation body, then apply to FDA for certification extension for DBT
0%	4.	Apply accreditation for DBT from State of Texas, then apply for the certificate from FDA
0%	5.	Apply accreditation for DBT from State of Iowa, then apply for the certificate from FDA

10

Answer: 3

Apply for accreditation for 2D from ACR or other accreditation body, then apply for certification extension for DBT from FDA

Explanation:

Normal FFDM accreditation process should be followed for 2D portion.

No accreditation body for DBT at the moment. Apply for certification extension for DBT directly from FDA

Reference: www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm

Available target/filter combinations and the maximum kVp for Hologic Dimensions are:

0% 1. Rh/Rh, W/Ag, W/Al, and 49 kVp

0% 2. Mo/Mo, Mo/Rh, Rh/Rh, and 35 kVp

0% 3. Rh/Rh, Rh/Ag, Rh/Al, and 39 kVp

0% 4. W/Rh, W/Ag, W/Al, and 39 kVp

0% 5. W/Rh, W/Ag, W/Al, and 49 kVp

Answer: 5.

W/Rh, W/Ag, W/Al, and 49 kVp

Explanation:

Available target/filter combo in 2D mode are W/Rh and W/Ag

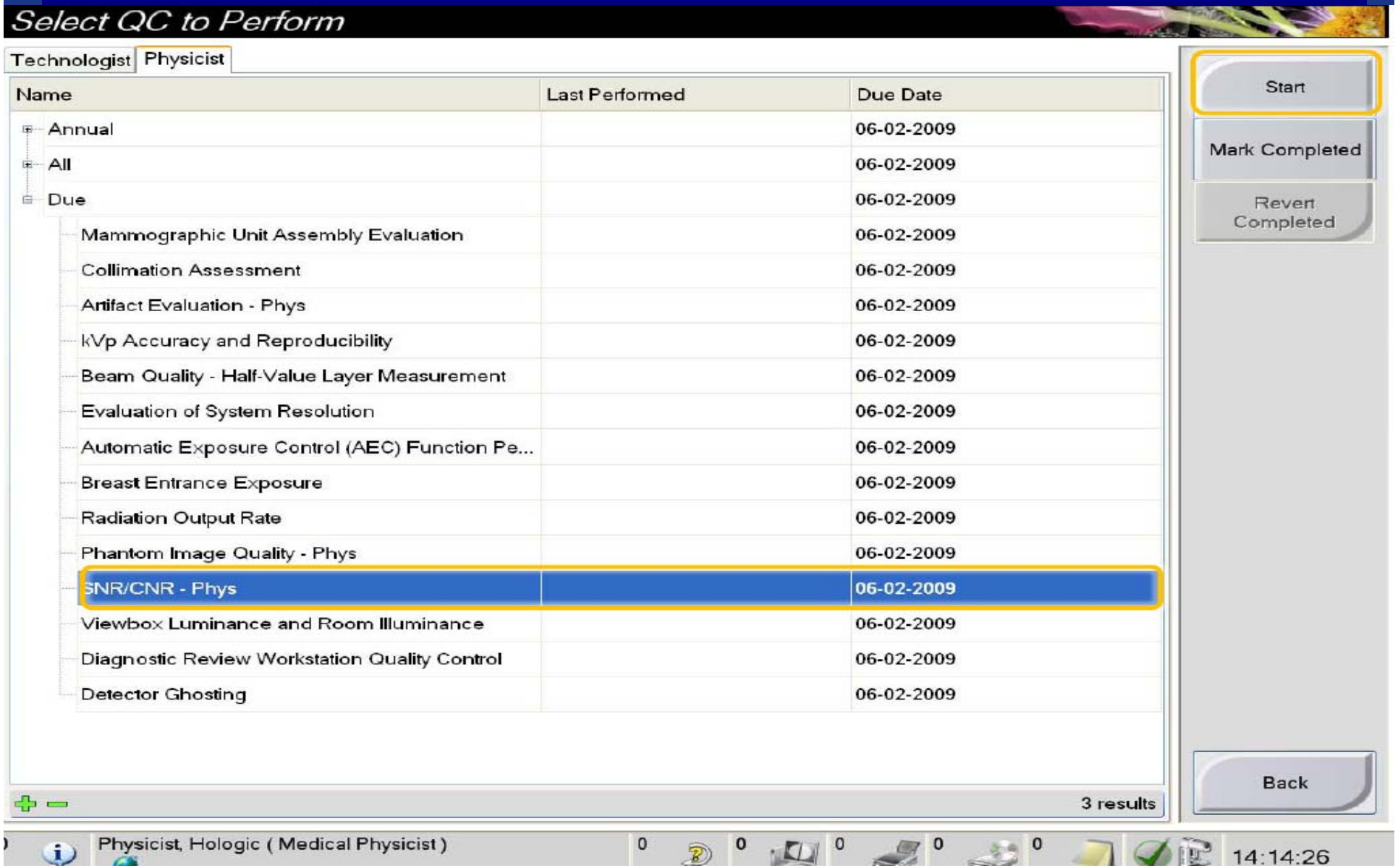
Available target/filter combo in DBT mode is W/Al

kVp range is between 20 and 49

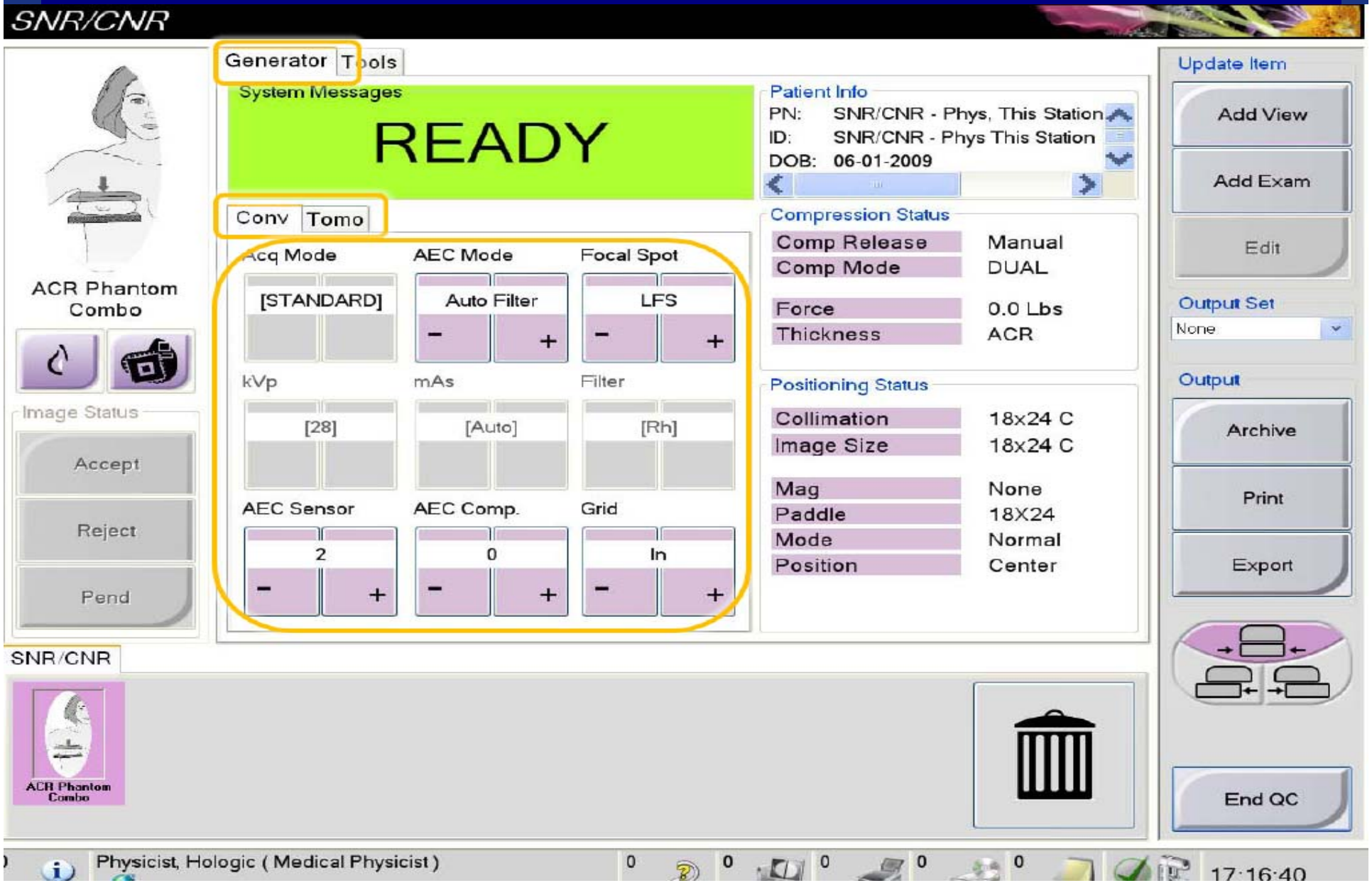
Reference:

Selenia Dimensions User Manual MAN-01964, page 81

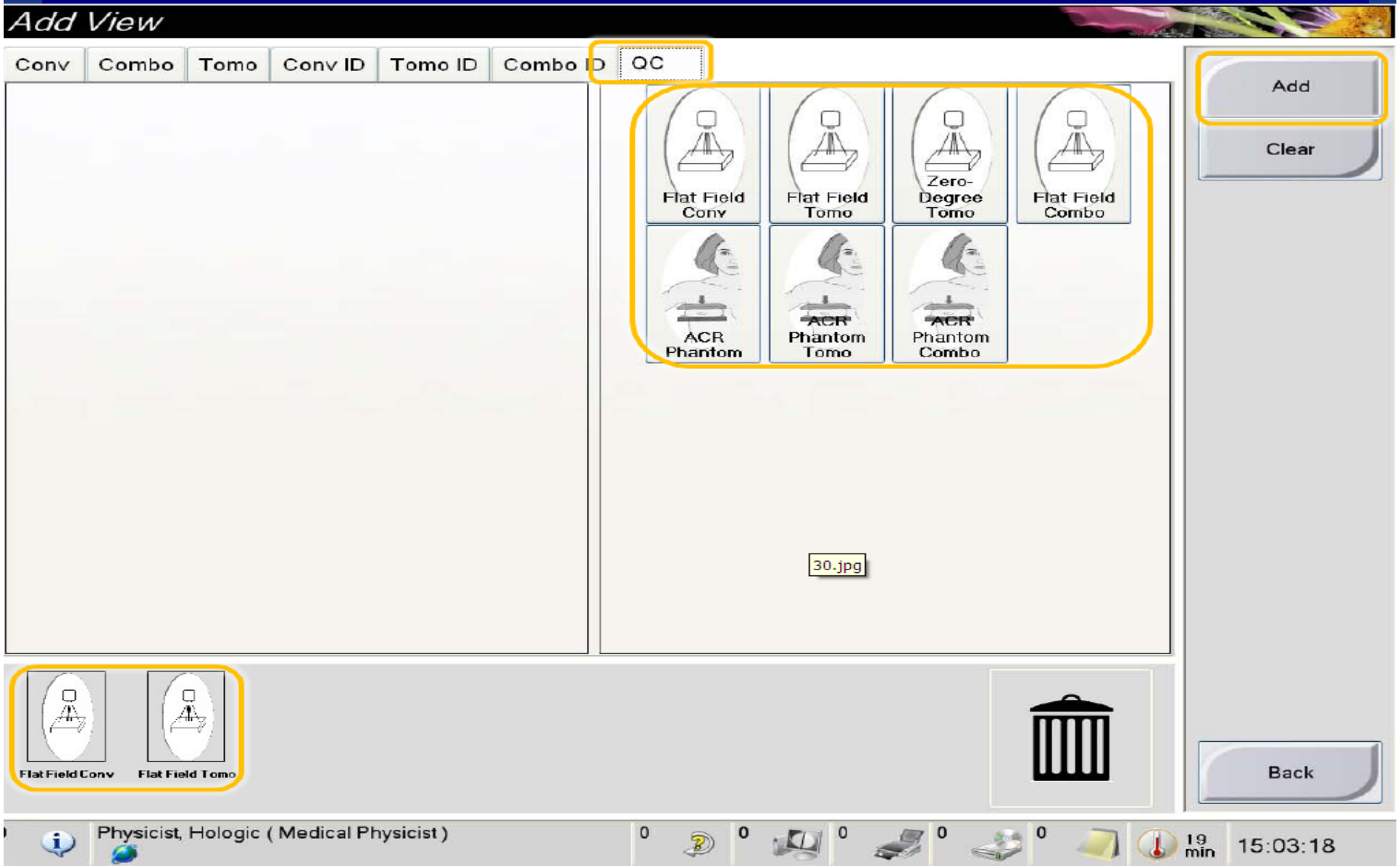
Selenia Dimensions: User Interface



Selenia Dimensions: User Interface



Selenia Dimensions: User Interface



QC Test: Artifact Evaluation

Flat field images to be acquired with 4 cm acrylic

✓2D contact mode (LFS) with Rh and Ag filters
✓2D mag mode (SFS) with Rh and Ag filters
✓3D DBT (LFS) with Al filter .

In 3D, central projection image is evaluated.
Artifacts due to reconstruction are not evaluated.

Image Review Condition:
WL = EI ; WW= 500
Full resolution

"Actual Pixel" button

QC Test: kVp Accuracy

- Target is W and kVp range is 20-49
- May need new sensor or kVp meter
- Use copper plate or lead sheet to protect detector

QC Test: HVL

- Use copper plate or lead sheet to protect the detector
- Use " Zero-Degree Tomo" in 3D mode

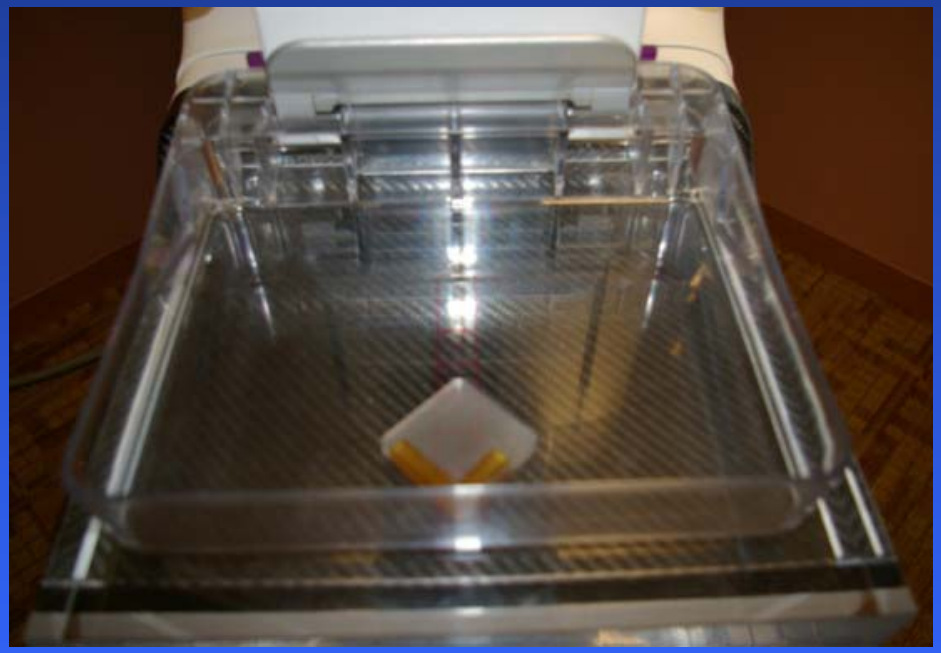
- Target and filters are unique and beam is harder More al sheets may be needed.
- Performance Criteria:

HVL > kVp/100 + 0.03 (mm Al)

QC Test: System Resolution

Image with line pair pattern

- One 2D acquisition
- One 3D acquisition



Performance Criteria:

- 2D: > 7 lp/mm at 45°
- 3D: > 3 lp/mm at 45°

You may need a new line pair phantom (2-15lp/mm)

Note: Z-resolution is not evaluated.

QC Test: AEC

AEC modes

Auto-Filter

- filter, kVp, mAs automatically determined

Auto-kV

- filter manually selected
- kVp and mAs automatically determined

Auto-Time

- filter and kVp manual selected
- mAs automatically determined

QC Test: AEC

Pay attention to:

- ✓AEC sensor position (must be at 2)
- ✓Compression thickness (must be precise)
- ✓Dose table or CNR correction table used

QC Test: AEC Performance – 2D

	Contact Imaging, LFS with Grid							
Phantom thickness	AEC Mode	Filter	kVp	mAs	Exp Comp Step	Exposure Index	CNR Factor	Pixel Value
2 cm	Auto filter	Rh	25	46	0	386	1	336
4 cm	Auto filter	Rh	28	86	0	386	1	336
6 cm	Auto filter	Rh	31	190	0	477	1.3	328
8 cm	Auto filter	Ag	32	270	0	636	1.7	345
	Magnification Imaging with 10x10 compression paddle, SFS without Grid							
4 cm	Auto kV	Rh	29	67	0	433	1.15	333
Mean Pixel Value	**Pixel Value Range**					**Allowed Pixel Value**		
336	328	to	345			302	to	369
Pass/Fail	**Pass**		**Pass**					

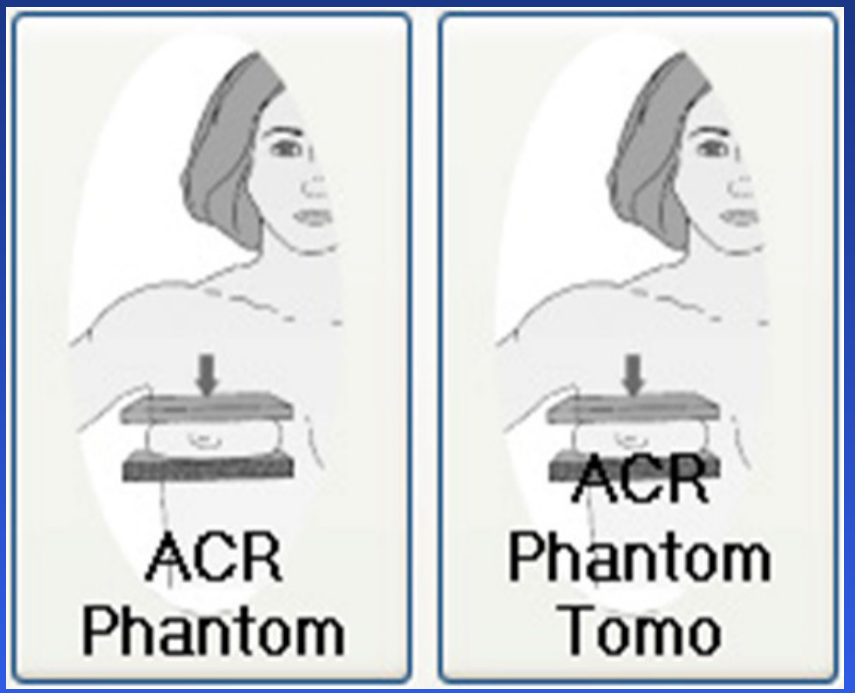
Pixel Value = (ROI mean - DC offset (50))/(CNR Correction Factor)

QC Test: AEC Performance – 3D

Contact Imaging, Tomo								
Phantom thickness	AEC Mode	Filter	kVp	mAs	Exp Comp Step	Exposure Index	CNR Factor	Pixel Value
2 cm	Auto filter	Al	26	32	0	207	0.7	224
4 cm	Auto filter	Al	29	45	0	252	0.91	222
6 cm	Auto filter	Al	33	61	0	365	1.46	216
8 cm	Auto filter	Al	38	74	0	566	2.37	218
Mean Pixel Value	**Pixel Value Range**					**Allowed Pixel Value**		
220	216	to	224			198	to	242
Pass/Fail	**Pass**		**Pass**					

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

QC Test: Dose



Performance criteria:

- AGD < 3.0 mGy (2D)
- AGD < 3.0 mGy (2D+ 3D)

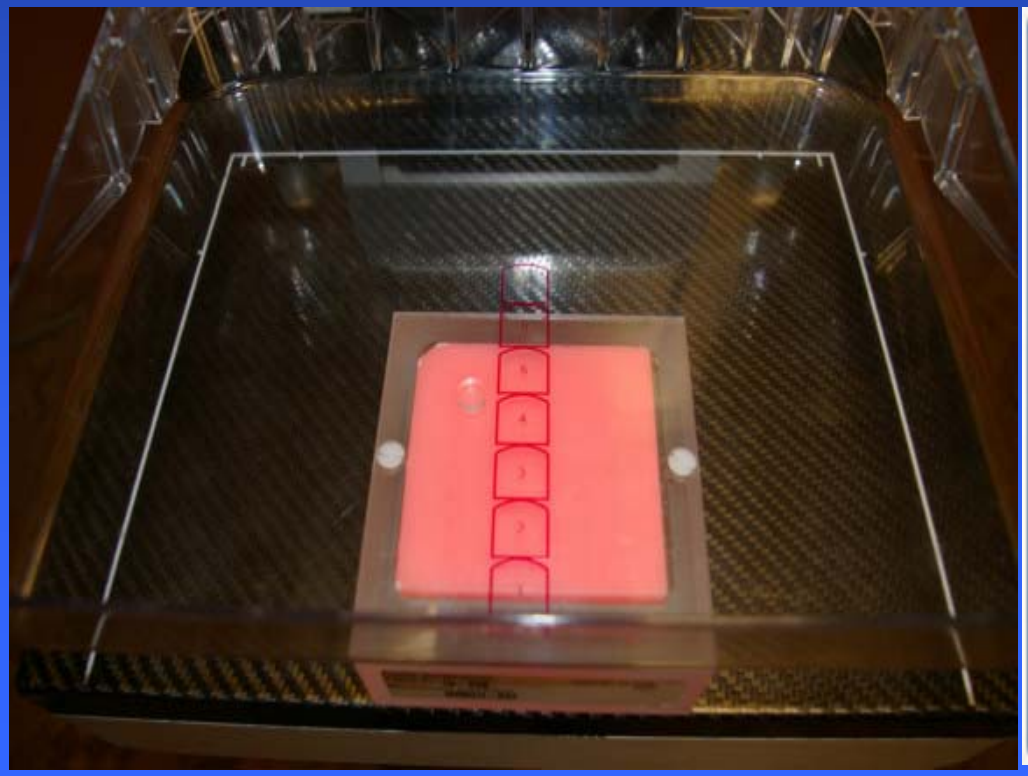
QC Test: Radiation Output

- ✓Use copper or lead sheet to protect the detector
- ✓Make exposure at 28 kVp with Rh filter, Max mAs
- ✓mA @ 28 kVp is 160
- ✓Performance criteria:

  Tube output rate >= 230 mR/s

QC Test: Phantom Image Quality

- ✓ Use "ACR Phantom View" provided by the system
- ✓ Acquire 2D and 3D phantom images using AEC



Phantom Image Quality Evaluation – 2D

"Actual Pixel" button

- Click the "Actual Pixel" button to bring the image to full resolution
- Score the phantom following 1999 ACR Mammography Quality Control Manual
- 2D Phantom Passing Score:

  - 5 fibers, 4 specs, 4 masses

  - Due to phantom variation, a score of (4.5, 4.0, 3.5) is acceptable if SNR and high contrast resolution tests pass

Phantom Image Quality Evaluation – 3D

"Actual Pixel" button

- Click the "Actual Pixel" button to bring the image to full resolution
- Scroll to the reconstruction slice in which the phantom elements are in focus
- Score the phantom following 1999 ACR Mammography Quality Control Manual
- 3D Phantom Passing Score:

  4 fibers, 3 specs, 3 masses

For Hologic Selenia Dimensions, which of following phantom scores is acceptable?

0%	1.	4 fibers, 3 speck groups and 3 masses for DBT; 5 fibers, 4 speck groups and 4 masses for 2D
0%	2.	4.5 fibers, 4 speck groups and 3.5 masses for DBT; 4.5 fibers, 4 speck groups and 3.5 masses for 2D
0%	3.	5 fibers, 4 speck groups and 4 masses for DBT; 5 fibers, 4 speck groups and 4 masses for 2D
0%	4.	4 fibers, 4 speck groups and 4 masses for DBT; 4 fibers, 4 speck groups and 4 masses for 2D
0%	5.	4 fibers, 3 speck groups and 3 masses for DBT; 4 fibers, 3 speck groups and 3 masses for 2D

Answer: 1.

4 fibers, 3 speck groups and 3 masses for DBT
5 fibers, 4 speck groups and 4 masses for 2D

Explanation:

Specified in Selenia Dimensions QC manual

Reference:

Selenia Dimensions QC Manual MAN-01965, page 40

For Hologic Dimensions, the total mean glandular dose to ACR mammographic Accreditation phantom in the combo mode (2D+DBT) must not exceed

0%	1. 6 mGy
0%	2. 3 mGy
0%	3. 4.5 mGy
0%	4. 2.5 mGy
0%	5. 3.5 mGy

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Answer: 2

3 mGy

Explanation:

Specified in Selenia Dimensions QC manual

Reference:

Selenia Dimensions QC Manual MAN-01965, page 34

For Hologic Selenia Dimensions, the HVL must satisfy

0%
1. HVL < kVp/100 + 0.30 mm Al

0%
2. HVL > kVp/100 + 0.03 mm Al

0%
3. kVp/100 + 0.03 mm Al < HVL < kVp/100 + 0.30 mm Al

0%
4. kVp/100 + 0.03 mm Al < HVL < kVp/100 + 0.22 mm Al

0%
5. kVp/100 + 0.03 mm Al < HVL < kVp/100 + 0.19 mm Al

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Answer: 2.

HVL > kVp/100 + 0.03 mm Al

Explanation:

Specified in Selenia Dimensions QC manual

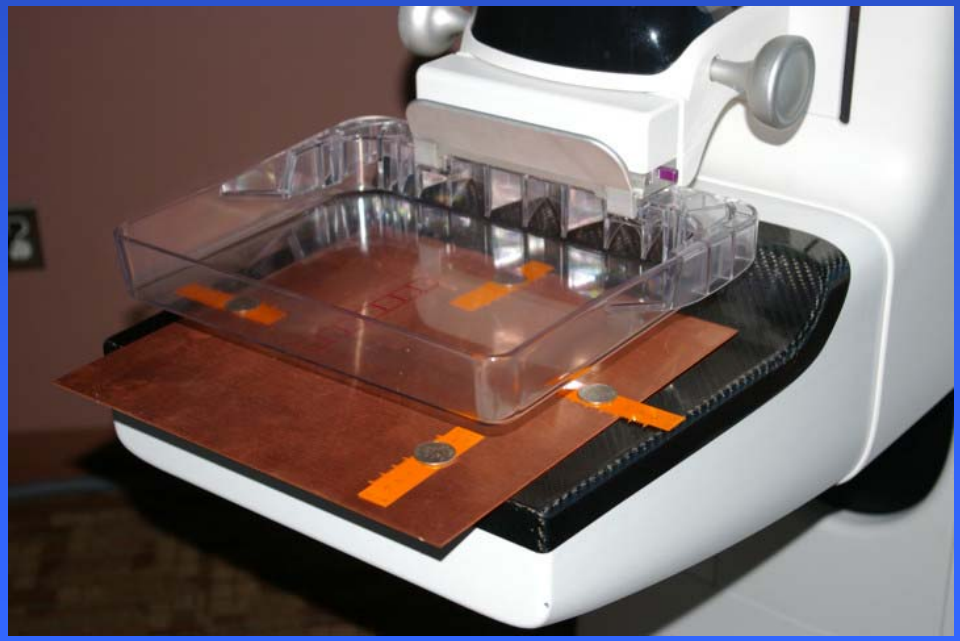
Reference:

Selenia Dimensions QC Manual MAN-01965, page 23

QC Test: Collimation Assessment

1. Deviation between X-ray field and light field

   - Measured on the breast holder in 2D
   - Only evaluated for 24 cm x 29 cm collimation

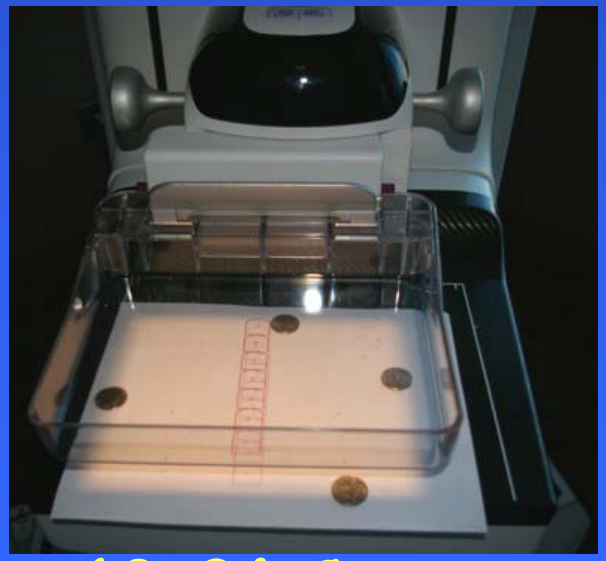


QC Test: Collimation Assessment

2. Deviations between X-ray field and detector

- 2D: 24 x 29 Center,
  18x24 Left, 18x24 Center, 18 x 24 Right

- 3D: 18 x 24 Center, Zero-Degree Tomo view



18x24 Center

18x24 Left

18x24 Right

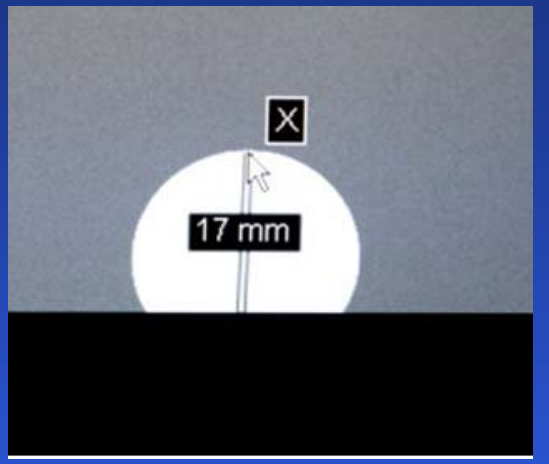
QC Test: Collimation Assessment

3. Alignment of paddle and the detector

- 2D: 18x24 Center and 24x29 Center

QC Test: Collimation Assessment

Comments



The size displayed

= the size on the image plane / ERMF

Default ERMF = 1.073

Other Optional Tests

- ✓Ghosting
- ✓Artifacts for reconstructed images
- ✓Z-resolution
- ✓...

Thank You !