Cleveland Clinic

Unique Features of the Siemens Inspiration Digital Breast Tomosynthesis System

March 6, 2016

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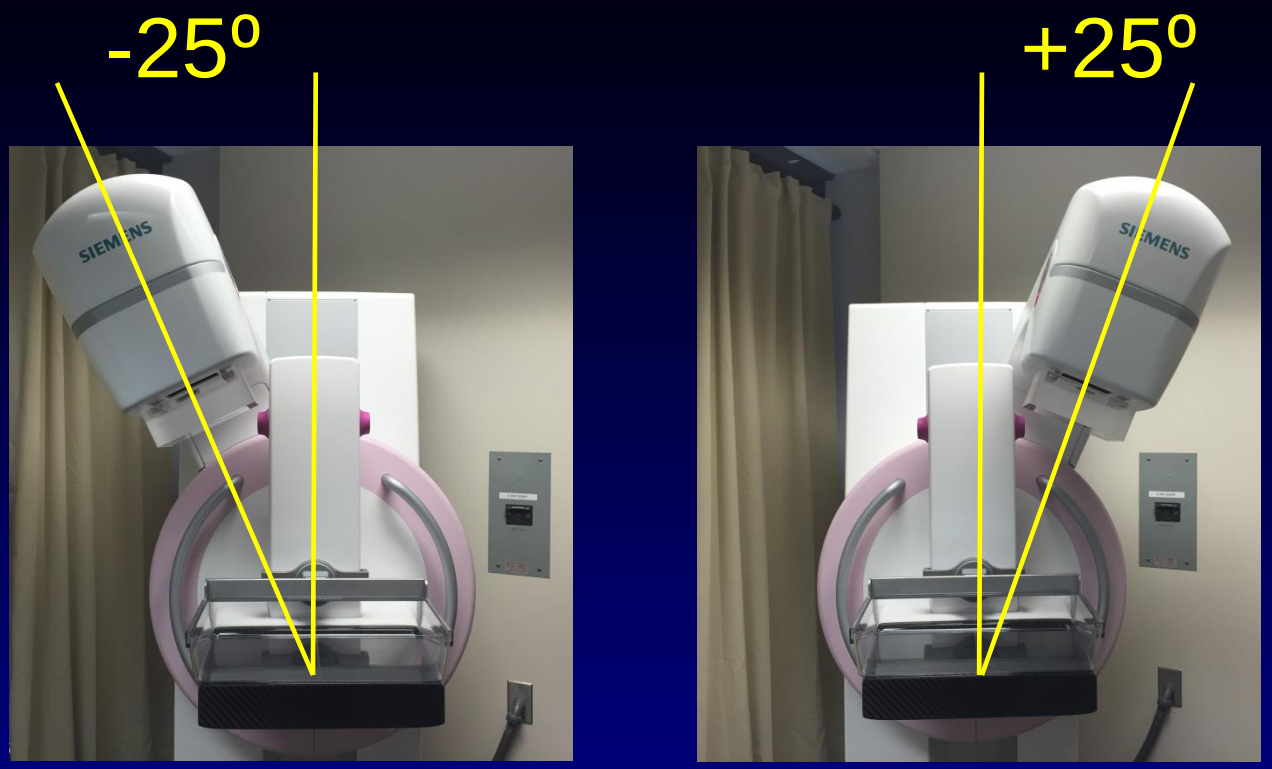
Overview of hardware and software features



- **25 projections**
  - **50º angular range (-25º to +25º)**
  - **Projections acquired every 2º**
  - **Continuous motion (not step-and-shoot)**

Rationale – Large Angular Range

- Increased z resolution
- Decreased slice thickness
  - (narrower focus)
- Reduced out-of-plane artifacts

Rationale – Large Angular Range

- **Cost: decreased FOV with stationary detector**
  - If compressed breast thickness is >80mm, some projections will not include data from 100% of the breast
  - Side note…..
    - Performing tomo scans on breasts with compressed breast thickness >90mm can result a in fatal error (requiring system to be rebooted multiple times)

Software upgrade VB30P solves this error, allowing tomo to be performed for breast thicknesses up to 100mm

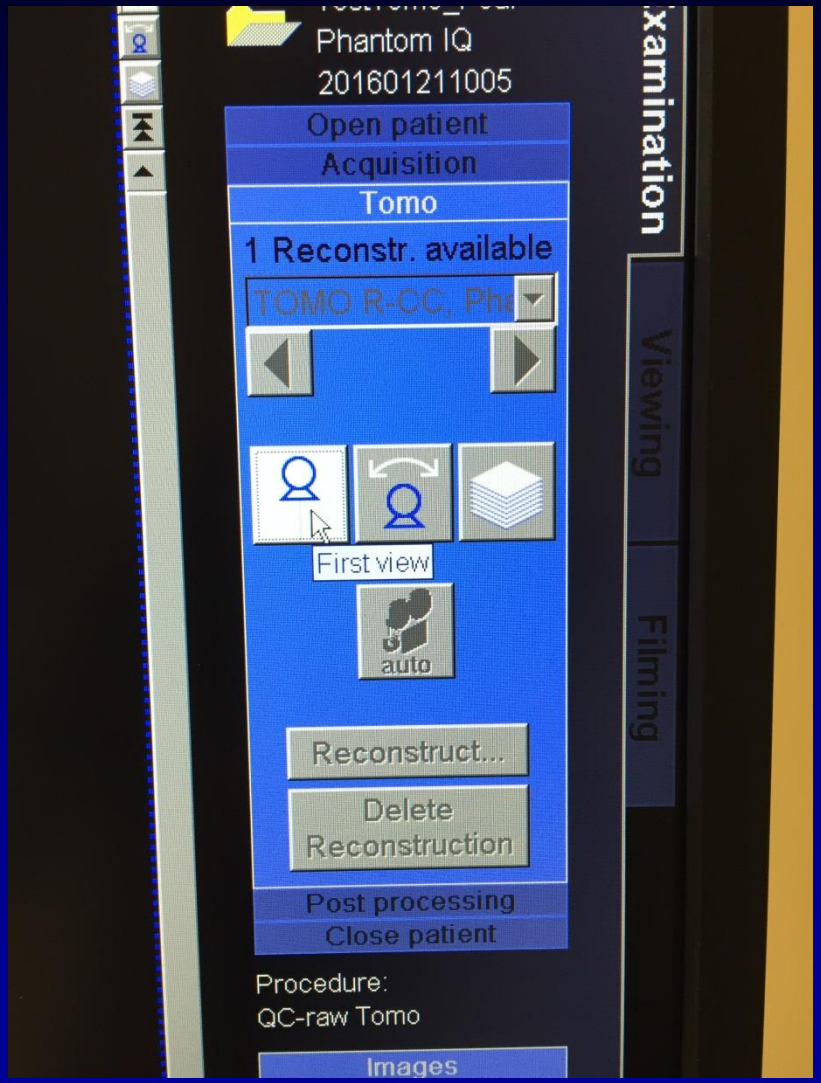
- **Stationary detector**
- **Grid removed for tomo projections**
- **W/Rh *<u>only</u>***

Tomo acquisition
~25 seconds

DBT Option Installation

- **DBT option installation on existing units may involve any of the following:**
  - Replacement of collimator with “tomo” collimator
  - Replacement of PC
  - Replacement of clutch (locks receptor in place while tube arm moves)
  - Software upgrade

Siemens Nomenclature



First View

Exposure taken when the swivel arm is at an angle of 0^{o}

- 5 mAs pre-shot in tomo-only mode
- 2D image in combo mode

Siemens Nomenclature

Projections

Individual low-dose images acquired at various projection angles during the tomo scan

Siemens Nomenclature

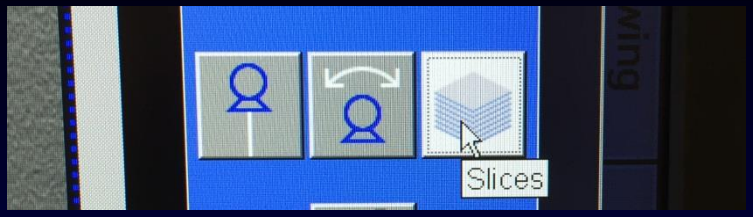
Slices

Calculated images parallel to the detector surface, reconstructed from the acquired projections

Slices are reconstructed at 1 mm increments

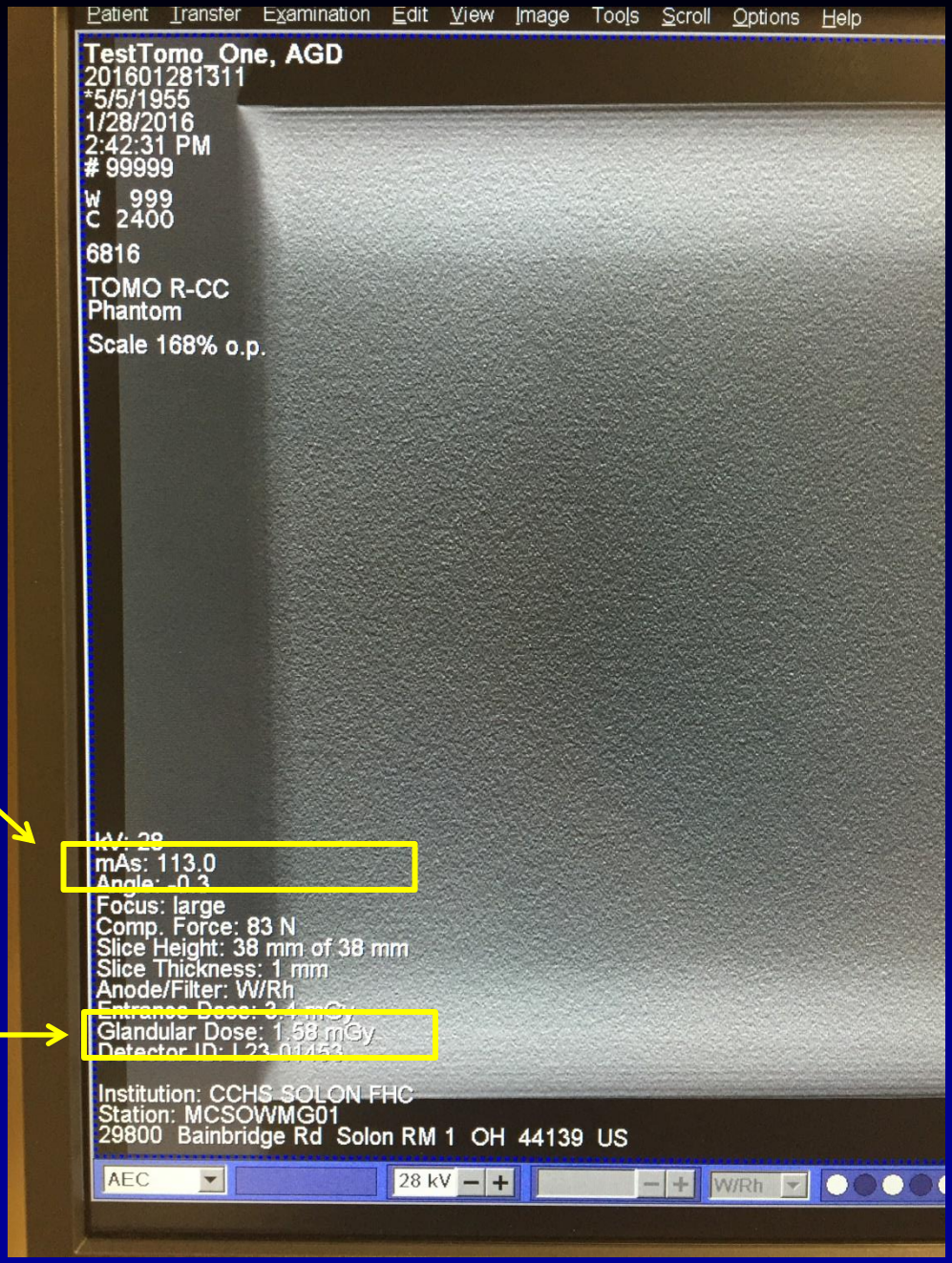
Displayed AGD

- **First View**
  - The glandular dose for the 2D exposure (combo mode)
  - The glandular dose for the 5 mAs pre-pulse (tomo-only mode)
- **Projections**
  - The glandular dose for a single projection
- **Slices**
  - The glandular dose for the entire tomo scan



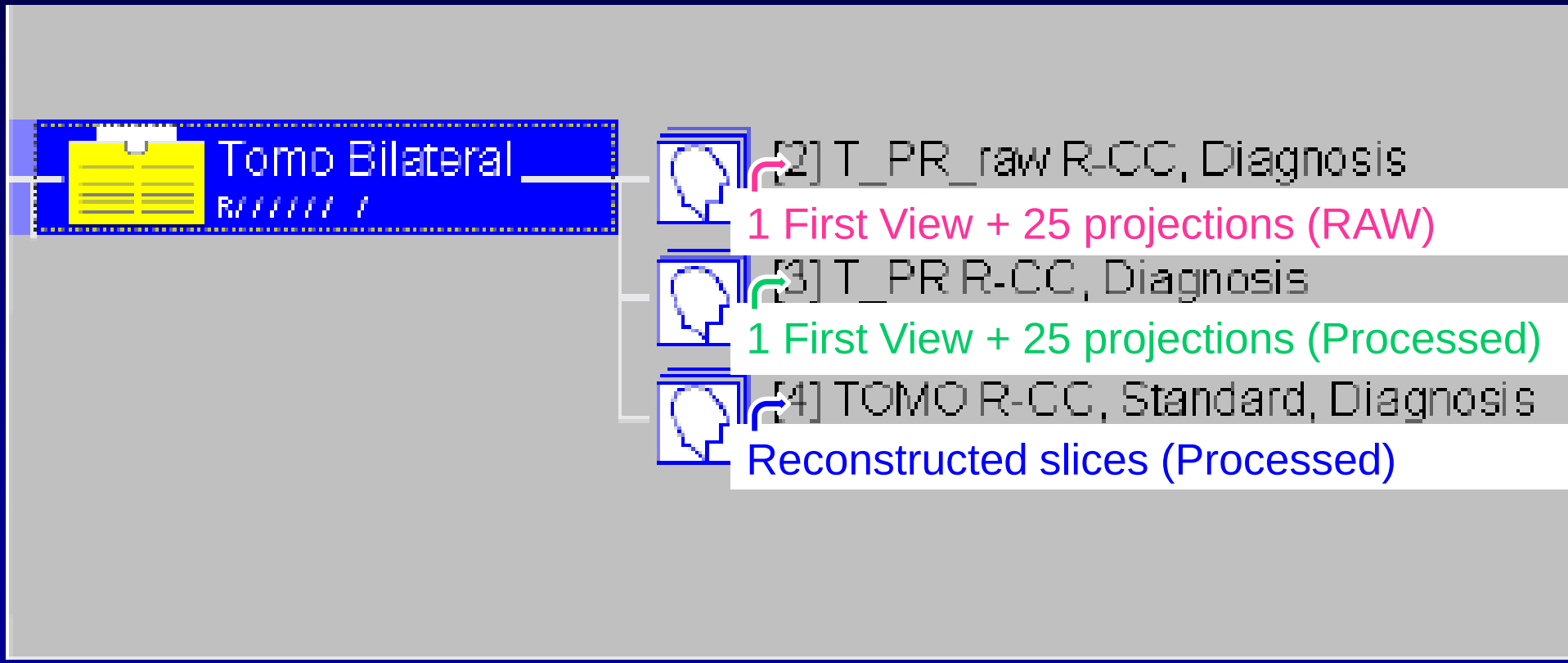
Display mAs **on tomo slices = total mAs for all tomo projections combined**

Displayed AGD **on tomo slices = total AGD for entire tomo scan**

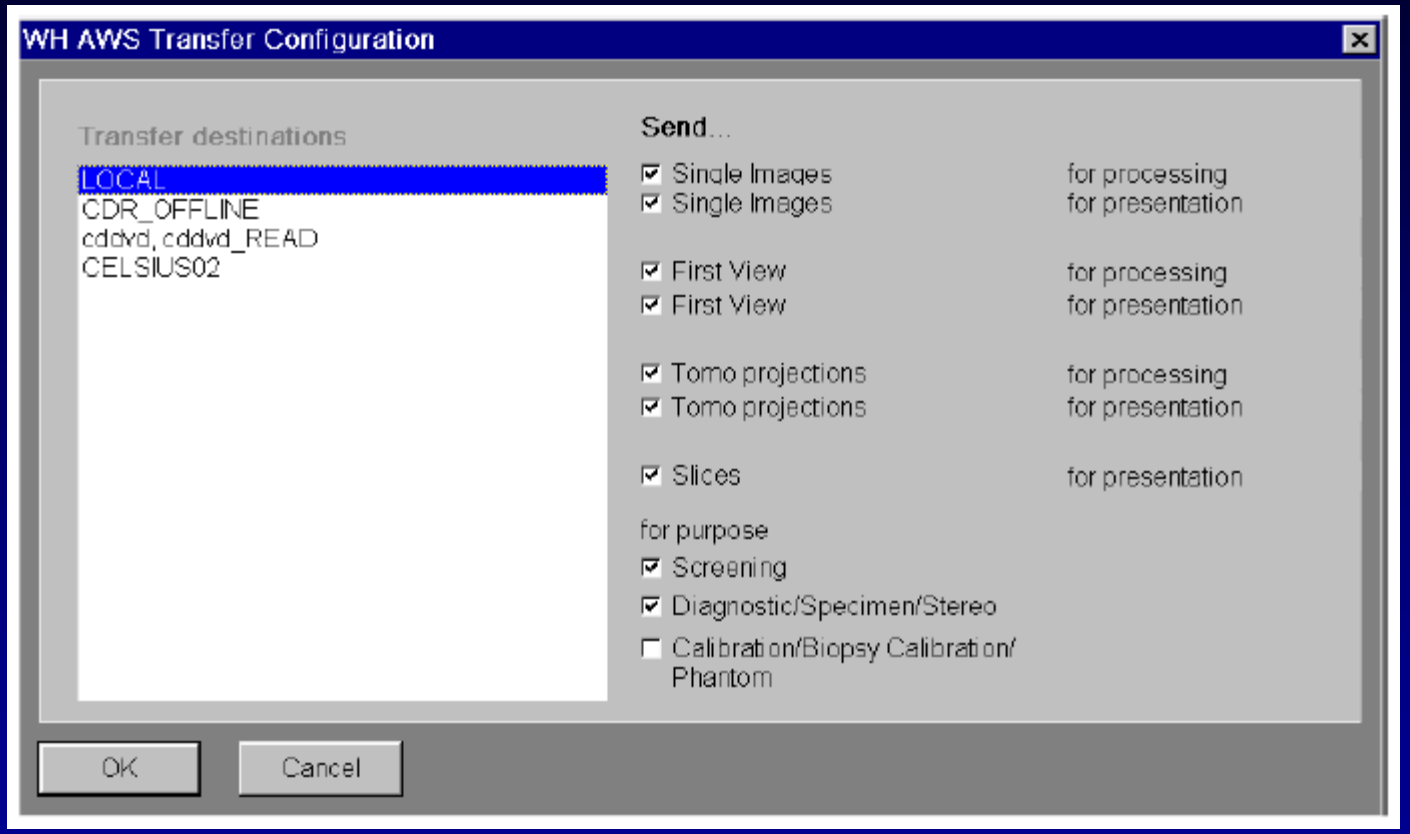


Siemens Nomenclature

1 Tomo Scan → 3 Series

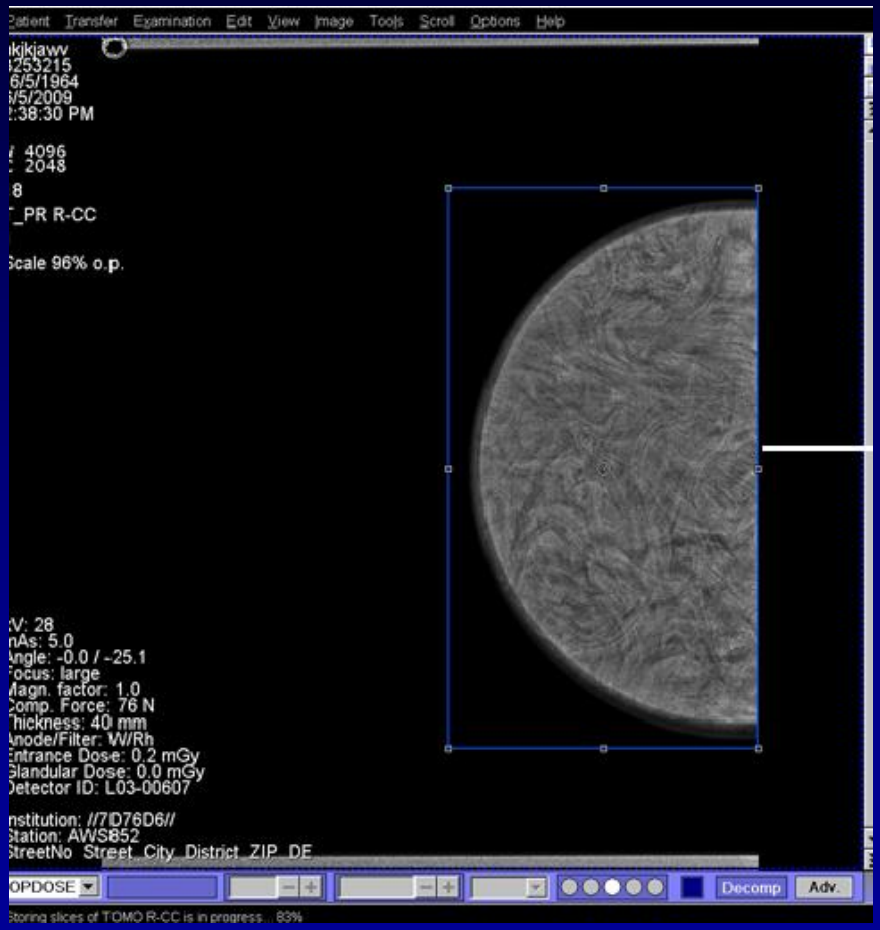


Transfer Rules



- Not possible to configure transfer rules to send First View to PACS *only* when “combo” mode is used….

Siemens Nomenclature



Order No. XPW7-330.621.53.01.24 (p25)

Bounding Box

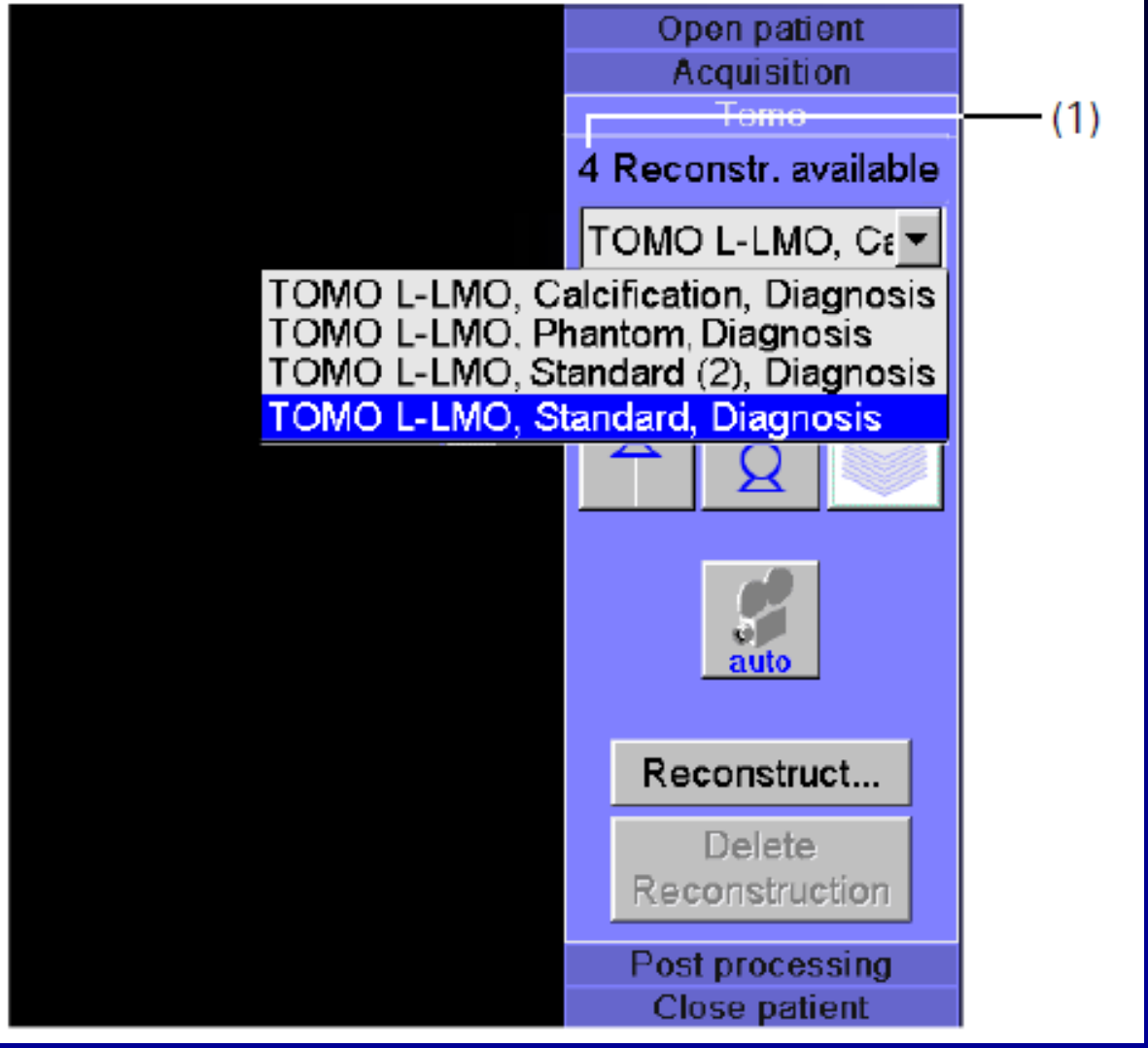
Defines the volume for calculation of the slices

- Displayed only on First View
- Bounding box can be adjusted to redefine volume, must reconstruct tomo scan for it to take effect

Tomo Reconstruction

- **Filtered back-projection**
- **Reconstruction Parameter Groups (RPGs)**
  - Default RPGs:
    - Standard
    - Calcification
    - Phantom
  - Selectable RPGs configured by applications specialist

Tomo Reconstruction

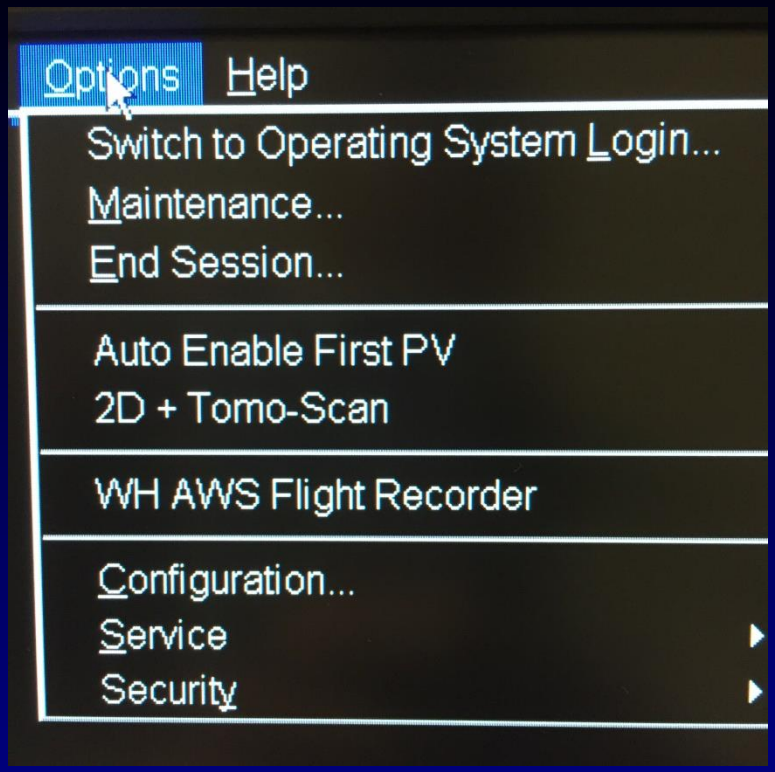


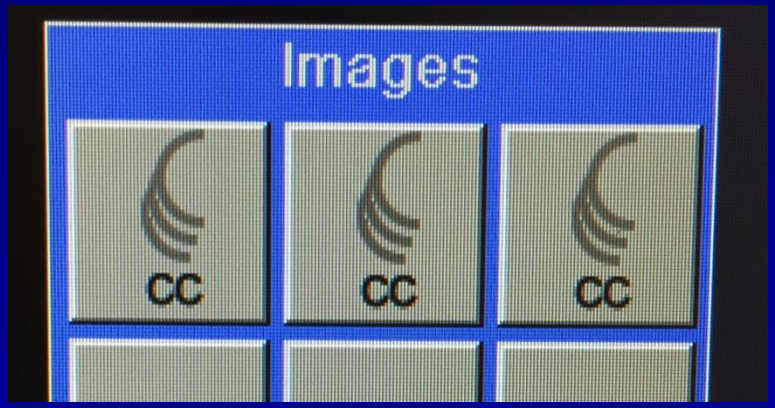
Order No. XPW7-330.621.53.01.24 (p29)

Modes of Acquisition

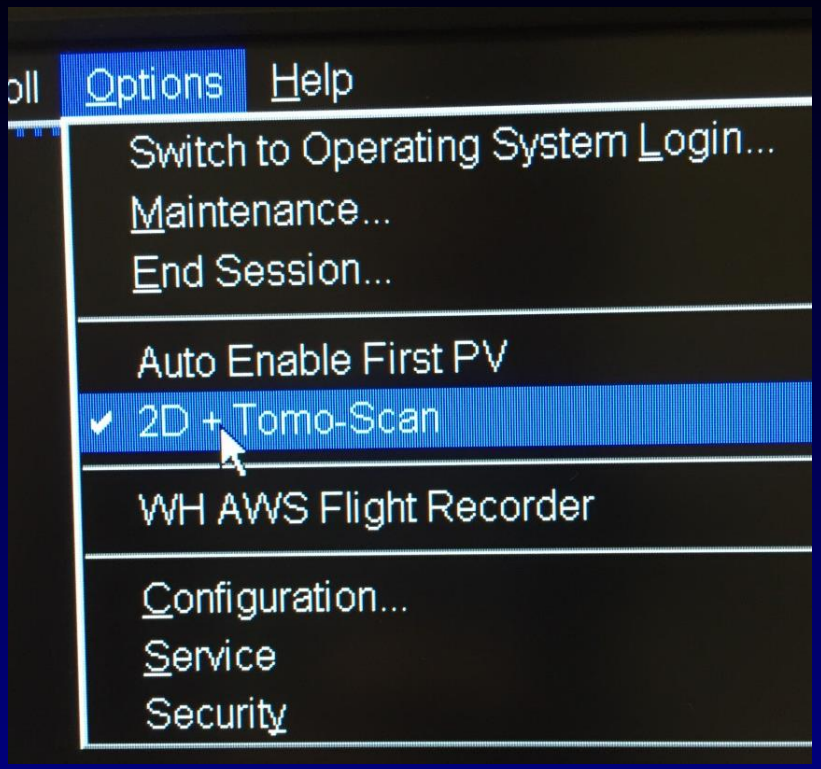
- **Tomo Scan (“Tomo-only” Mode)**
- **2D+Tomo Scan (“Combo” Mode)**

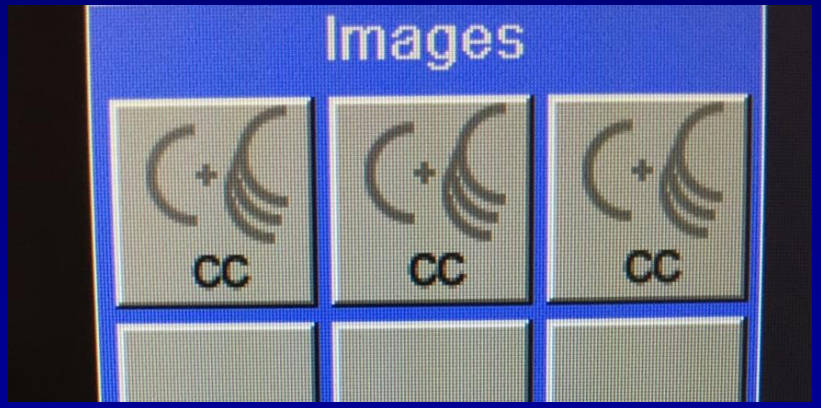
- Mode must be selected before the first exposure is performed
- Cannot switch modes while examination is open once an exposure has been performed
- Must close patient in order to switch modes





Combo Mode - OFF





Combo Mode - ON

2D Image

Pre-Shot
(5mAs)

2D image

Tomo-Only

Pre-Shot
(5mAs)

25 Tomo
Projections

Combo Mode
(2D+Tomo Scan)

Pre-Shot
(5mAs)

2D image

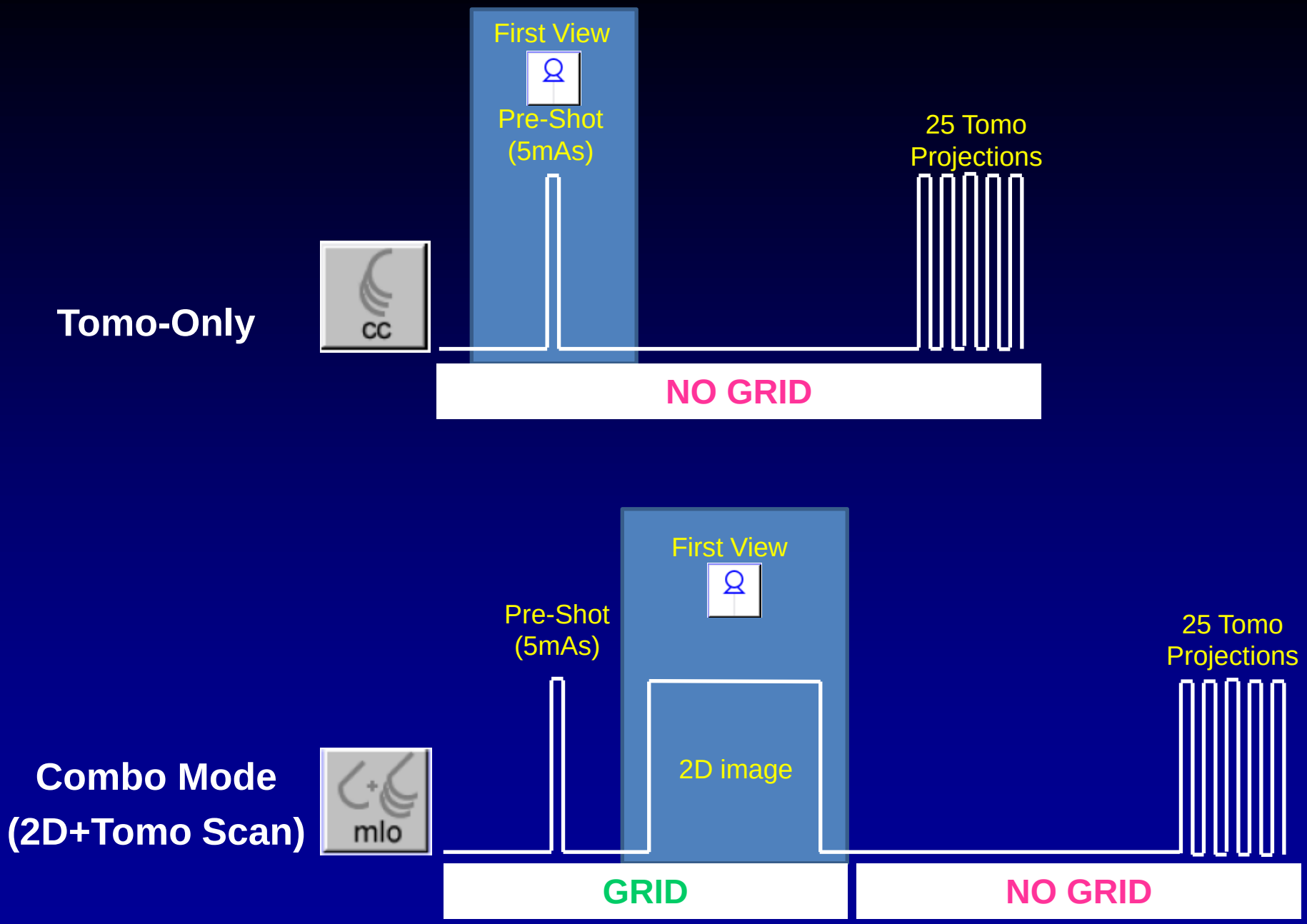
25 Tomo
Projections

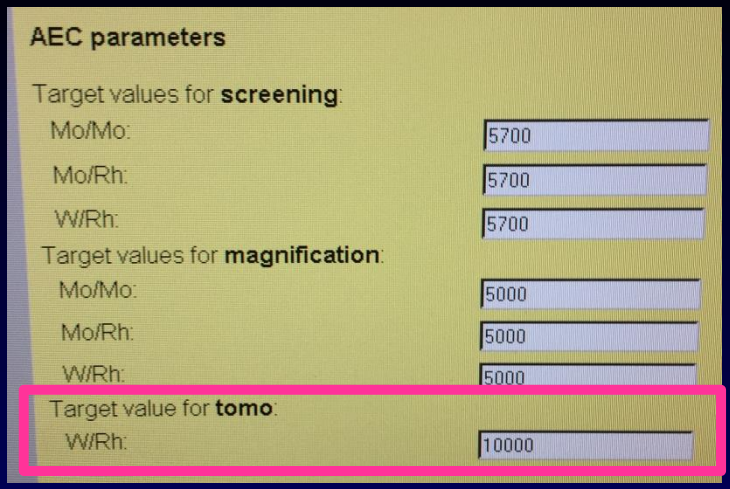
Tomo-Only vs. Combo Mode

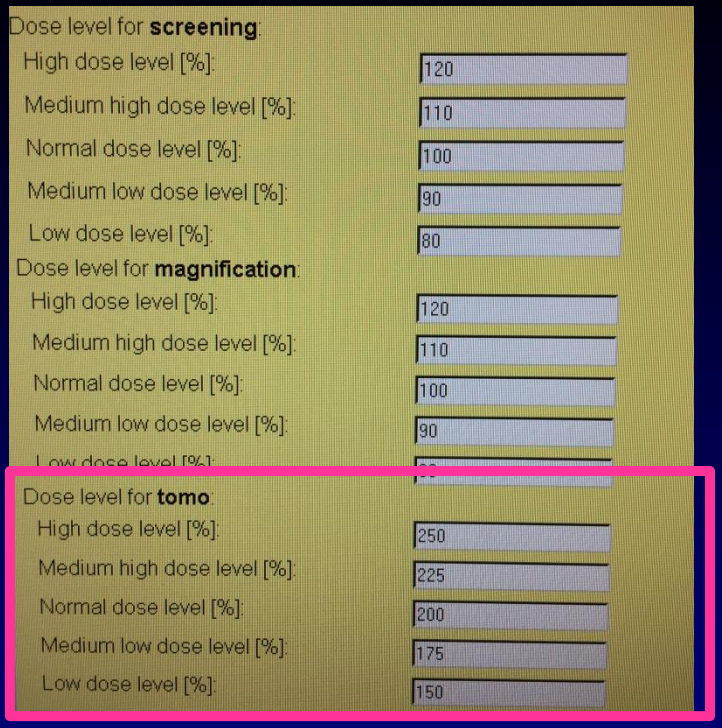
The only mention you will see regarding the difference in how the mAs/projection is determined between tomo-only and combo mode…

– in the case of manual 2D + 3D mode:
the set mAs value corresponds to the mAs value during the 2D exposure
the mAs value for 3D is twice as high

XPW7-330.621.53.01.24 (p45)


First View
Pre-Shot
(5mAs)
25 Tomo
Projections
Tomo-Only
cc
NO GRID
First View
Pre-Shot
(5mAs)
25 Tomo
Projections
Combo Mode
(2D+Tomo Scan)
mlo
2D image
GRID
NO GRID

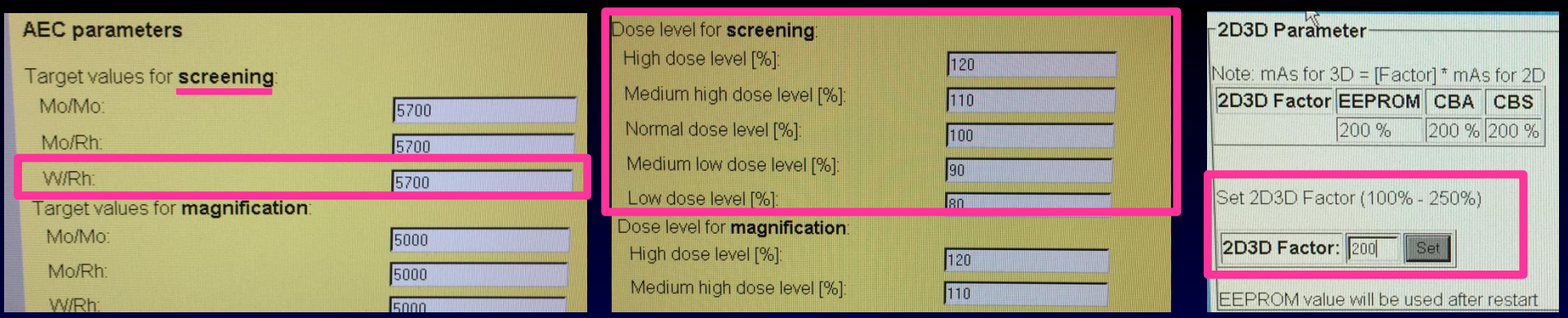




IMPORTANT:

In tomo-only mode, dose for tomo scan is dependent on:

- **AEC Target Value *for tomo (W/Rh)***
  - **Factory setting = 10000**
- **Dose Level *for tomo***
  - **Factory setting = 200% (Normal dose level)**



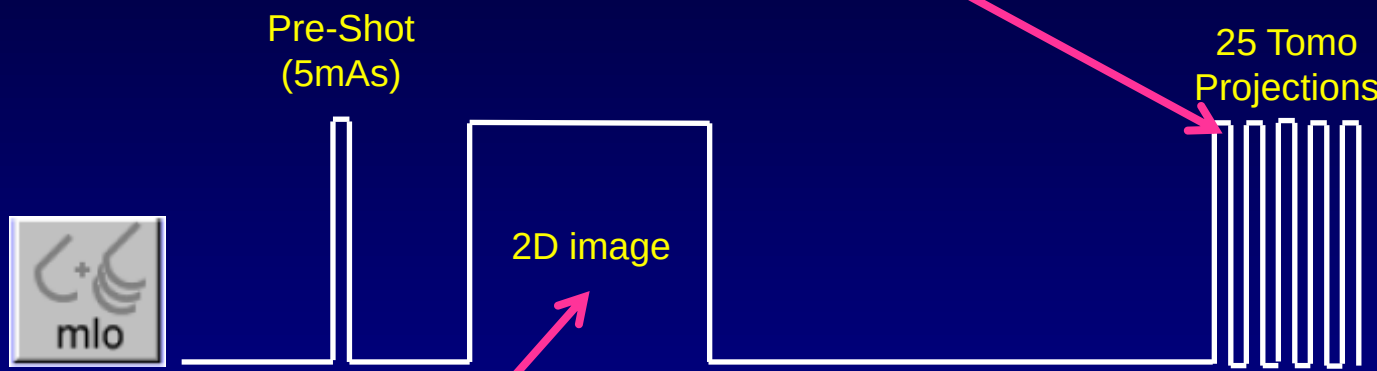
IMPORTANT:

In combo mode, dose for tomo scan is dependent on:

- **AEC Target Value *for screening (W/Rh)***
  - **Factory setting = 5700**
- **Dose Level *for screening***
  - **Factory setting = 100% (Normal dose level)**
- **2D3D Factor**
  - **Factory setting = 200**

2D3D Factor

Total mAs per projection = $\frac{\text{Total mAs for Tomo Scan}}{25}$



mAs for 2D image **X** $\frac{\text{2D3D Factor: 200 Set}}{100}$ = Total mAs for Tomo Scan

Factory setting (2D3D Factor = 200) → total mAs for all 25 projections combined is twice the mAs of the 2D image

Medical Physicist Required Tests

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

Recommended frequency of QC tests

The following table specifies when the different tests are to be performed and by whom:

Test	Annually	Daily
1. Glandular dose	MP	
2. Geometric accuracy in X and Y direction and Z-resolution	MP	
3. Radiation field	MP	
4. Phantom image quality	MP	T - only on days when tomo is performed - only the test with tube head at 0°
5. Artifact detection	MP	

MP = Medical Physicist

T = Technologist

If not otherwise specified, measurements are performed with the tube head in 0° position.

Point of Clarification

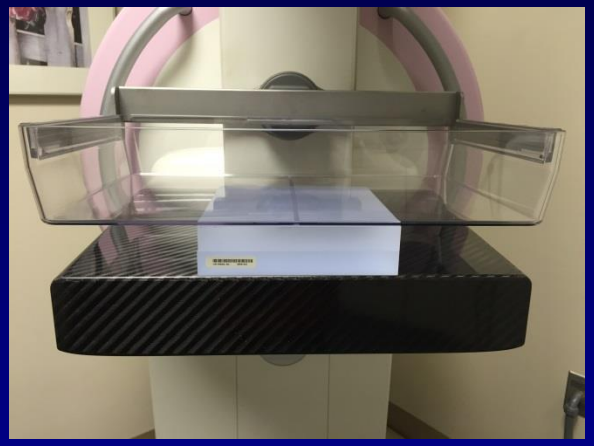
- **Siemens' use of the term "*Tomo scan*" in the QC manual refers specifically to a tomo scan acquired in "tomo-only" mode**
- **Per Siemens:**
  - *"If 2D+3D (aka Combo Mode) is activated, please disable prior to QC testing"*

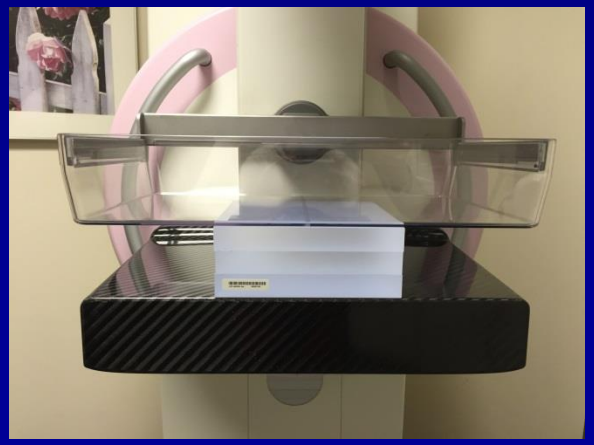
Test 1: Average Glandular Dose

- **Equipment:**
  - 15x15 PMMA plates (20mm, 40mm, 60mm)
  - 25 cm x 36 cm tomo compression paddle
- **Settings:**
  - Procedure: **QC-raw Tomo**
  - Mode: AEC
    - OPCOMP = **ON**
    - Auto Decompression = **Off**
    - AEC Segmentation = **Off**
    - Dose Level = **Normal**

Test 1: Average Glandular Dose

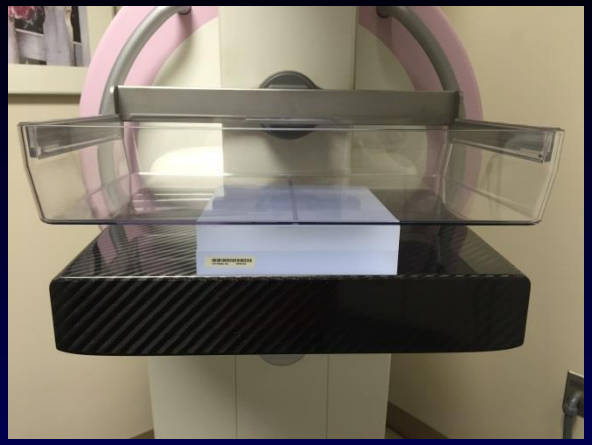
- **Procedure:**
  - **Place 20 mm thick PMM plate on object table**
  - **Perform compression until OPCOMP is reached**
  - **Perform a *Tomo scan* with the specified kVp value**
  - **Record the mAs and *displayed AGD***
  - **Repeat for 40 mm and 60 mm PMMA**

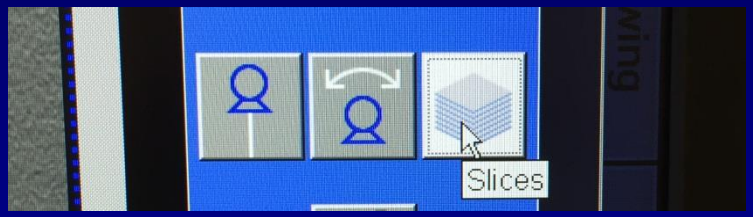




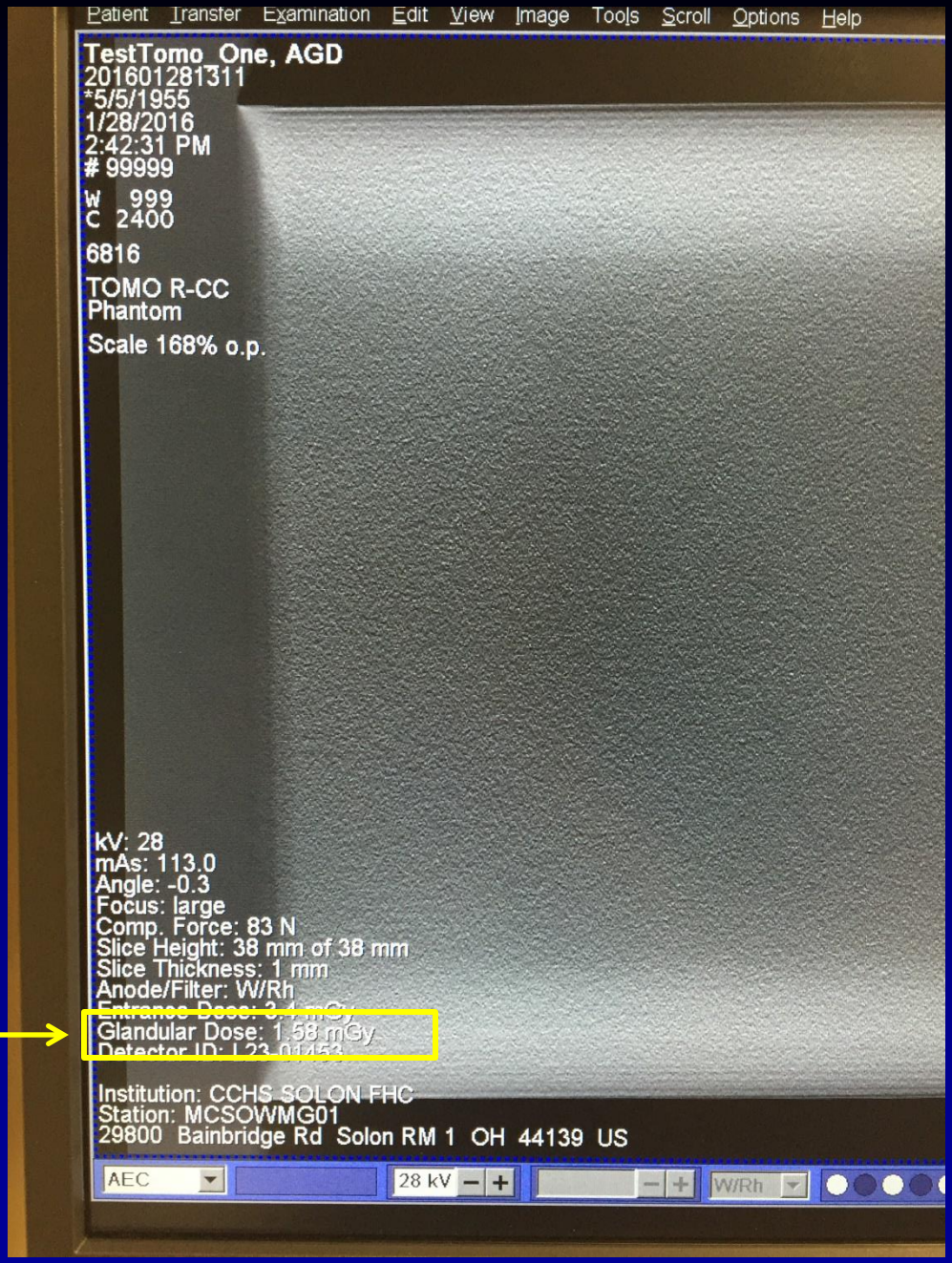
Tolerance Criteria (AGD_{tomo})

26 kVp	≤ 1.0 mGy
28 kVp	≤ 2.0 mGy
30 kVp	≤ 4.5 mGy





Record the *displayed AGD* for the tomo slices

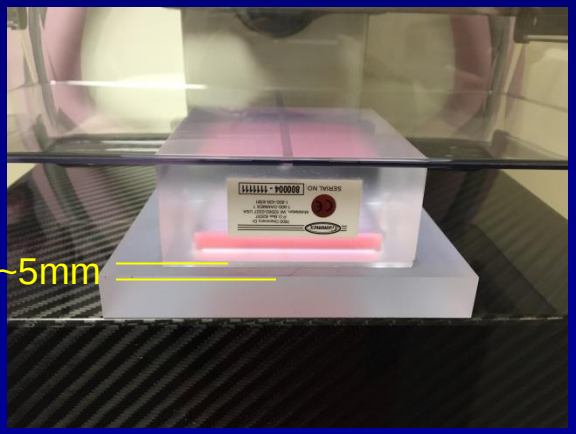


Test 2: Geometric Accuracy in X and Y Direction and Z Resolution

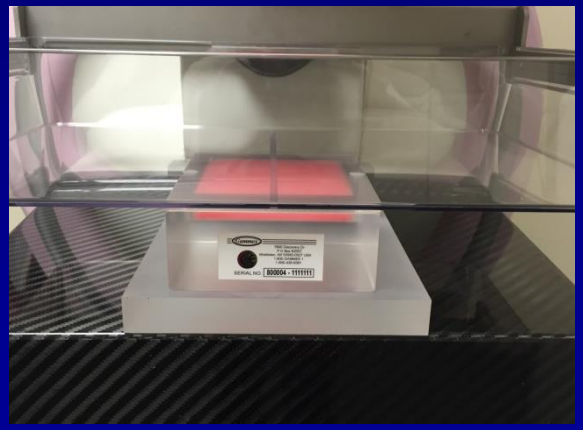
- **Equipment:**
  - 15x15 PMMA plate (20mm) + ACR Phantom
  - 25 cm x 36 cm tomo compression paddle
- **Settings:**
  - Procedure: **QC-raw Tomo**
  - Mode: AEC
    - OPCOMP = **Off** (≥90 N compression)
    - Auto Decompression = **Off**
    - AEC Segmentation = **Off**
    - Dose Level = **Normal**

Test 2: Geometric Accuracy in X and Y Direction and Z Resolution

- **Procedure:**
  - Compress to ≥ 90N
  - Perform three ***Tomo scans*** using the clinical kVp appropriate for this PMMA thickness (e.g 30kVp)



Scan No. 1

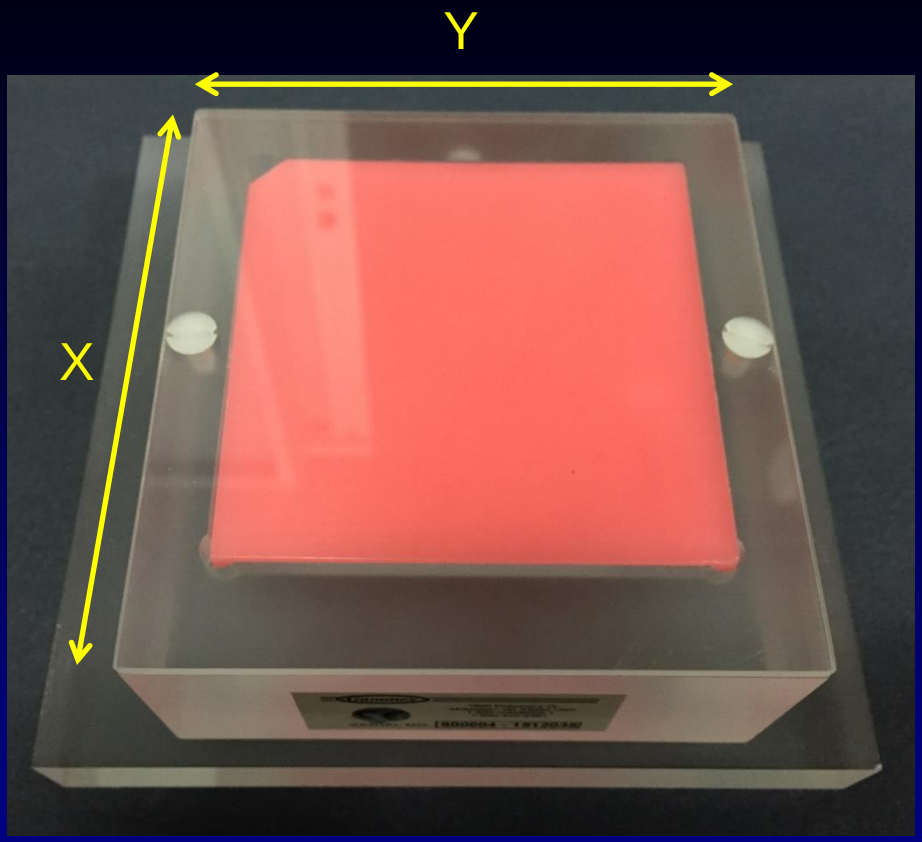


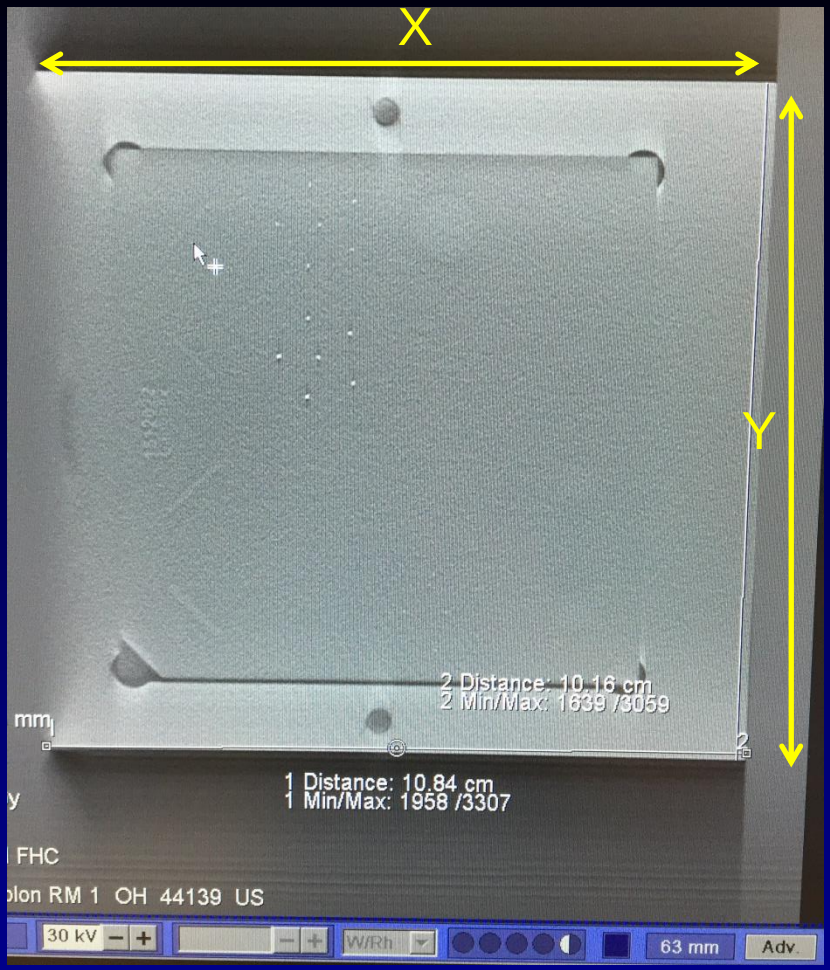
Scan No. 2

Scan No. 3

Test 2a: Geometric Accuracy in X and Y Direction

- **Procedure (cont.):**
  - Measure the physical outer dimensions (X and Y) of the ACR phantom, record values
  - For each of the three tomo scans:
    - Select slice where objects (Fibers, Specks, Masses) are best visible
    - Measure X and Y using the distance line tool (**Tools > Distance**), record values





- **Tolerance Criteria:**
  - X and Y must be measurable with an accuracy of ± 2%

Test 2b: Z-Resolution

- **Procedure:**
  - Use same three tomo scans from Test 2a

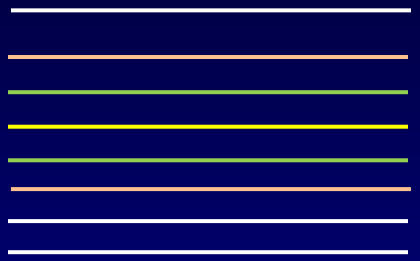
Artifact Spread Function (ASF)

- **Limited angular range results in reconstruction artifacts**
  - Typically manifests as blurred images of out of plane objects (out-of-plane artifact) in planes parallel to the detector
- **ASF attempts to quantify the out-of-plane blur**
  - Defined as the reconstructed image intensity of an object as a function of distance (in z-direction) from the location of the object

Wu(2004)
Zhou (2007)

Test 2b: Z-Resolution

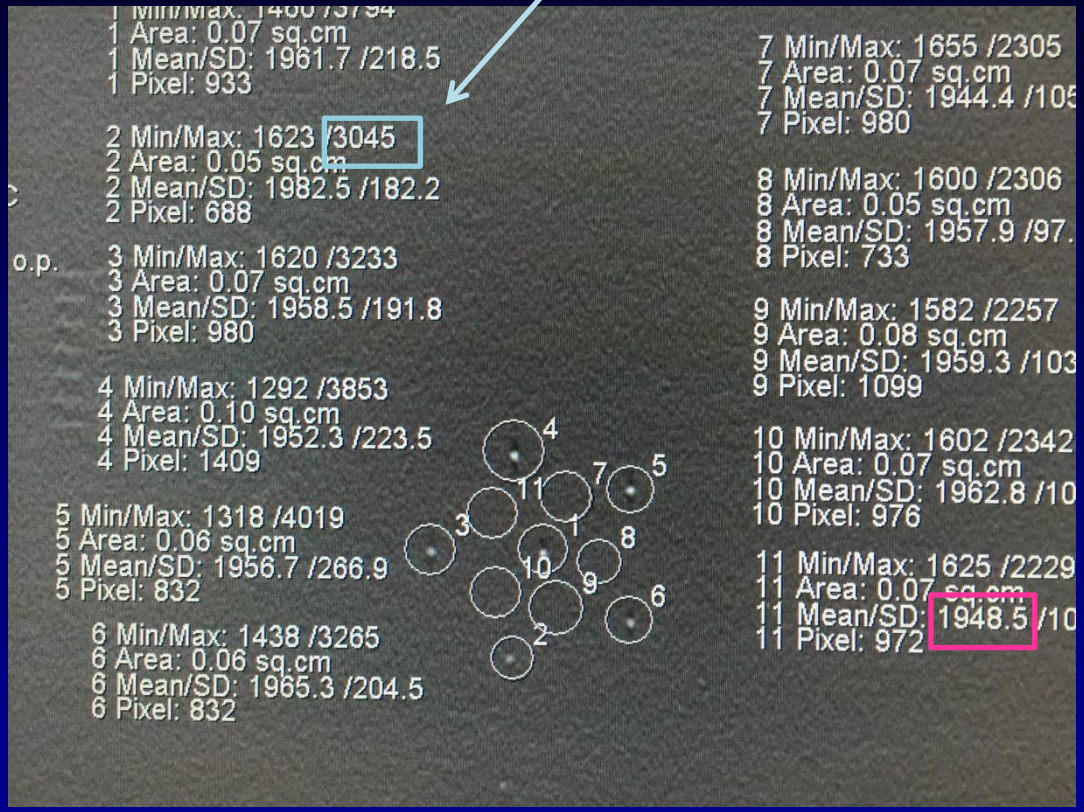
- **Procedure:**
  - Use same three tomo scans from Test 2a
  - For each of the three scans:
    - Determine slices where specks of the ACR phantom are best visible (i = 0)
      - NOTE: max pixel values for specks should be highest in this slice
    - For each of the five slices centered at i = -2, -1, 0, 1, and 2 measure the following:
      - $S(z_i)$: Average MAX pixel value of the 6 largest specks
      - $S(bg_i)$: Average MEAN pixel value of the background
        - » Measure between the 6 largest specks



S(z_i):

Measure the MAX pixel value for each speck

Calculate the mean value of the 6 maximum values



S(bg_i):

Measure the MEAN pixel value of the background between the specs

Calculate the mean value of the 5 mean values

Test 2b: Z-Resolution

- **Procedure:**
  - For each of the five slices centered at i = -2, -1, 0, 1, and 2 , calculate the ASF:

$$ASF(i) = \frac{S(z_i) - S(bg_i)}{S(z_0) - S(bg_0)}$$

  - Take the average of the ASF at i = ±1 and i = ±2:

$$ASF(a) = \frac{ASF(-1) + ASF(1)}{2}$$

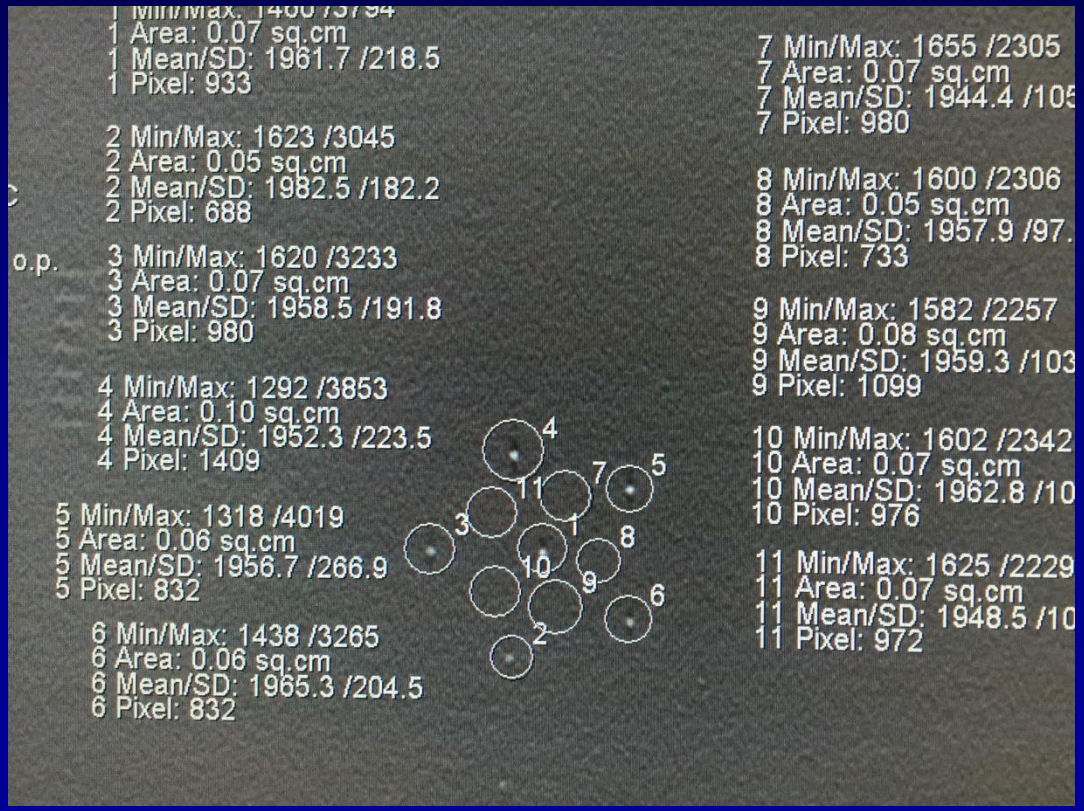
$$ASF(b) = \frac{ASF(-2) + ASF(2)}{2}$$

Test 2b: Z-Resolution

- **Tolerance Criteria:**
  - For each of the three tomo scans:
    - ASF(a) ≤ 0.9
    - ASF(b) ≤ 0.6
- The big question:
  - What do you do if it fails?????

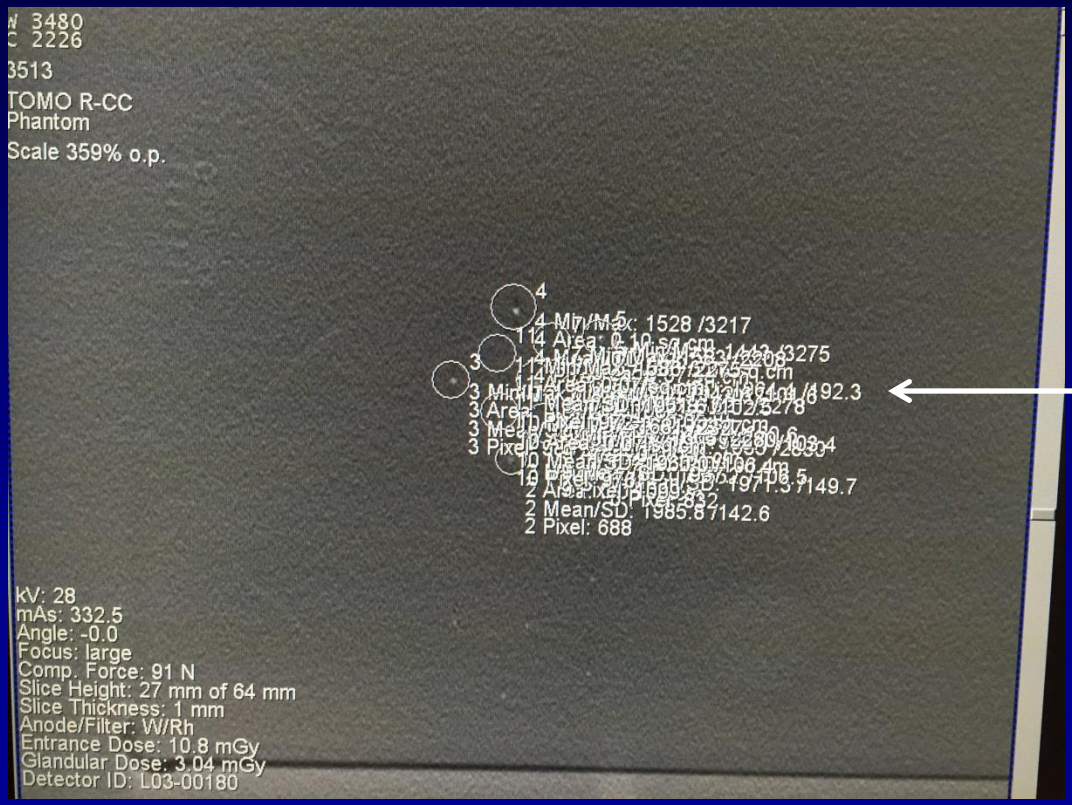
Time Saver!

Once you have finished drawing your pretty ROIs and arranging your text boxes…



They will automatically copy onto EVERY other slice …

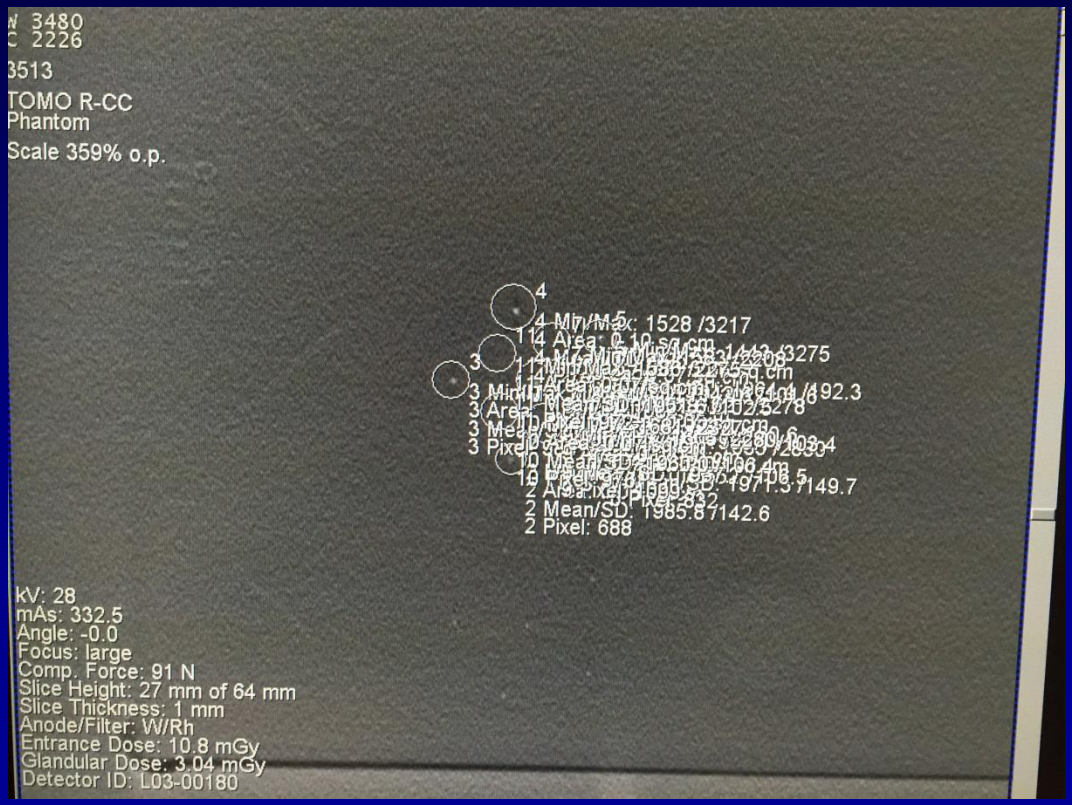
NOTE: if you figure out how to get it to NOT do this, let me know!!!!!

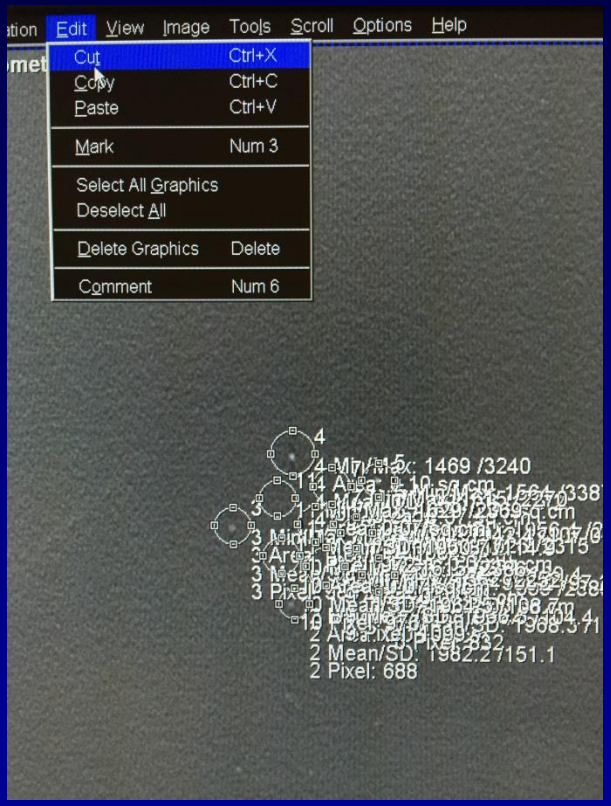


Not so pretty

For the four slices above and below i = 0:

- Edit → Select All Graphics
- Edit → Cut



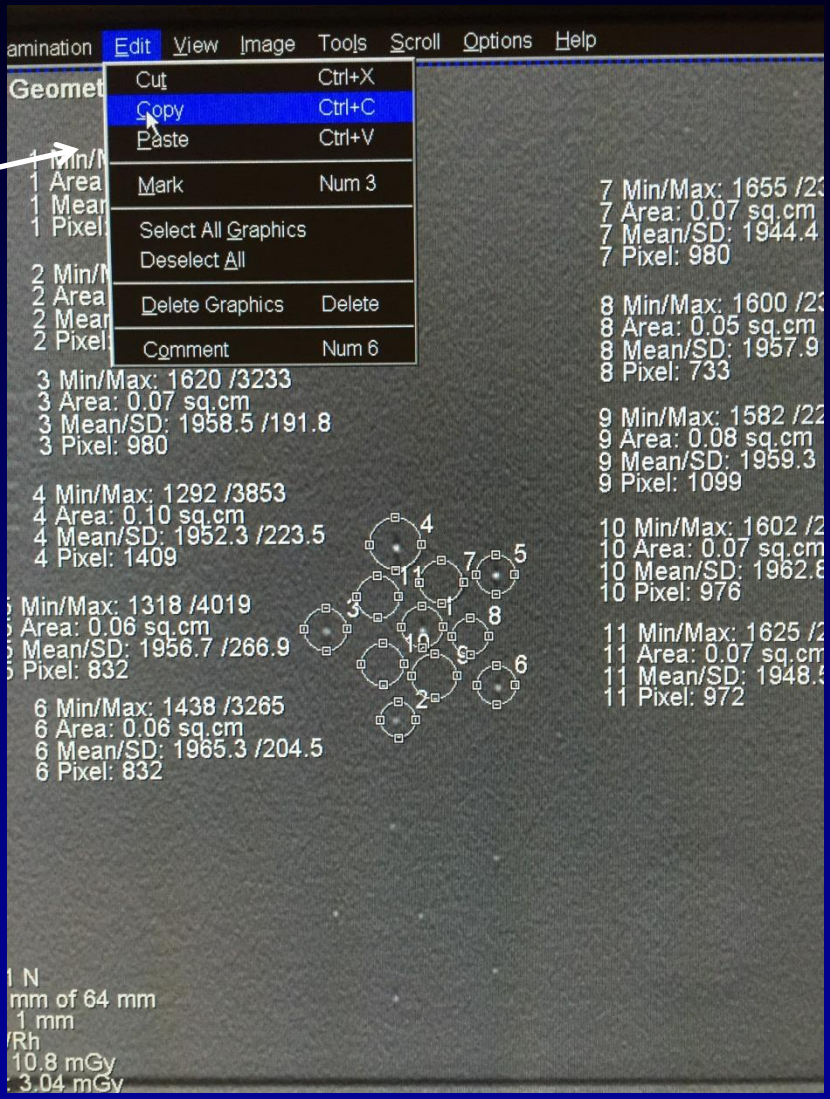


Then go to slice i = 0:

- Edit → Select All Graphics
- Edit → Copy

Return to the four slices above and below i = 0:

- Edit → Paste
- ROIs AND placement of text boxes will copy



Test 3: Radiation Field

- **Equipment:**
  - Collimator mounted plexi (40 mm PMMA)
  - 25cm x 36cm tomo paddle
- **Settings:**
  - Procedure: **QC-raw Tomo**
  - Mode: AEC
    - OPCOMP = **ON**
    - Auto Decompression = **Off**
    - AEC Segmentation = **Off**
    - Dose Level = **Normal**

Test 3: Radiation Field

- **Procedure:**
  - Touch compression paddle to object table
  - Perform *Tomo scan*

Test 3: Radiation Field

- **Procedure:**
  - Check if edges of the collimator or the compression plate are visible in the projection views
    - Look at -25º, 0º, and +25º projection views
    - View images at acquisition size

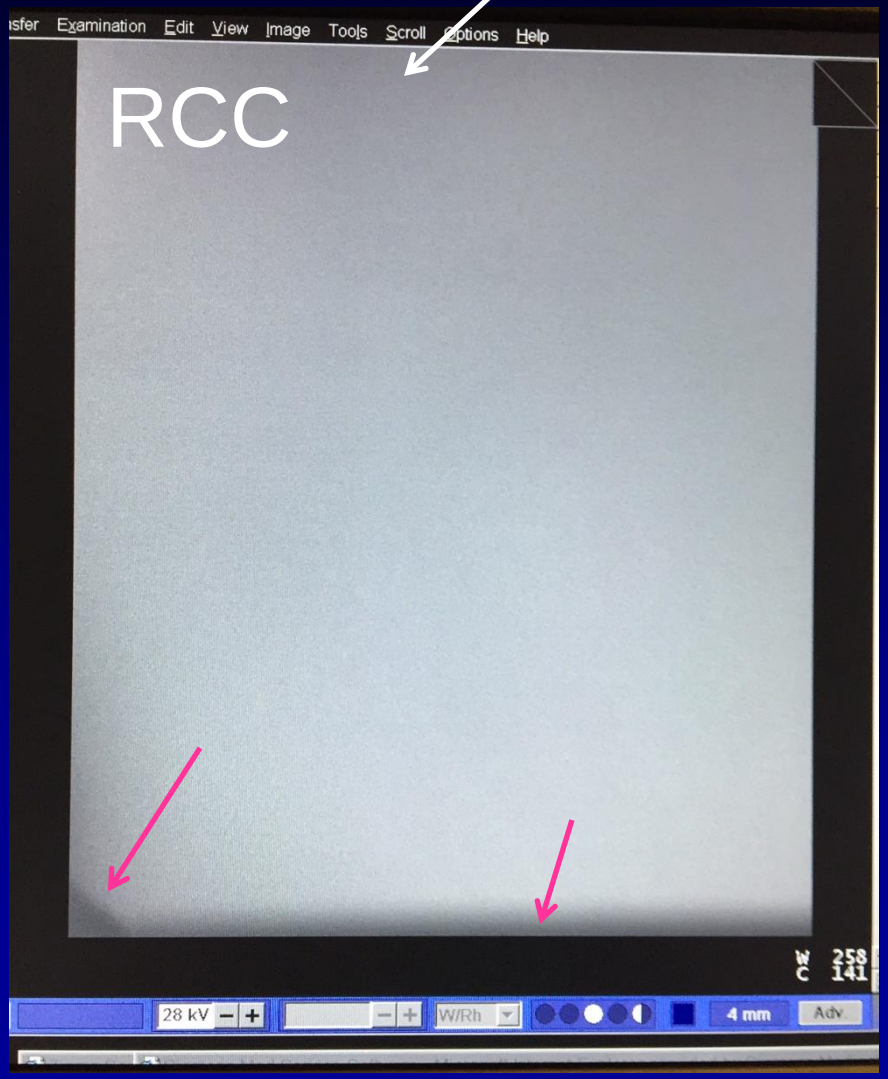
Test 3: Radiation Field

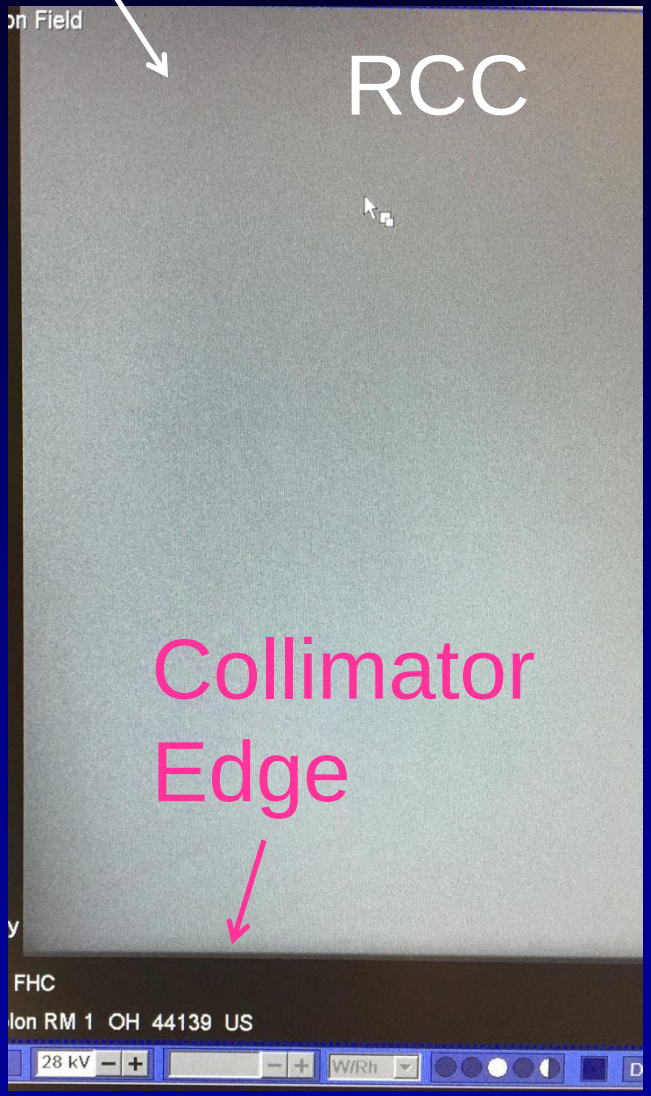
- **Tolerance Criteria:**
  - The image must not show any edges of the collimator or compression plate

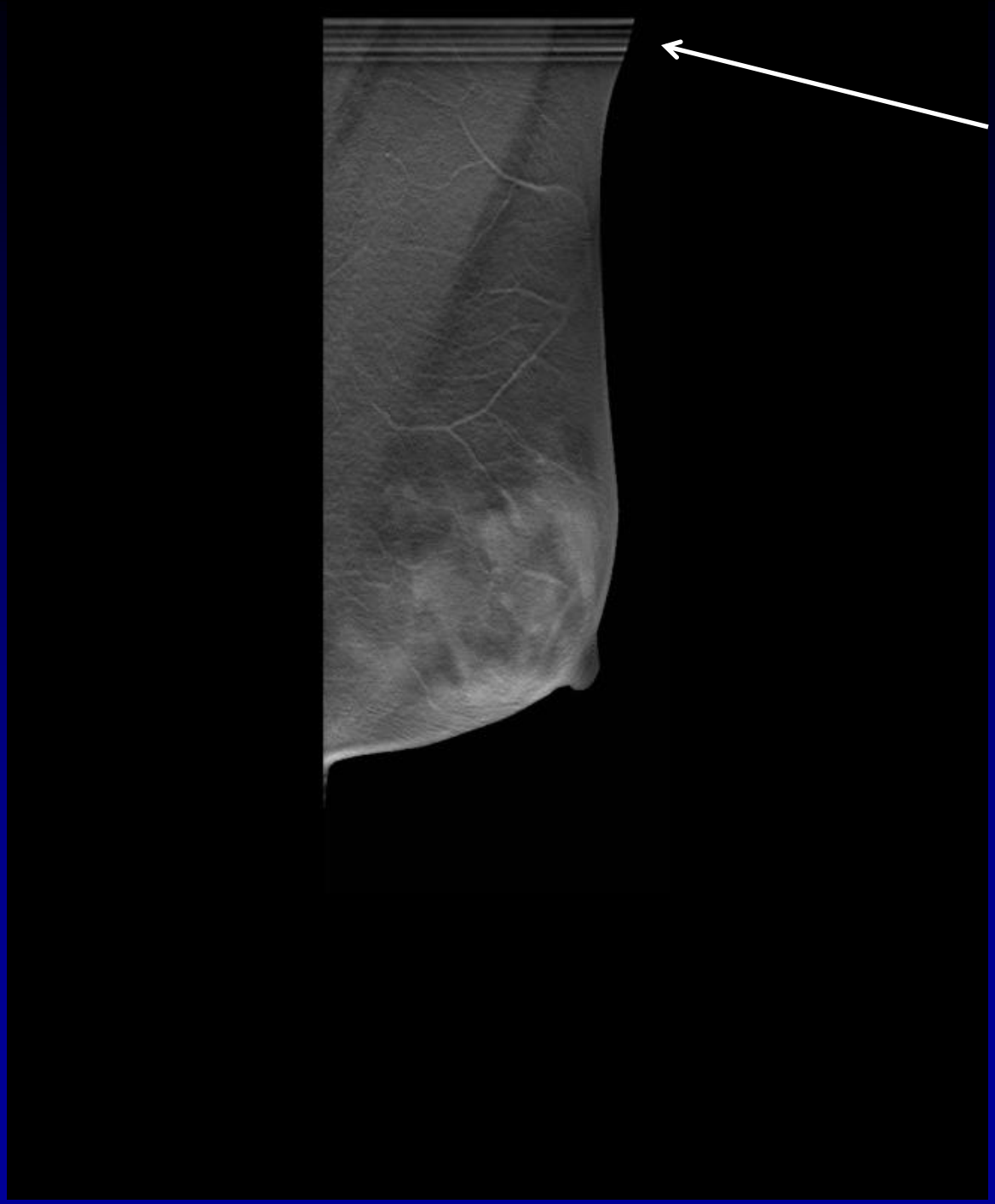
Test 3: Radiation Field

- **Comments:**
  - If x-ray to detector congruence is too good (i.e. x-ray field only extends 1-2 mm beyond active area of detector) you will fail this test
    - Will get artifacts on the edges of your images for MLO Tomo exams
    - Outside the bounding box for CC Tomo exams, no clinical impact
  - We adjust x-ray field to extend ~5-6 mm beyond active area of the detector on both left and right side (still less than 2% SID max deviation required by MQSA – allows 13 mm total)
  - Per Siemens - tube housing and cathode holder will still be visible on +/- 25 and +/-23 degree images once collimator blades have been brought out

About as good as it's gonna get (at ± 25º)







Artifact due to collimator blade being in the field of view

Test 4: Phantom Image Quality

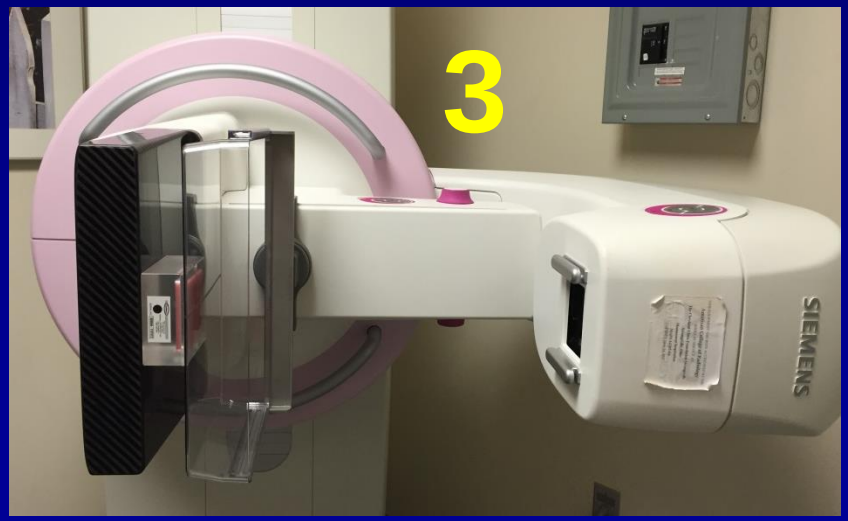
- **Equipment:**
  - ACR Phantom
  - 25cm x 36cm tomo paddle
- **Settings:**
  - Procedure: **QC-raw Tomo**
  - Mode: AEC
    - OPCOMP = **ON**
    - Auto Decompression = **Off**
    - AEC Segmentation = **Off**
    - Dose Level = **Normal**

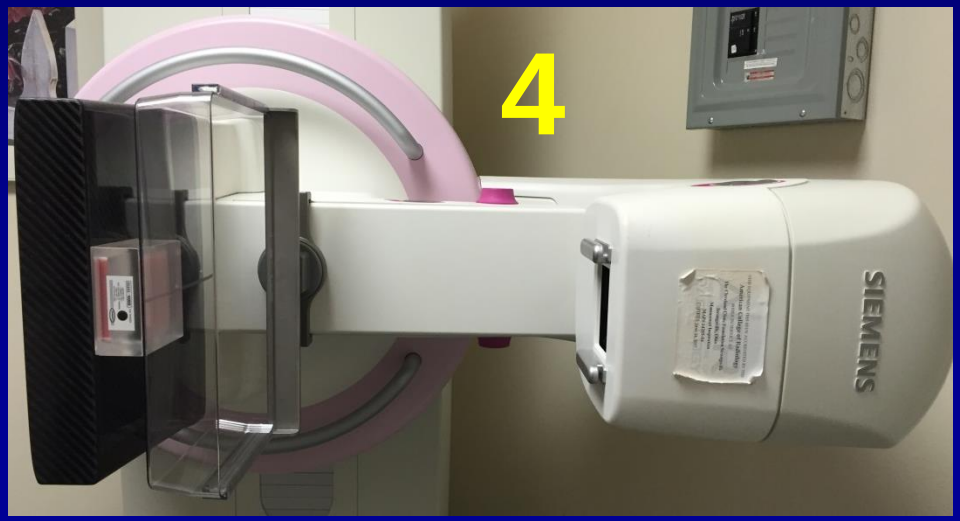
Test 4: Phantom Image Quality

- **Procedure:**
  - Acquire 4 *Tomo scans* at 28 kVp:
    - 0 degree angulation
    - 0 degree angulation with phantom upside down
    - 90 degree angulation
    - 90 degree angulation with phantom upside down
  - Scroll through each data set and select slice where objects are best visible
  - Score the phantom for each tomo scan


1
SIEMENS

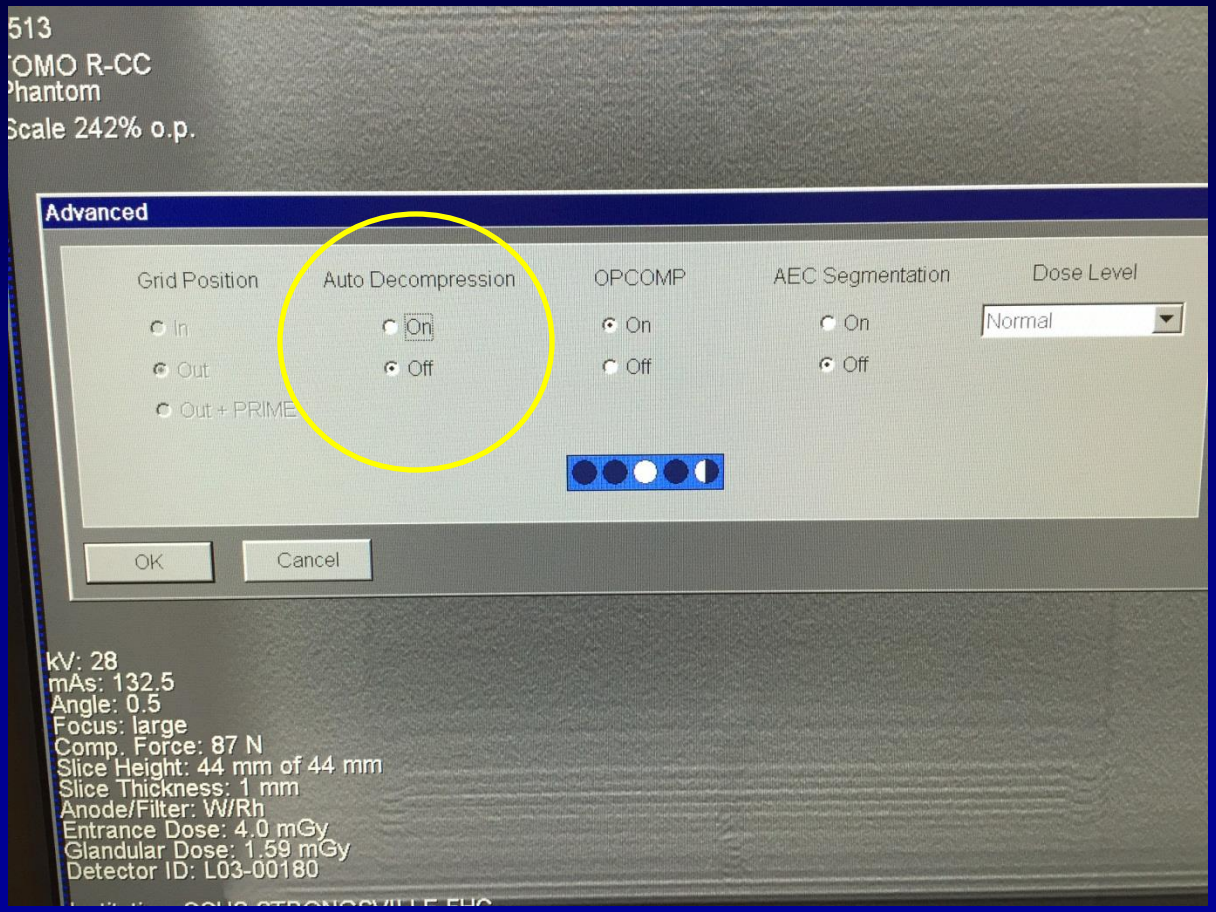

2
SIEMENS


3
SIEMENS


4
SIEMENS

Make sure Auto Decompression is turned OFF!!!!!

(unless you want to pay for broken ACR phantoms…)



Test 4: Phantom Image Quality

- **Tolerance Criteria:**
  - ≥ 4 Fibers
  - ≥ 3 Specks
  - ≥ 3 Masses

Test 5: Artifact Detection

Same setup as Test 3….

- **Equipment:**
  - Collimator mounted plexi (40 mm PMMA)
  - 25cm x 36cm tomo paddle
- **Settings:**
  - Procedure: **QC-raw Tomo**
  - Mode: AEC
    - OPCOMP = **ON**
    - Auto Decompression = **Off**
    - AEC Segmentation = **Off**
    - Dose Level = **Normal**

Test 5: Artifact Detection

Same setup as Test 3….

- **Procedure:**
  - Touch compression paddle to object table
  - Perform *Tomo scan*
  - Check projections and slices for clinically relevant artifacts (evaluate under acquisition size)

Test 5: Artifact Detection

- **Tolerance Criteria:**
  - There should be no clinically relevant artifacts visible in the images.

Final Comments (Physics Testing)

- **The QC manual does NOT require that the user verify that the combined dose of 2D+3D for the standard breast is <3mGy in combo mode**
  - **All testing (including AGD measurements) outlined in QC manual is for "tomo-only" mode**
- **However, compliance with this (not-so-explicit) regulation is expected by the FDA!!!**

21CRF 900.12(e)(6)

Quality Control Tests – **other modalities.**

For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

Ensuring 2D+3D AGD ≤3mGy Combo Mode

- **Unlikely to be an issue for new installs**
  - Factory settings generally ensure the *measured* AGD for 2D images is ~0.8-0.9 mGy for the standard breast
- **Potential issue for upgraded units**
  - CCF Experience
    - » 3 out of our 8 units that were initially upgraded could not meet Siemens' CNR criteria when AEC screening target was dropped to achieve AGD of 0.9 mGy for 2D images (previously operating at 1.0-1.1 mGy AGD)

Ensuring 2D+3D AGD ≤3mGy Combo Mode

- **Potential issue for upgraded units**
  - CCF Experience (continued…)
    - » Huge variation in measured CNR between phantoms…
    - » After initial set of upgrades, the following standard was set:
      - Nominal AGD of 0.9 mGy (as long as CNR ~2.2-2.3)
      - 2D/3D Factor of ~170 (found this best matched tomo dose between tomo-only and combo mode)

Ensuring 2D+3D AGD ≤3mGy Combo Mode

- **Potential issue for upgraded units**
  - CCF Experience (continued…)
    - For upgraded units where CNR is too low at 0.9 mGy AGD, the following standard was set:
      - Increase target dose for screening to achieve CNR ~2.3
      - Adjust 2D/3D factor to match tomo dose (at 4cm) between tomo-only and combo mode

Ensuring 2D+3D AGD ≤3mGy Combo Mode

Upgraded to DBT
New Install

							AEC Settings			ACR - Combo			ACR - Tomo Only		
Facility	Room	Thick	mAs	AGD	SNR	CNR	Screening	Tomo	2D/3D	mAs	Tomo mGy	Total mgy	mAs	Tomo mGy	Total mGy
Site A	1	40	95.0	0.99	60.7	2.28	125%	190%	150	138	1.75	2.76	134	1.61	2.6
	2	40	97.5	0.98	59.9	2.32	120%	170%	145	137.8	1.75	2.76	135.2	1.65	2.63
	3	41	91.5	1.027	62.8	2.44	120%	190%	155	140.5	1.73	2.8	137.5	1.63	2.66
	4	39	79.2	0.883	65	2.71	115%	200%	170	133.8	1.72	2.65	132	1.63	2.51
Site B	1	41	79.6	0.909	57.7	2.08	110%	180%	170						
	2	40	101.3	1.175	64	2.18	135%	190%	130	130.8	1.71	2.92	129	1.62	2.79
	3	41	83.2	0.881	58.2	2.37	115%	200%	170	138.8	1.76	2.68	134	1.61	2.49
Site C	1	43	74.3	0.712	52	2.19			200	149.3	1.92	2.64	137.3	1.7	2.41
	2	40	85.5	0.813	58.8	2.31			200	161	1.98	2.79	148	1.76	2.57
	3	40	80.2	0.813	62.1	2.51	115%	200%	170	130.3	1.68	2.52	130	1.61	2.42
	4	41	79.8	0.849	62.9	2.34	105%	185%	175	130.5	1.61	2.45	130.5	1.57	2.42
Site D	1	42	84.0	0.891	58.1	2.31	115%	175%	170	139.3	1.74	2.66	134.8	1.62	2.51
Site E	2	40	80.0	0.891	65.1	2.52	115%	200%	170	130.8	1.66	2.57	132	1.61	2.5

Technologist QC Program

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

Recommended frequency of QC tests

The following table specifies when the different tests are to be performed and by whom:

Test	Annually	Daily
1. Glandular dose	MP	
2. Geometric accuracy in X and Y direction and Z-resolution	MP	
3. Radiation field	MP	
4. Phantom image quality	MP	T - only on days when tomo is performed - only the test with tube head at 0°
5. Artifact detection	MP	

MP = Medical Physicist

T = Technologist

If not otherwise specified, measurements are performed with the tube head in 0° position.

Test 4: Phantom Image Quality

- **Equipment:**
  - ACR Phantom
  - 25cm x 36cm tomo paddle
- **Settings:**
  - Procedure: **QC-raw Tomo**
  - Mode: AEC
    - OPCOMP = **ON**
    - Auto Decompression = **Off**
    - AEC Segmentation = **Off**
    - Dose Level = **Normal**

Test 4: Phantom Image Quality

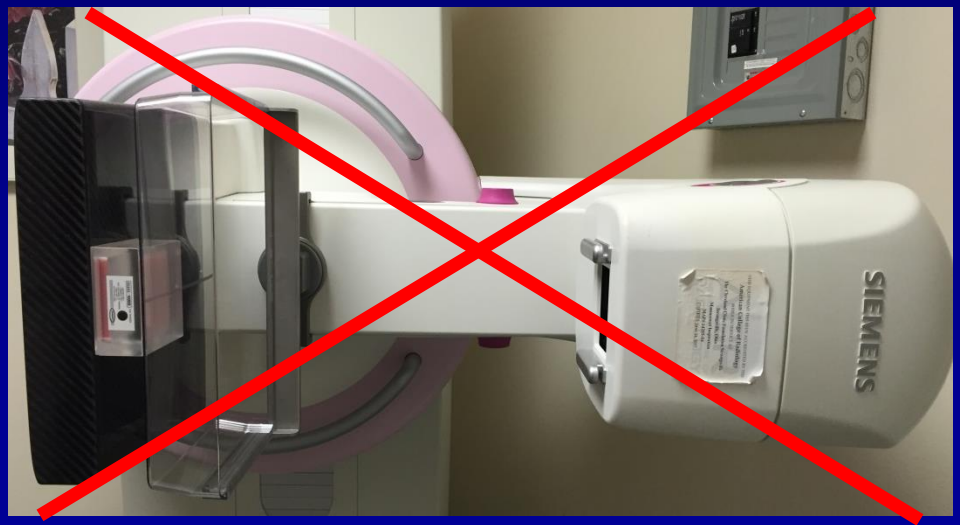
- **Procedure:**
  - Acquire 2 *Tomo scans** at 28 kVp:
    - 0 degree angulation
    - 0 degree angulation with phantom upside down
  - Scroll through each data set and select slice where objects are best visible
  - Score the phantom for each tomo scan

*As mentioned before, this refers specifically to a tomo scan acquired in tomo-only mode


1
SIEMENS


2
SIEMENS


SIEMENS


SIEMENS

Test 4: Phantom Image Quality

- **Tolerance Criteria:**
  - ≥ 4 Fibers
  - ≥ 3 Specks
  - ≥ 3 Masses

Tomo Detector Calibration

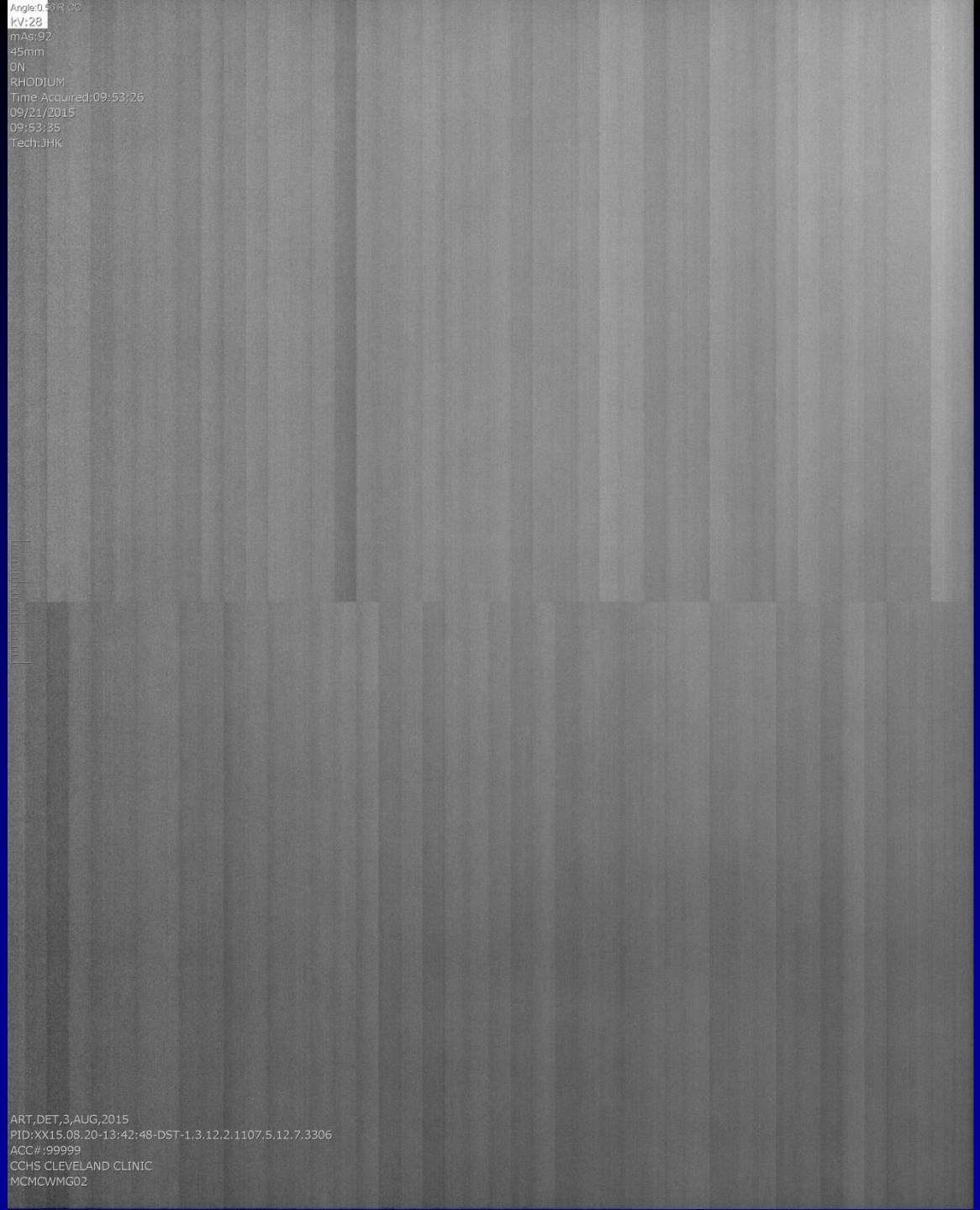
- **Procedure:**
  - Tube in 0^0 position – no paddle
  - 40 mm collimator mounted plexi
  - Minimum of 7 “scans”

Tomo Detector Calibration

- Should be calibrated every 3 months
- Should be calibrated if temperature of room deviates by more than 7^0C from temperature at the last calibration
- Recommended that tomo calibration be performed after contact calibration

Tomo Detector Calibration

- Note: we have encountered artifacts in contact and mag images after a tomo calibration has been run…
- Unit should be rebooted immediately following a tomo calibration



Segmentation artifact (contact mode) due to failure to reboot system after running tomo calibration

FDA Certificate Program Submission Requirements

DBT Submission Requirements

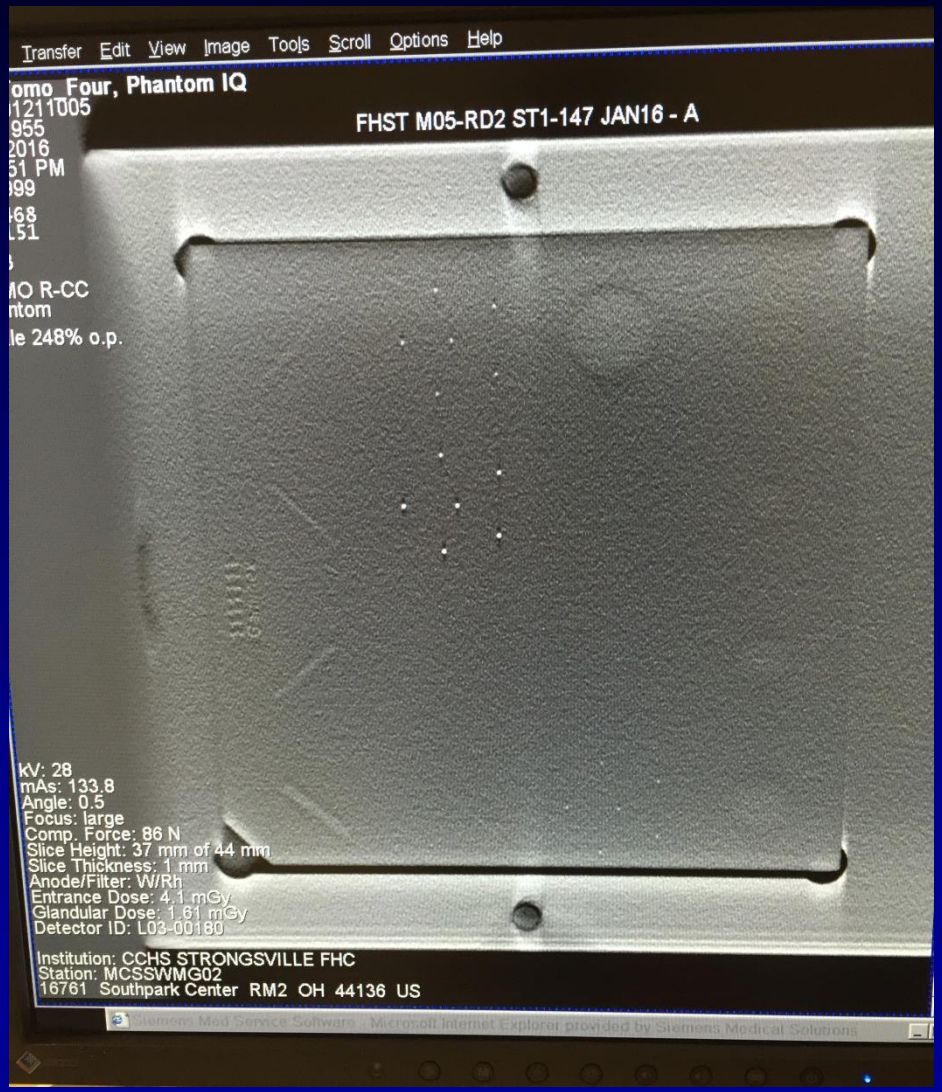
- **Detailed MEE completed within 6 months prior to request for facility extension**
- **All vendor required tests for tomosynthesis performed (and passed)**
- **Tomo phantom image**
  - Hard Copy or Soft Copy (CD or DVD, must be in DICOM format)

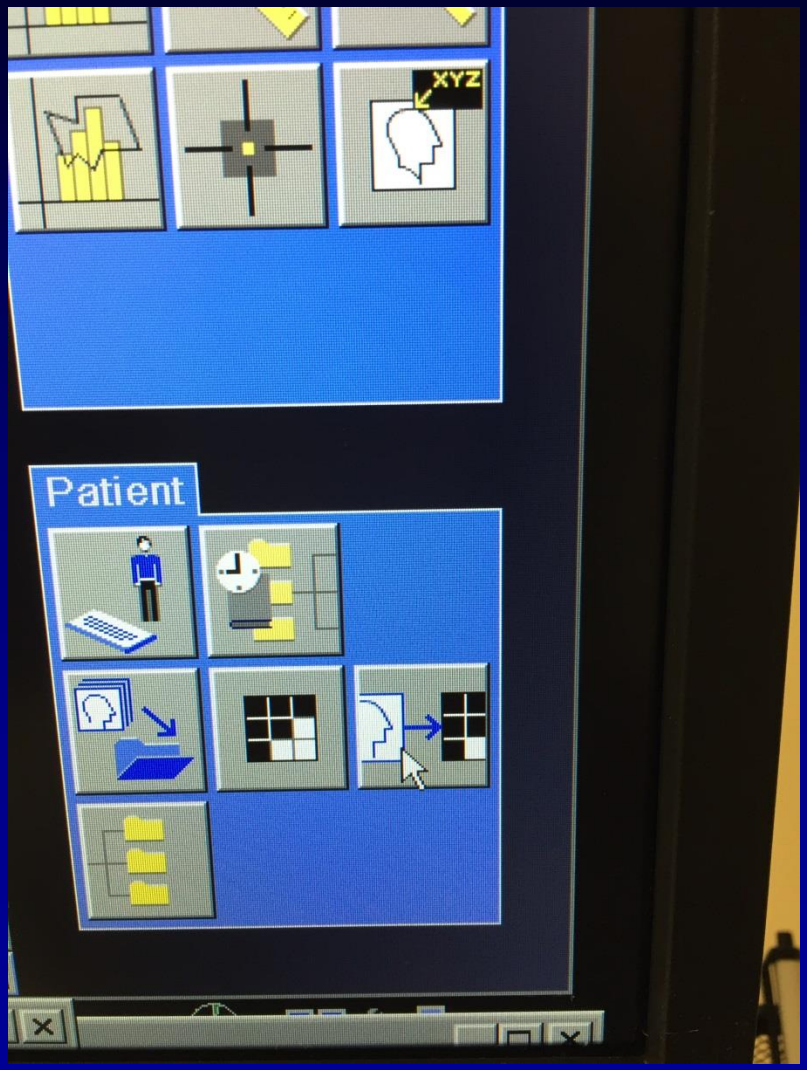
DBT Submission Requirements

- **Detailed MEE completed within 6 months prior to request for facility extension**
  - NOTE: most upgrades will require replacement of the collimator and pc, thus will require a post-repair evaluation prior to clinical use even if the 3D evaluation is done at a later date
  - Sites may not be aware of this!!!

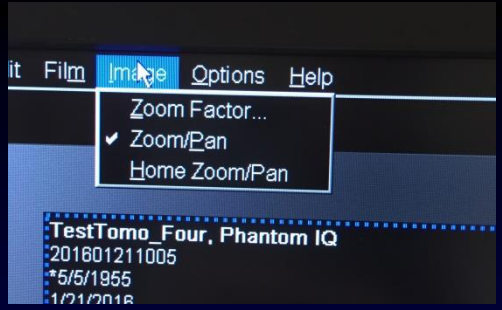
Hard copy image:

Select slice where objects are best resolved…



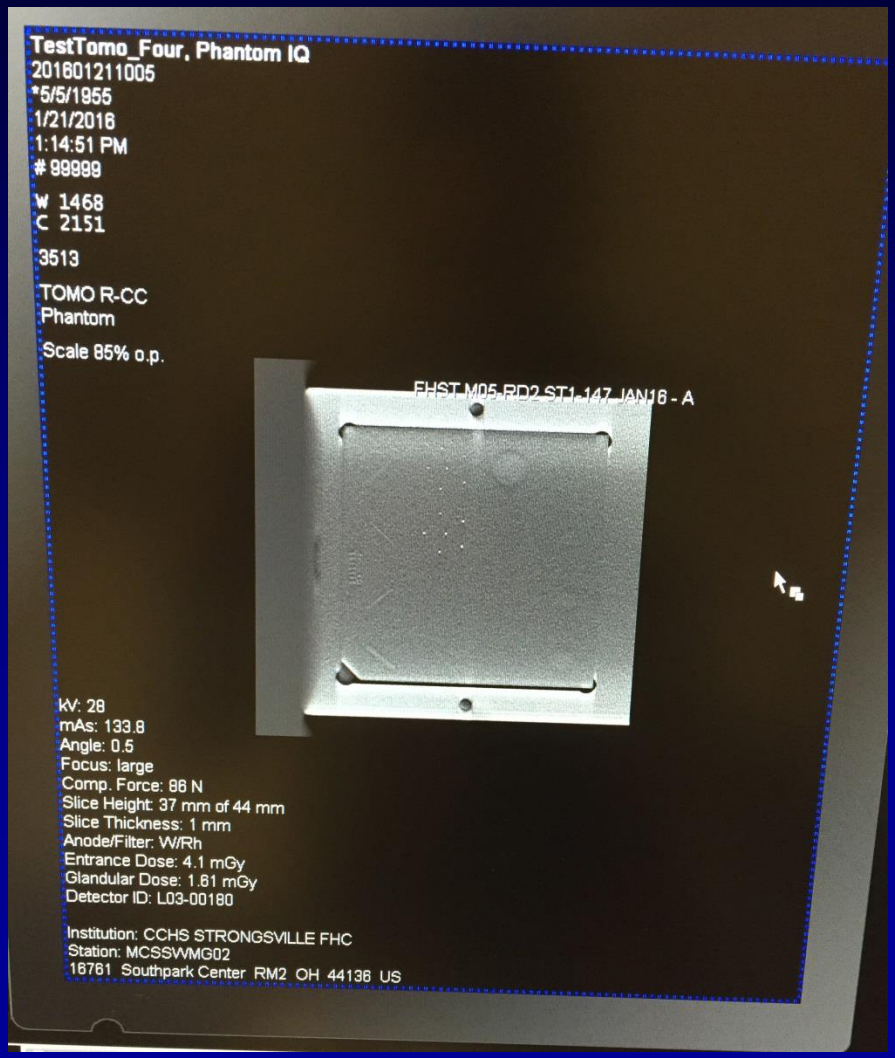


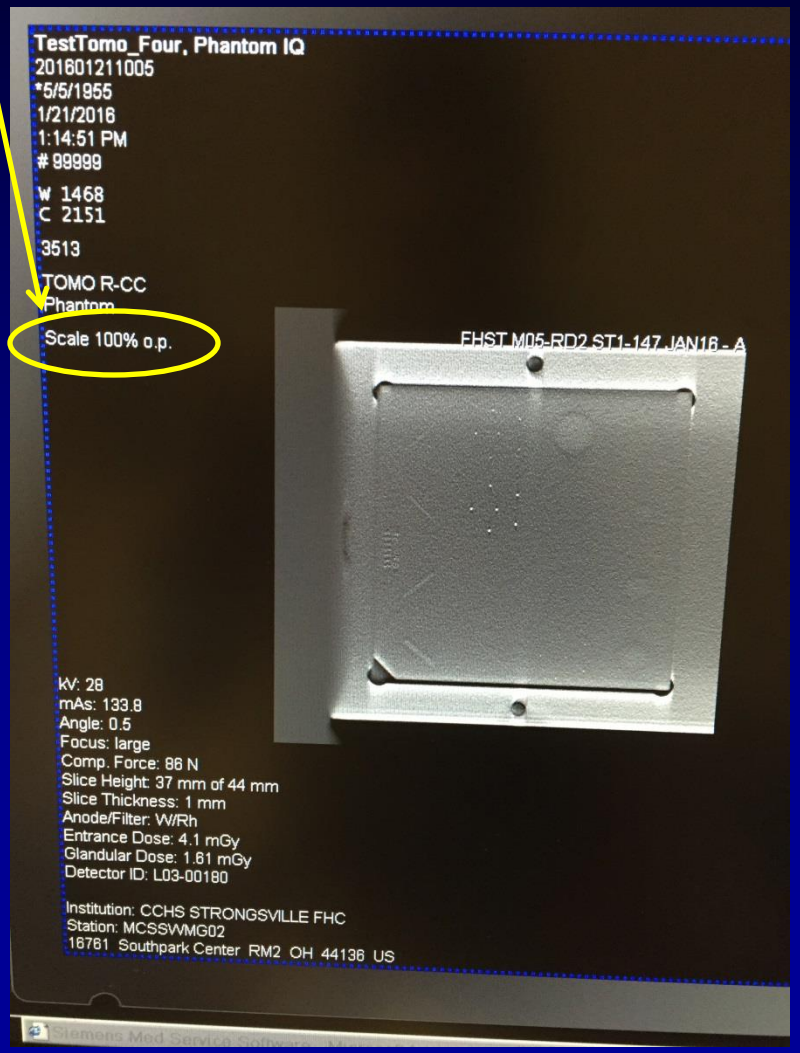
Copy to film sheet…



Window and level as needed

Set scale to 100%





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- MAMMOMAT Inspiration Tomosynthesis Option – Quality Control Manual VB30 or higher (XPW7-330.621.54.01.24 Version 1 Date 05.05.2015)
- MAMMOMAT Inspiration Tomosynthesis Option – Operator Manual (XPW7-330.621.53.01.24)
- MAMMOMAT Inspiration– Quality Control Manual VB30 or higher (SPB7-330.640.50.05.24 Version 5 Date 07.11.2013)

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