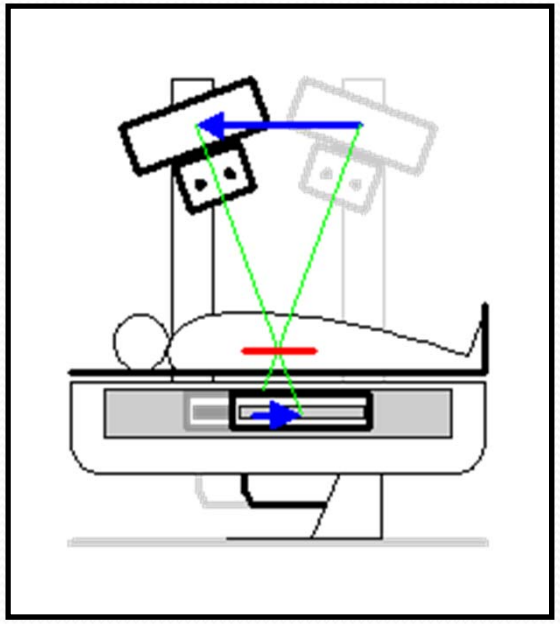
SEAAPM 2014

Clinical Experience with Breast Tomosynthesis

George David, MS, FAAPM, FACR
Associate Professor of Radiology
Georgia Regents University
Augusta, Georgia

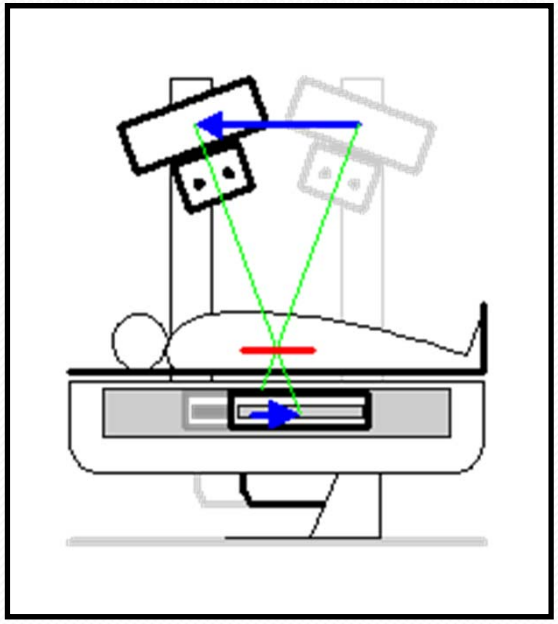
Body Section Tomography

- Not CT
- Body Section Imaging
- Goal
  - keep plane of interest in focus
  - blur all other plans
    - enhances contrast
- Popularity decreased because of
  - CT
  - MRI

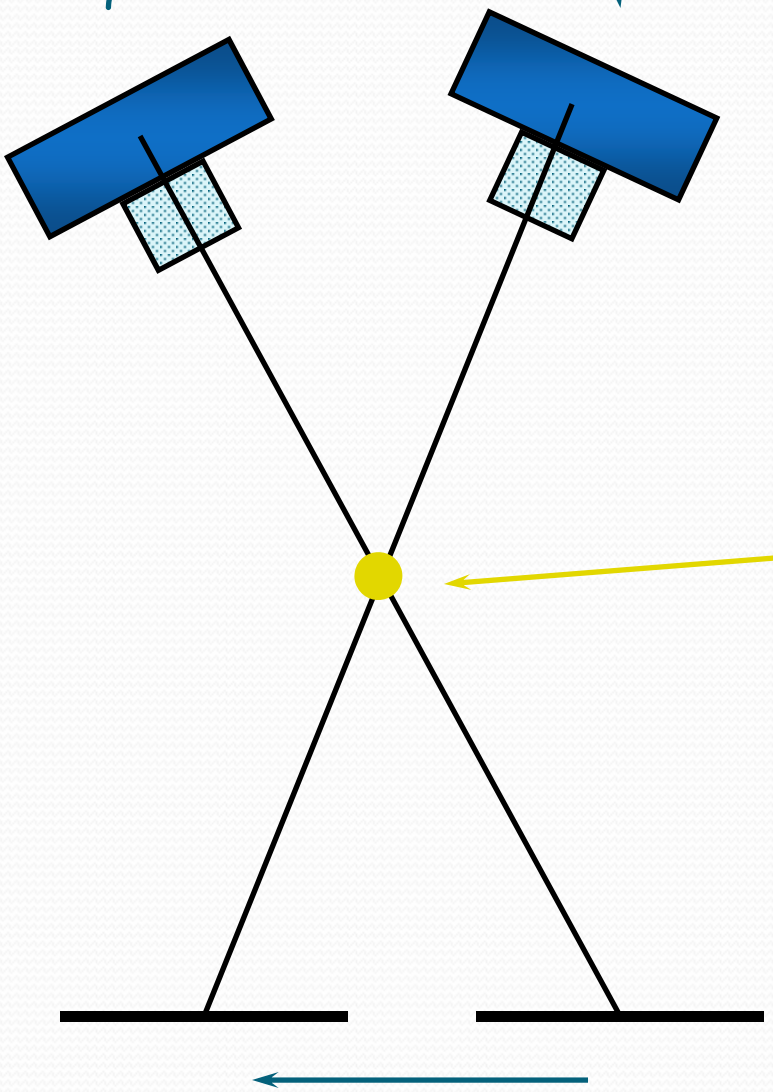


Tomography History

- Predates CT by decades
- Was popular for inner ear studies

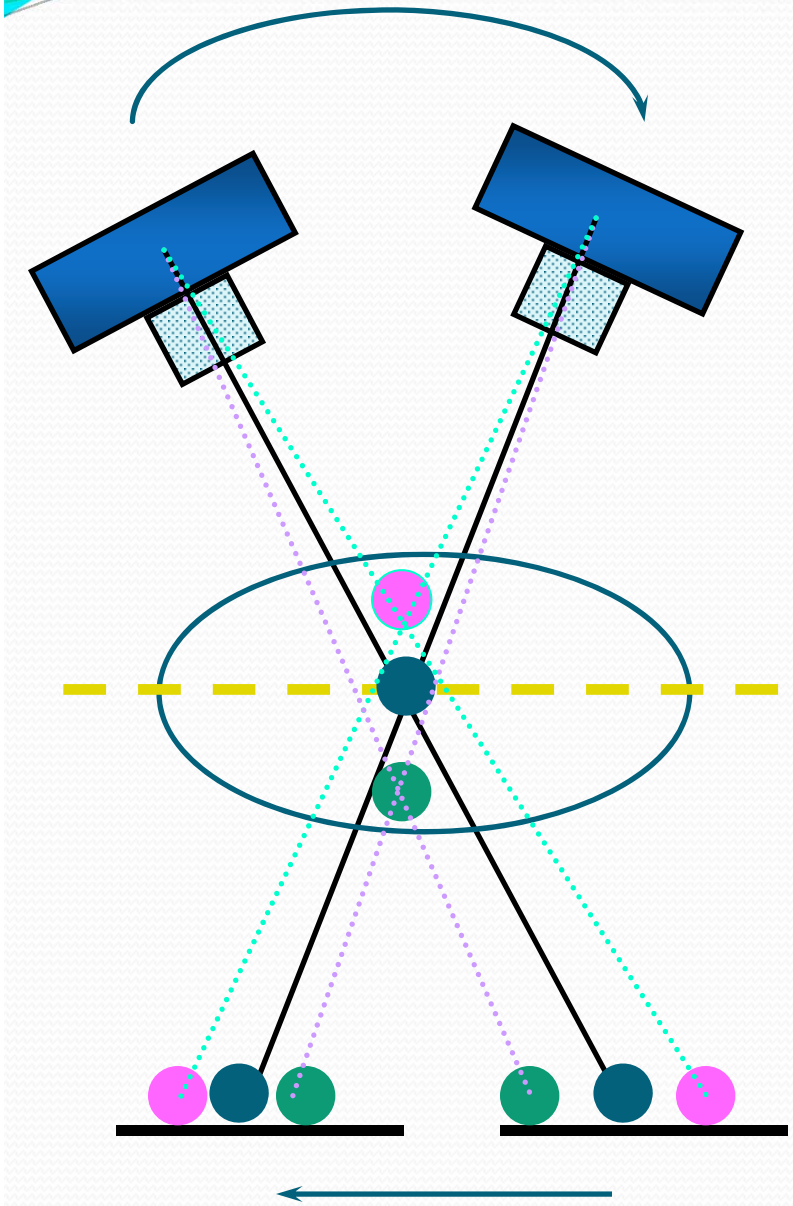


Tomography Blurring

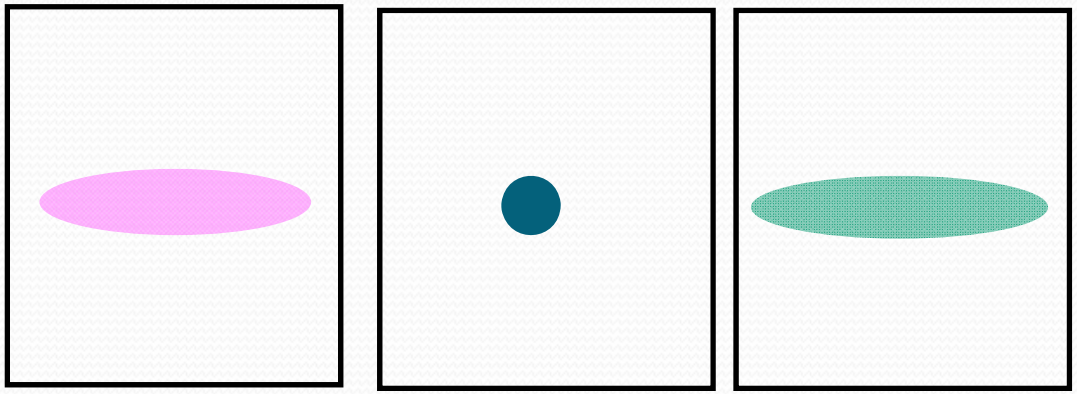


- Blurring accomplished by synchronous movement of tube & film
  - tube & bucky physically connected by rod
  - rod pivots around fulcrum
  - tube moves one direction
  - film moves in other direction

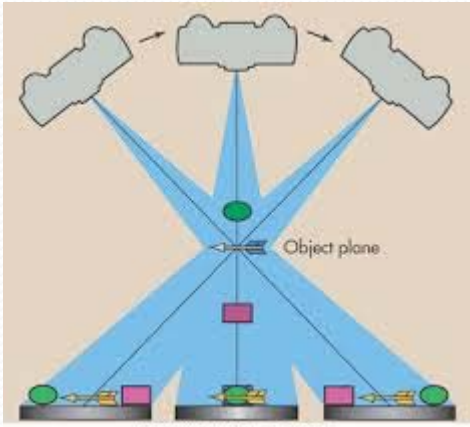
Conventional Tomography Blurring



- Image produced on film
- Objects above or below fulcrum plane change position on film & thus blur



Multiple Tomo Images



- Film: only one image per cut with
  - cuts at many levels routinely employed to find cut of interest
  - each cut exposes entire field
- Digital receptor: multiple images per cut
  - Computer simulates
    - Speed of receptor
    - Vertical position of fulcrum

FDA Approval of Tomosynthesis

- February 11, 2011

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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Selenia Dimensions 3D System - P080003

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Selenia Dimensions 3D System
PMA Applicant: Hologic, Inc.
Address: Hologic, Inc., 35 Crosby Dr., Bedford, MA 01730
Approval Date: February 11, 2011
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf8/p080003a.pdf

What is it? The Selenia Dimensions System is a mammography device that provides digital 2D and 3D images for the screening and diagnosis of breast cancer.

How does it work? The Selenia Dimensions 3D System is comprised of hardware and software upgrades to the Selenia Dimensions 2D full-field digital mammography system, which is FDA approved for conventional mammography. The hardware upgrades produces multiple, low-dose x-ray images of the breast; the software upgrade uses the low-dose images to create cross-sectional (tomosynthesis) views through the breast.

Specifications

- Tube
  - 0.3 / 1.0 mm focus
    - Tomo: 1.0
  - Tungsten target
- Filters
  - Rh
  - Ag
  - Al
- Detector
  - Amorphous selenium direct capture
  - 70 µm pixel
    - 2X2 pixel binning for tomo
  - 24 X 29 cm

Tomo Protocol

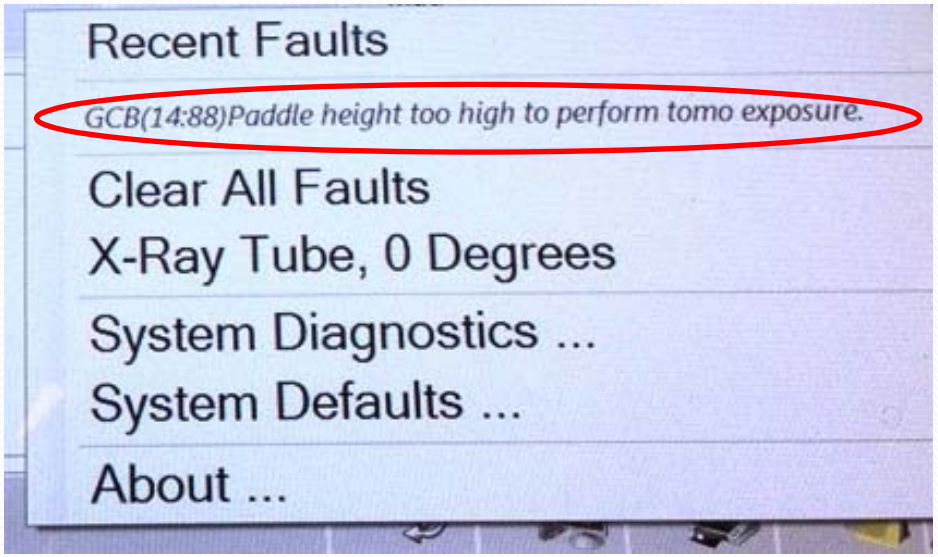
- No Grid
- Aluminum Filter
- Exposures
  - 15 short exposures over 15° range (-7.5 ° - 7.5°)

Assumption

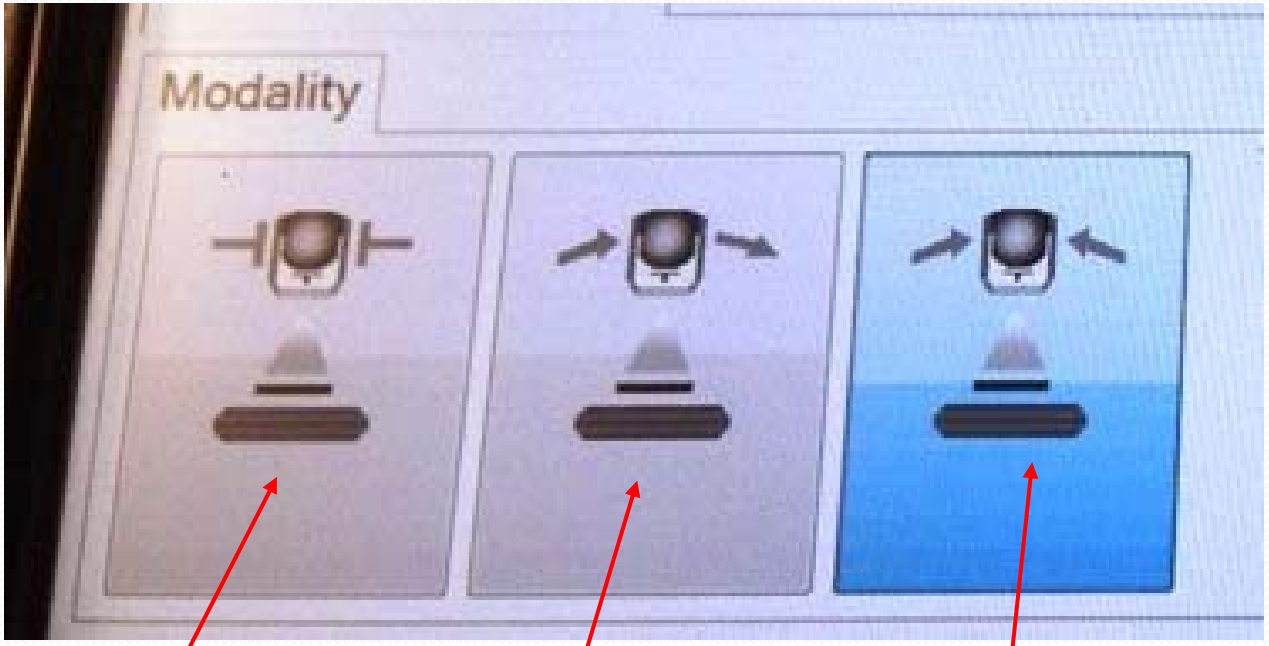
- Basic Familiarity with Digital Tomography Surveys

Warning

- Tomosynthesis exposure requires compression device < 24 cm

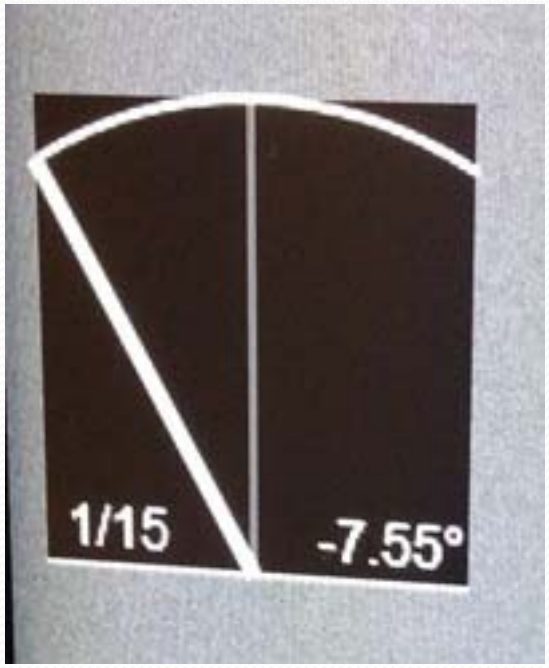


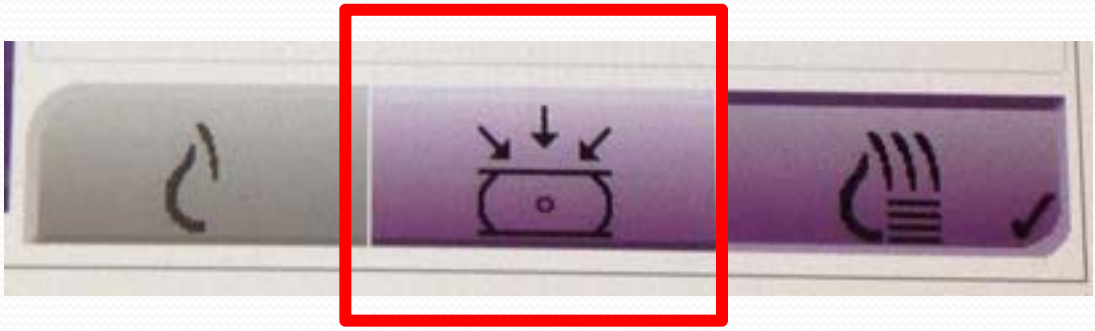
Exposure Flavors

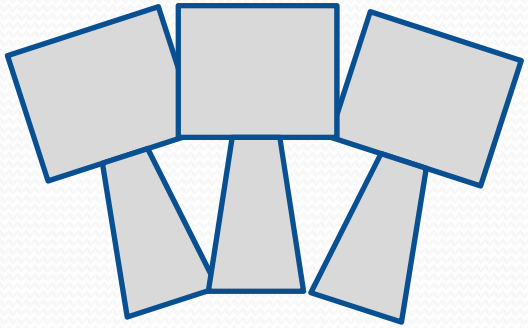


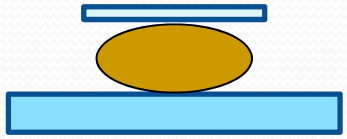
- Normal 2D projection
- Flat Field Tomo
  - 15 exposures
  - Tube moves
    - -7.5°-+7.5°
- Zero-degree Tomo
  - 15 exposures
  - Tube stationary

Tomo Viewing Options



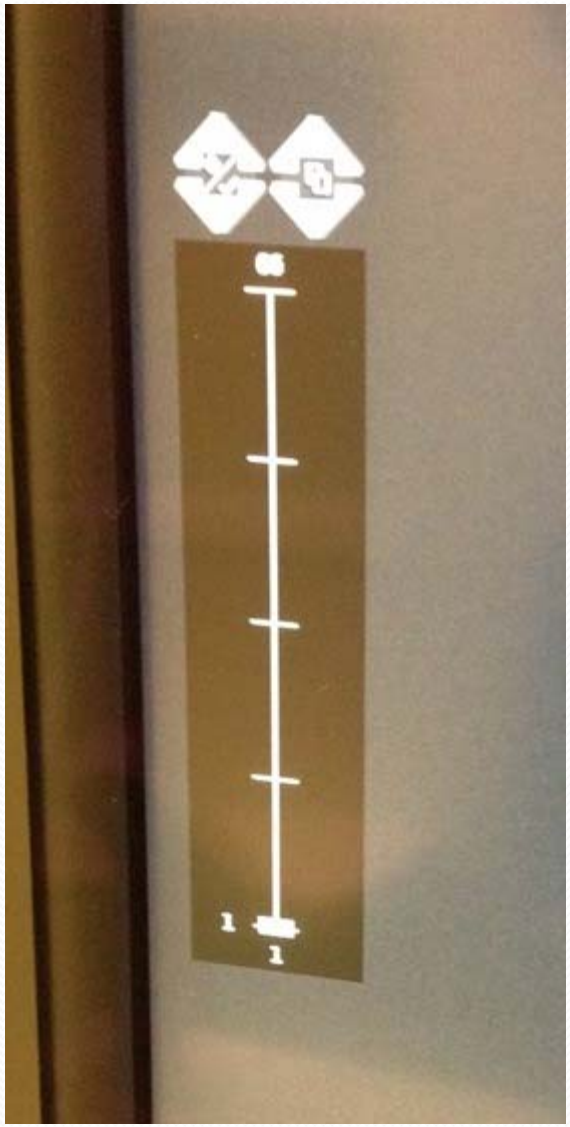


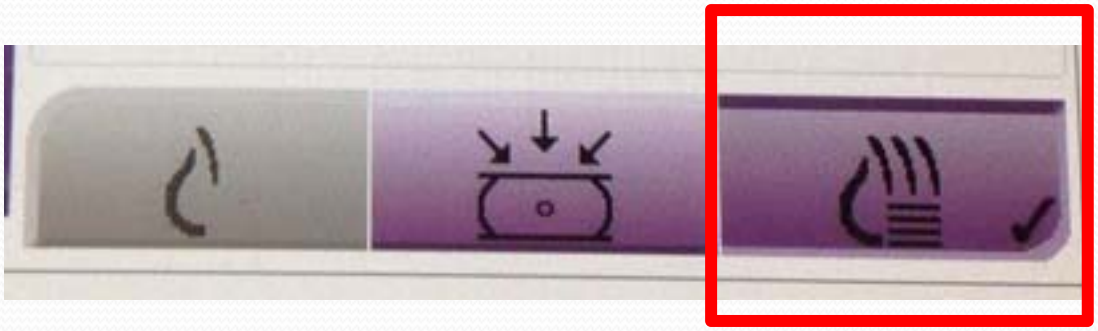




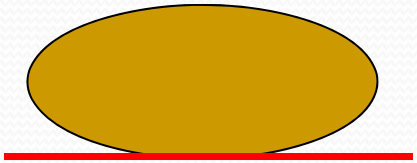
- Can view each of 15 projection images individually
- Controlled by roller device on console

Tomo Viewing Options



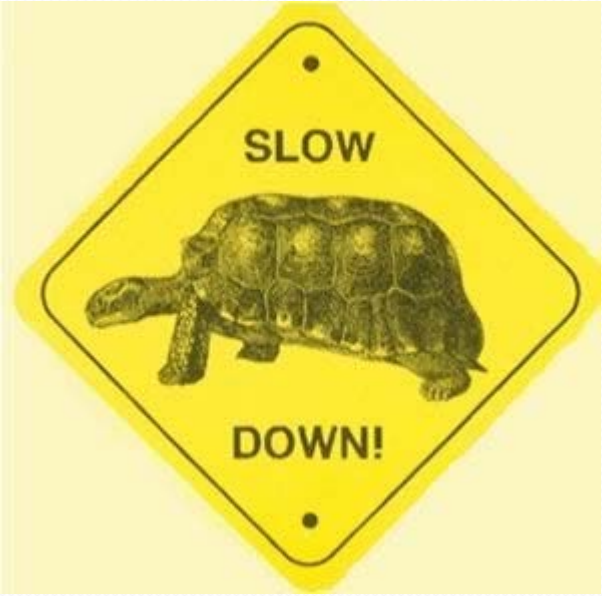


- Can view each 1 mm thick slice individually
- Controlled by roller device on console



Survey Differences for Tomo

1. Unit Evaluation
2. Collimation
3. Artifact Evaluation
4. kVp
5. Beam Quality
6. System Resolution



7. AEC
8. AEC Reproducibility and AGD
9. Output Rate
10. Phantom Image Quality
11. Signal/Noise
12. Review Workstation QC

Collimation & Tomosynthesis X-Ray – Receptor Alignment

	Collimation(cm)	24 x 29	18 x 24 (L)	18 x 24 (C)	18 x 24 (R	18x29 (C)*Tomo
Left Edge	Preview Measurment(cm)**	0.9	0.9	0.7	0.6	1
	f(ERMF)Corrected(cm)***	0.93	0.93	0.72	0.62	1.03
	Attenuator Difference(cm)****	0.77	0.77	0.98	1.08	0.67
	Total Deviation*****	0.92	0.92	1.01	1.12	0.69
	% of SID (retain sign)****	**1.31%**	**1.31%**	**1.45%**	**1.60%**	**0.99%**
Right Edge	Preview Measurment	1.20	1.00	1.20	1.30	1.20
	f(ERMF)Corrected	1.24	1.03	1.24	1.34	1.24
	Attenuator Difference	0.46	0.67	0.46	0.36	0.46
	Total Deviation	0.94	1.15	0.48	0.37	0.48
	% of SID (retain sign)	**1.34%**	**1.65%**	**0.68%**	**0.53%**	**0.68%**
Anterior Edge	Preview Measurment	1.2	0.8	0.9	0.9	1.0
	f(ERMF)Corrected	1.24	0.83	0.93	0.93	1.03
	Attenuator Difference	0.46	0.87	0.77	0.77	0.67
	Total Deviation	0.59	1.02	0.80	0.80	0.69
	% of SID (retain sign)	**0.85%**	**1.46%**	**1.14%**	**1.14%**	**0.99%**
Chest Edge	Preview Measurment	1.8	1.6	1.5	1.5	1.7
	f(ERMF)Corrected	1.86	1.65	1.55	1.55	1.76
	Attenuator Difference	-0.16	0.05	0.15	0.15	-0.06
	Total Deviation	-0.17	0.05	0.16	0.16	-0.06
	% of SID (retain sign)	**-0.24%**	**0.07%**	**0.22%**	**0.22%**	**-0.08%**

Zero-Degree Tomo

Artifact Evaluation & Tomosynthesis

- View middle projection
- View size: “Actual Pixels”

Flat-field Tomo

Acrylic Phantom

Image size (cm)	24x29	24x29	24 X 29*(tomo)	18x24	18x24
Target/Filter	W/Rh	W/Ag	W/Al	W/Rh	W/Ag
Focal spot	large	large	large	small	small
Acceptable?	Yes	Yes	Yes	Yes	Yes
Comments					

Beam Quality (HVL) & Tomosynthesis

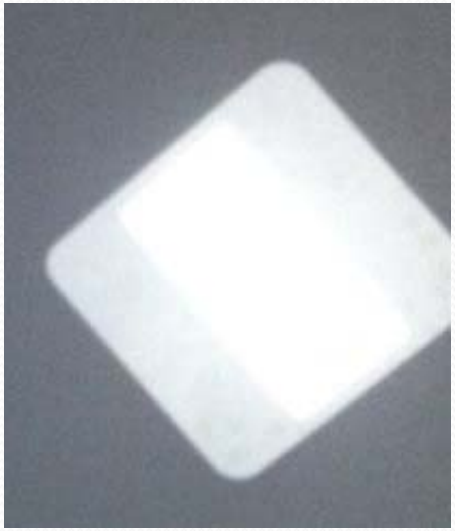
- Radiation exposure summed over 15 exposures
- Analysis identical to non-tomo
- All acquired @ 0° which avoids
  - foil thickness change with angle
  - Field coverage issues with moving tube

Zero-Degree Tomo

System Resolution & Tomosynthesis

Flat-field
Tomo

System Resolution & Tomosynthesis



System Resolution & Tomosynthesis

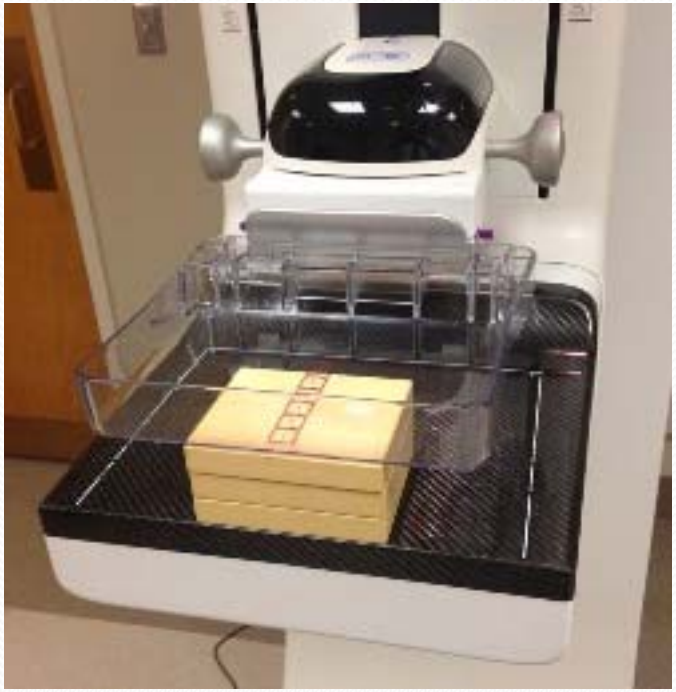
- Tomo Limiting resolution less than non-tomo
  - Pixel Binning

Minimum Limiting Resolution
cycles / mm

2D	3D
7	3

AEC Evaluation & Tomosynthesis

- Same as non-tomo with different correction factors for tomo
- Many flavors of correction factors
  - Coordinate with service engineer



Flat-field
Tomo

AEC Reproducibility, MGD, & Tomosynthesis

- Must check all 3 modes
  - 2D
  - 3D
  - Combo
    - 3D followed by 2D

DO NOT add 2D & 3D to get Combo mode MGD. They are calibrated separately

Multiple Exposures & RTI

- 2D Mode
  1. Pre-exposure
  2. Imaging Exposure
- 3D Mode
  1. Pre-exposure
  2. 15 exposures

- Must pre-set meter for filter
- Each mode produces two “mR” readings
- Must add 2 readings together

Combo Mode MGD on RTI

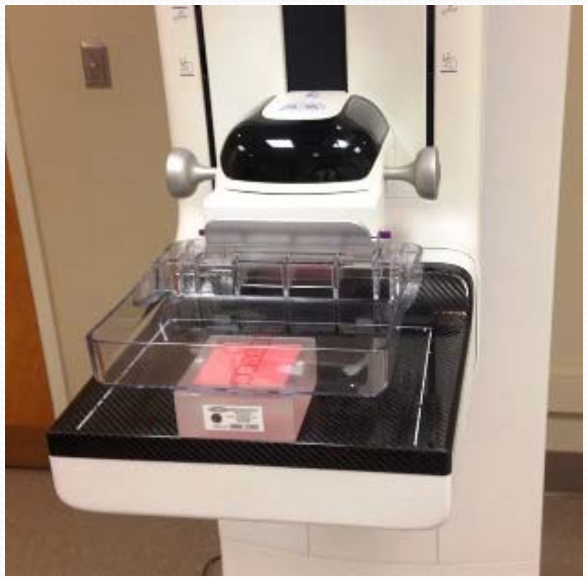
- 3D Mode (Al filter)
  1. Pre-exposure
  2. 15 exposures
- 2D Mode (Rh filter)
  3. Pre-exposure
  4. Imaging Exposure

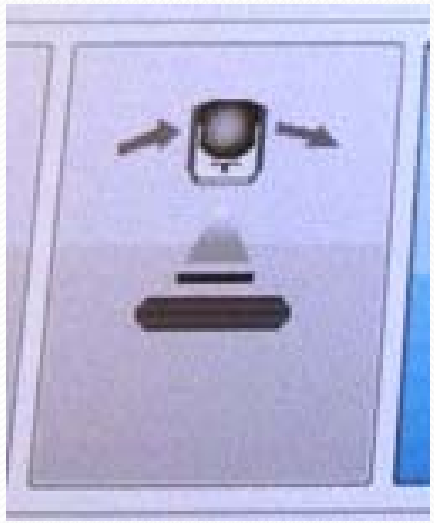
- Run combo mode 2X
- 1st run (3D)
  - Preset meter for W/Al
  - Record & Add #1 & #2 above
- 2nd run (2D)
  - Preset meter for W/RH
  - Record & Add #3 & #4 above
- Total combo mode MGD is sum of 1st & 2nd run

Phantom Image Quality, MGD, & Tomosynthesis

- Check only in plane of phantom objects
- Different scoring requirements from 2D

	2D	3D
Fibers	5	4
Speck Groups	4	3
Masses	4	3





Flat-field Tomo


THE
END


End