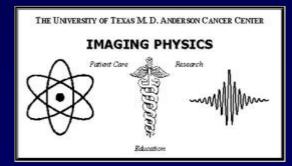
Implementation of a New Tomosynthesis Program: A Physicists Perspective

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Making Cancer History®





Conflict of Interest

None of the authors nor their immediate families have a financial relationship with a commercial organization that may have a direct or indirect interest in this content.

Learning Objectives

- Be able to assist with implementation of breast tomosynthesis at their facility
- Know process of accreditation and certification of DBT systems
- Understand additional shielding requirements and facility design for a facility installing digital breast tomosynthesis.

Introduction

- Why Breast Tomosynthesis?
- Facility Design Requirements
- PACs and Storage Requirements
- Review Station Requirements

FDA Approval

- Breast Tomosynthesis was approved by the FDA for use as a breast cancer screening tool in February 2011
 - Using combined study
 - Tomosynthesis run
 - Full dose 2D image
 - Need CC and MLO views (standard screening exam)
 - Double dose compared to standard 2D screening exam

The Latest on Tomosynthesis

- May 2013 C-View approved by the FDA
 - Synthesized 2D view
 - Webpage for guidance for coding when using C-view
 - <u>http://www.acr.org/News-Publications/News/News-Articles/2013/Economics/20130528-Coding-guidance-provided-for-performance-of-breast-tomosynthesis</u>

Publications, Posters, Presentations 2011

• RSNA

- 10 posters or presentations
- Same or better diagnostic accuracy
- Reduces recall rates
- Improvement in sensitivity, specificity and negative predictive value
- Others
 - 7 papers or presentations

Publications, Posters, Presentations 2012

• RSNA 2012

- 18 presentations or posters discussing DBT

- Others 2012
 - 8 other presentations, papers or posters at other meetings

From Hologic flier titled: Select Scientific Publications of Breast Tomosynthesis 2012

Where are we at?

- Certified systems as of 2/1/2013 ->300 installs
- Expected new certifications by 9/2013
 500 700 installs

Facility Design the Team

- Radiologist
- Department Administrator
- QC Technologist
- Medical Physicist
- Architect/Capitol Planning and Management
- Vendor Representative/Service Engineer
- PACS Administrator

Radiologist/Medical Physicist

- Reading Room
 - Lights
 - Review station
 - Table
 - Reporting system



QC Technologist

- System Layout
- QC Tools
- Printer
- Work Space Requirements

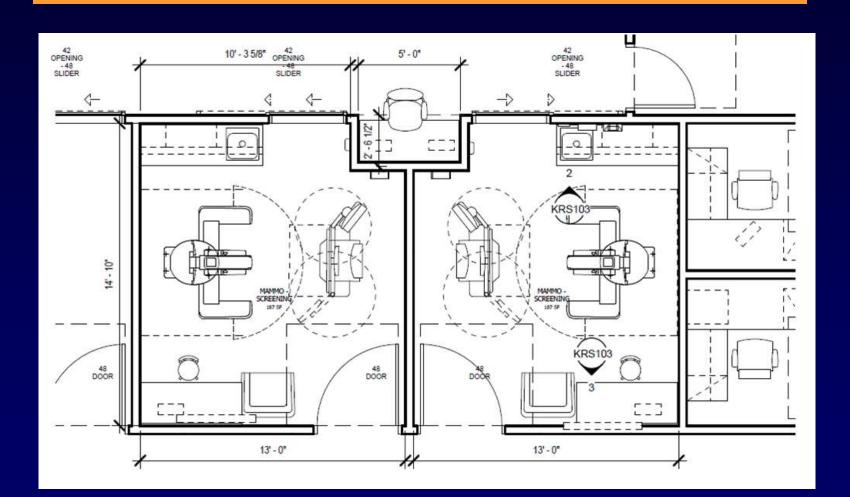
Medical Physicist

- Mammography System Specifications
- Room Design and Shielding
- Test Equipment and Storage
- Reading Environment
- PACS/DICOM

The Mammography Suite

- Use
 - Mammography only
 - Stereo attachment
 - Work flow manager included
 - Screening only
 - Diagnostic only
 - Both screening and diagnostic
 - Procedures (needle localizations, biopsies)

Room Design Space



Hologic Dimensions Specifications

- Technical specifications for the Dimensions
 SID = 70 cm
 - 200 mA Generator
- X-ray Tube
 - Tungsten target
- Filtration
 - Rh/Ag for mammography
 - Al for tomosynthesis

Shielding the Room

- Do you need more shielding than for a standard mammography suite?
- What information do you need?
 - Workload
 - Number of 2D exams?
 - Number of combined exams?
 - Anode filter combinations?

Shielding

- NCRP 147
 - The mammographic image-receptor assembly is required by regulation to serve as a primary beam stop to the vast majority of the primary radiation (FDA, 2003b). A small strip (<1.2 cm) of primary radiation up to two percent of the SID in width is allowed to miss the image receptor along the chest-wall edge of the beam. However, most of this radiation is attenuated to insignificant levels by the patients. Hence, only secondary radiation need be considered for mammography rooms.

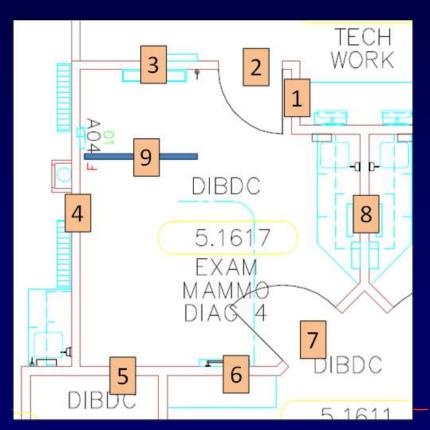
Shielding

- Differences in the shielding requirements between mammography beams generated by molybdenum, rhodium or tungsten anodes with molybdenum, rhodium and aluminum filtration at operating potentials not exceeding 35 kVp are not significant.
 - NCRP 147 Chapter 5 Section 5 Examples of Shielding Calculations: Mammography page 91
- It is a very rare occasion that you will exceed 35 kVp for 2D or 3D imaging

Shielding Results

• For most facilities shielding requirements will not change. However the medical physicist should perform a shielding calculation to verify that existing wall construction and doors will adequately shield all areas.

		Thicknes	s (mm)		
Barrier ID	Barrier	Shielding requirement	Present in the room	Acceptable	Barrier material
1	Wall to technologist workstation in hallway	6.295	14	Yes	Gypsum wallboard
2	Door to technologist hallway	-13.563	43	Yes	Solid wood
3	Wall to technologist hallway	0.927	14	Yes	Gypsum wallboard
4	Wall to technologist corridor	5.933	14	Yes	Gypsum wallboard
5	Wall to patient changing area	8.328	14	Yes	Gypsum wallboard
6	Wall to patient waiting area	6.295	14	Yes	Gypsum wallboard
7	Door to patient waiting area	48.183	43	No	Solid wood
8	Wall to exam room 3	15.717	14	No	Gypsum wallboard
9	Technologist workstation leaded glass	0.065	0.5	Yes	Lead-equivalent glass
10	Ceiling	2.764	100	Yes	Concrete
11	Floor	4.820	100	Yes	Concrete

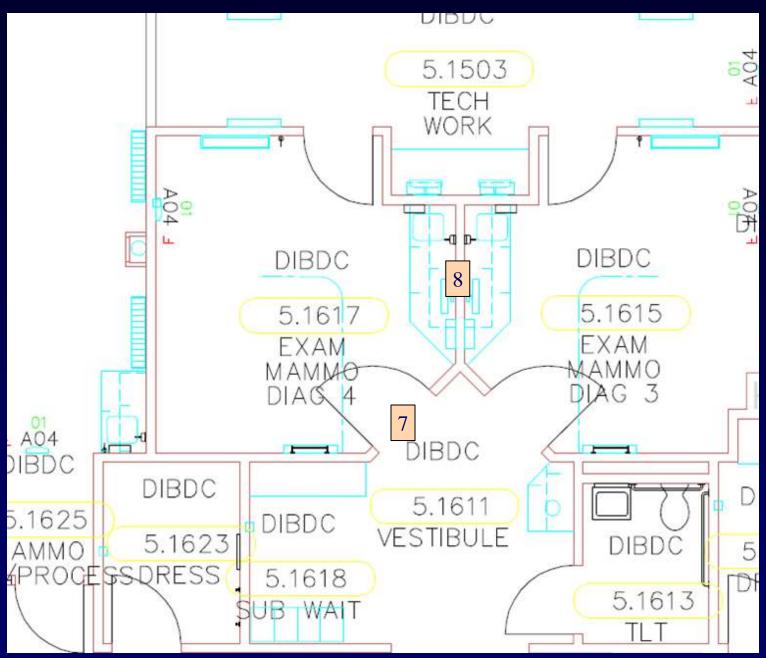


Occupancy

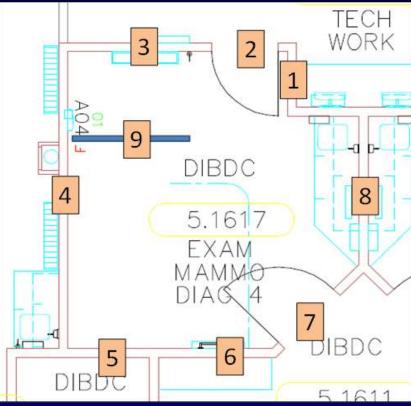
Barrier	Barrier ID	Distance from iscocenter (m)	1/r^2 correction	Occupancy factor (T)	Radiation exposure limits (mGy/week)
Wall to technologist workstation in hallway	1	3.00	0.111	1.00	0.10
Door to technologist hallway	2	3.31	0.091	0.13	0.10
Wall to technologist hallway	3	2.90	0.119	0.20	0.10
Wall to technologist corridor	4	1.40	0.510	0.20	0.10
Wall to patient changing area	5	1.20	0.694	0.05	0.02
Wall to patient waiting area	6	1.50	0.444	0.05	0.02
Door to patient waiting area	7	2.15	0.216	0.05	0.02
Wall to exam room 3	8	2.80	0.128	1.00	0.02
Technologist workstation leaded glass	9	1.22	0.672	1.00	0.10
Ceiling	10	1.70	0.346	0.05	0.02
Floor	11	1.10	0.826	0.05	0.02

Workload

- For screening will double



		Thicknes	s (mm)		
Barrier ID	Barrier	Shielding requirement	Present in the room	Acceptable	Barrier material
1	Wall to technologist workstation in hallway	6.295	14	Yes	Gypsum wallboard
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8	Wall to exam room 3	11.499	14	Yes	Gypsum wallboard
9	Technologist workstation leaded glass	0.065	0.5	Yes	Lead-equivalent glass
10	Ceiling	2.764	100	Yes	Concrete
11	Floor	4.820	100	Yes	Concrete



Storage - Questions and Answers

- New facility
 - Who is going to be our PACS vendor?
 - Main Hospital existing PACS?
 - Mammography system vendor solution?
- Existing facility
 - Use existing PACS?
 - Separate Mammography PACS?

Storage - Question and Answers

- New Facility
 - Existing PACS
 - Will PACS recognize Tomosynthesis DICOM modality?
 - Yes Send images as Tomosynthesis object
 - No Send images as MG or CT?
 - New PACS system
 - Insist that PACS is up to date and will recognize DBT DICOM modality

Legacy PACS Systems

- Relatively new
 - Should handle file sizes easily
- Older systems



- Rumors that old servers may not be able to handle large file sizes and system can crash
- May need new process server for mammography
- New PACS for mammography only

- Not able to view prior studies other modalities

Other things to think about

- Importing prior studies
- Exporting patient studies for patients going to new facility
- Will study fit on DVD?
 - Slice Size: 2457 rows x 1996 columns x 12 bits
 - 7.4 Mbytes per slice (12 bit)
 - 55 slices for a 5cm breast
 - 405 Mbytes/view!!

- Can study be broken up into image data sets?

Hologic DICOM

- Note: The Secondary Capture Image Storage object is used to encapsulate digital breast tomosynthesis data (Raw Projections, Processed Projections, Reconstructed Slices). Reconstructed Slices can be sent as Breast Tomosynthesis Image (preferred) or Secondary Capture Image, depending on what the remote storage AE supports.
- Can also be sent as Computed Tomography Image Storage

Image Review

- Question: How are your radiologists going to review Tomosynthesis data sets?
 - Mammography vendor workstation
 - After market mammography workstation
 - PACS workstation

Vendor Workstation

- Advantages:
 - Will easily accept tomosynthesis data
 - Has tools designed to allow reader to easily review tomosynthesis images
 - Has ready made hanging protocols for radiologist to choose from

Vendor Workstation

- Disadvantages
 - Need to pre-fetch priors from PACS
 - May not be able to view MRI, US or other modalities on workstation
 - Limited hanging protocols
 - May not display mammography images from other vendors properly (ww/wl, VOI lut...)

After Market Workstation

- Advantages
 - May be more easily upgraded to accept tomosynthesis data sets and display them properly
 - Be able to view mammography images from multiple vendors with proper display LUT
 - Other modalities may be displayed

After Market Workstation

- Disadvantages
 - Need to pre-fetch studies
 - Integration with current PACS system
 - May be limited in hanging protocol design
 - May not allow viewing of DBT as a image stack

PACS Review Station

- Advantages
 - Should be able to view all priors and other modalities in one place
 - No need to pre-fetch
 - Minimal training required

PACS Review Station

- Disadvantages
 - Legacy PACS may not recognize BTO image storage object
 - Hanging protocol development may be limited
 - Work station may not have necessary power to properly view tomosynthesis reconstructions

CT Object Storage

- We needed to read from PACS
- System would not stack reconstructions in either BTO or secondary capture.
- Hologic put in software that would convert tomo reconstructions to a modality CT object for storage.

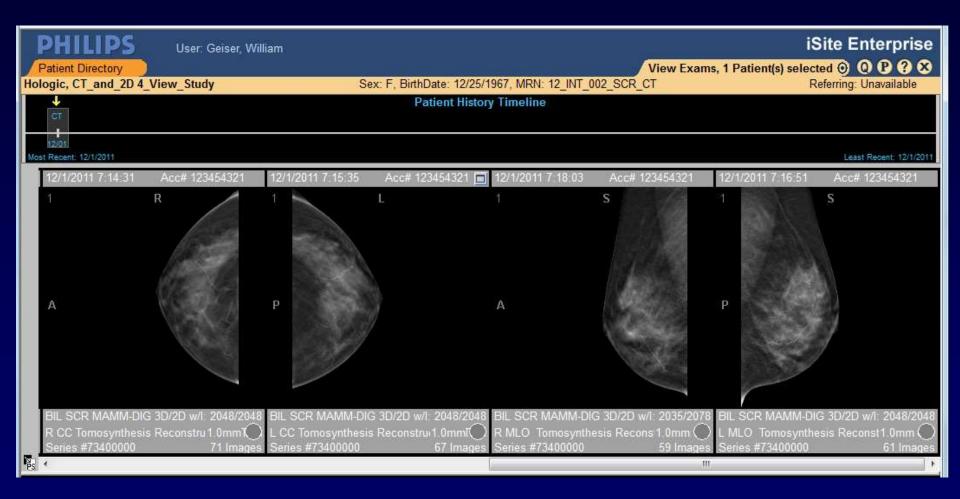
Standard Storage of MG Image Object



Review – Modality CT

PHILIPS Patient Directory	User: Geiser, Willia	m		1115	View Exan		Site Enterprise ted ⓒ Q P ? 🎗
Hologic, CT_and_2D 4_	View_Study	S	ex: F, BirthDate: 12/25/		02_SCR_CT	F	Referring: Unavailable
CT 12/01 Most Recent: 12/1/2011			Patient Histo	ry Timeline			Least Recent: 12/1/2011
12/1/2011 7:18:03	Acc# 123454321 🔳 1	2/1/2011 7:16:51	Acc# 123454321	12/1/2011 7:15:35	Acc# 123454321	12/1/2011 7:14:31	Acc# 123454321
A	s	4		1 A	R	1 A	R
10 Source of the Party of the P	sis Recons 1.0mm 🔘 L		esis Reconst1.0mm 🥘	the state of the s	s Reconstru:1.0mmī 🦳	the second s	G 3D/2D w/l: 2048/2048 is Reconstru 1.0mm 71 Images
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Review – Modality CT



Acceptance Testing

- Follow manufacturers QC manual
- Don't forget the MQSA Requirements for Mammography Equipment Checklist
- Results to ACR
- Full report to FDA

- Unit assembly evaluation
 - Compression thickness accuracy and force accuracy
 - Light field illuminance > 160 lux
- Collimation Assessment 2D and 3D
 - Three procedures
 - X-ray field to light field coincidence
 - X-ray field to image receptor
 - Compression paddle to image receptor

- Artifact Evaluation
 - 2D and 3D (Rh, Ag, Al filters)
- kVp accuracy and reproducibility
- Beam quality assessment Half Value Layer
- Evaluation of system resolution 2D and 3D

- Automatic exposure control function performance
 - Use correction factors in Appendix D CNR Correction Tables
 - Make sure you have the correct version for your software level and detector configuration

- Breast Entrance Exposure, AEC Reproducibility and AGD
 - 2D mode alone
 - 3D mode alone
 - Combined 2D and 3D
- Radiation output rate
- Phantom image quality
 - 2D and 3D

- Signal to noise and contrast to noise measurements
- Diagnostic review workstation quality control
- Detector Ghosting (Troubleshooting only)
- Light field illuminance
- Compression thickness accuracy
- Compression force and display accuracy

Equipment Needs – Acceptance Testing

- Non-invasive x-ray test system capable of measuring up to 40 kVp with W/Rh, W/Ag or W/Al anode/filter combinations
- Electrometer that will allow you to change trigger modes
- Resolution patterns that can measure >3 lp/mm and <15 lp/mm
- BR-12 or acrylic for AEC testing

Equipment Needs – Acceptance Testing

- ACR Accreditation Phantom
- X-ray Recording media for collimation (CR plates, self developing film...)
- Illuminance meter
- Luminance meter
- Bathroom scale

Equipment Needs – Acceptance Testing

- 4 cm thick acrylic phantom (supplied by manufacturer)
- Geometry test phantom (supplied by manufacturer

ACR Accreditation

Physicists credentials

MQSA Requirements for Mammography Equipment Checklist

Physics Testing Summary Sheet for the Hologic Dimensions Facility Name: Unit Manufacturer: Model: Medical Physicist: Room #: Signature: Date: FDA Requirements? Rule Applies (if NA, please explain) Section Feature Requirement to The assembly shall be capable of being fixed in any S-F & Yes No NA 3(i) position FFDM Motion of tube-image where it is designed to operate. Once fixed in any such receptor assembly S-F & 3(ii) This mechanism shall not fail in the event of pow er interrupt Yes No NA FFDM Systems using screen-film image receptors shall provide, S-F ☐ Yes No NA 4(i) at a minimum, for operation with image receptors of 18 x 24 cm and 24 x 30 cm. Systems using screen-film image receptors shall be S-F ☐ Yes No NA Image receptor sizes 4(ii) equipped with moving grids matched to all image receptor sizes Systems used for magnification procedures shall be S-F & ☐ Yes No NA capable of operation with the grid removed from betw een 4(iii) FFDM the source and image receptor. All systems shall have beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of S-F & 5(i) Yes No NA the FFDM image receptor. Beam limitation and liaht fields For any mammography system with a light beam that S-F & passes through the X-ray beam-limiting device, the light FFDM Yes No NA 5(ii) shall provide an average illumination of not less than 160 (except lux (15 ft-candles) at 100 cm or the maximum source-Fischer) image receptor distance (SID), whichever is less. Systems used to perform noninterventional problem-S-F & Yes No NA 6(i) solving FFDM procedures shall have radiographic magnification capability Magnification Systems used for magnification procedures shall provide, S-F & Yes No NA 6(ii) at a minimum, at least one magnification value within the FFDM range of 1.4 to 2.0. When more than one focal spot is provided, the system S-F & Yes No NA shall indicate, prior to exposure, which focal spot is 7(i) FFDM selected When more than one target material is provided, the S-F & Yes No NA 7(ii) system shall indicate, prior to exposure, the preselected FFDM Focal spot selection target material. When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a S-F & Yes No NA 7(iii) test exposure, the system shall display, after the FFDM exposure, the target material and/or focal spot actually used during the exposure.

MQSA Requirements for Mammography Equipment Checklist (adapted from from pages 315-319 of the 1999 ACR Mammography QC Manual)

Physics Testing Summary Sheet

• Everything must pass!!

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY Full-Field Digital – Lorad

014 N							
Site Name			Report Date				
Address			Survey Date				
Medical Physicist's Name			Signature				
X-Ray Unit Manufacturer	Lorad/Hologie	с	Model				
Date of Installation			Room ID				
QC Manual Version #			(use any version appli	cable to model; contact	t mfr if questions)		
Accessory Equipment	Manufacturer	Model	Location	QC Manual V	ersion #		
Review Workstation	*		🗌 On-site 🔲 Off-site				
Film Printer	*		🗌 On-site 🔲 Off-site				
*FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM. Survey Type							
("Pass" means all components of the test passes; indicate "Fail" if any component fails. Tests must be done for both on and off-site equipment.) PASS/FAIL							
1. Mammographic Unit A	ssembly Evaluation						
2. Collimation Assessme	•						
3. Artifact Evaluation							
4. kVp Accuracy and Reproducibility							
6. Evaluation of System Resolution							
7. Automatic Exposure C		erformance (NA	for systems without A	FC)			
-	. ,		•	20)			
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose							
9. Radiation Output Rate							
10. Phantom Image Qualit							
Phantom image	-	Specks	Masses				
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements (values required for all tests)							
SNR (value)							
CNR (value)							
CNR should not vary by more than ±15% (NA for Equipment Evaluation)							
12. Diagnostic Review Workstation (RWS) QC (for all RWS, even if located offsite; NA if only hardcopy read)							
13. DICOM Printer QC (Mammography Equipment Evaluations only)							
14. Detector Flat Field Calibration (Mammography Equipment Evaluations only)							
15. Compression Thickness Indicator (Mammography Equipment Evaluations only)							
16. Compression (Mammography Equipment Evaluations only)							
	······································	,			·		

What Phantom Image to send for Accreditation

- For MQSA facilities utilizing a 3D system in clinical practice, your accreditation/certification options are as follows:
 - If your facility's practice routinely utilizes **3D imaging with acquired 2D FFDM images**, then you may submit those 2D
 FFDM images to your accreditation body for accreditation of the 2D component of your unit.
 - If your facility's practice routinely utilizes 3D imaging with 2D images generated from the 3D image set (i.e., synthesized 2D images), then you may submit those synthesized 2D images to your accreditation body for accreditation of the 2D component of your unit.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandIn spection/ucm114148.htm

FDA Certification

- Website
 - <u>http://www.fda.gov/Radiation-</u>
 <u>EmittingProducts/MammographyQualityStandardsActa</u>
 <u>ndProgram/FacilityCertificationandInspection/ucm1141</u>
 <u>48.htm</u>
- Necessary forms
 - <u>http://www.fda.gov/Radiation-</u>
 <u>EmittingProducts/MammographyQualityStandardsActa</u>
 <u>ndProgram/FacilityCertificationandInspection/ucm2437</u>
 <u>65.htm</u>

Physics Requirements

• List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;

(2) began performing equipment evaluations and/or surveys of DBT mammography units after February 11, 2011; AND
(3) have 8 hours of initial training in DBT Mammography*. Note: Full Field Digital Mammography training can not be used as a substitute for DBT training.

Physics Report

Complete MEE to be sent in to include:

2D dose measurement 3D dose measurement Combined mode dose measurement

Film Image of Phantom with test objects in focus (usually slice 35, 36 or 37)

Part of Combo Exposure	Conventional	Tomosynthesis	Conventional	Tomosynthesis	
Breast Thickness (cm):	4.2	4.2	4.2	4.2	
Phantom Serial:					
KvP SETTING:	Auto Filter	Auto Filter	Auto Filter	Auto Filter	
Target material:	W	W	W	W	
Filter:	Rh	AI			
AEC Mode:					
AEC Position:					
Exp. Compensation Step:					
Measured HVL (mm Al):	#N/A	#N/A	#N/A	#N/A	
Average Glandular Dose	:				
Part of Combo Exposure	Conventional	Tomosynthesis	Conventional	Tomosynthesis	
Inverse square -corrected skin exp:					
Dose conversion factor from Tables 1-3 (mrad/R):	#N/A	#N/A	#N/A	#N/A	
Computed average glandular dose (mrad):					
Total Average Glandular Dose (mrad)*:	#VA	LUE!		0	

55

Conclusions

- Physicist input is needed
 - Shielding design or review
 - Reading room environment
- Acceptance Testing

 Proper equipment
 - Test procedures
- Administrative
 - Training
 - Full report all passing
 - Two phantom images
 - 2D to ACR
 - 3D to FDA