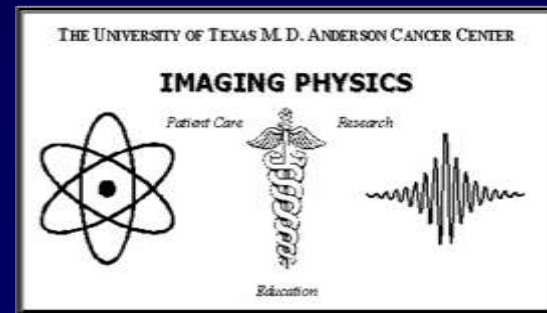


Implementation of a New Tomosynthesis Program: A Physicists Perspective

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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
 - <http://www.acr.org/News-Publications/News/News-Articles/2013/Economics/20130528-Coding-guidance-provided-for-performance-of-breast-tomosynthesis>

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

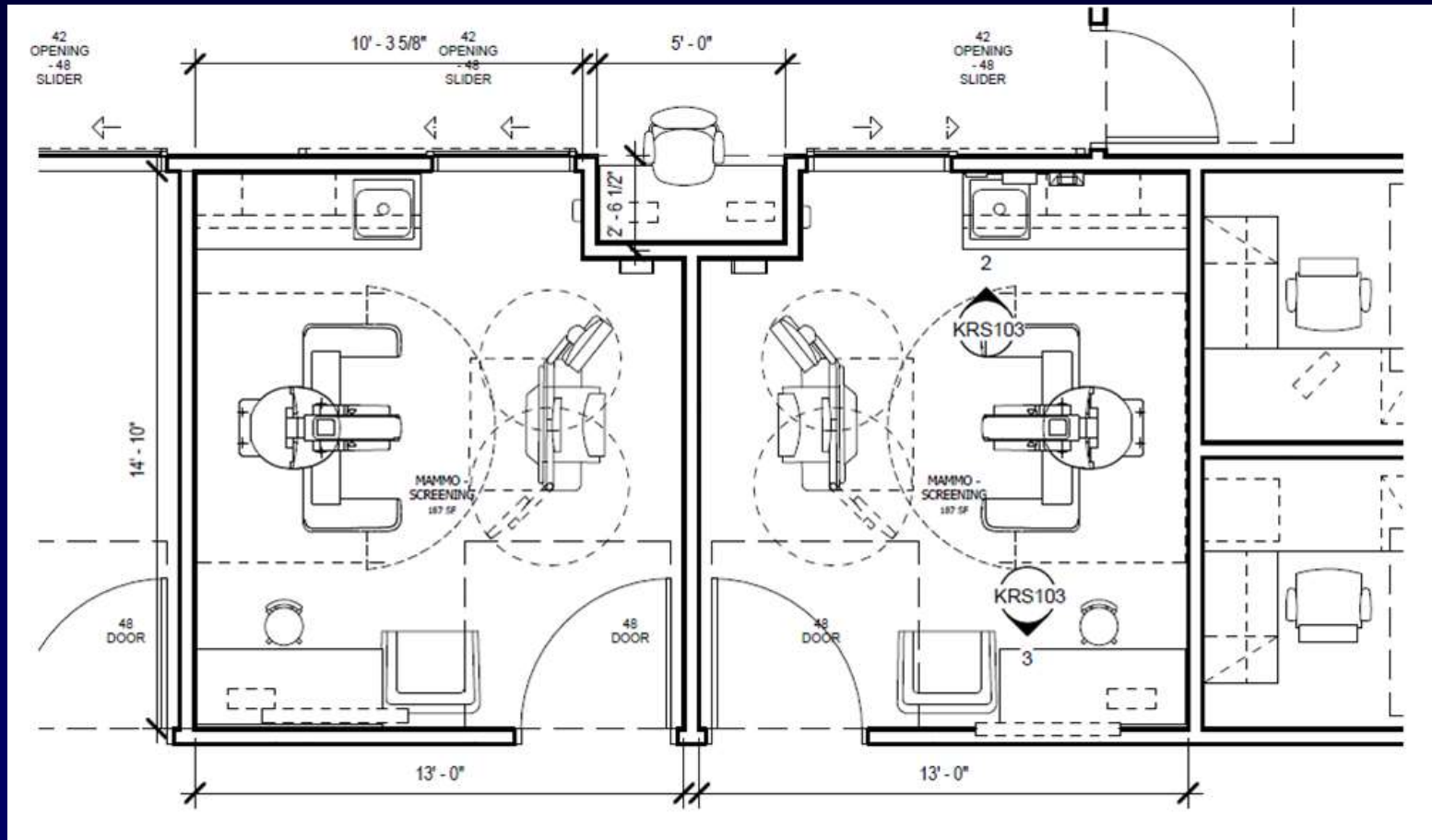
Medical Physicist

- 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.**

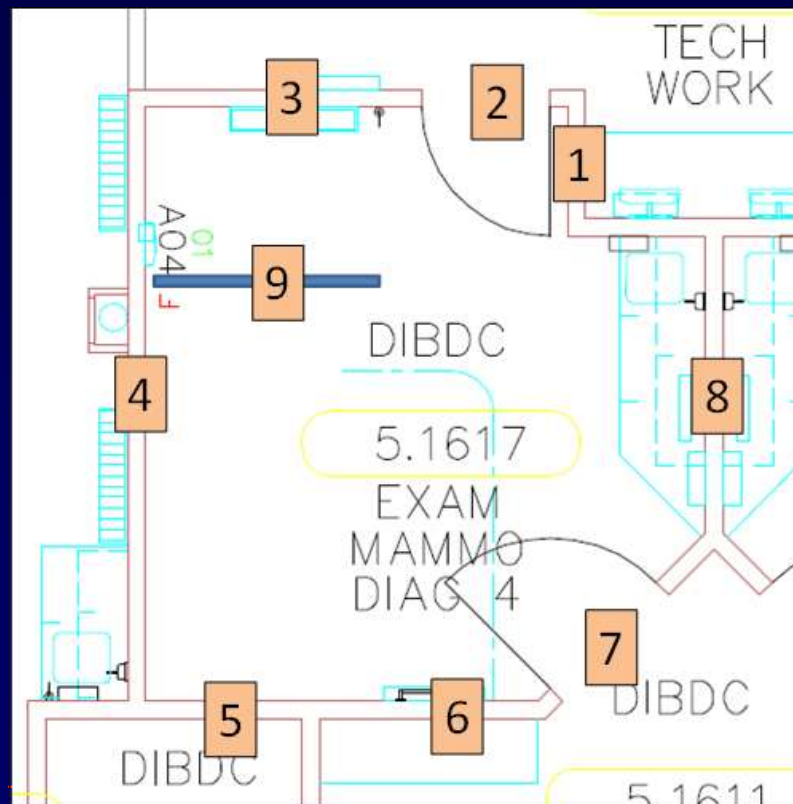
Shielding

- 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.

Barrier ID	Barrier	Thickness (mm)		Acceptable	Barrier material
		Shielding requirement	Present in the room		
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

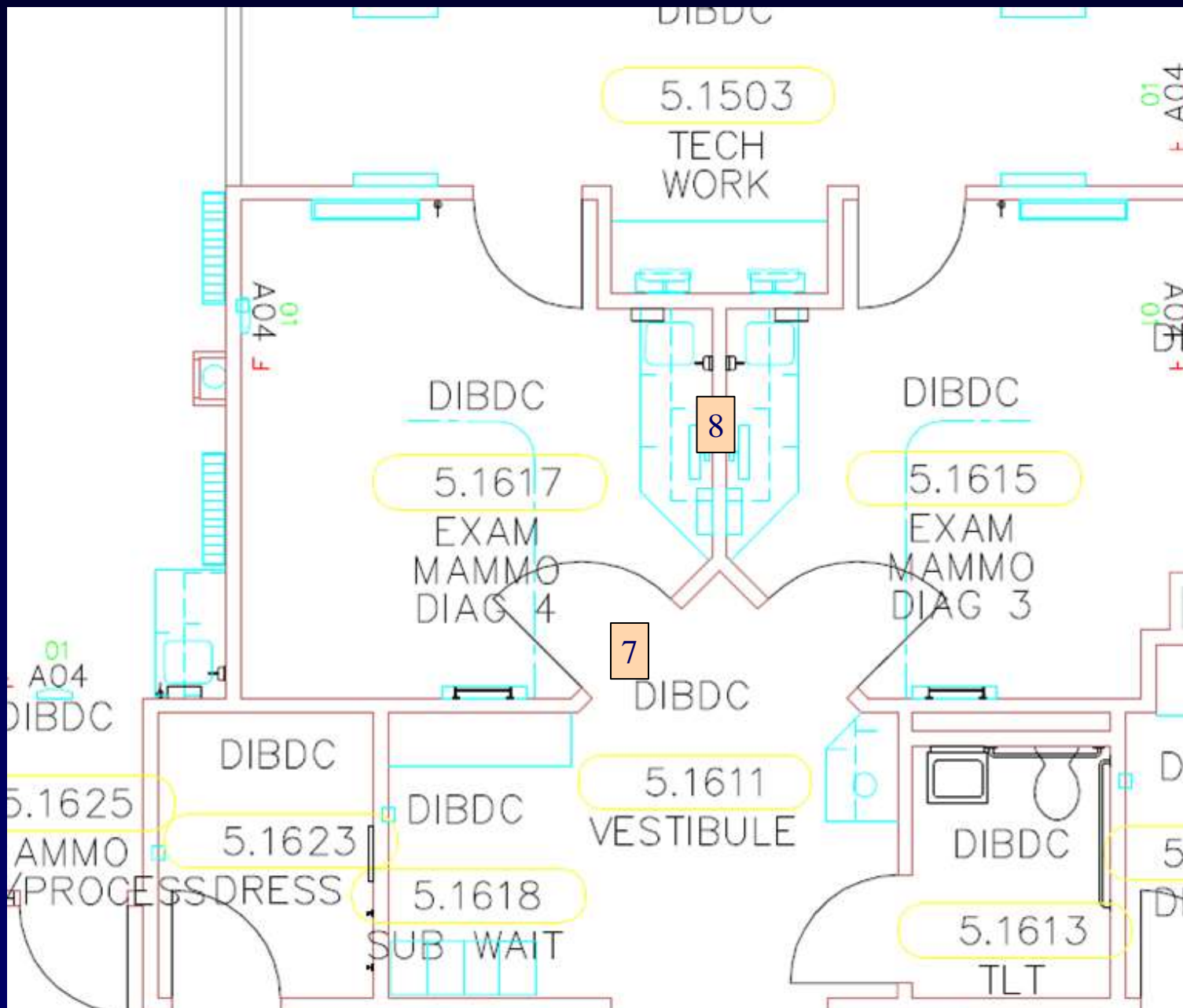


Occupancy

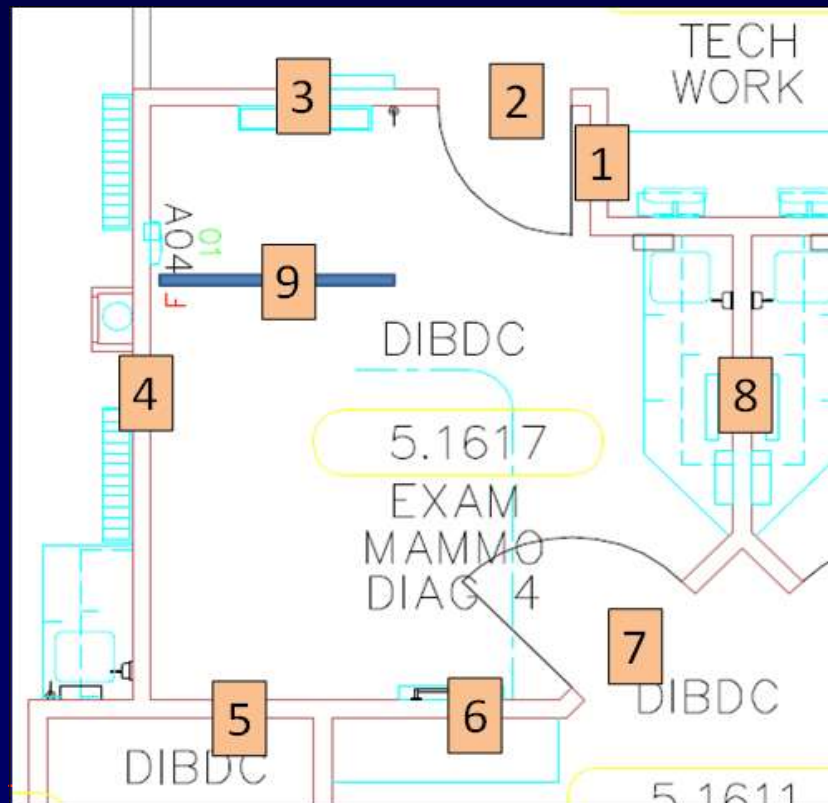
Barrier	Barrier ID	Distance from isocenter (m)	$1/r^2$ correction	Occupancy factor (T)	Radiation exposure limits (mGy/week)
Wall to technologist workstation in hallway	1	3.00	0.111	1.00	0.10
Door to technologist hallway	2	3.31	0.091	0.13	0.10
Wall to technologist hallway	3	2.90	0.119	0.20	0.10
Wall to 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



Barrier ID	Barrier	Thickness (mm)		Acceptable	Barrier material
		Shielding requirement	Present in the room		
1	Wall to technologist workstation in hallway	6.295	14	Yes	Gypsum wallboard
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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	18.701	43	Yes	Solid wood
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

PHILIPS User: Geiser, William Robert **iSite Enterprise**

Patient Directory View Exams, 1 Patient(s) selected Referring: STAFF, MDACC

Patient History Timeline

MG Brea 03/04 13:12 01/27 12:10 11/01 10:09 05/04 09:08 06/05 05/02 08:08 03/28 03/28 01/28 06:02 03/08

Most Recent: 3/4/2013 Least Recent: 3/8/2002

3/4/2013 13:42:24	Acc# 11133381	3/4/2013 13:47:04	Acc# 11133381	3/4/2013 13:44:08	Acc# 11133381	3/4/2013 13:45:36	Acc# 11133381	3/4/2013 13:39:04	Acc# 11133381
65		68		66		67		1	
Screening-Bilateral Mammogw/I: 4096/2047 R CC Series #1		Screening-Bilateral Mammogw/I: 4096/2047 L CC Series #2		Screening-Bilateral Mammogw/I: 4096/2047 R MLO Series #4		Screening-Bilateral Mammogw/I: 4096/2047 L MLO Series #3		Screening-Bilateral Mammogw/I: 256/128 R2 CAD SC Series #1	

Review – Modality CT

PHILIPS User: Geiser, William **iSite Enterprise**

Patient Directory View Exams, 1 Patient(s) selected

Hologic, CT_and_2D_4_View_Study Sex: F, BirthDate: 12/25/1967, MRN: 12_INT_002_SCR_CT Referring: Unavailable

↓
CT
12/01

Most Recent: 12/1/2011 Least Recent: 12/1/2011

Patient History Timeline

12/1/2011 7:18:03	Acc# 123454321	12/1/2011 7:16:51	Acc# 123454321	12/1/2011 7:15:35	Acc# 123454321	12/1/2011 7:14:31	Acc# 123454321
1 S A		1 I A		1 R A		1 R A	
BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 R MLO Tomosynthesis Recons 1.0mm Series #73400000 59 Images		BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 L MLO Tomosynthesis Reconst 1.0mm Series #73400000 61 Images		BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 L CC Tomosynthesis Reconstruct 1.0mm Series #73400000 67 Images		BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 R CC Tomosynthesis Reconstruct 1.0mm Series #73400000 71 Images	

Review – Modality CT

PHILIPS User: Geiser, William **iSite Enterprise**

Patient Directory View Exams, 1 Patient(s) selected Q P ? X

Hologic, CT_and_2D_4_View_Study Sex: F, BirthDate: 12/25/1967, MRN: 12_INT_002_SCR_CT Referring: Unavailable

↓ CT
12/01
Most Recent: 12/1/2011 Patient History Timeline Least Recent: 12/1/2011

12/1/2011 7:14:31	Acc# 123454321	12/1/2011 7:15:35	Acc# 123454321	12/1/2011 7:18:03	Acc# 123454321	12/1/2011 7:16:51	Acc# 123454321
1 R	1 L	1 S	1 S				
A	P	A	P				
BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 R CC Tomosynthesis Reconstruct 1.0mm Series #73400000 71 Images	BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 L CC Tomosynthesis Reconstruct 1.0mm Series #73400000 67 Images	BIL SCR MAMM-DIG 3D/2D w/l: 2035/2078 R MLO Tomosynthesis Reconstruct 1.0mm Series #73400000 59 Images	BIL SCR MAMM-DIG 3D/2D w/l: 2048/2048 L MLO Tomosynthesis Reconstruct 1.0mm Series #73400000 61 Images				

Acceptance Testing

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

Required Testing – Acceptance Testing

- 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

Required Testing – Acceptance Testing

- 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

Required Testing – Acceptance Testing

- 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

Required Testing – Acceptance Testing

- 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

Required Testing – Acceptance Testing

- 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

MQSA Requirements for Mammography Equipment Checklist (adapted from from pages 315-319 of the 1999 ACR Mammography QC Manual)				
Facility Name:				
Unit Manufacturer:		Model:		
Medical Physicist:		Room #:		
Signature:		Date:		
Feature	FDA Rule Section	Requirement	Applies to	Requirements? (if NA, please explain)
Motion of tube-image receptor assembly	3(i)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	3(ii)	This mechanism shall not fail in the event of power interrupt	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Image receptor sizes	4(i)	Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 cm and 24 x 30 cm.	S-F	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	4(ii)	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes	S-F	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	4(iii)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Beam limitation and light fields	5(i)	All systems shall have beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	5(ii)	For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.	S-F & FFDM (except Fischer)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Magnification	6(i)	Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	6(ii)	Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Focal spot selection	7(i)	When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	7(ii)	When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	7(iii)	When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

Physics Testing Summary Sheet

- Everything must pass!!

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY				
Full-Field Digital – Lorad				
Site Name			Report Date	
Address			Survey Date	
Medical Physicist's Name			Signature	
X-Ray Unit Manufacturer	Lorad/Hologic		Model	
Date of Installation			Room ID	
QC Manual Version #			(use any version applicable to model; contact mfr if questions)	
Accessory Equipment	Manufacturer	Model	Location	QC Manual Version #
Review Workstation*			<input type="checkbox"/> On-site <input type="checkbox"/> Off-site	
Film Printer*			<input type="checkbox"/> On-site <input type="checkbox"/> 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	<input type="checkbox"/> Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist) <input type="checkbox"/> Annual Survey			
Medical Physicist's QC Tests				
("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 Assembly Evaluation				
2. Collimation Assessment				
3. Artifact Evaluation				
4. kVp Accuracy and Reproducibility				
5. Beam Quality Assessment - HVL Measurement				
6. Evaluation of System Resolution				
7. Automatic Exposure Control (AEC) Function Performance <i>(NA for systems without AEC)</i>				
8. Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose				
Average glandular dose for average breast is ≤ 3 mGy (300 mrad)				
9. Radiation Output Rate				
10. Phantom Image Quality Evaluation				
Phantom image scores: Fibers <input type="text"/> Specks <input type="text"/> Masses <input type="text"/>				
11. Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements <i>(values required for all tests)</i>				
SNR (value) <input type="text"/>				
CNR (value) <input type="text"/>				
CNR should not vary by more than $\pm 15\%$ <i>(NA for Equipment Evaluation)</i>				
12. Diagnostic Review Workstation (RWS) QC <i>(for all RWS, even if located offsite; NA if only hardcopy read)</i>				
13. DICOM Printer QC <i>(Mammography Equipment Evaluations only)</i>				
14. Detector Flat Field Calibration <i>(Mammography Equipment Evaluations only)</i>				
15. Compression Thickness Indicator <i>(Mammography Equipment Evaluations only)</i>				
16. Compression <i>(Mammography Equipment Evaluations only)</i>				

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/FacilityCertificationandInspection/ucm114148.htm>

FDA Certification

- Website
 - <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm>
- Necessary forms
 - <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm>

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	Al		
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)*:	#VALUE!		0	

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