

RECENTLY APPROVED GE FFDM DBT TESTING PROCEDURES.

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History of mammography

- * During early 70's a balloon the size of basket ball was attached to a long cone.
- * The balloon was used as a compression mechanism
- * Conventional X-ray machine was used
- * Ready pack films were used like the one used for therapy localization

History

- * The next improvement was the use of zerogram.
- * An exposed charged plate was run through a processor.
- * The processor sprinkled a blue powder.
- * The iamges were printed in a large format.
- * Shades of blue.

History

- * Introduction of film screen mammography
- * Used films which were designed for mammography was used
- * High contrast
- * Single emulsion screen of the cassettes
- * Many manufacturers were approved for selling their mammo machines by FDA

ACR

- * ACR got involved in developing a set of standards for the equipment
- * Dose reduction and image quality was their priority
- * Institution participation was voluntary
- * Institutions meeting ACR standards were issued a sticker for display.
- * Feather in the cap of institutions
- * Participation was not 100%

MQSA

- * Betty Ford was diagnosed with breast cancer and went public.
- * Congress got involved in regulating standards early 90's
- * Mandated that all screening facilities must be approved by MQSA
- * Standards were published in 10 CFR part 21
- * Standards were analogous to ACR guide lines.
- * ACR manual was used as a bible by MQSA
- * Sites were inspected annually for compliance

INTRODUCTION OF DIGITAL MAMMOGRAPHY

- Digital mammography was introduced in 18x24 format.
- Hard copy of the images were printed for interpretation
- Radiologists were ramping up with their familiarity of the digital systems
- Viewing monitors were not of adequate quality for complete on screen interpretation
- Limitation and bad width of PACS system.

Proliferation of digital units

- * Many manufactures got into this business
- * GE, Siemens and Selenia were major players. There were also many others besides them
- * Viewing monitors of adequate resolution were available.
- * Full Field Digital Mammography FFDM was gaining grounds.
- * Presently most of them are FFDM units
- * Film Screen units have become extinct

FFDM

- * Great advantage of FFDM was ones ability to adjust window and level.
- * Viewing rooms with low light intensity were specially designed.
- * Gained universal acceptance.
- * Still lacked the ability to differentiate overlying objects.
- * Testing was very prescriptive by the manufacturer. There was no single set of instructions
- * Navy under the leadership of Capt Thomas was exploring tomographic concept.

GE FFDM and DBT

- * GE DBT has extensive testing to be performed before initially using on patients.
- * Not all screening procedures are approved on all units
- * Requires FFDM testing be performed as stand alone system
- * DBT 2D testing to be performed.
- * 3 D testing has to be performed.
- * Three times the work

Physicist Qualifications

- * ABR certified in diagnostic radiology physics
- * Had initial 8 hours of training in specific modality
- * Acquire 15 hours of CEU every there years
- * Have at least 3 units every year under the belt.

DBT IN UPRIGHT POSITION



DBT IN ANGULAR STARTING POSITION

STARTING POSITION OF GANTRY



DBT PADDLES



BLUE IS FOR 3D OPERATION

MTD

MOTORIZED TOMO
DEVICE



TRANSPORT CADDY FOR MTD



FDA/MQSA MANDATED TESTS FOR FFDM

1. MAMMO UNIT ASSEMBLY EVALUATION
 2. COLLIMATION
 3. SYSTEM RESOLUTION
 4. ARTIFACTS
 5. AEC ASSESSMENT
 6. ACR PHANTOM ASSESSMENT
 7. SNR AND CNR EVALUATION
 8. OUTPUT MEASUREMENT
 9. MEAN GLANDULAR DOSE MGD
 10. FLAT FIELD TEST
 11. KVP ACCURACY, REPRODUCIBILITY AND OUTPUT
 12. HVL ASSESSMENT
 13. SYSTEM RESOLUTION AND MTF
-

GE SIMPLIFIED APPRAOCH

- MOST OF THE QC TESTS ARE AUTOMATED
- QAP ICON ON THE MAIN SCREEN
- KVP AND HVL ASSESSES LIKE FILM SCREEN BUT WITH THE DETECTOR ADEQUATELY PROTECTED WITH LEAD
- IMAGE QUALITY OF THE PHANTOM ASSESSED ON BOTH ACQUISTION AND REVIEW WORK STATIONS
- ARTIFACT ASSESSED ON HARD COPY DEVICE IN ADDITION TO MONITORS
- AOP ASSESSED FOR 2.5, 5 AND 6 cm BREAST EQUIVALENT PHANTOM

DBT TESTS UNDER 2D MODE



QAP ICON BRINGS ONE TO THIS SCREEN. 2D AND 3D CAN BE SELECTED HERE

TESTS WITH MTD 2D

THE TESTS INDICATED IN THE PREVIOUS SLIDE IS REPEATED WITH MTD MOUNTED.

KVP AND HVL NEED NOT BE REPEATED

3D TESTS UNDER TOMO MODE

THE FOLLOWING TESTS ARE PERFORMED WITH MTD ON UNDER TOMO MODE.

TOMO IS ACTIVATED BY SELECTED 3D OPTION.

GANTRY HAS TO BE POSITIONED IN THE START POSITION

3D OPTION HAS TO CHOSEN AND DISPLATED ON MTD.



FOOT PEDAL HAS TO ENGAGED
DURING THE ENTIRE 3D
EXPOSURE



3D TESTS

- FLAT FIELD TEST
- PHANTOM IQ TEST
- CNT AND MTF
- ARTIFACT EVALUATION AND FLAT FIELD UNIFORMITY
- SUB SYSTEM MTF AND FOCAL SPOT
- MGD AND AEC REPRODUCIBILITY
- KVP ACCURACY AND REPRODUCIBILITY
- HVL
- UNIT ASSEMBLY
- GRID TEXTURE
- COMPRESSION PADDLE BORDER TO CW ALIGNMENT
- VOLUME COVERAGE
- ACR IMAGE ASSESSMENT

3D TESTS UNDER TOMO MODE CONTINUED

- ALL THESE TESTS ARE PERFORMED UNDER TOMO MODE EXCEPT
 - KVP
 - HVL
 - ARTIFACT EVALUATION
 - SYSTEM RESOLUTION

VOLUME TEST


- IMAGES ARE RECONSTRUCTED AT 1 mm INTERVAL.
- IT CAN BE DISPLAYED AT 1 mm INTERVAL OR
- IT CAN BE DISPLAYED AT 5 mm SLABS
- IT IS IMPORTANT TO ENSURE THAT THE LOCATION OF RECONSTRUCTED PLANE CORRESPONDS TO ACTUAL LOCATION.
- IT IS TESTED FOR 2.5 AND 6 cm THICKNESS
- 1 mm AL FILTERS ARE PLACED AT THE BOTTOM AND THE TOP OF THE PHANTOM
- RECONSTRUCTED IMAGE MUST DISPLAY SHARP IMAGES OF THE FILTERS BOTH AT THE SURFACE AND TOP OF THE PHANTOM.



TIME REQUIRED TO PERFORM THESE TESTS AND FREQUENCY

- IT TAKES A TOTAL OF TWO FULL DAYS OF PAIN TAKING MEASUREMENT
- IT TAKES AN ADDITIONAL DAY TO ANALYZE THE MEASURED DATA
- GE HAS PROVIDED A TEMPLATE FOR DATA SUBMISSION.
- I HAVE DEVELOPED AN EXCEL SPREAD SHEET FOR DATA ANALYSIS AND PRODUCTION OF REPORT.
- FREQUENCY OF EACH OF THESE TESTS ARE SPECIFIED BY GE

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SUMMARY OF MAMMOGRAPHY EQUIPMENT EVALUATION FOR G.E. BREAST TOMOSYNTHESIS				
FACILITY NAME AVERA ST LUKES HOSPITAL IMAGING CENTER				
FACILITY NAME 305 S STATE STREET ABERDEEN SD 57401				
				
INSTALLATION DATE	UNIT SERIAL #			
DATE OF SURVEY	4/2/2015	ROOM I D	1-HP-37	
MEDICAL PHYSICIST	S Guru Prasad	SIGNATURE		
TEST RESULTS				
1	GRID TEXTUTE TEST		PASS	FAIL
	TEXTURE LEVEL		0.0017	
	TEXTURE LEVEL MUST NOT > 0.002			
2	FLAT FIELD 3D & PHANTOM IQ 2D WITH MTD & 3D			
	PHANTOM IQ WITH MTD	AWS	PASS/FAIL	
	# OF FIBERS	5	PASS	
	# OF SPECK GROUPS	4	PASS	
	# OF MASSES	4	PASS	
	4 LARGEST FIBERS 3 LARGEST SPECK GROUPS AND 3 LARGEST MASSES MUST BE DETECTED			
	FLAT FIELD 3D			
		PASS	FAIL	
	BRIGHTNESS NON UNIFORMITY	6.14		
	SNR NON-UNIFORMITY	37.43		
	ALL FLAT FIELD CHECKS MUST PASS			
	PHANTOM IQ 3D	RWS	PASS/FAIL	
	# OF FIBERS	5	PASS	
	# OF SPECK GROUPS	3	PASS	
	# OF MASSES	4	PASS	
	4 LARGEST FIBERS 3 LARGEST SPECK GROUPS AND 3 LARGEST MASSES MUST BE DETECTED			

SUMMARY PAGE 2					
3	CNR & MTF MEASUREMENT				
	MTF PARALLEL AT 2 lp/mm	62.89			
	MTF PARALLEL AT 4 lp/mm	28.32			
	MTF PERPENDICULAR AT 2 lp/mm	60.36			
	MTF PERPENDICULAR AT 4 lp/mm	34.49			
	CNR	41.48			
	MTF PARALLEL AT 2 lp/mm> 49%				
	MTF PARALLEL AT 4 lp/mm > 18%				
	MTF PERPENDICULAR AT 2 lp/mm >49%				
MTF PERPENDICULAR AT 4 lp/mm >18%					
4	AOP 2D & SNR CHECK WITH MTD				
	EXP. PARAMETERS				
	ACRYLIC THICKNESS	TRACK/ FILTER	mAs	kV	SNR
	IN mm				
	25	MO/MO	37.9	26	127.85
	50	Rh/Rh	64.2	29	114.1
	60	Rh/Rh	56.6	31	98.16
	REQUIREMENT				
	EXP. PARAMETERS				
	ACRYLIC THICKNESS	TRACK/ FILTER	mAs	kV	SNR
	IN mm				
	25	MO/MO	20-60	26	>50
	50	Rh/Rh	40-90	29	>50
	60	Rh/Rh	45-95	30 or 31	>50

5	SUMMARY # 3 AOP 3D CHECK			
	EXP. PARAMETERS			
	ACRYLIC THICKNESS	TRACK/ FILTER	mAs	kV
	IN mm			
	25	MO/MO	45	26
	50	Rh/Rh	63	29
	60	Rh/Rh	72	31
	REQUIREMENT			
	EXP. PARAMETERS			
	ACRYLIC THICKNESS	TRACK/ FILTER	mAs	kV
	IN mm			
	25	MO/Rh	20-70	28
	50	Rh/Rh	40-90	29
	60	Rh/Rh	50-120	30 or 31
6	COMPRESSION PADDLE TO MTD C.W. ALIGNMENT			
	C.W. OF X-RAY FLD EXTENDS TO C.W. EDGE OF THE I.R.			PASS
	C.W. EDGE OF COMPRESSION PADDLE NOT VISIBLE IN IMAGE >I.R BY MORE THAN 1% OF SID			PASS
				FAIL
7	BREAST ENTRANCE EXPOSURE & MGD			
	MGD TO STANDARD BREAST			
	AOP CNT MODE			265.8
	AOP STD MODE			117.1
	AOP DOSE MODE			95.6
	OTHER(SPECIFY)			
	AOP			AUTO
	OTHER(SPECIFY)			115.0

SUMMARY # 4			
MGD TO THE STANDARD BREAST MUST NOT EXCEED 3 mGy (0.3 rad) PER VIEW			
ARTIFACT EVALUATION			
ARTIFACTS ARE NOT APPARENT OR ARE NOT EXPECTED TO MIMIC OR OBSCURE CLINICAL INFORMATION			PASS FAIL
VOLUME COVERAGE			
THE FOCAL PLANE OF TOP AI SHALL BE WITHIN THE RECONSTRUCTED VOLUME			PASS
THE FOCAL PLANE OF BOTTOM AI SHALL BE WITHIN THE RECONSTRUCTED VOLUME			PASS
VOLUME COVERAGE MUST PASS			

INFORMATION AND QUESTIONS

YOU CAN CONTACT ME AT air_n2847j@yahoo.com or 847-921-3462

THANK YOU