Surveying and QC for FFDM

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for sharing many of these slides

OVERVIEW

- Important pre-survey events
- Manufacturer's tests and equipment
- Performing the survey
- Summary of important points and what really matters

• Obtain proper training & CE credits (8 hours)

- Hands-on training on actual unit:

- Mechanics
- Software
- Artifacts
- Learn vendor specific tests and tricks

ACR Accreditation - <u>www.acr.org</u>

Download Specific Physicist's Evaluation Test Summary
 Forms for FFDM System being evaluated

- Download Updated Equipment Evaluation Form that is current for both digital and film/screen systems

- ACR Accreditation
 - Before clinical use
 - Medical Physicist equipment evaluation and indicate it passes
 - New unit application
 - Not required to wait for ACR response
 - However, no reimbursement without FDA receiving ACR app.
 - Approximately 3 days for accreditation approval from ACR

- Contact the site things to confirm:
 - Site is aware of ACR or FDA application process
 - FFDM unit is operable
 - Review workstation is operable
 - Images can be transmitted
 - Laser printer works, can print mammo images, and hooked up to all RWS's
 - Discuss QC issues
 - Many QC failures result in stopping clinical imaging
 - ACR Phantom do they have one on-site?

- Contact Manufacturer's Service Engineers
 - Is installation complete?
 - Can they be present?
 - If not, how can they be contacted?
 - Is the system working properly?
 - Can the laser printer service engineer be present?

- Gather Forms ACR and Manufacturer's
 - **Physics test forms**
 - Ensure you have tests that are required by manufacturer
- Gather test tools
 - Check required tests in manufacturer's manual
 - Artifact test tool 2 inches of acrylic
 - Lead sheet

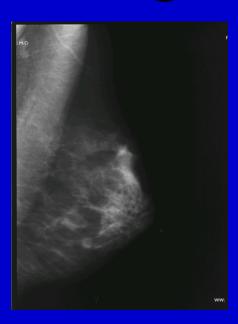
Performing the Survey

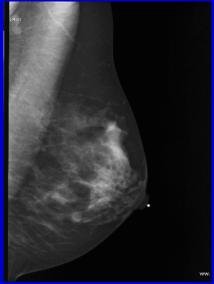
- Must perform manufacturer's tests
- Turn off auto push and/or auto print
 - Remember to turn them back on
- Order of tests is important
- Use "Raw" or "Processed" images for testing per manufacturer's specifications

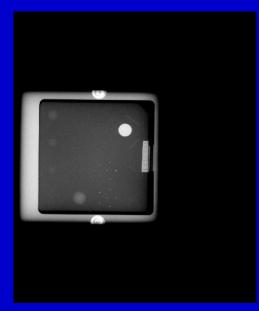
Performing the Survey

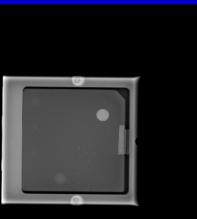
Raw Image

Processed Image



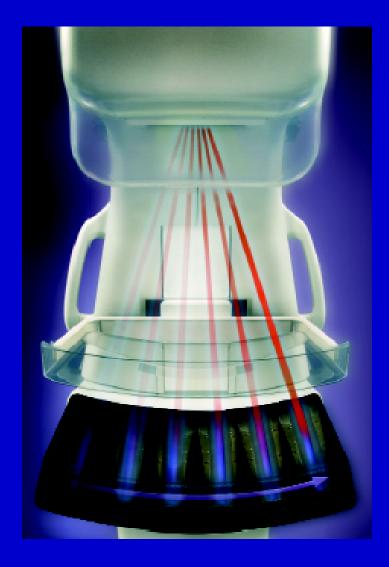




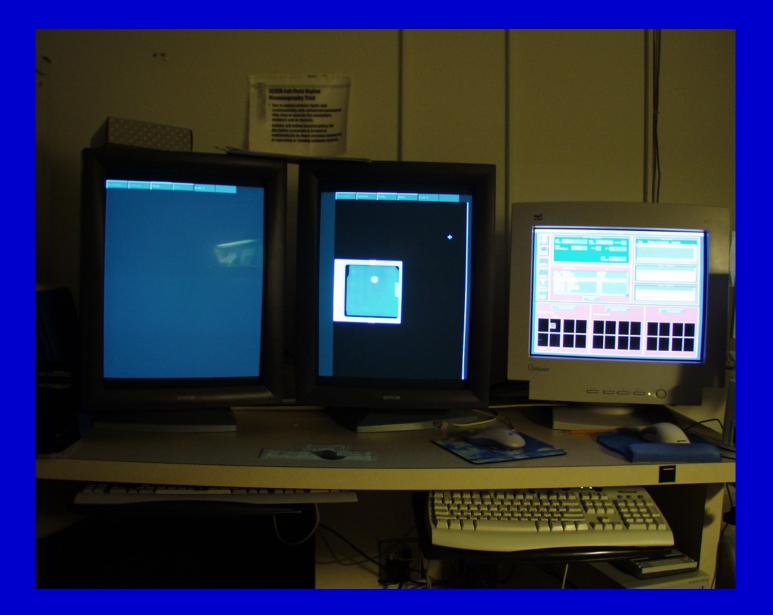


Fischer Senoscan





Fischer Senoscan



Fischer Senoscan - Performing the Survey

- Manufacturer's tests
 - X-ray field size and Chest wall missed tissue
 - Compression paddle alignment
 - kVp accuracy
 - Linearity, reproducibility, and accuracy
 - Beam Quality (HVL)
 - Dosimetry average glandular dose
 - Phantom image acquisition

Fischer Senoscan - Performing the Survey

- Manufacturer's tests
 - Image quality
 - System resolution/scan speed uniformity
 - Flat field test
 - Geometric distortion and resolution uniformity
 - Automatic decompression control
 - System artifacts
 - Image display monitor(s) check Tech Review
 - Image viewing room illuminance

Fischer Senoscan - Performing the Survey

- <u>Collimation</u>
 - Error between field-size markers and image receptor must be less than 2% of SID
 - Missed chest wall tissue less than 8.5 mm
 - Compression paddle: distance between image receptor at chest wall and inside of edge of paddle must be ≤ 8.5 mm



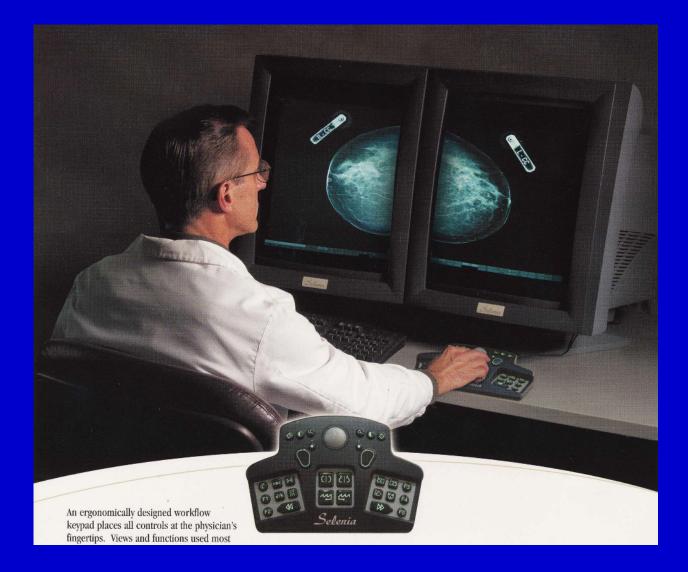
Hologic/LORAD Selenia







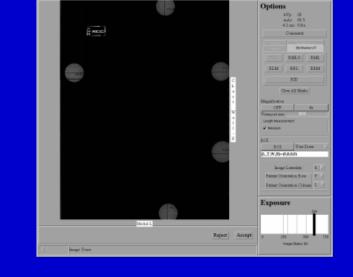
LORAD Selenia Softcopy Workstation



- Manufacturer's tests
 - Unit assembly evaluation *
 - Artifact evaluation *
 - Phantom image quality
 - Evaluation of system resolution
 - Signal-to-Noise and Contrast-to-Noise Measurements
 - Collimation assessment *
 - *30 Days to Repair

- Manufacturer's tests
 - kVp accuracy and reproducibility *
 - Beam quality— HVL *
 - Breast Entrance exposure and average glandular dose
 - Radiation output rate *
 - Viewbox luminance and room illuminance *
 - Softcopy Workstation QC
 - *30 Days to Repair

- <u>Collimation Assessment</u>
 - Use coin techniques as described in ACR Manual
 - Test 24x29 cm detector mode
 - Test 18x24 cm detector mode
 - X-Ray field to light field coincidence
 - X-Ray field to image receptor alignment



- Compression Paddle to Image Receptor Alignment

- Artifact Evaluation
 - 4 cm acrylic block
 - **Mo/Mo**
 - Mo/Rh
 - Large & Small Spot
 - Evaluate for artifacts at WW ~ 250
 - Print films check printer

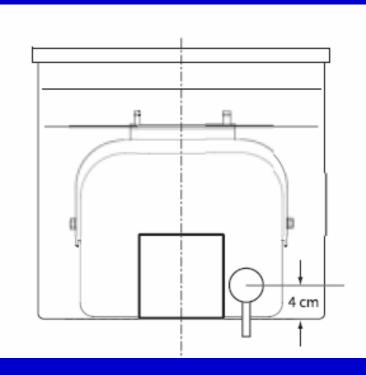
- <u>kVp</u> Desribed in the 1999 ACR QC Manual
- <u>HVL</u> Desribed in the 1999 ACR QC Manual
- Action Limits:
 - If measured HVL < kVp/100 + 0.03 (in mm Al) or
 - If measured HVL > kVp/100 + C (in mm Al) where C = 0.12 for Mo/Mo; C = 0.19 for Mo/Rh; and C = 0.22 for Rh/Rh, then seek service correction.

<u>Phantom Image Quality</u>

- 28 kVp, Auto Filter Mode, Photocell @ Position #2
- Print film measure OD and Contrast
- Score on each SCW (Soft Copy Workstation)
 - 5 fibers
 - 4 speck groups
 - 4 masses

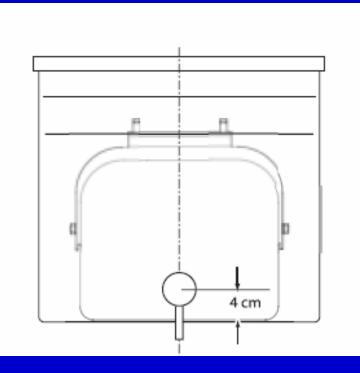
Minimum Passing Score for LORAD Selenia & Siemens Mammomat Novation

- Breast Entrance Exposure and Average Glandular Dose
 - Technique set to clinically image average breast 4.5 cm
 - 28 kVp, Auto Filter Mode
 - Photocell @ Position # 2
 - Calculated dose < 3.0 mGy</p>



<u>Radiation Output Rate</u>

- Cover detector for protection lead sheet
- Manual Mode Exposure
 - 28 kVp, 300 mAs
- Output Exposure > 800 mR/sec



• Evaluation of System Resolution

- 5-15 lp/mm Test Pattern
- 4-cm Attenuation Block
- Pattern at 45-Degree Angle

to the Detector

• The system limiting spatial

resolution must be > 7 lp/mm

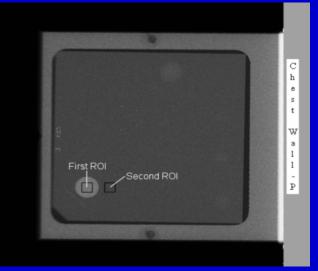


SNR and CNR Measurements

- SNR at least equal or greater than 40
 - $SNR = (Mean_{Bkgd} DC_{offset})/SD_{Bkgd}$ $DC_{offset} = 50$
- Establish CNR during acceptance testing
 - $CNR = (Mean_{Bkgd} Mean_{Disk})/SD_{Bkgd}$

CNR should stay within ±15% of measurement obtained during

acceptance testing



<u>SoftCopy Workstation QC</u>

- Use supplied photometer and run monitor QC software
 - White level = CRT and LCD Monitors (levels depend on model)
 - Black level = 0 cd/m² CRT Monitors Only
 - Quality Level Performance checks full monitor calibration automatically
 - Warning level = 5% Tolerance level = $10\% \rightarrow$ Recalibrate
 - CRT and LCD Monitors
 - Uniformity Performance minimize non-uniformities away from center of display
 - CRT Monitors Only

<u>Viewbox Luminance and Room Illuminance</u>

Mammographic viewbox is capable of a luminance of at least 3000 cd/sq m (nit)

Room illuminance (viewbox surface as seen by observer) is $\leq 50 \text{ lux}$

Room illuminance (monitor surface) is ≤ 20 lux for softcopy reading

GE Seno DS





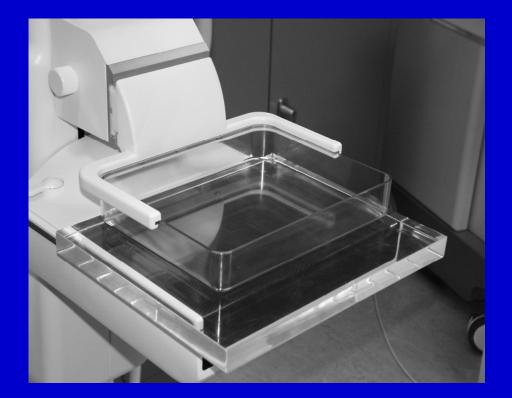
GE Senographe DS Seno Advantage RWS



Artifacts



Physicist must test all Target/Filter combinations and both sizes of focal spots for artifacts



GE Senographe Essential

Large and Small Fields Require Collimation Assessment of all three positions of small field plus large field for both target materials



GE Senographe Essential Control Panel

Laterality must be selected prior to each exposure

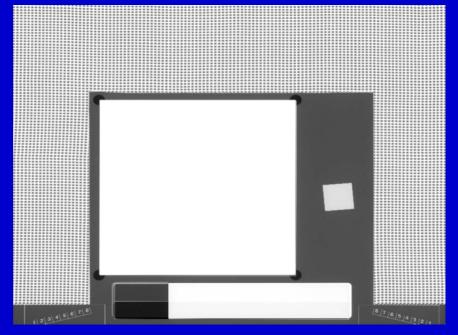


GE Senographe DS

Quality Assurance Plan

Automated Evaluative Procedure Patented Technology Tracks IQ Over Time Spatial Resolution Small Signal Contrast Dynamic Range Resolution Uniformity Distortion Other **Run by Technologist Pass/Fail Result In-Site Interactive Remote Corrections Automatic Service Dispatch**

GE Image Quality Signature Test (IQST) Phantom



QAP Not a calibration but a process that maximizes Senographe digital image quality consistency

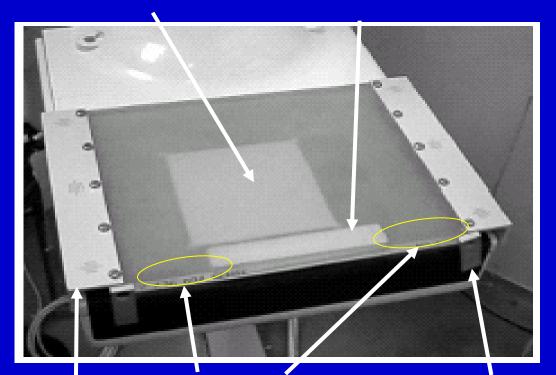
GE Senographe DS

QA Phantom Overview

Uniform area for noise power spectrum measurement

Step wedge for contrast measurement

Mesh for resolution uniformity measurement Edge object for MTF measurement





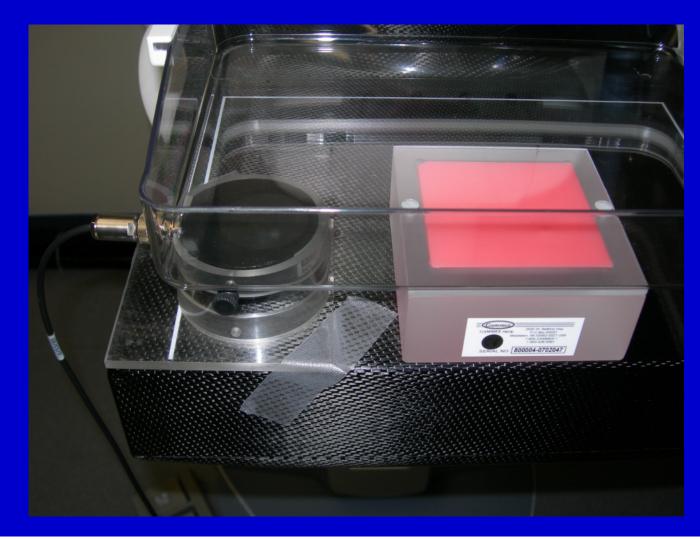
Rulers for measuring distance of detector from chest wall edge of Bucky

Tabs to position IQST with respect to chest wall edge of image receptor.

Rails to position the IQST left-to-right

GE Senographe Essential

Measure Entrance Skin Exposure with Ion Chamber at 5 cm from outside edge of detector area.



CR Plates

Fuji CRm System

CR Plate Reader



Fuji CRm System S-Value Confirmation

Measure Exposure Rate at Surface of Breast Support



Fuji CRm System

Dynamic Range Test



Fuji CRm System - CNR Test

CNR PER OBJECT THICKNESS

Auto	Гime						
3							
0							
Auto	Гime						
Target	Filter	kVp	mAs (Auto)	mAs (Manual)	CNR	CNR (relative to 4cm PMMA)	Acceptable level
Мо	Мо	25.0	27.2	28.0	17.197	114.4%	>110%
Мо	Мо	25.0	135.0	130.0	15.030	100.0%	100%
Мо	Rh	30.0	282.0	280.0	13.765	91.6%	>90%
	3 0 Auto 7 Target Mo Mo	Mo Mo Mo Mo	30Auto TimeFilterKVpMoMoMo25.0MoMo25.0	30Auto TimeFilterKVpmAs (Auto)TargetFilterkVpmAs (Auto)MoMo25.027.2MoMo25.0135.0	30Auto⊤meKVpTargetFilterKVpmAs (Auto)MoMo25.027.228.0MoMo25.0135.0130.0	30Auto TimeKVpmAs (Manual)CNRMoMo25.027.228.017.197MoMo25.0135.0130.015.030	Image: Second S

Inter Plate Consistency

Exposure Unite ID:	Lorad M-I

	AEC- mode	Targ et	Filter	kVp
Exposure conditions	Auto Time	Мо	Мо	25

Group: Small Cassettes

mAs limit is plus or minus 10 % from mean. SNR limit is plus or minus 15 % from mean.

Cassette ID	mAs	Accepta ble	SNR	Accepta ble
A456, #3	132	Yes	70.9 46	Yes
A234, #2	132	Yes	70.9 52	Yes
A123, #1	132	Yes	70.1 52	Yes
A222, #4	132	Yes	70.1 66	Yes
A111, #5	132	Yes	69.5 21	Yes
A777, #6	133	Yes	69.6 62	Yes

Fuji CRm - Monitor Tests

Site:	Med. Img Ctr of So Cal
Room #:	Reading Room

Date of Survey: <u>4/19/2007</u> Date of Installation: <u>Apr-07</u>

DOME©E5	Left Monitor	Right Monitor
Serial Numbers	703PNKN00011	703PNKN00028
Luminance Value Setting (cd/sq-m)	499.2	500.88

Target Value = 500 cd/sq-m

Is the CXtra icon present in the taskbar and shown as a green check mark?	✓ Yes	No
Manual Conformance report for both displays attached?	✓ Yes	No
Is DICOM calibration Graph for both displays attached?	✓ Yes	Νο

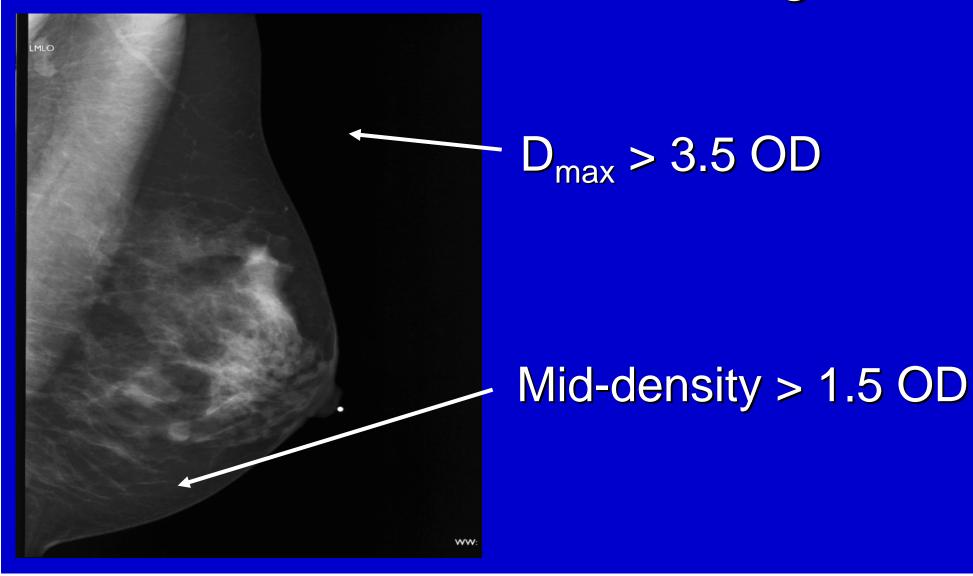
Laser Printer must be able to print images on mammography laser film



FDA-Approved Laser Imagers for Digital Mammography

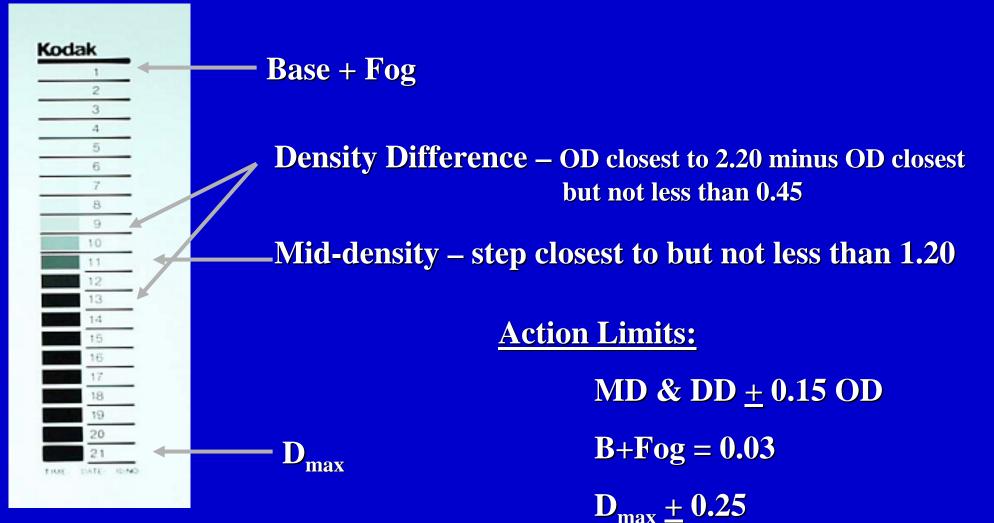
- Agfa LR5200 Laser Imager (Wet Chemistry)
- Agfa DS4500M
- Kodak 8600 & 8610 Laser Imagers
- Konica DryPro 793 Laser Imager
- Kodak 8900M
- Fuji Drypix 5000 & 7000 Laser Imagers
- Fuji Drypix FM-DP L

OD Requirements for Hi-Resolution Laser Imagers



Laser Processor QC

Kodak daily sensitometry

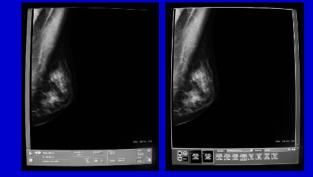


FDA Required Laser Printer QC

- GE 2000D & Senographe DS: Follow the laser printer manufacturer's QC manual
- Fischer Senoscan: Follow the laser printer manufacturer's QC manual
- Lorad Selenia: Follow the Lorad Selenia QC Manual
- Siemens Mammomat Novation DR: Follow the laser printer manufacturer's QC manual but conduct QC every day that images are printed.

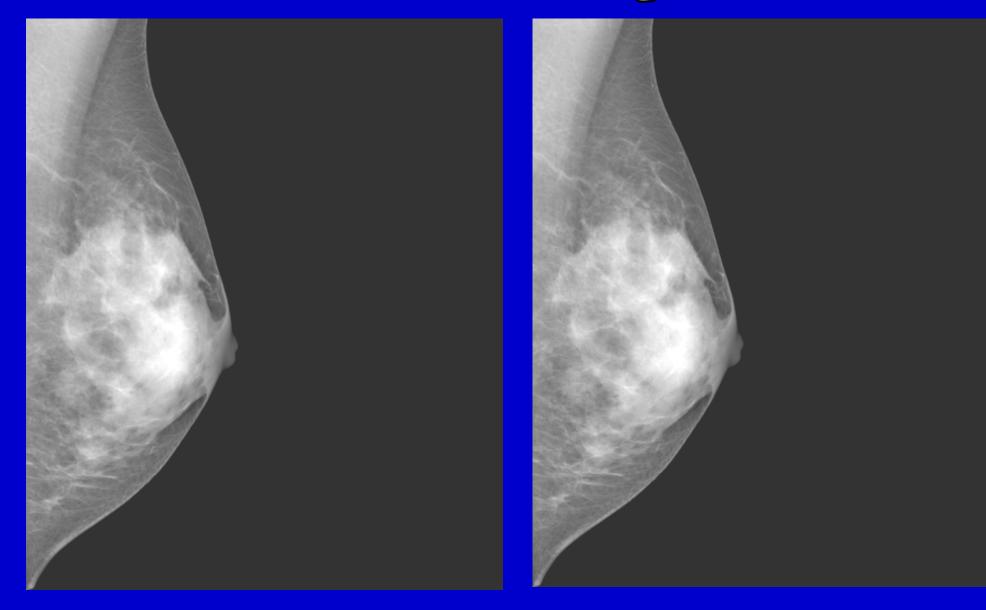
RWS Clinical Image Check

- Does the background match?
- Is the background dark enough?

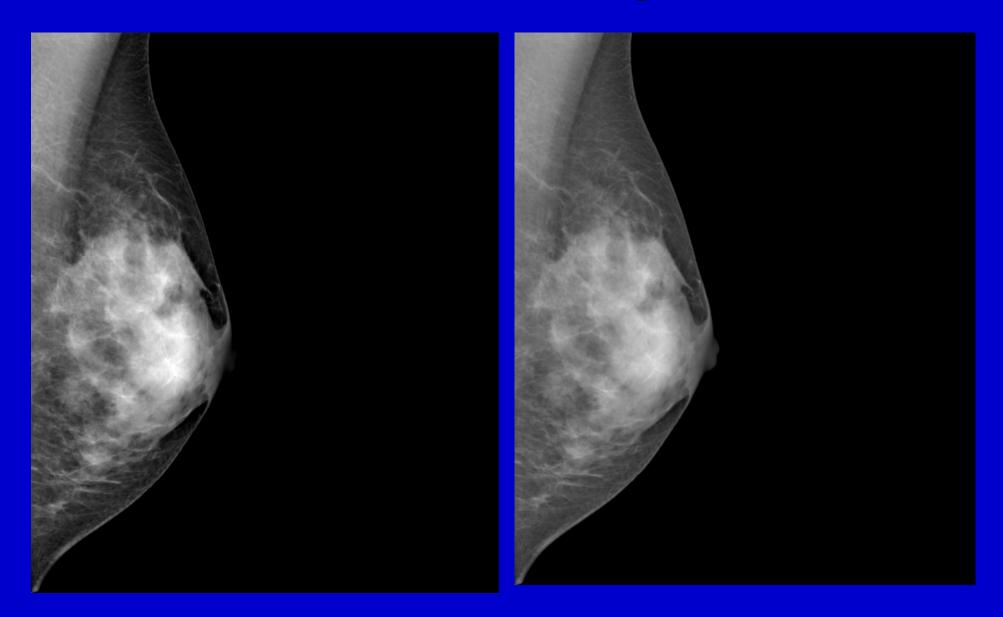


- Does the dense tissue area match?
- Is the dense tissue light enough?
- Is the contrast adequate?

RWS Clinical Image Check



RWS Clinical Image Check



Summary Points

- Obtain proper hands-on training
- ACR & FDA applications and forms
- Turn off and on auto print and/or auto push
- Artifacts most problems can be seen on this test
- Lead sheet protecting detector for Focal Spot, HVL & kVp
- Laser Printer
 - D_{max} at least 3.5 OD
 - Mid-density about 1.5 OD

Summary Points

- Review workstation monitors look at the clinical images!
 - Do they match?
 - Appropriate dark and light levels
- Do all work on correct images raw vs. processed
- Take your time and use your professional judgement



Phantom Images and Dose

		Av	erage Sco	ores	Ave Dose*
	# Units	Fibers	Specks	Masses	(mrads)
Screen-					
Film	14,574	4.70	3.60	3.74	168.7
(SD)		(0.48)	(0.4)	(0.41)	(31.4)
			0.05	1.00	400.0
FFDM	1711	4.84	3.85	4.00	128.6
(SD)		(0.54)	(0.33)	(0.39)	(38.6)

*as measured by TLD

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Average Glandular Dose in FFDM Systems

The average dose recorded in these FFDM units (GE 2000D, Fischer SenoScan, Siemens Novation and LORAD Selenia) is about 20% less than the dose of screen-film units measured by MQSA inspectors during the same time period of testing.



Mfr QC Manuals Are All Very Different Example: Medical Physicist Tests

Test Names

Test	Flat Field
GE	"Flat Field"
Fischer	"Flat Field"
Lorad	"Artifact Evaluation"
Siemens	"Detector Calibration"

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RADIOLOGY R	Required Medical Physicist Testing
Equipment Evaluati	valuations on FFDM Components
Item/Repair	MP Involvement
Bucky & detector replacement	MP must evaluate in person
Bucky (but not detector) replacement	tor) MP must oversee
Any detector replacement or repair	ent or MP must evaluate in person
Software modifications	ons MP must evaluate in person (some alternative standards otherwise)
Monitor (display) or printer replacement	inter Must follow FFDM mfr's QC manual



ACR's Current FFDM QC Requirements

- Same as FDA's
- ACR suggests using mfr's data forms
- Medical physicist <u>must</u> complete ACR's summary forms
 - MQSA Requirements for Mammography Equipment (checklist)
 - Medical Physicist's Mammography QC Test Summary form
 - Available on ACR website in Excel
- Forms provides ACR with essential pass/fail information
 - If medical physicist passes test, ACR accepts it
 - If he/she fails test, ACR requests corrective action
 - If he/she writes "N/A," "see comments" (or anything other than pass or fail), ACR will follow-up; accreditation will be delayed
- Different formats (even if they contain all the necessary information) will delay review

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Download Summary Forms from ACR Website (www.acr.org)

- Required for Equipment Evaluation report
- Addresses
 900.12(b) of
 the FDA
 regulations
- Same for S-F and FFDM
- In Excel format

м	QSA RI	MEDICAL PHYSICIST'S CHECKLIST EQUIREMENTS FOR MAMMOGRAPHY EC		іт
Facility Name: Unit Manufacturer: Medical Physicist: Signature:			Model: Room #: Date:	
Feature	FDA Rule Section	Requirement	Applies to	Meets FDA Requirements? (if NA, please explain)
Motion of tube-image	3(i)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	S-F & FFDM	Yes No NA
receptor assembly	3(ii)	This mechanism shall not fail in the event of power interruption.	S-F & FFDM	Yes No NA
	4(i)	Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18×24 cm and 24×30 cm.	S-F	Yes No NA
Image receptor sizes	4(ii)	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.	S-F	Yes No 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	Yes No NA

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Medical Physicist's Mammography QC Test Summary Forms

- Use for both Equipment Evaluations and Annual Surveys
- Addresses 900.12(e) of the FDA regulations
- All have been revised in July 2006 to further streamline
- Excel format
 - Built-in P/F drop-down boxes
- Use the one for your digital unit manufacturer
 - General Electric
 Fischer
 - Lorad Siemens
 - Fuji
- Check version of manufacturer's QC manual used
- Single overall review workstation assessment

MEDICAL PHYSICIST'S MAMMOGRAPHY OC TEST SUMMARY	SICIST'S MA	MMOGRA	НУ ОС ТЕ	ST SUMMARY
ш.	Full-Field Digital –	ital – Gene	General Electric	
Site Name			Report Date	
Address			Survey Date	
Medical Physicist's Name			Signature	
X-Ray Unit Manufacturer	General E	Electric	Model	
Date of Installation			Room ID	
QC Manual Version: (check one; must use version app	e; must use version applic	licable to unit tested; contact mfr if questions)	ntact mfr if questions)	2000D 2371472-100 Rev 0, 2003
DS 5133453-2-100 Rev 1, 2006	ESSENTIAL	5141465-2-100 Rev 1, 2006	OTHER (write in):	tte in):
Accessory Equipment:	Manufacturer	leboM	Location	QC Manual Version
Review Workstation*			On-site Off-site	
Laser 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, but	yrs and printers specifically	cleared for FFDM use	by FDA's Office of Dev	rice Evaluation (ODE) be used, but
the use of others is also legal. See FDA's Policy Guidance Help System Modification Document #9 (page 27) Survey Type: □ □ Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqp	to legal. See FDA's Policy Guidance Help System Modification Document #9 (page 27). Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist)	System Modification D it (include MQSA Rq	Nocument #9 (page 27) Imts for Mammo Eqp	t checklist)
	Medical PI	Medical Physicist's QC Tests	C Tests	PASS/FAII
1. Flat Field				 ^
2. Phantom Image Quality		Fibers Specks	Masses drop-o	Click in boxes to use drop-down lists
Phantom IQ Test on AWS	on AWS			
Finantom IQ Test on Printer		_		
15. Review Workstation (RWS) Tests*	IS) Tests* (for all RWS, e	(for all RWS, even if located offsite)		
Overall Results ("F	Overall Results ("Pass" means all tests pass; indicate "Fail" if any test fails)	indicate "Fail" if any te	st fails)	
*FDA requires that all RWS comply with a QC program that is substantially the same as that recommended by the image receptor manufacturer. If the RWS has been approved by the FDA's ODE for FFDM, the FDA considers the RWS's QC manual to be "substantially the same" and you may follow it for QC. (Check with the RWS manufacturer for their system's FDA clearance status and their QC manual.) If the	with a QC program that is approved by the FDA's OE (Check with the RWS manu	substantially the san DE for FFDM, the FDA ifacturer for their syste	ne as that recommend considers the RWS's (m's FDA clearance sta	ed by the image receptor QC manual to be "substantially the tus and their QC manual.) If the
RWS has not been approved by the FDA's ODE for FFDM, you must follow the QC manual provided by the image receptor manufacturer. (In	FDA's ODE for FFDM, you	r must follow the QC	manual provided by the	s image receptor manufacturer. (In
mis case, oneck with the image receptor manufacturer for their required rests.) *** YOUR MEDICAL PHYSICIST MUST SUMMARIZ	*** YOUR MEDICAL PHYSICIST MUST :	equired rests.) SUMMARIZE HIS/	SUMMARIZE HIS/HER RESULTS ON THIS FORM ***	V THIS FORM ***



Laser Film Printers

- FDA recommends only using printers cleared by FDA's Office of Device Evaluation for FFDM (but may legally use others)
 - Facility must have access to a laser printer (either onsite or someplace else)
 - Printer *must* exist and be tested by MP before the facility performs mammography
 - Laser film printer QC

FFDM Mfr	Model	FFDM Mfr's Printer QC Instructions
Ш Э	2000D, DS, Essential	Follow the laser printer mfr's QC
Fischer	SenoScan	Follow the laser printer mfr's QC
Lorad	Selenia	Follow the Lorad Selenia QC Manual
Siemens	Mammomat Novation DR	Follow the laser printer mfr's QC (but conduct QC every day you print)



- FDA MQSA regs state facilities must comply with a QA program substantially the same as recommended by the FFDM manufacturer (i.e., GE, Fischer, Lorad, Siemens, Fuji)
 - Impractical; sometimes impossible since some is software-based
- FDA has informed the ACR that
 - If the monitor/workstation has been approved by FDA's ODE for FFDM, the monitor's QC manual is "substantially the same" and facilities may follow
 - If monitor was not approved by FDA ODE for FFDM facilities must follow one by FFDM mfr
- FDA ODE approved monitors/workstations
 - Over 500 approved total
 - ??? have been approved for FFDM



Accreditation Testing Must Pass

- Clinical image review (fatty and dense breast)
- Phantom image review
- Dose (<300 mrads)
- Processor QC or
- Laser QC for FFDM
 - Follow your mfr QC manual
- Criteria the same for digital as with screen-film



- Tech QC
 - Laser printer density consistency (dry lasers) monthly –
 - ACRIN data shows it rarely fails
 - Darkroom fog test eliminate
 - MTF/System Resolution only for systems with moving parts (e.g., slot-scan, CR) – quarterly
- Medical Physicist QC
 - Eliminate annual kVp testing
 - ACRIN data shows it rarely fails with modern generators

SAM'S Questions

The data collected by MQSA and the ACR Mammography Accreditation Program indicate that the average patient mid-glandular dose for an exam on a FFDM unit relative to the same exam on a Film/Screen unit is as follows:

- 1. MGD on the FFDM unit is 50% greater than the average MGD on the FS unit
- 2. MGD on the FFDM unit is 20% greater than the MGD on the FS unit.
- **8%** 3. MGD on the FFDM unit is the same as the MGD on the FS unit

75% 4. MGD on the FFDM unit is 20% less than the MGD on the FS unit.

17% 5. MGD on the FFDM unit is 50% less than the MGD on the FS unit

Answer: d - approximately 20% less than the MGD on the Film-Screen units

• Reference:

ACR Accreditation Data presented at RSNA 2007 by Pam Wilcox. FDA/MQSA Information page on CDRH/MQSA website - data by Wally Murad, Ph.D., FDA. Using the Mammography Accreditation Phantom specified by the FDA and Accrediting bodies with the Hologic and Siemens FFDM units that use the amorphous selenium detector, the minimum acceptable phantom image quality scores are:

17%	1.	4 fibers, 3 speck groups, 3 masses
0%	2.	5 fibers, 3 speck groups, 4 masses
83%	3.	5 fibers, 4 speck groups, 4 masses
0%	4.	4 fibers, 4 speck groups, 4 masses
0%	5.	3 fibers, 4 speck groups, 4 masses

Answer: C - 5 fibers, 4 speck groups, 4 masses

• Ref: Hologic and Siemens Quality Assurance Manuals, 2007 Versions

The minimum acceptable Half Value Layer measurement on a FFDM unit at 28 kVp for Mo/Mo is:

27%	1.	0.28 mm Al
55%	2.	0.31 mm Al
9%	3.	0.34 mm Al
0%	4.	0.37 mm Al
9%	5.	0.40 mm Al

Answer: B - 0.31 mm Al

- Minimum HVL (Mo/Mo) = (kVp/100) + 0.03 mm Al
- Therefore, @ 28 kVp, minimum HVL = (28/100) + 0.03 = 0.31 mm Al
- Ref: Mammography Quality Control Manual -American College of Radiology (1999)

The minimal acceptable resolution for a digital detector is:

- **0%** 1. 3 lp/mm
- **0%** 2. 4 lp/mm
- **33%** 3. 5 lp/mm
- **67%** 4. 7 lp/mm
- **0%** 5. 10 lp/mm

Answer: D - 7 lp/mm

• Ref: GE, Hologic and Siemens Quality Assurance Manuals, 2007 Version

The maximum acceptable illuminance in a reading room for digital mammograms is:

17%	1.	50 lux
0%	2.	40 lux
83%	3.	20 lux
0%	4.	10 lux
0%	5.	5 lux

Answer: C - 20 lux

 Ref: "Medical Physicist's Evaluation Forms," American College of Radiology Website, February 2006 Version