Quality Control of Full Field Digital Mammography Units

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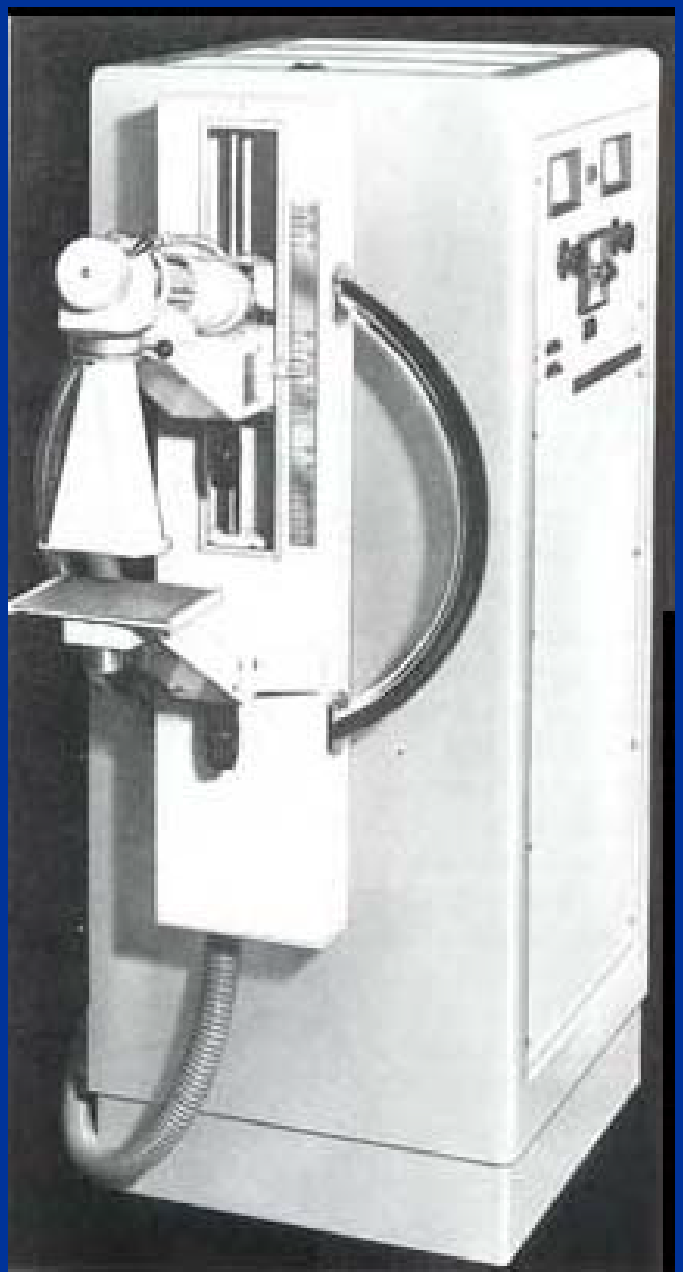
History of Mammography



1966:
First dedicated mammography system

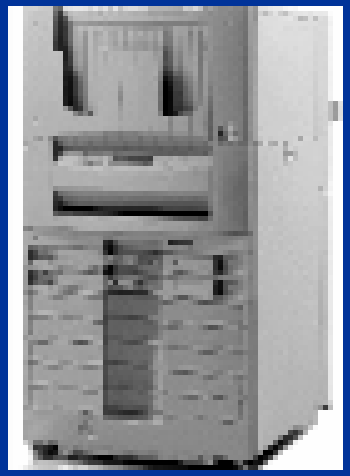
Screen-Film Mammography

For 35+ years, screen-film has been the “gold standard” for breast cancer detection

Screen Film Mammography

X-ray source

Screen-film cassette



Film Processor

Film viewer

Full Field Digital Mammography

X-ray source

Acquisition computer

Digital detector

Softcopy display

System Quality Control

- Pre-Acquisition
- Acquisition
- Image Processing and Display
- Storage/Archive

The system is only as good as the weakest link
-*more* than just the modality itself

QC Recommendations

- **Daily** QC checks (technologist)
  - System warmup
    - **Detector uniformity**
    - **Spatial resolution**
    - **Contrast resolution (signal to noise ratio)**
    - **Geometric accuracy**
    - **Clinical review and artifact identification**
  - Logging / preventive maintenance

FDA Approved Full-Field Digital Mammography Systems

GE Senographe 2000D
- January 28, 2000

Fischer SenoScan
– September 25, 2001

Lorad Selenia
– October 2, 2002

GE Senographe DS
– February 19, 2004

Siemens Mammomat Novation DR
- August 20, 2004

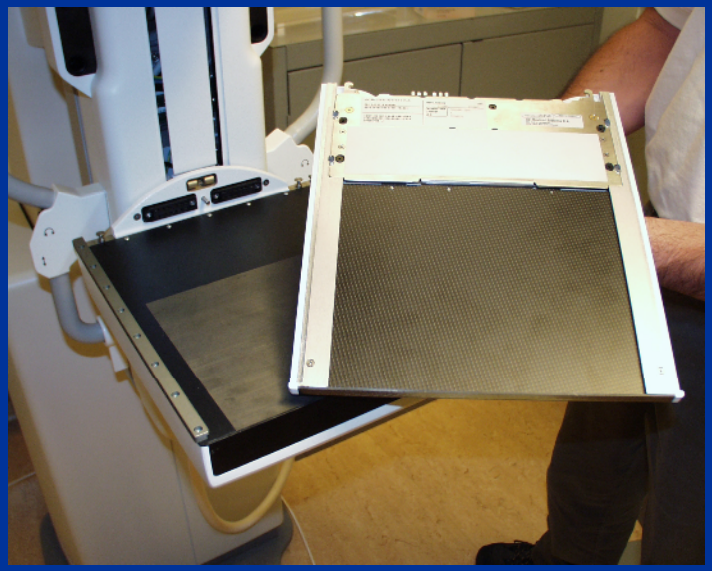
GE Senographe Essential
- April 11, 2006

Fuji FCRm
- July 10, 2006

Lorad Dimension
February 2009

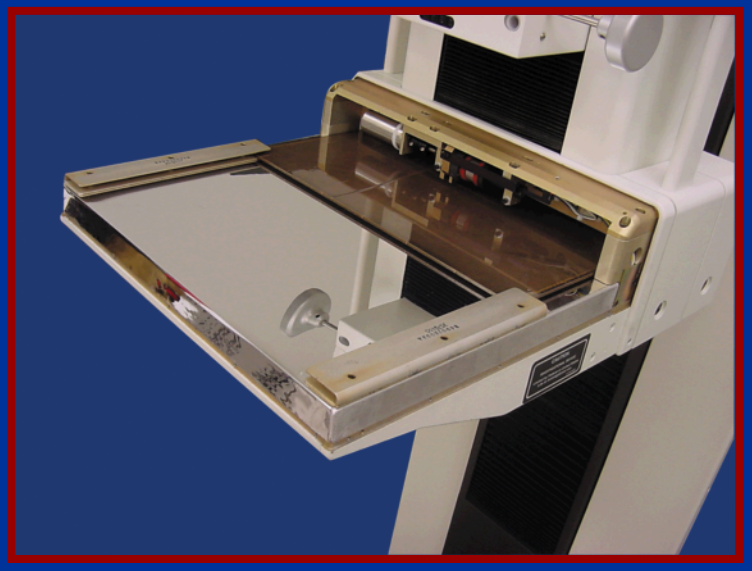
GE 2000D

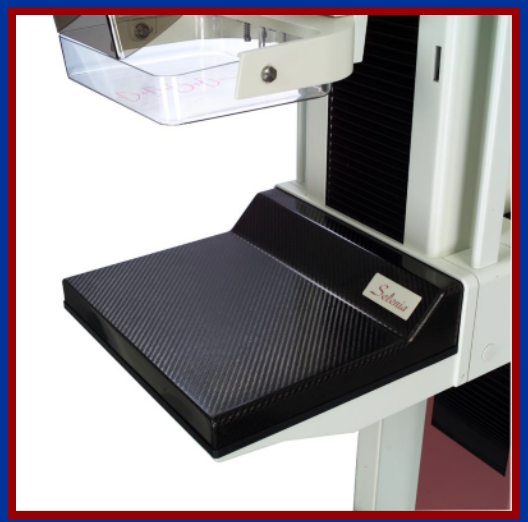
System Components



GE Seno DS & Essential

Lorad Selenia

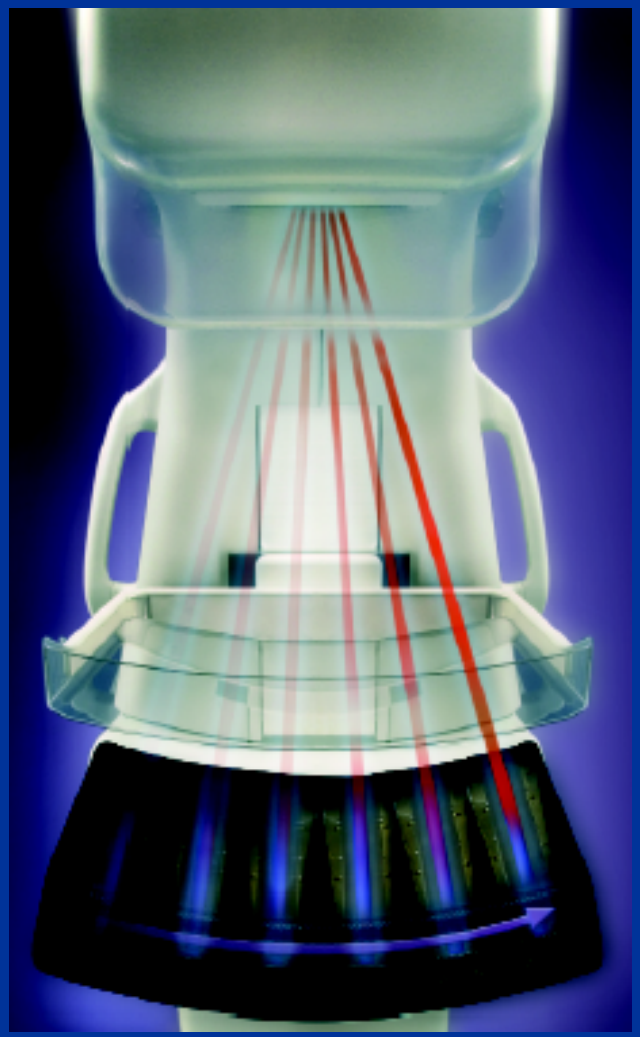




Siemens

Mammomat *Novation*^{DR}

Fischer Senoscan



MQSA National Statistics

- Certified facilities as of 4/1/09: 8764
- Certified facilities as of 10/1/2008: 8814
- Total accredited units (4/1/09): 13,052
- Certified facilities with FFDM units: 4371
  (4/1/09) - 50% of facilities
- Accredited FFDM units (4/1/09): 6577
  - 50.4% of all units

Why Full Field Digital Mammography?

- Technical Reasons
- Clinical Reasons
- Practical Reasons

Why FFDM - Technical Reasons

- Wider dynamic range
  - 3-4 times higher
- Linear detector response
  - Over full range
- Better low contrast resolution
  - Enhanced visualization of masses
- Higher DQE
  - Higher absorption efficiency
  - Dose or SNR
  - Important for detector as well as entire system

Why FFDM- Practical Reasons

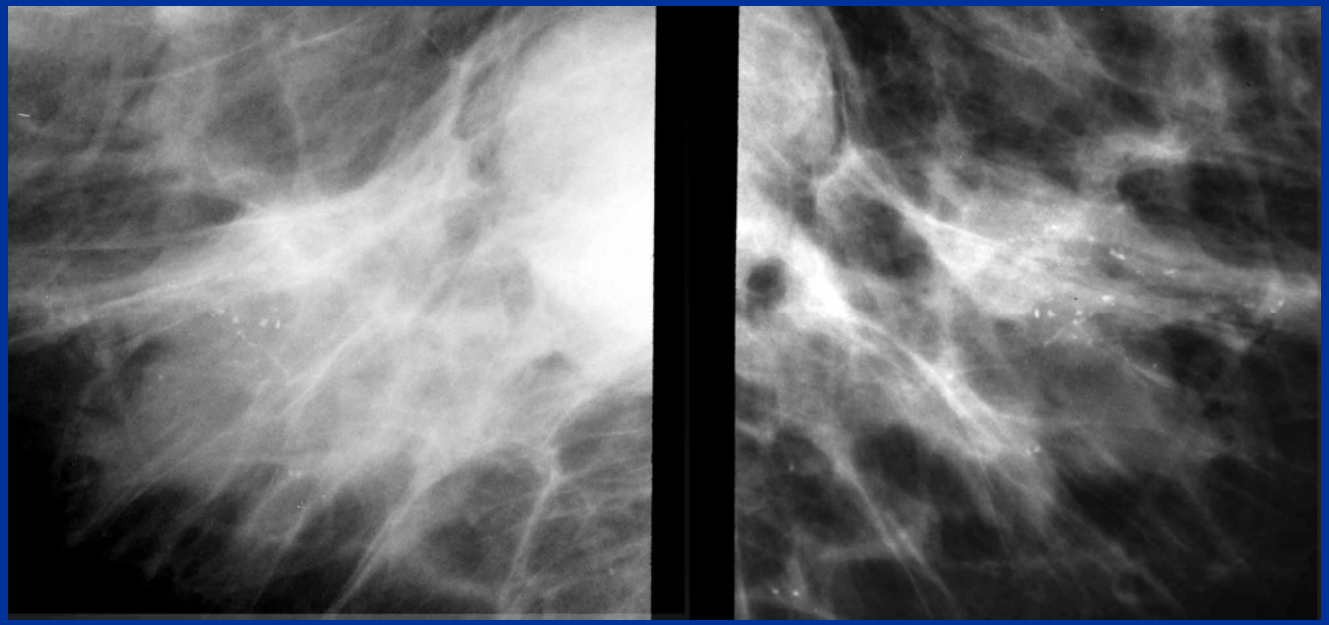
- Higher reimbursements
- Higher throughput
- Reduced retakes/call backs
- Completes PACS implementation
- Facility competitiveness
- User demand

Phantom Images and Dose

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

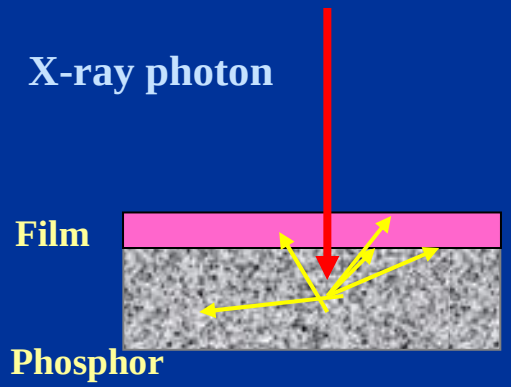
**as measured by TLD*

Digital Mammography Detector Technical Background

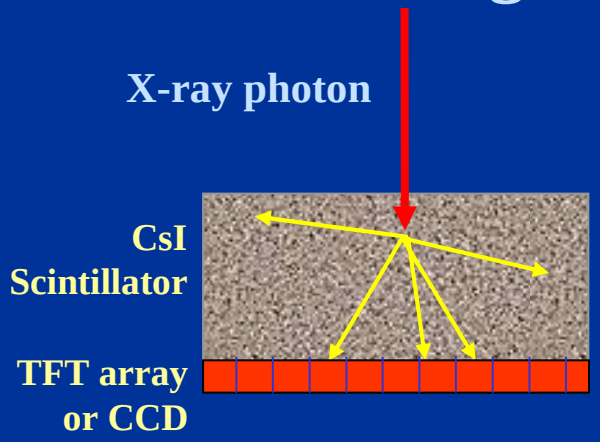


Direct Vs. Indirect Conversion

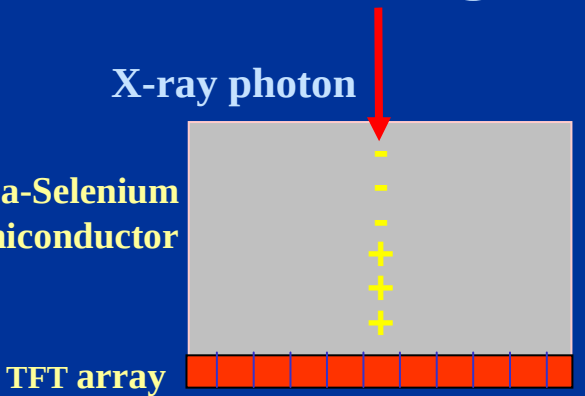
Film

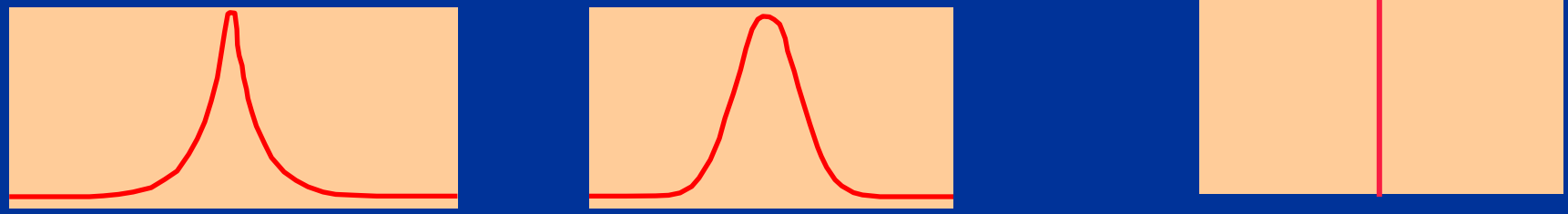


GE Senographe Indirect Digital



Selenia Direct Digital





Line spread functions

Currently Available FFDM Systems

•GE Medical Systems	Senographe 2000D, Senographe DS and Essential	Indirect conversion TFT
•Fischer Imaging (No longer available as new)	Senoscan	indirect conversion, slot scanning
•Hologic/Lorad	Selenia	direct conversion TFT
•Siemens Medical	Mammomat Novation (DR)	direct conversion TFT

FFDM Quality Control

- MQSA Final Regulation
  - Screen-Film QA/QC
  - Manufacturer QA/QC for FFDM System
- Manufacturer's FFDM QC Manual

LORAD Selenia QC Tests

QC Manual tests:

- Medical Physicist
  - Annually
- Radiologic Technologist
  - Daily
  - Weekly
  - Biweekly
  - Monthly
  - Quarterly
  - Semiannually

Medical Physics Annual Tests

- Mammographic Unit Assembly Evaluation
- Collimation Assessment
- Artifact Evaluation
- kVp Accuracy and Reproducibility
- HVL Measurement
- Evaluation of System Resolution
- Breast Entrance Exposure and Glandular Average Dose
- Radiation Output Rate
- Phantom Image Quality Evaluation
- Signal-To-Noise and Contrast-To-Noise Measurements
- Viewbox Luminance and Room Illuminance
- Softcopy Workstation QC

QC Tests for FFDM Units: Tests and Frequencies Differ

	Ex: Tech Test Frequencies			
Test	Soft Copy Display	SNR	Flat Field	MTF/ Sys Res
GE	Monthly	Monthly	Weekly	Monthly
Fischer	Daily	Weekly	Weekly	Monthly
Lorad	Weekly	Weekly	Bi-weekly	Not required

LORAD Selenia FFDM System

- RT QC Tests

Technologist QC Tests

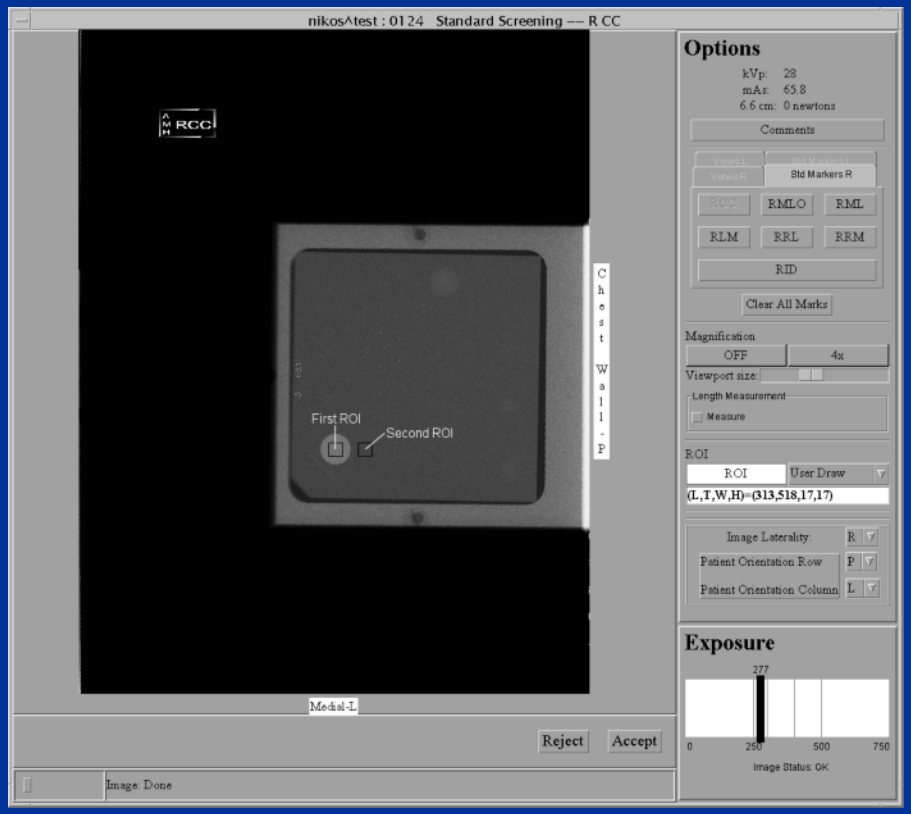
- Laser Printer Quality Control (Weekly)
- SNR and CNR Measurements (Weekly)
- Softcopy Workstation QC (Weekly)
- Phantom Image (Weekly)

Laser Printer Quality Control

- SMPTE Pattern from Acquisition Workstation
- Measure 10%, 40% and 90% Density Patches
- Daily Performance
  - 40% density tracks within ±15%
  - (40% - 10%) density tracks within ±15%
  - 90% density tracks within ±15%
- **NOTE**: Printer uses linear LUT

SNR and CNR Measurements

- ACR Accreditation Phantom with Disc (Weekly)
- Measure SNR and CNR from Image



SNR and CNR Measurements

- Passing Criteria
  - SNR at least equal or greater than 40
  - CNR should stay within ±15% of measurement obtained during acceptance testing of system

LORAD Selenia FFDM System

- Workstation QC

Room Illuminance

- From the ACR QC Manual, 1999, the room illuminance must be below 50 lux.
- From the February 2006 version of the Medical Physicist Equipment Evaluation forms from ACR, room illuminance for soft copy displays must be below 20 lux.

Softcopy Workstation QC

- Performed Weekly
  - Black level measurement
  - White level measurement
- Performed Monthly
  - LUT conformance
- Performed Quarterly
  - White field uniformity

Softcopy Workstation QC

- Data Logged by Software
- Warning Flags and Errors if Conformance Fails

Phantom Image

- Review Weekly Phantom Image Results
  - Measured film densities
  - Phantom objects seen (printer, monitors)
    - 5 fibers
    - 4 speck groups
    - 4 masses

QC Alternative Standard

- The majority of the required QC testing performed on a FFDM system applies to system components other than the digital image receptor.
- Only a small portion of the quality control testing performed on an FFDM system is specific to the digital image receptor.
- Thus, alternative standards has been approved by FDA on the QC testing of several of the FFDM systems.

Action Category A

- **Applies to performance testing of the digital image receptor**
- Corrective action shall be taken before any further examinations are performed
  - Evaluation of System Resolution
  - Breast Entrance Exposure and Average Glandular Dose
  - Phantom Image Quality Evaluation
  - SNR and CNR Measurements

Action Category B

- **Applies to performance testing of diagnostic devices used for mammographic image interpretation**
- Corrective action shall be taken before the device can be used for mammographic image interpretation
- Clinical imaging can be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation
  - Phantom Image Quality Evaluation
  - Softcopy Workstation QC
  - Laser Printer Quality Control

Action Category C

- **Applies to performance testing of rest of the system**
- Corrective action shall be taken within thirty days of the test date
- Clinical imaging and mammographic image interpretation can be continued during this period
  - All other tests

Quality Control Procedures for Senographe Digital Mammography Systems

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Display Systems

Review Workstation
(RWS)

Seno Advantage
(CRT or LCD)

The QC Manual

- QC Test Procedures for the Radiologic Technologist + Data Forms
- QC Test Procedures for the Medical Physicist + Data Forms
- Guidance
  - suggestions on performance of the tests
  - what to do when tests are not passed
  - references to publications
  - recommendations on commercial products

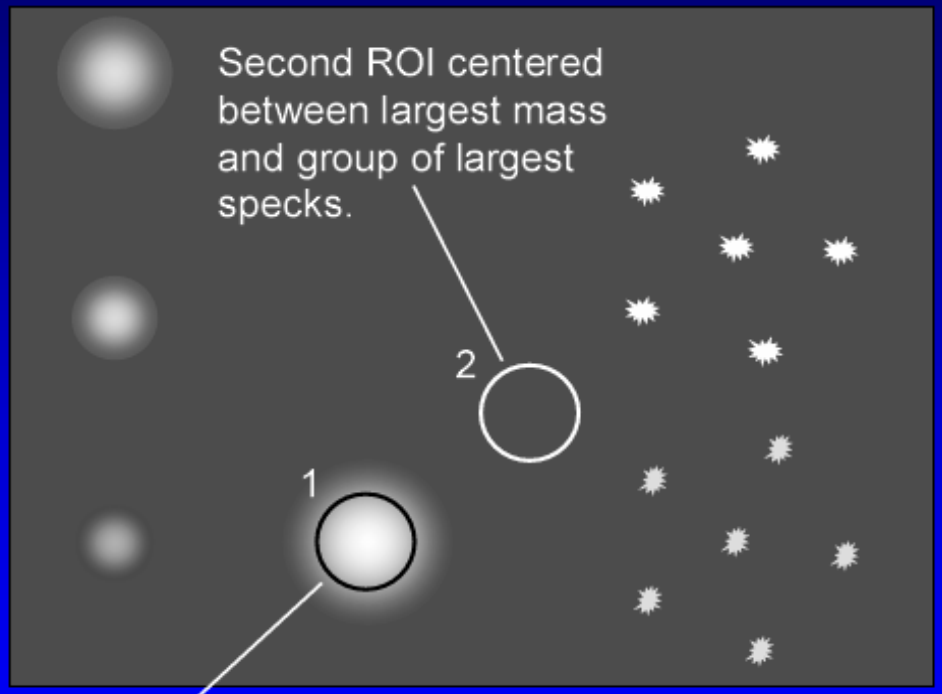
QC Tests for the Radiologic Technologist

Frequency	Procedure
Daily	Monitor Cleaning
	Viewing Conditions for review station
Weekly	Flat Field
	Senographe 2000 D Phantom Image on AWS, RWS, printer CNR Test Senographe DS, Essential Phantom Image on AWS CNR and MTF Measurement
	Viewbox and Viewing Conditions Test

QC Tests for the Radiologic Technologist

Frequency	Procedure
Monthly	MTF Measurement (Seno 2000 D)
	AOP Mode and SNR Check
	Visual Checklist
	Monitor Calibration Check SMPTE pattern evaluation on the diagnostic review station
Quarterly	Repeat Analysis Check
Semi-Annually	Compression Force Test

Change of CNR Test, 2000 D



- Difference of means measures contrast.
- Std. Dev. of background measures noise.

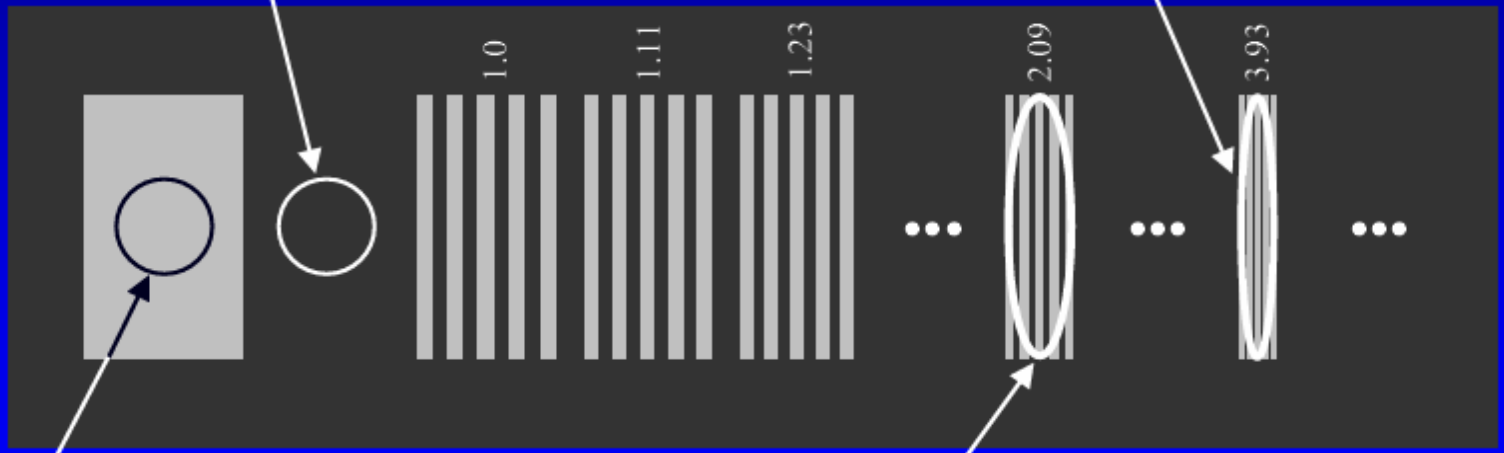
ΔCNR must not exceed 0.2.

MTF Measurement, 2000 D

MTF from Noise Measurements in ROIs

ROI to measure mean of "bar" material.

ROI to measure std. dev. of "4 lp/mm" pattern.



ROI to measure mean of "space" material.

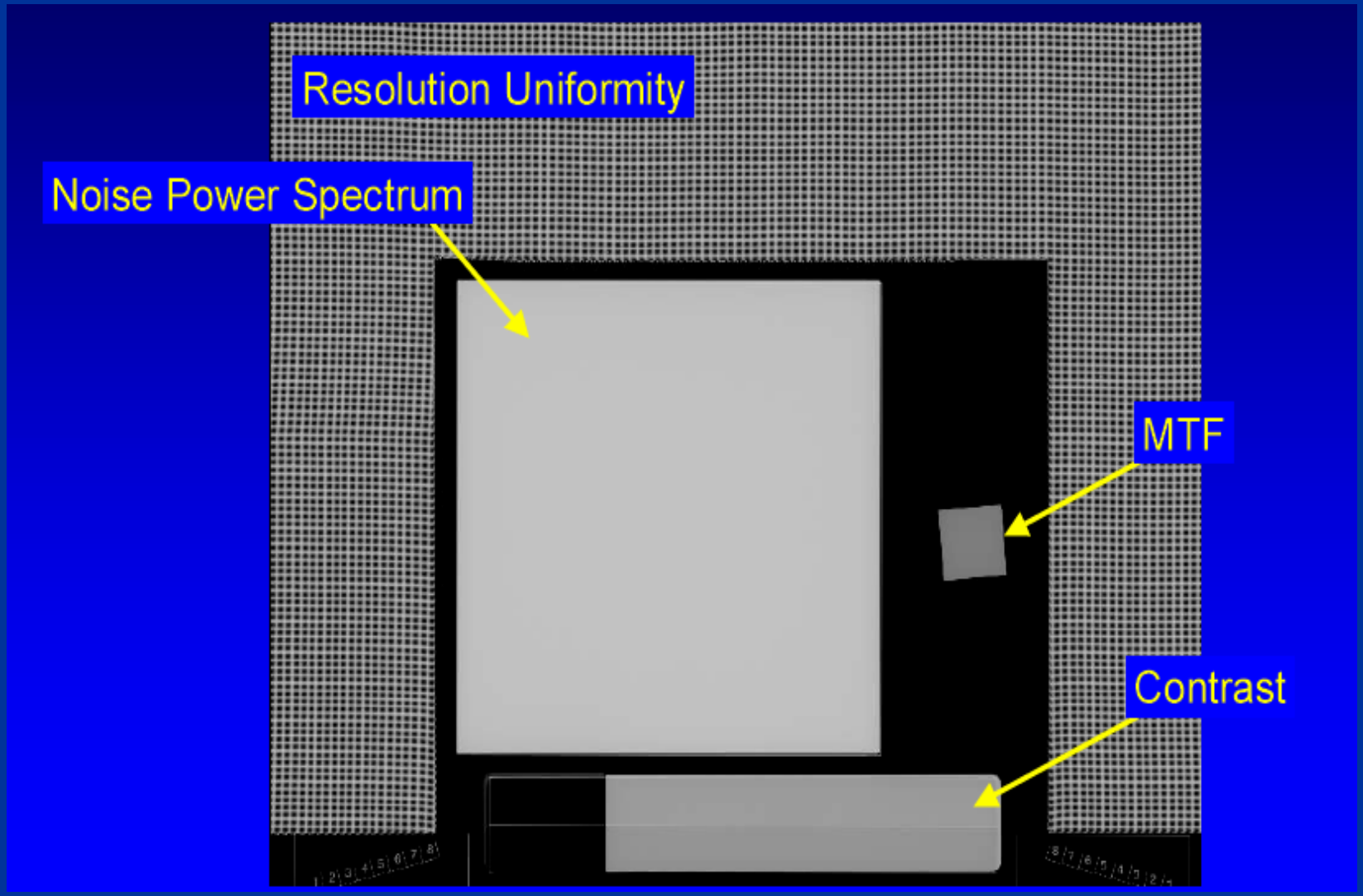
ROI to measure std. dev. of "2 lp/mm" pattern.

Seno DS, Essential – IQST

IQST – Image Quality Signature Test

Automates MTF and CNR Tests

Seno DS, Essential – IQST



AOP Mode and SNR Check

Check for correct selection of

- **kVp,**
- **anode track,**
- **filter, and**
- **mAs**

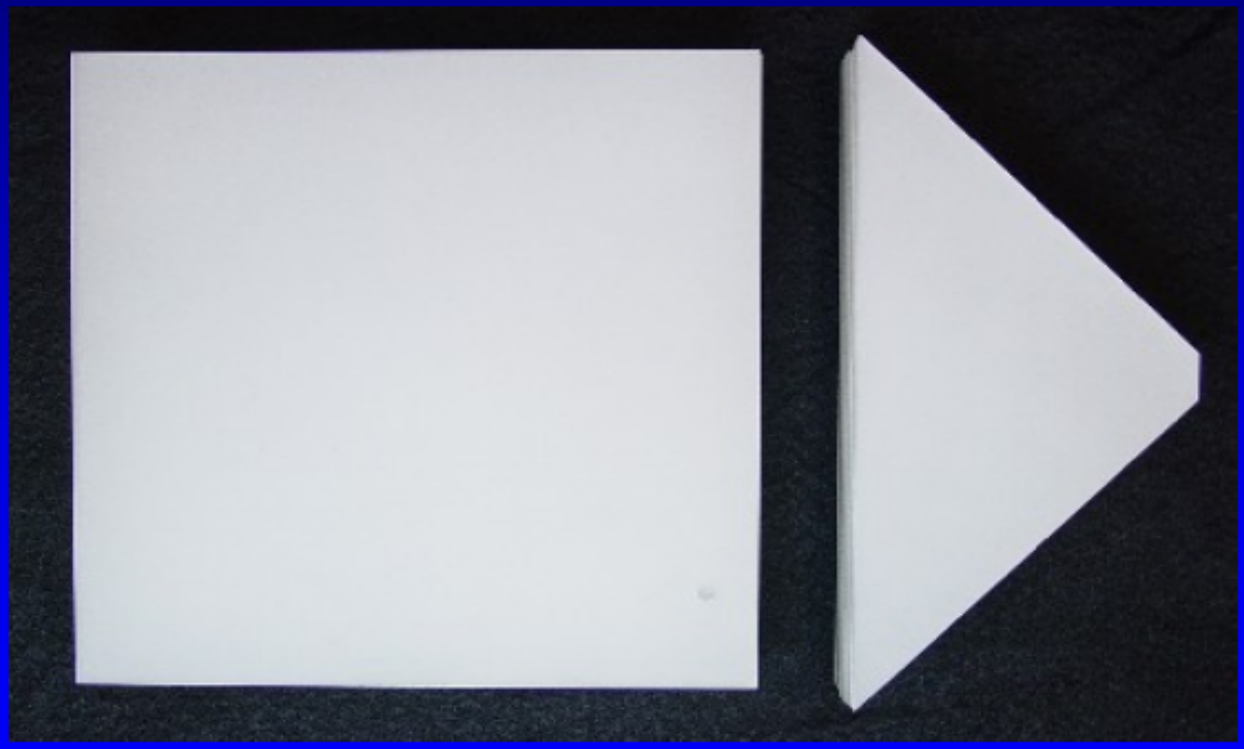
by the Automatic Optimization of Parameters (AOP) algorithm when varying phantom thickness and

- **correct level of SNR**

Automated for DS and Essential

AOP Test Change

Trapezoidal Plates for SNR/AOP Test



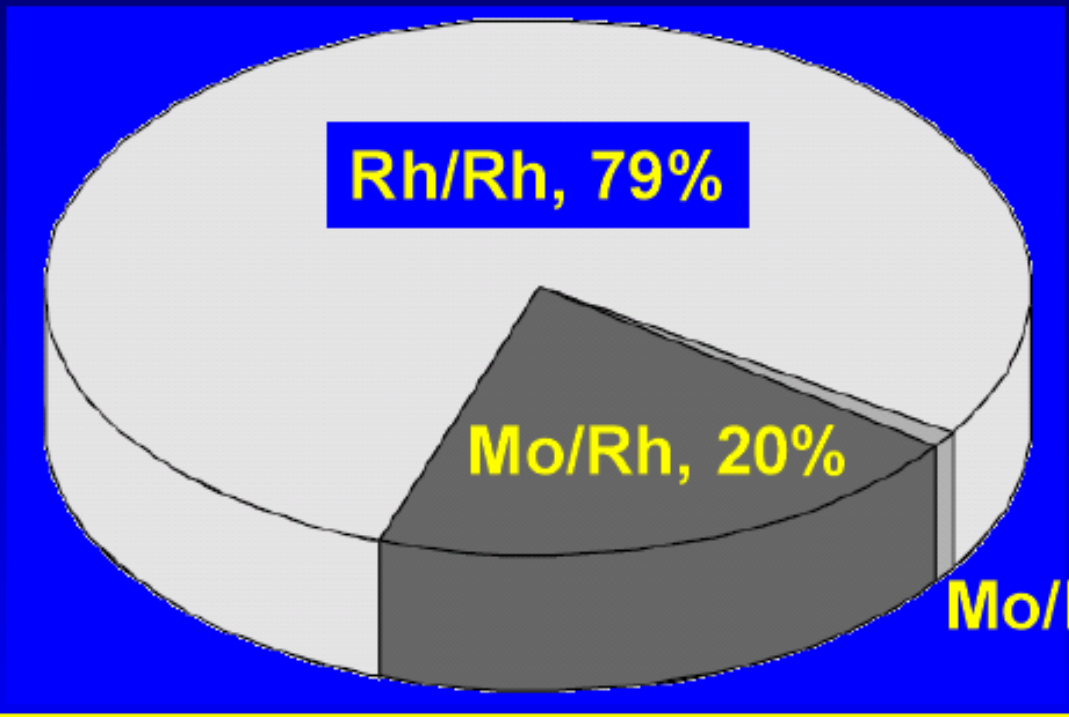
Seno 2000 D **Seno DS, Essential**

AOP Change & Phantom IQ

- Seno 2000 D
  - Mo / Mo, 26 kVp, 125 mAs
  - Simulates AOP CNT mode
  - “film-like”
- Seno DS and Essential
  - Rh / Rh, 29 kVp, 56 mAs
  - Simulates AOP STD mode
  - “digital”

AOP Change

Predicted Track / Filter Combination Use



Optimized for consistent CNR rather than detector exposure

Siemens Novation

SIEMENS

Quality Control Manual
MAMMOMAT *Novation* DR

SP

Required Tests
Acquisition Workstation Monitor Check

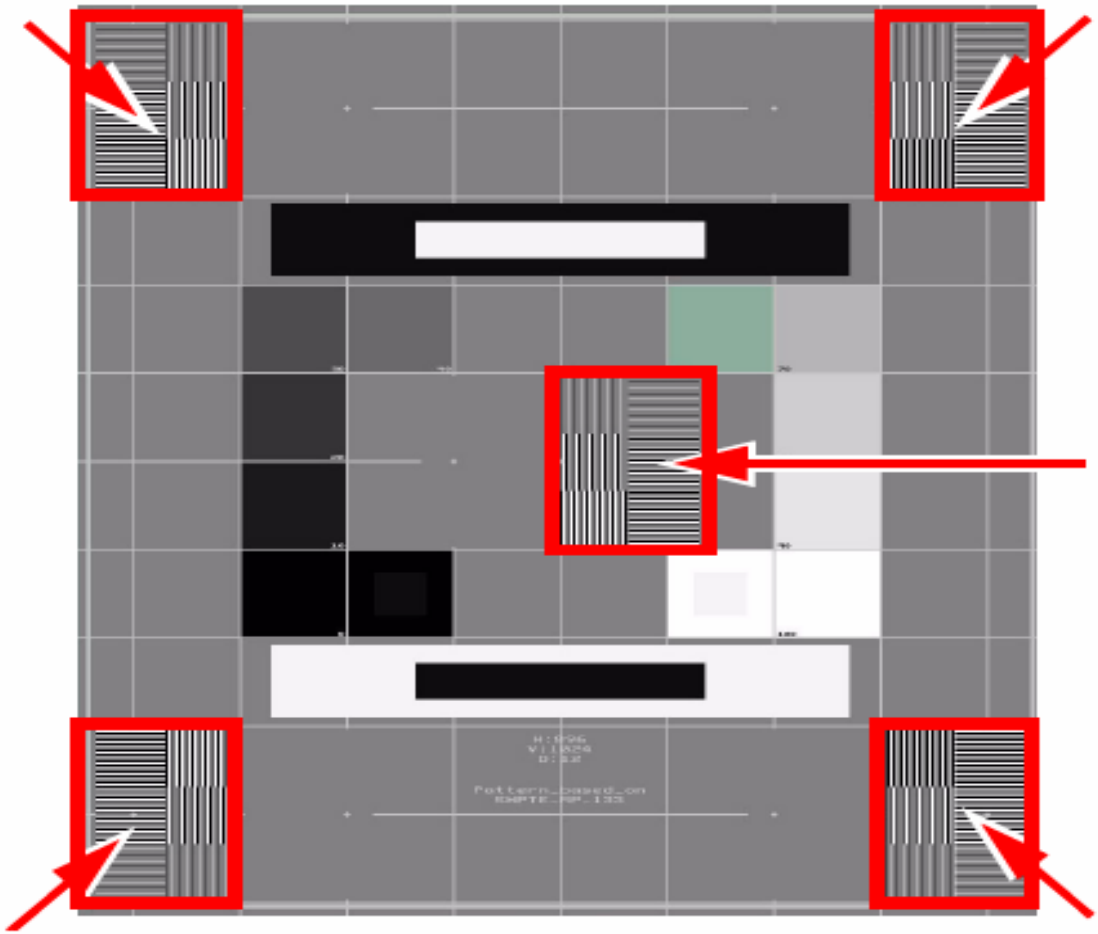


Figure 4-5 Location of Contrast Bar Patterns

Required Tests
Acquisition Workstation Monitor Check

Visually check the monitor's performance by looking for streaking, fluttering and shadows.

The spatial resolution (linearity) and aliasing (distortion) of the monitor are considered to be within acceptable limits if the high contrast bar patterns in the test image can be seen as patterns of white and black pairs. To use the pattern, inspect the 6 squares filled with varying widths of alternating black/white horizontal and vertical lines in each corner (see Figure 4-5) of the image as well as in the center. You should be able to differentiate all the lines, from wide to narrow (6 pixels, 4 pixels, and 2 pixels) both horizontally and vertically.

4.3.4 Performance Criteria and Corrective Action

- The 5% and 95% squares shall be visible. (The preset values for brightness and contrast on the monitor may not be adequate to fulfill this requirement. Adjust brightness and contrast (if not adequate enough) according to *5.6 Troubleshooting: Contrast and Brightness Settings on the Monitor* and repeat test *4.3 Acquisition Workstation Monitor Check*.
- All high contrast bar patterns in the four corners and in the center of the image (see Figure 4-5) shall be resolved.

If any level is found to be beyond any action level stated, the source of the problem must be identified and the problem corrected by a Siemens customer support engineer and successfully retested by the MP before further examinations are performed using the system.

Phantom Image Quality Check

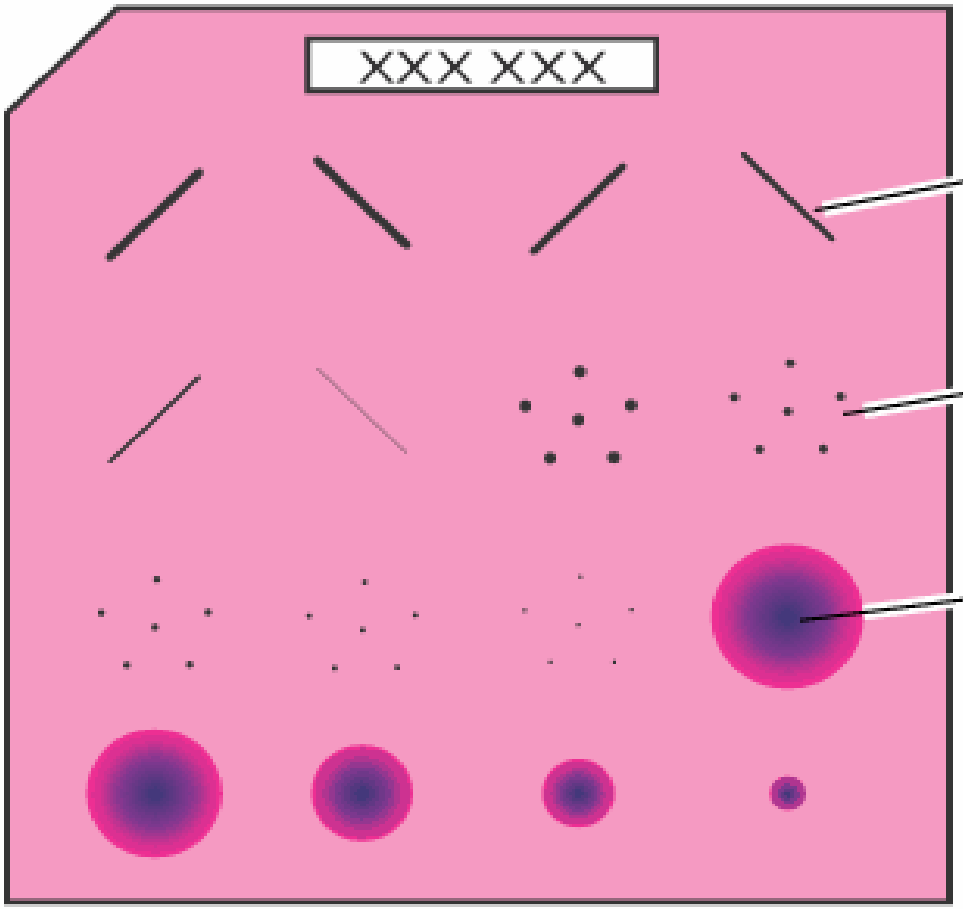


Figure 4-18 Potentially Visible Objects in the Accreditation Phantom

Fuji Digital Mammography QC Technologist's Tests

TEST	FREQUENCY
CNR-Contrast/Noise	Weekly
Phantom Image	Weekly
Printer/Monitor	Per Manufacturer
Visual Checklist	Monthly
Repeat Analysis	Quarterly
Compression	Semi-annual
IP Fog	Semi-annual

Fuji Digital Mammography QC Technologist's Tests

Phantom Images Test

Confirms image quality using ACR Phantom

Tools required - QC Cassette & ACR Phantom

Method - AEC Exposure, process IP using the Physics, ACR MAPP Menu

Visually inspect the image. Same scoring method as MQSA

Correction Period - Before any further examinations are performed

Fuji Digital Mammography QC Technologist's Tests

CNR (Contrast/Noise Ratio) Test

Evaluates Noise and Contrast using a fixed x-ray exposure

Tools needed - 4 cm acrylic block & 0.2 mm Al

Method - Fixed manual technique

CNR Measurement must be within +/- 20%

Correction Period - Before any further examinations are performed

Fuji Digital Mammography QC Technologist's Tests

Tests in Accordance with ACR/MQSA

Visual Checklist	**Monthly**
Repeat Analysis	**Quarterly**
Compression Test	**Semi-Annual**

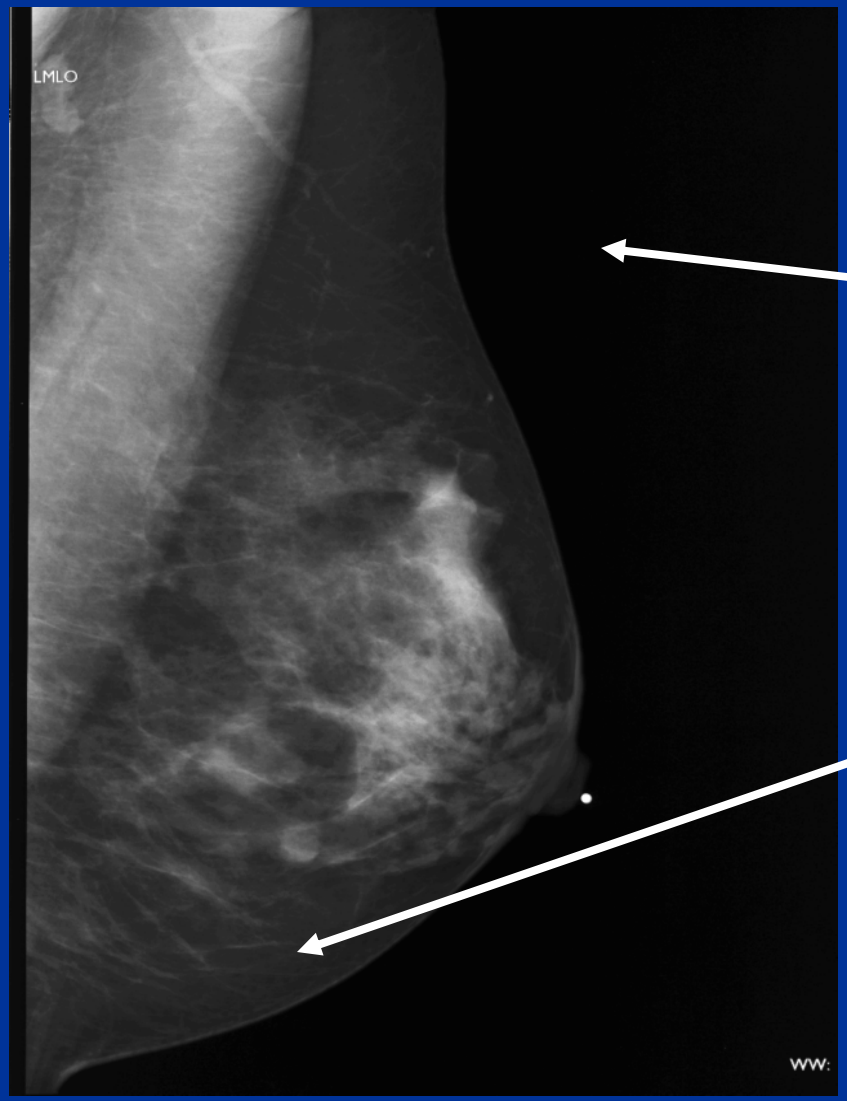
Same Action Limits and Corrective Action as MQSA

IP Fog replaces Darkroom Fog test - Semi Annual

There Are Currently Several FDA-Approved Laser Imagers for Digital Mammography

- Agfa DS4500M
- Kodak 8600 Laser Imager
- Kodak 8610 Laser Imager
- Kodak 8900M
- Fuji Drypix 7000 & 5000
- Fuji Drypix FM-DP L
- Konica DryPro 793

OD Requirements for Hi-Resolution Laser Imagers

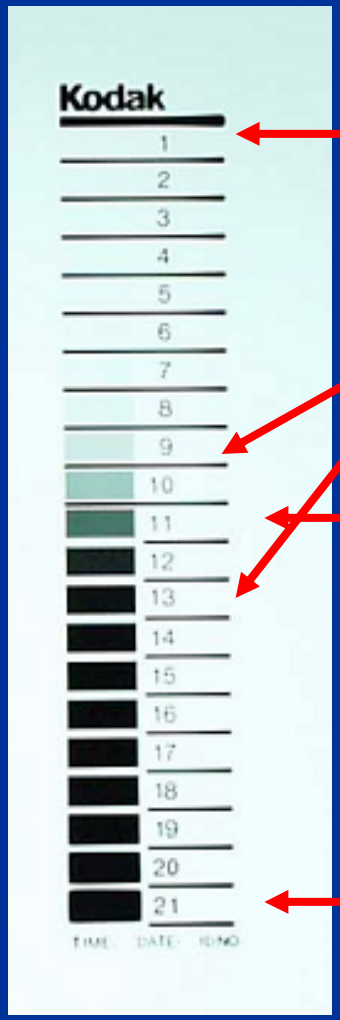


D_{max} > 3.5 OD

Mid-density > 1.5 OD

Laser Processor QC

Kodak daily sensitometry



Base + Fog

Density Difference – OD closest to 2.20 minus OD closest but not less than 0.45

Mid-density – step closest to but not less than 1.20

Action Limits:

MD & DD ± 0.15 OD

B+Fog = 0.03

D_{max}

D_{max} ± 0.25

Before a New Facility May Examine Patients

- Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass
- Facility must send ACR the Entry Application, fees and your Equipment Evaluation Pass/Fail results
  - ACR staff reviews and approves complete application and Equipment Evaluation and notifies FDA (or state certifier)
- Facility must receive 6-month provisional MQSA certificate (or interim notice)
  - Not more than 4 days from the time facility submits required documentation to ACR
- Recommend scheduling Equipment Evaluation 1 week before examining patients (including "applications")

Thank You !!!

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