Quality Control of Full Field Digital Mammography Units

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History of Mammography

1966: First dedicated mammography system
For 35+ years, screen-film has been the “gold standard” for breast cancer detection
Screen Film Mammography

X-ray source

Film Processor

Film viewer

Screen-film cassette
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
<table>
<thead>
<tr>
<th>System</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE Senographe 2000D</td>
<td>January 28, 2000</td>
</tr>
<tr>
<td>Fischer SenoScan</td>
<td>September 25, 2001</td>
</tr>
<tr>
<td>Lorad Selenia</td>
<td>October 2, 2002</td>
</tr>
<tr>
<td>GE Senographe DS</td>
<td>February 19, 2004</td>
</tr>
<tr>
<td>Siemens Mammomat Novation DR</td>
<td>August 20, 2004</td>
</tr>
<tr>
<td>GE Senographe Essential</td>
<td>April 11, 2006</td>
</tr>
<tr>
<td>Fuji FCRm</td>
<td>July 10, 2006</td>
</tr>
<tr>
<td>Lorad Dimension</td>
<td>February 2009</td>
</tr>
</tbody>
</table>
GE 2000D

System Components
GE Seno DS & Essential
Lorad Selenia
Siemens
Mammomat Novation\textsuperscript{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

<table>
<thead>
<tr>
<th></th>
<th># Units</th>
<th>Fibers</th>
<th>Specks</th>
<th>Masses</th>
<th>Ave Dose* (mrads)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen-Film</td>
<td>14,574</td>
<td>4.70</td>
<td>3.60</td>
<td>3.74</td>
<td>168.7</td>
</tr>
<tr>
<td>(SD)</td>
<td>(0.48)</td>
<td>(0.4)</td>
<td>(0.41)</td>
<td></td>
<td>(31.4)</td>
</tr>
<tr>
<td>FFDM</td>
<td>1711</td>
<td>4.84</td>
<td>3.85</td>
<td>4.00</td>
<td>128.6</td>
</tr>
<tr>
<td>(SD)</td>
<td>(0.54)</td>
<td>(0.33)</td>
<td>(0.39)</td>
<td></td>
<td>(38.6)</td>
</tr>
</tbody>
</table>

*as measured by TLD
Digital Mammography Detector Technical Background
Direct Vs. Indirect Conversion

**Film**
- X-ray photon
- Film
- Phosphor

**GE Senographe Indirect Digital**
- X-ray photon
- CsI Scintillator
- TFT array or CCD

**Selenia Direct Digital**
- X-ray photon
- a-Selenium Semiconductor
- TFT array

Line spread functions
<table>
<thead>
<tr>
<th>Currently Available FFDM Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GE Medical Systems</strong></td>
</tr>
<tr>
<td><strong>Fischer Imaging</strong></td>
</tr>
<tr>
<td>(No longer available as new)</td>
</tr>
<tr>
<td><strong>Hologic/Lorad</strong></td>
</tr>
<tr>
<td><strong>Siemens Medical</strong></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Test</th>
<th>Soft Copy Display</th>
<th>SNR</th>
<th>Flat Field</th>
<th>MTF/ Sys Res</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>Monthly</td>
<td>Monthly</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Fischer</td>
<td>Daily</td>
<td>Weekly</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Lorad</td>
<td>Weekly</td>
<td>Weekly</td>
<td>Bi-weekly</td>
<td>Not required</td>
</tr>
</tbody>
</table>
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
<table>
<thead>
<tr>
<th>Frequency</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>Monitor Cleaning</td>
</tr>
<tr>
<td></td>
<td>Viewing Conditions for review station</td>
</tr>
<tr>
<td>Weekly</td>
<td>Flat Field</td>
</tr>
<tr>
<td></td>
<td>Senographe 2000 D</td>
</tr>
<tr>
<td></td>
<td>Phantom Image on AWS, RWS, printer</td>
</tr>
<tr>
<td></td>
<td>CNR Test</td>
</tr>
<tr>
<td></td>
<td>Senographe DS, Essential</td>
</tr>
<tr>
<td></td>
<td>Phantom Image on AWS</td>
</tr>
<tr>
<td></td>
<td>CNR and MTF Measurement</td>
</tr>
<tr>
<td></td>
<td>Viewbox and Viewing Conditions Test</td>
</tr>
</tbody>
</table>
# QC Tests for the Radiologic Technologist

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly</td>
<td>MTF Measurement (Seno 2000 D)</td>
</tr>
<tr>
<td></td>
<td>AOP Mode and SNR Check</td>
</tr>
<tr>
<td></td>
<td>Visual Checklist</td>
</tr>
<tr>
<td></td>
<td>Monitor Calibration Check</td>
</tr>
<tr>
<td></td>
<td>SMPTE pattern evaluation on the diagnostic review station</td>
</tr>
<tr>
<td>Quarterly</td>
<td>Repeat Analysis Check</td>
</tr>
<tr>
<td>Semi-Annually</td>
<td>Compression Force Test</td>
</tr>
</tbody>
</table>
Change of CNR Test, 2000 D

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

$\triangle CNR$ 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
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

- Rh/Rh, 79%
- Mo/Rh, 20%
- Mo/Mo, 1%

Optimized for consistent CNR rather than detector exposure
Siemens Novation
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
<table>
<thead>
<tr>
<th>TEST</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNR-Contrast/Noise</td>
<td>Weekly</td>
</tr>
<tr>
<td>Phantom Image</td>
<td>Weekly</td>
</tr>
<tr>
<td>Printer/Monitor</td>
<td>Per Manufacturer</td>
</tr>
<tr>
<td>Visual Checklist</td>
<td>Monthly</td>
</tr>
<tr>
<td>Repeat Analysis</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Compression</td>
<td>Semi-annual</td>
</tr>
<tr>
<td>IP Fog</td>
<td>Semi-annual</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Checklist</td>
<td>Monthly</td>
</tr>
<tr>
<td>Repeat Analysis</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Compression Test</td>
<td>Semi-Annual</td>
</tr>
</tbody>
</table>

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

\[ D_{\text{max}} > 3.5 \text{ OD} \]

\[ \text{Mid-density} > 1.5 \text{ OD} \]
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} ± 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”)

Butler/Wilcox - RSNA 2006
Thank You !!!

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