QC for FFDM: What You Must Do and What Really Matters

Eric A. Berns, Ph.D.
Northwestern University Medical School
Lynn Sage Comprehensive Breast Center
Chicago, IL

OVERVIEW

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

Important Pre-Survey Events

• Obtain proper training & CE credits (8 hours)
  – Hands-on training on actual unit:
    • Mechanics
    • Software
    • Artifacts
    • Learn vendor specific tests and tricks

Important Pre-Survey Events

• ACR Accreditation - www.acr.org
  – GE Senographe 2000D
  – Fischer Senoscan
  – Lorad Selenia
• FDA Accreditation - www.fda.gov/cdrh/mammography/
  – GE Senographe DS
  – Siemens, Sectra, Fuji, etc., when approved
### Important Pre-Survey Events

**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

### Important Pre-Survey Events

**ACR Accreditation – Equipment Evaluation Forms**

- MQSA Certification Extension for **GE Senographe DS**
  - Site must already be screen-film certified by FDA
  - Three things to submit to FDA:
    - Application of qualifications
    - Medical Physicist Survey
    - Printed ACR Phantom
- Must have approval letter from FDA before clinical imaging can be performed
**Important Pre-Survey Events**

- 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**

- Complete re-calibration
- 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**

- Copy of ACR or FDA forms
- 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 – 1 or 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” of “Processed” images for testing
Performing the Survey

GE 2000D

http://www.gemedicalsystems.com/services/repl_parts/documentation.html

GE Review Workstation

GE 2000D - Performing the Survey

- Manufacturer's tests
  - Mammography unit evaluation
  - Flat field uniformity
  - Artifact evaluation
  - AOP Mode and SNR Check
  - ACR Phantom and Contrast-to-Noise Ratio (CNR) Check
  - MTF measurement
  - Collimation Assessment
  - Evaluation of Focal Spot

*30 Days to Repair
GE 2000D - Performing the Survey

- Manufacturer’s tests
  - Breast entrance exposure, average glandular dose, and reproducibility
  - Beam quality (HVL)
  - kVp accuracy and reproducibility *
  - Radiation output
  - Viewing conditions check and setting
  - Monitor calibration *
  - Image quality – SMPTE pattern
  - Analysis of RWS screen uniformity *

*30 Days to Repair

GE 2000D - Performing the Survey

- Flat-field uniformity
  - Test to ensure detector performance acceptable
  - Measures detector uniformity (signal & noise)
  - Measures bad pixels
  - System automatically calculates pass/fail

GE 2000D - Performing the Survey

- Artifact evaluation
  - 1 inch acrylic phantom
  - Use clinical techniques
  - Image at each target/filter
  - Image at each magnification mode
  - Review images at window width ~ 400 to 450
  - Review artifact images on RWS, AWS, and printed film

GE 2000D - Performing the Survey

- AOP Mode and SNR Check
  - Variable thicknesses of acrylic - 2.5, 4, 6 cm
  - Std, Auto
  - Evaluate:
    - Correct techniques?
    - Adequate SNR?

<table>
<thead>
<tr>
<th>Acrylic Thickness</th>
<th>Target-Filter</th>
<th>Selected kVp</th>
<th>Selected mAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 cm Mo-Mo</td>
<td>27 kVp</td>
<td>20-60</td>
<td></td>
</tr>
<tr>
<td>4.0 cm Mo-Rh</td>
<td>28 kVp</td>
<td>35-90</td>
<td></td>
</tr>
<tr>
<td>6.0 cm Rh-Rh</td>
<td>32 kVp</td>
<td>35-90</td>
<td></td>
</tr>
</tbody>
</table>

Each “raw” image must have a measured SNR of at least 50
**GE 2000D - Performing the Survey**

- **ACR Phantom Imaging**
  - Manual technique & 3 auto modes
  - Score the processed image
  - Acquisition workstation
  - Each monitor of the RWS
  - Laser imager

- **Contrast-to-Noise Test (CNR)**
  - To examine consistency of CNR ratio measured over time
  - Manual technique
  - Use the raw image
  - A control level is established over 5 days
  - >20% of baseline

\[
\text{CNR} = \frac{(\text{Mean}_{\text{background}} - \text{Mean}_{\text{mass}})}{\text{SD}_{\text{background}}}
\]

- **MTF Measurement**
  \[
  \text{MTF} = \text{(Std. Dev.) x 222} / (\text{Mean Dark ROI} - \text{Mean Light ROI})
  \]

- **Collimation**
  - Mo/Mo
  - Rh/Rh

MTF (%) = (Std. Dev.) x 222 / (Mean Dark ROI - Mean Light ROI)

MTF (%) @ 2 lp/mm > 58%

MTF (%) @ 4 lp/mm > 25%
**GE 2000D - Performing the Survey**

- **Focal Spot Evaluation**
  - Remove Compression Paddle
  - Mo/Mo
  - Rh/Rh
  - Large & Small Spots (1.5 mag)

**GE 2000D - Performing the Survey**

- **Beam Quality (HVL)**
  - Note the lead sheet

**GE 2000D - Performing the Survey**

- **Average Glandular Dose**
  - Measure using AOP system, or
  - Measure entrance exposure and calculate AGD

**GE 2000D - Performing the Survey**

- **kVp Accuracy**
GE 2000D - Performing the Survey

- **Monitor Quality Control**
  - Image Quality - SMPTE Pattern
  - Luminance Levels
  - RWS Screen Uniformity
  - Viewing Conditions Check

RWS SMPTE Patterns:
- 5% & 95% contrast boxes
- 10% contrast boxes
- High contrast line-pair resolution

Monitor Calibration

High Contrast Line Pair Patterns
- 1 pixel/line Vert Horiz
- 2 pixel/line Vert Horiz
- 4 pixels/line Vert Horiz

Measure luminance at:
- 10
- 60
- 120
- 180
- 255

Compare to baseline – must be within action limits
Analysis of Screen Uniformity

- Set monitor luminance to completely white (255) via menu
- Look at monitor at various angles to search for defects in glass or other non-uniformities

Viewing Conditions Check

- To ensure optimal viewing conditions
- Configure room for optimal viewing conditions
- Measure ambient room light at surface of monitors - < 20 lux
- Record data on form
- Post in reading room
- Update if there is a room reconfiguration

Fischer

Some slides courtesy of Fischer Imaging and Idris Elbakri, Ph.D.
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

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

- **Flat Field and Artifact Evaluation**
  - Use 4 cm acrylic
  - Exposure resulting in 1000 ADU’s
  - Display “raw” image
  - No Artifacts at WW ≥ 800
  - Compute deviation between corner and center means
  - Automatic in new software release
  - Must be within ±20% of center ROI

\[
\frac{\text{Mean}_{	ext{Corner ROI}} - \text{Mean}_{	ext{Center ROI}}}{\text{Mean}_{	ext{Center ROI}}} \times 100 = \% \text{Deviation}
\]
Fischer Senoscan - Performing the Survey

- **Collimation**

  - Error between field-size markers and image receptor size markers 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 $\leq 8.5$ mm

- **Compression Paddle Alignment**
**Fischer Senoscan - Performing the Survey**

- **kVp Accuracy**
  - Performed invasively through special BNC connectors
  - Non-invasive method under evaluation

- **Phantom Image Acquisition Test and Image Quality**
  - Select Techniques to give 1000 ADU
  - Compare background mean, StdDev, and ADU level difference to baseline values
  - Score: 4 fibers, 3 speck groups, and 3 masses

- **Mean Glandular Dose**
  - 30 kVp
  - mA between 150 to 190 to result in 1000 ADU
  - mRad/R conversion table provided in manual
  - Watch collimation!

- **Half-Value Layer**
  - Ion chamber affixed 5 cm to the right of center and close to chest wall
  - Position paddle 4.2 cm above chest wall
  - kVp = 30 mA = 100
  - Criterion: HVL ≥ 0.33 mm
**Exposure Linearity and Reproducibility**

- **Procedure:**
  - Center ion chamber on breast support near chest wall with paddle in the beam
  - Measure exposure at specified techniques

- **Calculate:**
  - \( \text{Output} = \frac{\text{Average exposure reading}}{\text{mA}} \)
  - \( \text{Linearity} = \frac{A-B}{A+B} < 0.08 \)
  - \( \text{Reproducibility} = \frac{\text{StdDev}}{\text{Avg}} < 0.035 \) for each technique

**System Resolution/Scan Speed Uniformity**

- **Purpose:** Ensure correct detector/beam alignment and constant scanning speed
- **Equipment:** line pair phantom
- **Perform imaging with scan lines parallel and perpendicular to scan direction**
- **Normal and high resolution modes**

**Geometric Distortion**

- Use a 40 mesh Cu screen
- Acquire image at low technique
- Visually inspect for distortions or blurring
Fischer Senoscan - Performing the Survey

- **Viewing Room Luminance**
  - Need a photometer
  - Monitors off
  - Measure luminance at the monitor screen and 50 cm away
  - Illuminance must be < 50 lux

**Lorad Selenia**

Some slides courtesy of Lorad and Nikolaos A. Gkanatsios, Ph.D.
Lorad Selenia - Performing the Survey

- **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

Lorad Selenia - Performing the Survey

- **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

Lorad Selenia - Performing the Survey

- **Collimation Assessment**
  - 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

Lorad Selenia - Performing the Survey

- **Artifact Evaluation**
  - 4 cm acrylic block
  - Mn/Mo
  - Mn/Rh
  - Large & Small Spot
  - Evaluate for artifacts at WW ~ 250
  - Print films – check printer
Lorad Selenia - Performing the Survey

- **kVp**
  - Described in the 1999 ACR QC Manual

- **HVL**
  - Described in the 1999 ACR QC Manual

- **Phantom Image Quality**
  - 28 kVp, 65 mAs, Mo/Mo – Until AEC system implemented
  - Print film – measure OD and Contrast
  - Score on each SCW (Soft Copy Workstation)
    - 5 fibers
    - 4 speck groups
    - 4 masses

Lorad Selenia - Performing the Survey

- **Breast Entrance Exposure and Average Glandular Dose**
  - Cover detector for protection – lead sheet
  - Technique set to clinically image average breast
    - 28 kVp, 65 mAs, Mo/Mo
  - Calculate dose < 3.0 mGy

Lorad Selenia - Performing the Survey

- **Radiation Output Rate**
  - Cover detector for protection – lead sheet
  - Technique set to clinically image average breast
    - 28 kVp, 320 mAs, Mo/Mo
  - Output Exposure > 800 mR/sec

Lorad Selenia - Performing the Survey

- **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
  \[ \text{SNR} = \frac{\text{Mean}_{\text{Bkgd}} - \text{DC}_{\text{offset}}}{\text{SD}_{\text{Bkgd}}} \]
  \[ \text{DC}_{\text{offset}} = 50 \]
- Establish CNR during acceptance testing
  \[ \text{CNR} = \frac{\text{Mean}_{\text{Disk}} - \text{Mean}_{\text{Bkgd}}}{\text{SD}_{\text{Bkgd}}} \]
- CNR should stay within \( \pm 15\% \) of measurement obtained during acceptance testing

Viewbox Luminance and Room Illuminance
- Described in the 1999 ACR QC Manual

SoftCopy Workstation QC
- Use supplied photometer and run monitor QC software
  - White level = 300 cd/m\(^2\) for Barco MG521 & 400 cd/m\(^2\) for Barco MG521M
    - Warning level = 2.5\%  Tolerance level = 5\%  Recalibrate
    - Black level = 0 cd/m\(^2\)
      - Warning level = 6.5\%  Tolerance level = 10\%  Recalibrate
  - Quality Level Performance – checks full monitor calibration automatically
    - Warning level = 5\%  Tolerance level = 10\%  Recalibrate
  - Uniformity Performance – minimize non-uniformities away from center of display
    - Warning level = 10\%  Tolerance level = 15\%  Recalibrate

GE Seno DS
- Some slides courtesy of GE and Vince Polkus and Marcia Hill
GE Senographe DS
Seno Advantage RWS

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
Quality Assurance Plan

CR Reader
CR Cassettes
Workstation

Fuji CR
Fuji FCR 5000 MA

CR QC Workstation

CR Cassettes
24 x 30 cm
18 x 24 cm
Fuji CR
Fuji FCR 5000 MA

Performing the Survey

- Manufacturer’s tests – Fuji
  - Physics tests unique to Fuji CR FFDM
    - CR reader sensitivity (“S” number)
    - CR reader shading correction
    - Imaging plate fogging test
    - Verification of AEC with CR cassettes on each unit that is tested

Siemens
Mammomat Novation DR

Siemens - Performing the Survey

- Manufacturer’s tests
  - AWS Monitor and Viewing Conditions
  - Chest Wall and Missed Tissue
  - Collimator
  - Compression Plate Position
  - Spatial Resolution
  - Phantom Image Quality
  - Mechanical Inspection
  - Detector Uniformity
  - Radiation Safety – (Optional in U.S.)
Siemens - Performing the Survey

- Manufacturer’s tests
  - kVp Accuracy and Reproducibility
  - HVL
  - Mean Glandular Dose
  - AEC Stability, Reproducibility & SNR
  - Ghost Image
  - SNR and CNR
  - AEC Thickness Tracking
  - Pixel Correction
  - Detector Calibration

Siemens - Performing the Survey

- Manufacturer’s tests
  - Film Printer
  - Viewing Conditions
  - Illuminance
  - Monitor Constancy

Sectra

Artifacts
Performing the Survey

- Artifact evaluation - windowing

Performing the Survey

- Artifact evaluation – Contact Mode GE

Performing the Survey

- Artifact evaluation – Mag mode 1.5

Performing the Survey

- Artifact evaluation – Mag mode 1.8
Performing the Survey

- Artifact evaluation

Performing the Survey

- Artifact evaluation

Performing the Survey

- Artifact evaluation

Performing the Survey

- Artifact evaluation
Performing the Survey

- Artifact evaluation

Performing the Survey

- Artifact evaluation
Performing the Survey

- Artifact evaluation

Artifact at edge of image receptor

Cause: hole in the graphite cover of the digital detector
There Are Currently Seven FDA-Approved Laser Imagers for Digital Mammography

- Agfa LR5200 Laser Imager (Wet Chemistry)
- Agfa DS4500M
- Kodak 8600 Laser Imager
- Kodak 8610 Laser Imager
- Kodak 8900M
- Fuji Drypix 7000
- Fuji Drypix FM-DP L

OD Requirements for Hi-Resolution Laser Imagers

- $D_{\text{max}} > 3.5 \text{ OD}$
- Mid-density $> 1.5 \text{ OD}$

Laser Processor QC

- Kodak daily sensitometry
- Base + Fog
- Density Difference = OD closest to 2.2 minus OD closest but not less than 0.48
- Mid-density = step closest to but not less than 1.20

Action Limits:
- $MD \& \, DD \leq 0.15 \text{ OD}$
- $B+Fog = 0.03$
- $D_{\text{max}} \leq 0.25$

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?
Key Take-home 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
  - Dmax at least 3.5 OD
  - Mid-density about 1.5 OD

Key Take-home 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
- Can be archiving physics test images on one workstation while working on another
- Take your time and use your professional judgement

Thank You