Digital Mammography
Quality Control – The Role of the Technologist

Presented By:
Mark Liddington
Objectives:

Introduce you to QC terminology in digital mammography

Introduce you to the different vendors in the marketplace

Review the quality control programs and testing protocols of a digital mammography program with focus on General Electric and Hologic FFDM units.
FDA Facility / FFDM Statistics

As of August 1, 2007

– Total certified facilities: 8,825
– Total accredited units: 13,402
– Certified facilities with FFDM units: 2,090 (24%)
– Accredited FFDM units: 3,077 (23%)

As of August 1, 2006

– Total certified facilities: 8,829
– Total accredited units: 13,556
– Certified facilities with FFDM units: 1,130 (13%)
– Accredited FFDM units: 1,604 (12%)
Digital Mammography Manufacturers

- General Electric
- Hologic
- Siemens
- Fuji – CR
- Fischer
- Sectra
GE 2000D
19cm x 23 cm detector

GE Essential
24cm x 30.7cm detector

GE SenoAdvntage Workstation
General Electric

- 2000D – Approved January 28, 2000
- Softcopy Review – Approved November 16, 2000
- DS – Approved February 19, 2004
- ES – Approved April 11, 2006
Hologic – (LoRad)

- Lorad Digital Breast Biopsy System approved March 15, 2002

- Hologic Selenia™ Amorphous Selenium Direct-Capture System approved October 2, 2002
Siemens

Siemens Mammomat Novation DR
Approved August 20, 2004

Uses the same detector as the Hologic Selenia™

Novation

Review and Acquisition Workstations

Mammo Report Plus
Fischer

Fischer Senoscan
Approved September 25, 2001
Fuji

Fuji Computed Radiography for Mammography (FCRm)
Approved July 10, 2006

Clear View – Single Plate Reader

Clear View – Multi-Plate Reader
Laser Printer Manufacturers

Agfa
Kodak
Fuji
The 1999 ACR QC Manual does not apply to Full Field Digital Mammography (FFDM) units.

The FDA requires you to follow the manufacturer’s QC manual for your machine.

21 CFR 900.12(e)(6)
“For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.”
That was then...this is now!

<table>
<thead>
<tr>
<th><strong>Film Screen QC</strong></th>
<th><strong>Digital QC</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine</td>
<td>Machine</td>
</tr>
<tr>
<td>Film Cassettes</td>
<td>Review Workstation</td>
</tr>
<tr>
<td>Processor</td>
<td>Printer</td>
</tr>
</tbody>
</table>
That was then…this is now!

<table>
<thead>
<tr>
<th>Old Terms</th>
<th>New Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Film Screen Contact</td>
<td>Flat Field Uniformity</td>
</tr>
<tr>
<td>Screen Cleaning</td>
<td>MTF</td>
</tr>
<tr>
<td>Darkroom Fog</td>
<td>CNR</td>
</tr>
<tr>
<td>Fixer Retention</td>
<td>SNR</td>
</tr>
</tbody>
</table>
Digital Mammography Terminology

**FFDM** – Full field digital mammography

**Flat Field uniformity** is an analysis of the homogeneity of the detector field

**MTF** (Modulation Transfer Function) is a measure of image sharpness.
Digital Mammography Terminology

**CNR (Contrast to Noise Ratio)** is a measure of the detectors ability to distinguish between objects in an image and the image noise.
SNR (Signal to Noise Ratio) compares the level of the desired signal to the level of background noise.

A higher SNR provides a better image.
Daily QC Tests – General Electric

FFDM Machine

2000D
Monitor Cleaning
Workstation Viewing Conditions

DS and Essential
Monitor Cleaning
Workstation Viewing Conditions
Daily QC Tests – General Electric

Review Workstations

**Seno Advantage**
Monitor Cleaning
Viewing Conditions Check

**Centricity PACS Mammo Module**
Monitor Cleaning
Viewing Conditions Check
Monitor Cleaning

Objective:
To ensure good image review conditions by keeping the monitor screens free of dust, finger prints, and other marks.

Equipment required:
Dry, soft, lint–free cloth or cleaning tissue. If necessary, the cloth or tissue may be lightly dampened with water before use. Never apply water or other fluids directly to electronic equipment.

Note: Any other cleaning methods may lead to damage of the anti-reflective screen coating.
Monitor Cleaning

Procedure:
Clean all monitor screens using the cloth or cleaning tissue to remove dust, fingerprints, and other marks.

Check the screen to verify that it is free from dust, fingerprints, and other marks.

Action Limit:
After the monitor is cleaned, the screen must be free from dust, fingerprints, and other marks.
Monitor Cleaning (Any Monitor!!!)

Check for fingerprints, dirt, scratches
Brush with nylon brush to remove dirt/dust

Use a Soft Cloth Only!
   Old Tee Shirt
   Camera – Microfiber Cloth

NO WINDEX!!!
Removes protective anti-glare coating on monitor

If Dirty and/or Greasy, clean with mild detergent solution
1 drop dishwashing liquid to 8 oz Warm Water

If a monitor needs to be replaced, both monitors should/will be replaced
Objective—to ensure optimal viewing conditions

Procedure:

Review the data form "Viewing Conditions Check and Setting" posted in the reading room during the most recent Medical Physicist's evaluation. In this data form you will find the reading room conditions established as optimal during this evaluation.

Compare the reading room configuration to the one described in the data form.

If differences exist between this configuration and the actual one, adjust the room configuration as described in the data form. For example, if desk lights were described to be turned off, turn them off, or, if the curtains were described to be closed, close them.
GE Medical Systems Seno Advantage

Revision 1 QC Manual 2391082-100

Chart 3 - Site and System Summary

Facility Name
SL Luke’s Hospital (North Facility Seno Advantage)

Address
Broadhead Road
Bethlehem, PA

Date of Installation
3/11/04
Room ID: SL North Reading Room

Date of Survey
6/1/2007

Serial Numbers
Mammographic Unit 5544
Workstation CPU 45512GE1

Left Monitor HXU300072
Right Monitor HXU300033

Chart 4 - Viewing Conditions Check and Setting

Monitor Position
See diagram below

Room Lights
Off

Desk Lights
Off

Others
Clinical films on viewer are masked to size (if needed)

Ambient Light value 3 lux

Note: confirmation of this value is not part of the daily check by the Radiologic Technologist.

Room Layout

The ambient light level must not exceed 20 lux. The measured value must be stable over one minute
(with a tolerance of a 5 lux over the measuring time with regards to the nominal lighting value).

If the system fails the test, the source of the problem must be identified and corrective action taken,
before any further mammographic images are reviewed or interpreted using the Seno Advantage.
Viewing Conditions Check for the Workstation

**Action Limit:**
On the "Viewing Conditions Check and Setting" data form posted by your Medical Physicist, you will find the nominal value of the ambient light. This is a record of the most recent measure and provides a comparison value for the next Medical Physicist survey. The Radiologic Technologist is not required to measure the ambient light level as part of the Viewing Conditions Check.

*If the reading room configuration has changed, the source of the problem must be identified, and corrective action taken, before any further mammographic images are reviewed or interpreted using this specific Centricity Workstation.*
Ideal Conditions in Digital Reading Rooms

Room light levels
   Keep lights off or low -- < 5 lux
   » 1 to 2 lux preferred

Equipment positioning
   View boxes and Softcopy displays should be parallel to one another … not at an angle or back to back

Need to avoid “crosstalk” between light sources
Daily QC Tests – Siemens

Novation

Image Quality (Phantom Image)
Procedure is nearly identical to film screen phantom testing

Exposure technique: Opdose program 2
Criteria: 5 fibers, 4 specks, 4 masses

MammoReportplus

Monitor Cleaning
Weekly QC Tests – General Electric

**2000D**
- Flat Field Test
- Phantom Image Quality (4, 3, 3)
  
  *(Technique specified by manufacturer: 26 kVp, 125 mAs, Mo/Mo)*
- CNR
- Viewbox and Viewing Conditions Test

• **DS**
  - Flat Field Test
  - Phantom Image Quality (4, 3, 3)
  - MTF and CNR
  - Viewbox and Viewing Conditions Test

• **Essential – Same as DS**
Weekly QC Tests – General Electric
Flat Field Test – Similar for all GE models

Hit QAP icon & bring up Flat Field

Place 25mm acrylic directly on the detector with no compression

Follow directions

Record on Image
Quality chart
Weekly QC Tests – General Electric
Flat Field Test – Similar for all GE models

The most common failure on this test is the “Bad Pixel ROI” measurement.

If this fails, run the collimator through a cycle of all sizes and repeat the test.

If it fails again, contact your service engineer.
Weekly QC Tests – General Electric

Phantom Image Quality – Similar for all GE models

Position the phantom the same as you do for film screen evaluation
(Select the 9 x 9 cm X-ray field size and use the light localizer to center the phantom laterally.)

Note: Careful attention to precise positioning of the phantom is critical to the reproducibility of the measurement.

Install the full-size compression paddle and apply about 5 daN of compression force to the phantom.

Select the following parameters: large focal spot, Mo/Mo track/filter, 26 kV, 125 mAs.

Score the processed phantom image on the AWS and RWS.
Weekly QC Tests – General Electric

CNR (Contrast to Noise Ratio) 2000D

Similar to phantom density difference (Does not use acrylic disk)

Use RAW Data and default ROI.

Measure mean of mass with ROI 1.
Measure mean and SD of background with ROI 2.

Difference of means measures contrast.
Std. Dev. of background measures noise.
**Weekly QC Tests – General Electric**

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**CNR, MTF, and SNR Worksheet**

**Note:** *All measurements must be made from Raw images.*

**CNR Test**

<table>
<thead>
<tr>
<th>Object</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>CNR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass</td>
<td>865.43</td>
<td>12.5</td>
<td></td>
</tr>
<tr>
<td>Background</td>
<td>913.36</td>
<td>11.89</td>
<td></td>
</tr>
</tbody>
</table>

\[
CNR = \frac{\text{mean}_{\text{background}} - \text{mean}_{\text{mass}}}{\text{sd}_{\text{background}}}
\]

- \(CNR_{ol} = 3.70\)
- \(CNR = 4.03\)
- \(\text{Change in CNR} = 0.089\)

\[
\text{Change in CNR} = \begin{cases} 
1 - \frac{CNR}{CNR_{ol}} & \text{for } CNR < CNR_{ol} \\
\frac{CNR}{CNR_{ol}} - 1 & \text{for } CNR > CNR_{ol}
\end{cases}
\]

To establish **Operating Level**, repeat this measurement once a day for five consecutive days and average the five values to determine \(CNR_{ol}\).

**Action Limit:**
Change in CNR cannot exceed 0.2
Weekly QC Tests – General Electric
CNR – DS and Essential

Uses a special (IQST) phantom supplied by GE

Position the IQST device on top of the Bucky. (The following parameters are selected automatically: Rh/Rh/30kV/56mAs.)

Perform one exposure.

After the image has been captured, the results of the tests are displayed
Weekly QC Tests – General Electric

MTF – DS and Essential

Uses (IQST) phantom supplied by GE

Position the IQST device on top of the Bucky.  
(The following parameters are selected automatically: Rh/Rh/30kV/56mAs.)

Perform one exposure.

After the image has been captured, the results of the MTF tests are displayed.

Record Results
Weekly QC Tests – General Electric

Viewboxes and Viewing Conditions Check - all units and workstations

This is the same test that you perform for a film screen mammography program
Monthly QC Tests – General Electric

2000D
– MTF
– AOP SNR
– Visual Checklist
– Monitor Calibration Test

• DS
– AOP SNR
– Visual Checklist

• Essential – Same as DS
Monthly QC Tests – General Electric 2000D

MTF Test

**Frequency:** Monthly

**Objective:** Monitor the contrast delivered by the detector

*Contrast at low frequencies (1–2 lp/mm) aids detection of masses and fibers.*

*Contrast at high frequencies (4–5 lp/mm) aids detection of microcalcifications.*

**Method:** Measure the fluctuation of a bar pattern signal in a region of interest (ROI)

*The greater the signal fluctuation, the greater the MTF.*
Monthly QC Tests – General Electric 2000D

MTF Test

Position resolution bar pattern with open on left

Align along the chest wall edge without the compression paddle

Make an exposure: 30 kVp, 28 mAs, Rh/Rh and LCC

Examine the RAW image
Monthly QC Tests – General Electric 2000D

MTF Test

Set the ZOOM factor to 1
Use ROI to measure

2.09 Standard Deviation
3.93 Standard Deviation

Mean space
Mean bar
Monthly QC Tests – General Electric 2000D

MTF Measurement – Sample Calculation

<table>
<thead>
<tr>
<th>Object</th>
<th>Mean</th>
<th>Std. Dev.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 lp/mm bars</td>
<td>4191.84</td>
<td>2876.92</td>
</tr>
<tr>
<td>4 lp/mm bars</td>
<td>3906.14</td>
<td>1829.08</td>
</tr>
<tr>
<td>Space</td>
<td>8798.99</td>
<td></td>
</tr>
<tr>
<td>Bar</td>
<td>136.64</td>
<td></td>
</tr>
</tbody>
</table>

MTF Test

Formula:

\[
MTF = \frac{SD \ lp/mm}{Mean \ Space - Mean \ Bar} \times 222
\]

MTF \(_{2\ lp/mm}\) = 73.73

MTF \(_{4\ lp/mm}\) = 46.88

MTF (2 lp/mm) must be > 58%

MTF (4 lp/mm) must be > 25%
Monthly QC Tests – General Electric All Units

AOP and SNR Test

Tested for 2.5cm, 4cm, 6cm thicknesses with the supplied acrylic tests phantoms

Position on image receptor as shown

Apply 5dNa compression

Make exposures in the STD mode

Record techniques on AOP Mode chart

Close exam & bring up raw data
Monthly QC Tests – General Electric All Units
AOP and SNR Test

Place ROI at chest wall on all 3 images

SNR = mean/sd

Record results on AOP Mode chart

<table>
<thead>
<tr>
<th>Thick</th>
<th>kVp</th>
<th>Track</th>
<th>Filter</th>
<th>mAs</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>SNR</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mm</td>
<td>27</td>
<td>Mo</td>
<td>Mo</td>
<td>26</td>
<td>764.55</td>
<td>10.93</td>
<td>69.95</td>
</tr>
<tr>
<td>40 mm</td>
<td>28</td>
<td>Mo</td>
<td>Rh</td>
<td>55</td>
<td>799.57</td>
<td>11.61</td>
<td>68.87</td>
</tr>
<tr>
<td>60 mm</td>
<td>32</td>
<td>Rh</td>
<td>Rh</td>
<td>59</td>
<td>749.05</td>
<td>12.07</td>
<td>62.06</td>
</tr>
</tbody>
</table>

Requirement:

<table>
<thead>
<tr>
<th>Acrylic Thickness (mm)</th>
<th>Track/Filter</th>
<th>mAs</th>
<th>kV</th>
<th>SNR</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Mo/Mo</td>
<td>20 - 60</td>
<td>27</td>
<td>&gt; 50</td>
</tr>
<tr>
<td>40</td>
<td>Mo/Rh</td>
<td>35 - 90</td>
<td>28</td>
<td>&gt; 50</td>
</tr>
<tr>
<td>60</td>
<td>Rh/Rh</td>
<td>35 - 90</td>
<td>32</td>
<td>&gt; 50</td>
</tr>
</tbody>
</table>
Monthly QC Tests – General Electric All Units
Visual Checklist

Similar to Visual checklist for film screen mammography
Quarterly QC Tests – General Electric 2000D

Repeat Analysis

Similar to repeat analysis for film screen mammography

Must manually record retakes and estimate number of exposures

Manually calculate retake percentages
Quarterly QC Tests – General Electric DS & ES

**Repeat Analysis**

Procedure is automated

Select the QAP icon in the browser, then click the *RRA* button to display the *Repeat and Reject Analysis* window.

In the *Repeat and Reject Analysis* window, select *From* and *To* dates for the analysis, then click *Preview analysis* to display the *Repeat Reject Exposures Analysis* table.

The table summarizes all exposures made during the chosen period, and gives the percentages for Repeated and Rejected exposures, together with their respective causes.
Semi-Annual QC Tests – General Electric All Units

Compression

Procedure is the same as a film screen unit
QC Tests – General Electric Seno Advantage
Review Workstations
Monitor Calibration (Monthly)

Verify that the 0%-5% contrast is visible

Verify that the 95%-100% contrast is visible

Verify that each gray level step from 0% to 100% can be distinguished from the adjacent squares.

Verify that the alphanumeric characters that appear on the pattern are sharp and in focus.

Verify that the high contrast line-pair images at the center and corners of the SMPTE pattern are distinguishable
QC Tests – General Electric Centricity Review
Workstations

Monitor Calibration (Weekly)

Monitor Calibration is automated after the program is set up

Tests:
- I-Guard
- Calibration Settings
- Measure Display White Field

Review Last Results log and record results
QC Tests – General Electric Centricity Review
Workstations

Measure Quality Level (Monthly)

Quality Level is automated after the program is set up

Review Last Results log and record results
Daily QC Tests – Hologic

Note: If wet processing is used the following tests must be performed:

- Darkroom cleanliness
- Processor QC

Tests will follow the 1999 ACR manual
Weekly QC Tests – Hologic Selenia

Laser Printer QC (dry laser)
(follow manufacturer’s manual)

Viewbox and Viewing Conditions
(follow 1999 ACR manual)

Diagnostic Review Workstation QC

Artifact test – Detector and Printer

Phantom with SNR and CNR
Weekly QC Tests – Hologic Selenia

Diagnostic Review Workstation QC

Workstations with CRT monitors use a photometer that is attached to the monitor. After following the on-screen instructions, the process is automated.

QC tests for workstations with flat panel monitors is automated. Technologists must retrieve the results and record them in the QC logbook.

Hologic workstations use MediCal Pro software. The same software that is used on the GE Centricity PACS workstations.
Weekly QC Tests – Hologic Selenia

Artifact Evaluation – Detector

Performed before the phantom test
Place acrylic on image receptor
Make exposure at 28 kVp, 65 mAs, Mo/Mo LFS
Rotate Acrylic 180° and repeat exposure
Using the Pan/Zoom feature, analyze the image for artifacts
Weekly QC Tests – Hologic Selenia
Artifact Evaluation – Detector

Common artifacts include

- Streaking
- Ghosting
- Dead Pixels
Weekly QC Tests – Hologic Selenia

Artifact Evaluation – Printer

Select test patterns from the Admin menu

Select SMPTE pattern from the drop down list

Send image to printer

Evaluate SMPTE patterns visually

Using a densitometer, measure the 40%, 10% and 90% contrast patches.

Record values on control sheet *(similar to processor QC)*
Weekly QC Tests – Hologic Selenia
Artifact Evaluation – Printer

Select test patterns from the Admin menu
Select flat field pattern from the drop down list
Send image to printer
Analyze the image for artifacts
Common artifacts are streaks and repeat lines
Weekly QC Tests – Hologic Selenia

**SNR** (signal to noise ratio)

**CNR** (signal to noise ratio)

Position the phantom and make an exposure using the clinical setting (Hologic requires the acrylic disk)

Make ROI measurements on the disk and in the background

Record the mean and standard deviation of the ROIs
Artifacts
Weekly QC Tests – Hologic Selenia

**SNR** (signal to noise ratio)

\[
\text{SNR} = \frac{\text{Mean (bkg)} - 50}{\text{STD (bkg)}}
\]

Compute the SNR using the SNR formula

The measured SNR must be greater than or equal to 40
Weekly QC Tests – Hologic Selenia

**CNR** (signal to noise ratio)

\[
\text{CNR} = \frac{\text{Mean (bkg)} - \text{Mean (disk)}}{\text{STD (bkg)}}
\]

- Compute the CNR using the CNR formula
- Compute the deviation from the original CNR using the CNR(diff) formula

\[
\text{CNR(diff)} = \frac{\text{CNR (base)} - \text{CNR (meas)}}{\text{CNR (base)}} \times 100\%
\]

- The deviation should not exceed \(\pm 15\%\) of original CNR
Weekly QC Tests – Hologic Selenia

Phantom Image Evaluation

Position the phantom the same as you do for film screen evaluation (you can use the phantom image from the CNR and SNR tests)

Print a film of the phantom

Score the phantom on film and the diagnostic review workstation

Make measurements with a densitometer on the film

Record the results on the QC forms
Bi-Weekly QC Tests – Hologic Selenia

Detector Flat Field Calibration

Select Calibrate from the Admin drop down menu (directions are displayed on the monitor)

Remove compression paddle, place the acrylic block on the image receptor and make a manual exposure

Review the image for foreign objects and collimation interference

Rotate the acrylic block 180° and press the Accumulate Calibration button.

Follow the remaining instructions
Bi-Weekly QC Tests – Hologic Selenia
Detector Flat Field Calibration

The calibration is performed automatically by software on the AWS

Review the image for foreign objects and collimation interference

If artifacts are seen, contact your medical physicist, radiologist and or service engineer to determine the cause of the artifact
Bi-Weekly QC Tests – Hologic Selenia
Composition Thickness Indicator

Position the ACR phantom on the image receptor and compress it with ~30 lbs. using the 7.5 cm spot compression paddle.

Record the thickness indicated on the compression device.

The compression indicator should be accurate to within ±0.5 cm from the actual thickness. *(Should read 3.7 to 4.7 cm for standard phantom)*
Monthly QC Tests – Hologic Selenia

Visual Checklist

Follow the procedure listed in the 1999 ACR Quality Control Manual

Use the visual checklist form in the 1999 ACR Quality Control Manual
Quarterly QC Tests – Hologic Selenia

Repeat Analysis

The Procedure is automated

Minimize the Selenia Application and double click the terminal shortcut icon

Enter the password and select repeat-reject analysis from the options list

Enter the start and end date of the monitoring period and submit the request.

Action levels are the same as stated in the 1999 ACR QC manual
Quarterly QC Tests – Hologic Selenia

Fixer Retention

Applies to those facilities printing digital mammo films to a wet laser printer.

Follow the 1999 ACR QC manual
Semi-annual QC Tests – Hologic Selenia Compression

Follow the 1999 ACR QC manual
Semi-annual QC Tests – Hologic Selenia

Darkroom Fog

Follow the procedure listed in the 1999 ACR Quality Control Manual

Use the visual checklist form in the 1999 ACR Quality Control Manual
At this time, Siemens uses the same detector as the Hologic Selenia. Therefore, the detector-related QC tests are similar to the Hologic QC program.
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References:

- GE Senographe 2000D QAP, QC Manual 2371472-100, Rev 0
- GE Senographe DS Acquisition System, QC Manual 5133453-2-100, Rev 1
- GE Senographe Essential Acquisition System, QC Manual 5133453-2-100, Rev 1
- GE Seno Advantage Review Workstation, QC Manual 2391082-100, Rev 1
- GE Centricity PACS Workstation, QC Manual 2028115-001, Rev 1
- Hologic Selenia™ Quality Control Manual 00093, Rev 6
- Quality Assurance Measurements Hands-on Workshop For Surveying Digital Mammography Units, Jerry A. Thomas, M.S., FAAPM, DABR, CHP, DABSNM
If you’d like to review this presentation, it will be available at www.WalterRobinson.com
Questions?